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AN ASSESSMENT OF REPORTED CONDOM DETERIORATION IN BANGLADESH

A Report Prepared By:
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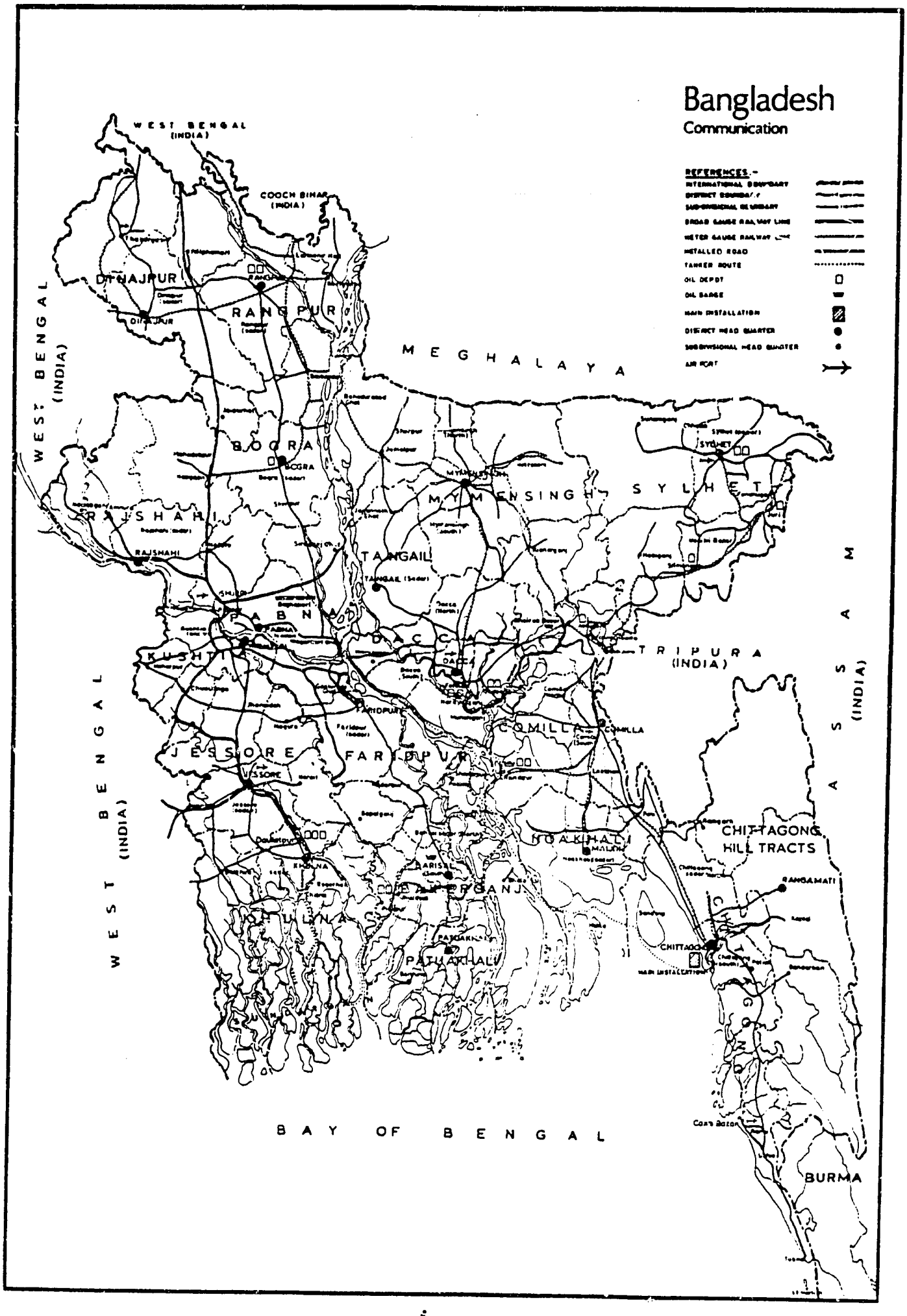
Bangladesh
Communication
REFERENCES.-
INTERNATIONAL BOUNDARY
DISTRICT BOUNDARY
SUBDIVISIONAL BOUNDARY
BROAD GAUGE RAILWAY LINE
METER GAUGE RAILWAY LINE
METALLED ROAD
TANKER ROUTE
OIL DEPOT
OIL BARGE
MAIN INSTALLATION
DISTRICT HEAD QUARTER
SUBDIVISIONAL HEAD QUARTER
AIR PORT
WEST BENGAL (INDIA)
COOCH BIHAR (INDIA)
DINAJPUR
RANGPUR
MEGHALAYA
BOGRA
RAJSHAHI
MYMENSINGH
SYLHET
TANGAIL
PABNA
DACCA
KUSHTIA
TRIPURA (INDIA)
ASSAM (INDIA)
COMILLA
JESSORE
FARIDPUR
NOAKHALI
CHITTAGONG HILL TRACTS
KHULNA
BARISAL
BAKERGANJ
PATUAKHALI
CHITTAGONG
BAY OF BENGAL
BURMA

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ABBREVIATIONS

AID	Agency for International Development
AID/W	Agency for International Development, Washington
AQL	Acceptable Quality Level
ASTM	American Society for Testing and Materials
CBFPS	Community-Based Family Planning Services
CDC	Centers for Disease Control
CDI	Condom Deterioration Index
FIFO	First In-First Out Method
FPA	Family Planning Assistant
FWA	Family Welfare Assistant
FWV	Family Welfare Visitor
GSA	General Services Administration
MOH	Ministry of Health
NFPB	National Family Planning Board
OC	Oral Contraceptive
PIACT	Program for the Introduction and Adaptation of Contraceptive Technology
PSI	Population Services International
SMP	Social Marketing Program
TEMO	Central Warehouse, Dacca
TFPO	Thana Family Planning Officer
UNFPA	United Nations Fund for Population Activities
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHS	Westinghouse Health Systems

I. INTRODUCTION AND BACKGROUND

Purpose of the Assignment

The results of 1981 PIACT/Bangladesh* air-burst and water-leak tests on condoms sampled from stocks in Bangladesh indicated a recommended high level of "rejected" lots and "alert" lots (see Appendix D).

The Office of Population of the United States Agency for International Development (USAID) requested that the condition of condoms which the Agency provides to Bangladesh and which are stored in-country be evaluated in accordance with the tensile-strength and water tests described in Interim Federal Specification, Condoms, Rubber Contraceptives, ZZ-C-001597A (GSA-FSS) (see Appendix A).

AID also desired that the results of the tests performed by PIACT/Bangladesh be analyzed and compared with the results of tests performed in the United States to accepted U.S. standards.

In addition, because storage conditions and the method(s) of distribution may critically affect condoms, a current assessment of clearing, warehousing, and distributing condoms in the Bangladesh program was included in the assignment.

This report contains observations on condom storage and distribution in Bangladesh; the results of tests performed by PIACT/Bangladesh and at Akwell Industries, in the United States; and the methods of testing, storing, distributing, monitoring, and packaging condoms in the United States.

Recommendations are proposed for the sampling and testing of condoms supplied by the Population Program of the Ministry of Health (MOH) in Bangladesh.

Background

In accordance with certain bilateral arrangements to support population programs, the Office of Population of the Agency for International Development (AID) provides assistance, in the form of contraceptive commodities, including condoms and oral contraceptives (OCs), to developing countries. Generally, the contraceptives are produced in the United States in accordance with established regulatory U.S. standards for such products. Contraceptive

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* PIACT = Program for the Introduction and Adaptation of Contraceptive Technology.

commodities for Bangladesh usually are shipped by sea, except in unusual circumstances, at which time shortages are filled by emergency air shipments. Contraceptives are distributed to users in-country through three primary channels, each of which is described below.

1. A network of family planning workers and assistants and family welfare assistants (FWAs) who work for the Division of Population Control and Family Planning, Ministry of Health and Population Control, receive condoms and pills from family planning offices in the thanas, the lowest administrative level. The contraceptives are provided free to users.

2. Family planning clinics affiliated with Ministry-operated hospitals provide free contraceptives to users.

3. Small local vendors sell condoms and pills directly to consumers at subsidized prices. These contraceptives are distributed through existing commercial channels. They have their own well-advertised brand names: Raja for condoms and Maya for pills.

The condoms distributed by the Ministry's program through thana family planning offices are supplied in bulk to the Ministry's program by AID. The clinics are supplied by district family planning offices. The district is the next highest administrative level. There are 20 districts in Bangladesh and approximately 400 thanas. The district warehouses are supplied from the central warehouse in Dacca (TEMO) and regional warehouses in Chittagong and Khulna (see map of Bangladesh, page i). The Chittagong regional warehouse also is the clearing and receiving agent for contraceptives shipped by AID to the Population Control and Family Planning Division of the MOH.

The Social Marketing Program (SMP) distributes contraceptives to retail vendors who sell them at subsidized prices. The contraceptives are shipped directly to the SMP by AID; cleared at the port by an agent of the SMP; repackaged at the SMP's central warehouse in strips of three packaged condoms in a small cardboard container; and then sent to commercial distributors and wholesalers who fill orders from vendors and retailers.

Condoms made from latex are subject to deterioration, because of aging over time and environmental factors, such as exposure to ultraviolet light, elevated temperature, ozone, changes in humidity, and mechanical pressure and stress. Manufacturers, working within the constraints of the costs and benefits of packaging materials, select materials designed to reduce the effect of such factors on the durability of the condoms prior to use.

Condoms in temperate zones often are usable, even though they may have been stored as many as five years after manufacture.

Deterioration may be exacerbated when the condoms are stored under tropical conditions. It is possible for condoms which have become defective over time to reach a user, if steps are not taken to ascertain periodically the products' suitability when the condoms have been stored for more than a year under tropical conditions.

The Program for the Introduction and Adaptation of Contraceptive Technology (PIACT), based in Seattle, has developed equipment and testing techniques to assist population program administrators in determining whether or not condoms are suitable and whether they should or should not be distributed (see Appendix C).

PIACT/Bangladesh was established in Bangladesh to assist the Division of Population Control and Family Planning in sampling and testing condoms stored in-country to evaluate whether or not they are acceptable for use. A summary of the steps in the 1981 evaluation is given below.

1. In early 1981, PIACT/Bangladesh sampled condoms at the request of the Bangladesh Ministry of Health and Population Control. The condoms were sampled from stores at TEMO, family planning district warehouses at Bogra and Rajshahi, and several thana family planning offices, and in the Social Marketing Program. Samples were selected in accordance with the standards of the American Society for Testing and Materials (ASTM) (see Appendix B).

2. The sampled condoms were subjected to air-burst and water tests in the spring and fall of 1981. In accordance with PIACT protocols, air-burst tests were conducted by PIACT/Bangladesh on lots of 100 condoms that had been sampled to reach confidence levels considered suitable by PIACT. Water tests were conducted on a sufficient number of pieces to establish whether a lot could pass the 0.4 percent Acceptable Quality Level (AQL) established by the American Society for Testing and Materials (see Appendix B).

3. PIACT described the results of the air-burst tests, using a condom deterioration index (CDI). The CDI provided the indication to "accept" (CDI<2.8), "alert" (CDI 2.8 to 3.4), or "reject" (CDI>3.4) the condoms (see Appendix B). The number of condoms that burst with less than 11 ml of air (.388 cu ft) also was an indication to "accept," "alert," or "reject" the product. (A total of 100 pieces was tested.)

4. Lots of condoms subjected to the water tests were either accepted, if an AQL of 0.4 percent was reached, or rejected, if the lots did not pass the acceptable AQL.

5. In its preliminary report (see Appendix D), the Ministry described the condom lots that were sampled and tested by PIACT/Bangladesh. Using the three criteria of the CDI, the results of the air tests (the number bursting with less than 11 ml of air), and the results

of the water tests, the Ministry indicated that virtually all the lots had been "rejected" or were "on alert." Only three of 22 lots were "accepted" (see Appendix D).

6. The test results released by PIACT/Bangladesh were corroborated by PIACT/Manila, which used the same PIACT protocols for air-burst and water tests.

The AID Office of Population now provides to population programs condoms obtained from two U.S. suppliers, Akwell Industries and Circle Rubber; however, the condoms tested by PIACT/Bangladesh in 1981 were manufactured by Akwell Industries.

Multi-colored 49mm Akwell Tahiti condoms, similar to condoms shipped to Bangladesh, were delivered to Thailand, Indonesia, and the Philippines. Akwell condoms shipped to and stored in these countries were sampled and tested in-country by PIACT-affiliated organizations using PIACT protocols, and were determined to be acceptable for use.

AID purchases condoms for bilateral assistance programs in accordance with the regulations contained in Interim Federal Specification, Condoms, Rubber Contraceptives ZZ-C-001597A (GSA-FSS), dated September 19, 1977 (see Appendix A). This specification includes sampling plans for a water-leakage test conducted in accordance with specifications MIL-STD-105, and for tests of tensile strength and elongation (described in ASTM D3492). Required tests of tensile strength are also listed among the standards of many other countries, including Great Britain and Japan.

Air-burst tests, as used by PIACT, are not usually performed on condoms that are to be distributed commercially in the United States; nor are air-burst tests applied to condoms supplied to programs sponsored by various government agencies or the U.S. military. Countries such as Sweden, Denmark, and Canada require that condoms that are to be imported pass air-burst tests, but, rather than use the levels established in the ASTM tests of tensile strength (D3492), they specify acceptance levels that differ from those in the PIACT protocol.

II. CONDUCT OF THE ASSIGNMENT

After reviewing the results of the PIACT/Bangladesh tests (see Appendix D), the consultant made an initial visit to one of AID's principal suppliers of condoms, Akwell Industries (now the Ansell Corporation), in Dothon, Alabama. The purpose of the trip was to review the comparative merits of tests of tensile strength and elongation of latex condoms, as called for in ASTM D3492, and air-burst tests, as used by PIACT/Bangladesh. A similar review with representatives of PIACT/Bangladesh and PIACT/Seattle was subsequently conducted in Dacca.

In Dacca, during a visit to PIACT's laboratories, the consultant arranged for the shipment to the United States of 100 condoms from each of seven lots sampled by PIACT/Bangladesh in 1981. The condoms were to be subjected to tests of tensile strength and elongation and to air-burst tests (see Appendix F). Subsequently, water tests also were conducted in the United States on these samples. To permit comparative analysis with the tests to be performed in the U.S., PIACT made available the details on the results of the tests conducted by PIACT/Bangladesh.

In April 1982, with the cooperation of the Office of Population, AID/Bangladesh, the consultant visited the TEMO central warehouse, the Chittagong regional warehouse, and thana and district stores in Chittagong, Tangail, Mymensingh, and Dacca. New samples were taken for comparative testing (see Appendix F). Two hundred pieces were taken from each of 19 lots, from which samples of 100 pieces from eight lots were shipped to the United States for tests of tensile strength, and air-burst and water tests (see Appendix G). The remaining 100 pieces were sent to PIACT/Bangladesh for in-country testing, using the PIACT protocol. Thirteen sites were visited to sample condom stocks and to ascertain conditions of storage and the movement of the product through the distribution system.

A visit also was made to the Social Marketing Program to ascertain whether any defects in the condom products had been reported and to examine the clearing and distribution system used by the SMP.

The consultant met with the director-general of the Division of Population Control and Family Planning, Ministry of Health and Population Control, to review the purposes of the study. Some initial observations were reviewed with the director-general. Briefings were held with staff of the Office of Population, AID/Dacca and AID/Washington (AID/W), subsequent to the field visit.

III. OBSERVATIONS AND FINDINGS

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Distribution and Storage

A summary of the consultant's principal findings on distribution and storage follows.

A. Shipping

1. Shipping time from the factory in the United States to Bangladesh ranges from three months to four months.

2. Little time is lost in the intervals between manufacture and packaging and packaging and shipping from the factory, because the manufacturers produce only enough condoms to fill orders and do not maintain factory inventories (as Akwell Industries used to do several years ago).

3. The lot number on a carton of 100 condoms indicates that a batch has been tested and packed together, but not dipped together. Dipping for different colors occurs at different times, perhaps on different dipping lines, and may be affected by formulation, dip and cure time, and atmospheric conditions.

4. It is unlikely that the failures of condoms which PIACT/Bangladesh has reported can be attributed to shipping. The time to reach Bangladesh by sea is only a few weeks longer than the time to reach Indonesia and Thailand. In neither Indonesia nor Thailand, where similar Tahiti 49mm-wide condoms of similar age were tested using the PIACT proctocol, were any problems revealed.

B. Clearance

1. Condoms shipments are cleared by Ministry staff through the port of Chittagong. To date, the time for clearance has ranged from 14 days to six months.

2. At the Chittagong regional warehouse, which the consultant visited in April 1982, it was learned that 30 million condoms in 5,000 cases (six consignments) had taken at least five months to clear. In contrast, a recent shipment of Circle Rubber con-

doms was cleared in 14 days. During the consultant's visit, 2.5 million pieces were released, with 27.5 million pieces remaining in storage. The delay seemed to be due to the disposition of demurrage and storage charges between the Ministry and the Port Authority. The delay caused a draw-down of stocks throughout the system. Continued delay would have limited the supply available to users.

3. Sheds were built at the port only two years ago. Before storage areas were provided, the goods waiting to be cleared were left outside, subjected to sunlight and rain, as well as heat and humidity. Even now, crates are sometimes left outdoors until they can be placed in sheds.

4. The Social Marketing Program uses a private clearing agent who routinely clears the program's incoming condoms in 14 days.

5. Normally, it should take 14 days to clear customs; the time should not exceed 21 days.

C. Warehousing

Regional

1. Administrators in Chittagong Region have responsibility for clearing customs and then shipping commodities to the TEMO central warehouse and the Khulna regional warehouse. The Chittagong regional warehouse, where goods are initially received from the port, is quite spacious. When this facility was visited, dunnage (crates supported off the floor to provide ventilation) was being used. The quantity in the warehouse was insignificant because of delays in clearing the port.

   For some time, Chittagong did not use consistently the first in-first out (FIFO) method to receive and disburse goods. Products were moved in and out, while condoms with earlier manufacturing dates remained for months. Now that the Chittagong warehouse is rather empty, the staff claim to be adhering to the FIFO method.

   If too many condoms are received at once, and the warehouse is not well-organized, the overflow may confound attempts to adhere to the FIFO method. Furthermore, if capacity at the regional warehouse is exceeded, the overflow is sent to the district warehouse in Chittagong, a small facility. If capacity at the district warehouse is exceeded, the district warehouse has difficulty maintaining the FIFO method, and thus pushes the goods to the thanas.

2. The TEMO central warehouse, a modern and spacious facility, was not completed until late 1978. Before that time, storage was poor. Stocks, which were low in April 1982, were provided with dunnage and ventilation and are now arranged to accommodate the FIFO method. However, recent shipments from TEMO to several districts (Tangail and Mymensingh) were of older stocks and did not reflect adherence to FIFO procedures.

3. The Khulna regional warehouse was to have been visited, but the trip had to be canceled because an AID car could not be made available on short notice.

4. The Ministry plans to build a regional warehouse in Bogra.

District

1. The capacity of storage facilities, storage conditions, and adherence to the FIFO method vary. Some facilities are very good; some are very limited.

2. If a district is supplied with more commodities than it can store, the condoms are moved directly to the thanas, where stock areas are limited. District records do not indicate stocks by date of manufacture.

3. One district still has 1978 stock. The storekeeper took the initiative not to distribute the stock.

Thanas

1. Often the stock area is in the office of the family planning officer, or in a small room. In some rare instances, a separate, spacious area is available for storage. Compliance with FIFO is erratic. A storekeeper usually is assigned the role of keeping records of stocks received and disbursed to each family planning assistant (FPA), family welfare assistant (FWA), and the family welfare (health) visitor (FWV).

   If it is supplied beyond capacity, the thana family planning office passes the condoms to field workers, without regard for these workers' requirements. Thana records do not identify stocks by date of manufacture.

2. Field workers are expected to distribute 200 condoms each month. (There are 100 pieces in each carton.) In a few industrial areas, workers may distribute 300-400 condoms each month. Field workers store the condoms and pills in their homes before they distribute them.

Some thana records reveal that field workers have received a shipping case of 60 cartons (6,000 condoms)--a sufficient supply for 30 months at 200 condoms per month. In one instance, it was explained that a field worker received a case because the FPA was responsible for supplying depot holders. Although direct distribution to users by field workers is monitored, depot holders--village chiefs, for example--receive condoms to sell, but they are not held accountable, nor are they monitored.

The thanas which the consultant visited have 25-40 family planning field workers and approximately 5-10 family welfare visitors, who also disburse condoms and pills.

D. Transportation

1. Condoms are shipped directly by rail to the TEMO central warehouse. If space in a railroad car is not available, the condoms are moved to the Chittagong regional warehouse, where they are stored until railway space becomes available.

2. Trucks provided by the United Nations Fund for Population Activities (UNFPA) are used to transport commodities from TEMO and the regional warehouses to the districts. If TEMO trucks are available to the district deputy director, they are used to transport goods to the thana offices. Because the inclination is to use UNFPA trucks, if they are available, the district warehouse tends to oversupply the thanas.

3. The thana family planning officer (TFPO) provides for local transport, using his or her own "contingency funds," if the thana's condom supply is low and stocks must be replenished from the district. The TFPO bills the district for reimbursement for transportation expenses, and waits for some time to receive payment. Payment, however, may not be received. Delays in reimbursement may encourage the TFPO to overstock supplies when a UNFPA truck is available, because, in this way, the TFPO can avoid incurring expenditures for transportation.

E. General

1. In some offices in thanas and districts, condoms with manufacturing dates prior to 1979 are not being distributed at the initiative of the storekeeper or the TFPO without formal authorization. In one instance, a TFPO requested condemnation. A condemnation procedure was approved by the Division of Population Control, but because a condemnation board had not been organized, the product had to await condemnation without being distributed.

2. Pre-1979 condoms examined by hand and blown up by mouth in the field seemed to have deteriorated. Few condoms were seen that were more than three years old (pre-1979).

Sampling and Testing

The consultant's principal findings on sampling and testing are summarized below.

1. PIACT/Bangladesh principally sampled condoms from a number of thana offices in several districts in the northwestern part of Bangladesh and Bogra, and stocks in Rajshahi District, as well as stocks at TEMO and at various locations where the Social Marketing Program is under way.

   The districts in the Northwest were selected at random, although the Northwest is, coincidentally, an area which experiences the hottest weather in the country, in May and June (higher than 100° F).

   Results of the PIACT/Bangladesh air-burst tests using the PIACT protocol and the results of the water-leak tests indicate that a large number of rejects can be found among condoms in the lots sampled in the thanas and districts (11 out of 22). Lot No. 19, from TEMO, which was about one and one-half years old, was considered to be "rejected." Four lots, including those from TEMO and SMP/Dacca, were considered for an "alert." Of the 22 lots, the three considered "acceptable" were all from the SMP (they were either stocks from the central warehouse or stocks sampled in the district).

   The SMP condoms (Raja brand), which did well in the PIACT tests, were (and are) manufactured and tested by Akwell Industries. Akwell applies the same standards (ASTM D3492) as the Ministry applies to the Tahiti brand.

2. There appears to be some correlation between the results of condoms considered "rejected" in the PIACT air-burst tests and the results of condoms which failed the water tests, which were conducted by PIACT using ASTM standards (see Appendix B).

   The failures which PIACT reported were replicated in air-burst and water tests performed at Akwell Industries on PIACT samples which were parts of lots of condoms sampled by Bangladesh in 1981.

   Although the samples failed both the air-burst and water tests which PIACT and Akwell performed, the condoms in the samples

fell within the limits of acceptability when tests of tensile strength and elongation were performed at Akwell in accordance with ASTM D3492 (see Appendix F).

3. According to Bradley Pugh of Akwell Industries, the combination of high tensile strength and measures of elongation indicates the structural qualities of good latex, determined by the formulation used; temperature and duration of curing; and environmental conditions at the time of dipping. Following manufacture, deterioration of the overall qualities of the rubber because of environmental factors (e.g., ozone, chemical pollutants, heat, and ultraviolet light) can be measured by changes in reduced tensile-strength measurements, as specified in ASTM D3492.

   Water-leakage testing, according to Bradley Pugh, measures the structural integrity of the latex film as it relates to the total effectiveness of the dipping process, and indicates whether impurities have created weak spots in the film, even though the latex formulation may be good.

4. The samples that failed the water tests at Akwell usually ruptured at Position Five on the condom (see Appendix I). Position Five is a curved position near the closed end of the condom. When a condom is rolled in a package, it is at the point of greatest stress on the condom, where there is greatest exposure to environmental changes.

   PIACT has observed that air-burst failures generally occur near the closed end; this observation is consistent with Akwell's findings on water-test failures.

   It appears that immediately after manufacture, condoms may pass tensile-strength and water tests, but that after aging in tropical conditions specific to Bangladesh, they may fail tests of tensile strength. Such failure may indicate weak spots in the structure which will pass water tests after manufacture but become particularly susceptible to factors contributing to deterioration.

5. Of eight lots of condoms sampled in April 1982, by R.L. Belsky (see Appendix E), three lots (two from Circle Rubber and one from Akwell Industries) revealed during tests of tensile strength that a larger number of condoms broke below 20 MPa (see Appendix G) than at any other point. Two of the lots, RLB-3 and RLB-6, were acceptable. The first 25 pieces of the third lot, RLB-8, were accepted, but the second 25 pieces that were tested were suitable for rejection, per ASTM D3492.

   Few of the condoms from the same lots, however, ruptured below 11 ml (.389 cu ft) of air. Significantly, the three lots, tested in May 1982, had manufacturing dates of May 1981, and August 1981, indicating that they were a year (or less) old.

The results seem to reflect Bradley Pugh's suggestion that the different aspects of the rubber measured by tests of tensile strength compare with tests of water and air.

6. PIACT has a method to assess test results which takes into consideration the fact that tests reveal that changes in condom properties, due to aging, do not conform to normal distribution. PIACT has suggested that the use of results based on the mean of either air-burst or tensile-strength tests as criteria for the acceptability of aged condoms does not reflect the large number of low outliers to the distribution curve for results of tests of products. PIACT has developed a condom deterioration index for air-burst tests to account for statistical variability (see Appendix C). The intent is to alert population program administrators to lots of deteriorating condoms (those with a CDI between 2.8 and 3.4), or to advise that lots with a CDI greater than 3.4 be rejected.

7. There are inherent difficulties in using a narrowly constructed statistical approach to evaluate the results of tests of aged condoms. The problems have less to do with variability in aging of condoms than with the accuracy and meaningfulness of the sampling procedures as they relate to the way condoms are manufactured, packaged by arbitrary lot assignments, and stored at various points in the distribution network.

   AID purchases variously colored condoms which are packaged at random in strips of plastic pouches. Condoms of different colors go through separate dippings. Therefore, there may be variability by individual color in the overall strength and surface integrity of the rubber in a lot sampled in the field, because of the effects of formulation and cure and the individual dipping process for different colors. It is interesting to note that breaks in water tests at Akwell Industries on PIACT/Bangladesh-sampled condoms affected only one or two of the colors in a lot.

   Lot numbers are assigned at the time of testing and during packaging of several colors in the factory, rather than after each individual condom is dipped in a particular color run.

8. A further skewing of results may occur during sampling at different points in the distribution chain.

   If the product is sampled at the regional warehouses or at the TEMO central warehouse, the person undertaking the random sample is confronted with sealed shipping cases, each of which contains 60 cartons. Each carton contains 100 condoms of three or four different colors.

If the number of shipping cases is large (75 or more), it may be extremely difficult physically to take a true random sample of the cases. If a warehouse is full, there is no easy way to spread out the cases, or to reach into the stacks, for good sampling.

In April 1982, when the TEMO warehouse was relatively empty, there were several different lots of shipping cases, one of which consisted of 60 cases, or a total of 360,000 condoms. Samples of condoms were selected by numbering the cases in the lot, and the cartons in a case, and asking observers to arbitrarily pick up a number. The result was a random selection for two cartons of 100 condoms. Presumably, but not necessarily, the condoms reflected the universe in the lot to be evaluated.

ASTM D3492 calls for tensile strength and elongation tests on 25 pieces from each lot, not to exceed 144,000 pieces. Accordingly, 75 pieces should have been tested for tensile strength. Actually, during the tests at Akwell Industries, of the 100 pieces available (100 remained in Bangladesh for tests by PIACT/Bangladesh), 50 pieces were used in tests of tensile strength and 50 in air-burst tests. The number of condoms for acceptance or rejection will have to be recalculated to obtain a meaningful statistical result.

9. Sampling at the thana level is feasible, because the stocks are small (six to ten shipping cases). Condoms sampled from different lots in the thana are particularly representative of the effects of shipping, storage, and the environment on the particular universe. However, in terms of the quality of those products with the same date of manufacture, the rejection of a lot from a specific thana may not necessarily have the same significance as rejection in other thanas (or in district or regional warehouses).

10. The results from testing samples from district warehouses have broad significance for identifying and acting on a poor-quality product, because the stocks (i.e., the universe) are larger. However, it is difficult to obtain a good random sample, because a lot may consist of as many as 50 cases, all crammed in an individual room of a house, making access to all cases in the lot very difficult.

11. The results of tests at Akwell Industries on PIACT/Bangladesh-sampled condoms and condoms sampled in April 1982, indicate that some condoms in the Ministry's program may deteriorate to an extent to cause breakage in use.

12. Circle Rubber condoms, manufactured in May and August of 1981, were tested for tensile strength as Lots RLB-3 and RLB-8, respectively; these condoms passed the tests, but the results, as noted by the number of tensile-strength breaks below 20 MPa, suggested that a significant degree of aging had occurred for condoms which were only one year old (or less). The results of water tests on RLB-8 and air-burst tests by PIACT (see Appendix J) confirm this. The lot should be condemned.

    Similarly, Akwell condoms, Lots RLB-4 and RLB-6, manufactured in May 1980 and May 1981, passed the test of tensile strength, but a few condoms broke at less than 20 MPa, which would indicate the beginning of aging. The air-burst tests conducted by PIACT (see Appendix J) would have indicated the rejection of these lots. However, tests performed at Akwell suggest that the lots may still be usable.

    Tahiti condoms (RLB-5) satisfactorily passed the Akwell tests of tensile strength, but, of the 50 pieces, two produced air-burst failures below 11 ml. In contrast, only one of 100 condoms from Lot RLB-5 burst below 11 ml in air-burst tests conducted by PIACT/Bangladesh.

    The results of tests of tensile strength (see Appendices G and H) at Akwell Industries on Lots RLB-1, -2, -5, and -7, Tahiti brand, dated July 1979 - May 1981, indicated a very good product.

    It would appear that the PIACT field tests are useful indicators of difficulty, but they cannot entirely predict a lot for rejection. The results of water tests on Lot RLB-8, a backup to air-burst tests and tests of tensile strength, do confirm when a lot should be rejected.

    According to Bradley Pugh of Akwell Industries, low tensile strength and low elongation readings suggest an incomplete cure (see findings on Circle Rubber condoms, Lot RLB-3), but low tensile strength and higher elongation readings indicate the effect of ozone or some other contaminant (see findings on Akwell condoms, Lot RLB-6).

13. During air-burst tests, the consultant observed how Circle Rubber's and Akwell Industries' condoms filled with air. Circle Rubbers' condoms stretch slowly from the end that is being filled with air toward the closed end, with the tip stretching very little. This indicates the presence of a thicker wall at the closed end. (Circle condoms measured between 0.005mm and 0.007mm in thickness in the area used for tensile-strength measurements). Akwell Industries' condoms quickly stretched from the closed end to the open

end; this suggests that the thickness is generally even over the entire length of the condom. (The thickness of Akwell Industries' condoms varied from 0.006mm to 0.0075mm.)

The Social Marketing Program

Akwell Industries' condoms sampled in 1981 by PIACT/Bangladesh from a lot to be distributed by the SMP were judged, according to the results of PIACT/Bangladesh tests, to be either "acceptable" or candidates for "alert." These condoms were manufactured to the same standards as the Akwell Tahitis in the Ministry's program. The principal difference was that the SMP repackaged and distributed the condoms in accordance with the wishes of retailers, who sent orders to wholesalers and distributors which were then forwarded to the SMP. From the time they arrived in Bangladesh, the condoms were not long in the distribution system.

According to SMP officials, stocks are maintained primarily at the SMP's central warehouse in Dacca after they are expeditiously cleared through customs. The stocks and shipments from AID are generally sufficient only to keep the pipeline full.

Although the SMP receives few complaints from users, SMP officials feel that a simple test for acceptability would be useful to detect a lot that may have deteriorated. These officials believe that PIACT/Bangladesh's CDI, which is based on the air burst, may be more complex than it need be.

Condoms Tested to PIACT Protocol in Other Countries

AID has supplied Tahiti condoms manufactured by Akwell Industries to population programs in Thailand, Indonesia, and the Philippines. Local organizations loosely affiliated with PIACT/Seattle, which is similar to PIACT/Bangladesh, have been established to monitor the quality of the contraceptives during storage and prior to distribution to users. Protocols to test condoms, similar to the protocol used by PIACT/Bangladesh, are applied during testing in these countries.

According to PIACT/Seattle, very few lots of condoms tested in Thailand, Indonesia, and the Philippines have been designated for rejection. Moreover, PIACT/Philippines has performed duplicate tests on condoms from lots sampled and tested by PIACT/Bangladesh, and it has replicated the results of tests by PIACT/Bangladesh.

Considering that the Tahiti condoms are shipped to all these tropical countries, and that tests reveal no deleterious effect as a result of storage and distribution by the population programs, there may be environmental factors and storage conditions unique to Bangladesh that are affecting the quality of the condoms.

IV. CONCLUSIONS AND RECOMMENDATIONS

The principal purpose of these recommendations is to ensure that acceptable condoms (i.e., condoms which are not liable to break during use) are made available to family planning clients. The provision of quality condoms is necessary to prevent inadvertent pregnancies, which may occur from use of a faulty product, and to avoid the adverse effect which poor quality condoms would have on condom usage in the program.

Condoms may age rapidly under certain environmental conditions, such as heat, ozone, light, humidity, and pollutants. Some of these conditions may be prevalent in Bangladesh. In addition, the deterioration of condoms may be accelerated as a result of the way the product is handled and stored in the distribution system.

Unfortunately, there are few clinical data to correlate various parameters, such as strength and elongation, at the point of breakage of the rubber, and to correlate the results of water-leakage tests and air-burst tests with actual breakage during use. The criteria now applied to test condoms after manufacture provide sufficient margin so that in temperate climates, condoms can be used for as many as five years after manufacture without results warranting appreciable public complaint. Although it is adequate for temperate conditions, the polyethylene-cellophane film used in the barrier package may be limited as a barrier to gas and vapor transmission for storage under certain tropical conditions. (The more effective foil-laminate films would be prohibitive for the incremental benefit.)

Experience in tropical countries other than Bangladesh indicates that condoms purchased by AID in the United States, packaged in poly-cellophane film and stored in cardboard cartons, are satisfactory for use for periods exceeding three years after manufacture. Under conditions peculiar to the condom distribution program of the Bangladesh Ministry of Population Control and Family Planning, a variety of steps may have to be taken to ensure the quality of the products. These steps are outlined in the recommendations that follow.

1. Condoms which are three or more years old which remain in Bangladesh demonstrate markedly increased rates of failure (in comparison to rates of failure during testing). Few condoms of this age should remain in the distribution system (see Appendix K). All condoms with a date of manufacture exceeding three years should be condemned and disposed of after a suitable record of the disposition has been made.

   This procedure would be appropriate, because the cost of sampling, testing, and arranging the disposition of a limited number of condoms would be significant, given the high potential for failure. Furthermore, although condemnation procedures have been established, no condemnation boards have been appointed.

2. It would be extremely desirable to distribute condoms through the Ministry's system to field workers within one and one-half years after their arrival in Bangladesh. If this approach is used, than the condoms will normally be not more than two and one-half years old (see Appendix K). Experience in the Social Marketing Program indicates that such timing is feasible.

   Specifically, the Ministry's program should routinely clear customs within 14-21 days, as it has done on earlier occasions, because storage in the port area is not within the control of the Ministry staff. The director-general should invest one of his staff with the authority to deal with customs on all issues relating to charges, or any matter which would delay the release of condoms from the port.

   The TEMO and Chittagong regional warehouses are better able to store condoms for long periods (more than four months) than the district warehouses, because they have sufficient space to ventilate the stocks and maintain first in-first out (FIFO) procedures.

   District and thana stores should not exceed the amount required for two months of turnover in each location, because storage conditions may not be suitable. The thana storekeepers should not oversupply the field workers. After a two month supply has been provided to a field worker, no more than 200-400 condoms, as appropriate, should be distributed each month, depending on each field worker's monthly needs.

3. It is imperative that FIFO procedures be maintained at all levels. The administrators and storekeepers should be knowledgeable about the procedures, because they are described in the logistics manual prepared by the Centers for Disease Control (CDC) for the Ministry's program.

   Adherence to the FIFO system, even by TEMO, is irregular, as was noted as recently as April 1982. The failure to follow FIFO procedures has been attributed to the size of the stock; apparently, an unmanageable amount of condoms is overwhelming the storekeepers. Overstocking can be avoided by prudently scheduling shipments from the United States and promptly clearing deliveries at the port.

   When they were visited in April 1982, the directors stated that the TEMO and regional warehouses were sufficiently empty, and that FIFO procedures could be established. The director-generals' director of logistics and supply and AID staff should closely monitor adherence to FIFO, because it is the primary means of ensuring that the products do not remain in the distribution system too long.

   Periodically, training sessions in FIFO should be provided for storekeepers, at least at the district level, and preferably at the thana level as well.

4. Records of shipments of lots should be the principal responsibility of the TEMO and regional and district warehouses. The records should clearly identify the date of manufacture and the manufacturing lot number so that adherence to FIFO may be monitored at each level. If a lot of condoms is questioned or evaluated to be unsuitable, the entire lot can be readily located and identified in the records. (Circle Rubber identifies lot numbers by manufacturing date by month and year, with a dash and an integer. Akwell Industries' lot numbers are more discrete; lots in a given month are, thus, more easily identifiable.)

5. To make adherence or non-adherence to FIFO more apparent and to enable Ministry management and AID staff to more easily monitor the situation, AID should require that the manufacturers (or the Ministry) mark the manufacturing date in bold numbers in red on the four sides and top of the shipping cases. Deviations from FIFO will become more readily apparent if such markings are made.

6. It would appear that constant testing at the thana level, which PIACT/Bangladesh undertook in 1981 and which was done in 1982, would be costly and unproductive. If a lot sampled from thana stores is considered to be unacceptable, only the remainder of that limited small lot would be subject to a condemnation request. By the time a request for condemnation was honored, the condoms probably would have been distributed to field workers.

7. Sampling should be done only at the TEMO and regional warehouses on lots scheduled to be shipped to district warehouses. With proper logistics control (a period of no more than four months to reach the user), condom lots that are accepted will probably remain good until they are used. Even if two or three months more elapse while the condoms are in the system, the rate of aging should not affect the condoms that have been tested and accepted.

   The proposed rejection of condom lots at either the TEMO or regional level would have significant implications for actions against a lot of 20 or more shipping cases (120,000 pieces), a quantity more meaningful to monitor in the region than in the thana.

8. Condoms should be tested no sooner than nine months from date of manufacture; a year would probably be sufficient. At least three months are needed to ship the products from the United States. It is unlikely that shipment from the United States influences aging, because shipments to Thailand and Indonesia have not been affected.

