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Development of Portable Wireless Device for Diagnosis of Male Erectile Dysfunction

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Abstract

Erectile dysfunction(ED) is the status that does not make the erection for satisfying sex and is a continued status that does not maintain the erection. The prevalence(ratio) of the patients with erectile dysfunction who accompany seriously threatening health factors such as cerebral infarction or myocardial infarction is continuously increasing as the ages increase. Whether or not the degree of erectile dysfunction is severe or light, there is no significant difference in the occurrence of diseases, so even if it's light erectile dysfunction, it is necessary to diagnose in the early stage and treat the disease. Like angina pectoris that occurs due to the malfunction in the coronary artery, erectile dysfunction, as one of the vascular diseases, occurs because of the dysfunction in a penile blood vessel. Males with erectile dysfunction have a higher rate of coronary heart diseases and peripheral vascular diseases, and most of the patients have at least more than one threatening health factor of cardiovascular disease. While a measuring tool for the erectile ability is currently monopolized by one company in the world over 30 years, through developing a portable wireless device for diagnosis of male erectile that is localized, the selling price becomes realized and supplying it to each hospital becomes a goal by making after-service convenient.

Keywords: Erectile dysfunction(ED), wireless device, dysfunction device, tumescence, rigidity

I. INTRODUCTION

Sexual dysfunction for males is the most representative disease that shows in the elderly male, and erectile dysfunction is caused by old age, smoking, drinking, diabetes, high blood pressure, and cerebrovascular diseases [1]. There are various reasons for erectile dysfunction, and it often happens to modern society's males because of modern society's psychogenic, congenital, and hormone problems such as stress, anxiety, and depression. Erectile dysfunction is a symptom of not getting enough erection or not being able to maintain the erection, and it typically occurs when blood flow is not amicably satisfied [2-8]. The rate of erectile dysfunction is recently increasing among 20-30's young people, and from one epidemiological survey in Korea, it was reported that more than 50% of males in 30's had experienced the erectile dysfunction and the rate is increasing based on the ages [9-10]. The treatments for erectile dysfunction have amazingly developed since the development of Viagra, but the diagnosis to measure the erection ability is very limited. Until now, for measuring diagnosis of the erectile dysfunction, questionnaire that depends on the patient's subjective statement, ultrasound to understand the penis's blood flow rate, and a large scan that can obtain the objective data of erectility obtained from nocturnal penile tumescence and rigidity and stimulation of the sight and hearing are being used [11]. Measuring the penis's erection ability is measuring the most basic ability for males, so it contains many potential patients, and accurate, continuous, and quantitative measurement and analyzing method is needed. To gain the objective diagnosing data of erectility, a large scan which can be used in Korea is the only diagnosis instrument. Large scan device which is the only measuring device for erection ability in the world was developed 30 years ago, but it is still monopolized and produced at one foreign company called DACMED [12]. In case of a large scan, medical teams are experiencing the inconvenience because after-service is not easy and the price is high. In addition, because the device is big, the patient is feeling the inconvenience when they are active while attaching the device and during bowel movement and urination. Sending method of erection data from measuring device to a computer has not been improved, so an old type of cable is being used. Also, it's not rechargeable, but using the old batteries, so there's cumbersomeness to buy the batteries and replace them every time. Measuring method of erectile dysfunction is generally measured through a sleeping process, and many studies are going on to measure the rigidness, and tumescence at a current device. It has not commercialized yet, and there are many inconveniences of the current product's size and wearing, so participants have the limitation in movement during the sleeping process. As they are disturbed in their sleeping, it is difficult to measure the erection ability of the penis during sufficient sleeping period [13-15]. Through this study, I try to find the installing methods that do not give disturbance during measuring while the control group is sleeping and the method to minimize the product's size. Besides, in the original product, the measuring part(O-ring) which is installed in the penis and main body (portable measurement unit) that stores the measured data and that can identify it in real-time are connected with the cable, so there was an inconvenience of the control group's sleeping. To improve this inconvenience, measuring part(O-ring) and the main body (portable measurement unit) are separated wirelessly. Also, even if the control group is tossing and turning while sleeping, the data cable was made not to

be twisted. The disturbing factors are removed during the control group's sleeping to diagnose the abnormality of male's erection and to treat it properly.

