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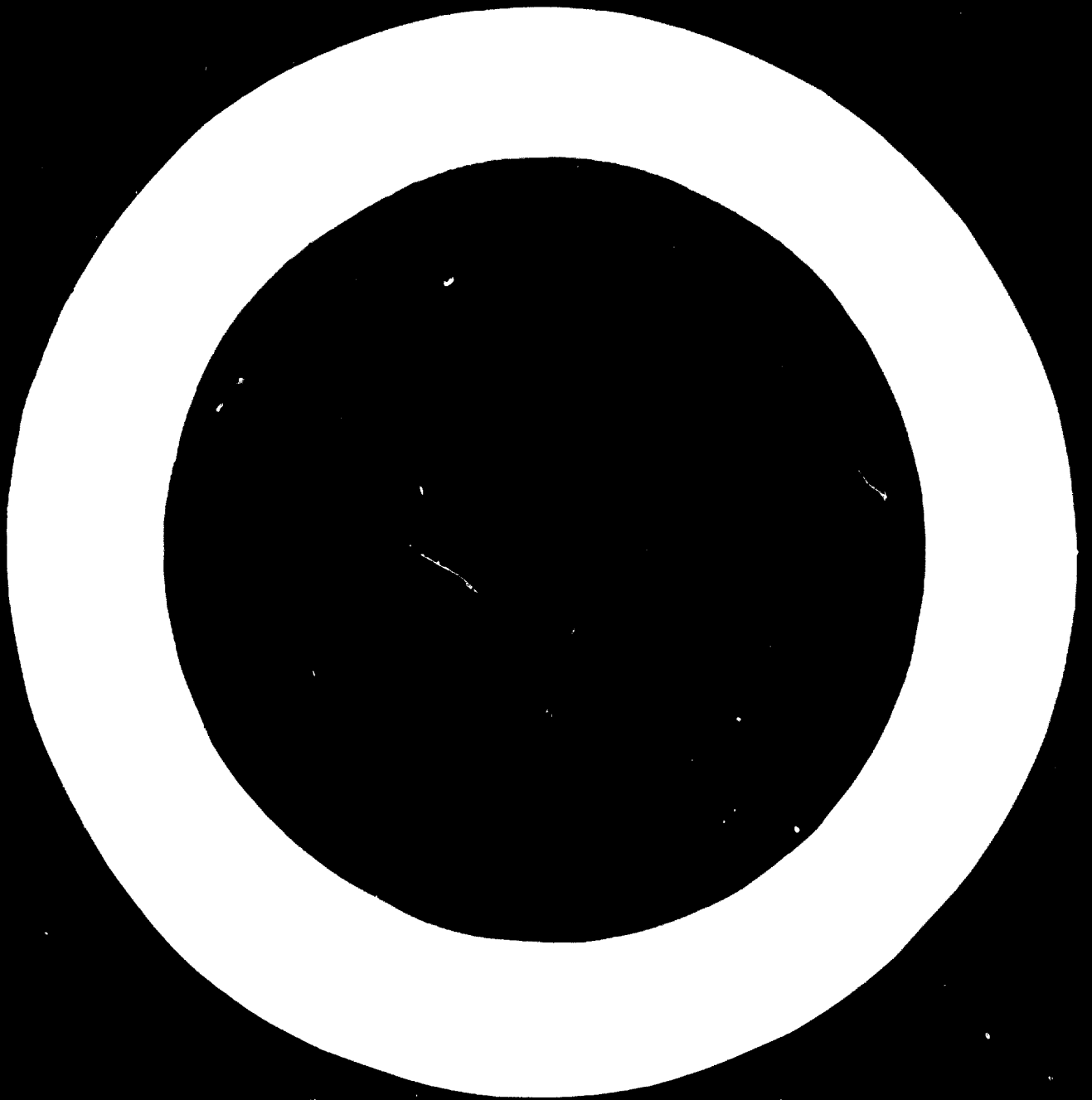
PRODUCTION AND DISTRIBUTION OF CONTRACEPTIVES
IN JAPAN^{1/}

by

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I. OUTLINE OF FAMILY PLANNING IN JAPAN

Results of a series of surveys carried out by the Mainichi Newspapers of Japan during the past two decades concerning public opinions on family planning in Japan are shown as follows:

(1) Response to the question - "What do you think about family planning?"

