Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Jesse K. Seidman, MS, RAC
Director, Global Regulatory Affairs
Medical Products - Renal
Baxter Healthcare Corporation
32650 N. Wilson Road, WG2-3S
Round Lake, IL 60073

NOV 15 2012

Re: Please see enclosed list

Dear Mr. Seidman:

We have reviewed your letter, dated October 31, 2012, stating that you have changed your address and/or contact information for the above referenced premarket notifications (510(k)s). Consequently, we cannot change the original address of the 510(k) submitter in our database. It will remain as it was listed when the final decision was rendered on your 510(k)s. We suggest that you update your address through the Establishment Registration website http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm. You may contact the Center for Devices and Radiological Health's Office of Compliance at (301) 796-5500 if you have any questions regarding your change of address.

If you have any other questions regarding this letter, please contact the 510(k) Staff at (301) 796-5640.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Director, Premarket Notification Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date:

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K791899/A001

To: Division Director: GU/DRGUD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: _____

Date: _____

K791899/A001

Baxter

R15

October 31, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Attn: Division of Reproductive, Gastro-Renal and Urological Devices

Re: Change of Official Correspondent
Change of Address of Official Correspondent
For the attached list of 510(k) Premarket Notifications

Dear Colleague:

This letter is to advise you of the change to the Official Correspondent and the change of address for the Official Correspondent for the 510(k) Premarket Notifications listed in the attached table. Effective immediately, please address all official correspondence to:

Jesse Seidman
Director, Global Regulatory Affairs
Medical Products - Renal
Baxter Healthcare Corporation
32650 N. Wilson Road, WG2-3S
Round Lake, IL 60073
Telephone: 224.270.4412
Fax: 224.270.4119

Thank you for making this change to our files. Please contact me at 224.270.4412 or via email at jesse_seidman@baxter.com with any questions regarding this request.

Sincerely,

(b)(6)

Jesse K. Seidman, MS, RAC
Director, Global Regulatory Affairs
Baxter Healthcare Corporation

List of 510(k)s Effected by Correspondent / Address Change

510(k) NUMBER	DEVICE NAME	CLEARANCE DATE
(b)(4)		

List of 510(k)s Effected by Correspondent / Address Change

510(k) NUMBER	DEVICE NAME	CLEARANCE DATE
(b)(4)		

List of 510(k)s Effected by Correspondent / Address Change

510(k) NUMBER	DEVICE NAME	CLEARANCE DATE
(b)(4)		

List of 510(k)s Effected by Correspondent / Address Change

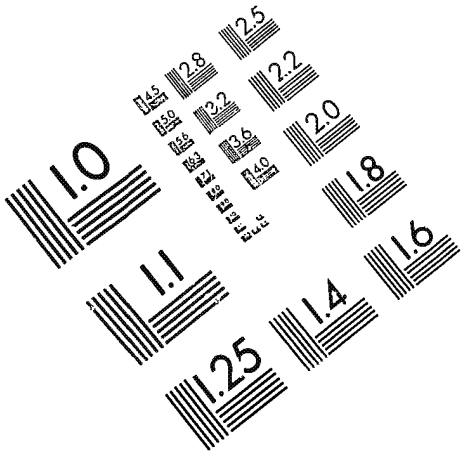
510(k) NUMBER	DEVICE NAME	CLEARANCE DATE
(b)(4)		
K791899	APD CYCLER SETS	11/13/1979
(b)(4)		

List of 510(k)s Effected by Correspondent / Address Change

510(k) NUMBER	DEVICE NAME	CLEARANCE DATE
(b)(4)		

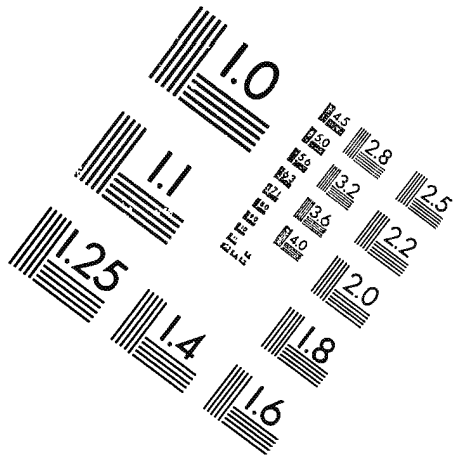
K791899

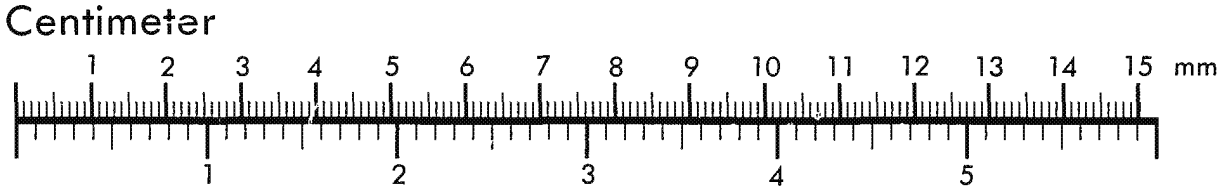
78

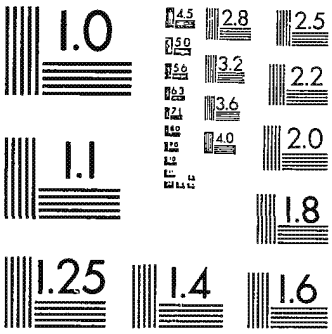


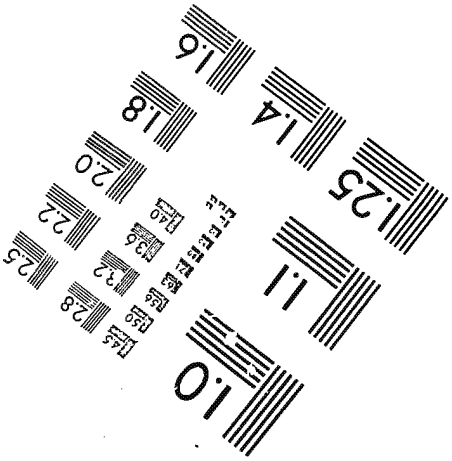
NATIONAL MICROGRAPHICS ASSOCIATION

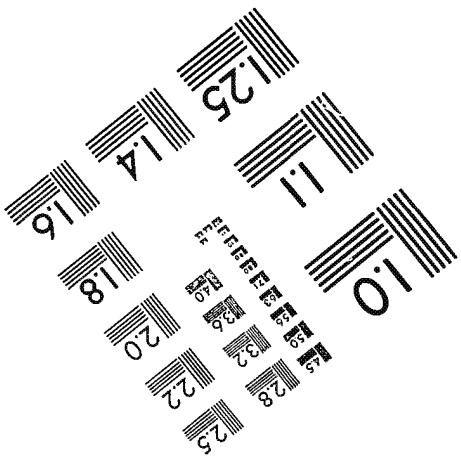
MS303-1980











K791899

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MARYLAND 20910

NOV 13 1979

Mr. Thomas D. Nickel
Manager, Medical Device
Regulatory Affairs
Travenol Laboratories, Inc.
Deerfield, Illinois 60015

Ref: K791899
Cycler Sets Model No's 5C4143,
5C4144 and 5C4145

Dear Mr. Nickel:

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 one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you 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 Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, MD 20857.

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Bureau of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, MD 20910.

Sincerely yours,

David M. Link, Director
Bureau of Medical Devices

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: Mr. Thomas D. Nickel
Manager, Medical Device
Regulatory Affairs
Travenol Laboratories, Inc.
Deerfield, Illinois 60015
(312) 948-4712

AND: Marie H. Reid
Nurse Consultant
Division of Gastro/Urology and General Use
Devices (HFK-420)

DATE: October 5, 1979

SUBJECT: 510(k) 791899 Cycler Sets for Peritoneal Dialysis

(b)(4)

I thanked Mr. Nickel for his continue co-operation and I indicated a response to this submittal would be forthcomming.

Marie H. Reid, R.N.

cc: HFK-20 ✓
HFK-420 MHReid
HFK-420 MHR Chron
HFK-420 CBruch
HFK-420 File

HFK-420/MHReid/mtc/10/19/79

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MARYLAND 20910

September 26, 1979

Section : 510(k)
Number : K791899
Received : 9/25/79
Product : Cycler Sets Model No.'s 5C4[illegible], 5C4144 and 5C4145

Travenol Labs., Inc.
Deerfield, Illinois 60015

Attn: Thomas D. Nickel

The information you have submitted as required by the above Section of the Federal Food, Drug, and Cosmetic Act for the referenced device has been received and assigned a unique document control number. Please cite this 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. Questions concerning this submission should be directed to:

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Spring, MD 20910
(301) 427-7059

Sincerely,

Sharon A. Heil

Sharon A. Heil, Chief
Document Control Center
Bureau of Medical Devices

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Robert S. Kennedy, Ph.D.
HFK-401

DATE:

FROM :

SUBJECT: 510(k) Notification # K791899

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

✓ (A) Is substantially equivalent to marketed devices MN Rec'd 10/23/79

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

_____ (C) Requires more data

_____ (D) Is an incomplete submission (see Submission sheet)

Additional Reviewer's Comments

Class Code with Panel # 78 - KDJ

Disposable tubing administration set for peritoneal dialysis

Review: _____ 10/29/79
Executive Secretary — Date

Final Review: _____
Division Director — Date

Optional Review: _____
Assoc. Director for Device Evaluation — Date

Optional Review: _____
Bureau Director — Date

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: Mr. Thomas D. Nickel
Manager, Medical Device
Regulatory Affairs
Travenol Laboratories, Inc.
Deerfield, Illinois 60015
(312) 948-4712

AND: Marie H. Reid
Nurse Consultant
Division of Gastro/Urology and General Use
Devices (HFK-420)

DATE: October 5, 1979

SUBJECT: 510(k) 791899 Cycler Sets for Peritoneal Dialysis

(b)(4)

I thanked Mr. Nickel for his continue co-operation and I indicated a response to this submittal would be forthcomming.

