

JUN 27 2002

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Lifestream Purification Systems, LLC
2001 South Lamar, Suite G
Austin, TX 78704
(512) 707-3773

Contact Person: Amy Heilman

Date of Preparation: November 30, 2000

II. DEVICE NAME

Proprietary Name: Angel of Water™

Common Name: Colon Hydrotherapy System

Classification Name: Colonic Irrigation System

III. PREDICATE DEVICES

Jimmy John III (Colon Therapeutics, Inc; K881720)
Libbe Rectal Tube (Tiller Mind and Body, Inc.; K962259)

IV. DEVICE DESCRIPTION

This device is an instrument for hydrotherapy of the colon. It introduces filtered water at a comfortable temperature into the large intestine, thus cleansing the colon of its contents when medically indicated, such as before radiological or endoscopic examination. It is hygienic, comfortable and painless. Water temperature is controlled by means of an audible alarm. Temperature, flow, and pressure are controlled by one switch operated by the user. The system is manually sanitized prior to each use with a suitable broad-spectrum disinfectant. The system includes disposable tubing and a sterile, disposable rectal nozzle intended for single use only.

V. INTENDED USE

For colon cleansing when medically indicated, such as before radiological or endoscopic examination.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2002

Ms. Amy Heilman
General Manager
Lifestream Purification Systems, LLC
2001 South Lamar, Suite G
AUSTIN TX 78704

Re: K003720
Trade/Device Name: Angel of Water™ Colon
Hydrotherapy System
Regulation Number: 21 CFR 876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: II
Product Code: 78 KPL
Dated: May 18, 2002
Received: May 20, 2002

Dear Ms. Heilman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|----------------------------------|----------------|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 003720

Device Name: Angel of Water™ Colon Hydrotherapy System

Indications for Use:

Colon cleansing when medically indicated, such as before radiological or endoscopic examination.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)

David L. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K003720

Premarket Notification: Angel of Water™ Colon Hydrotherapy System



RICHARD HAMER ASSOCIATES, INC.
REGULATORY CONSULTANTS

March 14, 2001

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

SK 41

RECEIVED
MAR 19 2 52 PM '01
FDA/CDRH/OCE/DMC

Re: K003720 Angel of Water Colon Hydrotherapy System
Lifestream Purification Systems, LLC, Austin Texas

Gentlemen:

Please refer to the subject premarket notification submitted on behalf of Lifestream Purification Systems, LLC on November 30, 2000. Reference is also made to Dr. Neuland's letter of March 2, 2001, requesting additional information.

In order to prepare a full and complete response to the questions raised, I hereby request an extension of the 510(k) review period until July 31, 2000. Your cooperation in this matter is most appreciated.

Sincerely,

Richard A. Hamer
Consultant to Lifestream Purification Systems, LLC

cc: Amy Heilman, Lifestream Purification Systems, LLC

Dr. Epstein
212-535-6661

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 10/20/06

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K003720 /A1

To: Division Director: GU/DRAED

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: *Katherine M. O'Leary*

Date: 12/18/06

Draft #2: 9/8/99
Draft #3: 1/3/00
Draft #4: 3/7/03

*DRAED
LO 12/18/06*

*changing nozzle
to another legally
marketed rectal
nozzle K050992*

DRAAD rec. 10-19-06
add-to-file



"Inspiring Ideas for Quality of Life"

K003720/A1

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: K003720
Trade/Device Name: Angel of Water® CM-1
Regulation Name: Colonic Irrigation Device
Regulatory Class: II
Product Code: KPL
Dated: 10 October 2006

RECEIVED
OCT 19 11:14
CDRH/CDER/CDR

Dear Ms. Brogdon,

I am writing to bring to your attention that we are adding a new rectal nozzle disposable to our device cleared at K003720. This new equivalent disposable rectal nozzle (irrigation nozzle) is cleared at K050992 with the same indication for use as our current one, which is for "colon cleansing when medically indicated, such as before radiological or endoscopic examination." It is designed and manufactured similarly and is constructed of like or similar materials as our current rectal nozzle disposable. This new device is held by Coned Corporation.

Additionally, I am informing you that we are (b)(4)
[Redacted]
[Redacted]
[Redacted] neither of which constitute a design change that requires a 510 K (4) submission.

Sincerely,

Amy Hellman
MR

Lifestream Purification Systems, LLC



Lifestream Purification Systems, LLC
2001 South Lamar Blvd., Suite G • Austin, Texas • 78704 • Phone: 512.707.8383 • Fax: 512.707.8484

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8448

K 20

7

2001 South Lamar Blvd., Suite G • Austin, Texas • 78704



Route
Undefined
Delivery Point
A-320B
10/12/06
BROGDON, NANCY
301-594-5072 HFZ-470 11:23:23
PO#
Sdr LIFESTREAM
700608100004844318

M102003L5C

2085043223-00



7006 0810 0004 8443 1842

470

Nancy E. Brogden
Director, Division of Reproductive, Abdominal,
and Radiological Genes
Office of Gene Evaluation
Center for Genes & Radiological Health
Food and Drug Administration
20850 Car Park Dr
Rockville, MD 20850

M

CERTIFIED MAIL™

UNITED STATES POSTAL SERVICE
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20850
U.S. POSTAGE
PAID
AUSTIN, TX
OCT 10, 06
AMOUNT
\$4.64
00046208-06



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2006

Ms. Amy Heilman
Lifestream Purification Systems, LLC
2001 South Lamar Blvd, Suite G
AUSTIN TX 78704

Re: K003720
Device Name: Angel of Water CM-1 Colonic Irrigation Device
Dated: October 10, 2006
Received: October 19, 2006

Dear Ms. Heilman:

We have reviewed the information dated October 10, 2006, regarding the 510(k) notification K003720 previously submitted for the device referenced above. Based solely on the change or modification that you have described, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). Additionally, we did not review any data submitted with this add to file. It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). Please refer to our guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" at www.fda.gov/cdrh/ode/510kmod.html. The information you have supplied will be added to the file.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

4

Ms. Amy Heilman
 Lifestream Purification Systems, LLC
 2001 South Lamar Blvd, Suite G
 AUSTIN TX 78704

Re: K003720
 Device Name: Angel of Water CM-1 Colonic Irrigation Device
 Dated: October 10, 2006
 Received: October 19, 2006

Dear Ms. Heilman:

We have reviewed the information dated October 10, 2006, regarding the 510(k) notification K003720 previously submitted for the device referenced above. Based solely on the change or modification that you have described, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). Additionally, we did not review any data submitted with this add to file. It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). Please refer to our guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" at www.fda.gov/cdrh/ode/510kmod.html. The information you have supplied will be added to the file.

Sincerely yours,

Nancy C. Brogdon
 Director, Division of Reproductive,
 Abdominal, and Radiological Devices
 Office of Device Evaluation
 Center for Devices and Radiological Health

FILE COPY

| OFFICE | SURNAME | DATE | OFFICE | SURNAME | DATE | OFFICE | SURNAME | DATE |
|--------|-----------|----------|--------|---------|------|--------|---------|------|
| 2-470 | Olvey | 12/18/06 | | | | | | |
| 2-470 | Lauritsen | 12/18/06 | | | | | | |
| 2-470 | Seymour | 12/18 | | | | | | |

U.S. GPO 1986-169-089



Lifestream Purification Systems, LLC
7303 Burleson Rd.
Suite 801
Austin, TX 78744
512.707.8383
Fax: 512.707.8484
www.angelofwater.com

FDA CDRH DMC
MAR 11 2015
Received

K003720/A002

March 3, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K 003720

To whom it may concern:

Lifestream Purification Systems, LLC is notifying you that the following changes are being made:

Lifestream Purification Systems, LLC currently purchases (b)(4)

(b)(4)

When this change goes into effect, Lifestream will document this within its quality system. Please see the attached revised pouch and box labels.

Sincerely,

A handwritten signature in black ink, appearing to read "Amy Heilman", with a long horizontal flourish extending to the right.

Amy Heilman
Managing Representative

Colon Cleansing Nozzle with Flex Tube

REF SPO001

Colon Cleansing Nozzle with Flex Tube
 Canule de nettoyage du colon avec tuyau flexible
 Darmreinigungsdüse mit Flexschlauch
 Ugello per irrigazione del colon con tubo flessibile
 Moedstuk voor darmreining met flexibele slang
 Kolonpolimunestycke med flexibel slang
 Cánula para limpieza de colon con Tubo Flexible
 帶接性管的結腸清洗噴嘴
 Аксепоруно ачагажууу түү үөлөү ие Луңгиртто оуактыр
 Tarmkylledyste med bejelig slange
 Bükülebilir Borulu Kolon Temizleme Nozulu
 Наводнение с гибким шлангом
 Canula de curăţare a colonului, provăzută cu tub flexibil
 Tarmskyllingsdykke med fleksibelt rør
 Vastagöblingsrör för kolonrening med flexibel slang
 Boquilla para limpieza de colon con tubo flexible

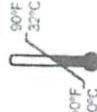
Australian Sponsor
 Emergo Australia
 Level 20, Tower 11
 Darling Park
 201 Sussex Street
 Sydney NSW 2000
 Australia



EMERGO EUROPE
 Molentstraat 15
 2513 BH, The Hague
 The Netherlands



Rx ONLY

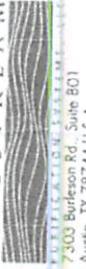


hygieacare. HyGieaCare System.



Models: 120G5 / 240G7

Manufactured for
L I F E S T R E A M



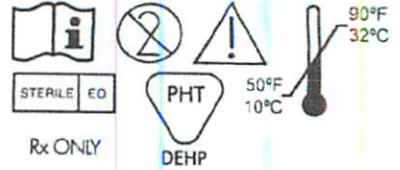
7300 Burleson Rd., Suite B01
 Austin, TX 78744 U.S.A
 ID-011 REV F 01/15

Colon Cleansing Nozzle with Flex Tube

REF SP0001

Colon Cleansing Nozzle with Flex Tube
 Canule de nettoyage du côlon avec tuyau flexible
 Darmreinigungsdüse mit Flexschlauch
 Ugello per irrigazione del colon con tubo flessibile
 Mondstuk voor darmreining met flexibele slang
 Kolonspolmunstykke med flexrør
 Cânula para limpeza do cólon com Tubo Flexível
 帶撓性管的结肠清洗喷嘴
 Ακροφύσιο καθαρισμού του κόλου με εύκαμπτο σωλήνα
 Tarmskylledyse med bøjelig slange
 Bükülebilir Borulu Kolon Temizleme Nozulu
 Накрайник с гъвкава тръба за пречистване на дебелото черво
 Canulă de curățare a colonului, prevăzută cu tub flexibil
 Tarmskylingsdyse med fleksibelt rør
 Vastagbéltisztító csap rugalmas tömlővel
 פייה לניקוי המעי הגס עם צינורית גמישה
 Boquilla para limpieza de colon con tubo flexible

50 / 



Australian Sponsor
 Emergo Australia
 Level 20, Tower II
 Darling Park
 201 Sussex Street
 Sydney NSW 2000
 Australia

EC REP
 EMERGO EUROPE
 Molenstraat 13
 2513 BH, The Hague
 The Netherlands
 CE 0086

hygieacare. HyGleaCare System. LOT 150129 1
 Angel of Water Angel of Water CM-1 Series Models: 120G5 / 240G7
 2020-01

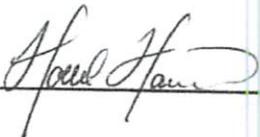
Manufactured for:
LIFESTREAM
 PURIFICATION SYSTEMS, LLC
 7303 Burleson Rd., Suite 801
 Austin, TX 78744 U.S.A.
 LD-067 REV F 01/15

PROOFREADABLE COPY FOR:

PART #: LD-007 REV: F

DESCRIPTION: ODL: Overpack, CAT# SP0001

CO #: _____

REVIEWED BY:  DATE 2/2/2015

FORM #WI-DC-05-F2, REV F 12/14



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2002

Ms. Amy Heilman
General Manager
Lifestream Purification Systems, LLC
2001 South Lamar, Suite G
AUSTIN TX 78704

Re: K003720
Trade/Device Name: Angel of Water™ Colon
Hydrotherapy System
Regulation Number: 21 CFR 876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: II
Product Code: 78 KPL
Dated: May 18, 2002
Received: May 20, 2002

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| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
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| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 003720

Device Name: Angel of Water™ Colon Hydrotherapy System

Indications for Use:

Colon cleansing when medically indicated, such as before radiological or endoscopic examination.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

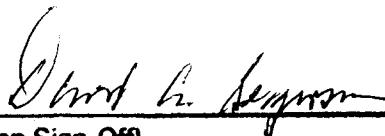
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K003720

Premarket Notification: Angel of Water™ Colon Hydrotherapy System

7

3



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2002

Lifestream Purification Systems, LLC
c/o Mr. Richard A. Hamer
Richard Hamer Associates, Inc.
Regulatory Consultants
P.O. Box 16598
Fort Worth, Texas 76162-0598

Re: K003720
Trade Name: Angel of Water™ Colon Hydrotherapy System
Dated: January 15, 2002
Received: January 17, 2002

Dear Mr. Hamer:

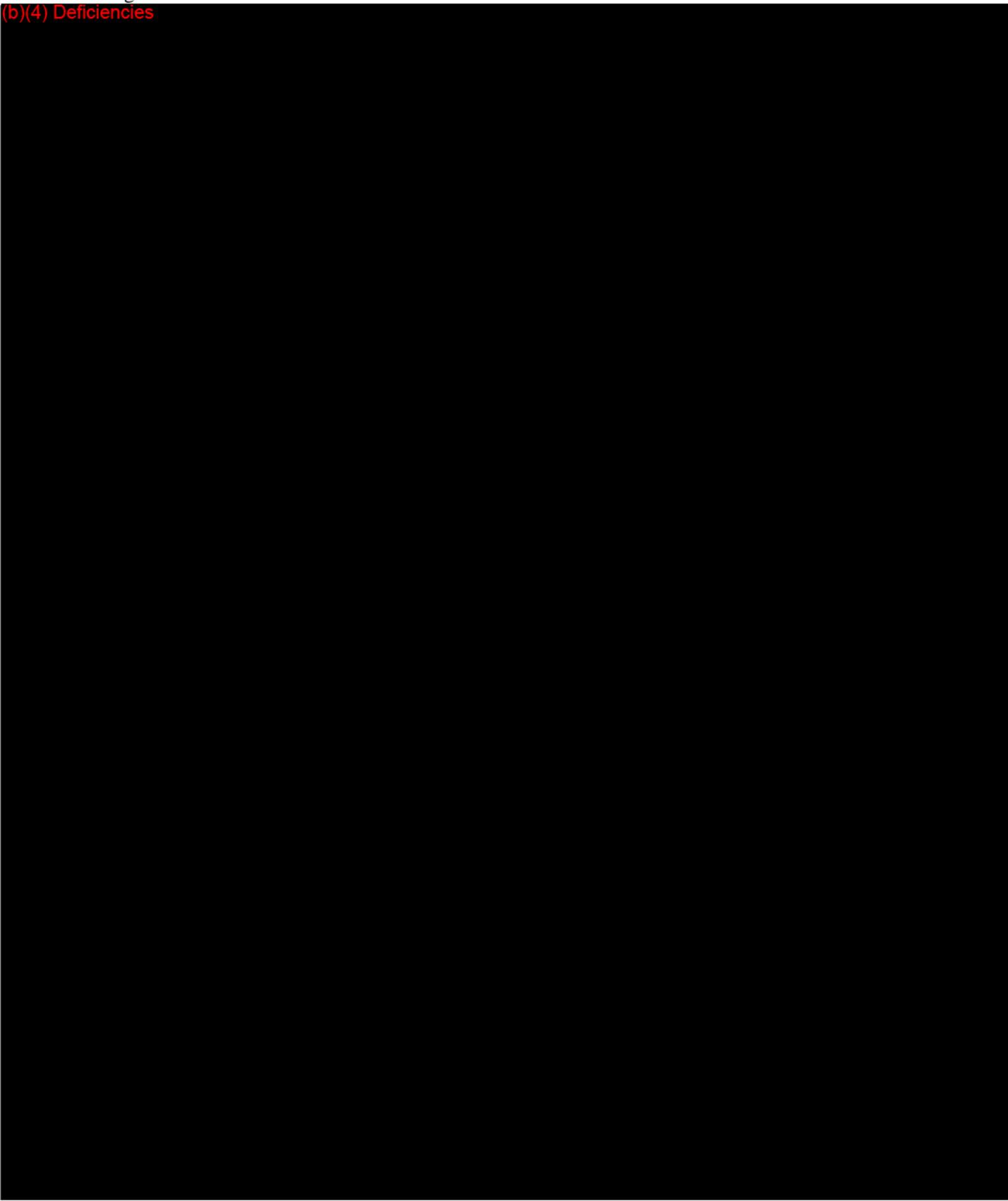
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device because you did not completely respond to the deficiencies listed in our October 30, 2001, letter. To complete the review of your submission, we require the following additional information:

(b)(4) Deficiencies



Page 2 – Mr. Richard Hamer

(b)(4) Deficiencies



Page 3 – Mr. Richard Hamer

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

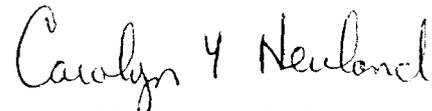
The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Page 4 – Mr. Richard Hamer

If you have any questions concerning the contents of the letter, please contact Ms. Kathleen M. Olvey at (301) 594-1220. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and
Renal Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

APR 17 2002

Lifestream Purification Systems, LLC
c/o Mr. Richard A. Hamer
Richard Hamer Associates, Inc.
Regulatory Consultants
P.O. Box 16598
Fort Worth, Texas 76162-0598

Re: K003720

Trade Name: Angel of Water™ Colon Hydrotherapy System

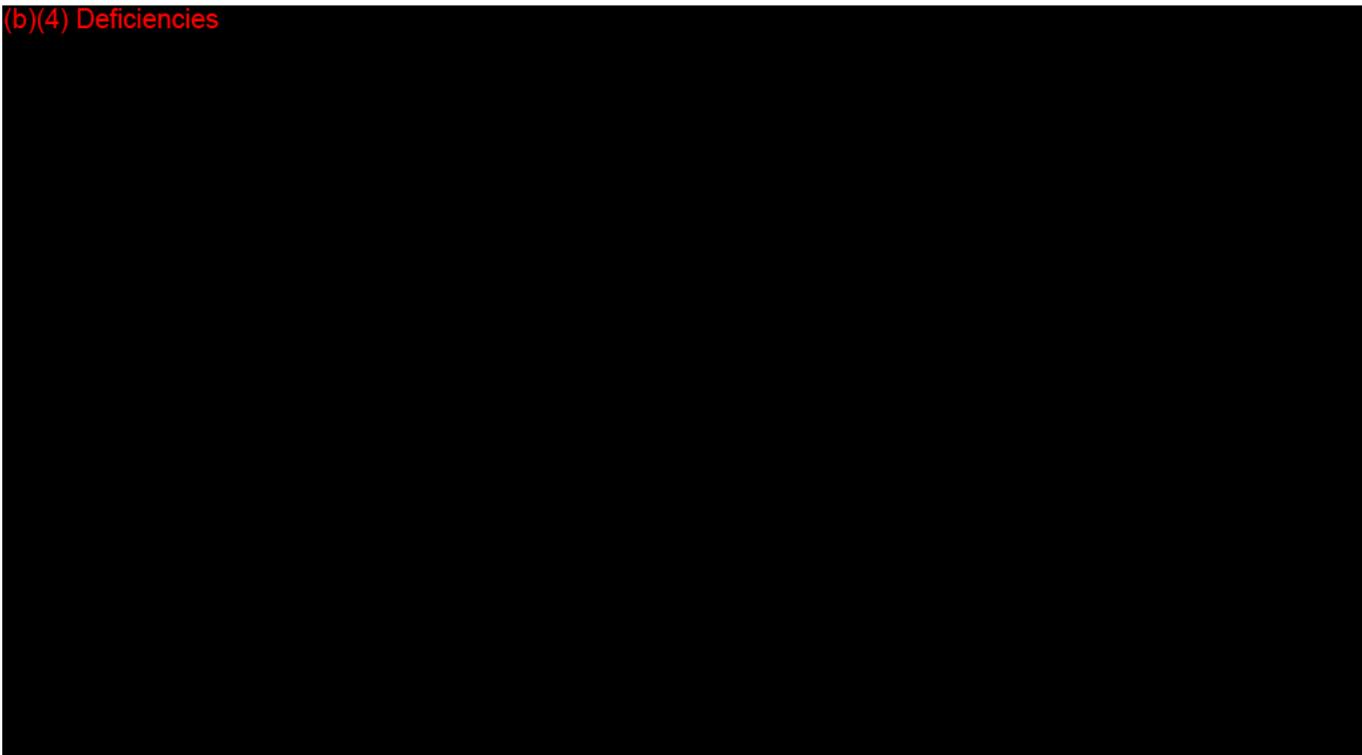
Dated: January 15, 2002

Received: January 17, 2002

Dear Mr. Hamer:

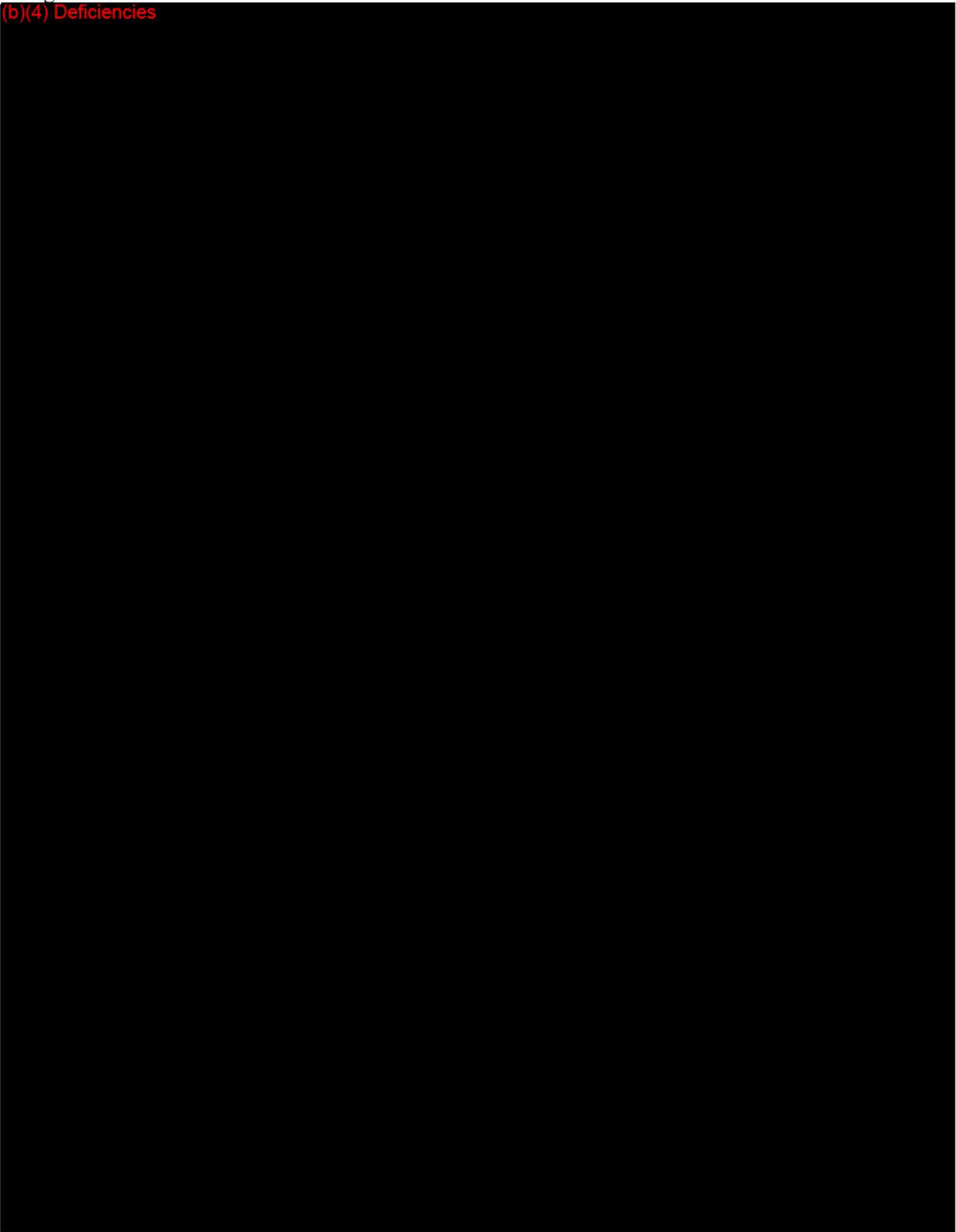
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device because you did not completely respond to the deficiencies listed in our October 30, 2001, letter. To complete the review of your submission, we require the following additional information:

(b)(4) Deficiencies



Page 2 – Mr. Richard Hamer

(b)(4) Deficiencies



Page 3 – Mr. Richard Hamer

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center web page at:
<http://www.fda.gov/cdrh/modact/leastburdensome.html>

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

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The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 4 – Mr. Richard Hamer

If you have any questions concerning the contents of the letter, please contact Ms. Kathleen M. Olvey at (301) 594-1220. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

JSI

Carolyn Y. Neuland, Ph.D.
 Chief, Gastroenterology and
 Renal Devices Branch
 Division of Reproductive, Abdominal,
 and Radiological Devices
 Office of Device Evaluation
 Center for Devices and
 Radiological Health

cc: HFZ-401 DMC
 HFZ-404 510(k) Staff
 HFZ-470 Division
 D.O.

HFZ470:KathyOlvey:irm:4.15.2002

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| OFFICE | SURNAME | DATE | OFFICE | SURNAME | DATE | OFFICE | SURNAME | DATE |
|--------|---------|---------|--------|---------|------|--------|---------|------|
| 2-470 | Olvey | 4/17/02 | | | | | | |
| HFZ470 | Neuland | 4/17/03 | | | | | | |
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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 12, 2001

LIFESTREAM PURIFICATION SYSTEMS, LLC 510(k) Number: K003720
C/O RICHARD HAMER ASSOCIATES, INC Product: ANGEL OF WATER
6401 MEADOWS WEST DR. COLON
FORT WORTH, TX 76132 HYDROTHERAPY
ATTN: RICHARD A. HAMER SYSTEM

Extended Until: 29-JAN-2002

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

135



RICHARD HAMER ASSOCIATES, INC.
REGULATORY CONSULTANTS

November 30, 2001

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RECEIVED
Nov 12 1 23 PM '01
FDA/CDRH/ONE/SHO

Re: K003720 Angel of Water Colon Hydrotherapy System
Lifestream Purification Systems, LLC, Austin Texas

Gentlemen:

Please refer to the subject premarket notification submitted on behalf of Lifestream Purification Systems, LLC on November 30, 2000 and amended on July 31, 2001. Reference is also made to Dr. Neuland's letter dated October 30, 2001, requesting additional information. Due to apparent delays in mail handling and delivery, this letter was not received until November 15th.

In order to prepare a full and complete response to the questions raised in Dr. Neuland's, I hereby request an extension of the 510(k) review period until January 15, 2002. Your cooperation in this matter is most appreciated.

Sincerely,

Richard A. Hamer
Consultant to Lifestream Purification Systems, LLC

cc: Amy Heilman, Lifestream Purification Systems, LLC

5/17

(817) 294-3644 • Fax (817) 294-3761 • E-mail: rhamer@hamerassoc.com



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 2001

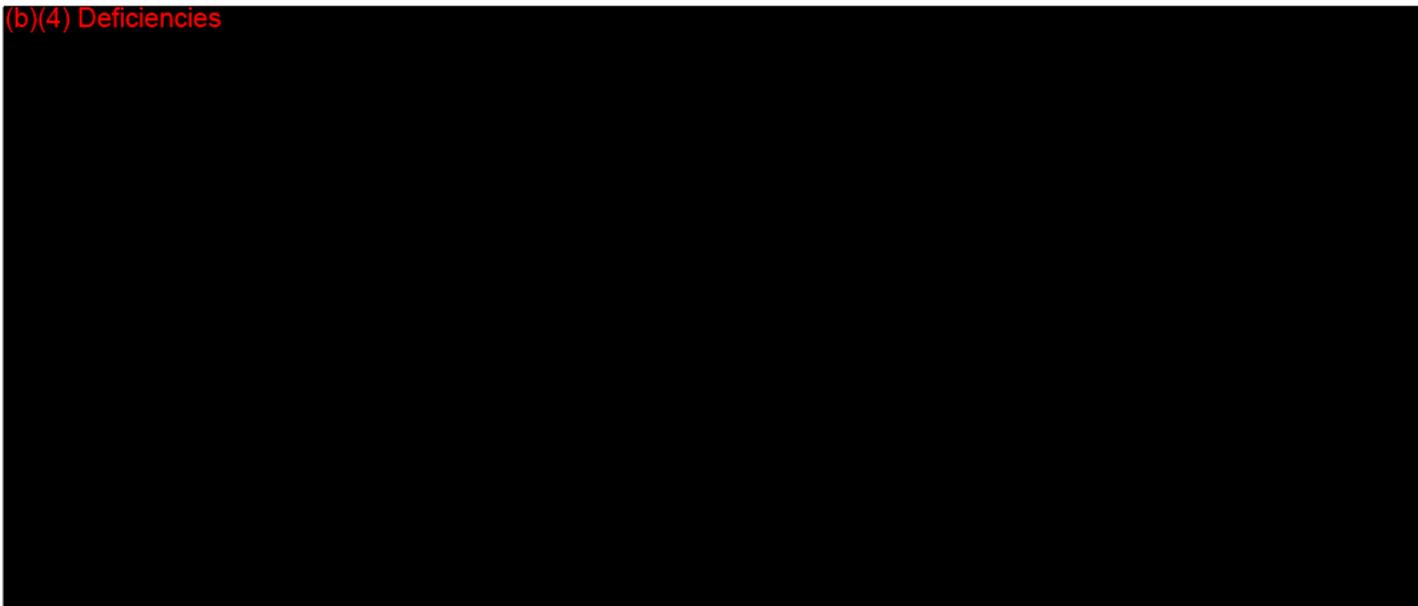
Lifestream Purification Systems, LLC
c/o Mr. Richard A. Hamer
Consultant
Richard Hamer Associates, Inc.
Regulatory Consultants
P.O. Box 16598
Ft. Worth, Texas 76162-0598

Re: K003720
Angel of Water™ Colon Hydrotherapy System
Dated: July 31, 2001
Received: August 1, 2001

Dear Mr. Hamer:

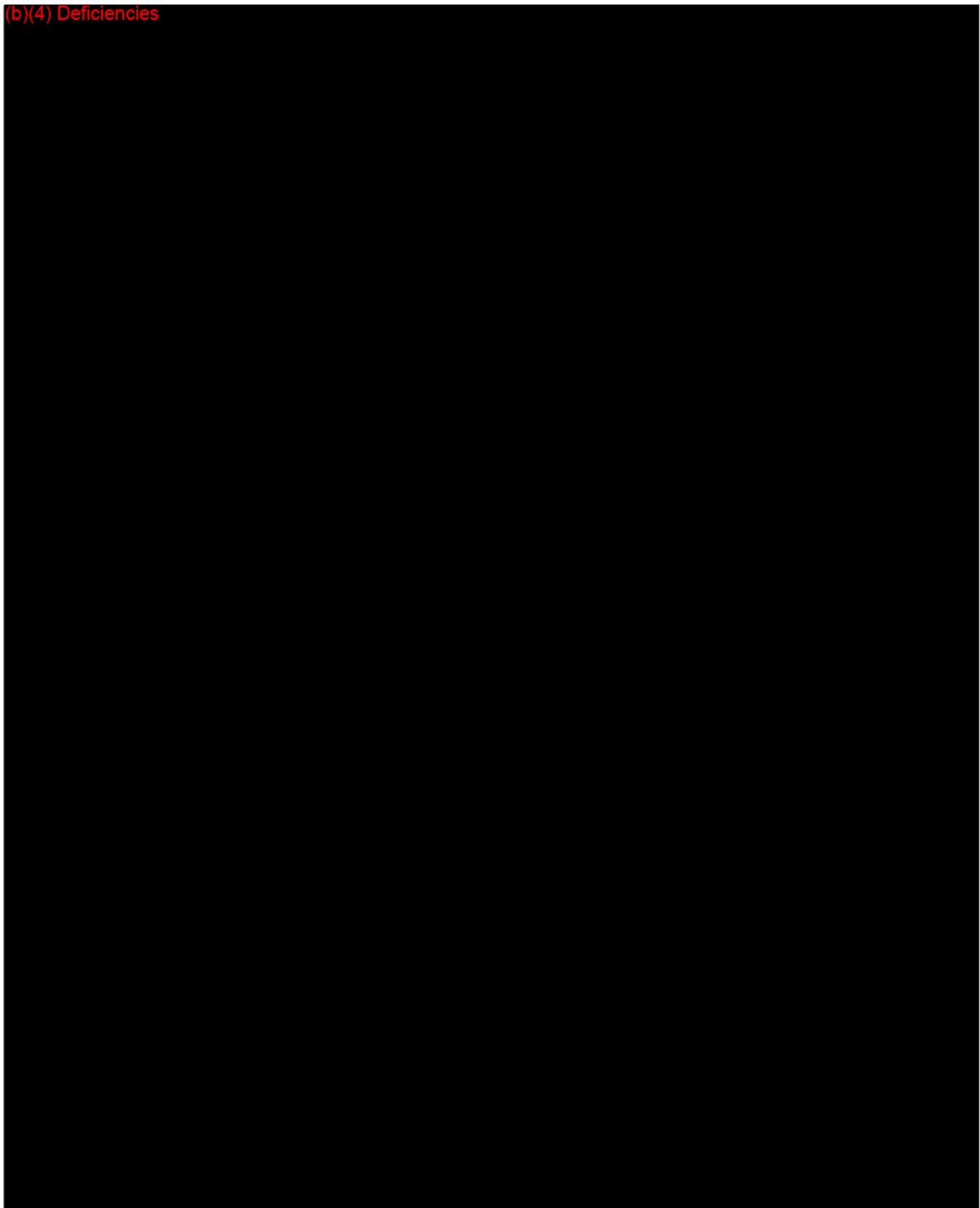
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device because you did not completely respond to the deficiencies listed in our March 2, 2001, letter, and your responses to the deficiencies in that letter raised new issues. To complete the review of your submission, we require the following additional information:

(b)(4) Deficiencies



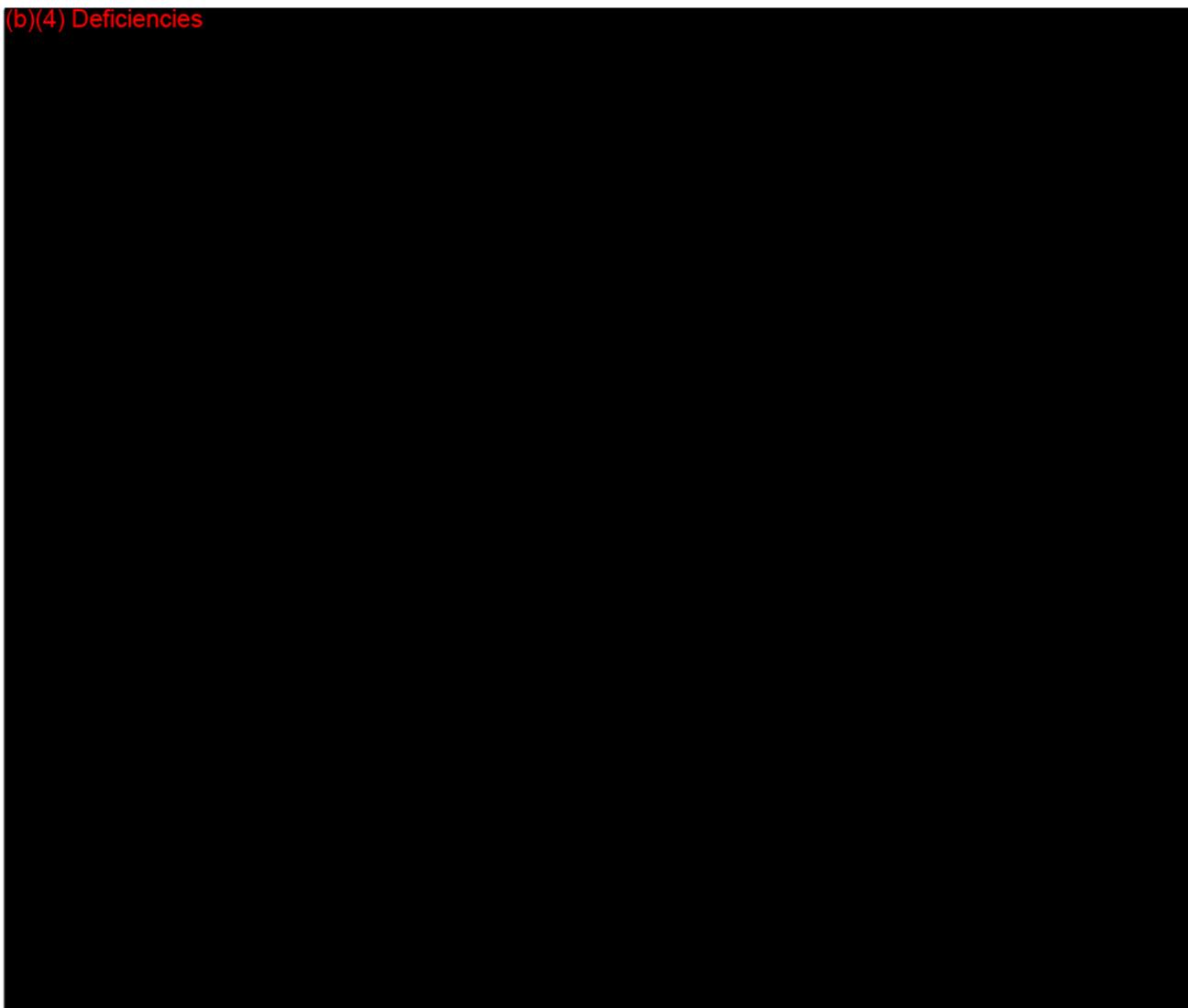
Page 2 – Mr. Richard Hamer

(b)(4) Deficiencies



Page 3 – Mr. Richard Hamer

(b)(4) Deficiencies



The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

You may not market this device until you have provided adequate information described above and required by 21 CFR §807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the

Page 4 – Mr. Richard Hamer

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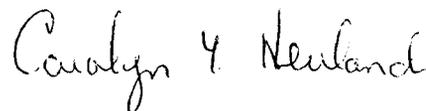
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Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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Sincerely yours,



Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and
Renal Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Lifestream Purification Systems, LLC
c/o Mr. Richard A. Hamer
Consultant
Richard Hamer Associates, Inc.
Regulatory Consultants
P.O. Box 16598
Ft. Worth, Texas 76162-0598

Re: K003720
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Dated: July 31, 2001
Received: August 1, 2001

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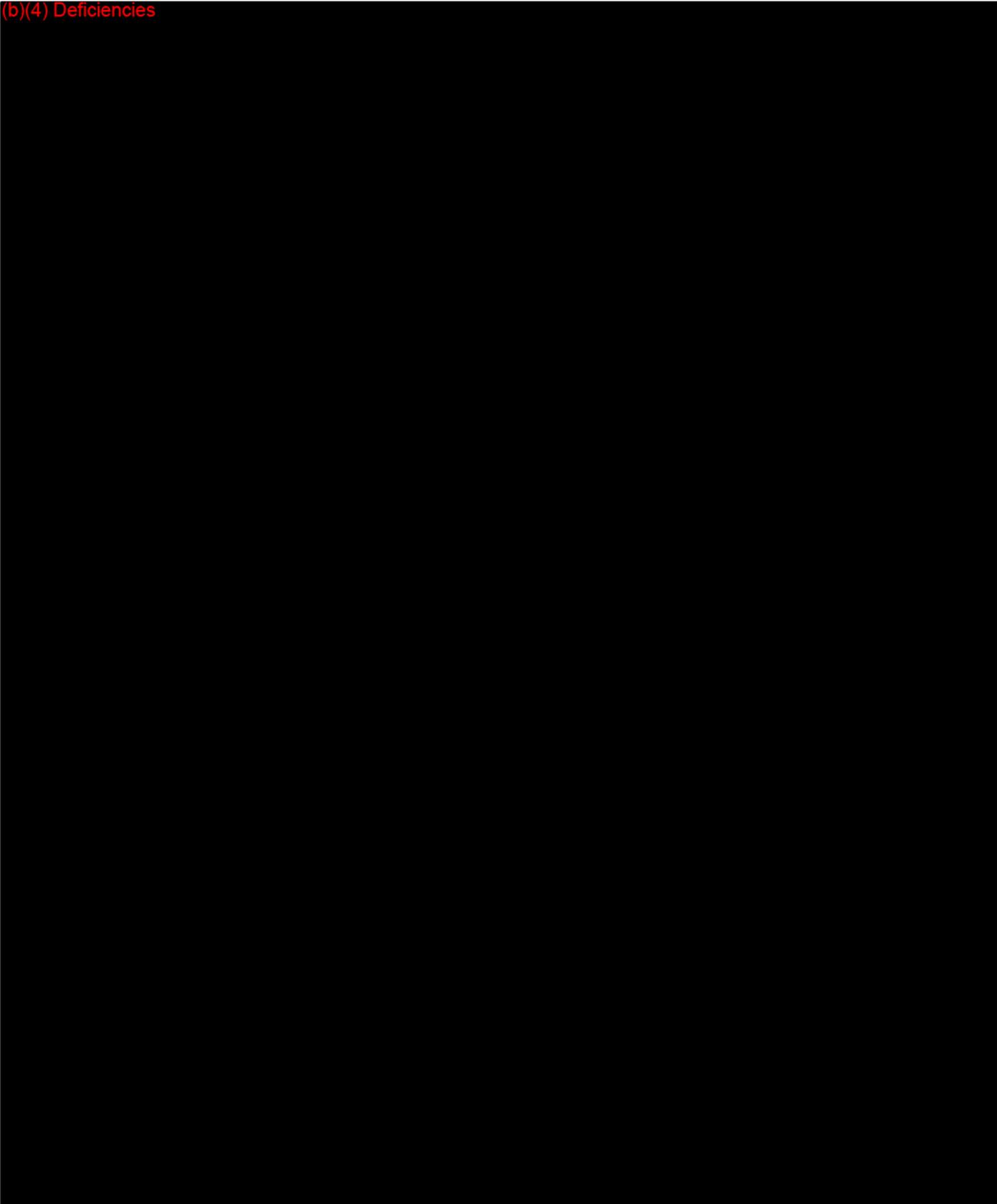
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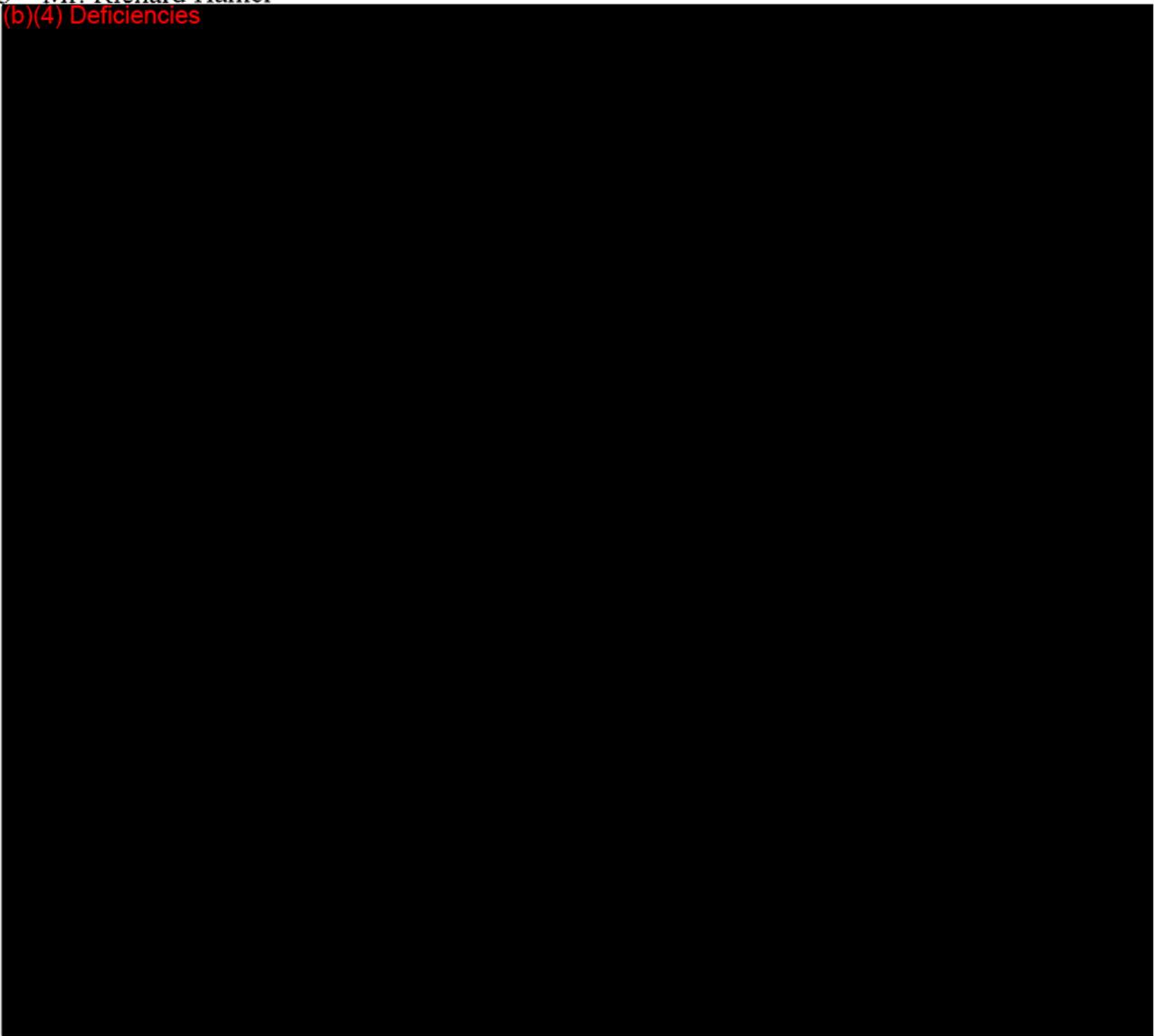
Page 2 – Mr. Richard Hamer

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Page 3 – Mr. Richard Hamer

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Page 4 – Mr. Richard Hamer

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Sincerely yours,



Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and
Renal Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Page 5 – Mr. Richard Hamer

cc: HFZ-401 DMC
 HFZ-404 510(k) Staff
 HFZ-470 Division
 D.O.