As summarized in the Table 1, it was demonstrated that the percentage of the response, "I think it is good", was 60% in 1950. This percentage has gradually increased year after year and has maintained the level of 80% or more since 1967.

The increase in the percentage of persons who answered that they thought family planning "good" seems to indicate a deeper understanding by the Japanese people about family planning.

Table 1. Response to the question - "What do you think about family planning?"

(Unit in %)

Survey Number	Time of Survey	Response				
		Good	neither good nor bad	Bad	Non-Committal	Others and no response
1	April 1950	60.7	-	15.0	13.5	10.8
2	May 1952	65.0	-	11.6	14.2	9.2
3	May 1955	67.4	-	10.7	8.7	13.2
4	May 1957	72.0	-	9.2	6.8	12.0
5	April 1959	74.2	-	8.8	5.9	11.1
6	April 1961	69.1	-	7.6	8.0	15.3
7	May 1963	88.0	1.9	0.6	6.1	3.4
8	May 1965	87.5	1.7	0.8	6.3	3.4
9	May 1967	84.9	2.8	1.3	7.5	3.5
10	June 1969	84.6	2.3	1.5	7.8	3.7
11	July 1971	85.4	3.0	1.1	7.4	3.1

(2) Response to the question - "Why do you practise family planning?"

As shown in Figure 1 the majority of Japanese families practise family planning for the purpose of "giving better education to fewer children" or "keeping the mother healthy".

II. CONTRACEPTIVE METHODS CURRENTLY USED IN JAPAN

In 1969 the Public Relations Section of the Prime Minister's Office in Tokyo released a report on the contraceptive methods currently used in Japan (Table 2).

As is evident from (Table 2), the condom is the dominant contraceptive method, followed by the rhythm method, foaming tablets and jelly in the percentage of their applications.

Figure 1: Response to the question - "Why do you practise family planning?"

Survey report July 1971

(Unit in %: The total percentage exceeds 100% due to multiple responses per person.)

The Reasons:

