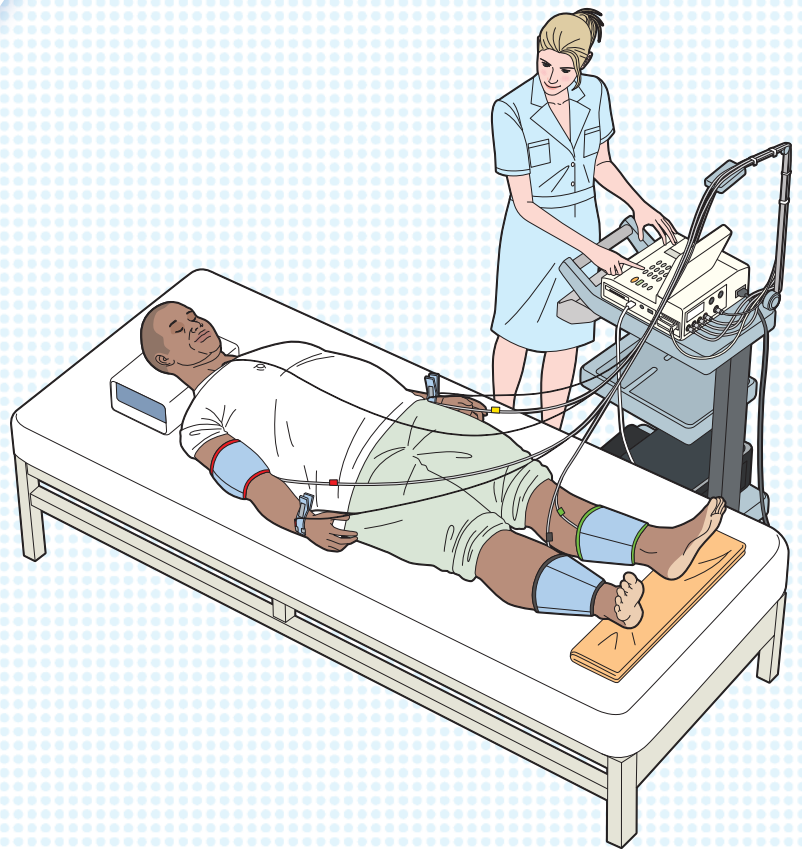


A Guideline for using
TM
VaSera
more effectively

What to do and check
when taking measurements



In special cases, the following may be taken into consideration

- In patients with severe arrhythmia, there may be some variation in the data.
- When taking measurements after administration of medications, (for example, vasodilators) it may affect the results of CAVI measurements.
- CAVI measurements cannot be performed for patients with Arteriosclerosis Obliterans (ASO).
- If the patient has asthma, noise may get into the heart sound and prevent a good measurement.
- Heart sound may not be picked up accurately in patients with aortic stenosis or aortic insufficiency
- Pay attention to the size of the cuffs and how the heart sound microphones are set for extremely obese or extremely thin patients.

Cautions regarding dialysis patients

Do not wrap the cuff on the brachial with the shunt in it.

Make sure to exclude the area with the shunt when setting the measurement position.

NOTE

Refer to the notes in the operation manual included with the equipment before use.

Please read this manual before using VaSera to gain better performance.

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You can significantly improve the precision of CAVI and ABI measurement day-to-day by checking the above matters. Please make sure to perform measurements according to the manual.

Refer to the user's guide attached to the equipment regarding other measurements.

1 Confirmation before measurement

1 Clothing at time of measurement

Please perform the test with the patient wearing light clothes (T shirt, shirt, etc. are acceptable).

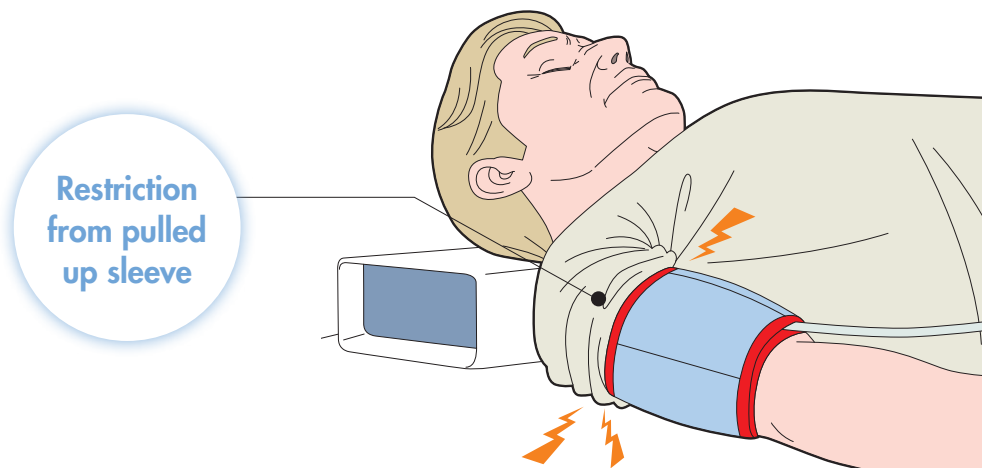
If the patient is only wearing a light shirt, there is no problem with wrapping the cuffs over the shirt.

The ideal clothing is an examination gown.

In the following cases, measurement precision may be affected.

If the sleeve of a thick sweater, etc. is rolled up, the brachial may be constricted, and it unables normal measurement. Make sure to have the patient remove any heavy clothing before taking measurements.

× Bad example



Start the measurements after the patient has removed clothing that constricts the body (stockings, etc.) as well as shoes and socks.

If the body is constricted with tight stockings, etc., it may not be possible to accurately measure the pulse waveform.

2 Room temperature of the examination room

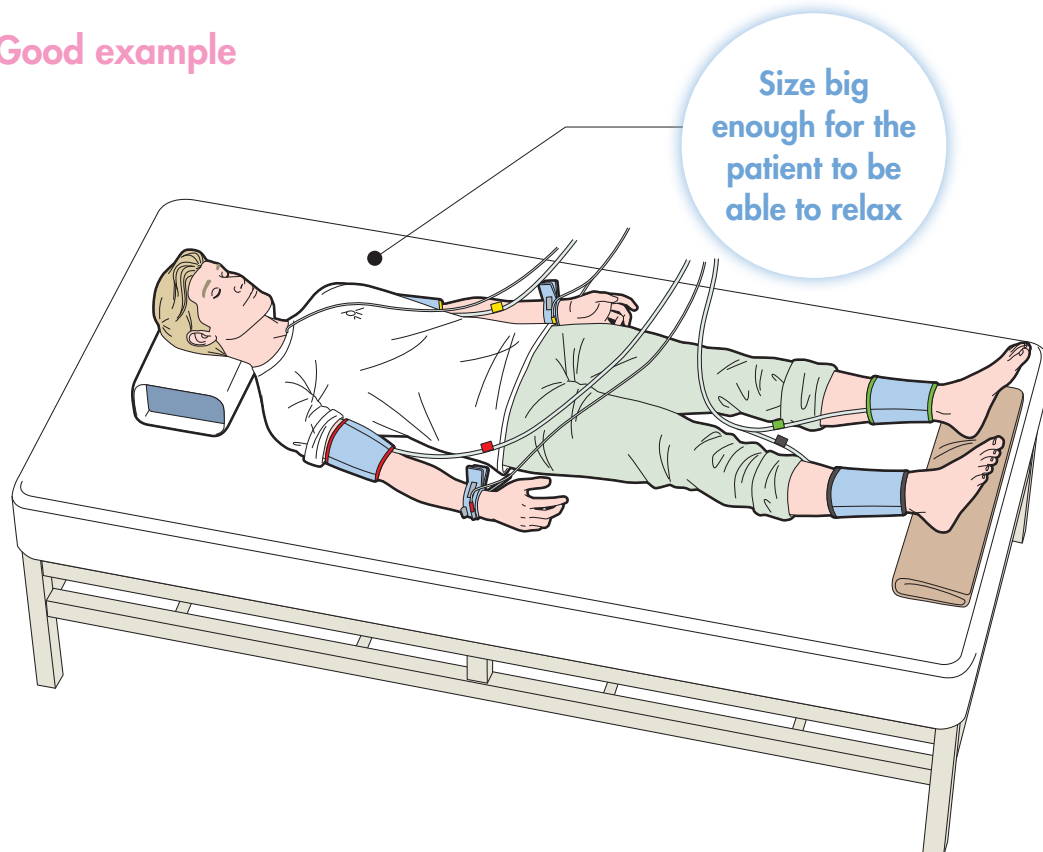
Keep the room temperature at about 25°C.

3 Resting time before the measurement

Make sure that the patient rest for at least five minutes.

The CAVI value falls immediately after exercise. Therefore, only start the measurements after the patient has rested for about 20 minutes after any exercise.

☉ Good example



KEY POINTS

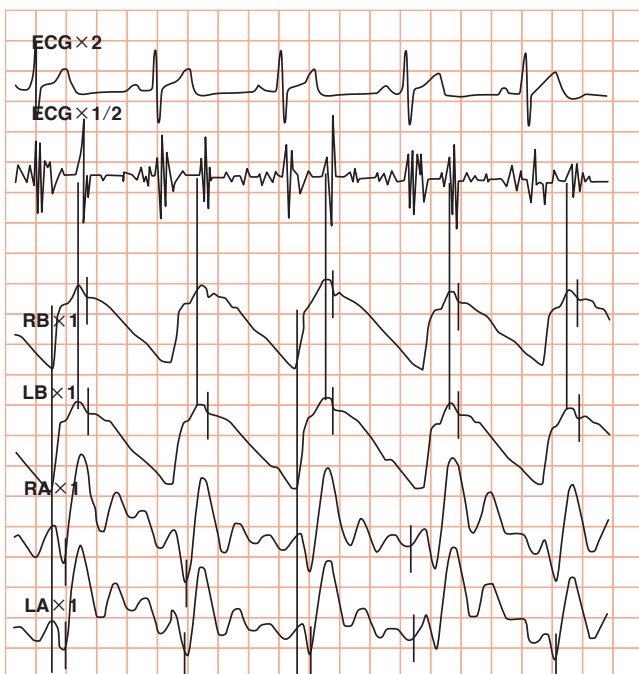
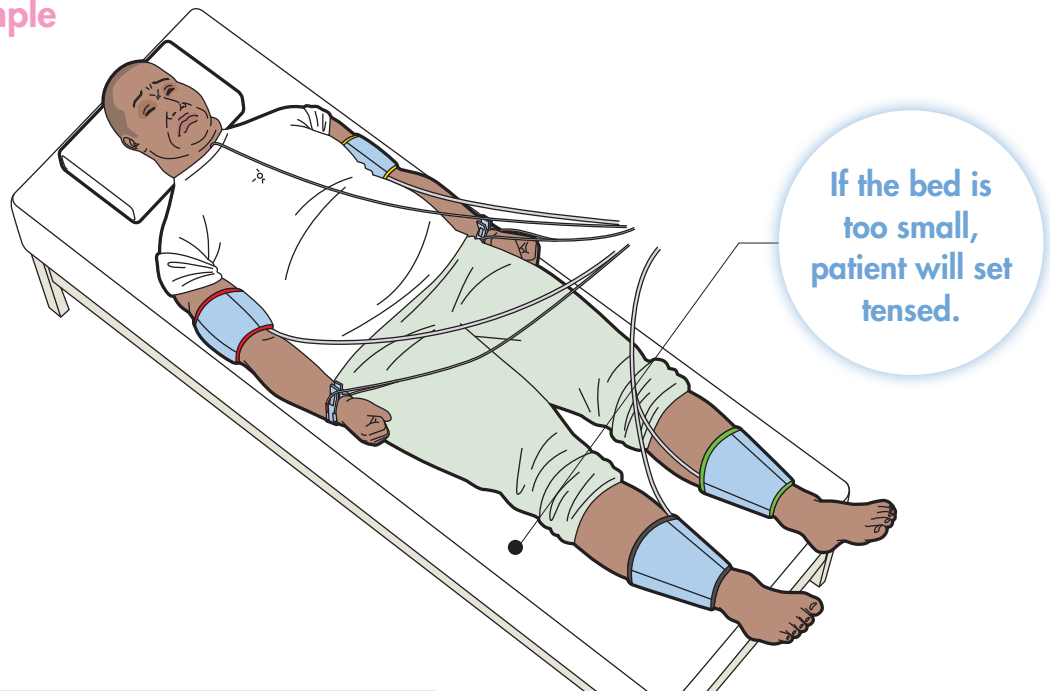
- ➔ A bath towel can be used to raise the ankles from the bed.
- ➔ If the pulse is still weak, then use a limb cushion.
- ➔ Do not perform measurements immediately after the patient smokes.
- ➔ The CAVI value tends to fall if the patient is asleep during measurement. Start the measurements after explaining to the patient that he/she should not sleep during the examination.
- ➔ Heart sound is also measured. Make sure that the patient does not speak during the measurement.
- ➔ Make sure that the patient does not move (except in case of an emergency).

