

**Service Manual**  
for Digital Blood Pressure Monitor

**DIGITAL 21**

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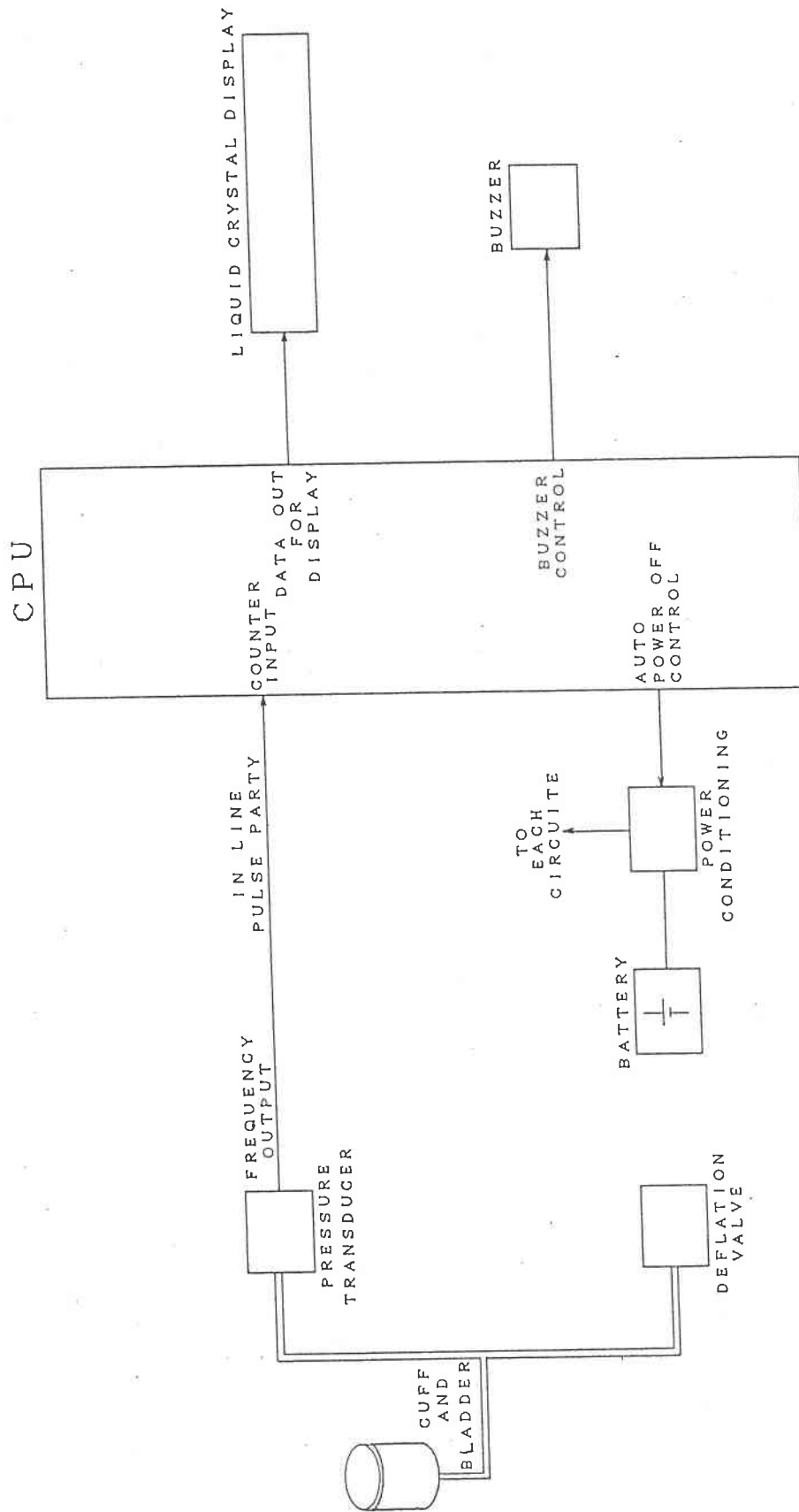
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- 1.MODEL :DS-106  
:Basic Digital Blood Pressure Monitor
- 2.FUNCTION :Blood Pressure Measuring  
:Pulse Rate Measuring  
:Automatic Power Shut-off  
(at 3 Minutes Unused)
- 3.INDICATORS :6-Digit LCD  
:Systolic/Diastolic/Pulse Rate  
:3 Error Messages
- 4.BLOOD PRESSURE MONITOR SPECIFICATIONS  
MEASURING METHOD  
:Oscillo-Metric Method  
MEASURING RANGE  
:0-300 mmHg Cuff Pressure  
:40-150 Pulse/min. Pulse Rate  
ACCURACY :Pressure  $\pm$  3 mmHg (Confirmed A.A.M.I)  
:Pulse Rate  $\pm$  5 % of Reading  
PRESSURE BUILD-UP  
:Squeeze Bulb  
DEFLATION METHOD  
:Pre.-Settable Exhaust System  
EXHAUST :Manual Valve  
CUFF :Locking Mechanical-Velcro with Metal Ring
- 5.POWER SOURCE :006P or 6F22 (9 Volt Battery) 1pc.
- 6.SIZE  
MAIN UNIT :152(W) x 80(D) x 30(H) mm  
CUFF UNIT :Standard adult size  
(Arm circumference 9 to 12.5 inches)
- 7.MAIN UNIT WEIGHT :Approx. 160gm (including battery)
- 8.STORAGE CASE :Soft Vinyl
- 9.RETAIL BOX :Dimensions 170 x 115 x 85 mm  
:Weight Approx. 450 gm

