





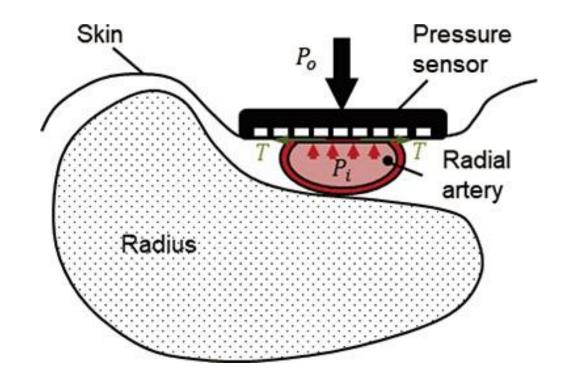
Nowadays, the culture has been established to utilize the information of blood pressure for heart disease treatment, management, and prevention by measuring it not only at hospitals but also at home. Reasons for the popularization of blood pressure measurement at home include the development of the oscillometric method, which does not require users to have special knowledge or techniques of blood pressure measusrement 1121, the promotion of studies which showed the importance of blood pressure measured at home represented by the Ohasaa Study, and the advancement of blood pressure measurement apparatus such as the automation and downsizing of instruments and the improvement of usability.

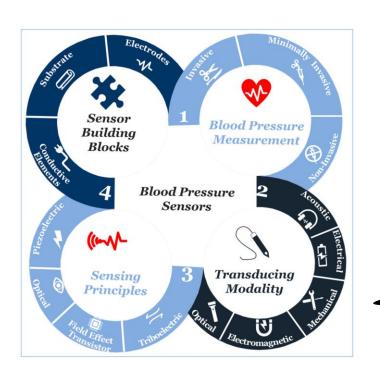
On the other hand, even today when home sphygmomanometers have become popular and medical treatments for high blood pressure have evolved, it is known that there are still cases where appropriate antihypertensive treatment is not performed 4. In the oscillometric method, because blood pressure is measured by wrapping a cuff around the upper arm or wrist for compression to interrupt the blood flow, it takes several tens of seconds for one measurement. However, it is considered that there are fluctuations in blood pressure with a high risk of developing cerebrovascular and cardiovascular diseases which cannot be detected by the oscillometric method, because the blood pressure actually varies beat by beat



TONOMETRY METHOD

 Unlike the oscillometric method in which the cuff worn on the upper arm or wrist compresses blood vessels, in the tonometry method, the pressure sensors are pressed directly against the skin to measure the pressure pulse wave and to calculate the blood pressure. If the pressure sensors are pressed against the skin above an artery, the dynamic equilibrium on the pressed surface can be expressed by the equation considering the thickness of the blood vessel wall based on Laplace's law.

