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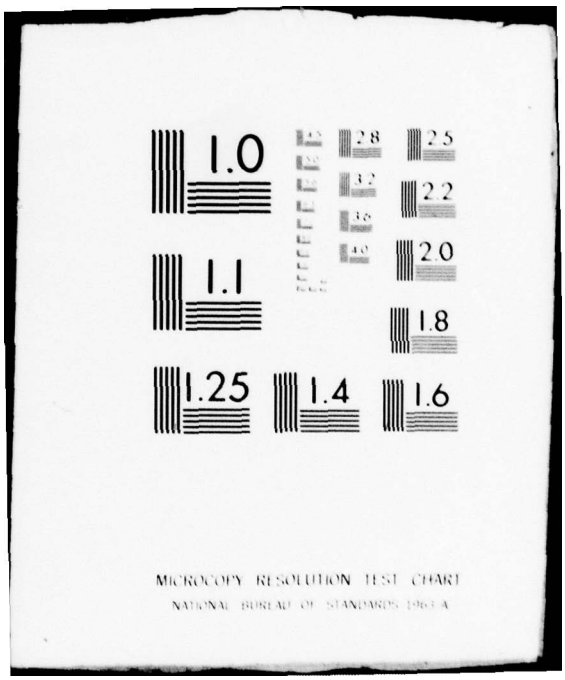
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INDICATOR, TEMPERATURE, REFRIGERATED PRODUCTS, FIELD

Final Report

January 1975

by

Frank Swindells, Ph. D.

Supported by

US Army Medical Research and Development Command
Fort Detrick, Frederick, Maryland 21701

Contract No. DAMD 17-74-C-4043

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Devices which indicate irreversibly at 7°, 10° and 13° C by means of a color change have been designed and tested. Under laboratory conditions the response of fresh made devices is highly reliable. Shelf life under normal storage conditions is unsatisfactory. However, if the devices are stored in the activated or frozen state the storage life is extended substantially. Thus, while some types of units may be shipped from manufacturer to user in the unactivated condition, they must be activated and stored cold immediately upon receipt. A means for attaching the device to a chilled blood bag is described.

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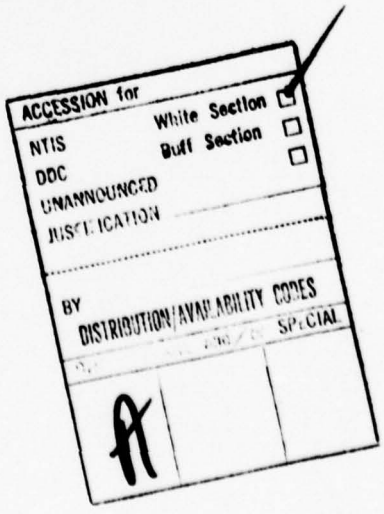

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ABSTRACT

Devices which indicate irreversibly at 7°, 10° and 13°C by means of a color change have been designed and tested. Under laboratory conditions the response of fres made devices is highly reliable. Shelf life under normal storage conditions is unsatisfactory. However, if the devices are stored in the activated or frozen state the storage life is extended substantially. Thus, while some types of units may be shipped from manufacturer to user in the unactivated condition, they must be activated and stored cold immediately upon receipt. A means for attaching the device to a chilled blood bag is described.

1. INTRODUCTION

This report presents results obtained during the period of November 1, 1973 to October 31, 1974 on contract DAMD17-74-C-4043. It is a continuation and extension of the previous contract DADA17-72-C-2167.

The objectives of this program are:

(a) to develop devices showing nominal response at 7°, 10° and 13°C.

(b) to continue development and testing of the 10° - 15°C devices resulting from the work on the previous contract.

The devices considered operate by showing a positive, irreversible color change when a specified response temperature is exceeded. Devices of this type - the ARTECH IWI(R)'s which are commercially available - are limited in their response temperature which cannot exceed 0°C, the melting point of ice. The system covered by this report operates on a different principle, as will be shown in the following sections of this report.

The new devices are expected to be useful in monitoring the storage and shipment of all types of perishable materials, which must be maintained at temperatures below the normal ambient room temperature but above 0°C.

2. DESIGN REQUIREMENTS

2.1 Principle of Operation

The devices described herewith are based on an observation that organic liquids frozen in gelatin capsules and then melted were partly expelled. A tentative explanation is that when the liquid freezes, with reduction in volume, air is drawn in thru the joint. When melting occurs, the rapid increase in volume causes some of the melted liquid to flow out through the joint between the two parts of the capsule. This effect is exploited by incorporation of a dye in the liquid and surrounding the capsule with paper or other medium to which the dye is substantive. Thus the temperature of indication is that at which the liquid melts and comes out of the capsule. It has been found, however, that other properties of the liquid must be considered in order to produce a stable, reliable indicator. The physical structure of the device is also of critical importance.

2.2 Selection of the Liquid

The following properties are to be considered:

(a) Melting Point. Melting must occur congruently at the temperature to be indicated.

(b) Tendency to Supercool. In order for a device to function it must first be "activated" by freezing the liquid. Most organic liquids, in small closed volumes must be subjected to a temperature below the melting point before freezing occurs. In theory it should be possible to control supercooling by addition of nucleating agents which initiate crystal growth. However, with one exception, materials for this purpose have not been found for the liquids considered in this program.

(c) Volume Change When Frozen. A large contraction is desirable to draw air into capsule when the liquid freezes. When melting occurs the expansion of the liquid as well as that of the air, expels some of the liquid thru the cracks.

(d) Thermal Expansion of Liquid Phase. High thermal expansion of the liquid is undesirable, causing some liquid to be expelled as the ambient temperature fluctuates. Unfortunately most organic liquids have a relatively high thermal expansion of the order of 0.8 ml/liter/℃. This property has a significant effect on the shelf life. An ideal liquid would have a large volume change on melting but a nearly negligible thermal expansion of the liquid phase.

(e) Vapor Pressure. Liquids which have a significant vapor pressure at normal room temperatures are lost from the device by evaporation during storage, thus reducing the shelf life.

(f) Viscosity. For best operation the liquid viscosity is critical. If too low, the liquid may bleed thru the joint over a period of time leading to "pre-spotting" or spurious indication. If too viscous it offers too much resistance to flowing thru the joint and the device fails to indicate. In practice, the viscosity is adjusted by adding a small amount of an organic high polymer such as ethyl cellulose to the liquid. A viscosity of the order of 40 cps is used.

(g) Gelatin-liquid Interfacial Tension. If the liquid wets the gelatin surface too easily it tends to bleed out through the cracks, resulting in prespotting and ultimately spurious indication as with low viscosity liquids. Liquid candidates were screened for this property by observing the spreading - contact angle - of a drop on the flat gelatin surface.

2.3 Device Structures

2.3.1 Adaptation of Standard IWI(R) Structure.

In devices developed for indication below 0°C the structure comprised three wax capsules containing the indicator liquid in contact with a piece of indicator paper, the whole being contained in a polyvinyl chloride blister

as shown in Fig. 1. The polyvinyl chloride film is 14 mils thick and is the type approved by the U.S. Department of Agriculture for use in food products.

The most direct adaptation of this structure to embody the new principle has the gelatin capsules replacing the wax balls, with the indicating paper wrapped around the three capsules as shown in Fig. 2. As reported previously the size of the capsules was found to be unimportant. For convenience of fabrication the #5 size* was adopted. After dissolving the indicator dye and adjusting the viscosity, the liquid was transferred to the capsules by vacuum filling. The empty but closed capsules were submerged in the fill liquid and held below the surface by a wire grid. The vessel was then evacuated which removed most of the air from the capsules. A slow release of the vacuum permitted the liquid to flow into the capsules thru the joints, nearly filling them. The filled capsules were then washed with a suitable solvent such as methanol.