HFZ470:KathyOlvey:lrn:10.30.2001

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| OFFICE | SURNAME | DATE | OFFICE | SURNAME | DATE | OFFICE | SURNAME | DATE |
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| Z-470 | Olvey | 10/30/01 | | | | | | |
| HFZ-470 | Howland | 10/30/01 | | | | | | |
| | | | | | | | | |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Lifestream Purification Systems, Inc.
c/o Richard A. Hamer Associates, Inc.
6401 Meadows West Drive
Fort Worth, Texas 76132

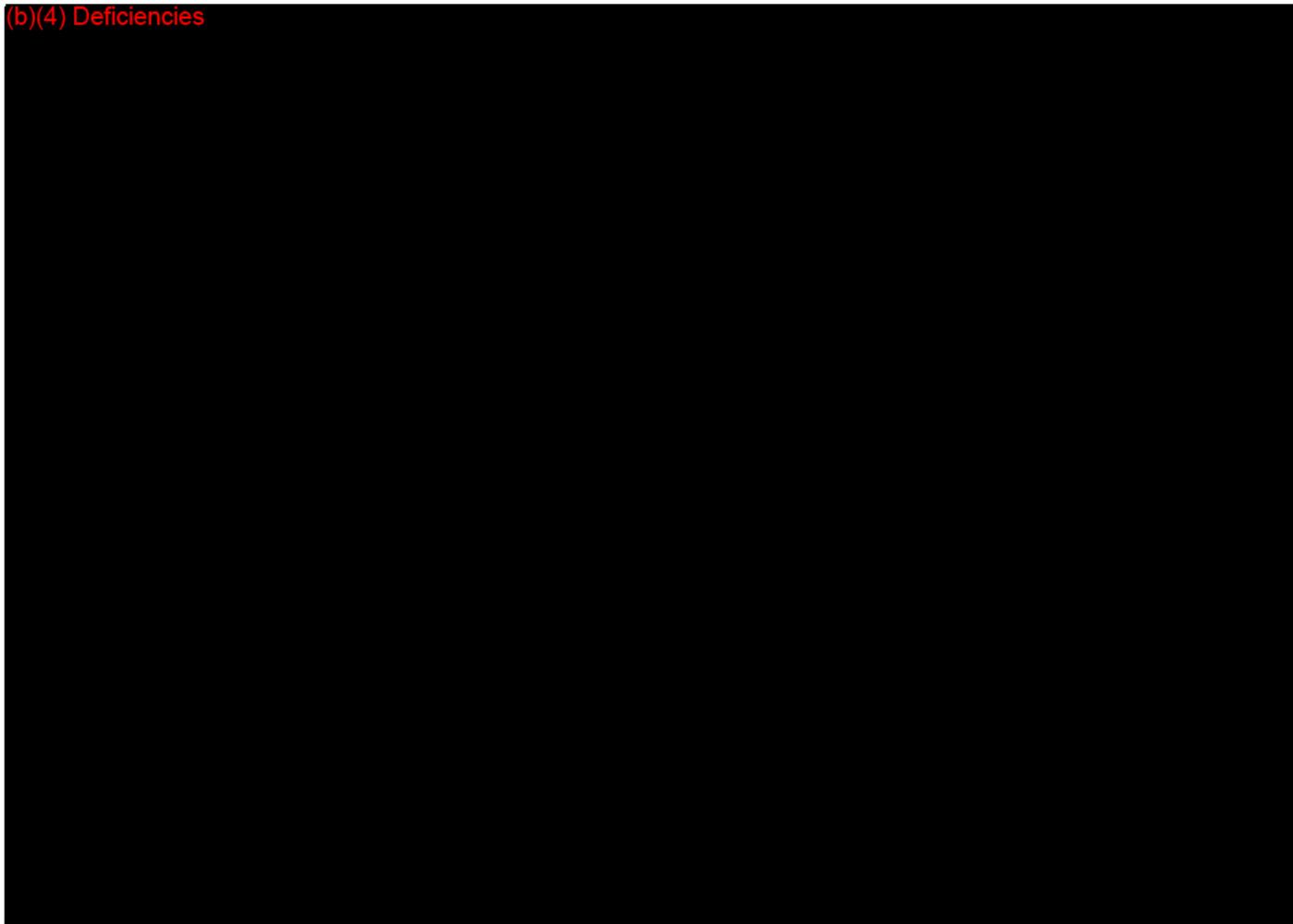
MAR 2 2001

Re: K003720
Angel of Water™ Colon Hydrotherapy System
Dated: November 30, 2000
Received: December 4, 2000

Dear Mr. Hamer:

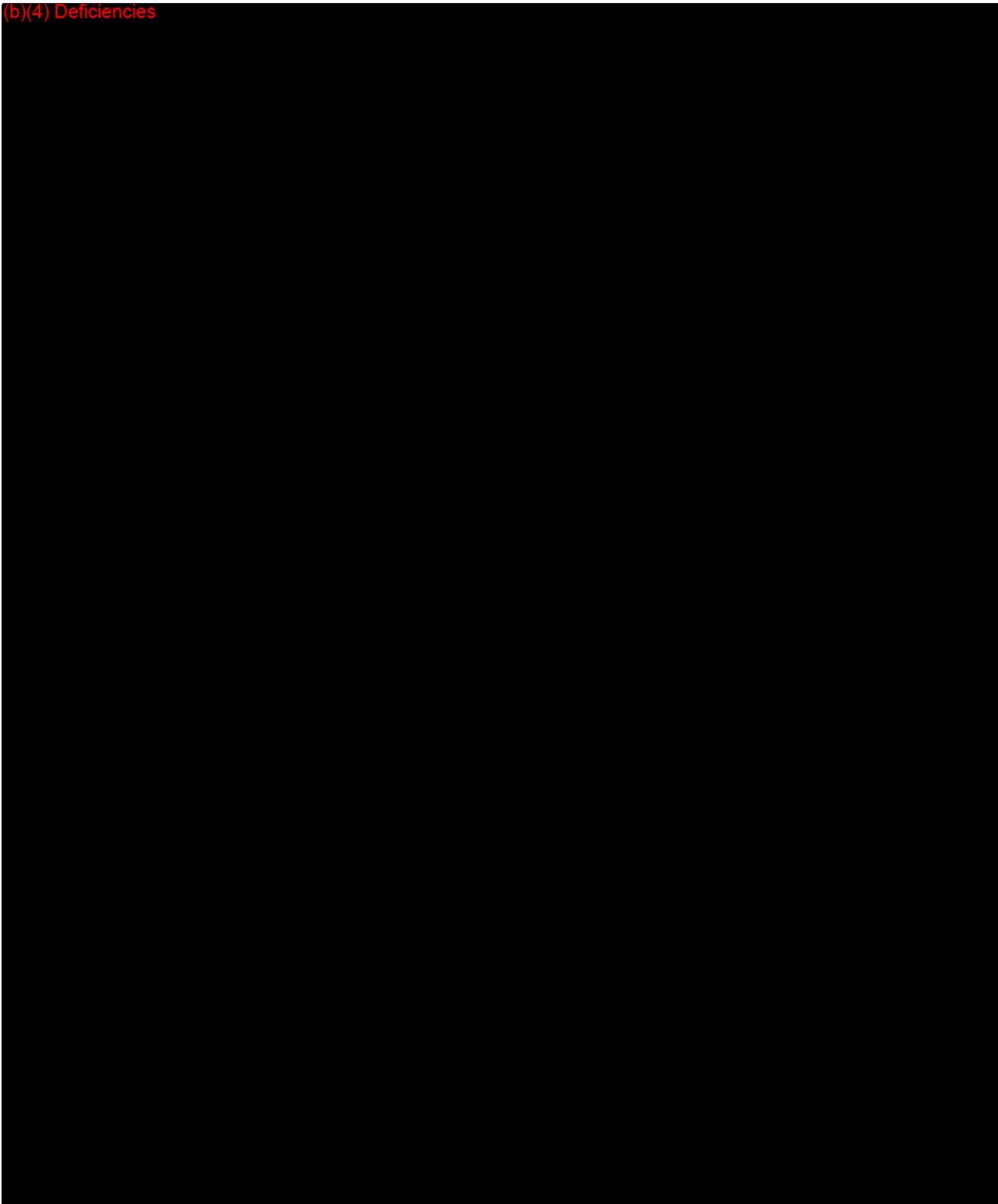
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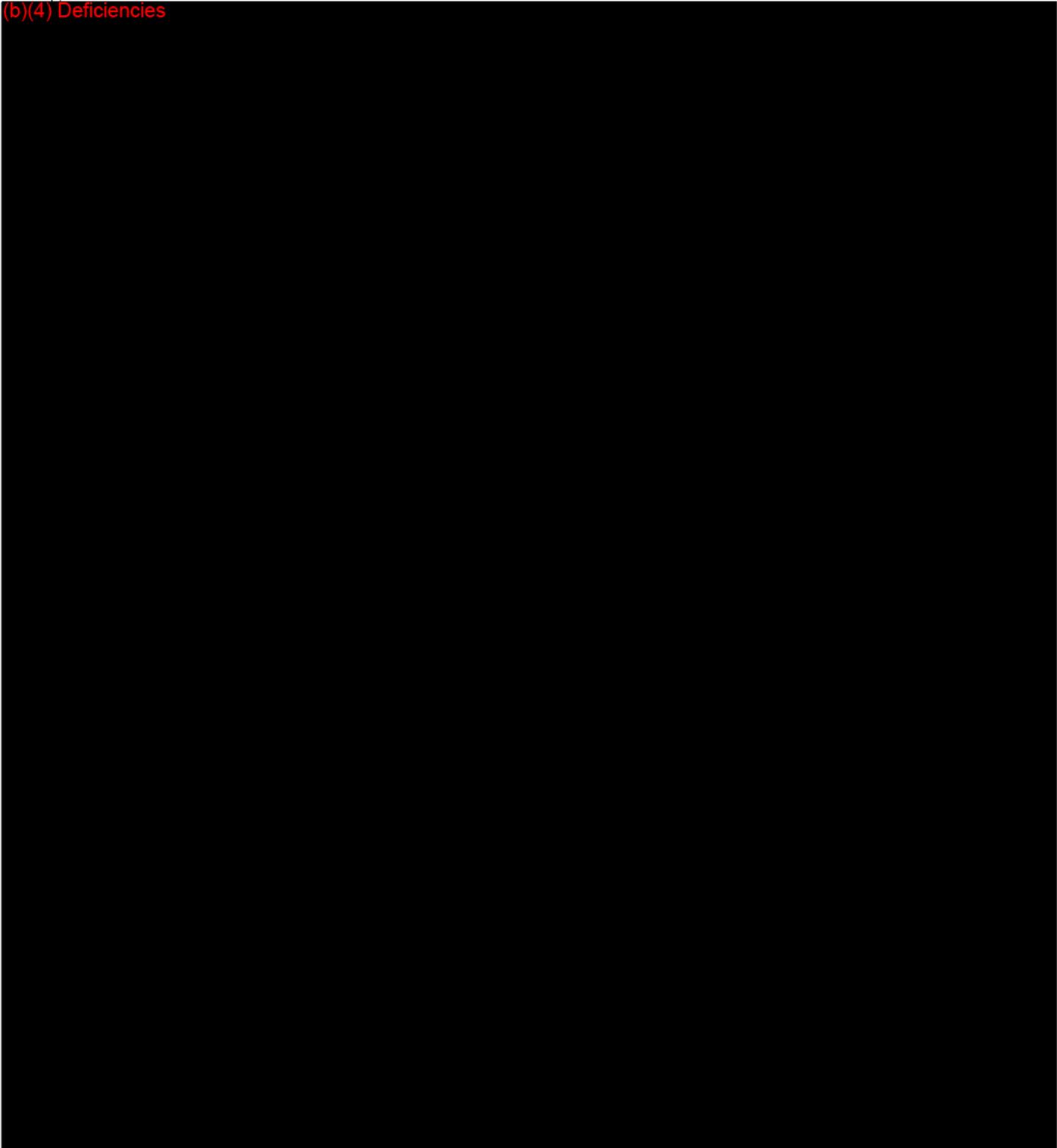
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Page 3 – Mr. Richard Hamer

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Page 4 – Mr. Richard Hamer

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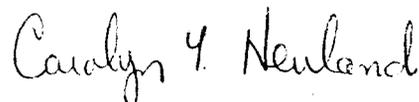
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Sincerely yours,



Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and Renal
Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

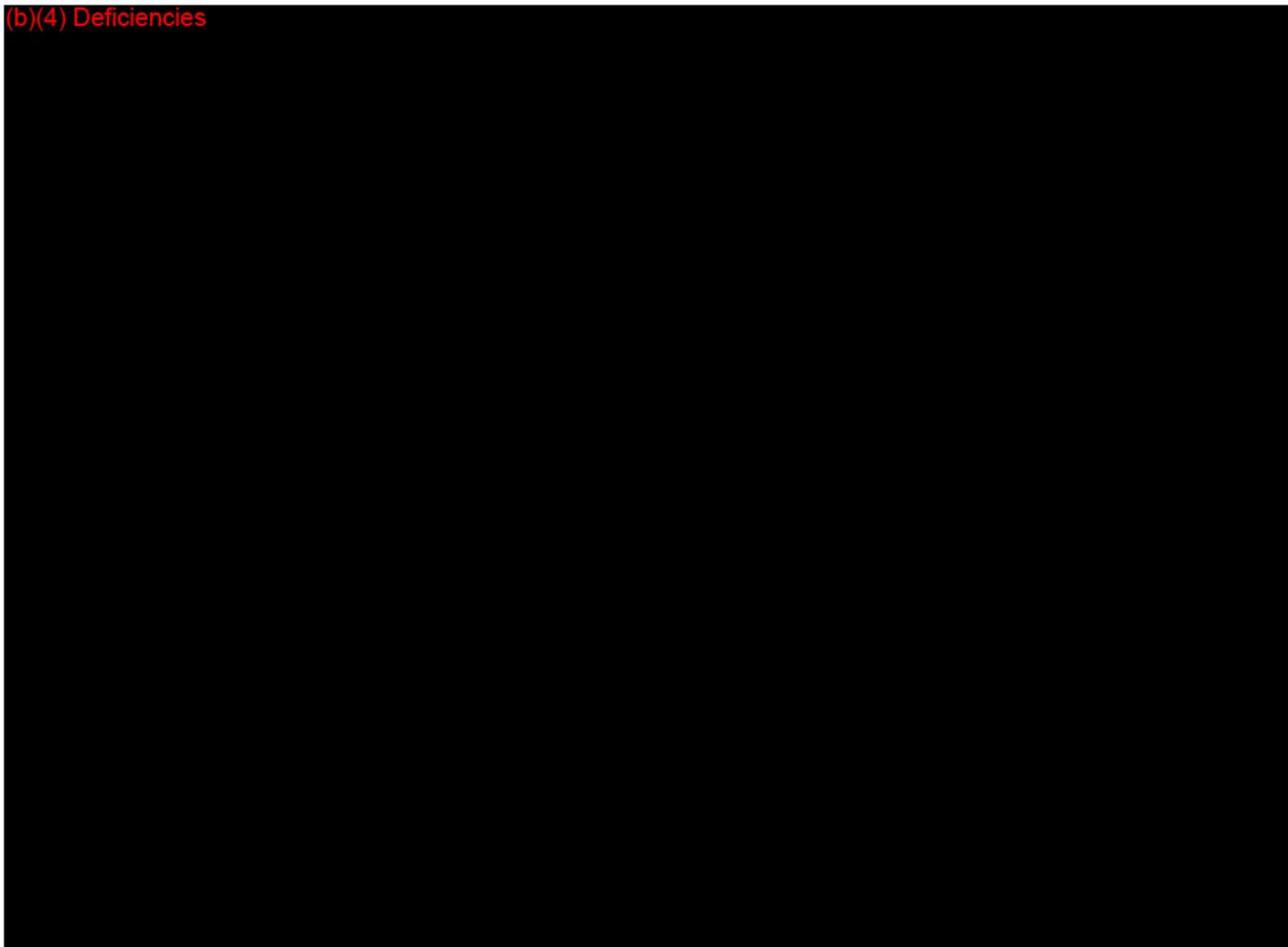
Lifestream Purification Systems, Inc.
c/o Richard A. Hamer Associates, Inc.
6401 Meadows West Drive
Fort Worth, Texas 76132

Re: K003720
Angel of Water™ Colon Hydrotherapy System
Dated: November 30, 2000
Received: December 4, 2000

Dear Mr. Hamer:

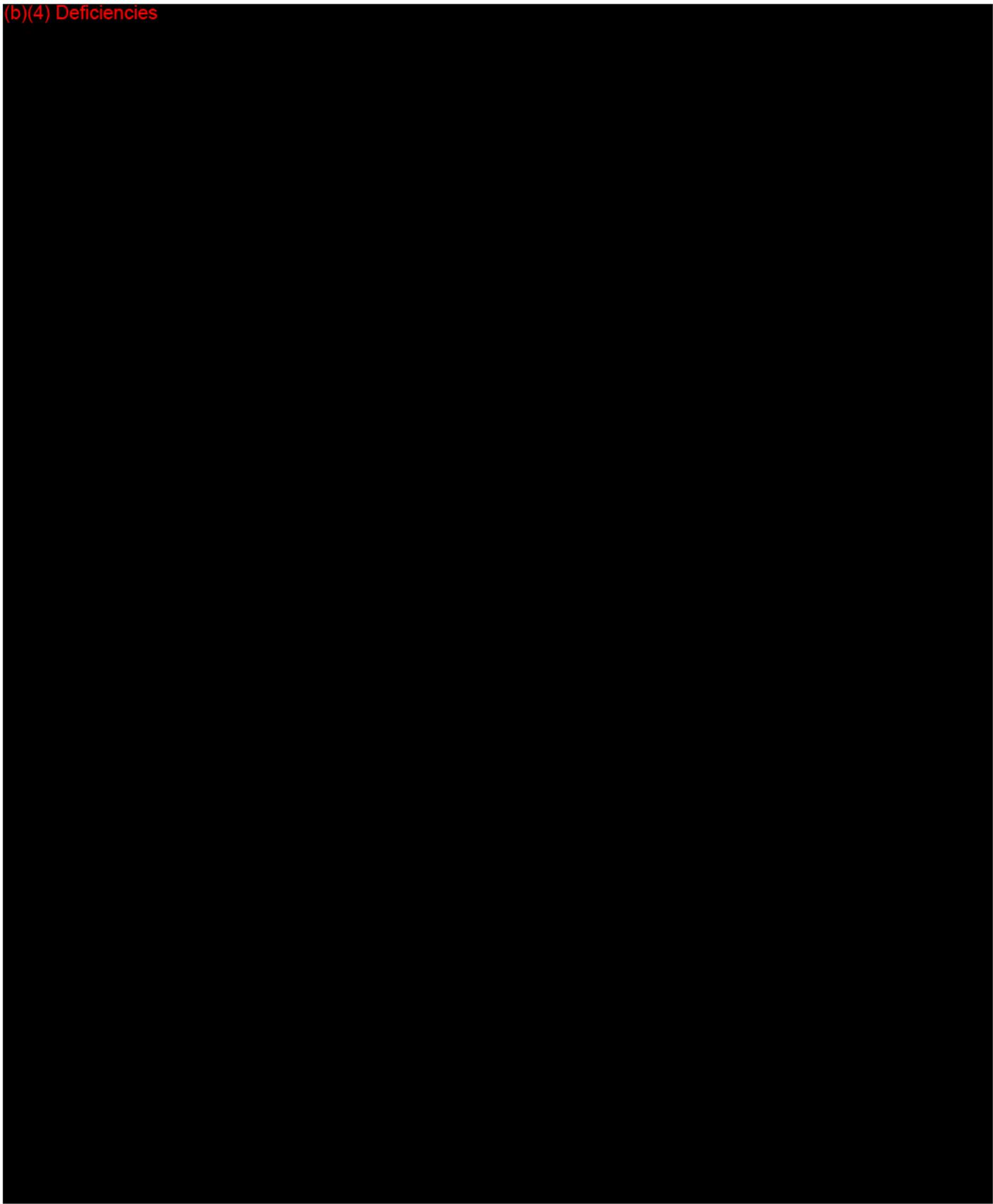
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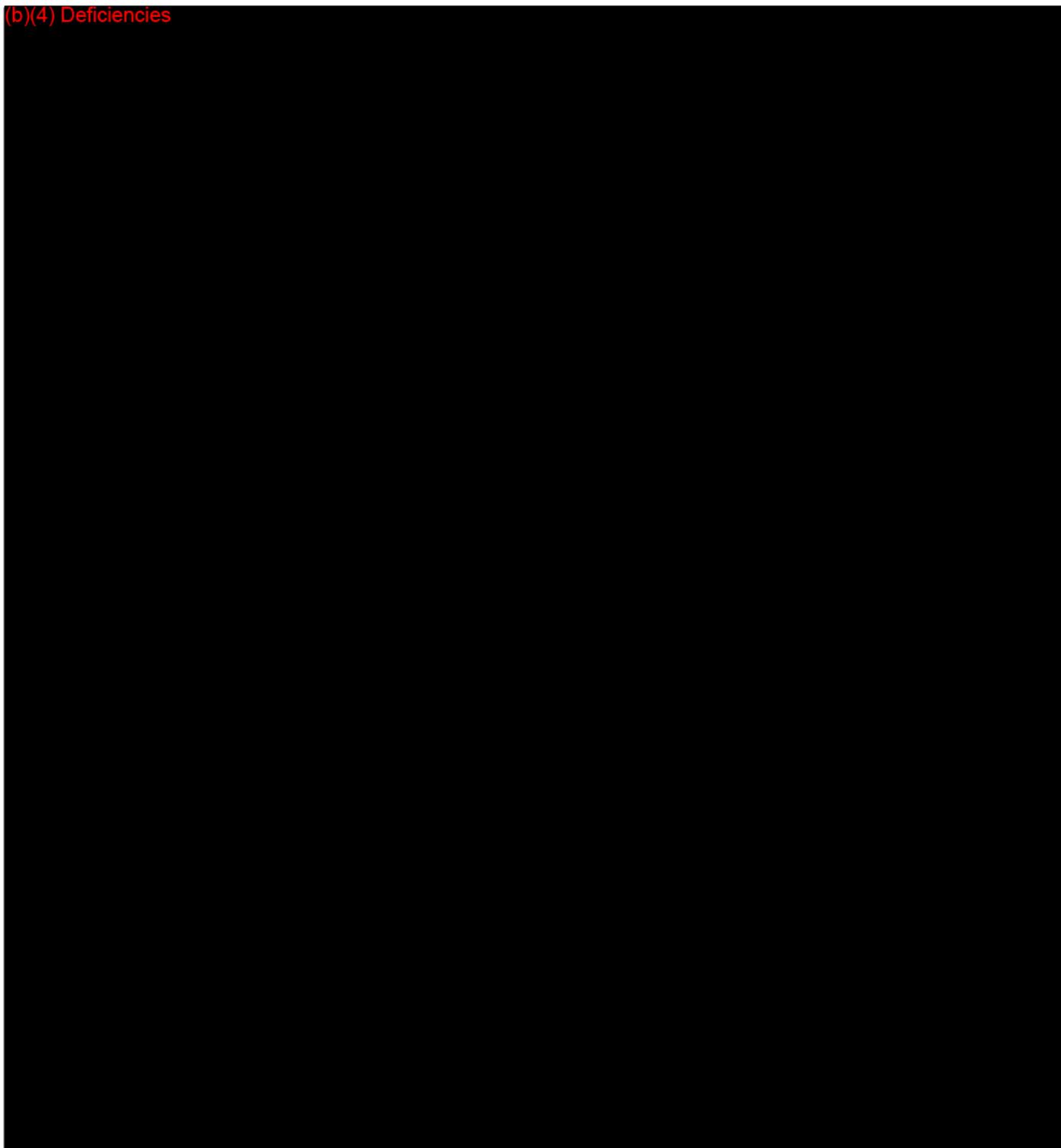
Page 2 – Mr. Richard Hamer

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Page 3 – Mr. Richard Hamer

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Page 4 – Mr. Richard Hamer

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9200 Corporate Boulevard
Rockville, Maryland 20850

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Sincerely yours,



Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and Renal
Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Page 5 – Mr. Richard Hamer

cc: HFZ-401
HFZ-404
HFZ-470
D.O.

HFZ470:KathyOlvey:lrn:3.2.2001

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| OFFICE | SURNAME | DATE | OFFICE | SURNAME | DATE | OFFICE | SURNAME | DATE |
|--------|---------|--------|--------|---------|------|--------|---------|------|
| HFZ470 | Newland | 3/2/01 | | | | | | |

365

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 04, 2000

LIFESTREAM PURIFICATION SYSTEMS, LLC 510(k) Number: K003720
C/O RICHARD HAMER ASSOCIATES, INC Received: 04-DEC-2000
6401 MEADOWS WEST DR. Product: ANGEL OF WATER COLON
FORT WORTH, TX 76132 HYDROTHERAPY SYSTEM
ATTN: RICHARD A. HAMER

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

388

K-173720

RICHARD HAMER ASSOCIATES, INC.
REGULATORY CONSULTANTS

VIA FEDERAL EXPRESS

November 30, 2000

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RECEIVED
NOV 30 11 05 AM '00
FDA/CDRH/ODE/DHC

In Re: Angel of Water™ Colon Hydrotherapy System
Lifestream Purification Systems, LLC, Austin, Texas
510 (k) Premarket Notification

Gentlemen:

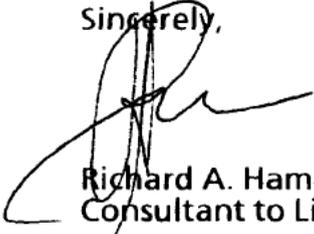
In accordance with the requirements of 21 CFR 807.81, I am pleased to submit here-with, on behalf of Lifestream Purification Systems LLC, duplicate copies of a 510 (k) notification for the subject device.

Please note that Lifestream Purification Systems LLC considers the information pro-vided in this submission to be proprietary and exempt from public disclosure under 21 CFR 20.61.

All data and information contained in this submission was furnished to us by Lifestream Purification Systems LLC. To the best of our knowledge, it is truthful and accurate, and no material fact has been omitted.

I look forward to your favorable consideration of this premarket notification at your earliest convenience.

Sincerely,



Richard A. Hamer
Consultant to Lifestream Purification Systems LLC

cc: Ms. Amy Heilman, Lifestream Purification Systems LLC.

GU
II
SK2

(817) 294-3644 • Fax (817) 294-3761 • E-mail: rhamer@hamerassoc.com

389

510(k) Premarket Notification

Angel of Water™
Colon Hydrotherapy System

Lifestream Purification Systems, LLC
2001 South Lamar, Suite G
Austin, Texas 78704

Submission Date: November 30, 2000

RECEIVED

Dec 4 11 06 AM '00

FDA/CDRH/OCE/DHC

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Angel of Water™ Colon Hydrotherapy System Lifestream Purification Systems, LLC

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Premarket Submission Cover Sheet

Date of Submission: **November 30, 2000** FDA Document Number:

| Section A | Type of Submission | | | | | | | | | | | | |
|---|---|---|------------------------------|---|--|--|---|---|-------------------------------------|--|-------------------------------------|--|---|
| <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> 510(k) Add'l information | <table style="width: 100%; border: none;"> <tr> <td style="width: 33%;"><input type="checkbox"/> IDE</td> <td style="width: 33%;"><input type="checkbox"/> PMA</td> <td style="width: 33%;"><input type="checkbox"/> PMA Supplement-Regular</td> </tr> <tr> <td><input type="checkbox"/> IDE Amendment</td> <td><input type="checkbox"/> PMA Amendment</td> <td><input type="checkbox"/> PMA Supplement-Special</td> </tr> <tr> <td><input type="checkbox"/> IDE Supplement</td> <td><input type="checkbox"/> PMA Report</td> <td><input type="checkbox"/> PMA Supplement-30 Day</td> </tr> <tr> <td><input type="checkbox"/> IDE Report</td> <td></td> <td><input type="checkbox"/> PMA Supplement-Panel Track</td> </tr> </table> | <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement-Regular | <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement-Special | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report | <input type="checkbox"/> PMA Supplement-30 Day | <input type="checkbox"/> IDE Report | | <input type="checkbox"/> PMA Supplement-Panel Track |
| <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement-Regular | | | | | | | | | | | |
| <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement-Special | | | | | | | | | | | |
| <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report | <input type="checkbox"/> PMA Supplement-30 Day | | | | | | | | | | | |
| <input type="checkbox"/> IDE Report | | <input type="checkbox"/> PMA Supplement-Panel Track | | | | | | | | | | | |

| Section B1 | Reason for Submission - 510(k)s Only |
|--|---|
| <input checked="" type="checkbox"/> New Device <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Change in technology, design, materials, or manufacturing process |

| Section B2 | Reason for Submission - PMAs Only |
|--|--|
| <input type="checkbox"/> New Device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion/extension of indications <input type="checkbox"/> Licensing agreement <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf life <input type="checkbox"/> Trade name <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in design, component, or: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor <input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Report submission: <input type="checkbox"/> Annual or periodic <input type="checkbox"/> Post-approval study <input type="checkbox"/> Adverse reaction <input checked="" type="checkbox"/> Device defect <input type="checkbox"/> Amendment <input type="checkbox"/> Response to FDA correspondence (specify below) <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site |

| Section B2 | Reason for Submission - IDEs Only |
|---|--|
| <input type="checkbox"/> New Device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion/extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input checked="" type="checkbox"/> Request waiver <input type="checkbox"/> Termination of study <input checked="" type="checkbox"/> Withdrawal of application <input type="checkbox"/> Unanticipated adverse effect <input type="checkbox"/> Emergency use: <input type="checkbox"/> Notification of emergency use <input type="checkbox"/> Additional information <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing <input type="checkbox"/> Protocol-feasibility <input type="checkbox"/> Protocol-other <input type="checkbox"/> Sponsor <input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approved <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input checked="" type="checkbox"/> Deficient investigator report <input checked="" type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting <input type="checkbox"/> IOL submission only: <input type="checkbox"/> Change in IOL style <input type="checkbox"/> Request for protocol waiver <input type="checkbox"/> Report submission: <input type="checkbox"/> Current investigator <input type="checkbox"/> Annual progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final |

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Section C **Product Classification**

Product Code: **78 KPL** C.F.R. Section: **876.5220** Device Class:
 Class I Class II
 Class III Unclassified

Classification Panel: **Gastroenterology - Urology**

Section D **Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:
 1. **78 KPL** 2. 3. 4.
 5. 6. 7. 8.

Summary of, or statement concerning safety and effectiveness data:
 510(k) summary attached
 510(k) statement

Information on devices to which substantial equivalence is claimed:

| 510(k) Number | Trade or proprietary or model name | Manufacturer |
|-------------------|------------------------------------|--------------------------------------|
| 1. K881720 | 1. Jimmy John III | 1. Colon Therapeutics, Inc. |
| 2. K962259 | 2. Libbe Rectal Tube | 2. Tiller Mind and Body, Inc. |
| 3. | 3. | 3. |
| 4. | 4. | 4. |
| 5. | 5. | 5. |
| 6. | 6. | 6. |

Section E **Product Information - Applicable to All Applications**

Common or usual name or classification name:
Colonic Irrigation System

| Trade or proprietary or model name | Model number |
|---|--------------|
| 1. Angel of Water™ Colon Hydrotherapy System | 1. |
| 2. | 2. |
| 3. | 3. |
| 4. | 4. |
| 5. | 5. |
| 6. | 6. |

FDA document numbers of all prior related submissions (regardless of outcome):

| | | | | | |
|----|----|----|-----|-----|-----|
| 1. | 2. | 3. | 4. | 5. | 6. |
| 7. | 8. | 9. | 10. | 11. | 12. |

Data included in submission: Laboratory testing Animal trials Human trials

Indications (from labeling):
For colon cleansing when medically indicated, such as before radiological or endoscopic examination.

Section F

Manufacturing / Packaging / Sterilization Sites

| | | | |
|--|---|--|---|
| <input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | FDA establishment registration number: Applied for | <input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer | <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler |
|--|---|--|---|

Company / Institution name: **Lifestream Purification Systems, LLC**

Division name (if applicable):

Phone number (include area code)
(512) 707-3773

Street Address: **2001 South Lamar, Suite G**

FAX number (include area code)
(512) 707-9665

| | | | |
|---------------------|----------------------------------|------------------------|-----------------------------------|
| City: Austin | State / Province Texas | Country: USA | ZIP / Postal Code 78704 |
|---------------------|----------------------------------|------------------------|-----------------------------------|

Contact name: **Amy Heilman**

Contact title: **General Manager**

| | | | |
|--|--|---|---|
| <input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | FDA establishment registration number: | <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer | <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler |
|--|--|---|---|

Company / Institution name:

Division name (if applicable):

Phone number (include area code)

Street Address:

FAX number (include area code)

| | | | |
|-------|------------------|----------|-------------------|
| City: | State / Province | Country: | ZIP / Postal Code |
|-------|------------------|----------|-------------------|

Contact name:

Contact title:

| | | | |
|---|--|---|---|
| <input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | FDA establishment registration number: | <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer | <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler |
|---|--|---|---|

Company / Institution name:

Division name (if applicable):

Phone number (include area code)
()

Street Address:

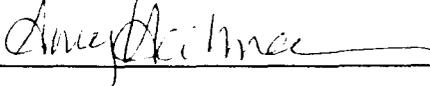
FAX number (include area code)
()

| | | | |
|-------|------------------|----------|-------------------|
| City: | State / Province | Country: | ZIP / Postal Code |
|-------|------------------|----------|-------------------|

Contact name:

Contact title:

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| | | | |
|--|----------------------------------|---|-----------------------------------|
| Section G | | Applicant or Sponsor | |
| Company / Institution name: Lifestream Purification Systems, LLC | | FDA establishment registration number: Applied for | |
| Division name (if applicable): | | Phone number (include area code) (512) 707-3773 | |
| Street Address: 2001 South Lamar, Suite G | | FAX number (include area code) (512) 707-9665 | |
| City: Austin | State / Province Texas | Country: USA | ZIP / Postal Code 78704 |
| Signature:  | | | |
| Name: Amy Heilman | | | |
| Title: General Manager | | | |

| | | | |
|--|----------------------------------|---|-----------------------------------|
| Section H | | Submission correspondent (if different from sponsor) | |
| Company / Institution name: Richard Hamer Associates, Inc. | | Phone number (include area code) 817-294-3644 | |
| Division name (if applicable): | | FAX number (include area code) 817-294-3761 | |
| Street Address: 6401 Meadows West Dr. | | FAX number (include area code) 817-294-3761 | |
| City: Fort Worth | State / Province Texas | Country: USA | ZIP / Postal Code 76132 |
| Contact name: Richard A. Hamer | | | |
| Contact title: Consultant to Lifestream Purification Systems, LLC | | | |



VIA FEDERAL EXPRESS

November 30, 2000

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

In Re: Angel of Water™ Colon Hydrotherapy System
Lifestream Purification Systems, LLC, A Division of
11/30/00 Premarket Notification

Gentlemen:

In accordance with the requirements of 21 CFR 807.81, I am pleased to submit herewith, on behalf of Lifestream Purification Systems LLC, duplicate copies of a 510 (k) notification for the subject device.

Please note that Lifestream Purification Systems LLC considers the information provided in this submission to be proprietary and exempt from public disclosure under 21 CFR 20.61.

All data and information contained in this submission was furnished to us by Lifestream Purification Systems LLC. To the best of our knowledge, it is truthful and accurate, and no material fact has been omitted.

I look forward to your favorable consideration of this premarket notification at your earliest convenience.

Sincerely,

Richard A. Hamer
Consultant to Lifestream Purification Systems LLC

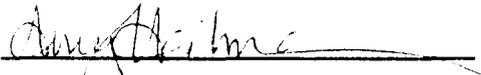
cc: Ms. Amy Heilman, Lifestream Purification Systems LLC.

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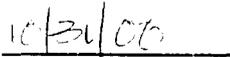
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PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87 (j))

I certify that, in my capacity as General Manager of Lifestream Purification Systems LLC, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



Amy Heilman



Date

K

510(k) Number (if known): _____

Device Name: Angel of Water™ Colon Hydrotherapy System ..

Indications for Use:

Colon cleansing when medically indicated, such as before radiological or endoscopic examination.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)

Premarket Notification: Angel of Water™ Colon Hydrotherapy System

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 1: GENERAL INFORMATION

- A. Device Name:**
Proprietary Name: Angel of Water™ Colon Hydrotherapy System
Classification Name: Colonic Irrigation System
- B. Establishment Registration No.:** Applied for
- C. Addresses of Manufacturing and Sterilization Facilities:**
Lifestream Purification Systems, LLC
2001 South Lamar, suite G
Austin, Texas 78704
- D. section 513 Classification:** Class II; 21 CFR §876.5220
- E. Reason for the Premarket Notification:** New Device
- F. Predicate Devices:**
Jimmy John III (Colon Therapeutics, Inc; K881720)
Libbe Rectal Tube (Tiller Mind and Body, Inc.; K962259)
- G. Performance Standards:**
To date, no performance standards have been established for this device under Section 514 of the Federal Food, Drug and Cosmetic Act. Accordingly, no action is currently required to be taken by Lifestream Purification Systems LLC.

SECTION 2: 510 (k) SUMMARY

A 510(k) summary conforming to the content and format requirements specified in 21 CFR §807.92 is provided on the following pages:

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Lifestream Purification Systems, LLC
2001 South Lamar, Suite G
Austin, TX 78704
(512) 707-3773

Contact Person: Amy Heilman

Date of Preparation: November 30, 2000

II. DEVICE NAME

Proprietary Name: Angel of Water™

Common Name: Colon Hydrotherapy System

Classification Name: Colonic Irrigation System

III. PREDICATE DEVICES

Jimmy John III (Colon Therapeutics, Inc; K881720)
Libbe Rectal Tube (Tiller Mind and Body, Inc.; K962259)

IV. DEVICE DESCRIPTION

This device is an instrument for hydrotherapy of the colon. It introduces filtered water at a comfortable temperature into the large intestine, thus cleansing the colon of its contents when medically indicated, such as before radiological or endoscopic examination. It is hygienic, comfortable and painless. Water temperature is controlled by means of an audible alarm. Temperature, flow, and pressure are controlled by one switch operated by the user. The system is manually sanitized prior to each use with a suitable broad-spectrum disinfectant. The system includes disposable tubing and a sterile, disposable rectal nozzle intended for single use only.

V. INTENDED USE

For colon cleansing when medically indicated, such as before radiological or endoscopic examination.