II. MATERIALS

To develop the portable wireless device for diagnosis of overall male erectile dysfunction that can be used in various forms suitable for clinically utilizing purpose by measuring and analyzing the erection ability of male penis, the device that has a new sensor, main body, and wireless sending method was developed by using the original principle. Two sensors designed to surround the penis in the ring form measure the penis's rigidness, tumescence, the number of erection, and maintaining time while sleeping, and the data is sent to the main body connected by the cable. Optimal sensor material through analyzing the sensor material was applied, and by examining the data transmitted from the main body to a sensor, generation and saving of diagnosis information about penis are possible. Also, when main body's data is backed up, the data is saved in individual PC and cell phone by using wireless and USB cable, and it's possible to see the analyzed data in the graph. Fig 1 represents a schematic diagram of strain gages which was used as a sensor. By attaching strain gages to the silicon band, silicon band attached to strain gages is produced in the form of circle ring. Silicon band in sensor part is connected to a measuring instrument, and as tests using the software are progressed, reference values are drawn through the repetitive test, and when the reference value is drawn, the suitable test device is produced. Table 1 shows the characteristic and property of O-ring band material which is a measuring part. To study the proper materials of a measuring part installed on the penis, tension (elongation ratio) of O-ring band material that deals with penis erection was identified. During penis erection, there is no pressure in the penis and by replying 1:1 to penis erection, the material to elongate was chosen. By considering the cleanliness, harmlessness for humans, and economic feasibility during O-ring's wearing on the penis, the study on the materials without inconvenience during wearing was done.

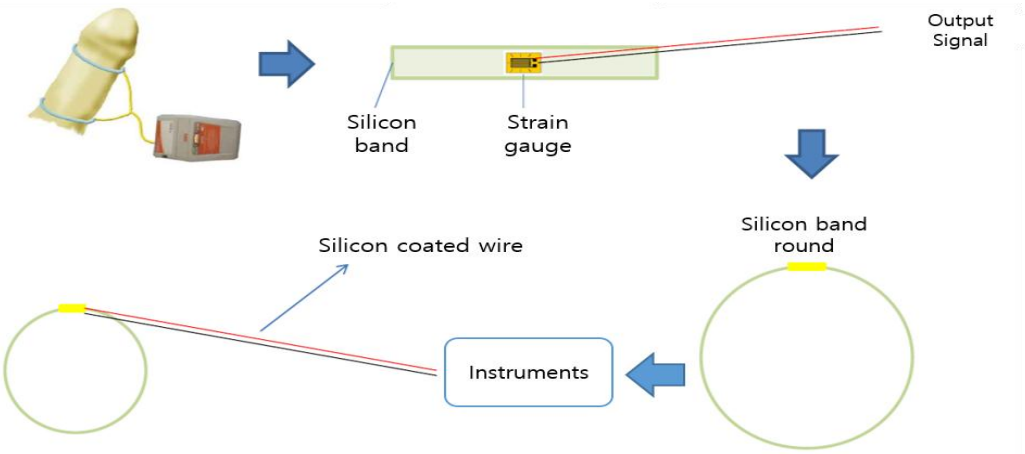


Fig. 1 Procedure for measuring data during tensile and compressing of strain gauge

Table 1. O-ring band material type

ASTM		NR	SBR	BR	CR	NBR	IIR
Weight of pure rubber		0.92	0.93~0.94	0.91~0.92	1.15~1.25	1.00~1.20	0.91~0.93
Polymeric Properties and Properties of Compound Rubber	Hardness (A)	30~90	40~90	40~90	40~90	40~90	35~90
	Tensile strength (kg/cm2)	70~280	50~230	50~230	60~250	50~250	50~150
	Strain(%)	100~600	100~500	100~500	100~500	100~500	100~600
	Elastic rebound(%)	A	B	A	A	A	
	Maximum Temperature(℃)	60	90	90	100	100	100
	Minimum Temperature(℃)	-40	-35	-45	-30	-25	-40
	Wear resistance	B	A	A	B	A	C
	Radius Bending Cracking	A	B	C	B	B	A
	Sanity check	D	D	D	B	D	A
	Gas permeability	C	C	C	B	B	A
	Heat-resisting property	D	D	D	B	D	D