The simple structure of Fig. 2 was found to have important shortcomings. After extended storage time, even at normal room temperature the liquid was lost by evaporation and diffusion thru the polyvinyl chloride blister. It was also noted that temperature fluctuations caused some of the liquid to be expelled from the capsules resulting in partial, premature indication.

2.3.2 Final Glass Structure.

The problems of loss of liquid and false indication ("prespotting") were partially overcome by enclosing the essential elements of the device in a sealed glass tube which was then sealed in an outer package composed of polyvinyl chloride films.

The preferred form of the device is shown in Figure 3. The three capsules are held in intimate contact with one side of the glass tube, a strip of paper-aluminum foil laminate covering one half of the circumference of the capsules with the aluminum side of the laminate in contact with the capsules. In this design the path between where the liquid is expelled from the capsule to the point of contact with the paper is considerably longer than with direct contact as in Figure 4.

---

* Manufactured by Eli Lilly.

When the liquid first leaves the capsule it tends to collect around the point of contact of the capsule joint and the glass tube. Traces of liquid remain there and at the interface with the aluminum foil and do not reach the paper. Larger amounts of liquid which are expelled when the device operates by melting of the liquid flow down the walls of the glass tube and are drawn into the paper by capillary action, producing a coloration. With this structure "pre-spotting" by small amounts of liquid, and sudden volume changes of the encapsulated liquid are reduced.

2.3.3 Fabrication of Preferred Devices.

(a) Glass tubes purchased from Fisher Scientific Co. Catalog #14458-5VA size 6mm diameter by 50mm long. Inspected for opening size-i.e. absence of construction.

(b) Gelatin capsules size #5 purchased from Eli Lilly Co., used as received without opening.

(c) Fill liquid prepared by dissolving dye and thickener if needed.

(d) Capsules filled as described in section 2.3.2. and allowed to stand at room temperature for two days with periodic rinsing with methanol.

(e) Aluminum foil-as used for preserving food. Laminated to coated side of polyethylene coated freeze paper with hot iron, and cut into pieces 10x40mm.

(f) A supply of polyethylene discs - 5mm in diameter, are punched out of a sheet.

(g) The components are assembled by forming a trough of the paper laminate with the aluminum on the inside, placing three capsules in the trough and inserting it in the tube.

(h) A polyethylene disc is put in the end of the tube, slightly depressed, and the well so formed filled with 24 hr. epoxy cement, and allowed to cure.

(i) The tube is then sealed in a polyvinyl chloride blister, as shown in Figure 3.

Before final assembly the sealed tubes are inspected after 48 hrs. for false indication, and again about two weeks after completion.

2.4 Testing Procedures

2.4.1 Screening Tests.

The greater part of the effort spent on testing was for screening of materials and structure. The tests included stability, activation conditions and response temperature. The stability was evaluated by visual observation after maintaining the device in various environments.

The activation temperature was determined by holding the devices at a series of low temperatures and then allowing them to return to room temperature. The activation conditions are estimated by the response at room temperature. The activation temperature can also be determined by visual observation of the freezing point of the liquid in the filled capsules.

The nominal response temperature is that of the melting point of the liquid. A practical test used was to first activate the device in a cold chamber, then immediately transfer it to a water-ethylene glycol bath held at a temperature below the expected temperature of indication, and allowing the bath to warm up at a rate of about 0.5°C per minute or slower, noting the temperature at which the device shows the first indication. Time - temperature curves are plotted on a strip chart recorder.

2.4.2 Practical Tests

In accordance with the contract a few tests to simulate performance under practical use were developed. In one type, specimens of the devices to be tested were attached in various locations in and out of a shipping container holding perishable food. The package with the indicators was exposed to controlled temperature variations, while the temperature of the contents was monitored. This is described in more detail in section 4.3.

A similar test procedure was used for monitoring the temperature of blood bags and is also described in section 5.3.

Pure ethyl cinnamate supercools to below -5°C. It was found that a small amount of graphite reduced the amount of supercooling as shown in Figure 4. The increase in volume of 6.3% accompanying the phase change is higher than that of the other two liquids. The thermal expansion of the liquid form is similar in magnitude to that of most organic liquids.

3. 7°C(45°F) DEVICE

3.1 Liquids Considered

Table 1 shows the liquids considered following a preliminary screening. Ethyl Cinnamate was selected after further testing. The fill solution was modified by adding 3% of ethyl cellulose to increase the viscosity. Figure 4 shows the freezing and thawing of this liquid, and Figure 5, the volume change as a function of temperature.

3.2 Tests Results

The devices should be activated at 3°C or below for a period of about one hour. The freezing compartment of an ordinary household refrigerator is ideal.

The response of the device was found to be highly reliable. As shown in Figure 6. 11 (of a group of 14 of the 7° devices) responded within the temperature range 7° to 8.3°C.

The thermal expansion and contraction of ethyl cinnamate during assembly and storage makes it difficult to confine the liquid in the capsule. It is important to store the unactivated devices with minimum exposure to temperature fluctuations. When stored under normal room conditions, 9 or 9% (of a group of 97 devices) showed prespotting in 18 days and 16 or 16.5% showed a similar failure after 50 days.

Table 1

Liquid Candidates for 7° Device

Liquid	MP Lit °C	MP Found	BP OC 760mm	Density (liq.)	Remarks
O-Chlorobenzaldehyde	12.1	8	212	1.248	Unstable
Citraconic Anhyclride	7-8	7	213	1.247	Unstable
Decyl Alcohol	5.5-6.5	5.5	229	0.8297	Too low melting point
Ethyl Anisate	6.5-8.5	7-8	269	1.108	Unstable in capsules
Ethyl Cinnamate	6.5-7.5	7.0	271	1.049	Used in device
Ethyl Myristate	12.3	7.0	295	0.857	Too expensive
2-Hydroxy Acetophenone	4.6	3.5	218	1.113	Too low melting point
Methyl Laurate	3-5	2.7	262	0.8702	Too low melting point
Phenyl Cyclohexane	7-8	5.5	235	0.9502	Too high vapor pressure

4. 10°C (50°F) DEVICE

4.1 Liquids Considered

Liquid candidates are shown in Table 2. Of these Dimethyl Adipate was chosen as the best liquid. The pure liquid melts at 10.3°C but some lots received have melting points as low as 8°C. It has minimum tendency to supercool, freezing at about 2°C., Figure 7. It shows less tendency to wet gelatin, which shows up as improved shelf life. It shows a 2.7% increase in volume on melting and has a thermal expansion coefficient of 0.814 ml/liter/°C. as shown in Figure 8.

4.2 Tests.

The reliability of response of the 10° devices is almost 100% and activation occurs at 2°C, which can be obtained in a household refrigerator. Figure 6 shows that of 21 devices all responded within the range 8.5° to 10.5°C.

Shelf life tests showed considerable failure due to prespotting. A group of 320 devices stored in normal room conditions showed a failure of 50 or 16% after 24 days and 102 or 32% after 56 days.