Marie H. Reid, RN

Marie H. Reid, R.N.

cc: HFK-20
HFK-420 MHReid
HFK-420 MHR Chron
HFK-420 CBruch
HFK-420 File

HFK-420/MHReid/mtc/10/19/79

TRAVENOL LABORATORIES, INC.

Deerfield, Illinois 60015
(312) 948-4712

March 14, 1979

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Spring, MD 20910

Re: 510(k) Notification K790067 - CF2300 Capillary Flow Dialyzer -
Supplementary Information

Gentlemen:

Ms. Marie Reid of the Bureau of Medical Devices called me on 3/13/79 and requested supplemental information to the above 510(k) submission of 1/5/79. Our response to her request is as follows:

(b)(4)

(b)(4)

When a final regulation issues, we intend to be in compliance.

Sincerely,

(b)(6)

Thomas D. Nickel
Manager, Medical Device Regulatory Affairs

TDN:mjd
Attach.

cc: Ms. Marie Reid - BMD (HFK-430)

TRAVENOL LABORATORIES, INC.

Deerfield, Illinois 60015

September 20, 1979

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Spring, MD 20910

re: 510(k) Notification
Cycler Sets for Peritoneal Dialysis

K791899

Gentlemen:

As required by Section 510(k) of the Medical Device Amendments of 1976 and in conformance with 21 CFR, Part 807, we are providing you with 90 days prior notice that we propose to market three Cycler Sets for intermittent peritoneal dialysis, specifically a 5C4143 Cycler Manifold Set, a 5C4144 Cycler Tubing Set, and a 5C4145 Cycler Drainage Set. The sets are to be used with existing intermittent peritoneal dialysis machines marketed by American Medical Products Corporation.

These sets have been tentatively classified by the Gastroenterological and Urological Devices Section of the General Medical Devices Panel in Class II, under the classification name Set, Tubing, Administration, Peritoneal Dialysis, Disposable, 78KDJ. To the extent applicable at this time we submit that we are in compliance with the requirements of Section 514 as to these devices. The establishment registration number applicable to the manufacture of the sets is 1419191, and the number applicable to the owner (i.e., the corporation) is 1417572.

The three new Travenol sets are substantially equivalent to similar competitive sets marketed by American Medical Products Corporation and Physio-Control Corporation. The AMP sets were marketed prior to May 28, 1976. The equivalency of the various products is supported by the following attachments:

1. Comparison of the new Travenol Cycler sets to pre-enactment competitive sets.

2. Draft labeling and directions for use - new Travenol Cycler sets.

3. Labeling - Physio-Control Corporation Cycler Manifold (Cat. No. 10300 01), Peritoneal Cycler Tubing Set (Cat. No. 10299 02), and Cycler Drainage Set (Cat. No. 10443 02).

4. American Medical Products Corporation Instruction Manual for Peritoneal Dialysis System, Model LJ-300 Series II, including Appendix III, which depicts the AMP Peritoneal Cycler Set (Cat. No. 20-001), 8-pronged connector set (Cat. No. 30-007), and Peritoneal Drainage Set (Cat. No. 20-015).

Sincerely,

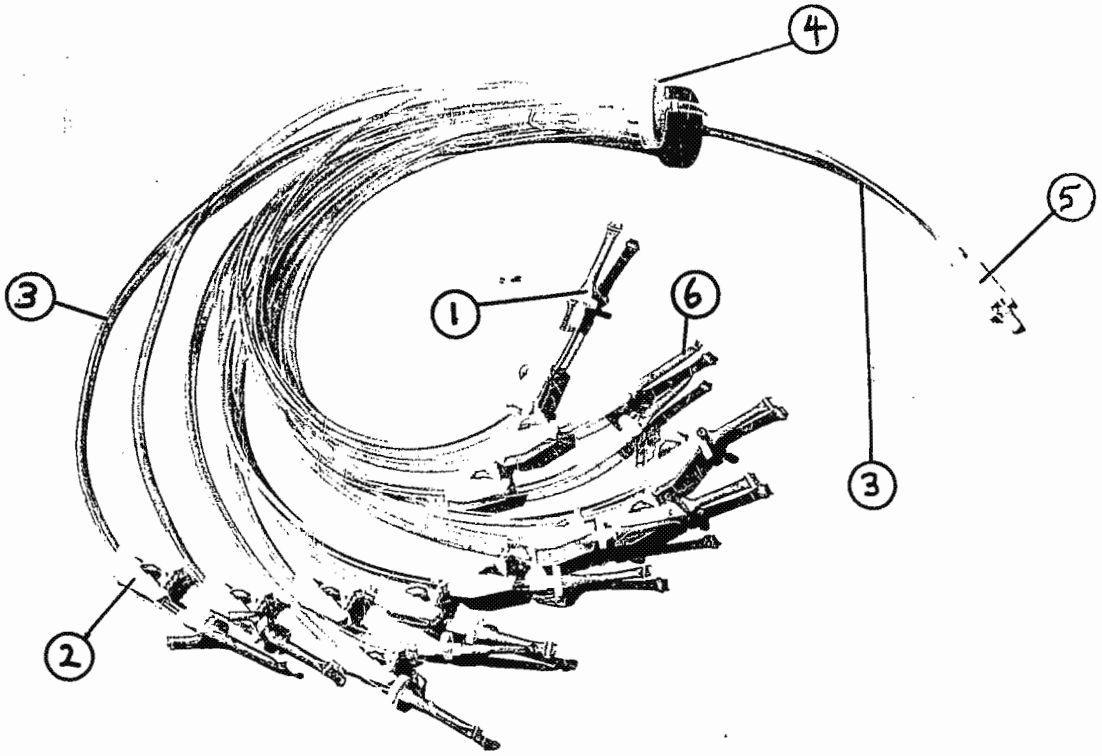
(b)(6)

Thomas D. Nickel
Manager, Medical Device Regulatory Affairs

TDN:mjd
Attach.

ATTACHMENT 1

Comparison of the New Travenol Cycler Sets to
Pre-enactment Competitive Sets

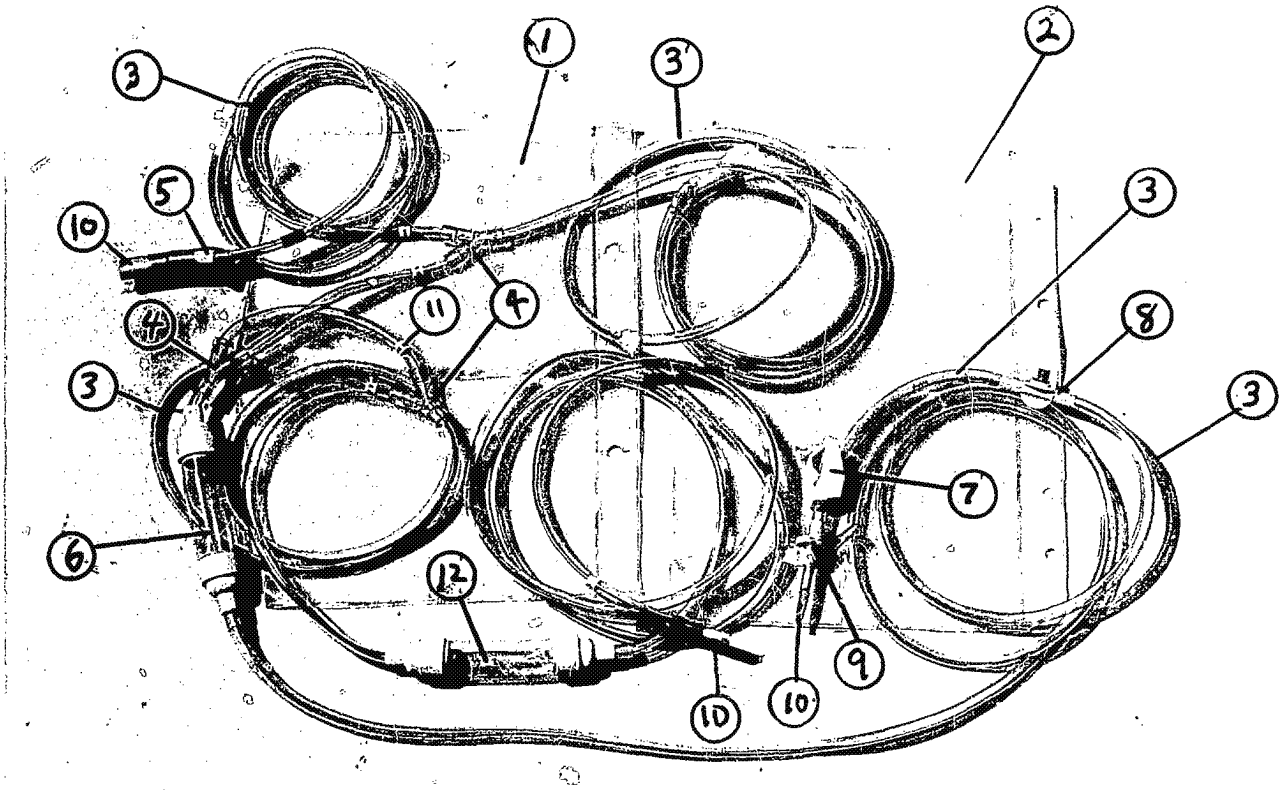


Travenol 5C4143 Cycler Manifold Set

Components

1. Acrylic Connector
2. Polypropylene Clamp
3. PVC Tubing
4. Acrylic Manifold
5. Acrylic Quik-Klik Connector
6. PVC Tip Protector