4 Confirmation of bed size

Have the patient lie face up on a wide bed for the examination.

If a person with a large body has to squeeze their arms up against their body because the bed is too small and excessive effort is made by holding the arms and legs in place, the blood pressure and pulse wave cannot be measured accurately.

× Bad example



This is an example in which the lower limbs moved during the measurement, causing noise to the pulse wave. The picture shows noise on the pulse waves of both ankles.

CAVI cannot be measured accurately with a waveform like this.

The body may move for various reasons. In some cases, the patient tries to force his/her body onto a narrow bed, resulting in body movement.

2 How to wrap the cuffs

ATTENTION

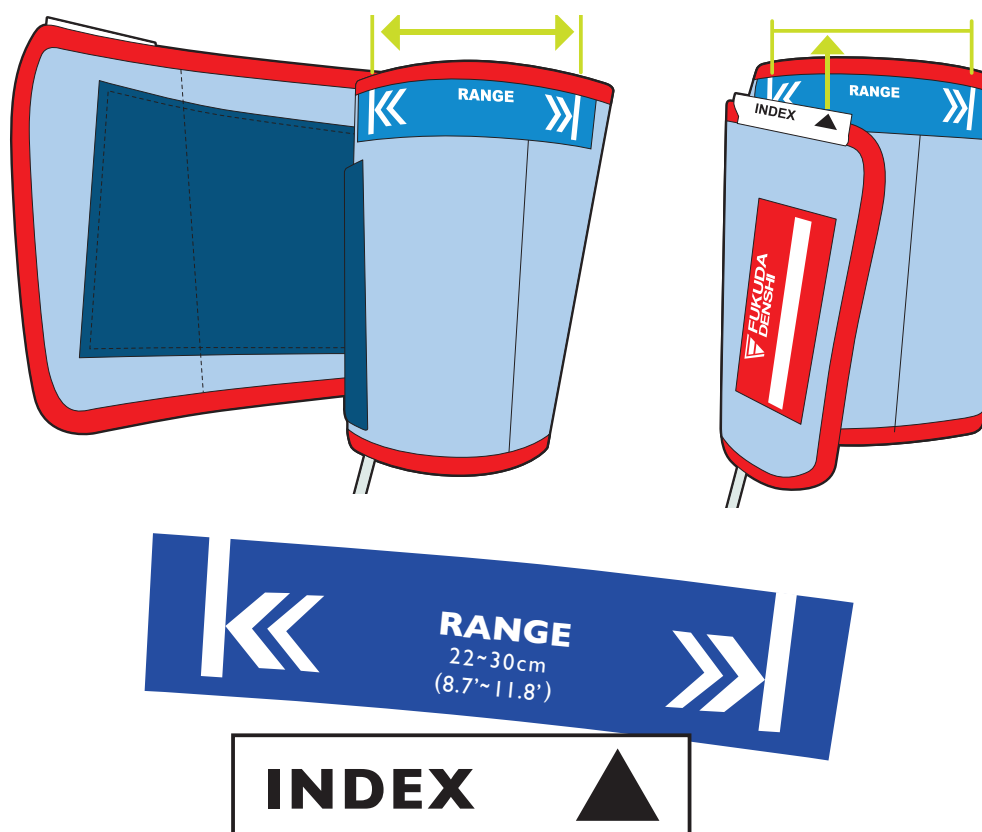
Attention should be made when wrapping the cuffs.
Make sure to follow the following points below.

1 Size and range of cuffs used

Use only cuffs that fits the brachia and ankles of the patient.

The cuffs used, are the right size if the INDEX mark (▲) is within the RANGE zone when the cuffs are wrapped over the brachial or ankle.

(Refer to the attached table for detailed cuff sizes, and brachial, ankle circumferences.)



Use cuffs where the ▲ mark is within the RANGE zone when the cuffs is wrapped as specified.

The cuffs come in S, M, and L sizes. (Only M and L sizes for ankles)

2 How to wrap the cuffs

The cuffs are labeled for the right brachial, left brachial, right ankle, and left ankle. Please refer to the colour of the edges of the cuffs to attach them to the correct limbs.

Right brachial: **red**, Left brachial: **yellow**, Right ankle: **black**, Left ankle: **green**

Size of cuff and circumference

Type	Position, size	Length of applicable brachial circumference /ankle circumference
CUF-129SR	Right brachial, S size	17 to 22cm (6.7" to 8.7")
CUF-129SL	Left brachial, S size	
CUF-129MR	Right brachial, M size	22 to 30cm (8.7" to 11.8")
CUF-129ML	Left brachial, M size	
CUF-138MR	Right ankle, M size	20 to 30cm (7.9" to 11.8")
CUF-138ML	Left ankle, M size	
CUF-129LR	Right brachial, L size	30 to 39cm (11.8" to 15.4")
CUF-129LL	Left brachial, L size	
CUF-138LR	Right ankle, L size	30 to 42cm (11.8" to 16.5")
CUF-138LL	Left ankle, L size	

ATTENTION

If the cuff used do not fit the size of the brachial circumference or the ankle circumference, blood pressure cannot be measured correctly.

If the cuff used is too small for the brachial or ankle of the patient, blood pressure measurement will be high and the CAVI value cannot be measured accurately.

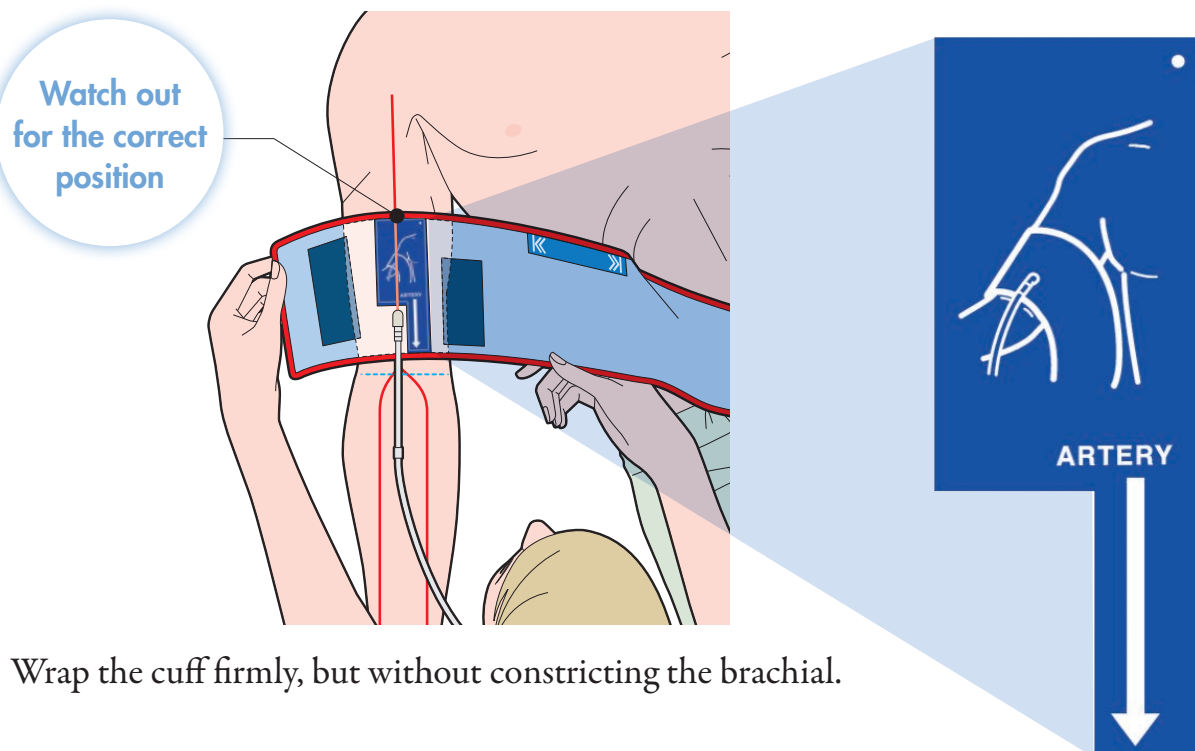
2 How to wrap the cuffs

The cuffs are designed exclusively for the blood pressure pulse wave test. Wrap them correctly while referring to the following instructions.

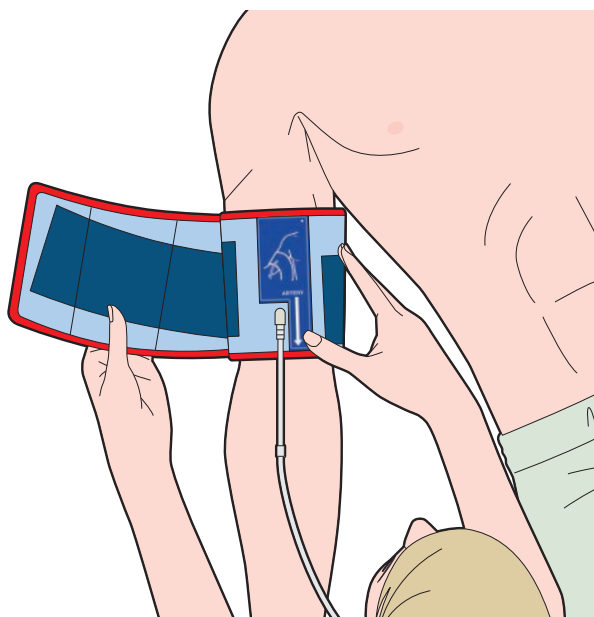
1 How to wrap the cuffs on the brachia.

Make sure that the air hose outlet of the cuff is lined up with the center of the brachial artery blood vessels on the inside of the brachium.

Position the cuff so that the bottom side of the cuff is immediately above the joint (the line when the elbow is bent).



Wrap the cuff firmly, but without constricting the brachial.

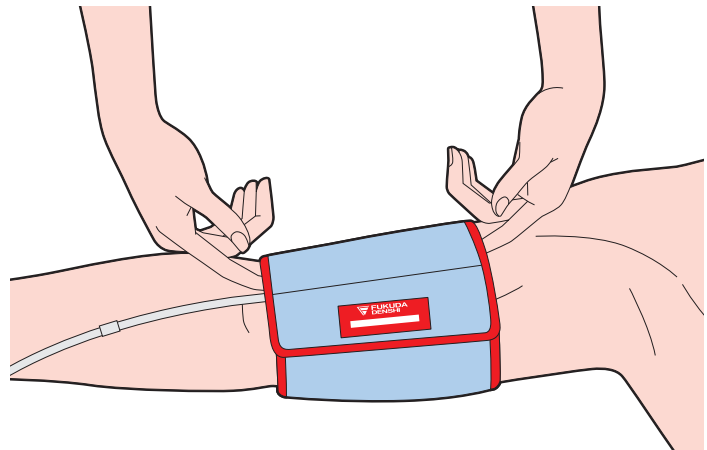


Wrap the cuff tightly without leaving any gaps.

2 How to wrap the cuffs

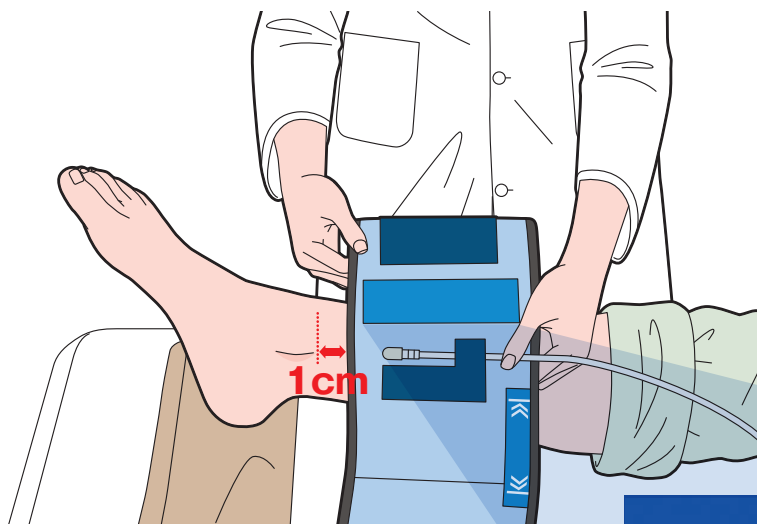
Wrap the cuff tight enough so that your finger cannot go all the way inside.

Your finger may go in up to the first joint only.



