DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

OCT 30 1990

Mr. Thomas E. Cane
Director of Medical Affairs
Fresenius/Delmed, Inc.
4090 Pike Lane
Concord, California 94520

Re: K902149
Fresenius/Delmed 90/2 Peritoneal
Dialysis System
Dated: Undated
Received: May 15, 1990
Regulatory Class: II

Dear Mr. Cane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is 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 the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. 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. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968 such as the requirement to submit an initial report prior to marketing radiation emitting devices, or other applicable Federal laws or regulations.

This letter immediately will allow you to begin marketing your device if you have met all other requirements described above. An FDA finding of substantial equivalence of your device to a pre-Amendment device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Halyna Breslawec

Halyna P. Breslawec, Ph.D.
Director
Division of Gastroenterology-Urology
and General Use Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date 10/29/90

From REVIEWER(S) - NAME(S) Ruth Hubbard, RN CNN

Subject 510(k) NOTIFICATION K902149/A

To THE RECORD

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

X (A) Is substantially equivalent to marketed devices.

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

_____ (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

876.5630 Automatic Delivery Peritoneal Dialysis System

The submitter requests under 21 CFR §807.95:

_____ No Confidentiality

✓ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

FKX 78 Class II

Additional Product Code(s) w/Panel (optional):

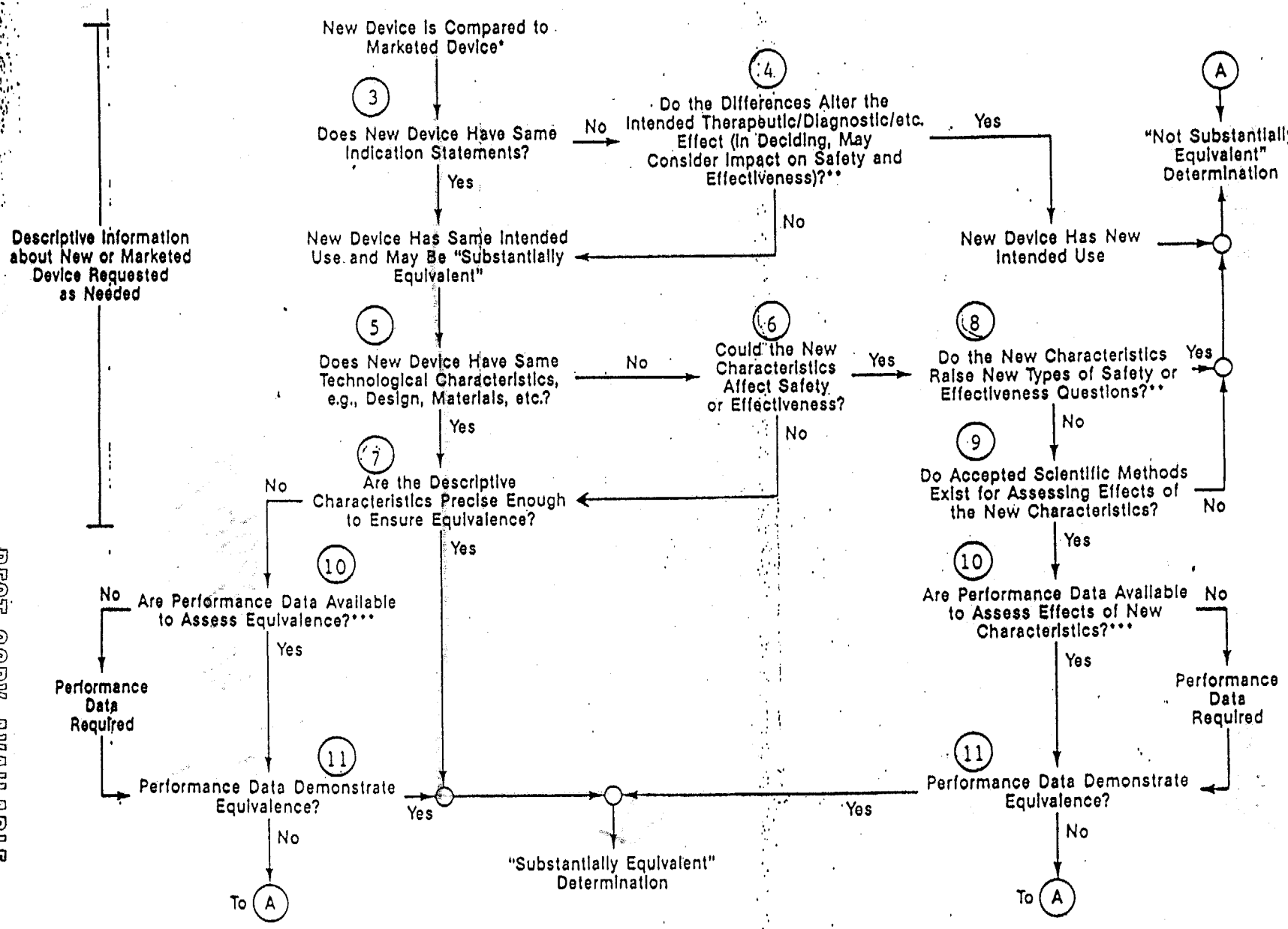
_____

REVIEW: E C Dewey 10/29/90
(BRANCH CHIEF) (DATE)

FINAL REVIEW: J Brezlance 10/29/90
(DIVISION DIRECTOR) (DATE)

X2

510(k) "Substantial uivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information If the Relationship Between Marketed and "Predicate"

** This Decision Is Normally Based on Descriptive Information Alone, But Limited Testing Information Is Sometimes Required.

*** Data May Be In the 510(k), Other 510(k)'s, The Center's Classification Files, or the Literature.

MEMO TO THE RECORD

DATE: 26 OCT 90
FROM: RUTH W. HUBBARD

OFFICE: HFZ-420
DIVISION: DGGD/GU

SUBJECT: K902149/A Fresenius/Delmed, Inc.
90/2 Peritoneal Dialysis System

CONTACT: Thomas E. Cane

PHONE: 415-676-1600

This submission now appears to contain all of the necessary information for a complete premarket notification.

This device, the Fresenius/Delmed 90/2 peritoneal dialysis (PD) cycler is similar in design, intended use and materials as the 80/2 PD cycler reviewed in previous 510(k)s. The 90/2 appears to be an updated version of the 80/2 and rather than having optional components that may be added to the cycler, this is a state of the art device and is one complete unit.

The 90/2 PD Cycler is a class II, prescription device that is intended for use in the treatment of patients requiring peritoneal dialysis for the treatment of acute or chronic renal failure either in the hospital or clinic environment or in the home. The 90/2 will include an ultrafiltration monitor, a last bag controller, a display screen, and an optional waste pump. It will be capable of providing Continous Cyclic Peritoneal Dialysis (CCPD), Intermittent Peritoneal Dialysis (IPD), Tidal Peritoneal Dialysis (TPD), or Nightly Intermittent Peritoneal Dialysis (NIPD). The micrprocessor will allow the 90/2 the versatility in providing the treatment best suited for the patient that the physician has prescribed.

An operator's manual will be provided to the user which has been revised and now includes instructions that will be easily understood by the home dialysis patient, a major portion of the population that will be using this device.

An engineering review of the software is provided by Laura Byrd and it appears that all of her concerns have been addressed satisfactorily.

Recommend substantial equivalence.

Ruth W. Hubbard, RN CNN

RUTH W. HUBBARD, R.N., C.N.N.
Division of Gastroenterology-Urology
and General Use Devices

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

AUGUST 28, 1990

FRESENIUS/DELMED, INC.
ATTN: THOMAS E. CANE
4090 PIKE LANE
CONCORD, CA 94520

D.C. Number : K902149
Received : 08-27-90
90th Day : 11-25-90
Product : FRESENIUS/DELMED
90/2 PERITONEAL
DIALYSIS SYSTEM

The additional information you have submitted has been received.

-- 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. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

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

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K 902149/A **"SUBSTANTIAL EQUIVALENCE" (SÈ) DECISION MAKING DOCUMENTATION**

REVIEWER: Ruth Hubbard, RN CNN **DIVISION/BRANCH:** DGGD

TRADE NAME: 90/2 Peritoneal Dialysis System **COMMON NAME:** Peritoneal Dialysis Cycler

PRODUCT TO WHICH COMPARED: Fresenius/Delmed 80/2 PD Cycler & Optional Components.
(510(k) NUMBER IF KNOWN)

		YES	NO	
1.	IS PRODUCT A DEVICE?	X		- IF NO STOP
2.	DEVICE SUBJECT TO 510(k)?	X		- IF NO STOP
3.	SAME INDICATION STATEMENT?	X		- IF YES GO TO 5
(4.)	DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5.	SAME TECHNOLOGICAL CHARACTERISTICS?	X		- IF YES GO TO 7
(6.)	COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7.	DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	X		- IF NO GO TO 10 - IF YES STOP - SE
(8.)	NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP - NE
9.	ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP - NE
10.	PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DAT
(11.)	DATA DEMONSTRATE EQUIVALENCE?	X		

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

NARRATIVE DEVICE DESCRIPTION

1. **INTENDED USE:** FOR USE IN THE DELIVERY OF DIALYSATE TO PATIENTS REQUIRING PERITONEAL DIALYSIS FOR THE TREATMENT OF ACUTE OR CHRONIC RENAL FAILURE.

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY: SEE ENCLOSED MEMO.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. **EXPLAIN WHY NOT A DEVICE:**_____

2. EXPLAIN WHY NOT SUBJECT TO 510(k):_____

3. **HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:**_____

4. **EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE:**_____

5. **DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:**_____

6. **EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS:**_____

7. **EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH:**_____

_____

_____

_____

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:_____

_____

_____

_____

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED:_____

_____

_____

_____

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED:_____

_____

_____

_____

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT:_____

_____

_____

_____

_____

_____

_____

_____

_____

ATTACH ADDITIONAL SUPPORTING INFORMATION

Computer Software Consulting Review

MEMO TO Ruth Hubbard & THE RECORD **DATE:** 10/12/90

FROM: Electrical Engineer **DIVISION:** DGGD/GU-I

SUBJECT: K902149A, Peritoneal Dialysis System

The Fresnius/Delmed 90/2 Peritoneal Dialysis System (90/2 PDS) is a fully integrated, microprocessor controlled machine which provides maximum versatility for the treatment of patients needing acute or chronic peritoneal dialysis either in a hospital, clinic, or a patient's home.

After consulting with Ruth Hubbard, I am assured that the home user will be given adequate supplies and instructions, through the operators manual and their personal physician, to use this dialysis system.

The information on software development was satisfactory, for a device of moderate concern, to insure safe and effective operation. No new information is requested, but including the summary of 90/2 alarm conditions in the labeling for the user is recommended.

Laura J. Byrd

Laura J. Byrd

 Add Info

K902149/A

FRESENIUS/DELMED 90/2

PERITONEAL DIALYSIS SYSTEM

510(k) NOTIFICATION

SUPPLEMENTAL INFORMATION

Fresenius/Delmed, Inc.
4090 Pike Lane
Concord, CA 94520
(415) 676-1600
8/24/90

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

Re: 510(k) Notification - Fresenius/Delmed 90/2 Peritoneal Dialysis System

SUPPLEMENTAL INFORMATION

This is a response to the request for additional information from the FDA.

The reviewers had five major areas of questions. We will state the question topic and then follow with the answer or additional information statement.

1. Instructions for use

Please refer to the revised Operators Manual seen in appendix A.

Specific emphasis has been placed towards making this document suitable for Home Peritoneal Dialysis Patients, that is, to make it readable and understandable by Patients.

2. Description of all of the components in the device

Gravity Scale (upper scale)

The Gravity Scale is a bending arm load cell with a range of 0-5000 grams. This load cell is alsoutilized in a currently marketed Peritoneal Dialysis Cycler sold by Baxter. The Gravity Fill bag is an integral part of the 90/2 cycler disposable tubing set. In use it is hung on the scale using a bag hook, similar to an IV pole hanger. The scale weight is used to determine the amount of dialysate delivered to the patient.

Drain Scale (lower scale)

The Drain Scale is identical to the Gravity scale. It is used to measure the amount of spent dialysate which is drained from the patient each cycle.

Heating Compartment

The Heating Compartment consists of two aluminum plates and a heat exchange bag (heater bag), which is an integral part of the 90/2 cycler disposable tubing set. The lower plate has a flexible silicone rubber heat pad, similar to that used in the Delmed 80/2 cycler, which is affixed to the bottom side. The provides the heat to warm the dialysate which is allowed to flow through channels in the heat exchange bag. The top plate is insulated and it serves as a backing plate for the occluder valves. The heat transfer is accomplished through transfer of heat from the bottom aluminum plate through the PVC wall of the heat exchange bag and into the dialysate solution. The heater plate has two temperature sensors which measure and control the dialysate temperature. There is one temperature sensor at the inlet and one at the outlet of the heat exchange bag. An additional temperature sensor which is not part of the control circuit shuts the patient valve if the dialysate temperature reaches 39°C.

Dialysate Transfer Pump

The Dialysate Transfer Pump is a peristaltic pump which is used to transfer the dialysate from the dialysate supply bags through the heating compartment and up to the Gravity Fill bag. A stepper motor drive system is operated by the system microprocessor. The pump is designed for use with the pump segment which is an integral part of the 90/2 disposable tubing set. This pump segment is keyed so that it can only be inserted in the proper orientation. The pump housing incorporates a sensing switch which will prevent the pump from operating during the treatment if the pump lid is not closed.

Waste Dialysate Pump

The Waste Dialysate Pump is identical to the Dialysate Transfer Pump, and is mounted on the cycler base.

3. The interface with an optional Printer

As noted in the Operators Manual, the 90/2 is equipped with an RS232 port with which to connect an optional printer to the device in order to make a "hard copy" of the treatment record (Data Sheet). This feature is not necessarily to be utilized by the home patient, but may be. Up to thirty days of records are stored in the 90/2 memory and can be downloaded to another computer or printed out at a later date if necessary.

Printers which are Epson compatible that accept serial communication (RS232 protocol) can be used with the 90/2. The physical connection is made with a standard serial communications cable which plugs into the rear of the cycler control unit at the 9 pin socket. The printer does not require graphics capability as the Treatment Data Sheet utilizes only text.

4. Hazard Analysis

The question of need for an "under temperature alarm" during the treatment was asked. There is no "under temperature" alarm on the 90/2. Many attending nephrologists prefer not to wake the patient in this circumstance since the dialysate is generally at room temperature, and that temperature is what is usual for the CAPD patient treatment. A record of the low temperature occurrence will be displayed at the end of the treatment so the cycler can be checked prior to the next treatment for the occurrence of an "under temperature" condition.

5. Software

5.1 Description of Device and depiction via flowcharts

Description of the features and functions:

The 90/2 Peritoneal Dialysis System is a fully integrated, microprocessor controlled machine which provides for treatment of patients needing acute or chronic peritoneal dialysis, either in a clinic or in the patients home.

Basic operation of the system

The 90/2 is a peritoneal dialysate cycler, that is it's main function is to route dialysate to and from the patient. The sequence is to drain, fill, and dwell, repeated over and over, as prescribed

and programmed into the system. The machine is actually passive in a sense, because all flow to the patient is by gravity, no pumps are used to route fluid to or from the patient. Essentially, the cycler is programed to fill a Gravity Bag with a pre-determined volume of dialysate by pumping it from a group of serially joined dialysate containers. During this pumping phase, the dialysate is warmed to a comfortable temperature by moving it through a heater on its journey up to the Gravity Bag.

After a valve opens and the patient has been allowed enough time to drain the previous cycle,'s dialysate, the fluid in the Gravity Bag is allowed to flow into the patient. A clock/timer then sets into motion another pre-determined cycle and the cycle is repeated as required.

Of course, during all cycle phases, the system monitors all pumps, valves, temperature sensors, and scales for malfunction. Appropriate alarms, both visual and audible are activated to alert the clinic staff or the patient if there is a problem.

Display Screen

As depicted in the Operator's Manual, the Fresenius/Delmed 90/2 has an electro-luminesent display screen which shows the status of the procedure through the use of pictures indicating the direction and routing of the fluids, and whether the patient is in a fill, dwell or drain mode.

Ultrafiltration Monitor

During the normal peritoneal cycler operation, the patient is connected to the machine via a PVC tubing set. The machine then alternately fills the patient with dialysis solution, allows the solution to dwell, and then drains the patient. During the dwell period, under certain conditions, the patient is either absorbing some of the dialysis fluid or is excreting excess body fluid into the dialysis fluid. This process is known as ultrafiltration. The amount and type (absorbtion or excretion) of ultrafiltration gives the attending physician valuable information on the effectiveness of the treatment.

The ultrafiltration can be determined by measuring the total volume of fluid delivered to the patient and then measuring the total volume of fluid drained from the patient. The difference is the ultrafiltration value. The most common method of measuring the fluid volume is by measuring the weight of the fluid which can be expressed as milliliters of patient weight loss or gain during the treatment.

The determination of the ultrafiltration is performed by weighing the outflow in the weigh bag, which is attached to a scale.

Last Bag Controller

Frequently, during the last cycle of a treatment, the patient does not drain the fluid from the peritoneal cavity, but disconnects from the machine and carries the fluid during the day, until the next cycling procedure. The fluid used for the last cycle is frequently a different concentration or volume than the previous bags used during the cycling procedure. Because of this, it may be desirable to have the cycler machine automatically select and use a different bag of solution for the last cycle.

The controller possesses two valves through which the tubing is placed to be either opened or occluded to control the flow of the last bag fluid.

Optional Waste Pump

An optional waste pump that can be used to pump the spent dialysate from the weigh bag to a remote drain can be installed on the Fresenius/Delmed 90/2 Cycler base. This is a convienence to the patient or staff, so they don't have to handle heavy drain bags. This option has no impact on the function of the cycler.

5.2 Clarification of the flow of action

Operational flow charts are located in Appendix B.

Main MPU Routine

The 90/2 main MPU Routine is shown in the flow chart located in Appendix B. Once the machine is switched "on", it begins an initialization routine which begins with a CPU check. If the CPU is not OK, a "critical failure" occurs.

If the CPU check is OK, RAM and ROM are tested in the same manner. Again, if the component fails the check, a "critical failure" occurs. If the check passes, RAM is initialized and a check is made of the Battery Backed-up RAM. If the Battery is not functional, a warning is issued via the Display Screen. If the Battery is OK, the same test is performed on the Backup Power Battery. If the Backup Power Battery is not functional, a warning is issued via the Display Screen. If the Backup Power Battery is OK, the CPU proceeds with a Watchdog test. If the Watchdog test fails, a "critical failure" occurs. If the Watchdog test is OK, it is locked and a check is made of the Hardware Input devices. A "critical failure" occurs if the Hardware Input test fails. If passed, the MPU will display either the Start Menu, or the Interrupted Menu (if there has been a power failure).

Main Program

The Start Menu is displayed and either Help, View Data, or Start Treatment (Drain or Fill Phase) can be selected by the operator. For the sake of brevity, the Start Menu will be described and flow charts included in this notification as an example, (the Help and View Data Menus will not be covered). A routine as also shown in flow chart form for the "Do Action" required for the current cycler phase, either Drain or Fill. A flow chart for the Start Menu is attached.

Upon startup, the operator must press either a Start, Stop, or Select Key on the 90/2 Control Panel.