ATTACHMENT 1, cont'd

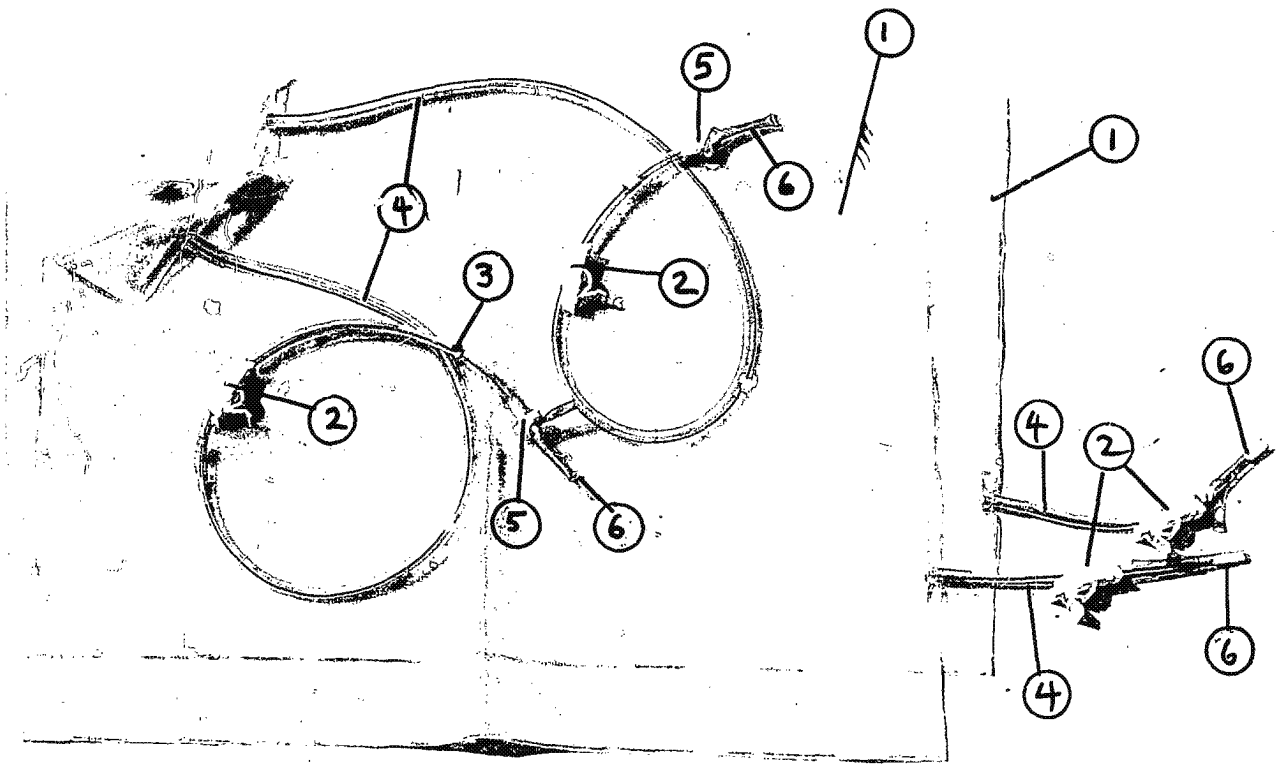


Travenol 5C4144 Cycler Tubing Set

Components

1. PVC Weigh Bag
2. PVC Heater Bag
3. PVC Tubing
4. PVC "Y" Connector
5. Acrylic Quik-Klik Connector
6. Acrylic and PVC Bubble Trap
7. Polypropylene Clamp
8. Injection Site - PVC and Syn Polyisoprene
9. Polyester Connector
10. PVC Tip Protector with or without cotton plug
11. Vinyl Cord Strap
12. Acrylic and PVC Retrograde Chamber

ATTACHMENT 1, cont'd



Travenol 5C4145 Cycler Drainage Set
(Consists of 2 pair of bags)

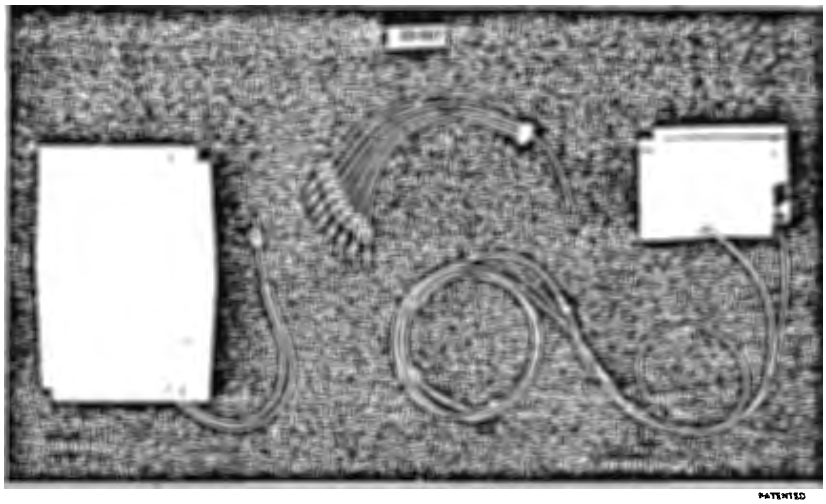
Components

1. PVC Drainage Bag
2. Polypropylene Clamp
3. Vinyl Coding Tape
4. PVC Tubing
5. Acrylic Connector
6. PVC Tip Protector with or without cotton plug

ATTACHMENT 1, cont'd

AMP Corporation - Cycler Set Information from Peritoneal Dialysis System Instruction Manual for Model LJ300 Series II

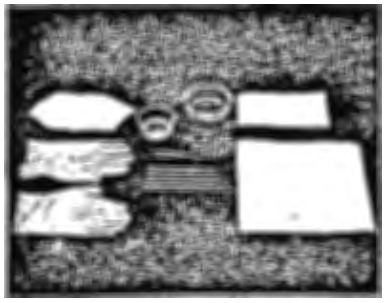
cycler tubing



PATENTED

catalog number	description
20-001	Peritoneal Cycler Set (see illustration above)
20-007	8-Pronged Connector Set (see illustration above)
20-015	Peritoneal Drainage Set (see illustration above)

on-off tray kit



catalog #20-010

Infection risks are minimized through use of the AMP on-off tray kit. American Medical Products offers the required items for beginning and ending dialysis in the form on one convenient sterile package. The items remain completely uniform and are always arranged in the same way from package to package.

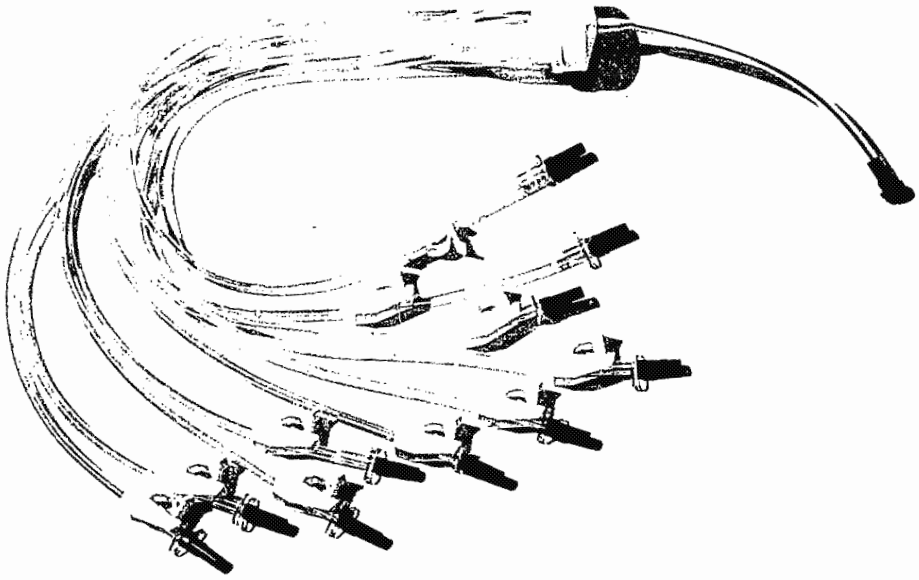
contents

10	4 x 4 sponges
6	applicators
2	8 oz. prep cups
1	sterile overwrap
1	fenestrated drape
1	pair of gloves
1	forceps

amp

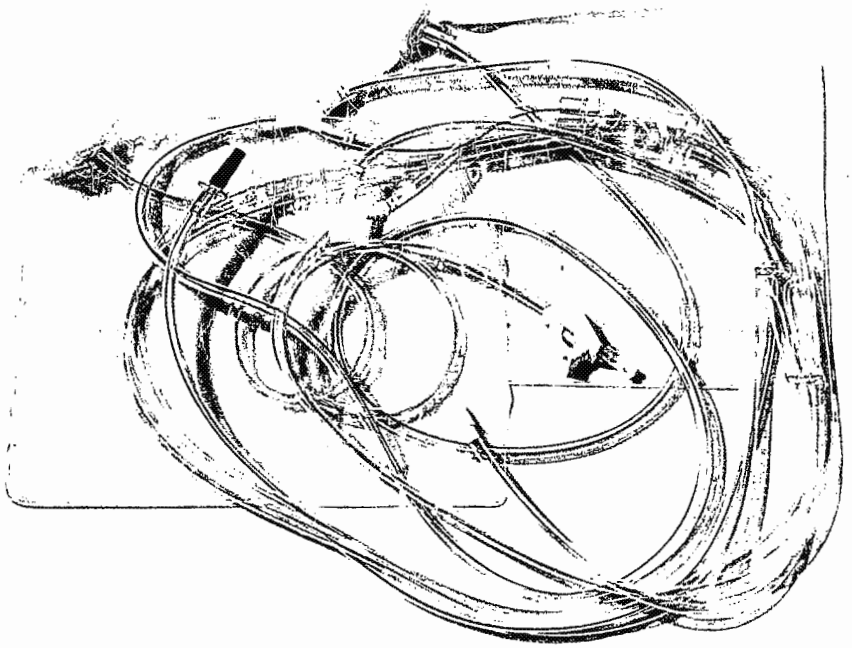
american medical products corporation
p.o. drawer 190, freehold, n.j., 07728, 201/431-5300