4.3 Practical Tests

The best location to attach irreversible warmup indicator on any shipping container must be determined by experiment. As Figure 9 shows sixteen 10° devices were placed on the outside of a cheese container whose temperature was below 10°C. A thermocouple was placed in the center of the cheese carton to record its interior temperature. Another thermocouple was placed inside a test chamber maintained at 0°C along with the cheese carton. The test chamber was allowed to warm up naturally to room temperature. It can be seen that as expected the indicators were monitoring the outside temperature of the box and not the surrounding air or the interior of the carton. The further into the carton the indicators are placed the more they will monitor the contents of the box.

Table 2

Liquid Candidates for 10° Device

Liquid	MP Lit	MP Found	BP °C 760mm	Density (liq)	Remarks
O'Chlorobenzaldehyde	12.1	8	212	1.248	Unstable
Dimethyl Adipate	10	10.3	113(13mm)	1.060	Used in devices
Ethyl Myristate	12.3	7°	295	0.857	Too expensive
Nananoic Acid	7-10	12.2	255	0.906	Good Prospect
Ethylene Dibromide	9.85		131.2	2.17	Too High Vapor pressure
4Methyl Quinoline	9-10		264	1.086	Excessive super-cooling

5. 13°C(55°F) DEVICES

5.1 Liquids Considered

The liquids tested for use in the 13° device are shown in Table 3. Ethyl anthranilate was selected as the best liquid in spite of its tendensy to supercool, as shown in Figure 10. The thermal expansion is slightly less than the other liquids, as shown in Figure 11. It also shows less tendency to wet gelatin. Two percent of ethyl cellulose is added to increase the viscosity.

5.2 Tests

As a result of the supercooling the devices must be activated in a deep freeze at -20°C(0°F).

The devices are highly reliable in their response. Figure 6 shows that all of a group of 21 devices responded between 13° and 13.8°C. However, the shelf life is poor in the presence of temperature fluctuations in the storage area. It was found that devices stored after activation in the frozen state retained their activity without prespotting for at least six months.

A group of 176 stored under fluctuating room conditions showed a failure of 71 or 40% after 14 days and 95 or 54% after 48 days.

5.3 Practical Tests

This device was originally designed specifically for monitoring blood bags. The blood bags are shipped in insulated ice filled containers. Attaching a device to a wet, cool, flexible blood bag is almost impossible with ordinary adhesive tape. One method we have found satisfactory is to attach a strip of double sided Scotch #463 Adhesive Transfer Tape to the empty blood bag while dry and at room temperature. Under these conditions the tape will adhere to the bag permanently. A similar piece of tape is attached to the back of each indicator. After the bag is chilled and filled and the device activated, the two pieces of tape will stick together provided the chilled blood bag is wiped clear of water.

Tests were conducted with four devices attached to a blood bag filled with water, the bags were placed in a controlled temperature water bath after filling with water and chilling in an ice bath. The temperature of the bath was allowed to warm about one degree per hour. The temperature increase was slow enough that a thermocouple placed inside the bag registered the same temperature as the water bath. The devices indicated as expected at 13°C to 14°C. There was enough heat trensfer between the liquid inside the bag and the bath to make both liquids thermally act as one at the slow warm up rate.

Table 3

Liquid Candidates for 13° Device

Liquid	MP Lit	MP Found	BP 760mm	Density (liq)	Remarks
Butyrophenone	11.5-13	11.5	228	0.988	Not enough change in volume
Ethyl Anthranilate	14.3	7.0	268	1.117	Used in devices
Hexadecane	17-18	17.2	287	0.773	Too high melting point
2-Undecanone	11-13	13	233	0.825	Will not stay in pills
P-Xylene	13-26	13	138.35	0.854	Too high vapor pressure

6. GENERAL CONCLUSIONS

Devices have been designed, built and tested which indicate reliably and irreversibly at temperatures of 7°, 10° and 13°C.

When stored in the unactivated state the shelf life is poor, and hence storage in the activated state is preferable where possible.

Means for attaching the 13° device to chilled blood bags have been found.

7. FUTURE WORK

To render the device more practical fabrication procedures requiring less labor must be developed. Redesign, including elimination of the glass enclosure appears feasible. The glass envelope serves to retard loss of liquid by evaporation and stabilizes volume changes due to short period temperature fluctuations. Storage in the frozen state would prevent escape thru the joints in the capsules, and the vapor pressure of the cold solid would be too low for significant evaporation. Elimination of the glass enclosure might reduce the cost, particularly the labor by a factor by as much as ten.

The major problem with storing the devices in a freezer is the danger of accidental thawing, either in shipment, neglect, or power failure. This danger can be reduced by storage in insulated containers. An ideal configurational concept would be to include in the container some phase change heat storage material. With proper design and selection of materials, a temperature of -10°C, for example, could be maintained for several days, independently of the ambient temperature.

In many situations the low temperature required for activation may be undesirable. In the case of the 7° device, the activation temperature was raised from below -5°C to about 3°c. by adding graphite as a nucleating agent. The demethyl adipate used in the devices can be activated at about 2°C., but the ethyl anthranilate in the 13°C device supercools to as low as -20°C. An effort should be made to find a suitable nucleating agent for these materials.

Studies of the type described in section 4.3 relating the location of the device on or in various packages and materials to the condition of the contents are necessary for practical applications involving monitoring of storage and shipment of prescribable materials.