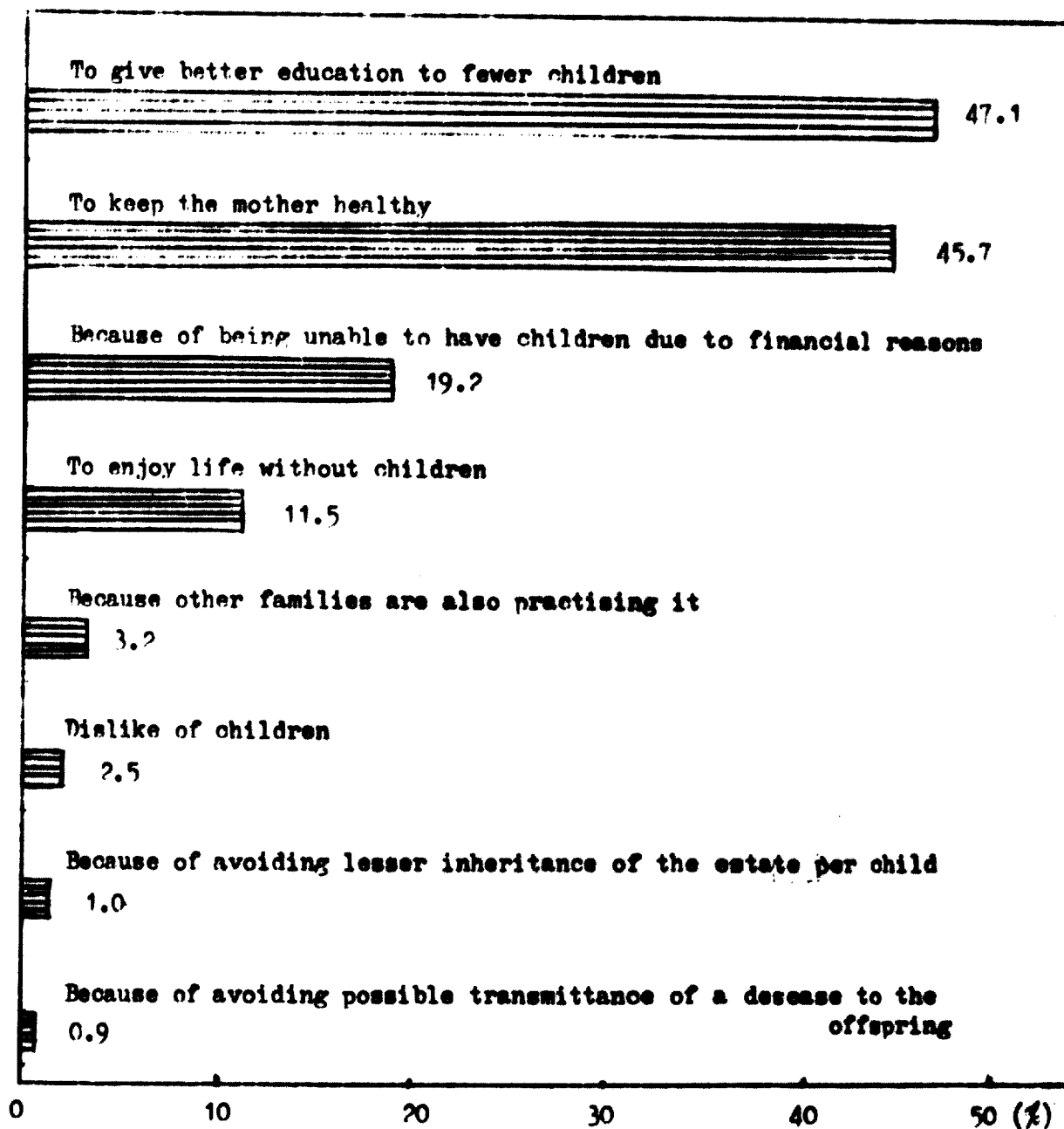


Table 2. Contraceptive Methods Currently Used by the Japanese people **

(1969)

Contraceptive Methods	%
Condoms	62
Rhythm Method	29
Basal Body Temperature Method	8
Foaming Tablets	6
Withdrawal	5
Jelly	15
Dianhrags	3
Miscellaneous	13

* (Total percentage exceeds 100% due to multiple responses per person; N=1,212)

** All the products, e.g. condoms, foaming tablets and jelly preparations were produced in Japan.

III. CONTRACEPTIVES AVAILABLE IN JAPAN

Pharmaceutical Affairs Regulations in Japan are strictly enforced to ensure professional quality and good practices in the manufacture and distribution of drugs, quasi-drugs, cosmetics and medical devices.

At the outset, the standards for the structure or equipment of the manufacturing establishments for drugs, quasi-drugs, medical devices or cosmetics are enforced under the specific ordinances of the Ministry of Health and Welfare; therefore if any structure or equipment is found not to conform with such standards as mentioned, the license for running the above mentioned manufacturing establishments is withheld.

Under stringent controls and regulations all pharmaceutical manufacturing establishments are frequently checked in detail to maintain the manufacture and distribution of standard quality products.

Each item for production is scrutinized by the Ministry of Health and Welfare for the nomenclature, ingredients, quality, usage and dosage, effect, efficacy and other relevant details prior to their manufacture or import.

Furthermore, the Central Pharmaceutical Affairs Council, one of the auxiliary organs of the Ministry of Health and Welfare, carries out investigations and deliberations in response to the request of the Ministry of Health and Welfare, concerning important pharmaceutical affairs including manufacture or import of new drugs or new medical devices.

