(b)(4) 3rd party manufacturers

K843146

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

AUG 17 1984

Mr. Mark J. Buch
President
Seabrook Medical Systems, Inc.
673 Wilmer Avenue
Cincinnati, Ohio 45226

Re: K843146
MICRO-TEMP™ Pumps and MICRO-TEMP Pads

Dated: July 31, 1984
Received: August 10, 1984
Regulatory Class: II

Dear Mr. Buch:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). This device has been placed into the regulatory class shown above, by a final regulation published in the Federal Register. All classes of devices are regulated by the general controls provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices must also meet present or future performance standards; class III devices will be required to undergo premarket approval at some time in the future. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Robert G Britain

Robert G. Britain
Director
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date: August 14, 1984

From: REVIEWER(S) - NAME(S) Ivana R. Williams

Subject: 510(k) NOTIFICATION K843146

To: THE RECORD

It is my recommendation that the subject 510(k) Notification:

_✓_ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

_____ (C) Requires more data.

_____ (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

Subs equiv to
Pack, Hot or Cold, Water Circulating
Class II

The submitter requests:

_____ No Confidentiality

_____ Confidentiality for 90 days

_X_ Continued Confidentiality exceeding 90 days

Class Code w/Panel: 89 ILO

REVIEW: _____ 8/15/84
(BRANCH CHIEF) (DATE)

FINAL REVIEW: Carl A. Larson 8/15/84
(DIVISION DIRECTOR) (DATE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

D.C. Number : K843146
Received : 8/10/84
Product : MICRO-TEMP™ Pumps and MICRO-TEMP Pads

Seabrook Medical Systems, Incorporation
Attn: Mark J. Buch
673 Wilmer Avenue
Cincinnati, OH 45226

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the above referenced device has been received and assigned a unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing your device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-7230.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

K843146

Seabrook Medical Systems, Inc.
673 Wilmer Avenue
Cincinnati, Ohio 45226
July 31, 1984

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Springs, Maryland 20910

"510(k) Notification"

Gentlemen:

We are a newly formed company which will be manufacturing and distributing medical devices. On July 20, I personally registered Seabrook Medical Systems, Inc. with the Food and Drug Administration, receiving assistance from Ms. Lynne Rice. We have not as yet received a registration number, as I was told it would take about 30 days.

Our first product system consists of heat therapy pumps and pads, which are substantially equivalent to devices introduced into interstate commerce by American Medical Systems (formerly Gorman-Rupp) and Gaymar Industries prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please consider this letter our Premarket Notification or 510(k) submission. The tradename of our products will be MICRO-TEMP™ Pumps and MICRO-TEMP Pads.

The system performs the same function (localized heating or cooling) as those of our competitors. For your review, we have enclosed two copies of the exterior view of the pumps (one analog version and the other digital, microprocessor based), and two 8 x 10 glossy photos of the pads. We have not finalized our product brochure or journal ad as yet. Nor do we have finished labels or labeling for the products. However, we do have final copy for those materials, which is being submitted to the printer this week. For your convenience in evaluating the similarity of our products, we are also enclosing copies of competitive literature.

We would appreciate FDA holding this Premarket Notification confidential until we begin commercial distribution. Our intent to market the devices has not been disclosed to scientists, market analysts, exporters, or the like. We have taken all possible precautions to protect the confidentiality of our intent to market the devices. We understand that submission of false information in response to these requirements is prohibited by federal law. When we disclose our intent to market to others outside the company, we will immediately notify FDA.

Thank you for your prompt attention to this matter.

Sincerely

Mark J. Buch

Mark J. Buch
President

Seabrook Medical Systems, Inc.
673 Wilmer Avenue
Cincinnati, Ohio 45226
July 31, 1984

Food and Drug Administration
Center for Devices and Radiological Health
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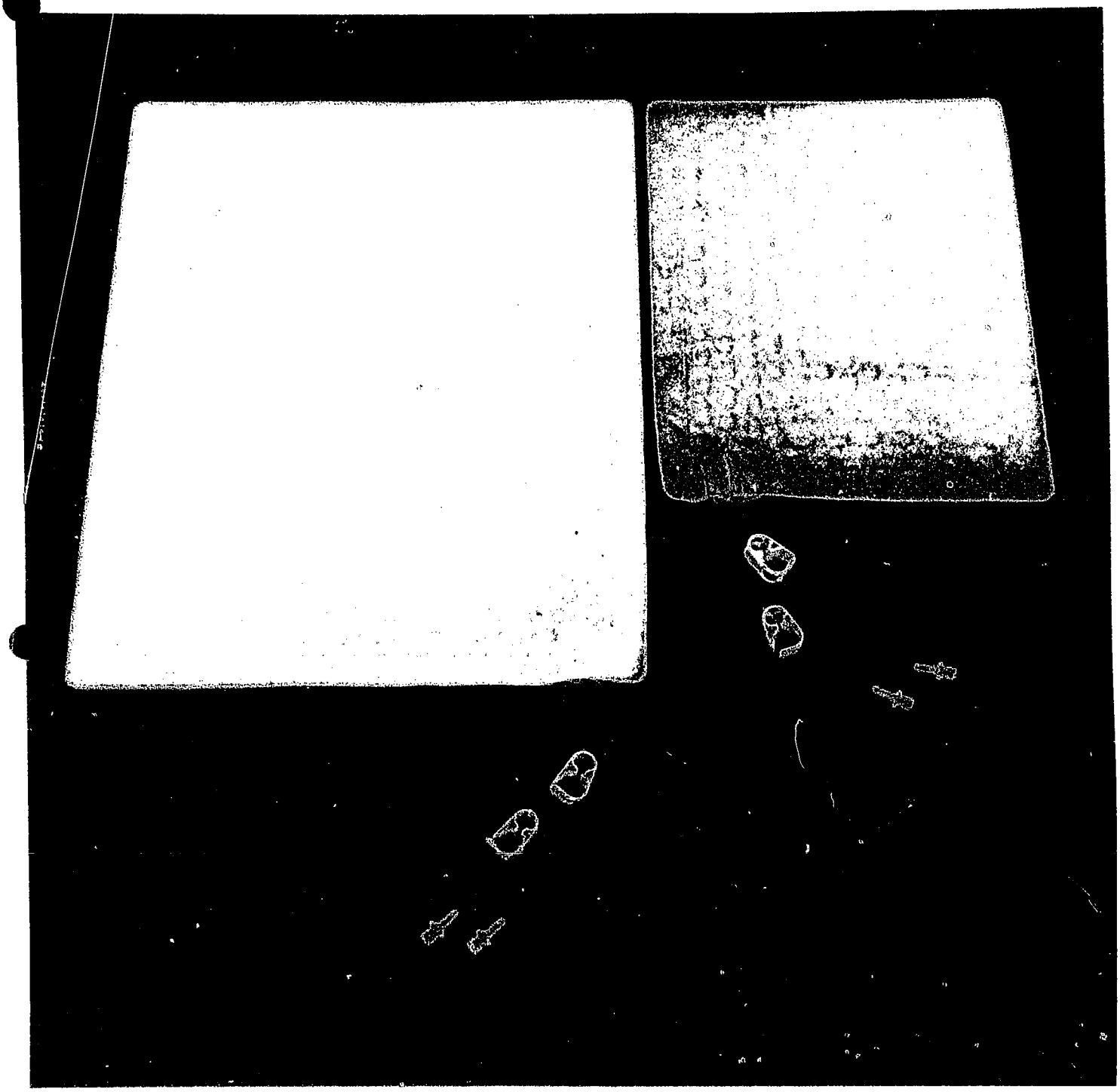