III. RESULTS AND DISCUSION

Fig 2 represents the measuring principle and kinds of the strain gauge. Strain gauges responsible for an O-ring sensor is a sensor that measures the tension forces such as tension and pressure, and it has various kinds based on the measuring parts. It is used when measuring the force on the objects under test, the direction of force, and tension force, and by considering the kinds of strain gauges and the condition of attaching direction, the most proper sensor is chosen and studied. Table 2 represents the principle of strain gauges by formulating it. Strain gauge represents the relative strain or relative strain ratio of measuring object. It is a measured value with the ratio of increasing or decreasing length(ΔL) compared to the original length(L0) in the condition that measuring object gets an external force. Strain does not have a unit, but it's usually written with ㎛/m to recognize easily. Fig 3 is an electrical network diagram of the strain gauge. To develop the module exclusive for measuring the strain gauge, by using potential measuring circuit(Strain gauge output : mV/V), OP Amp amplifier (IC Chip that amplifies the minute output mV/V voltage value of strain gauge), and AD converter(transformation output of Strain-gauge analog output value(mV) with digital value), the interface module was developed to transmit the data value measured in the strain gauge by using DSP(Digital signal processor) which is an integrated circuit that can be handled rapidly by a machine with digital signal.

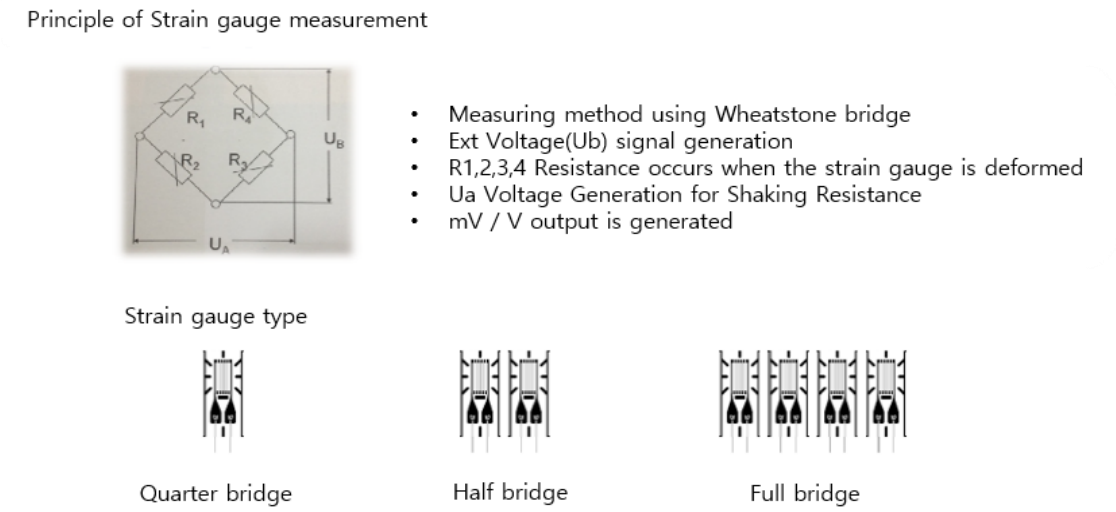


Fig. 2 Principle of strain gauge measurement

Table 2. Principle of strain gauge measurement

	mdification	Explanation
1-1	$R(\rho,L,S) = \rho \frac{L}{S}$	· The change in the resistance of the metal wire occurs when a force is applied to it as shown in Fig. 1-1. The total length L, the area S, the specific resistivity value p, and the total resistance of the metal wire as R, the relationship (1-1) is established.