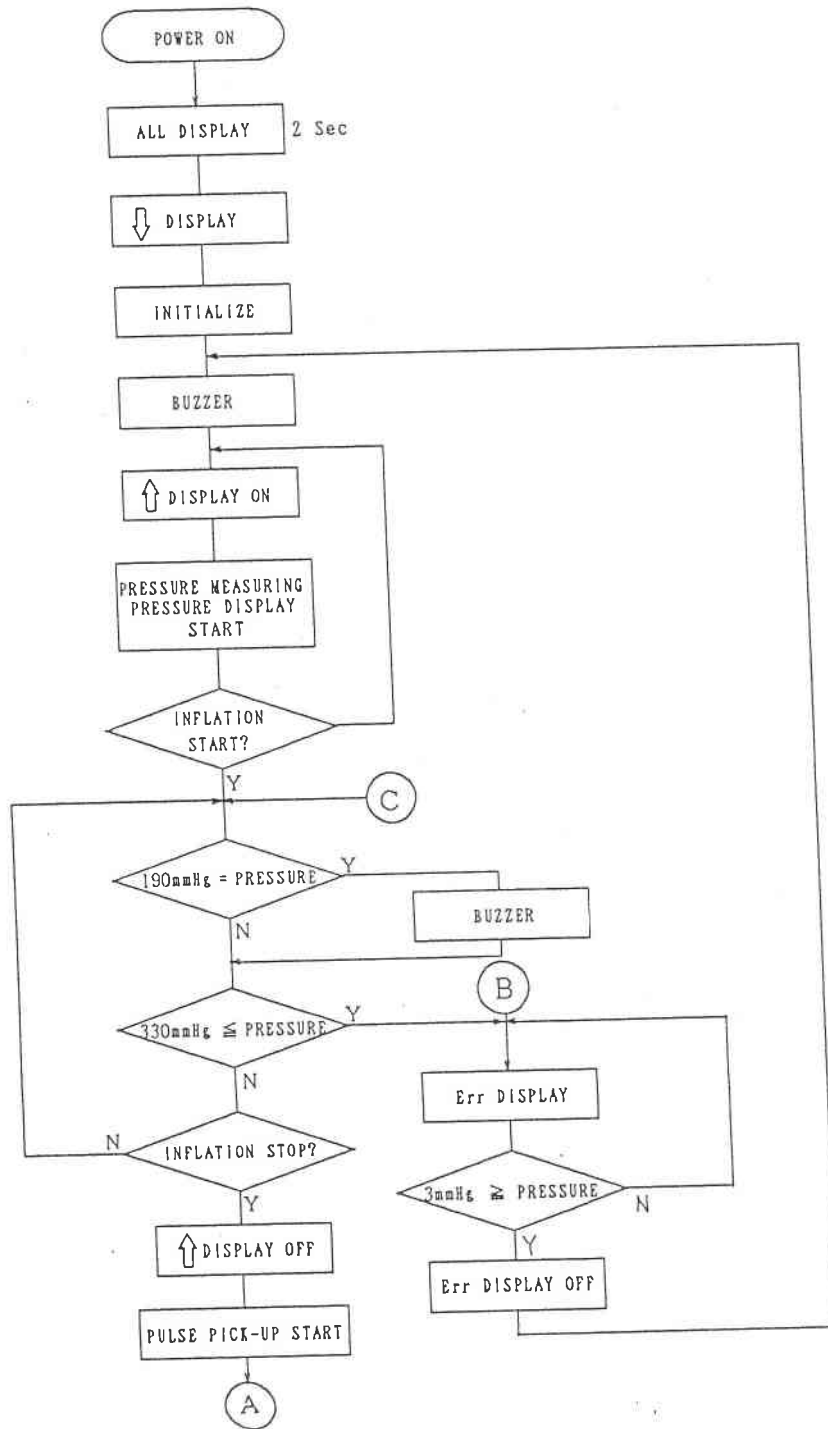
- \* Rubber bladder is inflated by rubber bulb.
- \* Deflation is controlled by self-bleeding valve.
- \* Pressure transducer transduce pressure and pressure pulsation (Oscillation) to digital (frequency) value.
- \* CPU counts frequency.
- \* CPU watches condition of amplitude and trend for oscillation and then systolic and diastolic are decided by it.
- \* After deciding diastolic, pulse rate are measured.
- \* Measurement result is displayed on LCD.
- \* After completing measurement, air is exhausted rapidly by self-bleeding valve.
- \* Battery weak mark is displayed when battery is weak. Impossible to measure.
- \* Please refer to flow chart when buzzer sounds.
- \* Power is automatically off in 3 minutes after measurement completion.
- \* Please refer to block diagram also.

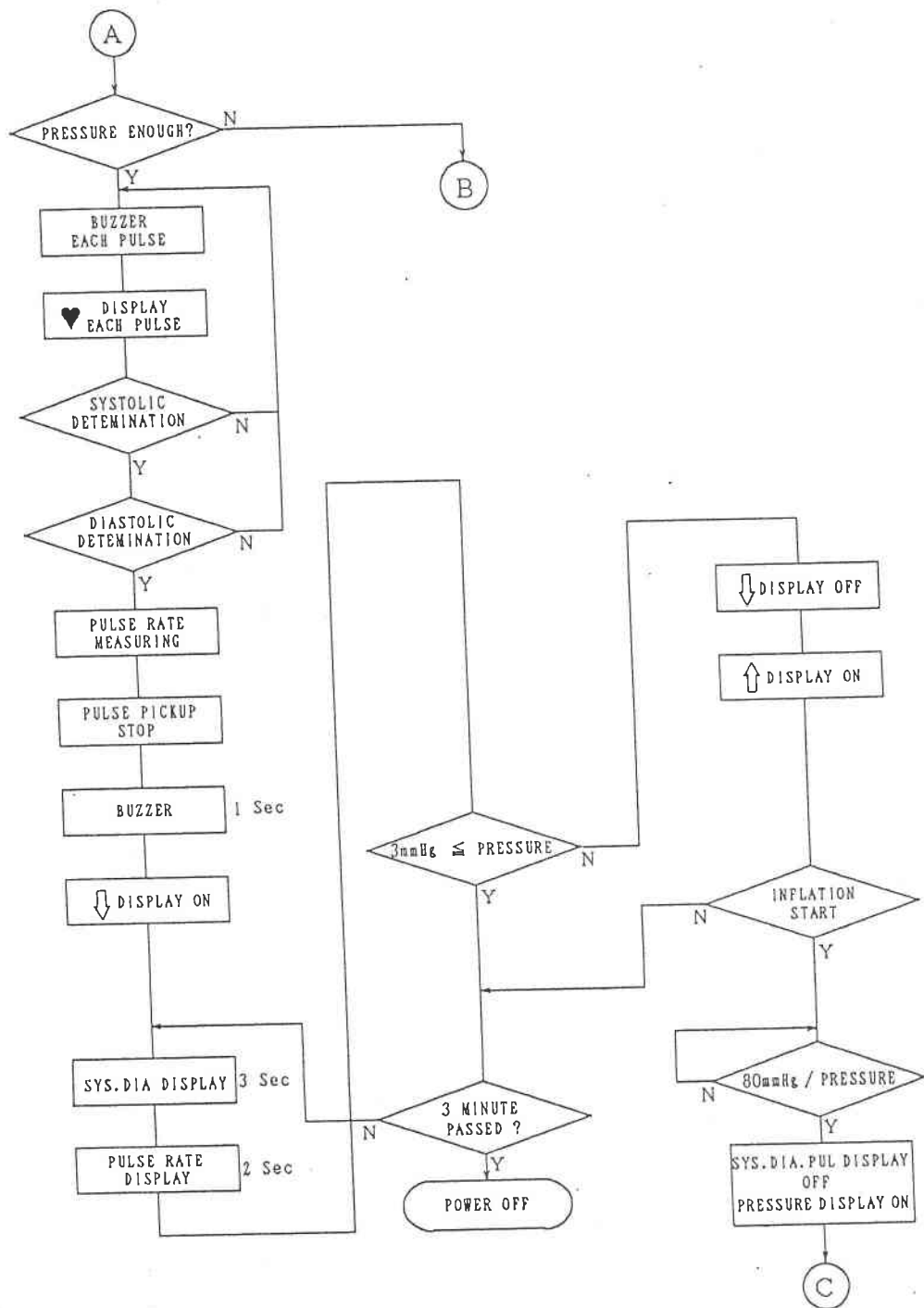
### 3. Block Diagram.