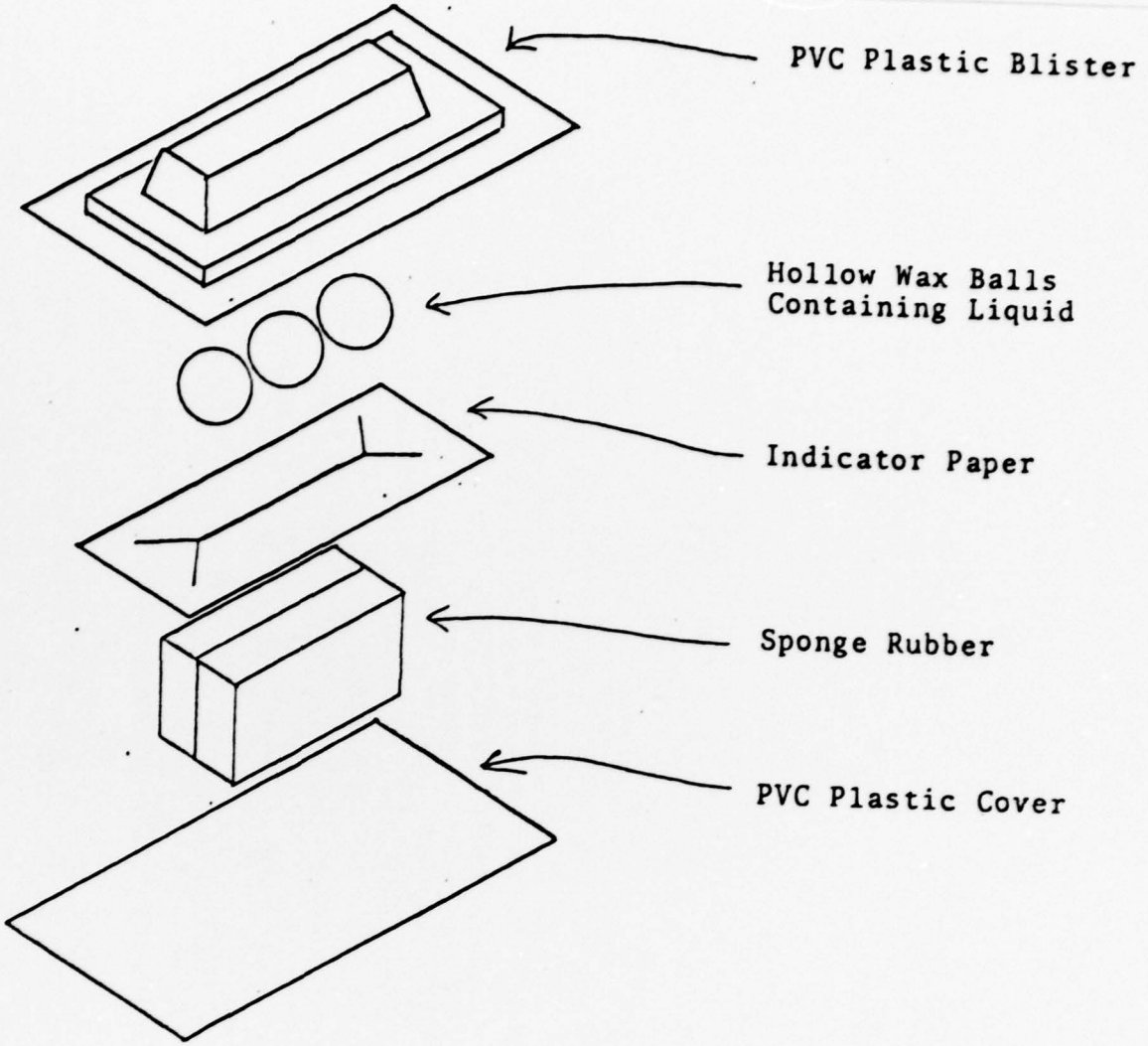


Figure 1
IWI(R) for Use Below 0°C

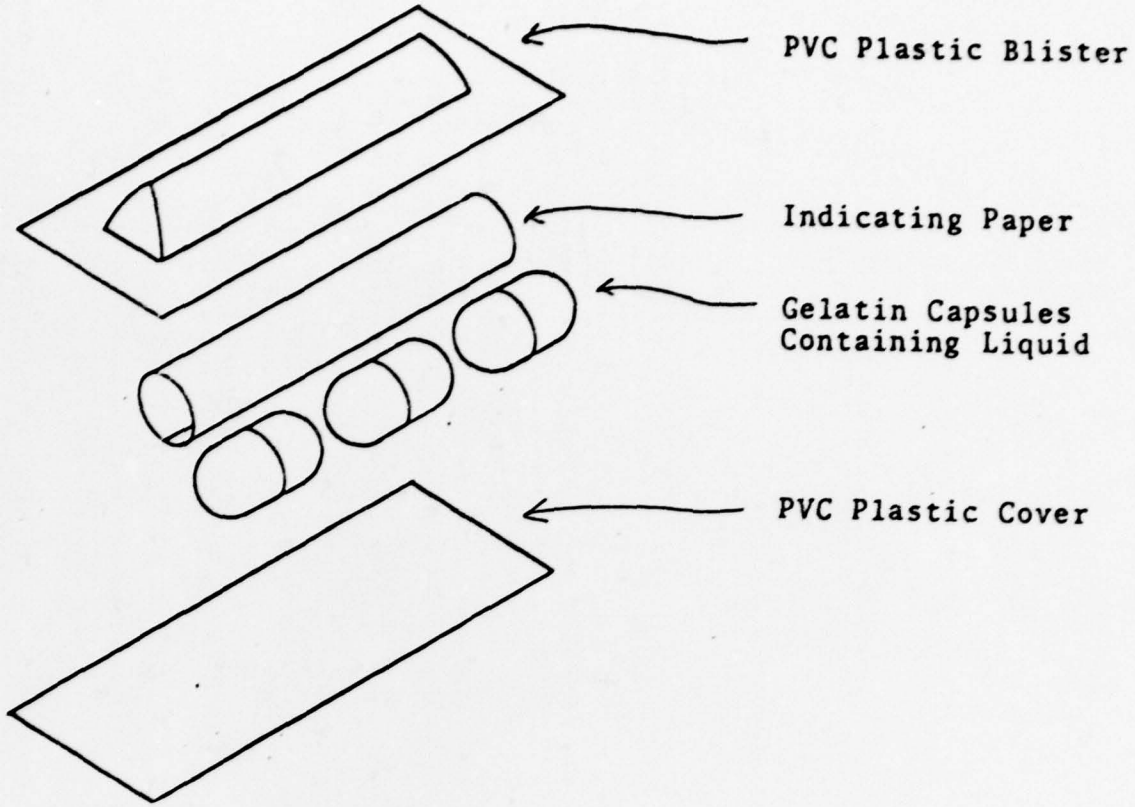


Figure 2

Plastic Device

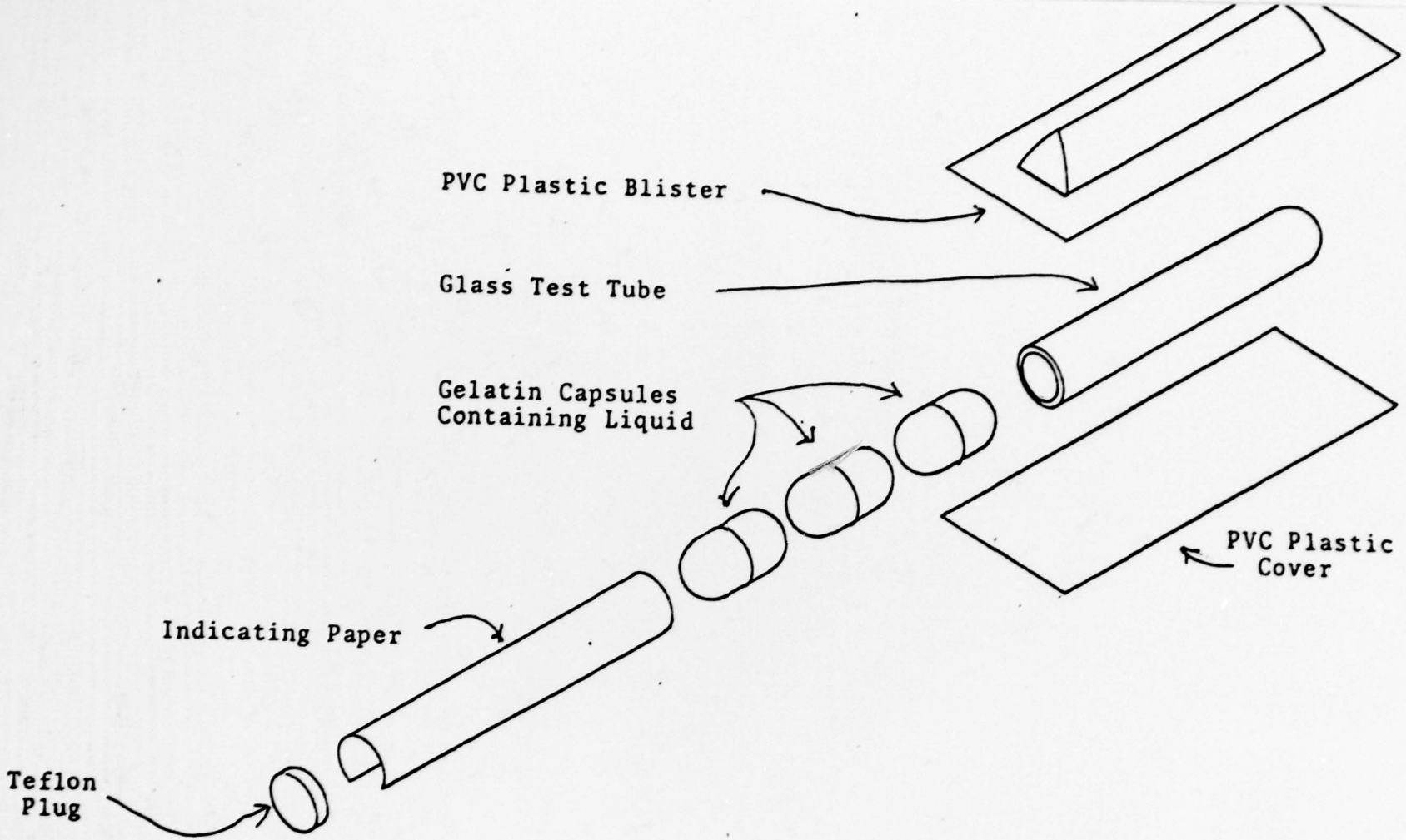


Figure 3

Glass Device

FIGURE 4