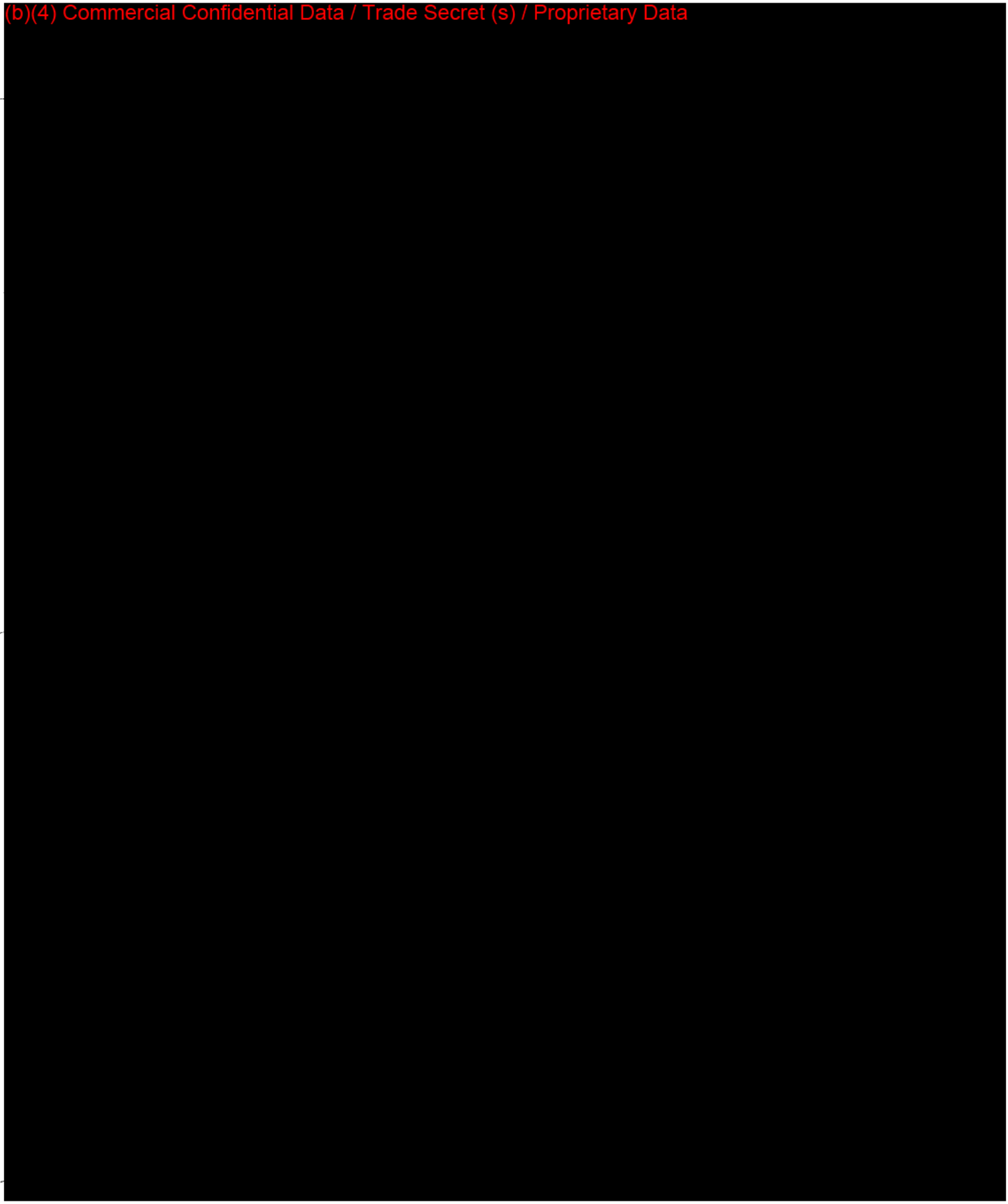
The Start Key prompts a display of these choices: Start Treatment with Drain cycle, Help, View Data, and Start Treatment with a Fill cycle. Starting a cycle automatically initiates a Self Test for Drain or Fill Phases.

"Do Action"

The "Do Action"flow chart for each phase, (Fill, Dwell, and Drain), is shown in the flow chart located in Appendix B. If the treatment reaches it's normal conclusion, (ie, treatment done), the display returns to the Start Menu. If the Stop Key is pressed, the system goes into a Safe Mode, and displays the Interrupted Menu, which allows choice of resuming treatment, allowing a Drain cycle, View Data, or End Treatment. If End Treatment is selected, choices are Cancel, End, Last Bag cycle, or Resume Treatment.

5.3A. Electronic Tests PD Cycler 90/2 Electronics Test

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data



5.3B. Startup Self Tests

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

5.4 "Alarms and corrective action are unclear"

Please note the changes in the Operators Manual in Appendix A. This is still only an initial draft, and it will be improved upon prior to distribution to home patients, but the basic elements are included.

5.5 Alarm Summaries and Hazard Analysis

The following text describes the potential cause of an alarm condition seen when using the 90/2 cycler. The possibilities are:

*Drain Alarm	*Fill Alarm
*Dialysate Transfer Pump Alarm	*Drain Pump Alarm
*Error Code Alarms	*Priming Alarms
*Gravity Scale Alarm	*Drain Scale Alarm

Each alarm condition requires the operator to press a keypad on the control panel of the 90/2 system. The text also provides some trouble shooting guidance.

Summary of 90/2 Alarm Conditions

DRAIN ALARM:

CAUSE: 85% OF VOLUME INFUSED IN LAST FILL CYCLE DID NOT RETURN DURING THE SET DRAIN TIME.

PRESS: STOP KEYPAD TO SILENCE THE ALARM. THE VOLUME SHORTFALL WILL BE DISPLAYED ON THE SCREEN.

IF SHORTFALL VOLUME IS LARGE, CHECK THE DRAIN CIRCUIT FOR: KINKS IN THE LINES, CLOSED TUBING CLAMPS, OR ANY FLOW BLOCKAGE. AFTER CORRECTING THE PROBLEM,

PRESS: START KEYPAD ONCE TO REPEAT DRAIN CYCLE.
or IF DRAIN VOLUME SHORTFALL IS ACCEPTABLE,
PRESS: START KEYPAD TWICE TO ADVANCE TO FILL.

***NOTE:** THIS ALARM MAY INDICATE INADEQUATE CATHETER FLOW. IF ALARM OCCURS FREQUENTLY, DRAIN TIME SHOULD BE INCREASED AND CATHETER CHECKED.

FILL ALARM

CAUSE: FILL VOLUME NOT INFUSED WITHIN THE SET FILL TIME.

PRESS: STOP KEYPAD TO SILENCE THE ALARM. THE VOLUME SHORTFALL WILL BE DISPLAYED ON THE SCREEN.

CHECK FOR KINKS OR FLOW BLOCKAGE IN FILL CIRCUIT. CORRECT ANY PROBLEMS. IF SHORTFALL VOLUME IS SIGNIFICANT AND GRAVITY BAG HAS FLUID IN IT.

PRESS: START KEYPAD ONCE TO REPEAT FILL CYCLE.
or IF SHORTFALL VOLUME IS ACCEPTABLE, OR GRAVITY BAG IS EMPTY,
PRESS: START KEYPAD TWICE TO ADVANCE TO DWELL.

DIALYSATE TRANSFER PUMP ALARM

CAUSES: THE DIALYSATE SOLUTION CONTAINERS ARE EMPTY. NOT ENOUGH SOLUTION IS IN THE GRAVITY BAG FOR NEXT FILL CYCLE. THE DIALYSATE SOLUTION CONTAINERS ARE FULL BUT THE PUMP IS UNABLE TO FILL THE GRAVITY BAG WITH ENOUGH SOLUTION FOR NEXT FILL CYCLE.

PRESS: STOP KEYPAD TO SILENCE THE ALARM. THE SHORTFALL VOLUME WILL BE DISPLAYED ON THE SCREEN.

IF MORE SOLUTION IS NEEDED TO COMPLETE THE TREATMENT, CONNECT ADDITIONAL BAGS.

PRESS: START KEYPAD ONCE TO CONTINUE TREATMENT. THE HEATER PLATE WILL WARM UP TO TEMPERATURE, AND THEN THE PUMP WILL TRANSFER THE ADDITIONAL DIALYSATE TO THE GRAVITY BAG.

IF THERE IS PLENTY OF SOLUTION, CHECK SOLUTION SUPPLY LINES FOR KINKS, AND CHECK TO SEE THAT THE PUMP LID IS CLOSED. AFTER PROBLEM IS CORRECTED,

PRESS: START KEYPAD ONCE TO CONTINUE TREATMENT. THE HEATER PLATE WILL WARM UP TO TEMPERATURE, AND THEN THE PUMP WILL TRANSFER THE ADDITIONAL DIALYSATE TO THE GRAVITY BAG.

IF THE SHORTFALL VOLUME IS ACCEPTABLE,

PRESS: START KEYPAD TWICE TO ADVANCE TO FILL.

DRAIN PUMP ALARM

CAUSES: KINKED LINE IN THE PUMP TO DRAIN CIRCUIT. LINES ARE FREE BUT SOME SMALL AMOUNT OF FLUID REMAINS IN THE WEIGH BAG.

PRESS: STOP KEYPAD TO SILENCE THE ALARM. AMOUNT OF FLUID REMAINING IN THE WEIGH BAG WILL BE DISPLAYED ON THE SCREEN.

IF THE AMOUNT IS ACCEPTABLE,

PRESS: START KEYPAD TWICE TO BYPASS THE ALARM. IF THE AMOUNT IS SIGNIFICANT, CHECK FOR KINKS IN THE DRAIN LINES, AND THAT THE PUMP LID IS CLOSED. AFTER CORRECTING THE PROBLEM,

PRESS: START KEYPAD ONCE TO START THE DRAIN PUMP CYCLE OVER.

ERROR CODE ALARMS

CAUSE: 90/2 MICROPROCESSOR HAS DETECTED A SYSTEM FAULT EITHER DURING AN INITIAL SELF TEST OR DURING THE TREATMENT ITSELF.

PRESS: STOP KEYPAD TO SILENCE THE ALARM. THE APPROPRIATE ERROR MESSAGE WILL BE DISPLAYED ON THE SCREEN.

THE DISPLAYED MESSAGE WILL BE ONE OF THE FOLLOWING:

*EPROM FAILURE	*RAM FAILURE
*BATTERY RAM FAILURE	*A/D FAILURE
*POWER SUPPLY HIGH	*POWER SUPPLY LOW
*12 VOLT HIGH	*12 VOLT LOW
*5 VOLT HIGH	*5 VOLT LOW

ACTION: RECORD THE ERROR MESSAGE. TURN THE MAIN POWER SWITCH OFF AND THEN BACK ON. IF THE CYCLER POWERS BACK UP NORMALLY RESTART THE TREATMENT. IF AN ERROR CODE APPEARS AGAIN STOP THE TREATMENT AND REPORT THE ERROR MESSAGE TO YOUR SERVICE REPRESENTITIVE.

PRIMING ALARMS

CAUSE: DURING THE PRIME CYCLE, ONE OR MORE OF THE VALVES OR PUMPS HAS FAILED TO OPERATE PROPERLY.

PRESS: STOP KEYPAD TO SILENCE THE ALARM. THE FAILURE MESSAGE WILL BE DISPLAYED ON THE SCREEN.

THE DISPLAYED MESSAGE WILL BE ONE OF THE FOLLOWING:

*POSSIBLE DRAIN VALVE FAILURE
*POSSIBLE MAIN BAG VALVE FAILURE
*POSSIBLE PATIENT VALVE FAILURE
*POSSIBLE DRAIN PUMP FAILURE
*POSSIBLE GRAVITY VALVE FAILURE
*POSSIBLE LAST BAG VALVE FAILURE
*POSSIBLE TRANSFER PUMP FAILURE

ACTION: CHECK TO MAKE SURE THAT THE HEAT EXCHANGE BAG IS PROPERLY PLACED ON THE HEATER PLATE, THAT ALL THE TUBING CLAMPS ARE OPEN AND THAT THE PUMP LIDS ARE CLOSED. AFTER CHECKING THESE ITEMS,

PRESS: START KEYPAD ONCE TO REPEAT THE PRIME CYCLE.

***NOTE:** THE PRIME CYCLE MUST BE COMPLETED SATISFACTORILY TO PROCEED WITH THE TREATMENT. IF THE ALARM OCCURS AGAIN AFTER REPEATING THE PRIME, THEN THERE IS A PROBLEM WITH A VALVE AND/OR PUMP, AND A SERVICE REPRESENTITIVE MUST BE CALLED.

GRAVITY SCALE ALARM

CAUSE: THE WEIGHT ON THE GRAVITY SCALE HAS CHANGED DURING A PORTION OF THE TREATMENT WHERE NO CHANGE IS EXPECTED.

PRESS: STOP KEYPAD TO SILENCE THE ALARM.

CHECK TO MAKE SURE NOTHING IS LEANING OR PULLING ON THE SCALE, THAT THERE IS NO LEAK IN THE TUBING SET, AND THAT THE HEATER PLATE LID IS SECURELY FASTENED. CORRECT IF POSSIBLE AND,

PRESS: START KEYPAD ONCE TO RESUME TREATMENT.

***NOTE:** IF ALARM RE-OCCURS, STOP THE TREATMENT AND CALL YOUR SERVICE REPRESENTITIVE.

DRAIN SCALE ALARM

CAUSE: THE WEIGHT ON THE DRAIN SCALE HAS CHANGED DURING A PORTION OF THE TREATMENT WHERE NO CHANGE IS EXPECTED.

PRESS: STOP KEYPAD TO SILENCE THE ALARM.

CHECK TO MAKE SURE NOTHING IS LEANING OR PULLING ON THE SCALE, THAT THERE IS NO LEAK IN THE TUBING SET, AND THAT THE HEATER PLATE LID IS SECURELY FASTENED. CORRECT IF POSSIBLE AND,

PRESS: START KEYPAD ONCE TO RESUME TREATMENT.

***NOTE:** IF ALARM RE-OCCURS, STOP TREATMENT AND CALL YOUR SERVICE REPRESENTATIVE.

5.6 Software Development

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

Please contact me at (415) 676-1600 if further information is required.

Sincerely,

Thomas E. Cane
Director of Medical Affairs

Appendix A.

Instructions For Use, (Revised)

Draft Operators Manual

Draft

FRESENIUS/DELMED

90/2

PERITONEAL DIALYSIS SYSTEM

* OPERATORS MANUAL *

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

FRESENIUS USA, INC.
Concord, CA 94520
DATE: 8/24/90
REVISION: #####

TABLE OF CONTENTS

INTRODUCTION

The 90/2 Peritoneal Dialysis System is a fully integrated, microprocessor controlled machine which provides maximum versatility for the treatment of patients needing acute or chronic peritoneal dialysis in either a hospital or clinic environment or at the patient's home.

The physician can select a choice of therapy from among:

CCPD (Continuous Cycling Peritoneal Dialysis)
IPD (Intermittent Peritoneal Dialysis)
TPD (Tidal Peritoneal Dialysis), and
NIPD (Nightly Intermittent Peritoneal Dialysis).

Because of the microprocessor control, the 90/2 can tailor the therapy to patients as patient models are developed clinically.

The front control panel display screen of the 90/2 enables both the staff and the patient to continuously monitor the treatment by virtue of simplified graphics and text messages. Help Screens serve as on-line troubleshooting guides, should problems arise with the treatment.

Treatment data can be printed out to provide a "hard copy" record, or can be stored internally and downloaded to a specified storage medium, either at the machine or via modem.

The 90/2 has a battery backup to enable the treatment to continue, (everything but the heater will work), during short power interruptions.

SPECIFICATIONS:

* Size:
  Base- 24 in. x 22 in.
  Height- 60 in. at minimum setting.

* Weight:
  Cycler control unit- 40 lbs.
  Base and Stand- 55 lbs.

* Electrical Requirements:
  120 VAC; 7 amp.

* Current Leakage:
  Under 100 microamperes

* Fill Volumes:
  Variable in 10 ml increments up to 3000 ml (3 Liters)

* Number of Cycles (Exchanges): 1-99

* Dwell Times:
  Variable in 1 min increments up to 9 hours and 59 minutes

* Ultrafiltrate Monitor:
  Accuracy; +/- 10 ml
  Range; 0-9000 ml Read out
  Per Exchange and Treatment total

Temperature Control:
  Accuracy; +/- 0.5° C

FUNCTIONAL DESCRIPTION

The 90/2 Peritoneal Dialysis System consists of a base and stand assembly, an upper scale assembly, and the main cycler control unit which includes the heating unit and the lower scale assembly. (See Fig. 1)

The cycler control unit consists of:

1. The heating unit which warms the dialysate.
2. Five occluders which control the flow of fresh dialysate to the patient, either from the main bags or the last bag, and the flow of the "spent" dialysate from the patient.
3. The front control panel which is the patient interface.
4. The system electronics.

Cycler

By plugging the 120 VAC power cord into a properly grounded wall receptacle you will provide power to both the cycler and the heating unit. The main components of the cycler are discussed below.

1. Front Control Panel

The front control panel provides the interface with the patient. It consists of a flat display screen and five keypads. The display screen will display to the user a series of screens consisting of both text and graphics that will prompt the user, display cycle and treatment data, display alarms, and give the user/patient some help messages. (See Fig. 2)

25

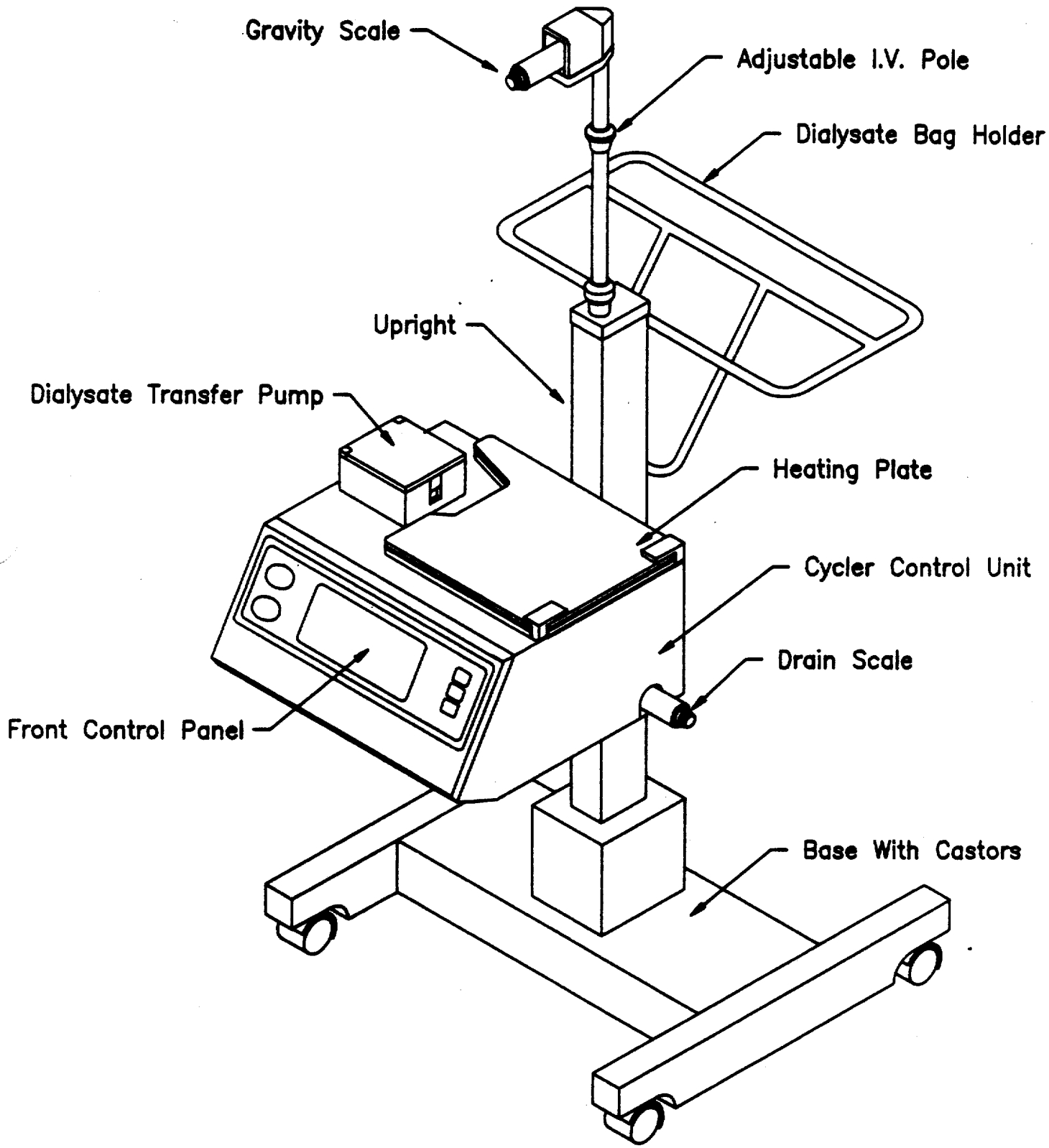


Fig. 1

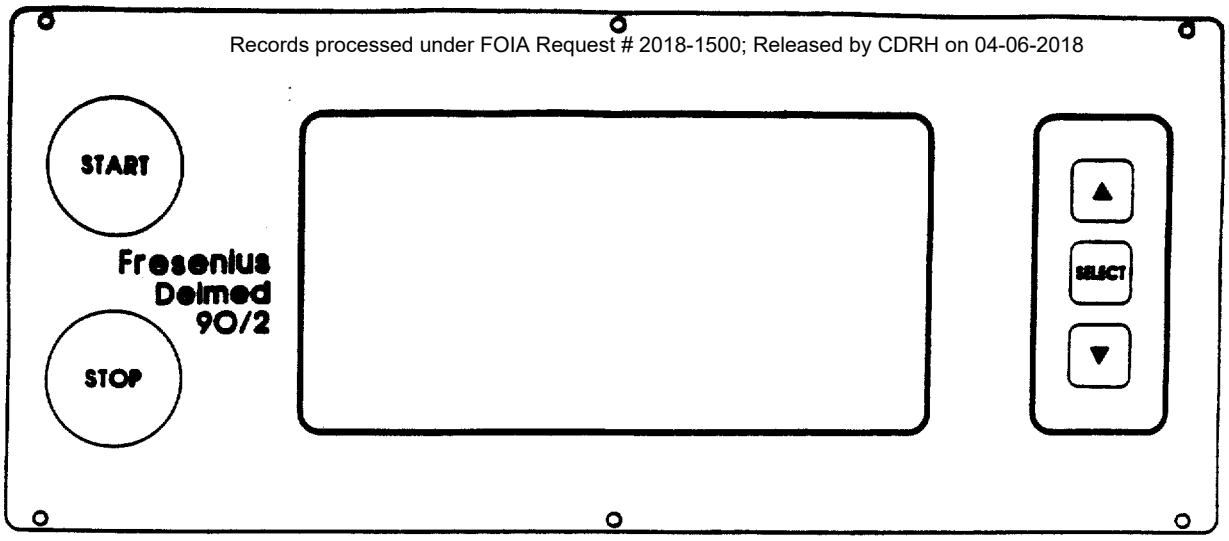


Fig. 2

The **Start** key pad is used to step through the normal sequence of the cycle and the **Stop** keypad is used to halt the treatment at any time and also to be able to drain the patients peritoneal cavity from any step in the main sequence. The **Select** and the **Up/Down** arrow keypads are used in conjunction with menu options displayed on the various screens.

