

Machinery and equipment such as 21 visceral function test instrument

## Non-invasive blood pressure module

# Blood pressure measurement module M3500

**Be sure to refer to the instruction manual**

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## Creation or revision date

\*\* March 1, 2012 (third edition)

\* October 17, 2011 (second edition)

## Approval and notification, etc.

### Brand Name

Blood pressure measurement module M3500

### Attached document management code

22200BZX00227000\_A\_01

### Approval Number

22200BZX00227000

### Approval date

March 2010

## General designation for

36551000

Non-invasive blood pressure module

**warning**

not listed

**Contraindications ban**

## Combination medical equipment (not to be used in place of the below)

Flammable anesthetic gas and the high concentration used in the oxygen atmosphere [explosion, or there is a danger of fire. ]

- In combination with high-pressure oxygen therapy device [explosion, or there is a danger of fire. ]

Magnetic resonance imaging apparatus There is a risk of causing accidents caused by combination [induced electromotive force of the (MRI devices). ]

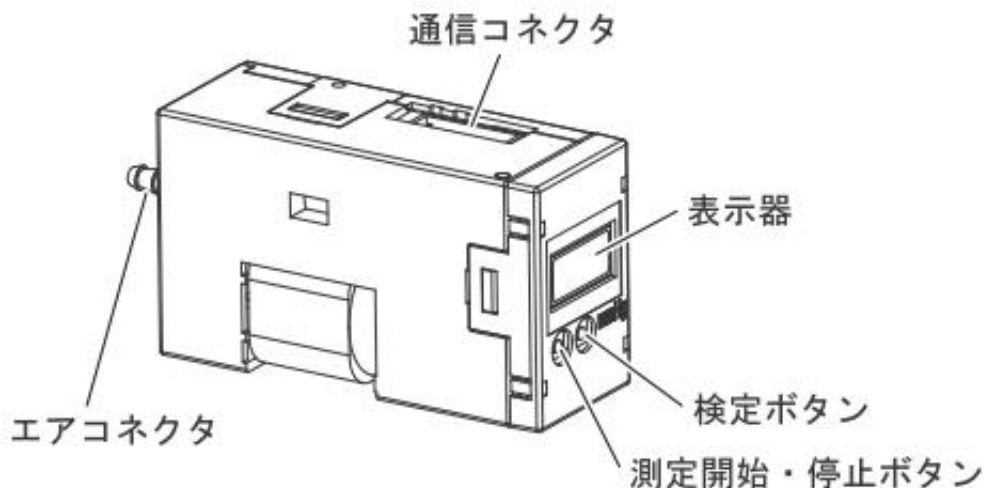
## how to use

- That you do not use If the exterior of the cuff there is corruption. [There is a risk of rupture during the measurement. ]

## Shape and structure and principles, etc.

This unit is a blood pressure measuring module designed to measure the non-invasive blood pressure (NIBP).

### 1.External view and each part of the name



### 2.Dimensions and mass

Dimensions: 40 (W) × 60 (H) × 105 (D) mm

Weight: about 220g ± 10%

### 3.Electrical Ratings

#### (1)Electrical rating

	12V specification	6V Specifications
Rated voltage	DC12V	DC6V
Power input	680mA	1,300mA
Inrush current	2A below	3A below

## (2)Classification of equipment

\*\* Blitz degree of protection against by the mounting portion of the classification: arm band B-shaped mounting portion

### Four.usage environment

Temperature: 0 ~ 50 °C

Humidity: 30 to 85% (non-condensing)

### Five.Standard accessory

The following as a standard accessory comes with one point.

\*\* · IEC adult cuff or GS cuff M

\*\* - Adult Kafuhosu (3.5m)

Silicon tube chassis joint / nut

### 6.Optional Accessories

Apart from the standard accessories, to this device can be combined with the product has the following.