9. Condoms should be sampled from a lot in sufficient quantity to permit the following tests:

   a. Air-burst tests in Bangladesh to PIACT air-burst protocols, using the condom deterioration index as a warning system and indicator only. The number of condoms that rupture below 11 ml (.388 cu ft) in a sample of 100 would indicate the need to consider rejection of the lot.

   b. Air-burst tests to validate results when lots are designated for rejection.

   c. Water-leakage tests (ASTM D3492) to corroborate findings to determine whether a lot should be rejected. Leakage and breaks of condoms in the water test are strong indicators of weak spots. The water test to the 0.4 percent Acceptable Quality Level is performed before condoms are shipped from the factory and is a suitable baseline for a test to accept or reject condoms that have been sampled from the warehouses.

   d. Tests of tensile strength (again using the ASTM D3492 protocols) on 25 pieces, for lots up to 144,000 pieces, should be performed on lots that have been rejected. AID should consider providing driven rollers for tensile-strength tests, appropriate dies for ring-sample tests (to cut ring specimens in sufficient quantities to replace nicked dies), and calipers to measure thickness. Tests of tensile strength should be performed only on those lots which fail the first set of air-burst tests.

10. If initial air-burst testing of a lot gives acceptable results, sampling and tests of the lot at TEMO and in the regional warehouse should not be undertaken again for at least nine months.

11. Another approach, which may be more feasible for ease of sampling, would be to sample and test the condoms before they are shipped from TEMO and the regional warehouses to the districts. A product of dubious quality could be held back until all validating tests have been performed for final disposition.

The rational movement of condoms in the system, using FIFO, appears to be the most effective way to eliminate or minimize the possibility that condoms will age to the point of becoming unacceptable. Periodic testing of condoms after storage in Bangladesh is useful to ensure that a good product reaches users. Testing should be done at the regional or district warehouse so that a deteriorating product can be readily controlled.

APPENDICES

Appendix A

INTERIM FEDERAL SPECIFICATION,
CONDOMS, RUBBER CONTRACEPTIVE,
ZZ-C-001597A (GSA-FSS),
FEBRUARY 10, 1970

ZZ-C-001597A(GSA-FSS)
September 19, 1977
SUPERSEDING
ZZ-C-001597(GSA-FSS)
February 10, 1970

INTERIM FEDERAL SPECIFICATION

CONDOMS, RUBBER CONTRACEPTIVE

This Interim Federal Specification was developed by the General Services Administration, Federal Supply Service, Washington, DC 20406, based upon currently available technical information. It is recommended that Federal agencies use it in procurement and forward recommendations for changes to the preparing activity at the address shown above.

1. SCOPE AND CLASSIFICATION

1.1 Scope. This specification covers the requirements for natural rubber contraceptive condoms.

1.2 Classification. Condoms covered by this specification shall be the following types, styles, classes, and sizes, as specified (see 6.2).

Type I - Noncontoured
Type II - Contoured (style B, only; see 3.2.1)

Style A - Round End
Style B - Reservoir End

Class A - Nonlubricated (powdered)
Class B - Lubricated

Size 1 (large) - 180 ± 10 mm in length
Size 2 (small) - 160 ± 10 mm in length

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2. APPLICABLE DOCUMENTS

2.1 The following documents, of the issues in effect on date of invitation for bids or request for proposal, form a part of this specification to the extent specified herein.

Federal Standards:

Fed. Std. No. 123 - Marking for Shipment (Civil Agencies)

(Activities outside the Federal Government may obtain copies of Federal Specifications, Standards, and Handbooks as outlined under General Information in the Index of Federal Specifications and Standards and at the prices indicated in the Index. The Index, which includes cumulative monthly supplements as issued, is for sale on a subscription basis by the Superintendent of Documents, U.S. Government Printing Office, Washington DC 20402.

(Single copies of this specification and other Federal Specifications required by activities outside the Federal Government for bidding purposes are available without charge from Business Service Centers at the General Services Administration Regional Offices in Boston, New York, Washington, DC, Atlanta, Chicago, Kansas City, MO, Fort Worth, Denver, San Francisc Los Angeles, Seattle, WA.

(Federal Government activities may obtain copies of Federal Specifications, Standards, and Handbooks and the Index of Federal Specificat ions and Standards from established distribution points in their agencies.)

Military Standards:

MIL-STD-105 - Sampling Procedures and Tables for Inspection by Attributes

(Copies of Military Specifications and Standards required by suppliers in connection with specific procurement functions should be obtained from the procuring activity or as directed by the contracting officer.)

2.2 Other publications. The following documents form a part of this specification to the extent specified herein. Unless a specific issue is identified, the issue in effect on date of invitation for bids or request for proposal shall apply.

American Society for Testing and Materials (ASTM) Standards:

D 3492 - Rubber Contraceptives (Condoms), Standard Specification for

(Application for copies should be made to the American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.)

National Motor Freight Traffic Association, Inc., Agent:

National Motor Freight Classification.

(Application for copies should be addressed to the American Trucking Associations, Inc., Traffic Department, 1616 P Street, N.W., Washington, DC 20036.)

Uniform Freight Classification.

(Application for copies should be addressed to the Uniform Classification Committee, Room 1106, 222 South Riverside Plaza, Chicago, IL 60606.)

Laws and Regulations:

21 CFR 1 - The Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act and regulations promulgated thereunder.

(The Code of Federal Regulations (CFR) and the Federal Register (FR) are for sale on a subscription basis by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. When indicated, reprints of certain regulations may be obtained from the Federal agency responsible for issuance thereof).

3. REQUIREMENTS

3.1 Materials.

3.1.1 Latex. Condoms shall be made of natural rubber latex, and shall be capable of meeting all requirements and passing all tests specified herein. The rubber latex used shall be free of embedded grit and discoloration. Condoms shall be transparent and either clear (i.e. natural colored) or colored, as specified (see 6.2). Colored condoms shall be available in the following manufacturer's standard colors: Red, Blue, Green, Pink, Black, and Yellow, as specified (see 6.2). The condoms shall not liberate toxic or otherwise harmful substances under normal conditions of use, and shall be in strict compliance with the applicable portions of 21 CFR 1 (see 4.4.8).

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3.1.2 Dressing and compounding materials. Dressing materials (e.g. powders, lubricants, etc.) and compounding materials (coloring agents and other additives) shall not have a deleterious effect on the condoms, nor shall they have a harmful or irritating effect on the human body. Such materials shall be in strict compliance with the applicable portions of 21 CFR 1 (see 4.4.8)..

3.2 Construction. Condoms shall consists of smooth surfaced, essentially cylindrical, latex sheaths with one open end. The open end shall have a thin ring consisting of several layers of latex contiguous with the sheath. When tested as specified in 4.4.4, condoms shall have a maximum weight of 1.70 grams. When tested as specified in 4.4.2.1, condoms shall have an average wall thickness of from 0.040 mm (min.) to 0.070 mm (max.), and no individual wall thickness measurement shall exceed 0.090 mm.

3.2.1 Type I and Type II. Type I condoms shall be straight, without constrictions. The closed end of Type I condoms may be straight or expanded, according to the manufacturer's standard practice. Type II condoms shall have a formfitting profile, consisting of an essentially cylindrical sheath for one-half to two-thirds of its length (measured from the open end), followed by a constricted portion, followed in turn by an expanded portion, and in all cases, terminating with a definite shoulder and reservoir tip (style B, only; see 1.2); when condoms are tested as specified in 4.4.2.2, the laid flat width of the expanded portion (at its maximum) shall never be less than the laid flat width of the "shank."

3.2.2 Style A and Style B. Style A condoms shall have a smoothly rounded tip, without additional features. The closed end of Style B condoms shall have a visible shoulder leading to a reservoir pouch at the tip.

3.2.3 Length and width. When condoms are tested as specified in 4.4.2.2, their lengths shall be as specified in 1.2; their widths shall be as specified in Table I.

TABLE I. Laid Flat Width Requirements

Classification	Point of Measurement (i.e. distance from the open end.)	Width
Type I:		
Size 1	80 ± 5 mm	52 ± 3 mm
Size 2	80 ± 5 mm	49 ± 2 mm
Type II:		
Size 1	80 ± 5 mm	52 ± 3 mm
	130 ± 15 mm	35 ± 5 mm
Size 2	80 ± 5 mm	49 ± 2 mm
	110 ± 15 mm	35 ± 5 mm

3.3 Class A and Class B condoms. Class A condoms shall be powdered to prevent the latex from sticking to itself, and to facilitate mechanical manipulation of the condoms. Class B condoms shall be dressed with a water based jelly or silicone oil type lubricant, as specified (see 6.2). When Class B condoms are tested as specified in 4.4.3, the amount(s) of lubricant used shall be as follows:

water-base jelly type - 350 mg (min.) to 550 mg (max.)
silicone oil type - 250 mg (min.) to 500 mg (max.)

Powders and lubricants shall be applied directly to the condoms in accordance with the manufacturer's standard practice. Powders and lubricants shall be as specified in 3.1.2.

3.4 Tensile strength and elongation. When tested as specified in 4.4.5, the tensile strength and elongation at break characteristics of the condoms shall be as specified in Section 6 of ASTM D3492.

3.5 Pinholes. Condoms shall show no evidence of pinholes when tested by an electronic testing machine, as specified in 4.4.6.

3.6 Water leakage. Condoms shall show no evidence of water leakage when tested as specified in 4.4.7.

3.7 Identification marking. Each individual condom shall have the manufac urer's name or symbol and the date (i.e. month/year) of manufacture imprinted on the condom, near the open end.

3.8 Workmanship. The workmanship shall be first class throughout. Condoms shall be free of defects which affect their durability, detract from their appearance, or which may impair their serviceability.

4. QUALITY ASSURANCE PROVISIONS

4.1 Responsibility for inspection. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the Specification where such inspections are deemed necessary to assure that supplies and services conform to prescribed requirements.

4.2 Objective evidence. The supplier shall provide objective evidence acceptable to the contracting officer that the requirements of 3.1.1 and 3.1 for which specific inspection has not been provided, have been satisfied (see 4.4.8).

4.3 Sampling. Sampling plans in tables II and III for the water leakage test are matched to certain plans in MIL-STD-105. The normal, tightened, and reduced inspection provisions of MIL-STD-105 may be used, as applicable, as sampling plans in this specification.

4.4 Examination and tests.

4.4.1 Visual examination. A visual examination for defects in materials, construction, and workmanship shall be performed on condoms selected for the water leakage test (see 4.4.7). Sample sizes and acceptance/rejection (Ac/Re) numbers, expressed in terms of percent defective, shall be identic to those specified in table II. The presence of one or more imperfections i material, etc., in the same condom shall constitute a defective condom. Results of the visual examination shall be kept seperately from the results c the tests.

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4.4.2 Dimensions. Five condoms shall be selected at random from each lot for determination of compliance with the applicable thickness, and length and width requirements of 3.2, 3.2.1, 3.2.3, and table I. Wall thickness measurements shall be made on condoms from which all dressing materials have been removed with water or isopropanol and then dried to a constant mass. The acceptance number for dimensional tests shall be zero (i.e. any evidence of noncompliance with specified requirements shall be cause for rejection of the lot.).

4.4.2.1 Wall thickness. The wall thickness of condoms shall be measured at three points, 10 ± 2 mm from the open end, 30 ± 5 mm from the closed end, and at the mid-distance between those two points. Lateral measurements made from the closed end of style B condoms shall exclude the reservoir tip. The individual measurements and the average value of all three measurements shall be recorded for each condom.

4.4.2.2 Length and width. Measurement of condom length shall be made from the open end to the furthest extension of the closed end (exclusive of the reservoir tip on style B condoms). Width measurements shall be made on laid flat condoms. Width measurements shall be taken at the points specified in table I. The expanded portion of type II condoms shall be inspected to assure compliance with the applicable requirements of 3.2.1.

4.4.3 Quantity of lubricant. Twenty individual condoms, selected at random from each lot shall be tested for compliance with the quantity of lubricant requirements of 3.3, as applicable. The test procedure(s) shall be as follows:

(a) water-based lubricant; lubricated condoms, sealed in their individual packets, shall be weighed on an analytical balance. Each packet shall be opened taking care to retain all pieces thereof. The packet and condom shall be washed in denatured ethanol until all lubricant is removed, dried to a constant mass, and then weighed again; the condom without its packet shall also be weighed. All weights shall be recorded to the nearest milligram (mg). Compliance with the requirements of 3.3 shall be determined by subtracting the weight of the washed and dried sample (packet and condom) from the initial weight of the sample prior to removal of the lubricant.

(b) silicone oil lubricant; this procedure shall be identical to that specified in (a), except that the condom packet shall be discarded prior to the initial weighing and shall not be used in any of the procedural steps; i.e., only the lubricated condom shall be used in this procedure.

4.4.3 In both (a) and (b), all procedural steps shall be completed for each sample before proceeding to subsequent samples. The acceptance number for this test shall be zero.

Individual condom weights recorded in (a) and (b), as applicable, shall be used to satisfy the requirements of 4.4.4.

4.4.4 Weight. The twenty condoms tested as specified in 4.4.3, from which all dressing materials have been removed, shall be dried to a constan mass and then weighed on an analytical balance to determine compliance with the applicable requirements of 3.2. The acceptance number for this test shall be zero.

4.4.5 Tensile strength and elongation test. Sample condoms shall be selected and tested as specified in Section 6 of ASTM D3492. The compliance and acceptance criterion shall be as specified therein.

4.4.6 Pinhole test. The test for pinholes shall be performed on a 100 percent basis (i.e. no sampling). The electronic testing shall be performed by utilizing an electronically charged liquid bath (wet method), or a gammete test (dry method) which examines the product dry. Condoms failing to meet the requirements of 3.5 shall be removed.

4.4.7 Water leakage test. After the pinhole test specified in 4.4.6, and prior to shipment, condoms shall be sampled and inspected in accordance with tables II and III, as applicable. Sample condoms shall be placed in a funnel rack approximately twelve (12) inches above the base support, and each condom shall then be filled with 300 cubic centimeters (ml) of water. The open end of the condom(s) shall then be closed by squeezing the beaded portion together. The filled condom(s) shall be laid on a piece of dry filter paper, rolled from side to side, and examined for water leakage in compliar with 3.6. Lot acceptability shall be based upon the acceptance (Ac) and rejction (Re) numbers (representing defective condoms) in tables II and III, : applicable.

Table II. Sampling Plans for Water Leakage Test *, and for Visual Examination (see 4.4.1).

*Area of examination: Between 25 mm from the open end and the closed end.

Lot size 35,000 and less			
Type of Sampling Plan	Cumulative Sample Size	Ac	Re
Single	500	2	3
Double	315	0	3
	630	3	4
Multiple	125	#	2
	250	0	3
	375	0	3
	500	1	4
	625	2	4
	750	3	5
	875	4	5

Lot size 35,001 - 150,000			
Single	800	5	6
Double	500	2	5
	1000	6	7
Multiple	200	#	4
	400	1	5
	600	2	6
	800	3	7
	1000	5	8
	1200	7	9
	1400	9	10

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Table II continued

Lot size 150,001 - 500,000			
Type of Sampling Plan	Cumulative Sample Size	Ac	Re
Single	1250	7	8
Double	800	3	7
	1600	8	9
Multiple	315	0	4
	630	1	6
	945	3	8
	1260	5	10
	1575	7	11
	1890	10	12
	2205	13	14
Lot size 500,001 and over			
Single	2000	14	15
Double	1250	7	11
	2500	18	19
Multiple	500	1	7
	1000	4	10
	1500	8	13
	2000	12	17
	2500	17	20
	3000	21	23
	3500	25	26

Table III. Sampling Plan for Water Leakage Test in the area between the open end, and 25 mm from the open end. This plan is applicable to all lot sizes.

Type of Sampling Plan	Cumulative Sample Size	Ac	Re
Single	500	21	22
Double	315	11	16
	630	26	27
Multiple	125	2	9
	250	7	14
	375	13	19
	500	19	25
	625	25	29
	750	31	33
	875	37	38

4.4.8 Added materials. Contractors shall provide adequate certification that the condoms, all dressing materials (powders, lubricants, etc.), and all compounding materials (coloring agents and other additives) are in compliance with the applicable portions of 21 CFR 1, and that they have been tested in accordance with applicable Food and Drug Administration regulations in force at the time of the manufacture of the condoms.

4.5 Inspection of preparation for delivery. An inspection shall be performed to insure that packaging, packing, and marking are in compliance with the requirements of Section 5. The inspection shall be conducted in accordance with MIL-STD-105. The lot size shall be the number of shipping containers and interior packages in the end item inspection lot. The inspection level shall be S-3, with an Acceptable Quality Level (AQL) of 2.5, expressed in terms of percent defective. For the purpose of exterior packing examination, the sample unit shall be one shipping container; for interior packaging examination, the sample unit shall be one package. Examination of interior packaging shall be performed on packages selected at random from sample shipping containers. Examination of defects of closure shall be performed on randomly selected shipping containers, fully prepared for delivery. Preparation for delivery defects shall be scored in accordance with table IV.

Table IV. Classification of Preparation for Delivery Defects

Examine	Defects
Contents	Number of condoms not as specified; packets or strips not as specified.
Marking (Exterior and Interior)	Omitted; incorrect; illegible; of improper size, location, sequence, or method of application.
Materials	Packaging/packing materials not as specified, missing, damaged, or nonserviceable.
Workmanship	Containers inadequately closed and secured, poor application or internal packaging and packing material; distorted intermediate packages.

5. PREPARATION FOR DELIVERY

5.1 Packaging. Packaging shall be level A or commercial, as specified (see 6.2).

5.1.1 Level A. Condoms shall be sealed in individual packets constructed of a suitable flexible metal foil, plastic film, or combination thereof. The sealed packets shall be provided in strips of three or four, separated by perforations to facilitate detachment. When colored condoms are specified in the contract or order, the sealed packets shall consist in part of transparent plastic film through which the color of the condom can be identified. One gross (144) of condoms shall be neatly packaged in a folding or set-up paperboard box.

5.1.2 Commercial. Condoms shall be preserved and packaged in accordance with normal commercial practice. The complete package shall be designed to protect the condoms against damage during shipment, handling and storage.

5.2 Packing. Packing shall be level A or commercial, as specified (see 6.2).

5.2.1 Level A. Condoms, packaged as specified in 5.1.1, shall be packed in corrugated fiberboard boxes made from Weather-Resistant fiberboard with a bursting test strength of not less than 275 pounds per square inch. The box flaps shall be secured with water resistant adhesive applied to not less than 75 percent of the area of contact between the flaps or with 3 inch wide water resistant tape applied to the full length of the center seams and extending over the ends not less than 3 inches. Alternatively, wirebound, cleated plywood, or nailed wood boxes shall be acceptable shipping containers when lined with a waterproof barrier material. The barrier material shall be sealed at the edges with waterproof tape or adhesive.

5.2.2 Commercial. Condoms, packaged as specified in 5.1.2, shall be packed in fiberboard boxes to insure safe delivery at destination, to provide for safe redistination by the initial receiving activity, and shall be acceptable by common carrier under National Motor Freight Classification or Uniform Freight Classification.

5.3 Unitization. When shipments to Government depots are full car or truckload, the shipping containers shall be unitized for shipment and handling in accordance with normal commercial practice. The unitized load shall not exceed 2,500 pounds in weight, 63 inches in height, 56 inches in length, and 45 inches in width.

5.4 Marking. In addition to markings required by the contract or order, packages, shipping containers, and unitized loads (when applicable) shall be marked in accordance with Fed. Std. No. 123.

6. NOTES

6.1 Intended use. Condoms covered by this specification are intended for use as contraceptive and prophylactic agents.

6.2 Ordering data. Purchasers should select the preferred options permitted herein, and include the following information in procurement documents.

(a) Title, number, and date of this specification.
(b) Type, style, class, and size condom required (see 1.2).
(c) Whether clear (natural colored) or colored condoms are required (see 3.1.1); if colored condoms are required, what colors are required (see 3.1.1).
(d) Whether the water-based or silicone oil type lubricant is required (see 3.3).
(e) Selection of applicable levels of packaging and packing (see 5.1 and 5.2).
(f) Unitization required (see 5.3).
(g) Marking required (see 5.4).

6.3 Definitions. The following terms, as used in this specification shall be defined as indicated.

laid flat width: one half of the circumference (of the condom) at the designated point.

shank: that portion of the condom lying between the open end and the first visible constriction, convolution or contour, etc., (see 3.3).

Appendix B

STANDARD SPECIFICATIONS FOR
RUBBER CONTRACEPTIVES,
ASTM D-3492-76

1976
ANNUAL BOOK OF ASTM STANDARDS

PART 38

Rubber Products, Industrial—Specifications and Related Test Methods; Gaskets; Tires

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Committee
D-11 on Rubber and Rubber-Like Materials
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Designation: D 3492 - 76

Standard Specification for RUBBER CONTRACEPTIVES (CONDOMS)[1]

This Standard is issued under the fixed designation D 3492; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval.

1. Scope

1.1 This specification covers requirements for condoms made of rubber latex intended for single use. The scope of the specification does not cover spermicidal or other dressing materials that may be applied to condoms.

1.2 This specification is intended to serve as a guide to permit obtaining condoms of consistent performance. The safe and proper use of condoms is excluded from the scope of this specification.

2. Applicable Documents

2.1 *ASTM Standards:*

D 412 Tests for Rubber Properties in Tension[2]

D 573 Test for Rubber Deterioration in an Air Oven[2]

D 865 Test for Rubber Deterioration by Heating in a Test Tube[2]

D 1076 Specification for Rubber—Concentrated, Ammonia Preserved, Creamed and Centrifuged Natural Latex[2]

2.2 *Other Documents:*

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes[3]

Code of Federal Regulations, Title 21—Food and Drugs[4]

3. Classification

3.1 Condoms covered by this specification shall be of the following types and classes:

Standard I—approximately 52 mm width.
Standard II—approximately 49 mm width.
Type I—smooth surface.
Type II—textured surface.
Form I—round end.
Form II—reservoir end.
Form III—form fitting.
Class A—dry.
Class B—lubricated.

4. Materials

4.1 Condoms shall be manufactured from good quality natural rubber latex conforming to Specification D 1076, and shall be free of embedded grit or discoloration. Condoms may be transparent, translucent, opaque, or colored.

4.2 The condoms and any dressing material applied to them shall not liberate substances that are known to be toxic or otherwise harmful under normal conditions of use. Any dressing materials, or compounding materials shall not have a deleterious effect on the condom. Materials used should be permitted by code of Federal Regulations Title 21, Part 121, Subparts E and F, which list materials safe for use in food packaging.

5. Design

5.1 *Rim*—The open end of the condom shall terminate in an integral rim.

5.2 *Dimensions*—From each lot or batch (not to exceed 144 000 pieces), ten condoms shall be drawn at random. Those condoms tested shall meet the requirements in Table 1.

---

[1] This specification is under the jurisdiction of ASTM Committee D-11 on Rubber and Rubber-Like Materials and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

Current edition approved March 26, 1976. Published May 1976.

[2] *Annual Book of ASTM Standards*, Part 37.

[3] Available from American National Standards Institute, 1430 Broadway, New York, N. Y. 10018.

[4] Available from the Superintendent of Documents, U. S. Government Printing Office, Washington, D. C. 20402.

If any one fails to meet these requirements, the lot or batch shall be rejected.

5.2.1 For Standard I, Form III condoms having a shaped profile about the closed end, the width of the profile, when laid flat, shall be not more than 70 mm.

5.2.2 For Standard II, Form III condoms, the width in 5.2.1 shall be not more than 62 mm.

5.3 *Procedures for Dimensional Test:*

5.3.1 The length of the condom excluding the teat shall be measured to the nearest 1 mm.

5.3.2 The width of the condom laid flat shall be measured at a distance greater than 85 mm from the rim. The measurement shall be reported to the nearest 0.5 mm.

5.3.3 The thickness shall be measured on condoms from which lubricant has been removed with water or isopropanol and then dried to constant mass. The micrometer shall conform to that specified in Method D 412. When a condom is textured, the thickness shall be measured in a nontextured area. The measurements shall be reported to the nearest 0.01 mm.

5.3.4 The mass of a condom after the thickness measurement shall be measured on a balance and reported to the nearest 1 mg.

6. Physical Requirements

6.1 *Tensile Strength and Elongation at Break.*—The tensile strength and elongation at break shall comply with the following requirements:

	Tensile Strength, min, MPa		Elongation at Break %, min %	
	mean	specimen	mean	specimen
Samples tested less than 12 month after manufacture in the as-sampled condition	20	15	750	675
Sample tested less than 12 months after manufacture and subjected to accelerated aging	17	15	700	625
Sample tested 12 months or more after manufacture in the as-sampled condition	17	15	700	625

From each lot or batch (not to exceed 144 000 pieces), 25 condoms shall be drawn at random for each test. The condoms tested should meet or exceed the appropriate mean values in the table, and if more than 1 out of 25 values for individual specimens falls below specimen values listed, the lot shall be rejected.

6.2 *Determination of Tensile Properties:*

6.2.1 *Conditioning*—Determine the tensile strength and elongation at break of 25 condoms after aging for 166 ± 2 h at 70 ± 2°C, in accordance with Methods D 573 or D 865. If Method D 573 is used, do not age condoms of different composition simultaneously in the same oven. Age condoms as received in original packages. After aging, condition condoms at 23 ± 2°C for not less than 16 h and prepare and test specimens as described in 6.2.2 within 96 h.

6.2.2 *Procedure*—Determine tensile strength and elongation at break of 25 condoms in accordance with Method D 412 using ring specimens as follows:

6.2.2.1 Cut the specimens perpendicular to the length direction of condom with a die having cutting edges 20.0 ± 0.1 mm apart and at least 70 mm long. Cut the specimens in the region of the condom about 80 mm from the rim. In textured condoms, cut the specimen from the nontextured region. Use only specimens cut by a single impact of the die.

6.2.2.2 Measure the thickness of three or more equidistant points around the ring to the nearest 0.001 mm and record the median value for the thickness.

6.2.2.3 Dust the specimen, lay the ring flat, and measure the distance between the two folded edges. Multiply the measurement by two to obtain the circumference of the ring.

6.2.2.4 Test the specimen to failure in a tester having a range of about 100 N at a speed of 8.5 ± 0.8 mm/s. Use roller grips at least 20 mm in width, between 5 and 15 mm in diameter, and lubricated on surfaces contacting the specimen with castor oil or other effective rubber lubricant. Record the force and grip separation at break.

6.2.3 *Calculations:*

6.2.3.1 Calculate the tensile strength as follows:

$$T = F/2WD$$

where:

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T = tensile strength, MPa,
F = breaking force, N,
W = width of ring, 20 mm, and
D = single thickness of wall, mm.

6.2.3.2 Calculate the elongation at break as follows:

$$E = 100\,[(2D + G - C)/C]$$

where:

E = elongation at break, %,
D = distance between centers of the rollers at break, mm,
G = circumference of one roller, mm, and
C = circumference of the specimen, mm.

7. Quality Assurance

7.1 *Responsibility for Inspection*—Unless otherwise indicated, the supplier is responsible for the performance of all inspection requirements.

7.2 *Leakage:*

7.2.1 *Sampling*—Inspection for leakage shall follow ISO 2859, General Inspection Level I for an acceptable quality level (AQL) of 0.4 %. Single, double, and multiple sampling plans for normal inspection are given in Table 2 for four ranges of lot sizes. Multiple sampling is preferable and shall be used in reference tests.

7.2.2 *Procedure*—Fill each condom in the sample with 300 cm³ of water. Twist rim end to form a seal. Wipe outside surface dry by rolling on filter paper or equivalent absorbant material. Inspect for holes. Reject lots of condoms that are too small to hold 300 cm³ of water or which have a number of leaks equaling or exceeding the appropriate rejection number in Table 2.

8. Marking

8.1 *Condom Identification*—Each con must be legibly marked to include the nam trademark of the manufacturer and the (month and year) of manufacture, codec explicit.

8.2 *Package Identification*—Packag shall have the name and address of the ma facturer or distributor, and the country manufacture.

9. Packaging and Storage

9.1 Unless otherwise specified, packagi shall be in accordance with manufacture commercial practice.

9.2 Proper packaging should protect co doms during storage for 10 years or mor Nevertheless, condoms should not be kept storage longer than necessary, especially i warm climates, and should be stored in a coo place in containers that protect them fror mechanical damage.

9.3 Condoms shall not be allowed to com into contact with oil-based antiseptics, phe nols and their derivatives, petroleum-based products, or other materials harmful to rub ber.

10. Retest

10.1 One retest for design and require ments is permissible before final rejection of lots not conforming to Sections 5 and 6.

10.2 No retest is permitted for lots not conforming to Section 7.

TABLE 1 Dimensional Requirements

	Length, mm	Width, mm	Thickness, mm	Mass, g, max
Standard I, Type I	180 ± 10	52 ± 3	0.04 ± 0.09	1.70
Standard II, Type I	160 ± 10	49 ± 2	0.04 ± 0.07	1.50
Standard I, Type II	180 ± 10	52 ± 3	0.04 ± 0.09	1.95
Standard II, Type II	160 ± 10	49 ± 2	0.04 ± 0.09	1.75

TABLE 2 Normal Inspection Sampling Plans for Water Leakage Test[a]

Lot Size 35 000 and less				Lot Size 35 001 to 150 000			
Type of Sampling Plan[b]	Cumulative Sample Size	AC[c]	RE[c]	Type of Sampling Plan[b]	Cumulative Sample Size	AC[c]	RE[c]
Single (IIA,K)	125	1	2	Single (IIA,L)	200	2	3
Double (IIIA,K)	80	0	2	Double (IIIA,L)	125	0	3
	160	1	2		250	3	4
Multiple (IVA,K)	32	[d]	2	Multiple (IVA,L)	50	[d]	2
	64	[d]	2		100	0	3
	96	0	2		150	0	3
	128	0	3		200	1	4
	160	1	3		250	2	4
	192	1	3		300	3	5
	224	2	3		350	4	5
Lot Size 150 001 to 500 000				**Lot Size 500 001 and over**			
Single (IIA,M)	315	3	4	Single (IIA,N)	500	[illegible]	6
Double (IIIA,M)	200	1	4	Double (IIIA,N)	315	[illegible]	5
	400	4	5		630	6	7
Multiple (IVA,M)	80	[d]	3	Multiple (IVA,N)	125	[d]	4
	160	0	3		250	1	5
	240	1	4		375	2	6
	320	2	5		500	3	7
	400	3	6		625	5	8
	480	4	6		750	7	9
	560	6	7		875	9	10

[a] Do not use samples with pinholes 25 mm from the open end.
[b] The table and sample size code letter in ISO 2859 are given in parentheses. The sampling plans are based on an AQL of 0.40 %.
[c] The acceptance (AC) and rejection (RE) numbers represent defectives.
[d] Acceptance not permitted.

The American Society for Testing and Materials takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, is entirely their own responsibility.

FILM

SPECIFICATIONS;

4 3/8 Web Width - 2 3/16 Web Width
Plain White Film
Material: 195 Cellophane/ 30# White Polyethylene (LD)
Yield: 8040 printed; 8280 plain

Printing: According to item specified by Akwell Codes

Method of Printing: Roto Gravure Style reverse printing on cellophane with 30# White polyethylene extruded to primed side of cellophane and slit to 4 3/8 with ± 1/64" tolerance

Pack: unit palletized not to exceed 80 pounds in individual shipping carton. Each shipping carton to have an individual case contents ticket on both outside and inside of the carton

SPECIFICATIONS:

4 3/8 Web Width - 2 3/16" Web Width
Plain ClearFilm

Material: 195 Cellophane/30# Clear Polyethylene

Yield: 8050 MSI printed
8280 Plain

Printing: According to order specified by Akwell Codes

Method of Printing: Roto Gravure Style reverse printing on cellophane with 30# Clear L.D. Polyethylene extruded to primed side of Cellophane and slit to 4 3/8 Web with ± 1/64th tolerance.

Pack: Unit Palletized not to exceed 80# per individual shipping carton. Each shipping carton to have an individual case contents ticket on both inside and outside of carton

Appendix C

A HANDBOOK ON TESTING CONDOMS IN THE FIELD,
PIACT/SEATTLE, VERSION 4,
OCTOBER 1981

TESTING OF CONDOMS IN THE FIELD
A HANDBOOK

Program for Introduction and Adaptation of
Contraceptive Technology (PIACT)
Canal Place
130 Nickerson Street
Seattle, WA 98109 USA

Version 4

October 15, 1981

Michael J. Free, Ph.D.

Amended 10/15/81

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PIACT
Canal Place
130 Nickerson Street
Seattle, Washington 98109 USA

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INTRODUCTION

National family planning programs, as well as major donors, have expressed the need for assistance in assessing the quality of various contraceptive products and in developing an indigenous capacity to carry out independent, in-country testing. This capability is desired not only to assess the quality of recently received goods, but also to assist in monitoring the quality of these items as they move through the distribution pipeline from family planning programs to the ultimate users.

Latex condoms from most established manufacturers are generally strong, uniform and free from holes, a testimonial to careful and largely voluntary Quality Control at the factory and by public sector standards institutions. However, little is known about the effects of sub-optimal storage conditions, especially in tropical and subtropical climates, so that condoms shipped to and stored under these conditions are essentially out of control.

Various claims of premature condom deterioration have been made in recent years. In the light of these, it is clear that the major problem is the complete lack of stored condom quality data available to program managers and distributors, to reassure them, motivate them to examine and make improvements in their logistical systems, or enable them to make stock adjustments and meaningful accept/reject decisions.

Managers in the field deal with a variety of condoms from different sources and at different stages of deterioration. These include:

(1) New condoms from large, established manufacturers
(2) New condoms from small plants or from manufacturers in the starting-up phase of production, sometimes with no electronic testing equipment or inadequate routine quality control procedures

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(3) New condoms from either of the above sources with, or without independent quality checks

(4) Aging condoms stored under various conditions

(5) Condoms of unknown vintage transferred from other programs.

A system of quality control is needed that is geared to these conditions. It must be simple, practical and rugged; require no special skills to operate, calibrate or maintain; and have a low capital cost. At the same time, the quality of the tests themselves should not be compromised. It will usually be operated at the level of the major distribution centers within any country so that it does not have to be adapted to rural conditions. However, the ability to transport it to, and use it in, remote sites may be an advantage. Quality tests selected for use in the field must relate in some meaningful way to tests recommended by national or international standards, organizations, and authorities. However, a heavy emphasis can be placed on monitoring programs, whereby the quality of condoms aging in storage can be continually related back to the same condoms at delivery. As long as the condoms are initially of uniform and reasonable strength, this approach would avoid problems associated with comparisons among different brands, types, shapes, or sizes which inevitably fall into dispute because of different philosophies of latex curing, different aging characteristics and differences in data related to size, thickness or geometry. The relative testing approach would provide information on rate of deterioration, sudden changes in strength or uniformity of a population of condoms and, if degree of deterioration can be related to failure rate during use, the overall acceptability of the condom stocks in question even beyond their shelf-life expiration date.

Of course, some absolute quality value must be obtained from the test parameters. Newly delivered condoms or existing stocks at the start of a monitoring program must fall within a prescribed range of strength, freedom from holes and uniformity that will allow them to survive in usable condition for several years. Older condoms in storage

must be of sufficient strength and uniformity to ensure that they will be reasonably reliable during normal use. Unfortunately, there is no body of published data that adequately describes the relationship between condom test data and the rate of failure during actual use.[a] Until more information becomes available, the results of preliminary studies and the traditional norms for condom quality are utilized. However, individual condoms are known to deteriorate at very different rates even within the same lot or shipment, thus uniformity of strength becomes the prime consideration in assessing quality of stored condoms.

With these thoughts in mind, PIACT initiated a program to develop a comprehensive package of equipment, information, training, and calibration for field testing of condoms. This handbook is part of that package. It provides the distribution program director, stock manager, and test equipment operator with a detailed approach to sampling, testing, and continuous monitoring of condoms in the field. The test protocols are intended to generate three types of data including:

(1) Conformity with specifications for new condom stocks. (e.g., dimensions, quantity of lubricant, incidence of pinholes)

(2) Uniformity of strength in new or stored condom stocks, (permitting managers to evaluate stocks on the basis of how many very weak condoms exist in each lot).

(3) Changes in Median Strength and Incidence of Weak Condoms in different condom stocks, (permitting managers to monitor and compare changes in strength of stored condoms over time. This information will indicate appropriate adjustments to be made in storage conditions, packaging specifications, and regional inventories in order to achieve maximum shelf life and to insure that only high-strength products reach the user).

---

[a] A recent study by PIACT (Contraception, Vol. 22, p. 31, 1980) provides some preliminary data on strength-failure relationship.

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Equipment to carry out these tests is provided on a long-term loan basis to affiliate organizations in developing countries. This equipment is loaned subject to certain conditions relating to the maintenance of proper function. These conditions include:

1. Record keeping for data and calibration checks according to the appropriate PIACT protocol.

2. Full participation in PIACT QA Calibration Control and Validation Scheme (see Appendix 7 for details).

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SAMPLING AND STATISTICS

Sampling Units

It is assumed that condoms are stored in identifiable LOTS. A LOT usually consists of 40- or 80-gross (5,760-11,520 condoms) shipping cases. Each LOT (as far as is practicable), consists of condoms of the same type, style, class, and size, manufactured by a single manufacturer under essentially the same conditions, and at (essentially) the same time.[a] CASES of a LOT should be stored under the same light, temperature, and humidity conditions.

Each CASE in a lot must be assigned a unique number. The BOXES within a CASE are numbered 1 through 40 (or 1 through 80), based on their position in the CASE. Individual condoms within a BOX are numbered 1 through 144, based on their position in the BOX. An example of such a numbering system is illustrated in Figure 1 (p. 5).

Initial Sampling of New Condoms or Stored Condoms That Have Not Been Previously Tested

A SAMPLE consists of one or more condoms drawn from a LOT, the condoms of the sample being selected at random without regard to their quality. The number of condoms in the SAMPLE is the SAMPLE SIZE.

A three-stage random sampling technique will be used to select condoms from the LOT. Cases will be randomly selected in the first stage, BOXES within CASES in the second stage, and individual condoms within BOXES in the third stage.

---

[a] The term "LOT", as used in the Handbook, does not necessarily refer to the manufacturer's coded lot. Sometimes several different lot code numbers will be present in a shipment, or even within individual cases, e.g. packages containing condoms of several colors. In this event, the basic sampling unit may consist of the whole shipment or parts of the shipment that can be discretely identified because of different manufacturer, type, style, class, size, date of manufacture, storage site or storage condition. Details of this choice should be recorded under comments, Form A2-8.