The following are some of the examples involving the regulations by the Ministry of Health and Welfare concerning contraceptive products.

(1) Condoms

1 The quality is prescribed by Japanese Industrial Standards annexed at the end of this paper. It is prohibited to manufacture and sell the products if the quality does not comply with these standards. In addition, it must conform with the standards stipulated by the Ministry of Health and Welfare under the provisions of the Pharmaceutical Affairs Law.

Furthermore, the manufacturers make effort to ensure that high quality is maintained by establishing their own standards.

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Furthermore, the manufacturers make effort to ensure that high quality is maintained by establishing their own standards.

ii The manufacturers are as follows:

Okamoto Rubber Industries Co. Ltd.	2071, 4-chome, Hirai Edogawa-ku Tokyo
Sagami Rubber Industries Co. Ltd.	9-8,, 3-chome, Uchikanda Chiyoda-ku Tokyo
Fuji Latex Industries Co. Ltd.	22-1, 2-chome, Higashi- Tateishicho, Katsushika-ku Tokyo

These manufacturers mentioned above account for 95% of the total production. The remaining 5% are produced by a few manufacturers.

(2) Diaphragm

i It is prescribed that the quality shall accord with the standards specified by the Ministry of Health and Welfare under the provisions of the Pharmaceutical Affairs Law.

ii A few manufacturers are engaged in this production.

(3) Intra-Uterine Devices

IUD's are not legally permitted to be manufactured and sold in Japan. This is due to the fact that data on side effects such as irregular haemorrhage, haemorrhagic leukorrhoea or prolonged menstruation etc. has not yet been obtained. However, The Japanese Society of Obstetrics and Gynaecology has been performing clinical tests and studies of influence on tissue in 22 universities in order to respond to an inquiry made by the Ministry of Health and Welfare.

Upon obtaining the results of this investigation, the Central Pharmaceutical Affairs Council will deliberate the pros and cons of its marketability.

(4) Jelly and Foaming Tablets

i Quality Standards:

Under the stipulation provided in the Article 43 of the Pharmaceutical Affairs Law of Japan, any and all contraceptive jelly or foaming tablets shall not be sold nor distributed unless they have passed the tests made by the person or such independent and competent corporation as the National Hygienic Institute which is designated by the Ministry of Health and Welfare.

At present two kinds of surfactants are permitted as active compounds for contraceptives in Japan. Oxyquinoline sulfate and phenylmercuric acetate are now marketed for the manufacture of contraceptives.

(a) Foaming Tablets

A foaming tablet containing menfegol is one of its active ingredients, is a new contraceptive marketed in Japan since 1969. Manufacturing and selling licenses were issued by the Government on the basis of pre-clinical and clinical data, including controlled studies on more than 500 married couples who used the foaming tablets for a year or more.

Menfegol, a surfactant, possesses so potent a spermicidal activity that spermatozoa completely lose their fertilizing ability within a minute even at such a low concentration as 0.06%. In spite of the potent spermicidal activity of menfegol, the number of living bacterial count such useful vaginal bacteria as Doederlein bacilli, is not decreased after incubation with 8% of menfegol for 60 minutes. The foaming tablet, containing menfegol, is rapidly dissolved to effervesce in normal vaginal secretions; this phenomenon, besides the potent spermicidal activity of menfegol ensures the prevention of mobility of spermatozoa in the uterus. It was confirmed by clinical examinations that the foaming tablet did not cause any significant loss of natural feeling nor any serious side-effects. Moreover, any significant changes in the pH value of vaginal secretions were absent following the administration of the foaming tablets. Pregnancy rates during the use of foaming tablets have been reported to range between 2.3 - 6.8, (according to the Stix-Notestein methods) based on the results of well-controlled studies with 587 couples at five hospitals and 13 medical institute in Japan.

(b) Jelly

The active ingredient Polyoxyethylene nonylphenyl ether is a kind of surfactant, with no influence on the human body and is available for continual use.