2. Heating Unit

The heating unit sits directly on the top part of the cycler. This unit is designed to use only the heat exchange bag that is part of the Delmed tubing set sold for use with this cycler. The dialysate is warmed as it is pumped from the supply bags to the gravity bag. The gravity bag holds the warmed dialysate until it is allowed to enter the patient.

3. Occluders

The five occluder valves are used to separate the various flow paths in the heat exchanger bag. Two valves control whether the supply to the patient is drawn from the main bags or from the last bag. One is used to enable filling the patient and one is used to enable routing of the spent patient fluid to the drain. Both of these valves are used in conjunction with a redundant patient valve. (See flow diagram, Fig. 3)

4. Main Electronics

The main electronics which operates the 90/2 cycler, consisting of the analog, digital, and microprocessor circuitry, is housed in the cycler control unit. Connections made via the rear electrical panel supply signals to the upper scale, an optional waste pump, and a RS 232 port which is used to download treatment data from the cycler to a Epson-compatible serial printer or to any suitably equipped computer, (serial interface capability).

5. Lower Scale

This scale measures, (by weight) the fluid drained from the patient. It is located on the right side of the cycler control unit. (See Fig. 1)

Caution: it is important that the scale and drainage bag, which is hung on the scale be able to hang freely, (not lodged up against a bed or wall, or any other object).

Cycler Shelf

The cycler sits on the cycler shelf, which can be adjusted to the appropriate gravity height, depending on the height of the patient.

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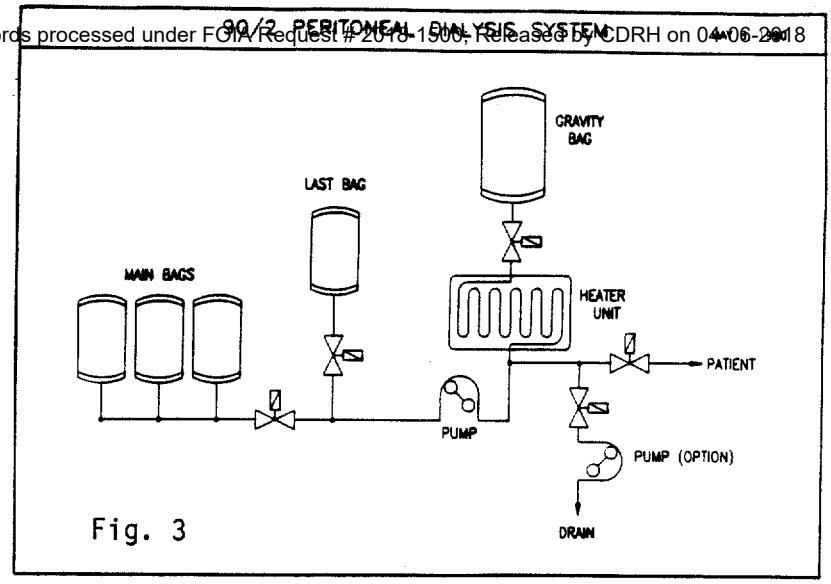


Fig. 3

Base with Castors and Waste Pump (Option)

The cycler base adds extra weight to stabilize the equipment. The castors allow portability.

Caution: care should be taken when moving the 90/2 Cycler after tubing or dialysate containers have been set up.

An optional waste pump that can be used to pump spent dialysate from the weigh bag to a remote drain can be installed on the 90/2 base. This is a convenience for the patient and/or staff to eliminate the need to handle the heavy drain bags.

OPERATIONAL DESCRIPTION

Preparation

The supplies needed for a treatment using the 90/2 Peritoneal Dialysis System include fresh dialysate containers (bags) with the appropriate formula and concentration as prescribed by your physician, the Delmed tubing set that is designed for use with this machine, a drain line extension, (if using the optional waste pump), or a drainage set, and any ancillary equipment that you normally utilize.

Plug in the 90/2 Peritoneal Dialysis System to a properly grounded outlet and turn on the power with the on/off switch on the back of the machine. The Title Screen, (See Fig. 6), will be displayed. Pressing the **Start** keypad will change the display to the Start Screen. (See Fig. 7).

Select the menu option View/Change Data by using the **Up/Down** keypads to move the cursor to that option. Pressing the **Select** keypad. The display will change to the Settings 2 screen (see Fig. 8). Enter in the treatment parameters: fill volumes-normal "Exchange" and Last Bag, Dwell time, total number of exchanges and tidal volume if tidal dialysis has been selected. After the treatment parameters have been entered, return to the Start Screen by pressing the Select keypad.

Hang the dialysate bags of the prescribed volume and concentration on the supply rack. It is recommended that each bag be tested for leaks by squeezing it prior to placing on the supply rack. If the last bag procedure has been selected, hang the last bag at the left side of the cycler, as this is where the last bag line is located. Add any medication to the bags prior to hanging the bags.

Place the Delmed tubing set on the 90/2 Peritoneal Dialysis System. Open the lid of the heating unit and place the heat exchange bag on the locating pins. The patient line will then extend

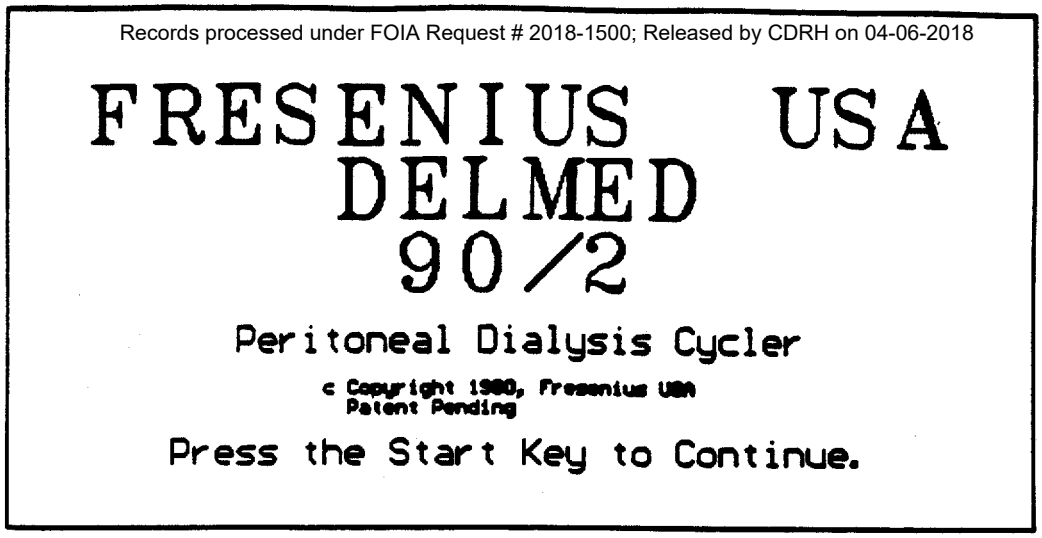


Fig. 6

out the front of the cycler and the rest of the lines out the back. Open the lid on the dialysate pump and thread the tubing segment into the pump by pressing the push button on the pump housing. The pump will automatically load the pump segment and stop after the pump segment is in place. Note that the pump segment is keyed so it can only be placed in the pump in one way so that the direction of flow is always correct. Do not force the pump segment to fit. Close the pump lid, and close and tighten the heater unit lid. If either of these are not closed, an alarm message will be given when the cycle is started.

Now hang the empty gravity bag portion of the Delmed tubing set from the top scale and place the weigh bag portion of the Delmed tubing set on the lower scale.

If an optional waste pump is used, connect the drain line to the pump and the drain extension to a remote drain location. If this pump is not utilized, then connect the drain line to the drainage set. The dialysate bags can now be connected to the tubing set and the system is ready to be primed.

Note: It is a good idea at this time to check the whole tubing system for any twists or kinks in the lines that could restrict or prohibit flow during the treatment.

Priming the System and System Self Test

Prior to the connection of the patient line to the catheter, the prime procedure must be performed in order to remove air from the system.

When the user is ready to prime the system and initiate the treatment, open clamps connected to bags one at a time, allow the air to come down the first line and up the second line; open the second clamp and be sure that the air travels up into the bag. If the air hesitates or seems to stop when it reaches the connector, tap the connector to dislodge the air. Proceed in this fashion as you open the remaining lines, paying particular attention to the last one that is opened.

The 90/2 Peritoneal System will automatically prime itself. During this priming cycle the machine will run a self test which tests the valves, pump(s) and scales. The microprocessor circuitry was previously tested during the "power up" sequence, when the system was turned on. Any failures of the self test will display an error message on the display screen. If there is no failure, a test passed message will be displayed, and the patient can now be connected to the cycler.

Unclamp the patient line allowing the fluid to flow and fill it. The priming cap may be left in position to accomplish this. When all the air in the patient line has been displaced with solution,

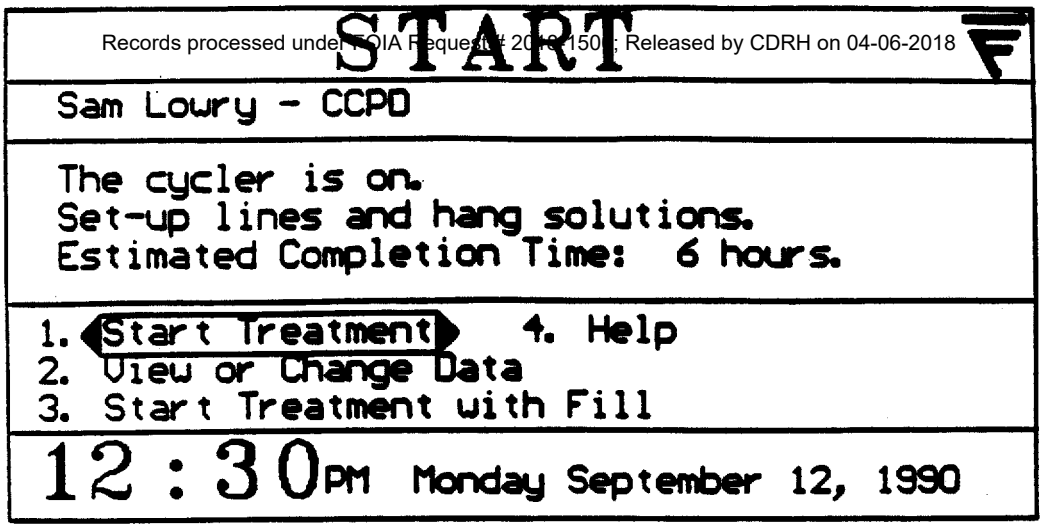


Fig. 7

clamp the patient line. Now perform the catheter connection procedure according to the clinic's and the physician's instructions.

Start Treatment

After the patient has been properly connected to the 90/2 Peritoneal Dialysis System the treatment can begin. Select the Start Treatment menu option and press the **Start** keypad. The treatment is now automatic, and will progress from cycle to cycle according to the treatment parameters which were entered during the set up of the machine. Press the **Stop** keypad at anytime during any cycle to immediately halt the treatment and give the patient a choice of options, (See Fig. 9), including an immediate drain of the fluid in the peritoneal cavity. Any alarm condition detected by the machine will also halt the treatment and display an alarm message.

One complete cycle or exchange consists of a patient drain, a patient fill, and a dwell mode.

Patient Fill Mode

Pre-warmed dialysate solution is gravity fed to the patient from the gravity bag. The solution passes through the heat exchange bag wherethe final heating is done to ensure dialysate delivered to the patient is at the proper temperature. When the predetermined fill volume (monitored by the upper scale) has reached the patient, the 90/2 switches into the dwell mode. During the fill mode, the display screen shows the parameters associated with that mode in both text and graphics. (See Fig. 10).

Dwell Mode

The dialysis tratment takes place during the dwell mode and the patient is isolated from the cycler by the closed patient valve. During the dwell mode, spent dialysate that has been collected in the weigh bag is either pumped to a remote drain location or gravity drained into a drain bag. Also toward the end of the dwell mode, fresh dialysate is pumped from either the main supply bags or the last bag, through the heat exchanger bag, where it is warmed to the specified temperature, and routed up into the gravity bag. When the required amount of fluid for the next fill cycle has reached the gravity bag (monitored by the upper scale), and the dwell time has ended, the 90/2 will switch into the drain mode. During the dwell mode, the display screen shows the parameters associated with that mode in both text and graphics. (See Fig. 11).

Patient Drain Mode

Spent dialysate drains by gravity from the patient to the weigh bag which is positioned on the lower scale. This scale monitors the drain flow rate and an alarm is generated if the rate or total volume collected is outside of specified limits.

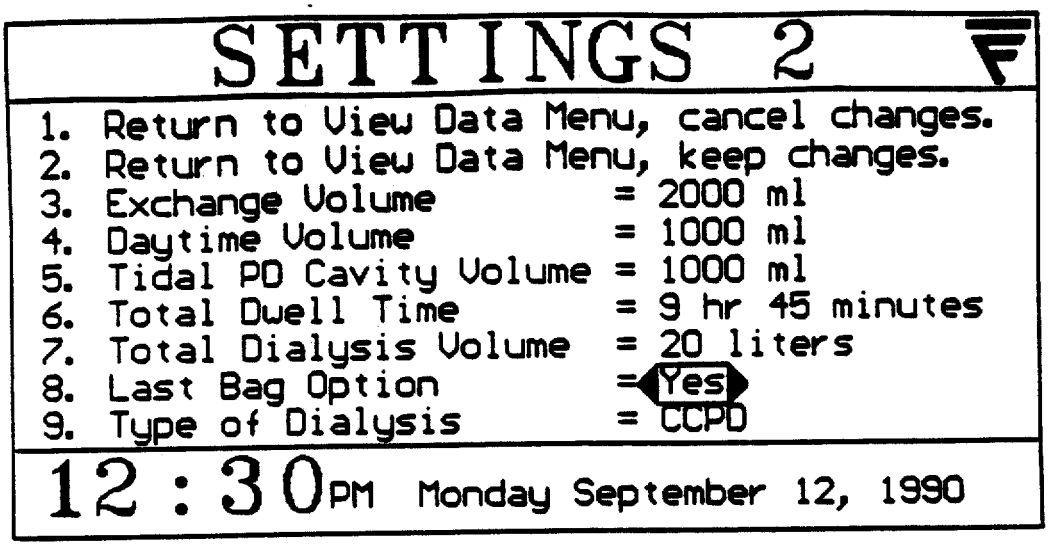


Fig. 8

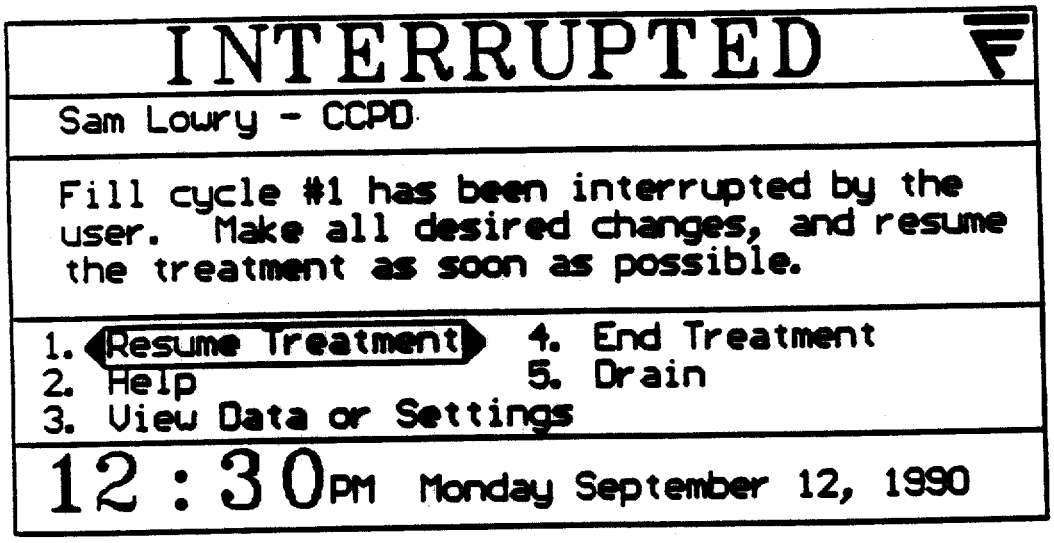


Fig. 9

The amount of fluid collected in the weigh bag is also used in conjunction with the amount of fluid delivered to the patient (determined by the upper scale), in order to calculate and display the net ultrafiltration or fluid removed from the patient. When an adequate drain volume has been reached, the 90/2 switches into the fill mode and the cycle starts over again. During the drain mode, the display screen shows the parameters associated with that mode in both text and graphics. (See Fig. 12)

At the end of the treatment, when all the pre-determined exchanges have taken place, the display will show a completion screen, and prompt the patient to disconnect the patient line according to the physician's instructions and to disconnect the Delmed tubing set from the 90/2.

Cycle and Treatment Data

Data for the current cycle as well as the whole treatment thus far is continuously updated and can be displayed at any time during the treatment by selecting the View Data menu option. (See Fig. 13 & 14)

A Treatment Record or Data Sheet, (See Fig. 15), can be printed out after the treatment has been completed, if an optional printer has been hooked up to the RS 232 port on the back of the 90/2. Treatment records are stored in memory and can be accessed at a later date and printed out or downloaded to a central computer or other memory retention device. The 90/2 Peritoneal Dialysis System can store approximately 30 days of records for a single patient.

When the treatment is complete and the patient and tubing set disconnected from the machine, turn the power off to the 90/2 with the switch on the back.

ALARM SUMMARY

DRAIN ALARM

Lower scale did not register weight increase at proper rate. Machine is in safe state with all valves and pumps off.

Things to check:
- Height of patient and equipment
- Lower scale
- Kinked tubing
- Catheter restriction
- Patient and/or drain valve

FILL ALARM

Upper scale did not register weight decrease at proper rate. Machine is in safe state with all valves and pumps off.

Things to check:
- Upper scale
- Patient and/or gravity valve
- Kinked tubing
- Catheter restriction

PUMP ALARM

Upper scale did not increase fast enough during the time the gravity bag was being filled. Machine is in safe state with all valves and pumps off.

Things to check:
- Upper scale
- Feed pump
- Adequate solution available
- Main bag valve or last bag valve
- Gravity bag valve

TEMPERATURE ALARM

Dialysate temperature is too high. Patient valve closes and heater is shut off by separate circuit. Rest of valves and pumps are shut off in normal control mode.

Things to check:
- Temperature sensors
- Heater unit

VOLTAGE ALARM

One or more of the internal supply voltages is out of specification. Machine will shut down and suspend treatment. Alarm message will appear. Treatment data will be stored in memory. The cause of this alarm is electronic-call your service representative.

BATTERY ALARM

The backup battery voltage is low. Since this is a backup or emergency power source, the 90/2 can continue to operate normally. Battery should be replaced at earliest convenience.