## BLOCK DIAGRAM

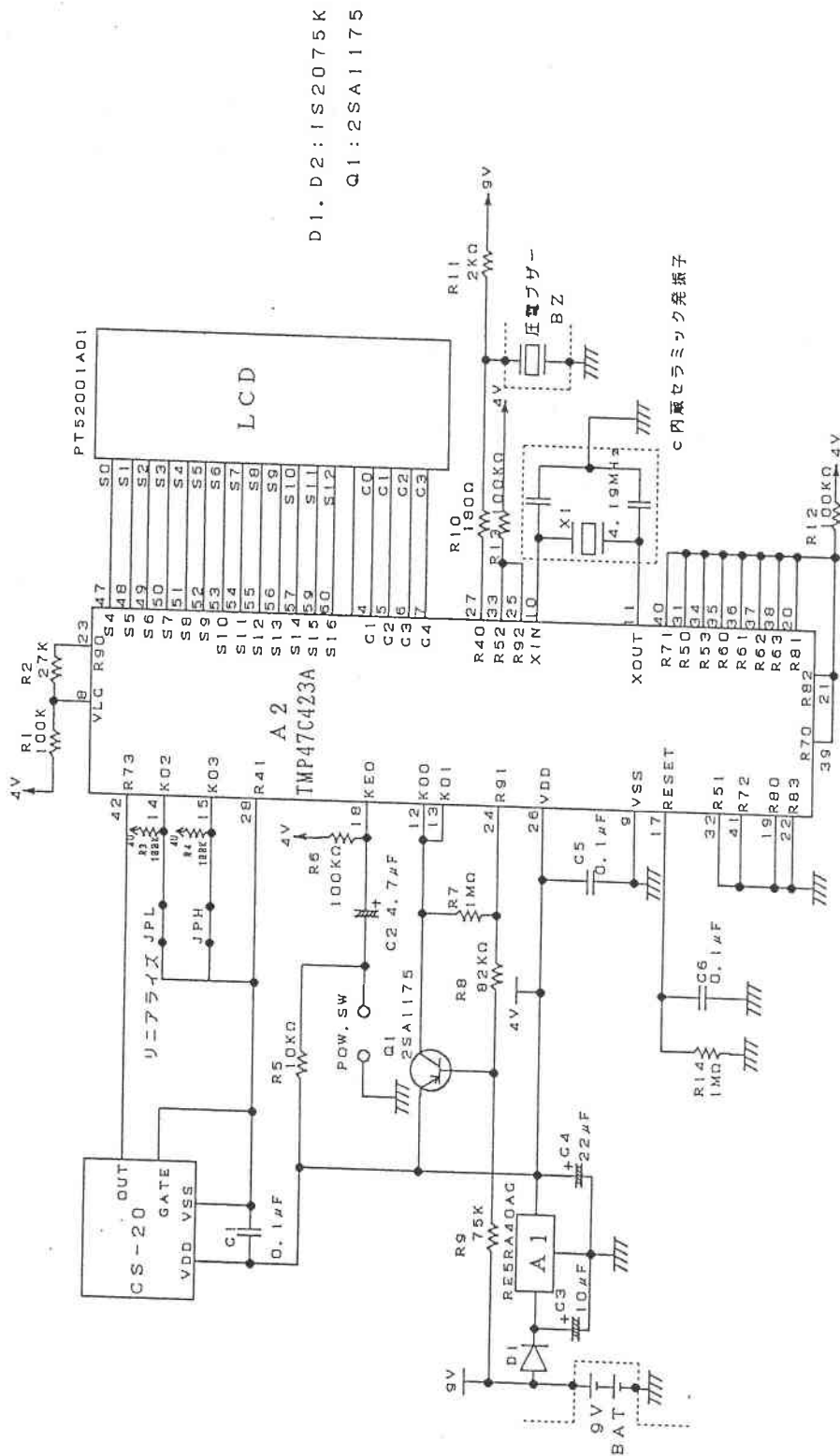


#### 4.Operation Flow Chart.





### 5.Circuits Diagram.



D1: D2: 1S2075K

Q1: 2SA1175



## 6. Operating Instructions.

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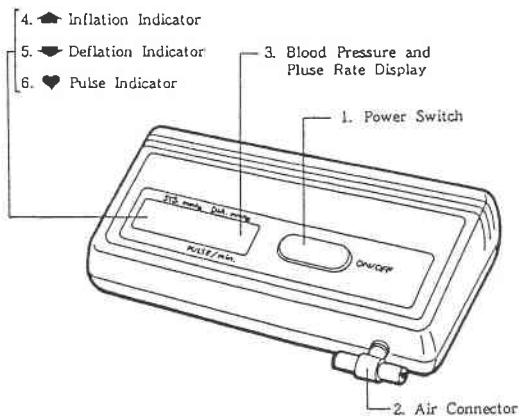
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### HINTS ON TAKING YOUR BLOOD PRESSURE

1. Rest for five minutes before taking your blood pressure.
  2. Take your blood pressure when relaxed in a quiet room. Do not move your body when taking your blood pressure.
  3. If you are wearing a shirt which might restrict circulation in your upper arm, remove your shirt before taking your blood pressure.
  4. Since exercise, eating, drinking, and smoking affect your blood pressure reading, avoid these activities before taking your blood pressure.
  5. Room temperature should be about 70°F (20°C) when taking your blood pressure.
- ※ Blood pressure readings will vary over the course of a day. Blood pressure is low in the morning and increases from afternoon to evening. Blood pressure is lower in the summer and higher in the winter.

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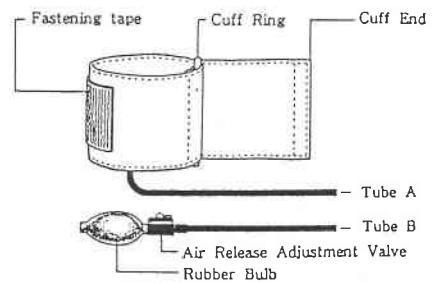
### MAIN UNIT



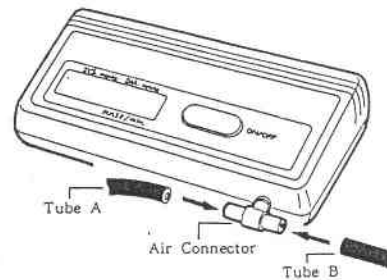
1. Power Switch..... Push switch to ON position. Push again to switch OFF.
2. Air Connector..... To connect the tube A and B.
3. Blood Pressure and Pulse Rate Display..... Systolic and diastolic blood pressure and pulse rate.
4. Inflation Indicator..... Flashes when the unit is ready to operate.
5. Deflation Indicator..... Appears before or after measurement.
6. Pulse Indicator..... Flashes when the Pulse is detected.

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### CUFF UNIT



### INTERCONNECTION DIAGRAM



Insert the Tube A and B into the Air Connector.

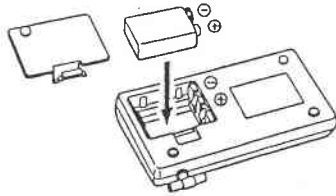
- 4 -

## POWER SUPPLY

Insert the battery in the main unit.

- 1) Pressing lightly on the battery compartment cover, remove the cover.
- 2) Connect a 9-Volt cell battery to the battery snap in the compartment, making sure that the positive and negative poles are properly connected.
- 3) After inserting the dry cell battery, put the battery cover on the main unit.

Note: If the LCD display or the functioning of the unit is not normal after changing the battery, take out the battery and place it again correctly in the battery compartment.



## AUTO DEFLATION VALVE

1. This unit is equipped with a semi-fixed air release rate of 2-3 mmHg per second for an ordinary individual who has an upper arm circumference of approximately 11 inches.

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## OPERATING THE UNIT

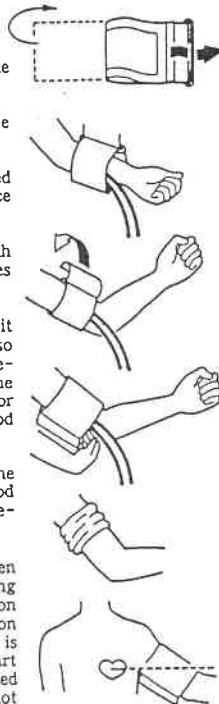
### Wrapping the Cuff

1. Place the cuff on a flat surface with the fastening tape face down.
2. Insert about two inches of the opposite end of the cuff in the cuff ring.
3. With the tube of the cuff positioned in the direction of the fingertips, place it on the left arm.
4. Wrap the cuff around the arm with the edge of cuff approximately 1 inches above the elbow.

※ When wrapping the cuff, wrap it loosely enough around the arm so that two fingers can be placed between the cuff and the arm. If the cuff is wrapped more tightly or loosely than this, inaccurate blood pressure readings may result.