VI. COMPARISON TO PREDICATE DEVICE

A comparison of the technological characteristics of the Angel of Water and Jimmy John II devices appears below:

| Parameter | Angel of Water | Jimmy John III K881720 |
|---|--|--|
| Water Source | Household/Commercial | Household/Commercial |
| Water Flow | Gravity Flow | Gravity Flow |
| Water Flow Control Valve | Yes | Yes |
| Mixing Valve | Yes | Yes |
| Drainage System | Gravity Flow | Gravity Flow |
| Fittings | Brass | Brass |
| Composition Basin Cabinet | Fiberglass Plywood Laminated | Fiberglass Plywood Laminated |
| Cabinet Design | Tank Wall Mount or Floor Mount | Tank Wall Mount or Floor Mount |
| Mode of Operation | Continuous Water Flow Gravity Flow Drainage Manual Operation | Continuous Water Flow Gravity Flow Drainage Manual Operation |
| Major Separate System Components | Mixing Valve Monitoring System (Temperature) Basin Viewing Assembly Lighting Assembly Drainage Assembly Disposable rectal nozzle | Mixing Valve Monitoring System (Temperature) Basin Viewing Assembly Lighting Assembly Drainage Assembly Disposable rectal nozzle |
| Intended Use | Colonic Irrigation | Colonic Irrigation |
| Monitoring Systems Water Temperature | Yes | Yes |
| Fluid Pathway | Lines protected by backflow prevention and disinfected after each use; disposable tubing and rectal nozzle | Lines protected by backflow prevention and disinfected after each use; disposable tubing and rectal nozzle |

| Parameter | Angel of Water | Jimmy John III K881720 |
|-------------------------------------|---|---|
| System Check Valves | Yes | Yes |
| Gauges Water Temperature | Yes | Yes |
| Electrical Requirements | 110/120V AC 50/60 Hz service, power outlet to be grounded and polarized and GFI | 110/120V AC 50/60 Hz service, power outlet to be grounded and polarized and GFI |
| View Tube Assembly Back Lighting | Yes | Yes |

Based on this comparison, Lifestream Products, Inc. concludes that the "Angel of Water"™ Colon Hydrotherapy System is safe and effective for its intended use and performs at least as well as the predicate device.

SECTION 3: PROPOSED LABELING

Copies of the proposed pouch label for the disposable rectal nozzle and operating manual for the Angel of Water™ Colon Hydrotherapy System are provided on the following pages:

Order NO.
Lot NO. (b)(4)
(b)

Angel of Water™ Sterile Rectal Nozzle
*For Colon Hydrotherapy Use
For Single Use Only.*
Sterility guaranteed if package is unopened and undamaged.

Lifestream Purification Systems, LLC
Austin, Texas
Tel. (512) 707-3773
www.angelofwater.com
Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician or health care practitioner.

Lifestream

Purification Systems, LLC

Operations Manual

Angel of Water™

Purification System

DRAFT

2001 South Lamar, Suite G
Austin, Texas 78704

(512) 707-3773

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Lifestream Purification Systems, LLC

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Introduction

The Angel of Water System is a very simple, safe, comfortable, and hygienic way to irrigate the colon for endoscopic and/or radiological purposes. The following sequence of events briefly describes the experience and how the person can control temperature, pressure, and flow of the system, once the system has been sanitized as specified in Chapter 1 of this manual.

The tank is filled with hot and cold water controlled by a water mixing valve on the basin right topside. The proper **temperature** of the water falls between 99 - 104 degrees Fahrenheit and is monitored by the temperature gauge visible on the front of the tower cabinet. If **at any time** the water falls below or rises above the comfort range of 99 - 104 degrees Fahrenheit, the temperature gauge provides an audible warning prompt indicating that the water should be cooled before proceeding.

After the person has comfortably positioned himself on the basin (with the pillow and cushioned backrest in place) and inserted the nozzle into the rectum, water flow can be started by simply turning the FLOW switch. This is located on the wall-mounted control panel to the person's left. Water flow can be stopped **at any time** by simply turning the FLOW switch OFF. The tank line to the basin nipple has a backflow prevention valve as a permanent plumbing safety feature. It is located underneath the fiberglass basin and is connected directly to the basin nipple through an opening in the basin wall. It prevents water from flowing back into the line once it has passed through the basin nipple into the nozzle and into the person's rectum.

The system only has one **pressure** and that is the controlled pressure created by gravity as water exits the elevated tank in the tower cabinet as activated by the FLOW switch. The person experiencing the session has only to turn OFF the FLOW switch next to him on the wall-mounted control panel on his left to stop the water **at any time** and thus stop the pressure created by gravity.

In summary, **at any time**, the temperature, flow, and pressure of the Angel of Water System can be controlled by simply turning OFF the FLOW switch at either control panel **or** by the person simply sliding back off the nozzle and resting on the basin.

After the session proceeds for a duration to ensure complete evacuation of the contents of the colon (the session usually lasts about 30 minutes), the person turns OFF all three switches (U.V., CYCLE, FLOW) and slides back off the nozzle so that it naturally drops away from his body. The person can now drain comfortably on the ergonomic basin, sitting up erect or leaning back in a lounge position to fully drain his colon. After this is done, the person can rinse himself using the sprayer and its control valve on the basin left topside. Tempered water is delivered to the sprayer by the same water mixing valve on the right topside of the basin that also sends water to the system tank. The person can then towel dry himself before dressing and leaving the privacy of the colon irrigation room.

Chapter 1

Cleaning the Angel of Water System

Safety First

Safety is your primary responsibility. **You must always assume the system is NOT ready until you prepare it immediately before use. Always clean your system immediately after use, and immediately before each use. This means that you chemically sterilize and inspect the unit right before a session, even if you cleaned it the night before or hours before.**

If you clean the system and then leave the building where your system is located, and then you return to use the system, clean it again. You do not know what may have transpired in your absence.

This attitude assures that you ALWAYS begin each session hygienically. Plus, it gives you enormous peace of mind in serving others.

Tools and Procedures for Cleaning

The tools needed and procedures described below are considered the minimum requirements for proper sterilization and upkeep of your system.

REMEMBER, always clean your system immediately after use and immediately before each use!

Tools For Sanitizing

- 1) **Zep Attack A¹**- broad-spectrum disinfectant
- 2) **Zep Conquer** - disinfectant and deodorizer
- 3) **Chlorine bleach (sodium hypochlorite)** - disinfectant and stain remover

¹ *Attack A* and *Conquer* are products of Zep Manufacturing Company. A comparable broad-spectrum disinfectant may be substituted for *Attack A* and a comparable disinfectant/deodorizer may be substituted for *Conquer*.

- 4) **Degreaser and Tether Mop** - for periodic cleaning of Viewing Tube
- 5) **3 Buckets (one gallon size)/ with Soft Mops** - two for Attack A mixture, the third for chlorine bleach solution for basin cleaning
- 6) **Body Protection** - rubber gloves, eye or face shield, towel or respirator for lung protection
- 7) **Miscellaneous** - 2 spray containers (one for Attack A mixture, one for Conquer mixture), cotton balls, funnel for safe pouring, paper towels for used nozzle wrapping and disposal

Other items are needed for a successful session; the following items make a session more hygienic:

wastebasket with spring-open lid and plastic liners
petroleum jelly lubricant
paper towels and/or toilet tissue
cotton balls (sterile)
facial tissues
towels for hand wiping and drying of system
floor rug of a non-slip type
disposable gloves

Procedure For Sanitizing

Regardless of whether the system was cleaned previously, clean the system again if you left the premises where it is located, even if only for a few hours.

Pre-Session Preparation -

- 1) **Turn System LIGHTS Switch On**
- 2) **Protect Yourself**
 - a) Put on rubber gloves, eye shields, and protect respiratory channels with towel or respirator before next step.

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3) Inspect Tank, Chlorine bleach Tank and Lines

- a) Visually inspect system to make sure nothing foreign has gotten into tank (e.g., obvious dust). Clean out if necessary.
- b) Run 1 fluid ounce of chlorine bleach (use measuring cup supplied with system) in a gallon of water inside tank and through lines, bypassing UV Light Filter (close valve #6 and open #3, #4, #5, and #7) to flush and disinfect entire system. After cleaning and rinsing thoroughly, finish filling tank with water between 99 - 104 degrees Fahrenheit.

4) Spray Attack A on Basin, Rinse Lines, Towel Dry

- a) Allow Attack A to contact basin surface for at least **10 minutes** to disinfect *everything*.
- b) Run water from tank through nipple for a couple minutes to flush out line.
- c) Towel dry system surfaces.

5) Connect Sterilized Flex Tube and Nozzle, Do Final Room Inspection

- a) Connect sterilized flex tube and new disposable nozzle to flex tube, then lubricate nozzle to conduct session.
- b) Make final room inspection for readiness before having person enter room for session.

Post-Session Cleaning -

1) Protect Yourself

- a) Put on rubber gloves, eye shields, and protect respiratory channels with towel or respirator before using chemicals.

2) Remove Soiled Linens from System Area

- a) Place soiled linens in laundry basket.

3) Spray Attack A Disinfectant and Water Rinse, then Mop with Attack A Disinfectant (Bucket #1), Water Rinse

- a) Spray entire basin area with Attack A, then water rinse obvious waste material down drain. Turn on View Tube Flush valve as needed to clear drain line.
- b) Mop wash entire basin *and* used nozzle with Attack A (Bucket #1) before nozzle and flex tube removal. Water rinse everything down drain again.

4) Remove Used Nozzle and Flex Tube, Rinse Out Line

- a) With paper towel, grasp and pull out nozzle from flex tube or pull both off together. Bend nozzle in half and wrap it and used flex tube in paper towel and dispose of both in wastebasket.
- b) Turn water flow on and rinse out line.

5) Mop with Attack A Disinfectant (Bucket #2), Water Rinse

(Degrease View Tube as needed)

- a) Mop wash entire basin area again with Attack A after nozzle and flex tube removal.
- b) Water rinse entire basin again well.
- c) Degrease Drain Pipe Viewing Tube in this step when build-up of petroleum jelly lubricant warrants this procedure. Use the tether mop and degreaser to scrub tube.

6) Mop with Chlorine Bleach Disinfectant (Bucket #3), Water Rinse

- a) Mop wash entire basin area with diluted chlorine bleach solution and wait for a few minutes. Chlorine bleach acts both as a disinfectant and stain remover.
- b) Run 1 fluid ounce of chlorine bleach (sodium hypochlorite) in a gallon of water inside tank and through lines, bypassing UV Filter (close valve #6, open #3, #4, #5, and #7), to flush and disinfect entire system.
- c) Water rinse chlorine bleach residue down drain. Do not mix chlorine bleach with other chemicals. Dangerous gases may form. Rinse well. After

cleaning and rinsing thoroughly, finish filling tank with water between 99 - 104 degrees Fahrenheit.

7) Spray Attack A, Spray Conquer, Towel Dry

- a) Spray a fine mist of Attack A on all surfaces or on a linen hand towel and wipe all knobs, control panels, and personal shower sprayer.

Cumulative contact time of chemicals for the entire cleaning process must be at least 10 minutes to disinfect thoroughly.

- b) Spray a fine mist of Conquer on all surfaces or on a linen towel and wipe all surfaces and backrest to deodorize.
- c) Towel dry and wipe all surfaces of excess chemicals and water.

8) Replace Linens, Do Final Inspection

- a) Place a fresh cover over the pillow and supply a fresh cover cloth. Rotate and launder the pillow if it got wet for any reason. Have a number of linens/pillows to rotate and have clean and ready as required.
- b) Wipe lavatory, glasses, and mirrors and inspect room for overall cleanliness before next session or before finishing for the day.

(If another session is to be conducted continue to #9)

9) Run Properly Tempered Water through Line, Connect Sterilized Flex Tube and Nozzle

- a) Rinse out line with properly tempered water, 99 to 104 degrees Fahrenheit.
- b) Connect sterilized flex tube and new disposable nozzle to flex tube, then lubricate nozzle to conduct session.
- c) Make final room inspection for readiness before having person enter room for session.

It is recommended that you always clean system directly after a session. Do not postpone for any reason. Clean it, and clean it properly NOW! Always give the first impression and guarantee of cleanliness and hygiene.

Chapter 2

Control Switch Panels

When setting up the Angel of Water system, always connect the electrical power plug for the system into a GFCI (ground fault circuit interrupter) wall outlet. Consult with a qualified electrician if necessary.

The Angel of Water has two control switch panels: one is on the wall beside and for the use of the person experiencing the colon irrigation and the other is on the tower by the tank for the monitoring assistant or health care practitioner to use.

Switches on both panels must be in the ON position for the function to operate, which means that if a switch is turned OFF, such as the FLOW switch, then that function will not work.

The switches are described below:

LIGHTS - (on tower control panel only) - Turns on all lights for the inside and outside viewing tube areas and inside tower cabinet to illuminate tank water level and make it visible through tower cabinet side and front windows. This switch also activates all other switches. When this switch is ON, the other switch functions listed below can also be ON. When this switch is OFF, all other switches and their functions are OFF.

UV - activates ultraviolet light in U.V. Filter. This should only be turned ON just prior to water flowing to the person on the system. Turn OFF when session temporarily stops for more than a couple of minutes or when session is finished. Turn ON again as session resumes.

CYCLE - activates the water cycling device to move water from larger main tank to small recirculating tank. This keeps water temperature evenly mixed throughout entire tank contents and maintains an even and constant

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stream of gravity-fed water to the person experiencing the colon irrigation.

The water cycling device should only be on when water is flowing through it. When water in large main tank runs out, turn **CYCLE** switch OFF until tank is filled with more water. Then resume session with **CYCLE** switch ON to maintain even and constant stream of gravity-fed water again.

FLOW - activates electrical gate valve that allows water flow from tank into the person who is on system. A small round indicator light next to the **FLOW** switch lights up and is visible when water is flowing to person.

Temperature Gauge

The Temperature Gauge on the P is located on the front of the tower cabinet, visible to the person experiencing the colon irrigation or to a monitoring assistant or health care practitioner.

It shows the water temperature and, with the push of a button, the room temperature. **It is programmed to give an audible sound and verbal warning when the temperature of the water drops below or exceeds the comfort range of 99 - 104 degrees Fahrenheit. Should a warning be given, the person on the system should**

- a) simply turn the **FLOW** switch OFF temporarily,
- b) change the water temperature in the Tank using the Water Mixing valve within reach on right topside of basin, and then
- c) resume session once water temperature is in the comfort range of 99 - 104 degrees Fahrenheit by turning **FLOW** switch ON.

This highly reliable and simple-to-use gauge is battery operated and acts independently of any electrical supply. It therefore provides reliable readings during Regular or Manual modes of operation.

Consult the temperature gauge manual included in the system parts packet for information regarding functions.

Chapter 3

Valves

Each of the valves on the Angel of Water System is numbered and has a description label next to it. Turning valves ON or OFF achieves the following: directs certain flow patterns, allows water into the tank, allows tank to drain, allows bypassing of certain electrical components such as the water cycle device or electrical gate valve so that the system may be operated with or without electricity.

Be assured, the valves and their functions are easy to learn and can be mastered in a short period of time. Their descriptions are as follows:

Valves #1 and #2 are accessed through the small side door located on the tower cabinet:

#1 Tank Fill - allows water into tank

#2 Tank Drain - empties tank

Valves #3 - #9 are accessed through the back bifold door located on the tower cabinet:

#3 Tank Exit - used for manual flow operation (without electricity)

#4 Manual Flow Inlet - allows water to flow to user (without electricity)

#5 Electrical Gate Valve Bypass - allows water to flow without going into Electrical Gate Valve

#6 UV Inlet - allows water into ultraviolet filter

#7 Recirculating Tank Exit - allows water to leave small tank

#8 Recirculating Tank Bypass - keeps water from entering small tank

#9 Recirculating Tank Inlet - allows water into small tank

Valves #10 and #11 are accessed through the large door located on the basin cabinet:

#10 Cold Inlet - allows cold water source into system

#11 Hot Inlet - allows hot water source into system

The following three valves are located on the fiberglass basin topside:

Shower Sprayer Volume Control Valve (left side) - adjusts sprayer water volume

Viewing Tube Flush Valve (right side) - flushes material through viewing tube line and down drain

Water Mixing Valve (right side) - mixes hot and cold water for tank fill and shower sprayer use

The following valve is located inside large main tank:

Tank Fill Valve - automatically shuts off when fill into large main tank

The following valve is the only electrical valve on the system and is located on the middle shelf of the tower cabinet. It is accessed by opening the back bifold doors of the tower cabinet:

Electrical Gate Valve - activated by FLOW control panel switch

The following valve is a permanent plumbing safety feature. It is located underneath the fiberglass basin and is connected directly to the basin nipple through the basin wall:

Backflow Prevention Valve - prevents water from flowing back into the line once it has passed from the nipple to the nozzle and into the person's rectum.

Chapter 4

Valve Sequences for System Operation

There are two modes of operation with the Angel of Water. **Regular Operation** functions by electricity and through electrical components and **Manual Operation** works with or without electricity and without the use of the electrical components.

Study the following valve sequences and actually go through each one on your system to see the operation of each.

1) Regular Operation (electrical)

This is the primary mode of operation. Regular Operation functions by circulating from the large tank via the water cycling device to the smaller tank. Then an even and constant stream of gravity-fed water flows through the U.V. Filter to the person experiencing the colon irrigation.

Follow this valve sequence:

a) Open valves #6, 7, 9, (10 and 11 were turned ON when system was set up and should be left on always unless system plumbing maintenance requires otherwise.) All other valves are closed. Then open #1 and turn on and adjust Water Mixing valve to fill tank with water between 99 to 104 degrees Fahrenheit.

Close #1 or shut off Water Mixing valve to *stop* water to large main tank at any level. However, water level inside tank shuts off automatically by Tank Level valve once level has reached top (about 12 gallons). Once full, close #1 and/or turn off Water Mixing valve. As water is needed in tank, open #1 and/or turn on Water Mixing valve to refill tank.

b) Occasionally, the person experiencing the colon irrigation may feel as if no water is coming into their colon. This may indicate that the nozzle inserted into them is clogged at the tip with waste material. The monitoring

assistant or health care practitioner can unclog nozzle in the following way *without* having the person on the system come off the nozzle in order to check it. To unclog nozzle with additional flow from large main tank, close #7 and #9. Then **slowly** open #8 **partially** until flow is felt again by person experiencing the irrigation. Then open #7 and #9 again, and close #8 completely.

2) Manual Operation (with or without electricity)

This mode and valve sequence allows a monitoring assistant or health care practitioner to send water to the person experiencing the colon irrigation directly from the large main tank with or without the activation of the FLOW control switch or with or without the use of electricity. (Of course, without electricity, the Water Control Valve will not send water to the recirculating tank, the Electrical Gate Valve will not work by the FLOW control switch, nor will there be U.V. treatment of the water as it is flowing to the person.)

There are two manual modes:

a) NO electricity and NO U.V. water treatment - open valve #1 and Water Mixing valve to fill tank to proper water temperature between 99 to 104 degrees Fahrenheit. When monitoring assistant or health care practitioner is ready to send water to the person experiencing the colon irrigation, open only valves #3 and #4. Close valve #4 when person on the system is finished with session or wants an intermission from session.

b) WITH electricity and WITH U.V. water treatment - open valve #1 and Water Mixing valve to fill tank to proper water temperature between 99 to 104 degrees Fahrenheit. When monitoring assistant or health care practitioner is ready to send water to the person experiencing the colon irrigation, open only valves #3 and #6. Close valve #6 when person on the system is finished with session or wants an intermission from session. If session stops longer than a couple of minutes, be sure to

turn OFF U.V. control switch temporarily also during the intermission. Turn U.V. control switch ON when session resumes and valve #6 is opened again.

Chapter 5

System Maintenance

Your Angel of Water system is designed to be virtually maintenance free, aside from sanitizing the unit prior to and after each use.

However, some items will need to be replaced occasionally and can be ordered directly from Lifestream or found at most good hardware stores. The following items will need to be replaced because of normal usage:

1) Filters

The **carbon cartridge** in the Standard Carbon Filter canister (for initial water filtration before water enters the large main tank) and the **sediment cartridge** in the U.V. Filter are the items that require changing most frequently. **Changing filters will be a function of how frequently the system is used and the municipal water supply the system is connected to. Filters need to be changed when tank filling becomes too slow or when flow to the person through the U.V. Filter seems to slow down or become almost imperceptible.**

Simply unscrew filter housing, replace old filter with a new one, and screw housing back on properly.

2) Batteries in Temperature Gauge

The Tank Water and Room Temperature gauge on the front of the tower cabinet is battery operated. **Always pay close attention to the proper operation of the temperature gauge. When gauge display begins to fade, simply replace the two old "AAA" batteries with new ones by removing back panel of gauge. Always have spare batteries on hand and never operate system without a functioning temperature gauge.**

3) Diaphragm Plunger inside Electrical Gate Valve

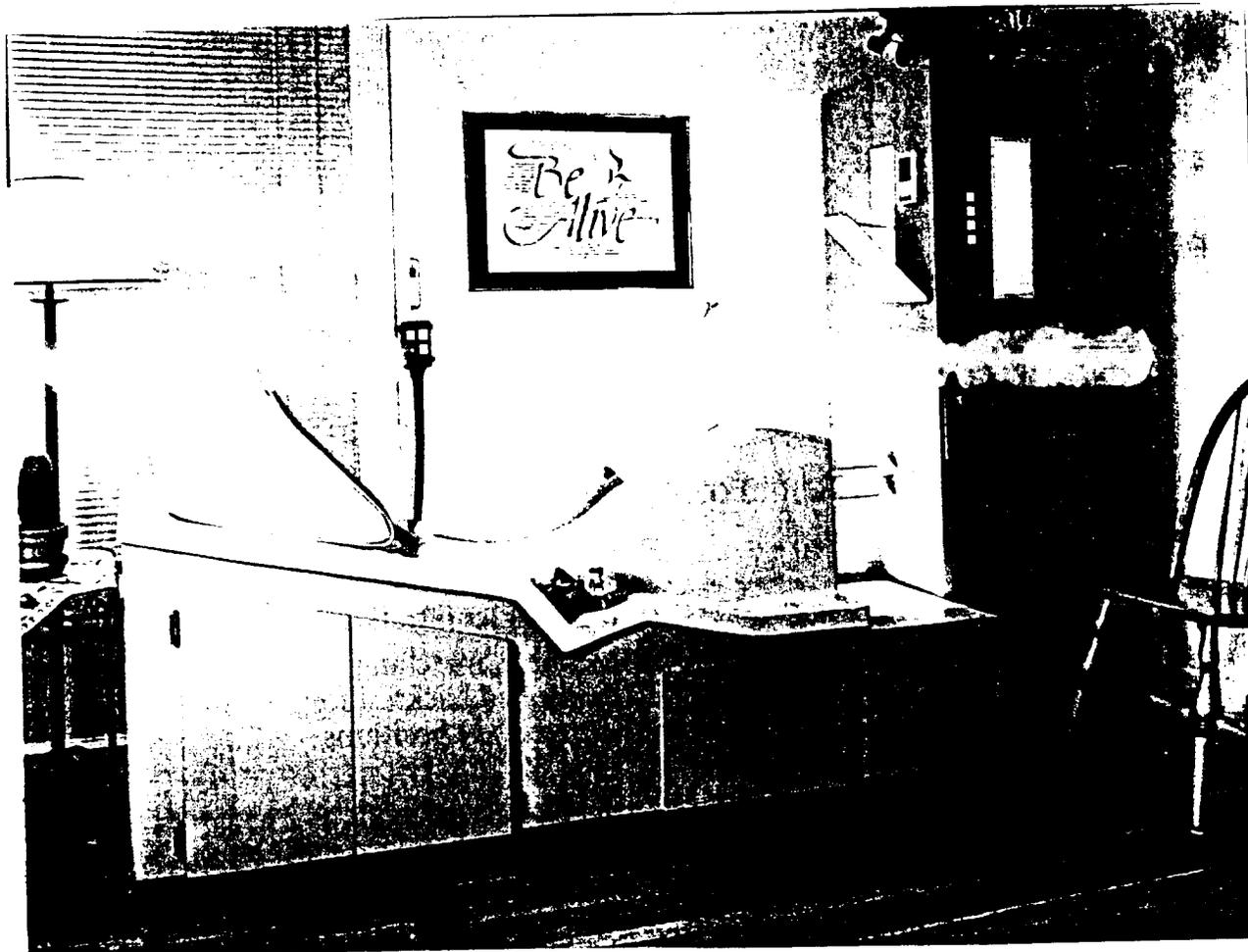
The Electrical Gate valve has a diaphragm plunger inside the brass body that will begin to leak water slightly when it needs to be replaced. In other words, when the FLOW switch is OFF, water may leak slightly and be noticeable as it drips at the basin nipple or through sterilized nozzle prior to session beginning.

To replace, first unplug electrical power supply to system. Then simply unscrew four screws on valve housing, take old plunger out, and put in new plunger. Replace housing and screws. Reconnect to electrical power supply and test operation of Electrical Gate valve.

4) Light Bulbs

The viewing tube, tubes have been chosen for their longevity. They should last from 9000 to 10,000 hours. Remember, do not look at the U.V. bulb directly when in operation. Make sure it is safely in its housing before testing the new replacement bulb. Follow instructions in system parts packet on U.V. bulb replacement.

Simply replace bulbs when they go out by unscrewing or removing old bulb and replacing with new bulb.

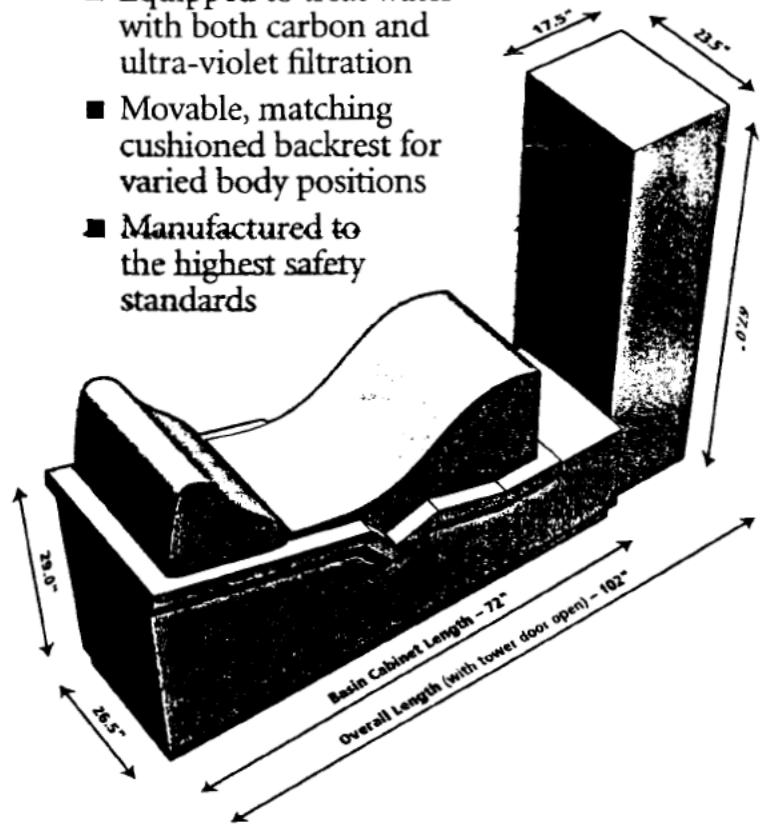


The graceful, ergonomic design of the basin and backrest affords the individual different positions for comfort and for complete elimination, both during and at the end of the session.



Virtues of the Angel of Water Purification System:

- Session may be self-administered or facilitated by an assistant
- Basin design allows release of the contents of the colon and bladder at will
- Uses pencil-sized, single-use (disposable), sterilized nozzle
- Manual flushing valve for clearing the view tube
- Shower sprayer with volume control for personal hygiene and for system cleaning
- Simple to clean and hygienically disinfect
- Designed for long life and low-maintenance
- Equipped to treat water with both carbon and ultra-violet filtration
- Movable, matching cushioned backrest for varied body positions
- Manufactured to the highest safety standards



For information call: (512) 707-3773
 or visit our website: angelofwater.com
 email: info@angelofwater.com



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SECTION 4: DEVICE DESCRIPTION

The components of the Angel of Water™ colon hydrotherapy system are described in the schematic drawings on the following pages:

The tank is filled with filtered hot and cold water controlled by a water mixing valve on the basin right topside. The proper temperature of the water falls between 99 and 104°F and is monitored by a temperature gauge visible on the front of the the tower cabinet. If, at any time, the water falls below or rises above the comfort range of 99 and 104 °F, the temperature gauge provides provides an audible warning prompt indicating that the water should be cooled or heated before proceeding.

After the person has comfortably positioned him or herself on the basin (with the pillow and cushioned backrest in place) and inserted the sterile, disposable nozzle into the rectum, water flow can be activated by by turning the FLOW switch to the ON position. This switch is located on the wall-mounted control panel to the person's left. Water flow can be stopped at any time by simply turning the FLOW switch to the OFF position. The tank line to the basin nipple has a backflow prevention valve as a permanent plumbing safety feature. It is located underneath the fiberglass basin and is connected directly to the basin nipple through an opening in the the basin wall. It prevents water from flowing back into the line once it has passed through the basin nipple into the nozzle and into the person's rectum.

The system only has one pressure, and that is the controlled pressure created by gravity as water exits the elevated tank in the tower cabinet as activated by the FLOW switch. The person undergoing irrigation has only to turn the FLOW switch to the OFF position to stop the water at any time. In summary, the temperature, flow and pressure can be controlled by turning the FLOW switch to the OFF position, or by the person simply sliding back off the nozzle and resting on the basin.

The sterile disposable rectal nozzle is manufactured by (b)(4) in accordance with their (b)(4). It is identical to the Libbe Rectal Tube (K962259), also manufactured by (b)(4). It is packaged in a (b)(4).

(b)(4) package and supplied sterile (b)(4)
(b)(4) intended for single use only. Also provided for each use is a 5 1/2 inch disposable (b)(4) tube (3/8" I.D. x 9/16" O.D.) that connects the rectal nozzle to the water supply. This tubing is manufactured and supplied non-sterile by (b)(4)
(b)(4)

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SECTION 5: COMPARATIVE INFORMATION

A. Statement of Equivalence:

For purposes of Section 510 (k) of the Federal Food, Drug, and Cosmetic Act, Lifestream Purification Systems LLC considers the Angel of Water™ Colon Hydrotherapy System to be substantially equivalent to similar devices, such as the Jimmy John III (Colon Therapeutics, Inc.), initially placed in commercial distribution pursuant to 510(k) premarket notification K88172. As shown in the tabular comparison of technological characteristics on the following pages, the two devices are similar in composition, design and function.

Similarly, the rectal nozzles supplied with the Angel of Water™ Colon Hydrotherapy System for each individual use are substantially equivalent to the Libbe Rectal Tube (Tiller Mind and Body, Inc.), initially placed in commercial distribution pursuant to 510(k) premarket notification K962259). Substantial equivalence is obvious in that they are of the same composition and design, and manufactured and supplied by the same manufacturer, (b)(4)

Table of Comparison to Legally Marketed Device

| Parameter | Angel of Water | Jimmy John III K881720 |
|----------------------------------|--|--|
| Water Source | Household/Commercial | Household/Commercial |
| Water Flow | Gravity Flow | Gravity Flow |
| Water Flow Control Valve | Yes | Yes |
| Mixing Valve | Yes | Yes |
| Drainage System | Gravity Flow | Gravity Flow |
| Fittings | Brass | Brass |
| Composition Basin Cabinet | (b)(4) | |
| Cabinet Design | Tank Wall Mount or Floor Mount | Tank Wall Mount or Floor Mount |
| Mode of Operation | Continuous Water Flow Gravity Flow Drainage Manual Operation | Continuous Water Flow Gravity Flow Drainage Manual Operation |
| Major Separate System Components | Mixing Valve Monitoring System (Temperature) Basin Viewing Assembly Lighting Assembly Drainage Assembly Disposable rectal nozzle | Mixing Valve Monitoring System (Temperature) Basin Viewing Assembly Lighting Assembly Drainage Assembly Disposable rectal nozzle |
| Intended Use | Colonic Irrigation | Colonic Irrigation |

Table of Comparison to Legally Marketed Device (Cont'd)

| Parameter | Angel of Water | Jimmy John III K881720 |
|---|--|--|
| Monitoring Systems Water Temperature | Yes | Yes |
| Fluid Pathway | Lines protected by back-flow prevention and disinfected after each use; disposable rectal nozzle | Lines protected by back-flow prevention and disinfected after each use; disposable rectal nozzle |
| System Check Valves | Yes | Yes |
| Gauges Water Temperature | Yes | Yes |
| Electrical Requirements | 110/120V AC 50/60 Hz service, power outlet to be grounded and polarized and GFI | 110/120V AC 50/60 Hz service, power outlet to be grounded and polarized and GFI |
| View Tube Assembly Back Lighting | Yes | Yes |

SECTION 5: COMPARATIVE INFORMATION (continued)

B. Comparative Labeling:

Available labeling for the Libbe Rectal Tube is provided on the following page:

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**FOR R-
USE**

Camera Ready Art

For Single Use Only!!!

REORDER NO. LR1009688
LOT NO. 960888 Polyvinyl Chloride



LIBBE Rectal Tube

For Colon Hydrotherapy Use
Sterility guaranteed if package is unopened and undamaged.

STERILE

Tiller MIND BOD
Equipment • Training •
2204 N.W. Loop 41
San Antonio, TX 782
Ph: (210) 349-0631 • Fax: (2

Caution: Federal law (U.S.A.) restricts
by or on the order of a physician or heal

For Single Use Only!!!

REORDER NO. LR1009688
LOT NO. 960888 Polyvinyl Chloride



LIBBE Rectal Tube

For Colon Hydrotherapy Use
Sterility guaranteed if package is unopened and undamaged.

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by or on the order of a physician or heal

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SECTION 6: BIOCOMPATIBILITY ASSESSMENT

The rectal nozzle is the only component of Angel of Water™ Colon Hydrotherapy system that comes into direct contact with the patient. The biocompatibility and suitability for use of the rectal nozzle has been previously established in K962259 for the Libbe Rectal Tube and/or in K813066 for the Argyle Yankauer suction tube as manufactured by (b)(4), the successor to (b)(4). Accordingly, no additional biocompatibility testing has been performed by Lifestream Purification Systems, LLC.

SECTION 7: STERILIZATION INFORMATION

The rectal nozzle manufactured and supplied by (b)(4) is sterilized by (b)(4)
Assurance Level (SAL) of 1 x (b)(4) Other components of the Angel of Water™ Colon Hydrotherapy System are provided non-sterile.

Memorandum

m: Reviewer(s) - Name(s) Kathleen M. Olvey

Subject: 510(k) Number K003720-52

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

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

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

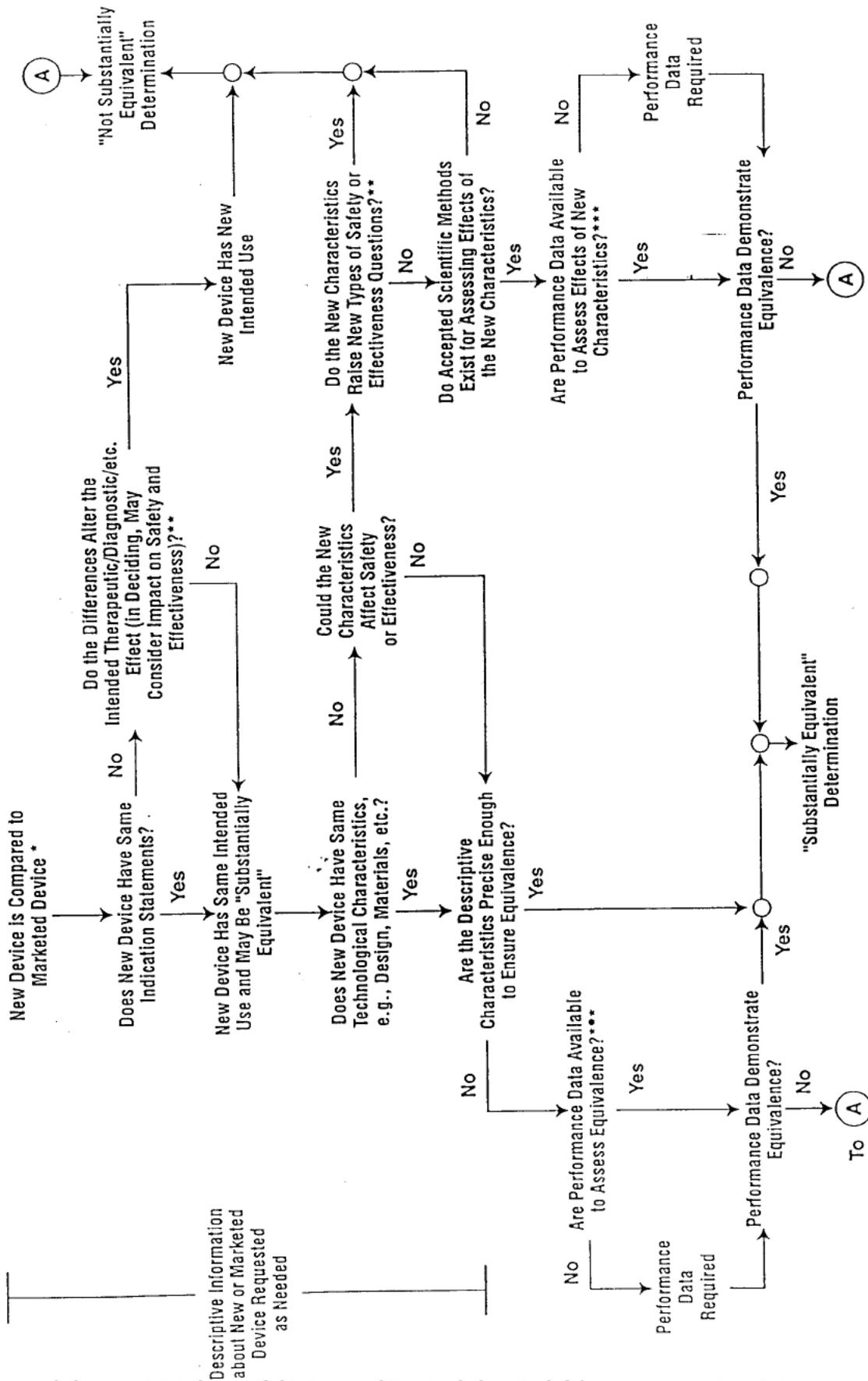
Additional Product Code(s) with panel (optional):

Review: Candlyn Y Newland GRDB 4/17/02
(Branch Chief) (Branch Code) (Date)

Final Review: _____ (Date) COM
(Division Director)

Revised: 8/17/99

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

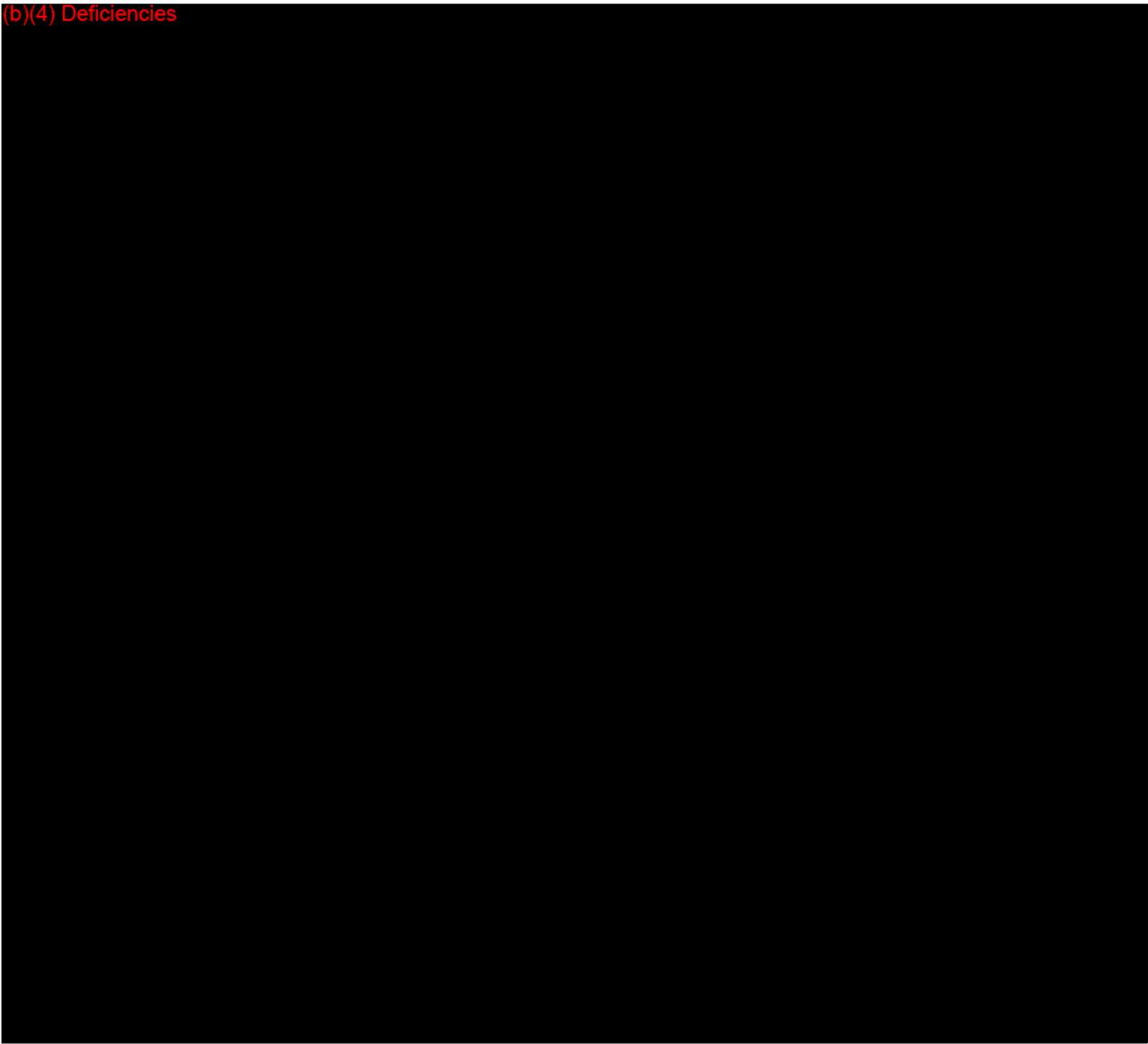


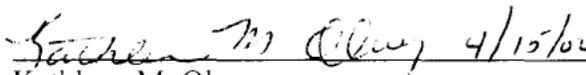
* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** 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.