1-2	$\frac{\Delta R}{R} = \frac{\Delta p}{p} + \frac{\Delta L}{L} - \frac{\Delta S}{S}$	· It increases by △L giving the tensile force of the metal wire. The cross sectional area is smaller by △S, and the resistance change rate a is the same as (1 - 2).
1-3	$\frac{\Delta S}{S} = -2v\frac{\Delta L}{L} = -2v\varepsilon$	· In general, if Poisson's ratio is v, then the rate of change of the cross-sectional area is given by (1-3).
1-4	$\frac{\Delta R}{R} = \frac{\Delta p}{p} + (1+2v)\,\varepsilon$	· In this case, the strain ε is dimensionless and generally expressed as μst (micro strain, 10-6). Substituting equation (1-3) into equation (1-2), the rate of change in resistance is given by (1-4).
1-5	$\frac{\Delta R}{R} = (1+2v)\,\varepsilon = F\varepsilon$	· In the range of strain considered, the rate of change of the metal specific resistance can be neglected, so it can be approximated as the following (1-5).
· F is called a gauge factor, and it depends on the resistance wire material to be used, and it has a characteristic value of roughly the second place.		

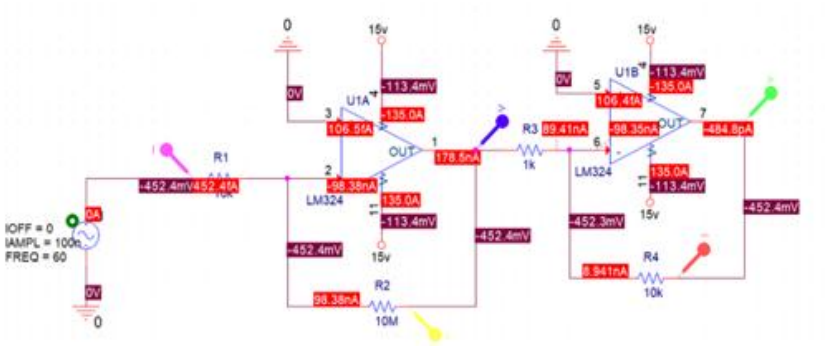


Fig. 3 Strain gauge schematic diagram

Fig 4 represents the wireless transmission circuit diagram, and Fig 5 represents the wireless receiver circuit diagram. From the reference value of strain gauge, as a calculating method of tumescence and rigidness about penis erection, the data from actual patients of erectile dysfunction was collected by using a new device. Males usually get 3-5 times of erection during sleeping, and clinical value of this phenomenon can be a useful index that can classify a healthy man and man with erectile dysfunction. For example, when penis erection occurs during sleeping, it's judged to be normal. If the status of penis erection is weak or when the erection is not formed, it's decided to be erectile dysfunction.