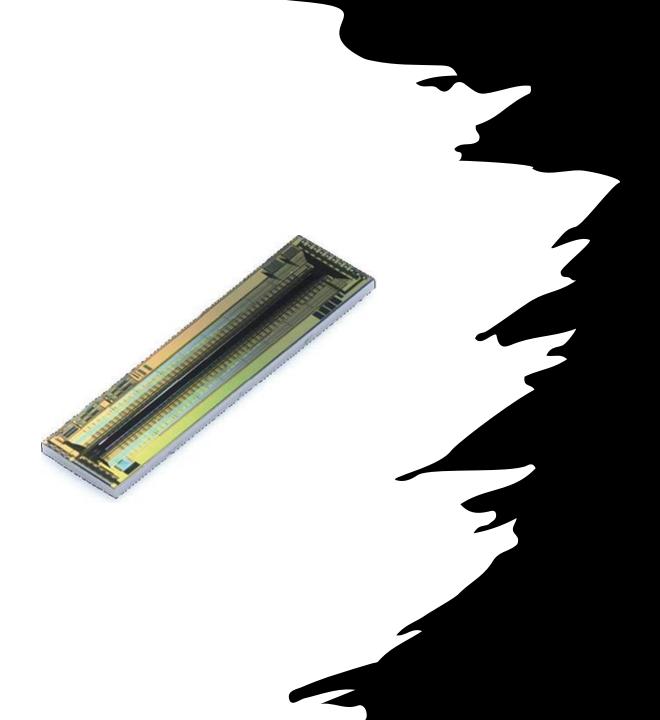




REQUIREMENT OF SENSOR TECHNOLOGY

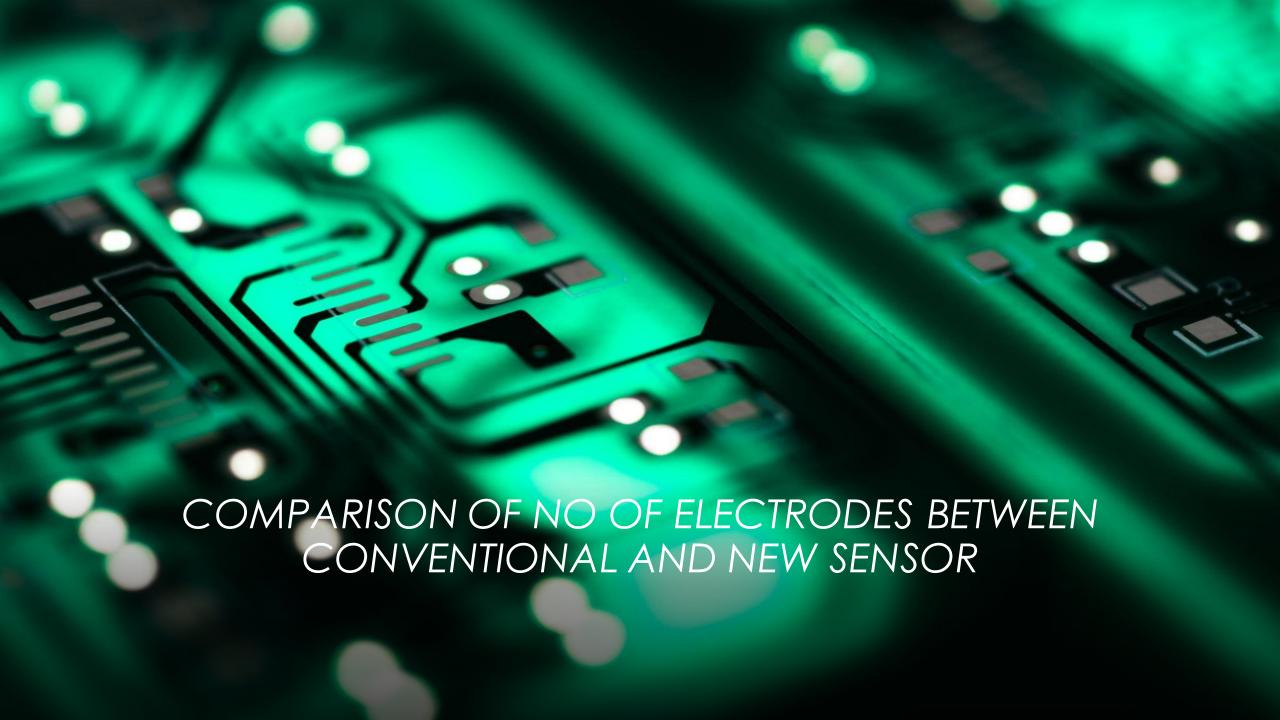
The first requirement is the number of pressure sensors. In the tonometry method, it is necessary to press the pressure sensors directly against the skin and determine the blood vessel and pressure sensor positions correctly, to detect the pressure pulse wave transmitted to the surface of the skin directly above the center of the blood vessel. Therefore, in the case of the radial artery of the wrist, a few dozen pressure sensor elements need to be placed at intervals of hundreds of micrometers. In addition, sphygmomanometers based on the oscillometric method are only required to ensure the accuracy of a single pressure sensor which measures the pressure in the cuff. On the other hand, in the case of the tonometry method, it is necessary to assure the accuracy of all pressure sensors which are placed at narrow intervals.

