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Development of a Complex Examination Device for QST in Medical Institutions

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Abstract: In medical institutions, the manner in which quantitative sensory testing (QST) is conducted is an issue. A complex-type inspection device has been investigated and developed for use in testing for the senses of vibration and temperature. The stimulus probe for testing the sense of temperature is configured by a Peltier element. Using the prototype of the stimulus probe, the differences in how the stimulus was felt between patients suspected of having a sensory impairment and those who are healthy were tested. Upon comparing patients and healthy subjects, it was revealed that the proportion of patients who detected the stimulus correctly was lower than that of healthy subjects at each temperature. To generate the same stimulus as a tuning fork in order to examine the sense of vibration, a sense of vibration stimulus probe that combines an electromagnetic coil and an elastic material has been devised. As a result, the prototype device was able to generate a vibration force nearly equal to the tuning fork. We are currently working on adding a new function to the temperature stimulus probe so as to allow us to measure the temperature of the tested area of subjects.

Keywords: QST, Sense of Temperature Stimulus, Sense of Vibration Stimulus, Peltier Element, Magnet Coil

1. Introduction

As society continues to age, the number of patients suffering from sensory impairments such as cerebrovascular disorders, diabetes and spinal disorders will likely continue to increase. Sensory testing mainly deals with somatic sense. Somatic sense is further categorized into superficial sensation, which occurs on the surface of the skin or the mucous membranes, and deep sensation, on periostea, muscles and joints. Therefore, the senses of touch, pain and temperature, for instance, are superficial sensations, whereas the senses of vibration and movement are deep sensations. In medical institutes, sensory tests are performed on these somatic senses for the purposes of symptom diagnosis, recovery status confirmation and treatment effect confirmation [1].

There are many different sensory tests. For example, in a tactile examination, patients close their eyes and are then lightly touched with a soft brush, cotton wool or a feather. They have to answer "yes" when they feel something touch them. In a temperature sensation test, patients are touched with a test tube containing warm water (40-45°C) or cold water (5-10°C) for a few seconds. They have to answer whether they feel "warm" or "cold". Meanwhile, in a vibratory sensation test, patients are touched with a tuning fork that vibrates at a frequency of 128Hz or 256Hz in bone areas in which fewer soft tissues are present. They have to answer "yes" once they can no longer sense the vibration.

The time from the application of the tuning fork to the point at which the patient cannot sense the vibration is measured. In these tests, the extent of sensitivity in the tested areas is generally compared to that in sensory intact areas in order to ascertain differences. As mentioned above, there are many types of sensory response tests performed in medical and rehabilitation institutes. However, the reality is that most of those utilize test tubes, tuning forks, brushes and other tools. As such, developing a method of performing Quantitative

Sensory Testing (QST) while also reducing the workload of testers but without placing burden on subjects is a challenge. Several QST devices have been proposed thus far. Most notably, a pencil-type thermal aesthesiometer (Yufu Itonaga) for a temperature sensation testing device, and Vibration II (Sensortek) for a vibratory sensation testing device were developed, and the utility of these devices has been proven [2]. However, the devices invented thus far are all for use in single sensory tests, and our investigation indicates that there is no such device that integrates more than one sensory test.

Focusing on the senses of touch/pressure and temperature, which are both superficial sensations, and the sense of vibration, which is a deep sensation, we have continued to carry out research with the ultimate aim of developing a complex examination device which can test all of these senses at once [3-8]. The final purpose of this study are to develop a small and lightweight portable testing device which may one day become the standard device for sensory screening, and to establish testing methods using the device.

It is predicted that if a diagnosis method using this technology were to be established, then it would become a standard for screening tests. This study was started by conducting experiments using a temperature stimulus device with a personal computer as a controller [3]. The experiments into vibration stimulation using eccentric motors also were carried out [4-5]. Next, the personal computer acting as the controller was replaced with a microcomputer, thus enabling us to create a more practical device [6]. The performance level of the device has been raised to a level at which it is ready to be tested in temperature stimulus tests in medical institutions [7-9].