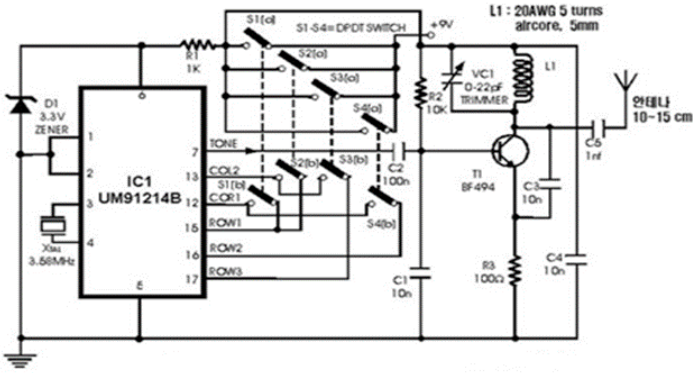


Fig. 4 Wireless transmit circuit schematic diagram

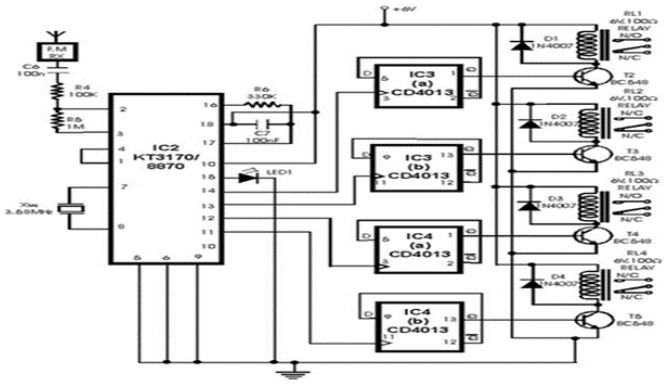
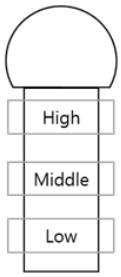


Fig. 5 Wireless receiver circuit diagram

Night measurement of erection during sleeping occupies the critical parts for the treatment of erectile dysfunction. Diagnosis system of erection by using a new device is composed of a sensor ring, connecting line, and communication device. Sensor ring directly touches on users' particular body parts and senses the change of body parts based on the time, and it generates sensing signal or sensing information. Sensor ring that makes the sensing signal measured in the sensor ring as data and saves it in the device in real-time compares the information about penis's rigidity, circumference and length of penis, skin temperature of penis, and temperature due to the blood flow inside penis with the original data, and sends it to the device by recognizing as sensing information. When the reaction by a physiological phenomenon that occurs during users' sleeping appears as the measurable degree at a detected signal in sensor ring and goes over the measuring threshold value, this is considered as valid data. Measuring threshold value measures the detected signal's size and duration time of a detected signal, and it is measured as valid information when it has the stroke numbers over a particular standard and the size. Table 3 represents the acquiring method of measuring the data.

Table 3. Measuring part data acquisition method

Purpose : Data acquisition in case of erection of various conditions (penis size, erection direction of the penis etc) through the selected measuring part (O - Ring) material and strain gauge (Strain-gauge).	
a. Acquisition of data by type of subject's penis size. b. Data acquisition according to direction (up, down, left, right) at erection of penis c. Data acquisition according to the fastening position (upper, middle, lower) of the measuring part (O-Ring). d. Data acquisition according to quantity (1 or 2) of measuring part (O-Ring).	
Derive a standardized strain gauge reference value for penile erection.	

The existing computer erection analyzer measures the night tumescence of penis by hanging the ring at glans and the bottom part of the penis, but it can disturb the control group's sleeping because its volume is significant and measuring time gets longer. Newly developed device for erectile dysfunction is a small device that makes sensing signal measured at sensor ring as data and can attach to the body. So, accurate data can be obtained while the control group does not experience the inconvenience during sleeping and tossing/turn by attaching it to the body part. Stored data in the device is simply sent to a desktop by using Bluetooth, not cable, and information can be analyzed. Fig 6 is an example of developing wireless measurement. Through individual mobile devices, data can be analyzed and checked easily at anywhere. With the protocol that was initially developed to send the storing or acquiring data by using the PC's serial port, the method to displace the data with scaling and replacing it with power was applied. By using the PC's serial communication, to send the data of tumescence and

rigidity at the same time, two data have to be sent by binding as one continuous packet, and at PC's serial communication, data is continuously transmitted by one byte from acquisition module.