※ If you roll up your sleeve over the upper arm, you constrict the blood flow and prevent accurate measurements.

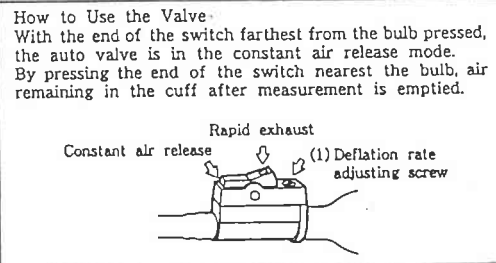
5. The position of the individual when being measured may be either lying down or sitting. In the sitting position however make sure that the location on the upper arm to be measured is about at the same height as the heart and that the forearm is extended naturally on the table and does not move.



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2. The rate of pressure drop will be slower if the upper arm of the individual to be measured is larger than 12 inches and the rate of pressure drop will be faster if the individual's upper arm is less than 10 inches in circumference. Also, the rate of pressure drop may change somewhat according to how the cuff is wrapped. Adjust the semi-fixed air release valve so that the air release rate becomes 2-3 mmHg per second for the individual whose blood pressure is being measured.

Note: In the measurement of blood pressure, it is very important that the air release rate be 2-3 mmHg per second in order to obtain accurate results.



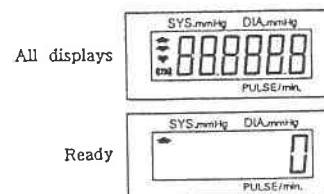
3. Adjust the rate of pressure drop according to the following procedure.

- 1) Turn the part marked (1) in the diagram with a screwdriver.
- 2) The rate of pressure drop will become slower if this part is turned in the clockwise direction. The rate of pressure drop will increase if this part is turned in the counter-clockwise direction. Adjust the valve according to the procedure noted above so that air release rate is 2-3 mmHg per second.

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### Measurement Procedures

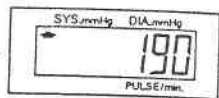
1. Insert the Tube A and B into the Air Connector. (See page 4)
2. If there is some air remaining in the cuff, press the rapid deflation side of the Auto Deflation Valve. Continue to press the rapid deflation side of the valve until air is completely gone from the cuff.
3. Turn the Power Switch to ON. All the panel displays will appear on the display. And then, Deflation Mark "◀" will start flashing and "0" will appear on the display.  
※ If panel displays do not light, the unit is malfunctioning.
4. The buzzer will sound and Inflation Mark "▲" will start flashing on the display.



5. Wrap the arm cuff around the upper left arm. (See page 7)
6. Press the constant air release side of the Auto Deflation Valve.
7. Squeeze the rubber bulb rapidly to inflate the cuff to 30-40 mmHg above your systolic pressure (upto minimum 125 mmHg, or otherwise the unit will not go into measuring mode) or until you hear the beeping signal.

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\* Buzzer beeps when the cuff pressure is over 190 mmHg.



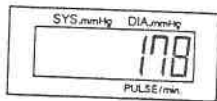
\* When the pressurization is insufficient, the buzzer will sound and the Inflation Mark "▲" will flash in the LCD display. Inflate the cuff again, upto 30-40 mmHg above the last inflation.

\* For a hypertensive individual, a cuff pressure higher than 190 mmHg is required and, in this case, pumping may be continued regardless of the beeping. However, if "Err330" appears in the LCD and the beeping continues, it indicates "over-pressurizing". Stop pumping and release all air from the cuff by setting the Auto Deflation Valve to the exhaust side. (See an illustration of the Valve in 1)

8. Place the rubber bulb quietly on the table.

\* Note : Sit quietly during measurement. Moving your arm and body during measurement may cause reading errors, Err mark display or indication of insufficient pressurization.

1) The cuff pressure will begin to decrease.



2) As the cuff pressure decreases, at a certain point, the heart mark will be displayed with beeping sounds in synchronization with your heart beats. If an error indication appears, set the Valve to the rapid exhaust side, then, repeat measurement by referring to "ERROR DISPLAYS" in Page 11.

9. Enter the display results of your systolic and diastolic blood pressures in a record book.

10. Turn the power switch to OFF.

\* If the unit is not used for approximately 3 minutes, power will automatically be turned OFF even if the power switch is set to ON.

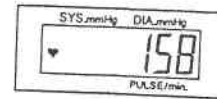
\* In case of repeat measurements, allow the arm to rest for a at least five minutes. Follow the same measurement procedures from step 1.

### ERROR DISPLAYS

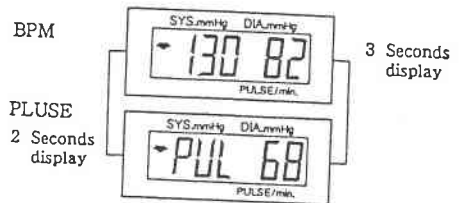
When an error indication appears on the display panel, repeat measurement by referring to the error numbers shown.

	Wrong Operation	Correct Operation
1. "Err" is indicated. 	The cuff was not inflated to more than 30-40 mmHg above your systolic pressure. Arm and body were moved during measurement.	Raise the set pressure value by another level. Do not move during measuring.
2. "Err330" is indicated. 	The cuff was inflated to more than 330 mmHg.	Deflate the cuff. Do not inflate above in 330 mmHg.
3. Battery mark is displayed. 	Battery is weak.	Replace with new battery.

3) While the heart mark flashes with beeping sounds, the measurement continues. Remain still without moving your arm and body.



4) The measurement completes when the beeping sound lasts for one second and your systolic and diastolic pressure readings will be displayed for three seconds. Then, your pulse rate will be displayed for two seconds. The display will show those readings alternately.



5) Set the Auto Deflation Valve to the rapid exhaust side and release all air from the cuff. After the air is completely deflated from the cuff, the Inflation Mark will appear.



\* These valves will be held until the power switch is set to OFF.

### CARE AND MAINTENANCE

1. This unit uses precision parts, care should be taken to avoid extremes in temperature variations, humidity shock, dust and in direct sunlight.

2. Do not drop or strike this unit.

3. When cleaning this unit, use only a soft, dry cloth.

4. If the unit is to be stored for a long period, be sure to remove the batteries before storage.

5. We suggest that you have your blood pressure monitor checked every 2 or 3 years.

6. If your doctor detects you have high blood pressure, he may suggest that you monitor your own pressure between regular doctor's check-ups. High blood pressure can lead to serious medical complications, therefore, regular monitoring can be very important to you.

7. This unit is designed and intended for use on an adult's arm (Coverrange circumference 9 to 12 1/4 inches). An inaccurate reading may result if this instrument is used on a child's arm. Consult your physician if you wish to take a child's blood pressure.

## 7. Analysis of Returns.

### 1. Check of General Performance.

Each unit claimed to be defective should be re-checked to determine whether it is really due to a failure of the device. There are many cases where customer returns the unit due to improper handling of the unit. Check the unit to find out whether the handling by the customer was appropriate or the unit is defective. The accuracy of reading will be affected by the conditions of the followings.

- (a) Cuff wrapping -- If the cuff is wrapped tightly or loosely inaccurate blood pressure readings may result.
- (b) Connections of air tube.
- (c) Battery power being left.
- (d) Battery connection -- The contact should be tight.
- (e) Inflation -- Desirable inflation level is more than 50mmHg above systolic. When squeeze the rubber bulb, squeeze rapidly and continuously.
- (f) Ambient noise and temperature, arm moving.
- (g) Whether customer was still while measuring.