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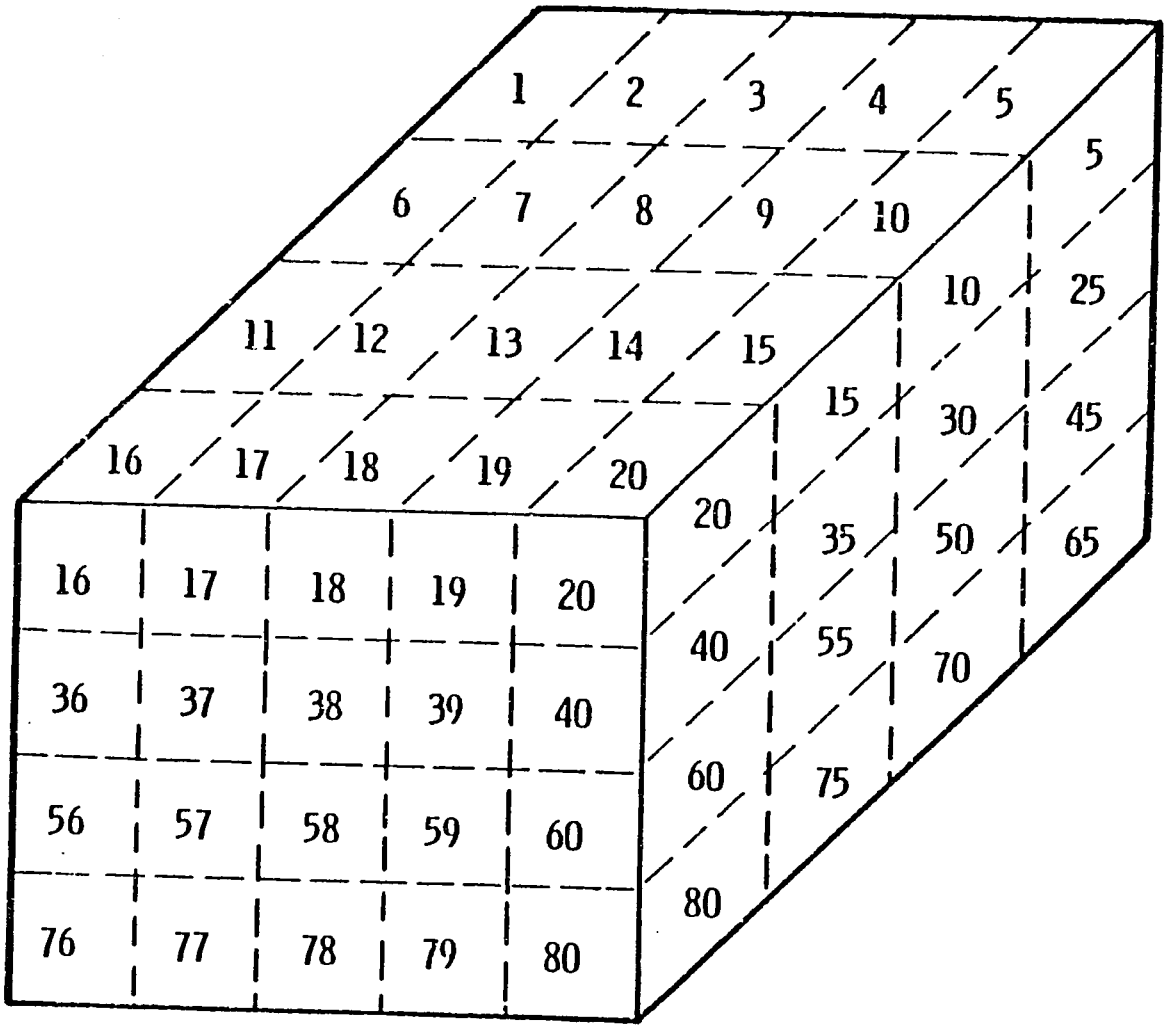

FIGURE 1. Divisions of a CASE of Condoms for the Purpose Sampling.

SAMPLE SIZE will depend on the size of the LOT. To collect a sample sufficient to perform all of the tests and measurements, select sample size according to LOT size, as indicated in Table 1 (p. 7).

A random number table (Appendix 1), or a random number generator program for a calculator, will be used to identify the units to be selected at each stage. A brief description of how a random number table is used to select a sample is also given in Appendix 1. If a calculator with a random number generator program is available, directions on the use of the program will be given in the calculator manual and should be followed.

Each Test Lot will be given a TEST CODE consisting of 2 letters designating the country in which the tests were conducted, and 6 numbers designating the year, month, and day that the tests were conducted or started. If more than one LOT is tested on a given day, a code letter can be added.

EXAMPLE: Test Code PH800211 indicates a Test Lot tested in the Philippines commencing Feb. 11, 1980.

The Test Code should be recorded in the designated box on all DATA COLLECTION FORMS and should be entered into the box in the upper right-hand corner of all REPORTING FORMS (see Appendix 2).

Sample size, data to be recorded, and acceptance criteria (if available) for each test and measurement are as follows:

Dimensions: Twenty condoms selected at random from each LOT are to be checked for Package Seal Integrity and determination of thickness, length, weight, and quantity of lubrication (see Checking Condom Dimensions, Lubrication, and Packaging, p. 14). Use data collection forms as shown in Appendix 2 (FORM A2-2). ALL sample condoms must fall within the specified dimensions in order to comply with generally accepted standards for new condoms.

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TABLE 1.

Lot Size	Sample Size	RANDOMLY SELECT		
		Cases[a] from each lot	Boxes from each case	Condoms from each box
Less than 35,000	384	4	8	12
35,000 to 150,000	480	12	4	10
150,001 to 500,000	640	20	4	8
More than 500,000	900	25	4	9

(a) Assumes 40 gross per case. For different size cases, adjust all selections proportionally.

Water Test: Condoms are sampled in accordance with Table 2, p. 9, and tested for pinholes (see Water Test for Pinholes, p. 19). Use data collection forms shown in Appendix 2 (Form A2-3). LOT ACCEPTABILITY is determined by the acceptance (AC) and rejection (RE) numbers given in Table 2, p. 9.

Air Inflation Test: One hundred condom samples are tested for Bursting Volume and Bursting Pressure (see The Air Inflation Test, p. 24). Use data collection forms shown in Appendix 2 (FORM A2-5). Plot the data distribution using form A2-10. Then calculate the Condom Deterioration Index (CDI) (Table 3, p. 10) using the Bursting Volume data. Form A2-6 (see Appendix 2) should be used as the worksheet for this calculation.

TABLE 2. Multiple Sampling Plans for Water Test[a] (Adapted from ANSI/ASTM (1977) Standards)

INSTRUCTIONS

Test the number of condoms indicated for the LOT size at SAMPLE STAGE 1. If the number of defective condoms equals or exceeds the number indicated for that LOT size under Re, then reject the LOT. No further testing is required in this case.

If defective condoms are less than Re, then increase the total number of condoms tested up to the number indicated in SAMPLE STAGE 2. Compare the number of defectives with the number indicated for AC (less or equal, accept the LOT) and Re (equal or more, reject the LOT).

If the number of defectives falls in between the Ac and Re numbers, then proceed to SAMPLING STAGE 3 and repeat the procedure. Repeat the procedure until an accept or reject decision can be made.

SAMPLE STAGE	LOT SIZE: 35,000 and less			35,001 to 150,000			150,001 to 500,000			500,001 and over		
	Total (Cumulative) Sample Size	Number of Defectives Ac	Re	Total (Cumulative) Sample Size	Number of Defectives Ac	Re	Total (Cumulative) Sample Size	Number of Defectives Ac	Re	Total (Cumulative) Sample Size	Number of Defectives Ac	Re
1	32	No decision	2	50	No decision	2	80	No decision	3	125	No decision	4
2	64	No decision	2	100	0	3	160	0	3	250	1	5
3	96	0	2	150	0	3	240	1	4	375	2	6
4	128	0	3	200	1	4	320	2	5	500	3	7
5	160	1	3	250	2	4	400	3	6	625	5	8
6	192	1	3	300	3	5	480	4	6	750	7	9
7	224	2	3	350	4	5	560	6	7	875	9	10

(a) These sampling plans are based on an Acceptable Quality level of 0.4%

TABLE 3. CALCULATION OF THE CONDOM DETERIORATION INDEX (CDI)

1. USE THE WORKSHEET SHOWN IN APPENDIX 2 (FORM A2-6)
2. THE NUMBER OF CONDOMS TESTED (N) SHOULD BE EITHER 100 OR 50 AS INDICATED IN THE SAMPLING PROTOCOLS
3. CALCULATE A AND B USING FORM A2-6 IN THE FOLLOWING WAY:

VOLUME LEVELS WITHOUT DATA MUST BE LEFT BLANK (DO NOT RECORD AS ZERO)

NUMBER OF CONDOMS TESTED N	BURST VOLUME LITERS	COUNT THE NUMBER BURSTING AT EACH VOLUME LEVEL = Z	DIVIDE Z BY N = X	TAKE THE NATURAL LOG OF X = Y	MULTIPLY X BY Y = XY	
	35					
	34					
	33					
	32					
	31					
	30					
	29					
	28					
	27					
	26					
	25					
	24					
	23					
	22					
	21					
	20					
	19					
	18					
	17					
	16					
	15					
	14					SUM OF XY ABOVE THE LINE = A
	13					
	12					
	11					A =
	BELOW 11 LITERS					XY BELOW THE LINE = B
						B =

4. CALCULATE THE CDI AS FOLLOWS (IGNORE THE NEGATIVE SIGNS OF A AND B)

$$A + 5B = CDI$$

TABLE 4. Test for Normal Distribution

1. Calculate mean ($\bar{x}$) and standard deviation (S) (see Appendix 4).
2. Perform the following calculations

$\bar{x} - 1.5(S) = A$	$\bar{x} + 0.5(S) = D$
$\bar{x} - 1.0(S) = B$	$\bar{x} + 1.0(S) = E$
$\bar{x} - 0.5(S) = C$	$\bar{x} + 1.5(S) = F$

3. Record the number of condoms falling within each of the following Intervals (Observed Frequency), and calculate $\frac{(O_i-E_i)^2}{E_i}$

Interval	Observed Frequency (O_i)	Theoretical Frequency (E_i)	$\frac{(O_i-E_i)^2}{E_i}$
Zero to A		0.0668 x sample size =	
greater than A to B		0.0919 x sample size =	
greater than B to C		0.1498 x sample size =	
greater than C to $\bar{x}$		0.1915 x sample size =	
greater than $\bar{x}$ to D		0.1915 x sample size =	
greater than D to E		0.1498 x sample size =	
greater than E to F		0.0919 x sample size =	
greater than F		0.0668 x sample size =	

4. Add together all the $\frac{(O_i-E_i)^2}{E_i}$ values to find χ^2 =
5. If χ^2 is GREATER THAN 11.07, then proceed to an ACCEPT/REJECT test by counting all condoms that burst under 10 liters and referring to Table 3 for ACCEPT/REJECT decisions. If the number of condoms bursting under 10 liters falls between the Accept (Ac) and Reject (Re) numbers, then proceed to the next sampling stage in Table 3 until an ACCEPT/REJECT decision can be made (see Instructions for Use and Multiple Sampling Plans: Table 2).
6. If χ^2 is LESS THAN 11.07, then proceed to set up the monitoring charts as described in the next section.

Sampling for Routine Monitoring of Condoms in the Field

If the new or stored condoms have passed the dimension specifications and Water Test and exhibit acceptable, uniformly distributed Air Burst Volume data according to the Initial Sampling protocols described in the previous section, they will usually be stored in a warehouse[a] and dispensed to regional stores or retail outlets over a period of months or years. It is recommended that a random sample be taken every 6 months from each identifiable lot or shipment and tested. Results from these tests, when plotted on control charts will show trends in the strength and uniformity indicating Rate of Deterioration of the condoms. For the purpose of field testing, the Bursting Volume, and Bursting Pressure, may be used to monitor the Rate of Deterioration. The MONITORING CHART for each identifiable Lot or shipment of condoms is constructed in the following way using the Form A2-7 (shown in Appendix 2):

Monitoring Chart Construction

1. Every 6 months, collect one sample, each sample consisting of fifty condoms from each LOT. Check Package Seal Integrity on all of these (p. 16). Then test sample by Air Inflation (p. 24).

2. Plot the MEDIAN of the Burst Pressure and the MEDIAN of the Burst Volume on Form A2-7. Note: The median values can be found by starting at the weakest condom on the distribution chart (Form A2-7) and counting upward, until half the total sample has been counted (e.g., the 25th weakest condom in a sample of 50). The Burst Value of this condom is the MEDIAN value.

3. Calculate the Condom Deterioration Index (CDI) (see Table 3; p. 10 for instructions and plot on Form A2-7.

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[a] For proper warehousing techniques, see "The Purchase, Shipment, Storage and Distribution of Contraceptives in Developing Countries," Dr. S. Bruce Schearer. The Population Council, One Dag Hamarskjold Plaza, New York, NY 10017, USA.

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4. If a sudden change occurs in either the MEDIAN Burst Pressure or Burst Volume values or if the CDI is in the Intermediate Zone or the Unacceptable Zone, take another random sample consisting of 100 condoms and retest.

5. If the results of the second test show the condoms to be in an Intermediate Stage of deterioration, the condoms in that Lot or shipment should be distributed only at the discretion of the appropriate authority and retested every 90 days for the duration of their shelf life.

If the condoms are in the Unacceptable Zone, distribution of these stocks should be suspended, if possible, and additional random samples consisting of 300 condoms taken. One hundred condoms from this additional sample should be tested by Air Burst (see page 8 and page 24). The remaining 200 condoms should be packed carefully and sent for independent evaluation to:

QA Laboratory
PIACT/ASIA
MCC P.O. Box 189
Makati 3117
Manila, The Philippines

An Independent Check Report will be returned within 60 days. (If the Unacceptable result is confirmed by the independent check, a standard report (Appendix 2: Forms A2-7 through A2-12) should be submitted to the appropriate authority with the recommendation that the lot of condoms sampled are of UNACCEPTABLE QUALITY and should not be distributed for their stated purpose.

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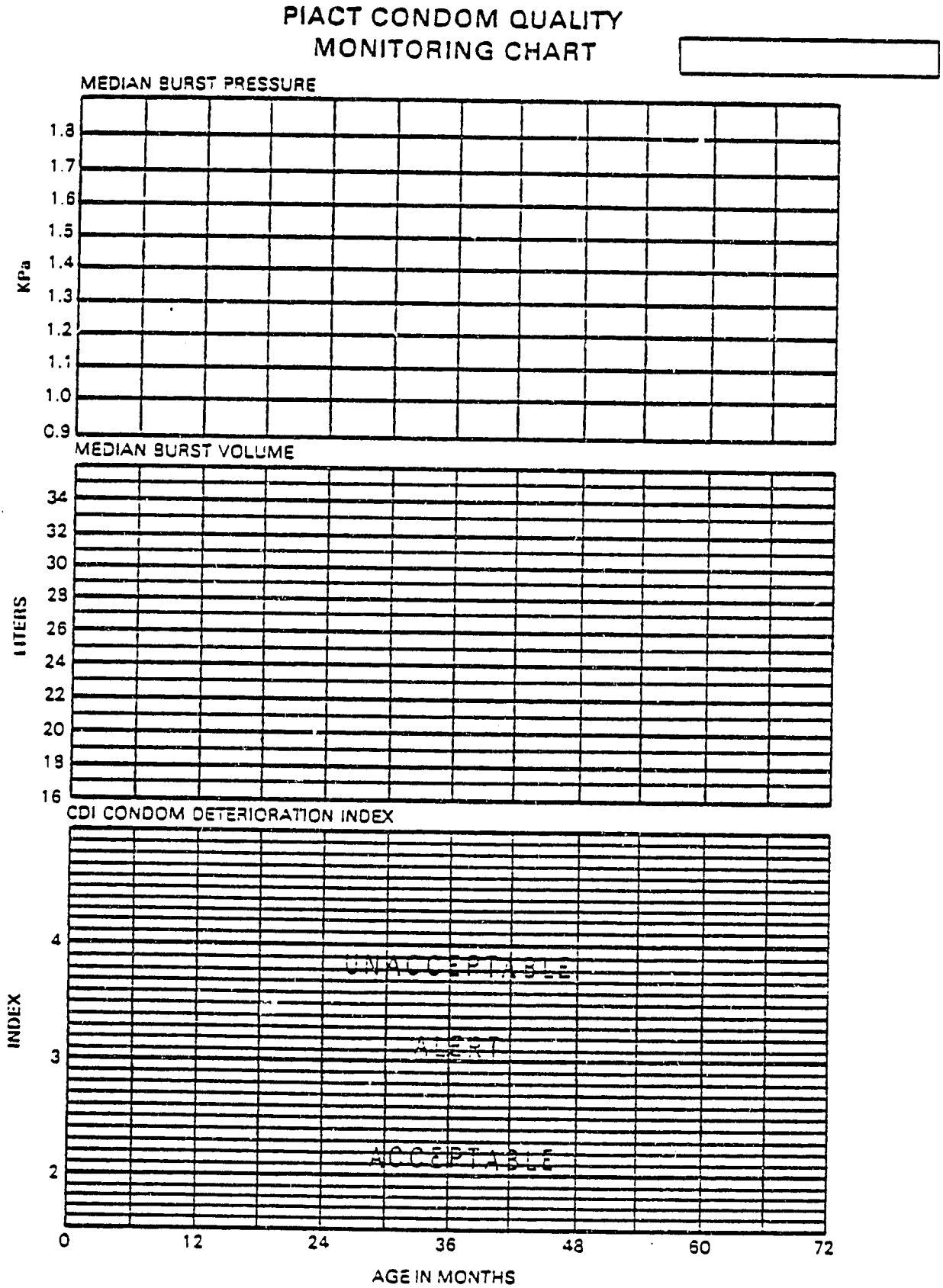

FIGURE 2. Example of Form A2-7 (Appendix 2) used for monitoring strength of condoms during aging.

CHECKING CONDOM DIMENSIONS, LUBRICATION, AND PACKAGING

The following procedures for measuring dimensions and lubricants are derived from published International Standards Organization Standards (ISO4074-1980) or, where these have not yet been formulated, from ANSI/ASTM D3492-77 Standard Specifications for Rubber Condoms and United States General Services Administration Specification 22-C-001597A (GSA-FSS) 1977, Interim Federal Specifications-Condoms, Rubber, Contraceptive.

A method of examining the package for a tight seal measured as Package Seal Integrity has also been included because many unsealed packets have been reported among condoms stored in hot and humid climates.

Procedures for Measuring Dimensions and Lubricants

1. The length of the condom, excluding the teat, is measured to the nearest 1 mm. This can best be achieved by unrolling the condom onto the plastic pin shown in Figure 3. Unroll the condom, stretch it slightly twice to smooth out the wrinkles caused by the condom having been rolled up. Put the condom over the mandrel and let it hang freely, stretched only by its own weight. Note, to the nearest millimeter, the smallest value of the length of the condom that can be read on the scale outside the open end of the condom.
2. To measure the width of the condom, unroll the condom and lay it flat over the edge of a steel ruler, allowing it to hang freely. Measure to the nearest millimeter the width of the condom at any point up to 85 mm from the open end. For tapered condoms, measure the width at the 85 mm point. For flaired condoms, measure width of the parallel portion.
3. The double wall thickness is measured[a] on condoms from which lubricant has been removed with water or isopropanol, and are then dried to constant mass. If Quantity of Lubricant is measured

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[a] Micrometers. The dial micrometer used to measure the thickness of flat specimens should be capable of exerting a pressure of 25 ± 5 kPa (3.6 ± 0.7 psi) on the specimens, and of measuring the thickness to within ± 0.01 mm (0.0004 in.). The foot in contact with specimens should be at least 6 mm (0.236 in.) in diameter. The anvil of the micrometer should be at least 35 mm (1.4 in.) in diameter, be parallel to the face of the contact foot.

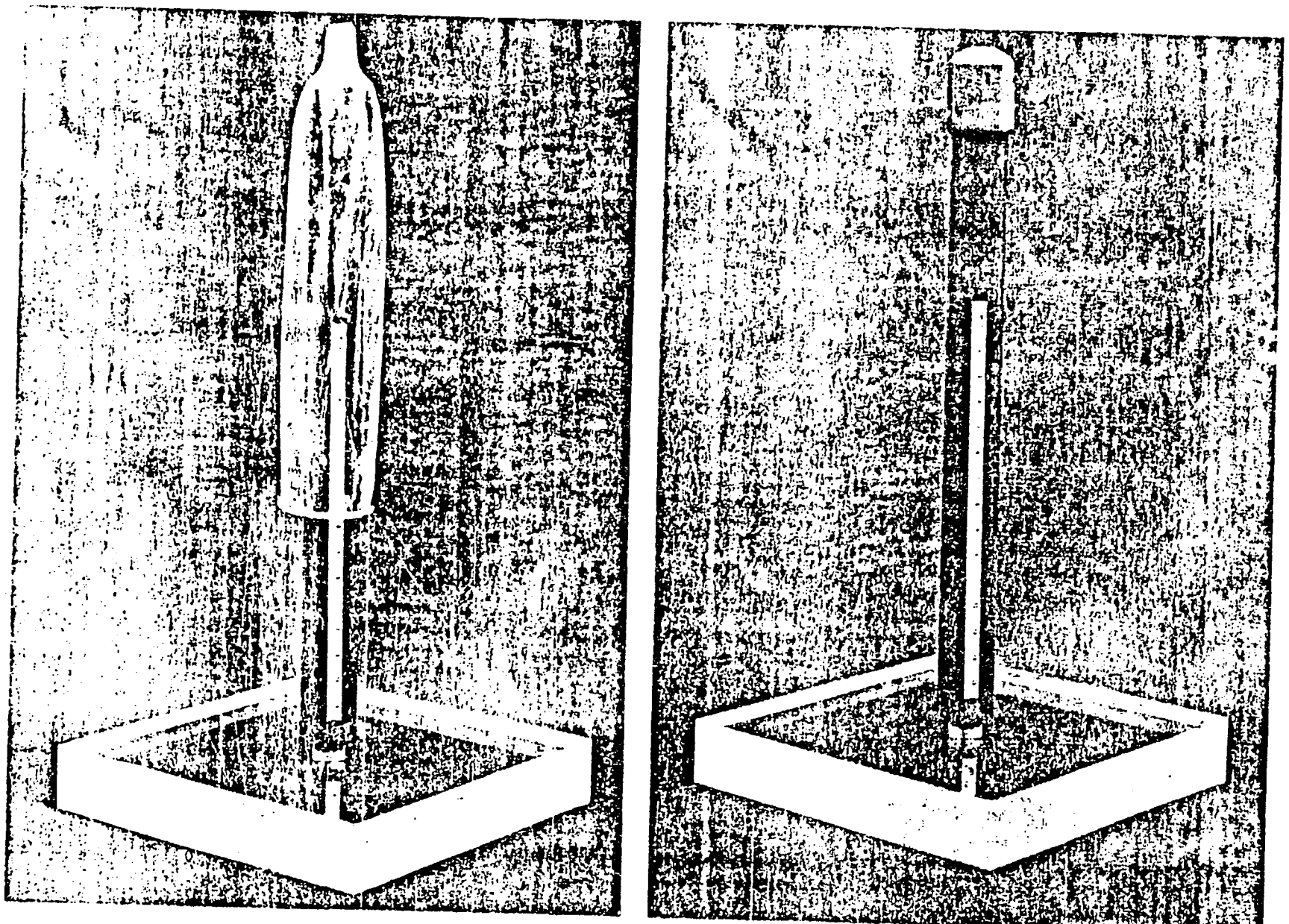

FIGURE 3. The Condom Unrolling Pin for Length Measurements

as outlined in 5 (below), the same condoms may be used for this thickness measurement. When a condom is textured, the thickness is measured in a nontextured area. The measurements are usually reported to the nearest 0.01 mm. The wall thickness of condoms is measured at three points: 10 ± 2 mm from the open end, 30 ± 5 mm from the closed end, and at the mid-distance between those two points. Lateral measurements made from the closed end of reservoir style condoms should exclude the reservoir tip. The individual measurements, and the average value of all three measurements, are to be recorded for each condom on Form A2-2 (Appendix 2).

4. After the thickness measurement, condom weight is measured on a balance and reported to the nearest 1 mg. This measurement may be made in conjunction with measurement of quantity of lubrication (see below).

5. Lubricant is measured by weighing the sealed package on an analytical balance. Each packet is then opened, taking care to retain all pieces. The packet and condom are washed in isopropanol until all lubricant is removed; they are then dried to a constant weight. All weights are recorded to the nearest milligram (mg). (Use data collecting form shown in Appendix 2. Form A2-2) Weight of the lubricant is determined by subtracting the weight of the washed and dried sample (packet and condom) from the initial weight of the sample prior to removal of the lubricant.

Checking Package Seals

A package can be checked for leakage as measured by Package Seal Integrity. Place the packaged condom in the clear plastic chamber supplied and couple the chamber to the vacuum pump, sealing the chamber. Switch on the vacuum and observe the package. Air trapped in the well-sealed packages at atmospheric pressure will cause them to balloon out under vacuum and collapse when the vacuum is removed. Record good (✓) or bad (x) on data collecting forms shown in Appendix 2. Use the Measurements form (Appendix 2, Form A2-2) if condoms are new or are being tested for the first time. Use the Air Inflation forms (Appendix 2, Form A2-5) if the condoms are being tested under a routine monitoring schedule.

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Recommended Characteristics:

1. Different designs are codified as follows:

Norm A: Nominal width 52 mm
Norm B: Nominal width 49 mm
Type 1: Smooth surface
Type 2: Textured surface
Shape a: Parallel-sided
Shape b: Shaped.

Norms, types, and shapes may be present in any combination.

Dimensional requirements for condoms are defined by specific nationally-accepted criteria and by proposed international standards (ISO/TC 157 N83 E). They are as follows:

2. Length:
Norm A: 180 mm ± 10 mm (range)
Norm B: 160 mm ± 10 mm (range)
In both cases the length of the teat, if present, is excluded.

3. Width:
Norm A: 52 mm ± 3 mm (range)
Norm B: 49 mm ± 2 mm (range)
Norm A, Shape b: Parallel-sided portion, as for Norm A; bulb portion, not more than 70 mm
Norm B, Shape b: Parallel-sided portion, as for Norm B; bulb portion, not more than 62 mm

4. Thickness: Not more than 0.16 mm for double-wall thickness, measured on smooth portions

5. Weight:
Norm A, type 1: Each condom, not more than 1.70 g
Norm B, type 1: Each condom, not more than 1.60 g
Norm A, type 2: Each condom, not more than 1.90 g
Norm B, type 2: Each condom, not more than 1.80 g
Weight should be determined on a balance accurate to 0.005 g.

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6. Nonlubricated and lubricated condoms. Nonlubricated condoms are powdered to prevent the latex from sticking to itself, and to facilitate mechanical manipulation of the condoms. Lubricated condoms are dressed with a water-base jelly or silicone-oil-type lubricant. When lubricated condoms are tested as specified on page 16, the normal amount(s) of lubricant will vary with the country of manufacture.

For USA condoms, the following limits apply:

Water-base jelly	350 to 550 mg
Silicone-oil type	250 to 500 mg

For Japanese condoms, less than 100 mg of silicone oil is normal.

THE WATER TEST FOR PINHOLES

Description of the Apparatus

The water test apparatus (Figure 4) is designed to test condoms for pinholes, according to specifications laid down by the following authorities:

American Society for Testing and Materials ANSI/ASTM D3492-77; Para. 7.2.2

SIDA (Swedish) Specifications for Rubber Condoms P:4, Para. 6.1

British Standards Institution, BS3704 1979 Appendix C

International Standards Organization Standards 4074/Part 5, First Edition 1980-10-01.

The apparatus is a compact, portable unit composed of two identical water metering and dispensing systems with condom holders, arranged as shown in Figure 5.

Supplies Required:

1. Large sheets of blotting paper (a colored paper, particularly green, is preferred by many operators)
2. Sheets of absorbent paper (newspaper can be used)
3. Vinyl, latex or thin cotton gloves
4. Container for disposal of condoms

Instructions for Use of the Water Test Apparatus:

1. Attach MASTER ON-OFF VALVE to a domestic water supply running at a pressure between 70 and 700 kPa (approx. 10-100 pounds

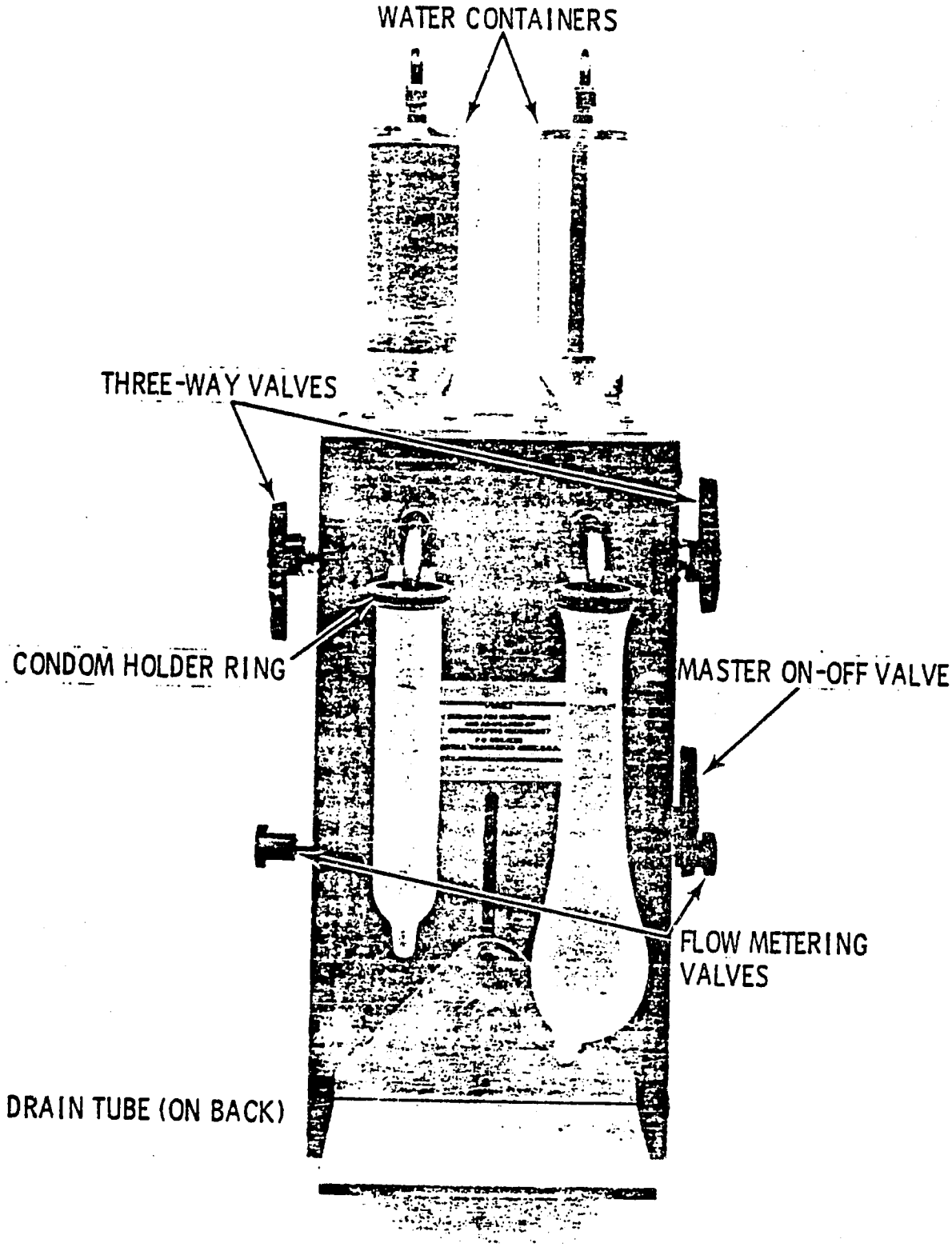
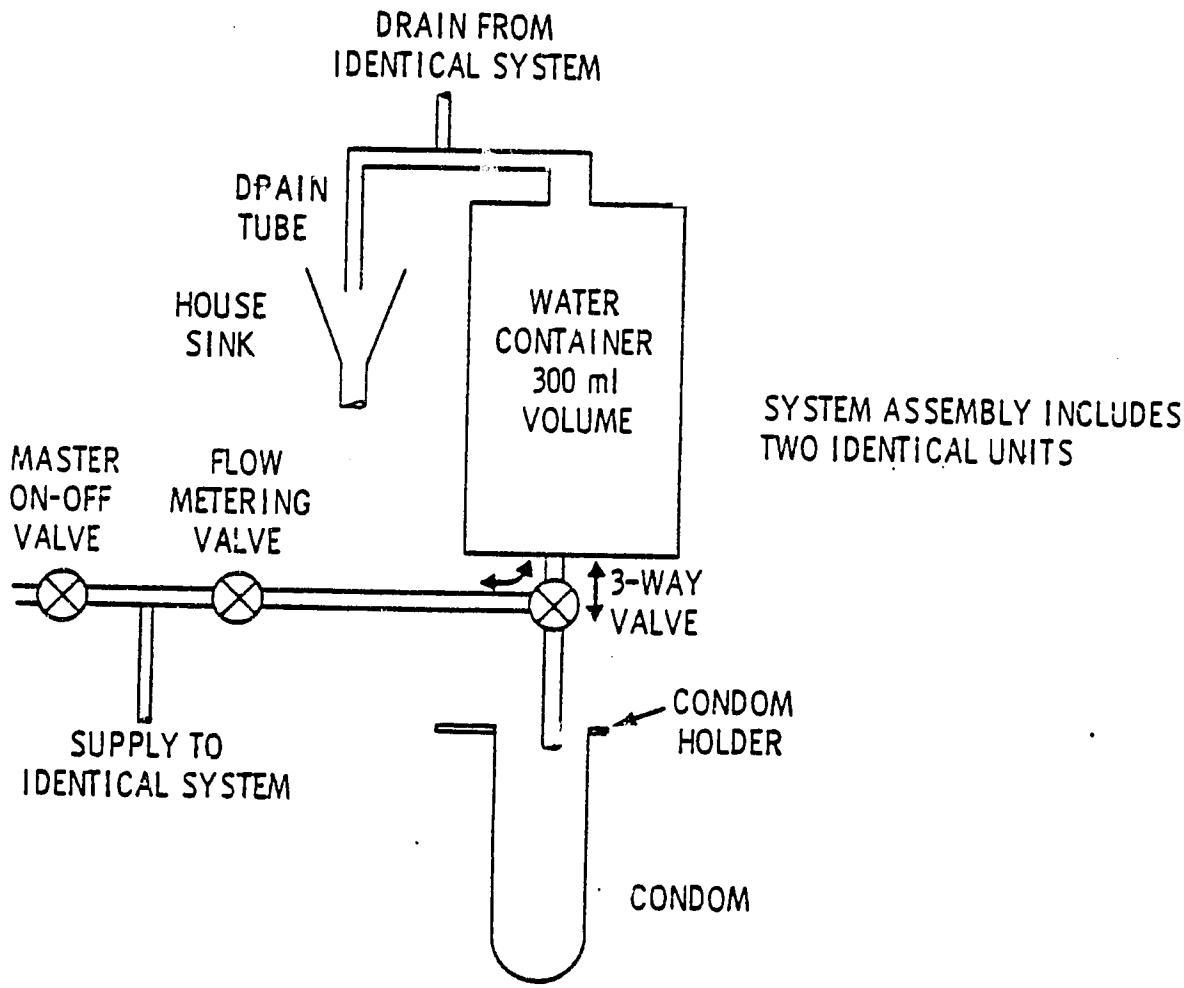


FIGURE 4. Water Test Apparatus



FLOW RATE TO FILL CONTAINER

300 ml/15 sec = 20 ml/sec

$\simeq 7 \times 10^{-4}$ ft^3/sec

$\simeq 1.2 \times 10^{-5}$ ft^3/min

FIGURE 5. Schematic Diagram of Water Test Apparatus

per square inch). Place the DRAIN TUBE into a suitable sink, drain or storage vessel. This sink should be close to and lower than the apparatus to provide a height difference of at least 0.6 meters between the drain outlet at the back of the apparatus and the end of the drain tube.

2. Turn both THREE-WAY VALVES so that the arrows point upward, and adjust the FLOW-METERING VALVES until the WATER CONTAINERS fill in about 15 seconds. The water should be left running throughout the testing period. When the water containers are full, water will overflow into the drain tube.
3. Place absorbent paper on the CONDOM SUPPORT PLATFORM.
4. Using gloves to avoid damage to condoms from rough skin or fingernails, fully unroll a test condom (the plastic pin, shown in Figure 3, page 15, can be used to facilitate unrolling). Slip the ring at the open end of the condom over the rim of the first CONDOM HOLDER RING, and give the condom a gentle downward pull to position it properly on the holder.
5. Make sure the WATER CONTAINER is full and overflowing; then adjust the THREE-WAY VALVE so that the arrow on the valve handle is pointing downward.
6. Prepare and mount a second condom on the second CONDOM HOLDER, following instructions 4 and 5.
7. As the first water-filled condom hangs on the holder, tap it to break bubbles inside, then inspect for visible water leakage (spraying or beading) through the condom wall. Condoms with obvious leaks should be recorded as failures.
8. If no leaks are evident from visual inspection, turn the THREE-WAY VALVE so that the arrow points upward. Grasp the condom just below the holder, remove it from the holder, and twist the open end firmly shut. Roll the water-filled condom three times on a sheet of absorbent paper to remove excess lubricant and any exterior water droplets resulting from removal of the condom from the holder.

9. Firmly roll the water-filled condom three times over a sheet of dry blotting paper. Also stand the condom on its closed end while exerting firm pressure. After each procedure, inspect the paper for signs of water leakage from the condom. When any condoms leave wet marks on the blotting paper, locate the position of the hole by re-rolling and/or pressing the water-filled condom to squeeze water drops through the hole. Mark the hole with a felt-tip marking pen, empty the condom and measure the position of the hole from the closed end (excluding any teat). Using a record form such as that shown in Appendix 2 (Form A2-3), record as failures any condoms with holes at any position from the tip up to 25 mm from the open end. Record the distance of the hole from the open end.
10. Place another test condom on the first CONDOM HOLDER, following steps 4 and 5.
11. Test the condom on the second CONDOM HOLDER by following steps 7, 8 and 9.
12. Continue testing in this way until the sample set is completed. Destroy all condoms tested.

Maintenance and Repair

No routine maintenance is required. Internal leaks can be repaired by simple plumbing techniques. Delivered Volume should be checked weekly by collecting the contents of the reservoirs into graduated cylinders. Adjustment of the volume is achieved by loosening the clamp nuts on the overflow tubes at the top of the reservoirs and sliding the tubes up or down to achieve the desired volume (300 ml) of water. In rare cases, wherein condoms will not hold 300 ml of water, the tubes should be lowered as much as possible. This will result in the delivery of approximately 270 ml of water.

11

THE AIR INFLATION TEST

Description of the Apparatus

The Air Inflation Apparatus (Figure 6) is designed to test condoms for Bursting Volume and Bursting Pressure according to specifications laid down by the following authorities:

SIDA (Swedish) Specifications for Rubber Condoms P. 4, Para. 7.

International Standards Organization Standards 4074/Part 6, First Edition 19811-01-15.

It is a compact portable unit composed of two identical air-metering and dispensing systems, condom holders and pressure gages. Air is supplied to the condoms at a constant mass flow rate through an orifice. Volume at Burst can be obtained by recording the time to burst; Bursting Pressure can be read directly off the gages. The system is arranged as shown in Figure 7.