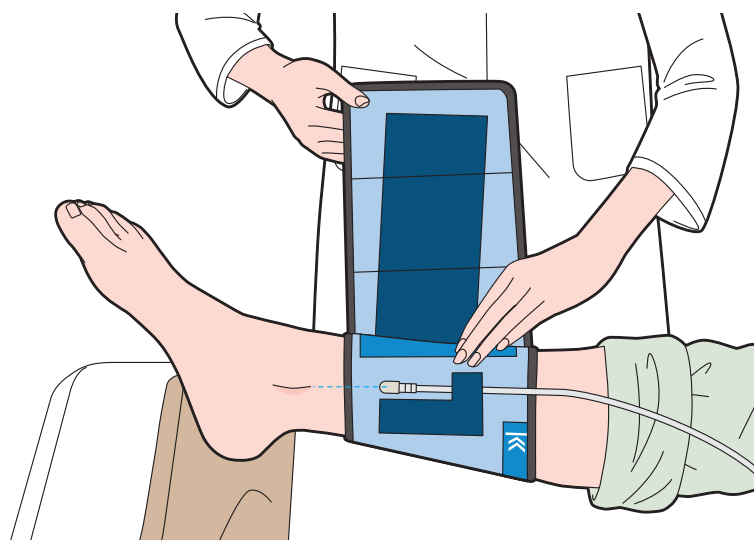
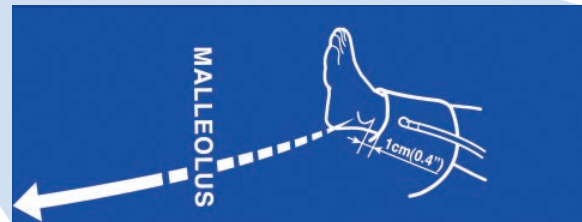
② How to wrap the cuffs on the ankles

Position the cuff so that its bottom edge is 1 cm above the malleolus.



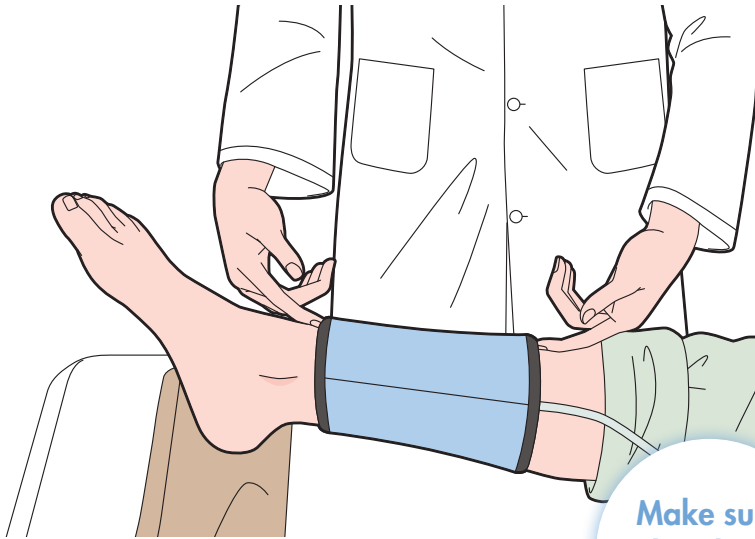
Make sure that the hose outlet is extending upward from the medial malleolus.

If you wrap the cuff correctly, the arrow on the label points at the malleolus.



The ankle cuffs are easier to wrap if the patient bends his/her knees.

Firmly attach both the upper edge and lower edge of the cuff with the same strength so that there are no gaps.



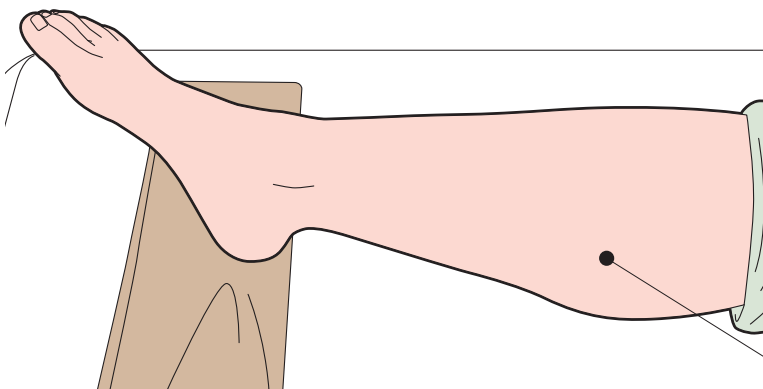
Firmly wrap the cuff while ensuring that it does not constrict the ankle, and confirm that your finger cannot enter between the cuff and the ankle.

Also make sure that both the upper and lower edges of the cuff have no gap

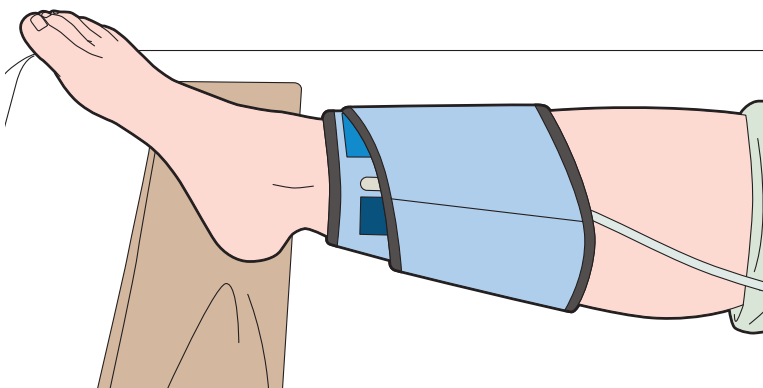
Make sure that there are no gaps

③ Another way to wrap the ankle

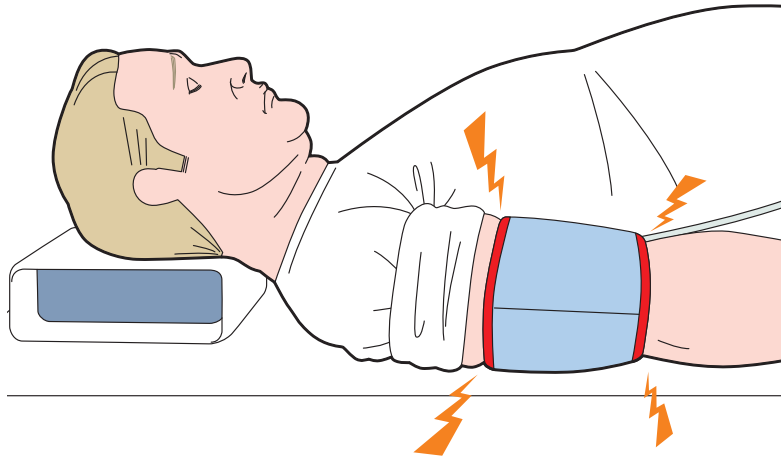
When the circumference of the ankle is smaller than the calf, wrap the cuff slightly in a spiral shape (see picture below) so that uniform pressure is applied to the top and bottom of the cuff and also to prevent a gap between the cuff and the ankle.



if the circumference of the ankle is smaller than the calf



✗ **Bad example**



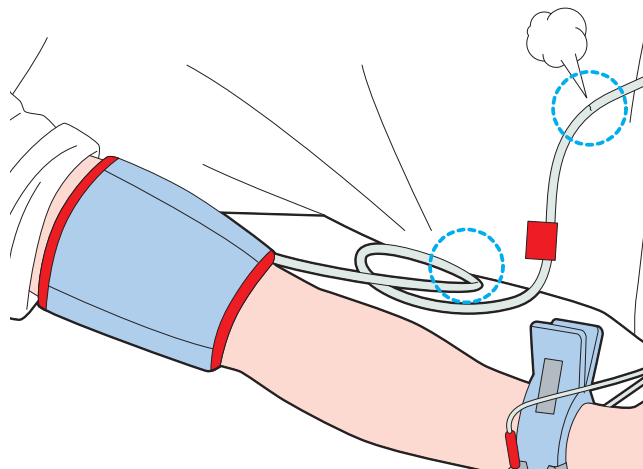
As shown in the illustration, if the cuff is too tight or a cuff with the wrong size is used, the blood pressure and pulse wave cannot be measured correctly. Do not constrict the brachials and ankles excessively with the cuffs.

ATTENTION

It is important to wrap the cuffs firmly. However, they should not constrict the limbs excessively.

Confirm that the cuffs and air hoses are not damaged or bent before starting the measurement.

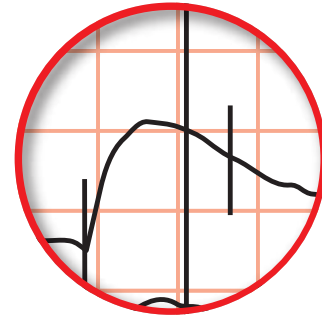
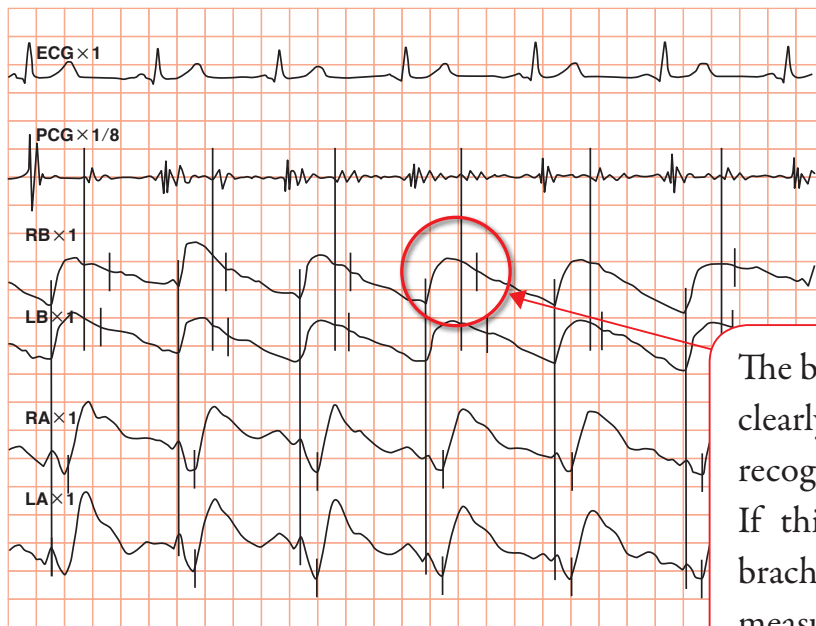
Also make sure that nothing is placed on top of the air hoses.



✗ **Bad example**

● **Example of a case with loose cuffs ①**

This is an example in which the cuffs were wrapped too loosely. And the brachial notch could not be detected, and there was big variation in the Tb (pulse wave transmission time from the aortic valve area to the middle of the brachial cuff), so the CAVI value varied greatly.



The brachial notch does not appear clearly, resulting in variation in the recognition line.

If this happens, please wrap the brachial cuffs again and repeat the measurement.

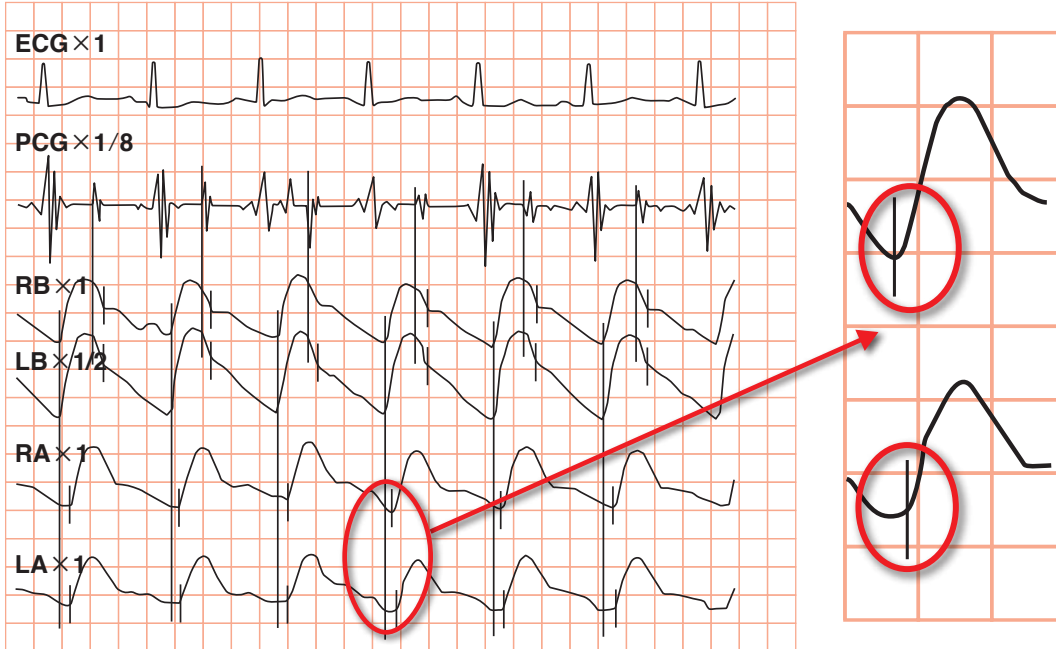
ITEM	MEAN	BEAT 1	BEAT 2	BEAT 3	BEAT 4	BEAT 5	BEAT 6
R-CAVI	◎ 5.3	× 3.2	× 6.0	5.0	5.5	5.4	5.4
L-CAVI	◎ 5.5	× 3.2	6.0	5.1	5.5	5.5	5.8
R-tb [ms]	◎ 89	× 156	84	96	91	87	85
L-tb [ms]	○ 93	95	97	88	× 149	× 71	× 74
R-tba [ms]	◎ 98	× 100	× 91	98	93	89	101
L-tba [ms]	◎ 95	× 98	91	98	93	97	98

The × indicates that there are variations in the values.