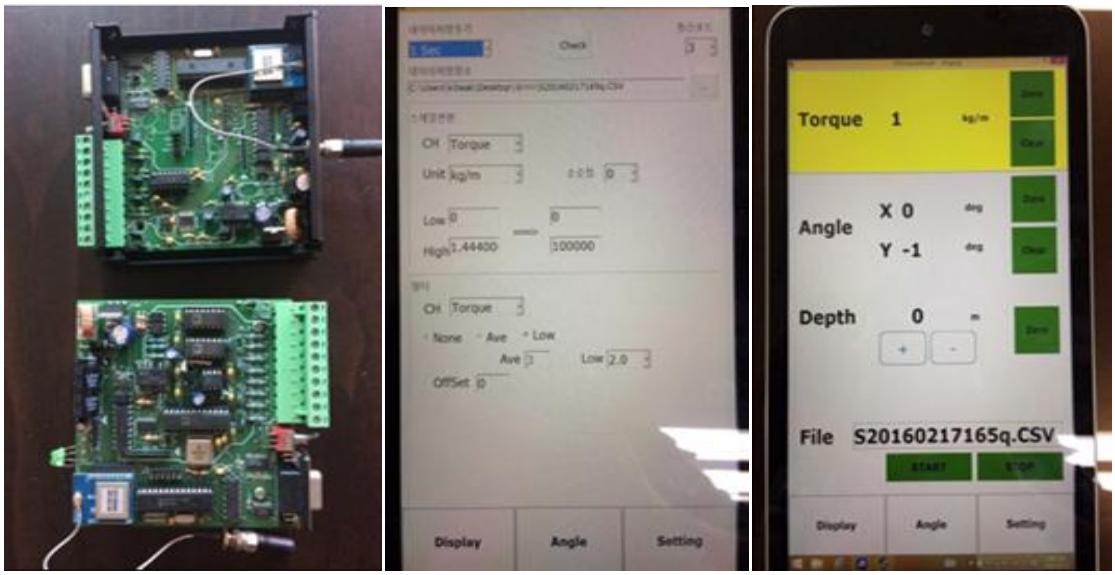


Fig. 6 Wireless measurement development case

The 4-bytes of data structure transmitted can be stated as follows: tumescence, tumescence, rigidity, rigidity. Stored data in a buffer from transmitting is read in multiples of 4 in the window program, and rigidity and tumescence are expressed as 2 bytes each. When using 2 bytes, expression of data from 0 to (2)16-1 is possible. To consider the data's direction obtained from the encoder, it is marked for the output from 0 to (2)15-1 in a clockwise rotation, and the value from (2)1 to (2)16-1 was expressed in a counter-clockwise rotation. The number of revolutions data of a sent encoder has to go through the scaling to replace the displacement. The measuring method of tumescence and rigidity is a converting method from the displacement by penis's expansion to revolutions of the encoder, so the sent data has to be changed to the displacement again. Rotations of the measured encoder will have positive and negative numbers.

After controller adds the value of (2)15 to this and converts it to the positive value, 2-bytes of data have to be sent. To obtain the existing number of encoder revolutions that considers the direction, (2)15 is first subtracted from 2-bytes of value sent. When multiplying the displacement change criterion (sf=2 πr/encoder pulse per 1 rotation) that conforms to encoder's one revolution, final displacement can be obtained which is necessary for the calculation of rigidity and tumescence. The equation of conversion and rigidity to change to the displacement is stated below. Displacement change criterion measures the encoder and the diameter of the connecting part and has to be entered in the program in advance. Rigidity is expressed as a percentage (%) about the solid without elasticity and tumescence is represented in an integer that has mm units.

$$y^i = (x^i - 2^{15}) \times sf$$
$$sf = 2\pi r / (encoder\ pulse\ per\ 1\ rotation)$$
$$rigidity(\%) = y^i \times 100$$

The operation and drive graph of the device are shown in Fig. 7, where the X axis represents time and the Y axis represents the size change of the penis. The graph shows the duration of erection, and can measure the number of erections during the experiment. In this experiment, we could obtain a strain-gauge graph by fabricating a prototype based on it, purchasing a substitute for a penis that expands and contracts in volume. Fig. 8 shows the shape and operation graph of the actual prototype. (a) is an actual photograph and a measured graph of a substitute for a penis indicating erection. It can be seen that there is no change in the Y-axis according to the change of the X-axis changes. (b) is an actual photograph and a measured graph of penis substitute indicating erection, and the change of the Y axis can be known as the volume of the substitute product expands, that is, as the penis erects.