### 2. Customer Educations in case of Unit not being out of Order.

In case general performance of the unit is in our specifications the reason of the return would fall into either one of the followings.

- (i) The readings did not agree with that from his or her doctor.
- (ii) Proper reading could not be obtained due to the special heart or body characteristics peculiar to the particular user.

The following causes can be considered for the above (i).

- (i-a) Blood pressure varies by physical rhythm such as by time in a day-morning, daytime and evening, or right after meal and/or movement.
- (i-b) By stability of mine (there are many people having pressure raise in front of doctor due to a tension.
- (i-c) By ambient temperature (blood pressure varies by season- summer, winter, etc.).
- (i-d) By exercise and / or work.

The following causes can be considered for the above (ii).  
(ii-a) Abnormality of his or her circulation system (Such as an absence of a beat or irregularity of pulses) will make the proper reading difficult.  
(ii-b) Exceptionally low level of pulse due to a condition special to that individual.

For the above (i-a) through (i-b), detailed explanations to the customer should be provided to have better understanding on the variation of the blood pressure and theory of the measurement.

For the above (ii-a), explanation about peculiarity of his or her circulation system should be explained. Most of the people having irregularity of pulses will become to be able to read his or her blood pressure correctly after some training. However the customer having such abnormality should consult his or her doctor.

For the above (ii-b), the customer may or many not be able to use electronic blood pressure monitor depending on his or her condition. If his or her pulse level is low, another try with proper cuff wrapping should be made. If correct reading still can not be obtained, he or she should give up use of electronic blood pressure monitor.

## 8. Trouble Shooting

Condition	Trouble	Fixing
1. Cuff setting trouble	Cuff broken	Replace cuff
2. Display is not ON	Battery is too weak	Replace battery
	Battery terminal	Replace circuits board
	Circuits	Replace circuits board
3. All display is not all ON	LCD soldering	Re-soldering
	LCD	Replace circuits board
4. Can not inflate	Intake valve	Replace valve
	Control valve	Replace valve
	Bladder	Replace bladder
5. Pressure display is not increase	Pressure sensor or Circuits	Replace circuits board
6. Deflation is too fast	Control valve	Replace valve or Re-adjust *1
	Bladder burst	Replace bladder
	Air connector cracked	Replace connector
7. No beeping	Buzzer soldering	Re-Soldering
	Buzzer broken	Replace buzzer
	Circuits	Replace circuits board
8. Heart mark is not	Circuits	Replace circuits board
9. Systolic, Diastolic is not measured	Circuits	Replace circuits board
10. Mark is very often	Deflation too fast	See item-7
	Circuits	Replace circuits board
11. Accuracy of reading	Circuits	Check *2 and replace circuits board
	Compare with auscultatory method *3	

\*1. Deflation rate adjustment. see page 15

\*2. Pressure accuracy check. see page 16

\*3. Comparison with auscultatory method. see page 18

## 9. Deflation rate Adjustment

Raise the pressure to around 200 mmHg and begin to release the air. Adjust so that the descent from 160 mmHg to 80 mmHg takes 20 to 30 seconds. (A shorter method is to measure from 160 mmHg to 140 mmHg and control it to 3.5 to 5.3 seconds.) As shown in Fig 7-1 turn the slot (1) with a screwdriver.

Deflation Rate	Adjustment
Increase	Counter clockwise
Decrease	Clockwise

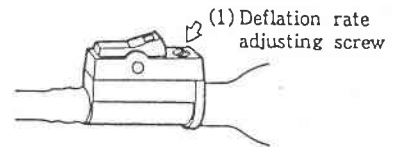


Fig.7-1 Deflation rate adjustment

If adjustment cannot be made within this range, replace.

## 10. Pressure Accuracy Check

Compare the reading with standard pressure gauge.

- a) Connect the unit to the standard gauge as shown in Fig.8-2
- b) Wait for "Inflation" and "O" for the cuff pressure.
- c) Raise pressure to "300 mmHg" and confirm product display "300 mmHg  $\pm$  3mmHg".
- d) To be "150 mmHg" next and confirm product display "150 mmHg  $\pm$  3 mmHg".
- e) To be "O" and confirm product display "O or 1 mmHg".
- f) Deflation must be slow, Mercury column must not bounce.
- g) When accuracy exceed  $\pm$  3 mmHg, replace the circuits board.

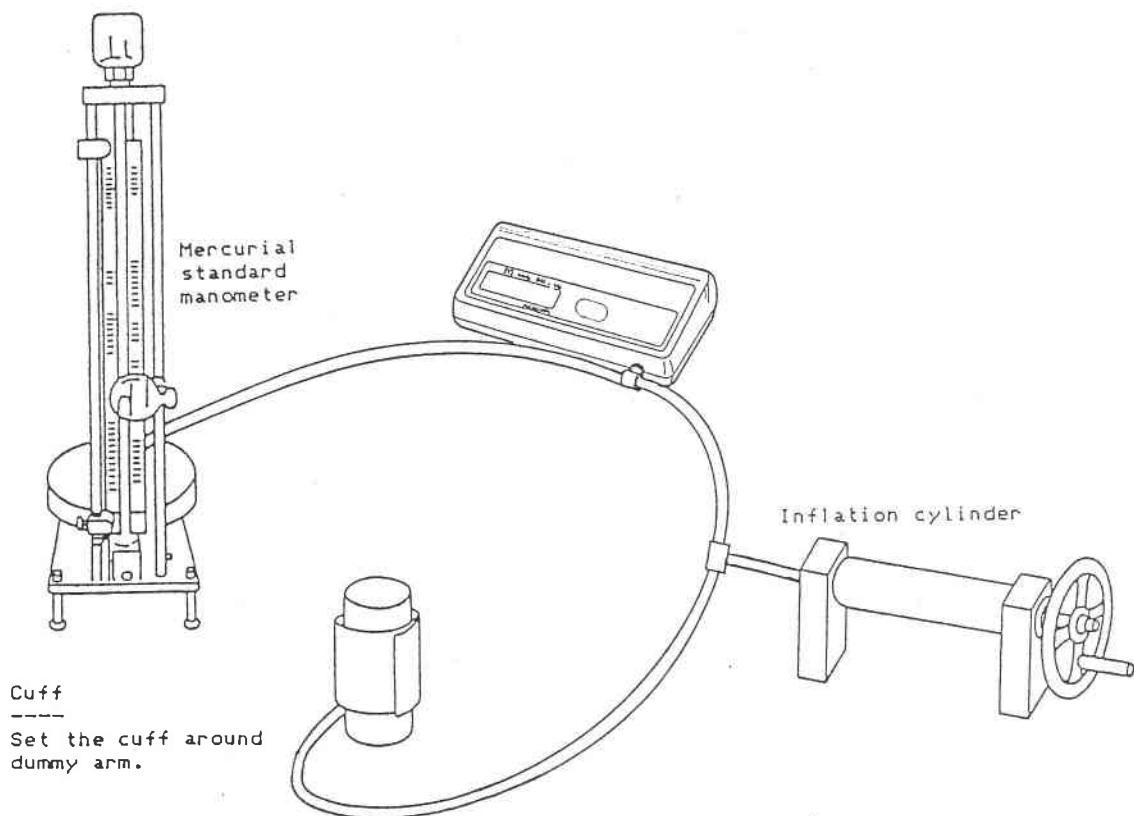


Fig. 8-2



## 11. Comparison with Auscultatory Method

Reference : AAMI STANDARD-----See next page.

Subject : 3 persons minimum.