2. Hardware

2.1. Controller

As described above, in outpatient and rehabilitation care situations, sensory tests are performed on somatic senses for the purposes of symptom diagnosis, recovery status confirmation and treatment effect confirmation. Instruments used in screening tests must be easy to use, must not require much preparation time, and must not place time or physical constraints on patients. Sensory tests include temperature sensation tests, vibratory sensation tests, tactile examinations, and pressure and pain sensation tests. Of these, the devices for temperature sensation tests, vibration tests and tactile examinations have already been currently developed. Our aim is to develop a device with an interchangeable cartridge-type stimulus probe which is capable of stimulating each sense with just one controller [8]. Using an 8-bit microcomputer as a controller, stimulus signals are generated via PWM. Figure 1 shows the control box of the testing device, the size of which is 130×80×40mm. The main electronic components inside the control box are a microcomputer, a power source (two 9V dry cell batteries) and a driver circuit. The circuit configuration is shown in Figure 2. The output terminals of the driver circuit connect directly to the temperature stimulus probe and the vibration stimulation probe. They also connect to a temperature sensor in the temperature stimulus probe via the microcomputer.

2.2. Temperature Stimulus Probe

Figure 3 and 4 show a prototype temperature stimulus probe and its structure respectively. It is 80mm in length and 10mm in diameter, with a contact area size of 9×9mm. A Peltier element, which is a semiconductor element, is used as a temperature stimulus probe to stimulate patients' sense of temperature. Starting from the contact area and moving outwards, the probe consists of a copper plate, a connector, a temperature sensor, a Peltier element and a heat sink in that order. TEFC1-03112 was used for the Peltier element and UM35DZ was used for the temperature sensor. By applying the contact area to a patient's skin and then providing surface temperature by gradually raising the temperature stimuli in 5°C intervals from 5°C to 50°C, the quantitatively stimuli can be generated [6]. Table 1 shows the specifications of the temperature stimulus probe.

The current I to the Pielter element is controlled by a PID controller as defined below in order to adjust the temperature of the Pielter element and the connected copper plate.

$$I = k_1 e_1 + k_2 s + k_3 (e_1 - e_2) \quad (1)$$

e_1: Temperature deviation

e_2: Last temperature deviation s: Sum of deviations

k_1, k_2, k_3: Arbitrary constant

e denotes the deviation between the target temperature and the measured temperature. The PID parameters are set to k_1=300.0, k_2=2.0 and k_3=100.0 respectively, based on the results of the preliminary experiment. These values are used in the temperature stimulus experiment described later.

Figure 1. *Control box.*

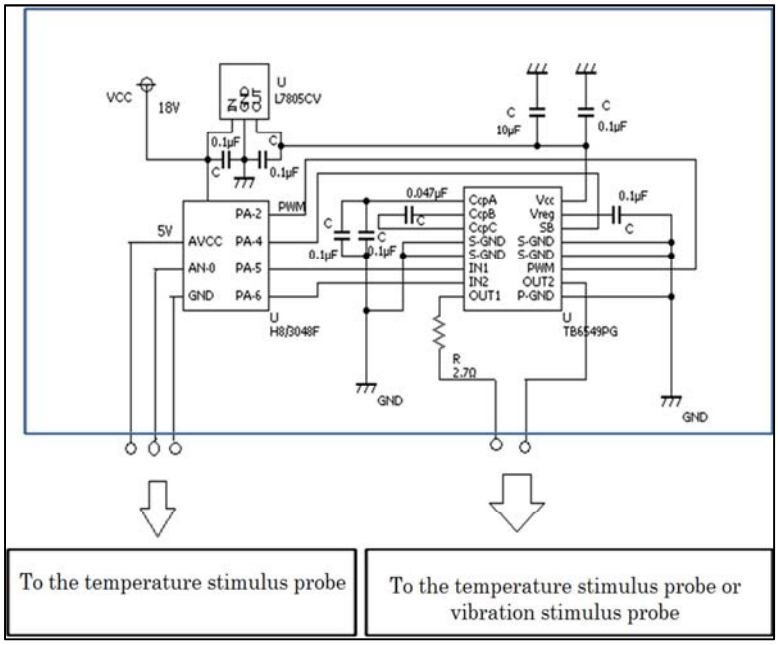

Figure 2. *Circuit diagram in the co ntrol box.*

Table 1. *Specification of the temperature stimulus probe.*

Item	Specifications
Setting temperature	5, 10, 15, 20, 25, 30, 35, 40, 45, 50°C Max. temp. 55°C, Min. temp. 5°C
Contact area	9×9mm
Weight	49g
Size	Length: 80mm, Diameter: 10mm