· IEC adult oversized cuff · IEC children cuff (9cm, 7cm)

\*\* - Adult cuff (S, M, L, XL)

\*\* · GS cuff (SS, S, L, XL)

And neonatal / infant Disupokafu (No.10, No.11, No.12, No.13)

\*\* - Adult Kafuhosu (1.5m)

And neonatal for Kafuhosu (3.5m)

Air filter

### 7.Operating and operation principle

In the oscillometric method blood pressure measurement oscillometric method, it captured the pulsation of the artery as the vibration of the cuff pressure, to measure the blood pressure. It pressed enough pressure to the cuff wound to the upper arm and the blood flow will stop, but the beat of the artery is present, also vibration cuff internal pressure in response to it. Then, when gradually reduce the cuff pressure vibration of the cuff pressure is gradually increases, eventually it reached a peak,

In addition go and vibration by reducing the cuff pressure would be Ikima smaller. The relationship between the increase and decrease of the vibration of the cuff pressure and cuff pressure in this series of processes and memory and calculation, to determine the blood pressure value.

Systolic blood pressure cuff internal pressure of typically, when vibration is rapidly increased, And the lowest blood pressure cuff internal pressure at the time of the decrease rapidly.

In addition, the cuff pressure when the vibration of the peak is the mean arterial pressure.

## **Intended use, efficacy or effect**

This device, by the non-invasive measurement of arterial blood pressure is used to display the systolic and diastolic blood pressure.

## **Item specifications, etc.**

### 1.Error of blood pressure measurement by the clinical performance test

Error average of the auscultation:  $\pm 5$ mmHg within the standard deviation: 8mmHg within

2. Cuff pressure display of error: within  $\pm 3$ mmHg

3. Quick exhaust

Adult (children and infants):

The time required in order to rapidly exhaust to 15mmHg from 260mmHg: 10 seconds or less  
newborn:

The time required in order to rapidly exhaust to 5mmHg from 150mmHg: less than 5 seconds

Four. Cuff pressure display of stability:

10,000 change in the display value of the cycle cuff pressure after the simulated measurement of:  
3mmHg below

Five. \*\* Maximum pressure

Adults: 300mmHg

Newborn: 150mmHg

## Method of operation or use method and the like

Since that is operated by the operation buttons of the assembled multi-item monitoring, operation button of the device is not used.

Method of operation is as follows for the operation check.

1. Method of operation

(1) Wrap the cuff on the arm of the subject.

(2) Power is supplied to the unit, and then to the blood pressure measurement possible state.

(3) Measurement start and press the stop switch, to start the measurement.

(Four) After the measurement, remove the cuff from the subject.

## PRECAUTIONS

In the case of the following, or please carefully apply to the following of the subject.

- The direction from the doctor has been pointed out the bleeding tendency or hypercoagulable state (can cause faulty circulation by point-like bleeding or blood clots after tightening the arm in the cuff.)

And natural rubber (latex) the subject of allergy: the cuff being attached genus or option on this device may have the use of natural rubber. Please check whether there is an abnormality in the site where the hose touches. Natural rubber, itching, redness, nettle rash, swelling, fever, breathing difficulties, asthma-like symptoms, decrease in blood pressure, may cause rare allergic symptoms such as shock or be. In such a case that caused the symptoms, please immediately subjected to a mid-sealed appropriate measures to use. The presence or absence of natural rubber use mosquito off the document attached Please check

## Important Precautions

In the periphery of, the apparatus and the person to be measured, the power supply, such as mobile phones and small radio (PHS terminal that is allowed to use is excluded) because it is not concerned with the cut again.

- Unmeasurable and when you have doubts about the measurements, please make sure the person to be measured first.
- Please use devices also document attached to the cuff to be used from read them carefully to measure. In this package document it does not has indicated up to those notes.

Specifying the consumables, please do not use other than the optional accessories.

- For each person to be measured, or please make sure that the alarm settings are appropriate before use.

### [Non-invasive blood pressure measurement]

Such as, infusion and transfusion, please do not wound the cuff to a limb that has been vein secured.

- Please do not wound the cuff to the limb with an artificial dialysis shunt.
- Please measure with an appropriate cuff size. Doing so may result of measurement error.
- From time to time, to check the measurement site, please change the measurement site if there is an abnormality. Or causing the peripheral circulatory failure, rash caused by sweat, and cause internal bleeding.
- Please note the bending of the Kafuhosu. Peripheral dysfunction due to the fact that not exhaust may occur.
- If the following can not be unmeasurable or measured correctly.
  - Peripheral circulatory failure and significant hypotension, the case of hypothermia
  - If a high frequency of arrhythmia
  - If there is a weak continuous vibration from the heart massage in and outside
  - Convulsions, tremors, involuntary movements, if there is a body movement such as trembling
  - If the cuff mounting portion is different from the height of the heart (10cm is different when the blood pressure value height might maximum 7 ~ 8mmHg different)
  - If you talk or move during the measurement
  - If you attach the cuff from the top of the thick clothing

If you have pressure on the arms, it was raised tucked clothing

- If you are using a heart-lung machine (because there is no beat)
- In the case of pseudo-hypertension

## Interaction

- The periphery of the person at the time of defibrillator use please away from the device and the cords that are connected to the subject and the subject. We received a blitz by energization energy of the defibrillator.