ATTACHMENT 1, cont'd



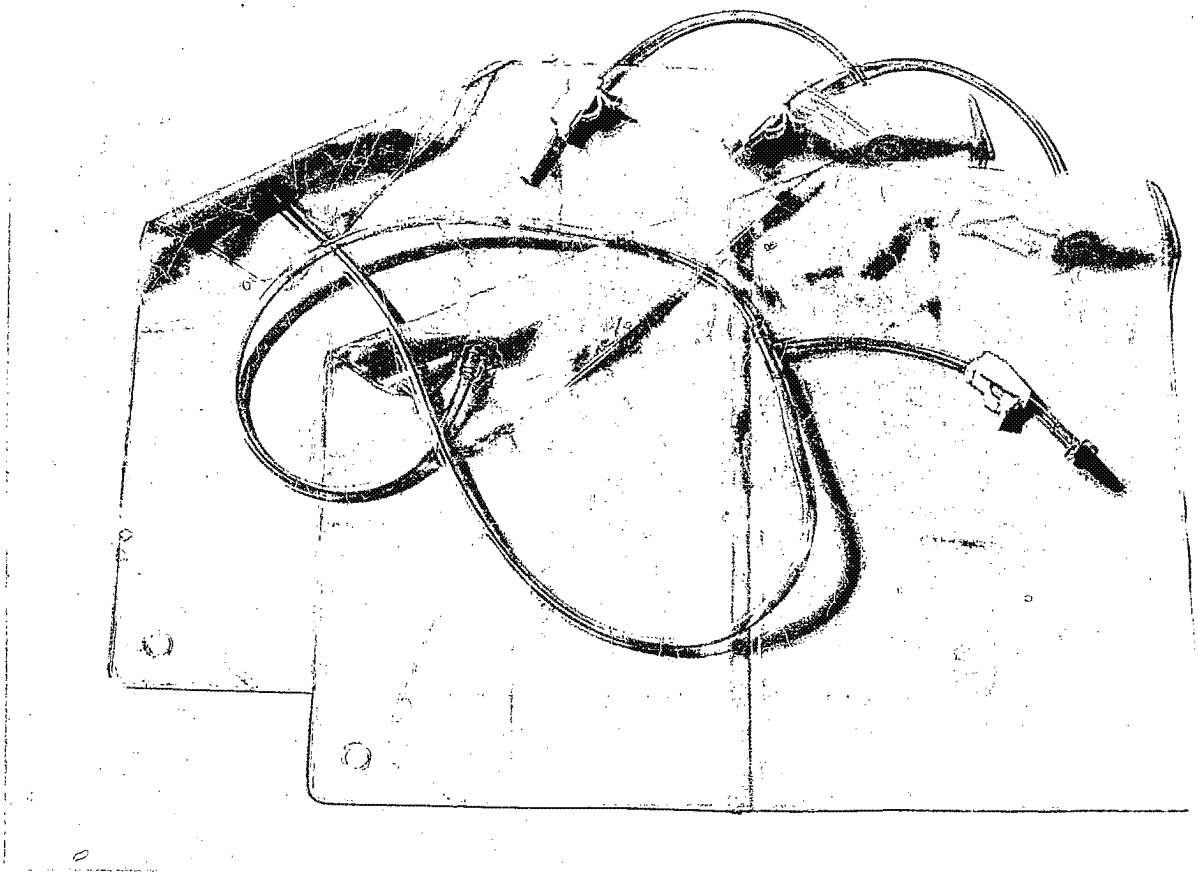
Physio-Control Corporation Cycler Manifold,
Cat. No. 10300 01

ATTACHMENT 1, cont'd



Physio-Control Corporation Peritoneal Cycler Tubing Set,
Cat. No. 10299 02

ATTACHMENT 1, cont'd.



Physio-Control Corporation Cycler Drainage Set,
Cat. No. 10443 02.

ATTACHMENT 2

Draft Labeling and Directions for Use -
New Travenol Cycler Sets

5C4143 Cycler Manifold Set Pouch Label

logo®
TRAVENOL

one 5C4143

Cycler Manifold

Sterile, nonpyrogenic fluid path

Use aseptic technique.

Do not use if package has been previously opened or damaged.

Refer to instruction manual for Automatic Peritoneal Dialysis System, Models LJ-100, LJ-100A and LJ-300 series for use.

Caution: Federal (U.S.A.) law restricts this device to sale by or on order of a physician.

LOT

ARTIFICIAL ORGANS DIVISION
TRAVENOL LABORATORIES, INC.
Deerfield, Illinois 60015, U.S.A.

ATTACHMENT 2, cont'd

5C4144 Cycler Tubing Set Pouch Label

logo®
TRAVENOL

one 5C4144

Cycler Tubing Set

Sterile, nonpyrogenic fluid path

Use aseptic technique.

Do not use if package has been previously opened or damaged.

Refer to instruction manual for Automatic Peritoneal Dialysis System, Models LJ-100, LJ-100A and LJ-300 series for use.

Caution: Federal (U.S.A.) law restricts this device to sale by or on order of a physician.

LOT

ARTIFICIAL ORGANS DIVISION
TRAVENOL LABORATORIES, INC.
Deerfield, Illinois 60015, U.S.A.

ATTACHMENT 2, cont'd

5C4145 Cycler Drainage Set Pouch Label

logo®
TRAVENOL

one 5C4145

Cycler Drainage Set

Sterile, nonpyrogenic fluid path

Use aseptic technique.

Do not use if package has been previously opened or damaged.

Refer to instruction manual for Automatic Peritoneal Dialysis System, Models LJ-100, LJ-100A and LJ-300 series for use.

Caution: Federal (U.S.A.) law restricts this device to sale by or on order of a physician.

LOT

ARTIFICIAL ORGANS DIVISION
TRAVENOL LABORATORIES, INC.
Deerfield, Illinois 60015, U.S.A.

ATTACHMENT 3

Labeling - Physio-Control Cycler Sets

Pouch Labels
(Note - See Attachment 4 for directions for use)

CYCLER MANIFOLD

Cat.# 103 00 01
Lot# 120/212

Contents of unbroken package are sterile.

CAUTION: Federal law restricts product to sale by or on the order of a physician.

Physio-Control
11811 Willows Road
Redmond, WA 98052
206-883-1181

ASSEM VA 29

PERITONEAL CYCLER TUBING SET

Cat.# 10299 02
Lot# 090/212

Contents of unbroken package are sterile.

CAUTION: Federal law restricts product to sale by or on the order of a physician.

Physio-Control
11811 Willows Road
Redmond, WA 98052
206-883-1181

E.A. 149

[illegible] DRAINAGE SET

Cat.# 10443 02

Lot#

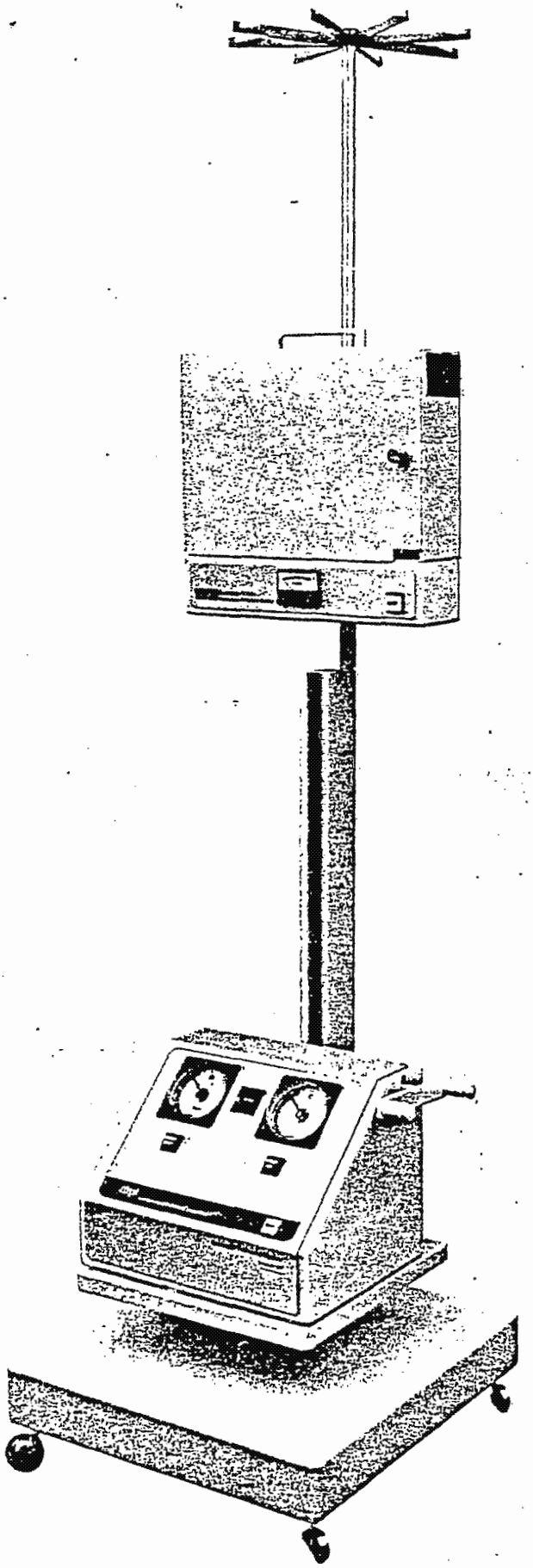
Contents of unbroken package are sterile.