Figure 3. *Temperature stimulus probe.*

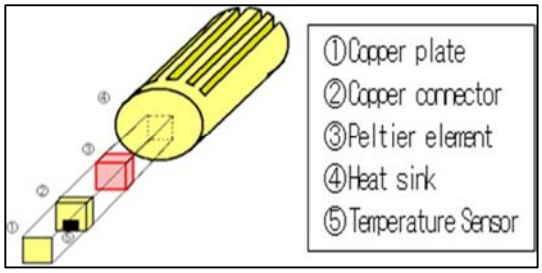

Figure 4. *Configuration of the temperature stimulus probe.*

2.3. Sense of Vibration Stimulus Probe

Conventional vibration stimulus tests are performed using a tuning fork with a vibration frequency of 128 Hz or 256 Hz. The tuning fork is made to vibrate and is then immediately applied to a bony area of a patient's body. The patient has to say "Yes" once he/she becomes insensitive to the vibration. The time from the application of the tuning fork to the point at which he/she becomes insensitive is measured. In order to ascertain the vibration intensity of the tuning fork, the minimum acceleration and maximum acceleration were measured using a 3D acceleration sensor (Crossbow CXL10HF3, Input Range: ±10G, 1G=9.8m/s^2, Sensitivity: ±100mV/G, Noise: 0.3mG rms, Measurement resolution: 1mV=0.01G).

As a result of the measurement, the maximum acceleration was found to be 1.98G, while the minimum acceleration was found to be

0.13G (Table 2). This indicates that our vibration testing device needs to generate vibration of about 0.1 – 2 G. To create a tester which generates similar stimuli to the tuning fork, a structure which combines an electromagnetic coil and an elastic body was devised.

The prototype sense of vibration stimulus probe is shown in Figure 5 and 6. This structure combines an electromagnetic coil and shock absorbing gel in order to vibrate the iron core using electromagnetic force generated by the electromagnetic coil and restoring force of the shock absorbing gel. Thus, generated vibration is transmitted through shock absorbing gel to the case, and the sense of vibration of the patient is stimulated by applying the left end of the case shown in Figure 6. Being able to generate force in electromagnetic coil by changing voltage applied to the coil, it is possible to change generating vibration with constant frequency by setting applied voltage as voltage waveform with constant pulse waveform. Applied voltage is changed at duty ratio of the PWM signal.