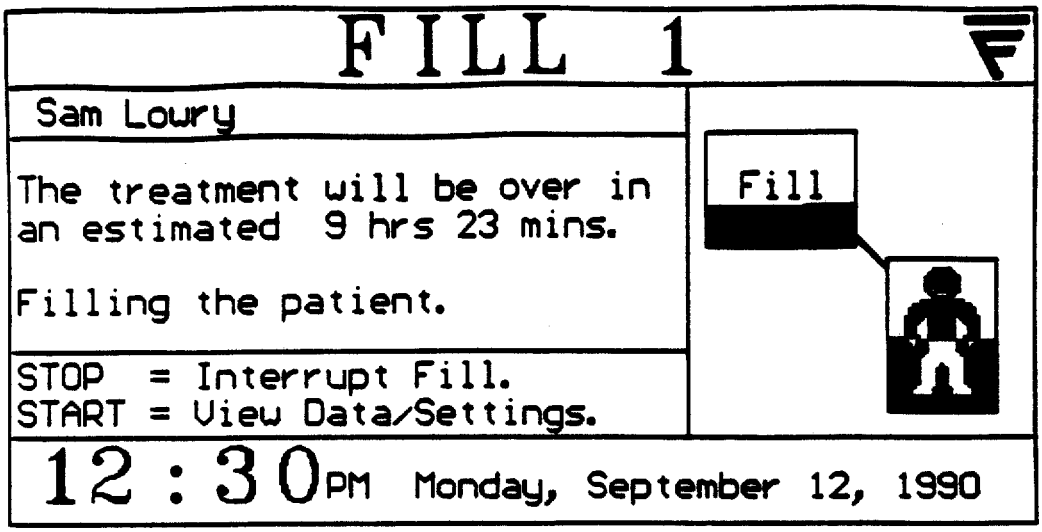


Fig. 10

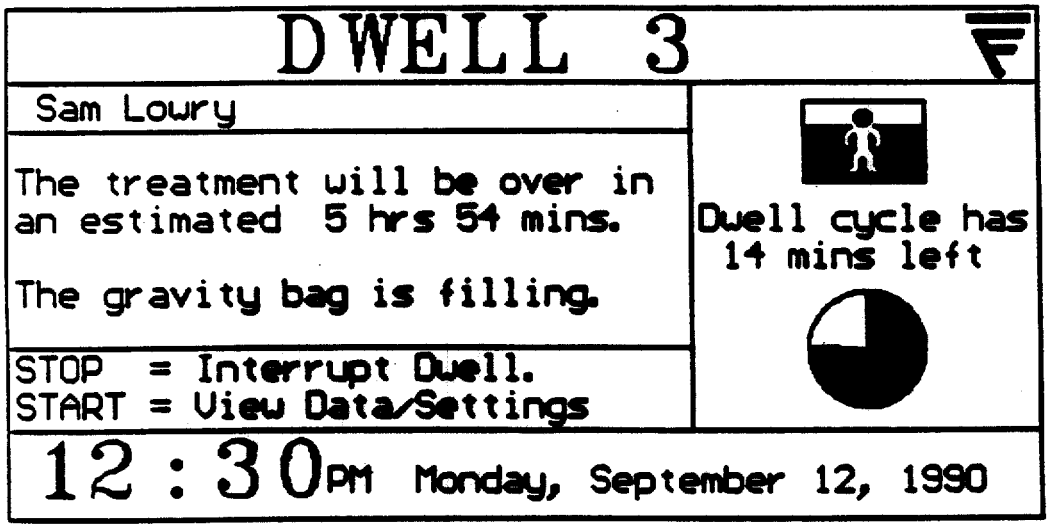


Fig. 11

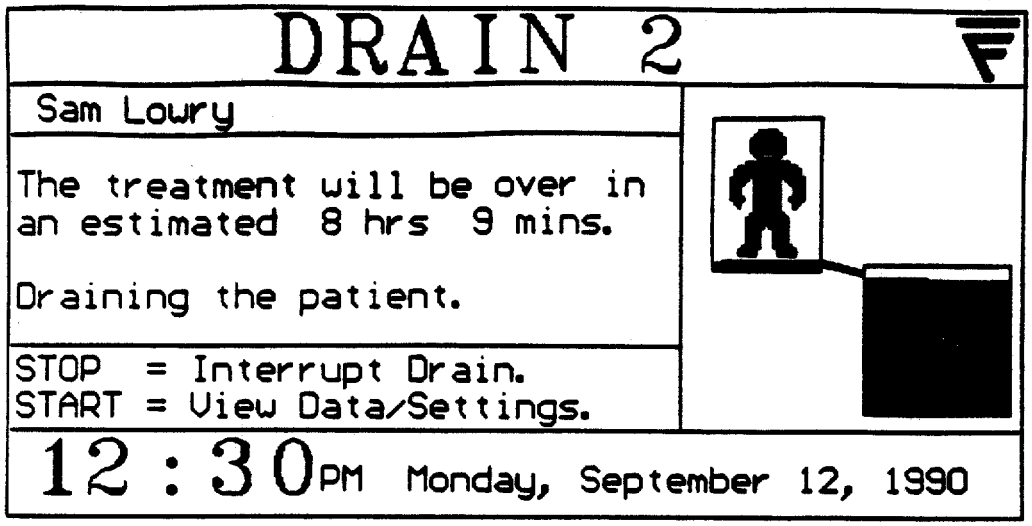


Fig. 12

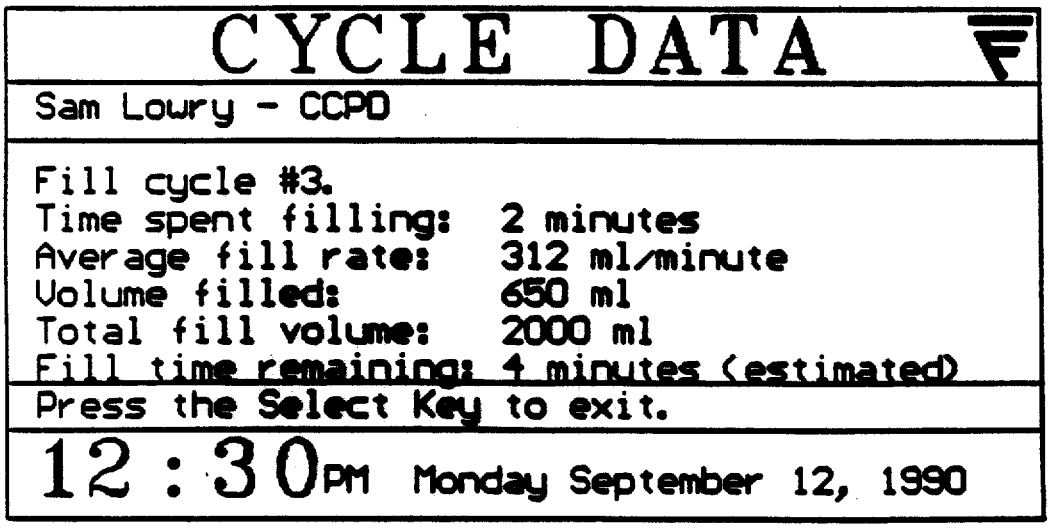


Fig. 13

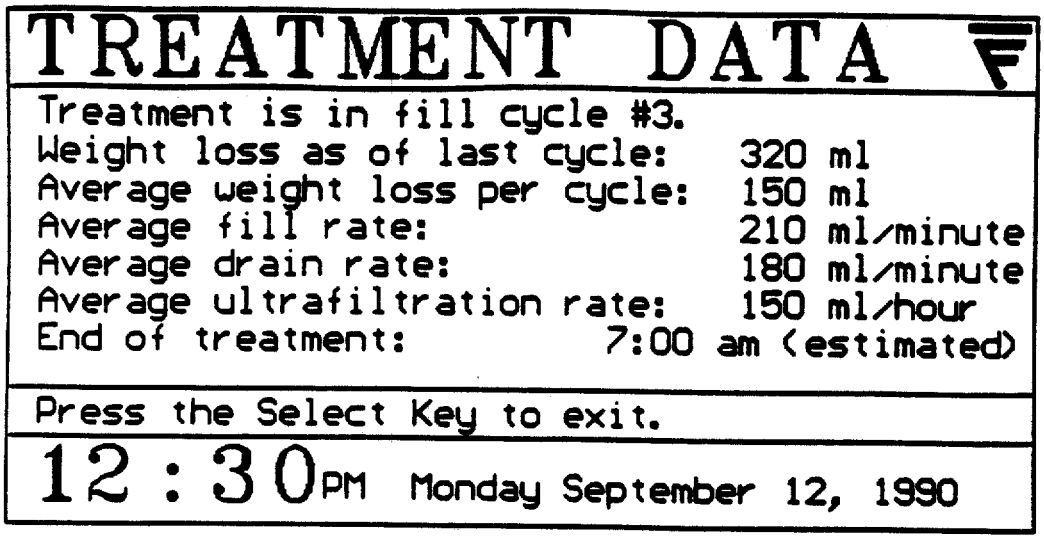


Fig. 14

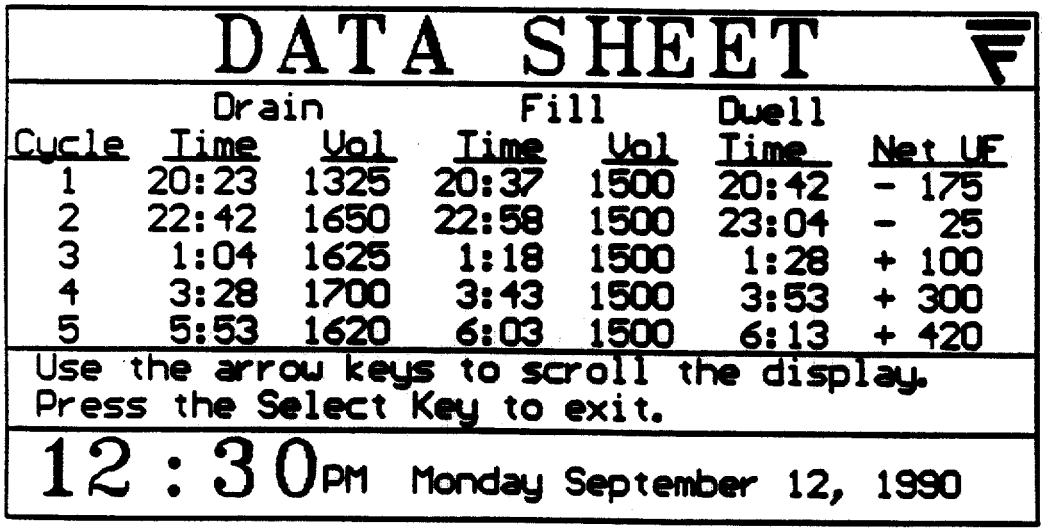


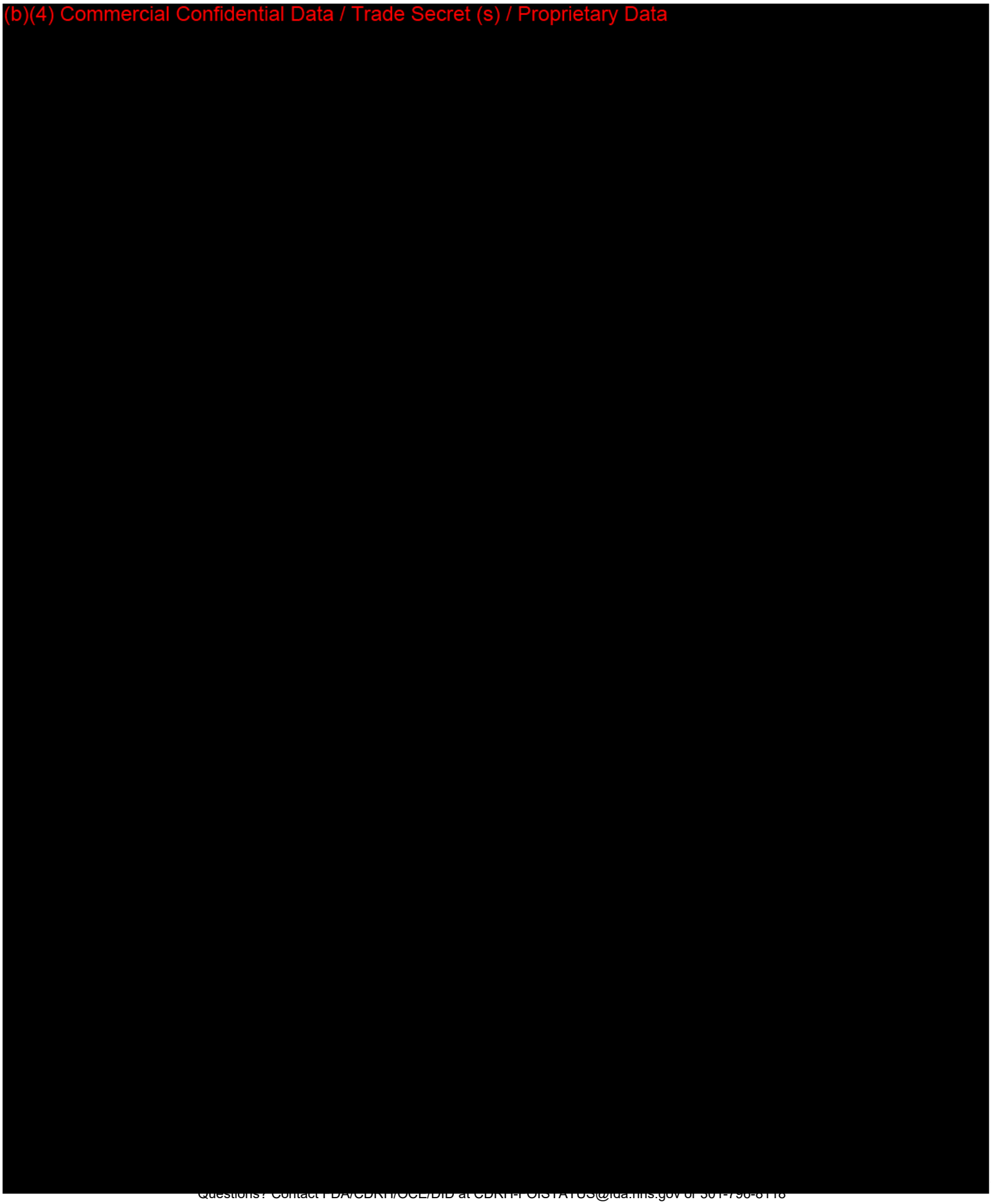
Fig. 15

HAZARD ANALYSIS

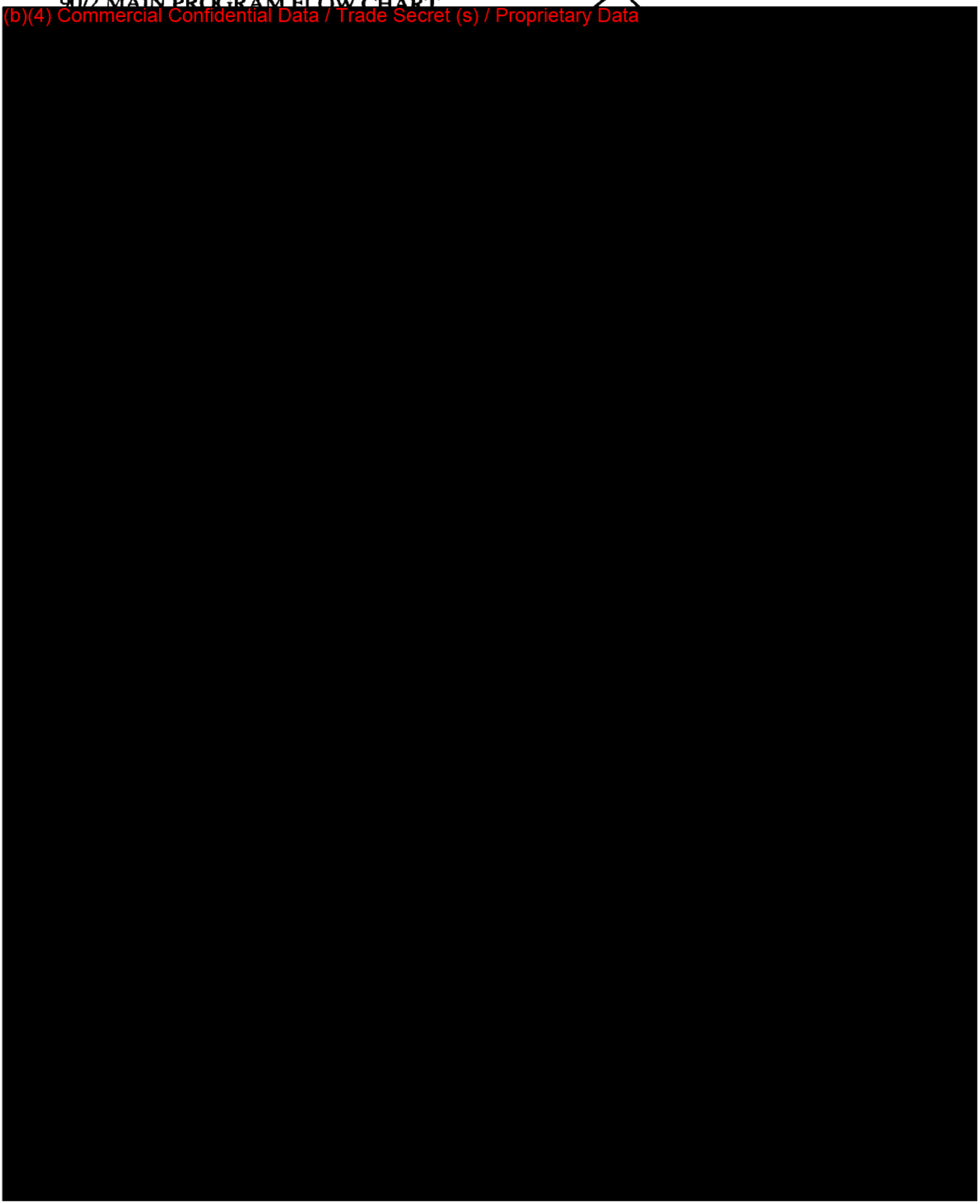
PROBLEM	MACHINE REACTION	REMARKS
* POWER FAILURE	ALL OCCLUDERS CLOSED	POWER FAIL ALARM
* OVERTEMPERATURE	PATIENT VALVE CLOSES THERMOSTAT SHUTS DOWN HEATER	TEMPERATURE ALARM MESSAGE
* OCCLUDER FAILS TO OPEN	SCALES DETERMINE NO FLOW AND GIVE ALARM	ALARM MESSAGE- DEPENDS ON THE OCCLUDER
* OCCLUDER FAILURE	SCALES DETERMINE FLOW, AND GIVE ALARM	ALARM MESSAGE- DEPENDS ON THE OCCLUDER
* PUMP FAILS	SCALES DETERMINE NO FLOW TO PUMP AND GIVE ALARM	ALARM MESSAGE- DEPENDS ON WHICH PUMP
* MICROPROCESSOR FAILURE	WATCHDOG CIRCUITRY (HARDWARE) SHUTS DOWN TO SAFE STATE	ALARM MESSAGE

Software flow charts:

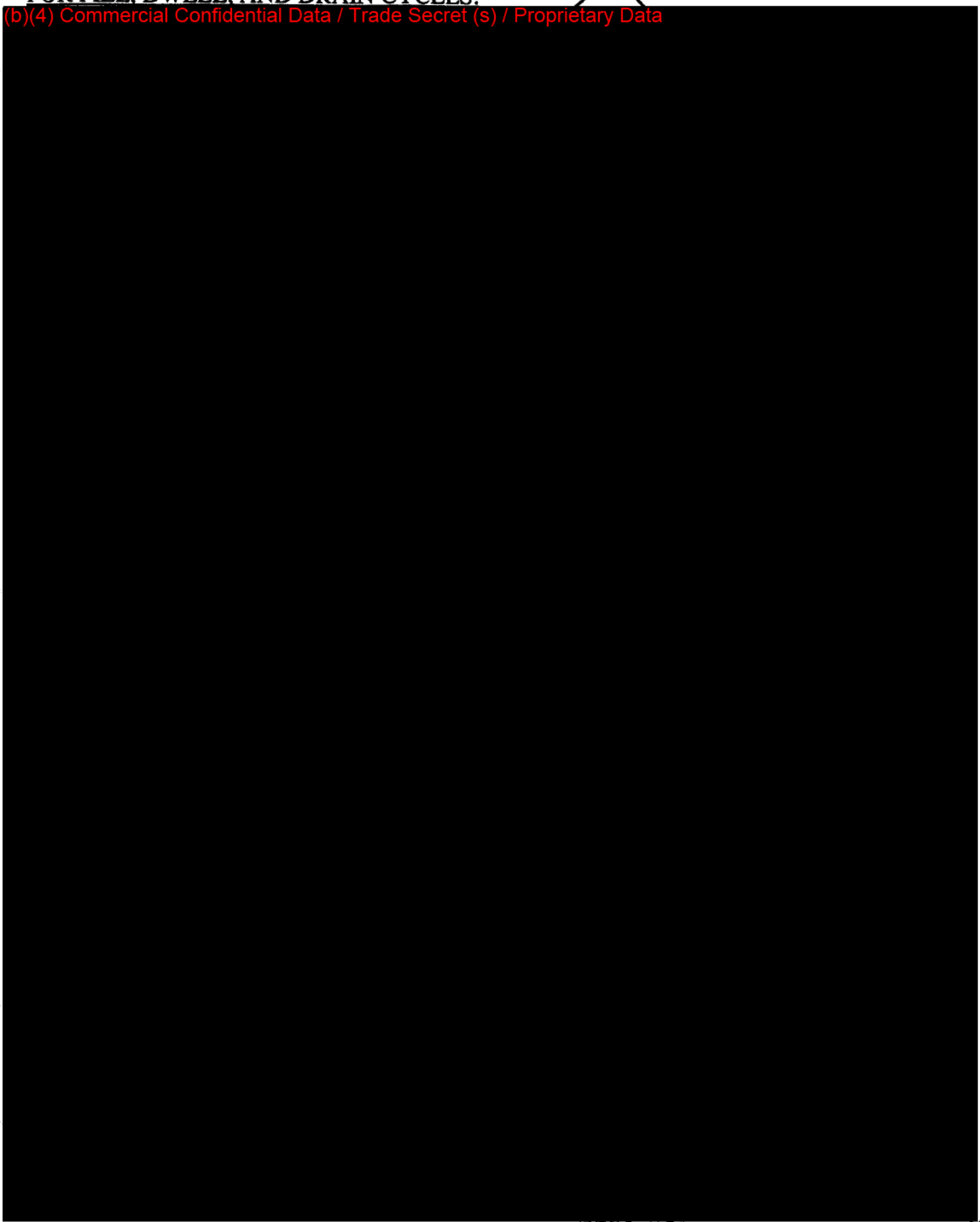
90/2 Main MPU Routine



90/2 MAIN PROGRAM FLOW CHART

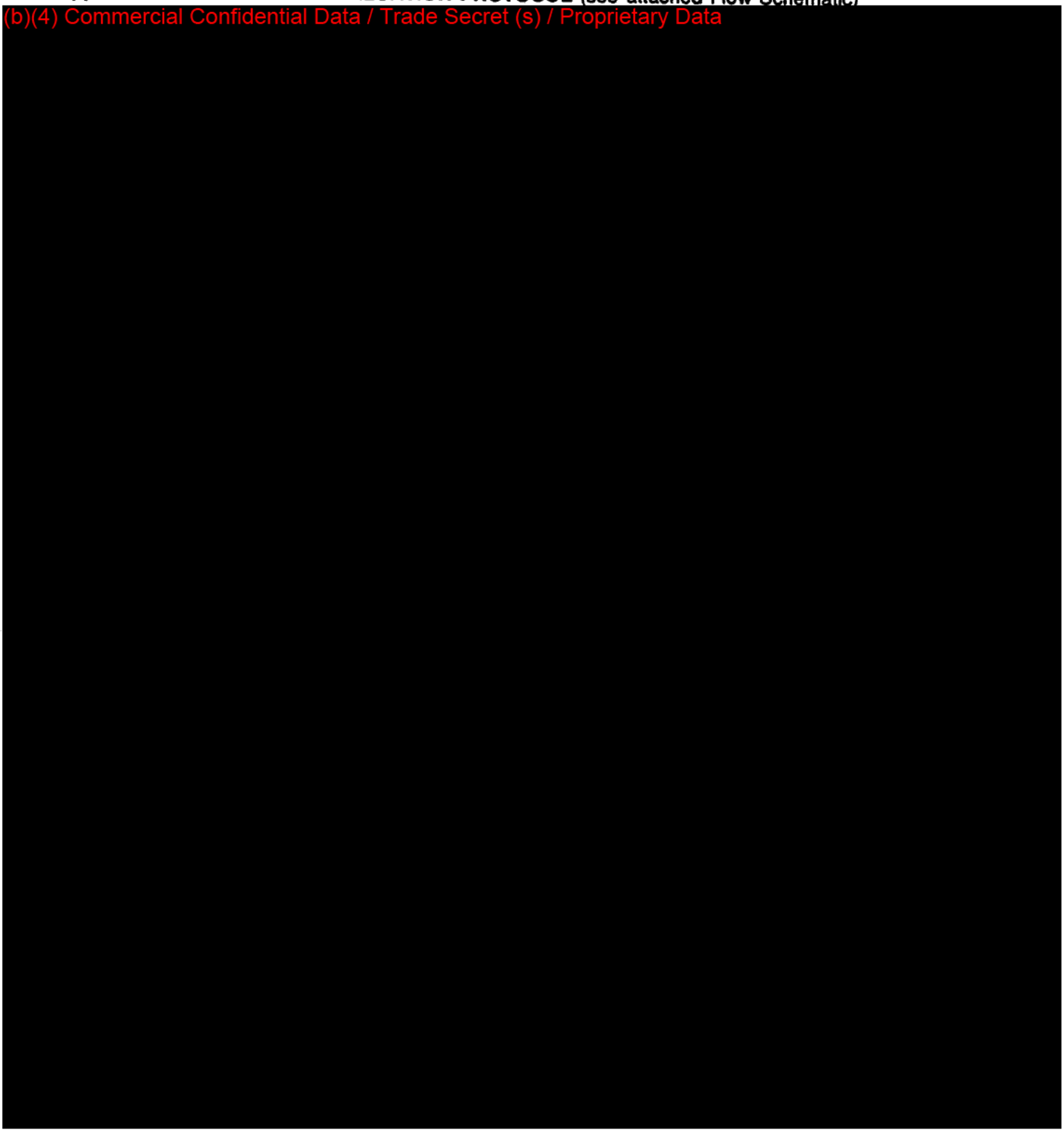


90/2 "DO ACTION" FLOW CHART FOR FILL, DWELL, AND DRAIN CYCLES.

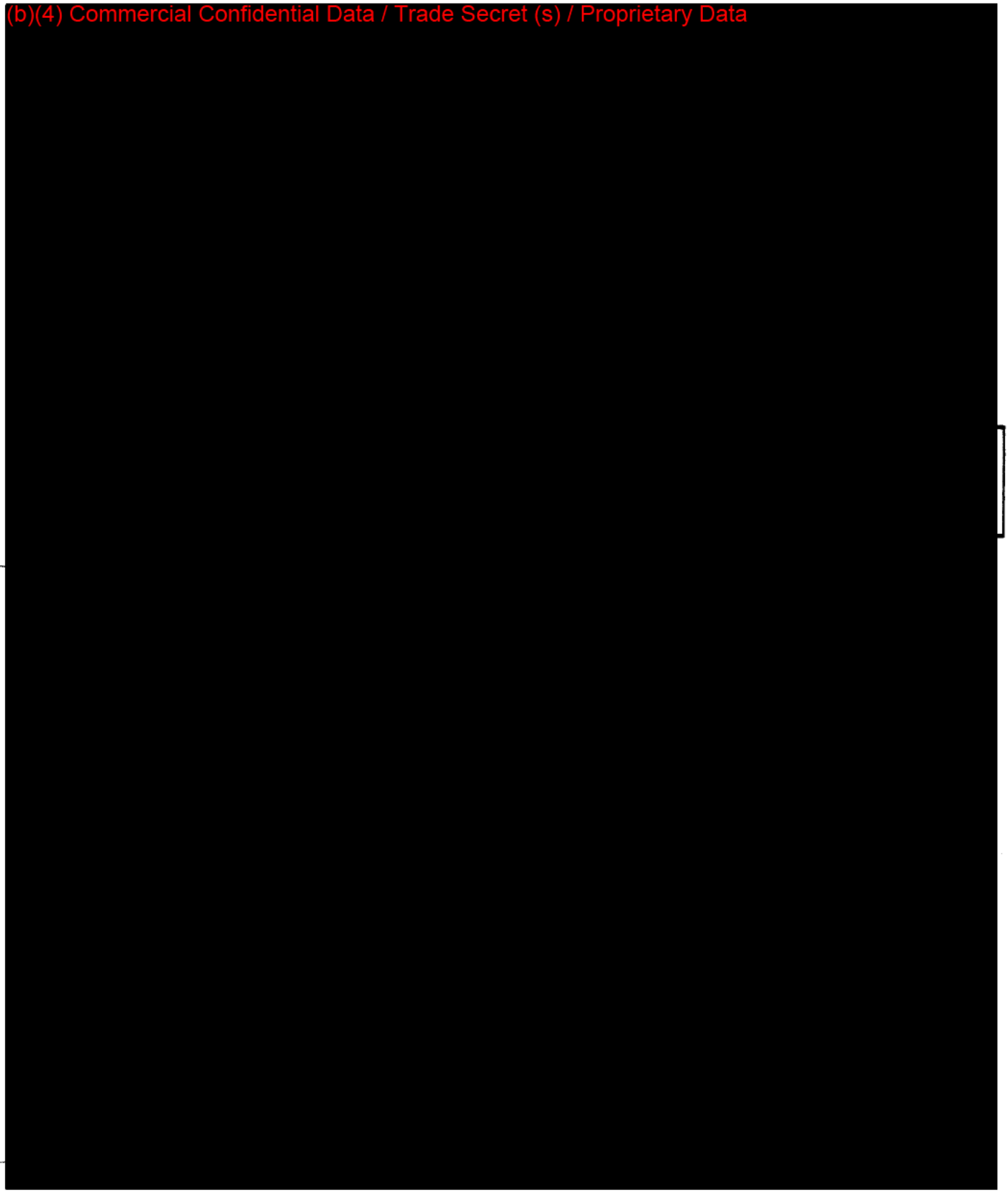


Appendix C. SOFTWARE EVALUATION PROTOCOL (see attached Flow Schematic)

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data



SOFTWARE EVALUATION PROTOCOL
FLOW SCHEMATIC



DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

JULY 26, 1990

FRESENIUS/DELMED, INC.
ATTN: THOMAS E. CANE
4090 PIKE LANE
CONCORD, CA 94520

D.C. Number: K902149
Product : FRESENIUS/DELMED
90/2 PERITONEAL
DIALYSIS SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information and all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center at the above address (21 CFR 807.90). Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

When your additional information is received by the Office of Device Evaluation Document Mail Center (address above), the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission and proceed to withdraw your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

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

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-90-2149 7/26/90

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
FRESENIUS/DELMED, INC. ATTN: THOMAS E. CANE 4090 PIKE LANE CONCORD, CA 94520	/ /	05/15/90	08/13/90
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K902149
SHORT NAME: FRESDELM	ESTABLISHMENT NO: 1713747		

TO:	
ODE/DMC	CONT. CONF.: ? STATUS : H REV PANEL : GU PAN/PROD CODE(S): GU/ / /

SUBJECT:
FRESENIUS/DELMED 90/2 PERITONEAL DIALYSIS SYSTEM

DECISION: DECISION DATE: / /	RQST INFO DATE: 07/26/90 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /	INFO DUE DATE: 08/25/90 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

7/25/90

From REVIEWER(S) - NAME(S) Rick Hubbard RW cwd

Subject 510(k) NOTIFICATION K902149

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.

__X__ (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

The submitter requests under 21 CFR §807.95:

_____ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

_____

Additional Product Code(s) w/Panel (optional):

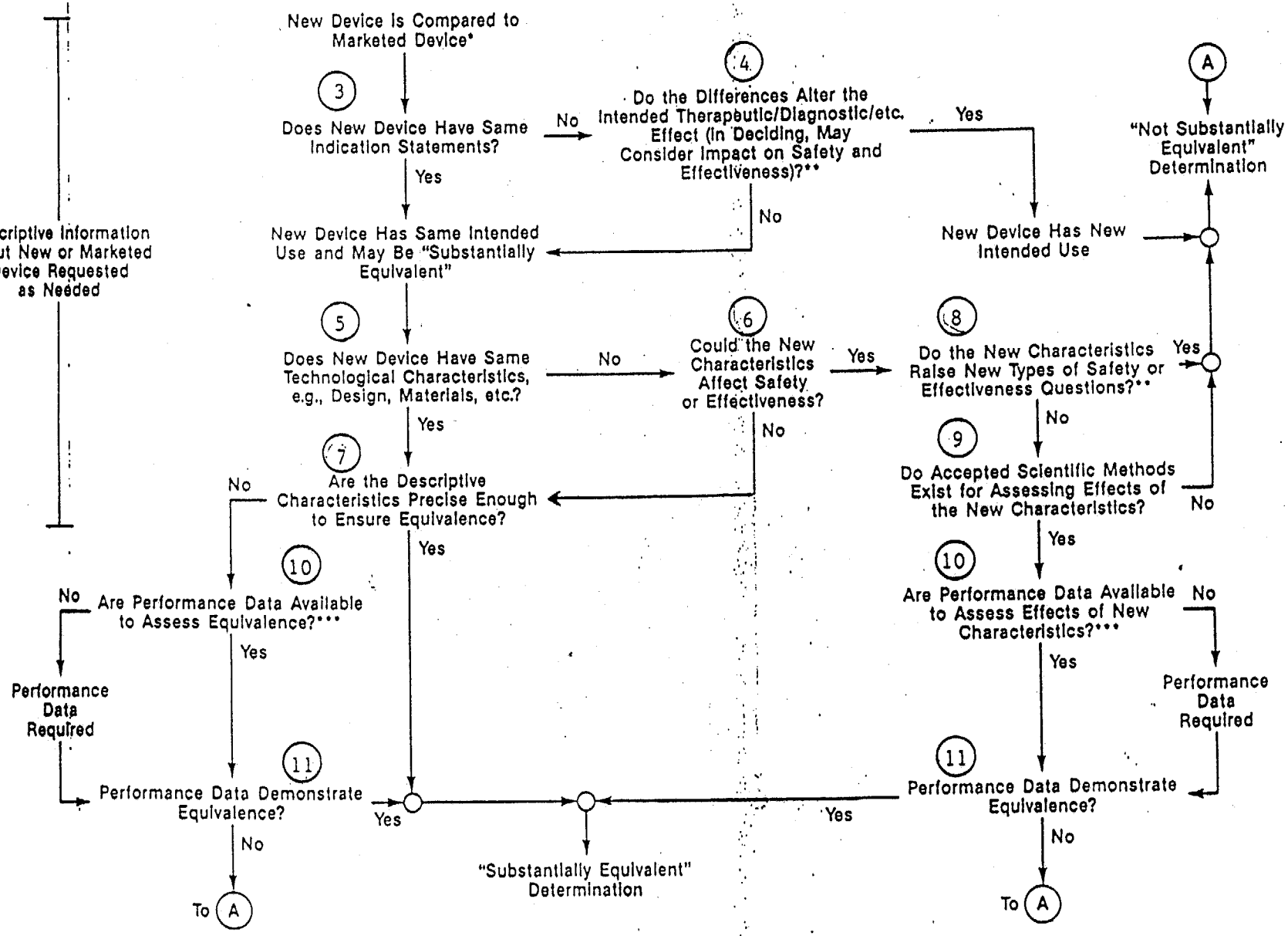
_____

REVIEW: EC Derrer 07/26/90
(BRANCH CHIEF) (DATE)

FINAL REVIEW: _____
(DIVISION DIRECTOR) (DATE)

1 of 44

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate"

** This Decision Is Normally Based on Descriptive Information Alone, But Limited Testing Information Is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)'s, The Center's Classification Files, or the Literature.

MEMO TO THE RECORD

DATE: 13 JUL 90
FROM: RUTH W. HUBBARD

OFFICE: HFZ-420
DIVISION: DGGD/GU

SUBJECT: K902149 Fresenius/Delmed 90/2 PD System

CONTACT: Thomas Cane, Director of Medical Affairs **PHONE:** 415-676-1600

This submission is for a peritoneal dialysis cycler, the 90/2, which appears to be an updated version of the Delmed 80/2 cycler. The 90/2 will contain an ultrafiltration monitor, a last bag controller, a display screen, and an optional waste pump. Brief descriptions of these components have been provided.

The DRAFT instructions for use are included. The instructions appear to be missing diagrams, are unclear, and at this point would not be easily understood by the home dialysis patient, which will be a primary user of this device. The instructions need to be complete and to be spelled out sufficiently for these patients, i.e., diagrams showing where lines are to be hung, which components are what, what disposable items are compatible with this device, and a trouble shooting guide.

A complete device description is not provided, only that the materials are "substantially the same" as those in the 80/2. Diagrams and/or pictures of the complete device and components would be helpful and these should be identified in the instructions for use. It must also be clarified whether this device interfaces with a printer and if so, to what printer is it compatible?

In the hazard analysis there is no discussion provided for there being an "under temperature" situation. This would be necessary to know as there would be a possibility of cooling the patient's core temperature to an undesirable temperature and peritoneal dialysate looses its efficiency when it is not body temperature.

An engineering review of the software validation is provided.

I have discussed the above issues with Mr. Cane and requested that additional information be provided to correct these items. I have informed him that this document is being placed on hold. Review will continue upon receipt.

Ruth W. Hubbard RN CNN 07/25/90
RUTH W. HUBBARD, R.N., C.N.N.
Division of Gastroenterology-Urology
and General Use Devices

Computer Software Consulting Review

MEMO TO Ruth Hubbard & THE RECORD **DATE:** 7/13/90

FROM: Electrical Engineer **DIVISION:** DGGD/GU-I

SUBJECT: K902149, Peritoneal Dialysis System

The Fresnius/Delmed 90/2 Peritoneal Dialysis System (90/2 PDS) is a fully integrated, microprocessor controlled machine which provides maximum versatility for the treatment of patients needing acute or chronic peritoneal dialysis either in a hospital, clinical, or a patient's home.

The 90/2 PDS requires additional information for a software driven device of a moderate concern. The following information, specific to this system, is requested:

1. The description of the dialysis system, as a device, and the flowchart (figure 3) is inconsistent. Clarify.

2. The flow of action for the dialysis system is unclear and inconsistent in the written description and the flow charts (pages 12-14). Clarify the operation.

3. Describe in greater detail the microprocessor self test, priming procedure, and system self test including, but not limited to, specific functions, possible failures, error messages, integration, etc..

4. The alarms and associated corrective actions are not user friendly. Alarms and "Things to Check" need to be stated in such a way for a home user to be able to understand and correct.

5. The Alarm Summary and Hazard Analysis tables are inconsistent. Compile a comprehensive list of all possible hazards, controls taken to prevent these, and associated alarms (written and audible).

Laura J. Byrd

Laura J Byrd

The follow is a general list of software information required:

1. Provide a written description of the software requirements, as well as the device performance requirements, including a statement of potential system hazards and software and/or hardware functions implemented as a result of such potential hazards.

2. Describe the software development activities, including the performance of hazard and fault-tree analyses, verification and validation activities, and a description of software maintenance (QA) procedures after the device is on the market.

3. Describe how the software verificatin and validation was performed, how the implementation of system safeguards was assured, and which verification and validation activities were performed prior to and after software/hardware integration. Over what performance specifications/ranges were these tests conducted? A summary of these results should be provided.

4. Provide written affirmation stating that the described software was developed and tested according to the stated procedure/method and tests showed requirements were met.

Laura J. Byrd

Laura J Byrd

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

MAY 16, 1990

FRESENIUS/DELMED, INC.
ATTN: THOMAS E. CANE
4090 PIKE LANE
CONCORD, CA 94520

D.C. Number : K902149
Received : 05-15-90
90th Day : 08-13-90
Product : FRESENIUS/DELMED
90/2 PERITONEAL
DIALYSIS SYSTEM

The Premarket Notification you have submitted as required under Section 510(k) of th Federal Food, Drug, and Cosmetic Act for the above referenced device has been receiv and assigned an unique document control number (D.C. Number above). Please cite thi 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. We intend to comple our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until afte ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

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

K902149

FRESENIUS/DELMED 90/2

PERITONEAL DIALYSIS SYSTEM

510(k) NOTIFICATION

Fresenius/Delmed, Inc.
4090 Pike Lane
Concord, CA 94520
(415) 676-1600
5/11/90

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K902149

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

Re: 510(k) Notification - Fresenius/Delmed 90/2 Peritoneal Dialysis System

Gentlemen:

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data This equipment has been assigned the indicated 510(k) numbers and is currently marketed in the USA by Fresenius USA:

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

This equipment (except for those pending), has been found to be substantially equivalent to other dialysis equipment currently being marketed in interstate commerce.