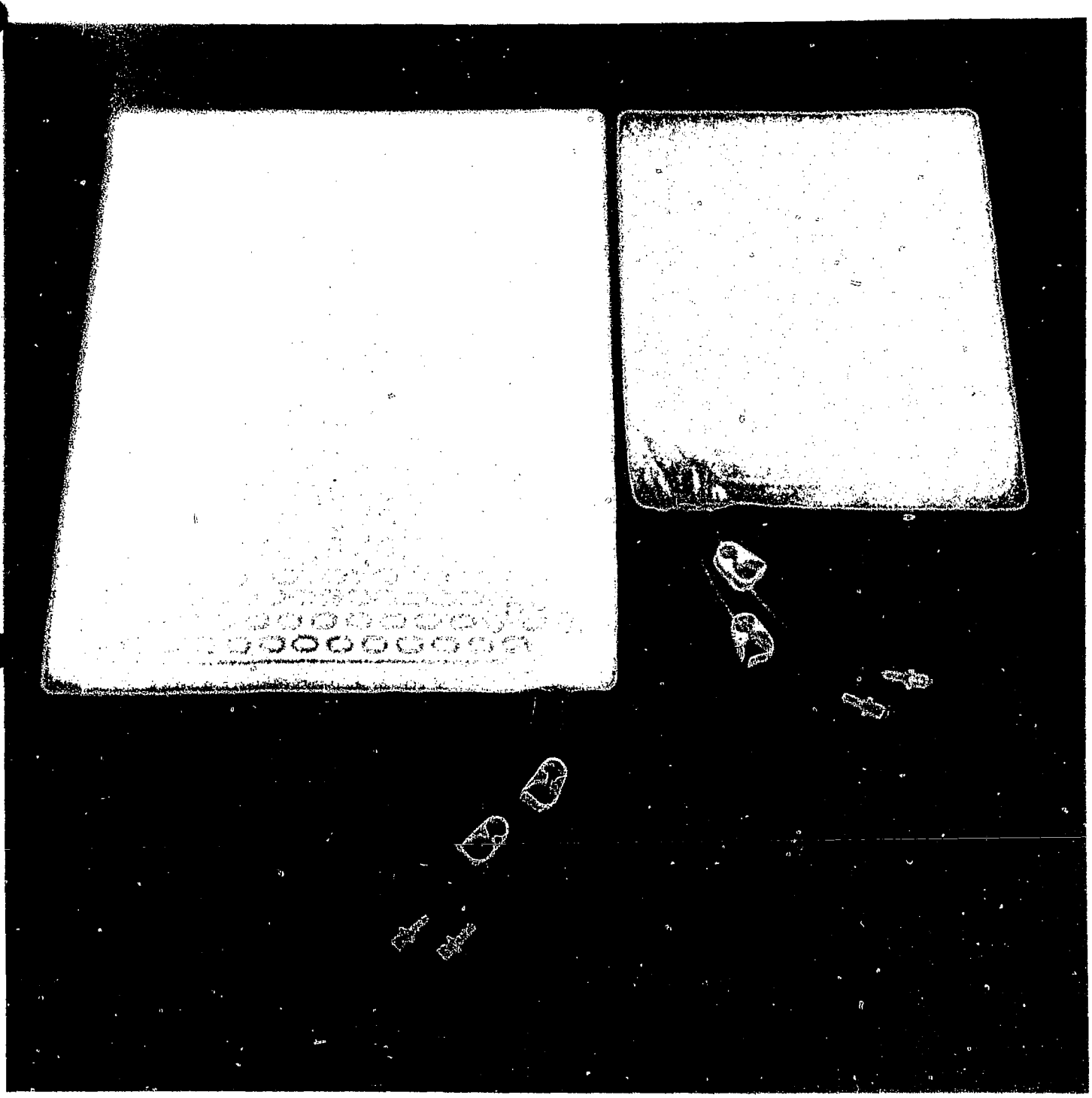

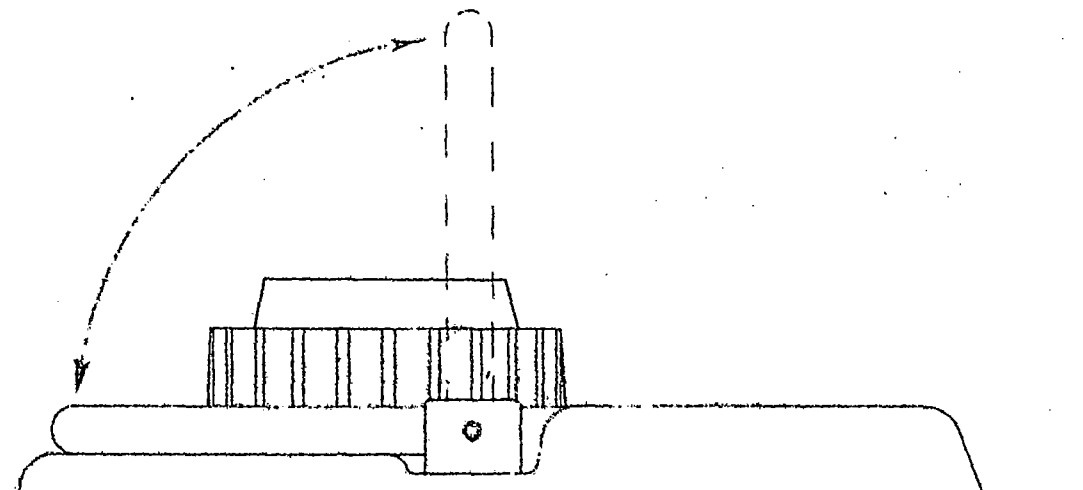

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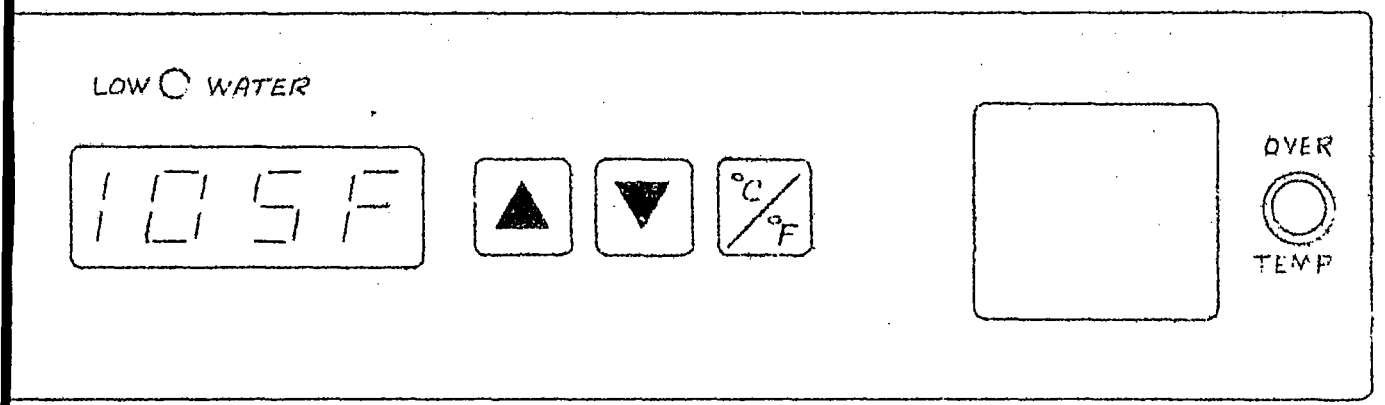
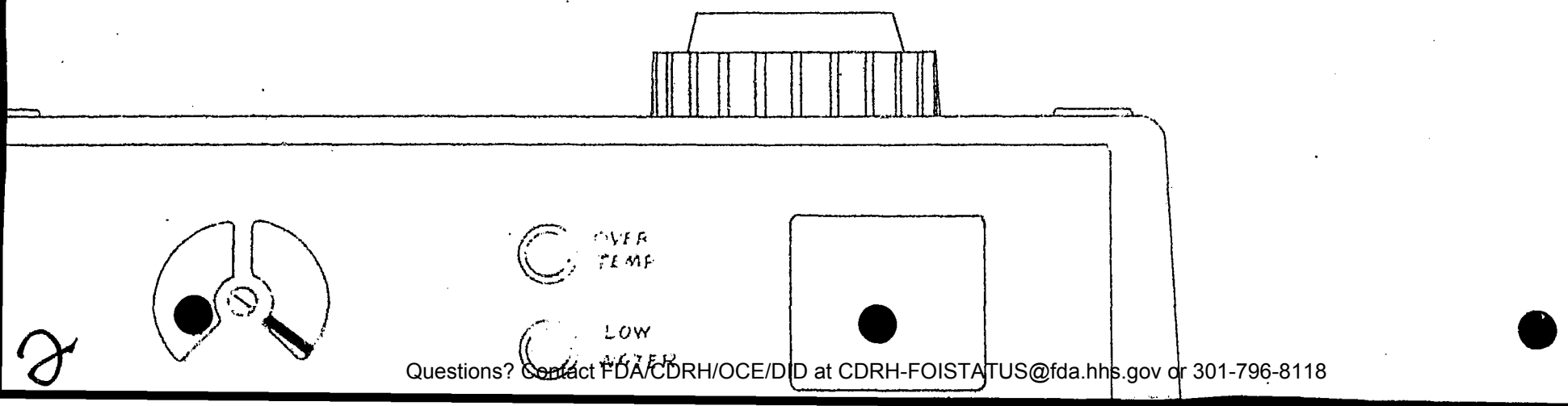
ITEM	PART NO.	QTY.	DESCRIPTION