(b)(4) Deficiencies

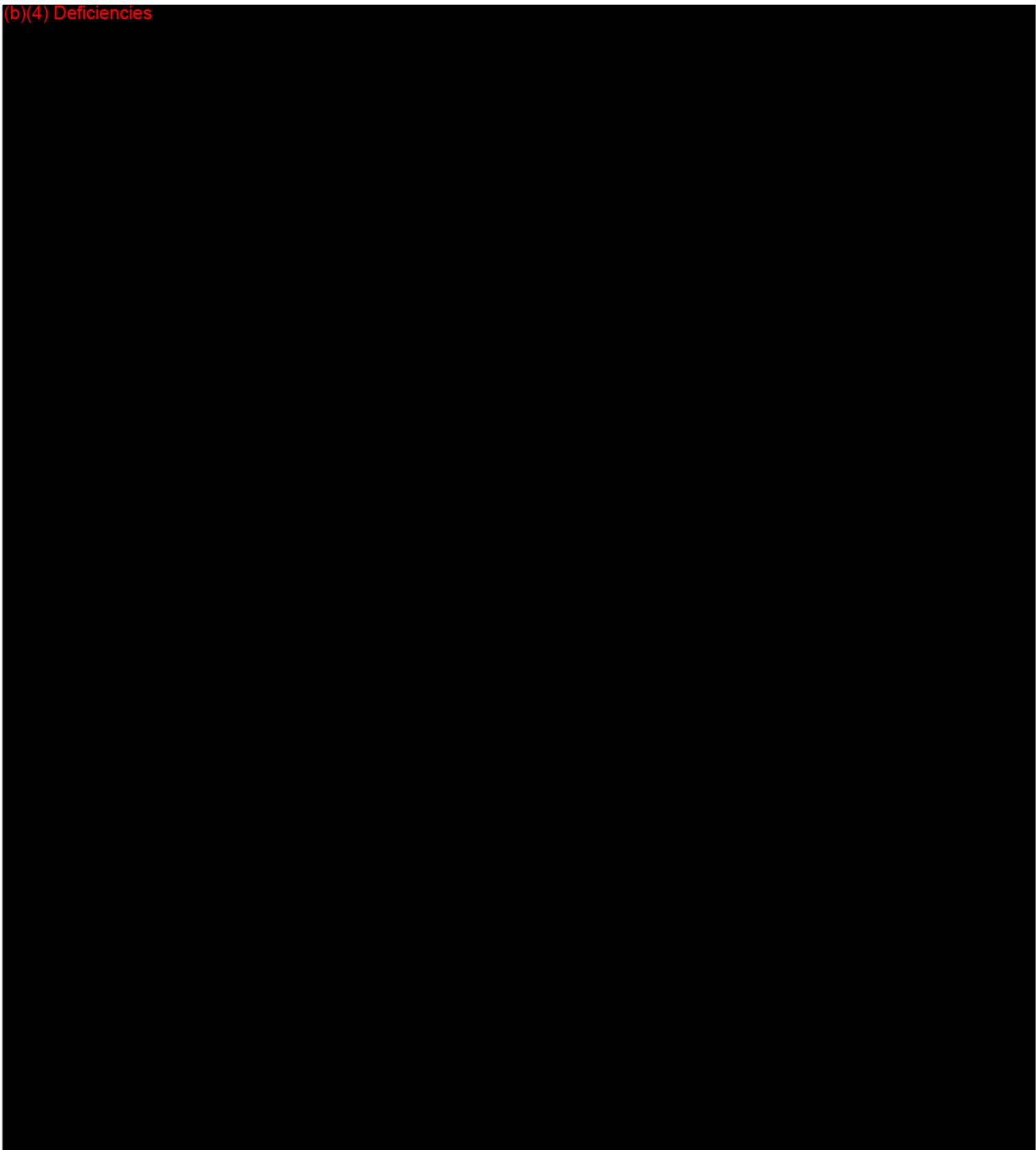



Kathleen M. Olvey

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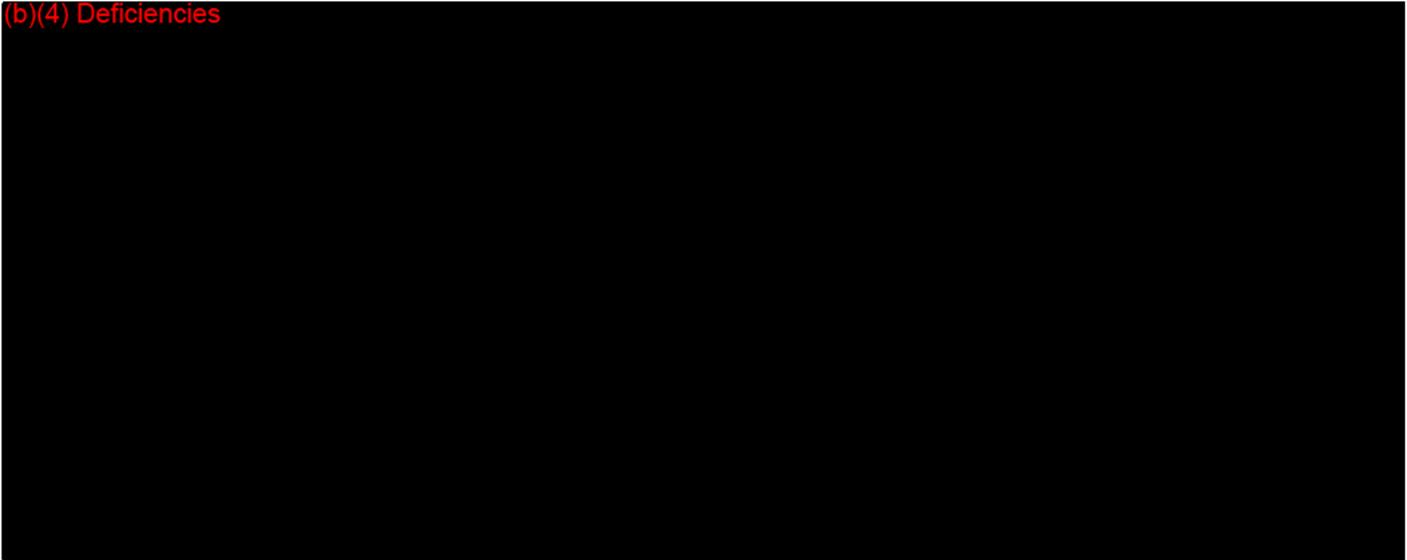
K003720, Angel of Water Colon Hydrotherapy System

(b)(4) Deficiencies



K003720, Angel of Water Colon Hydrotherapy System

(b)(4) Deficiencies



Olvey, Kathleen M.

From: Pellerite, Harold A.
Sent: Monday, April 15, 2002 2:25 PM
To: Olvey, Kathleen M.
Subject: RE: Prescription Statement Question

Kathy,

Unfortunately, I believe that the firm may be correct. The individual states determine who is authorized/licensed to prescribe certain drugs or devices in their state. Consequently, it is not misleading to use the term licensed health care practitioner, regardless of where the devices are being shipped. We don't have any authority to impose different labeling requirements based on where the devices will be shipped.

Wally

-----Original Message-----

From: Olvey, Kathleen M.
Sent: Monday, April 15, 2002 11:08 AM
To: Pellerite, Harold A.
Subject: Prescription Statement Question

Wally,

I have a question about prescription statements. The sponsor for a 510(k) for a colon irrigation device was asked to modify their prescription statement to the standard "Caution, Federal law restricts this device to sale by or on the order of a physician." They came back and stated that they don't have to because 801.109 allows them to use "Caution, Federal law restricts this device to sale by or on the order of a physician or licensed health care practitioner." (I don't like licensed health care practitioner because these things are really quack devices) There is at least one state, Florida, which allows colon therapist to use/sell these devices. The sponsor believes that since at least one state allows the sale of these devices by other than a physician they can use the second prescription statement for all the devices. I think that if they are selling the device to someone in one of these states they can use the second prescription statement but for everywhere else the standard prescription statement must apply. Am I correct?

Thanks,

Kathy



How to be Certified by I-ACT

Exams and their requirements

The Foundation Level

Requirements:

1. Provide proof of completing a 100 hour course of Colon Hydrotherapy training from an I-ACT approved School and/or an I-ACT Certified Instructor, or proof of a minimum of one year of practice with at least 100 colon hydrotherapy sessions.

2. Must be a full I-ACT member in good standing.

3. Must send your resume and proof of all related education.

Seminars completed, degrees and experience in both practice and theory. Copies please.

4. Must send pictures of your facility showing waiting area, Colon Hydrotherapy room, bathroom, etc...

5. Must send documentation of 25 different client colon hydrotherapy sessions you have given during your 100 hour course internship.

6. send 3 (blank) copies of your Health Questionnaire.

7. Must carry Liability Insurance and give insurance policy number - if liability insurance is not available or not required in your country (outside the US), then this requirement will be waived for certification purposes.

8. Must take and pass an I-ACT Level 1 written exam (\$75.00 US exam fee).

The Intermediate Level

Requirements:

1. Completed 500 hours of Colon Hydrotherapy training from approved school and/or an I-ACT Certified Instructor or have proof of 2 years of practice.

2. Must be certified, by I-ACT, at the Foundation Level and be an I-ACT member.

3. Make any corrections on your resume - update continuing education, recent seminars, etc.

4. Share 15 to 25 minutes, choose A, B, or C:

A handwritten mark or signature in the bottom right corner of the page.

A: Take us on a video journey with your client as you teach them how they may assist themselves during a session.

B: Read your essay of 1000 words in personal experience.

C: Demonstrate the expertise you have developed through your work in Colon Hydrotherapy.

5. Must take and pass the I-ACT Intermediate Level 2 Exam (\$75.00 US exam fee).

*Above presentations may be at an I-ACT approved school, a regional seminar, or an I-ACT convention (minimum 8 people in attendance).

The Advanced Level

Requirements:

1. Completed 1000 hours of Colon Hydrotherapy training from approved school and/or an I-ACT Certified Instructor or have proof of 3 years of practice.
2. Must be certified, by I-ACT, at the Intermediate Level and be an I-ACT member.
3. Must take and pass the I-ACT Advanced Level 3 Exam (\$75.00 US exam fee).

The Instructor Level

Requirements:

1. Minimum 1,000 hours of training or 3 years of practice.
2. Must be certified, by I-ACT, at the Advanced Level and a must be a Full I-ACT Member and keep membership current while providing training.
3. Demonstrate 4 hours of teaching at an I-ACT approved school, Regional Meeting, or I-ACT Convention meeting (at least one hour must be at an I-ACT Convention) - eight people in attendance desired.
4. Submit outline of teaching to headquarters 1 month prior to seminar.
5. Write a test of 50 questions on Colon Hydrotherapy- multiple choice -with answers (provide answers on separate pages and also provide source documentation for each question). Submit this test to I-ACT.

International Association for Colon Hydrotherapy

P.O. Box 461285, San Antonio, TX 78246-1285

Office: 210-366-2888

Fax: 210-366-2999

Glossary

| | | |
|--------------------|----------------------|---------------|
| Colon hydrotherapy | Colon hydrotherapist | Instrument |
| Equipment | Device | Session |
| Client | Table | Rectal Nozzle |
| Rectal Tube | Speculum | Obturator |

Colon hydrotherapy

1. Hydrates the waste and the body. (hydrated bodily fluids are able to carry nutrients and waste more effectively, these fluids include lymph, blood, mucus, intercellular fluid and extra cellular fluid)
2. Softens and loosens waste. (it is easier for the bowel to evacuate softened, hydrated waste than a hard, dehydrated mass)
3. Water enters the bowel, softening and loosing waste, this creates the reflex for evacuation. The colon evacuates through normal peristalsis. This may be repeated several times during a session, thereby exercising the muscles which make up the colon.

Colon hydrotherapist

A person who has been trained to assist during the colon hydrotherapy session.

Equipment, Instrument, Device

Colon hydrotherapy equipment does not have a motor nor a generator. It does not generate force, it controls force. Please do not call colon hydrotherapy equipment a machine, use the term equipment, instrument, or device.

Session

Colon hydrotherapy is a service not a treatment. Colon hydrotherapists are not medical providers unless they have completed their education in one of the medical fields.

Client

Colon hydrotherapy clients are not patients. They are receiving a specific service, for reasons of their own. If they require a medical provider, help them by knowing who in your area provides good quality medical help and refer them to that person.

Table

The cushioned surface upon which a client of colon hydrotherapy rests is called a table.

Rectal Tube or Rectal Nozzle

The small hollow tube which is inserted into the rectum approximately 3 inches and allows water to flow into the rectum and colon. This small tube remains in place during the evacuation of waste.

Speculum

A rigid tube about five and a half inches long, a little less than three quarters of an inch in diameter, which enters approximately two and a half to three inches into the anal canal. A quarter inch water tube attaches to the side of the speculum that is away from the body, with a one inch waste tube attached on the far end.

Obturator

The obturator is a stick with a smooth, half sphere on one end and a small handle on the other end. It is placed within the speculum to allow the speculum to enter the anal canal without disturbing the tissue.

Other Notes

Please don't put the initials for colon hydrotherapist after your name, write it out in full.

According to state law in most states, initials after your name is not allowed unless you have a degree from an accredited professional school.

For certification, education is a must for a colon hydrotherapist. To complete Level 1 Certification through I-ACT, the colon hydrotherapist must have completed 100 hours of training.

Homepage

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Kathleen Gray

Subject: 510(k) Number K003720

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

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

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

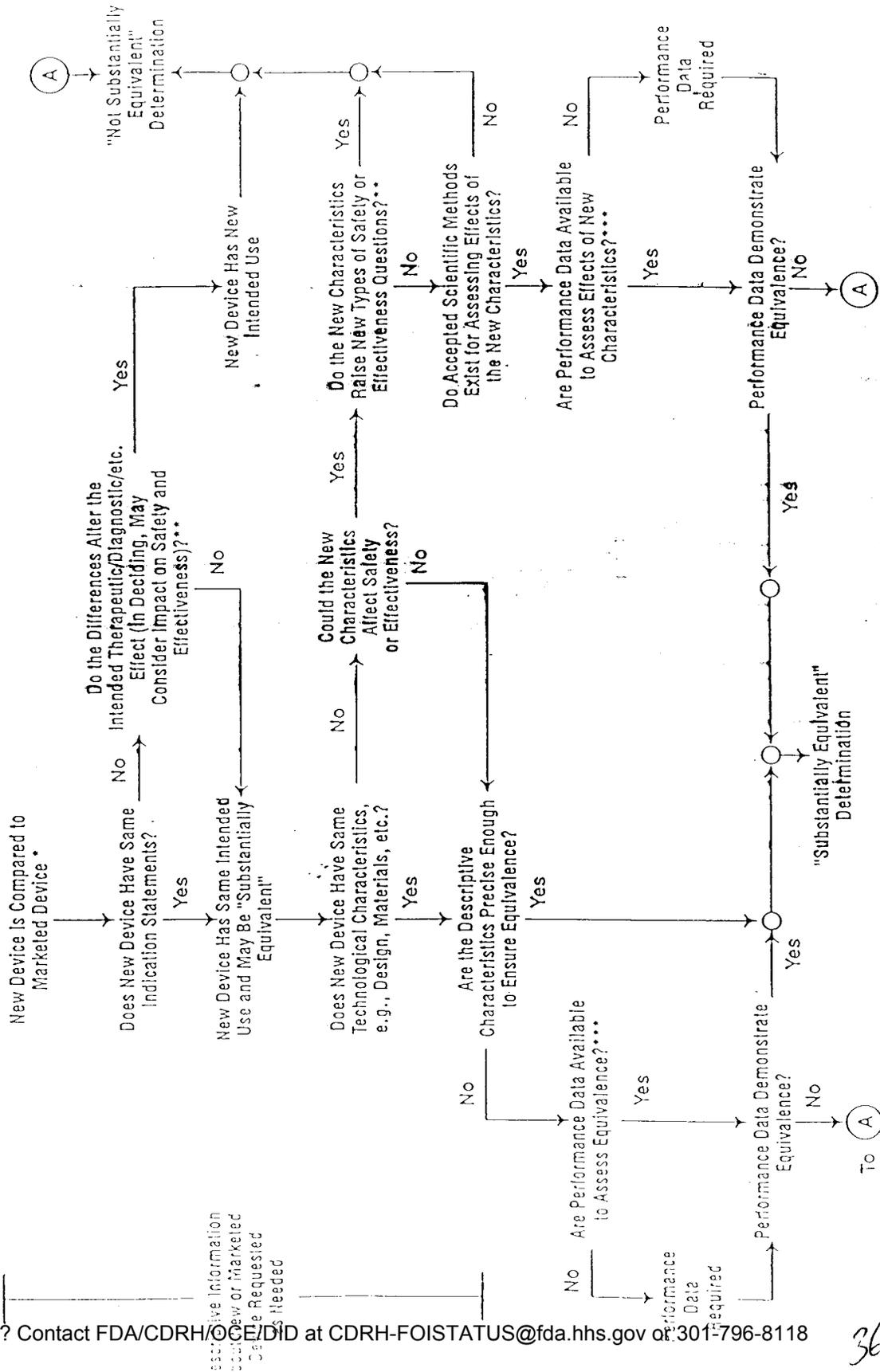
Class II 876.5220

Review: Carolyn Y Newland GRPB 3/2/01
 (Branch Chief) (Branch Code) (Date)

Final Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
 (Division Director) (Date)

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



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.
 *** Data May Be In the Form of Test Reports, Other 510(k)s, The Center's Classification Files, or the Literature.

510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information to Assess Relationship Between Marketed and "Predicate" (Pre-Amendments or Modified Post-Amendments) Devices is Unclear.

DATE: February 23, 2001

FROM: Kathleen Olvey, Biologist
Gastrointestinal and Renal Devices Branch, DRAERD

SUBJECT: Lifestream Purification System "Angel of Water" Colon Hydrotherapy System,
K003720

TO: The Record CONTACT: Richard Hamer (Consultant)
(817) 294-3644
(817) 294-3761 (Fax)

The premarket notification for the Angel of Water Colon Hydrotherapy System was received on December 4, 2000 (dated November 30, 2000). The contact for this submission is Richard Hamer, consultant with Richard Hamer Associates.

The proposed device is a new device and is indicated for colon cleansing when medically indicated, such as before radiological or endoscopic examination.

The manufacturer of the device is Lifestream Purification Systems, LLC in Austin, Texas. The contact for the sponsor is Amy Heilman.

The sponsor has included a Truthful and Accurate Statement, an Indication for Use Statement, and a 510(k) Summary.

INDICATIONS FOR USE

Colon cleansing when medically indication, such as before radiological or endoscopic examination. Comment: This indication is consistent with CFR 876.5220.

DESCRIPTION OF DEVICE AND DEVICE COMPONENTS

The hydrotherapy device introduces filtered water at a "comfortable" temperature into the large intestine. Water temperature is controlled by means of an audible alarm. Temperature, flow, and pressure are controlled by one switch operated by the user. The system is sanitized prior to each use with a broad-spectrum disinfectant. The system includes disposable tubing and a sterile, disposable rectal nozzle (single use only). Comment: This description is taken from the 510(k) Summary.

Section 4, beginning on page 35, contains the device description for the "Angel of Water" colon hydrotherapy system. There are several diagrams listing the components. It appears that the components of the system are:

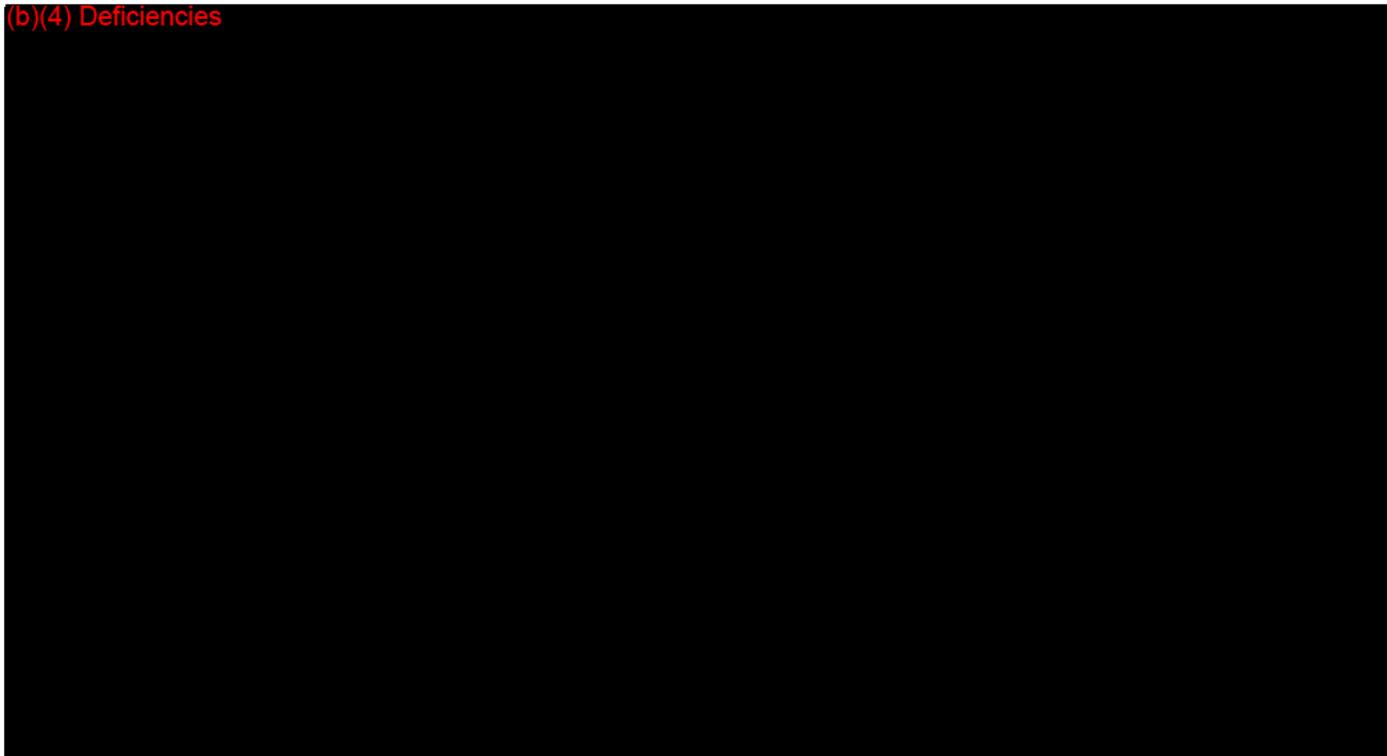
- 1-3 Laminated plywood cabinet with storage doors and storage drawer.
- 4-6 Laminated plywood "tower" with side and front door.
- 7 Vinyl covered movable backrest
- 8 Fiberglass basin
- 9 Fiberglass splash guard

K003720, Angel of Water Colon Hydrotherapy System

- 10 Hot and cold mixing valve
- 11 Viewing tube flush valve
- 12 Sprayer volume control valve
- 13 Spray nozzle
- 14 Wall mounted control panel
- 15 Gravity flow line to user
- 16 Water tank fill line
- 17 Clear plastic viewing tube
- 18 Viewing lights
- 19 Standard carbon filter
- 20 Ultraviolet light filter
- 21 Electronic flow gate
- 22 Tank water cycling device
- 23 Tank #2 with lid (b)(4)
- 24 Tank #1 with lid (b)(4)
- 25 Water tank autofill shutoff valve
- 26 Clear (b) flexible tubing
- 27 Anal (4) probe (rectal nozzle)

The pictures of the device provided by the sponsor are not very clear. The promotional material (page 34) states that the session may be self-administered or facilitated by an assistant. In addition, the device is equipped to treat water with both carbon and ultra-violet filtration.

(b)(4) Deficiencies



K003720, Angel of Water Colon Hydrotherapy System

BIOCOMPATIBILITY

The only component which directly contacts the patient is the rectal nozzle. This component was originally cleared as the Yankauer suction tube (K813066) but was also cleared as a rectal nozzle under K962259 (Tiller Mind Body LIBBE Rectal Tube).

(b)(4) Deficiencies
[Redacted]

SUBSTANTIAL EQUIVALENCE

The proposed device is substantially equivalent to the Jimmy John III (K881720) and the Libbe Rectal Tube (K962259). In the 510(k) Summary and beginning on page 41 the sponsor provided a table comparing the characteristics of the proposed device to the Jimmy John III (K881720). The proposed and predicate devices have similar designs.

The sponsor has provided comparative labeling for the rectal nozzle. The predicate is the Libbe Rectal Tube. This component is supplied sterile, for single use only.

PERFORMANCE TESTING

Performance testing that is needed for this type of device includes temperature shutoff and shutoff if the pressure in the patient's colon becomes higher than 2psi. In this submission, the sponsor states that water temperature is controlled by means of an audible alarm. The device will not shut off is the temperature exceeds 104°F.

(b)(4) Deficiencies
[Redacted]

The sponsor states that the pressure cannot exceed 2 psi because the system has only one pressure and "that is the controlled pressure created by gravity as water exits the elevated tank in the tower cabinet as activated by the FLOW switch." (b)(4) Deficiencies

[Redacted]

K003720, Angel of Water Colon Hydrotherapy System

(b)(4) Deficiencies



STERILITY

The only component of the device that is sterile is the disposable rectal nozzle. On page 47, the sponsor states that the rectal nozzle is manufactured and supplied by (b)(4) and is sterilized by (b)(4) (b)(4) to provide a Sterility assurance level of 10⁻⁶ as described in K813066. **b**

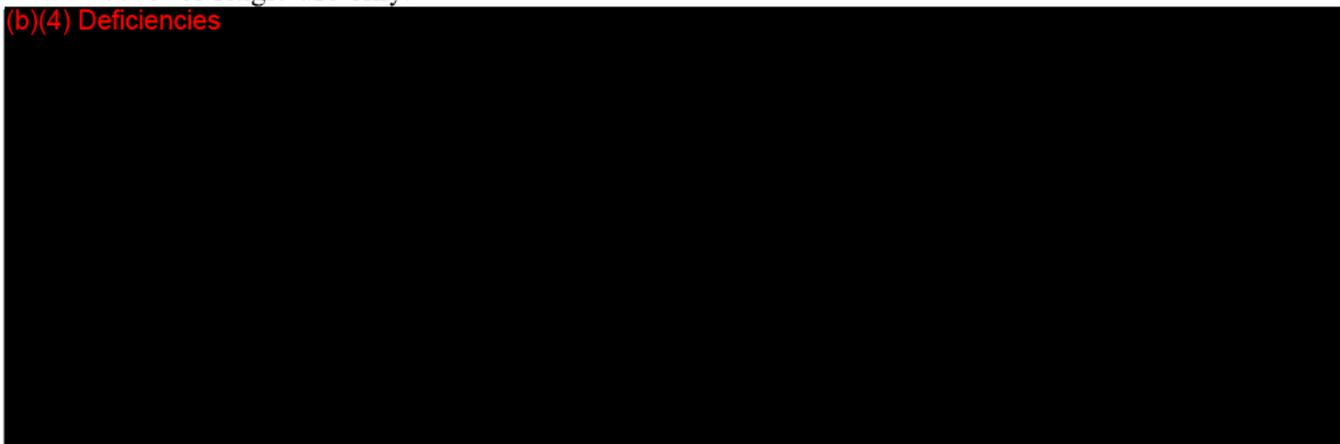
(b)(4) Deficiencies



LABELING

The labeling for the rectal nozzle includes the name (Angel of Water Sterile Rectal Nozzle), a prescription statement, the company name and address, the lot number, and a statement that the device is for single use only.

(b)(4) Deficiencies



Instructions for Use (page 15)

The sponsor has provided a draft Operations Manual for the Angel of Water Purification System. In the Introduction, the device is described as a way to irrigate the colon for endoscopic and/or radiological purposes. The tank is filled with water controlled by a mixing valve and the temperature should be between 99 – 104°F. A temperature gauge is used to monitor the temperature and if the water falls below or raises above 99 – 104°F an audible warning prompt indicates that the water should be cooled before proceeding.

The nozzle is inserted in to the patient's rectum and water flow begins by turning ON the FLOW switch. Turning the FLOW switch to OFF will stop water flow. The tank line is described as

K003720. Angel of Water Colon Hydrotherapy System

having a backflow prevention valve as a permanent plumbing feature. This component is located under the fiberglass basin and is connected directly to the basin nipple through an opening in the basin wall. It functions to prevent water from flowing back into the line once it has passed through the basin nipple into the nozzle and into the patient's rectum.

The system has only one pressure since this is a gravity flow device. This pressure is developed as the water exits the elevated tank. (b)(4) Deficiencies

The session usually lasts about 30 minutes and after completion, the person turns OFF all three switches (U.V., Cycle, Flow) and slides off the rectal nozzle.

In Chapter 1 under "Cleaning the Angel of Water System" the instructions states that the user must always assume that the system is not ready until they prepare it immediately before use. "This means that you chemically sterilize and inspect the unit right before a session, even if you cleaned it the night before or hours before." (b)(4) Deficiencies

Under Tools and Procedures for Cleaning (page 19), the tools for sanitizing are:

1. Zep Attack A¹ – broad spectrum disinfectant
2. Zep Conquer – disinfectant and deodorizer
3. Chlorine bleach (sodium hypochlorite) – disinfectant and stain remover
4. Degreaser and tether mop – for periodic cleaning of viewing tube
5. 3 Buckets (one gallon size)/ with Soft Mops – two for Attack A mixture, the third for chlorine bleach solution for basin cleaning
6. Body Protection – rubber gloves, eye or face shield, towel or respirator for lung protection
7. Miscellaneous – 2 spray containers (one for Attack A mixture, one for Conquer mixture), cotton balls, funnel for safe pouring, paper towels for used nozzle wrapping and disposal

Under "Procedure for Sanitizing" the user is told to turn on the lights and to protect themselves with rubber gloves, eye shields, and respirator (or towel). The system is then visually inspected, 1 fluid oz of chlorine bleach in a gallon of water is run inside and tank and through lines, bypassing UV light filter to flush and disinfect the entire system. After cleaning and rinsing thoroughly, the tank is filled with water between 99 – 104°F.

(b)(4) Deficiencies

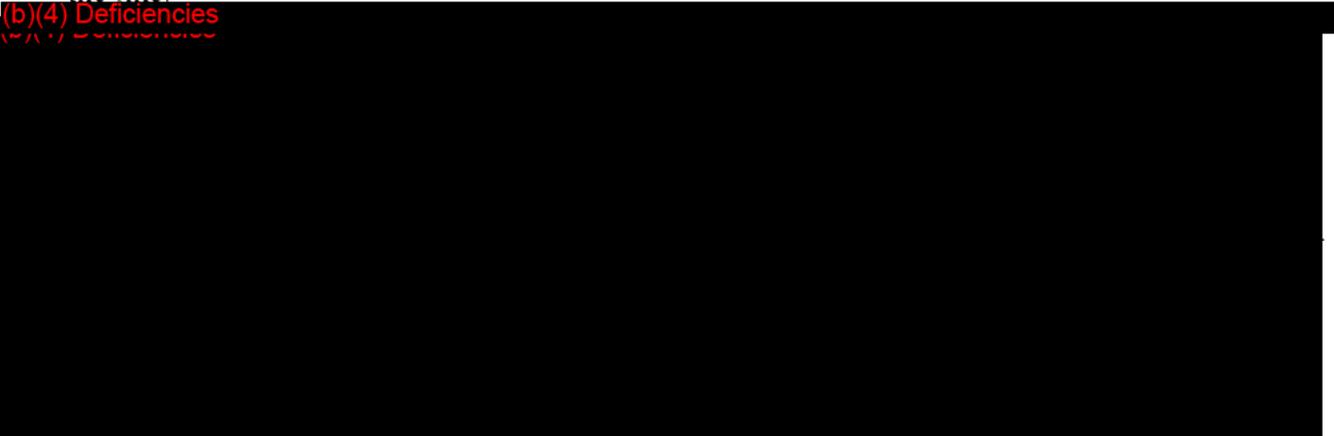
K003720, Angel of Water Colon Hydrotherapy System

(b)(4) Deficiencies



Attack A is sprayed on the basin and allowed to remain for at least 10 minutes to “disinfect everything.” Water is run from the tank through the nipple for a couple of minutes to wash out the line.

(b)(4) Deficiencies



The “sterilized” flex tube and new disposable nozzle are connected. The nozzle is then lubricated.

Under “Post Session Cleaning” the user is told to put on rubber gloves, eye shields and respirator before using chemical. The basin area is sprayed with Attack A. Water is used rinse “obvious waste material down drain.” The view tube flush valve is turned to clear the drain line. The basin and used nozzle are mopped with Attack A (bucket #1) before nozzle and flex tube removal.

The nozzle is removed from the flex tube, or both are pulled off together, then wrapped in a paper towel and disposed in wastebasket. The water is turned on to rinse out the line. The entire basin area is again mopped with Attack A after the nozzle and flex tube has been removed. The drainpipe viewing tube is degreased “when buildup of petroleum jelly lubricant warrants this procedure. The tether mop and degreaser are used to scrub the tube.

The entire basin area is mopped with diluted chlorine bleach solution which is allowed to remain in contact with the surface for several minutes. To flush and disinfect the system, one ounce of chlorine bleach in a gallon of water is run from inside the tank through the lines, bypassing the UV filter. Water is then used to rinse the chlorine bleach residue down the drain. The user is instructed not to mix chlorine bleach with other chemicals as dangerous gases may form.

A fine mist of Attack A is sprayed on all surfaces, knobs, control panels, and personal shower sprayer. The instructions also state “*Cumulative contact time of chemicals for the entire cleaning process must be at least 10 minutes to disinfect thoroughly.*” A fine mist of Conquer is sprayed on all surfaces to deodorize.

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Chapter 2 describes the uses of the control switch panels (page 24). The user is told that when setting up the device always use a ground fault circuit interrupter (GFCI) wall outlet. There are two control switch panels:

- One on the wall beside and for the use of the patient undergoing colonic irrigation
- One on the tower by the tank for the monitoring assistant or health care practitioner to use.

Switches on both panels must be in the ON position for the device to operate. If one switch is turned OFF that function will not work. A description of the switch is provided.

Lights – on control tower only. This switch turns on all lights for the inside and outside viewing tube areas and inside tower cabinet to illuminate tank water level. This switch also activates all other switches. When this switch is OFF all other switches and their function is OFF.

UV – activates the ultraviolet light in UV filter. Should be turned ON just prior to water flowing to the patient. Should be turned OFF when session stops for more than a couple of minutes.

Cycle – activates the water cycling device to move water from larger main tank to small recirculating tank. This is suppose to keep water temperature evenly mixed throughout entire tank. The water cycle device should only be used when water is flowing through it. When water in the large main tank runs out, turn cycle switch OFF until tank is filled with more water. Then resume session with cycle switch ON to maintain constant stream of gravity fed water.

Flow – activates electrical gate valve to allow water flow from tank to the patient. There is a small indicator light next to the flow switch that lights up when the water is flowing.

Temperature Gauge – located on the front of the tower cabinet, visible to the patients or the health care practitioner. It shows the water temperature and can also show the room temperature (button is pushed). It is programmed to give an audible sound and verbal warning when the temperature of the water drops below or exceeds the comfort range of 99 – 104 F. Should a warning be given, the patient should

- a. Turn the FLOW switch to OFF temporarily
- b. Change the water temperature in the tank using the water-mixing valve,
- c. Resume session once water temperature is in the comfort range.

COMMENT: according to the description, this gauge is battery operated and acts independently of any electrical supply. It provides reliable readings during regular or manual modes of operation.

Chapter 3 describes the valves. Use of the valve can bypass certain electrical components, such as the water cycle device or electrical gate valve, so that the system may be operated with or without electricity. A brief description of the valves begins on page 26.

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1. *Tank fill* – allows water into tank (accessed through side door on tower cabinet)
2. *Tank drain* – empties tank (accessed through side door on tower cabinet)
3. *Tank exit* – used for manual flow operation (without electricity)
4. *Manual flow inlet* – allows water to flow to user (without electricity)
5. *Electrical gate valve bypass* – allows water to flow without going into electrical gate valve
6. *UV inlet* – allows water into ultraviolet filter
7. *Recirculating tank exit* – allows water to leave small tank
8. *Recirculating tank bypass* – keeps water from entering small tank
9. *Recirculating tank inlet* – allows water into small tank
3-9 accessed through the back bifold door located on the tower cabinet

10. *Cold inlet* – allows cold water source into system (accessed through the door on basin cabinet)
11. *Hot inlet* – allows hot water source into system (accessed through the door on basin cabinet)

There are also several valves located inside the large main tank:

Tank level valve – automatically shuts off water fill into large main tank.

Electrical gate valve – activated by flow control panel switch. It is the only electrical valve on the system and is located on the middle shelf of the tower cabinet.

Backflow prevention valve – prevents water from flowing back into the line once it has passed from the nipple to the nozzle and into the patient. It is a permanent plumbing safety feature (whatever that means) and is located underneath the fiberglass basin.

Chapter 4 describes the valve sequences for system operation. There are two modes of operation, regulation operation functions using electricity and through electrical components and manual operation that works with or without electricity and without use of the electrical components.

Regulator Operation (electrical)

This is the primary mode of operation and features water circulating from the large main tank via the water cycling device to the smaller tank. An “even and constant stream of gravity fed water flows through the UV filter to the person experience the colon irrigation.” To operate the machine valves #6, 7, 9 are opened. Valve 10 and 11 (hot and cold water inlets) were turned on when system was set up.

6. *UV inlet* – allows water into ultraviolet filter
7. *Recirculating tank exit* – allows water to leave small tank
8. *Recirculating tank bypass* – keeps water from entering small tank
9. *Recirculating tank inlet* – allows water into small tank
3-9 accessed through the back bifold door located on the tower cabinet

All other valves are closed. Valve #1 (tank fill) is opened and the water mixing valve turned on

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to fill tank with water. At any water level valve #1 can be closed or the water mixing valve shut off to stop water flowing to the large main tank. The water level inside the large main tank will shut off automatically by the tank level valve once the water reaches the top (about 12 gallons).

(b)(4) Deficiencies

In the instructions on the bottom of page 29, the user is told that if the patient cannot feel water coming into their colon, the tip of the nozzle may be clogged with waste material. "Additional flow from the large main tank" may be used to unclog the nozzle without the patient removing the nozzle. Valves #7 and 9 are closed and then valve #8 is partially opened until flow is felt again. Then valves #1 and 9 are opened and #8 closed completely.

7. *Recirculating tank exit* – allows water to leave small tank
8. *Recirculating tank bypass* – keeps water from entering small tank
9. *Recirculating tank inlet* – allows water into small tank

Comment: (b)(4) Deficiencies

Manual Operation (with or without electricity)

This mode and valve sequence allows a "monitoring assistant or health care practitioner" to send water to the patient directly from the large main tank with or without activation of the Flow control switch or with or without the use of electricity. There are two manual modes:

No electricity and no UV water treatment

Valve #1 and the water mixing valve are opened to fill tank. Next valves #3 and 4 are opened. Valve #4 is closed when the patient is finished with the session or wants to interrupt the session.

1. *Tank fill* – allows water into tank (accessed through side door on tower cabinet)
3. *Tank exit* – used for manual flow operation (without electricity)
4. *Manual flow inlet* – allows water to flow to user (without electricity)

With electricity and with UV water treatment

Valve #1 and the water mixing valve are opened to fill tank. Next valves #3 and 6 are opened. Valve #6 is closed when the patient is finished with the session or wants to interrupt the session. If session stops longer than a couple of minutes, the UV control switch should be turned off.

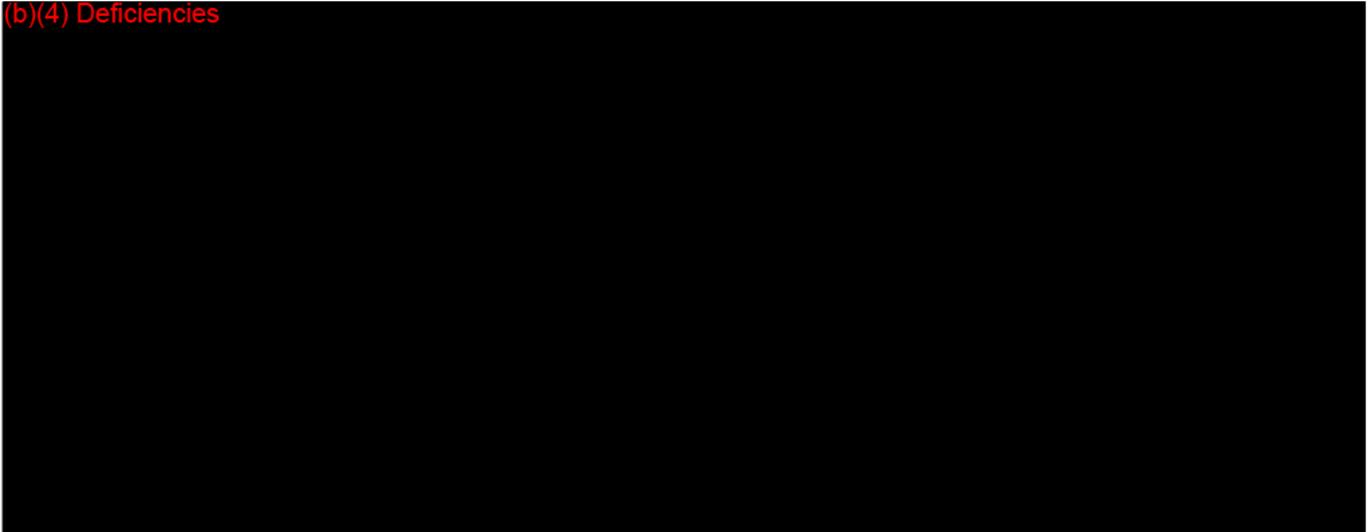
1. *Tank fill* – allows water into tank (accessed through side door on tower cabinet)
3. *Tank exit* – used for manual flow operation (without electricity)
6. *UV inlet* – allows water into ultraviolet filter

Chapter 5 describes the "System Maintenance." Although the system is designed to be "virtually maintenance free" there are some items that will occasionally need to be replaced.

Filters – carbon cartridge (for initial tank filtration before water enters large main tank) and the sediment cartridge in the UV filter. Changing filters will be a function of how frequently the system is used. Filters need to be changed when tank filling becomes too slow or when flow to the patient through the UV filter seems to slow down or become almost imperceptible.

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(b)(4) Deficiencies



Batteries in Temperature Gauge – when the gauge display begins to fade, the “AAA” batteries should be replaced. The user is told to never operate the system without a functioning temperature gauge.

Diaphragm Plunger inside Electrical Gate Valve – this valve has a diaphragm plunger inside the brass body that will begin to leak water when it needs to be replaced.

Light bulbs – the bulbs for the viewing tube, tank tower and UV bulbs should last from 9000 to 10,000 hours. “Remember, do not look at the UV bulb directly when in operation.” Follow instruction in the packet on UV bulb replacement.

→ The instructions raise questions about the components, as the description of the components is incomplete. Of particular concern are the filters and the UV system. The sponsor will be asked several questions to address these issues.