The brachial notch has not been measured, so there is a big variation in tb time.

● **Example of a case with loose cuffs ②**

This is an example in which the cuff on the left ankle was loose, preventing accurate detection of the rise of the pulse wave, and Tba (ha transmission time – hb transmission time) became longer.



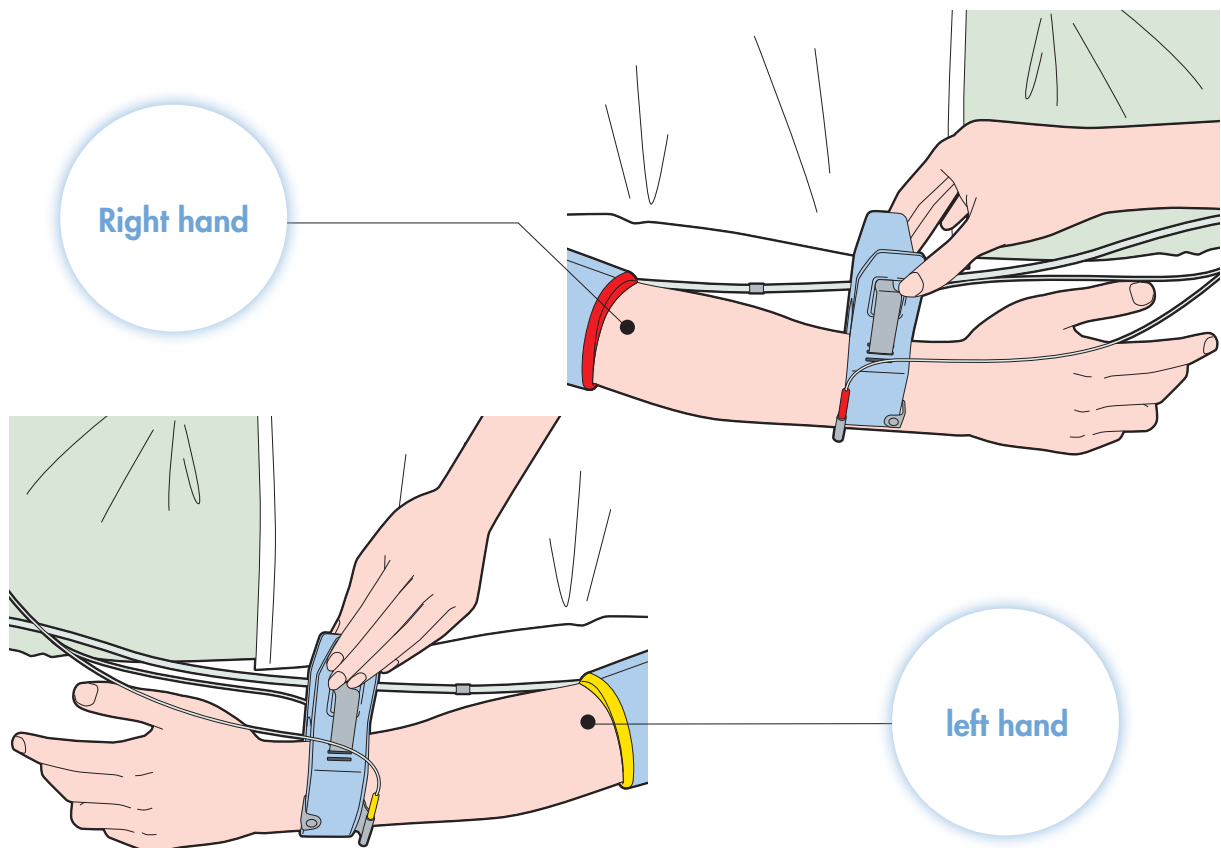
A comparison of the pulse wave rise of the left and right ankles shows that the rise of the pulse wave of the left ankles is sluggish.

If this happens, please wrap the left ankle cuff again and repeat the measurement.

3 Attachment of the electrocardiogram electrodes

Confirm that the electrode plates are not rusty or dirty before attaching the electrodes. If the skin or electrodes are dirty, the contact resistance becomes higher and the electrocardiogram will become unstable.

Attach the electrodes to the right and left hands.



KEY POINTS

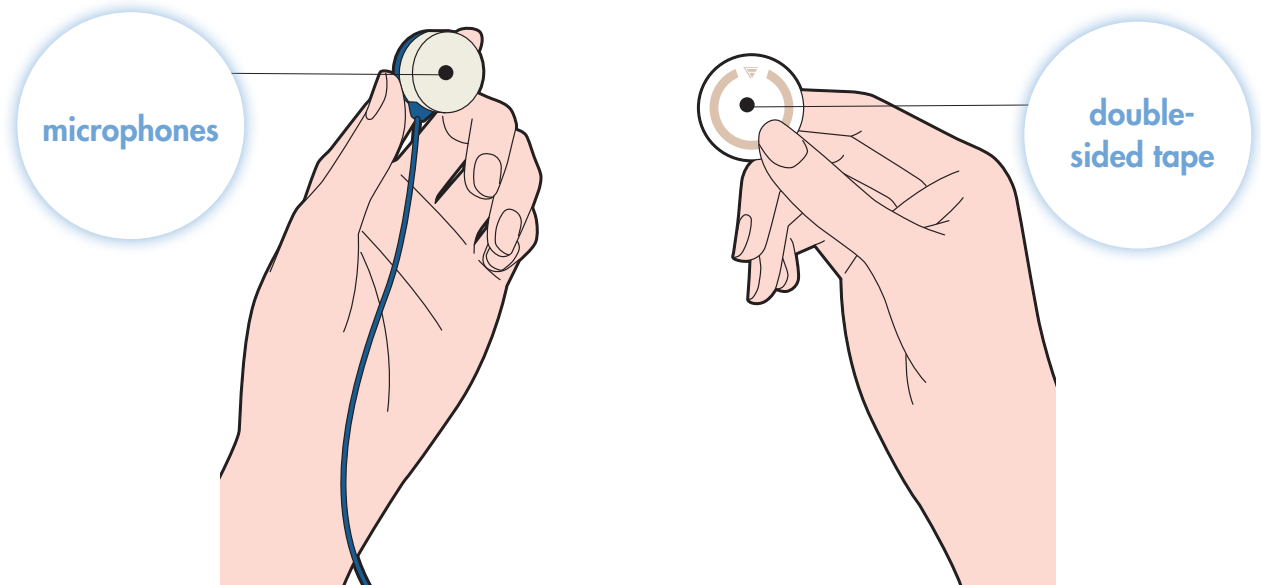
After attaching the electrodes, check on the screen of the machine that the electrocardiogram waveform is correctly displayed.

If noise is getting mixed into the waveform, check the following:

- ➔ Is the hand tense, causing the electromyogram measurements to be mixed with those of the electrocardiogram?
- ➔ Is ECG cream applied and ECG electrode pad properly attached to the electrode plates?

4 Attachment of the heart sound microphone

Firmly attach the heart sound microphone over the sternum between the second ribs using double-sided tape (DA-30).

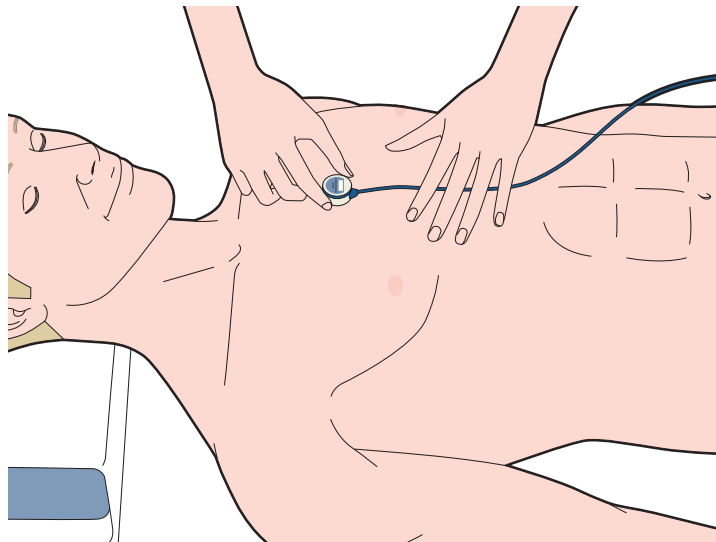
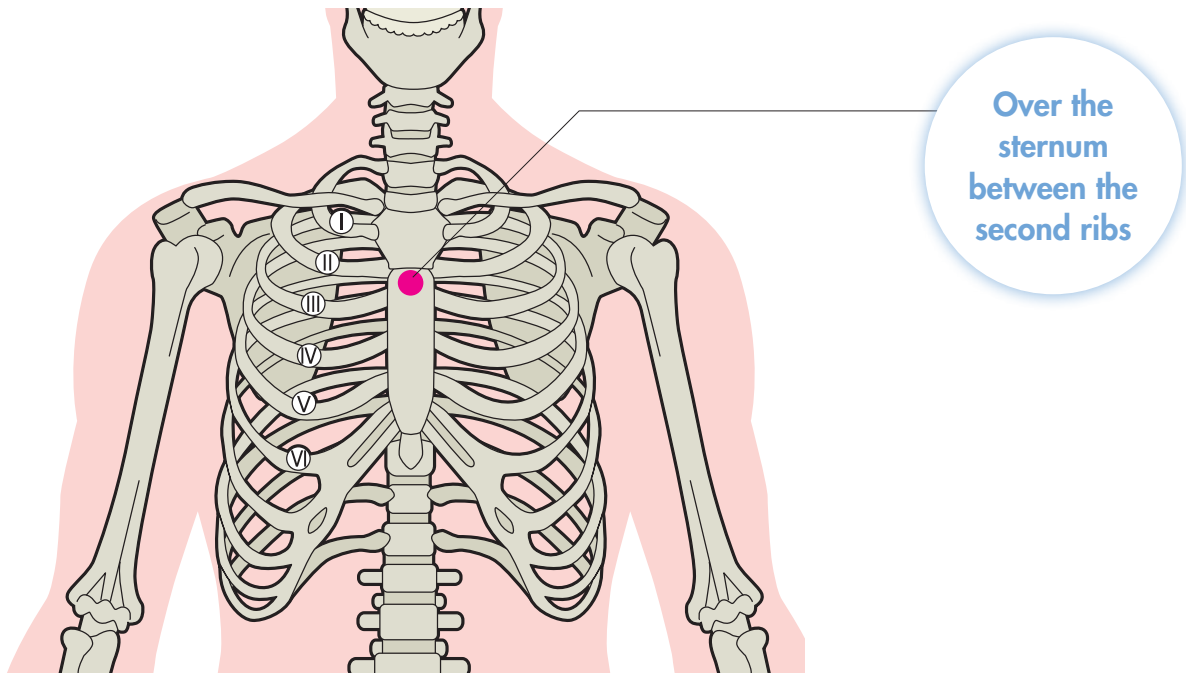


The heart sound microphone transmits the heart sound to the sensor via bone conduction. Position the sensor over the sternum and avoid spots with excessive fat as much as possible.

Before starting the measurement, confirm that the microphone has not become detached from the skin due to body movement, etc.

KEY POINTS

- ➔ Attach the heart sound microphone closely to the skin in a way that it does not become detached.
- ➔ For patients who are obese and heart sound is difficult to detect, position the microphone over the sternum at a slightly higher location. If the microphone is attached above excessive fat, the sound will not be detected.
- ➔ For patients who have thick body hair and the heart sound microphone easily becomes detached from the body, use surgical tape or a bean bag to keep the microphone close to the body.
- ➔ Make sure that the cord of the heart sound microphone does not have any tension.