Fresenius USA Inc. and Delmed, Inc., as required by 21 CFR section 807, is requesting through this notification that the Commissioner determine that the Fresenius/Delmed 90/2 Peritoneal Dialysis System is substantially equivalent to other dialysis equipment being marketed in the U.S prior to May 28,1986.

A. Product Name

1. Fresenius/Delmed 90/2 Peritoneal Dialysis System

2. Common or Usual name: Peritoneal Dialysis Cycler System

3. It is manufactured by:

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

The product is Assembled, Tested, Calibrated, and Quality Controlled by Delmed Inc. in Ogden, Utah, or by Fresenius USA in Concord, CA. It will be marketed by Fresenius USA from offices located in Concord, CA.

B. Registration Identification

51

The Federal FDA Registration number for (b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data
The Federal FDA Registration number for

C. Classification

This device has been classified under section 510(k) of the Food, Drug & Cosmetic Act by the Gastroenterology and Urology Panel in Class II.

D. Action Taken

Since the device has been classified, no action under Section 514 and 515 has been taken.

E. Labeling

1. The typical unit identification and label is shown Appendix A.

2. A copy of the DRAFT Operators Manual is shown in Appendix B.

F. Statement of Equivalence

1. The Fresenius/Delmed 90/2 Peritoneal Dialysis System is substantially equivalent for medical purposes to the following equipment:

AMP Cycler, Cat.# LJ300S which was in commercial distribution prior to 5/28/76.
Delmed 80/2 Peritoneal Cycler/Heater, (K791584).

2. The **materials** used in manufacture of the Fresenius/Delmed 90/2 Dialysis System are substantially the same as used for the currently marketed Delmed 80/2 .

3. The **physical appearance** and basic function of the Fresenius/Delmed 90/2 Dialysis System is similiar to the currently marketed Delmed 80/2.

4. The **function** of the Fresenius/Delmed 90/2 Dialysis System is exactly the same as the Delmed 80/2 with the addition of these functions:

* Ultrafiltration monitor
* Last Bag Controller ✓
* Display Screen
* Optional Waste Pump

The Monitor now contains a microprocessor. The software validation information is contained in Appendix C.

Description of the added functions:

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

52

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

Please contact me at (415) 676-1600 if further information is required.

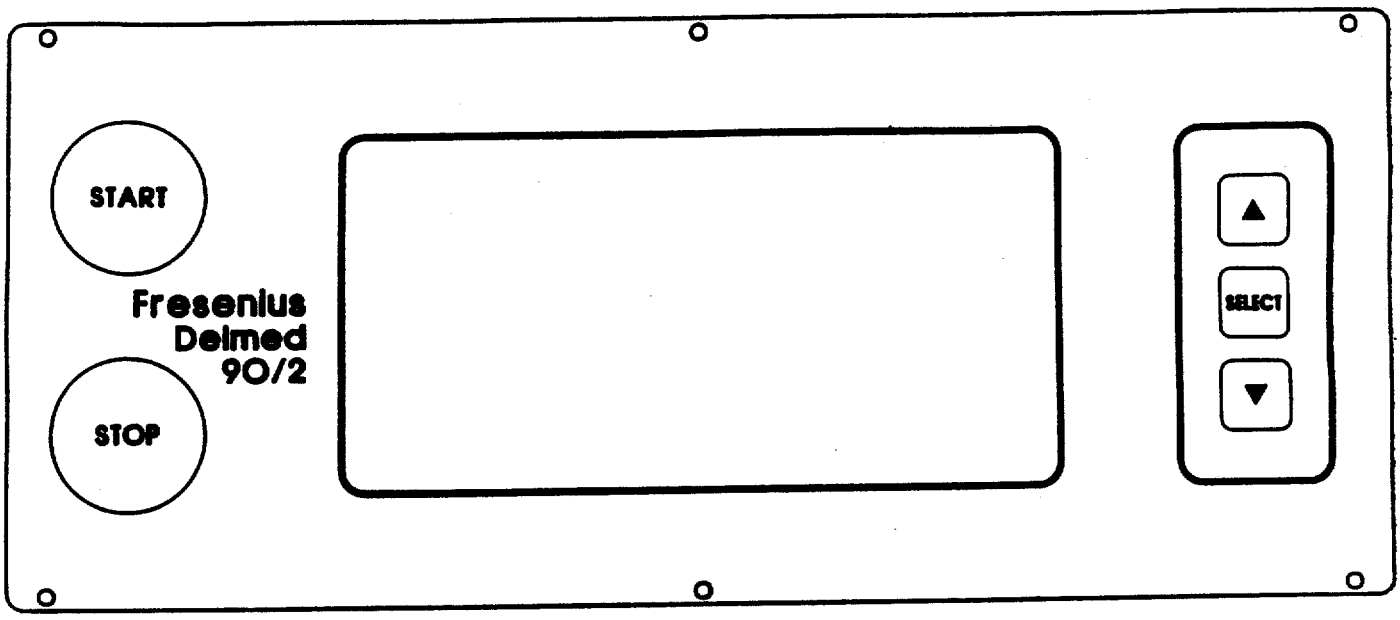
Sincerely,

Thomas E. Cane

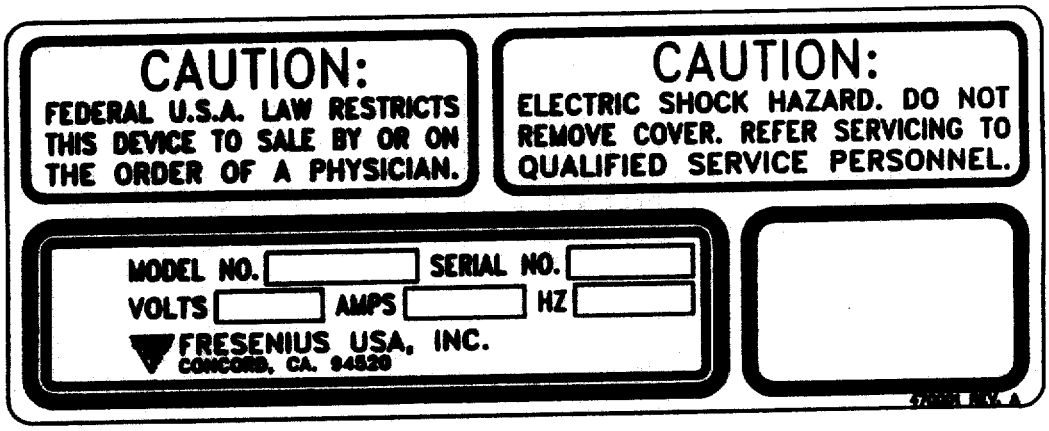
Thomas E. Cane
Director of Medical Affairs

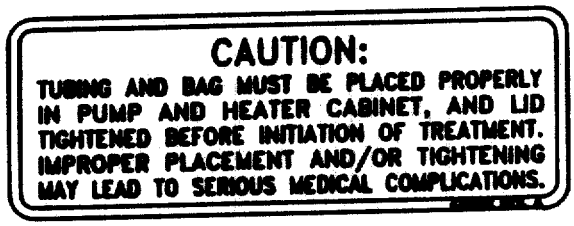
Appendix A

Typical unit identification: Control panel



TYPICAL UNIT LABEL





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Appendix B

Draft Operators Manual

OPERATORS MANUAL

Draft

FRESENIUS/DELMED

90/2

PERITONEAL DIALYSIS SYSTEM

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

FRESENIUS USA, INC.
Concord, CA 94520

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INTRODUCTION

The 90/2 Peritoneal Dialysis System is a fully integrated, microprocessor controlled machine which prcvides maximum versatility for the treatment of patients needing acute or chronic peritoneal dialysis in either a hospital or clinic environment or at the patient's home.

The physician can select a choice of therapy from among CCPD (Continuous Cycling Peritoneal Dialysis), IPD (Intermittent Peritoneal Dialysis), TPD (Tidal Peritoneal Dialysis), or NIPD (Nightly Intermittent Peritoneal Dialysis). Because of the microprocessor control, the 90/2 can tailor the therapy to patients as patient models are developed clinically.

The front control panel display screen of the 90/2 enables both the staff and the patient to continuously monitor the treatment by virtue of simplified graphics and text messages. Help screens serve as an on-line troubleshooting guide should problems with the treatment arise.

Treatment data can be printed out to have a hard copy record, or can be stored internally and downloaded to a specified storage medium, either at the machine or via modem.

The 90/2 has a battery backup to enable the treatment to continue (only the heater will not work) during short power interruptions.

SPECIFICATIONS:

Size
Base- 24 in. (61 cm.) x 22 in. (56 cm.)
Height- 60 in. (152 cm.)* minimum

Weight
Cycler control unit- 40 lbs. (18 kg.)*
Base and Stand- 55 lbs. (25 kg.)*

***approximate**

Electrical Requirements
120 VAC; 7 amp.

Current Leakage
Under 100 microamperes

Fill Volumes
Variable in 10 ml increments up to 3000 ml (3 Liters)

Number of Cycles (Exchanges)
1-99

Dwell Times
Variable in 1 min increments up to 9 hours and 59 minutes

Ultrafiltrate Monitor
Accuracy; +/- 10 ml
Range; 0-9000 ml
Read out; Per exchange and Treatment Total

Temperature Control
Accuracy; +/- 0.5 degrees C

FUNCTIONAL DESCRIPTION

The 90/2 Peritoneal Dialysis System consists of a base and stand assembly, an upper scale assembly, and the main cycler control unit which includes the heating unit and the lower scale assembly. (see Fig. 1)

The cycler control unit consists of 1. the heating unit which warms the dialysate, 2. five occluders which control the flow of fresh dialysate to the patient, either from the main bags or the last bag, and spent dialysate from the patient, 3. the front control panel which is the patient interaction, and 4. the system electronics.

Cycler

Plugging the 120 VAC power cord into a properly grounded wall receptacle will provide power to both the cycler and the heating unit. The main components of the cycler are discussed below.

1. Front Control Panel- The front control panel provides the interaction with the patient. It consists of a flat display screen and five keypads. The display screen will display to the user a series of screens consisting of both text and graphics that will prompt the user, display cycle and treatment data, display alarms, and give the user/patient some help messages. (see Fig. 2)

The Start keypad is used to step through the normal sequence of the cycle and the Stop keypad is used to halt the treatment at any time and also to be able to drain the patients peritoneal cavity from any step in the main sequence. The Select and the Up/Down arrow keypads are used in conjunction with menu options displayed on the various screens.

2. Heating Unit- The heating unit sits directly on the top part of the cycler. This unit is designed to use only the heat exchange bag that is part of the Delmed tubing set sold for use with this cycler. The dialysate is warmed as it is pumped from the supply bags to the gravity bag that is used to fill the patient as well as on its way to the patient.

3. Occluders- The five occluder valves are used to separate the various flow paths in the heat exchanger bag. Two control whether the supply to the patient is drawn from the main bags or the last bag. One is used to enable filling the patient and one is used to enable the patient to drain. Both of these are used in conjunction with a redundant patient valve. (see flow diagram, Fig. 3)

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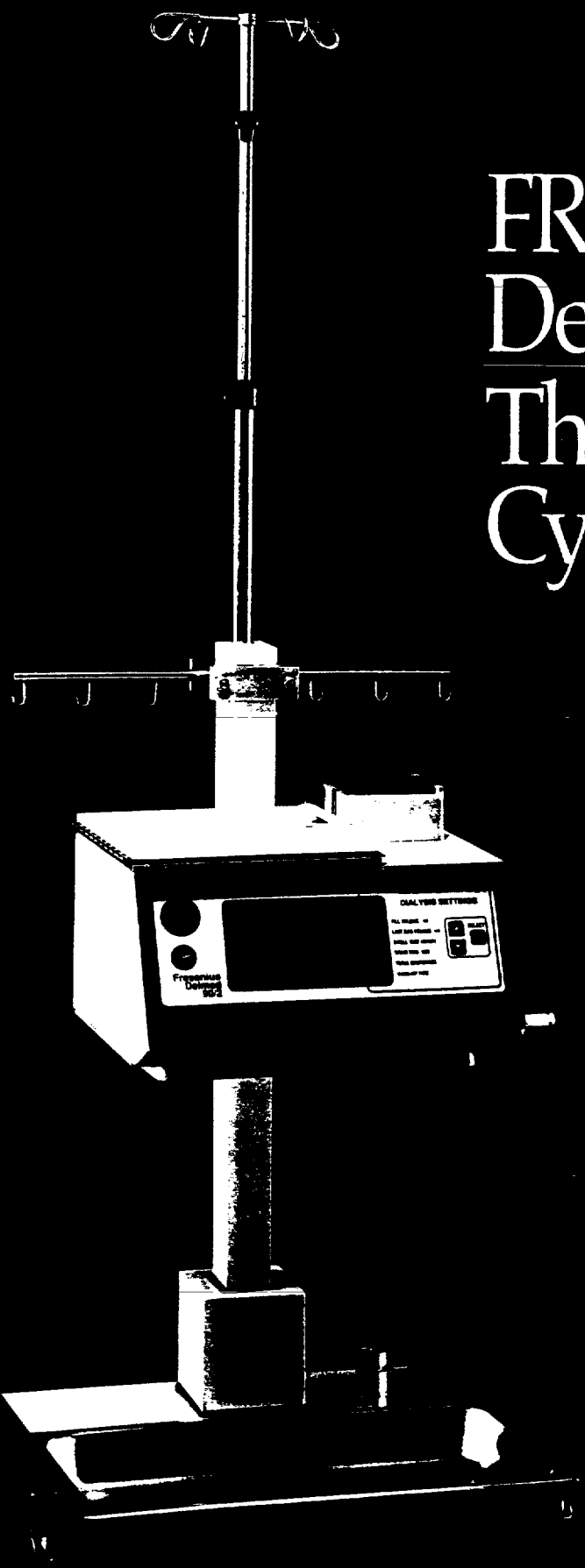

FRESENIUS Delivers The CCPD 90/2 Cycler System

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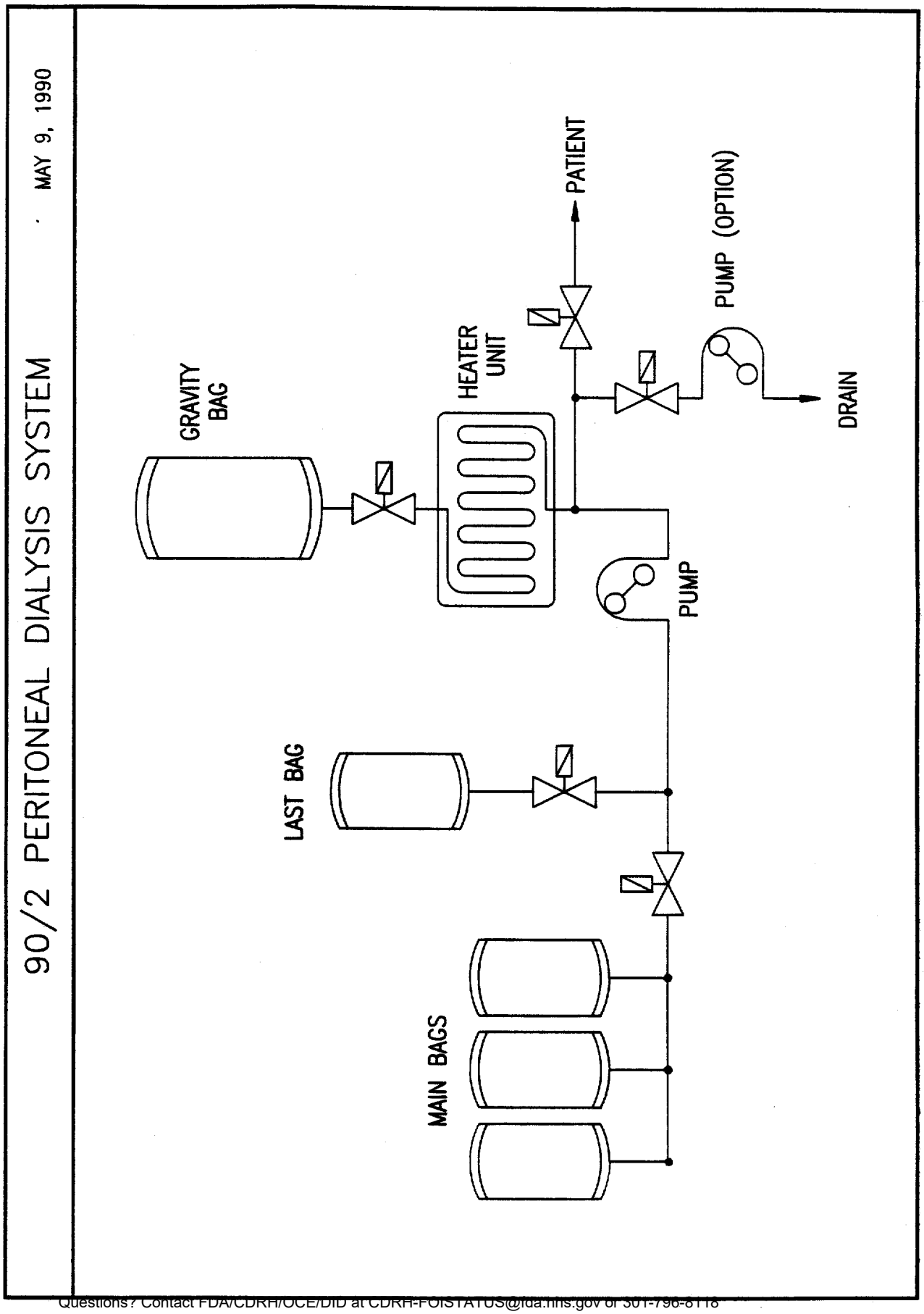
Fresenius USA

Fig. 3



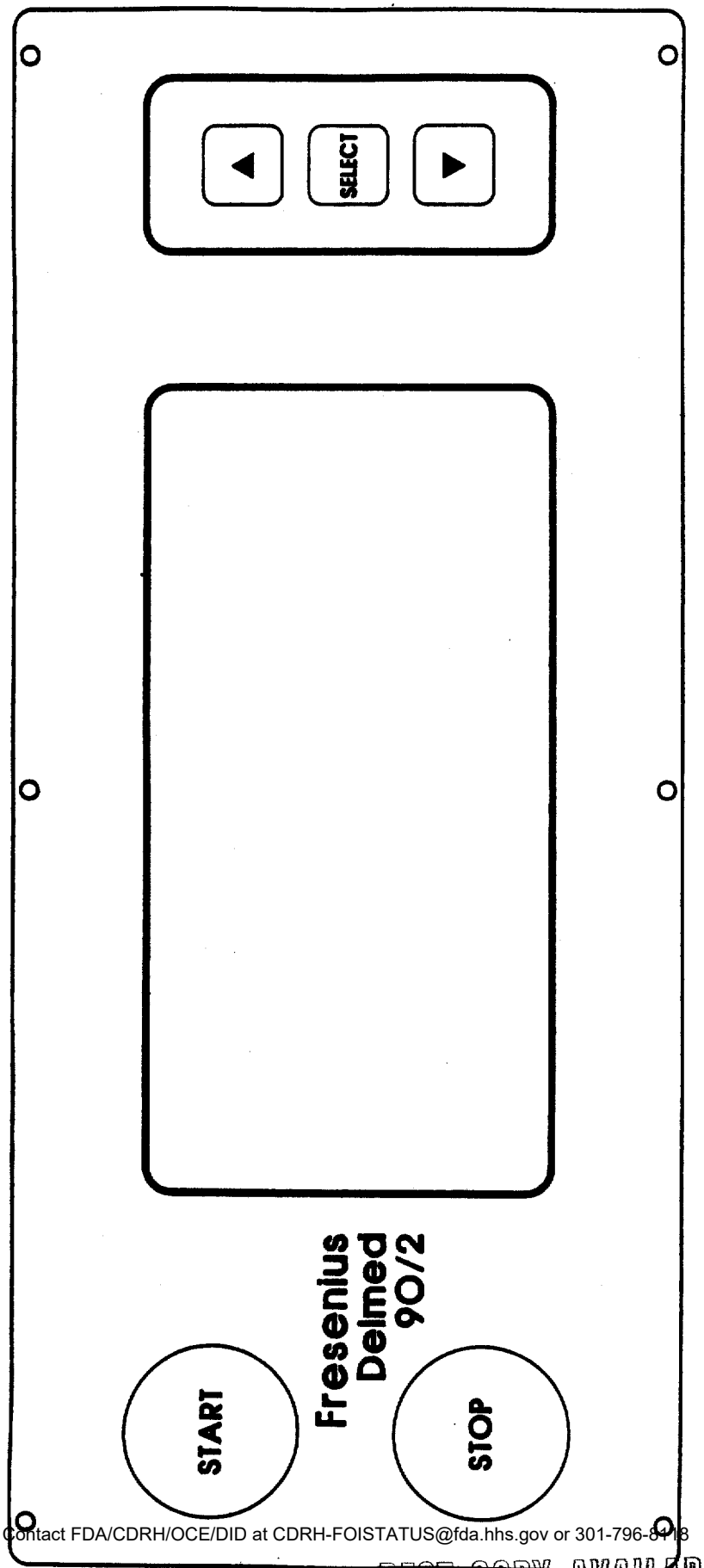


Fig. 2

4. Main Electonics- The main electronics that operates the 90/2 cycler, consisting of the analog, digital, and microprocessor circuitry is housed in the cycler control unit. Connections made via the rear electrical panel supply signals to the upper scale, an optional waste pump and a RS 232 port tc download treatment data from the cycler.