CAUTION: Federal law restricts product to sale by or on the order of a physician.

Physio-Control
11811 Willows Road
Redmond, WA 98052
206-883-1181

E.A. 148

ATTACHMENT 4



peritoneal dialysis system

LJ 300 Series II

WARRANTIES AND LIMITATIONS

American Medical Products Corporation warrants that it has exercised the necessary care during the manufacture of its products to make them suitable for use as indicated. American Medical Products Corporation may, at its option, repair or replace any nonconforming product without charge to the buyer. THIS WARRANTY IS IN LIEU OF ANY OTHER LIABILITY FOR DEFECTS. AMERICAN MEDICAL PRODUCTS CORPORATION MAKES NO WARRANTY OF LIABILITY, NOR ARE THERE ANY OTHER WARRANTIES, EXPRESSED OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE: THIS COMPANY DISCLAIMS ALL OTHER WARRANTIES. AMERICAN MEDICAL PRODUCTS CORPORATION DISCLAIMS ANY LIABILITY FOR ANY ACCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE DIRECTLY OR INDIRECTLY ARISING FROM THE USE OF THIS PRODUCT. American Medical Products Corporation will make any repairs to its medical device equipment without charge to the buyer for a period of six months. The six month period shall begin on the date the equipment is received or purchased, whichever provides the longest coverage. Repairs and/or modifications made to this product without the expressed authorization of American Medical Products Corporation voids all warranties and liabilities. No representative of American Medical Products Corporation may change or alter any of the foregoing, and the buyer hereby accepts the products subject to all the terms set forth herein.

CAUTION: Federal [U.S.A.] law restricts this device to sale by or on the order of a physician.

INSTRUCTION MANUAL
FOR
PERITONEAL DIALYSIS SYSTEM
Model LJ-300 Series II

A. — INITIAL INSTALLATION

Cycler Stand, Contents

The stand is shipped in two cartons. The larger carton contains the base, shelf, an eight-pronged hanger with mounting device, and one locking pin. The smaller carton contains the vertical support and the adjustable vertical pole.

Cycler Stand, Assembly

(Refer to Appendix I, Figure A)

1. Open the larger carton and remove packing materials.
2. Remove the pronged hanger, shelf, and envelope containing hardware and instruction sheet.
3. Remove the base from the carton and place on floor, castor side down.
4. Open the smaller carton, remove contents and place next to base.
5. Loosen locking nuts in base and insert the vertical support through the rectangular hole on the top of the base (open channel facing front.)
6. Carefully tilt the unit back and tighten the two bolts, making sure that the lock nuts are in the proper position to lock onto the vertical support. Return the entire unit to the upright position.
7. Attach the cycler shelf to the vertical support with the bolt and lock nut supplied using hole in the shelf bracket.

note

The top of the shelf should be approximately 12" from the floor and approximately 18"-24" below the level of the patient's back in a supine position.

8. Place the pronged hanger on the end of the adjustable vertical pole where a 3/16" diameter hole is located. Align the holes in both pieces, insert the cap screw through holes and thread acorn nut on end of screw. Tighten with allen key supplied.
9. Place the adjustable vertical pole at the desired height (the pronged hanger should be approximately 80" from the floor), and insert the locking pin through one of the holes in the vertical support.

Heater, Contents

The heater cabinet is shipped in one carton. One knob screw, one heater bag rod, one instruction manual and one maintenance manual are packed inside.

Heater, Assembly

(Refer to Appendix I, Figure A.)

1. Open the carton and remove packing materials.
2. Remove heater; open front door and remove contents.
3. Turn the knob screw into the hole in the center of the clamp on the back of the heater.
4. Attach the heater cabinet to the adjustable vertical pole. The top of the cabinet should be approximately 19" below the pronged hanger.

Cycler, Contents

The cycler is shipped in one large carton.

Cycler, Assembly

(Refer to Appendix I, Figure A)

1. Open the carton and remove cycler with packing materials.
2. Carefully remove packing materials from each end of the cycler.

3. Place the cycler onto the stand shelf, being careful to align the "feet" of the cycler into the shelf holes.
4. Plug power cable from heater cabinet into the convenience outlet on the back of the cycler.

note

In assembling the cycler and heater on the stand, proper heights are essential for adequate flow of solution. Gravity determines flow rates, therefore, the dialysate must hang above the heater cabinet, the heater cabinet above the patient, patient above the cycler and cycler above the floor drain.

B. — FUNCTIONAL DESCRIPTION

(See Appendix I, Figure B and C)

An initial operational test should be made at this point without the use of fluids or fluid disposable sets.

Connect the power cord from the Cycler to a convenient, grounded, 120VAC receptacle. Depression of the ON-OFF BUTTON will place the Cycler in the drain mode for the duration of the time set on the DRAIN TIMER. The Cycler will then automatically change to the fill mode after completion of the drain cycle. Depressing the FILL BUTTON prior to completion of the drain cycle will manually override the drain cycle, and go to fill cycle. These cycles may be manually overridden whenever necessary throughout the treatment.

At the left side of the Cycler are 2 plungers which operate alternately to determine the fluid flow through the tubing.

During the drain cycle, tubes numbered 1 and 2 are open and tubes numbered 3 and 4 are closed, allowing the dialysate to flow into the heater bag and concurrently, to drain from the patient into the weigh bag.

During the fill cycle, tubes numbered 1 and 2 are closed and tubes numbered 3 and 4 are open, allowing the pre-heated dialysate from the heater bag to enter the patient and permitting the liquid from the weigh bag to flow into the two 7-liter drain bags.

The appropriate DRAIN or FILL TIMER will complete the time cycle for which it was initially adjusted, closing a pair of normally open contacts, and energizing the opposite (DRAIN or FILL) relay coil which will cause the equipment to cycle automatically from Fill to Drain.

A COUNTER is provided to indicate the number of completed exchanges and will advance each time the cycler enters the Fill mode.

A TEMPERATURE METER is provided to indicate the operating temperature of the heater plates which are inside of the heater cabinet. The meter needle should always indicate in the green when dialyzing. The red section indicates too warm, and the blue indicates too cold.

Depression of the ON-OFF BUTTON located on lower right hand side of the Heater Cabinet will energize the heater plates and illuminate the switch. The TEMPERATURE METER on the Series II is centrally located at the bottom of the Heater Cabinet.

Setting The Timer

1. Set the FILL TIMER to the number of minutes required to Fill the patient plus any additional Dwell minutes desired.

note

The Fill Timer incorporates both Fill and Dwell periods, eg; if a patient should fill in 10 minutes and you require a 15 minute Dwell period, set the Fill Timer for 25 minutes. The Cycler should never be ON when adjusting either timers, as damage may result if Timer is adjusted while functioning.

2. Set DRAIN TIMER for the number of minutes that the patient requires to drain.

note

Drain Timer also controls the dwell time of the dialysate in the HEATER CABINET and should be set at or above the recommended dialysate warming time (see Section E, 3), as a lower setting will not allow sufficient warming of the dialysate. The warming time is the minimum recommended drain time regardless of a faster patient drain time. Do Not set the Drain Timer for any time less than the setting on the Internal Timer, as this will nullify the patient drain alarm (see Section F, Alarm Systems). The factory setting for the Internal Timer is 15 minutes. If a drain time of

other than 15 minutes is desired, the Internal Timer must be adjusted as outlined in Section F.

Adjusting Inflow Volume In Heater Cabinet

1. Determine exchange volume as ordered by physician.
2. Loosen knobs on top right and left sides of Heater Cabinet by 1/2 turn counterclockwise.
3. Grasp Both knobs and move pointer located on right hand side to desired volume.
4. Secure Both knobs firmly by turning clockwise to lock in place.

note

It is imperative to tighten both knobs securely to insure proper volume.

The Patient Drain Alarm weighing system must also be re-adjusted to accomodate the new inflow volume - see below.

Adjusting Weigh Arm

(Refer to Appendix I, Figure D)

1. Remove 2 black screws from upper left and right sides of cycler.
2. Remove cover from machine.
3. Lift panel forward to stop.
4. Loosen screw protruding from weight. Align sliding weight and hole in weigh arm for appropriate volume location of appropriate mark is indicated on top of sliding weight.
5. Tighten screw to secure weight in place.
6. Close panel, replace cover and install screws.

D. — TUBING SET UP

(An Aseptic Technique is Required)

(See Appendix I, Figure C)

note

The following procedure should be used when preparing each dialysis. Setting up the tubing, while simple, is still critical to the correct and efficient operation of the equipment. As a word of caution, the tubing is supplied sterile, and extreme care should be taken when making connections that no contaminates are introduced into the lines. If there is any doubt regarding sterility, the tubing set should be disposed of and a new set used in its place.

1. Make sure Plastic Cover is in place to protect Cycler.
2. Remove the Peritoneal Cycler Tubing Set (Catalog #20-001) from the over-wrap and carefully open the box lid.
3. Open the Heater Cabinet and remove the Rod that hangs on the two upper hooks.
4. Insert the Rod through the horizontal opening provided at the top of the Heater Bag.
5. Hang the Rod on the two hooks in the Heater Cabinet and run the tubing through the cut out in the door of the Cabinet, making sure not to pinch the tubing.
6. Close the Heater Cabinet Door and make sure that the arrow on the knob is pointing <u>UP</u> for doors opening upward, and pointing to the <u>RIGHT</u> for doors opening from the right.

note

Do not open the Cabinet Door during dialysis, because the Door, when closed also functions to control exchange volume.