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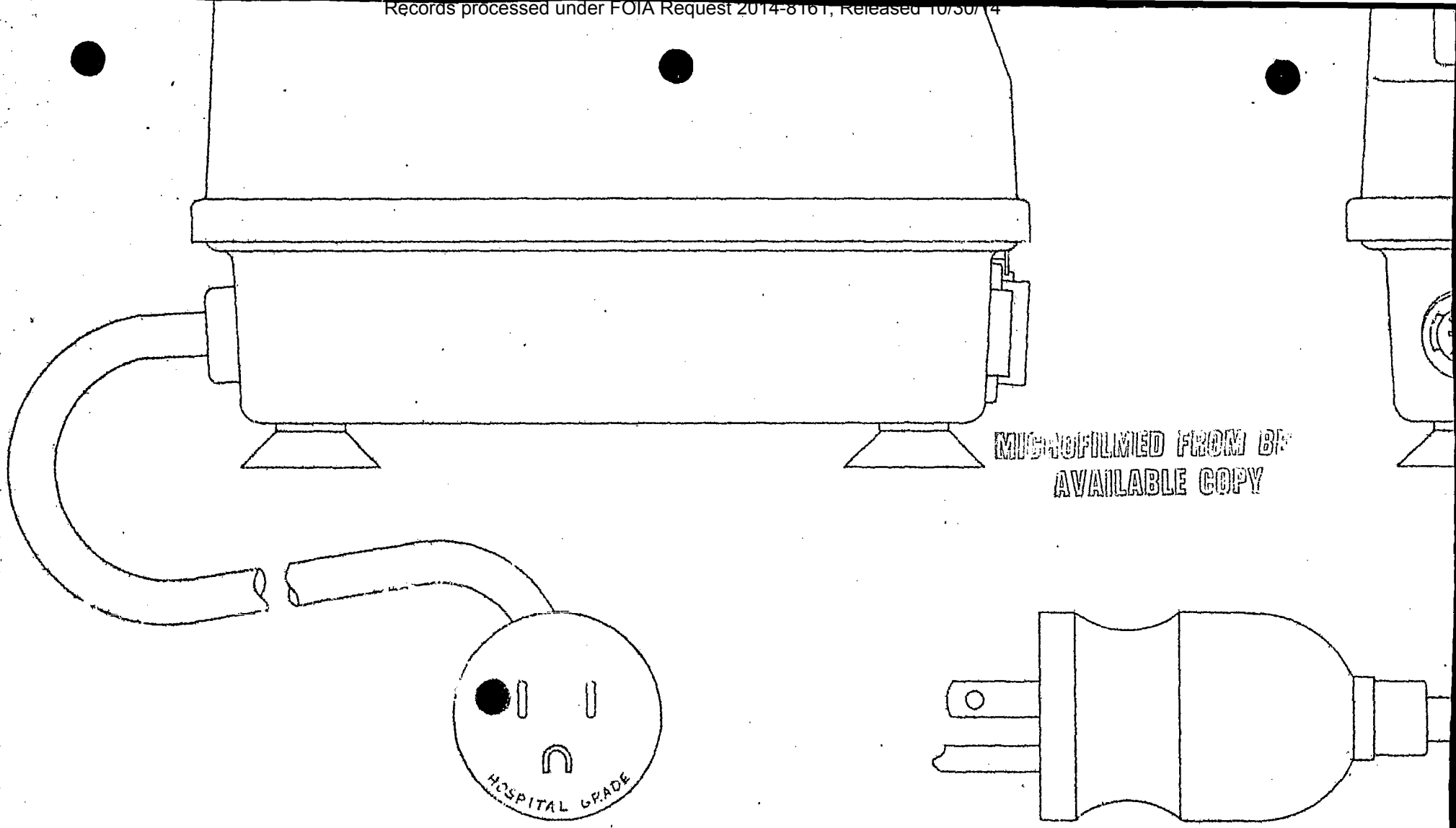

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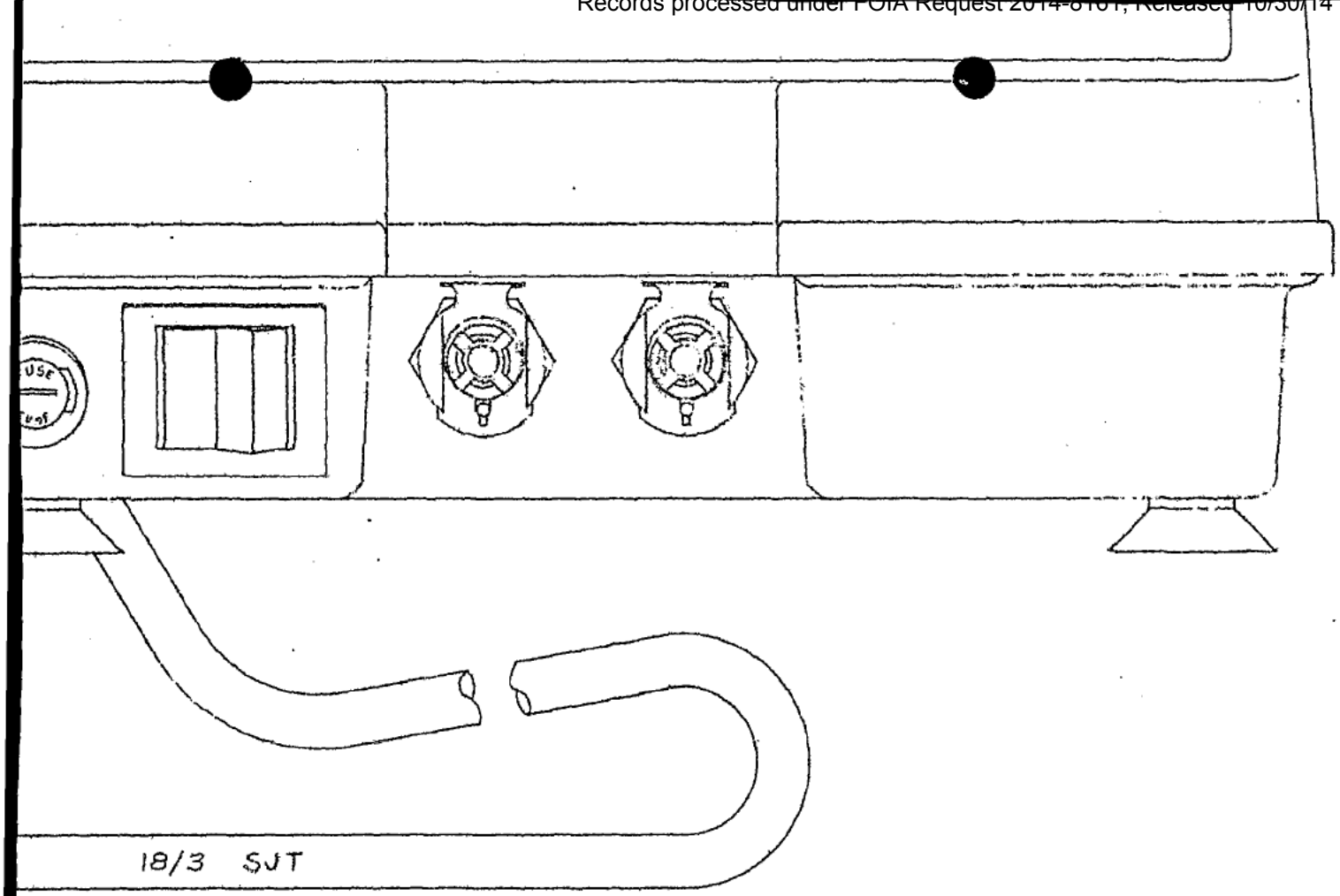


18/3 SJT

TOLERANCE
UNLESS OTHERWISE SPECIFIED

(b)(4) [redacted]

ANGLES ±

DRAWN BY (b) (6) [redacted]

APPROVED BY

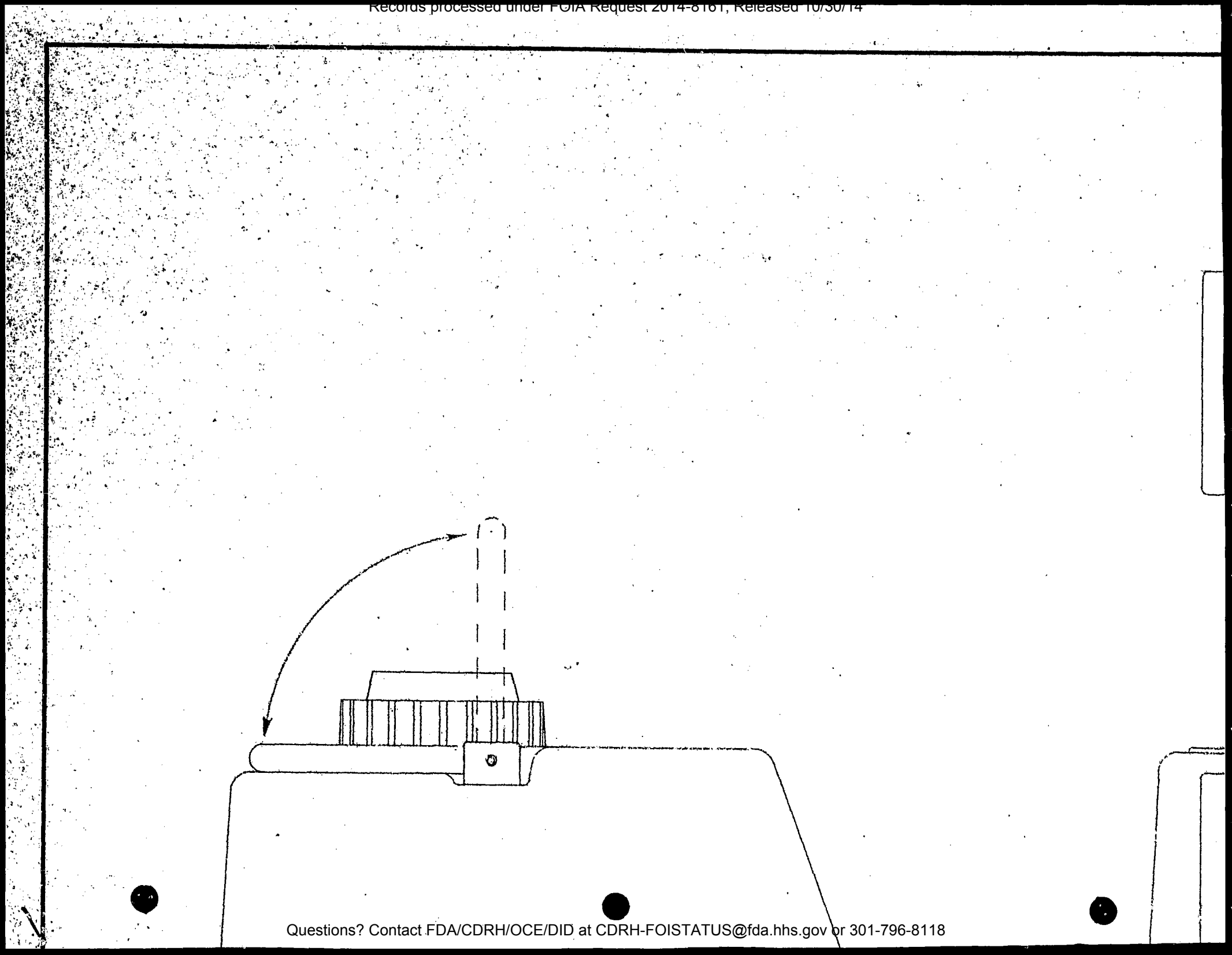
Seabrook Medical Systems Inc.