Table 2. *Measured acceleration vales of the tuning fork.*

	Acceleration
Maximum	1.98G
Minimum	0.13G

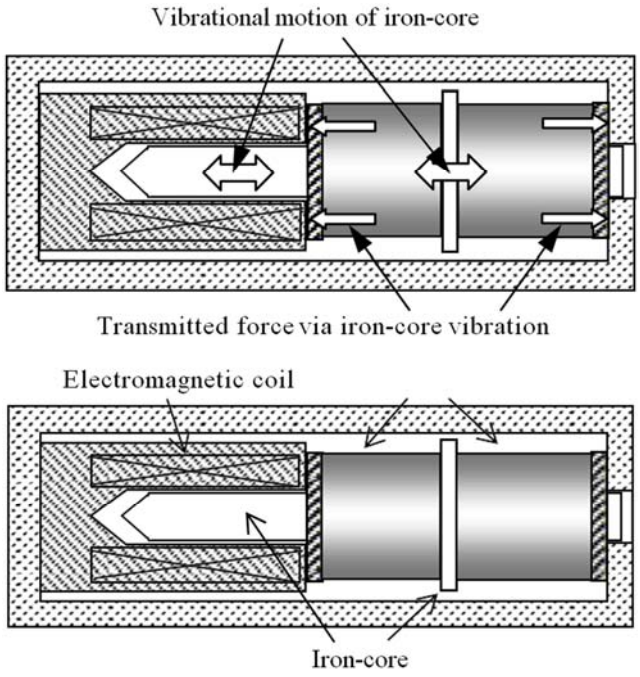

Figure 5. *Vibration generating structure using an electromagnetic coil.*

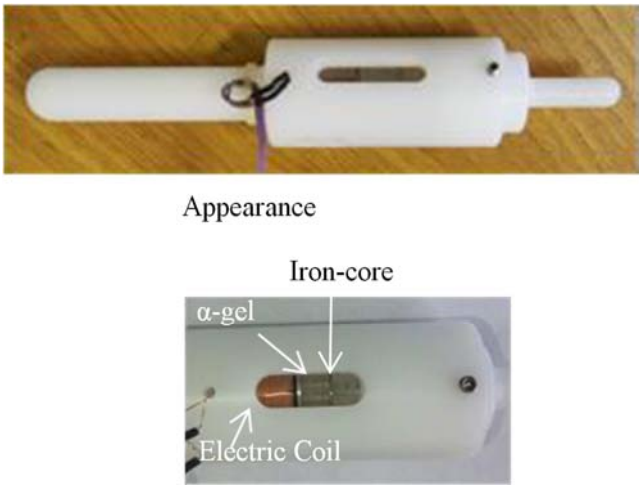

Figure 6. *Prototype vibration generator using an electric coil.*

3. Experiment

3.1. Experiment on the Temperature Stimulus Probe

3.1.1. Operation Test

The temperature on the probe contact area for each preset temperature is measured with a thermometer (AM-2001). Thermal transition at 45°C, 25°C and 5°C is shown in Figures 7, 8 and 9 respectively. The temperature of the probe contact area is within ±1°C compared to that measured by a thermometer, guaranteeing sufficient performance as a stimulus probe. Initial temperature on the graph indicates the environmental temperature. The time required to reach the preset temperature from the initial temperature is about 5 seconds for a preset temperature of 45°C and 15 seconds for a present temperature of 5°C. The reason why more time is required for the stimulus probe to reach 5°C than to reach 45°C is thought to be because the current in the Peltier element generates Joule heat independently of the heating and cooling functions, which leads to poor cooling efficiency.