It mixes well with the semen and shows sufficient spermicidal effect immediately because it is supplied in dissolved form.

It also has the characteristic of easy after-use procedure because it is composed of an aqueous substance with a proper viscosity.

This is permitted because there is sufficient data over a long term and the product has been marketed since 1966.

ii The manufacturers in Japan are as follows:

Foaming Tablet:

Eisai Co. Ltd.

6-10, 4-chome
Koishikawa, Bunkyo-ku
Tokyo

Jelly:

Daichi Yakuhin Sangyo Co. Ltd.

3, 2-chome
Nihombashi-Edobashi
Chuo Tokyo

Yamanouchi Pharmaceutical Co. Ltd.

5, 2-chome
Nihombashi-Honcho
Chuo-ku Tokyo

Oral Pill

This is under deliberation in the Central Pharmaceutical Affairs Council. No product has been permitted in Japan because there is an academic matter concerning side effects in cases where it is administered for a long time.

IV. PRODUCTION AND PRODUCTABILITY

The production of contraceptives in Japan is as indicated in the table on page 9. The production of every item is increasing in accordance with the diffusion of proper knowledge of contraception and with the demand for export. These products are being manufactured by modernized facilities and advanced techniques, which make it possible to produce an increased volume by as much as 50% over the level of 1970, providing production is operated at its full capacity.

Under these circumstances, any possible additional demand coming from developing countries could easily be met.

	1961	1962	1963	1964	1965	1966	1967	1968	1969	1970
Condom	2,491,837	2,384,541	2,447,704	2,986,075	3,065,643	3,548,063	4,278,302	4,586,678	5,348,718	5,727,044
Dianhrene	158,555	401,336	1,072,576	165,947						
Sponges	17,700	16,700	16,700	11,000						
Irrigator	9,712	6,708	7,447	7,800						
Foaming Tab.	15,053	22,755	26,841	51,398	40,396	45,048	26,572	38,552	36,364	37,607
Jelly and Cream	70,714	75,568	66,425	52,238	74,892	63,234	61,199	53,124	39,537	68,110

The production after this is unknown. (The effect of contraception by means of irrigators is not approved)

* Gross
 ** 1000 Tablets

JAPANESE INDUSTRIAL STANDARD
for
Condoms

1. Scope

This standard specifies condoms of latex, hereinafter referred to as the "condoms".

2. Material

The material for condoms shall be of natural rubber latex as specified in JIS K 6381 - Natural Rubber Latex. When non-adhesive substances, lubricants or colouring agents are used, such shall not be harmful to human beings.

3. Dimension

The full length of condoms, in principle, shall not be less than 17 cm.

4. Quality

4.1 Appearance The condoms shall be of uniform thickness free from such defects as flaws, pinholes, bubbles and inclusion of impurities. When a preventive device against detachment is provided, such shall be for this specific purpose.

4.2 Elongation, Tensile Strength and Elongation after Ageing

(1) Test shall be carried out according to the methods specified in 5.3 (1) and 5.4, and satisfy the requirements of Table 1.

Table 1.

<u>Elongation</u> %	<u>Tensile Strength</u> kg/cm ²	<u>Elongation after ageing</u> %
Not less than 600	Not less than 200	Not less than 540

(2) Test by method of 5.3 (2) shall show no irregularities.

4.3 Pinhole Tests by method 5.5 shall show that the resistance value is not less than 200 k Ω .

5. Test

5.1 Test Items The test items for condoms shall be as follows:

(1) Dimension and appearance.

- (2) Tension test
- (3) Ageing test
- (4) Pinhole test

5.2 Dimension and Appearance Matters specified in 3. and 4.1 shall be examined.

5.3 Tension Test The tension test shall be made as follows:

- (1) Test for elongation and tensile strength by using No. 2 test piece in accordance with method specified in 3. Tension Test of JIS K 6301-Physical Testing Methods for Vulcanized Rubber.
- (2) Put 2 marks (10 cm apart) in the middle of the test sample. Hold both ends of the test sample under normal temperature, stretching it until the distance between the 2 marks becomes 50 cm. After holding it under these conditions for 5 minutes, examine if any irregularities appear in the area between the two markings.