TITLE HEAT THERAPY PUMP

SCALE FULL	CODE
DATE 7-24-84	NEXT LEVEL

STATUS	DRAWING NO.	SHEET OF

4



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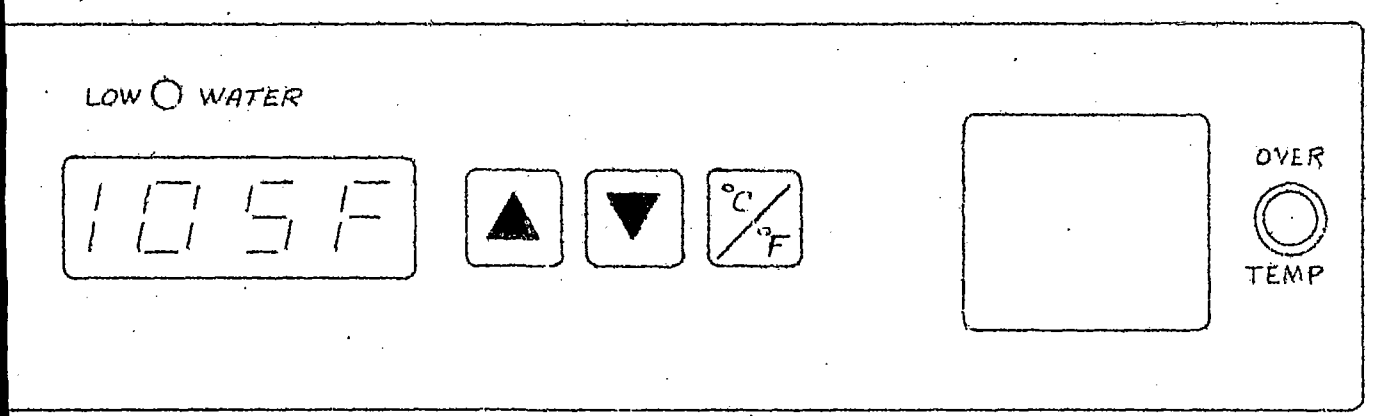