7. Hang the Weigh Bag on the two studs of the Weighing Arm with the outlet facing the Cycler to prevent kinking of the line.
8. Loosen the two retaining wing nuts and remove the Tube Holder from the Cycler.
9. Place the Peritoneal Cycler Tubing Set lines numbered 1, 2, 3, and 4 in the corresponding numbered tube clips.

note

It is imperative for proper function of the machine that tubing is placed securely in both upper and lower appropriately numbered clips.

10. Make sure that the arrow on the Tube Holder is pointing UP and that the Retrograde and Bubble Chambers are suspended downward, hanging freely.
11. Place the Tube Holder against the Cycler and tighten the two wing nuts snugly.

note

At this point check the tubing at the Tube Holder for proper set up. A visual check from above for the upper set of clips as well as feeling clips and tubing under Tube Holder will insure proper installation.

12. Close shut-off clamp on patient line and keep off the floor.

13. Remove the 8-Pronged Connector Set (Catalog No. 20-007) from the package and close off all the clamps.

14. Connect the single blue striped end to the tube on the Peritoneal Cycler Tubing Set (Catalog No. 20-001) marked with a blue stripe (Line 1) using aseptic technique.

note

A secure connection is made by first pushing the spike into the tubing end and then twisting.

15. Remove the Drainage Set (Catalog No. 20-015) from the package and connect to the tube on the Peritoneal Cycler Tubing Set (Catalog No. 20-001) marked with a yellow stripe (Line 4) using aseptic technique.

16. Clamp off the outflow lines of the two 7-liter Drain Bags and place the bags on the floor.

17. Connect the containers of Dialysate to the spikes on the 8-Pronged Connector Set and hang them upside down from the hanger.

note

When inverting the containers of Dialysate, do not allow dripping fluid to come in contact with any part of the equipment. Make sure that the protective Plastic Cover is in place over the Cycler prior to hanging containers. If Plastic Cover is lost, immediately contact American Medical Products for replacement. Any waterproff plastic sheet may be used in an emergency.

E. — INITIATING DIALYSIS

(See Appendix I, Figure B.)

note

At this point, the equipment should be set up and the tubes and bags connected as outlined in the MACHINE PREPARATION and TUBING SET UP sections of this manual. The Heater Cabinet power cord should be connected to the three-pronged receptacle in the back of the Cycler Cabinet and the Cycler power cord should be connected to a standard 120VAC grounded wall receptacle.

1. To start the equipment, both heater and cycler ON-OFF BUTTONS must be depressed.
2. Open the clamps on the 8-Pronged Connector Set.

note

When initially energized, the equipment will always start in the DRAIN cycle, thus allowing the Dialysate to flow into the Heater Bag, where it is heated to the desired temperature. This also reduces the possibility of filling an already full patient with Dialysate.

3. Allow the dialysate to warm in the Heater Cabinet for a sufficient amount of time to provide patient comfort upon in-flow of the dialysate. The recommended minimum warming times are 10 minutes for 1000 ml. - 1500 ml. volumes and 15 minutes for 2000 ml. volumes.
4. Press the PATIENT FILL BUTTON to override the automatic controls and put the equipment into a Fill cycle.
5. Remove the protective cap over the Luer lock on the Patient Line and release the clamp to allow enough Dialysate to flow out to remove any air bubbles that might be trapped in the line.

note

Due to variability of heights in hospital beds and equipment, both the VERTICAL POLE and CYCLER SHELF are adjustable to assist in meeting optimum in-flow and drainage characteristics.

6. Complete and secure the connection to the catheter, using the prescribed aseptic technique, and release the clamp on the Patient Line.
7. Reset the COUNTER to zero by pressing the red button located on the COUNTER.

note

It is advisable to monitor the operation of the equipment for one full cycle before allowing the unattended automatic operation.

F. — ALARM SYSTEMS

Patient Drain Alarm

This buzzer type alarm is provided to monitor patient drainage and is activated only during the Drain cycle. The Cycler will not begin a new Fill cycle until a predetermined amount of dialysate is drained from the patient over a preset time. The factory setting for 2000 ml. exchanges is 1500 ml. in 15 minutes. (If the patient does not drain 1500 ml. of dialysate in 15 minutes, the alarm will sound.) An appropriately marked Red Light located in the DRAIN TIMER will indicate actuation of this alarm.

To re-set

Push the ON/OFF BUTTON twice. This will turn off the alarm and reset the DRAIN TIMER, allowing the patient to continue draining. The reason for the patient's drainage problem should be determined and corrected if possible. Otherwise the alarm system should be adjusted to accomodate slower drain times. (See following paragraph.)

To adjust

(Refer to Appendix I, FIGURE D.)

Unplug the Cycler from the wall outlet and open the Cycler Front Panel by removing the screws located on the top right and left sides of Cycler Cabinet. You will note in the lower right corner, a TIMER which can be adjusted by rotating the black knob from 0-60 minutes. This internal TIMER Should be adjusted to approximately 5 minutes less than DRAIN TIMER. Supporting the weigh bag is a bar extending inside the upper portion of the Cycler Cabinet on which a sliding weight will be found positioned by a thumbscrew. To adjust the volume factor (sliding weight) in the alarm system, refer to Section C. MACHINE PREPARATION, ADJUSTING WEIGH ARM.

note

The internal TIMER should never be adjusted to a greater time than the external DRAIN TIMER, as this will nullify the alarm system.

Heater Alarm

This alarm, also a buzzer type, is located in the Heater Cabinet and is activated when the heater plates reach an overheated condition. This alarm is controlled by a thermostat that will interrupt the heating process when activated. This alarm works independently of the TEMPERATURE INDICATOR.

To re-set

If the Heater Alarm should go off, the following steps must be taken to reactivate the Heater.

1. Turn Cycler and Heater off and disconnect power cord: remove Heater Bag and leave Cabinet Door open until heater plates reach room temperature. (Approx. 30-40 min.)
2. Firmly press button located on back of Heater Cabinet. A slight metallic click should be heard when reset has occurred. If the metallic click is not heard, heater plates have not reached room temperature and reset has not occurred.
3. After resetting, plug in power cord and turn Cycler and Heater ON. If the alarm does not sound, the Thermostat has been reset and dialysis may be continued, but it will be necessary to monitor the equipment for another complete cycle.
4. If Heater alarm again goes off, discontinue use of the equipment and contact American Medical Products Corporation.

To adjust

Adjustments to the heater should be carried out only by personnel authorized by American Medical Products Corporation. These procedures are covered under a separate maintenance manual.

System Drain Alarm

Particulate matter or kinked tubing can cause the weigh bag not to drain in the usual manner. To prevent the eventual back-up of fluids in the tubing, the System Drain Alarm (also a buzzer type) is incorporated. This alarm will sound when fluid cannot drain from the weigh bag and is immediately visible by the distended condition of the bag during the end of the FILL cycle. An appropriately marked Red Light located in the FILL TIMER will indicate actuation of this alarm.

To re-set

Turn Cycler OFF. Determine the reason for the blockage of the weigh bag, correct and turn Cycler ON. Switch Cycler back to Fill, as weigh bag will only empty during the Fill cycle.

To adjust

There are no adjustments for this alarm.

Adding Medication and Obtaining Fluid Samples

Medications are often added to dialysate prior to administration. This may be done in the same manner any medication is added to parenteral fluids. The rubber stopper should be intact when injecting to safeguard against contaminants. It is best to add medication to each dialysate container rather than put all the medication in one container (this reduces the possibility of error during administration). A self-sealing injection site is also provided on the patient line near the catheter connection for both adding medications and removing peritoneal fluids. This site may also be used in catheter irrigation procedures.

Fluid Balance Measurements

In order to calculate fluid balance, it is necessary to know both in-flow volume and the amount drained from the patient. In-flow volume is determined by first knowing exchange volume the heater cabinet is adjusted for i.e. 2000 ml, 1500 ml. The COUNTER located on the front panel of the Cycler when reset to zero at the beginning of the dialysis procedure will indicate the number of exchanges the patient has received. Multiplying this number times the exchange volume will give you the total in-flow volume. Out-flow volume is contained in the two drain bags located on the floor and can either be weighed or measured by means of a graduated container.

note

Fluid can only be measured or weighed accurately when Weigh Bag (located on the right side of the Cycler) is empty.