Supplies Required

1. Stop watch or digital timer calibrated in seconds
2. Container for disposal of condoms
3. Centigrade thermometer
4. Barometer, calibrated in mm Hg (preferably a laboratory, mercury-column barometer).
5. Vinyl, latex or thin cotton gloves.
6. Calibrated Rotameter Flowmeter
7. Ear protectors
8. Safety glasses or goggles
9. Wire for cleaning orifice (1.3 mm diameter)

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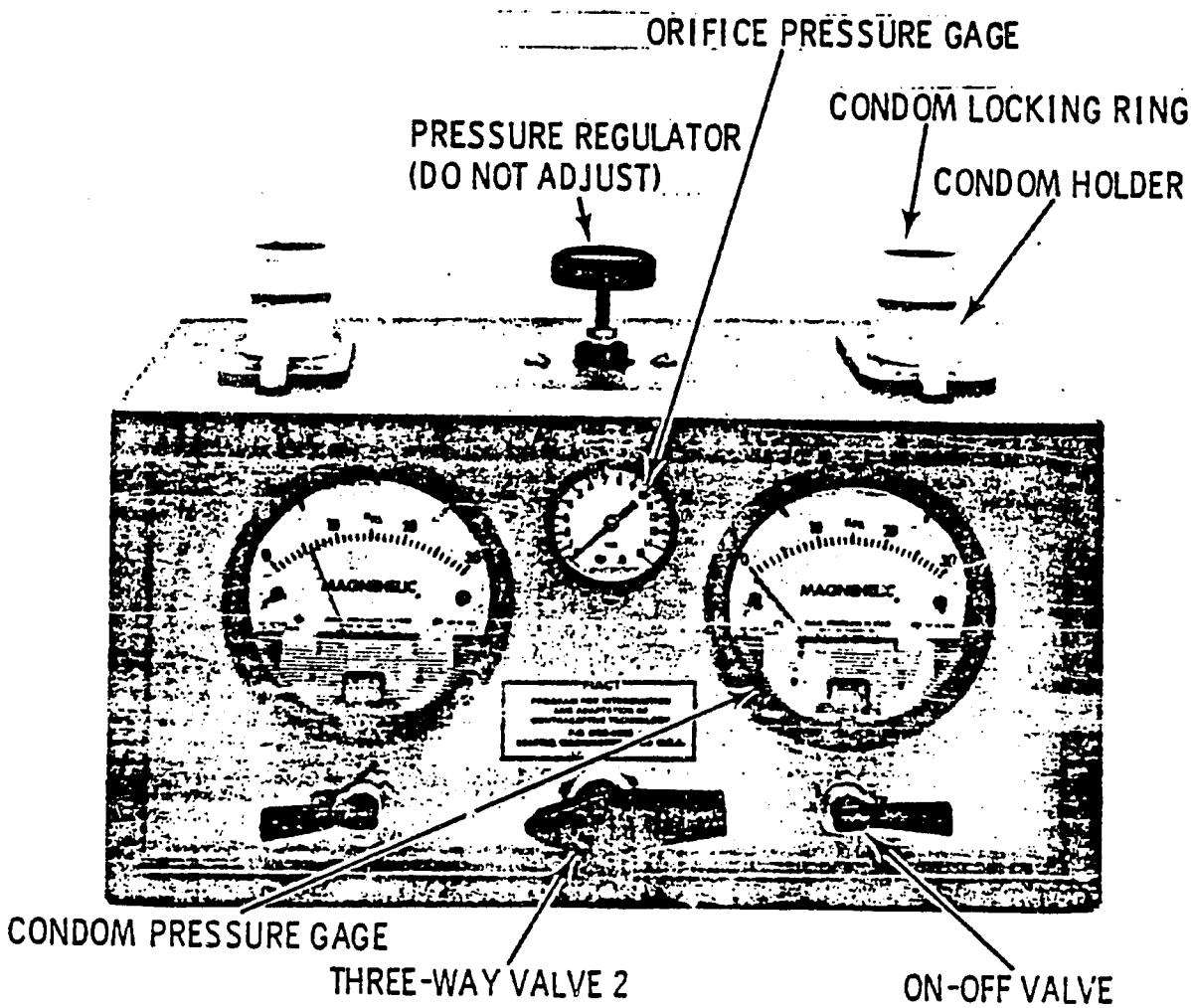

FIGURE 6. Air Inflation Apparatus

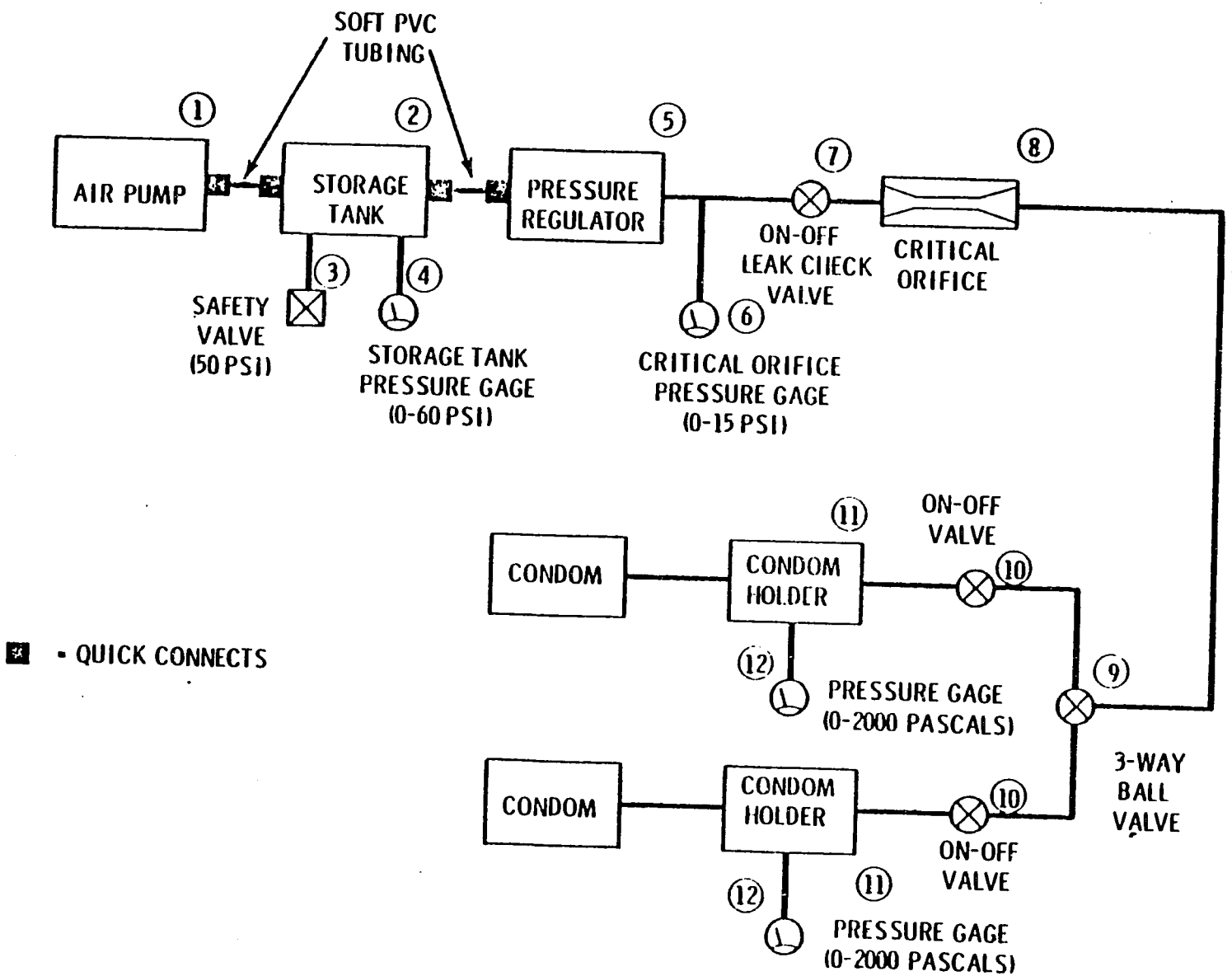

FIGURE 7. Block Diagram of Air Inflation Apparatus

Best Available Document

PSI	in/H_2O	in/Hg	mm/H_2O	mm/Hg	mbar	kPa
.001	.0277	.0020	.7031	.0517	.0690	.0069
.002	.0554	.0041	1.406	.1034	.1379	.0138
.003	.0830	.0061	2.109	.1551	.7068	.0207
.004	.1107	.0081	2.312	.2069	.2758	.0276
.006	.1561	.0122	4.218	.3103	.4137	.0414
.008	.2214	.0163	5.625	.4137	.5516	.0552
.01	.2768	.0204	7.031	.5171	.6895	.0690
.02	.5536	.0407	14.06	1.034	1.379	.1379
.03	.8304	.0611	21.09	1.551	2.068	.2068
.04	1.107	.0814	28.12	2.069	2.758	.2758
.05	1.384	.1018	35.15	2.586	3.447	.3447
.06	1.561	.1222	42.18	3.103	4.137	.4137
.07	1.938	.1425	49.22	3.620	4.826	.4826
.08	2.214	.1629	56.25	4.137	5.516	.5516
.09	2.491	.1832	63.28	4.654	6.205	.6205
.10	2.768	.2036	70.31	5.171	6.895	.6895
.11	3.045	.2240	77.34	5.689	7.584	.7584
.12	3.322	.2443	84.37	5.206	8.274	.8274
.13	3.598	.2647	91.40	6.723	8.963	.8963
.14	3.375	.2850	98.43	7.240	9.652	.9652
.15	4.152	.3054	105.5	7.757	10.34	1.034
.16	4.429	.3258	112.5	8.274	11.03	1.103
.17	4.706	.3461	119.5	8.792	11.72	1.172
.18	4.982	.3565	126.6	9.309	12.41	1.241
.19	5.259	.3868	133.6	9.826	13.10	1.310
.20	5.536	.4072	140.6	10.34	13.79	1.379
.21	5.813	.4276	147.6	10.86	14.48	1.448
.22	6.090	.4479	154.7	11.14	15.17	1.517
.23	6.367	.4683	161.7	11.89	15.86	1.586
.24	6.643	.4886	168.7	12.41	16.55	1.655
.25	6.920	.5090	175.8	12.93	17.24	1.724
.26	7.197	.5294	182.8	13.45	17.93	1.793
.27	7.474	.5497	189.8	13.96	18.62	1.862
.28	7.751	.5701	196.9	14.48	19.30	1.930
.29	8.027	.5904	203.9	15.00	19.99	1.999
.30	8.304	.6108	210.9	15.51	20.68	2.068
.31	8.581	.6312	218.0	16.03	21.37	2.137
.32	8.858	.6515	225.0	16.55	22.06	2.206
.33	9.135	.6719	232.0	17.07	22.75	2.275
.34	9.411	.6922	239.0	17.58	23.44	2.344
.35	9.688	.7126	246.1	18.10	24.13	2.413
.36	9.965	.7330	253.1	18.62	24.82	2.482
.37	10.24	.7533	260.1	19.13	25.51	2.551
.38	10.52	.7737	267.2	19.65	26.20	2.620
.39	10.80	.7940	274.2	20.17	26.89	2.689
.40	11.07	.8144	281.2	20.69	27.58	2.758
.41	11.35	.8348	288.3	21.20	28.27	2.827
.42	11.63	.8551	295.3	21.72	28.96	2.896
.43	11.90	.8755	302.3	22.24	29.65	2.965
.44	12.18	.8958	309.4	22.75	30.34	3.034
.45	12.46	.9162	316.4	23.27	31.03	3.103
.46	12.73	.9366	323.4	23.79	31.72	3.172
.47	13.01	.9569	330.4	24.31	32.40	3.240
.48	13.29	.9773	337.5	24.82	33.10	3.310
.49	13.56	.9976	344.5	25.34	33.78	3.378
.50	13.84	1.018	351.5	25.86	34.47	3.447
.51	14.12	1.038	358.6	26.37	35.16	3.516
.52	14.39	1.059	365.6	26.89	35.85	3.585
.53	14.67	1.079	372.6	27.41	36.54	3.654
.54	14.95	1.099	379.7	27.93	37.23	3.723
.55	15.22	1.120	386.7	28.44	37.92	3.792
.56	15.50	1.140	393.7	28.96	38.61	3.861
.57	15.78	1.160	400.8	29.48	39.30	3.930
.58	16.05	1.181	407.8	29.99	39.99	3.999
.59	16.33	1.201	414.8	30.51	40.68	4.068
.60	16.61	1.222	421.8	31.03	41.37	4.137
.61	16.88	1.242	428.9	31.55	42.06	4.206
.62	17.16	1.262	435.9	32.06	42.75	4.275
.63	17.46	1.283	442.9	32.58	43.44	4.344
.54	17.72	1.303	450.0	33.10	44.13	4.413
.65	17.99	1.323	457.0	33.61	44.82	4.482
.66	18.27	1.344	464.0	34.13	45.50	4.550
.67	18.55	1.364	471.1	34.65	46.19	4.619
.68	18.82	1.384	478.1	35.17	46.88	4.688
.69	19.10	1.405	485.1	35.68	47.57	4.757
.70	19.38	1.425	492.2	36.20	48.26	4.826
.71	19.65	1.446	499.2	36.72	48.95	4.895
.72	19.93	1.466	506.2	37.23	49.64	4.964
.73	20.21	1.486	513.2	37.75	50.33	5.033
.74	20.48	1.507	520.3	38.27	51.02	5.102
.75	20.76	1.527	527.3	38.79	51.71	5.171
.76	21.04	1.547	534.3	39.30	52.40	5.240
.77	21.31	1.568	541.4	39.82	53.09	5.309
.78	21.59	1.588	548.4	40.34	53.78	5.378
.79	21.87	1.608	555.4	40.85	54.47	5.447
.80	22.14	1.629	562.5	41.37	55.16	5.516
.81	22.42	1.649	569.5	41.89	55.85	5.585
.82	22.70	1.670	576.5	42.41	56.54	5.654
.83	22.97	1.690	583.6	42.92	57.23	5.723
.84	23.25	1.710	590.6	43.44	57.92	5.792
.85	23.53	1.731	597.6	43.96	58.60	5.860
.86	23.81	1.751	604.7	44.[illegible]	59.30	5.929
.87	24.08	1.771	611.7	44.99	59.98	5.998
.88	24.36	1.792	618.7	45.51	60.67	6.067
.89	24.64	1.812	625.7	46.03	61.36	6.136
.90	24.91	1.832	632.8	46.55	62.05	6.205
.91	25.19	1.853	639.8	47.06	62.74	6.274
.92	25.47	1.873	646.8	47.58	63.43	6.343
.93	25.74	1.893	653.8	48.09	64.12	6.412
.94	26.02	1.914	660.9	48.61	64.81	6.481
.95	26.30	1.934	667.9	49.13	65.50	6.550
.96	26.57	1.955	675.0	49.65	66.19	6.619
.97	26.85	1.975	682.0	50.16	66.88	6.688
.98	27.13	1.995	689.0	50.68	67.57	6.757
.99	27.40	2.016	696.1	51.20	68.26	6.826
1.0	27.68	2.036	703.1	51.71	68.95	6.895

PSI	in/H_2O	in/Hg	mm/H_2O	mm/Hg	mbar	kPa
1.1	30.45	2.240	770.4	56.89	75.84	7.584
1.2	33.22	2.443	843.7	62.06	82.74	8.274
1.3	35.98	2.647	914.0	67.23	89.63	8.963
1.4	38.75	2.850	984.3	72.40	96.52	9.652
1.5	41.52	3.054	1055	77.57	103.4	10.34
1.6	44.29	3.258	1125	82.74	110.3	11.03
1.7	47.06	3.461	1195	87.92	117.2	11.72
1.8	49.82	3.665	1266	93.09	124.1	12.41
1.9	52.59	3.868	1336	98.26	131.0	13.10
2.0	55.36	4.072	1406	103.4	137.9	13.79
2.1	58.13	4.276	1476	108.6	144.8	14.48
2.2	60.90	4.479	1547	113.8	151.7	15.17
2.3	63.67	4.683	1617	118.9	158.6	15.86
2.4	66.43	4.886	1687	124.1	165.5	16.55
2.5	68.20	5.090	1758	129.3	172.4	17.24
2.6	71.97	5.294	1828	134.5	179.3	17.93
2.7	74.74	5.497	1898	139.6	186.2	18.62
2.8	77.51	5.701	1969	144.8	193.0	19.30
2.9	80.27	5.904	2039	150.0	199.9	19.99
3.0	83.04	6.108	2109	155.1	206.8	20.68
3.1	85.81	6.312	2180	160.3	213.7	21.37
3.2	88.58	6.515	2250	165.5	220.6	22.06
3.3	91.35	6.719	2320	170.7	227.5	22.75
3.4	94.11	6.922	2390	175.8	234.4	23.44
3.5	96.88	7.126	2461	181.0	241.3	24.13
3.6	99.65	7.330	2531	186.2	248.2	24.82
3.7	102.4	7.533	2601	191.3	255.1	25.51
3.8	105.2	7.737	2672	196.5	262.0	26.20
3.9	108.0	7.940	2742	201.7	268.9	26.89
4.0	110.7	8.144	2812	206.9	275.8	27.58
4.1	113.5	8.348	2883	212.0	282.7	28.27
4.2	116.3	8.551	2953	217.2	289.6	28.96
4.3	119.0	8.775	3023	222.4	296.5	29.65
4.4	121.8	8.958	3094	227.5	303.4	30.34
4.5	124.6	9.162	3164	232.7	310.3	31.03
4.6	127.3	9.366	3234	237.9	317.2	31.72
4.7	130.1	9.569	3304	243.1	324.0	32.40
4.8	132.9	9.772	3375	248.2	331.0	33.10
4.9	135.6	9.976	3445	253.4	337.8	33.78
5.0	138.4	10.18	3515	258.6	344.7	34.47
5.1	141.2	10.38	3586	263.7	351.6	35.16
5.2	143.9	10.59	3656	268.9	358.5	35.85
5.3	146.7	10.79	3726	274.1	365.4	36.54
5.4	149.5	10.99	3797	279.3	372.3	37.23
5.5	152.2	11.20	3867	284.4	379.2	37.92
5.6	155.0	11.40	3937	289.6	386.1	38.61
5.7	157.8	11.60	4008	294.8	393.0	39.30
5.8	160.5	11.81	4078	299.9	399.9	39.99
5.9	163.3	12.01	4148	305.1	406.8	40.68
6.0	166.1	12.22	4218	310.3	413.7	41.37
6.1	168.8	12.42	4289	315.5	420.6	42.06
6.2	171.6	12.62	4359	320.6	427.5	42.75
6.3	174.4	12.83	4429	325.8	434.4	43.44
6.4	177.2	13.03	4500	331.0	441.3	44.13
6.5	179.9	13.23	4570	336.1	448.2	44.82
6.6	182.7	13.44	4640	341.3	455.0	45.50
6.7	185.5	13.64	4711	346.5	461.9	46.19
6.8	188.2	13.84	4781	351.7	468.8	46.88
6.9	191.0	14.05	4851	356.8	475.7	47.57
7.0	193.8	14.25	4922	362.0	482.6	48.26
7.1	196.5	14.46	4992	367.2	489.5	48.95
7.2	199.3	14.66	5062	372.3	496.4	49.64
7.3	202.1	14.86	5132	377.5	503.3	50.30
7.4	204.8	15.07	5203	382.7	510.2	51.02
7.5	207.6	15.27	5273	387.9	517.1	51.71
7.6	210.4	15.47	5343	393.0	524.0	52.40
7.8	215.9	15.88	5484	403.4	537.8	53.78
8.0	221.4	16.29	5625	413.7	551.6	55.16
8.2	227.0	16.70	5765	424.1	565.4	56.54
8.4	232.5	17.10	5906	434.4	579.2	57.92
8.6	238.0	17.51	6047	444.7	592.9	59.29
8.8	243.6	17.92	6187	455.1	606.7	60.67
9.0	249.1	18.32	6328	465.4	620.5	62.05
9.2	254.7	18.73	6468	475.8	634.3	63.43
9.4	260.2	19.14	6609	486.1	648.1	64.81
9.6	265.7	19.54	6750	496.5	661.9	66.19
9.8	271.3	19.95	6890	506.8	675.7	67.57
10.0	276.8	20.36	7031	517.1	689.5	68.95
11.0	304.5	22.40	7734	568.9	758.4	75.84
12.0	332.2	24.43	8437	620.6	827.4	82.74
13.0	359.8	26.47	9140	672.3	896.3	89.63
14.0	387.5	28.50	9843	724.0	965.2	96.52
14.7	407.9	29.93	10340	760.2	1014	101.4
15.0	415.2	30.54	10550	775.7	1034	103.4
16.0	442.9	32.58	11250	827.4	1103	110.3
17.0	470.6	34.61	11950	879.1	1172	117.2
18.0	498.2	36.65	12660	930.9	1241	124.1
19.0	525.9	38.68	13360	982.8	1310	131.0
20.0	553.6	40.72	14060	1034	1379	137.9
21.0	581.3	42.76	14770	1086	1448	144.8
22.0	609.0	44.79	15470	1138	1517	151.7
23.0	636.7	46.83	16170	1189	1586	158.6
24.0	664.3	48.86	16870	1241	1655	165.5
25.0	692.0	50.90	17580	1293	1724	172.4

CONVERSION FACTORS

PSI x 27.68 = in. H_2O
PSI x 2.036 = in. Hg
PSI x 703.1 = mm H_2O
PSI x 51.71 = mm Hg
PSI x .0703 = kg/cm2

PSI x .0690 = bar
PSI x 68.95 = mbar
PSI x 6895 = Pa
PSI x 6.895 = kPa

NOTE: CONVERSION FACTORS ROUNDED

15

Instructions for Use of the Air Inflation Apparatus

1. Wear ear protectors to protect against loud noise and goggles to protect against latex fragments.
2. Connect the apparatus to an air pump or suitable air supply, capable of supplying at least 25 liters per minute at greater than 275 kPa (40 pounds per square inch). If a reciprocal air pump is used, a storage tank of at least 4 liters should be used to damp pressure surges. The air supply should be well filtered to eliminate oil water and particles greater than 10 microns diameter.
3. Turn on the air supply and wait until the STORAGE TANK PRESSURE GAGE (on the pump) registers the maximum pressure of 275-345 kPA (40-50 pounds per square inch).
4. The ORIFICE PRESSURE GAGE should register between 55 and 83 kPa (8-12 pounds per square inch). This setting has been calibrated in the laboratory and should not need routine adjustment.
5. Position the LEAK CHECK VALVE (on back of apparatus) in the USE position.
6. Using vinyl, latex or thin cotton gloves to avoid damage from skin or fingernails, fully unroll a test condom. (The plastic pin, shown in Figure 3, page 15, can be used to facilitate unrolling.) Slip the CONDOM LOCKING RING off the first CONDOM HOLDER and place the open end of the condom over the black rubber FLANGE. Pass the closed end of the condom through the CONDOM LOCKING RING and gently pull the condom upward while pushing the CONDOM LOCKING RING firmly into place.
7. Position THREE-WAY VALVE so that it points toward the condom that is to be inflated.
8. Open the ON-OFF VALVE, simultaneously starting a timer or stopwatch.

9. Focus attention on the CONDOM PRESSURE GAGE on the same side of the apparatus as the condom that is being inflated. When the condom bursts, instantaneously switch off the timer or stopwatch and record the peak pressure. Close off the ON-OFF VALVE; record Time to Burst and Pressure at Burst.

10. If a second operator is available, a second condom can be loaded on the other CONDOM HOLDER while the first condom is inflating. To start inflation of the second condom, switch THREE-WAY VALVE to the second condom, reset timer, and turn on ON-OFF VALVE and timer simultaneously.

11. To obtain Volume at Burst (in liters), multiply the Time to Burst (in seconds) by the Corrected Volumetric Flow Rate (in liters per second). The Corrected Volumetric Flow Rate (V) is calculated at the beginning of each test session, using the following equation:

$$V = \frac{44.1 \times Vo \quad \sqrt{T + 273}}{P}$$

where Vo is the Standard Flow Rate (set at 0.4 liters/sec in this apparatus),

T is ambient temperature in °C, and
P is barometric pressure in mm Hg.

(See Appendix 5 for discussion of this equation.)

Record Form A2-5 (Appendix 2) provides a convenient format for recording results and calculations for this test.

12. If air inflation testing has not been performed for several days or weeks, or if a new operator is using the apparatus, test six surplus condoms as practice (without recording results) before starting on the test sample.

Amended 10/15/81

Calibration, Maintenance and Repair

All calibration adjustments and instrument repairs should be recorded on copies of Form A2-4 (Appendix 2) and kept as a permanent record.

The ORIFICE PRESSURE GAGE (Figure 6) provides a continuous check of calibration of the mass flow rate through the orifice. It measures the pressure between the pressure regulator and the orifice. Since this pressure and the orifice diameter are the major determinants of mass flow through the system, maintenance of this pressure within narrow limits will insure accurate flow except in the unlikely instance of a narrowing of the critical orifice itself, or if the system develops a leak. The apparatus is calibrated against a mass flow meter and a gasometer before shipping, and the PRESSURE REGULATOR (Figure 6) is locked in place with a locking nut. It will not usually require adjustment, but should be checked, as follows, at the beginning of each day of testing.

1. Place the ROTAMETER FLOWMETER firmly into one of the CONDOM HOLDERS and turn on the air. The ball of the flowmeter should float between the two calibration marks.
2. If the FLOWMETER ball is not floating between the calibration mark, first check for leaks following steps 3 through 5 below, then proceed to step 6.
3. Place the two condoms, (one inside the other) on each CONDOM HOLDER and clamp in place with the condom locking rings (Figure 6). Turn both ON-OFF VALVES to the on position and the THREE-WAY VALVE to the right. When the right-hand CONDOM PRESSURE GAGE registers 30 kPa, turn the THREE-WAY VALVE to the left. When the left-hand CONDOM PRESSURE GAGE registers 30 kPa, turn the LEAK CHECK VALVE (on back of apparatus) to the check position. Observe the pressure gages for 2 minutes. If no significant pressure drop occurs on either side, the LEAK CHECK VALVE can be turned back to the use position; the condoms can be removed from the holders. Proceed directly to step 6.

4. If a significant drop in pressure occurs on the right side, check first to see that the condoms are not at fault by replacing them on that side with two new condoms. If the pressure still drops, unscrew the back of the apparatus and use soap solution to trace the leak in the line between the THREE-WAY VALVE and the right-hand CONDOM PRESSURE GAGE or CONDOM HOLDER.
5. If a significant drop in pressure occurs on the left side, again, first check for faulty condoms by replacing the condoms and re-checking. If properly sealed, then turn the LEAK CHECK VALVE to the use position until the left CONDOM PRESSURE GAGE registers 30 kPa, then turn the LEAK CHECK VALVE to check and turn the THREE-WAY VALVE toward the right-hand side. If the leak is no longer evident, then the leak is confined to the connections between the LEAK TEST VALVE and the THREE-WAY VALVE (Figure 7). If the leak persists, trace the leak in the line between the THREE-WAY VALVE and the left-hand CONDOM PRESSURE GAGE or CONDOM HOLDER. Leaks may occur in the connection between hoses and valves or gages, between the face and body of the Magnahelic pressure gages; or, more rarely, in the hoses themselves. Tighten the connections or meter face clamps, or replace hoses as necessary. Repeat the leak test to assure an intact system before proceeding with testing.
6. If the FLOWMETER does not read correctly and no leaks are found then loosen the locking nut on the PRESSURE REGULATOR and adjust the regulator until the FLOWMETER reads correctly. Retighten the locking nut and the system is ready for use.
7. If large or frequent adjustments of the PRESSURE REGULATOR are required in order to achieve a proper FLOWMETER READING an obstruction of the orifice is indicated. The orifice should be disassembled and cleaned with acetone and a 1.3 mm wire.
8. Clean the filter on the air supply pump and drain the pump air tank (refer to Pump Handbook). Clean and drain the in-line filter situated in the air hose between the pump and the Air Inflation apparatus.

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Any persistent or difficult problems should be reported to the nearest PIACT office (see Appendix 7).

APPENDIX 1
GENERATION OF RANDOM NUMBERS

Random Number Table

Procedure for selecting random numbers is as follows:

1. Select, by any method, one of the four pages of tabled values (Table A-1).
2. Without direction, bring a pencil point down on the printed page so as to point to a digit.
3. Read this digit and the next three to the right. For example, 7742.
4. Let the first two digits specify the table row, and the last two the table column.
5. This is your starting point in the table of random sampling numbers. If you are interested in selecting four cases out of a lot of 20, read this number and the next digit to the right. If this number is 20 or less, this would be the number of the first case you would select. Using row 77 and column 42 (in the example given above), the first case selected would be number 10.
6. Since you wish a sample of size four, you must also read the three two-digit numbers immediately below 10 that are 20 or less, and that are not equal to a previously selected number; namely 06, 02 and 08. It may be necessary to continue to the next two columns if you have not reached the required sample size when you reach the last row in the table.

	00–04	05–09	10–14	15–19	20–24	25–29	30–34	35–39	40–44	45–49
50	93873	86558	72524	02542	73184	37905	05882	15596	73646	50798
51	08761	47557	02216	48086	56190	89959	69975	01589	23779	76697
52	61270	98773	40298	26077	80196	08166	35723	61933	13985	19102
53	73758	15578	95748	02967	35122	36539	72822	68241	34803	42457
54	17132	32196	60523	00514	73700	70122	27962	85597	36011	79971
55	26175	29791	44848	84314	82748	22246	70691	57953	39780	17791
56	06401	01516	06250	03536	81451	30767	37928	26986	07396	64611
57	31687	73753	36327	73704	61561	59434	90938	01967	97420	19913
58	27865	08255	57859	04746	79700	68823	16002	58115	07589	12675
59	89424	51114	96320	26786	77101	05795	49036	34686	98767	32281
60	99190	80312	60745	87616	10058	84834	89145	08775	19011	61375
61	02852	51339	25496	20587	85921	06761	68873	35567	42627	54973
62	10850	45788	94737	74519	74296	13054	46816	32141	02533	25618
63	38301	18507	33151	69314	80103	02603	61110	89395	67621	67025
64	48181	95478	62739	90148	00156	09338	41558	53271	87519	45974
65	24098	23720	76508	69084	56581	90124	21634	35999	09234	95116
66	25104	82019	21120	06165	43324	77577	15774	44091	69687	67576
67	22295	40198	86884	23403	57306	51915	03126	66700	45993	36668
68	61975	05064	29617	40622	70330	18518	45112	57921	23188	82361
69	58710	75278	47730	26093	16436	38868	76861	85914	14162	21984
70	12140	72905	26022	07675	16162	31504	47740	39923	04081	03162
71	73226	39830	47958	97219	14146	34543	76162	74158	59739	67447
72	12320	86217	66162	70911	58910	58006	80731	66680	02183	94678
73	41364	64156	23000	23188	64915	33815	32881	76955	56574	61666
74	97881	80867	70117	72011	03554	29037	19767	71838	80585	64402
75	88295	87271	82812	97588	09960	06312	03050	77332	25977	18385
76	95321	89836	78230	40017	72183	87533	74571	88859	26908	55626
77	23337	14264	30185	36753	22113	81737	62926	76191	93536	75502
78	00718	66303	75009	91431	64245	61863	16738	23127	89135	45109
79	38093	10328	96998	91386	34967	40407	48380	09115	59367	49596
80	87651	31701	29974	56777	66751	35181	64887	95091	20056	84990
81	87142	91818	51857	85061	17890	39057	41506	00969	32912	54734
82	04614	27142	26199	50147	01685	70252	91453	75952	66753	50664
83	73356	64131	05068	56334	34387	78253	67681	09916	63885	88491
84	29889	11378	65915	66776	95014	81447	98015	16815	68432	63020
85	48257	36438	48479	72173	31418	14035	81219	02012	40109	11715
86	38125	29162	79880	45713	90019	01136	72426	25077	61361	94284
87	38226	31868	38650	12135	28346	17552	03293	42618	44151	78438
88	80189	30031	15435	76738	58565	29817	36775	68007	47912	16754
89	33298	31475	95219	29832	71569	50667	90569	66717	46958	01820
90	19750	48564	49090	43352	53884	80125	47795	99701	06800	22794
91	62820	23174	71124	36040	31873	95650	79059	23891	58534	78296
92	95737	34362	81520	79381	26142	37826	76806	01580	83713	94272
93	61612	62961	37566	41064	69372	83763	92823	91391	61056	44895
94	77636	60163	14915	50741	95611	99316	39741	01407	72910	87936
95	43633	52102	93561	31010	11299	52661	79014	17910	88492	60753
96	93686	41960	61280	96529	52924	87371	34855	67125	40279	10166
97	23775	33302	28647	42314	51213	29116	26243	40243	32137	25177
98	91325	61698	58868	63107	09993	96400	66855	11567	80604	72299
99	58129	44367	31924	73586	24122	92799	28963	36444	01315	10226

	50–54	55–59	60–64	65–69	70–74	75–79	80–84	85–89	90–94	95–99
50	37686	78520	31209	83677	99115	93024	09286	58927	24078	16770
51	58108	29344	11825	51955	50618	99753	02200	50503	32466	50055
52	71545	42326	66429	93607	55276	85482	24449	41764	19884	46443
53	93304	90557	79166	90097	01627	96690	77434	06402	05379	59549
54	36731	37929	13079	83036	31525	35811	59142	65257	03731	86704
55	49781	31581	80391	84608	23390	30133	08240	85136	80060	43651
56	65995	91208	58785	01370	44192	91852	01129	28739	08705	54538
57	19663	09309	07836	52223	90814	92786	96747	46014	54765	76001
58	88479	21367	63812	47615	17220	27942	11785	49931	03923	35432
59	95407	95906	95121	20811	76761	47475	58865	06201	36543	81002
60	22789	87011	61926	97996	10604	80855	48714	52754	98279	96467
61	96783	18103	36779	18760	30810	73087	91565	68682	15792	60120
62	63933	05665	12261	23954	01581	75411	04460	83939	66528	22576
63	68791	13000	20066	98963	95383	51165	63358	12373	13877	37580
64	40537	31604	60324	51235	65516	85117	15647	09617	73520	48525
65	41739	42501	91773	81579	02882	74657	73765	18932	74607	83825
66	08813	83525	30329	33141	76584	89996	07834	67266	96820	15128
67	46609	30917	29996	98838	39555	09233	58988	82131	69232	76762
68	68541	09324	92072	57937	05563	80727	67053	35433	00881	56511
69	09926	84219	30089	08843	24998	27105	18197	79071	40738	73876
70	30515	76116	49597	37900	98601	05857	51729	19006	15239	27129
71	21601	26316	01877	71581	55724	39616	64618	36811	60915	34108
72	47410	83767	56451	96768	27001	83712	01215	27256	57991	75758
73	18572	31234	41015	61110	61807	72472	78059	60701	78681	17356
74	28078	02819	02459	33308	96546	15817	78694	81476	87856	99737
75	50641	50130	31562	25842	67724	02918	55603	55195	88219	39676
76	27331	48055	18928	47763	61966	64507	06559	81329	29181	03660
77	32050	21521	32929	07739	00816	39497	94176	27133	96857	52987
78	27027	69762	65362	90211	89572	52054	43067	73077	87664	01293
79	56471	68839	09969	45853	72627	71793	49920	61544	71874	74051
80	22689	19799	18870	49272	74783	38777	76176	40961	18089	32499
81	71261	82217	66681	90239	67686	48963	30812	59153	31551	87966
82	61084	57386	89278	27187	52142	96305	87193	80161	95518	82742
83	23121	10194	09911	37062	43346	09107	47156	70179	00858	92326
84	78906	48090	76745	65814	51167	87755	66881	12718	14951	47937
85	87257	20005	21541	37223	53288	72056	96396	67099	49116	91891
86	39529	98126	33691	29025	91308	24126	63072	51411	01718	49891
87	89632	11406	87159	89108	06295	51055	15530	46432	49871	37982
88	23708	95919	14307	53722	58779	92849	04176	24870	56698	25805
89	51415	46758	42024	27910	61237	10086	95601	53924	85209	79385
90	23849	65272	24741	39860	27314	99925	29744	87270	05773	21797
91	78614	15411	31568	57198	25872	61792	91599	60931	98908	38918
92	90691	27996	91181	87428	41135	29461	72716	68956	67871	72459
93	96772	86829	36303	40087	67456	21071	39019	91937	45280	00066
94	24527	40701	56891	73327	00789	97573	09304	11701	95772	95372
95	31596	70876	46807	06741	29352	23829	52165	00316	24155	61871
96	31613	99249	17240	05212	19535	52702	64761	66691	06150	13820
97	02911	09514	50864	80622	20017	59019	43150	75913	08567	40517
98	02481	71068	01671	19646	41951	05111	31011	574	87481	48994
99	69259	75545	73007	15216	01572	44870	53280	25132	70276	87331

TABLE A-1. (Continued)

	00 04	05 09	10 14	15 19	20 24	25 29	30 34	35 39	40 44	45 49
00	39591	64082	48626	95780	55228	87189	75717	97012	19096	48614
01	46301	97377	43462	21739	14566	72533	60171	29021	77581	72760
02	99547	69779	22731	23678	44195	89767	18249	41702	35850	40543
03	06713	61537	21551	77225	91743	79148	12753	95986	78098	48019
04	69568	65196	49033	88577	98606	92156	08846	54912	12691	13170
05	68198	69571	34349	74111	42640	44721	30162	35075	33475	47407
06	25974	13009	77428	61111	39008	60189	66780	55199	80812	57706
07	56552	20688	02769	63037	15491	71781	70559	58158	54437	46216
08	74687	02033	98290	62635	88877	28599	63652	35566	03271	05651
09	49403	76629	71897	30990	62923	36686	96167	11492	90333	84501
10	89734	39184	52026	14997	15140	18250	62831	51236	61236	09179
11	71012	50717	02617	11316	01884	82066	55913	72122	13971	61209
12	81706	31375	67053	73367	95319	31074	36898	42782	89290	48002
13	83661	21365	28882	48996	45145	60577	85270	02777	06878	27561
14	47813	74851	73388	11385	99108	97878	32858	17473	07682	20166
15	00171	56525	38880	54702	09517	47281	15995	98450	25233	79718
16	81182	48133	27431	55806	25389	40774	72978	16835	65066	28732
17	75212	35901	73077	21547	81351	48902	03178	42867	01552	66034
18	96239	80216	07000	09555	55051	49596	44629	88225	28195	44598
19	82988	17310	85311	03360	38176	51462	86070	03924	81113	92363
20	77599	29133	89088	57593	60016	17297	30923	36224	46327	96266
21	61433	33118	53488	82981	43709	63655	61386	00198	14115	57514
22	76008	15045	45140	81062	52363	18079	33726	43301	86216	99727
23	26191	76598	85834	10811	56300	02244	72118	96510	98388	80161
24	40570	88558	77533	33359	07830	84752	53260	46755	36881	98535
25	73995	41532	87931	79930	14310	64833	49020	70067	99726	97007
26	93901	38276	75514	19679	82899	11365	22896	42118	77165	08734
27	41925	28215	40966	93501	45416	27913	21708	01788	81404	15119
28	80720	02782	24326	41328	10157	86883	80086	77138	57072	12100
29	92596	39116	50362	04424	04561	58179	54188	44978	14322	97056
30	39693	58559	45839	47278	38548	38885	19875	26829	86711	57005
31	86923	37863	14330	30929	01079	65274	03040	15106	09362	82972
32	99700	79217	18172	58879	56221	65644	33331	87502	32961	40996
33	60248	21953	52321	16984	03252	90133	97301	50181	71026	01916
34	29136	71987	03992	67025	31070	78448	47823	11013	13047	47732
35	57171	42913	85212	42819	92901	97727	04775	94396	38154	25238
36	57424	93817	03269	56496	95028	11019	76128	64747	27301	65529
37	56768	71691	61361	80836	38841	71875	40911	51827	01887	53822
38	70100	81531	02148	41411	26582	27481	81262	14081	42409	62950
39	05151	88118	48616	99565	36615	85196	18891	77271	26891	00889
40	80911	56136	47061	96311	19067	59790	68752	68010	85685	88076
41	06919	46237	50676	11238	75647	41086	95123	52867	06891	32089
42	00152	23997	41751	74756	50975	75165	70158	67663	51431	46175
43	88505	71625	71783	82511	13661	63178	39291	76796	74736	10980
44	64511	80967	33515	09582	86429	58152	05931	35961	70069	12142
45	25280	53807	99651	96366	49378	80971	10119	12981	70572	11575
46	71292	63716	93210	59312	39491	21252	54819	29754	41497	79228
47	49731	50198	08974	05901	68172	02864	10991	22182	12912	17920
48	43075	09754	71880	92614	99928	94121	86455	87549	91499	11459
49	15116	10611	03981	06566	14050	33671	03814	48856	41267	76252

	50 54	55 59	60 64	65 69	70 74	75 79	80 84	85 89	90 94	95 99	
	25178	77518	41773	39926	09843	29694	41801	69276	44707	23455	00
	45801	95106	85816	33166	37383	76832	37024	06581	22587	24827	01
	15532	30898	14922	13923	44987	45122	86515	55836	96165	19650	02
	99068	35153	32152	12078	01913	06083	06645	93310	40016	85421	03
	70981	88359	95583	70818	24101	67502	25692	42496	77732	19278	04
	71181	48289	03153	18779	65702	03612	64608	81071	47588	09982	05
	44052	59163	74033	86112	27731	46135	63092	59171	44816	12354	06
	91555	87708	70964	43346	56811	08725	75139	77674	82467	41899	07
	54307	12188	58089	71745	35569	97352	77301	37684	36823	69218	08
	63641	23919	06785	13892	89918	76211	09362	34292	17640	65907	09
	46832	30801	98898	28954	97793	20825	36775	71974	15574	09184	10
	05914	82632	39310	74857	61725	50569	81937	16820	85416	51168	11
	28199	90116	59501	49025	73005	84954	11587	97691	90115	84685	12
	08391	05660	00624	95068	33775	44985	01505	76911	45539	32181	13
	29611	13021	96568	15124	55092	41043	31073	92371	51288	33378	14
	61509	18812	79201	46151	68594	98120	68110	91062	42095	61839	15
	87888	23013	69837	65661	15130	44649	42515	83861	50721	36110	16
	91585	15218	74818	61809	92293	85100	46934	08531	70107	65707	17
	87043	91915	34898	79913	70013	27573	39256	35167	35070	47095	18
	79131	10022	82199	78976	22702	37936	10145	96846	81927	69715	19
	79344	39236	41333	11473	15019	47930	99029	97150	82275	55149	20
	15384	41585	18773	89733	40779	59661	81328	25162	58758	17761	21
	38802	90957	32910	97485	10358	88588	95310	22252	19143	69011	22
	85874	18100	28151	29541	63706	43197	65726	91117	22169	91806	23
	26200	72680	12364	40010	92208	59103	60417	45389	56122	85353	24
	13772	75282	81418	42188	66529	47981	92548	10079	68179	40915	25
	91876	07434	96946	98382	97374	34444	17992	42811	01579	48741	26
	31721	21713	83632	40405	24227	53219	05382	86768	53239	24812	27
	92570	53242	98133	81706	78018	29645	29136	66091	05793	25922	28
	02880	29407	73734	66148	64739	74645	29562	13999	17492	49891	29
	80982	14681	31038	85302	98349	57313	86171	33938	10768	60837	30
	38000	43364	91825	32413	46781	09685	69058	56614	85531	55171	31
	14218	94289	79484	61868	40031	22546	68726	14735	89844	13466	32
	74358	21910	40280	22231	09123	49375	55091	46113	54016	51771	33
	39049	14986	94000	26619	13037	34609	45186	89515	63214	66866	34
	48727	06300	91486	67316	84576	11100	37589	49629	83224	46321	35
	22719	29784	40682	96715	40745	57458	70048	48106	50270	87521	36
	33980	36769	51977	01689	79071	20279	64787	48877	44061	93733	37
	23885	66721	16542	12618	65986	43104	45583	75729	35118	58742	38
	85190	41068	78177	69131	58981	96501	41232	74809	25266	74872	39
	33451	36333	45814	78128	55914	89829	43251	41634	48188	49151	40
	98236	11489	97210	01578	30779	75214	80039	68895	95271	19654	41
	21295	53563	43009	48439	87427	88065	09892	58524	43815	31310	42
	28335	79819	69814	71669	38770	54145	48736	04212	83181	85403	43
	95149	35273	62581	85522	45813	31475	97514	72819	16387	31649	44
	88167	03878	89105	55461	73248	48620	31732	47317	06252	51652	45
	86131	62596	98785	02360	54271	26212	93735	20752	17116	18115	46
	71134	90264	30126	08586	97497	61678	81930	08907	39096	02082	47
	02664	51438	76839	52290	77999	05799	94744	16631	84924	31344	48
	90664	96876	16661	25608	67140	84619	67167	13192	81774	58619	49

TABLE A-1. Random Number Tables

A2-1

APPENDIX 2
SAMPLE DATA COLLECTION AND REPORTING FORMS

The forms included in this appendix are designed to record and report all the data in the condom field test handbook.