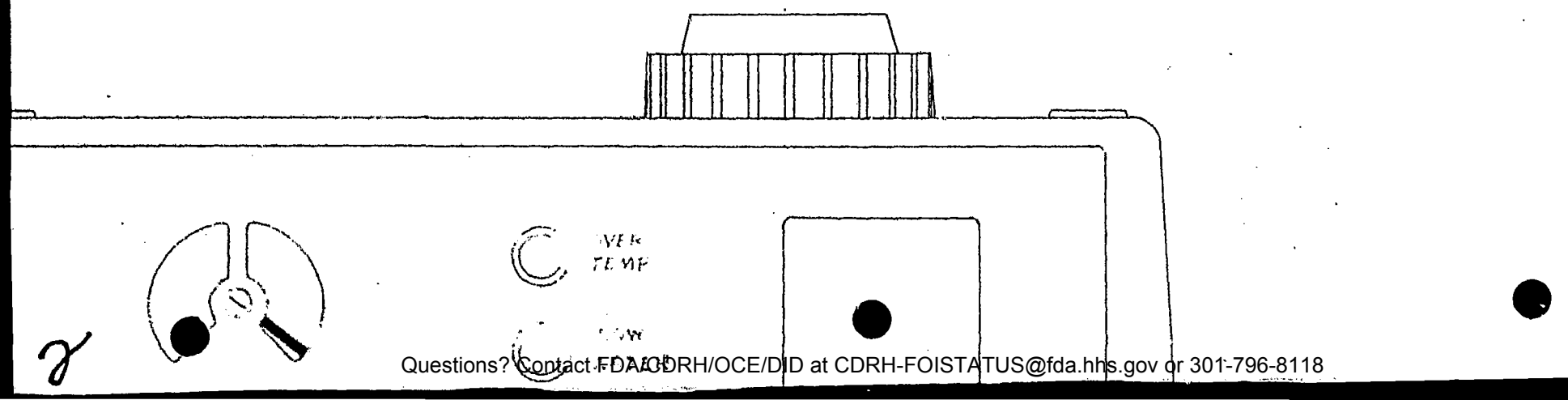

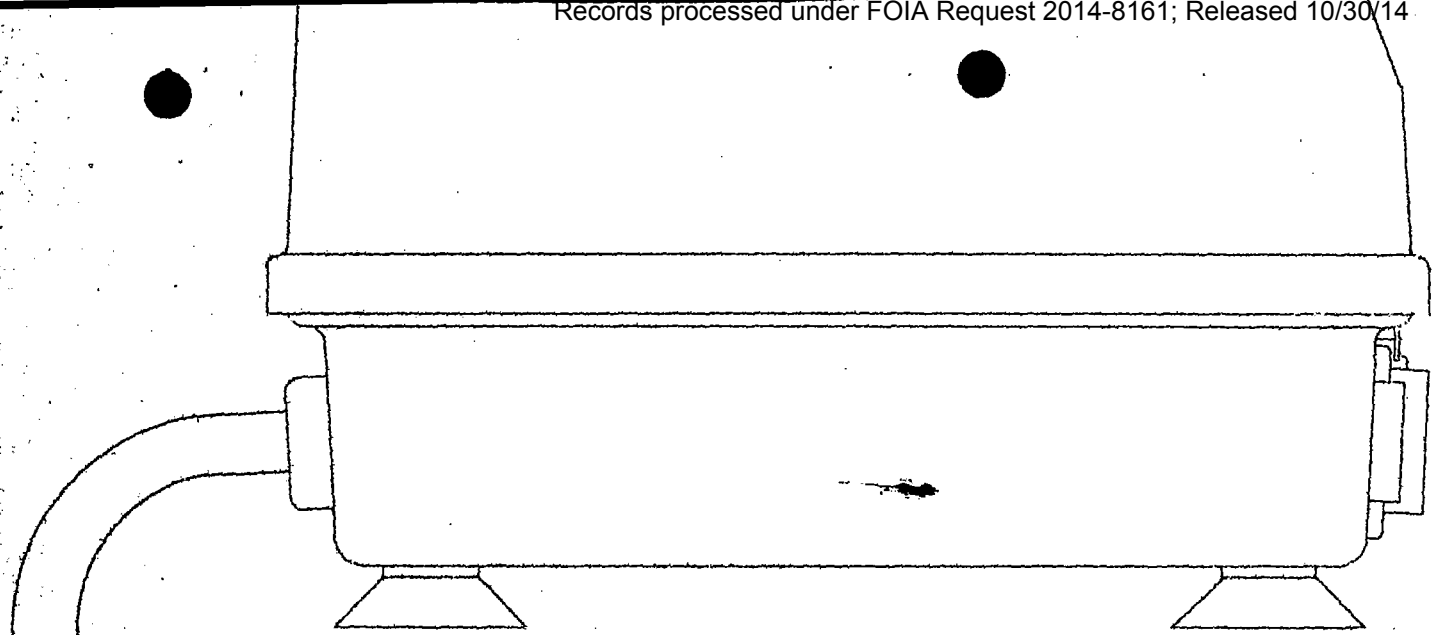

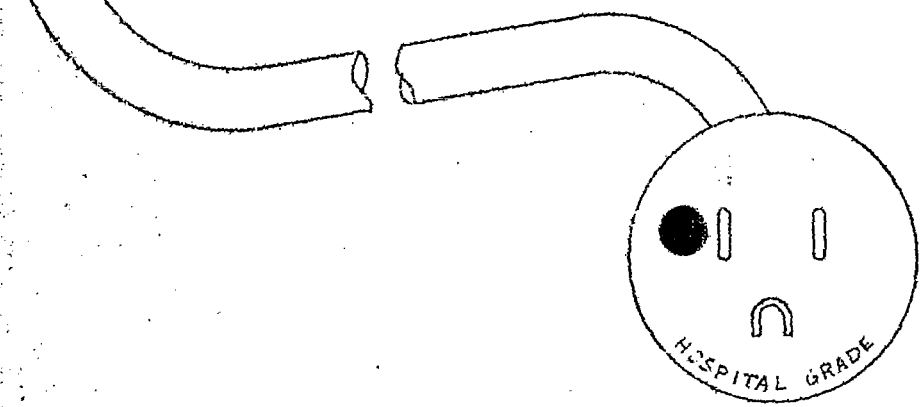

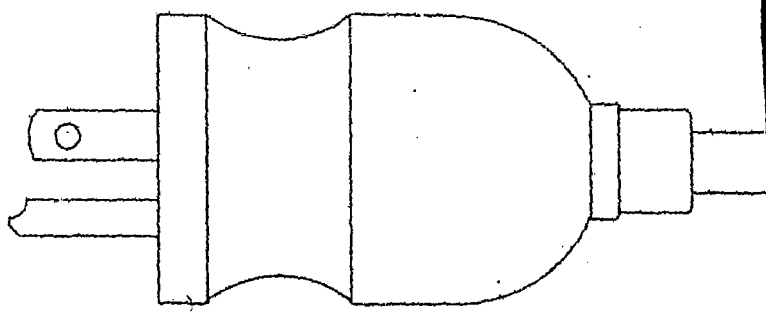

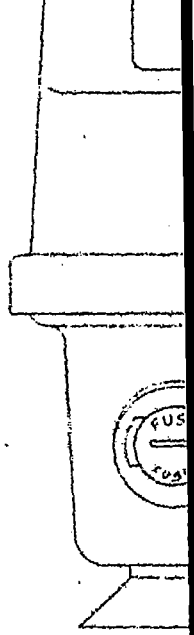

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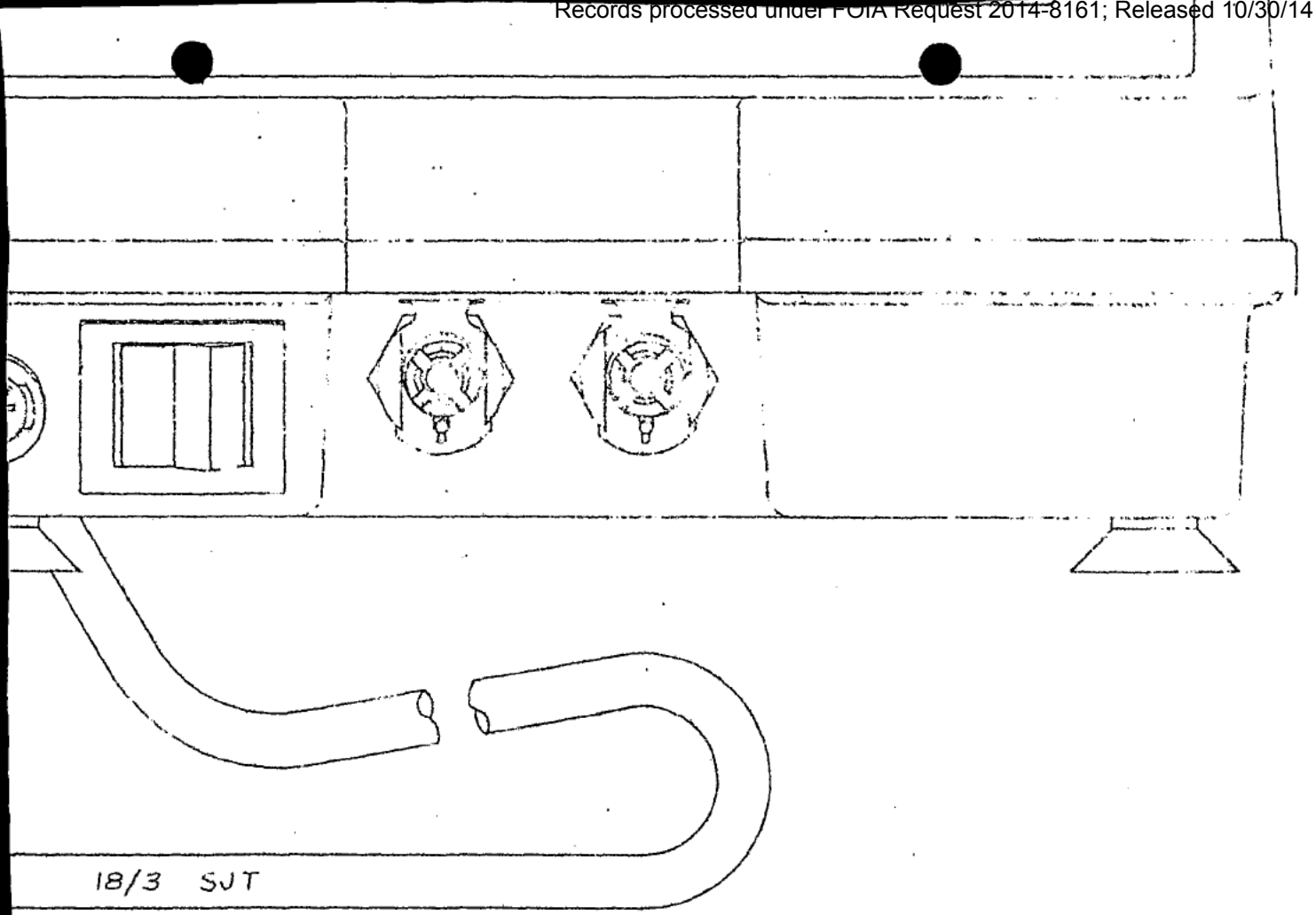

CONFIDENTIAL PROPERTY

This document and any accompanying data pertaining thereto, is the property of Seabrook Medical Systems, Inc. It contains confidential information, and is regarded as unpublished manuscript. This material shall be used by the recipient only for the purpose intended as indicated by stamping or accompanying document of transmittal. It shall not be duplicated, revealed, sold or shared with others without the written permission of Seabrook Medical Systems, Inc. All rights of design and invention are reserved.

TOLERANCE
UNLESS OTHERWISE SPECIFIED

(b)(4) [redacted]

ANGLES ±

DRAWN BY (b) (6) [redacted]

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TITLE HEAT THERAPY PUMP		
SCALE FULL		CODE
DATE 7-24-84		NEXT LEVEL
STATUS	DRAWING NO.	SHEET OF