5. Lower Scale- This scale that measures the t of fluid drained from the patient is located on the right side of the cycler control unit. (see Fig. 1) Caution: it is important that the scale and drainage bag which is hung on the scale be able to move freely (not lodged up against a bed or wall).

Cycler Shelf

The cycler sits on the cycler shelf, which can be adjusted to the appropriate gravity height, depending on the height of the patient.

Base with Castors and Waste Pump (Option)

The cycler base adds extra weight to stabilize the equipment. The castors allow portability. Caution: care should be taken when moving the 90/2 Cycler after tubing or dialysate containers have been set up.

An optional waste pump that can be used to pump spent dialysate from the weigh bag to a remote drain can be installed on the 90/2 base. This is a convenience for the patient and/or staff so they don't have to handle the drain bags.

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OPERATIONAL DESCRIPTION

Preparation

The supplies that are needed for a treatment using the 90/2 Peritoneal Dialysis System include fresh dialysate containers with the appropriate formula and concentration prescribed by your physician, the Delmed tubing set that is designed for use with this machine, a drain line extension (if using the optional waste pump), or drainage set, and any ancillary equipment that you normally utilize.

Plug in the 90/2 Peritoneal Dialysis System to a properly grounded outlet and turn on the power with the on/off switch on the back of the machine. The title screen (see Fig. 6) will be displayed. Pressing the Start keypad will chage the display to the Start screen (see Fig. 7).

Select the menu option View/Change Settings by using the up/down keypads to move the cursor to that option and pressing the select keypad. The display will change to the Settings 2 screen (see Fig. 8). Enter in the treatment parameters: fill volumes-normal exchange and last bag, dwell time, total number of exchanges and tidal volume if tidal dialysis has been selected. After the treatment parameters have been entered, return to the start screen.

Hang the dialysate bags of the prescribed volume and concentration on the supply rack. It is recommended that each bag be tested for leaks by squeezing it prior to placing on the supply rack. If the last bag procedure has been selected, hang the last bag at the left side of the cycler, as this is where the last bag line is located. Add any medication prior to hanging the bags.

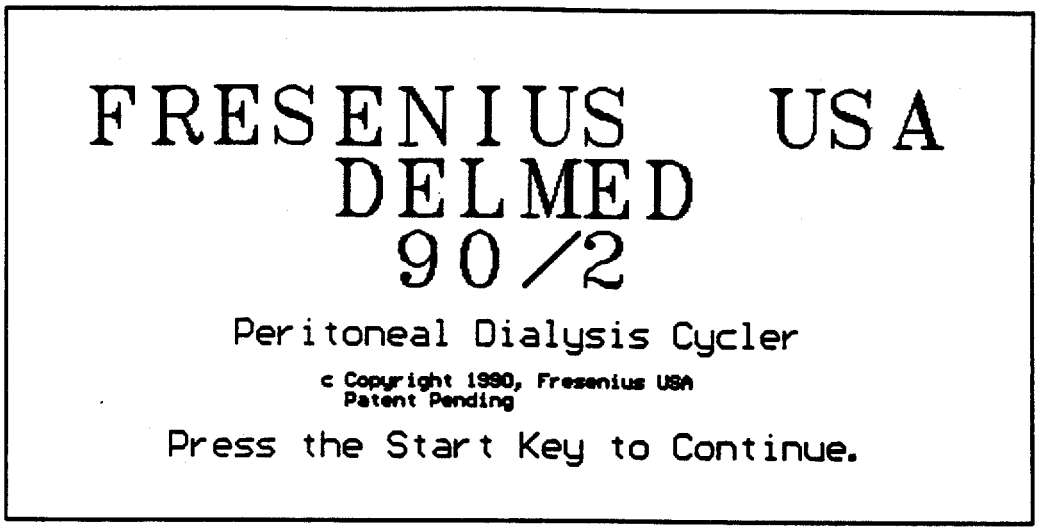

Fig. 6

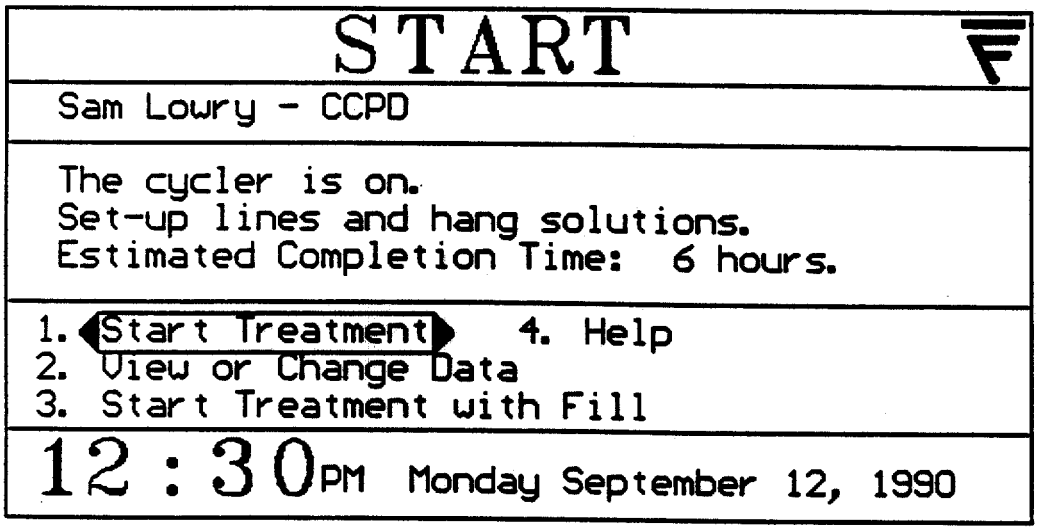

Fig. 7

Place the Delmed tubing set on the 90/2 Peritoneal Dialysis System. Open the lid of the heating unit and place the heat exchange bag on the locating pins. The patient line will then extend out the front of the cycler and the rest of the lines out the back. Open the lid on the dialysate pump and thread the tubing segment into the pump by depressing the push button on the pump housing. The pump will automatically stop after the pump segment is in place. Note that the pump segment is keyed so it can only be placed in the pump in one way so that the direction of flow is always correct. Close the pump lid and close and tighten the heater unit lid. If either of these are not closed, an alarm message will be given when the cycle is started.

Now hang the empty gravity bag portion of the Delmed tubing set from the top scale and place the weigh bag portion of the Delmed tubing set on the lower scale. If an optional waste pump is used, connect the drain line to the pump and the drain extension to a remote drain location. If this pump is not utilized, then connect the drain line to the drainage set. The dialysate bags can now be connected to the tubing set and the system is ready to be primed. Note: It is a good idea at this time to check the whole tubing system for any twists or kinks in the lines that could restrict or prohibit flow during the treatment.

Priming the System and System Self Test

Prior to the connection of the patient line to the catheter, the prime procedure must be performed to remove air from the system.

When the user is ready to prime the system and initiate the treatment, open clamps connected to bags one at a time allowing air to come down the first line and up the second line; open the second clamp and be sure that the air travels up into the bag. If the air hesitates or seems to stop when it reaches the connector, tap the connector to dislodge the air. Proceed in the same fashion as you open the remaining lines, paying particular attention to the last one that is opened.

The 90/2 Peritoneal System will automatically prime itself and during this priming cycle the machine will run a self test which tests the valves, pump(s) and scales. The microprocessor circuitry has been previously tested upon power up. Any failures of the self test will display an error message on the display screen. If there is no failure, a test passed message will be displayed, and the patient can now be connected to the cycler.

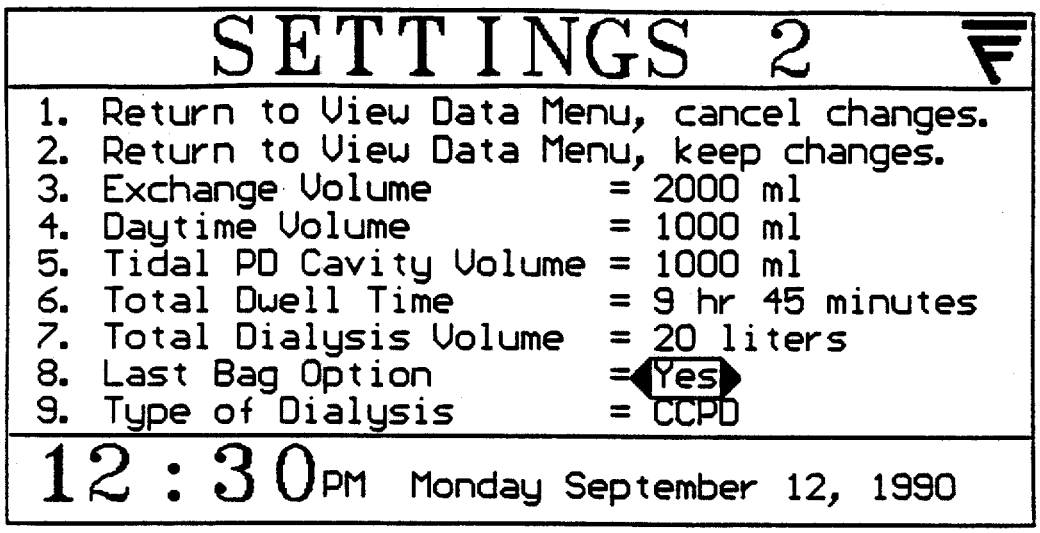

Fig. 8

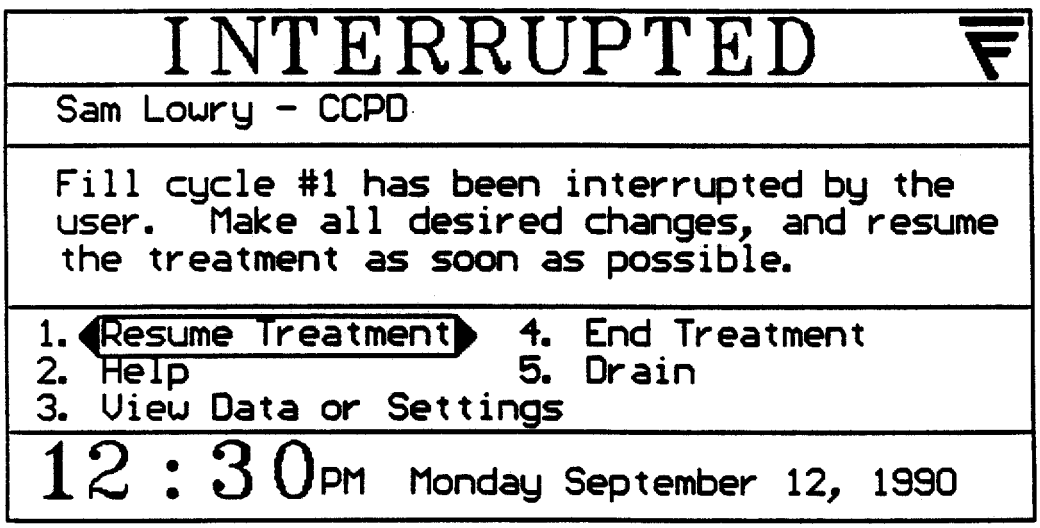

Fig. 9

Unclamp the patient line allowing the fluid to flow and fill it. The priming cap may be left in position to accomplish this. When all the air in the patient line has been displaced with solution, clamp the patient line. Now perform the catheter connection procedure according to the physician's instructions.

Treatment

After the patient has been properly connected to the 90/2 Peritoneal Dialysis System the treatment can begin by selecting the Start Treatment menu option and pressing the Start keypad. The treatment is now automatic, and will progress from cycle to cycle according to the treatment parameters which were entered during the set up of the machine. Pressing the Stop keypad at anytime during any cycle will immediately halt the treatment and give the patient a choice of options (see Fig. 9), including immediate drain of the peritoneal cavity. Any alarm condition detected by the machine will also halt the treatment and display an alarm message.

One cycle or exchange consists of a patient drain, a patient fill, and a dwell mode.

Patient Fill- Pre-warmed dialysate solution is gravity fed to the patient from the gravity bag. The solution passes through the heat exchange bag where a final trim heating is done to ensure delivery to the patient is at the proper temperature. When the predetermined fill volume (monitored by the upper scale) has reached the patient, the 90/2 switches into the dwell mode. During the fill mode, the display screen shows the parameters associated with that mode in both text and graphics. (see Fig. 10).

Dwell- The dialysis tratment takes place during the dwell mode and the patient is isolated from the cycler by the closed patient valve. During the dwell mode spent dialysate that has been collected in the weigh bag is either pumped to a remote drain location or gravity drained into a drain bag. Also toward the end of the dwell mode, fresh dialysate is pumped from either the main supply bags or the last bag, through the heat exchanger bag where it is warmed to the specified temperature, up into the gravity bag. When the required amount of fluid for the next fill cycle had reached the gravity bag (monitored by the upper scale), and the dwell time has ended, the 90/2 switches into the drain mode. During the dwell mode, the display screen shows the parameters associated with that mode in both text and graphics. (see Fig. 11)

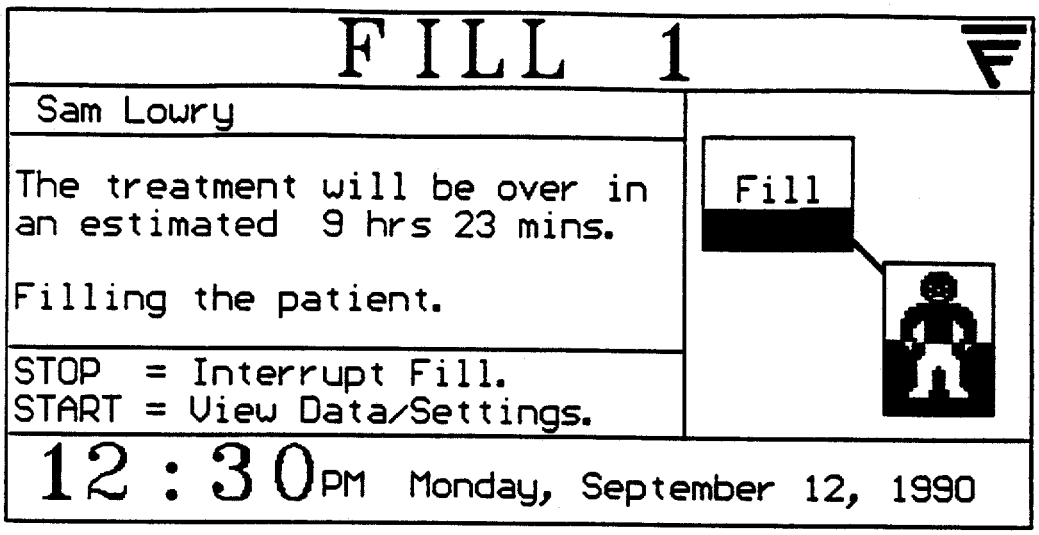

Fig. 10

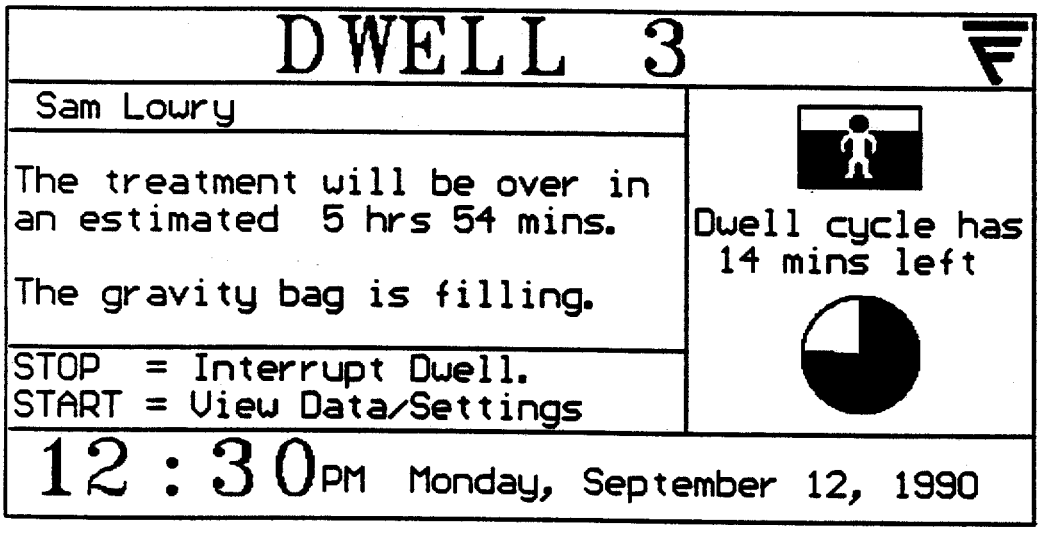

Fig. 11

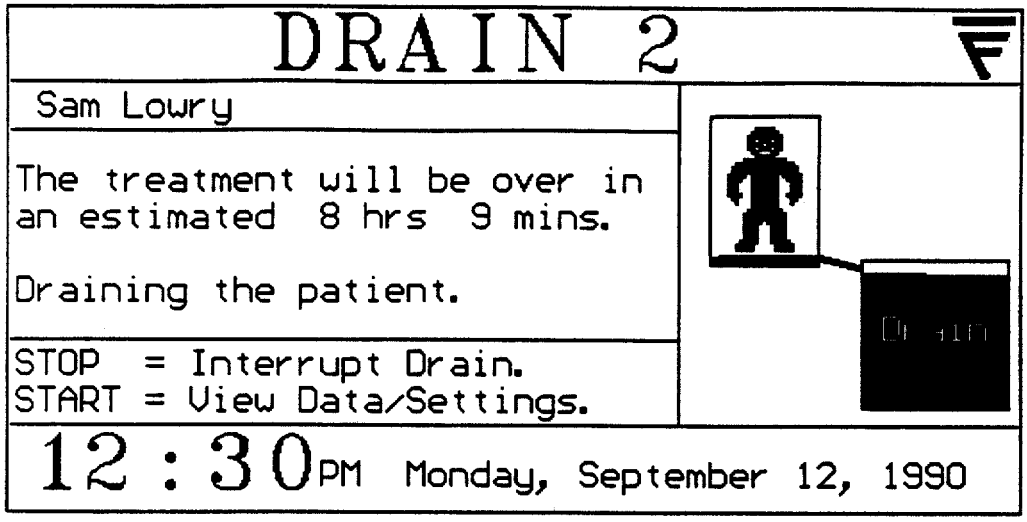

Fig. 12

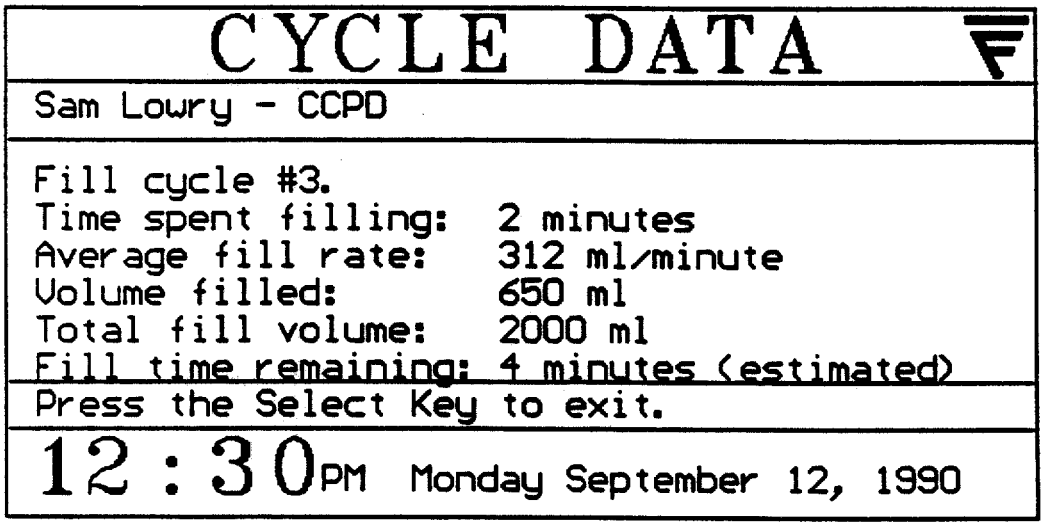

Fig. 13

Patient Drain- Spent dialysate drains by gravity from the patient to the weigh bag which is positioned on the lower scale. This scale monitors the drain flow rate and an alarm is generated if the rate or total volume collected is outside of specified limits. The amount of fluid collected in the weigh bag is also used in conjunction with the amount of fluid delivered to the patient (determined by the upper scale), to calculate and display the net ultrafiltration or fluid removed from the patient. When an adequate drain volume had been reached, the 90/2 switches into the fill mode and the cycle starts over again. During the drain mode, the display screen shows the parameters associated with that mode in both text and graphics. (see Fig. 12)

At the end of the treatment when all the predetermined exchanges have taken place, the display will show a completion screen, and prompt the patient to disconnect the patient line according to the physician's instructions and to disconnect the Delmed tubing set from the 90/2.