### 3.4 Performance Requirements

3.4.1 Pressure Transducer/Indicator<sup>1</sup> Accuracy. The pressure indicated by the device under test, in the range of 0 - 250 mm Hg, shall not vary from the pressure indicated by the reference standard, as expressed in millimeters of mercury, by more than  $\pm 3$  mm Hg or  $\pm 2$  percent of reading, whichever is greater.

*NOTE: If a zero or range control is provided, proper instructions for operation and verification must be attached to the device as a highly visible label. If the zeroing function is performed automatically, then the device must automatically reset to zero when required and meet the accuracy requirement of this section without operator intervention.*

3.4.2 Overall System Efficacy. The manufacturer shall determine, for purposes of design qualification, that the overall performance of the system meets the following requirement: Mean pressure measurements obtained by the system shall, over a range of 60 mm Hg (diastolic) to 180 mm Hg (systolic), be within a  $\pm 5$  mm Hg mean difference, with a standard deviation of  $\pm 8$  mm Hg, of the mean measurements obtained by the auscultatory method or by direct pressure measurements via indwelling arterial catheters (see test method 4.4.2 and Appendices B and C).

3.4.3 Requirements for Battery-Powered Devices. Battery-powered devices shall incorporate either means of detecting battery condition or means of protective shutdown in case of battery failure. Any of the following methods may be used:

- (1) An operator-initiated test;
- (2) An automatic indication of impending power system degradation;

---

The indicator may be a manometer.

subject to deflate the cuff can be verified by visual inspection.

4.3.2 Electrical Safety. Test methods for determining current leakage are provided in the American National Standard, *Safe Current Limits for Electro-medical Apparatus*, ANSI/AAMI SCL-12/78.

4.3.3 Inhalation Anesthetics. Test methods for the requirement of 3.3.3 are provided in the National Fire Protection Association's *Standard for the Use of Inhalation Anesthetics (Flammable and Nonflammable)*, NFPA 56-A.

#### 4.4 Performance Requirements

4.4.1 Pressure Transducer/Indicator Accuracy. The accuracy of the pressure transducing/indicating system is determined by applying a "Y" adaptor to the pressure line and attaching a reference standard having a maximum error of  $\pm 0.5$  mm Hg and traceable to the National Bureau of Standards. The line pressure is then stepped in not more than 30-mm Hg intervals, in the manner in which the device is used, and the accuracy of the indicated pressure with respect to the reference standard is determined.

4.4.2 Design Verification of Overall System Efficacy. The efficacy of the overall system shall be determined by statistically comparing the blood pressure measurements obtained with the system to those obtained by either (1) the auscultatory method, or (2) direct blood pressure measurements via indwelling arterial catheters.

For either method, a sufficiently large and diverse subject group must be used in order to allow a high level of confidence (a mean difference and standard deviation of less than or equal to 5 mm Hg  $\pm$  8 mm Hg) over a blood pressure measurement range of 180 mm Hg (systolic) to 60 mm Hg (diastolic). The subject data base and method shall be documented, and in no event shall it contain less than 50 individuals for method (1) and 15 individuals for

method (2).

Technical recommendations for conducting these comparison tests are provided in Appendix B (the auscultatory method) and Appendix C (the direct blood pressure measurement method) of this standard.

*NOTE: Due to the complexity of these tests, these methods for determining overall system efficacy are not intended for quality assurance purposes. It is intended that they be used for design qualification only.*

4.4.3 Battery-Powered Devices. That means have been provided by the manufacturer to detect battery condition or to initiate protective shutdown in the event of battery failure, can be verified by visual inspection.

still heard at zero pressure, either or both of the following decisions may be made: the beginning of Phase 4 may be recorded as the diastolic blood pressure, and/or the diastolic pressure may be recorded when the sounds in Phase 4 suddenly become reduced in intensity. The selection of the diastolic criterion is determined by the device's principle of operation, which may not be based on the above definitions of diastolic pressure, but on a more accurate definition of "Korotkoff" sounds.

## B2. General Considerations in Utilizing the Auscultatory Technique for Verification of Overall System Efficacy of Electronic Sphygmomanometers

B2.1 It is recommended that all automated (electronic) devices that measure indirect arterial blood pressure have the capability of providing simultaneous, same-arm measurements with standard stethoscope mercury manometers, by allowing the connection of the automated device via a T-tube connector between the two instruments (see Figure B3).

B2.2 It should be noted that there are individual differences in both patient condition and operator proficiency, and that testing should incorporate techniques designed to lessen the errors due to such variables.

B2.3 All testing must be done by qualified personnel, and both the measurement design and results must be documented and available for inspection.

B2.4 To assure accuracy, the patient must be quiet, rested and relaxed.

B2.5 Results of such testing, utilizing a population of at least 50 subjects representing a blood pressure range of 60 to 180 mm Hg, must yield a mean difference in simultaneous measurements not greater than 5 mm Hg, with a standard deviation not greater than 8 mm Hg.

## B3. Procedure

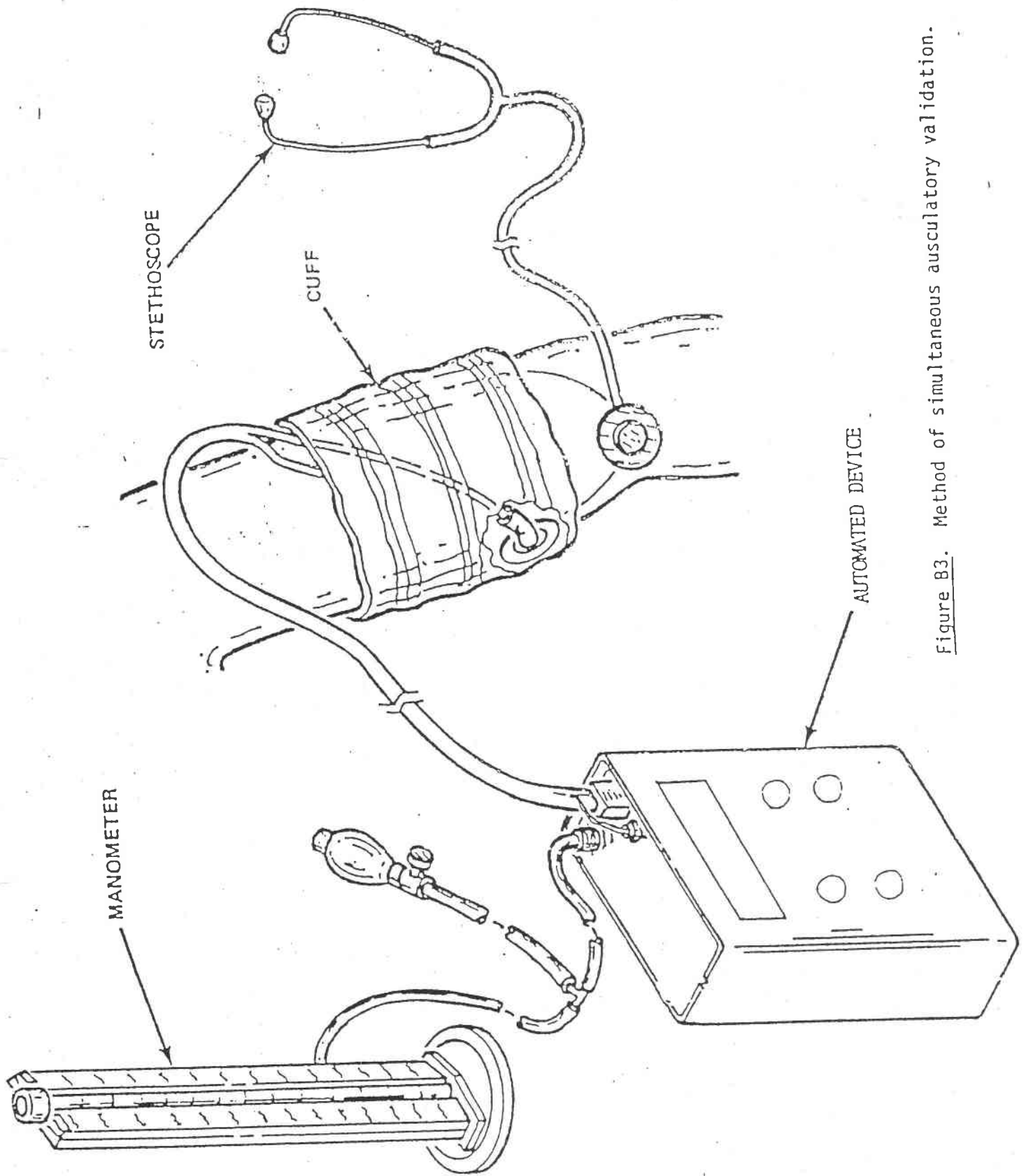


Figure 83. Method of simultaneous auscultatory validation.