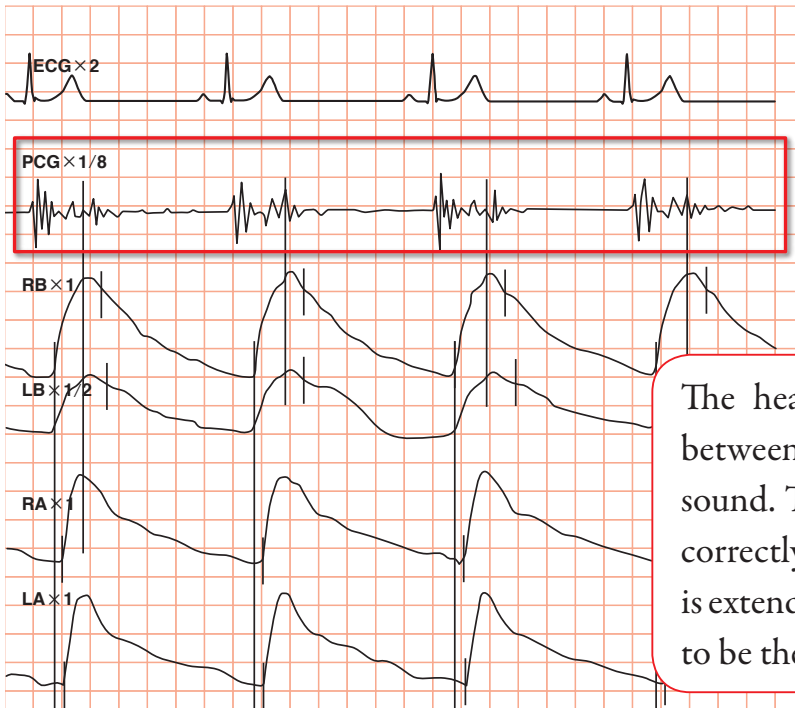


Heart sound microphone is a high-sensitivity microphone. Do not speak to the patient, and start the measurement in a quiet room.

✗ **Bad example**

● **Example of noise mixed in with the heart sound ①**

This is an example in which the heart sound is not measured correctly and noise is mixed in with the heart sound.



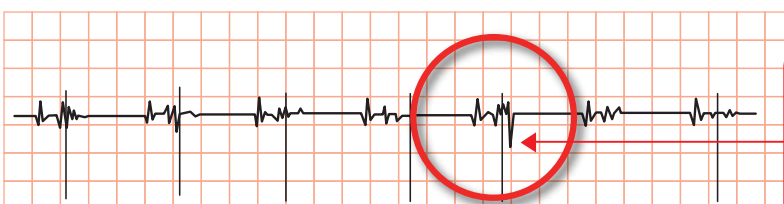
The heart sound indicates noise in between the first and second heart sound. The second heart sound is not correctly recognized, and the tb time is extended. A low CAVI value is likely to be the result.

ITEM	MEAN	BEAT 1	BEAT 2	BEAT 3	BEAT 4	BEAT 5	BEAT 6
R-CAVI	○ 4.0	× 5.0	4.0	3.9	3.9	× 5.9	
L-CAVI	○ 3.7	× 4.7	3.8	3.7	3.7	× 5.4	
R-tb [ms]	○ 126	× 102	125	126	126	× 88	
L-tb [ms]	○ 138	139	× 122	× 189	145	130	
R-tba [ms]	○ 53	× 53	52	53	53	× 53	
L-tba [ms]	○ 60	× 59	58	60	61	× 60	

The tb and tba time show a difference at each heartbeat.

● **Example of noise mixed in with the heart sound ②**

This is an example in which there is a noise in the second heart sound because the patient is a dialysis patient with valvular disease, and Tb (pulse wave transmission time from the aortic valve area to the middle of the brachial cuff) cannot be measured.



There is noise between the first and second heart sound. If the noise cannot be removed, this suspects that the patient has valvar disease.

5 Pre-test confirmation

Make sure to check the following before starting measurements.

Pre-test check

Check items	Check box
Is the room temperature optimal?	
Is the patient relaxed? Are the legs and arms free of tension?	
Is the patient refraining from speaking?	
Is the patient still?	
Is the patient awake? (Not snoring?)	
Are the surroundings quiet?	
Is the room quiet with no vibrations?	
Is the electrocardiogram and phonocardiogram free of noise?	
Is the demarcation line of the second heart sound in the correct position?	
Are the cuffs wrapped in the correct position without being loose?	
Has the patient information been entered correctly?	

ATTENTION

If the height or age of the patient information is incorrect, the vascular length and vascular age will not be calculated correctly.

6

Explanation to the patient

Make sure to provide the patient with an overview of the measurement to ensure that he or she will remain still and not be surprised during the measurement.

① Explain the test procedures.

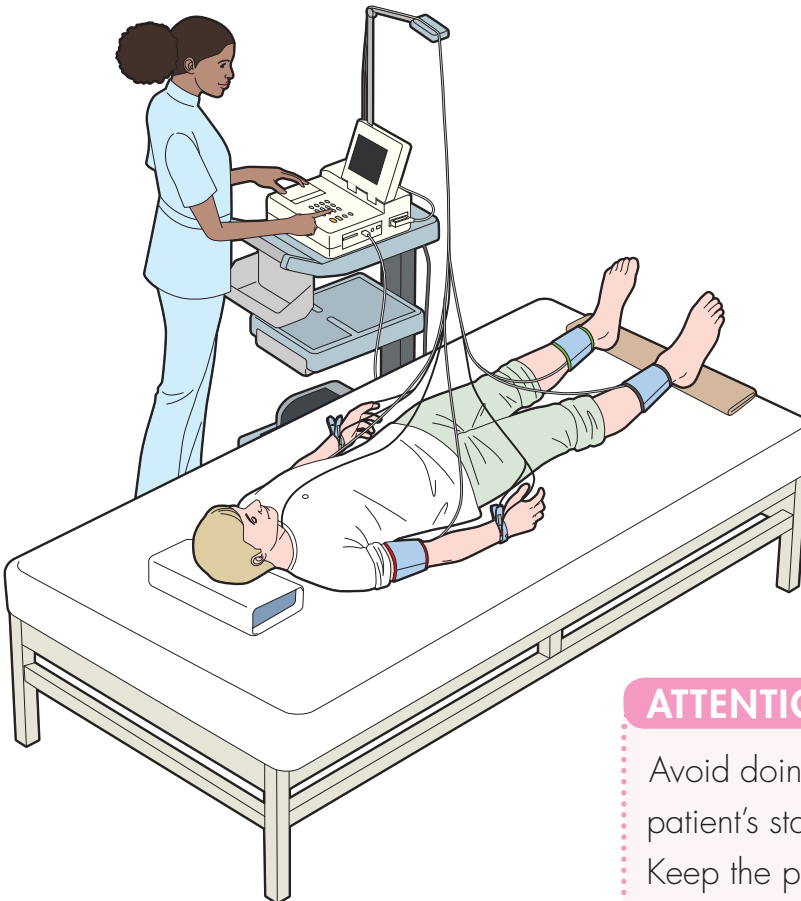
- ① CAVI measurement Application of 50 mmHg (weak) pressure to the four limbs
- ② ABI measurement (right side) Right brachial, right ankle blood pressure measurement
- ③ ABI measurement (left side) Left brachial, left ankle blood pressure measurement

The test takes approximately five (5) minutes.

Provide the patient with details of the test to avoid unnecessary stress.

Get the patient to take two or three deep breaths before starting the measurement.

② Make sure to tell the patient that the test will start before actually starting.



ATTENTION

Avoid doing anything that may interrupt the patient's state of rest.
Keep the patient from speaking or moving.

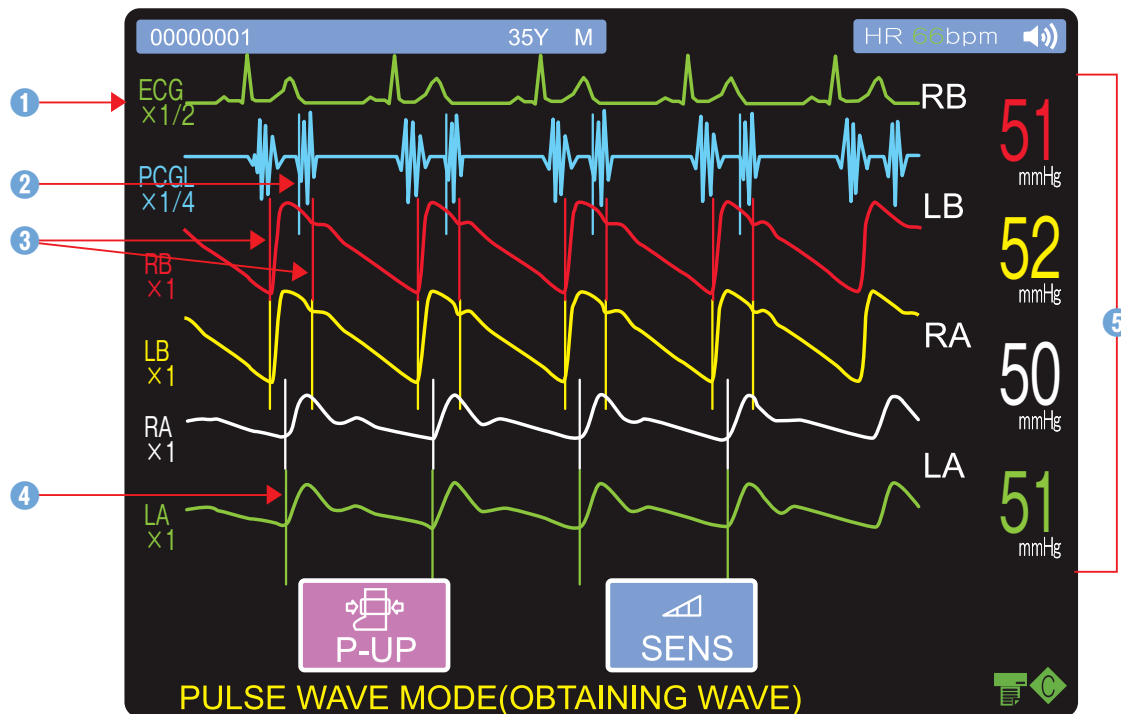
7 Check during CAVI measurement

Waveform check during CAVI measurement

Check the waveforms immediately after pressing the start button and commencing the measurement.

Confirm that each type of waveform is being accurately recorded on the screen.

The key point is to confirm that the heart sound, brachial notch, and rise of the pulse wave are detected without any problems.



Check items	Check box
Is the electrocardiogram free of arrhythmia? ①	
Is the position of the demarcation line for the second heart sound correct? Is it the sound free of noise? ②	
Are the positions of the brachial pulse wave rise and the demarcation line of the notch correct? ③	
Is the position of the demarcation line of the ankle pulse wave rise correct? ④	
Is the form of the pulse waves free of noises? ⑤	

NOTE

If there is arrhythmia, the CAVI value cannot be accurately measured. Please repeat the measurement and make sure that there is no arrhythmia before starting measuring CAVI.

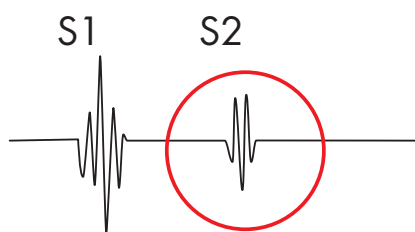
Sometimes when there is stenosis or valvular insufficiency (AS, AR), noise gets into the heart sound or the notch disappears.

Please press the "P-UP" button when the rise of the four limbs pulse wave or the notch cannot be recorded accurately.

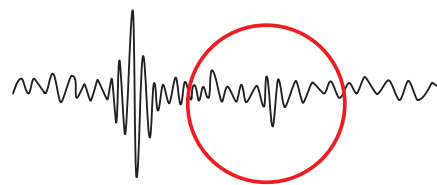
Waveform checkpoints

PCG: Check that there is a primary radical wave in the second heart sound.

Good waveform

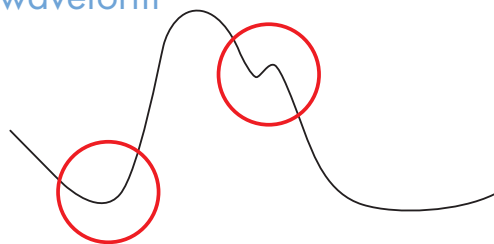


Bad waveform

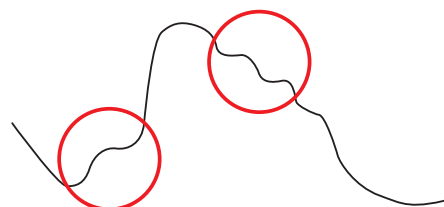


Brachial pulse wave. Check that the pulse wave rises smoothly and that there is a notch on the downward slope.

