Receipt Number: NO. NE-3089

Test Results Report

Client:	*Please contact Panmedic for this info if needed*
Address:	Aichi Prefecture, Nagoya, Higashi-ku, 18-3, Tokugawa 2-chome
Article tested:	thermotherapy device
Trade name of article:	Sonotron
Manufacture number:	HS-00073
Date of testing:	4 April 1992
Testing standards:	JIS T1001 (general safety rules for electronic devices for medical use) as well as the manufacturer's standards.
Test results:	as attached

We affirm that the test results are those described above.

13 April 1992

Machine Electronics Inspection and Verification Association (Foundation)
(referred to hereafter as JMI)
Nakabe Center
Manager: Masamitsu Kitagawa

JMI **Seal of Approval**

Test Results

Ambient conditions: temperature 21°C; humidity 59%
Rated voltage: AC 100 V; 50/60 Hz

Type of protection against electric shock: Class I device
Degree of protection against electric shock: B-type device

Summary Description of the Item to be Tested

The device relieves the pain of joint inflammation by applying to the surface skin of the patient radio energy, together with heat, in the form of electromagnetic waves. This is done at a radio frequency of 430 kHz, modulated through an audio frequency of 3 kHz~5 kHz, which, utilizing a discharge tube, comes from a discharge electrode.
The discharge electrode is contained in the plastic housing of the applicator and, thus, by maintaining a fixed distance between the housing and the surface of the patient's skin, treatment is administered without any contact.

1. Power Source Input Test

   After pre-heating, we measured the continuous (input) electric current when we applied the rated voltage to the test unit while it was operating under normal conditions.

   279 VA

2. Voltage Resistance Test

   We determined whether there was any discharge or insulation breakage. After pre-heating and humidifying the unit, we applied the test voltage corresponding to the reference voltage. Such was done for a period of one minute. (Insulated portions and test voltages are displayed in the table included in the section on testing requirements.)

   Nothing unusual.

3. Current Leakage Test

After pre-heating and humidifying, we measured for current leakage as noted below, operating the item with 1.1 times the rated voltage.

	After Pre-heating		After Humidifying	
Path of the current	Normal conditions	Simple failure conditions	Normal Conditions	Simple failure conditions
Ground leakage current	0.078	0.051	0.096	0.066
Sheathing leakage current	0.058	0.078	0.061	0.096
1				
Patient leakage current 2				
3				
Patient measured current				

4. Resistance Test of Protective Ground Circuit

Running a 20 A current, we measured, with an energy source of 6 V 60 Hz no-load voltage, (1) the resistance between the portion of potential conductivity contact and the protective ground terminal and (2) the resistance between the ground prong of the removable energy-source cord and the protective ground terminal that can arise under simple failure conditions.

(1) Between the portion of possible conductivity contact and the protective ground terminal 0.02 Ω
(2) Between the ground prong of the energy-source cord and the protective ground terminal 0.08 Ω

5. Temperature Test

We measured the temperature, as noted below, operating the unit with 1.1 times the rated voltage.

(converted to ambient temperature of 40°C)

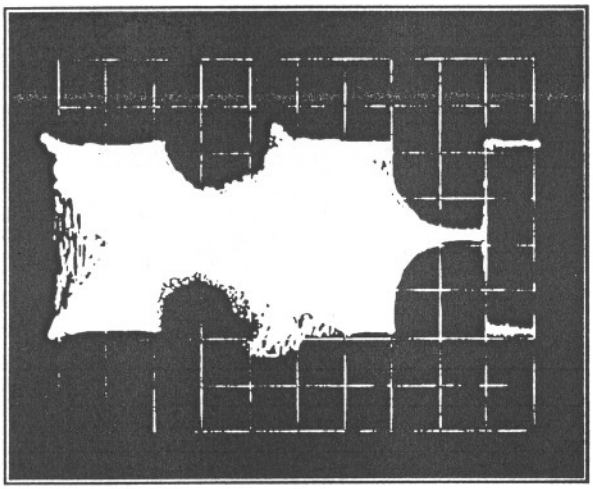
Surfaces of portions such as handles, knobs, and clips that one touches continuously under normal operating conditions (molded materials). . . 56°C