B3.1 The cuff should be placed on the bare upper arm over the brachial artery of the subject, and wrapped snugly so as to eliminate any residual air that may have been left in the bladder. Cuff placement should be firm, but not overly constricting.

B3.2 The cuff should be inflated rapidly to 100 mm Hg while the radial pulse is palpated. Stepped inflations of 20 to 30 mm Hg should continue until the radial pulse has been occluded by the cuff pressure. This occluding pressure should be noted, and the cuff deflated. A sufficient time should elapse as to allow return of normal circulation (at least 30 seconds).

B3.3 The cuff should then be inflated to a pressure 30 mm Hg higher than the previously recorded occluding pressure, and the bleed valve should be opened to allow deflation at a rate of approximately 2 to 4 mm Hg per heart beat or 3 mm Hg per second.

- NOTES: (1) *Assure that upon opening of the valve at the upper pressure range, the initial escape does not exceed the above deflation rate.*
- (2) *The valve must be manipulated in such a manner as to continue a linear deflation rate of 2 to 4 mm Hg per heart beat throughout the measurement period. (It should also be noted that as the pressure in the cuff decreases, the valve opening must be changed to assure this linear rate.)*

B3.4 With the stethoscope placed over the brachial artery distally, systolic pressure is to be recorded when the first Korotkoff sound is detected. Diastolic pressure is to be recorded at the onset of either the fourth or fifth phases of the Korotkoff sounds, or under other conditions, depending on the device's principle of operation.

#### B4. Major Sources of Error

Major sources of error for the auscultatory technique include the following:

- (1) Inappropriate cuff/arm relationship;
- (2) Stethoscope or transducer not over the brachial artery;

- (3) Hearing acuity and/or incorrect technique of the operator;
- (4) Agitated or talking patient;
- (5) Cuff deflation that is too fast.

For example, in the case of (5), assume a patient's systolic pressure is actually 149 mm Hg at a given time and the heart rate is 60 beats per minute. The chart below illustrates how the cuff deflation rate can contribute to measurement error:

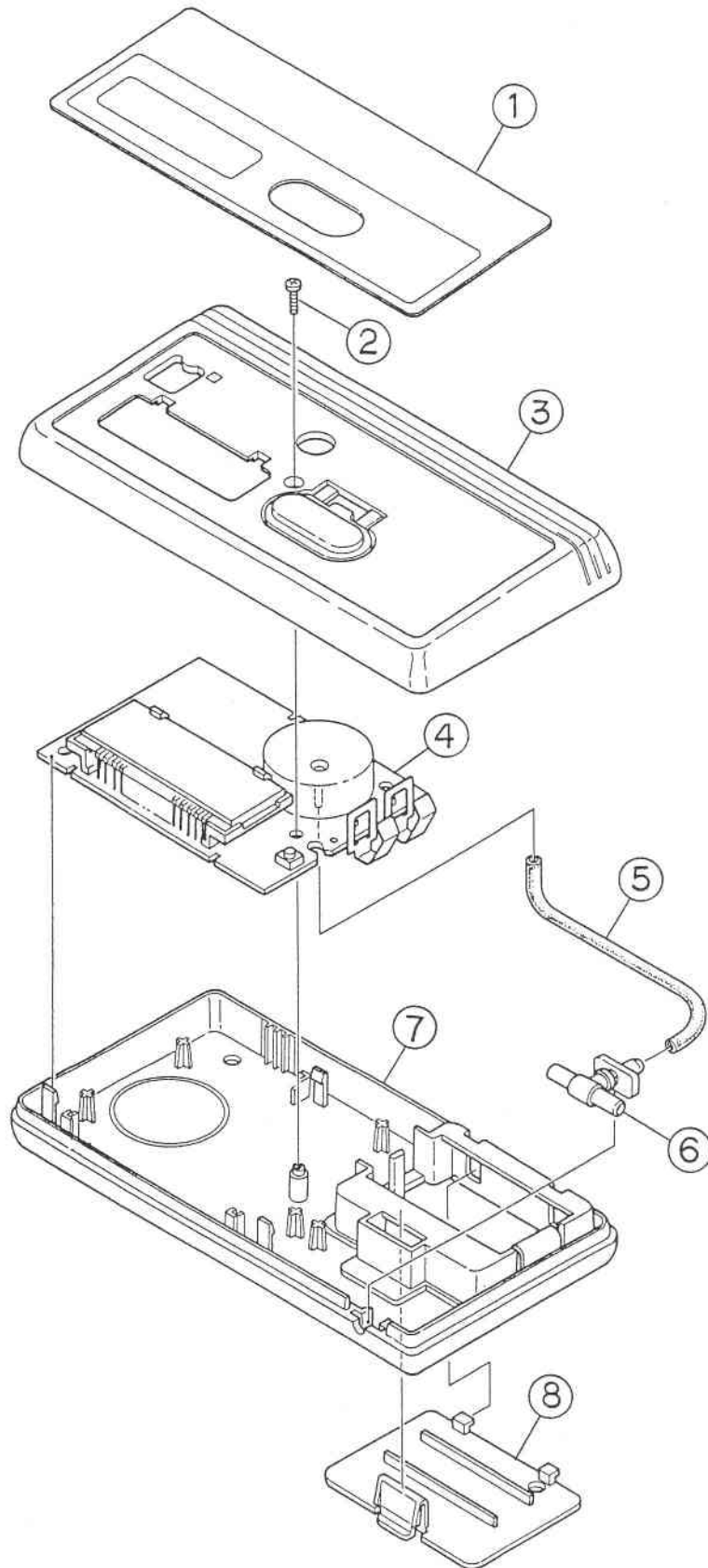
Deflation rate per second:	10 mm Hg	3 mm Hg
Cuff pressure 150 mm Hg:	No K sound	No K sound
First K sound produced:	140 mm Hg	147 mm Hg

In the above simplified example, the first operator, using a 10-mm-Hg-per-second deflation rate, recorded a systolic pressure of 140 mm Hg (9 mm Hg below the actual pressure of 149 mm Hg); while the second operator, using a correct deflation rate, recorded a systolic pressure of 147 mm Hg (2 mm Hg below actual).