Good waveform

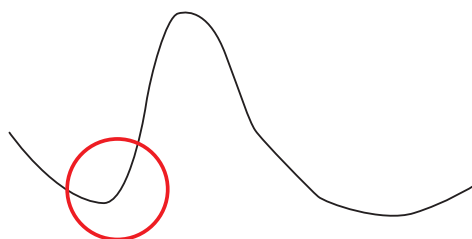


Bad waveform

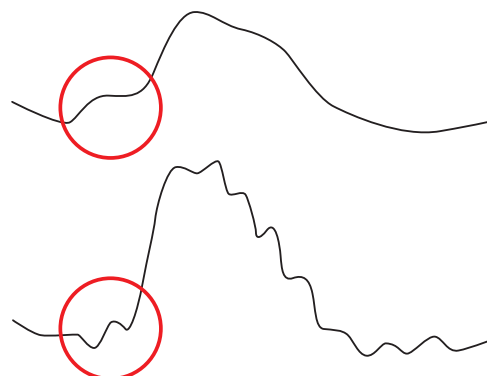


Ankle pulse wave. knee pulse wave. Check that the pulse wave rises smoothly.

Good waveform



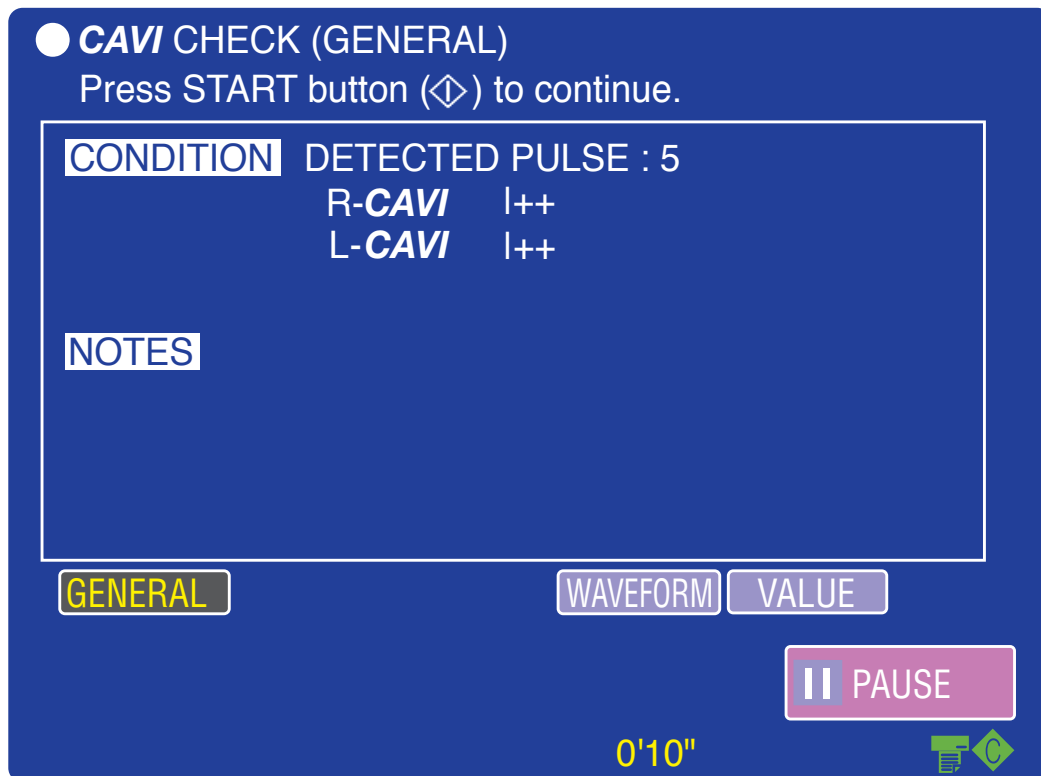
Bad waveform



8 CAVI check

Finally, confirm that the CAVI check condition is “++” or “+”.

If the CAVI check condition is “–” or “--”, please reconfirm that the electrocardiogram electrodes, cuffs, and heart sound microphone are attached correctly. Then repeat the measurement.



“++” :Measurement is stable with four heartbeats or more used for CAVI measurement.

“+” :Measurement is relatively stable with three heartbeats used for CAVI measurement.

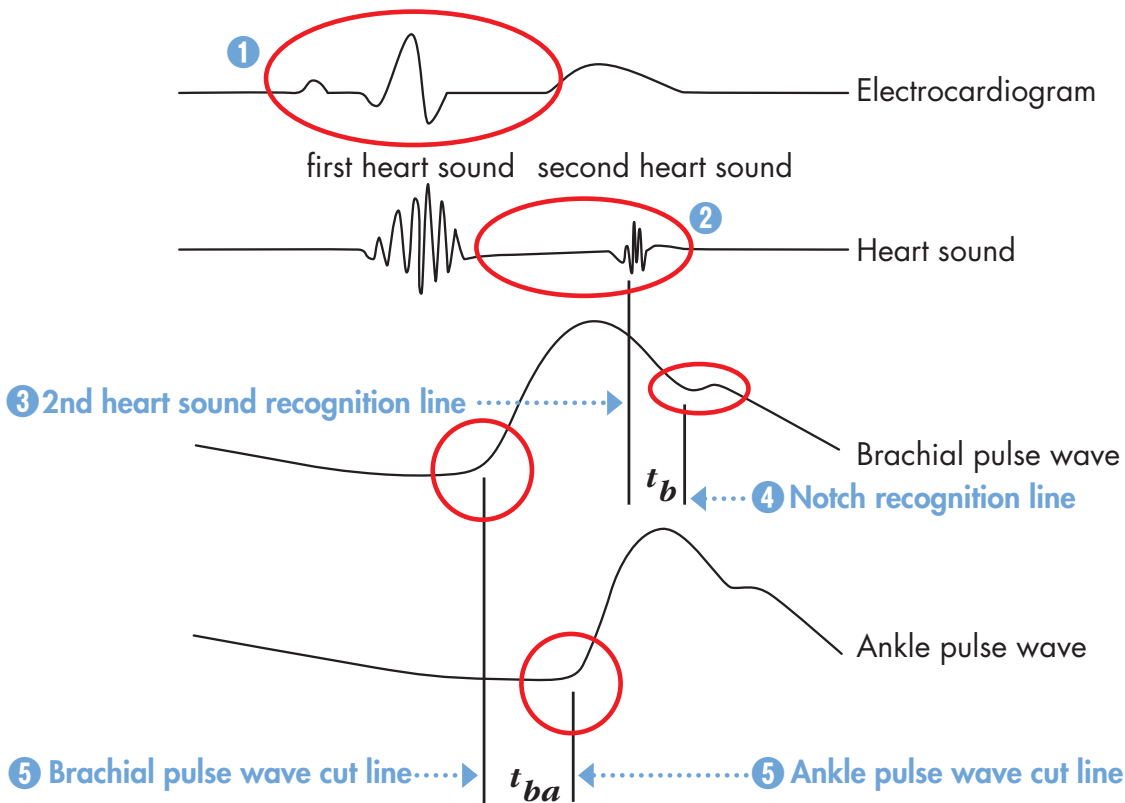
“–” :Only two heartbeats could be used for CAVI measurement, so measurement is not stable.

“--” :Only one heartbeat is used for CAVI measurement, which shows that there is variation in the data used to calculate CAVI. Measurement should be repeated until at least there is one “+”!

9 Post-test check

1 Data check after CAVI measurement

Confirm the following waveforms.



Check items	Check box
Is the electrocardiogram free of arrhythmia? ①	
Is the interval between the first and second heart sound free of noise? ②	
Is the position of the demarcation line for the second heart sound correct? ③	
Is the position of the brachial notch correct? ④	
Is the rise position of the pulse waveform of the four limbs correct? ⑤	
Is the t_b time from the second heart sound to the notch for each heart-beat free of variation?	
Is the t_{ba} time from the rise of the pulse wave of the brachial to the rise of the pulse wave of the ankles for each heartbeat free of variation?	

The variation of each heartbeat can be confirmed with the detailed measurement values.

◎ Good example

ITEM		MEAN	BEAT 1	BEAT 2	BEAT 3	BEAT 4	BEAT 5	BEAT 6
R-CAVI		◎ 5.5	5.7	5.5	5.5	5.5	5.4	
L-CAVI		◎ 5.5	5.6	5.5	5.4	5.5	5.4	
R-tb	[ms]	◎ 108	104	107	108	109	110	
L-tb	[ms]	◎ 110	108	109	110	112	112	
R-tba	[ms]	◎ 113	113	113	113	111	113	
L-tba	[ms]	◎ 113	114	114	114	112	113	

A ◎ symbol next to the mean value of CAVI means that there is little variation in the value per heartbeat.

× Bad example

ITEM		MEAN	BEAT 1	BEAT 2	BEAT 3	BEAT 4	BEAT 5	BEAT 6
R-CAVI		△ 7.0	× 4.6	× 8.9	7.0	× 5.9	× 4.1	7.0
L-CAVI		△ 4.9	4.9	× 8.4		× 9.4		4.9
R-tb	[ms]	○ 106	129	× 104	98	× 108	× 100	92
L-tb	[ms]	◎ 115		115	126	103	× 125	114
R-tba	[ms]	△ 97	× 116	× 59	94	× 103	× 162	100
L-tba	[ms]	△ 125	106	× 66		× 46		143

A △ symbol next to the mean value of CAVI means that there is a big variation in the value per heartbeat. The figures are thus marked with an ×.

Symbols that prefix the measurements indicate measurement quality, a value that depends on the number

of measurements not prefixed by “×”.

×: Insufficient △: Almost sufficient ○: Good ◎: Excellent

ATTENTION

“()” will be added to indicate that R-CAVI, L-CAVI, may not be correctly measured. If added, check the resulting waveform.

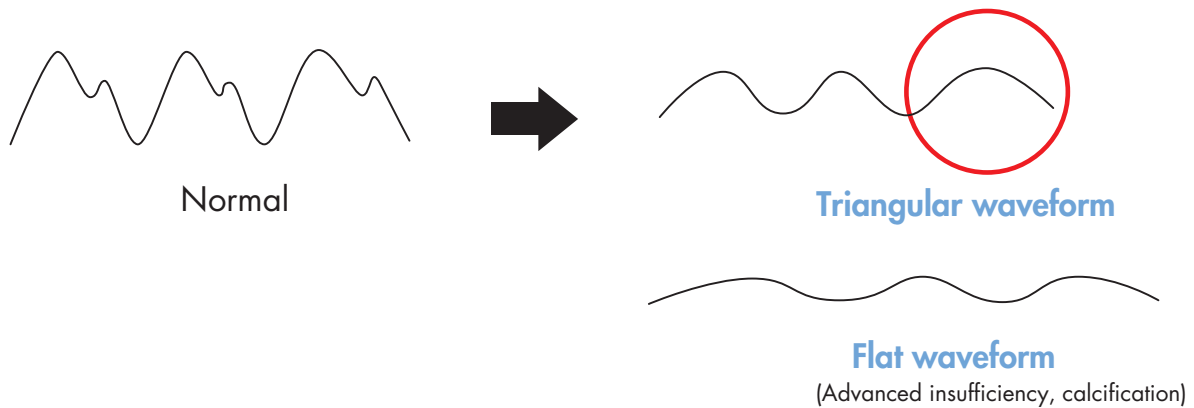
“()” will be added for the following conditions.

1. ABI is less than 0.90.
2. The accepted number of pulse beats are 2 beats or less. (The pulse beats are inconsistent.)

× Bad example

If the patient has stenosis or insufficiency, pulse wave waveforms like the following occur.

In this case, the notch and rise cannot be recognized, so the measurement cannot be taken.



CAVI standard values

Normal range.	CAVI < 8.0
Normal range but borderline.	8.0 ≤ CAVI < 9.0
The CAVI value is high.	9.0 ≤ CAVI

When ABI is below 0.9, there is a possibility of peripheral arterial disease, and a low CAVI value may be measured.

NOTE

If the conditions are good, a stable CAVI can be measured.