They can be removed and photocopied for routine use. The original copies should be replaced in the handbook.

Forms A2-2 to A2-6 are used for data recording.

Forms A2-7 to A2-11 are used for reporting.

Forms A2-12 is used for both recording and reporting.

Amended 10/15/81

CONDOM FIELD TEST DATA SHEET: MEASUREMENTS

Program for Introduction and Adaptation of Contraceptive Technology (PIACT)

Storage Site	Shipping Date	Test Site	Test Date
	Test Code		Tested By: Signature

Brand	Color	Pack Type	
Date of Manufacture	Other	Lubrication	Teat or Plain End
			Parallel or Flared Sides
			Smooth or Textured Walls

CONDOM #	WIDTH mm	LENGTH mm	PACKAGE SEAL	WEIGHT mg		WEIGHT OF LUBRICATION mg B-A	WEIGHT OF CONDOM mg	THICKNESS mm			
				BEFORE WASHING B	AFTER WASHING A			SITE			AVERAGE
								1	2	3	
TOTAL											
MEAN											
RANGE											

CONDOM FIELD TEST DATA SHEET: WATER TEST				Program for Introduction and Adaptation of Contraceptive Technology (PIACT)
Storage Site	Shipping Date	Test Site	Test Date	
	Test Code		Tested by Signature	

Brand	Color	Pack Type	
Date of Manufacture	Other	Lubrication	Comments

#	Pass	Fail	#	Pass	Fail	#	Pass	Fail	#	Pass	Fail	#	Pass	Fail

A2-4

AIR BURST CALIBRATION CHART

EQUIPMENT _____ TYPE _____

EQUIPMENT NUMBER _____

DATE INSTALLED _____ PLACE INSTALLED _____

PRESSURE GAUGE _____

FREQUENCY OF TEST _____

Date	Before calibration		After calibration		Repairs/replacement
	Pg, Psi	Flowmeter	Pg. Psi	Flowmeter	

CONDOM FIELD TEST DATA SHEET: AIR INFLATION TEST

PROGRAM FOR INTRODUCTION AND ADAPTATION OF CONTRACEPTIVE TECHNOLOGY (PIACT)

STORAGE SITE	SHIPPING DATE	TEST SITE	TEST DATE
	TEST CODE		TESTED BY SIGNATURE

BRAND	COLOR	PACK TYPE	
DATE OF MANUFACTURE	OTHER I.D.	LUBRICATION	TEAT OR PLAIN END

TEMPERATURE °C = T	BAROMETRIC PRESSURE mm Hg = P	CORRECTED VOLUMETRIC FLOW RATE liter/sec $V = \frac{44.1 \times 0.4 \sqrt{T + 273}}{P} =$	PARALLEL OR FLARED SIDES / SMOOTH OR TEXTURED WALLS

CONDOM #	COLOR	PACKAGE SEAL	PRESSURE AT BURST kPa	TIME TO BURST seconds = S	BURSTING VOLUME liters V x S	BURST VOLUME UNDER 11 LITERS ✓		
TOTAL								
MEAN								
RANGE								
STANDARD								

98

A2-6

CONDOM FIELD TEST DATA SHEET: CONDOM DETERIORATION INDEX

PROGRAM FOR INTRODUCTION AN
ADAPTATION OF CONTRACEPTIVE
TECHNOLOGY (PIACT)

TEST CODE

TEST DATE

NUMBER OF CONDOMS TESTED N	BURST VOLUME LITERS	NUMBER BURSTING AT EACH VOLUME LEVEL Z	DIVIDE Z BY N X	NATURAL LOG OF X Y	MULTIPLY X BY Y XY	
	40					
	39					
	38					
	37					
	36					
	35					
	34					
	33					
	32					
	31					
	30					
	29					
	28					
	27					
	26					
	25					
	24					
	23					
	22					
	21					
	20					
	19					
	18					
	17					
	16					
	15					SUM OF XY ABOVE THE LINE
	14					
	13					
	12					
	11					A =
	BELOW 11 LITERS					XY BELOW THE LINE
						B =

CDI = A + 5B =

89

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SUMMARY OF RESULTS AND RECOMMENDATIONS

Test Code	Brand	Storage Site	Date of Receipt	Supplies Remaining	Strength	Pinholes	Package Integrity/ Appearance	Recommendations†

† KEY: RECOMMENDATION/ACTION:

If ACCEPTABLE/then, distribute for use.
If MARGINAL/then, distribute at the discretion of project director and retest at 90 day intervals.
A recommendation of UNUSABLE means that the condoms have been retested, checked by an independent laboratory and found to contain severe defects. These condoms should be destroyed.

90

A2-8

SAMPLE IDENTIFICATION

STORAGE SITE	MANUFACTURER	DATE OF MANUFACTURE
	BRAND	DATE OF TEST

DONOR	QUANTITY REMAINING IN STORES	TEST SITE
DATE RECEIVED AT STORAGE SITE		TESTED BY SIGNATURE _____

OTHER IDENTIFICATION OR CODES	COLOR	TEAT OR PLAIN END
	PACK SHAPE	PARALLEL OR FLARED SIDES
LUBRICANT	PACK MATERIAL	SMOOTH OR TEXTURED WALLS

NUMBER TESTED	WIDTH mm	LENGTH mm	WEIGHT mg		DOUBLE WALL THICKNESS mm				PACKAGE SEAL % BROKEN
			CONDOM	LUBRI-CANT	SITE			AVERAGE	
					OPEN	MID	CLOSED		
MEAN									
RANGE									

COMMENTS

LETTERS AND REPORTS: PIACT LETTERS AND REPORTS ARE ISSUED FOR THE EXCLUSIVE USE OF CLIENTS TO WHOM THEY ARE ADDRESSED. NO QUOTATIONS FROM REPORTS OR USE OF THE PIACT NAME IS PERMITTED EXCEPT AS EXPRESSLY AUTHORIZED IN WRITING. LETTERS AND REPORTS APPLY ONLY TO THE SPECIFIC MATERIALS, PRODUCTS OR PROCESSES ACTUALLY TESTED, EXAMINED OR SURVEYED AND ARE NOT NECESSARILY INDICATIVE OF THE QUALITIES OF APPARENTLY IDENTICAL OR SIMILAR MATERIALS, PRODUCTS OR PROCESSES. THE LIABILITY OF PIACT WITH RESPECT TO THIS REPORT SHALL NOT EXCEED THE AMOUNT OF THE CONSIDERATION PAID FOR THE SERVICES IN PREPARING THIS REPORT AND SHALL NOT INCLUDE ANY CONSEQUENTIAL

A2-9

WATER TEST

Number of Condoms in LOT

Number of Condoms Tested

Number of Condoms with Pinholes

Number of condoms bursting

CONDOM #	COLOR	DISTANCE OF PINHOLE FROM CLOSED END (Excluding Teat)

According to U.S. (ASTM-1977) standards for a lot of this size, the number of condoms with pinholes required for:	Number of condoms with pinholes found in this sample
REJECTION OF LOT ACCEPTANCE OF LOT	

Amended 5/22/80

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AIR BURST TEST SUMMARY

PRESSURE AT BURST
KPa × 0.01

21
20
19
18
17
16
15
14
13
12
11
10
09
08
07
06
05

ISO Proposed Minimum Mean Burst Pressure

VOLUME AT BURST
LITERS × 0.1

40
39
38
37
36
35
34
33
32
31
30
29
28
27
26
25
24
23
22
21
20
19
18
17
16
15
14
13
12
11
10
09
08
07
06
05
04
03

PIACT Minimum Burst Volume

NUMBER OF CONDOMS TESTED (N) =	
MEDIAN BURST PRESSURE =	
MEDIAN BURST VOLUME =	
CDI (CONDOM DETERIORATION INDEX) =	

IF CDI BETWEEN 2.8 AND 3.4-ALERT: REPEAT TEST WITH N = 100
IF CDI GREATER THAN 3.4-UNACCEPTABLE: REPEAT TEST WITH N = 100

Y Standards for Air Burst Volume

The following standards used by the Swedish authorities (SIDA) and proposed for use by the International Standards Organization (ISO) are based on coefficients of variation of 50 sample condoms. Since coefficients of variation (mean/standard deviation) are only meaningful when the data are "normally" distributed, the Y tests may not be meaningful for the present data distribution because it is not "normal." However, these are listed here for reference:

Authority	Equation	Minimum Y value for Acceptance	Y value for present sample
SIDA	$\frac{\bar{x} - 18}{s}$	1.5	
SIDA (aged)	$\frac{\bar{x} - 12}{s}$	1.5	
ISO	$\frac{\bar{x} - 10}{s}$	2.6	

A3-1

APPENDIX 3
CONVERSIONS AND EQUIVALENTS

Since international standard dimensions have not yet been universally adopted, the following equivalents for PRESSURE and VOLUME may be useful:

One kiloPascal (kPa) = 0.14504 pounds per square inch (psi)
One kiloPascal (kPA) = 0.29516 inches of mercury (in Hg)
One KiloPascal (kPa) = 0.74970 millimeters of mercury (mm Hg)
One liter (ℓ) = 0.03532 cubic feet (cu ft)
One liter (ℓ) = 0.26417 gallons (gal)

To convert °F to °C, use the following equation:

$$\frac{(°F - 32)}{1.8} = °C.$$

A detailed table of pressure equivalents is given on the following page.

A4-1

APPENDIX 4
THE CONDOM DETERIORATION INDEX (CDI)

Condom Strength Standards

Present standards utilize stress and strain measurements on small samples of condoms (USA - 25 condoms; UK - 10 condoms) to focus upon the mean strength of the production lot. The Swedish standards demand Inspection by Variables and attempt also to take uniformity of strength into account by using a coefficient of variation $Y = (\bar{X}-10)/S$.

One primary object of condom strength standards is to maintain a high reserve of condom strength since this provides some protection against adverse storage conditions, rough handling, and general misuse. And since each individual condom must be strong enough for normal use, breakage rates of just a few percent are unacceptable. Therefore, it is insufficient for quality standards to focus solely upon the average condom strength. The weakest condoms at the low end of the strength scale may be too few in number to depress the mean strength to a significant degree, but will have a disproportionate impact upon breakage rates. The Swedish standards authorities have sought to limit the scatter around the mean by utilizing Inspection by Variables, thereby permitting their standard to reflect the standard deviation of the sample. However, Standard Deviation is a statistic of normal distribution and quite often condom strength is not normally distributed. Furthermore, the standard is too sensitive to high strength outliers which do not contribute to the probability of breakage during use.

These limitations of existing standards for new condoms are further compounded when condoms have been stored for some time in tropical countries or under otherwise sub-optimal conditions. Under such conditions, the number of very weak condoms increases rapidly at a certain stage of deterioration. To meet the need for evaluation of stored condoms, PIACT focuses upon the weak end of the strength distribution spectrum and has devised the CONDOM DETERIORATION INDEX (CDI) as an indicator of condom strength.

Amended 10/15/81

A4-2

Condom Strength Tests

The question of how best to assess the incidence of low-strength condoms in qualified lots of condoms is complicated by the debate on interpretation of air tests versus tensile tests. The Air Tests favored by Scandinavian countries, Canada, and Australia reflect the characteristics and integrity of the entire condom while the Tensile Tests, at least theoretically, provide a simpler set of parameters unconfounded by differences in condom dimensions. The two tests measure similar characteristics of the latex and monitor ultraviolet evoked changes in condom strength in a remarkably similar fashion.

As long as the test objective is to characterize mean condom strength, Tensile Test parameters, (particularly ultimate elongation or elongation at break) are the logical choice for general application as standards. Tensile Tests are traditional in the testing of rubber by industry and a great deal of intuitive judgement has been developed around them by professionals in the condom industry. Small dumbell-shaped strips or one-inch wide ring specimens cut from the center of the condoms are stretched in one dimension. The result of the strain measurement is expressed as a simple percentage of the original specimen length. The Stress Measurement takes thickness into account, being expressed as force per unit cross-sectional area. All of these factors - 1) confinement of the test to a small part of the condom, 2) stretch in one direction, 3) relationship of final stretch to original specimen length and, 4) normalizing of stress data for thickness and width, should serve to control in the Tensile Test some of the variables which may confound results of the burst test.

The impact of some of these confounding variables on the Air Burst Test, (e.g., thickness, three dimensional stretch and shape) appears to be quite small in practice, especially within a single production lot of condoms. Differences in width and length do not appear to increase the variance substantially within condom lots since the standard deviations for air burst and tensile parameters are quite similar when viewed in proportion to the normal range of values. However, different lots of condoms of disparate size will result in variation in the air burst strain

results. Although length can be effectively controlled by blowing up only a standard length of the condom, width variation remains as an uncontrollable variable accounting for more than 30% in starting volume between the narrowest and widest allowable condom.

Discussion in the preceding paragraph was based upon the question of the Burst Test for universal use in characterizing and comparing the mean strength of condom material. Tensile Tests may hold the advantage over Air Burst in this regard. However, the importance of low outliers (maverick condoms at the low end of the strength range) in determining the quality of a condom batch, calls for a test that can effectively measure the full range of functional strength. A condom weak in any of its parts is a weak condom regardless of how strong the other parts may be. It follows that strength tests aimed at determining weak outliers must test the entire condom, not just a small part of it. The sub-population of weak condoms that accumulate while aging in the laboratory or in storage is probably made up of condoms that were orginally the weakest in the lot. Significant number of weak, newly manufactured condoms could have a substantial impact on the immediate effectiveness of condoms distributed as well as upon their useful shelf life. Field tests of condoms must focus upon the low outliers because they offer the most sensitive method of monitoring changes in condom strength over time. Based on these considerations and the objective of detecting changes in condom quality before they result in increased breakage during use, Air Burst Tests are utilized in the PIACT field protocol for condom quality assessment.

A5-1

APPENDIX 5
BURSTING VOLUME CALCULATION AND FLOW CALIBRATION THEORY

Correction of Volumetric Flow Rates

The Bursting Volume is calculated by multiplying the Volumetric Flow Rate through the orifice by the Time to Burst. The orifice is actually a mass-flow-limiting device, and the downstream volumetric flow rate is therefore a function of ambient pressure and temperature. To further complicate matters, the mass flow from the orifice is a function of upstream temperature as well as the pressure across the orifice. This pressure is controlled at a constant by the pressure regulator. The upstream temperature is equal to the ambient temperature plus a maximum of about 2°C added temperature from the pump. The temperature added by the pump represents less than 0.2% effect on the flow calculation, and, for practical purposes, will be ignored. However, an increase in ambient temperature of 10°C will decrease the mass flow by about 2% and, therefore, must be considered in the calculation.

As mentioned above, the volumetric flow rate is also affected by both downstream temperature and pressure. At altitudes higher than sea level, due to rarification of the air, the volumetric flow rate will be increased. For example, at 2500 m (8202 ft) the volumetric flow rate will be 36% greater than at sea level. An increase in temperature will also rarefy the gas, increasing the volumetric flow rate. For example, at 35°C the flow will be 4% greater than at 24°C. To derive the true volumetric flow rate, the following equation should be used:

$$V = V_o \underbrace{\sqrt{\frac{T_o}{T_A}}}_{\text{due to upstream temperature changes}} \cdot \underbrace{\frac{T_A}{T_o} \cdot \frac{P_o}{P_A}}_{\text{due to downstream temperature and pressure changes}} = V_o \sqrt{\frac{T_A}{T_o}} \cdot \frac{P_o}{P_A}$$

A5-2

where V = true volumetric flow rate (ℓ/sec),

V_o = standard flow rate (0.4 ℓ/sec at 760 mm Hg and 24°C),

P_o = standard pressure (760 mm Hg, 101 kPa),

T_o = standard temperature (297°K),

T_A = ambient temperature (°K), and

P_A = ambient pressure (mm Hg, kPa).

This equation reduces to:

$$V = \frac{44.1 \times 0.4 \sqrt{T + 273}}{P_A}$$

where T = ambient temperature (°C)

as given in the data collection form for the Air Inflation Test (Appendix 2, Form A2-5).

APPENDIX 6

ADDRESSES OF PIACT OFFICES

* PIACT
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Telex: International: 4740019
Domestic: 152348

PIACT/ASIA
P.O. Box 2030
Jakarta
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Telephone: 77-46-92

PIACT de Mexico, A.C.
Shakespeare No. 27
Mexico 5, D.F., Mexico
Telephone: (905) 533-5228

** PIACT/ASIA QA Laboratory
MCC P.O. Box 189
Makati 3117
Manila, The Philippines
Telephone: 87-70-60
Cable: PIACTASIA
Telex: 722-23102 (PIAA PH)

* PIACT QA Coordinator for all regions except Asia
** PIACT/ASIA QA Coordinator

Amended 10/15/81

A7-1

APPENDIX 7

CALIBRATION CONTROL AND VALIDATION SCHEME

Equipment used to perform Quality Control tests on contraceptive products is provided by PIACT to affiliate organizations on a long-term loan basis. The equipment is loaned subject to certain conditions relating to maintenance of proper function. These conditions include:

1. Record keeping for data and calibration checks according to the appropriate PIACT manual.

2. Full participation in PIACT QA Calibration Control and Validation Schemes.

3. Data sharing with the central PIACT data pool for the purpose of research and development.

4. Conforming to the guidelines for reporting and recommended action, particularly in the case of goods which are suspect or unsatisfactory on the basis of tests made with the PIACT equipment.

A more detailed explanation of these activities is as follows:

1. Record Keeping for Data and Calibration Checks

   Calibration checks should be performed routinely according to the appropriate PIACT manual. Calibration and data record forms provided with the manual should be used routinely and kept on file in the test laboratory.

Amended 10/15/81

A7-2

2. Calibration Control and Validation

Calibration control will be carried out by the regional PIACT QA Coordinator and will take the form of periodic visits by the QA Coordinator or a designated representative. During the visit, the calibration of all equipment will be checked. Records will be examined and test lots will be run. In addition, standardized samples of products will be sent to the affiliate laboratory periodically. These should be tested and results of these tests returned to the regional PIACT QA Coordinator as soon as possible (see Appendix 6 for address of nearest QA Coordinator).

Copies of all test and calibration records and reports should be sent to the regional PIACT QA Coordinator on a regular monthly basis or as they may become available.

When lots or shipments of products fail to pass the tests, they should be resampled and retested. Samples of these suspect products should also be sent to the regional PIACT QA Coordinator for independent testing. Sizes of samples and instructions for mailing and reporting are given in the appropriate manual (see Condom Handbook page 12).

3. Data Sharing

The copies of test records sent monthly to the regional coordinator will be stored in a central data file and periodically analyzed according to region, condom brand, environmental conditions, packaging and other factors. These results will be shared with the affiliate laboratories and other agencies concerned with assessing and improving condom quality as well as storage and handling practices.

Amended 10/15/81

4. Guidelines for Reporting and Recommended Action

Because of the imperfections of sampling under difficult environmental conditions and in view of the economic and programmatic implications of destroying large quantities of stored products, great care should be taken in following the procedures for Resampling, Retesting and Independent Checking of suspect products before designating lots as UNUSABLE. In some cases, PIACT may request that samples be sent for additional checks to other laboratories or manufacturers prior to issuing a final report.

The importance of regular MONITORING must be emphasized, particularly for condoms. Plotting deterioration trends over time will permit action to be taken before the product becomes UNUSABLE, thereby avoiding the high cost of replacing deteriorated condoms as well as protecting users from risks associated with the use of weak condoms.

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Amended 10/15/81

Appendix D

A PRELIMINARY REPORT ON CONDOM TESTING IN BANGLADESH

A PRELIMINARY REPORT ON CONDOM TESTING IN BANGLADESH

M. ABDAL HUSAIN

SUBMITTED TO POPULATION CONTROL AND FAMILY PLANNING DIVISION, MINISTRY OF HEALTH AND POPULATION CONTROL, GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

PROGRAM FOR THE INTRODUCTION AND ADAPTATION OF CONTRACEPTIVE TECHNOLOGY
(PIACT/BANGLADESH)

JULY 1981

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Introduction

National family planning programs, as well as major donors, have expressed the need for assistance in assessing the quality of various contraceptive products and in developing an indigenous capacity to carry out independent, in-country testing. This capability is desired not only to assess the quality of recently received contraceptives, but also to assist in monitoring the quality of these items as they move through the family planning programs to the ultimate users.

Latex condoms from most established manufacturers are generally strong, uniform and free from holes. However, little is known about the effects of suboptimal storage conditions, especially in tropical and subtropical climates.

Various claims of premature condom deterioration have been made in recent years. In the light of these, it is clear that there are no reliable data relating to condom quality available to program managers and distributors, to enable them to make meanginful accept/reject-decisions.

Managers in the field deal with a variety of condoms from different sources and at different stages of deterioration. These include:

(1) New condoms from large, established manufacturers.

(2) New condoms from small plants or from manufacturers in the starting-up phase of production, sometimes with no electronic testing equipment or inadequate routine quality control procedures.

(3) New condoms from either of the above sources with, or without independent quality checks.

(4) Aging condoms stored under various conditions.

(5) Condoms of unknown vintage transferred from other programs.

There is, therefore, a need for a system of quality control that may be geared to these conditions. It must be simple, practical and rugged;

require no special skills to operate, calibrate or maintain; and have a low capital cost.

With these considerations, PIACT initiated a program to develop a comprehensive package of equipment, information, training, and calibration for field testing of condoms. Three types of data are generated by the test protocols:

(1) Tests of new condom stocks for conformity with specifications (e.g., dimensions, quantity of lubricant, incidence of pin-holes).

(2) Tests for uniformity of strength in new or stored condom stocks, permitting managers to evaluate stocks on the basis of how many very weak condoms exist in each lot.

(3) Rapid, low cost tests for monitoring changes in median strength and incidence of weak condoms in different condom stocks, permitting managers to monitor and compare changes in strength of stored condoms over time. This information will allow appropriate adjustments to be made in storage conditions, packaging specifications, and regional inventories in order to achieve maximum shelf life and to insure that only high-strength products reach the user.

PIACT International have set-up contraceptive quality assurance laboratories in different developing countries such as Indonesia, Thailand, The Philippines, and Bangladesh.

The standard testing procedures are given below:

TESTING PROCEDURE

Sampling:

For testing condoms, we consider LOTS. A LOT usually consists of 40-or 80-gross (5760-11,520 condoms) shipping cases. Each LOT, as far as practicable, consists of condoms from a single manufacturer, of the same type, style, class, and size, manufactured under essentially the same conditions, and at essentially the same time. CASES of a LOT should be

stored under the same light, temperature, and humidity conditions.

A three-stage random sampling technique is employed to select condoms from the lot. Cases are randomly selected in the first stage, boxes within the cases in the second stage and individual condoms within boxes in the third stage. Sample size depends on the size of the lot. To collect a sufficient sample to perform all the tests and measurements, one has to proceed according to lot size as indicated in the table-1 below.

Table-1

Lot size	Sample size	Cases from each lot	Boxes from each case	Condoms from each box
Less than 35,000	384	4	8	12
35,000 to 150,000	480	12	4	10
150,001 to 500,000	640	20	4	8
More than 500,000	900	25	4	9

CHECKING CONDOM DIMENSIONS, LUBRICATION, AND PACKAGING

The following procedures for measuring dimensions and lubricants are derived from published International Standard Organization's Standards (ISO4074-1980) or, where these are not yet formulated, from ANSI/ASTM D3492-77 Standard Specifications for Rubber Condoms and United States General Services Administration Specification 22-C-001597A (GSA-FSSO 1977 Interim Federal Specifications-Condoms, Rubber, Contraceptive. A method of examining the package for a tight seal has been added because many unsealed packets have been observed among stored condoms in hot and humid climates.

PROCEDURES FOR MEASURING DIMENSIONS AND LUBRICANTS

1. Length of condom

The length of the condom, excluding the teat, is measured to the nearest 1mm by using mandrel. The condom is put over the mandrel to hang freely, stretched only by its own weight. The length of the condom that can be read on the scale outside the open end of the condom is noted to the nearest mm, the smallest value.

2. Width of condom

To measure the width of the condom, the condom is unrolled and laid flat over the edge of a steel ruler, allowing it to hang freely. The width of the condom at any point up to 85mm from the open end is measured to the nearest millimetre. For tapered condoms, the width at the 85mm point is measured. For flaired condoms, the width of the parallel portion is measured.

3. Thickness of condom

The double wall thickness is measured on condoms from which lubricant has been removed with isopropanol, which are then dried to constant mass. If quantity of lubricant is measured the same condoms may be used for this thickness measurement. When a condom is textured, the thickness is measured in a nontextured area. The measurements are usually reported to the nearest 0.01mm. The wall thickness of condoms is measured at three points: 10 ± 2 mm from the open end, 30 ± 5 mm from the closed end, and at the mid-distance between those two points. The average value of all three measurements are recorded for each condom.

4. Weight of condom

The weight of a condom after the thickness measurement is measured on a balance and reported to the nearest 1 mg. This measurement may be made in conjunction with measurement of quantity of lubricant.

5. Weight of lubricant

Lubricant is measured by weighing the sealed package on an analytical balance. Each packet is then opened, taking care to retain all pieces. The packet and condom are washed in isopropanol until all lubricant is removed; they are then dried to a constant weight. All weights are recorded to the nearest milligram (mg). Weight of the lubricant is determined by substracting the weight of the washed and dried sample (packet and condom) from the initial weight of the sample prior to removal of the lubricant.

Checking Package Seals

A package can be checked for leakage by placing it in the clear plastic chamber supplied, coupling the chamber to the vacuum pump, sealing the chamber, switching on the vacuum and observing the package. Air trapped in the well-sealed packages at atmospheric pressure cause them to swelling under vacuum and collapse when the vacuum is removed.

Recommended Characteristics

Different designs are codified as follows:

Norm A : Nominal width 52 mm
Norm B : Nominal width 49 mm
Type 1 : Smooth surface
Type 2 : Textured surface
Shape a: Parallel-sided
Shape b: Shaped

Norms, types, and shapes may be present in any combination.

Dimensional requirements for condoms as defined by currently accepted criteria or by proposed international standards (ISO/TC 157 N83 E) are as follows:

2. Length: Norm A : 180 mm ± 10 mm (range)
Norm B : 160 mm ± 10 mm (range)
In both cases the length of the teat, if present, is excluded.

3. Width: Norm A : 52 mm ± 3 mm (range)
Norm B : 49 mm ± 2 mm (range)
Norm A, Shape b: Parallel-sided portion, as for Norm A; bulb portion, not more than 70 mm
Norm B, Shape b: Parallel-sided portion, as for Norm B; bulb portion, not more than 62 mm

4. Thickness: Not less than 0.06 mm for double-wall thickness, measures on smooth portion.

5. Weight: Norm A, type 1 : Each condom, not more than 1.70 g
Norm B, type 1 : Each condom, not more than 1.60 g
Norm A, type 2 : Each condom, not more than 1.90 g
Norm B, type 2 : Each condom, not more than 1.80 g
Weight should be determined on an analytical balance accurate to 0.005 g.

6. Nonlubricated and lubricated condoms

Nonlubricated condoms are powdered to prevent the latex from sticking to itself, and to facilitate mechanical manipulation of the condoms. Lubricated condoms are dressed with a water-base jelly or silicone-oil-type lubricant. When lubricated condoms are tested as specified, the recommended amount(s) of lubricant used should be as follows:

Water-base jelly	350 to 550 mg
Silicone-oil type	250 to 500 mg

WATER TEST FOR PIN-HOLES

Condoms are tested for pinholes by using water test apparatus in accordance with the table 2 (see ~~enclosure~~ page 8).

The water test apparatus is designed to test condoms for pinholes, according to specifications laid down by the following authorities:

American Society for Testing and Materials ANSI/ASTM D3492-77; Para. 7.2.2.

SIDA (Swedish) Specifications for Rubber Condoms P:4, Para. 6.1.

British Standards Institution, BS3704 Revision 1977 Appendix A.

International Standards Organization Proposed Standards ISO/TC 157 doc N5.

The apparatus is a compact, portable unit composed of two identical water metering and dispensing systems with condom holders.

Lot acceptability is based upon the acceptance (AC) and rejection (Re) number from the table 2.

AIR INFLATION TEST

A sample of 100 condoms are tested for bursting volume and bursting pressure, by using air inflation apparatus.

This air inflation apparatus is designed to test condoms for bursting volume and pressure according to specifications laid down by the following authorities:

SIDA (Swedish) Specifications for Rubber Condoms P. 4, Para. 7.

International Standards Organization Proposed Standards ISO/TC 157 N62.

It is a compact portable unit composed of two identical air-metering and dispensing systems, condom holders and pressure gauge. Air is supplied to the condoms at a constant mass flow rate through an orifice. Volume at burst can be obtained by recording the time to burst; bursting pressure can be read directly off the gauges.

TABLE 2. Multiple Sampling Plans for Water Test[a] (Adapted from ANSI/ASTM (1977) Standards)

INSTRUCTIONS

Test the number of condoms indicated for the LOT size at SAMPLE STAGE 1. If the number of defective condoms [illegible] or exceeds [illegible] for that LOT size under Re, then reject the LOT. No further testing is required in this case.

If defective condoms are less than Re, then increase the total number of condoms tested up to the number indicated in SAMPLE STAGE 2. Compare the number of defectives with the number indicated for AC (less or equal, accept the LOT) and Re (equal or more, reject the LOT).

If the number of defectives falls in between the Ac and Re numbers, then proceed to SAMPLING STAGE 3 and repeat the procedure. Repeat the procedure until an accept or reject decision can be made.

SAMPLE STAGE	LOT SIZE: 35,000 and less			35,001 to 150,000			150,001 to 500,000			500,001 and over		
	Total (Cumulative) Sample Size	Number of Defectives Ac	Re	Total (Cumulative) Sample Size	Number of Defectives Ac	Re	Total (Cumulative) Sample Size	Number of Defectives Ac	Re	Total (Cumulative) Sample Size	Number of Defectives Ac	Re
1	32	No decision	2	50	No decision	2	80	No decision	3	125	No decision	4
2	64	No decision	2	100	0	3	160	0	3	250	1	5
3	96	0	2	150	0	3	240	1	4	375	2	6
4	128	0	3	200	1	4	320	2	5	500	3	7
5	160	1	3	250	2	4	400	3	6	625	5	8
6	192	1	3	300	3	5	480	4	6	750	7	9
7	224	2	3	350	4	5	560	6	7	875	9	10

(a) These sampling plans are based on an Acceptable Quality level of 0.4%

THE CONDOM DETERIORATION INDEX

Condom Strength Standards

Present standards utilize strain and stress measurements on small samples of condoms (USA - 25 condoms; UK, Sweden - 50 condoms) to focus on the mean strength of the production lot. The Swedish standards attempt also to take uniformity of strength into account by using a coefficient of variation $Y = (X-10)/S$.

Certainly, one primary focus of strength standards is to maintain the high reserve of condom strength since this provides insurance against adverse storage conditions and degrees of rough handling and general misuse. However, since unacceptability of condoms is thought of in terms of breakage rates of a few percent - just a small fraction of the production lot - it is not enough for standards to focus solely upon the average strength. The weaklings at the low end of the strength scale may be too few in number to depress the mean strength to a significant degree, but will have a disproportionate impact upon breakage rates. The Swedish standards have sought to limit the scatter around the mean by taking into account in their standard the standard deviation of the sample. Furthermore, the standard is too sensitive to high strength outliers which do not contribute to the probability of breakage during use.

These limitations of present standards for new condoms are severely compounded when condoms have been stored for some time in tropical countries or under otherwise sub-optimal conditions because the number of very weak condoms increases rapidly at a certain stage of deterioration. To meet the need for evaluation of stored condoms, focusing upon the weak end of the strength distribution scale, PIACT has devised the Condom Deterioration Index (CDI).

PIACT Condom Deterioration Index (CDI)

The CDI is an index based primarily on the number of condoms bursting at very low volume (below 11 liters) and, secondarily, on the scatter of strength data on either side of the median.

The mathematical equation is as follows:

$$CDI = (-\sum_{1}^{Na} X_i \ \ln X_i - 5\ Y_i \ \ln Y_i)$$

X = Fraction of condoms bursting at each volume level at 11 liters or above

Y = Fraction of condoms bursting below 11 liters

Na = Range of burst volume levels above 10 liters

The CDI of more than forty condom lots stored in eight countries and produced by nine manufacturers have been examined and classified on the basis of probability of failure during use. This classification is based upon clinical trials carried out by PIACT in which condoms artificially deteriorated to several different strength levels were used by sterilized couples and the breakage rate recorded (Contraception, Vol.22, p.31, 1980).

In order to simplify decision making, zones of Acceptability, Alert (intermediate) and Unacceptability were drawn on a plot of CDI against sample size (N), either side of a line described by the empirically derived equation:

$$CDI = 0.65 \times \ln(\frac{1}{N})$$

These zones were used to define the maximum acceptable CDI value for sample sizes of 50 and 100 condoms as recorded on the data distribution chart (see enclosure-A).

PERFORMANCE OF COAL IN BANGLADESH

1. In July 1980 we tested a sample of condoms (brand Tahiti) from the Central Warehouse (TEKO), Dacca.

   Conclusion : The lot was alert.

2. In September 1980 we tested a sample (brand Raja) from Social Marketing Project (SM), Dacca.

   Conclusion : The lot was alert.

3. In January 1981 we tested a sample (brand Tahiti) from Nilphamari in in the district of Rangpur.

Conclusion : The lot was alert.

Storage condition: The store room at Nilphamari is a tin-shade house with katchha floor without ceiling. Condoms were stored haphazardly on the floor. It is to be mentioned here that cockroaches and rats were found inside the cases. In the summer season sunlight directly enters the room. In the rainy season water drops in the room.

4. In January 1981 we tested a sample (brand Tahiti) from Saidpur in the district of Rangpur.

Conclusion : The lot was rejected.

Storage condition: Condoms and other contraceptives were stored haphazardly on racks and on the floor. During the summer the store room becomes very hot and in the rainy season it becomes damp.

5. In January 1981 we tested a sample (brand Tahiti) from Mithapukur in the district of Rangpur.

Conclusion : The lot was rejected.

Storage condition: In Mithapukur there is no store room to preserve condoms. These are kept in a pucca room of a hospital building. We found the room dirty and many cockroaches living in the room.

6. In January 1981 we collected a sample (brand Tahiti Conture) from Birgonj in the district of Dinajpur.

Conclusion : The lot was rejected.

Storage condition: The store room at Birgonj was a pucca room attached with a building. The condoms were kept openly on a rack. Cockroaches and insects were found living in the room.

7. In January 1981 we collected a sample (brand Conture) from Birol in the district of Dinajpur. The condition of the condoms were so bad that no test could be performed with those condoms.

Conclusion : This lot was outright rejected.

Storage condition: The storage condition of Birol was very bad. The condoms and other contraceptives were preserved haphazardly on the floor. Cockroaches and other insects were living comfortably in the store room. In every corner of the room there were lots of spider-webs.

8. In April 1981 we tested a sample (brand Tahiti) from the Central Warehouse (TEMO), Dacca.

Conclusion : The lot was rejected.

Tabular form of the results of tests performed by the CQAL, PIACT/Bangladesh

Sl. No.	Site of collecting condoms	Brand	Manufacturer	Date of manufacture	Sample size	Test date	Value of CDI	Remarks*
1.	TEMO/Dacca	Tahiti	Akwell Inds. U.S.A.	April 1979	900	3-7-80	3.3	The lot is alert (~~see annexure-B~~)
2.	SMP/Dacca	Raja	"	Jan. 1980	900	18-9-80	2.8	The lot is alert (~~see annexure-C~~)
3.	Nilphamari, Rangpur	Tahiti	"	April 1978	480	12-1-81	3.1	The lot is alert (~~see annexure-D~~)
4.	Saidpur, Rangpur	Tahiti	"	Oct. 1977	480	14-1-81	3.9	The lot is rejected (~~see annexure-E~~)
5.	Mitapukur, Rangpur	Tahiti	"	Dec. 1977	480	23-1-81	3.6	The lot is rejected (~~see annexure-F~~)
6.	Birgonj, Dinajpur	Tahiti Conture	"	Nov. 1976	640	4-2-81	3.9	The lot is rejected (~~see annexure-G~~)
7.	Birol, Dinajpur	Conture	"	June 1977	480	10-2-81	-**	The lot is out-right rejected
8.	TEMO/Dacca	Tahiti	"	Sept. 1978	900	29-4-81	3.5	The lot is rejected (see annexure-H)

* If CDI is in the intermediate zone i.e. 2.8 to 3.4, the lot is alert. This means the lot is neither accepted nor rejected.
If the value of CDI is below 2.8, the lot is accepted.
If the value of CDI is above 3.4, the lot is rejected.