REDUCTION IN SUPERCOOLING OF ETHYL CINNAMATE CAUSED BY TRACE OF GRAPHITE

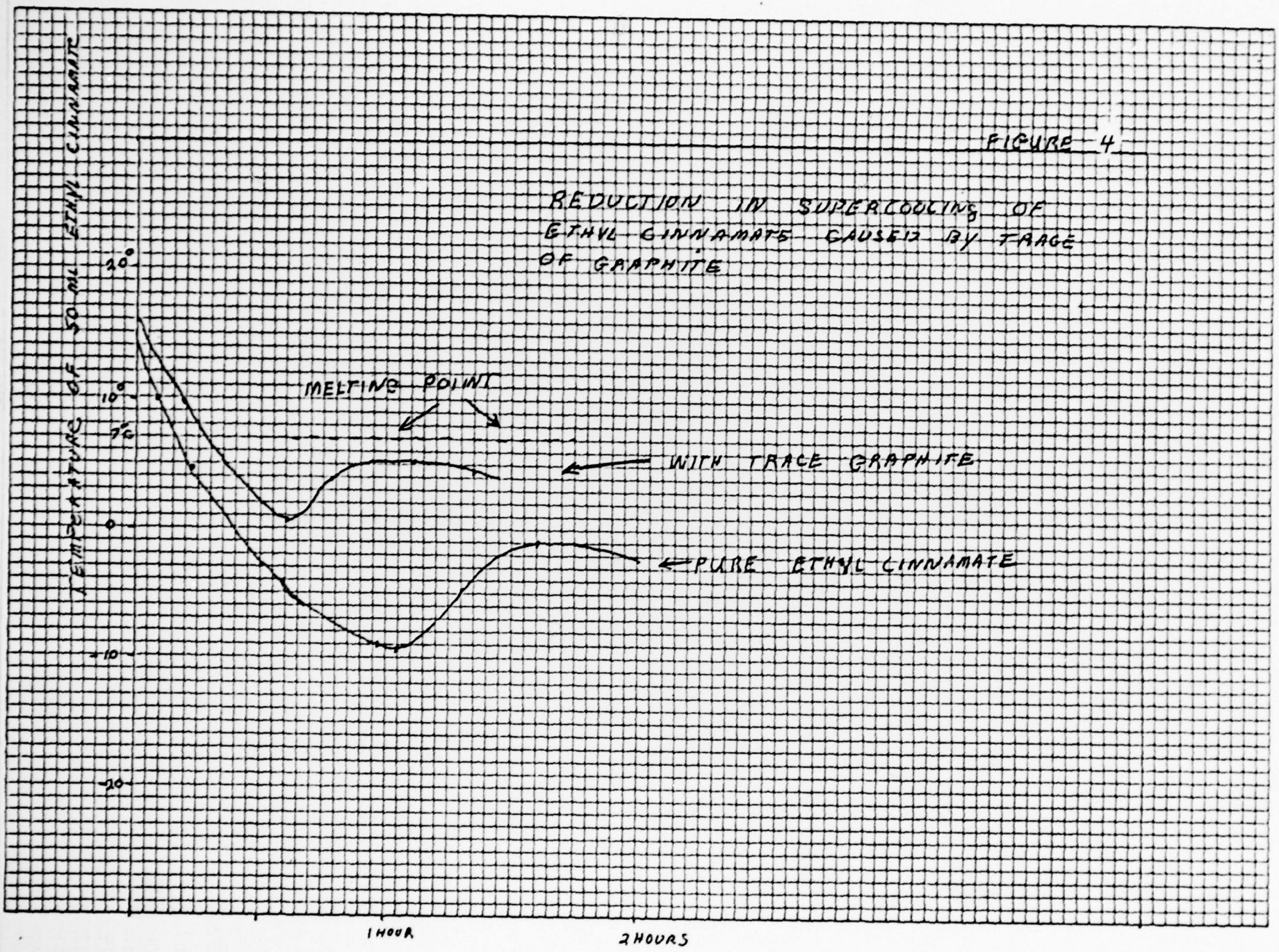


FIGURE 5

ETHYL CINNAMATE

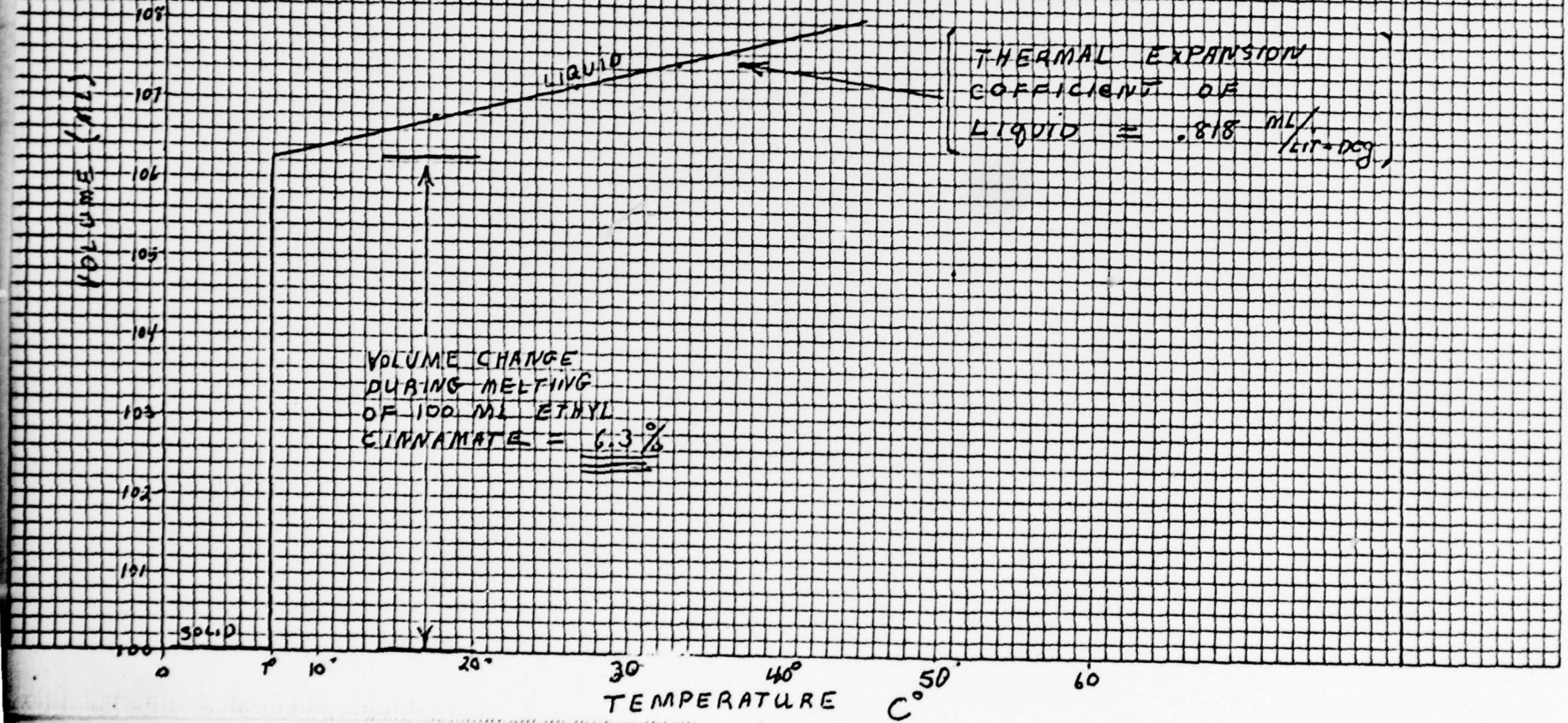
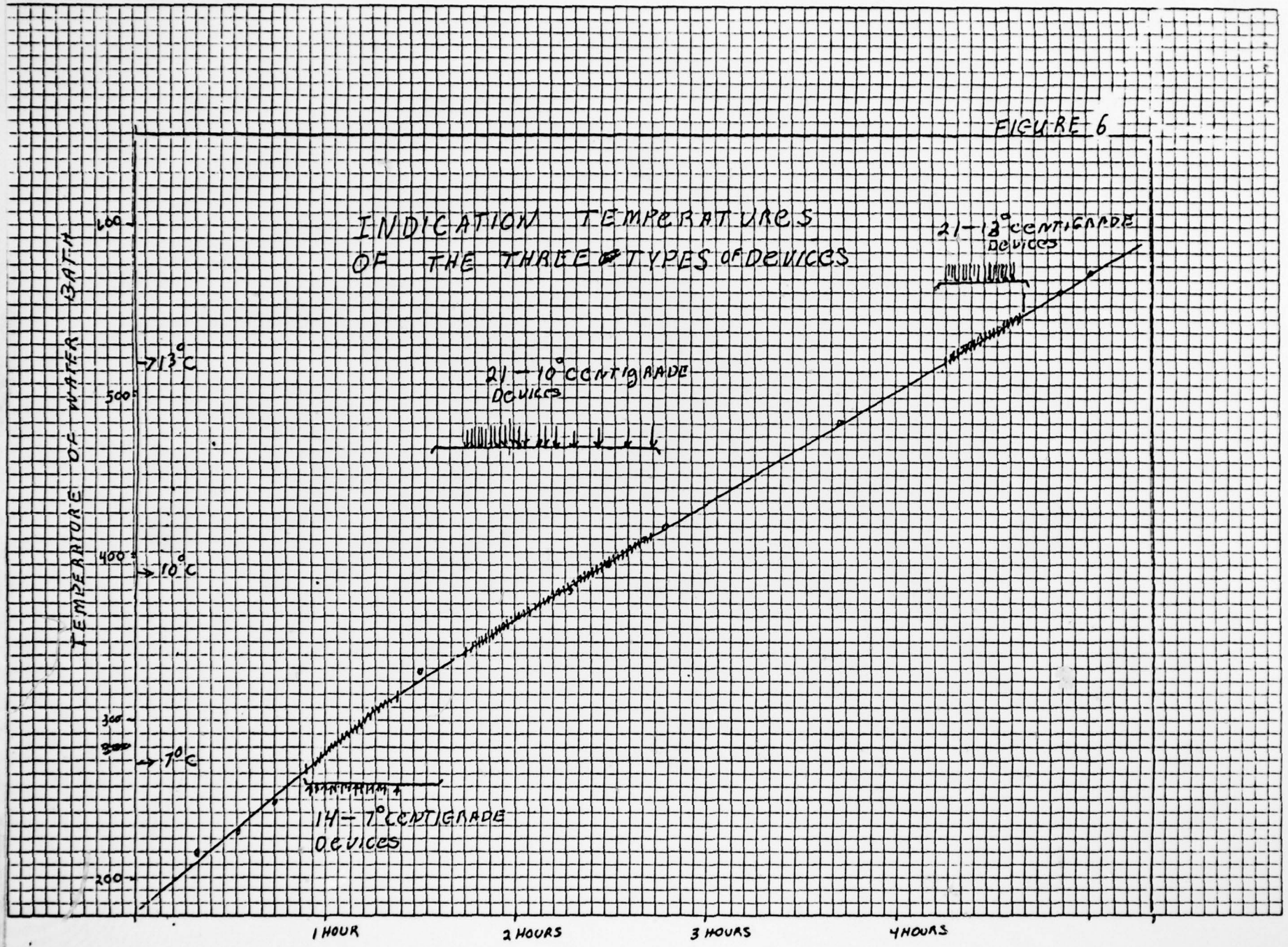


FIGURE 6


INDICATION TEMPERATURES
OF THE THREE TYPES OF DEVICES
TEMPERATURE OF WATER BATH
600
500
400
300
200
13°C
10°C
7°C
21 — 13° CENTIGRADE DEVICES
21 — 10° CENTIGRADE DEVICES
14 — 7° CENTIGRADE DEVICES
1 HOUR
2 HOURS
3 HOURS
4 HOURS