Surfaces of portions such as handles, knobs, and clips that one touches for a short period of time under normal operating conditions (molded materials). . . . . 55°C

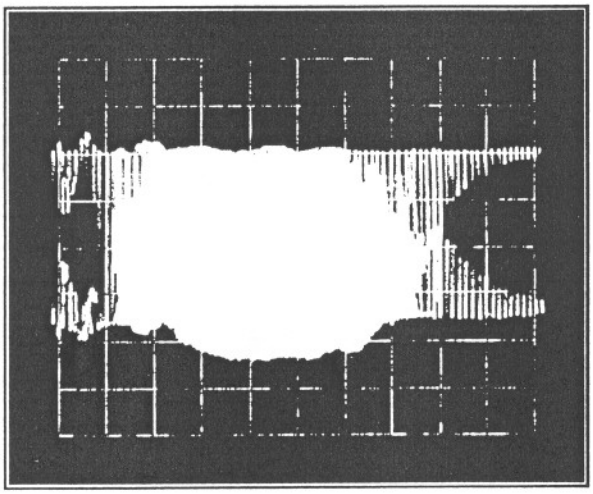
Sheathing of the unit . . . . . 58°C

6. Wave-Pattern Observation

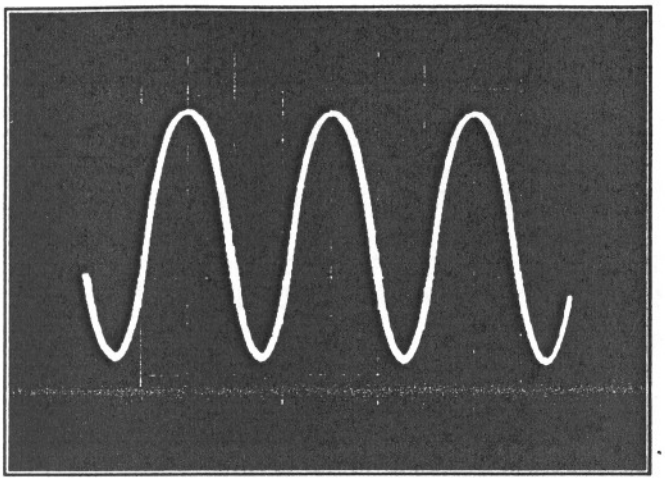
We observed the wave patterns, as shown below, that were released from the discharge electrode when we operated the unit with the rated voltage.
We made a lead-wire ring of approximately 8 cm around the cylinder portion of the applicator and connected to that ring a 10-kΩ resistor. Next, to both ends of that resistor we twisted and attached a lead-wire of approximately 5 cm in length and, using an oscilloscope, we observed the wave pattern that was output on either side.



1 V/DIV
20 μ sec/Div



1 V/DIV
200 μ sec/Div



1 V/DIV
1 μ sec/Div

7. Temperature Test

Adding the rated voltage to the unit, we measured the temperature after 5 minutes of operation, which consists of an alternation between 15 seconds of operation and 6 seconds of rest.
We assumed the distance between the end of the applicator, where the discharge electrode is contained, and the surface of the patient's skin to be 0.5 cm, as at the time of treatment.

(converted to ambient temperature 40°C)

73°C

Hereafter, blank.

Test Requirements

Prior to each test, we carried out the following preparatory measures.

Pre-heating: We carried out the pre-heating treatment in accordance with JIS T 10003 3.4.1.

Humidifying: We placed the item in the humidifying vat and carried out humidifying treatment in according with JIS T 1003 3.4.2.

Voltage Resistance Test

Marking of insulated portions is done according to JIS T1001 6.3.2.

Insulated portion	B-type device	BF • CF-type device
	Test voltage (V)	Test voltage (V)
A – a	1000	
A – e	1000	
A – f	1000	
A – g		
A – h		
A – j		
A – k	1000	
B – a		
B – d		
B – e		
B – f		

In this test, the testing standards as well as the items to be tested were specified by the client. The unit satisfactorily passed all the tests to which it was subjected.

I affirm that this data was compiled on the basis of results from tests that I, myself, carried out.

Engineer who performed tests: Masao Ohashi