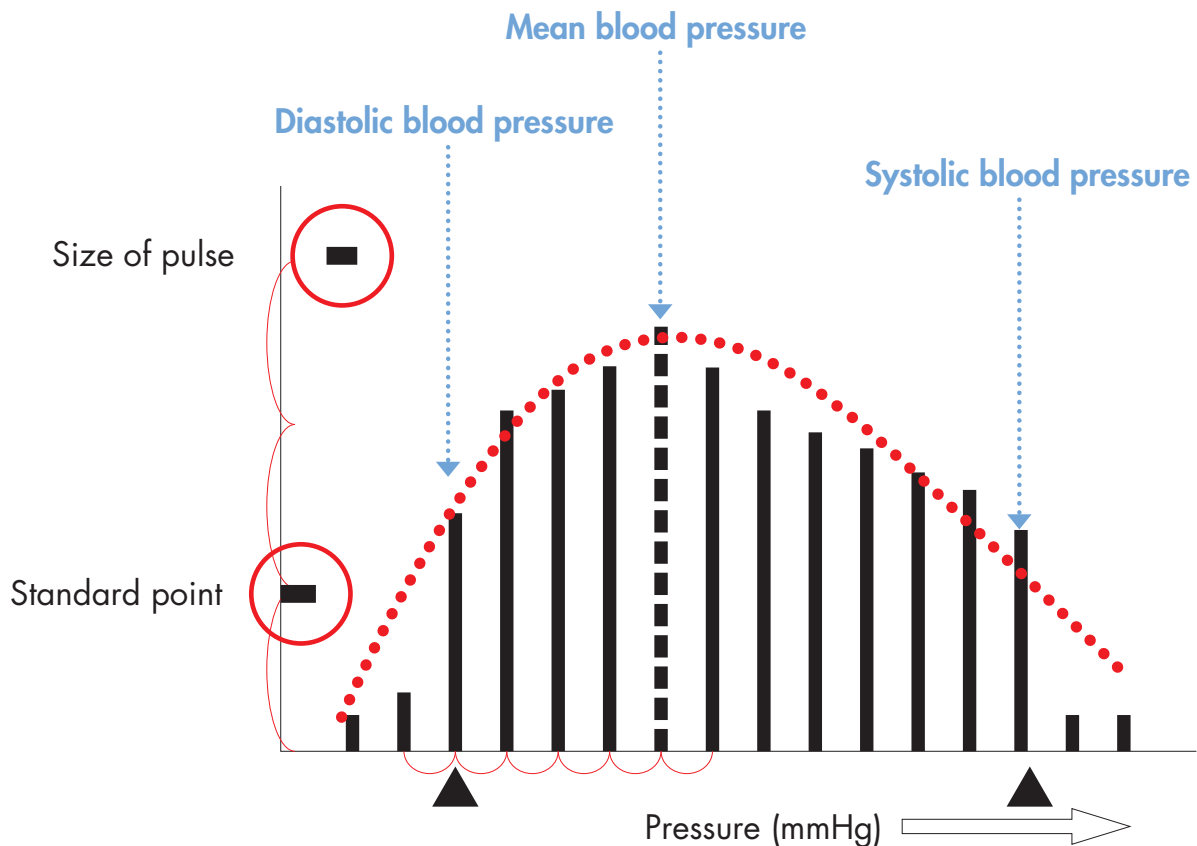
If CAVI is 0.5 or more different from the previous test, check whether the measurement was taken without any problems such as variations between demarcation lines.

If the measurement was done correctly, a change must have occurred with the patient.

(Refer to the Appendix, P27~)

② Data check after ABI (blood pressure) measurement

Confirm the following on the pulse wave amplitude graph.



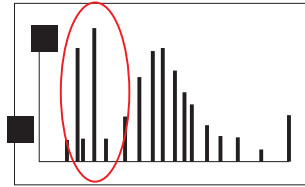
The ▲ symbol shows the points at which the gently-sloping distribution fluctuates rapidly. Using oscillometric methods, these points represent the systolic and diastolic blood pressure.

Check items	Check box
Is there only one peak for each of the four limbs, and is the shape smooth?	
Are the intervals of each of the lines aligned?	
Is the pulse amplitude smooth (not jagged)?	
Is the height of the black ■ mark for magnitude of pulse sufficient?	

✗ Bad examples

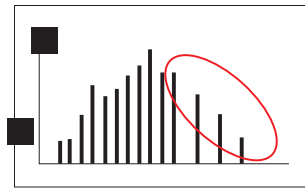
In the case that a measurement should be repeated

Body movement



High or low results are seen in some places.
If the patient moves while applying pressure, apply the pressure again. Agitation of the baseline can be seen in the pulse wave waveform.

Leak (air escapes)

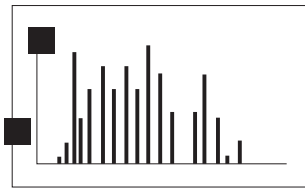


The interval becomes wider after the start.
If air escapes while applying pressure, apply the pressure again.

In the case that the measured value is used for reference only

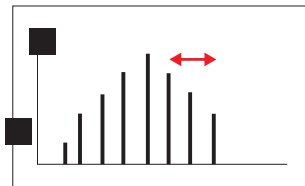
Arrhythmia occurs frequently

(The R-R interval of the electrocardiogram waveform is not fixed.)



The height and interval are not aligned

Bradycardia

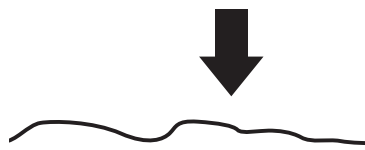


The interval is wide (comb shaped)

Advanced calcification Advanced insufficiency



Pulse pressure is too low
Blood pressure is 30mmHg or less.



The pulse wave waveform is flat

Complies with 2005 ACC/AHA standard (if ACC/AHA is selected for ABI criteria)

Noncompressible.	$1.30 \leq R/L-ABI$
Normal.	$1.00 \leq R/L-ABI \leq 1.29$
Borderline(equivocal).	$0.91 \leq R/L-ABI \leq 0.99$
Mild-to-moderate peripheral arterial disease.	$0.41 \leq R/L-ABI \leq 0.90$
Severe peripheral arterial disease.	$0.00 \leq R/L-ABI \leq 0.40$

Complies with TASC II standard (If TASC II is selected for ABI criteria)

Noncompressible.	$1.41 \leq R/L-ABI$
Normal.	$1.00 \leq R/L-ABI \leq 1.40$
Borderline(equivocal).	$0.91 \leq R/L-ABI \leq 0.99$
Possible peripheral arterial disease.	$0.00 \leq R/L-ABI \leq 0.90$

If there is no problem with the measurement results, please remove the cuffs, heart sound microphone, and electrodes. Then explain the results to the patient.



Appendix

CAVI TREND data

This section presents CAVI time series data. This data is made from measurements collected daily.

Correct data collection based on this manual allows observation of time series changes in CAVI.

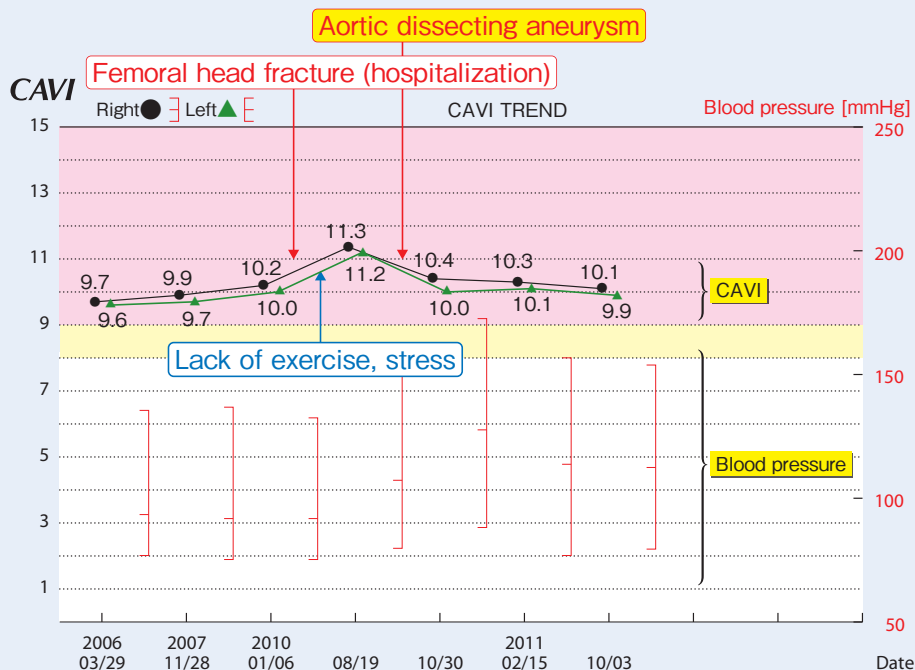
Observation of time series changes enables confirmation of the effects of the administration of drugs and the improvement of lifestyle habits using CAVI.

Case 1

Example of a 75 years old female (type 2 diabetes mellitus patient)

The patient was hospitalized with a femoral head fracture, and her CAVI rose due to a lack of exercise and due to stress.

This is a case in which an aortic dissecting aneurysm was discovered in subsequent tests.

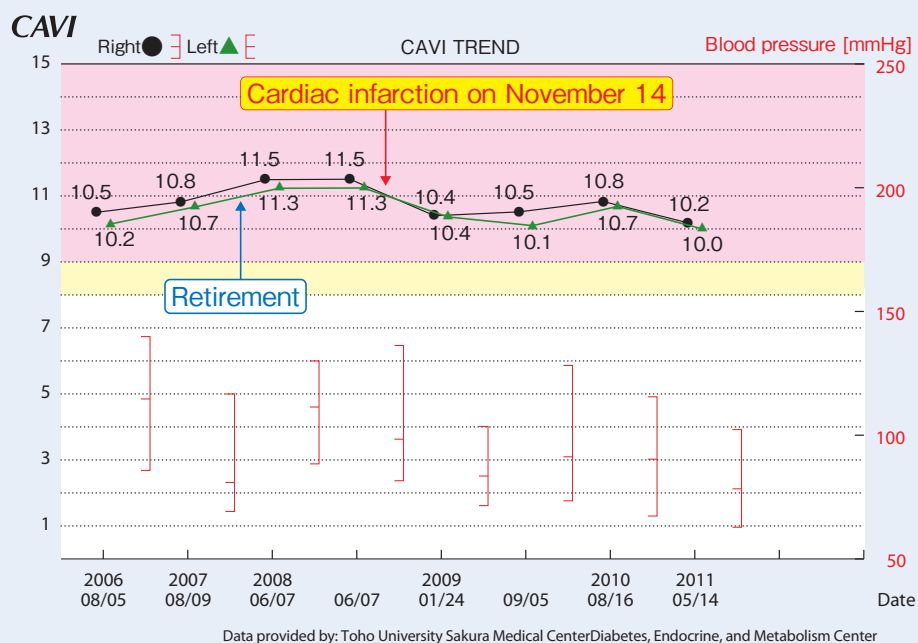


Data provided by: Toho University Sakura Medical Center Diabetes, Endocrine, and Metabolism Center

Case 2

Example of a 68 years old male

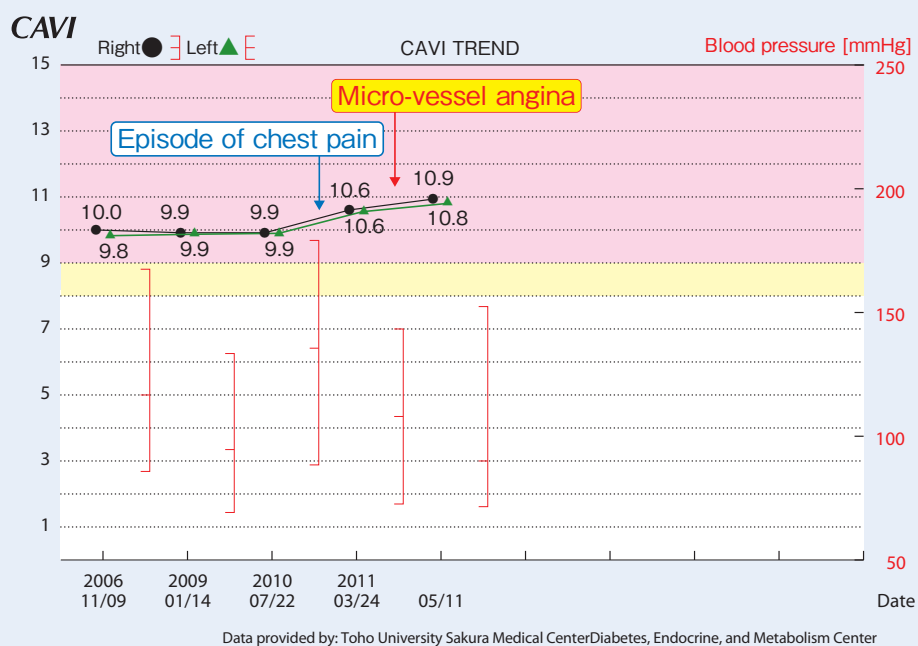
This is a case where the patient's CAVI rose after retiring from his job and he subsequently suffered a cardiac infarction.



Case 3

Example of a 66 years old male (high blood pressure patient)

In this case, the patient had an episode of chest pain and his CAVI rose. Subsequently, micro-vessel angina was found.