K003720, Angel of Water Colon Hydrotherapy System

RECOMMENDATION

The submission for the Angel of Water Colon Hydrotherapy System is incomplete. The sponsor did not provide (b)(4) Deficiencies

[REDACTED]

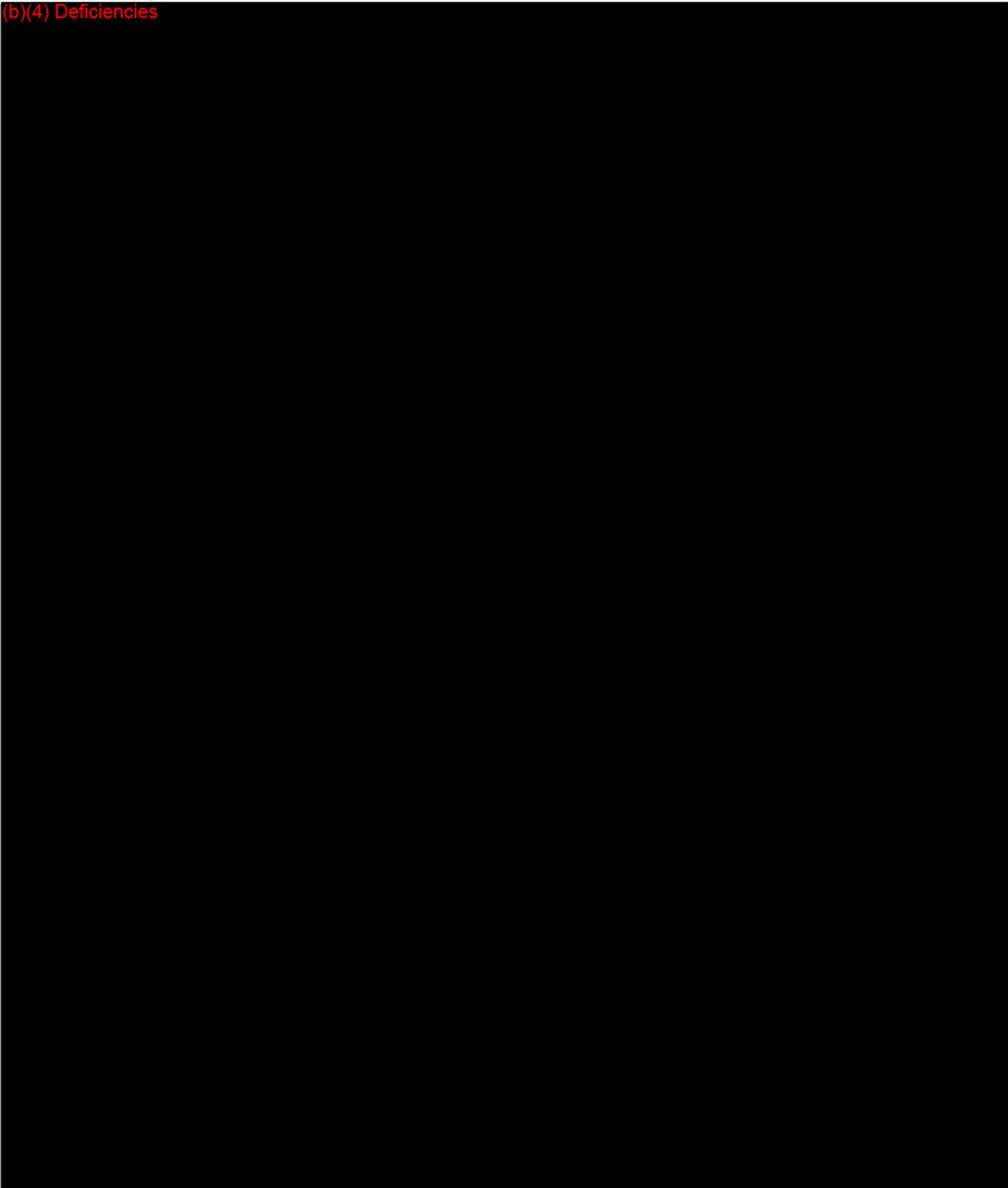
[REDACTED] am recommending that this submission be placed on hold until additional information is provided.


Kathleen M. Olvey

C. Neubond
5/2/01

K003720. Angel of Water Colon Hydrotherapy System

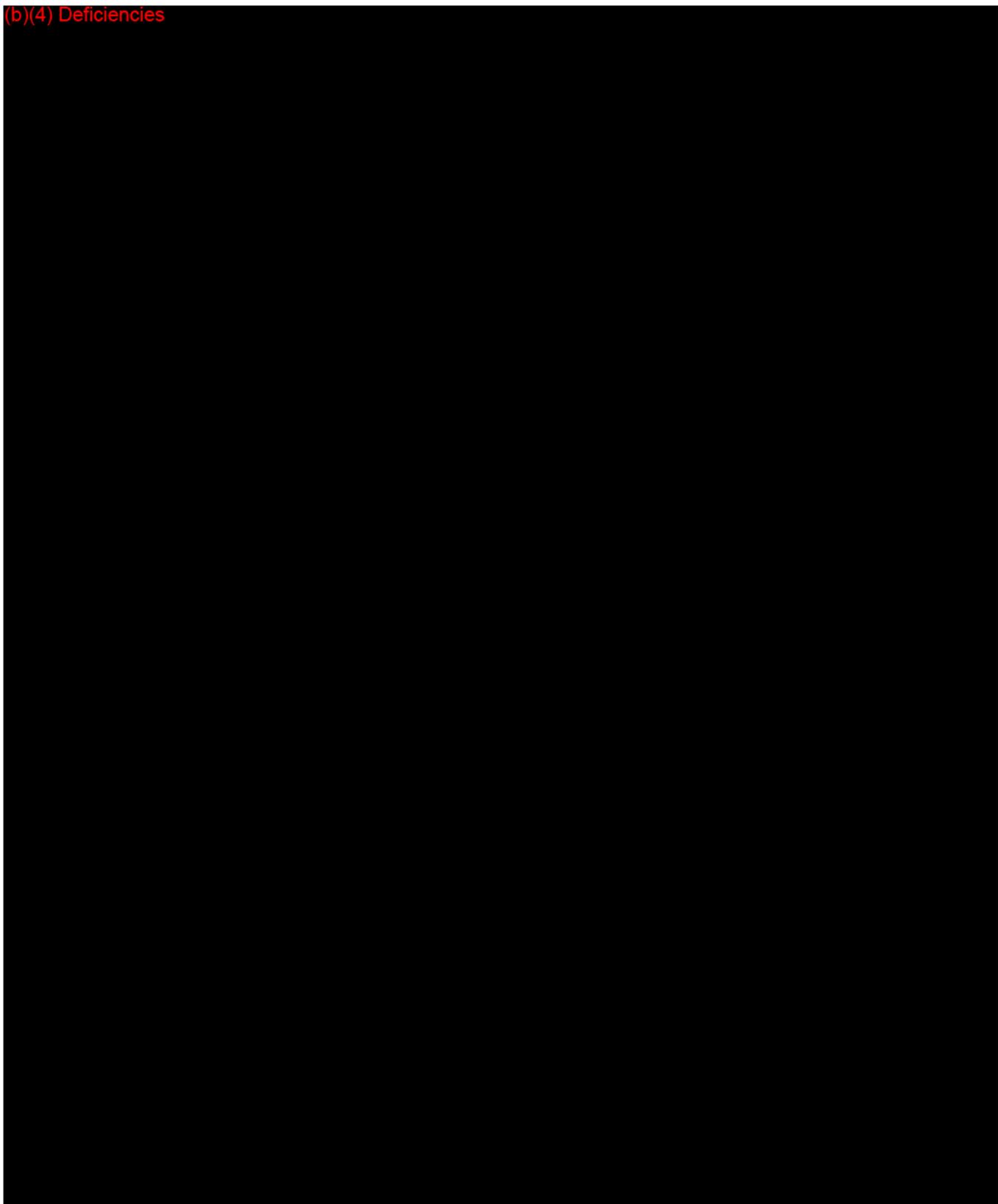
(b)(4) Deficiencies



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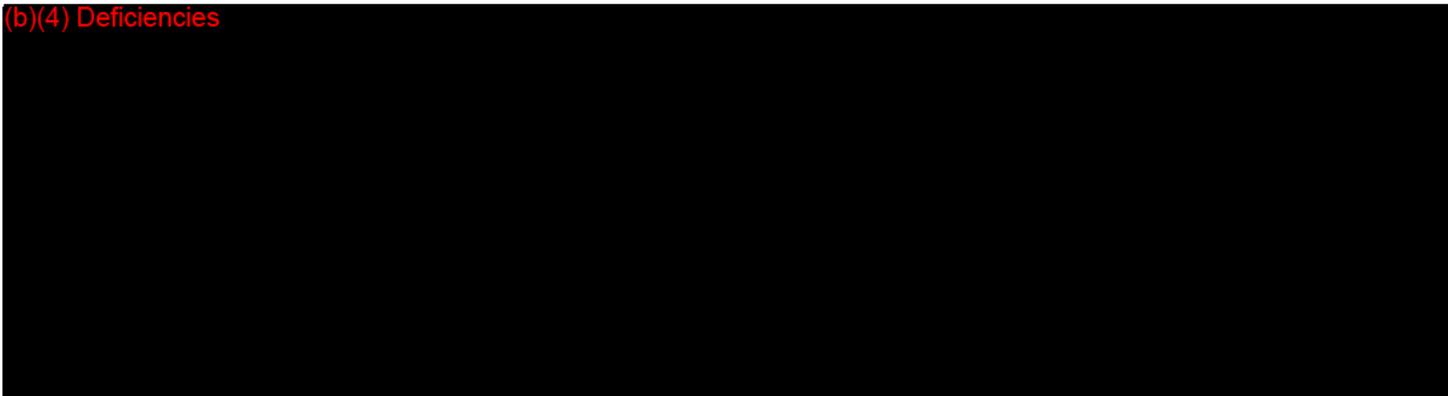
K003720, Angel of Water Colon Hydrotherapy System

(b)(4) Deficiencies



K003720. Angel of Water Colon Hydrotherapy System

(b)(4) Deficiencies



Screening Checklist For all Premarket Notification 510(k) Submissions

| | | | | | | | | | | | | | |
|---|--|--|--|--|--|--|--|---|--|---|------------------------|---|--|
| Device Name: | | | | | | K | | | | | | | |
| Submitter (Company): | | | | | | | | | | | | | |
| Items which should be included <i>(circle missing & needed information)</i> | | | | | | S P E C I A L | | A B B R E V I A T E D | | T R A D I T I O N A L | | ✓ IF ITEM IS NEEDED AND IS MISSING | |
| | | | | | | YES | | NO | | YES | | NO | |
| 1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k) | | | | | | GO TO # 2,3 | | GO TO # 2,4,5 | | GO TO #2, 5 | | | |
| 2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS | | | | | | | | | | | ✓ IF ITEM IS NEEDED | | |
| Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) | | | | | | NA | | YES | | NO | | AND IS MISSING | |
| | | | | | | SPECIALS | | ABBREVIATED | | TRADITIONAL | | | |
| | | | | | | YES | | NO | | YES | | | |
| a) trade name, classification name, establishment registration number, device class | | | | | | | | | | ✓ | | | |
| b) OR a statement that the device is not yet classified | | | | | | FDA-may be a classification request; see coordinator | | | | | | | |
| c) identification of legally marketed equivalent device | | | | | | NA | | | | ✓ | | | |
| d) compliance with Section 514 - performance standards | | | | | | NA | | | | | | | |
| e) address of manufacturer | | | | | | | | | | | | | |
| f) Truthful and Accurate Statement | | | | | | | | | | ✓ | | | |
| g) Indications for Use enclosure | | | | | | | | | | ✓ | | | |
| h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES) | | | | | | | | | | ✓ | | | |
| i) Class III Certification & Summary (FOR ALL CLASS III DEVICES) | | | | | | | | | | | | | |
| j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals | | | | | | | | | | ✓ | | | |
| k) Proposed Labeling: | | | | | | | | | | ✓ | | | |
| i) package labeling (user info) | | | | | | | | | | | | | |
| ii) statement of intended use | | | | | | | | | | | | | |
| iii) advertisements or promotional materials | | | | | | | | | | | | | |
| i) MRI compatibility (if claimed) | | | | | | | | | | | | | |
| l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include: | | | | | | | | | | ✓ | | | |
| i) Labeling | | | | | | | | | | | | | |
| ii) intended use | | | | | | | | | | ✓ | | | |
| iii) physical characteristics | | | | | | | | | | ✓ | | | |
| iv) anatomical sites of use | | | | | | | | | | | | | |
| v) performance (bench, animal, clinical) testing | | | | | | NA | | | | | | ✓ | |
| vi) safety characteristics | | | | | | NA | | | | | | | |
| m) If kit, kit certification | | | | | | | | | | | | | |
| 3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE | | | | | | | | | | | | | |
| a) Name & 510(k) number of legally marketed (unmodified) predicate device | | | | | | | | | | | | | |
| b) STATEMENT - INTENDED USE AND INDICATIONS FOR | | | | | | | | | | | | | |
| | | | | | | | | | | | | * If no - STOP not a special | |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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| | | | | |
|---|--|--|------------------------------|--|
| USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED* | | | | |
| c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED* | | | * If no - STOP not a special | |
| d) Design Control Activities Summary | | | | |
| i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis | | | | |
| ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied | | | | |
| iii) A declaration of conformity with design controls. The declaration of conformity should include: | | | | |
| 1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met | | | | |
| 2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review. | | | | |

| | SPECIALS | | ABBREVIATED | | TRADITIONAL | | ✓ IF ITEM IS NEEDED AND IS MISSING |
|---|----------|----|-------------|----|-------------|----|------------------------------------|
| | YES | NO | YES | NO | YES | NO | |
| 4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE | | | | | | | |
| a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type | | | | | | | |
| b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach. | | | | | | | |
| c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following: | | | | | | | |
| i) An identification of the applicable recognized consensus standards that were met | | | | | | | |
| ii) A specification, for each consensus standard, that all requirements were met, except for | | | | | | | |

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| | | | |
|--|--|--|--|
| inapplicable requirements or deviations noted below | | | |
| iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed | | | |
| iv) An identification, for each consensus standard, of any requirements that were not applicable to the device | | | |
| v) A specification of any deviations from each applicable standard that were applied | | | |
| vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference | | | |
| vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations | | | |
| d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards | | | |

| 5. Additional Considerations: (may be covered by Design Controls) | | | | | | | |
|--|--|--|--|--|--|--|--|
| a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation: | | | | | | | |
| i) component & material | | | | | | | |
| ii) identify patient-contacting materials | | | | | | | |
| iii) biocompatibility of final sterilized product | | | | | | | |
| b) Sterilization and expiration dating information: | | | | | | | |
| i) sterilization method | | | | | | | |
| ii) SAL | | | | | | | |
| iii) packaging | | | | | | | |
| iv) specify pyrogen free | | | | | | | |
| v) ETO residues | | | | | | | |
| vi) radiation dose | | | | | | | |
| c) Software validation & verification: | | | | | | | |
| i) hazard analysis | | | | | | | |
| ii) level of concern | | | | | | | |
| iii) development documentation | | | | | | | |
| iv) certification | | | | | | | |

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No
 Date: 12/1/00

Reviewer: [Signature]
 Concurrence by Review Branch: C Newland

3/2/01 3/4

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

YES NO

| | YES | NO | |
|--|-----|----|--------------------------------------|
| 1. Is Product A Device | | | If NO = Stop |
| 2. Is Device Subject To 510(k)? | | | If NO = Stop |
| 3. Same Indication Statement? | | | 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? | | | If YES = Go To 7 |
| 6. Could The New Characteristics Affect Safety Or Effectiveness? | | | If YES = Go To 8 |
| 7. Descriptive Characteristics Precise Enough? | | | 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 Data |
| 11. Data Demonstrate Equivalence? | | | Final Decision: |

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:
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. 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.

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

Internal Administrative Form

K 003720

| | YES | NO |
|---|-----|----|
| 1. Did the firm request expedited review? | | ✓ |
| 2. Did we grant expedited review? | | ✓ |
| 3. Have you verified that the Document is labeled Class III for GMP purposes? | N/A | |
| 4. If, not, has POS been notified? | ✓ | |
| 5. Is the product a device? | ✓ | |
| 6. Is the device exempt from 510(k) by regulation or policy? | | ✓ |
| 7. Is the device subject to review by CDRH? | ✓ | |
| 8. Are you aware that this device has been the subject of a previous NSE decision? | | |
| 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)? | | ✓ |
| 10. Are you aware of the submitter being the subject of an integrity investigation? | | ✓ |
| 11. If, yes, consult the ODE Integrity Officer. | | |
| 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991. | | |

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Kathleen Avery
Subject: 510(k) Number K003720/S1
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

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

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

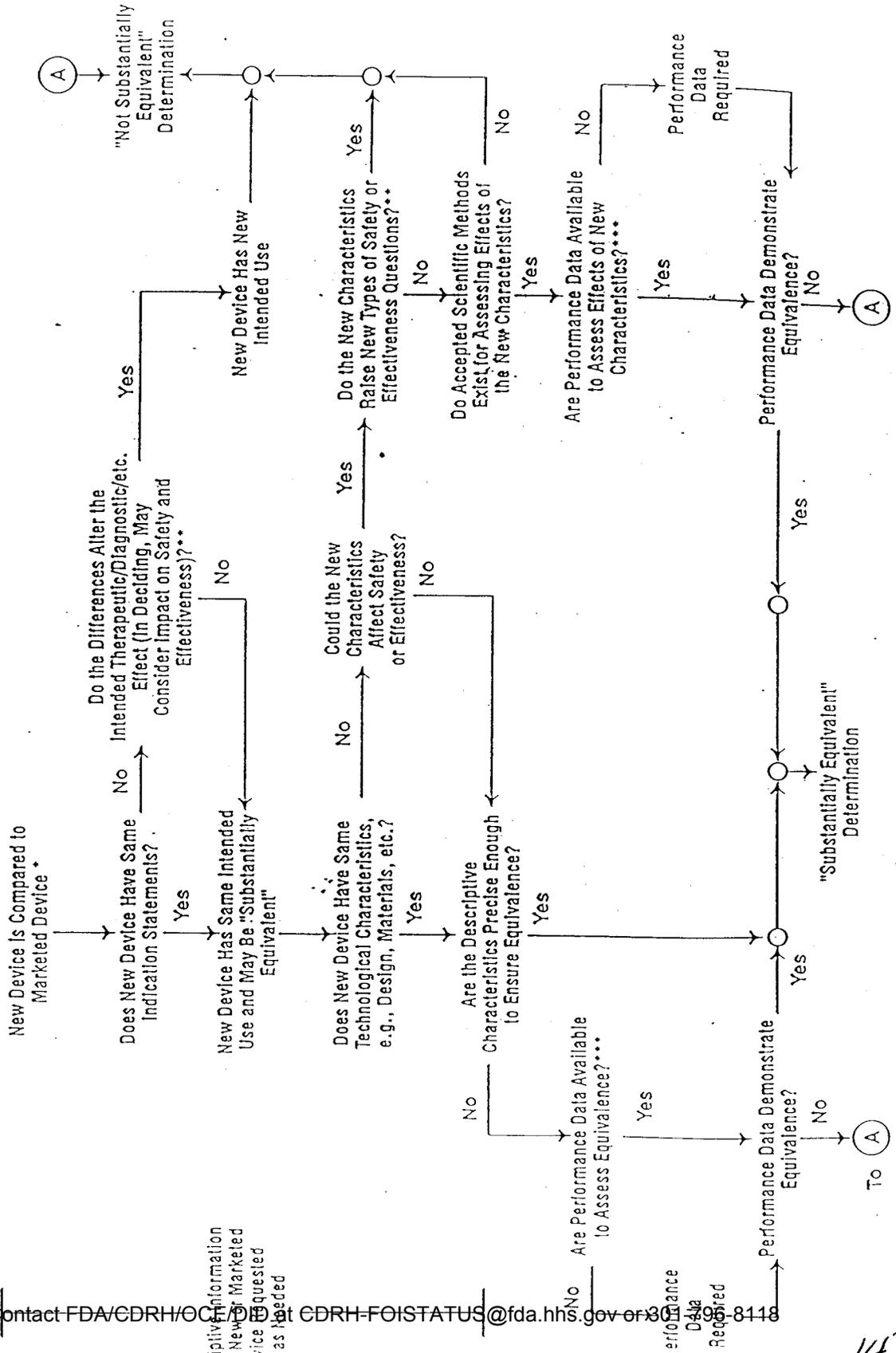
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Class II 20 476.5220

Review: Cavilyn Y Neuland GRDB 10/30/01
(Branch Chief) (Branch Code) (Date) JMS

Final Review: _____
(Division Director) (Date)

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



Questions? Contact FDA/CDRH/OCE/DTP at CDRH-FOI@FDA.HHS.GOV or 301-795-8118

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510(k) Submissions are 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.

To (A)

DATE: October 12, 2001

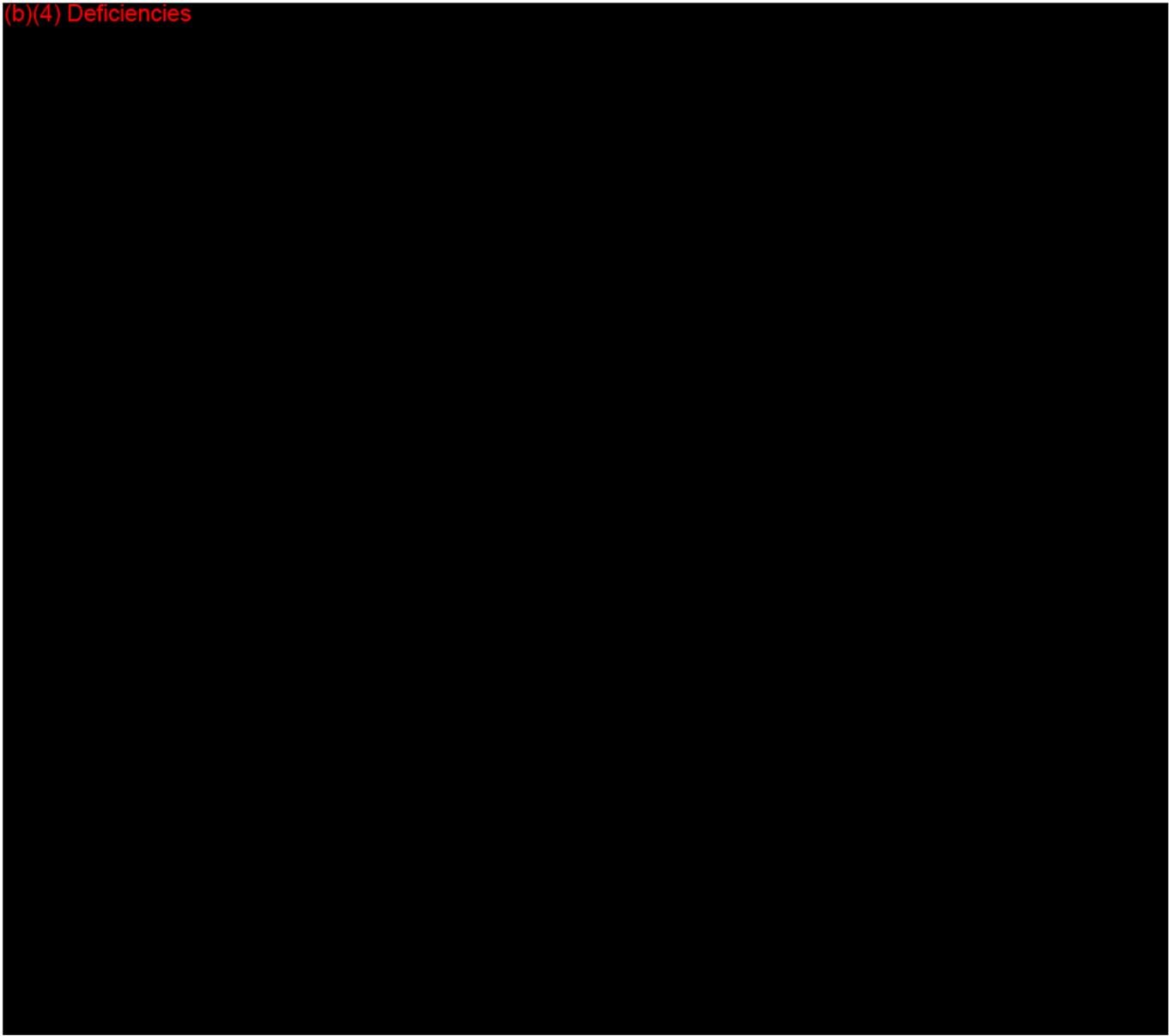
FROM: Kathleen Olvey, Biologist, GRDB, DRARD

SUBJECT: Lifestream Purification System "Angel of Water" Colon Hydrotherapy System, K003720

TO: The Record CONTACT: Richard Hamer (Consultant)
(817) 294-3644
(817) 294-3761 (Fax)

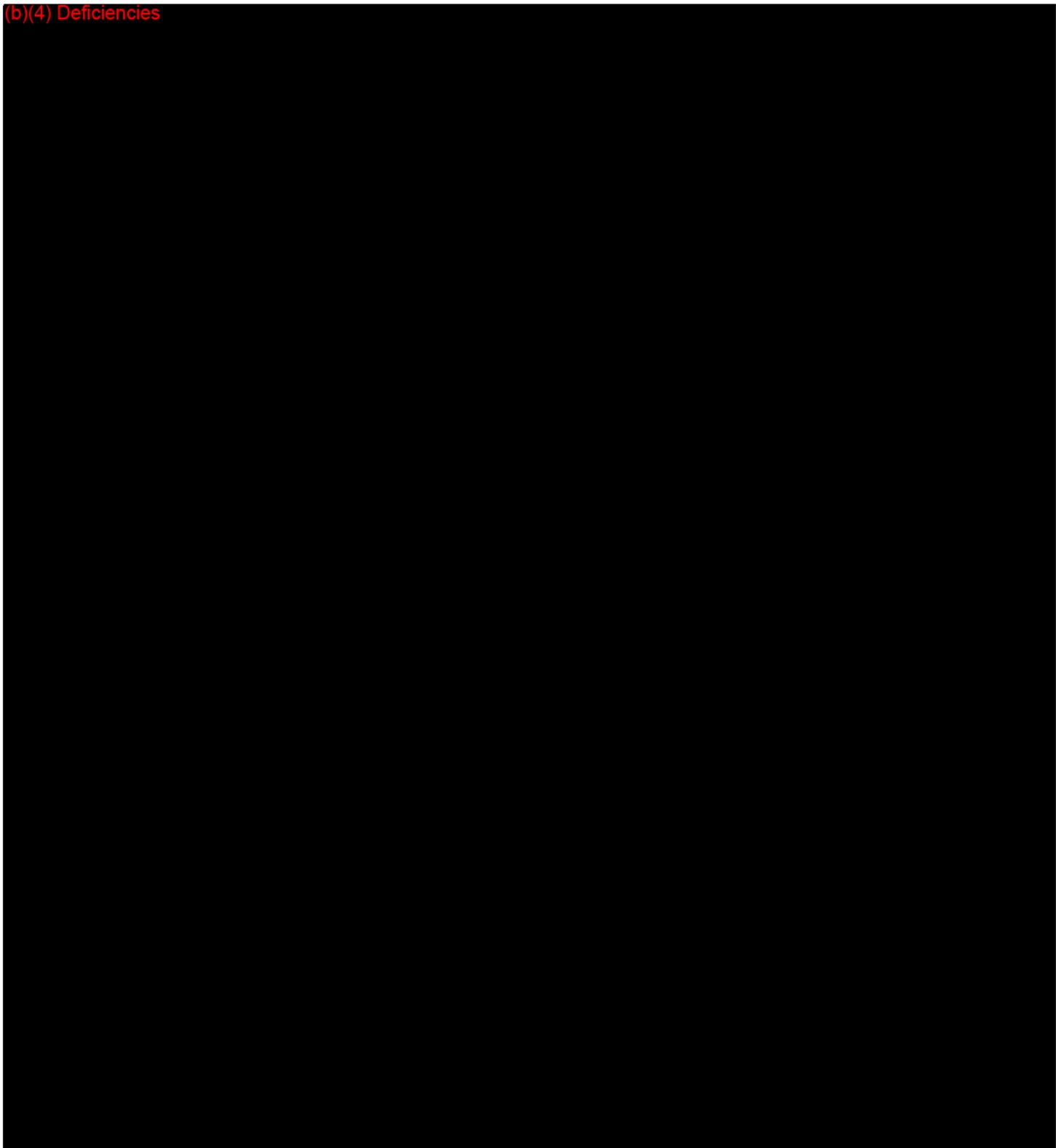
The premarket notification for the Angel of Water Colon Hydrotherapy System was originally received on December 4, 2000. A request for additional information was sent to the sponsor on March 2, 2001. The sponsor's response was received on August 1, 2001 (dated July 31, 2001).

(b)(4) Deficiencies



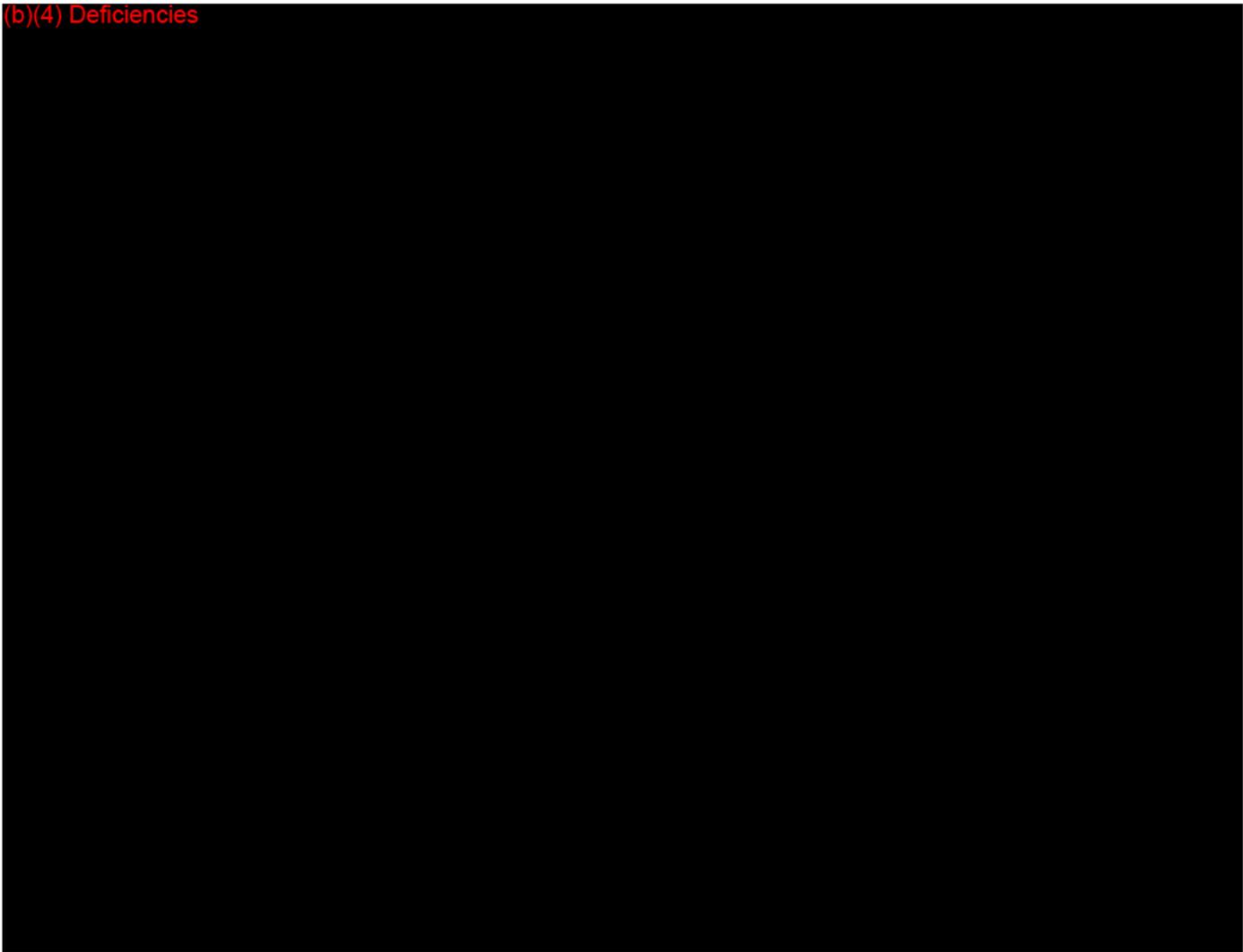
K003720, Angel of Water Colon Hydrotherapy System

(b)(4) Deficiencies



K003720, Angel of Water Colon Hydrotherapy System

(b)(4) Deficiencies



RECOMMENDATION

The sponsor has addressed many of the issues from our March 2, 2001 letter, however, they have not adequately addressed the issue of (b)(4)

This needs to be addressed. There are also several other minor issues that need to be clarified. I am recommending that this submission be placed on hold until this information is provided.

Kathleen M. Olvey 10/29/01
Kathleen M. Olvey

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*C Newland
10/29/01*

Memorandum

From: Reviewer(s) - Name(s) Kathleen M. Olvey

Subject: 510(k) Number K003720/S3

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?

YES NO MA

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

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices N/A

The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

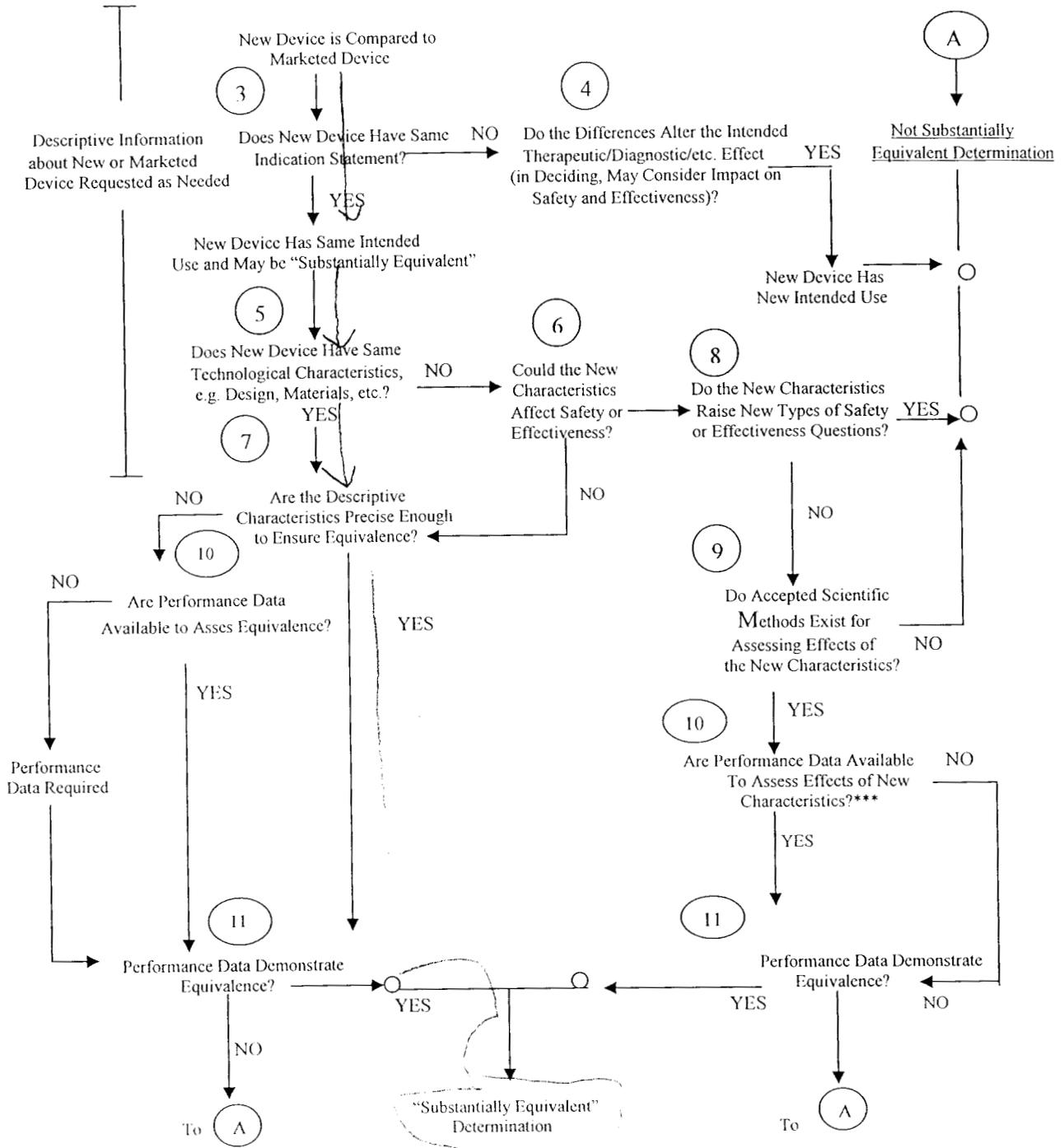
Class II KPL 78 876.5220

Review: Catalyn Y Neuland GRDB 6/27/02
(Branch Chief) (Branch Code) (Date) (Gms)

Final Review: David G. Ingram 6/27
(Division Director) (Date)

Revised: 8/17/99

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ 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.

K003720 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENT

REVIEWER: Kathleen Olvey DIVISION/BRANCH: DRARD/GRDB

TRADE NAME: Angel of Water Colon Hydrotherapy System COMMON NAME: colonic irrigation device

PRODUCT TO WHICH COMPARED: Jimmy John III, Libbe Rectal Tube
(510(k) NUMBER IF KNOWN) K881720, K962259

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

NOTE: IN ADDITION TO COMPLETING PAGE 2, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11. AND EVERY NO RESPONSE REQUIRES AN EXPLANATION ON PAGE 3 AND/OR 4.

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE:

The Angel of Water™ Colonic Irrigation System is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examination.

2. DEVICE DESCRIPTION: (b)(4)

[REDACTED]

SUMMARY:

DESCRIPTION OF DEVICE AND DEVICE COMPONENTS

The proposed colon irrigation device, the Angel of Water™ Colonic Irrigation System, introduces water into the large intestine to cleanse the colon when medically indicated (before radiological or endoscopic examination). Temperature, flow, and pressure are controlled by the user. The System includes a multi-use colonic irrigator and two disposable single use components, the flex tube and a sterile, disposable rectal nozzle (single use only).

The only component which directly contacts the patient is the single use disposable rectal nozzle. This component was originally cleared as the Yankauer suction tube (K813066) but was also cleared as a rectal nozzle under K962259 (Tiller Mind Body LIBBE Rectal Tube).

A (b)(4) 'flex tube' is used to connect the brass nipple to sterile disposable rectal nozzle. This component is not sterile but is disposable and for single patient use only. It is currently marketed by (b)(4)

A session usually takes 30 to 40 minutes and uses approximately 12 gallons of water, which is the total volume capacity of the main tank.

There are two water tanks in the proposed device, the main water tanks holds 12 gallons of water and a smaller recirculating tank. A pump is used to circulate water from main tank to small tank and back, to keep water temperature even and to provide a consistent flow of water to the patient as water level in the main tank decreases. Before entering the main tank the water is filtered through a carbon filter (capacity of 15,000 gallons) to reduce sediment, rust and chlorine. The tubing in the System is manufactured from PVC.

A solenoid valve allows the water to be sent to patient electrically by activation of the flow switch. There is a tank level valve which fills and automatically shuts off water once the main tank is full.

There are several safety features:

- The basin backflow prevention valve prevents water entering the colon from being pushed back into the line.
- Water temperature controller and temperature sensor senses water temperature and automatically closes the solenoid valve during operation if water flowing to patient exceeds 104°F.
- View tube sprayer backflow prevention (spring-loaded) valve prevents water flushed into view tube from backing into clean water line.
- The rectal nozzle is disposable and for single use only. It allows water from the System to enter the patient's colon.
- Ultraviolet (UV) unit designed to handle water flow rates between 0.5 and 1 gallon per minute. The unit contains a 154-nm UV lamp enclosed in a protective quartz sleeve and rated for 7,500 hours of continuous use. The water is exposed to UV before entering the patient. It should be noted that it is common for this type of device to contain an ultraviolet source, however, none of the labeling for these devices claim that the water is 'sterilized' by the UV. No data have been presented substantiating such a claim.

SUBSTANTIAL EQUIVALENCE

The proposed device is substantially equivalent to the Jimmy John III (K881720) and the Libbe Rectal Tube (K962259).

Both devices have a similar mode of operation, continuous gravity water flow and similar components (mixing valve, lighting, back flow check valves, and electrical requirements). Both use disposable rectal nozzles.

PERFORMANCE TESTING

Testing was conducted to demonstrate that the device will shut off if the water temperature exceeds 104°F

Testing was conducted to demonstrate that the colon pressure would not exceed 2 psi. The results demonstrated that even when the rectal nozzle was fully blocked, as seen in an obstruction, the pressure did not exceed 1.1psi. The design of the rectal nozzle used with this device allows water to flow around the nozzle and exit the patient automatically which would make it difficult for the patient to physically retain enough water to significantly increase the pressure within their colon.

The Angel of Water™ Colonic Irrigation System complies with electrical safety standard UL 2601.

The components of the device which indirectly contact the patient, the tanks and lines

must be disinfected between each patient treatment. An intermediate level disinfectant, Cavicide manufactured by Metrex is recommended. Cavicide was cleared by the FDA in 1995 (K951123) before intermediate level disinfectants were taken over by EPA.

Cavicide is a multi-purpose, broad spectrum, cleaner and disinfectant for use on the surfaces of inanimate objects. It is intended for disinfection of non-critical precleaned instruments (appropriate for use with the proposed device). The lumen should be filled with solution, or immersed, in undiluted Cavicide solution and allowed to remain submerged for 10 minutes room temperature. Follow by wiping the surface using a clean paper or cloth towel; or rinse and allow surface to air dry or wipe rinsed surface dry prior to use. The manufacturer, Metrex, informed the sponsor that two complete rinses should be completed, using a gallon of water for each rinse. The sponsor's instructions for use call for three rinses.

Cavicide will clean and disinfect inanimate surfaces, including those made of plastics (e.g., polyvinylchloride, polypropylene, polyethylene and polystyrene), stainless steel, painted surfaces, glass and other hard non-porous surfaces.

STERILITY

The only component of the device that is sterile is the disposable rectal nozzle which is sterilized by (b)(4) to a sterility assurance level of 10⁻⁶.

LABELING

The label on the front of the system reads:

Angel of Water Colon Hydrotherapy System

For colon irrigation before radiological or endoscopic examination.

Caution: Federal law (USA) restricts this device to use by or on the order of a physician or health care practitioner.

The company name, address, and phone number are all included.

The labeling for the rectal nozzle includes the name (Angel of Water™ Sterile Rectal Nozzle), a prescription statement, the company name and address, the lot number, and a statement that the device is for single use only.

Instructions for Use

The sponsor has provided a draft Operations Manual for the Angel of Water Purification System. In the Introduction, the device is described as a way to irrigate the colon for endoscopic and/or radiological purposes. The tank is filled with water controlled by a mixing valve and the temperature should be between 99 – 104°F. If the temperature raises above 103°F the temperature sensor control will shutting off the flow stopping water flow to the patient

The nozzle is inserted in to the patient's rectum and water flow begins by turning ON the FLOW switch. Turning the FLOW switch to OFF will stop water flow. The tank line has a backflow prevention valve as a permanent plumbing feature. This component is located under the fiberglass basin and is connected directly to the basin nipple through an

opening in the basin wall. It functions to prevent water from flowing back into the line once it has passed through the basin nipple into the nozzle and into the patient's rectum.

The system has only one pressure since this is a gravity flow device. This pressure is developed as the water exits the elevated tank. The session usually lasts about 30 minutes and after completion, the person turns OFF all three switches (U.V., Cycle, and Flow) and slides off the rectal nozzle.