BLANK

APPENDIX I

FIGURES

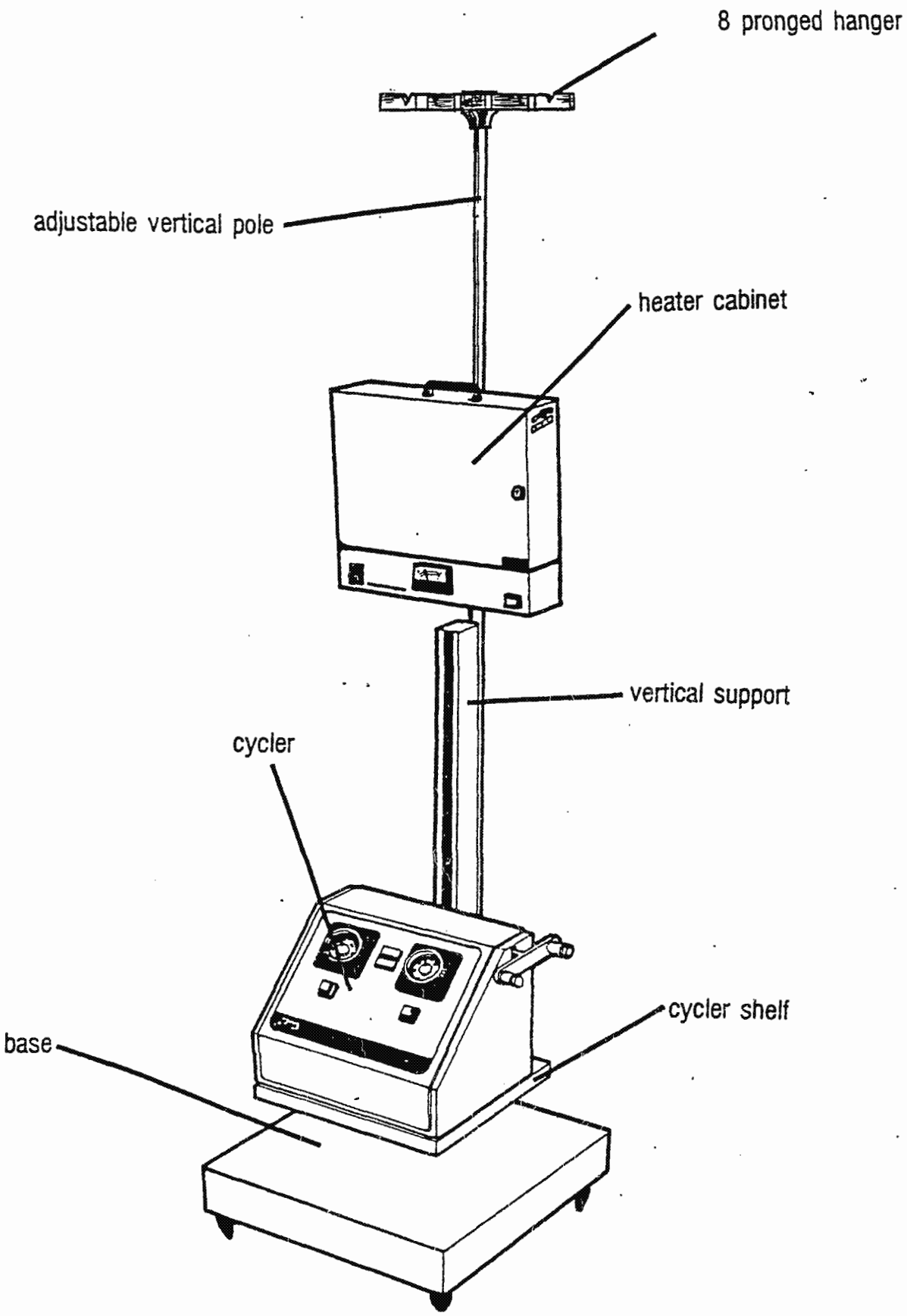


FIGURE A.

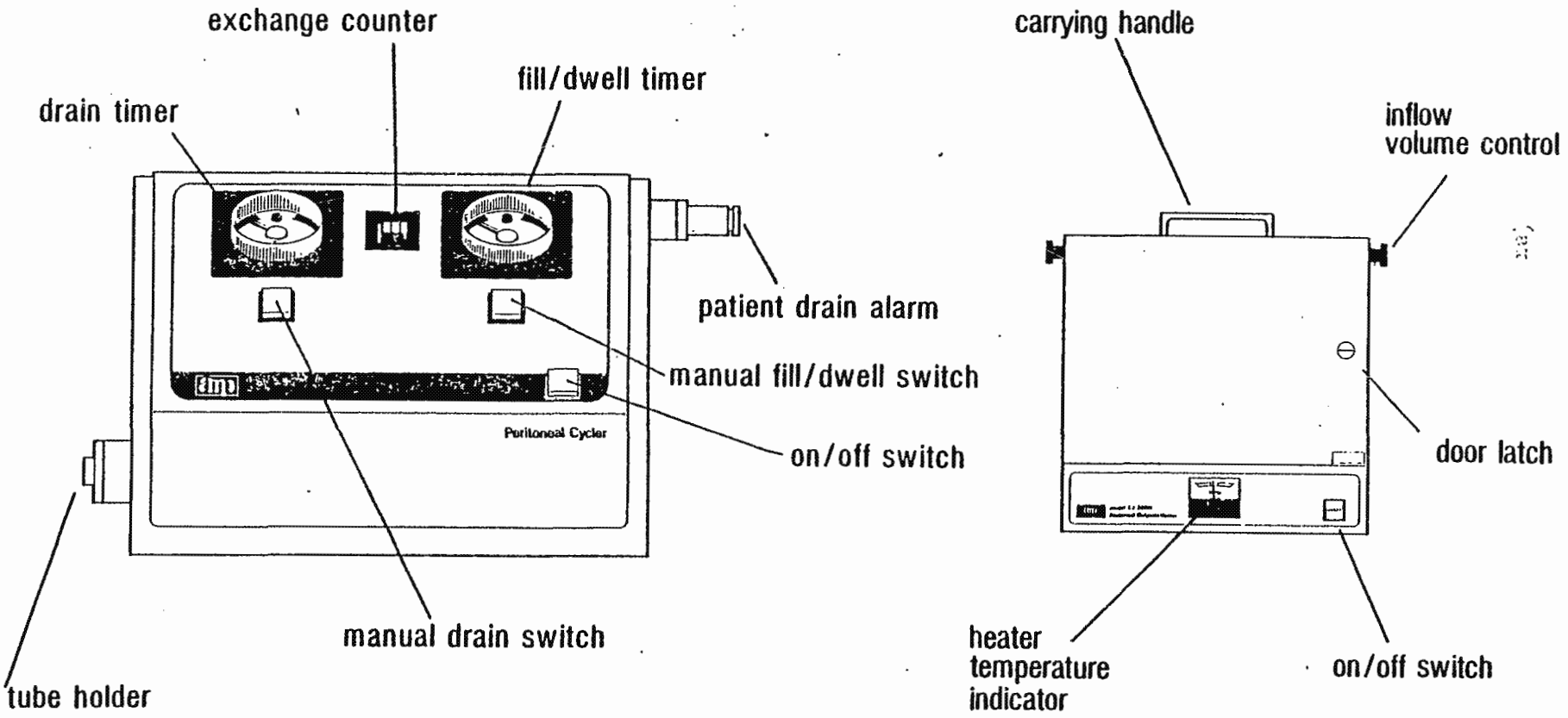
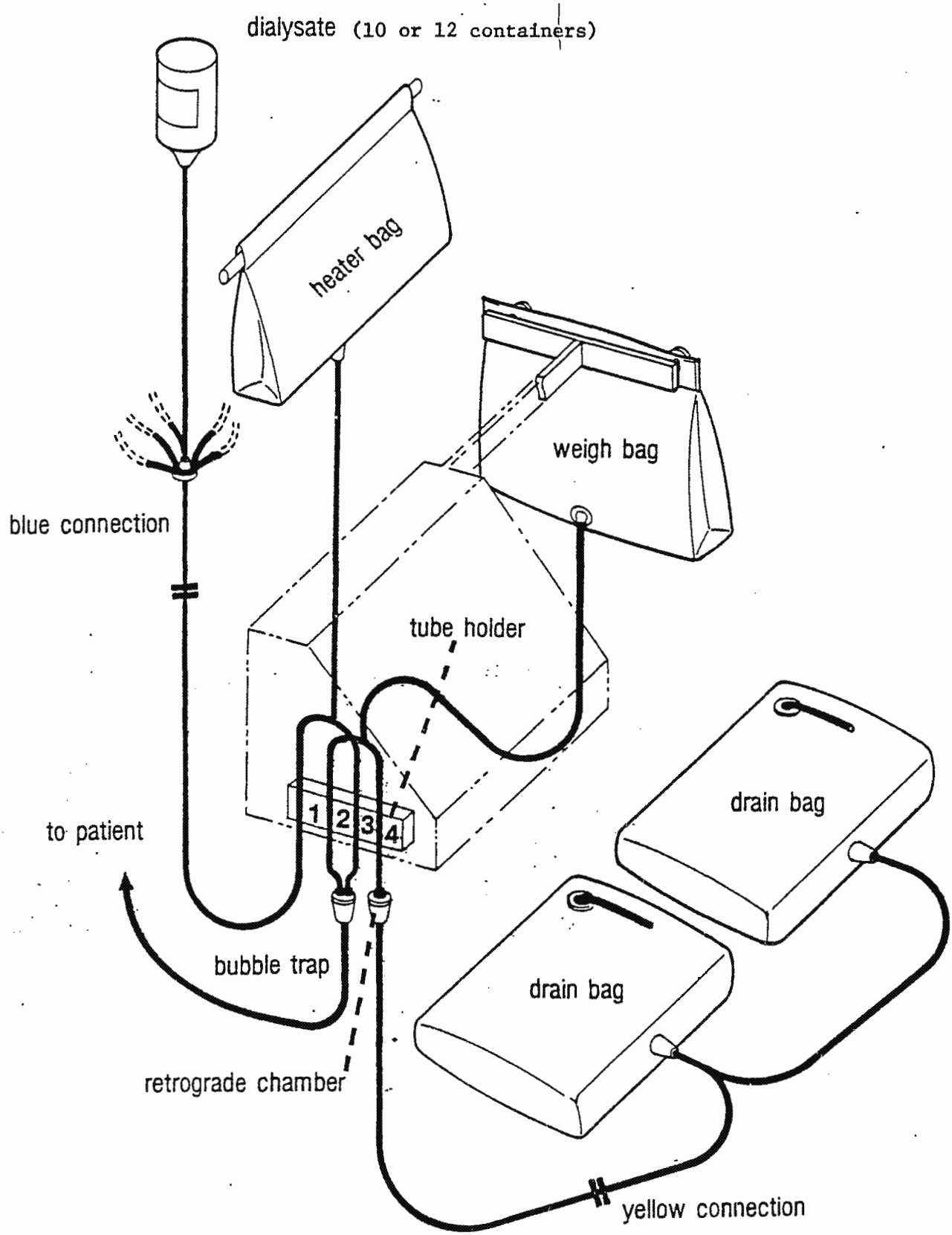


FIGURE B.