** The condition of these condoms were so bad that no test could be performed and so no CDI could be calculated.

Appendix E

BANGLADESH CONDOM STOCKS
SAMPLED IN APRIL 1982

Appendix E

BANGLADESH CONDOM STOCKS
SAMPLED OR CONTACTED, APRIL 15, 1982 - APRIL 21, 1982,
AND TESTED. MAY 1982

LOCATION/CASES Y (6,000 pieces)			MANUFACTURING DATE	SAMPLE	TEST LOT NO. RLB
Region	District	Thana			
TEMO 60			5-81 Akwell	X	(5)
60			11-81 Circle	X	
few			7-79 Akwell	X	
	Dacca (no stock)			--	
		Sabar 3	5-81 Circle	X	
		5	5-80 Akwell	X	(4)
		Dardebur 5	5-81 Circle	X	(3)
		1	8-79 Akwell	X	
		Kahakair 4	11-81 Circle	X	
Chittagong 51			7-79 Akwell	X	(1)
200			11-81 Circle	X	
200			12-81 Circle		
	Chittagong		11-81 Circle	--	
		Panchlarsh 12	7-79 Akwell	X	(2)
		Double Moor 5	8-79 Circle	X	
		2	6-77		
TEMO	Mymensingh* 3		5-80/5-81 Akwell	X	(7)
	48		8-81 Circle		(8)
		Trisal 7	2-80 Akwell	X	
		Muktagashr ½	2-80 Akwell	X	
	Tangail~20		5-81 Circle	--	
		Madhupur 7	5-81 Circle	X	(6)

* The Mymensingh storekeeper had approximately 10 cases from 1978 and earlier which he was not distributing.

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Appendix F

RESULTS OF TESTS ON CONDOMS SAMPLED
BY PIACT/BANGLADESH IN 1981
(AKWELL, MAY 1982)

Appendix F

RESULTS OF TESTS ON CONDOMS SAMPLED
BY PIACT/BANGLADESH IN 1981
(AKWELL, MAY 1982)

Lot No. PIACT-Bangladesh			N	Tensile Strength at Break: Mean < 17 MPa	No. Specim. < 15 MPa	No. Failures < 20 MPa	% Elongation at Break: Mean < 700	No. Specim. < 625	Air Burst: Number below 11 mL (0.388 cf) or less	Water Test: Number Leaks/Breaks
11	a	12-78 TAHITI	25	OK	0	0	OK	0	12	
	b		50							
	c									
12	a	3-79 TAHITI	25	OK	0	0	OK	0	4	5
	b		50							
	c		25							
13	a	3-79 TAHITI	25	OK	0	0	OK	0	4	2
	b		50							
	c									
14	a	3-79 TAHITI	25	OK	0	0	OK	0	9	8
	b		50							
	c									
15	a	4-79 TAHITI	25	OK	0	0	OK	0	10	3
	b		50							
	c									
17	a	4-79 TAHITI	25	OK	0	0	OK	0	1	7
	b		50							
	c									
18	a	4-79 TAHITI	25	OK	0	0	OK	0	14	5
	b		50							
	c		25							

Appendix G

RESULTS OF TESTS ON CONDOMS SAMPLED
BY R.L. BELSKY IN APRIL 1982
(AKWELL, MAY 1982)

RESULTS OF TESTS ON CONDOMS SAMPLED BY R.L. BELSKY IN APRIL 1982 (AKWELL, MAY 1982)

4/82

Lot No.			N	Tensile Strength at Break: 1 Mean < 20 MPa	2 Mean < 17 MPa	No. Specim. < 15 MPa	No. Lies < 20 MPa	% Elongation at Break: 3 Mean < 750	No. Specim. < 675	4 Mean < 700	No. Specim. < 625	9	Air Burst Number ml (0.38 cf) or less	Water Test 17	13 Leaks/Blows
RLB															
1a	7-79 TAHITI		25		OK	0	0			OK	0		0		
b			25		OK	0	0			OK	0		0		
c			25												
d			25												
2a	7-79 TAHITI		25			0	0			OK	0				
b			25			0	0			OK	0				
c															
d															
3a	5-81 CIRCLE		25		OK	1	OK 8			OK	0		2		
b			50												
c			25												
4a	5-80 TAHITI		25		OK	0	0			OK	0				
b			25			1	OK 4								
c			50												
5a	5-81 TAHITI		25		OK	0	0			OK	0				
b			25		OK	0	0			OK	0				
c			50												
6a	5-81 TAHITI		25		OK	1	OK 3						2		
b			50												
c			25										0		
7a	5-80 TAHITI		25		OK	0	1								
b			25		OK	0	0								
c			50												
8a	8-81 CIRCLE		25	OK	0		0	OK	0						
b	8-81		25	OK	2 [illegible]		0	OK	0						
c			50												

1 Leak later

G-1

Appendix H

HISTOGRAMS:
RESULTS OF TESTS AT AKWELL,
MAY 1982

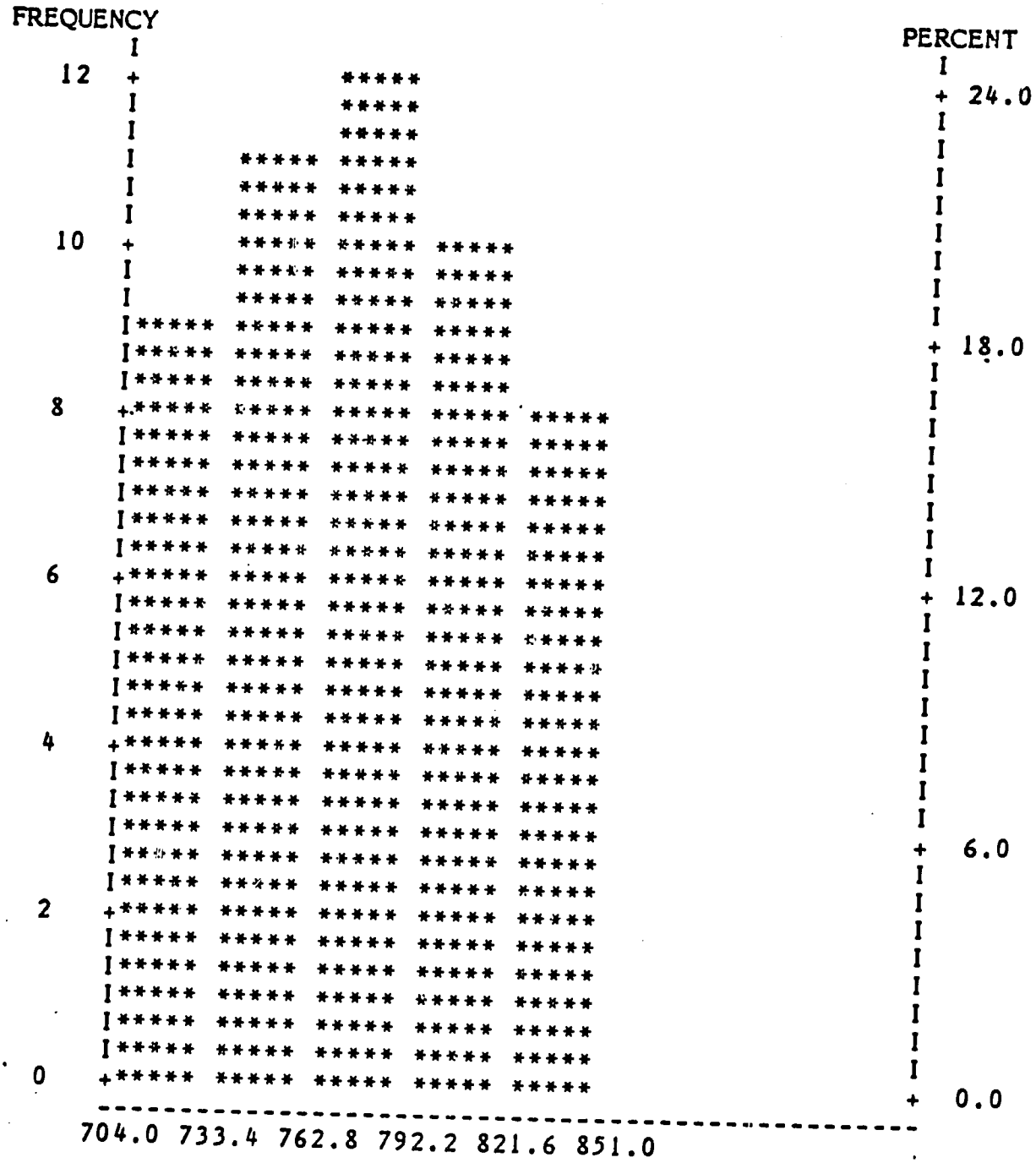
H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                           I
   19     +                *****                                      +  38.0
          I                *****                                      I
          I                *****                                      I
          I                *****                                      I
          I                *****                                      I
          I                *****                                      I
   16     +                *****                                      I
          I                *****                                      I
          I                *****                                      I
          I                *****                                      I
          I                *****                                      +  28.5
          I                *****                                      I
   13     +                *****                                      I
          I                *****                                      I
          I                *****                                      I
          I                *****  *****                               I
          I                *****  *****                               I
          I        *****   *****  *****                               I
   10     +        *****   *****  *****                               I
          I        *****   *****  *****                               +  19.0
          I        *****   *****  *****                               I
          I        *****   *****  *****                               I
          I        *****   *****  *****                               I
          I        *****   *****  *****                               I
          I        *****   *****  *****                               I
    7     +        *****   *****  *****  *****                        I
          I        *****   *****  *****  *****                        I
          I        *****   *****  *****  *****                        I
          I        *****   *****  *****  *****                        I
          I*****   *****   *****  *****  *****                        +   9.5
          I*****   *****   *****  *****  *****                        I
    4     +*****   *****   *****  *****  *****                        I
          I*****   *****   *****  *****  *****                        I
          I*****   *****   *****  *****  *****                        I
          I*****   *****   *****  *****  *****                        I
          I*****   *****   *****  *****  *****                        I
          I*****   *****   *****  *****  *****                        I
    0     +*****   *****   *****  *****  *****                        I
          ----------------------------------------------------------- +   0.0
          23.3   26.7   30.2   33.7   37.2   40.7
```

T E N S I L E # 1 B E L S K Y

129

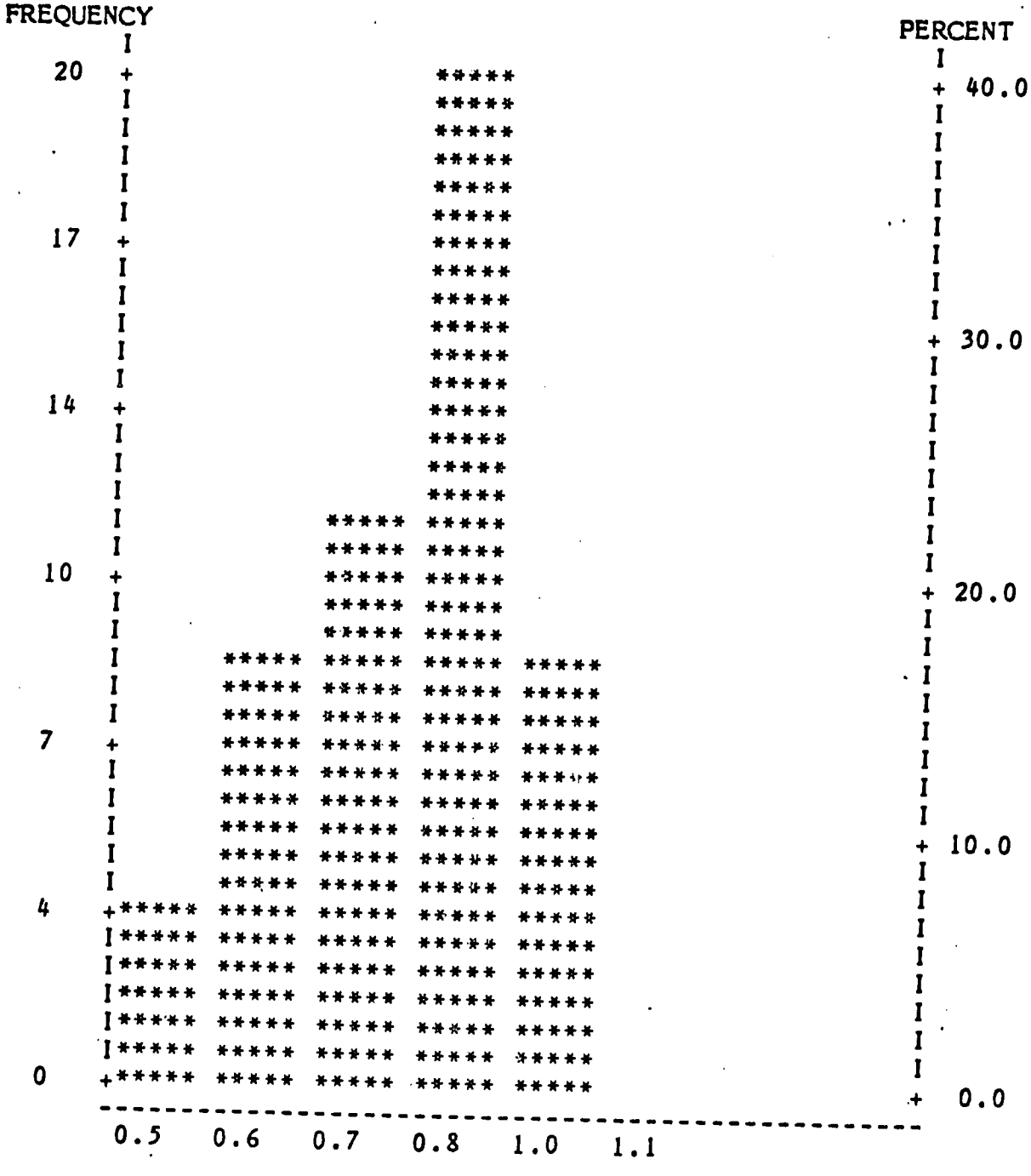
H I S T O G R A M



E L O N G . # 1 B E L S K Y

130

H I S T O G R A M



A I R I N F L A T I O N # 1 B E L S K Y

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                           I
   16     +                    *****                                  +  32.0
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
   14     +                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  +  24.0
          I                    *****                                  I
   11     +                    *****                                  I
          I       *****        *****                                  I
          I       *****        *****                                  I
          I       ***** ***** *****                                   I
          I       ***** ***** *****                                   I
          I       ***** ***** *****                                   I
   8      +       ***** ***** ***** *****                             +  16.0
          I       ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
   6      +***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              +   8.0
          I***** ***** ***** ***** *****                              I
   3      +***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
   0      +***** ***** ***** ***** *****                              +   0.0
          ----------------------------------------------------------
          25.5  27.7  29.9  32.2  34.4  36.7
```

T E N S I L E # 2 B E L S K Y

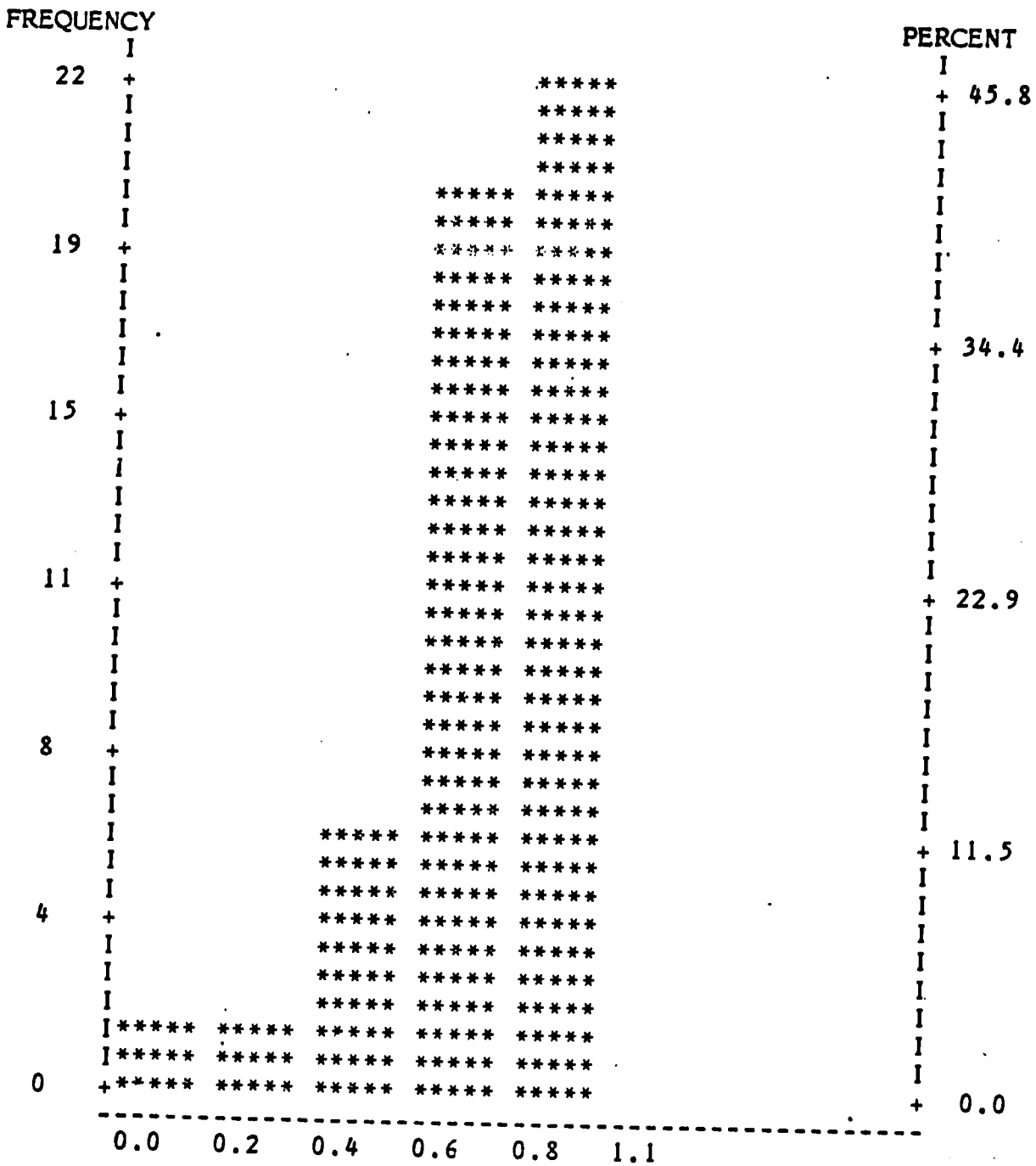
132

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                           I
   20     +                *****                                      + 40.0
          I                *****                                      I
          I                *****                                      I
          I                *****                                      I
          I                *****                                      I
          I                *****                                      I
   17     +                *****                                      I
          I                *****                                      I
          I                *****                                      I
          I                *****                                      + 30.0
          I                *****                                      I
          I                *****                                      I
   14     +                *****                                      I
          I                *****                                      I
          I                ***** *****                                I
          I                ***** *****                                I
          I                ***** *****                                I
          I                ***** *****                                I
   10     +                ***** *****                                + 20.0
          I                ***** *****                                I
          I                ***** *****                                I
          I                ***** ***** *****                          I
          I                ***** ***** *****                          I
          I                ***** ***** *****                          I
    7     +                ***** ***** *****                          I
          I                ***** ***** *****                          I
          I                ***** ***** *****                          I
          I***** ***** ***** ***** *****                              + 10.0
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
    4     +***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
    0     +***** ***** ***** ***** *****                              +  0.0
          ---------------------------------------------------------
        708.0 730.8 753.6 776.4 799.2 822.0
```

E L O N G . # 2 B E L S K Y

H I S T O G R A M



A I R I N F L A T I O N # 2 B E L S K Y

H I S T O G R A M

```
FREQUENCY                                                    PERCENT
          I                                                     I
   11     +              *****                                  I
          I              *****                                  + 44.0
          I              *****                                  I
          I              *****                                  I
          I              *****                                  I
          I              *****                                  I
   10     +              *****                                  I
          I              *****                                  I
          I              *****                                  I
          I              *****                                  I
          I              *****                                  + 33.0
          I              *****                                  I
    8     +              *****                                  I
          I              *****                                  I
          I              *****                                  I
          I              *****                                  I
          I              *****                                  I
          I              *****                                  I
    6     +              *****                                  I
          I*****         *****                                  + 22.0
          I*****         *****                                  I
          I*****         *****                                  I
          I***** ***** ***** *****                              I
          I***** ***** ***** *****                              I
    4     +***** ***** ***** *****                              I
          I***** ***** ***** *****                              I
          I***** ***** ***** *****                              I
          I***** ***** ***** *****                              I
          I***** ***** ***** *****                              + 11.0
          I***** ***** ***** *****                              I
    2     +***** ***** ***** *****                              I
          I***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                        I
          I***** ***** ***** ***** *****                        I
          I***** ***** ***** ***** *****                        I
          I***** ***** ***** ***** *****                        I
    0     +***** ***** ***** ***** *****                        I
          ----------------------------------------------------  + 0.0
          14.3  18.0  21.7  25.5  29.2  33.0
```

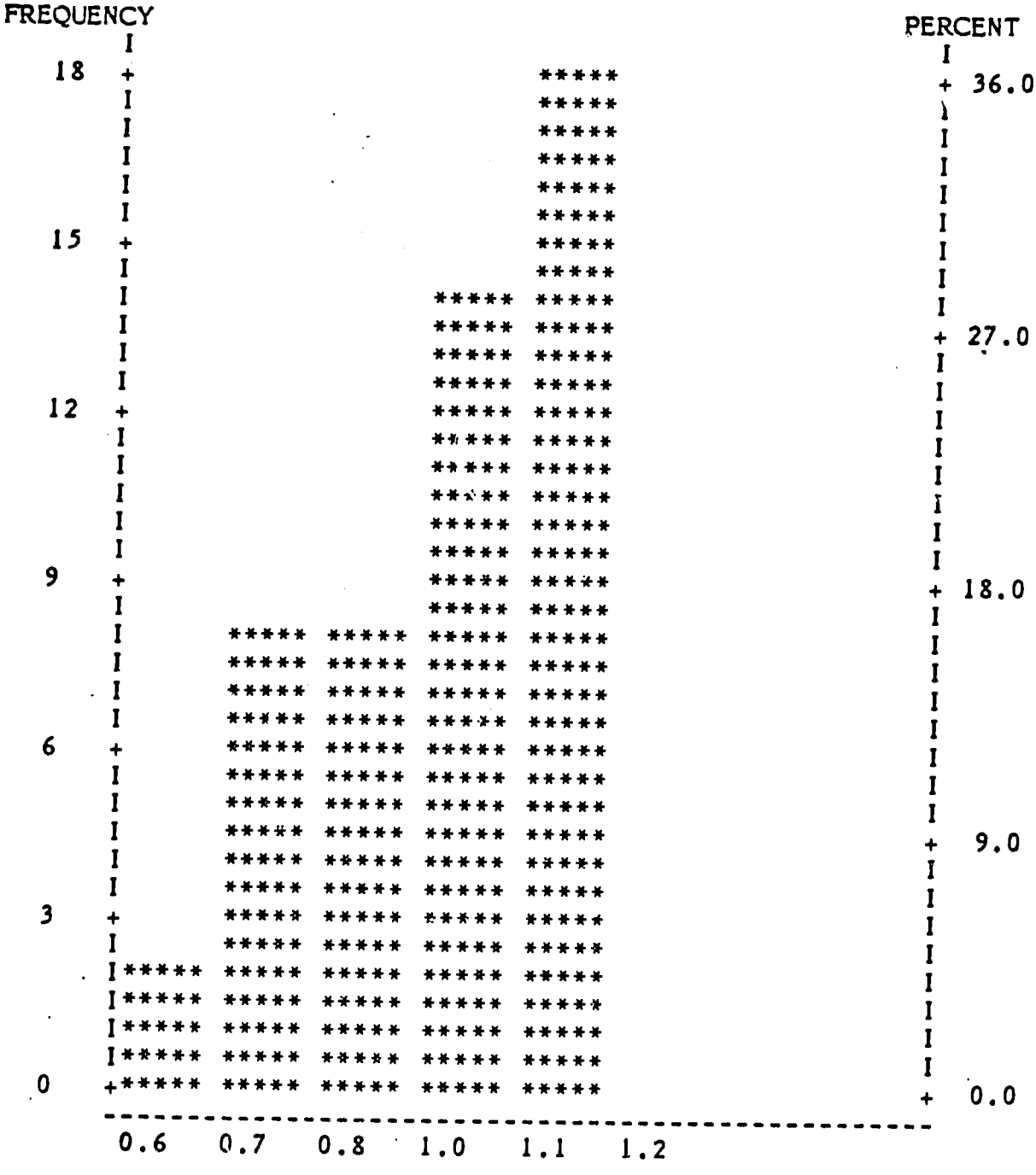
T E N S I L E # 3 B E L S K Y C I R R U B

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
         I                                                            I
   8     +*****                                                       +  32.0
         I*****                                                       I
         I*****                                                       I
         I*****                                                       I
         I*****                    *****                              I
         I*****                    *****                              I
   7     +*****                    *****                              I
         I*****                    *****                              I
         I*****                    *****                              I
         I*****                    *****                              I
         I*****                    *****                              +  24.0
         I*****                    *****                              I
   6     +*****                    *****                              I
         I*****        *****       *****                              I
         I*****        *****       *****                              I
         I*****        *****       *****                              I
         I*****        *****       *****                              I
   4     +*****        *****  *****  *****                              +  16.0
         I*****        *****  *****  *****                              I
         I*****        *****  *****  *****                              I
         I*****        *****  *****  *****                              I
         I*****        *****  *****  *****                              I
   3     +*****        *****  *****  *****                              I
         I*****        *****  *****  *****                              I
         I*****        *****  *****  *****                              I
         I*****        *****  *****  *****                              +   8.0
         I*****        *****  *****  *****                              I
   2     +*****        *****  *****  *****                              I
         I*****  *****  *****  *****  *****                              I
         I*****  *****  *****  *****  *****                              I
         I*****  *****  *****  *****  *****                              I
         I*****  *****  *****  *****  *****                              I
   0     +*****  *****  *****  *****  *****                              +   0.0
         ----------------------------------------------------------------
         769.0 787.4 805.8 824.2 842 6 861.0
```

E L O N G . # 3 B E L S K Y C I R R U B

H I S T O G R A M



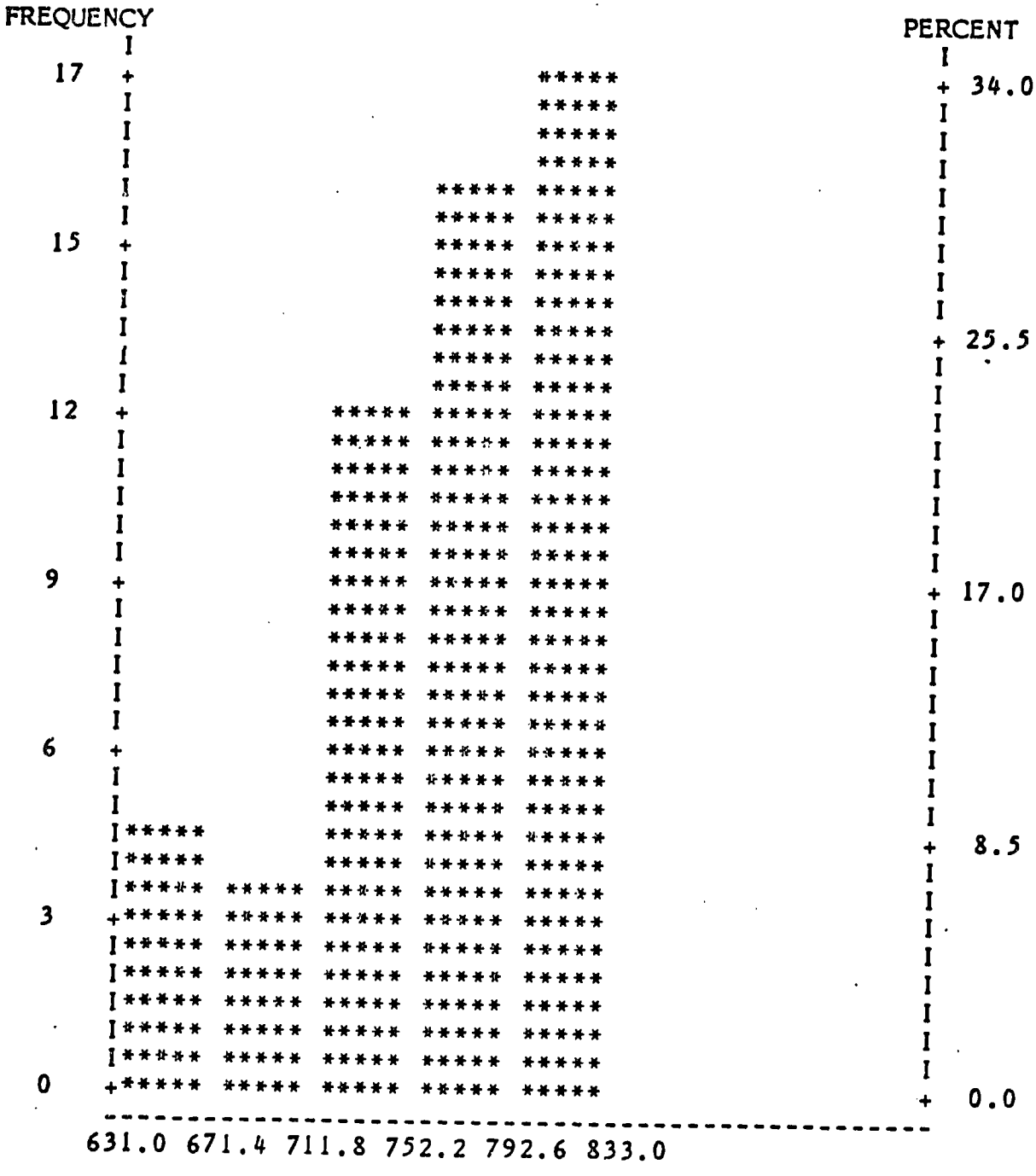
A I R I N F L . # 3 B E L S K Y C I R R U B .

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
        I                                                                I
   17   +                    *****                                       +  34.0
        I                    *****                                       I
        I                    *****                                       I
        I                    *****                                       I
        I              ***** *****                                       I
        I              ***** *****                                       I
   15   +              ***** *****                                       I
        I              ***** *****                                       I
        I              ***** *****                                       I
        I              ***** *****                                       I
        I              ***** *****                                       +  25.5
        I              ***** *****                                       I
        I              ***** *****                                       I
   12   +              ***** *****                                       I
        I              ***** *****                                       I
        I              ***** *****                                       I
        I              ***** *****                                       I
        I              ***** *****                                       I
        I              ***** *****                                       I
        I              ***** *****                                       I
    9   +              ***** *****                                       I
        I              ***** ***** *****                                 +  17.0
        I              ***** ***** *****                                 I
        I              ***** ***** *****                                 I
        I              ***** ***** *****                                 I
        I       ***** ***** ***** *****                                  I
    6   +       ***** ***** ***** *****                                  I
        I       ***** ***** ***** *****                                  I
        I       ***** ***** ***** *****                                  I
        I*****  ***** ***** ***** *****                                  I
        I*****  ***** ***** ***** *****                                  +   8.5
        I*****  ***** ***** ***** *****                                  I
    3   +*****  ***** ***** ***** *****                                  I
        I*****  ***** ***** ***** *****                                  I
        I*****  ***** ***** ***** *****                                  I
        I*****  ***** ***** ***** *****                                  I
        I*****  ***** ***** ***** *****                                  I
        I*****  ***** ***** ***** *****                                  I
        I*****  ***** ***** ***** *****                                  I
    0   +*****  ***** ***** ***** *****                                  I
        ----------------------------------------------------------------+   0.0
        13.3  19.7  26.1  32.6  39.0  45.5
```

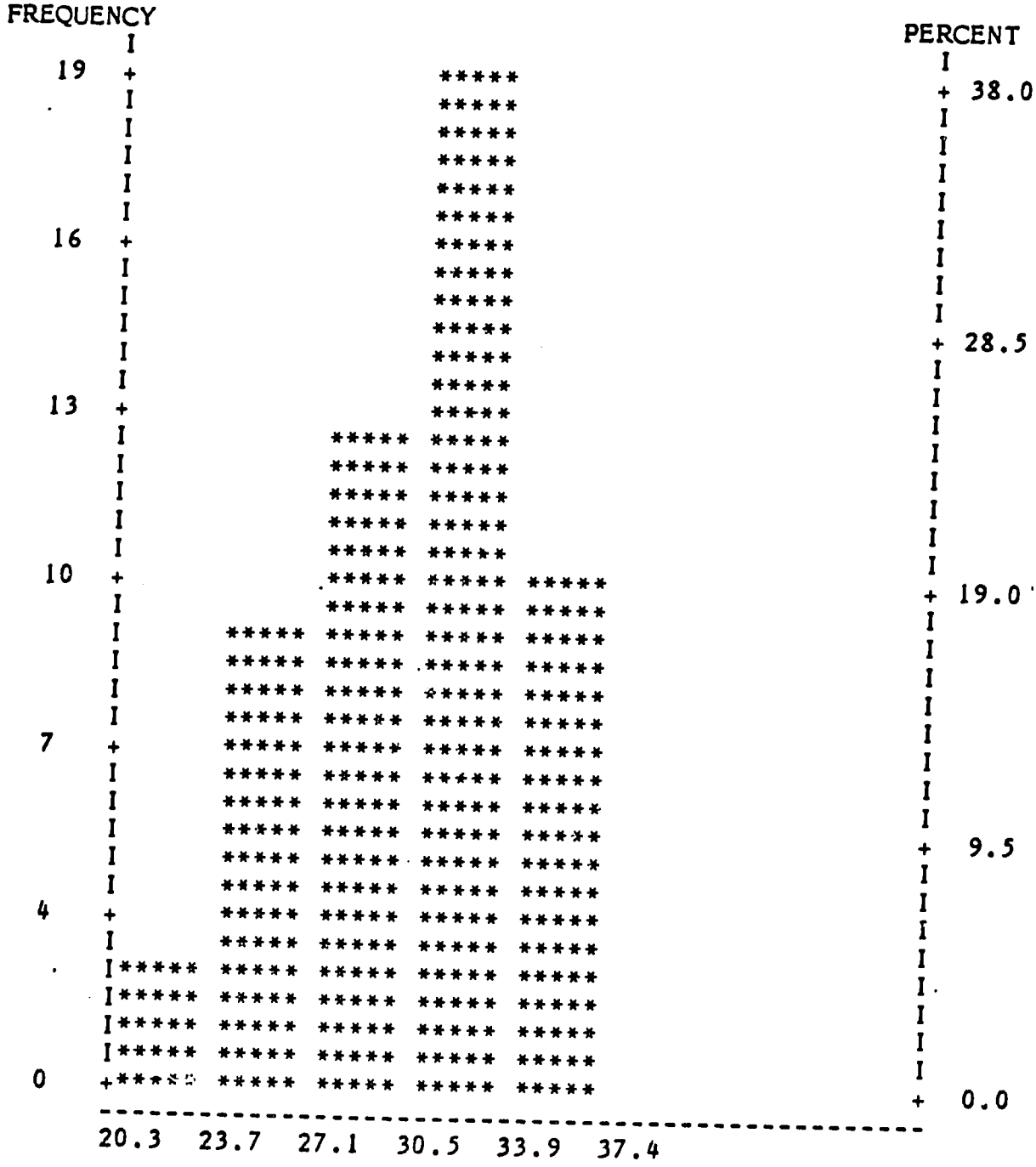
T E N S I L E # 4 B E L S K Y

H I S T O G R A M



E L O N G . # 4 B E L S K Y

H I S T O G R A M



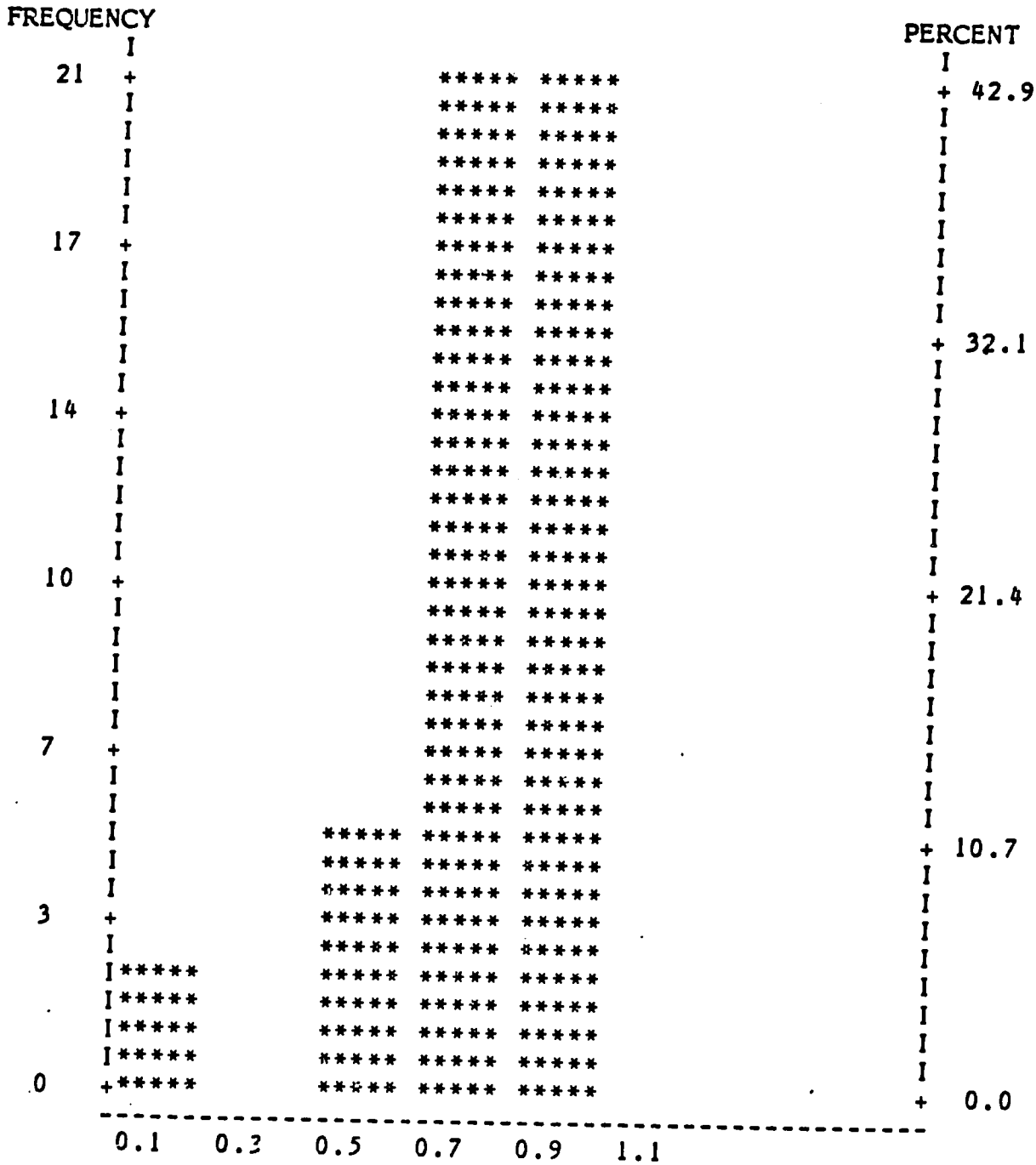
T E N S I L E # 5 B E L S K Y

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                          I
   15     +             *****                                        + 30.0
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I       ***** *****                                        I
          I       ***** *****                                        I
   12     +       ***** *****                                        I
          I       ***** *****                                        I.
          I       ***** *****                                        I
          I       ***** *****                                        I
          I       ***** *****                                        + 22.5
          I       ***** *****                                        I
   10     +       ***** *****                                        I
          I       ***** *****                                        I
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
    7     +***** ***** ***** *****                                   + 15.0
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
    5     +***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             + 7.5
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
    2     +***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
    0     +***** ***** ***** ***** *****                             + 0.0
          ----------------------------------------------------------
         712.0 737.8 763.6 789.4 815.2 841.0
```