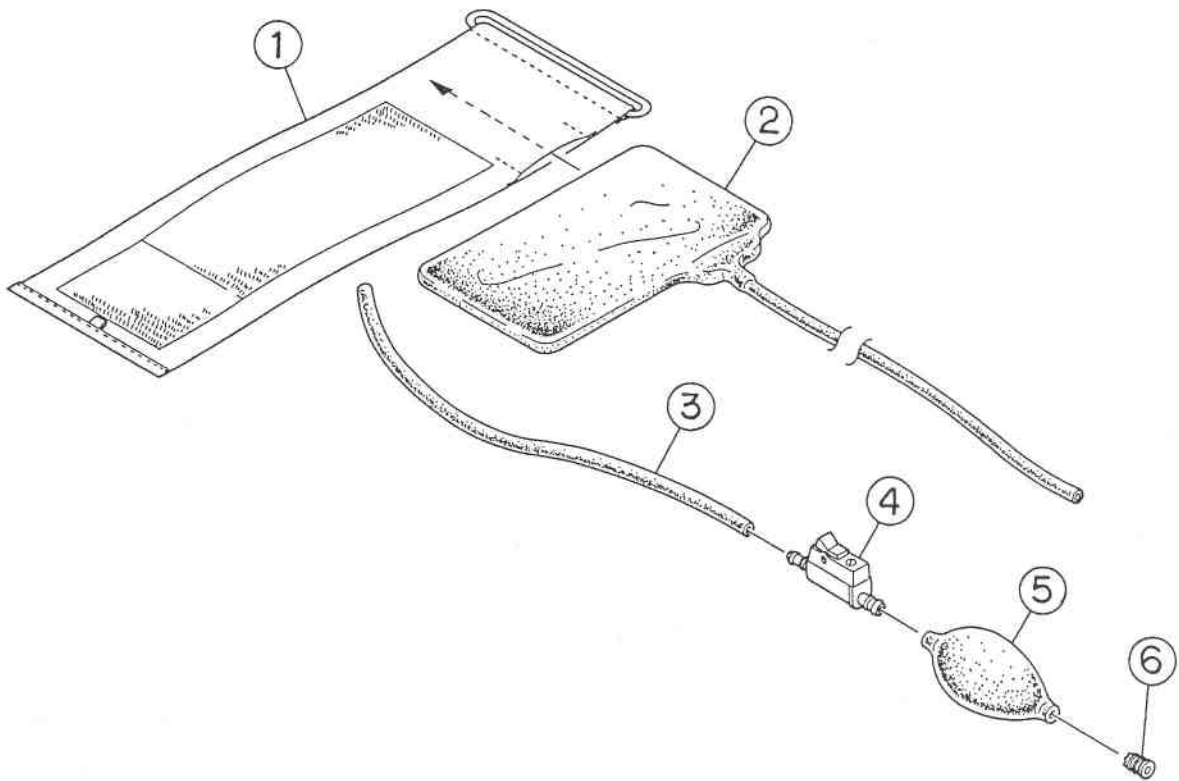


# Component Drawing and Parts list

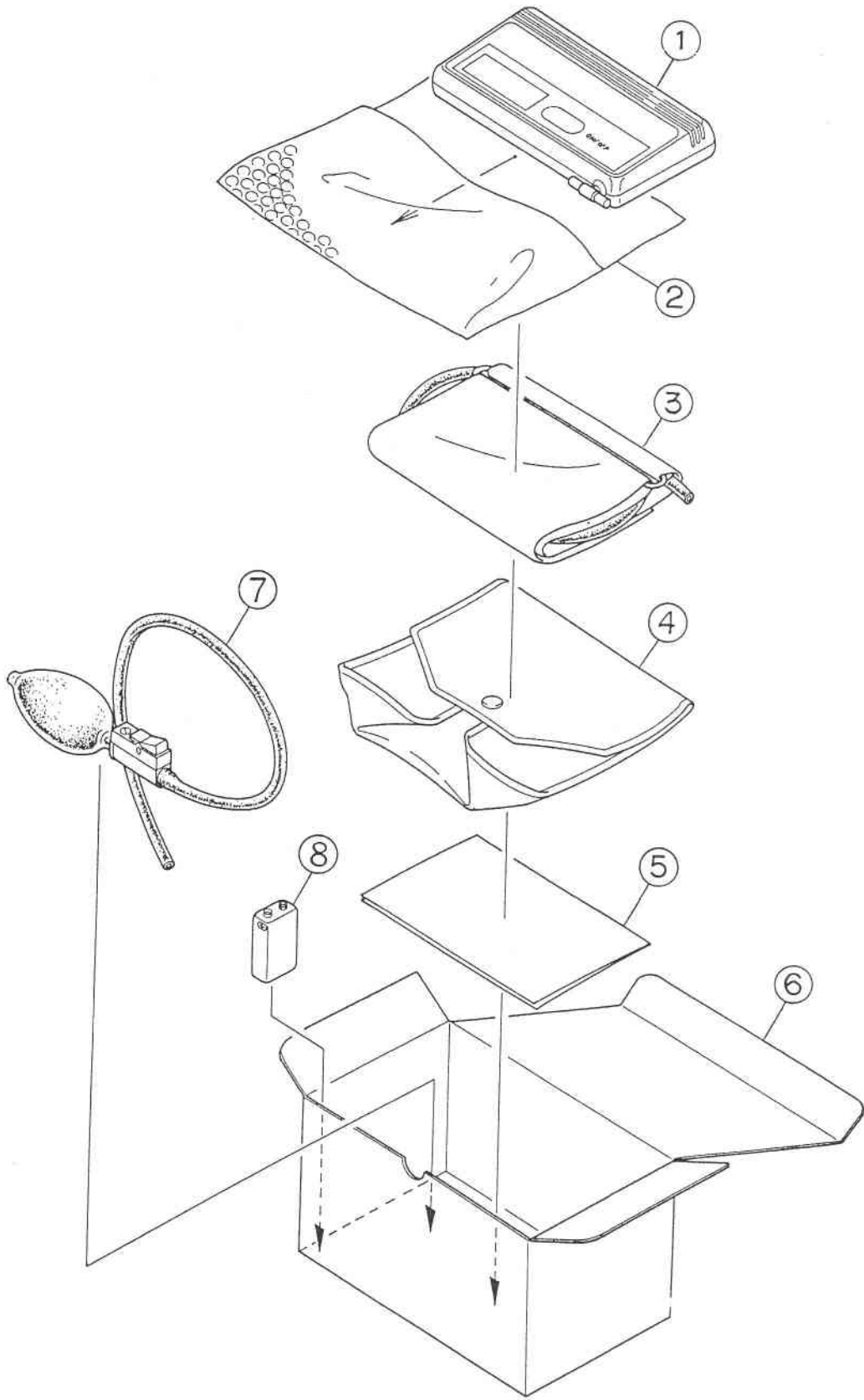
## Main unit exploded view



# Cuff unit exploded view



Packing exploded view



Main unit parts list.

No.	Parts name	Parts No.	Quantity/unit
1	Panel	60036PS	1
2	Screw	47873PM	1
3	Upper case	60035PM	1
4	circuits board	47509BM	1
5	Air tube	60024PM	1
6	Air connector	47327PM	1
7	Bottom case	47325PM	1
8	Battery cover	47326PM	1

Cuff unit parts list

No.	Parts name	Parts No.	Quantity/unit
1	Cuff	40531BM-385	1
2	Bladder	45345PM-031	1
3	Air tube	30009PM	1
4	Air control valve	48214AM	1
5	Inflation bulb	30036PM-001	1
6	Intake valve	45347AM	1

Packing unit parts list

No.	Parts name	Parts No.	Quantity/unit
1	Main unit	(DS-106E-01)	1
2	Air pack	44568PM	1
3	Cuff assembly	46286AM	1
4	Storage case	41640PM-144	1
5	Instruction sheet	60031PM-1846	1
6	Retail box	60136PM-883	1
7	Inflation bulb assembly	46288BM	1
8	Battery	38002PE	1