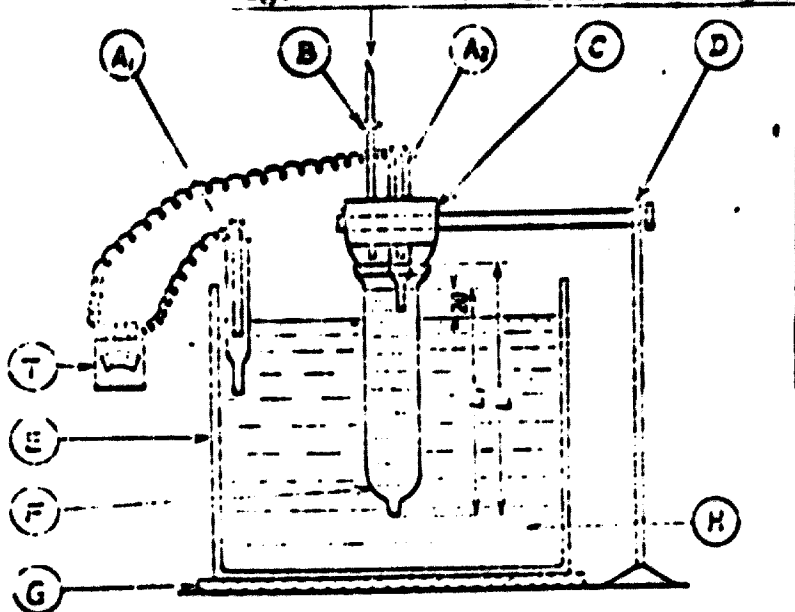
5.4 Ageing Test Take test piece similar to (1) of 5.3 and after 72 continuous hours of air heating ageing test as specified in 6.3 of JIS K 6301, conduct test (1) of 5.3 and measure elongation.

5.5 Pinhole Test As indicated in Fig. 1, fix electrode shown in Fig. 2 to the container filled with a 1% sodium chloride solution and insert the other electrode in the test sample. Next, submerge the test sample while filling 9/10ths of it with the same solution (height of the solution level in the test sample should be about 20 mm above the height of the surrounding solution), and about 30 seconds later measure the resistance between the electrodes.

Measuring instruments used shall conform to JIS C 1202-Testers, and the temperature of the solution shall be maintained at 20° - 30°C.

Fig. 1 Sketch of Pinhole Test Container

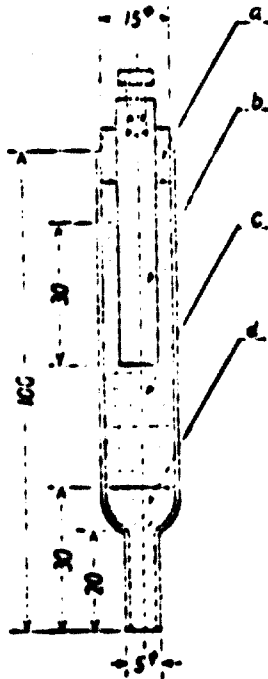
Unit: mm



- A₁, A₂: electrodes
- B: cock for pouring in 1% sodium chloride solution
- C: test sample holder (polyethylene or glass)
- D: support
- E: container
- F: test sample
- G: insulator (paraffin plate)
- H: 1% sodium chloride solution
- T: circuit meter
- L: full length of test sample
- L₁: approximately 9/10ths of full length