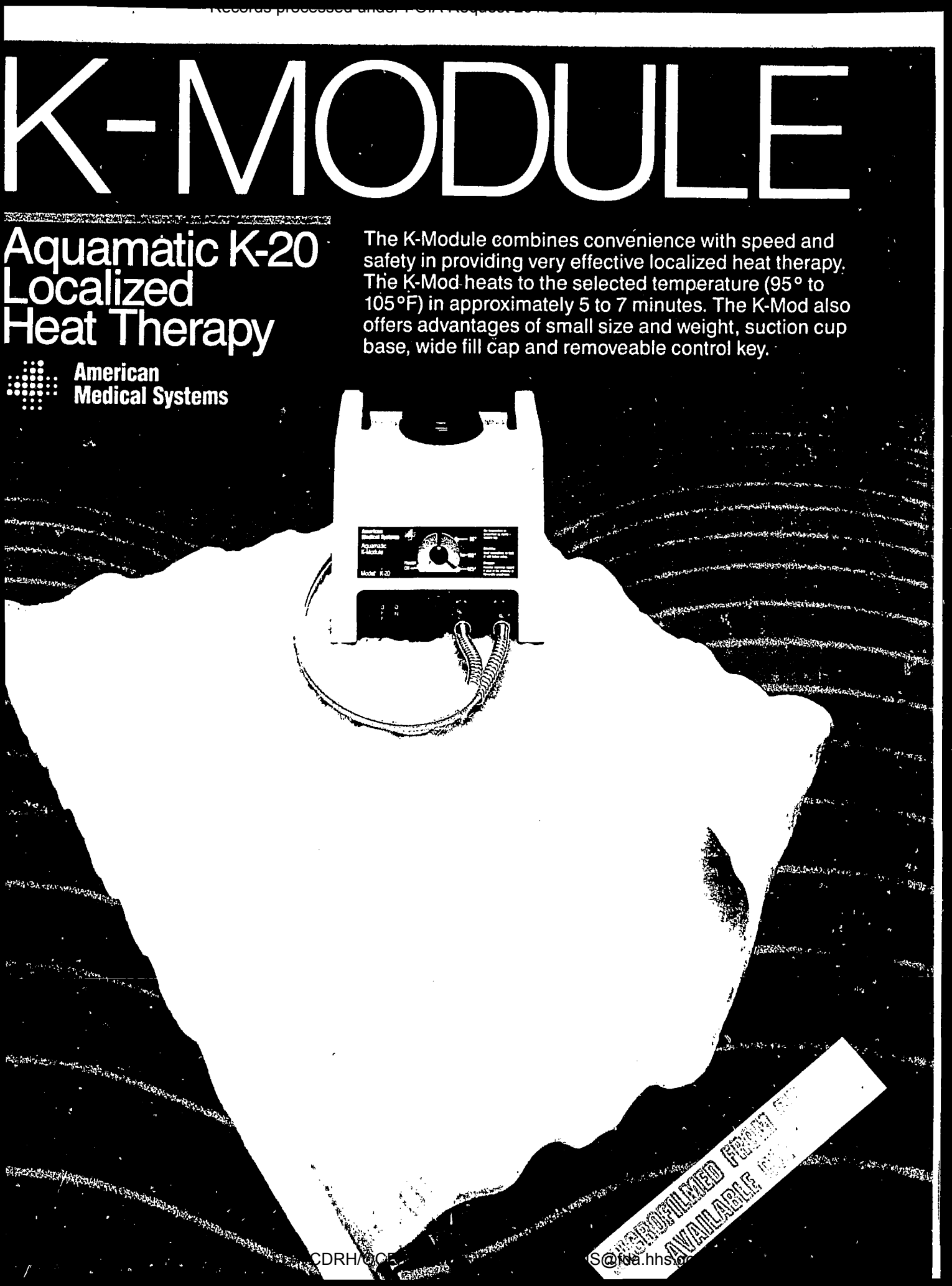
4

K-MODULE

Aquamatic K-20 Localized Heat Therapy

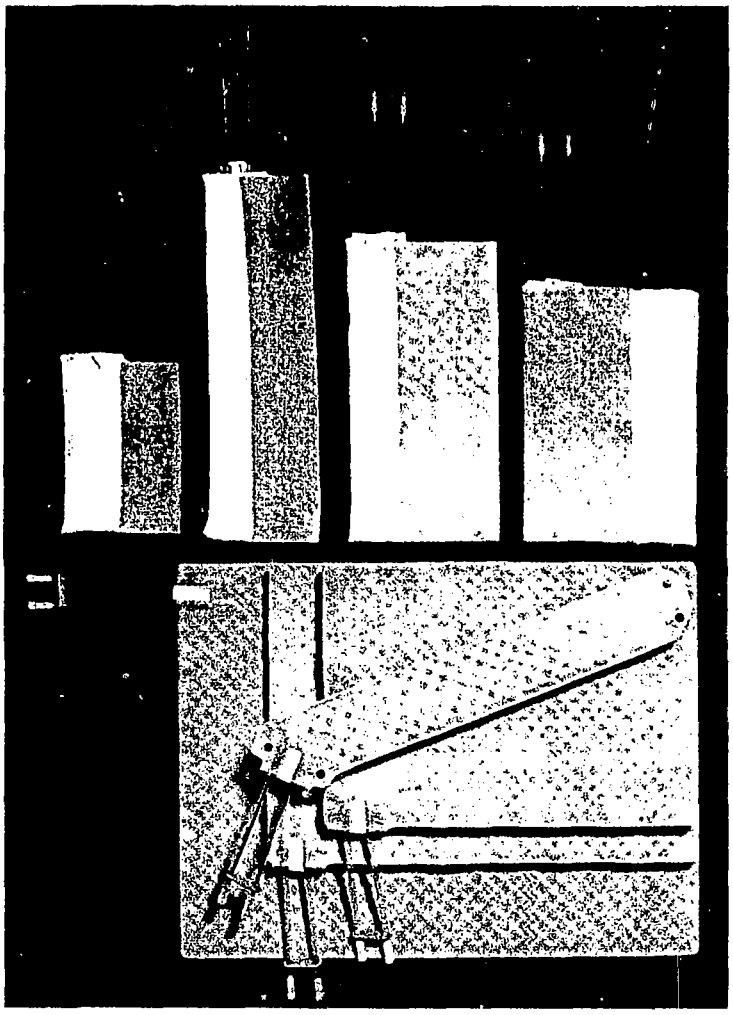
American Medical Systems

The K-Module combines convenience with speed and safety in providing very effective localized heat therapy. The K-Mod heats to the selected temperature (95° to 105°F) in approximately 5 to 7 minutes. The K-Mod also offers advantages of small size and weight, suction cup base, wide fill cap and removeable control key.



Duo-Therm Pads Complete the K-Mod System.

When used with American Medical Systems K-Module, Duo-Therm Pads provide a system for effective localized heat therapy. Constructed of soft nonwoven material, Duo-Therm Pads contour comfortably to patient treatment areas for maximum thermal transfer. Water may be placed upon the white "wet side" for the efficient application of moist heat therapy. The blue side may be used for dry heat therapy. Duo-Therm is available in a variety of sizes from 20″ x 3″ up to 18″ x 24″ pads. In addition, four sizes of Special Use Pads utilize sewn on spandage to effectively hold pads in place over limbs are available.



Specifications and Ordering Information

UL544 listed (medical and dental equipment)
Dimensions — 6.25″ x 5.0″ x 6.25″
Weight — 4 lbs.-2 oz. (reservoir empty)
Electrical Rating — 115 Volts, 60 Hertz, 178 Watts, 1.6 Amps
Heating Rate — 5-7 minutes
Temperature Range — 95°F to 105°F, 35°C to 40°C
Reservoir Capacity — 20 ounces distilled water
Current Leakage — Less than 50 micro amps
Power Cord — 10′ with hospital grade plug

AHS CATALOG NUMBER	DESCRIPTION
11185-010	K-Module
11175-RNT	K-Module Rental
11202-900	Connector tubing
11235-069	K-Kooler
11202-003	20″ x 3″ Duo-Therm
11202-017	17″ x 12″ Duo-Therm
11202-020	14″ x 20″ Duo-Therm
11202-024	18″ x 24″ Duo-Therm
11202-508	9″ x 8″ Special Use Pad
11202-517	9″ x 17″ Special Use Pad
11202-614	12″ x 14″ Special Use Pad
11202-612	14″ x 12″ Special Use Pad

Operation, Service, and Technical Manual available upon request.
Information in this literature is the latest available at the time of printing. Unit specifications are subject to change without notice. Contact your American Medical Systems' representative for further information.

American Medical Systems

Division of
American Hospital Supply Corporation
134 Merchant Street Suite 200
Cincinnati OH 45246
Telephone 513 772-7778

AT-1098
May '83

K-MODULE

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American Medical Systems

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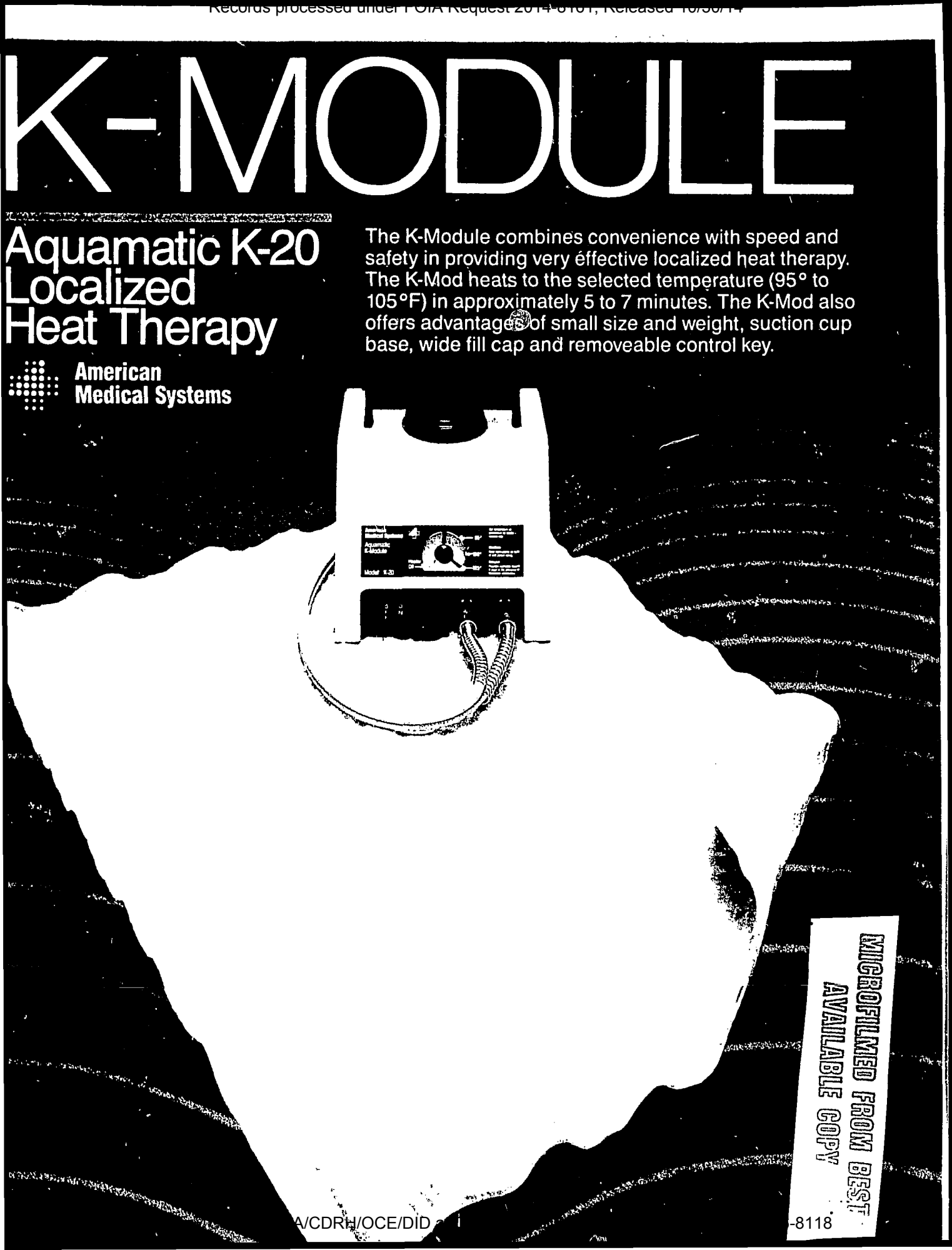