Or - at the time of defibrillator use is energized as much as possible away from the electrodes attached to the chest, please instead of attaching the electrodes to the appropriate position. When the defibrillator paddles to energize while touching the electrode, it will cause burns to the site.

And electric knife during use and after use be sure to check the operation of the machine. It may indicate the measurements wrong by the noise of the electric knife.

- Of the electric knife if attachment of the return electrode is inappropriate, it can cause burns in the subject mounting portion. Please carefully read the instruction manual of the electric knife for more information.

Microwave therapy equipment equipment that generates the noise, such as you might not be able to if measured correctly in the vicinity.

- Such as the commercially available personal computer to the external I / O connector, please do not direct connection with the equipment that does not meet the medical safety standards (IEC60601-1 or IEC safety standards). Please connect Ri by the company designation of ways to connect. If an unspecified connection you may want to shock due to the leakage current.

## Other Notes

And non-invasive blood pressure measurement is done by squeezing the arm.

Or feel a strong pain in some people, it may be transient Madaragami by subcutaneous hemorrhage. This plaque is Suga disappears over time, the possibility of a person to be measured to be made in care We tell you that the "Madaragami is there is a Rukoto", you may need to refrain from the measurement.

## Storage and storage method and duration of use, etc.

### 1.Storage condition

(1) Please keep to the environment, such as the following.

\*\* Temperature: -20 ~ 70 °C (standard accessories, optional accessories are excluded)

Humidity: 30% to 95% (non-condensing)

### 2.Life

Six years after installation (self by our data authentication)

However, this is a case that has been used in the recommended environment, such as regular maintenance and inspection, there may be a difference through the use situation arises.

## **Matters relating to the maintenance and inspection**

### **[User, and skilled in the art by the maintenance and inspection matters]**

#### 1. Notes

- For a while when you re-use the equipment that was not used, make sure that you always the equipment before use to operate successfully and safely.
- Body, accessories, connector, in the opening portion of the housing, with blowing liquid Ketari, pouring, please do not spill. Otherwise, you may get an electric shock.
- Disposable products in order to prevent infection, do not re-use. (There is also a thing that can be re-used only the same person to be measured.)
- Do not use paint thinner, solvents such as benzene to clean. These solvents will damage the surface of the plastic.

#### 2. Inspection before use

- In appearance, there is no deformation such as by dropping, Ri was dirty, Please check not wet.
- Cuff, please make sure that you are using the specified ones.

#### 3. Inspection after the power is turned on

- Smoke or out, or there is no strange smell, please check whether the abnormal noise is not heard.

### **[Maintenance and inspection matters by the trader]**

#### 1. Notes

- Clean, because there is a risk of electric shock, please be performed by far the communication connector.
- \* Please insert the communication connector After cleaning from the well dried.
- The unit, autoclave, can not be used gas sterilization (formaldehyde gas, EOG, high concentration ozone, etc.). The equipment will cause a deterioration.

#### 2. Inspection before use

- That the cords are not damaged (exposure of the core, disconnection, etc.), Please make sure that there is no slack in the cords of connection.
- Please check do not place heavy objects on top of the code.

#### 3. Inspection after the power is turned on

- Press the each switch, make sure that the function is activated.
- Each measurement is performed normally, please make sure the measurement error is within the reference value.

**Four.Care**

- When the body is dirty, to include an anti-venom for the alcohol that was neutral detergent or diluted and diluted, drop the dirt by wiping with a soft cloth that has been squeezed tightly. However, please do not wipe the electrical connector portion.

**Packing**

Packed in a single unit

**Manufacturing distributors and manufacturers of name and address, etc.****Name or name**

Omron Healthcare Co., Ltd.

First-class medical equipment manufacturing and sales

**Address, etc.**

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**phone number**

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