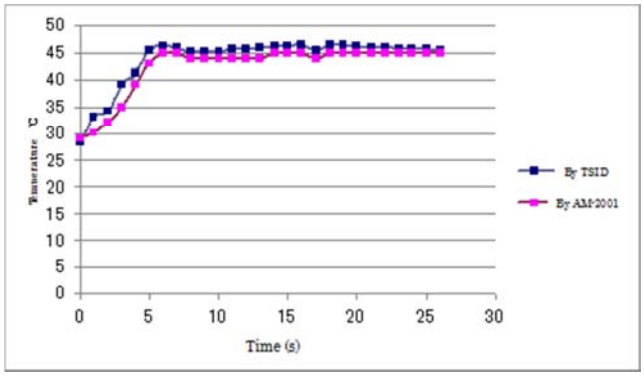

Figure 7. *Temperature transition of the temperature stimulus probe at 45°C.*

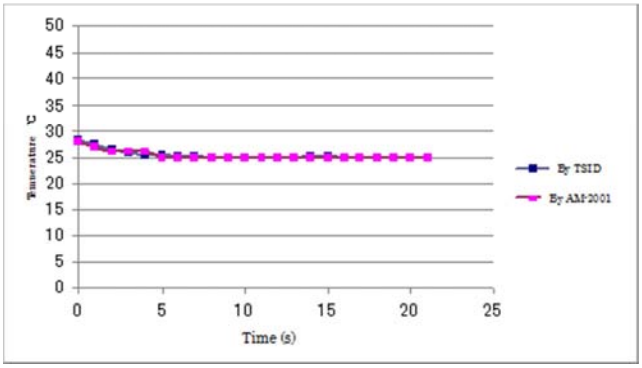

Figure 8. *Temperature transition of the temperature stimulus probe at 25°C.*

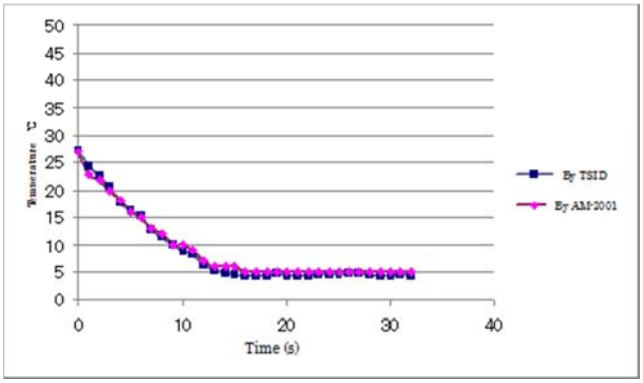

Figure 9. *Temperature transition of the temperature stimulus probe at 5°C.*

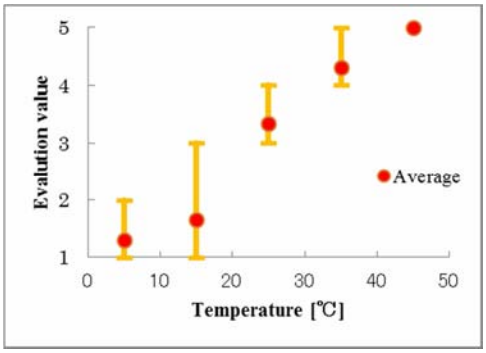

Figure 10. *Sensory evaluation results of the temperature stimulus probe.*

Next, the experiments were carried out on 23 healthy university students. The temperature of the probe was changed by 10°C within a range from 5°C to 45°C, and it was investigated how test subjects felt. The experiment was performed on the back of the dominant hand of the subjects, in a laboratory at 25°C. Evaluations were made according to a five-grade standard: 1 is "Cold", 2 is "Cool", 3 is "Feel nothing", 4 is "Warm", and 5 is "Hot". The results of the experiments on the subjects are shown in Figure 10. The y-axis indicates the average evaluation score all subjects, while the x-axis shows the preset temperature. The average evaluation score rose as the temperature went up, and all subjects felt "Hot" at 45°C. On the other hand, the fact that there was little difference between the temperature evaluations at 15°C and 5°C may reflect a seasonal effect — some people are more or less sensitive to cold depending on the season, and so they may feel that 15°C is "Chilly" enough at times.

3.1.2. Clinical Evaluation

Once we had confirmed the effectiveness of the prototype temperature stimulus probe at a laboratory level, we carried out experiments on threshold and temperature insensitivity as sensory characteristics, in association with the Rehabilitation Department of Kumamoto University Hospital [7]. The threshold temperature indicates the temperature at which a subject starts feeling stimuli, while temperature insensitivity indicates the temperature range at which a subject cannot perceive stimuli. After consultation with clinical institutes, the threshold temperature was defined as the temperature at which 75% of subjects recognized the temperature stimulus, and temperature insensitivity as the temperature range at which 50% of subjects or more answered that they had recognized the stimulus.

The procedure of the sensory test performed is as follows. Firstly, the temperature stimulus probe, which was fixed to a stand, was applied to the subject's skin to allow the subject's sense of contact pressure to adapt. Next, the temperature stimulus probe was set randomly at a temperature between 5°C and 45°C, and give a temperature stimulus was given to the subject. Subjects had to give one of three answers regarding the temperature stimulus: "Hot", "Cold" or "Feel nothing". Those who answered "Hot" or "Cold" at each temperature were recorded as responders, and those who answered "Feel nothing" at each temperature as non-responders was recorded.

First, sensory tests using the temperature stimulus probe were carried out on 10 healthy subjects and on 27 patients suspected of sensory impairment, who were chosen from among patients staying at or receiving outpatient services at Kumamoto University Hospital. Patients included those with central nervous system or spinal cord disorders, peripheral disease and systemic disease. Additionally, 16 patients suffered from diabetes. While it was noted that the different diseases affect different parts of the body, such as the myelomere, motor control areas, the entire body or just the periphery, fingers were conducted analysis to create the same test conditions as those used for the healthy subjects this time.

The sense of temperature characteristics of healthy subjects and possibly sensory-impaired patients were analyzed. The results of the healthy subjects are shown in Figure 11. The x-axis indicates the probe temperature and the y-axis the percentage of subjects. The percentage of "responders" to the temperature stimulus was very high at 25°C or less and at 45°C or more; indeed, it accounted for 90-100% of all subjects. On the other hand, between 30°C and 40°C it decreased sharply to 30-60%.