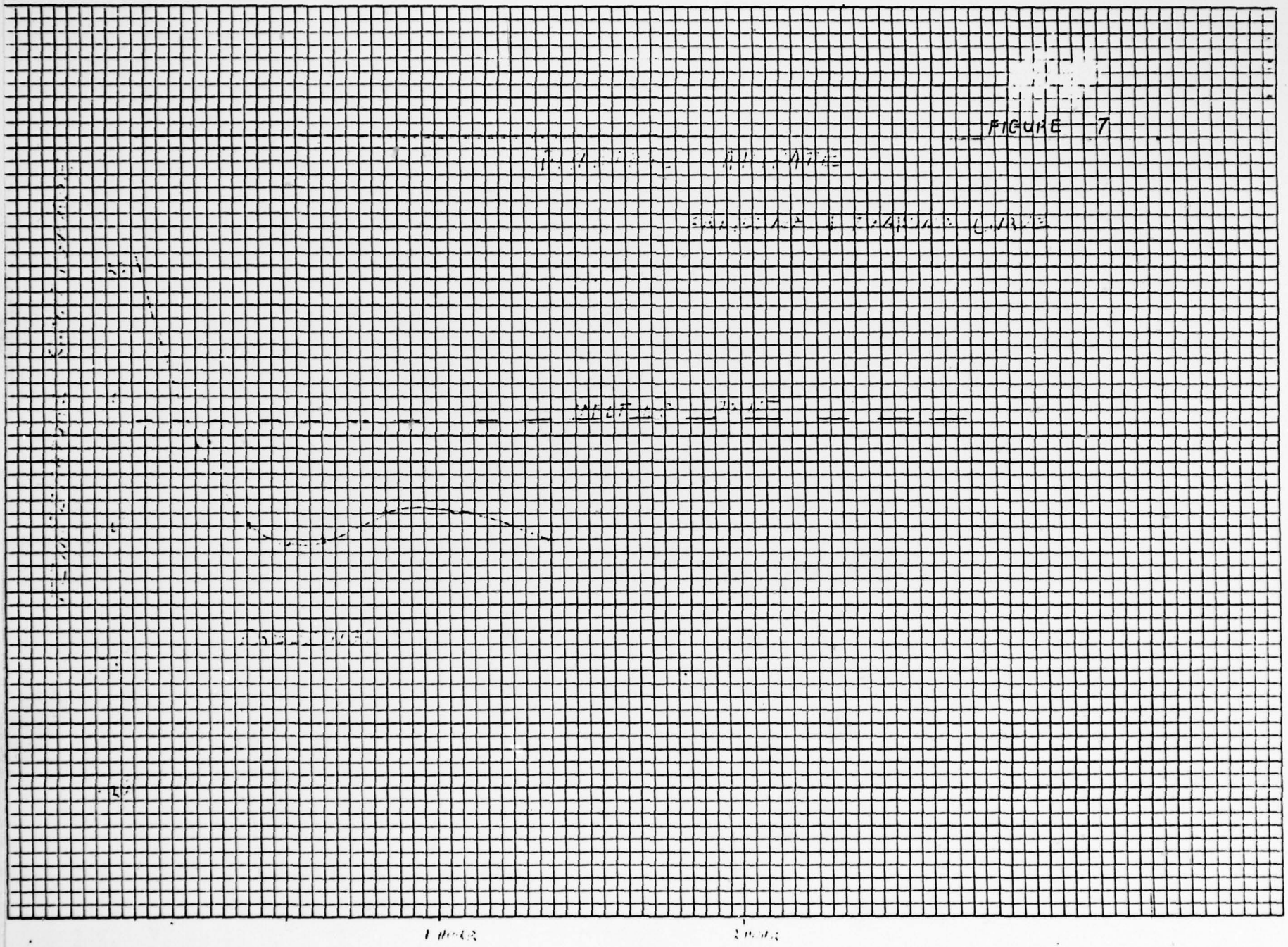


FIGURE 7
TIME

FIGURE 8.

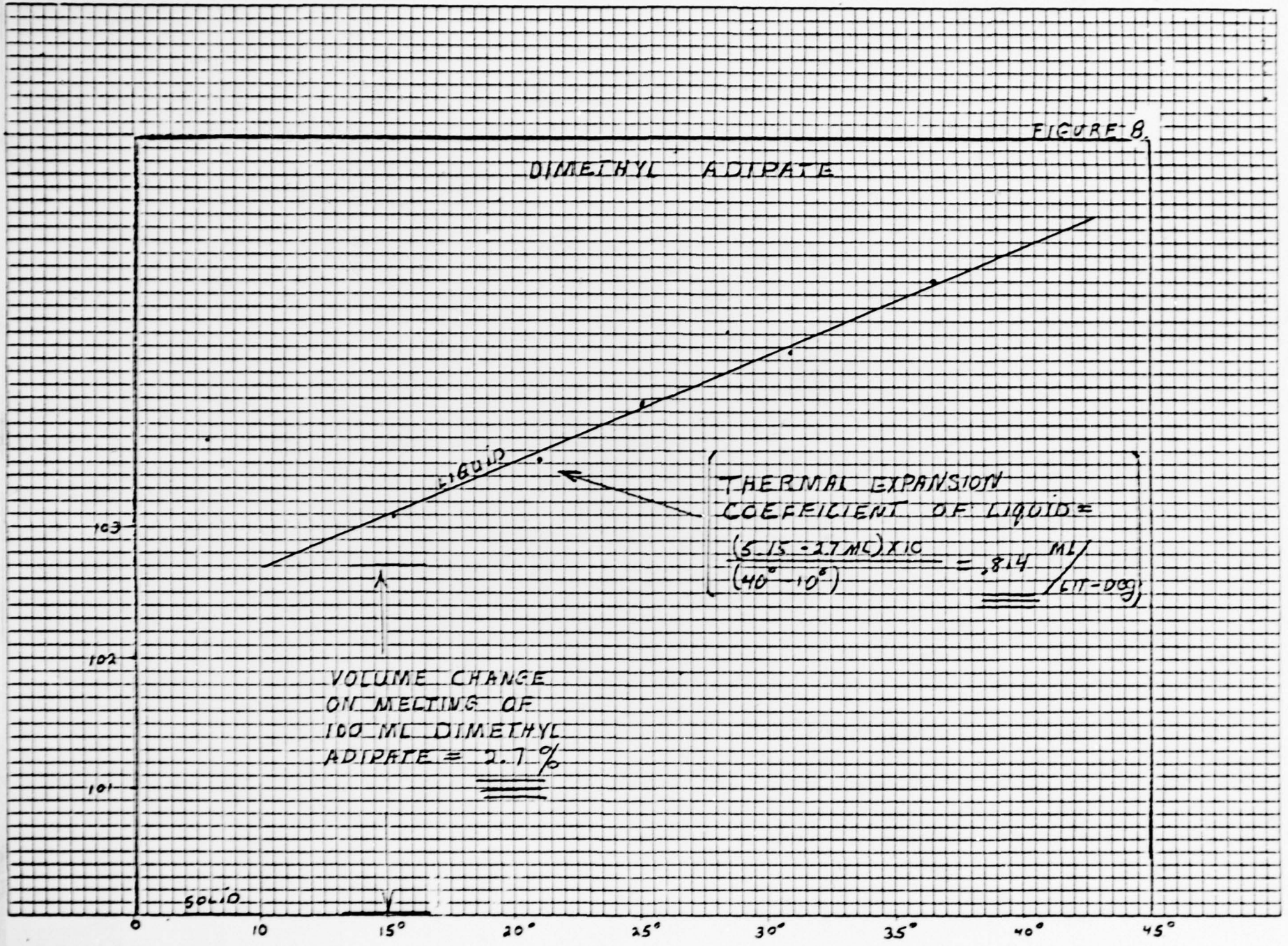

DIMETHYL ADIPATE
LIQUID
THERMAL EXPANSION COEFFICIENT OF LIQUID =
(5.15 - 2.7 ML) X 10 / (40° - 10°) = .814 ML / (LIT - DEG)
103
102
101
VOLUME CHANGE ON MELTING OF 100 ML DIMETHYL ADIPATE = 2.7 %
SOLID
0
10
15°
20°
25°
30°
35°
40°
45°