Cycle and Treatment Data- Data for the current cycle as well as the whole tratment thus far is continuosly updated and can be displayed at any time during the treatment by selecting that menu option. (see Fig. 13, 14,)

A Treatment Record (Data Sheet) (see Fig. 15) can be printed out after the treatment has been completed if an optional printer has been hooked up to the RS 232 port on the back of the 90/2. Treatment records are stored in memory and can be accessed at a later date and printed out or downloaded to a central computer or other memory retention device. The 90/2 Peritoneal Dialysis System can store approximately 30 days of records for a single patient.

When the treatment has been finished and the patient and tubing set disconnected from the machine, turn the power off to the 90/2 with the switch on the back.

TREATMENT DATA

Treatment is in fill cycle #3.

Weight loss as of last cycle:	320 ml
Average weight loss per cycle:	150 ml
Average fill rate:	210 ml/minute
Average drain rate:	180 ml/minute
Average ultrafiltration rate:	150 ml/hour
End of treatment:	7:00 am (estimated)

Press the Select Key to exit.

12:30PM Monday September 12, 1990

Fig. 14

DATA SHEET

	Drain		Fill		Dwell	
Cycle	Time	Vol	Time	Vol	Time	Net UF
1	20:23	1325	20:37	1500	20:42	- 175
2	22:42	1650	22:58	1500	23:04	- 25
3	1:04	1625	1:18	1500	1:28	+ 100
4	3:28	1700	3:43	1500	3:53	+ 300
5	5:53	1620	6:03	1500	6:13	+ 420

Use the arrow keys to scroll the display.
Press the Select Key to exit.

12:30PM Monday September 12, 1990

Fig. 15

ALARM SUMMARY

DRAIN ALARM- Lower scale did not register weight increase at proper rate. Machine is in safe state with all valves and pumps off.
Things to check: Height of patient and equipment
Lower scale
Kinked tubing
Catheter restriction
Patient and/or drain valve

FILL ALARM- Upper scale did not register weight decrease at proper rate. Machine is in safe state with all valves and pumps off.
Things to check: Upper scale
Patient and/or gravity valve
Kinked tubing
Catheter restriction

PUMP ALARM- Upper scale did not increase fast enough during the time the gravity bag was being filled. Machine is in safe state with all valves and pumps off.
Things to check: Upper scale
Feed pump
Adequate solution available
Main bag valve or last bag valve
Gravith bag valve

TEMPERATURE ALARM- Dialysate temperature is too high. Patient valve closes and heater is shut off by separate circuit. Rest of valves and pumps are shut off in normal control mode.
Things to check: Temperature sensors
Heater unit

VOLTAGE ALARM- One or more of the internal supply voltages is out of specification. Machine will shut down and suspend treatment. Alarm message will appear. Treatment data will be stored in memory.
The cause of this alarm is electronic-call your service representative.

BATTERY ALARM- The backup battery voltage is low. Since this is a backup or emergency power source, the 90/2 can continue to operate normally. Battery should be replaced at earliest convenience.

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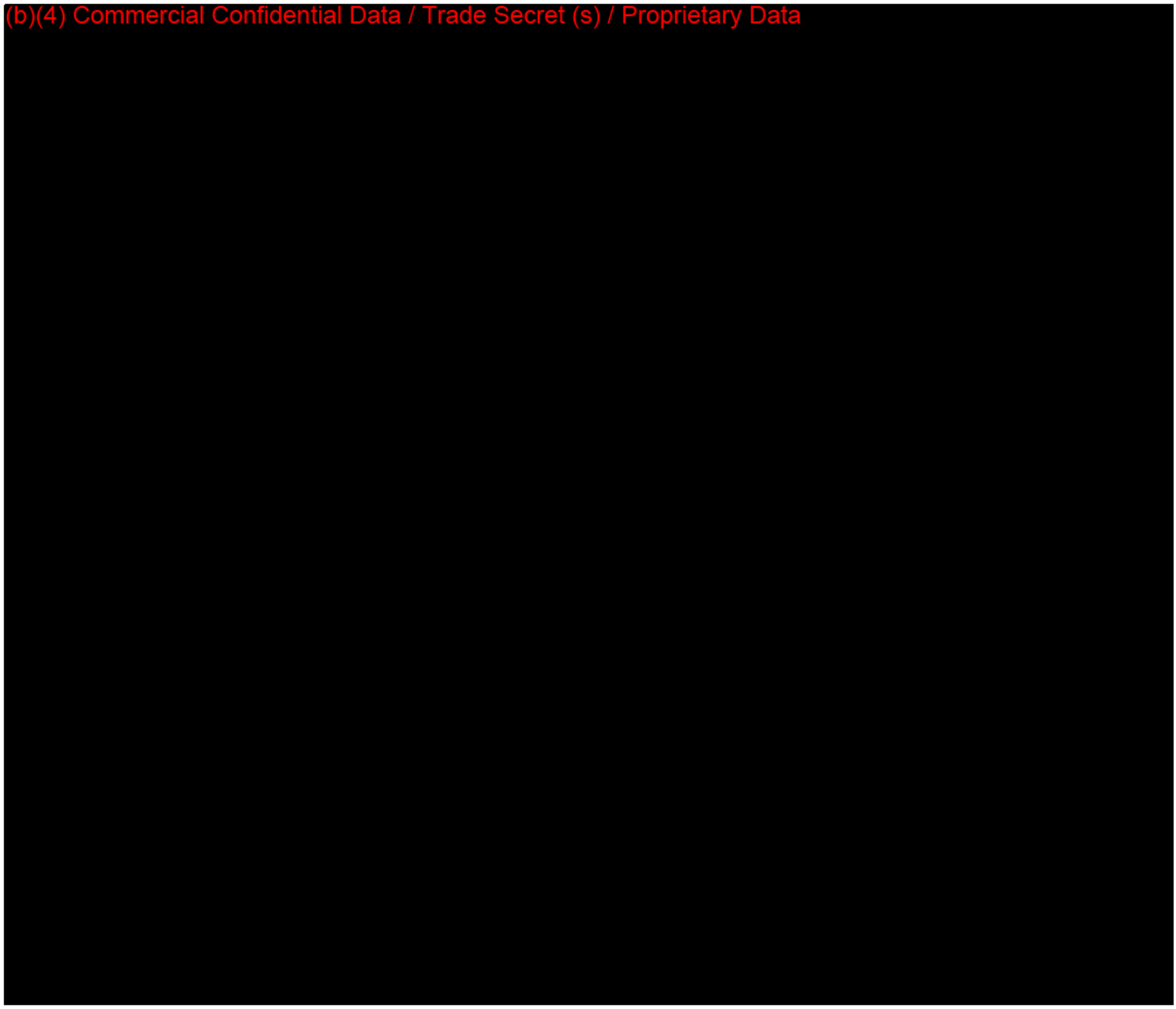
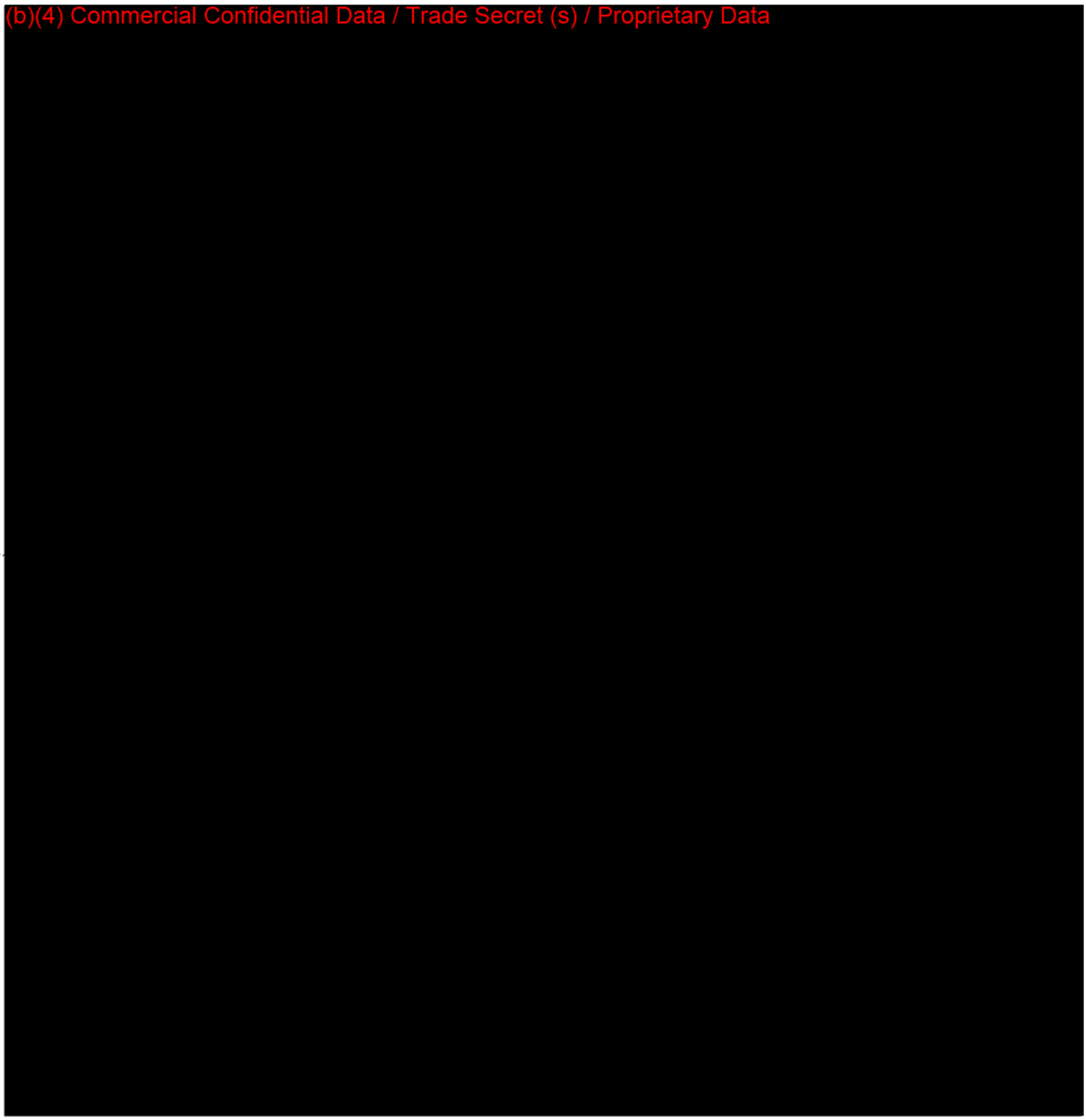
Appendix C. SOFTWARE EVALUATION PROTOCOL (see attached Flow Schematic)

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

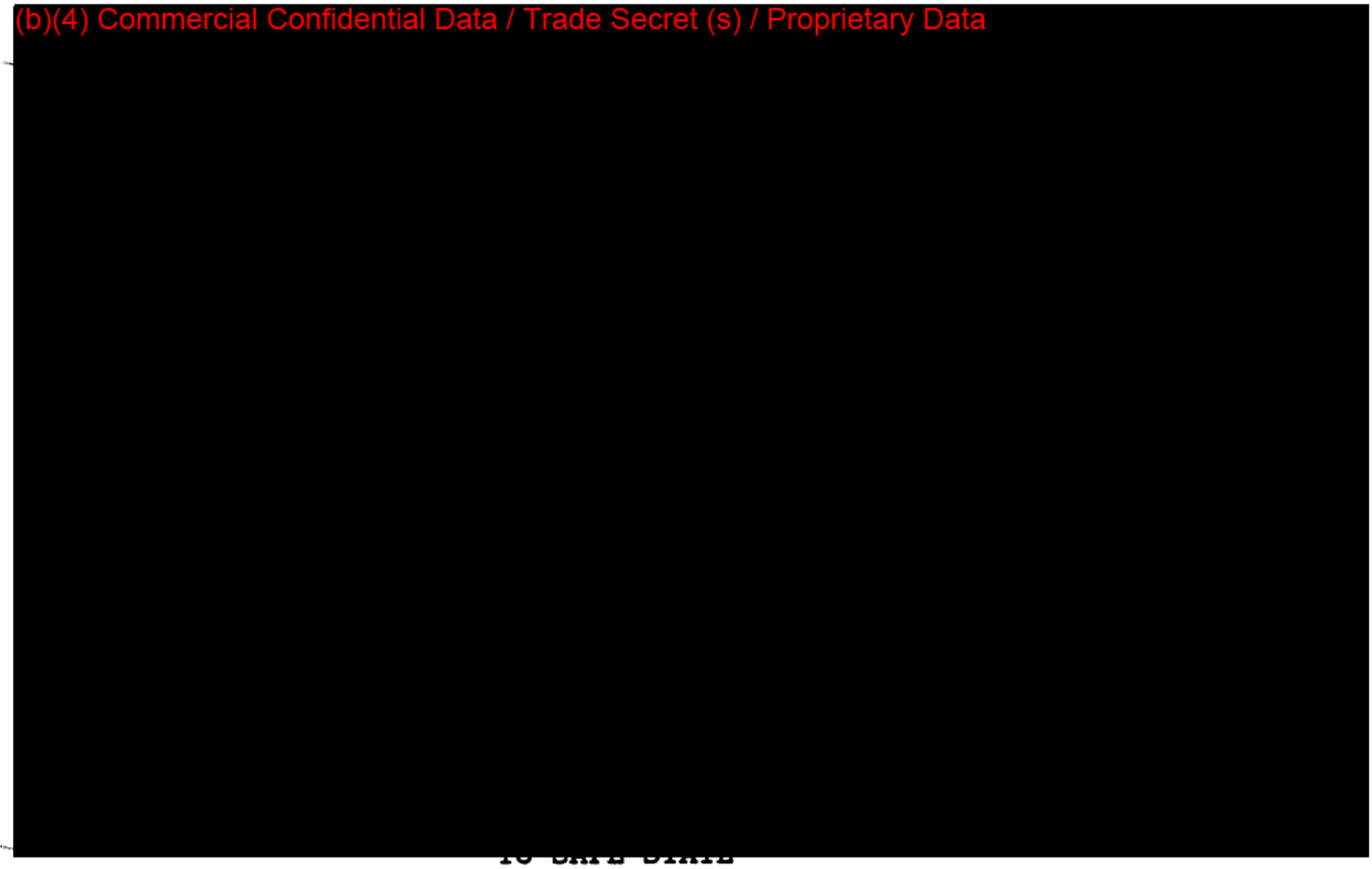


SOFTWARE EVALUATION PROTOCOL
FLOW SCHEMATIC



Software Validation

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data



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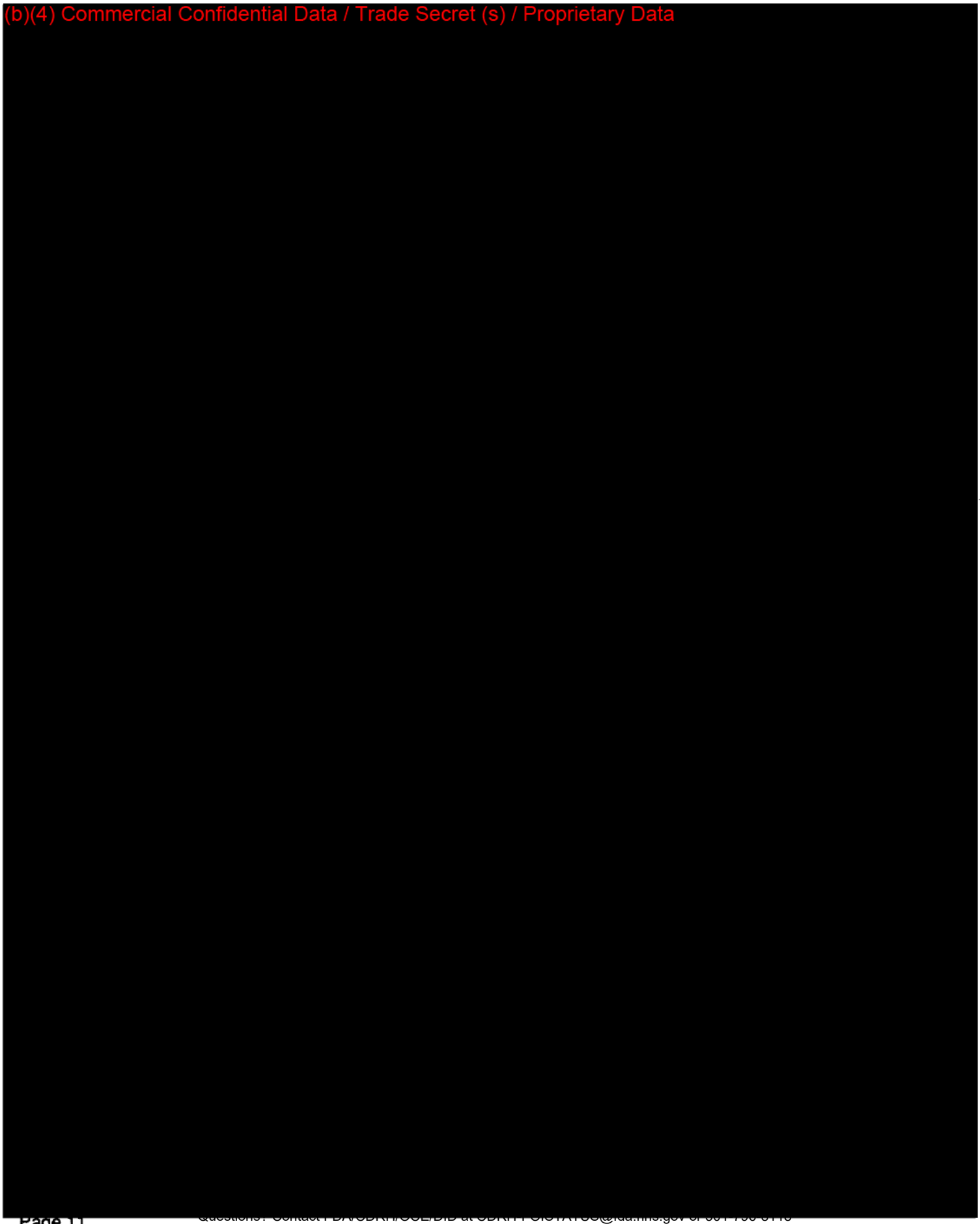
EMPIRICAL/ PRACTICAL TESTING

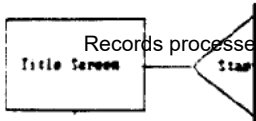
(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

Software flow charts:

90/2 Main MPU Routine





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90/2 Main Program

Software Flow Sheet Diagram

(b