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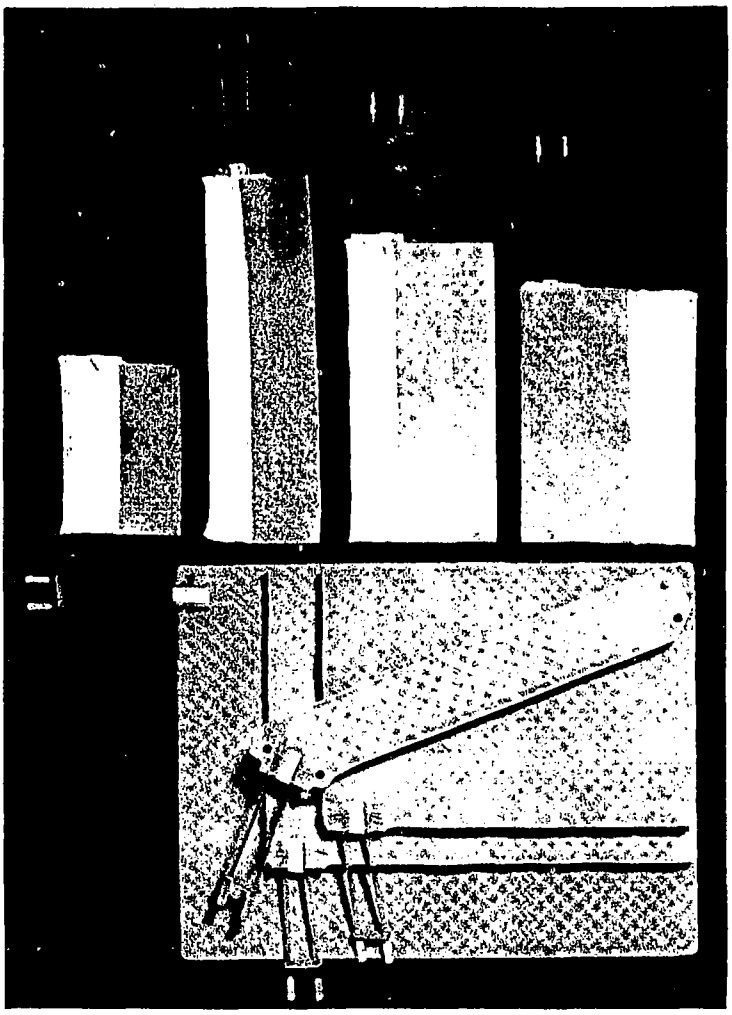

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11175-RNT	K-Module Rental
11202-900	Connector tubing
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American Medical Systems

Division of
American Hospital Supply Corporation
134 Merchant Street Suite 200
Cincinnati OH 45246
Telephone 513 772-7778

EXACTLY what the doctor ordered...

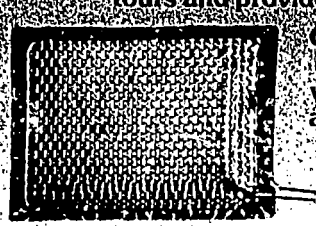
heat therapy without flow interruption

Maximum temperature coverage is maintained while T-Pads work continually for the length of time the doctor ordered.

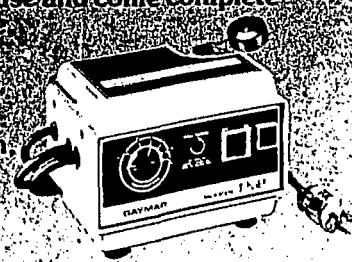
No more soggy towels or dressings. The Non-Woven surface can be placed hot or cold, moist or dry directly on patient.

GAYMAR T•Pads fold down to any dimension without kinking, conform easily to anatomical contours and provide uninterrupted water flow.

T•Pads & Mul•T•Pads adapt to any pump, are ideal for single patient use and come complete with easy to open and close, leakproof Clik-Tite Connectors.



GAYMAR Mul•T•Pads offer all the T-Pad features with the added convenience and versatility of a comfortable Non-Woven surface on one side for effective moist therapy.



Safe, reliable T•Pumps feature a Call Nurse system, visible water level window, a fill cap that can't get lost . . . and more.

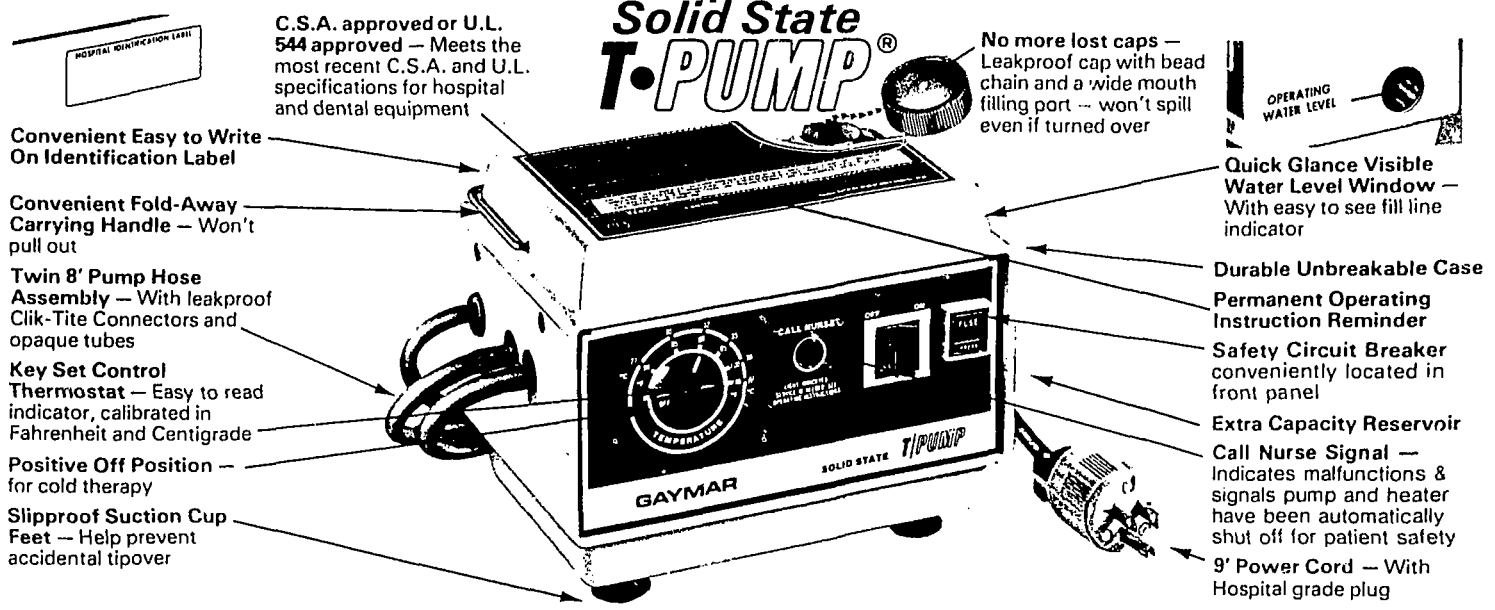
Easy to use, Economical and Dependable . . . the System Busy Nurses can Trust!

GAYMAR

. . . Exactly what the doctor ordered

Gaymar Industries, Inc. One Bank Street, Dept. 4 Orchard Park, New York 14127 • [716] 662-2551

The Dependable Solid State T•PUMP®



C.S.A. approved or U.L. 544 approved — Meets the most recent C.S.A. and U.L. specifications for hospital and dental equipment

Convenient Easy to Write On Identification Label

Convenient Fold-Away Carrying Handle — Won't pull out

Twin 8' Pump Hose Assembly — With leakproof Clik-Tite Connectors and opaque tubes

Key Set Control Thermostat — Easy to read indicator, calibrated in Fahrenheit and Centigrade

Positive Off Position — for cold therapy

Slipproof Suction Cup Feet — Help prevent accidental tipover

No more lost caps — Leakproof cap with bead chain and a wide mouth filling port — won't spill even if turned over

Quick Glance Visible Water Level Window — With easy to see fill line indicator

Durable Unbreakable Case

Permanent Operating Instruction Reminder

Safety Circuit Breaker conveniently located in front panel

Extra Capacity Reservoir

Call Nurse Signal — Indicates malfunctions & signals pump and heater have been automatically shut off for patient safety

9' Power Cord — With Hospital grade plug

Separate Back-Up Safety Thermostat Automatically turns off pump and heater and activates call nurse signal if temperature in reservoir exceeds safe limits.

Quiet Will not disturb patient.
Full 12 Month Free Repair or Replacement Warranty Covers all defects in materials and workmanship.

Tipover Switch: Heater automatically shuts off if accidentally tipped over. Automatic restart when returned to operating position.

Size: 8"x5¾"x6¼"
Weight: 5 lb. 2 oz. (unfilled, with hose attached)
Temperature Range: 80°F - 105°F
Attached Hose Length: 8' double channel

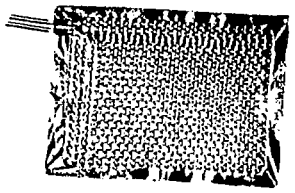
Power Supply: 115 volt, 60 Hz., 200 watts
Fuse: 2 amperes, 125 volts, 3AG type
Wattage: 200 watts max.
Maximum Current Leakage: 100 μa

A New Dimension in Heat and Cold Therapy

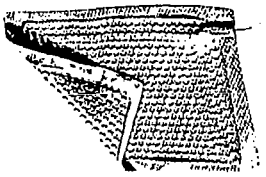
Unique T•PAD™ Pat. Pend

Non-Kinking T•Pads Feature Uninterrupted Flow

Unique "button design" T•Pads fold to any size, and conform easily to anatomical contours without interruption of water flow. Maximum temperature coverage is maintained while T•Pads work continually for duration of treatment.