The Indications for Use read “colon irrigation can be administered when medically indicated, such as before radiological or endoscopic examination.” Contraindications include:

| | |
|--------------------------|--------------------------------------|
| Congestive heart failure | intestinal perforation |
| Carcinoma of the rectum | fissures or fistula |
| Severe hemorrhoids | abdominal hernia |
| Renal insufficiency | recent colon or rectal surgery |
| Abdominal surgery | first or last trimester of pregnancy |
| Cirrhosis | |

Chapter 1 “Cleaning the Angel of Water System” – provides instructions on cleaning and disinfecting the System. The user is to always assume that the system is not ready until they prepare it immediately before use. “This means that you disinfect and inspect the unit right before a session, even if you cleaned it the night before or hours before.”

Under Disinfectants, Sanitizers, and Tools and Procedures for Cleaning and Disinfection, the procedures described are to be used in exact accordance with the instructions provided. Only the disinfectants listed may be used with the System.

- Zep Attack A¹ – broad spectrum disinfectant used on the basin.
- Zep Conquer – disinfectant and deodorizer used on the basin.
- Chlorine bleach – deodorizer and stain remover used on the basin
- Metrex Cavicide – intermediate level disinfectant used for cleaning and disinfection of the tanks and exit lines of the system. according to the instructions, use full strength in spray bottle and thoroughly wet the sides and bottom of the precleaned main tank. Let the excess flow down into the exit lines. Pour 8 oz of full strength Cavicide down the previously drained exit lines to fill up the entire line, allow the Cavicide to stand in the tank and lines for a total of 10 minutes for disinfection. Rinse once for 30 seconds and drain tank. Rinse a second time by filling tank to 1 gallon mark and drain, repeat for a third rinse.

Chapter 2 – Control Switch Panels

Lights – on control tower only. This switch turns on all lights for the inside and outside viewing tube areas and inside tower cabinet to illuminate tank water level. This switch also activates all other switches. When this switch is OFF all other switches and their function is OFF.

UV – activates the ultraviolet light in UV filter. Should be turned ON just prior to water flowing to the patient. Should be turned OFF when session stops for more

than a couple of minutes.

Cycle – activates the water cycling device to move water from larger main tank to small recirculating tank. This is supposed to keep water temperature evenly mixed throughout entire tank.

Flow – activates solenoid valve that allows water flow from tank to the patient. There is a small indicator light next to the flow switch that lights up when the water is flowing.

Temperature Gauge and Temperature Controller with Sensor – located on the front of the tower cabinet, visible to the patients or the health care practitioner. It shows the water temperature and can also show the room temperature (button is pushed). If the water temperature exceeds 104°F the solenoid valve shuts off the water flow.

Chapter 3 – Valves provides a brief description for all of the valves

Chapter 4 describes the valve sequences for system operation.

Chapter 5 describes the System Maintenance. Although the system is designed to be “virtually maintenance free” there are some items that will occasionally need to be replaced.

Filters – carbon cartridge (for initial tank filtration before water enters large main tank) should be replaced every 15,000 gallons or 3 months. The sediment filter in the UV light filter should be replaced every 16,000 gallons or 4 months.

Batteries in Temperature Gauge – when the gauge display begins to fade, the “AAA” batteries should be replaced. The user is told to never operate the system without a functioning temperature gauge.

Diaphragm Plunger inside Solenoid Valve – this valve has a diaphragm plunger inside the brass body that will begin to leak water when it needs to be replaced.

Light bulbs – the bulbs for the viewing tube and tank tower should last from 9000 to 10,000 hours.

UV Lamp – the UV lamp is rated for 7,500 hours of continuous use and not longer than 24 months of intermittent use. The practitioner should keep a log of UV lamp replacement and servicing dates to know when 7,500 hours or 24 months have elapsed.

Chapter 6 Trouble Shooting Guide – provides a description of a problem and the corrective action.

RECOMMENDATION

The sponsor has provided adequate information for their premarket notification for the proposed device. They have demonstrated that the device:

1. will shut down if the water temperature exceeds 104°F,
2. that because this is a gravity flow device and the speculum does not occlude the colon while in use, that the colon pressure will not exceed 2 psi, and
3. the System is disinfected between each patient using an intermediate level disinfectant.

I am recommending that the Angel of Water™ Colon Hydrotherapy System be found substantially equivalent to their legally marketed colon irrigation devices.

Kathleen M. Olvey, 6/27/02
Kathleen M. Olvey

*C Neuland
6/27/02*

- | | |
|---|------------------------------------|
| 1. Is the device life-supporting or life sustaining? | no |
| 2. Is the device implanted (short-term or long-term)? | no |
| 3. Is the device software-driven? | no |
| 4. Is the device sterile? | no (irrigator)/yes (rectal nozzle) |
| 5. Is the device for single use? | no |
| 6. Is the device for home use? | no |
| 7. Is the device for prescription use? | yes |
| 8. Does the device contain a drug or biological? | no |
| 9. Is this device a component of a kit? | no |

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

1. EXPLAIN WHY NOT A DEVICE:

2. EXPLAIN WHY NOT SUBJECT TO A 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:

DATE: June 19, 2002

FROM: Kathleen Olvey, Biologist
Gastrointestinal and Renal Devices Branch, DRARD

SUBJECT: Lifestream Purification System "Angel of Water" Colon Hydrotherapy System, K003720

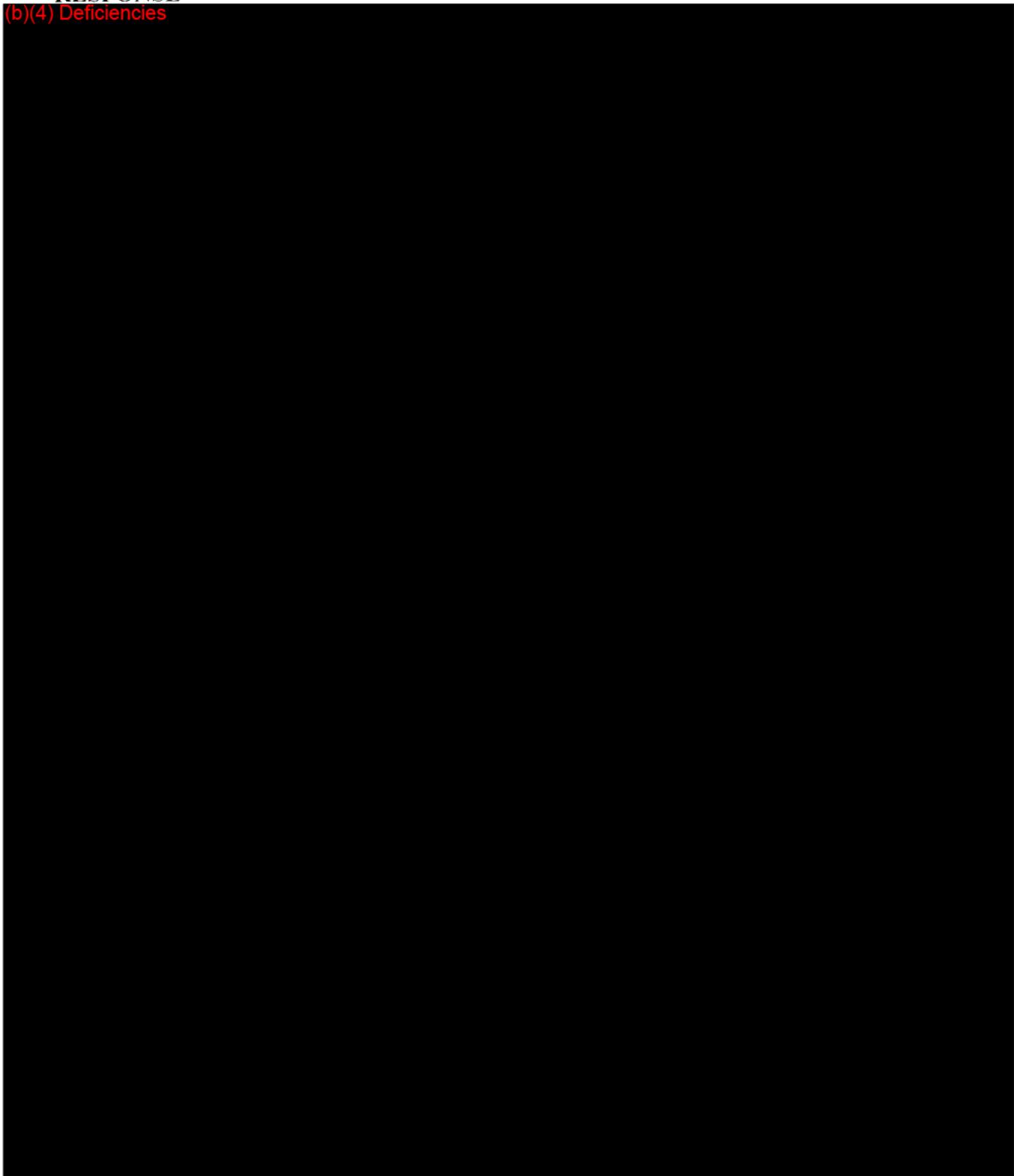
TO: The Record CONTACT: Amy Heilman
(512) 707-3773

The premarket notification for the Angel of Water Colon Hydrotherapy System was originally received on December 4, 2000. A request for additional information was sent to the sponsor on March 2, 2001 (response received 8/1/01), and another request for information was sent on October 30, 2001 (response received on 1/17/02). After reviewing that response it appeared that the sponsor was confused regarding our request (b)(4) Deficiencies [REDACTED]. The sponsor was sent a final request for information on April 17, 2002. The sponsor contacted the FDA to discuss our questions and before their response was submitted we discussed (b)(4) [REDACTED] (b)(4) [REDACTED] with their device. The sponsor then responded to our request for additional information (letter received on May 20, 2002). The contact for the submission is now Amy Heilman from Lifestream and not the consultant Richard Hamer.

(b)(4) Deficiencies [REDACTED]

RESPONSE

(b)(4) Deficiencies



(b)(4) Deficiencies

RECOMMENDATION

Although it has taken four rounds of review the sponsor has adequately addressed all the issues pertaining to their premarket notification. They have demonstrated that the device:

1. will shut down if the water temperature exceeds 104°F,
2. that because this is a gravity flow device and the speculum does not occlude the colon while in use, that the colon pressure will not exceed 2 psi, and
3. the System is disinfected, using an intermediate level disinfectant, between patients.

I am recommending that the Angel of Water™ Colon Hydrotherapy System be found substantially equivalent to their legally marketed colon irrigation devices.

Kathleen M. Olvey 6/27/02
Kathleen M. Olvey

*C. Newland
6/27/02*

Lifestream

Purification Systems, LLC
2001 South Lamar, Suite G
Austin, Texas 78704
Phone 512-707-3773

Facsimile Cover Sheet

Date: 6/26/02
To: Kathy Olvey, FDA
Fax number: 301-594-2339
From: Amy Heilman, General Manager

Number of pages (including cover): 3
Special instructions:

www.angelofwater.com

Lifestream

Purification Systems, LLC
2001 South Lamar, Suite G
Austin, Texas 78704
Phone 512-707-3773

VIA FAX

26 June 2002

Office of Device Evaluation
Document Mail Center (HFZ - 401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: K003720 Angel of Water™ Colon Hydrotherapy System
Amendment #3
Lifestream Purification Systems, LLC, Austin, Texas

Dear Kathy,

The Indications for Use, the Patient Population (both in the manual), and the physical label on the actual system now all agree in their language:

This device is for colon irrigation when medically indicated, such as before radiological or endoscopic examination.

Just as soon as you have our clearance letter, please fax it to the Radisson Hotel in Orlando:

Fax number: 407-345-2995
C/O Lifestream Purification Systems, LLC
Rocco benRoy, guest
Arrival date: 6/27/02

Sincerely and gratefully,



Amy Hellman
General Manager

A portion of the proceeds from the sale of these systems goes to charitable purposes.
www.angelofwater.com, www.angelofwater.net

Lifestream

Indications for Use

This device is for colon irrigation when medically indicated, such as before radiological or endoscopic examination.

Patient Population

This device is for patients in need of colon irrigation when medically indicated, such as before radiological or endoscopic examination.

Setting

The Angel of Water™ Colon Hydrotherapy System is intended for use in a clinical setting by a trained and certified health care practitioner under the order of a physician.

Contraindications for Use

The contraindications for the use of the Angel of Water Colon Hydrotherapy System include, but may not be limited to:

- congestive heart failure
- intestinal perforation
- carcinoma of the rectum
- fissures or fistula
- severe hemorrhoids
- abdominal hernia
- renal insufficiency

Lifestream

Purification Systems, LLC
2001 South Lamar, Suite G
Austin, Texas 78704
Phone 512-707-3773

Facsimile Cover Sheet

Date: 6/21/02
To: Ms. Kathleen M. Olvey,
Gastroenterology and
Renal Devices Branch, FDA
Fax number: 301-594-2339
From: Amy Heilman, General Manager

Number of pages (including cover):
Special instructions:

16

Dear Kathy,

Here is the missing information you requested.

Thanks,

Amy

① Answer to Question #3
omitted from Amendment 3

② (b)(4) Deficiencies [redacted] Chapter 1
in its

entirety.

www.angelofwater.com



Lifestream

Purification Systems, LLC
2001 South Lamar, Suite G
Austin, Texas 78704
Phone 512-707-3773

VIA FAX

21 June 2002

Office of Device Evaluation
Document Mail Center (HFZ - 401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

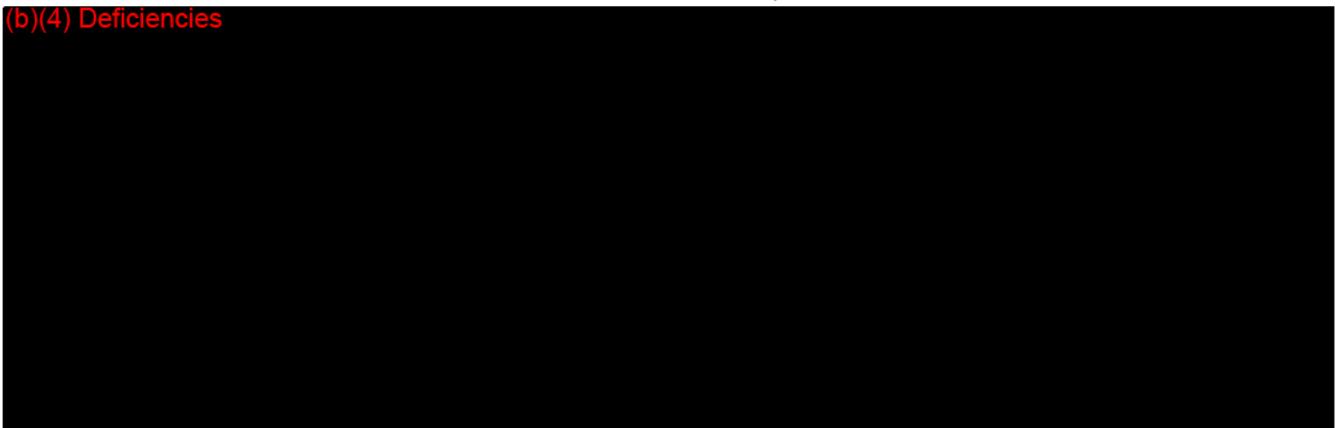
Re: K003720 Angel of Water™ Colon Hydrotherapy System
Amendment #3
Lifestream Purification Systems, LLC, Austin, Texas

Dear Dr. Neuland,

Reference is made to the subject 510(k) premarket notification submitted on behalf of Lifestream Purification Systems, LLC on November 30, 2000 as amended on July 31, 2001 and again on January 15, 2002.

Here is the answer to the missing Question 3 of our May 18, 2002 Amendment #3 document:

(b)(4) Deficiencies



25

4

(b)(4) Deficiencies



Please alert me if there are any issues requiring further clarification and thank you for this opportunity to redress missing information via fax. We are very grateful.

Sincerely,



Amy Heilman
General Manager

A portion of the proceeds from the sale of these systems goes to charitable purposes.
www.angelofwater.com, www.angelofwater.net

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Chapter 1

Instructions for Use

THE ANGEL OF WATER™ COLON HYDROTHERAPY SYSTEM, INCLUDING THE TANKS AND WATER LINES, MUST BE DISINFECTED BETWEEN EACH PATIENT ACCORDING TO THE PROTOCOLS SET FORTH IN THIS CHAPTER.

Safety First

Safety is your primary responsibility. You must always assume the System is **NOT** ready until you prepare it immediately before use. Always clean and disinfect your System immediately after use, and immediately before each use. This means that you disinfect and inspect the unit right before a session, even if you cleaned and disinfected it the night before or hours before.

If you clean and disinfect the System and then leave the building where your System is located, and then you return to use the System, clean and disinfect it again. You do not know what may have transpired in your absence.

This attitude assures that you **ALWAYS** begin each session hygienically. Plus, it gives you enormous peace of mind in serving others.

Disinfectants, Sanitizers, and Tools and Procedures for Cleaning and Disinfection

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The disinfectants, sanitizers, and tools and procedures described below are to be used in exact accordance with the instructions provided below for the care and upkeep of your System. Only the disinfectants given here may be used with the Angel of Water™ Colon Hydrotherapy System.

WARNING: No other disinfectant, sanitizer, tool, or procedure may be substituted for those given here in the cleaning and disinfection protocols for your System.

REMEMBER: Always clean and disinfect your System immediately after use and immediately before each use!

Disinfectants and Sanitizers for use on the Angel of Water™ Colon Hydrotherapy System

1) **Zep Attack-A¹:**

Broad-spectrum hospital grade disinfectant with label claim for virucidal activity against HIV used for the pre-session preparation and the post-session cleaning and disinfection of the **basin** of the System.

Instructions for Use: Mix 1 oz. of Attack-A per one gallon of water for your buckets #1 and #2 and spray bottle containers as described below. Allow Attack-A solution to contact basin surface and parts for a total of 10 minutes for

¹ *Attack-A* and *Air Fair Conquer* are products of Zep Manufacturing Company and are available through Lifestream Purification Systems, LLC.

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disinfection, per manufacturer's labeling instructions.

- 2) **Chlorine bleach (sodium hypochlorite):**
Deodorizer and stain remover used during the post-session cleaning and disinfection of the **basin** of the System.

Instructions for Use: Mix 1 capful of bleach per one gallon of water for a 200ppm solution in your Bucket #3. Allow bleach solution to contact basin surface for 1 minute to act as a deodorizer and stain remover ONLY.

- 3) **Zep Air Fair Conquer¹:**
Deodorizer used during the post-session cleaning and disinfection of the **basin** of the System.

Instructions for Use: Use full-strength Conquer in spray bottle to spray a fine mist into basin trough and on splashguard to act as a deodorizer ONLY. Towel dry and wipe surfaces dry of excess chemicals, per manufacturer's labeling instructions.

- 4) **Metrex Cavicide²:**
Intermediate-level disinfectant with tuberculocidal activity for post-session cleaning and disinfection of the **tanks and exit line** of the System.

Instructions for Use: Use full-strength Cavicide in spray bottle to spray a strong spray of disinfectant and thoroughly wet the sides and bottom of the pre-cleaned main tank. Let the excess flow down into

² Cavicide is a product of Metrex and is available through Lifestream Purification Systems, LLC.

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the exit lines. Pour 8 oz. of full-strength Cavicide from the manufacturer's container down into the previously drained exit lines to fill up the entire line. Allow Cavicide to stand in the tank and lines for a total of 10 minutes for disinfection, per manufacturer's labeling instructions.

After 10 minutes, thoroughly rinse the tank and lines in the following manner: Rinse once for 30 seconds and drain tank. Rinse a second time by filling tank to 1-gallon mark and drain. Rinse a third time by filling tank to 1-gallon mark and drain.

NOTE: You will now be taken through the instructions for use and the cleaning and disinfection protocols of the Angel of Water™ Colon Hydrotherapy System step by step and in full detail.

The following are the tools you will need:

- 1) **Degreaser and Tether Mop** - for periodic cleaning of Viewing Tube
- 2) **3 Buckets (one gallon size) / with Soft Mops** - two for Attack-A mixture, the third for chlorine bleach solution for deodorizing and stain removal
- 3) **Body Protection** - rubber gloves, eye or face shield, towel or respirator for lung protection
- 4) **Miscellaneous** - 3 spray containers (one for Attack-A mixture, one for Air Fair Conquer mixture, one for Cavicide); cotton balls; funnel for safe pouring;

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paper towels for used nozzle and flex tube wrapping and disposal; flex tube line stopper for cleaning and disinfection protocol for tanks and exit line after each session.

The following items are needed also for a successful, hygienic session:

wastebasket with spring-open lid and plastic liners
petroleum jelly lubricant and tube dispenser
paper towels and/or toilet tissue
cotton balls (sterile)
facial tissues
towels for hand wiping and drying of System
floor rug of a non-slip type
disposable gloves

Procedures For Sanitizing and Disinfection

Regardless of whether the System was cleaned and disinfected previously, clean and disinfect the basin of the System again if you left the premises where it is located, even if only for a few hours.

A. Pre-Session Preparation:

- 1) Turn System LIGHTS Switch On
- 2) Protect Yourself

Cifestream

- a) Put on rubber gloves, eye shields, and protect respiratory channels with towel or respirator before next step.

3) Spray Attack-A on Basin, Rinse Lines, Towel Dry

- a) Allow a mixture of 1 oz. Attack-A to one gallon of water per manufacturer's instructions to contact basin surface for at least **10 minutes** for maximal disinfection.
- b) Run water from tank through nipple for a couple of minutes to wash out line.
- c) Towel dry System surfaces.

4) Visually Inspect Main Tank

- a) Visually inspect main tank. In the event that tank needs rinsing, do so and drain before filling with water for first session.

5) Connect New Flex Tube and Sterile Rectal Nozzle, Do Final Room Inspection

- a) Connect new flex tube and new sterile, disposable rectal nozzle to flex tube, then lubricate nozzle to conduct session.
- b) Inspect room for readiness before having person enter for session.

B. Post-Session Cleaning and Disinfection:**1) Protect Yourself**

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- a) Put on rubber gloves, eye shields, and protect respiratory channels with towel or respirator before using chemicals.

2) Remove Soiled Linens from System Area

- a) Place soiled linens in laundry basket.

3) Spray Attack-A Disinfectant into Basin and Water Rinse, then Mop with Attack-A Disinfectant (Bucket #1), Water Rinse

- a) Spray a fine mist of Attack-A into the basin trough, including used nozzle and flex tube, personal shower sprayer, and all basin topside control knob handles.
- b) Water rinse obvious waste material down drain. Turn on View Tube Flush Valve as needed to clear drain line.
- c) Mop wash entire basin *and* used nozzle and flex tube with Attack-A (Bucket #1)(1 oz. Attack-A to one gallon of water). Water rinse everything down drain again.

4) Remove Used Nozzle and Flex Tube, Rinse Out Line

- a) With paper towel, grasp and pull out nozzle and flex tube from brass nipple together. Bend nozzle in half and wrap it and used flex tube in paper towel and dispose of both in wastebasket.
- b) Turn water flow on and rinse out line.

*Cifestream***5) Disinfect Main Tank and Exit Line to Basin Nipple**

At the end of every session, you must disinfect the main tank and the exit line of the Angel of Water™ Colon Hydrotherapy System. These components are considered indirect patient-contacting components and must therefore undergo the following protocol after each session:

- a) Drain main tank completely and then close Valves #2 and #6. Open Valves #3 and #4.
- b) Place the **flex tube line stopper** (provided with your System) onto the end of the brass nipple in the basin trough in order to block the exit line.
- c) Using your spray bottle of **Cavicide**, apply **Cavicide**, a ready-to-use, full-strength formulation, to the sides of the main tank, making sure you have a good, strong spray of disinfectant to thoroughly wet the sides and bottom of the tank. Let the excess flow down into the line.
- d) Pour 8 oz. of Cavicide into the bottom of the main tank so that it can flow into and fill the entire exit line. Go back and temporarily remove flex tube line stopper to release excess air from the line. Once air escapes, replace stopper onto brass nipple. Cavicide can now fill entire line for disinfection.

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- c) Allow Cavicide to stand in the line for **10 minutes at room temperature** while continuing to clean and disinfect the basin, using the personal shower sprayer as your rinse water source.

6) Mop with Attack-A Disinfectant (Bucket #2), Water Rinse**(Degrease View Tube as needed)**

- a) Mop wash entire basin area again with Attack-A (Bucket #2)(1 oz. Attack-A to one gallon of water).

Per manufacturer's instructions, make sure that the combined contact time of Buckets #1 and #2 (Zep Attack-A solution) on the basin surface is at least **10 minutes** for maximal disinfection.

- b) Water rinse entire basin again well.
- c) Degrease Drain Pipe Viewing Tube in this step when build-up of petroleum jelly lubricant warrants this procedure. Use the tether mop and degreaser to scrub tube.

7) Mop with Chlorine Bleach Deodorizer (Bucket #3), Water Rinse

- a) Mop wash entire basin area with diluted chlorine bleach solution (Bucket #3)(1 capful to one gallon of water for a 200ppm solution). Let solution contact surface for 1 minute. Chlorine bleach acts as a deodorizer and stain remover **ONLY**.

8) Spray Air Fair Conquer, Towel Dry

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- a) Spray a fine mist of Air Fair Conquer into the basin trough and splashguard to deodorize **ONLY**.
- b) Towel dry and wipe all surfaces of excess chemicals and water.

9) Finish Disinfection of Main Tank and Line

- a) After cleaning and disinfecting the basin and at the end of **10 minutes**, again using the shower sprayer as your rinse water source, remove the flex tube line stopper and thoroughly rinse the main tank for 30 seconds of full-force spray. (This will exceed 1 gallon of water). Allow rinse water to flow out through the brass nipple in the basin trough. This is **Rinse #1**.
- b) Close Valve #4 (Valve #2 is still closed) and allow water in tank to fill up to 1-gallon rinse water mark on main tank for **Rinse #2**. Drain water by opening Valve #4 so that water comes out through basin nipple again.
- c) Close Valve #4 **AGAIN** and allow water in tank to fill up to 1-gallon rinse water mark on main tank for **Rinse #3**. Drain water **AGAIN** by opening Valve #4 **AGAIN**.
- d) Now close Valves #3 and #4 and open Valve #6.

10) At the conclusion of the treatment day, drain all water from the main tank, the recirculating (small) tank, and the lines. If another session is to be conducted continue to Step 11. If the treatment day is concluded, however, you must drain all water from the

Ctfestream

system. Do this by opening Valves #2, #3, and #4. **Remember to reset valve sequence to that of Regular Operation Mode (Close #2, #3, and #4, and Open #6) at the beginning of the next treatment day.**

11) Replace Linens, Do Final Inspection

- a) Put on a fresh pillowcase and supply a fresh cover cloth. Rotate and launder the pillow if it got wet for any reason. Have a number of linens/pillows to rotate and have them clean and ready as required.
- b) Wipe lavatory, glasses, and mirrors and inspect room for overall cleanliness before next session or before finishing for the day.

12) Run Properly Tempered Water through Line, Connect New Flex Tube and New Sterile, Disposable Rectal Nozzle

- a) Rinse out line with properly tempered water, 99 to 103 degrees Fahrenheit.
- b) Connect new flex tube and new sterile, disposable rectal nozzle to flex tube, then lubricate nozzle to conduct session.
- c) Inspect room for readiness before having next person enter for session.

Always clean and disinfect the System directly after a session. Do not postpone for any reason. Clean and disinfect the System properly NOW! Always give the first impression and guarantee of cleanliness and hygiene.

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 10, 2001

LIFESTREAM PURIFICATION SYSTEMS, LLC 510(k) Number: K003720
C/O RICHARD HAMER ASSOCIATES, INC Product: ANGEL OF WATER
6401 MEADOWS WEST DR. COLON
FORT WORTH, TX 76132 HYDROTHERAPY
ATTN: RICHARD A. HAMER 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. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K003720/S'

K003720

510(k) Premarket Notification Amendment

Angel of Water™

Colon Hydrotherapy System

RECEIVED

AUG 1 3 12 PM '01

FDA/CDRH/OCE/DMC

Lifestream Purification Systems, LLC

2001 South Lamar, Suite G

Austin, Texas 78704

Submission Date: July 31, 2001

SKH1

160

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Premarket Submission Cover Sheet

Date of Submission: July 31, 2001

FDA Document Number:

Section A

Type of Submission

- | | | | |
|--|---|--|---|
| <input type="checkbox"/> 510(k) | <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement Regular |
| <input checked="" type="checkbox"/> 510(k) Add Information | <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement Special |
| | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report | <input type="checkbox"/> PMA Supplement 30 Day |
| | <input type="checkbox"/> IDE Report | | <input type="checkbox"/> PMA Supplement Panel Track |

Section B1

Reason for Submission - 510(k)s Only

- | | | |
|--|---|--|
| <input checked="" type="checkbox"/> New Device | <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in technology, design, materials, or manufacturing process |
| <input type="checkbox"/> Other reason (specify): | | |

Section B2

Reason for Submission - PMAs Only

- | | | |
|---|--|---|
| <input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf life <input type="checkbox"/> Trade name <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Response to FDA correspondence (specify below) <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site | <input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor <input type="checkbox"/> Report submission: <input type="checkbox"/> Annual or periodic <input type="checkbox"/> Post-approval study <input type="checkbox"/> Adverse reaction <input type="checkbox"/> Device defect <input type="checkbox"/> Amendment |
|---|--|---|

Section B2

Reason for Submission - IDEs Only

- | | | |
|---|--|--|
| <input type="checkbox"/> New Device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion/extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <input type="checkbox"/> Termination of study <input type="checkbox"/> Withdrawal of application <input type="checkbox"/> Unanticipated adverse effect <input type="checkbox"/> Emergency use: <input type="checkbox"/> Notification of emergency use <input type="checkbox"/> Additional information <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing <input type="checkbox"/> Protocol feasibility <input type="checkbox"/> Protocol other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current investigator <input type="checkbox"/> Annual progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final | <input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approved <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input type="checkbox"/> Deficient investigator report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting <input type="checkbox"/> IDE submission only: <input type="checkbox"/> Change in IDE style <input type="checkbox"/> Request for protocol waiver |
|---|--|--|

161

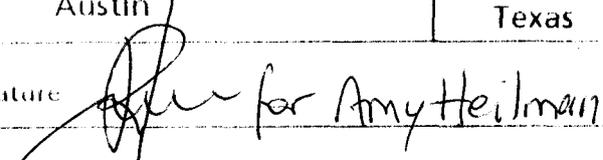
| | | | | | |
|--|------------------------------------|--------------------------|---|---|-----|
| | | | | FDA Document Number: | |
| Section C | | | Product Classification | | |
| Product Code: 78 KPL | | C.F.R. Section: 876.5220 | | Device Class: | |
| Classification Panel: Gastroenterology - Urology | | | | <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified | |
| Section D | | | Information on 510(k) Submissions | | |
| Product codes of devices to which substantial equivalence is claimed: | | | | Summary of, or statement concerning safety and effectiveness data. | |
| 1. 78 KPL | 2. | 3. | 4. | <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement | |
| 5. | 6. | 7. | 8. | | |
| Information on devices to which substantial equivalence is claimed: | | | | | |
| 510(k) Number | Trade or proprietary or model name | | | Manufacturer | |
| 1. K881720 | 1. Jimmy John III | | | 1. Colon Therapeutics, Inc. | |
| 2. K962259 | 2. Libbe Rectal Tube | | | 2. Tiller Mind and Body, Inc. | |
| 3. | 3. | | | 3. | |
| 4. | 4. | | | 4. | |
| 5. | 5. | | | 5. | |
| 6. | 6. | | | 6. | |
| Section E | | | Product Information - Applicable to All Applications | | |
| Common or usual name or classification name: | | | | | |
| Colonic Irrigation System | | | | | |
| Trade or proprietary or model name | | | | Model number | |
| 1. Angel of Water™ Colon Hydrotherapy System | | | | 1. | |
| 2. | | | | 2. | |
| 3. | | | | 3. | |
| 4. | | | | 4. | |
| 5. | | | | 5. | |
| 6. | | | | 6. | |
| FDA document numbers of all prior related submissions (regardless of outcome): | | | | | |
| 1. | 2. | 3. | 4. | 5. | 6. |
| 7. | 8. | 9. | 10. | 11. | 12. |
| Data included in submission <input type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal trials <input type="checkbox"/> Human trials | | | | | |
| Indications (from labeling): | | | | | |
| For colon cleansing when medically indicated, such as before radiological or endoscopic examination. | | | | | |

| | | | |
|--|---|--|---|
| | | FDA Document Number: | |
| Section F | | Manufacturing / Packaging / Sterilization Sites | |
| <input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | FDA establishment registration number: Applied for | <input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer | <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler |
| Company / Institution name: Lifestream Purification Systems, LLC | | | |
| Division name (if applicable): | | Phone number (include area code) (512) 707-3773 | |
| Street Address: 2001 South Lamar, Suite G | | FAX number (include area code) (512) 707-9665 | |
| City Austin | State / Province Texas | Country: USA | ZIP / Postal Code 78704 |
| Contact name: Amy Heilman | | | |
| Contact title: General Manager | | | |
| <input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | FDA establishment registration number: | <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer | <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler |
| Company / Institution name: | | | |
| Division name (if applicable): | | Phone number (include area code) | |
| Street Address: | | FAX number (include area code) | |
| City | State / Province | Country: | ZIP / Postal Code |
| Contact name: | | | |
| Contact title: | | | |
| <input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | FDA establishment registration number: | <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer | <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler |
| Company / Institution name: | | | |
| Division name (if applicable): | | Phone number (include area code) () | |
| Street Address: | | FAX number (include area code) () | |
| City | State / Province | Country: | ZIP / Postal Code |
| Contact name: | | | |
| Contact title: | | | |

FDA Document Number:

Section G

Applicant or Sponsor

| | | | |
|--|----------------------------------|---|-----------------------------------|
| Company / Institution name: Lifestream Purification Systems, LLC | | FDA establishment registration number: Applied for | |
| Division name (if applicable): | | Phone number (include area code) (512) 707-3773 | |
| Street Address: 2001 South Lamar, Suite G | | FAX number (include area code) (512) 707-9665 | |
| City: Austin | State / Province Texas | Country: USA | ZIP / Postal Code 78704 |
| Signature:  | | | |
| Name: Amy Heilman | | | |
| Title: General Manager | | | |

Section H

Submission correspondent (if different from above)

| | | | |
|--|----------------------------------|---|-----------------------------------|
| Company / Institution name: Richard Hamer Associates, Inc. | | Phone number (include area code) 817-294-3644 | |
| Division name (if applicable): | | FAX number (include area code) 817-294-3761 | |
| Street Address: 6401 Meadows West Dr. | | | |
| City: Fort Worth | State / Province Texas | Country: USA | ZIP / Postal Code 76132 |
| Contact name: Richard A. Hamer | | | |
| Contact title: Consultant to Lifestream Purification Systems, LLC | | | |



RICHARD HAMER ASSOCIATES, INC.
REGULATORY CONSULTANTS

VIA FEDERAL EXPRESS

July 31, 2001

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20857

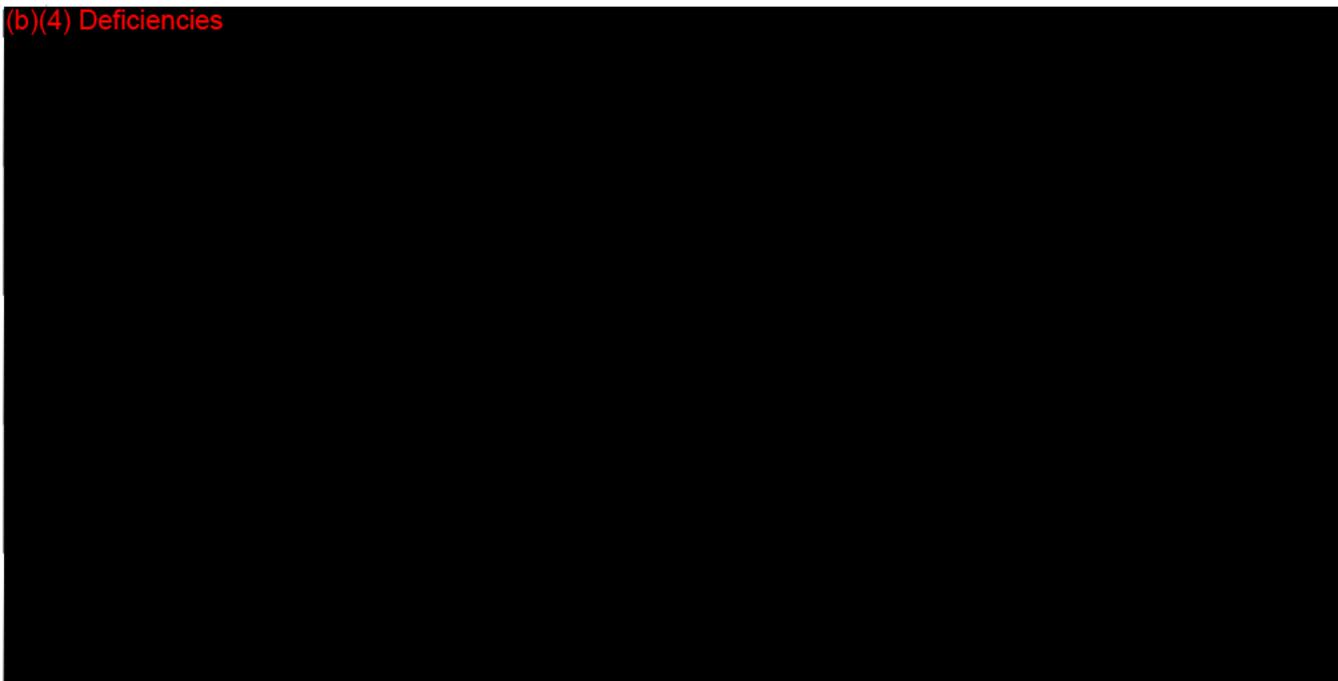
Re: K003720 Angel of Water™ Colon Hydrotherapy System
Lifestream Purification Systems LLC, Austin, Texas

Gentlemen:

Please refer to the subject premarket notification submitted on behalf of Lifestream Purification Systems, LLC on November 30, 2000. Reference is also made to Dr. Neuland's letter of March 2, 2001 requesting additional information, and to our letter of March 14, 2001, requesting an extension of the 510(k) review period until July 31, 2001.

We are pleased to submit herewith, on behalf of Lifestream Purification Systems, LLC, duplicate copies of an amendment to K003720 addressing each of the questions raised in Dr. Neuland's letter. For convenience of the reviewer, each of the questions is listed below, followed by our response:

(b)(4) Deficiencies



(817) 294-3644 • Fax (817) 294-3761 • E-mail: rhamer@hamerassoc.com

Questions? Contact ~~Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, Washington, DC 20205~~ or 301-796-8118
Mailing address: P.O. Box 16598, Ft. Worth, TX 76162-0598

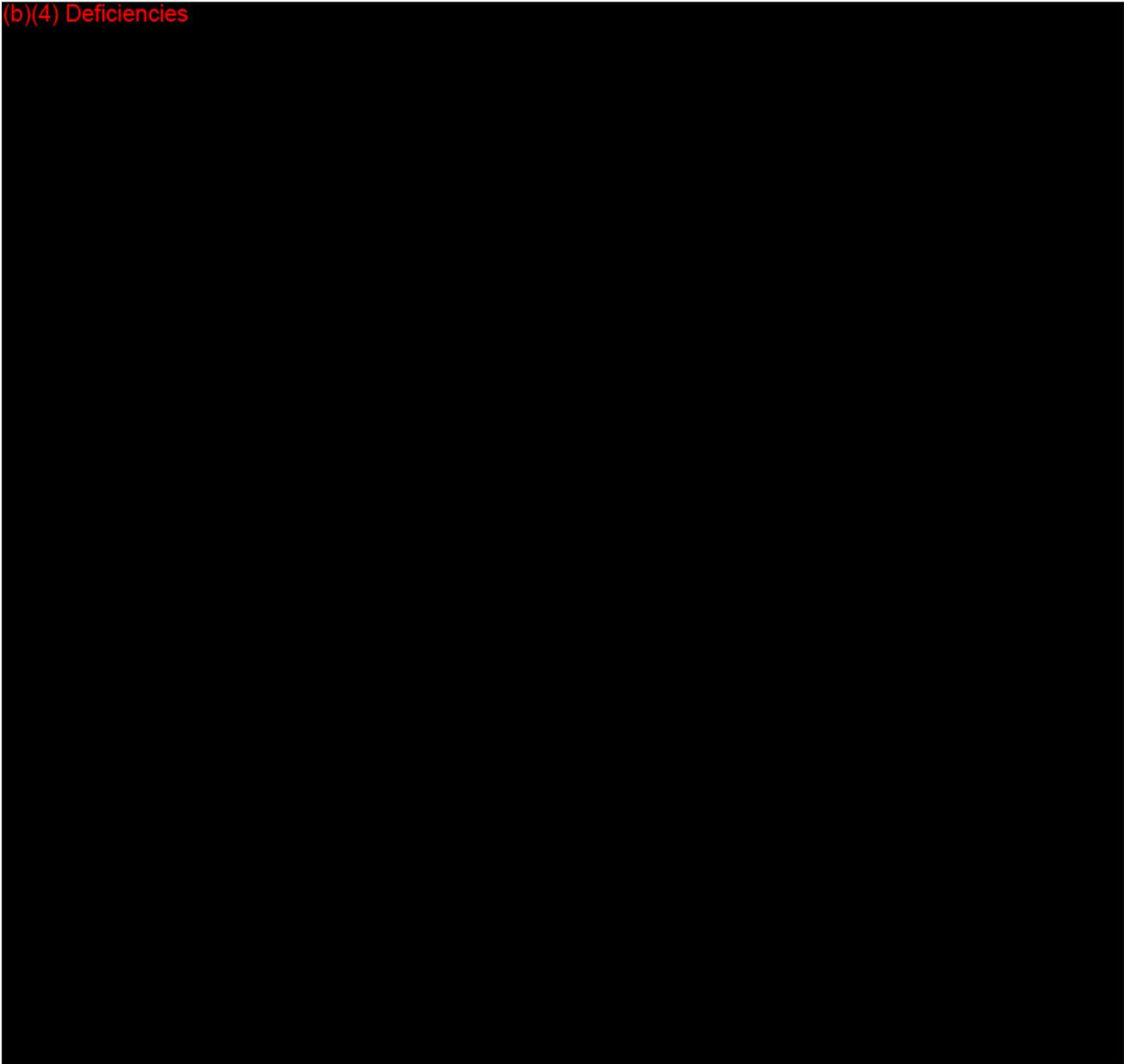
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FDA/CDRH/ODE

K003720

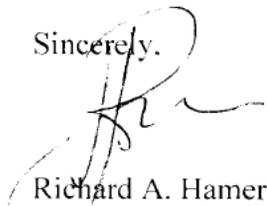
Page 7

(b)(4) Deficiencies



We trust that the information provided herewith will permit you to complete a satisfactory review of this 510(k) premarket notification and to issue a substantial equivalence determination. Should you have any questions or require additional information, please do not hesitate to call me.