Next, the results of possibly sensory-impaired patients are shown in Figure 12. Compared to healthy patients, the percentage of "responders" was lower at all temperatures, and between 30°C and 35°C in particular. At that range, the percentage of "non-responders" constituted about 90% of all patients, while the ratio of "responders" decreased drastically.

Figure 13 shows a comparison of the results of healthy subjects and possibly sensory-impaired patients. The yellow dashed line indicates the ratio of "responders" among the healthy subjects, and the orange dashed line among the patients. In the case of the healthy subjects, the threshold temperature is somewhere between 40-45°C for the sense of warmth and 20-30°C for the sense of cold. In contrast, the threshold temperature of possibly sensory-impaired patients was 45°C or more for the sense of warmth and 5°C or less for the sense of cold. Moreover, temperature insensitivity was 30-45°C for the healthy subjects and 25-40°C for the patients. These results show that the patients suspected of sensory impairment were less sensitive to temperature stimuli than the healthy subjects.

As shown in Table 3, the threshold temperature for activation of the temperature receptors differed from receptor to receptor. It is known that TRPV2, for instance, is activated at 52°C or higher, and TRPA1 at 17°C or lower [10]. As the temperature stimulus probe can be set incrementally, it can be expected that the developed device will be able to conduct examinations for each receptor.

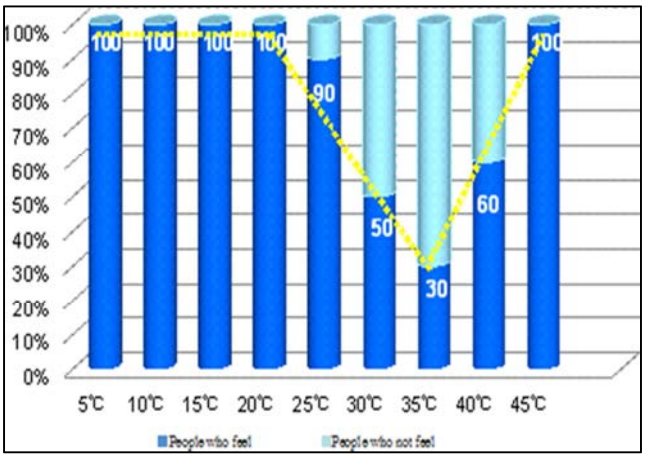

Figure 11. *Results of the clinical trial (Healthy subjects).*

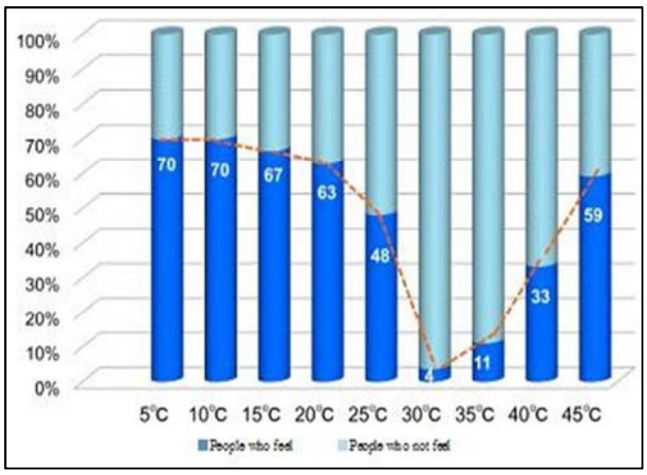

Figure 12. *Results of the clinical trial (patients who are suspected of sensory impairment).*

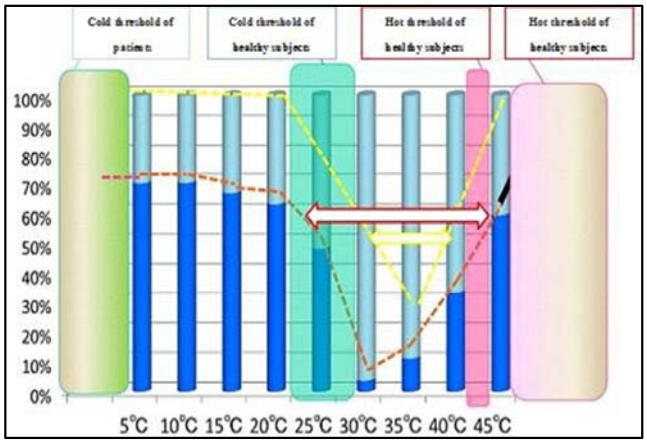

Figure 13. *Comparison of the experiment results between healthy subjects and possibly sensory-impaired patients.*