S.No.	Category	Issue
1	Sensor	There are a large no. Of electrodes and the mounting yield drops. The resistance to noise is poor.
2	Sensor Mounting	Applying the resin deteriorates the sensor characteristics. Applying the resin causes a drop in yield
3	System	The instrumetn is large and the measuring environment is limited



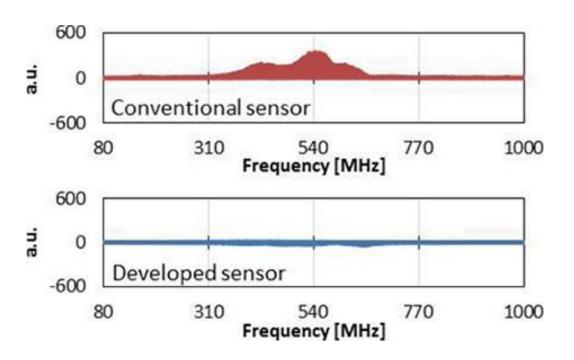
DEVELOPMENT OF SENSOR CHIP AND ASSEMBLY METHOD

For the drastic improvement of the properties and mounting yield of the pressure sensor for the aforementioned continuous sphygmomanometer, we developed a new multi-element MEMS pressure sensor (hereinafter referred to as "sensor chip") as shown in Fig. 2 The sensor chip we developed, which is 11.5 mm in length, 3.0 mm in width and 400 µm in thickness, has a diaphragm measuring 9.5 mm long, 0.26 mm wide and 5 µm thick in the center, and piezoresistance is formed on the diaphragm. If the diaphragm deforms under pressure, the stress is generated depending on the deformation amount, and this stress changes the electric conductivity, i.e., resistivity, in the piezoresistance. By forming a bridge circuit with the piezoresistance, the variation in resistance depending on the pressure is detected in the electric voltage. The pressure sensor we developed has 46 bridge circuits of piezoresistance on the diaphragm at short intervals of 200 µm and multiple temperature sensors on the sensor chip. Placing multiple temperature sensors on the sensor chip enables the direct measurement of the sensor chip temperature, but not the atmospheric temperature. this sensor can be used for the temperature correction of pressure conversion formula. Furthermore, the sensor chip developed is also equipped with ASIC (Application Specific Integrated Circuit), and a multiplexer, operational amplifier and filter circuit are mounted on the sensor chip.



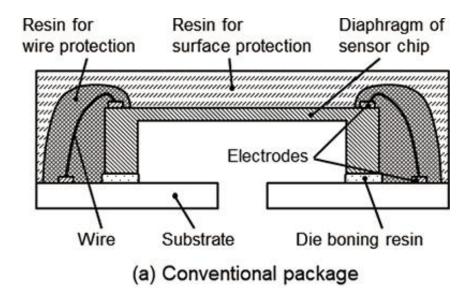
Instrument No. Of Elements No. Of electrodes 30ch for Conventiona 72 pressure+4ch for **I** sensor temperature 46ch for 22 pressure+2ch for temperature

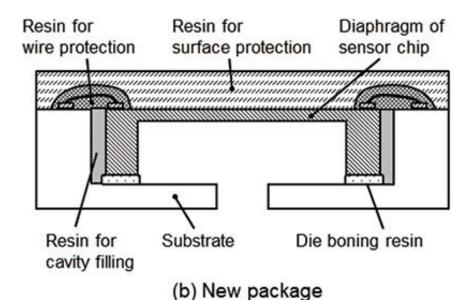
COMPARISON OF NOISE RESITANCE BWN CONVENTIONAL AND NEW SENSOR

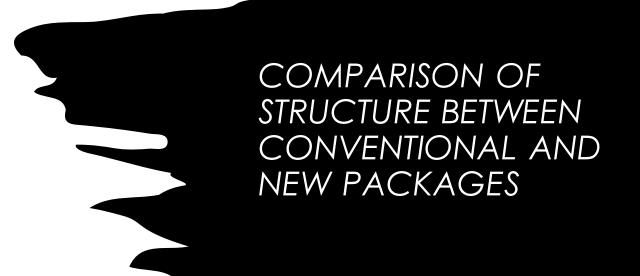


NEW PACKAGE STRUCTURE

 In blood pressure measurement based on the oscillometric method, the pressure in the cuff is directly transmitted to the semiconductor pressure sensor through the medium of air. On the other hand, in continuous blood pressure measurement based on the tonometry method, it is necessary to press the pressure sensor directly against the skin, as already stated. Therefore, the pressure sensor needs to be sealed with highly biocompatible resin (hereinafter referred to as "potting"). However, if the elastic modulus of the resin used for potting is too low, the deformation amount will be high and the pressure will not be transmitted properly. For these reasons, it is necessary to select a resin with hardness to some extent. On the other hand, if the elastic modulus is too high, potting the pressure sensor with the resin generally deteriorates the properties significantly, because the resin makes stress reside in the sensor chip during curing and also expands and shrinks with changes in the atmospheric temperature. Therefore, it is necessary to develop a new package structure and assembly method which will not cause deterioration in properties even if the pressure sensor is potted with a resin with a high elastic modulus. In particular, it is important to conduct packaging to ensure uniformity for all 46 pressure sensors, as well as pressure measurement accuracy.