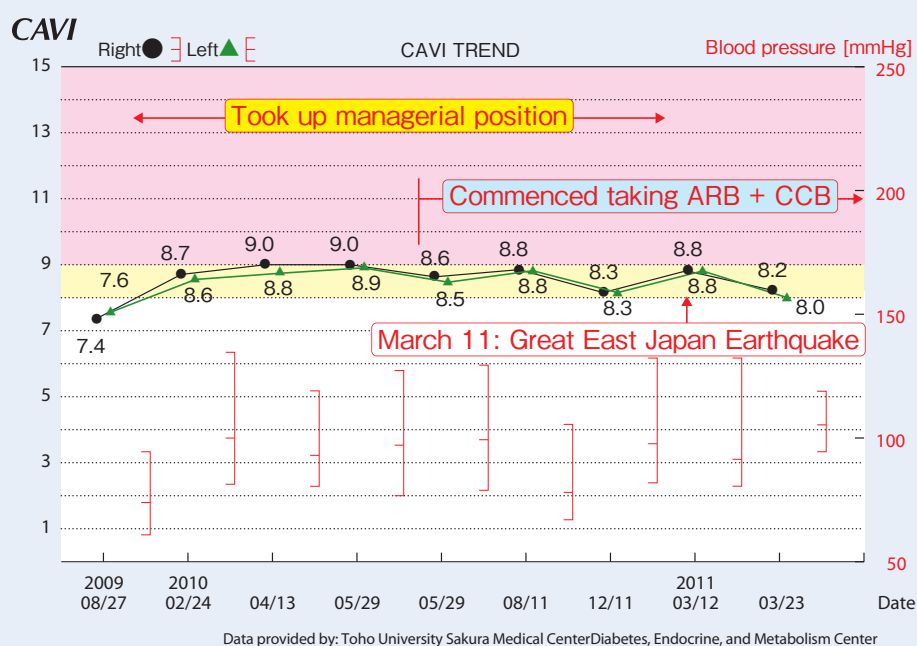


Case 4

Example of a 63 years old male (high blood pressure patient)

The patient's CAVI rose as soon as he took up a management position at work, and taking ARB and CCB (calcium antagonist agent) reduced his CAVI.

His CAVI rose on the day after the Great East Japan Earthquake (March 11, 2011). This case reflects well the high sensitivity of CAVI.

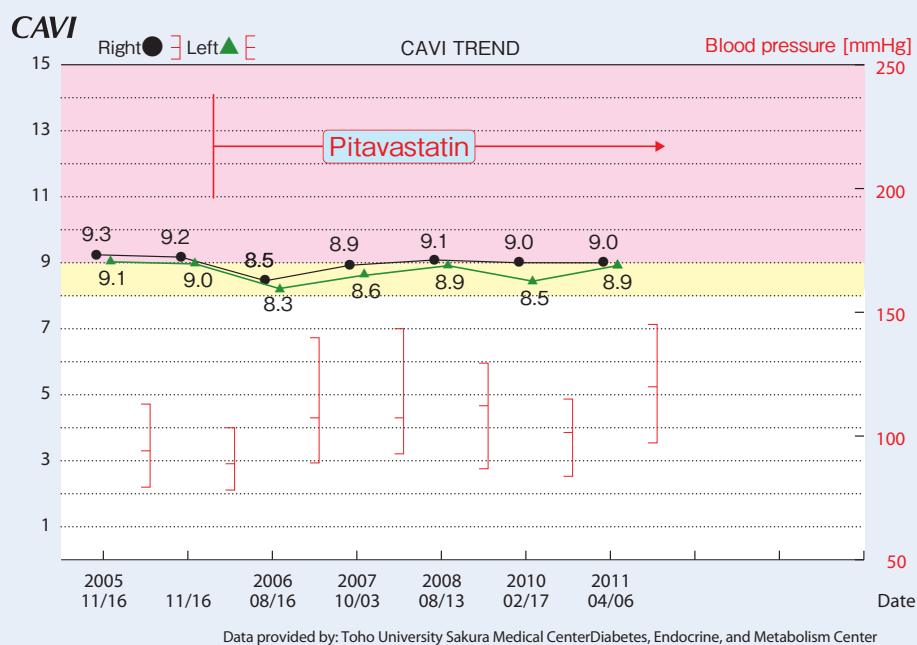


Effects of medication and CAVI

Case 5

Example of a 65 years old female

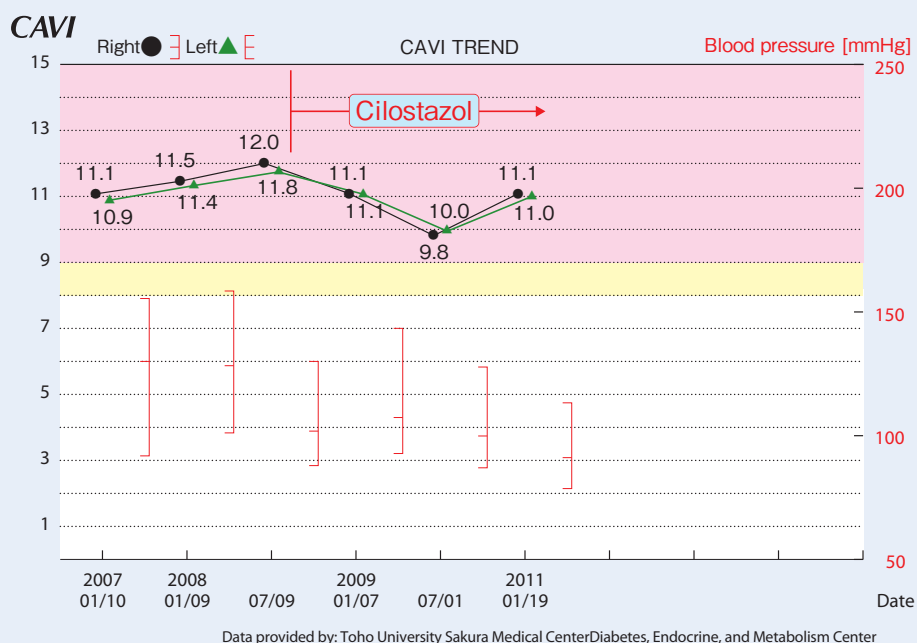
This is a case where a rise in CAVI was stopped by having the patient take Pitavastatin.



Case 6

Example for a 69 years old male

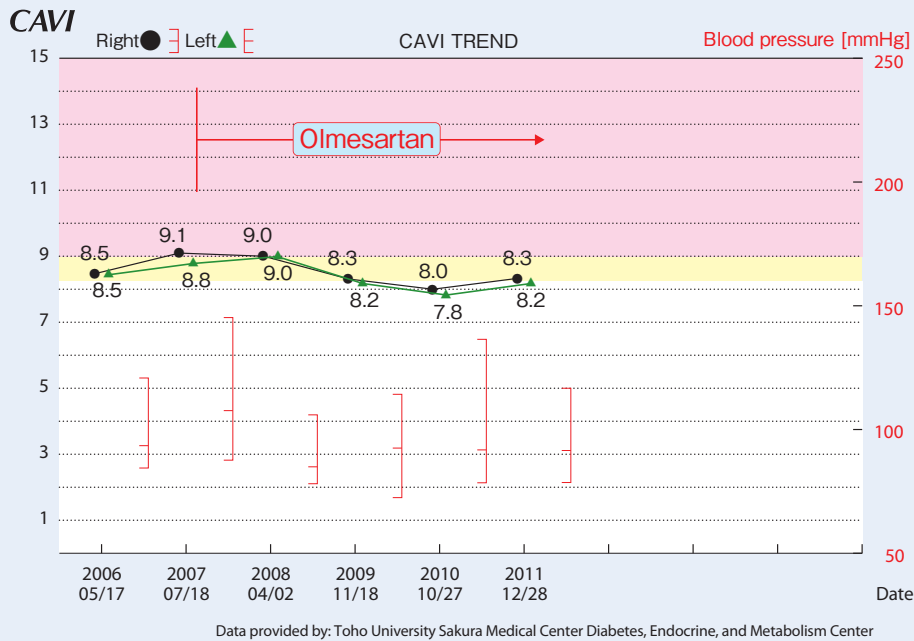
This is a case where CAVI tended to decline when the patient took Cilostazol.



Case 7

Example for a 69 years old male

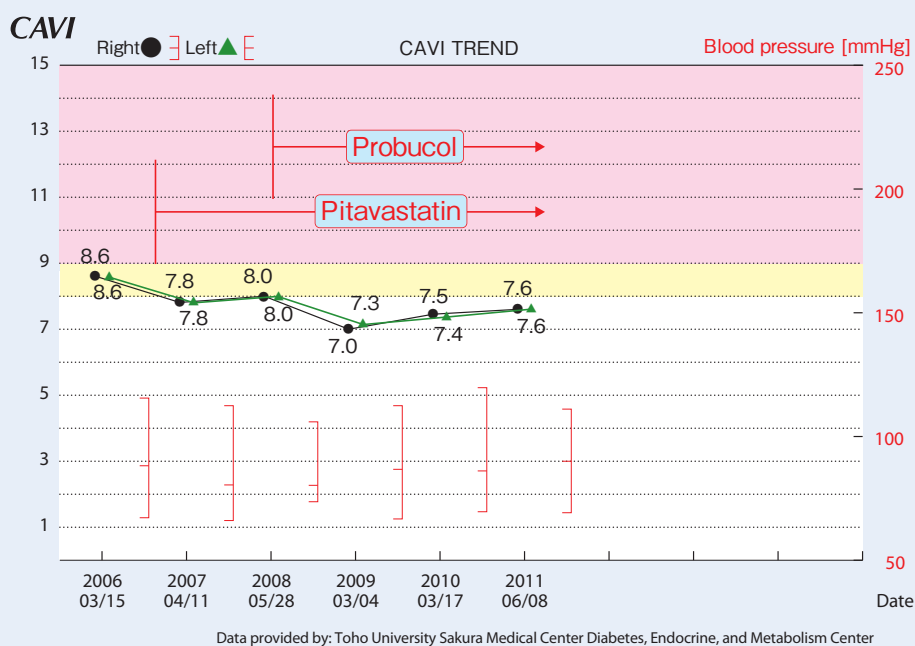
This is a case where CAVI clearly decreased when the patient took Olmesartan.



Case 8

Example for a 54 years old female

This is a case where CAVI decreased when the patient took Pitavastatin and Probuocol.

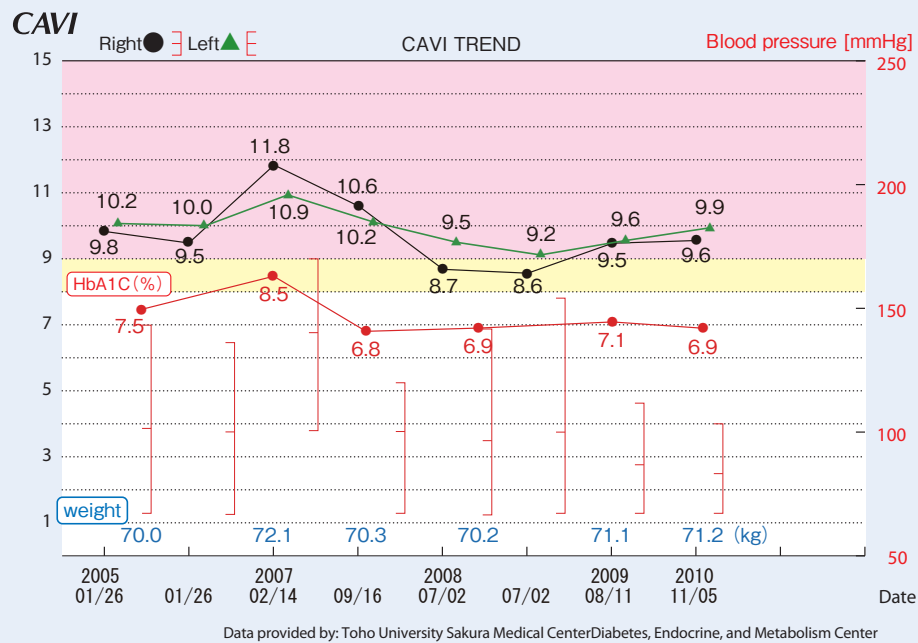


Case 9

Example for a 57 years old male (type 2 diabetes mellitus)

This is where CAVI rose when the body weight and HbA1C rose.

This suggests that a control of HbA1C and control of body weight are important for type II diabetes mellitus patients.



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The Date of publication: April 12, 2012
Publishing House: ME TIMES Inc.
Copyright ©2012 FUKUDA DENSHI CO.,LTD.
Printed in Japan
Third Edition

Printed in Japan Mat.No.12X570®