Table 3. *Temperature receptor and threshold temperature for activation.*

Temperature receptor	Threshold temperature for activation
TRPV2 (VRL-1)	52°C <
TRPV1 (VR1)	43°C <
TRPV3	32-39°C <
TRPV4	27-35°C <
TRPM8 (CMR1)	< 25-28°C
TRPA1 (ANKTM1)	< 17°C

3.2. Experiment on the Sense of Vibration Stimulus Probe

3.2.1. Operation Test

Experiments were performed to measure the vibration acceleration of the sense of vibration stimulus probe equipped with a vibration generation structure. Examining vibration generation in a 128Hz tuning fork for sense of vibration tests, which will act as the standard, was started. Figure 14 shows the tuning fork's vibration force measured by an acceleration sensor. Next, the vibration generation of the prototype sense of vibration stimulus probe was examined. Figure 15 shows the results of FFT analysis carried out on the probe. In addition to the fundamental frequency at 128Hz, the generation of vibration at multiple frequencies was detected. Figure 16 and 17 show the results of the vibration force measurement. Comparing Figure 14 with 16, it was found that the probe was able to generate almost the same vibration force as that of the tuning fork for sense of vibration tests. Moreover, a tuning fork is only available in vibration attenuation mode, whereas the prototype device is controllable with a microcomputer. This allows us to also provide an increment mode (Ramp+ Mode) in which vibration accelerates from 0 upwards, in addition to the usual attenuation mode (Ramp－Mode). Figure 17 shows the Ramp+ mode. It hereafter needs to verify what kind of vibration patterns are effective in clinical trials.

During the experiments, a problem concerning vibration noise arose. However, the problem was settled by attaching a buzzer on the vibration generator so as to mask the vibration noise with the buzzer noise.

3.2.2. Clinical Evaluations

Using the prototype vibration generator, vibration test were carried out on 5 healthy subjects in addition to the conventional test using a tuning fork, and subsequently made comparisons between them. Tests were carried out on the ulna styloid protrusion of the right and left (R, L) wrists six times per subject using a tuning fork, Ramp- Mode and Ramp+ Mode respectively. The results are shown in Figure 18. In tests using the vibration generator, for tests using Ramp – Mode, subjects were asked to indicate when they became insensitive to vibration as the same way that they do in tests using a tuning fork, while for tests using Ramp + Mode, subjects were asked to indicate when they could sense vibration. In tests using a tuning fork or Ramp – Mode, the vibration gradually attenuates, so the longer the time taken to indicate insensitivity, the more sensitive to vibration the subject is.

On the other hand, for tests using Ramp + Mode, the vibration gradually increases, so the shorter the time taken to indicate insensitivity, the more sensitive to vibration the subject is. In other words, if the measurement results of the tuning fork and Ramp - Mode are in correlation and those of the tuning fork and Ramp + Mode are in inverse correlation, the prototype device can be considered suitable for sense of vibration tests. As shown in Figure 18, the results clearly highlight a usefulness of this device. Stricter evaluation tests are planned hereafter.