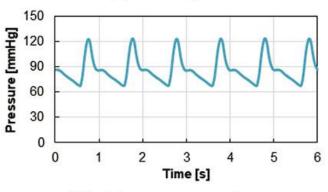








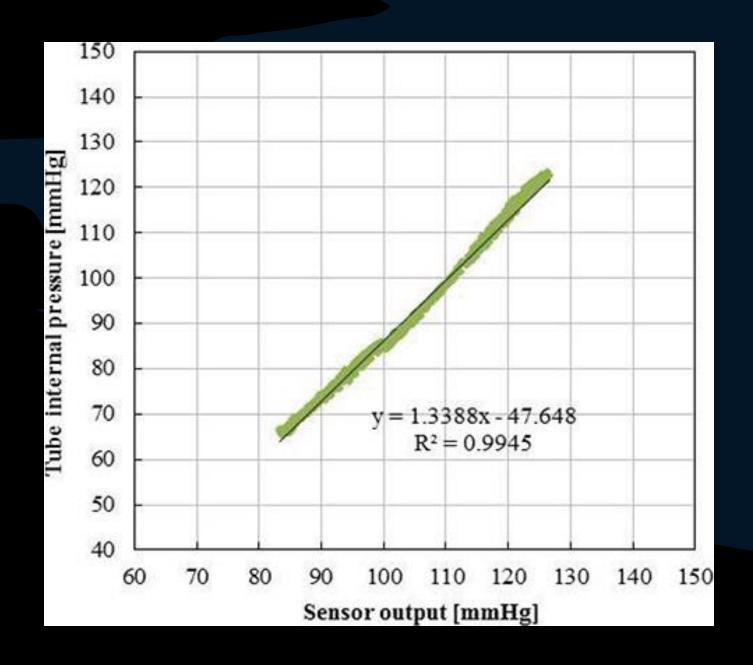
Tube simulated blood vessel Rubber sheet simulated skin Rubber sheet simulated tissue (a) Outline figure



(b) In-tube pressure waveform

Continued..

Although we applied pressure and temperature to the sensor module to evaluate its properties as a general pressure sensor i, the conditions were different from those where the sensor module is directly pressed against a human body, because the pressure was applied by the air and was static. Therefore, we not only conducted the evaluation of properties as a general pressure sensor, but also developed a wrist phantom, which is close to actual conditions and has superior reproducibility, to conduct evaluation. shows the sensor evaluation system based on the wrist phantom we developed. The wrist phantom is composed of a tube simulating the radial artery, a rubber sheet simulating the skin, and a rubber sheet simulating the tissue, as shown in F. The composing elements were selected in advance with the material parameters which can simulate a living body in a mechanical manner. The simulated blood vessel is filled with water, and the pressure simulating the arterial pulse of human body is applied from outside.





CONCLUSION

n continuous blood pressure measurement utilizing the tonometry method, a special sensor, in which the pressure sensors are arranged in an array, is required. Conventional multi-element MEMS pressure sensors had issues such as deterioration in mounting yield due to many electrodes for extracting signals as well as high difficulty in the subsequent stage, large subsequent circuit size due to poor noise resistance, and etc. To address these issues, we developed a new multi-element MEMS pressure sensor equipped with ASIC, achieving the drastic improvement of the above issues. In addition, although the application of materials, which generate stress and deteriorate the properties such as resin, is generally avoided as much as possible when mounting in the packaging of pressure sensors, it was required to actively apply a resin to the pressure sensor chip in continuous blood pressure measurement utilizing the tonometry method. As a result, deterioration in sensor properties and mounting yield due to application of resin was an issue. Therefore, we developed a new packaging structure which does not deteriorate the sensor properties even if a resin is applied, as well as its assembly method