Fig. 2 View of Electrode

Unit: mm



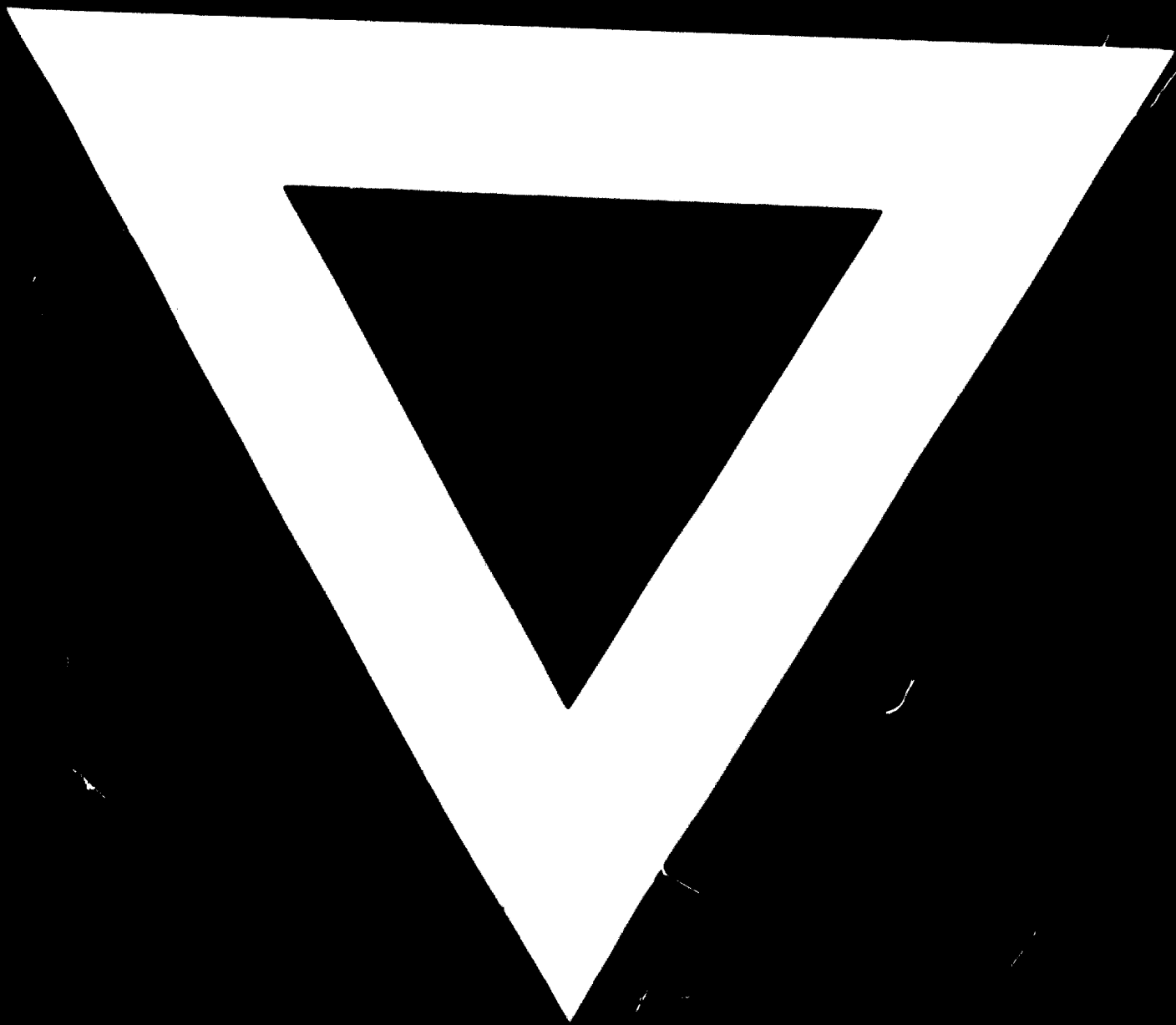
- a: cork or rubber
- b: zinc electrode
- c: saturated zinc sulfate solution
- d: agar (3 g agar and 3 g potassium chloride dissolved in 100 ml of water)

Markings

The following particulars must be indicated on each condom package:

- (1) Designation
- (2) Quantity
- (3) Name of manufacturer
- (4) Date of manufacture or other code markings





11.3.74