CYCLER SET

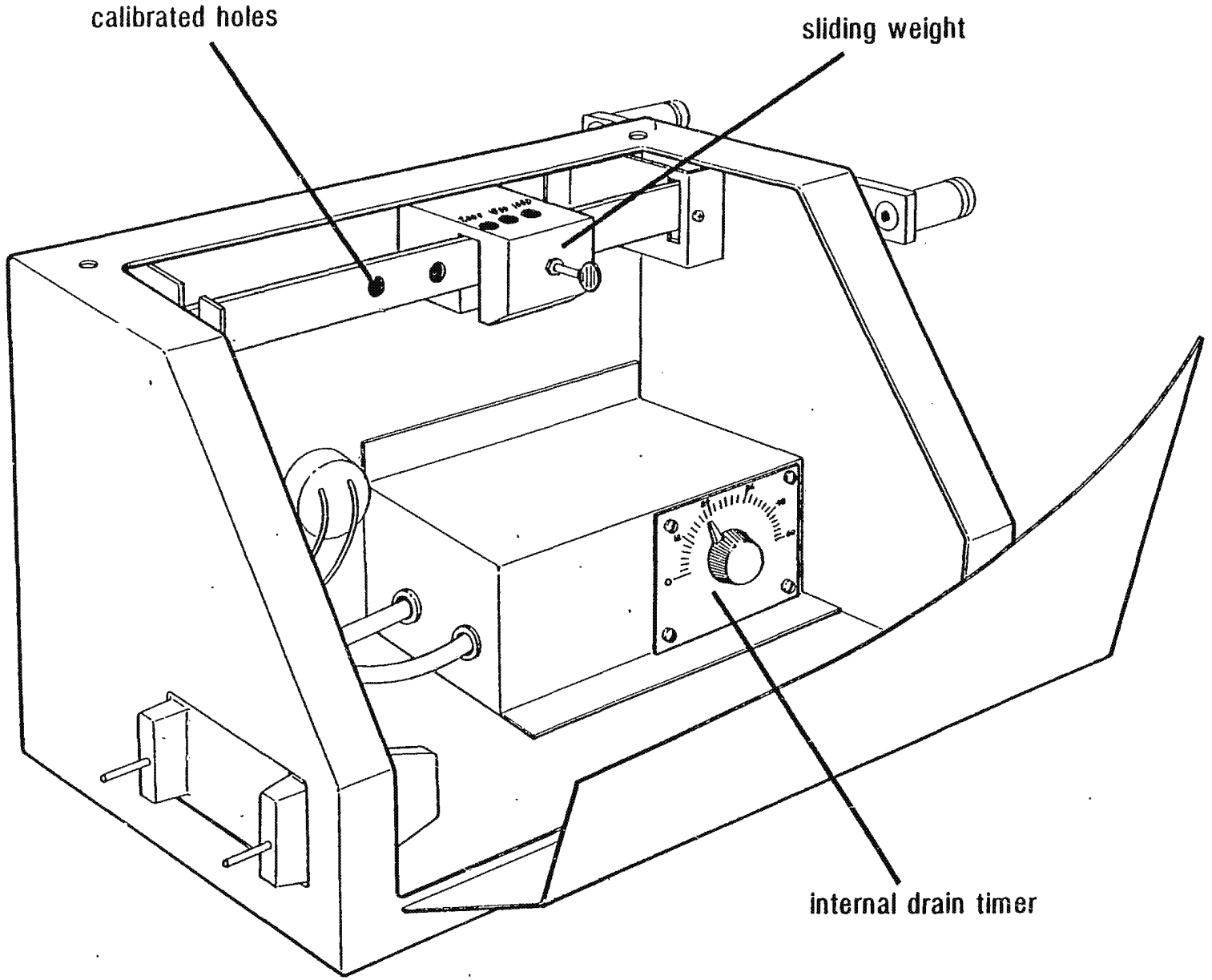


FIGURE D.

APPENDIX II

PROBLEM SOLVING CHART

AMERICAN MEDICAL PRODUCTS CORPORATION

PROBLEM SOLVING CHART

PROBLEM	OBSERVATION	PROBABLE CAUSE	CORRECTIVE ACTION

(b)(4)

(Continued)

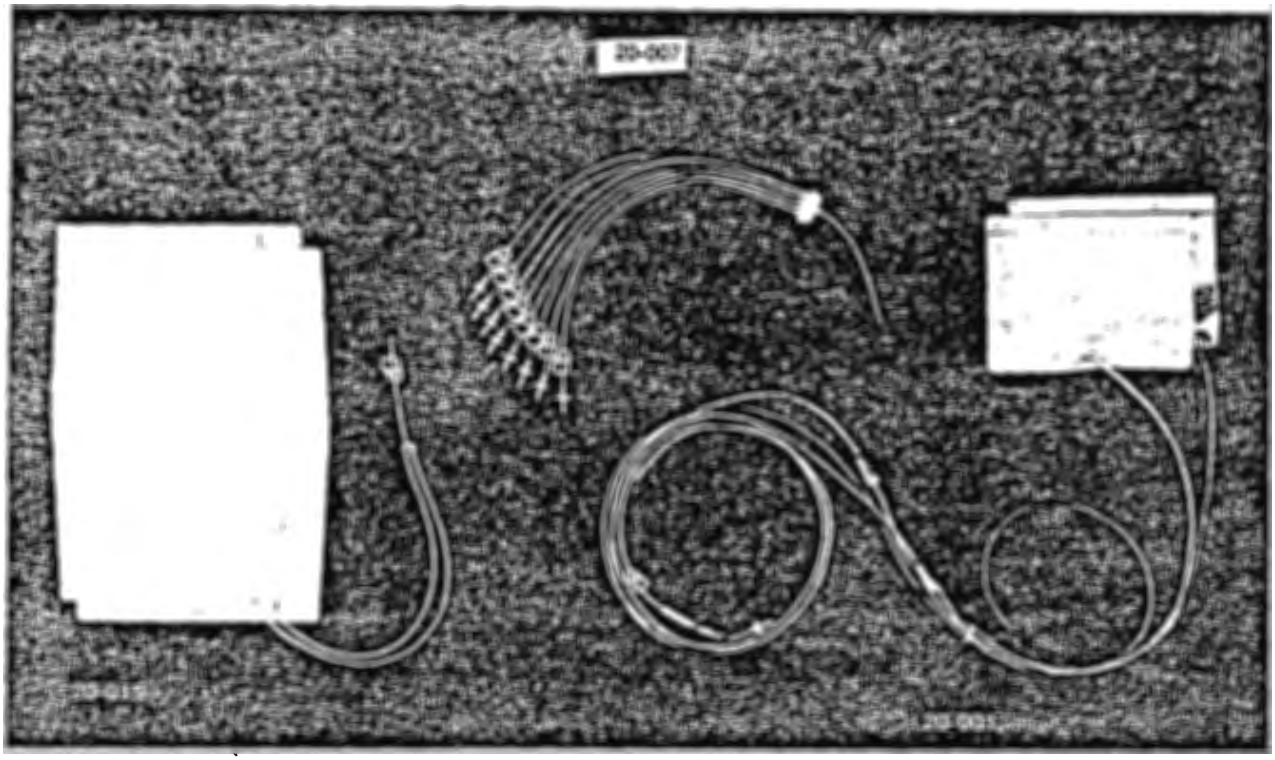
PROBLEM	OBSERVATION	PROBABLE CAUSE	CORRECTIVE ACTION

(b)(4)

APPENDIX III

ORDERING INFORMATION

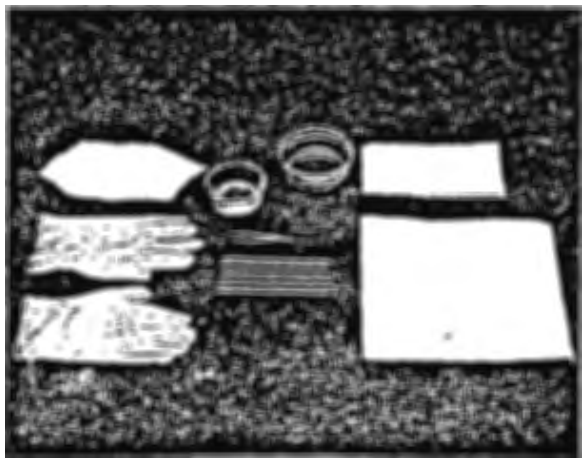
cycler tubing



PATENTED

catalog number	description
20-001	Peritoneal Cycler Set (see illustration above)
20-007	8-Pronged Connector Set (see illustration above)
20-015	Peritoneal Drainage Set (see illustration above)

on-off tray kit



catalog #20-010

Infection risks are minimized through use of the AMP on-off tray kit. American Medical Products offers the required items for beginning and ending dialysis in the form on one convenient sterile package. The items remain completely uniform and are always arranged in the same way from package to package.

contents

10	4 x 4 sponges
6	applicators
2	8 oz. prep cups
1	sterile overwrap
1	fenestrated drape
1	pair of gloves
1	forceps

amp
american medical products corporation
p.o. drawer 190, freehold, n.j., 07728, 201/431-5300