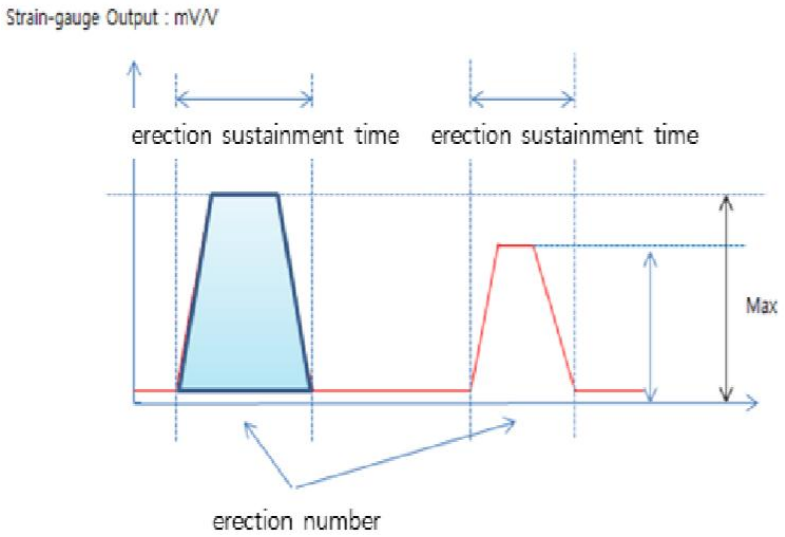


Fig. 7 Device operation and drive graph

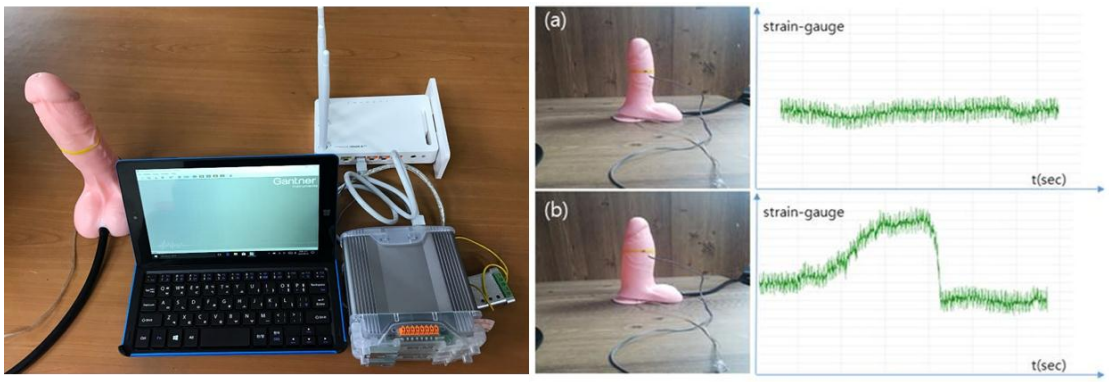


Fig. 8 Date graph of strain gauge achieved: (a) before erection (b) after erection

IV. CONCLUSION

As a technology to provide data suitable for the purpose by measuring and analyzing the erection ability of male penis, the device to diagnose the insensible erection phenomenon during sleeping was developed by measuring the tumescence and rigidity of night erection of the penis. By developing the software to analyze objectively, as individual tendency and distinct characteristic were measured, diagnosis and treatment of erection ability were suggested, and wireless, portability, and convenience increase by lightning and downsizing the device. The existing sensor and ring can be damaged easily, and the repair is not easy, so by improving the durability of the new material, it brings the life extension effect of the device. Also, by visually displaying the sensing information and the health status of upper body parts based on the sensing time, health status can be easily identified. By building the database based on this data, the program that can synthetically and professionally measures and analyzes the male's erection ability was developed. Localization aspects model can be suggested by replacing the foreign device used initially, and medical prediction diagnosis, securing of technology, and IT technology professionalism in the medical area can be improved. Through improving the convenience of technology to diagnose the erection dysfunction and the technology of predicting the diseases, promotion of people's health and prevention and decreasing of diseases are expected, and improvement of medical diagnosis technology's work can be predicted.

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