Sincerely,



Richard A. Hamer
Consultant to Lifestream Purification Systems, LLC

**Description of Components Used in the
Angel of Water™ Purification System**

| Components | Dimensions (Approx. L x W x H) | Materials | Function |
|---|--|--|---|
| Basin Cabinet | 72" x 25" x 24" | Laminated 3/4" ply-wood | Cabinet for system foundation |
| Tower Cabinet | 23" x 8" x 67" | Laminated 3/4" ply-wood | Cabinet for system foundation |
| Backrest (movable) | 16" x 21" x 12" | Vinyl-covered foam rubber | Back support for various positions |
| Basin and Splash-guard | 60" x 25" x 16" | Fiberglass | Console seat and backrest foundation on which patient reclines |
| Pipes | 1/2", 3/4", and 2" diameter | (b)(4) | For lines, drain pipes assembly, and tank overflow plumbing |
| Hot and Cold Mixing Valve | 2.5" x 2.5" x 4.5" | Brass and chrome body and acrylic handle | Mixes hot and cold water before it enters into main tank and mixes water for the personal shower sprayer |
| Viewing Tube Flush Sprayer | 4.5" x 1" | Brass | Creates a jet stream of water to flush the viewing tube |
| Viewing Tube Flush Valve | 3.25" x 1" x 5.5" | Brass and chrome | Flushes viewing tube of waste matter |
| Sprayer Volume Control Valve | 3.25" x 1" x 5.5" | Brass and chrome | Modulates the flow of water for personal shower sprayer |
| Personal Shower Sprayer | 5.5" x 1" | Plastic and chrome | Personal rinsing of the body after evacuation session. Rinses the basin after disinfection. |
| Main Water Tank | 26.25" x 14" cylindrical tank, conical shaped bottom | (b)(4) | Holds 12 gallons for average 30 to 40 minute session. |
| Recirculating (Small) Tank | 24" x 2.5" cylindrical shaped 2" PVC pipe | (b) | To recirculate water from main tank to small tank and back again to keep water temperature even and to provide an even, consistent flow of water to patient as water level in main tank decreases |
| Carbon Filter (See System Parts Packet for Keller housing and GE FXWTC Cartridge) | 12.5" x 5.25" 3/4" NPTF Max temp. 125 degrees F. | Housing Head: (b) (b)(4) Clear bowl: (b)(4) | Filters the water before it enters main tank and system. Reduces sediment, rust and chlorine. |
| U.V. Filter (See System Parts Packet for Ultradynamics housing and GE FXWPC Cartridge) | 15" x 5" x 6" | Corrosion proof, reinforced (b)(4) reactor chamber | To U.V. treat and filter sediment from water leaving tank before entering patient. |
| Solenoid Valve (See System Parts Packet for ASCO literature) | 2.75" x 2" x 3.5" | Brass construction. General purpose (b)(4) Solenoid enclosure. | To allow water to be sent to patient electrically by activation of the FLOW switch |

**Description of Components Used in the
Angel of Water™ Purification System (Cont'd)**

| | | | |
|---|---|--|--|
| Water Cycling Device (Pump) (See System Parts Packet for Little Giant Pump Co. literature) | 4.75" x 2.5" x 3.75" | Plastic parts are (b)(4); Spindle shaft is (b)(4); Thrust washers are (b)(4); Impeller driven magnet is (b)(4); seal is (b)(4) | Circulates water from main tank to small tank |
| Delta Tank Level Valve | 3.5" x 2.5" x 12" | (b)(4) body | To fill and automatically shut off water once the main tank is full |
| Viewing Mirror | 12" x 6" x 1/8" | Acrylic | Allows patient to view waste matter and water leaving the body in basin viewing tube |
| Basin Viewing Tube | 12" x 2.5" | (b)(4) | Allows patient and procedure monitor to view waste matter and water leaving through clear drain |
| External Viewing Tube | 24" x 2.5" | (b)(4) | Allows patient and procedure monitor to view waste matter and water leaving through additional clear drain section |
| Basin Viewing Window | 13.75" x 1/4" x 12.5" | Clear Acrylic | Covers the basin cabinet viewing box |
| Tower Viewing Window | Side: 15" x 2" x 4" Front: 15" x 2" x 4" | Clear and White Acrylic | Provide viewing windows for water level in tower cabinet |
| Clean, Disposable Flex Tube | I.D. .375" O.D. .563" 5.5" Long | (b)(4) | Connects brass nipple of basin to sterile, disposable rectal nozzle |
| Sterile, Disposable Rectal Nozzle K962259 | 10.5" x 1/4" | (b)(4) | To allow water from system to enter into colon |
| Basin Backflow Prevention (Ball Check) Valve | 4" x 12" x 2" | (b) | Prevents water entering colon from being pushed back into line. Positioned directly behind the brass nipple coming through the fiberglass wall |
| Viewing Tube Sprayer Backflow Prevention (Spring-loaded) Valve | 4" x 2" x 2" | (b) | Prevents water flushed into viewing tube from backing into clean water line |
| Temperature Gauge | 3" x 0.5" x 2.25" | Plastic body and sensor on wire. Requires one AAA battery | To measure water temperature and give a digital. Read-out visible to patient and to monitoring technician. |
| #1 Tank Fill Valve | 1/2" threaded full port valve body: 2" x 1" handle: 3.5" x 5/8" | Brass and (b)(4) | When open, steel ball allows water to enter Delta tank level valve and then to enter into main tank |
| #2 Tank Drain Valve | 3/4" threaded full port valve. body: 2" x 1.25" handle: 3.5" x 5/8" | Brass and (b)(4) | When open, drains water from main tank into drain line |

3
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**Description of Components Used in the
Angel of Water™ Purification System (Cont'd)**

| | | | |
|------------------------------------|--|--------------------------------|---|
| #3 Tank Exit Valve | 1/2" threaded full port valve. body: 2" x 1" handle: 3.5" x 5/8" | Brass and stainless steel ball | When open, allows water to leave main tank (in conjunction with Manual Flow Inlet Valve [#4]) without flowing through water cycling device. When open, used for disinfection of tank and lines. This valve is closed in Regular Operation Mode. |
| #4 Manual Flow Inlet Valve | 1/2" threaded full port valve body: 2" x 1" handle: 3.5" x 5/8" | Brass and stainless steel ball | Allows water to leave either tank and flow directly to basin (bypassing Solenoid valve and U.V. filter). When open, used for disinfection of tank and lines. This valve is closed in Regular Operation Mode. |
| # 5 Solenoid Bypass Valve | 1/2" threaded full port valve body: 2" x 1" handle: 3.5" x 5/8" | Brass and stainless steel ball | Allows water to bypass Solenoid valve if necessary. This valve is open during tank and line disinfection in order to bypass Solenoid valve. |
| #6 U.V. Inlet Valve | 1/2" threaded full port valve body: 2" x 1" handle: 3.5" x 5/8" | Brass and stainless steel ball | Allows water to flow into U.V. filter for treatment. When closed, prevents water from entering U.V. filter. |
| #7 Recirculating Tank Outlet Valve | 1/2" solvent weld valve | (b)(4) | Open for regular operation, allows water to exit small recirculating tank. When closed, prevents water in small tank from leaving |
| #8 Recirculating Tank Bypass Valve | 1/2" threaded full port valve body: 2" x 1" handle: 3.5" x 5/8" | Brass and stainless steel ball | Closed when # 9 valve is open. When open, and # 9 valve is closed, allows water to bypass recirculating tank. For improved flow if necessary. |
| #9 Recirculating Tank Inlet Valve | 1/2" threaded full port valve body: 2" x 1" handle: 3.5" x 5/8" | Brass and stainless steel ball | Allows water into small tank from the main tank via water cycling device (pump). |
| #10 Cold Water Inlet Valve | 1/2" threaded full port valve body: 2" x 1" handle: 3.5" x 5/8" | Brass and stainless steel ball | Allows cold water into system mixing valve |
| #11 Hot Water Inlet Valve | 1/2" threaded full port valve body: 2" x 1" handle: 3.5" x 5/8" | Brass and stainless steel ball | Allows hot water into system mixing valve |
| Cold Water Connection | 1/2" male threaded nipple | (b)(4) | To connect system to external cold water source. It is the top fitting (marked C) located at top left-hand backside of basin cabinet. |
| Hot Water Connection | 1/2" male threaded nipple | (b)(4) | To connect system to external hot water source. It is the lower fitting (marked I-I) located at top left hand backside of basin cabinet. |
| Electrical Terminal Box | 8" x 4" x 8" | (b)(4) (b)(4) | To house electrical terminal block and wire connections. |

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AB

**Description of Components Used in the
Angel of Water™ Purification System (Cont'd)**

| | | | |
|--|---|--|--|
| Water Temperature Controller and Temperature Sensor | 4.75" x 2.25" x 5.5" | Independent Energy Controller: model - SP-34 Sensor: model IM-4 | To sense water temperature and to automatically close Solenoid valve during Regular Mode of Operation if water flowing to patient exceeds 104 degrees F. |
| Tower Control Panel (Lights, UV, Cycle, Flow) | 4.5" x 2" x 7.5" | Selecta Switches mounted in (b)(4) wet location box with acrylic face plate | Electrical switches for the monitoring assistant to activate the, LIGHTS, U.V., CYCLE, and FLOW functions. The LIGHTS switch turns on basin viewing light, tower light, and external viewing tube light as well as activates the other switches. The U.V. switch controls the U.V. Filter. The CYCLE switch activates the water cycling device (pump). The FLOW switch controls the Solenoid valve. The function switch needs to be in ON position in both Tower and Wall-mounted Control panels in order for that function to work. |
| Wall-mounted Control Panel (UV, Cycle, Flow) with cord and connector | 2.75" x 2" x 4.5" box with 7-foot-long cord | Selecta Switches Electrical switches mounted in (b)(4) box with acrylic face plate. Indicator light: Selecta SL53411-6-BG Cable: Alpha 5447C Male Connector: Connxall 13182-7PG-321 Female Connector: Connxall 14182-7SG-300 | Electrical switches within reach of patient that control the U.V., CYCLE, and FLOW functions. Indicator light indicates FLOW is ON. The function switch needs to be in ON position in both the Wall-mounted and Tower control panels in order for that function to work. Cable connects wall-mounted side of tower cabinet (female end) |
| Basin Viewing Tube Light | 5.5" x 2.5" lamp 2.75" x 2" x 4.5" box | Lamp. Held by (b)(4) lamp-holder. Installed in (b)(4) wet location box with (b)(4) blank cover. Direct wired with (b)(4) power supply cord. Connector: (b)(4) straight fitting | Illuminates, basin cabinet clear viewing tube. Plugged into viewing tube receptacle located on lower left front of tower cabinet. |

**Description of Components Used in the
Angel of Water™ Purification System (Cont'd)**

| | | | |
|--|---|---|---|
| Tower Light | 5.5" x 2.5" lamp 2.75" x 2" x 4.5" box | Lamp. Held by (b)(4) lamp-holder. Mounted in (b)(4) wet location box with (b)(4) cover. | Illuminates inside of tower cabinet to allow viewing of main tank water level through tower front and side windows. |
| External Light Fixture for External Viewing Tube Drain | 20" x 1 1/4" x 2 1/4" | | Portable light fixture that plugs into tower viewing tube receptacle outlet. |
| GFCI Reset Switch | 2.75" x 2" x 4.5" | Leviton. Cat. No. 64 - 190. Mounted in (b)(4) wet location box with Carlon GFCI outlet cover #E98GFCN | Ground fault circuit interrupter for entire system. Located above electrical terminal box in lower part of tower cabinet. |
| Single receptacle for U.V. Filter | 2.75" x 2" x 4.5" | Hubbell HBL 8210GY Mounted in (b)(4) wet location box with single receptacle cover. | Electrical outlet located above electrical terminal box in lower part of tower cabinet for plugging in U.V. filter light ballast. |
| Duplex Receptacle for Viewing Tube | 1.5" x 1 1/4" x 2.75" for receptacle 2.75" x 2" x 4.5" for box | Hubbell HBL 8200GY Mounted on tower front through plywood wall directly into Carlon E989N terminal box. Has wet location (b)(4) duplex cover. | Electrical outlet for plugging in the basin cabinet viewing tube. |
| Flanged Appliance Inlet | 1.75" x 1.75" | Hubbell HBL 5278C | The power source inlet connection mounted on front left lower part of the tower. The power supply cord plugs into it. |
| Power Supply Cord | 10' | Hubbell (hospital grade) HBL18GYGY with Hubbell (hospital grade) HBL8219C connector | For connecting to power source outlet |
| Extra Duplex Receptacle | 1.5" x 1 1/4" x 2.75" | | Supplied with system to plug system into clinic wall. Must be installed in wall outlet box according to electrical code |

Lifestream

Purification Systems, LLC

Angel of Water™ SYSTEM PARTS PACKET

2001 South Lamar, Suite G
Austin, Texas 78704

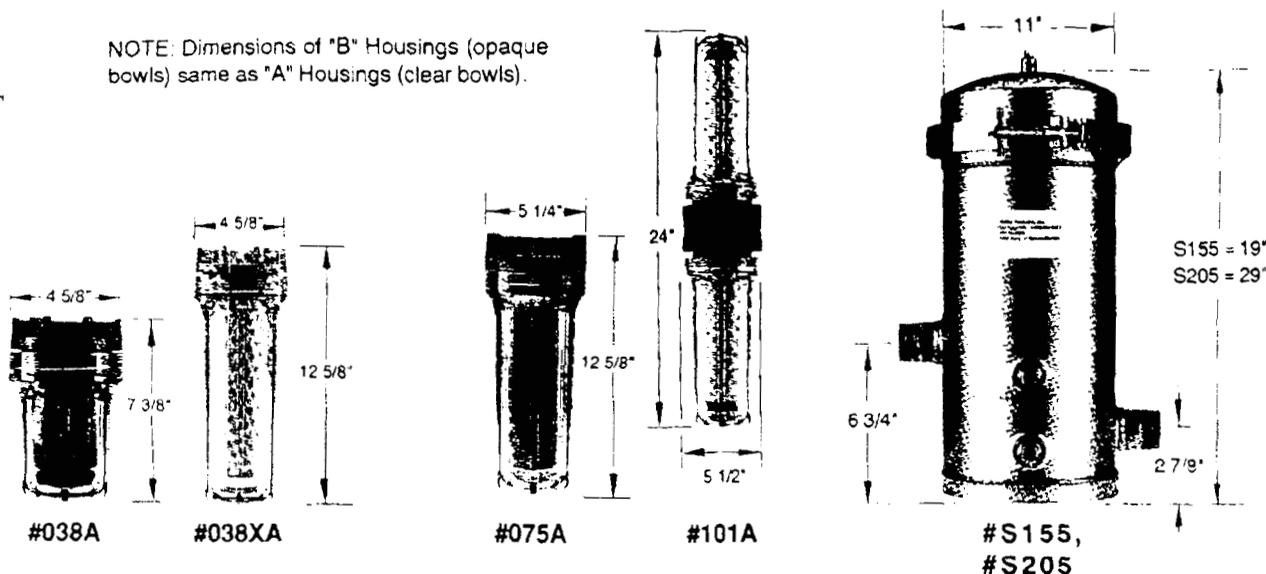
(512) 707-3773

Carbon Filter

Specifications and Ordering Information

KELLER

NOTE: Dimensions of "B" Housings (opaque bowls) same as "A" Housings (clear bowls).



Filter Housing Specifications

| Housing Designation | 038A,B | 038XA,B | 075A,B | 101A,B | S155 | S205 |
|---------------------------------|---|-----------|-----------|---------|---------------------|---------|
| Port Size | 3/8" NPTF | 3/8" NPTF | 3/4" NPTF | 1" NPTF | 1-1/2" NPTM | 2" NPTM |
| Flow Rate @ 5 psi drop | 2 gpm | 4 gpm | 5 gpm | 10 gpm | 20 gpm | 40 gpm |
| Filter Element Length, Nominal | 5 in. | 10 in. | 10 in. | 10 in. | 10 in. | 20 in. |
| Number of Filter Elements | 1 | 1 | 1 | 2 | 4 | 4 |
| Max. Pressure at 65°F | 125 psig | | | | | |
| Max. Temperature | 125°F | | | | | |
| Materials of Construction: Head | Polypropylene | | | | 304 Stainless Steel | |
| Materials of Construction: Bowl | Clear Bowl: SAN; Opaque Bowl: Polypropylene | | | | 304 Stainless Steel | |
| Weight | 3 lbs. | 5 lbs. | 5 lbs. | 13 lbs. | 29 lbs. | 34 lbs. |

Ordering Information

Filter Housings Only

| Housings with Clear Bowls | 038A | 038XA | 075A | 101A | Not Avail. | Not Avail. |
|----------------------------|------|-------|------|------|------------|------------|
| Housings with Opaque Bowls | 038B | 038XB | 075B | 101B | S155 | S205 |

Filter Housings with Disposable Elements Installed

| With 10 micron Filter, Clear Bowl | 038A-3010 | 038XA-3010 | 075A-3010 | 101A-3010 | Not Avail. | Not Avail. |
|------------------------------------|-----------|------------|-----------|-----------|------------|------------|
| With 10 micron Filter, Opaque Bowl | 038B-3010 | 038XB-3010 | 075B-3010 | 101B-3010 | S155-3010 | S205-3010 |
| With 5 micron Filter, Clear Bowl | 038A-3500 | 038XA-3500 | 075A-3500 | 101A-3500 | Not Avail. | Not Avail. |
| With 5 micron Filter, Opaque Bowl | 038B-3500 | 038XB-3500 | 075B-3500 | 101B-3500 | S155-3500 | S205-3500 |
| With Carbon Element, Opaque Bowl* | 038B-CRB | 038XB-CRB | 075B-CRB | 101B-CRB | S155-CRB | S205-CRB |

*NOTE: Assemblies with Carbon Elements are supplied with opaque bowls as standard. To order assemblies with Carbon elements and clear bowls (3/8-inch through 1-inch line sizes only), specify "A" in place of "B" in ordering designation. Example: 075A-CRB.

Filter Elements Only

| 10 micron Filter Elements | R05-3010 | R10-3010 | R10-3010 | R10-3010 | R10-3010 | R20-3010 |
|---------------------------|----------|----------|----------|----------|----------|----------|
| 5 micron Filter Elements | R05-3500 | R10-3500 | R10-3500 | R10-3500 | R10-3500 | R20-3500 |
| Carbon Elements | R05-CRB | R10-CRB | R10-CRB | R10-CRB | R10-CRB | R20-CRB |

Model: FXWTC

GE SmartWater™

Household Replacement Filter

Bonus Pack

Reduces

- Sediment
- Rust
- Chlorine

For Use in ALL Major Brand* Sediment Filtration Systems

GE SmartWater™
Part of the GE SmartWater™ Family

We bring good things™ life.

de remplacement domestique

Fiche technique—Filtre

| |
|--|
| Modèle: FXWTC |
| Capacité (gal): 15,000 ¹ |
| Durée utile (ms): 3 |
| Réduction des autres particules |
| Chlore |
| Réduction des métaux |
| Chlorure |

¹La capacité peut varier selon les conditions de l'eau locale.

***Compatible con las principales marcas** como Inix, Culligan, Ametek, Karmore, Flotec, Telejoy, Master Plumber, entre muchas otras.

Para cambiar el filtro: Siga todas las instrucciones de manual del propietario del sistema de filtración.

Nota: Después de haber instalado el filtro, abra cualquier llave de agua fría por cerca de 30 minutos.

Advertencia: No utilice el filtro con agua que sea resaca desde el punto de vista microbiológico ni calidad desconocida, sin desinfectarla adecuadamente antes o después de ser tratada por este sistema.

Retire la envoltura plástica del carucho del filtro antes de hacer la instalación.

Filtro de reemplazo para uso doméstico

Dato técnicos

| |
|--------------------------------------|
| Modelo: FXWTC |
| Capacidad (gal): 15,000 ¹ |
| Vida útil (meses): 3 |
| Réduccion de particulas |
| Cloro |
| Réduccion de metaux |
| Chlorure |

¹La capacidad puede variar dependiendo de las acciones del agua local.

***Es compatible con las principales marcas** como Inix, Culligan, Ametek, Karmore, Flotec, Telejoy, Master Plumber, entre muchas otras.

Para cambiar el filtro: Siga todas las instrucciones de manual del propietario del sistema de filtración.

Nota: Después de haber instalado el filtro, abra cualquier llave de agua fría por cerca de 30 minutos.

Advertencia: No utilice el filtro con agua que sea resaca desde el punto de vista microbiológico ni calidad desconocida, sin desinfectarla adecuadamente antes o después de ser tratada por este sistema.

Retire la envoltura plástica del carucho del filtro antes de hacer la instalación.

GE SmartWater™

System Tested GXWH08C

Filter Facts

Model: FXWTC

Filter Capacity (gal): 15,000¹

Filter Life (months): 3

Particulate Reduction

| | |
|-----------------------|-----------|
| Chlorine | Class III |
| Particulate Reduction | Class III |

¹Capacity may vary with local water conditions.

Tested and Certified by NSF International against ANSI/ NSF Standard 42 for use in GE SmartWater Models GXWH08C, GXWH08C.

*See Performance Data Sheet for specific claims.

THIS MODEL WILL REPLACE THE MINI T01 FILTER.

To Change Filter: Follow all filtration system owner's manual procedures.

Note: After filter installation turn on cold water faucet for approximately 30 minutes.

Warning: Do not use with water that is microbiologically unsafe or of unknown quality, without adequate disinfection before or after the system.

Remove shrink wrap from filter cage before installing.

***Fits! Major Brands including** On Culligan, Ametek, Kenmore, Flo, Telejoy, Master Plumber and more.

0 8469179482 0

General Electric Company,
Appliance Park,
Louisville, Kentucky 40225
GE Answer Center 1.800.626.2000
www.geappliances.com/smartwater

Made in U.S.A.

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Ultraviolet Light Filter

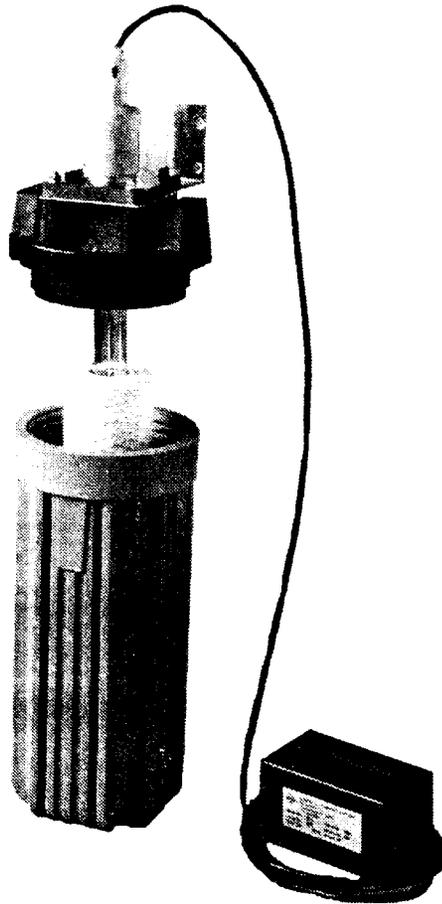
**Instruction Manual —
Residential Faucet Purifiers
Series 8101-P/PP**

SEVERN

TRENT

SERVICES

ULTRADYNAMICS



1 INTRODUCTION

1.1 General

This manual covers installation, operation and maintenance requirements for UltraDynamics® Residential Purifier Series 8101-P/PP.

1.2 Equipment Description

The Residential Faucet Purifier Series 8101-P/PP consists of four purifier models designed to handle clear fresh water and high purity water flow rates between 0.5 and 7 GPM (Gallons Per Minute). The purifier consists of corrosion-proof, reinforced polypropylene reactor chamber and remote, and plug-in type power supply with lamp-out indicator. The germicidal 254 nanometer UV lamp is enclosed in a protective pure fused quartz sleeve and rated for 7,500 hours of continuous use. The inlet/outlet connections are ¼" NPT fittings. A 5 micron filter is a standard feature on PP models. P-models feature built-in flow control as a standard feature. Operation at 220 Vac/50 Hz is optional. The unit is provided with a mounting bracket for easy installation and should be mounted vertically.

1.3 Specifications

1.3.1 General Specifications (All Models)

| | |
|----------------------------|---|
| Type of Liquid: | Clear Fresh Water |
| UV Lamps: | Germicidal 254 nanometers UV lamp(s) rated for 7,500 hours of continuous use (See Figure 1 for lamp quantities) |
| Operating Pressure: | 100 psig Maximum |
| UV Dosage: | 30,000 μ Wsec/cm ² (based on published flow rates) |
| Electrical: | 120 Vac/60 Hz or 220 Vac/50 Hz |
| Filter: | 5 micron, 3" x 10" cartridge filter (PP-models only) |
| Flow Control: | P-models only |
| Material: | Corrosion-proof, reinforced polypropylene reactor chamber |
| Mounting: | Vertical |

1.3.2 Model Specific Specifications

| Model Number | Maximum Flow Rate | | Lamp Quantity and Length | Shipping Weight | Dimensions L x W x H Inches (mm) |
|--------------|-------------------|-------------------|--------------------------|-----------------|----------------------------------|
| | Clear Fresh Water | High Purity Water | | | |
| 8101-PP.5 | 0.5 GPM | 1 GPM | 1-12" | 7 lb | 15 X 5 X 6 |
| 8101-PP3 | 1.5 GPM | 2 GPM | 1-17" | 12 lb | 25 X 5 X 6 |
| 8101-P5 | 4 GPM | 5 GPM | 1-12" | 7 lb | 15 X 5 X 6 |
| 8101-P7 | 6 GPM | 7 GPM | 1-17" | 12 lb | 25 X 5 X 6 |

Figure 1 – Model-Specific Specification Chart

| Model Number | Kilowatts | | Amps | |
|--------------|-----------|-----------|-----------|-----------|
| | @ 120 Vac | @ 220 Vac | @ 120 Vac | @ 220 Vac |
| 8101-PP.5 | 0.07 | 0.07 | 0.6 | 0.3 |
| 8101-PP3 | 0.07 | 0.07 | 0.6 | 0.3 |
| 8101-P5 | 0.07 | 0.07 | 0.6 | 0.3 |
| 8101-P7 | 0.07 | 0.07 | 0.6 | 0.3 |

Figure 2 – Model-Specific Power Requirements

1.4 Warranty Considerations

Your UltraDynamics® UV Purifier is protected by a limited warranty provided separately from this manual.

The following installation or operating conditions are considered hazardous or damaging to the equipment and can compromise the ability of the unit to perform as intended. In addition, any such condition may void equipment warranty.

- 1.4.1 Failure to connect proper electrical service to the unit.
- 1.4.2 Failure to properly ground the unit.
- 1.4.3 Failure to eliminate excessive vibration or water hammer.
- 1.4.4 Operation of visually damaged equipment.
- 1.4.5 Use of components other than those provided or authorized by UltraDynamics®.
- 1.4.6 Failure to correct compression nut seal leaks which result in damage to the electrical components.

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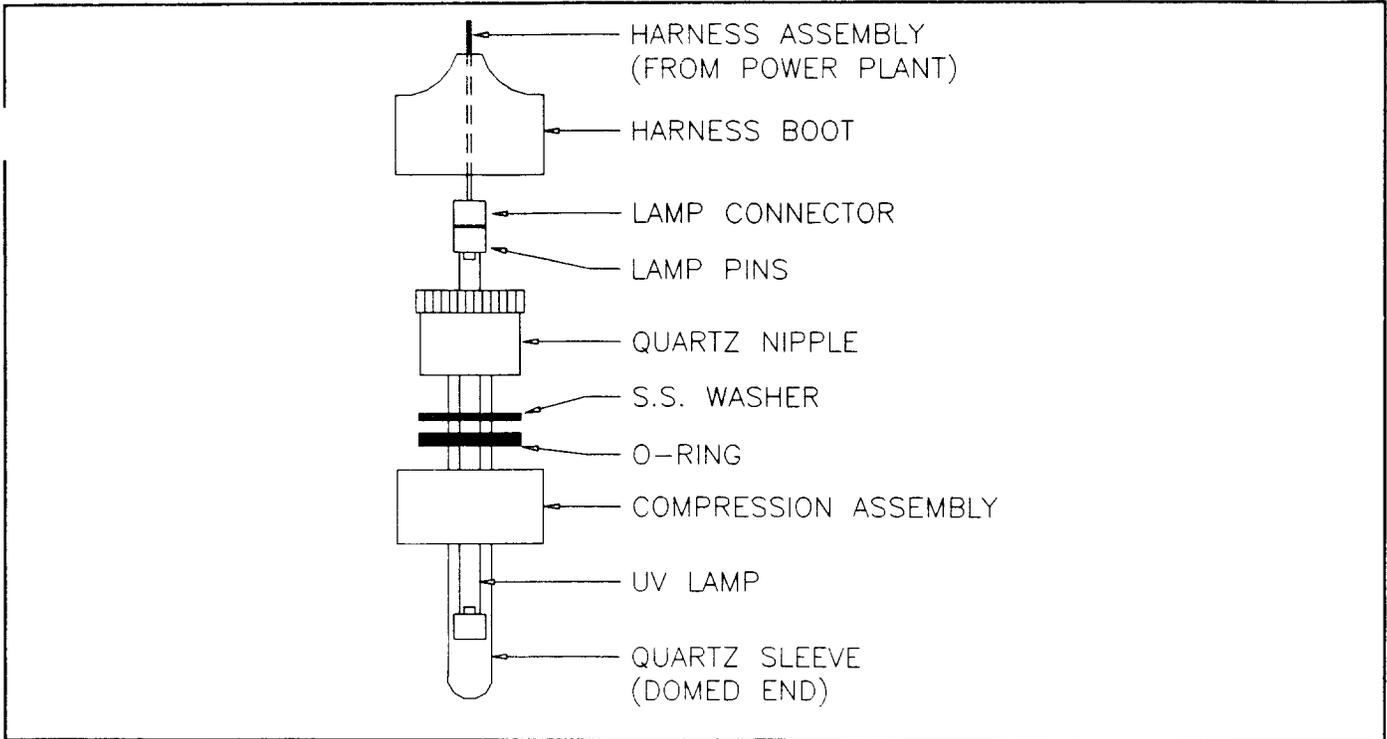


Figure 3 - UV Lamp/Closed End Quartz Sleeve Assembly

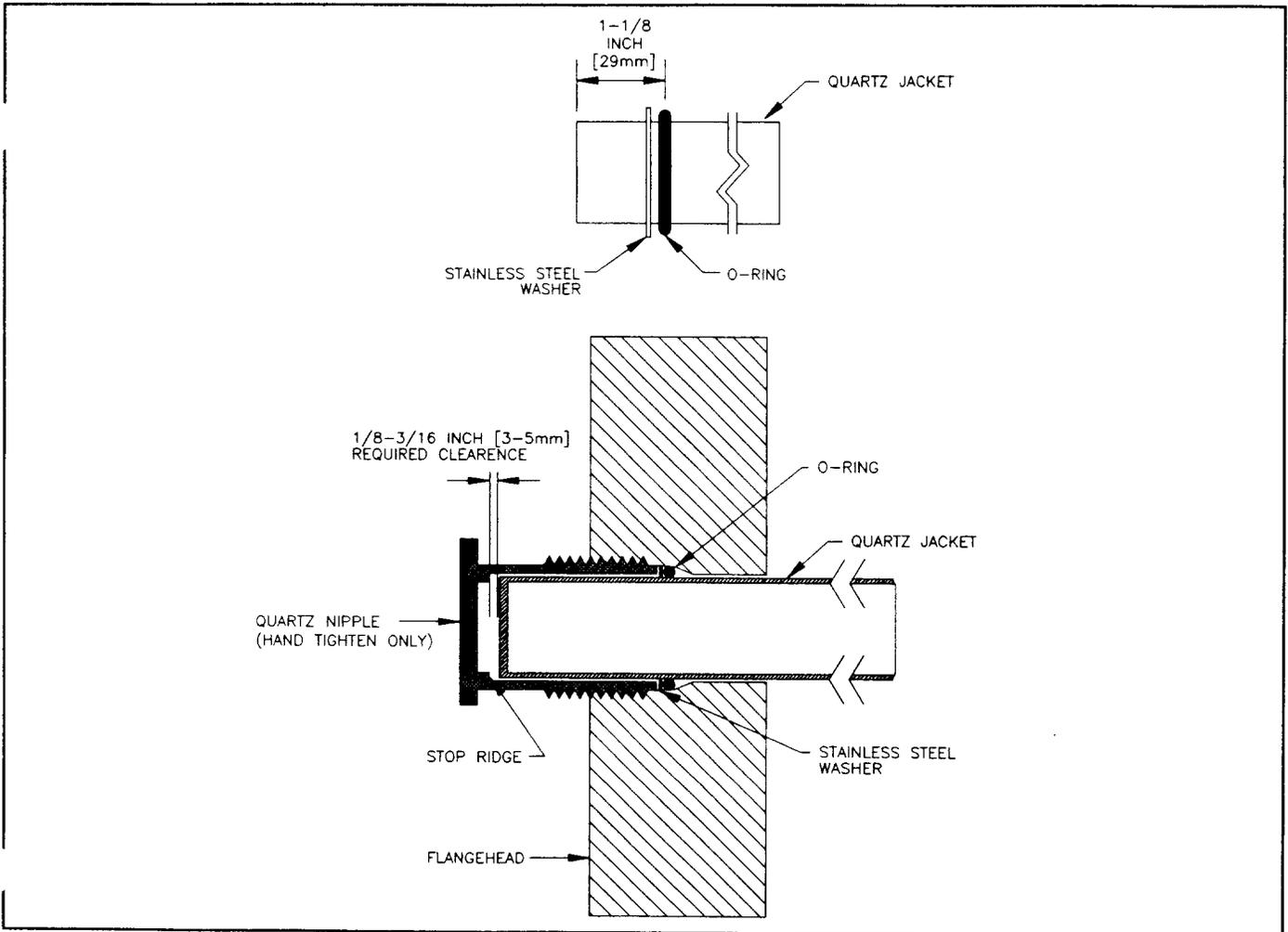


Figure 4 - Quartz Sleeve Installation

3.3 UV Intensity Monitor

For models with UV Intensity Monitor, install the monitor sensor in the UV Sight/Monitor Port located on the chamber.

3.4 Pressure Testing for Leaks

To pressurize purifier, open the outlet valve on the purifier and turn on spigot. Slowly open the inlet valve and flush all the air, then close the spigot.

Slowly pressurize the purifier, and check the quartz nipple for leaks. If there is a small leak, do not tighten the quartz nipple if the edge of the quartz sleeve is against the quartz nipple stop ridge. Depressurize the purifier and unscrew the leaking nipple. Inspect the end of the quartz sleeve and the O-ring for possible damage. Then carefully reinstall the O-ring, stainless steel washer and quartz nipple, and tighten. As your purifier is supplied with a quartz sleeve with only one open end, gently push the quartz sleeve 1/8" to 1/4" farther into the purifier chamber. This will allow proper clearance for the quartz nipple stop ridge when reassembled into the purifier head. By hand, tighten the quartz nipple, repressurize the purifier and check again for leaks.

3.5 UV Lamp Installation

WARNING
NEVER LOOK AT A LIGHTED UV LAMP. NEVER OPERATE
A UV LAMP OUTSIDE THE CHAMBER. SEVERE IRRITATION
TO EYES AND SKIN MAY RESULT

Straighten the UV lamp wiring harness (See Figure 5). Install the UV lamp in the quartz sleeve. Slide lamp in carefully, push on the lamp all the way in. Be sure there are no marks or fingerprints on the UV lamp. Clean with denatured alcohol and cotton, if necessary.

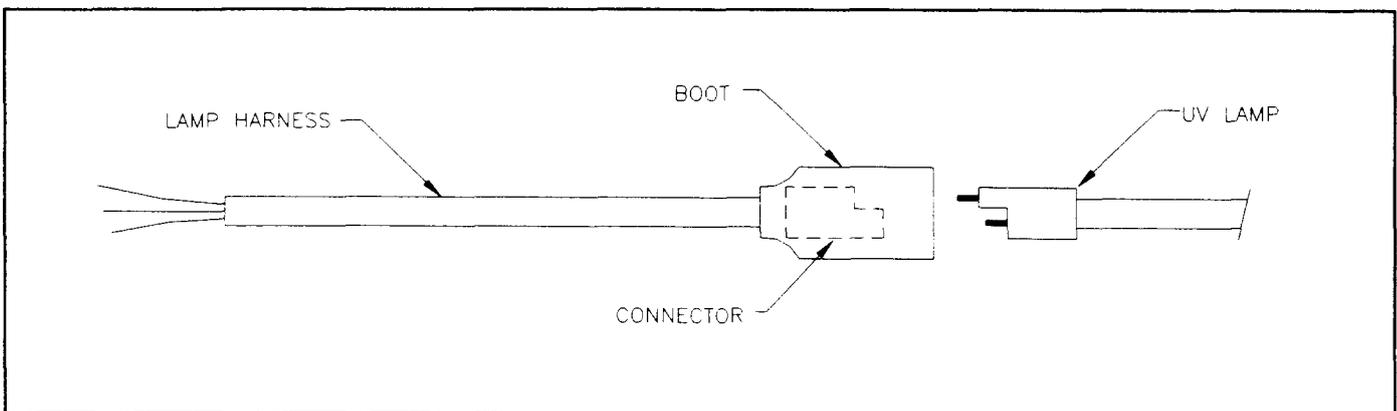


Figure 5 - UV Lamp Wiring Harness

NOTE
A UV LAMP FAILING TO OPERATE IS USUALLY DUE TO
AN IMPROPER SOCKET CONNECTION

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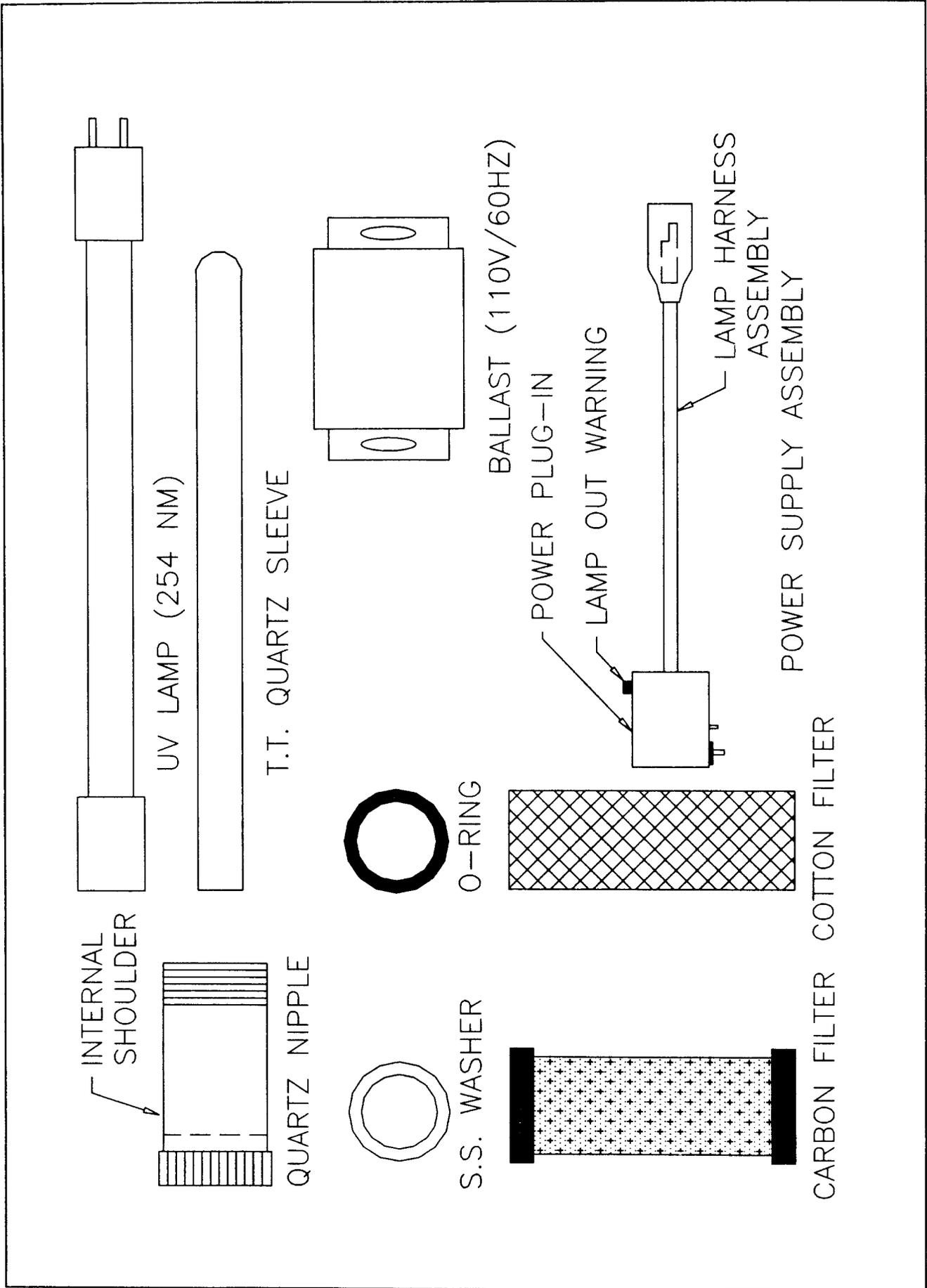


Figure 7 - Replacement Parts Drawing

6 TROUBLE SHOOTING CHART

| Trouble | Probable Cause | Corrective Action |
|---------------------------------------|--|--|
| 1. Low UV output | a. Dirty quartz sleeve b. Old or broken quartz sleeve c. Old UV lamps d. Water or condensation inside quartz sleeve | a. Remove and clean quartz sleeve b. Replace quartz sleeve c. Replace UV lamps d. Remove quartz sleeve and dry internal quartz |
| 2. UV Lamp out or will not light | a. Bad UV lamp b. Defective lamp ballast | a. Replace UV lamp b. Replace ballast |
| 3. Leak at quartz nipple | a. Defective or cracked O-ring b. O-ring not seated properly c. Quartz sleeve cracked | a. Replace O-ring b. Replace O-ring c. Replace quartz sleeve |
| 4. Low UV transmission | a. Dirty, cloudy or high mineral content of water | a. Install pre-filter or demineralizer |
| 5. UV Monitor Sensor malfunctioning | a. Water or condensation inside sensor b. Sensor cable not connected | a. Remove and dry inside sensor b. Verify that the sensor cable is connected to the monitor |
| 6. UV Intensity Monitor not operating | a. Sensor cable not connected b. Monitor switch in the OFF position c. No power to monitor | a. Verify that the sensor cable is connected to the monitor b. Verify that the monitor switch is in the ON position c. Verify power to monitor |

Design improvements may be made without notice.