MUL•T•PAD™ Pat. Pend Versatile



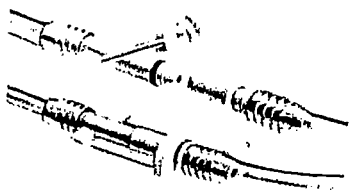
for Dry or Moist Heat Therapy

Along with the features of the T•Pad, GAYMAR'S Mul•T•Pads offer the added convenience and versatility of a Non-Woven surface on one side for effective moist therapy. No more soggy towels or dressings, pillow cases or wraps.

T•Pads and Mul•T•Pads . . .
are economical for single patient use, eliminate cleaning and handling in Central Supply and are available in several sizes.

PAT. PENDING

Easy to use, leakproof Clik-Tite Connectors are now standard on all Gaymar T Pumps, T Pads and hoses. Just push to connect, squeeze to release.



. . . eliminates capital investment in T Pumps. We supply the T Pumps when you contract for the T Pads you will need over a 24 month period.

No Capital Outlay
You receive title to T Pumps with first T Pad shipment.

No Advance Billing
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24 Month Price Protection
T Pads are shipped at contract price for two years, regardless of inflation. You may order any additional T Pads as you need them.

Order Only the T Pads You Will Need
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Two Year Extended T Pump Warranty
The standard repair or replacement warranty is extended to cover the full two year T.P.C. contract period!

Gaymar Industries, Inc. One Bank Street, Orchard Park, New York 14127 • [716] 662-2551

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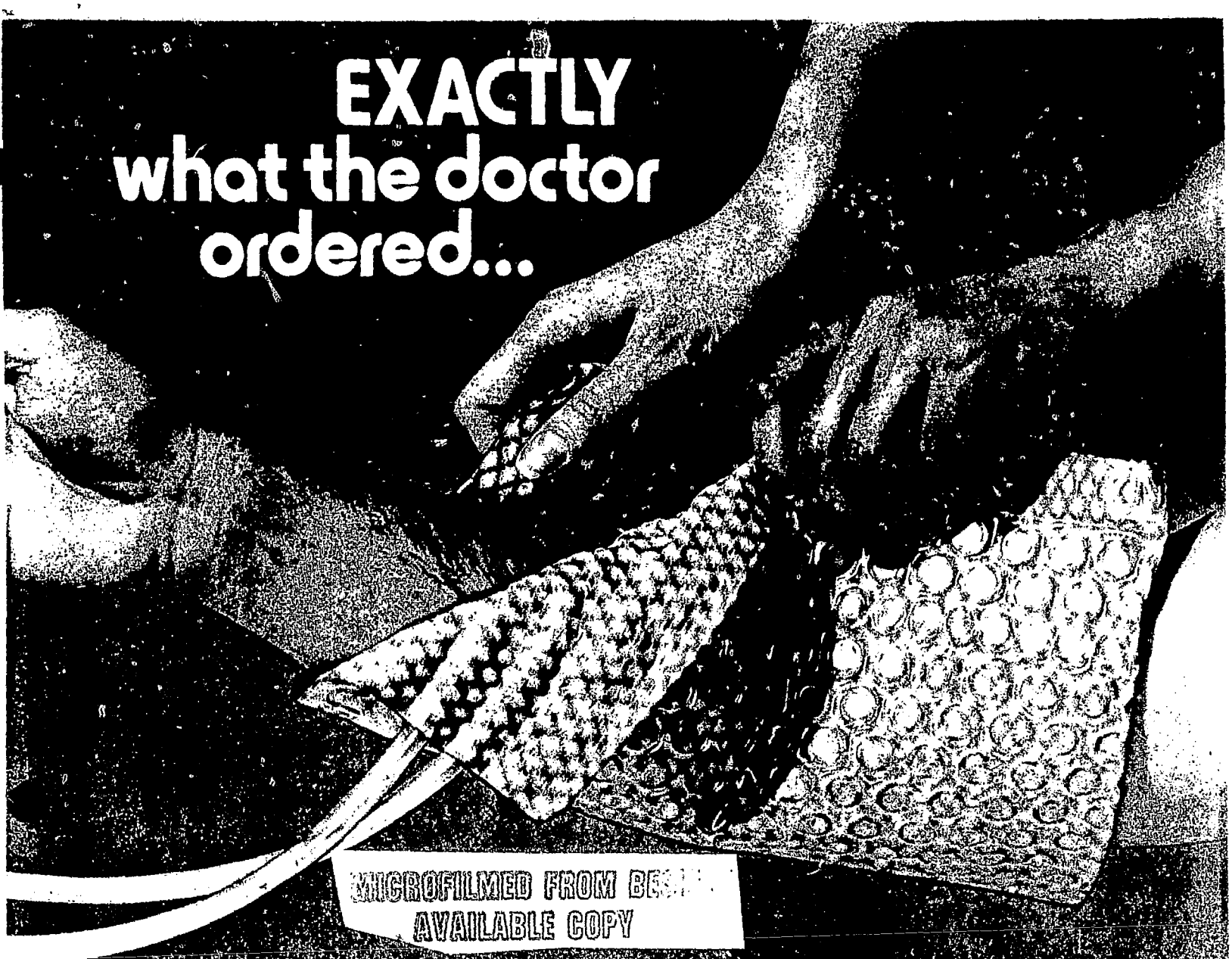
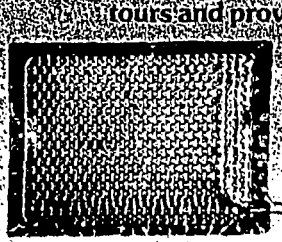
EXACTLY what the doctor ordered...



heat therapy without flow interruption

Maximum temperature coverage is maintained while T-Pads work continually for the length of time the doctor ordered.

GAYMAR T•Pads fold down to any dimension without kinking, conform easily to anatomical contours and provide uninterrupted water flow.

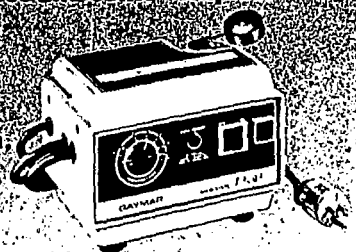


GAYMAR Mul•T•Pads offer all the T-Pad features with the added convenience and versatility of a comfortable Non-Woven surface on one side for effective moist therapy.

No more soggy towels or dressings. The Non-Woven surface can be placed hot or cold, moist or dry, directly on patient [illegible]

T•Pads & Mul•T•Pads adapt to any pump, are ideal for single patient use and come complete with easy to open and close leakproof Clik-Tite Connectors.

Safe, reliable T•Pumps feature a Call Nurse system, visible water level window, a fill cap that can't get lost . . . and more.



Easy to use, Economical and Dependable . . . the System Busy Nurses can Trust!

GAYMAR

. . . Exactly what the doctor ordered

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The Dependable Solid State T•PUMP®

C.S.A. approved or U.L. 544 approved — Meets the most recent C.S.A. and U.L. specifications for hospital and dental equipment

Convenient Easy to Write On Identification Label

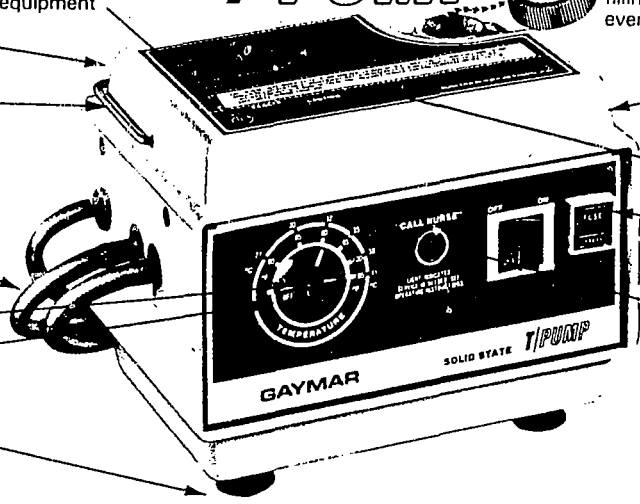
Convenient Fold-Away Carrying Handle — Won't pull out

Twin 8' Pump Hose Assembly — With leakproof Clik-Tite Connectors and opaque tubes

Key Set Control Thermostat — Easy to read indicator, calibrated in Fahrenheit and Centigrade

Positive Off Position — for cold therapy

Slipproof Suction Cup Feet — Help prevent accidental tipover



No more lost caps — Leakproof cap with bead chain and a wide mouth filling port — won't spill even if turned over

Quick Glance Visible Water Level Window — With easy to see fill line indicator

Durable Unbreakable Case

Permanent Operating Instruction Reminder

Safety Circuit Breaker conveniently located in front panel

Extra Capacity Reservoir

Call Nurse Signal — Indicates malfunctions & signals pump and heater have been automatically shut off for patient safety

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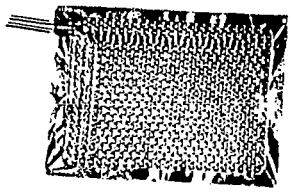

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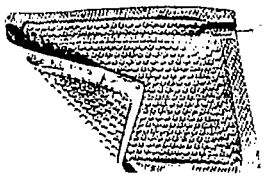

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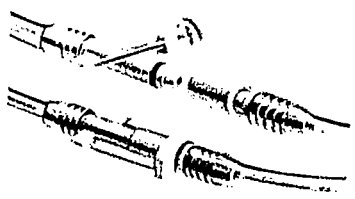

TPC (Temp Pump Control) Program . . .

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