E L O N G . # 5 B E L S K Y

H I S T O G R A M



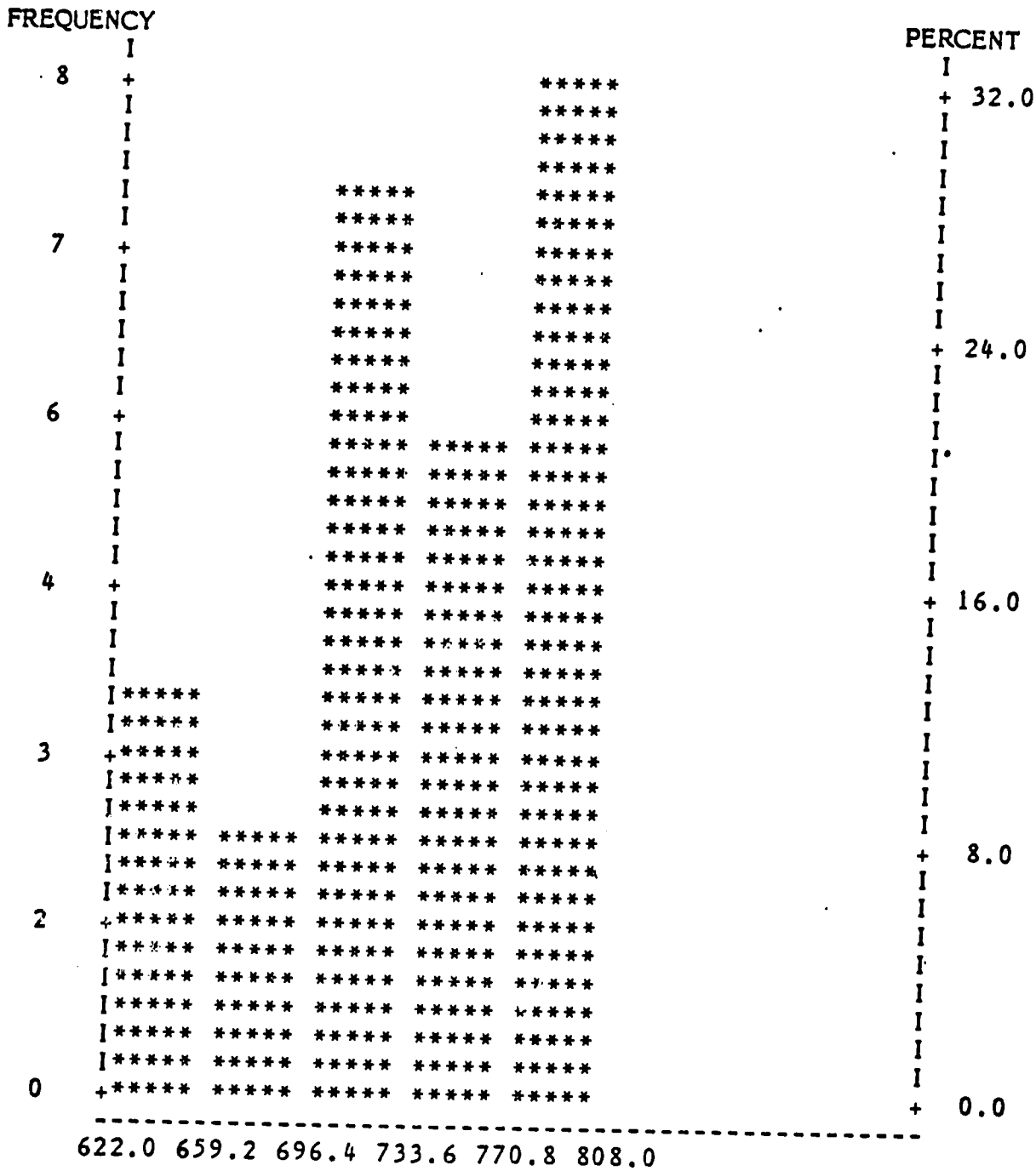
A I R I N F L A T I O N # 5 B E L S K Y

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                          I
   10     +             *****                                       + 40.0
          I             *****                                       I
          I             *****                                       I
          I             *****                                       I
          I             *****                                       I
          I             *****                                       I
   9      +             *****                                       I
          I             *****                                       I
          I             *****                                       I
          I             *****                                       I
          I             *****                                       + 30.0
          I             *****                                       I
   7      +             *****                                       I
          I             *****                                       I
          I       ***** *****                                       I
          I       ***** *****                                       I
          I       ***** *****                                       I
          I       ***** *****                                       I
   5      +       ***** ***** *****                                 + 20.0
          I       ***** ***** *****                                 I
          I       ***** ***** *****                                 I
          I       ***** ***** *****                                 I
          I       ***** ***** *****                                 I
          I       ***** ***** *****                                 I
   4      +       ***** ***** *****                                 I
          I***** ***** ***** *****                                  I
          I***** ***** ***** *****                                  I
          I***** ***** ***** *****                                  I
          I***** ***** ***** *****                                  + 10.0
          I***** ***** ***** *****                                  I
   2      +***** ***** ***** *****                                  I
          I***** ***** ***** *****                                  I
          I***** ***** ***** ***** *****                            I
          I***** ***** ***** ***** *****                            I
          I***** ***** ***** ***** *****                            I
          I***** ***** ***** ***** *****                            I
   0      +***** ***** ***** ***** *****                            +  0.0
          ----------------------------------------------------------
          14.8  21.0  27.2  33.4  39.6  45.8
```

T E N S I L E # 6 B E L S K Y

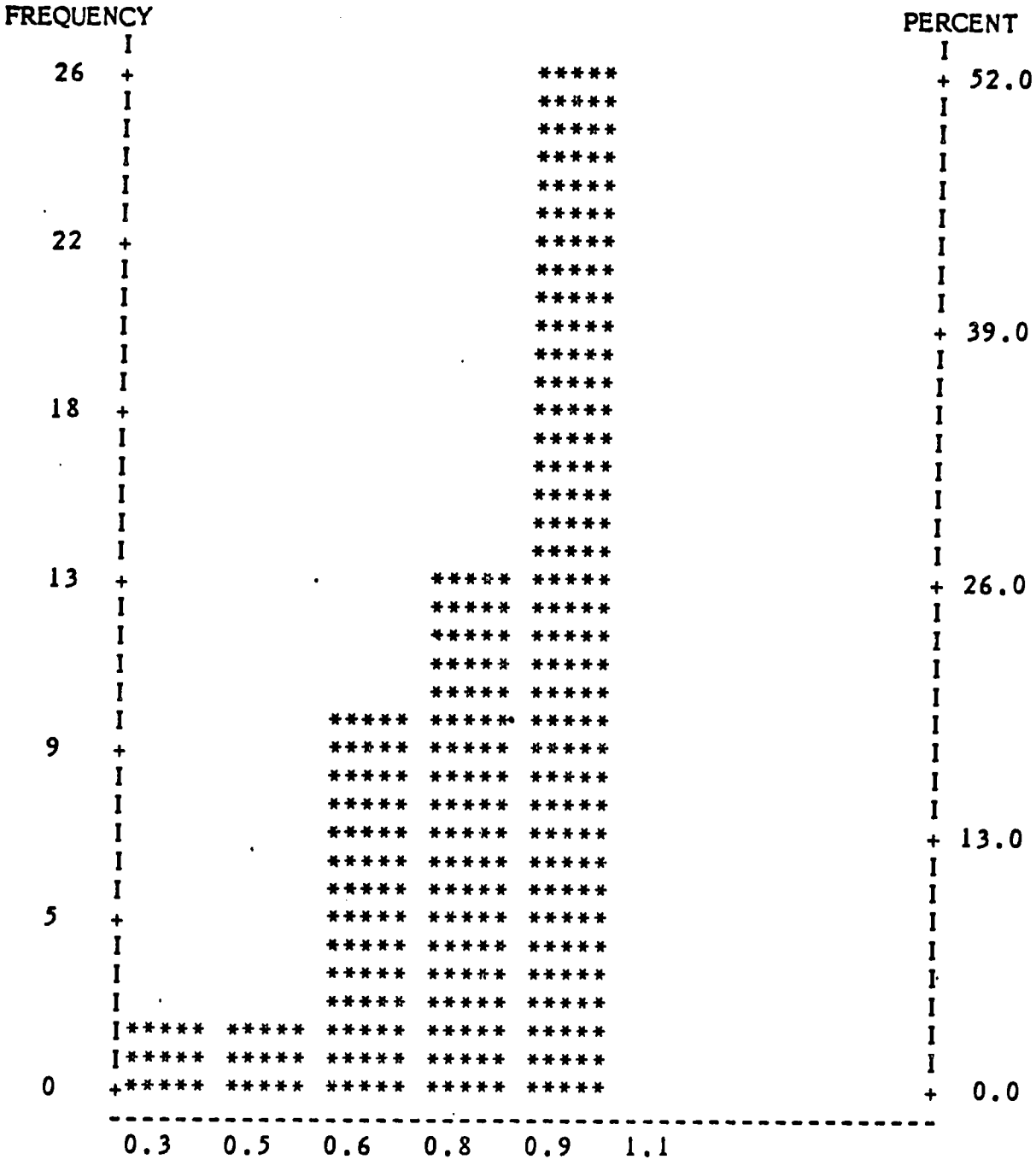
H I S T O G R A M



E L O N G . # 6 B E L S K Y

144

H I S T O G R A M



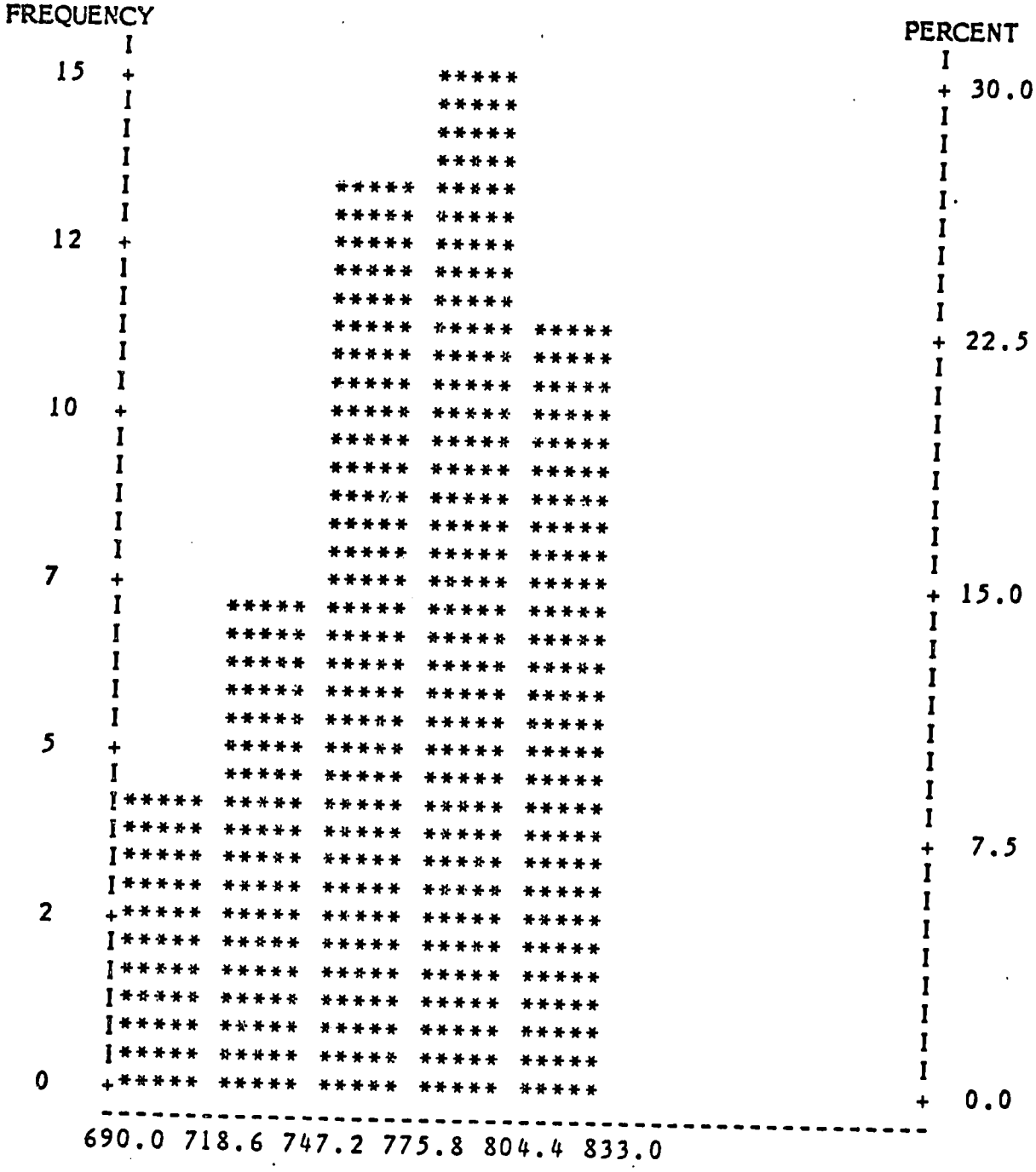
A I R I N F L A T I O N # 6 B E L S K Y

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
         I                                                            I
   28    +            *****                                           + 56.0
         I            *****                                           I
         I            *****                                           I
         I            *****                                           I
         I            *****                                           I
         I            *****                                           I
   24    +            *****                                           I
         I            *****                                           I
         I            *****                                           I
         I            *****                                           I
         I            *****                                           + 42.0
         I            *****                                           I
   19    +            *****                                           I
         I            *****                                           I
         I            *****                                           I
         I            *****                                           I
         I            *****                                           I
         I            *****                                           I
   14    +            *****                                           I
         I            *****                                           + 28.0
         I            *****                                           I
         I            *****                                           I
         I            *****                                           I
         I            *****                                           I
   10    +            *****                                           I
         I            ***** *****                                     I
         I            ***** *****                                     I
         I            ***** *****                                     I
         I      ***** ***** *****                                     + 14.0
         I      ***** ***** *****                                     I
    5   +***** ***** ***** ***** *****                                I
         I***** ***** ***** ***** *****                               I
         I***** ***** ***** ***** *****                               I
         I***** ***** ***** ***** *****                               I
         I***** ***** ***** ***** *****                               I
         I***** ***** ***** ***** *****                               I
    0   +***** ***** ***** ***** *****                               I
         ----------------------------------------------------------   + 0.0
         18.6  23.6  28.7  33.8  38.9  44.0
```

T E N S I L E # 7 B E L S K Y

H I S T O G R A M



E L O N G . # 7 B E L S K Y

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                           I
   17     +            *****                                          + 34.0
          I            *****                                          I
          I            *****                                          I
          I            *****                                          I
          I            *****                                          I
          I            *****                                          I
   15     +            *****                                          I
          I            *****                                          I
          I            *****                                          I
          I            *****                                          + 25.5
          I            *****                                          I
          I            *****                                          I
   12     +       ***** *****                                         I
          I       ***** *****                                         I
          I       ***** ***** *****                                   I
          I       ***** ***** *****                                   I
          I       ***** ***** *****                                   I
          I       ***** ***** *****                                   I
   9      +       ***** ***** *****                                   + 17.0
          I       ***** ***** *****                                   I
          I       ***** ***** *****                                   I
          I***** ***** ***** *****                                    I
          I***** ***** ***** *****                                    I
          I***** ***** ***** *****                                    I
   6      +***** ***** ***** *****                                    I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              + 8.5
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
   3      +***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
          I***** ***** ***** ***** *****                              I
   0      +***** ***** ***** ***** *****                              + 0.0
          ----------------------------------------------------------
          13.2  17.9  22.6  27.3  32.0  36.7
```

T E N S I L E # 8 B E L S K Y

148

H I S T O G R A M

```
FREQUENCY                                                    PERCENT
          I                                                     I
   19     +                  *****                              + 38.0
          I                  *****                              I
          I                  *****                              I
          I                  *****                              I
          I                  *****                              I
          I                  *****                              I
   16     +                  *****                              I
          I                  *****                              I
          I                  *****                              I
          I                  *****                              + 28.5
          I                  *****                              I
          I            ***** *****                              I
   13     +            ***** *****                              I
          I            ***** *****                              I
          I            ***** *****                              I
          I            ***** *****                              I
          I            ***** *****                              I
          I            ***** *****                              I
   10     +            ***** ***** *****                        + 19.0
          I            ***** ***** *****                        I
          I            ***** ***** *****                        I
          I            ***** ***** *****                        I
          I            ***** ***** *****                        I
          I            ***** ***** *****                        I
    7     +      ***** ***** ***** *****                        I
          I      ***** ***** ***** *****                        I
          I      ***** ***** ***** *****                        I
          I      ***** ***** ***** *****                        +  9.5
          I      ***** ***** ***** *****                        I
          I      ***** ***** ***** *****                        I
    4     +***** ***** ***** ***** *****                        I
          I***** ***** ***** ***** *****                        I
          I***** ***** ***** ***** *****                        I
          I***** ***** ***** ***** *****                        I
          I***** ***** ***** ***** *****                        I
          I***** ***** ***** ***** *****                        I
    0     +***** ***** ***** ***** *****                        +  0.0
          ----------------------------------------------------
        729.0 761.6 794.2 826.8 859.4 892.0
```

E L O N G . # 8 B E L S K Y

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                          I
    9     +                    *****                                 + 36.0
          I                    *****                                 I
          I                    *****                                 I
          I                    *****                                 I
          I                    *****                                 I
          I                    *****                                 I
    7     +                    *****                                 I
          I                    *****                                 I
          I                    ***** *****                           I
          I                    ***** *****                           + 27.0
          I                    ***** *****                           I
          I                    ***** *****                           I
    6     +                    ***** *****                           I
          I                    ***** *****                           I
          I                    ***** *****                           I
          I                    ***** *****                           I
          I                    ***** *****                           I
          I                    ***** *****                           I
    4     +                    ***** *****                           + 18.0
          I                    ***** *****                           I
          I       *****        ***** *****                           I
          I       *****        ***** *****                           I
          I       *****        ***** *****                           I
          I       *****        ***** *****                           I
    3     +***** *****         ***** *****                           I
          I***** *****         ***** *****                           I
          I***** *****         ***** *****                           I
          I***** *****         ***** *****                           + 9.0
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
    1     +***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
    0     +***** ***** ***** ***** *****                             + 0.0
          ---------------------------------------------------------
          23.7  26.4  29.1  31.8  34.5  37.3
```

T E N S I L E # 1 1 P I A C T

150

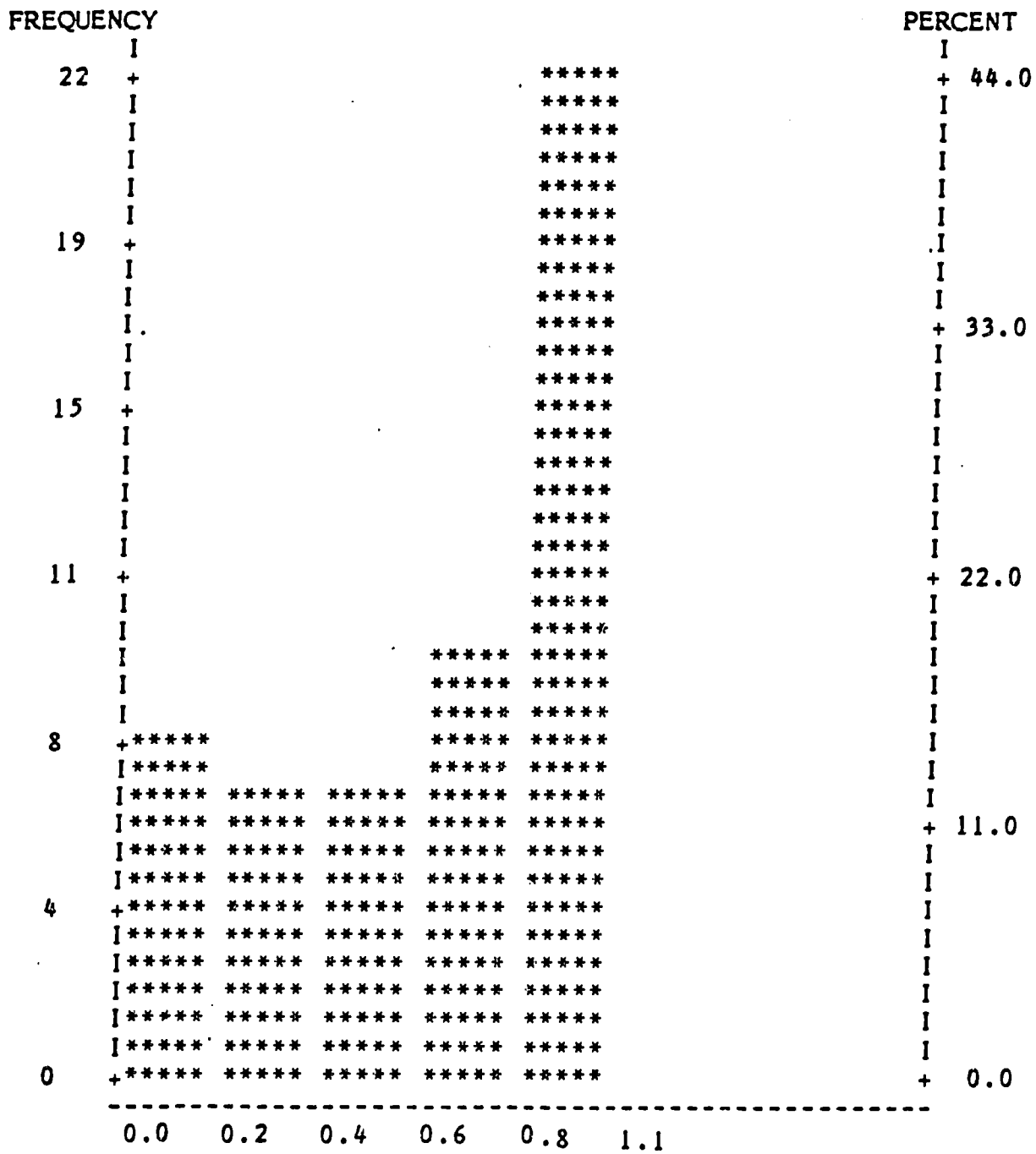
H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                           I
   11     +             *****                                        +  44.0
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
   10     +             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        +  33.0
          I             *****                                        I
    8     +             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             ***** *****                                  I
          I             ***** *****                                  I
    6     +             ***** *****                                  +  22.0
          I             ***** *****                                  I
          I             ***** *****                                  I
          I             ***** *****                                  I
          I       ***** ***** *****                                  I
          I       ***** ***** *****                                  I
    4     +       ***** ***** *****                                  I
          I       ***** ***** *****                                  I
          I       ***** ***** *****                                  I
          I       ***** ***** *****                                  +  11.0
          I       ***** ***** *****                                  I
          I***** ***** ***** ***** *****                             I
    2     +***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
    0     +***** ***** ***** ***** *****                             +   0.0
          ---------------------------------------------------------
        710.0 747.6 785.2 822.8 860.4 898.0
```

E L O N G . # 1 1 P I A C T

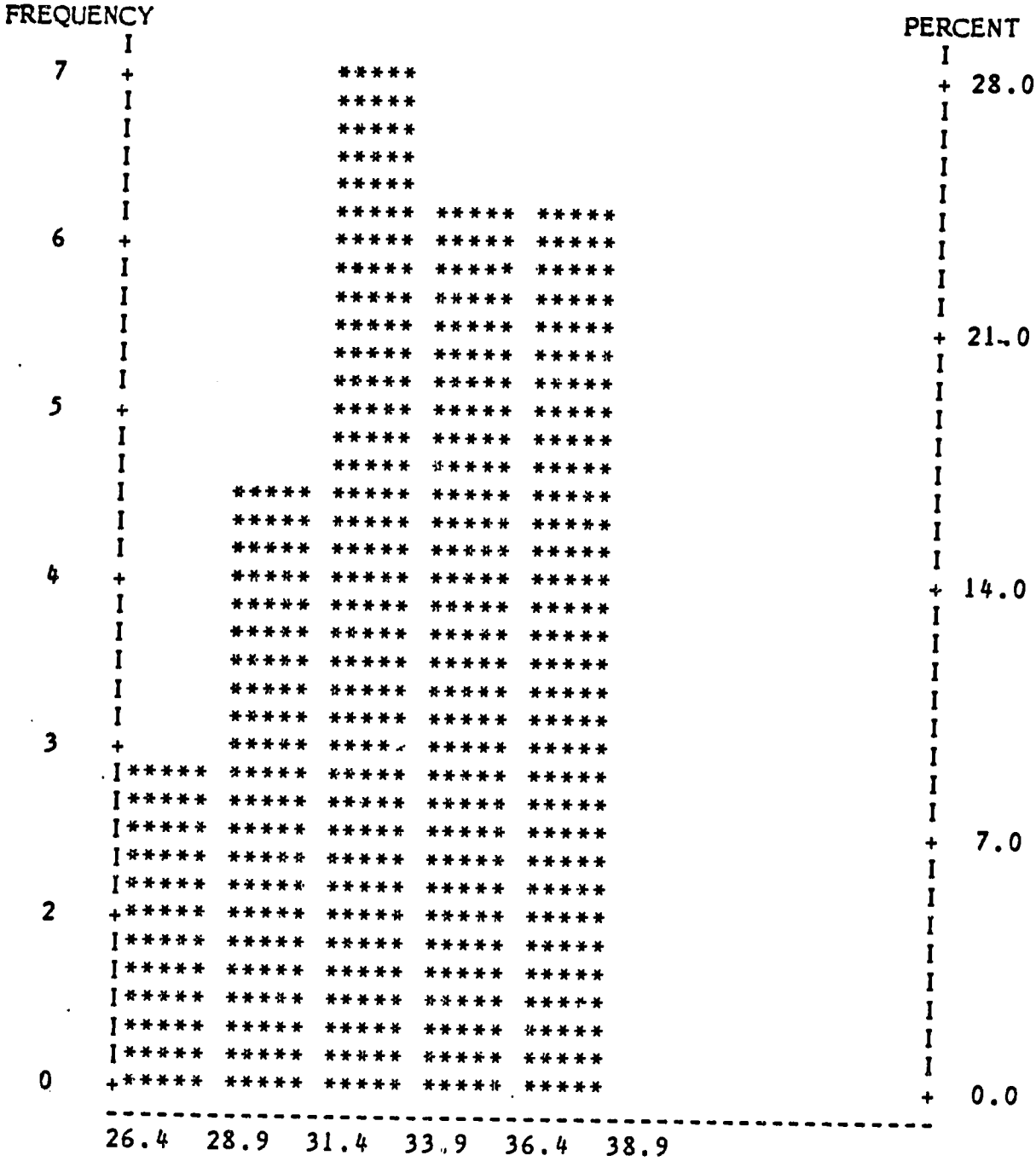
151

H I S T O G R A M



A I R I N F L A T I O N # 1 1 P I A C T

H I S T O G R A M



T E N S I L E # 1 2 P I A C T

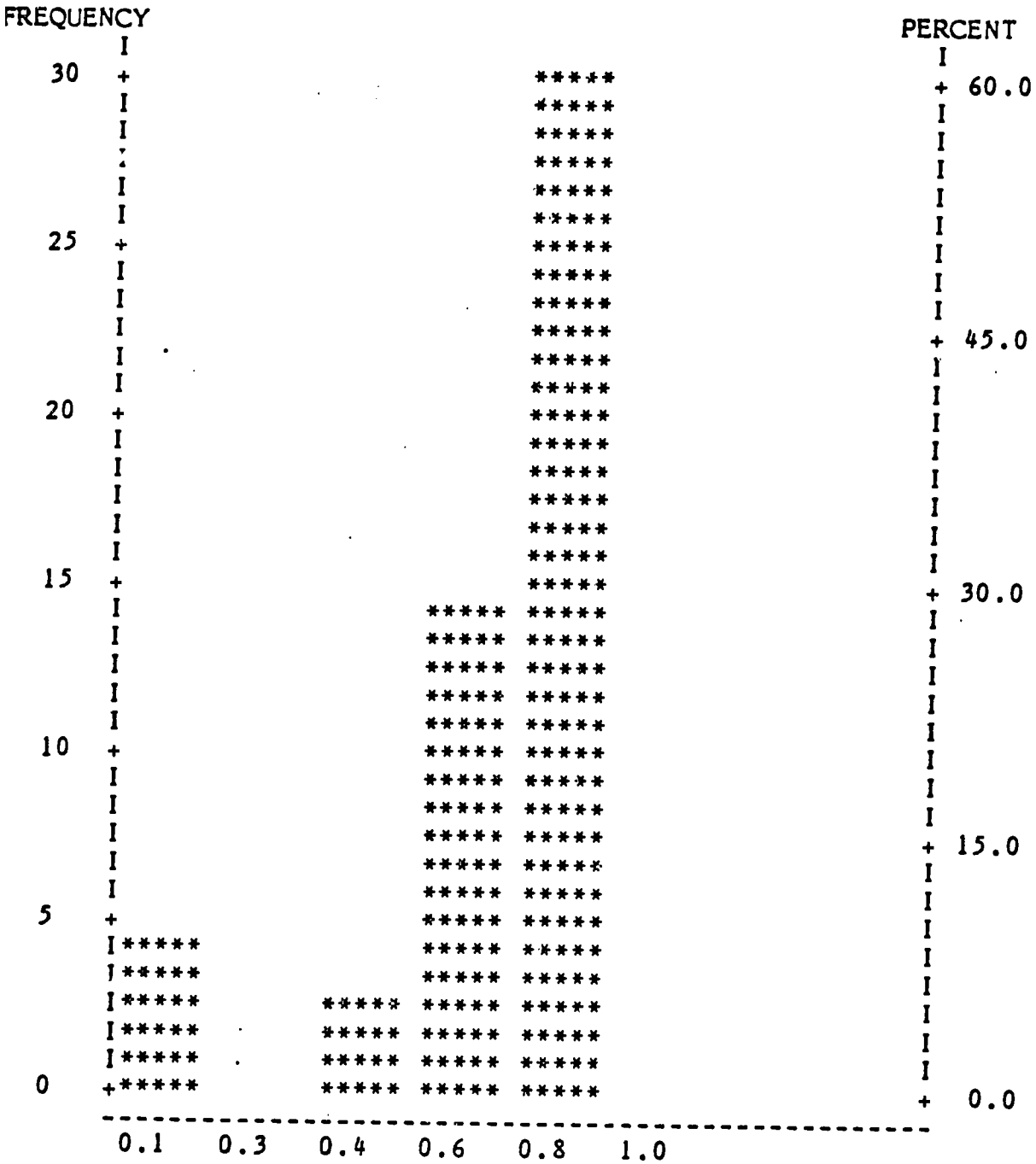
H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                           I
   12     +                    *****                                  +  48.0
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
   10     +                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  +  36.0
          I                    *****                                  I
    8     +                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
    6     +              *****  *****                                  I
          I              *****  *****                                  +  24.0
          I              *****  *****                                  I
          I              *****  *****                                  I
          I              *****  *****                                  I
          I              *****  *****                                  I
    4     +              *****  *****                                  I
          I              *****  *****                                  I
          I              *****  *****                                  I
          I              *****  *****                                  I
          I*****         *****  *****                                  +  12.0
          I*****         *****  *****                                  I
          I*****         *****  *****                                  I
    2     +*****  *****  *****  *****  *****                           I
          I*****  *****  *****  *****  *****                           I
          I*****  *****  *****  *****  *****                           I
          I*****  *****  *****  *****  *****                           I
          I*****  *****  *****  *****  *****                           I
          I*****  *****  *****  *****  *****                           I
    0     +*****  *****  *****  *****  *****                           +   0.0
          ----------------------------------------------------------
          724.0 741.2 758.4 775.6 792.8 810.0
```

E L O N G . # 1 2 P I A C T

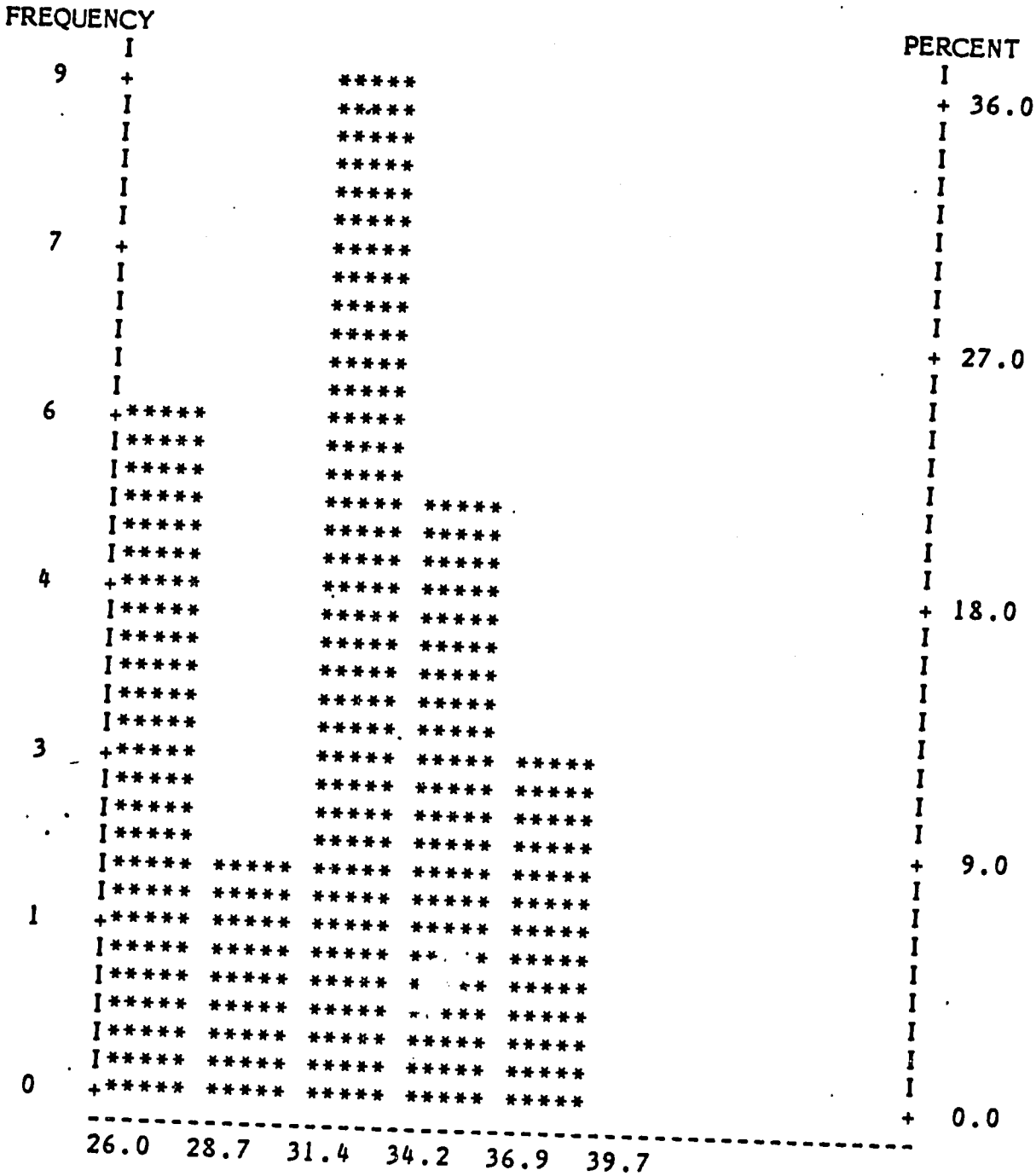
154

H I S T O G R A M



A I R I N F L A T I O N # 1 2 P I A C T

H I S T O G R A M



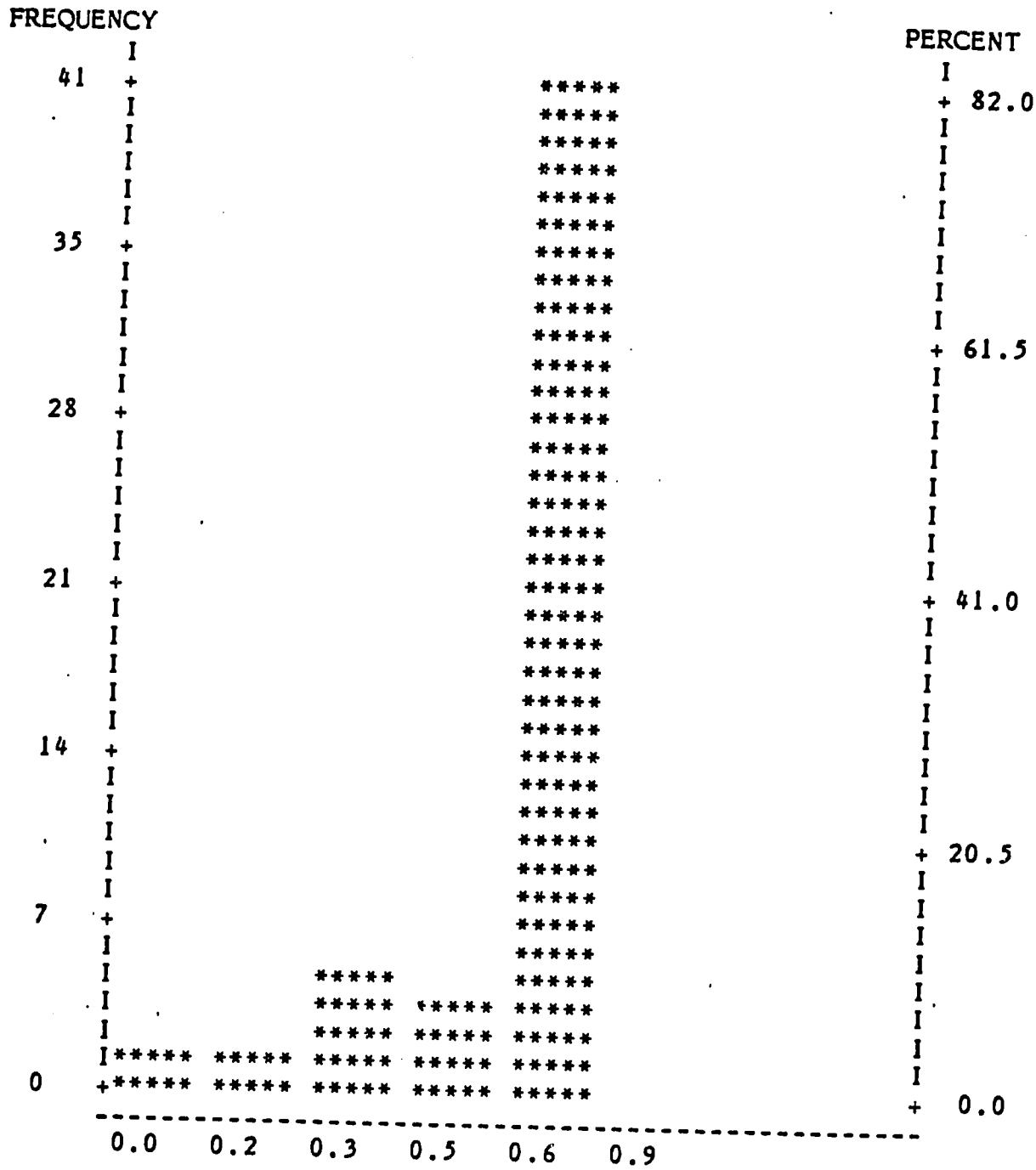
T E N S I L E # 1 3 P I A C T

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
         I                                                          I
   8     +                         *****                            + 32.0
         I                         *****                            I
         I                         *****                            I
         I                         *****                            I
         I                *****    *****                            I
         I                *****    *****                            I
   7     +                *****    *****                            I
         I                *****    *****                            I
         I                *****    *****                            I
         I                *****    *****                            I
         I                *****    *****                            + 24.0
         I                *****    *****                            I
         I                *****    *****                            I
   6     +                *****    *****                            I
         I                *****  *****  *****                       I
         I                *****  *****  *****                       I
         I                *****  *****  *****                       I
         I                *****  *****  *****                       I
         I                *****  *****  *****                       I
   4     +                *****  *****  *****                       + 16.0
         I                *****  *****  *****                       I
         I                *****  *****  *****                       I
         I                *****  *****  *****                       I
         I       *****    *****  *****  *****                       I
         I       *****    *****  *****  *****                       I
   3     +       *****    *****  *****  *****                       I
         I       *****    *****  *****  *****                       I
         I       *****    *****  *****  *****                       I
         I*****  *****    *****  *****  *****                       + 8.0
         I*****  *****    *****  *****  *****                       I
         I*****  *****    *****  *****  *****                       I
   2     +*****  *****    *****  *****  *****                       I
         I*****  *****    *****  *****  *****                       I
         I*****  *****    *****  *****  *****                       I
         I*****  *****    *****  *****  *****                       I
         I*****  *****    *****  *****  *****                       I
         I*****  *****    *****  *****  *****                       I
   0     +*****  *****    *****  *****  *****                       + 0.0
         ----------------------------------------------------------
        698.0 723.2 748.4 773.6 798.8 824.0
```

E L O N G . # 1 3 P I A C T

H I S T O G R A M



A I R I N F L A T I O N # 3 P I A C T

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                           I
   11     +                    *****                                  + 44.0
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
   10     +                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  + 33.0
          I                    *****                                  I
   8      +                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
          I                    *****                                  I
   6      +                    *****                                  I
          I             *****  *****                                  + 22.0
          I             *****  *****                                  I
          I             *****  *****                                  I
          I             *****  ***** *****                           I
          I             *****  ***** *****                           I
   4      +             *****  ***** *****                           I
          I             *****  ***** *****                           I
          I       *****  *****  ***** *****                           I
          I       *****  *****  ***** *****                           I
          I       *****  *****  ***** *****                           + 11.0
          I*****  *****  *****  ***** *****                           I
   2      +*****  *****  *****  ***** *****                           I
          I*****  *****  *****  ***** *****                           I
          I*****  *****  *****  ***** *****                           I
          I*****  *****  *****  ***** *****                           I
          I*****  *****  *****  ***** *****                           I
          I*****  *****  *****  ***** *****                           I
   0      +*****  *****  *****  ***** *****                           +  0.0
          ----------------------------------------------------------
          24.2  26.9  29.6  32.4  35.1  37.9
```