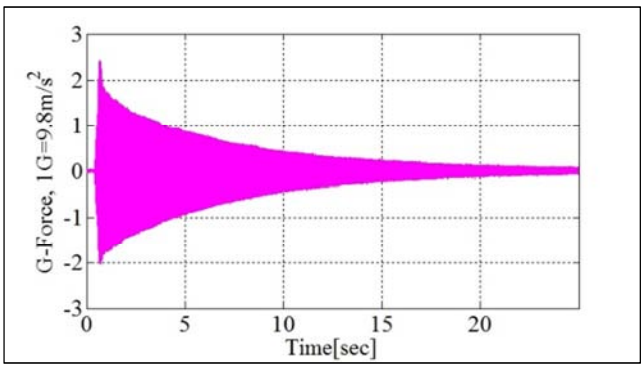

Figure 14. *The result of the vibration force measurement using a tuning fork.*

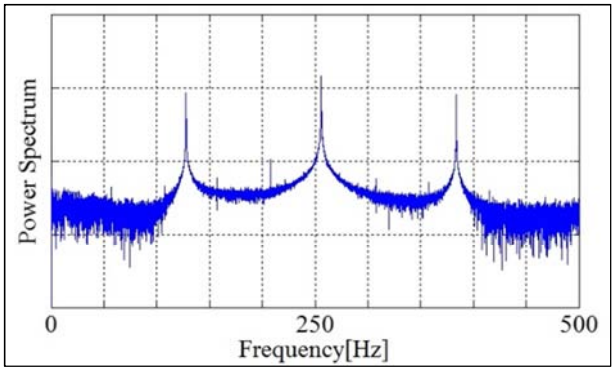

Figure 15. *The result of vibration force FFT analysis of the prototype vibration generator using an electric coil.*

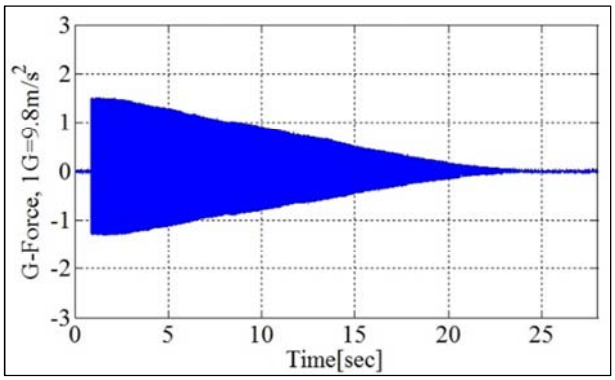

Figure 16. *The result of vibration force measurements in the Ramp ⁻Mode of the prototype vibration generator using an electric coil.*

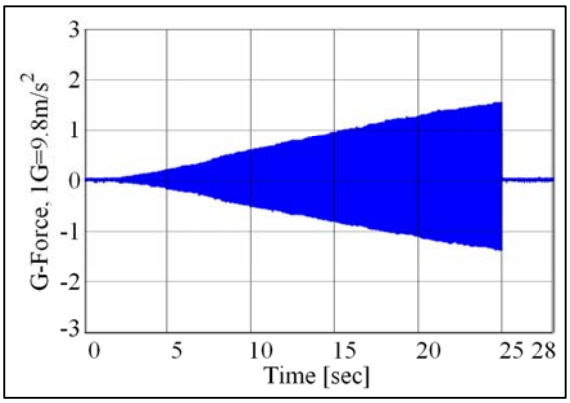

Figure 17. *The result of a vibration force measurement in the Ramp+ Mode of the prototype vibration generator using an electric coil.*

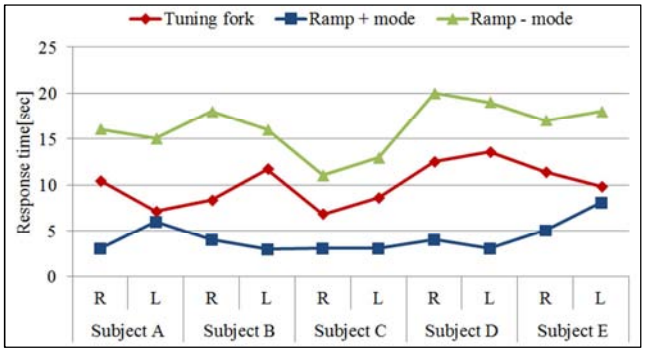

Figure 18. *Comparison of the sense of vibration tests using a tuning fork with those using our device.*

4. Conclusions

In this paper, the basic structure of and the evaluation test results for a temperature stimulus probe and a vibration stimulus probe as part of a sense testing device for use in the medical scenarios are demonstrated. We are currently working on adding a new function to the temperature stimulus probe to allow us to measure the temperature of the tested area of subjects [9]. It is anticipated that this addition will enable us to provide optimal temperature stimuli. Moreover, the sense of vibration probe is under clinical evaluation now, and a sense of touch testing function is also under development.

Acknowledgements

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