FIGURE 9

PRACTICAL TEST
OF 10°C DEVICE

TEMPERATURE

600
13°C → 500
400
10°C →
300
7°C →
200
100

OUTSIDE AIR TEMPERATURE

INSIDE CHEESE TEMPERATURE

INDICATION TIME →

3 4 6 11 12 14 13 1 5 7 8 10 2 9 15

0 1 2 3 4 5 6

HOURS

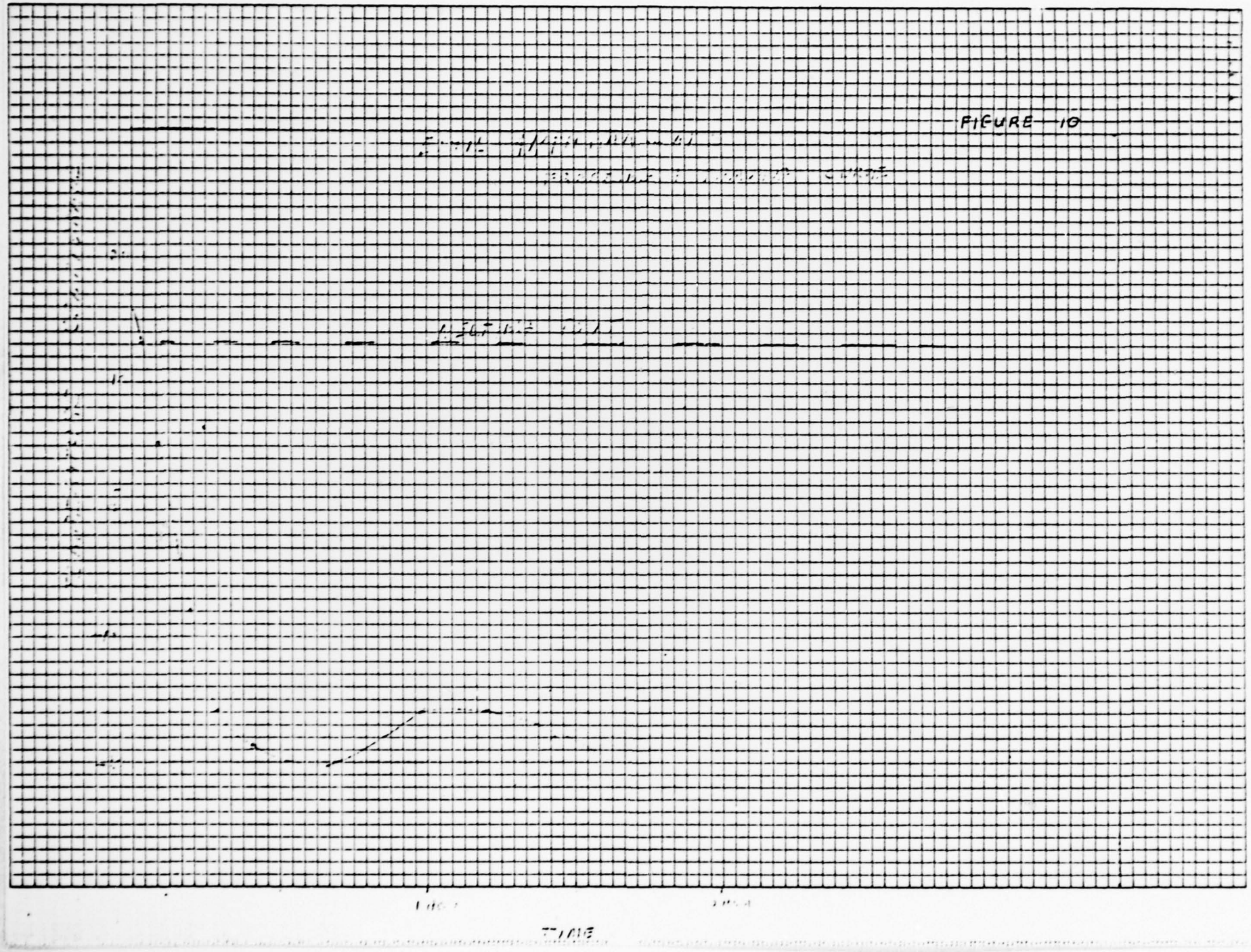
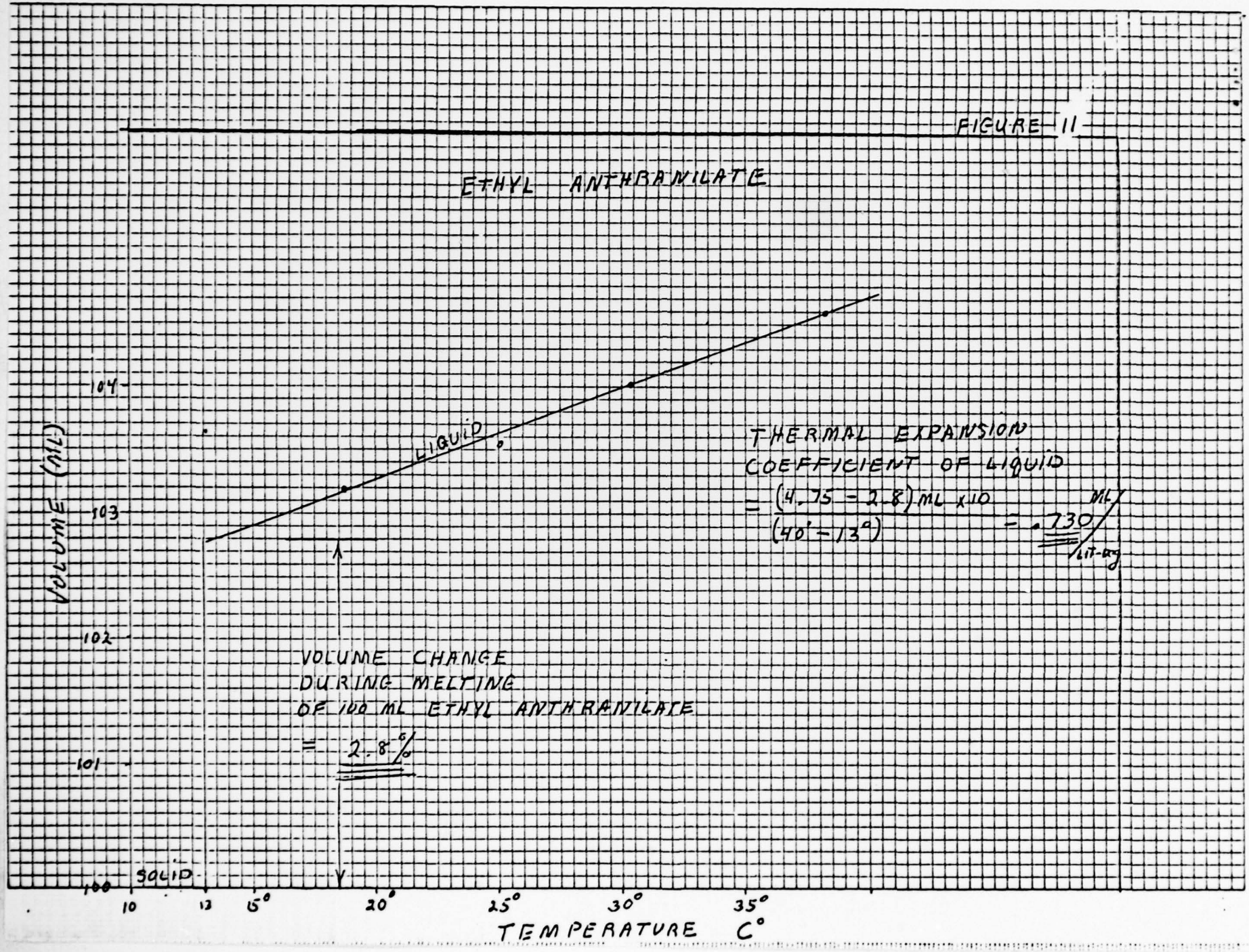


FIGURE 10
TIME

FIGURE 11


ETHYL ANTHRANILATE
LIQUID
VOLUME (ML)
104
103
102
101
100
SOLID
10
12
15°
20°
25°
30°
35°
TEMPERATURE C°
VOLUME CHANGE
DURING MELTING
OF 100 ML ETHYL ANTHRANILATE
= 2.8%
THERMAL EXPANSION
COEFFICIENT OF LIQUID
= (4.75 - 2.8) ML x 10 / (40° - 13°) = .730 ML/LIT-deg

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