T E N S I L E # 1 4 P I A C T

159

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
         I                                                            I
   10    +             *****                                        + 40.0
         I             *****                                        I
         I             *****                                        I
         I             *****                                        I
         I             *****                                        I
         I             *****                                        I
    9    +             *****                                        I
         I             *****                                        I
         I             *****                                        I
         I             *****                                        I
         I             *****                                        + 30.0
         I             *****                                        I
    7    +             *****                                        I
         I             *****                                        I
         I       ***** *****                                        I
         I       ***** *****                                        I
         I       ***** *****                                        I
         I       ***** *****                                        I
    5    +       ***** *****                                        I
         I       ***** *****                                        + 20.0
         I       ***** *****                                        I
         I       ***** ***** *****                                  I
         I       ***** ***** *****                                  I
         I       ***** ***** *****                                  I
    4    +       ***** ***** *****                                  I
         I***** ***** ***** *****                                   I
         I***** ***** ***** *****                                   I
         I***** ***** ***** *****                                   I
         I***** ***** ***** ***** *****                             + 10.0
         I***** ***** ***** ***** *****                             I
    2    +***** ***** ***** ***** *****                             I
         I***** ***** ***** ***** *****                             I
         I***** ***** ***** ***** *****                             I
         I***** ***** ***** ***** *****                             I
         I***** ***** ***** ***** *****                             I
         I***** ***** ***** ***** *****                             I
    0    +***** ***** ***** ***** *****                             I
         ----------------------------------------------------------+  0.0
         753.0 775.0 797.0 819.0 841.0 863.0
```

E L O N G . # 1 4 P I A C T

160

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
         I                                                            I
   32    +                    *****                                   +  64.0
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
   27    +                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   +  48.0
         I                    *****                                   I
   22    +                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
   16    +                    *****                                   +  32.0
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
   11    +                    *****                                   I
         I*****               *****                                   I
         I*****               *****                                   I
         I*****               *****                                   I
         I*****               *****                                   +  16.0
         I*****               *****                                   I
    6    +*****               ***** *****                             I
         I*****               ***** *****                             I
         I*****               ***** *****                             I
         I***** ***** *****   ***** *****                             I
         I***** ***** *****   ***** *****                             I
         I***** ***** *****   ***** *****                             I
    0    +***** ***** *****   ***** *****                             +   0.0
         ---------------------------------------------------------------
          0.0   0.3   0.6   0.8   1.1   1.5
```

A I R I N F L A T I O N # 1.4 P I A C T

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                          I
   11     +                    *****                                 +  44.0
          I                    *****                                 I
          I                    *****                                 I
          I                    *****                                 I
          I                    *****                                 I
          I                    *****                                 I
   10     +                    *****                                 I
          I                    *****                                 I
          I                    *****                                 I
          I                    *****                                 I
          I                    *****                                 +  33.0
          I                    *****                                 I
          I                    *****                                 I
    8     +                    *****                                 I
          I                    *****                                 I
          I                    *****                                 I
          I                    *****                                 I
          I       *****        *****                                 I
          I       *****        *****                                 I
    6     +       *****        *****                                 I
          I       ***** *****  *****                                 +  22.0
          I       ***** *****  *****                                 I
          I       ***** *****  *****                                 I
          I       ***** *****  *****                                 I
          I       ***** *****  *****                                 I
          I       ***** *****  *****                                 I
    4     +       ***** *****  *****                                 I
          I       ***** *****  *****                                 I
          I       ***** *****  *****                                 I
          I       ***** *****  *****                                 I
          I       ***** *****  *****                                 +  11.0
          I       ***** *****  *****                                 I
          I       ***** *****  ***** *****                           I
    2     +       ***** *****  ***** *****                           I
          I       ***** *****  ***** *****                           I
          I***** ***** *****  ***** *****                           I
          I***** ***** *****  ***** *****                           I
          I***** ***** *****  ***** *****                           I
          I***** ***** *****  ***** *****                           I
          I***** ***** *****  ***** *****                           I
    0     +***** ***** *****  ***** *****                           +   0.0
          ----------------------------------------------------------
          23.4  26.2  29.1  32.0  34.9  37.8
```

T E N S I L E # 1 5 P I A C T

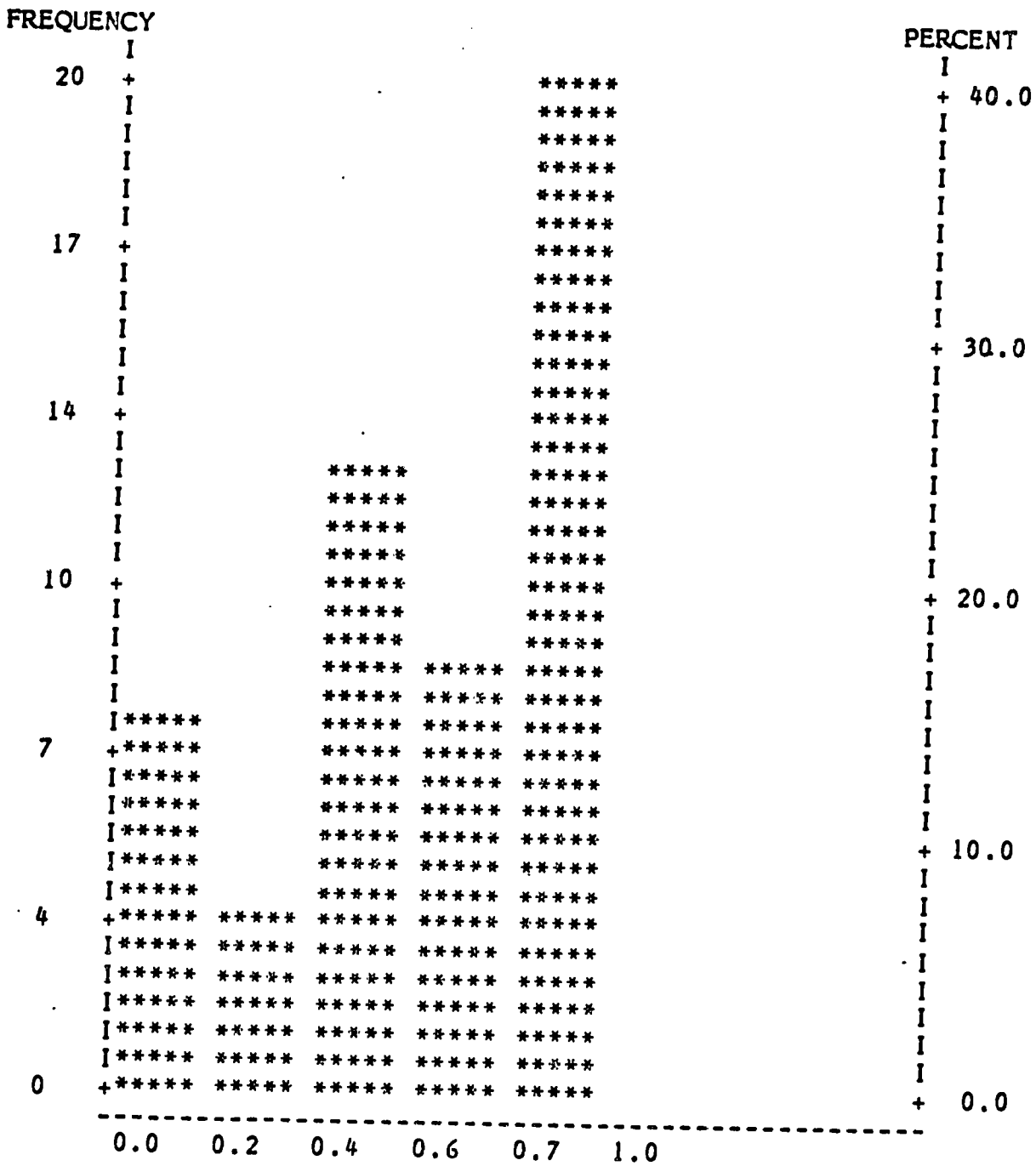
162

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                           I
   12     +             *****                                        + 48.0
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
   10     +             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        + 36.0
          I             *****                                        I
    8     +             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
    6     +             *****                                        + 24.0
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
    4     +*****        *****                                        I
          I*****        *****                                        I
          I*****        *****                                        I
          I***** ***** ***** ***** *****                             + 12.0
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
    2     +***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
    0     +***** ***** ***** ***** *****                             +  0.0
          ---------------------------------------------------------
        751.0 766.2 781.4 796.6 811.8 827.0
```

E L O N G . # 1 5 P I A C T

H I S T O G R A M



A I R I N F L A T I O N # 1 5 P I A C T

164

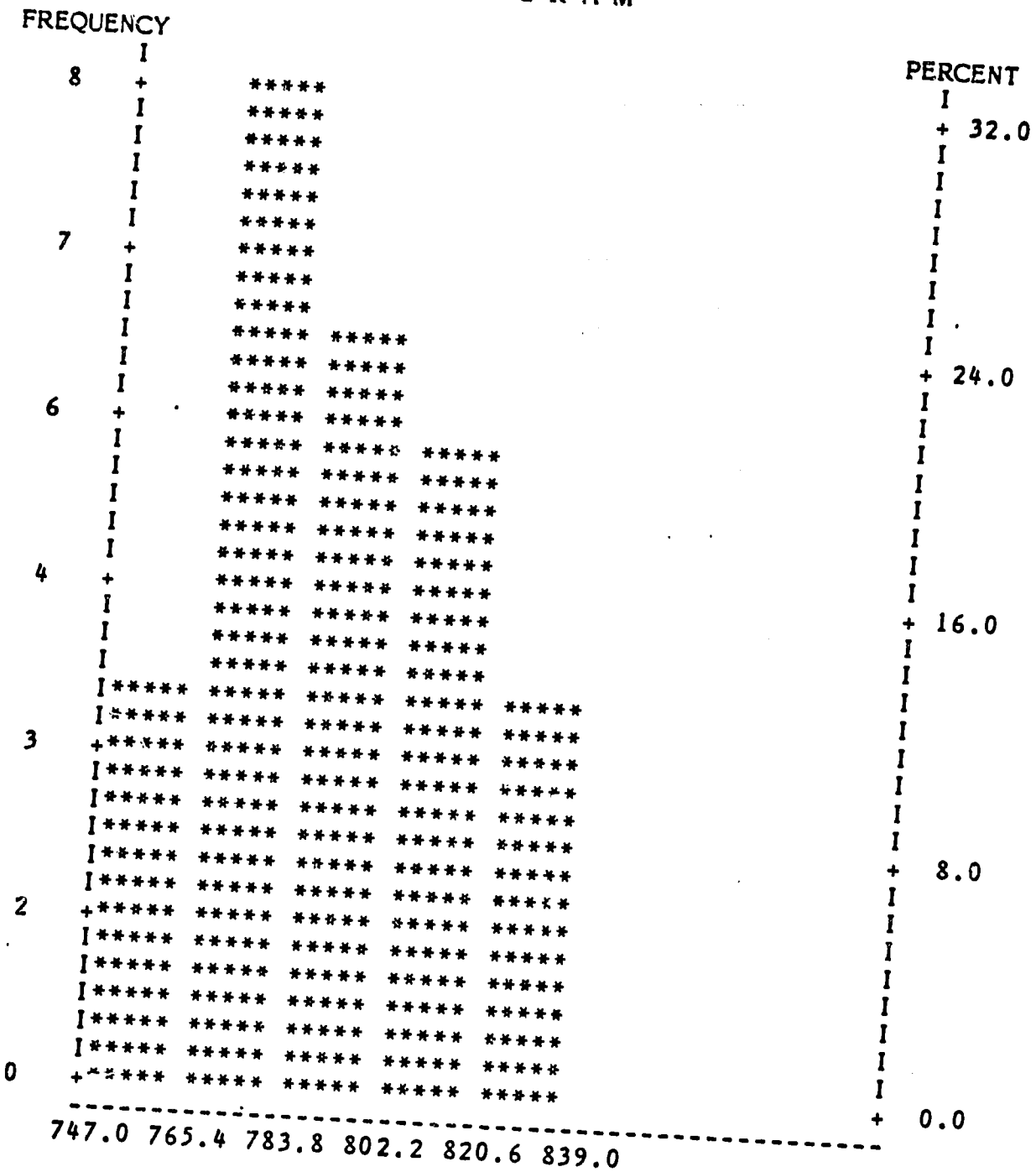
H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                          I
    9     +             *****                                        + 36.0
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        I
    7     +             *****                                        I
          I             *****                                        I
          I             *****                                        I
          I             *****                                        + 27.0
          I             *****                                        I
          I             *****                                        I
    6     +             ***** *****                                  I
          I             ***** *****                                  I
          I             ***** *****                                  I
          I*****        ***** *****                                  I
          I*****        ***** *****                                  I
          I*****        ***** *****                                  I
    4     +*****        ***** *****                                  + 18.0
          I*****        ***** *****                                  I
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
    3     +***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   +  9.0
          I***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
    1     +***** ***** ***** *****                                   I
          I***** ***** ***** *****                                   I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
          I***** ***** ***** ***** *****                             I
    0     +***** ***** ***** ***** *****                             +  0.0
          ----------------------------------------------------------
          24.4  27.8  31.3  34.8  38.3  41.8
```

T E N S I L E # 1 7 P I A C T

165

H I S T O G R A M



E L O N G . #17 P I A C T

166

H I S T O G R A M

```
FREQUENCY                                                    PERCENT
         I                                                     I
   32    +                 *****                               + 64.0
         I                 *****                               I
         I                 *****                               I
         I                 *****                               I
         I                 *****                               I
         I                 *****                               I
   27    +                 *****                               I
         I                 *****                               I
         I                 *****                               I
         I                 *****                               + 48.0
         I                 *****                               I
         I                 *****                               I
   22    +                 *****                               I
         I                 *****                               I
         I                 *****                               I
         I                 *****                               I
         I                 *****                               I
         I                 *****                               I
   16    +                 *****                               + 32.0
         I                 ***** *****                         I
         I                 ***** *****                         I
         I                 ***** *****                         I
         I                 ***** *****                         I
         I                 ***** *****                         I
   11    +                 ***** *****                         I
         I                 ***** *****                         I
         I                 ***** *****                         I
         I                 ***** *****                         + 16.0
         I                 ***** *****                         I
         I                 ***** *****                         I
    6    +                 ***** *****                         I
         I                 ***** *****                         I
         I                 ***** *****                         I
         I       *****     ***** *****                         I
         I***** *****      ***** *****                         I
         I***** *****      ***** *****                         I
    0    +***** *****      ***** *****                         +  0.0
         ---------------------------------------------------
          0.1   0.3   0.6   0.8   1.1   1.4
```

A I R I N F L A T I O N # 1 7 P I A C T

167

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
         I                                                            I
    8    +                    *****                                   + 32.0
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
    7    +                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   I
         I                    *****                                   + 24.0
         I                    *****                                   I
         I                    *****                                   I
    6    +                    *****                                   I
         I       *****        ***** *****                             I
         I       *****        ***** *****                             I
         I       *****        ***** *****                             I
         I       *****        ***** *****                             I
         I       *****        ***** *****                             I
    4    +       ***** *****  ***** *****                             + 16.0
         I       ***** *****  ***** *****                             I
         I       ***** *****  ***** *****                             I
         I       ***** *****  ***** *****                             I
         I***** ***** *****  ***** *****                             I
         I***** ***** *****  ***** *****                             I
    3    +***** ***** *****  ***** *****                             I
         I***** ***** *****  ***** *****                             I
         I***** ***** *****  ***** *****                             I
         I***** ***** *****  ***** *****                             + 8.0
         I***** ***** *****  ***** *****                             I
         I***** ***** *****  ***** *****                             I
    2    +***** ***** *****  ***** *****                             I
         I***** ***** *****  ***** *****                             I
         I***** ***** *****  ***** *****                             I
         I***** ***** *****  ***** *****                             I
         I***** ***** *****  ***** *****                             I
         I***** ***** *****  ***** *****                             I
    0    +***** ***** *****  ***** *****                             + 0.0
         ----------------------------------------------------------
         26.3  28.7  31.1  33.6  36.0  38.5
```

T E N S I L E # 1 8 P I A C T

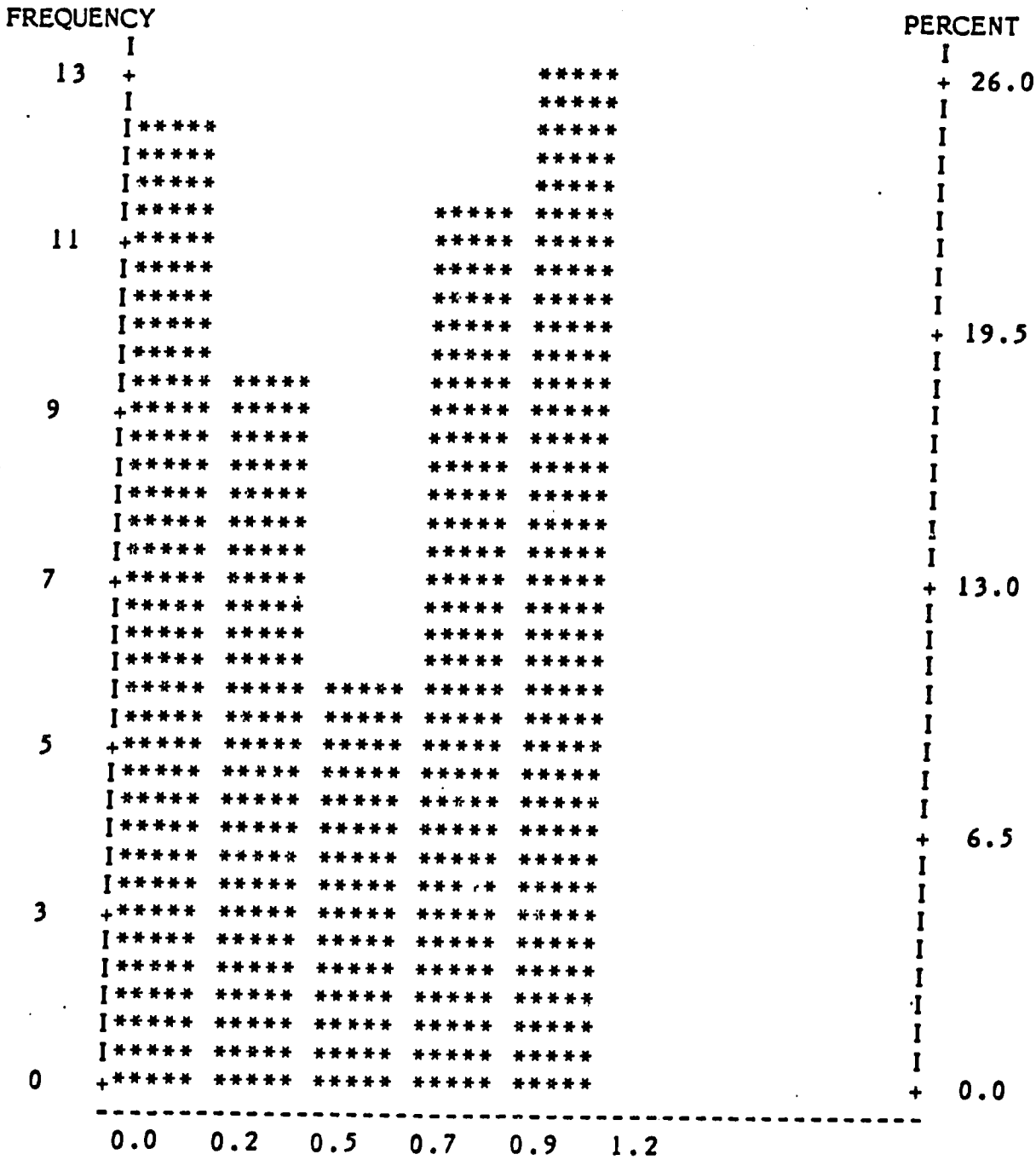
168

H I S T O G R A M

```
FREQUENCY                                                          PERCENT
          I                                                          I
    8     +                    ***** *****                          + 32.0
          I                    ***** *****                          I
          I                    ***** *****                          I
          I                    ***** *****                          I
          I                    ***** *****                          I
          I                    ***** *****                          I
    7     +                    ***** *****                          I
          I                    ***** *****                          I
          I                    ***** *****                          I
          I                    ***** *****                          + 24.0
          I                    ***** *****                          I
          I                    ***** *****                          I
    6     +                    ***** *****                          I
          I                    ***** *****                          I
          I                    ***** *****                          I
          I                    ***** *****                          I
          I                    ***** *****                          I
          I                    ***** *****                          I
    4     +              ***** ***** *****                          + 16.0
          I              ***** ***** *****                          I
          I              ***** ***** *****                          I
          I              ***** ***** *****                          I
          I       ***** ***** ***** *****                          I
          I       ***** ***** ***** *****                          I
    3     +       ***** ***** ***** *****                          I
          I       ***** ***** ***** *****                          I
          I       ***** ***** ***** *****                          I
          I***** ***** ***** ***** *****                           +  8.0
          I***** ***** ***** ***** *****                           I
          I***** ***** ***** ***** *****                           I
    2     +***** ***** ***** ***** *****                           I
          I***** ***** ***** ***** *****                           I
          I***** ***** ***** ***** *****                           I
          I***** ***** ***** ***** *****                           I
          I***** ***** ***** ***** *****                           I
          I***** ***** ***** ***** *****                           I
    0     +***** ***** ***** ***** *****                           +  0.0
          ----------------------------------------------------------
        745.0 763.0 781.0 799.0 817.0 835.0
```

E L O N G . # 1 8 P I A C T

H I S T O G R A M



A I R I N F L A T I O N # 1 8 P I A C T

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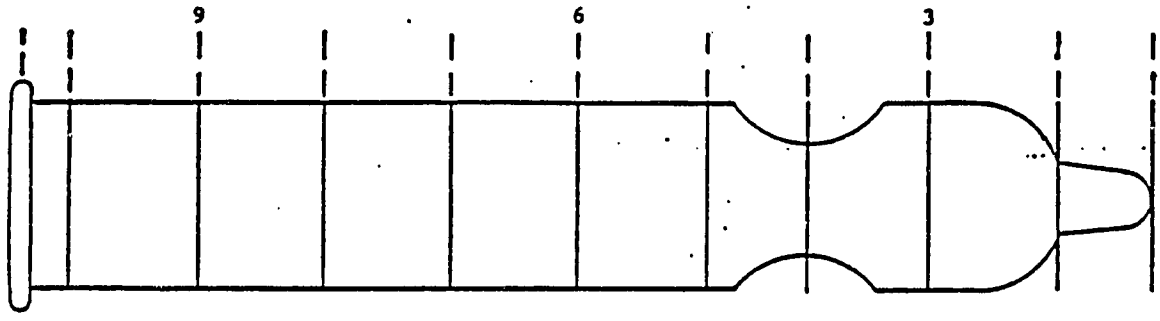
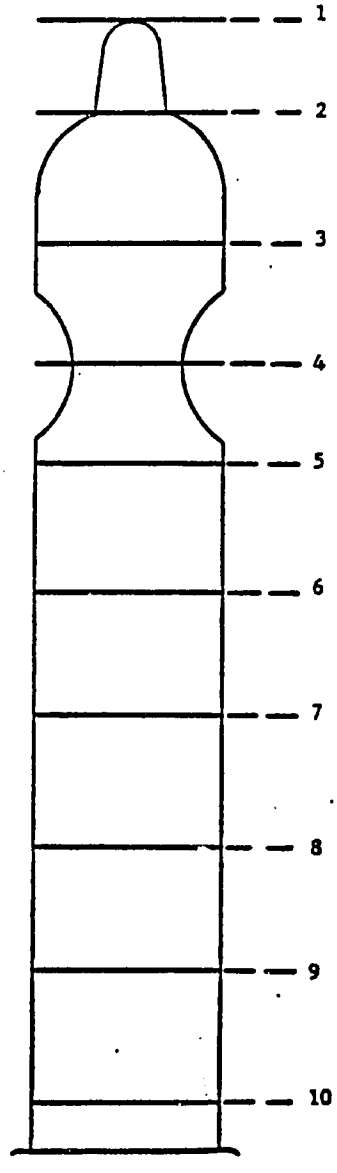
Appendix I

CODE TO IDENTIFY LEAKS OR BREAKS
OF CONDOMS IN WATER TEST

Appendix I

CODE TO IDENTIFY LEAKS OR BREAKS
OF CONDOMS IN WATER TEST





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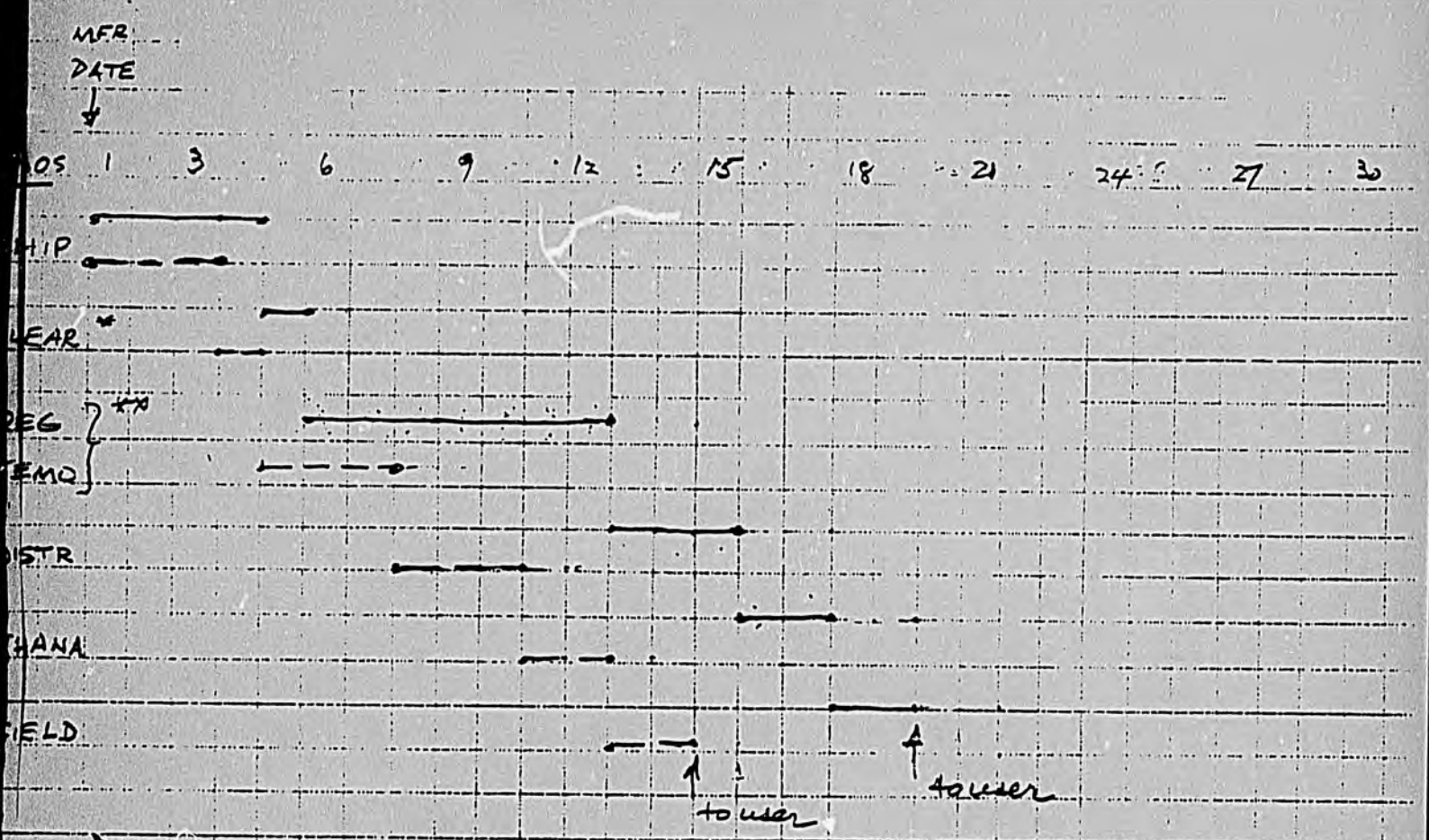
Appendix J

PROJECTION OF TIME FOR AID CONDOMS
TO REACH USERS IN BANGLADESH
POPULATION MINISTRY PROGRAM
(ASSUMING CLEARANCE WITH FIFO)

Appendix J

PROJECTION OF TIME FOR AID CONDOMS
TO REACH USERS IN BANGLADESH
POPULATION MINISTRY PROGRAM
(ASSUMING COMPLIANCE WITH FIFO)



* Includes transport to Central (TEMO) and Regional warehouse

** Includes transport to district warehouse

——— Worst case - assumes that in country condom reserves allow for some condoms to take one year to user after clearing customs.

— — — Optimal for condoms that are distributed immediately (May be as little as 6 months from date of manufacture if system is empty).

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Appendix K

AID CABLE ON CONDOM TESTING REPORT
FROM PIACT, BANGLADESH, JUNE 3, 1982

Appendix K

AID CABLE ON CONDOM TESTING REPORT FROM PIACT, BANGLADESH, JUNE 3, 1982

UNCLASSIFIED

Department of State

INCOMING TELEGRAM

PAGE 01 DACCA 03602 0307062 9718 006188 AID4656

ACTION AID-35

ACTION OFFICE ASTA-01

INFO ASEM-01 ACDP-02 ACPD-03 AAST-01 C-01 CASI-02 CPI-01 CPS-02 STHE-01 POP-04 MHS-09 RELO-01 MAST-01 ASBI-03 /033 A4 83

INFO OCT-00 AMAD-01 OES-09 /045 W

251718 0307062 /38

P 0304472 JUN 82

FM AMEMBASSY DACCA

TO SECSTATE WASHDC PRIORITY 6561

UNCLAS DACCA 3602

AIDAC

FOR ASIA/TR/PHNR

E.O. 12065: N/A

SUBJ: POPULATION: PIACT CONDOM TESTING RESULTS

REF: STATE 139233

FOLLOWING IS THE CONDOM TESTING REPORT FROM PIACT:

1. TEST CODE ENG 820428; SITE WAS TEMO DACCA; NO. CONDOMS TESTED-100; BRAND - TAHITI; MANUFACTURE DATE-MAY 81; NO; NO. OF CONDOMS BURSTING BELOW 11 LITERS - 1; NO. OF CONDOMS BURSTING BETWEEN 11-15 LITERS - 5; MEDIAN BURST PRESSURE-21.0; MEDIAN BURST VOLUME - 27.2; VALUE OF CDI- 3.14. RLB-5

2. TEST CODE BNG 820430; SITE WAS MYMANSINGH DISTRICT WARE HOUSE; NO. CONDOMS TESTED -100; BRAND - TAHITI; MANUFACTURE DATE-MAY 80; NO. OF CONDOMS BURSTING BELOW 11 LITERS - 4; NO. OF CONDOMS BURSTING BETWEEN 11-15 LITERS -4; MEDIAN BURST PRESSURE-19.4; MEDIAN BURST VOLUME-26.6; VALUE OF CDI - 3.57. RLB-7

3. TEST CODE BNG 820504; SITE WAS CHITTAGONG REGIONAL WAREHOUSE; NO. CONDOMS TESTED -96; BRAND - TAHITI; MANUFACTURE DATE-JULY 79; NO. OF CONDOMS BURSTING BELOW 11 LITERS -0; NO. OF CONDOMS BURSTING BETWEEN 11-15 LITERS -2; MEDIAN BURST PRESSURE-21.0; MEDIAN BURST VOLUME - 24.7; VALUE OF CDI - 2.65. RLB-1

4. TEST CODE BNG 820506; SITE WAS SAVAR THANA, DACCA; NO. CONDOMS TESTED - 100; BRAND - TAHITI; MANUFACTURE DATE-MAY 80; NO. OF CONDOMS BURSTING BELOW 11 LITERS-5; NO. OF CONDOMS BURSTING BETWEEN 11-15 LITERS - 1; MEDIAN BURST PRESSURE-21.6; MEDIAN BURST VOLUME - 29.2; VALUE OF CDI - 3.56. RLB-4

5. TEST CODE BNG 820510; SITE WAS MADHUPUR THANA, TANGAIL; NO. CONDOMS TESTED - 100; BRAND - TAHITI; MANUFACTURE DATE-MAY 81; NO. OF CONDOMS BURSTING BELOW 11 LITERS - 5; NO. OF CONDOMS BURSTING BETWEEN 11-15 LITERS - 1; MEDIAN BURST PRESSURE -21.0; MEDIAN BURST VOLUME-28.2; VALUE OF CDI - 3.53. RLB-6

6. TEST CODE BNG 820524; SITE WAS PANCHLAISH THANA, CHITTAGONG, NO. CONDOMS TESTED - 94; BRAND - TAHITI; MANUFACTURE DATE-JULY 79; NO. OF CONDOMS BURSTING BELOW 11 LITERS - 2; NO. OF CONDOMS BURSTING BETWEEN 11-15 LITERS -0; MEDIAN BURST PRESSURE - 19.2; MEDIAN BURST VOLUME- 24.3; VALUE OF CDI -3.24. RLB-2

7. TEST CODE BNG 820525; SITE WAS MYMENSINGH DISTRICT WAREHOUSE; NO. OF CONDOMS TESTED - 100; BRAND - CONTROURED; MANUFACTURE DATE- AUGUST 81; NO. OF CONDOMS BURSTING BELOW 11 LITERS - 6; NO. OF CONDOMS BURSTING BETWEEN 11-15 LITERS -7, MEDIAN BURST PRESSURE - 14.5; MEDIAN BURST VOLUME 28.4; VALUE OF CDI- 13.75. RLB-8

8. TEST CODE BNG [illegible]; SITE WAS JOYDEB PUR; NO. OF RLB-3

DACCA 03602 0307062 9718 006188 AID4656

CONDOMS TESTED - 97; BRAND - CONTOURED; MANUFACTURE DATE MAY 81, NO. OF CONDOMS BURSTING BELOW 11 LITERS - 3; NO. CONDOMS BURSTING BETWEEN 11-15 LITERS - 8; MEDIAN BURST PRESSURE - 14.6; MEDIAN BURST VOLUME - 28.0, VALUE OF CDI - 3.41. RLB-3

9. IF CDI IS IN THE INTERMEDIATE ZONE I.E 2.8 TO 3.4, THE LOT IS ALERT. THIS MEANS THE LOT IS NEITHER ACCEPTED NOR REJECTED. IF THE VALUE OF CDI IS BELOW 2.8, THE LOT IS ACCEPTED. IF THE VALUE OF CDI IS ABOVE 3.4, THE LOT IS REJECTED.

COON

4 JUN 1982

UNCLASSIFIED

Appendix L

LIST OF PERSONS CONTACTED

Appendix L

LIST OF PERSONS CONTACTED

United States

U.S. Agency for International Development (USAID)

D. Newman, Office of Population, AID/W

J. Speidel, M.D., Office of Population AID/W

J. Shelton, M.D., Office of Population, AID/W

A. Boni, Office of Population, AID/W

V. Peterson, Office of Population, AID/W

Akwell Industries*

R. Martin, President

B. Pugh, Vice President, Research and Development and Quality Control

R. Culp, Quality Control

R. Fee, Research and Development

J. Quinn, Vice President, Public Sector Marketing

C. Milner, Senior Vice President and General Manager

PIACT/Seattle

Michael Free, Ph.D.

Bangladesh

USAID

W. Joslin, Deputy Director

S. Olds, Population Officer

C. Carpenter-Yaman, Deputy Population Officer

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* Now known as Ansell Corporation.

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H. Al-Rashid, Logistics

Sr. Ali Noor, Demographer

Bangladesh Ministry of Health and Population Control, Division of Family Planning

Colonel H. Ali, Director-General, Implementation

A. Harque Buhyia, Deputy Director, Logistics

Dr. J. Ahmed, Deputy Director-General, Supply

Deputy Directors (Region and District), Chittagong, Mymensingh and Tangail

15 Thana Family Planning Officers

PIACT/Bangladesh

Y. Chowdury, Executive Director

Social Marketing Program, Bangladesh

A. Ali, Project Director

W. Schellsteade, Adviser

United Nations Fund for Population Activities (UNFPA)

D. Gupta, Adviser, Supply

J. Lal Das, Logistics Officer