Represented by:



ULTRADYNAMICS

Residential Products

82 Burlews Court, Hackensack, NJ 07601
Tel: 201-489-0044 • Fax: 201-489-9229

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3000 Advance Lane, Colmar, PA 18915
Tel: 215 997-4000 • Fax: 215 997-4062
e-mail: uv@capitalcontrols.com
Web: <http://www.capitalcontrols.com>
UNITED KINGDOM • UNITED STATES
HONG KONG • INDIA • ITALY • MALAYSIA

3
189

Filtre de remplacement domestique

Fiche technique - Filtre

Modèle: FXWPC
 Capacité (gal) : 16,000¹
 Durée (ml) (mois) : 3
Reduction des matières particulaires

1 La capacité peut varier selon les conditions de l'eau locale.

***Compatible à toutes les grandes marques** dont Omni, Culligan, Ametek, Kenmore, Flotec, TeleDyne, Master Plumber et plus encore.

Pour changer le filtre: Suivez toutes les procédures du manuel du propriétaire de systèmes de filtration.

Note: Après l'installation du filtre, faites couler de l'eau de tout robinet d'eau froide pendant environ 30 minutes.

Précaution: Ne pas utiliser si l'eau est microbiologiquement dangereuse ou la qualité incertaine sans système de désinfection adéquat en amont ou en aval du système.

Retirez la cartouche de filtration de l'emballage thermoscellé avant l'installation.

Filtro de reemplazo para uso domestico

Datos técnicos

Modelo: FXWPC
 Capacidad (gal) : 16,000¹
 Vida útil (meses) : 3
Reducción de materias particulaires

1 La capacidad puede variar dependiendo de la composición del agua local.

***Es compatible con las principales marcas** como Omni, Culligan, Ametek, Kenmore, Flotec, TeleDyne, Master Plumber, entre muchas otras.

Para cambiar el filtro: Siga todas las instrucciones del manual del propietario del sistema de filtración.

Note: Después de haber instalado el filtro, abra cualquier llave de agua fría por cerca de 30 minutos.

Advertencia: No utilice el filtro con agua que sea insegura desde el punto de vista microbiológico o de calidad desconocida sin desinfectarla adecuadamente antes o después de ser tratada por este sistema.

Retire la envoltura plástica del cartucho del filtro antes de realizar la instalación.



GE SmartWater™

Household Replacement Filter

For Use in ALL Major Brand* Sediment Filtration Systems

Model: FXWPC

Bonus Pack

Reduces Sediment Rust

GE SmartWater™
 Part of the GE SmartWater™ Family

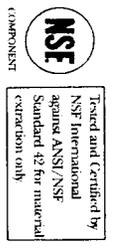
We bring good things to life

GE SmartWater™

Filter Facts

Model: FXWPC
 Filter Capacity (gal) : 16,000¹
 Filter Life (months) : 3
Particulate Reduction

1 Capacity may vary with local water conditions



To Change Filter: Follow all filtration systems owner's manual procedures.

Note: After filter installation, turn on any cold water faucet for approximately 30 minutes.

Warning: Do not use with water that is microbiologically unsafe or of unknown quality, without adequate disinfection before or after the system.

Remove shrink wrap from filter cartridge before installing.

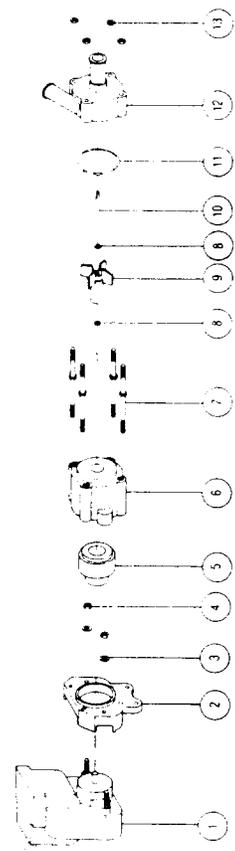
Fits All Major Brands including Omni, Culligan, Ametek, Kenmore, Flotec, TeleDyne, Master Plumber and more.



General Electric Company,
 Appliance Park,
 Louisville, Kentucky 40225
 GE Answer Center 1.800.626.2000
 www.geappliances.com/smartwater

Made in U.S.A.

**Water Cycling Device
(pump)**



NOTE: Only the part numbers shown can be purchased for replacement.

NOTE: Seules les pièces dont les numéros sont indiqués peuvent être achetées pour remplacement.
 NOTA: Solamente las piezas con número de referencia pueden adquirirse para repuestos.

| ITEM NO. | MFR'S PART NO. | PART DESCRIPTION | QTY. |
|----------|----------------|-----------------------|------|
| 1 | 971054 | Motor, 115 Volt | 1 |
| 2 | 188030 | Adapter | 1 |
| 3 | 921028 | Lock Washer, #6 | 2 |
| 4 | 920002 | Nut, #6-32 | 2 |
| 5 | 188121 | Drive Magnet Assembly | 1 |
| 6 | 188001 | Housing | 1 |
| 7 | 911503 | Stud, Collard #8-32 | 4 |
| 8 | 921065 | Thrust Washer | 2 |
| 9 | 188100 | Impeller Assembly | 1 |
| 10 | 188050 | Shaft, Impeller | 1 |
| 11 | 924025 | O-Ring | 1 |
| 12 | 188010 | Volute | 1 |
| 13 | 920020 | Nut, #8-32 | 4 |

W. W. GRANGER, INC.—1250 Busch Pkwy., Buffalo Grove, IL 60015
 Toll Free # IL 1-800-225-7149—Out-Of-State 1-800-323-0620



Little Giant Pump Company

P. O. Box 12019
 Oklahoma City, OK 73157-2010
 (405) 947-2511 • Fax: (405) 947-8720

STOCK NO. M. EL NO.
 La Réserve Pas. N° du Modèle
 Abastezca No. Numero de Modelo
 2P037 1-AA-MD

Records and under FOIA, Released by DRIH on 05/17/25

PUMP CONSTRUCTION

The patented Little Giant magnetic drive pump design consists of a cylindrical drive magnet attached to the motor shaft which rotates around a chemically resistant plastic separator housing. Inside this housing is a magnet fixed to the impeller. The impeller assembly is free to rotate on a spindle that is supported at both ends. The spindle is held captive and does not turn. Front and rear thrust washers are utilized as wear bearings. The washers are held captive and do not rotate. This prevents wear on the shaft. The magnetic coupling between the motor drives the impeller. This coupling eliminates the conventional shaft seal and its possibility of leakage.

PUMP MATERIALS

Plastic parts on pump are made of glass-filled polypropylene. The spindle shaft is 316 stainless steel. Thrust washers are Rulon J. Impeller driven magnet is uncoated ceramagnet A (barium ferrite) type ceramic. Static O-Ring seal is Viton®.

INSTALLATION

Your Little Giant pump is delivered to you completely preassembled and pretested from the factory. It is ready for immediate use. The pump may be installed in any position. It may be mounted vertically with the pump head down. Proper plumbing connections should be made. See specification table to determine what size intake and discharge your pump has. Make sure the wing nuts are tight before operating the pump.

Motor nameplates list all electrical data. Make sure the pump is connected to proper voltage before operating. When wiring pumps with no plug, the green (or green/yellow) wire is the ground. The other two wires are line (live). If fused type plug is used, a 2.0 amp fuse is recommended.

Do not allow the pump to run dry (without fluid). These pumps are not submersible. Operate the pumps only in the in-line mode. Do not put the units in liquid. Pump should be installed in a dry area and protected from splash. These pumps are not self-priming models. They must be installed so that the pump head (volute) is flooded at the time the pump is to be started. Do not restrict the intake side of the pump. Connections on the intake side should not be of smaller inside diameter pipe or tubing or hose than the intake inside diameter of the intake thread designation. If reduced flow is required restrict the discharge side. Installing a valve on either side of the pump is not recommended. Do not restrict the discharge side of the pump. When using a valve the pump can be throttled to provide various flow rates and pressures without harming the motor or the pump parts.

SERVICE INSTRUCTIONS



MAKE CERTAIN THE UNIT IS DISCONNECTED FROM THE POWER SOURCE BEFORE ATTEMPTING TO SERVICE OR REMOVE ANY COMPONENT!

1. The motor's sleeve bearings should be lubricated every six months with two to three drops of SAE 20 weight non-detergent oil. The oil holes are located on top at each end of the motor.
2. All wetted parts can be serviced by removing the (4) wingnuts (item 12) to the housing. The pump head components can easily be replaced in the field if necessary.
3. Lightly clean any corrosion or debris which may clog the impeller.
4. If pump is tripping circuit breakers (GFCI) or not operating properly after cleaning, return to Little Giant or its authorized service center. DO NOT attempt repairs yourself.
5. Be certain lower cord is in good condition and contains no nicks or cuts.

COMPOSITION DE LA POMPE

La conception brevetée de la pompe à entraînement magnétique Little Giant consiste en un cylindre magnétique d'entraînement fixé à l'arbre du moteur qui tourne autour d'un boîtier séparateur de plastique résistant aux produits chimiques. La conception brevetée de la pompe à entraînement magnétique Little Giant consiste en un cylindre magnétique d'entraînement fixé à l'arbre du moteur qui tourne autour d'un boîtier séparateur de plastique résistant aux produits chimiques. Cet aimant est fixé à la turbine. Celle-ci tourne sur un mandrin qui ne tourne pas. Des rondelles de butée avant et arrière servent de coussinets d'usure. Afin de prévenir l'usure du mandrin, les rondelles sont immobilisées et ne tournent pas. Le couplage de l'aimant entraîne le moteur qui fait tourner la turbine. Le couplage élimine le presse-étoupe de l'arbre et du même coup le risque de fuite.

MATÉRIAUX DE CONSTRUCTION

Les pièces de plastique de la pompe sont faites de polypropylène vitrifié. Le mandrin est en acier inoxydable 316 et les rondelles de butée sont en Rulon J. L'aimant de la turbine est en céramique de type « ceramagnet » A (ferrite de baryum) non enduite. Le joint torique statique est en Viton®.



Little Giant Pump Company
 P. O. Box 12010
 Oklahoma City, OK 73157-2010
 405.947.2511 • Fax: 405.947.8720

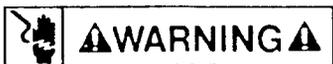
INTRODUCTION

Enclosed with your Little Giant pump is an instruction sheet which provides you with information required to safely own and operate your Little Giant pump. The instruction sheet primarily covers the standard models of each pump series. The form is applicable to other models in the series not listed by catalog number in the replacement parts list section of the instruction sheet. If the catalog number of your pump is not listed in the replacement parts list section, then caution should be exercised when ordering replacement parts. Always give the catalog number of your pump when ordering replacement parts.

The Little Giant unit you have purchased is of the highest quality workmanship and material. It has been engineered to give you long and trouble-free service. The Little Giant pumps are carefully packaged, inspected and tested to insure safe operation and delivery. When you receive your pump, examine it carefully to determine that there are no broken or damaged parts that may have occurred during shipment. If damage has occurred, make notation and notify the firm that you purchased the pump from. They will assist you in replacement or repair, if required.

READ INSTRUCTIONS CAREFULLY BEFORE ATTEMPTING TO INSTALL, OPERATE OR SERVICE THE LITTLE GIANT PUMP. KNOW THE PUMP APPLICATION, LIMITATIONS, AND POTENTIAL HAZARDS. PROTECT YOURSELF AND OTHERS BY OBSERVING ALL SAFETY INFORMATION. FAILURE TO COMPLY WITH INSTRUCTIONS COULD RESULT IN PERSONAL INJURY AND/OR PROPERTY DAMAGE! RETAIN INSTRUCTIONS FOR FUTURE REFERENCE.

SAFETY GUIDELINES



1. Make certain that the unit is disconnected from the power source before attempting to service or remove any component.
2. Do not use to pump flammable or explosive fluids such as gasoline, fuel oil, kerosene, etc. Do not use in explosive atmospheres. Pump should only be used with liquids compatible with pump component materials.
3. Do not handle pump with wet hands or when standing on a wet or damp surface or in water.
4. This pump is supplied with a grounding conductor and/or grounding type attachment plug. To reduce the risk of electric shock, be certain that it is connected to a properly grounded grounding type receptacle.
5. In any installation where property damage and/or personal injury might result from an inoperative or leaking pump due to power outages, discharge line blockage, or any other reason, a backup system(s) and/or alarm should be used.
6. Support pump and piping when assembling and when installed. Failure to do so may cause piping to break, pump to fall, motor bearing failures, etc.
7. If pump is an oil-filled pump, the motor housing is filled with a dielectric lubricant at the factory for optimum motor heat transfer and lifetime lubrication of the bearings. Use of any other lubricant could cause damage and void the warranty. This lubricant is non-toxic, however, if it escapes the motor housing, it should be removed from the surface quickly by placing newspapers or other absorbent material on the water surface to soak it up, so aquatic life is undisturbed.

ELECTRICAL CONNECTIONS

1. Check the pump label for proper voltage required. Do not connect to voltage other than that shown.
2. If pump is supplied with a 3-prong electrical plug, the third prong is to ground the pump to prevent possible electrical shock hazard. **DO NOT REMOVE** the third prong from the plug. A separate branch circuit is recommended. Do not use an extension cord. Do not cut plug from the cord. If the plug is cut or the cord is shortened, then this action will void the warranty.
3. If the cord is equipped with stripped lead wires, such as on 230v models, be sure that the lead wires are connected to a power source correctly. The (green/yellow) wire is the ground. The (blue or white) and the (brown or black) are live.

CONSULT INSTRUCTION SHEET ILLUSTRATIONS FOR PROPER ASSEMBLY AND DISASSEMBLY OF YOUR LITTLE GIANT PUMP.

LIMITED WARRANTY

Your Little Giant product is guaranteed to be in perfect condition when it leaves our Factory. It is warranted against defective materials and workmanship for a period of 12 months (90 day warranty on Models: 1-AA-OM, GKPK-SC, PP-1, PPS-1, PP-12, PPS-12, PP-230 and Cooler King) from date of purchase by the user. No warranty on brush wear in Model 3S-OM and impeller or cam in Models PP-1, PP-12, and PP-230.

Any product that should fail for either of the above two reasons and is still within the warranty period will be repaired or replaced at the option of Little Giant as the sole remedy of buyer. For our customers in the CONTINENTAL UNITED STATES: Please return the defective unit, postage paid, to the factory at 301 North MacArthur Blvd., Oklahoma City, OK 73127-6616. All defective product returned under warranty will be fully inspected to determine the cause of failure before warranty is approved.

For our customers located elsewhere, it is not economical, due to duties and freight, to return the pump to the factory for inspection. Please return the defective unit to any authorized distributor or dealer with a brief written explanation of the problem. If there are no apparent signs of customer abuse, unit will be repaired or replaced. If dispute arises over replacement of the pump, the distributor or dealer is to segregate such items and hold for inspection by a representative of Little Giant Pump Company or notify factory with details of the problem for factory disposition and settlement of warranty claim.

DISCLAIMER:

THE FOREGOING WARRANTY IS AN EXCLUSIVE WARRANTY IN LIEU OF ANY OTHER EXPRESS WARRANTIES, ANY IMPLIED WARRANTIES (INCLUDING, BUT NOT LIMITED TO ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) TO THE EXTENT EITHER APPLIES TO A PUMP SHALL BE LIMITED IN DURATION TO THE PERIODS OF THE EXPRESS WARRANTIES GIVEN ABOVE.

Warranty will be VOID if any of the following conditions are found:

1. Sealed motor housing opened
2. Cord cut off to a length less than three feet
3. Cord cut off to a length less than three feet
4. Pump allowed to operate dry (fluid supply cut off)
5. Pump used to circulate anything other than fresh water, light oils, or other mild liquids at approximately room temperature.
6. Product abuse by customer

Any oral statements about the product made by the seller, the manufacturer, the representatives of any other parties, do not constitute warranties, shall not be relied upon by the user and are not part of the contract for sale. Seller's and manufacturer's only obligation, and buyer's only remedy, shall be the replacement and/or repair by the manufacturer of the product as described above. **NEITHER SELLER NOR THE MANUFACTURER SHALL BE LIABLE FOR ANY INJURY, LOSS OR DAMAGE, DIRECT, INCIDENTAL OR CONSEQUENTIAL (INCLUDING, BUT NOT LIMITED TO INCIDENTAL OR CONSEQUENTIAL DAMAGES FOR LOST PROFITS, LOST SALES, INJURY TO PERSON OR PROPERTY, OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL LOSS), ARISING OUT OF THE USE OR THE INABILITY TO USE THE PRODUCT AND THE USER AGREES THAT NO OTHER REMEDY SHALL BE AVAILABLE TO IT.** Before using, the user shall determine the suitability of the product for the intended use, and user assumes all risk and liability whatsoever in connection therewith.

Some states and countries do not allow limitations on how long an implied warranty lasts or the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state and country to country.

The National Electric Code (in the USA) and similar codes in other countries require a Ground Fault Circuit Interrupter (GFCI) to be installed in the branch circuit supplying fountain equipment rated above 15 volts. 115 volt GFCI's (with various cord lengths) are in stock, and we recommend each pump be used with a GFCI.

INTRODUCTION

La présente notice d'emploi comporte tous les renseignements nécessaires pour utiliser en toute sécurité les pompes Little Giant. Elle concerne en particulier les modèles standard de chaque série. Ainsi, que les modèles des séries non listés par numéro de catalogue sur la liste des pièces à recharger. Si le numéro de catalogue de la pompe achetée ne fait pas partie de la liste des pièces à recharger, certaines précautions seront à prendre lors des commandes de pièces de rechange. Ne pas oublier d'indiquer le numéro du catalogue sur le bon de commande.

La qualité d'exécution et les matériaux du modèle Little Giant achetez sont parfaits. Cette pompe a été conçue pour fonctionner sans problèmes de façon durable. Les pompes Little Giant sont soigneusement emballées et testées avec soin pour procurer à l'acquéreur un fonctionnement et un rendement sûrs. A la réception, veillez à examiner attentivement la pompe afin de s'assurer qu'aucune pièce n'a été endommagée pendant le transport. Si tel n'est pas le cas, prendre note des dommages et aviser le distributeur chez qui la pompe a été achetée afin de la faire réparer ou d'obtenir son remplacement.

LIRE ATTENTIVEMENT LE MODE D'EMPLOI AVANT L'INSTALLATION, L'UTILISATION OU L'ENTRETIEN DE LA POMPE LITTLE GIANT. PRENDRE ATTENTIVEMENT CONNAISSANCE DES POSSIBILITÉS D'UTILISATION, DES RESTRICTIONS ET DES DANGERS S'Y RATTACHANT. ASSURER SA PROPRE PROTECTION ET CELLES DES AUTRES EN OBSERVANT TOUTES LES DIRECTIVES DE SECURITE. LE NON-RESPECT DE CES DIRECTIVES POURRAIT ETRE LA CAUSE DE BLESSURES OU DE DOMMAGES MATERIELS. CONSERVER LE MODE D'EMPLOI POUR UN USAGE ULTERIEUR.

DIRECTIVES DE SECURITE



1. Veiller à débrancher l'appareil de sa source d'alimentation électrique avant l'entretien ou la dépose d'une ou de plusieurs pièces.
2. Ne pas pomper des fluides explosifs ou inflammables tels qu'essence, mazout, kérosène, etc. Ne pas employer dans une atmosphère comportant des risques de déflagration. La pompe ne doit servir qu'à pomper des liquides compatibles avec les matériaux utilisés pour la fabrication des éléments qui la composent.
3. Ne pas manipuler la pompe les mains humides, les pieds posés sur une surface mouillée, ou humide, ou les pieds dans l'eau.
4. Cette pompe est équipée d'un conducteur de mise à la terre et/ou d'une borne de branchement à prise de terre. Pour réduire les risques d'électrocution, s'assurer qu'elle est bien raccordée à une prise de courant appropriée comportant une borne de mise à la terre.
5. Dans le cas de toute installation ou des dommages matériels ou des blessures pourraient survenir par suite de l'emploi d'une pompe qui ne fonctionnerait pas ou qui ferait cause d'une panne de courant, d'une canalisation de refoulement bouchée ou de toute autre raison, prévoir l'emploi d'un dispositif(s) de secours ou d'alarme voulu(s).
6. Veiller à bien étayer la pompe et la tuyauterie lors du montage et de la mise en place. Sinon, non seulement les tuyaux risqueraient de se déchirer mais la pompe pourrait également faire défaut et les roulements du moteur pourraient subir des dommages, etc.
7. Si la pompe est remplie d'huile, le carter est rempli d'huile diélectrique servant de caloporteur pour la chaleur engendrée par le moteur et de lubrifiant pour les paliers. L'emploi d'un autre lubrifiant quel qu'il soit pourrait endommager l'appareil et annuler la garantie. Bien que cette huile ne soit pas toxique, en cas de fuite, l'enlever rapidement à l'aide de journaux posés rapidement à la surface de l'eau pour que la vie aquatique ne soit pas perturbée.

CONNEXIONS ELECTRIQUES



1. Consulter l'étiquette de la pompe pour connaître la tension appropriée. Ne pas raccorder à une source autre que la tension spécifiée.
2. Si la pompe est équipée d'une borne d'alimentation électrique à trois broches, la prise de terre est destinée à raccorder la pompe à la terre pour éliminer les risques d'électrocution. **NE PAS ENLEVER** cette troisième broche ou cordon d'alimentation. Un circuit de branche séparé est recommandé. Ne pas utiliser un prolongateur. Ne pas couper la fiche du cordon. Couper la fiche ou raccorder le cordon entraînera l'annulation de la garantie.
3. Si le cordon est muni de conducteurs codés à l'aide de rayures, comme pour les modèles en 230 volts, s'assurer que ces fils sont correctement raccordés à la source d'alimentation électrique. Ainsi, le fil vert/jaune est prévu pour le retour à la terre alors que les deux autres (bleu ou blanc) sont sous tension.

LIRE ATTENTIVEMENT LE MODE D'EMPLOI AVANT LE MONTAGE OU LE DEMONTAGE DE LA POMPE LITTLE GIANT.

Solenoid Valve

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INSTALLATION AND MAINTENANCE INSTRUCTIONS

2-WAY INTERNAL PILOT OPERATED SOLENOID VALVES
HUNG DIAPHRAGM - 3/8, 1/2 AND 3/4 N.P.T.
NORMALLY CLOSED OPERATION

8210
8211

ASCO

Form No. V-5825

DESCRIPTION

Bulletin 8210's are 2-way, normally closed, internal pilot operated solenoid valves. Valve body and bonnet are of brass construction. Standard valves have a General Purpose, NEMA Type 1 Solenoid Enclosure.

Bulletin 8211's are the same as Bulletin 8210's except the solenoids are equipped with an enclosure which is designed to meet NEMA Type 4 Watertight, NEMA Type 7 (C or D) Hazardous Locations - Class I, Group C or D, and NEMA Type 9 (E, F or G) Hazardous Locations - Class II, Group E, F or G. The explosion-proof/watertight solenoid enclosure is shown on a separate sheet of Installation and Maintenance Instructions, Form No. V-5380.

Bulletin 8210 and 8211 valves with suffix 'HW' in the catalog number are specifically designed for hot water service.

OPERATION

Normally Closed: Valve is closed when solenoid is de-energized and opens when solenoid is energized.

MANUAL OPERATOR (Optional)

Valves with suffix 'MO' in catalog number are provided with a manual operator which allows manual operation when desired or during an interruption of electrical power. To operate valve manually, push in knurled cap and rotate clockwise 180°. Disengage manual operator by rotating knurled cap counterclockwise 180° before operating electrically.

MANUAL OPERATOR LOCATION (Refer to Figure 3)

Manual operator (when shipped from factory) will be located over the valve outlet. Manual operator may be relocated at 90° increments by rotating valve bonnet. Remove bonnet screws (4) and rotate valve bonnet with solenoid to desired position. Replace bonnet screws (4) and torque in a crisscross manner to 110 ± 10 inch pounds.

If valve is installed in system and is operational, proceed in the following manner:

WARNING: Depressurize valve and turn off electrical power supply.

1. Remove retaining cap or clip and slip the entire solenoid enclosure off the solenoid base sub-assembly. CAUTION: When metal retaining clip disengages, it will spring upwards.
2. Remove bonnet screws (4) and rotate valve bonnet to desired position.
3. Replace bonnet screws (4) and torque in a crisscross manner to 110 ± 10 inch pounds.
4. Replace solenoid enclosure and retaining clip or cap.

INSTALLATION

Check nameplate for correct catalog number, pressure, voltage and service.

TEMPERATURE LIMITATIONS

For maximum valve ambient and fluid temperatures refer to chart. The temperature limitations listed are for UL applications. For non UL applications, higher ambient and fluid temperature limitations are available. Consult factory. Check catalog number on nameplate to determine maximum temperatures.

| Construction | Coil Class | Catalog Number Prefix | Maximum Ambient Temp. °F. | Maximum Fluid Temp. °F. |
|--|------------|-----------------------|---------------------------|-------------------------|
| A-C Construction (Alternating Current) | A | None or DA | 77 | 180 |
| | F | DF or FT | 122 | 180 |
| | H | HT | 140 | 180 |
| D-C Construction (Direct Current) | A, F or H | None, FT or HT | 77 | 150 |
| Catalog Numbers Suffix 'HW' (A-C Construction (Alternating Current)) | A | None or DA | 77 | 210 |
| | F | DF or FT | 77 | 210 |
| | H | HT | 122 | 210 |

POSITIONING/MOUNTING

Valve may be mounted in any position. For mounting bracket (optional feature) dimensions, refer to Figure 1.

PIPING

Connect piping to valve according to markings on valve body. Apply pipe compound sparingly to male pipe threads only; if applied to valve threads, it may enter the valve and cause operational difficulty. Pipe strain should be avoided by proper support and alignment of piping. When tightening the pipe do not use valve as a lever. Wrenches applied to valve body or piping are to be located as close as possible to connection point. **IMPORTANT: Valves with suffix 'HW' in the catalog number have a special diaphragm material which is specifically compounded for hot water service. This material can be attacked by oil and grease. Wipe the pipe threads clean of cutting oils and use teflon tape to seal pipe joints.**

IMPORTANT: For the protection of the solenoid valve, install a strainer or filter suitable for the service involved in the inlet side as close to the valve as possible. Periodic cleaning is required depending on the service conditions. See Bulletins 8600, 8601 and 8602 for strainers.

WIRING

Wiring must comply with Local and National Electrical Codes. Housings for all solenoids are provided with connections for 1/2 inch conduit. The general purpose solenoid enclosure may be rotated to facilitate wiring by removing the retaining cap or clip. CAUTION: When metal retaining clip disengages it will spring upwards. Rotate to desired position. Replace retaining cap or clip before operating.

NOTE: Alternating Current (A-C) and Direct Current (D-C) Solenoids are built differently. To convert from one to the other, it is necessary to change the complete solenoid including the solenoid base sub-assembly and core assembly.

SOLENOID TEMPERATURE

Standard catalog valves are supplied with coils designed for continuous duty service. When the solenoid is energized for a long period, the solenoid enclosure becomes hot and can be touched with the hand for only an instant. This is a safe operating temperature. Any excessive heating will be indicated by the smoke and odor of burning coil insulation.

MAINTENANCE

WARNING: Turn off electrical power and depressurize valve before making repairs. It is not necessary to remove valve from pipe line for repairs.

196

6

CLEANING

Records processed under FOIA Request # 2016-1725; Released by CDRH on 05-23-2016
A periodic cleaning of all solenoid valves is desirable. The time between cleanings will vary, depending on media and service conditions. In general, if the voltage to the coil is correct, sluggish valve operation, excessive leakage or noise will indicate that cleaning is required.

PREVENTIVE MAINTENANCE

1. Keep the medium flowing through the valve as free from dirt and foreign material as possible.
2. While in service, operate valve at least once a month to insure proper opening and closing.
3. Periodic inspection (depending on media and service conditions) of internal valve parts for damage or excessive wear is recommended. Thoroughly clean all parts. Replace any parts that are worn or damaged.

IMPROPER OPERATION

1. **Faulty Control Circuit:** Check electrical system by energizing solenoid. A metallic click signifies the solenoid is operating. Absence of the click indicates loss of power supply. Check for loose or blown-out fuses, open circuited or grounded coil, broken lead wires or splice connections.
2. **Burned-Out Coil:** Check for open circuited coil. Replace coil if necessary.
3. **Low Voltage:** Check voltage across coil leads. Voltage must be at least 85% of nameplate rating.
4. **Incorrect Pressure:** Check valve pressure. Pressure to the valve must be within range specified on nameplate.
5. **Excessive Leakage:** Disassemble valve and clean all parts. Replace worn or damaged parts with a complete Spare Parts Kit for best results.

COIL REPLACEMENT (Refer to Figure 2)

Turn off electrical power supply and disconnect coil leads. Proceed in the following manner:

1. Remove retaining cap or clip, nameplate and cover. CAUTION: When metal retaining clip disengages, it will spring upwards.
2. Remove spring washer, insulating washer and coil. Insulating washers are omitted when a molded coil is used.
3. Reassemble in reverse order of disassembly paying careful attention to exploded view provided for identification and placement of parts.

CAUTION: Solenoid must be fully reassembled as the housing and internal parts are part of and complete the magnetic circuit. Place insulating washer at each end of coil if required.

VALVE DISASSEMBLY (Refer to Figures 2 and 3)

Depressurize valve and turn off electrical power supply. Proceed in the following manner:

1. Remove retaining cap or clip and slip the entire solenoid enclosure off the solenoid base sub-assembly. CAUTION: When metal retaining clip disengages, it will spring upwards.
2. Unscrew solenoid base sub-assembly and remove bonnet gasket.
3. Remove valve bonnet screws (4) and valve bonnet.
4. For normal maintenance, it is not necessary to disassemble the manual operator (optional feature) unless external leakage is evident. To disassemble remove stem pin, manual operator stem, stem spring and stem gasket.
5. Remove core spring, core/diaphragm sub-assembly and body gasket. CAUTION: Do not damage or distort hanger spring between core/diaphragm sub-assembly.
6. All parts are now accessible for cleaning or replacement. Replace worn or damaged parts with a complete Spare Parts Kit for best results.

VALVE REASSEMBLY

1. Reassemble in reverse order of disassembly paying careful attention to exploded views provided for identification and placement of parts.
2. Replace body gasket and core/diaphragm sub-assembly. Locate the bleed hole in core/diaphragm sub-assembly approximately 45° from the valve outlet.
3. Replace core spring with wide end in core first; closed end protrudes from top of core.
4. If removed, replace manual operator stem, stem spring, stem gasket and stem pin.
5. Replace valve bonnet and bonnet screws (4). Torque bonnet screws (4) in a crisscross manner to 110 ± 10 inch pounds.
6. Replace bonnet gasket and solenoid base sub-assembly. Put solenoid base sub-assembly to 175 ± 25 inch pounds.
7. Replace solenoid enclosure and retaining cap or clip.
8. After maintenance, operate the valve a few times to be sure of proper opening and closing.

SPARE PARTS KITS

Spare Parts Kits and Coils are available for ASCO valves. Parts marked with an asterisk (*) are supplied in Spare Parts Kits.

ORDERING INFORMATION FOR SPARE PARTS KITS

When Ordering Spare Parts Kits or Coils Specify Valve Catalog Number, Serial Number and Voltage.

PARTIAL VIEW OF MOUNTING BRACKET (OPTIONAL)

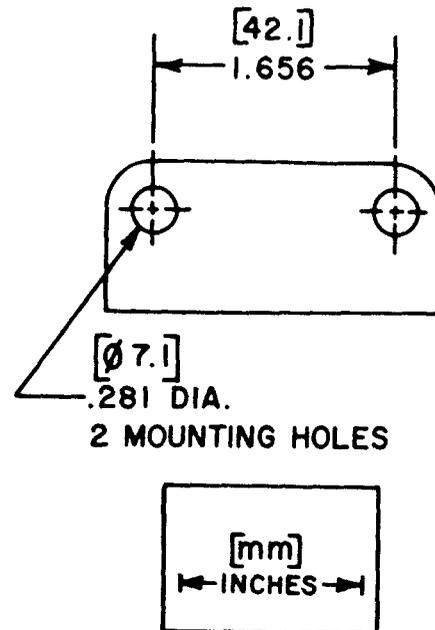
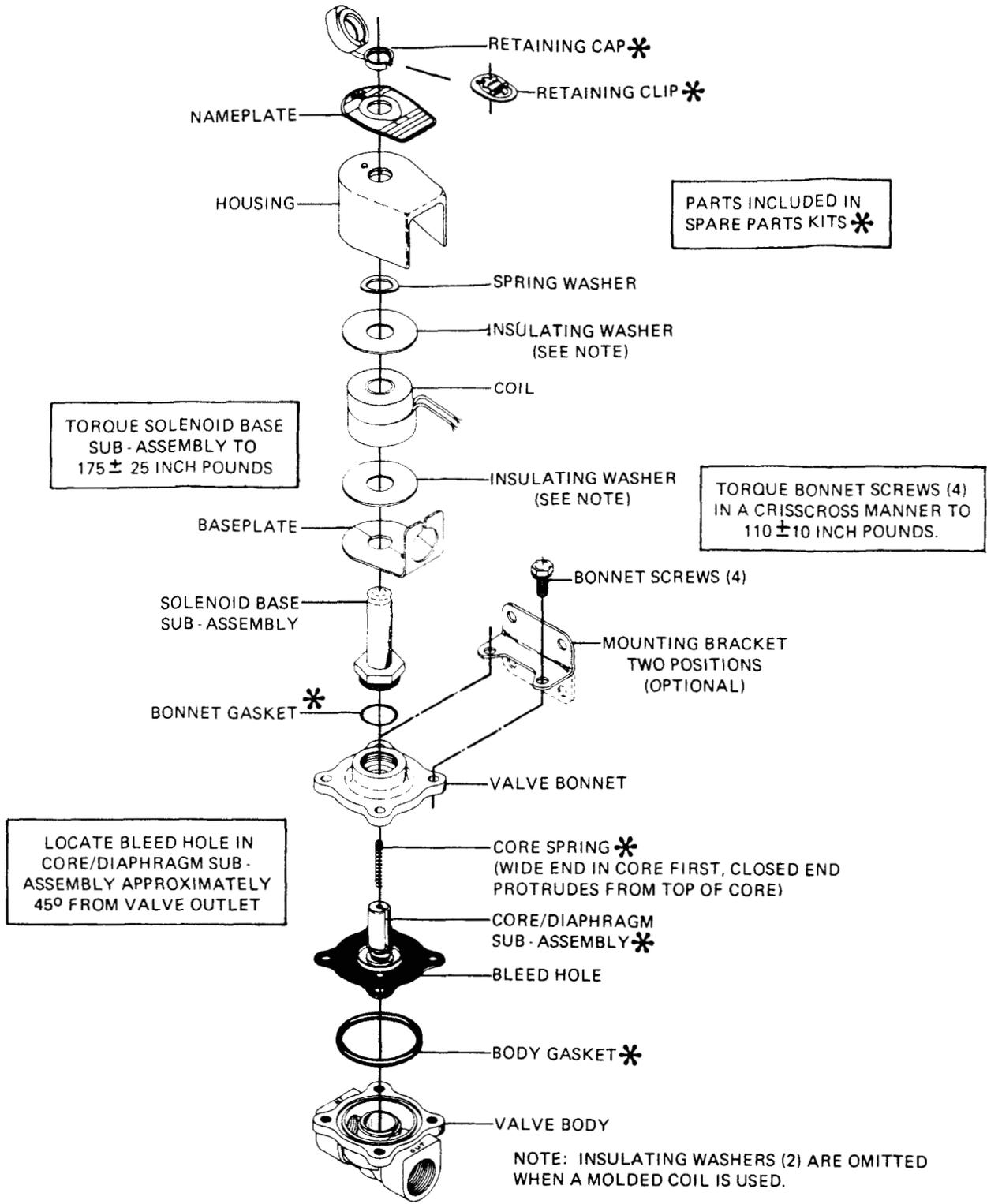


Figure 1. Dimensions For Mounting Bracket (Optional Feature)



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Bulletin 8210 — 3/8, 1/2 & 3/4 N.P.T. — A-C Construction
 General purpose solenoid enclosure shown.

For explosion-proof/watertight solenoid enclosure used on Bulletin 8211, see Form No. V-5380.

Figure 2.

198
3

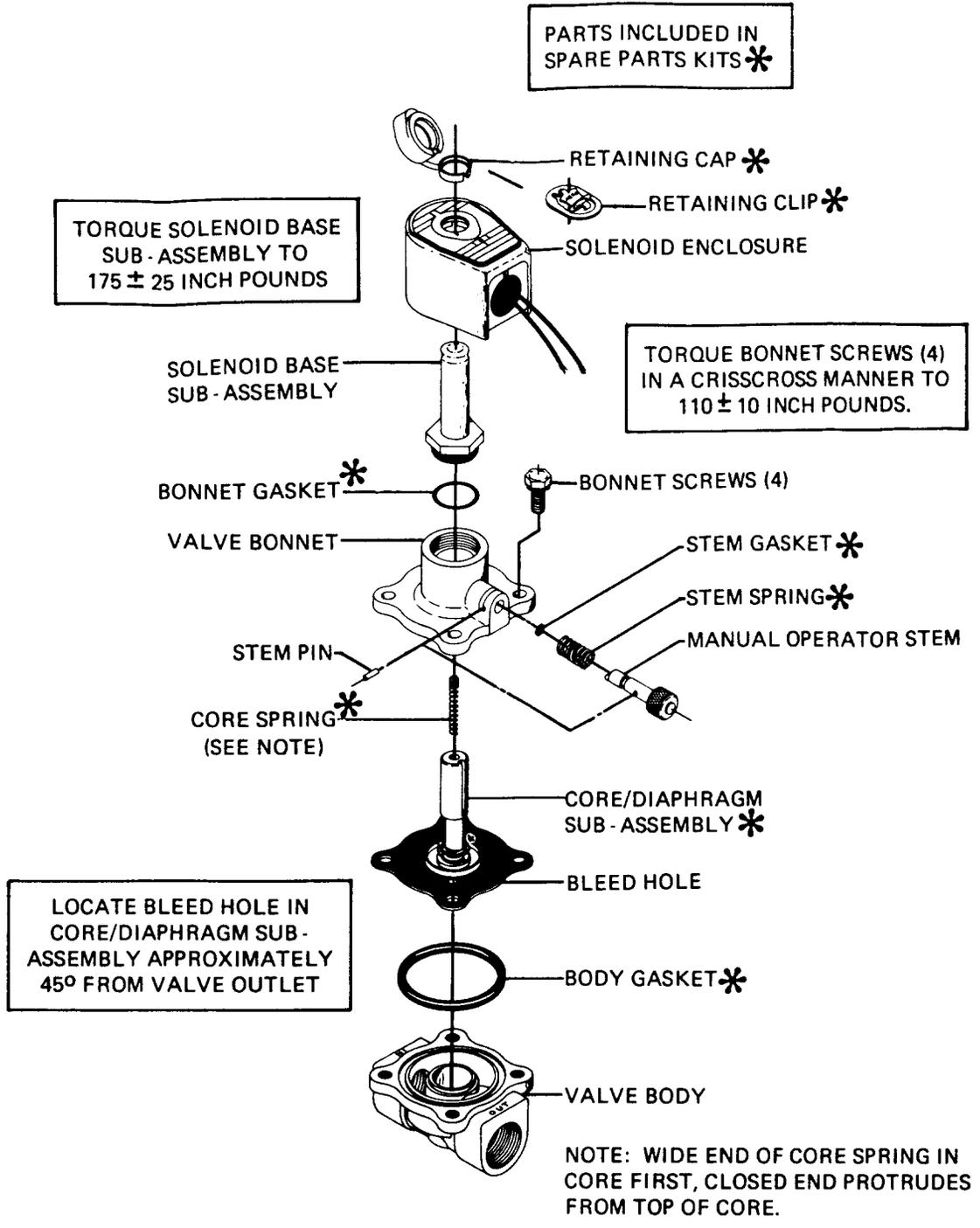


Figure 3.

Bulletin 8210 — Manual Operator
General purpose solenoid enclosure shown.
For explosion-proof/watertight solenoid enclosure used on Bulletin 8211, see Form No. V-5380.

1099

Temperature Controller and Sensor

**SP-32, SP-32D
SP-33, SP-33D
SP-34, SP-34D**



**Single Stage
Temperature Control**

Description

The SP-3x and SP-3xD series of controls are single stage, general purpose, temperature controls with wide application in HVAC, refrigeration, and industrial applications. The setpoint temperature ranges are:

- SP-32 & SP-32D** -26°F to 190°F
- SP-33 & SP-33D** 40°F to 104°F
- SP-34 & SP-34D** 90°F to 200°F

The SP-3xD controls are identical to the SP-3x, except for one additional relay. The SP-3x controls provide one isolated SPDT relay output while the SP-3xD provides two (effectively DPDT). The SP-3xD also provides "R-W" interrupt spade terminals for Class II interlocks on the Output 2 relay. The relays on both the SP-3x and SP-3xD are controlled by comparing the thermistor temperature sensor to a setpoint temperature. The installer can select either "heat" mode (relay operates on

temperature fall) or "cool" mode (relay operates on temperature rise). The control setpoint can be set using the internal setpoint dial (factory setting) or you can wire a remote setpoint (see Goldline RSP series of remote setpoints) or you can wire a fixed setpoint (see Goldline ESP series of fixed setpoints) which provides high accuracy and prevents unauthorized tampering with the setting. The SP-3xD series controls also feature a plug in connector for a 1D-SP Digital Display Monitor which displays sensor and setpoint temperatures.

Power can be provided from a 24VAC, 24VDC, 115VAC or 240VAC power source. Relay contacts are completely isolated so the outputs can switch any voltage, regardless of the power source. On SP-3xD models, one relay output can switch high voltage, the other switch low voltage. A movable divider is provided to separate high and low voltage wiring compartments.

Specifications

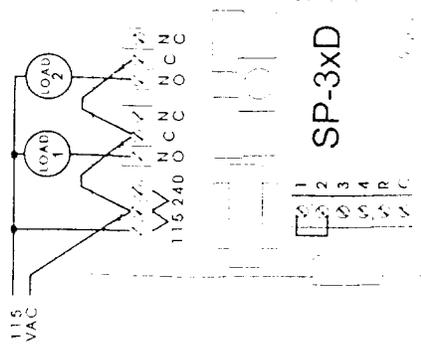
- | | |
|---|--|
| <p>Power: Approx. 2VA required from any power source.</p> <p>21-27VAC, 50-60Hz 21-27VDC 105-130VAC, 50-60Hz 195-250VAC, 50-60Hz</p> | <p>Setpoint: SP-32, SP-32D -26 to 190°F SP-33, SP-33D 40 to 104°F SP-34, SP-34D 90 to 200°F</p> |
| <p>Outputs: SPDT isolated (dry) contacts, 1HP @ 115VAC, 2HP @ 240VAC rating @ 240VAC: 20A on NO contacts 10A on NC contacts</p> | <p>Differential: SP-32, SP-32D 1-25°F SP-33, SP-33D 1-15°F SP-34, SP-34D 1-25°F</p> |
| <p>Sensors: Thermistor, 10K @ 25°C/77°F Type SW supplied with control Interchangeable with any IE temperature sensor 1000 ft. maximum wire run</p> | <p>Accuracy: +/- 1°F</p> <p>Environment: -30 to +130°F 0-95% RH, non-condensing</p> |

Operation

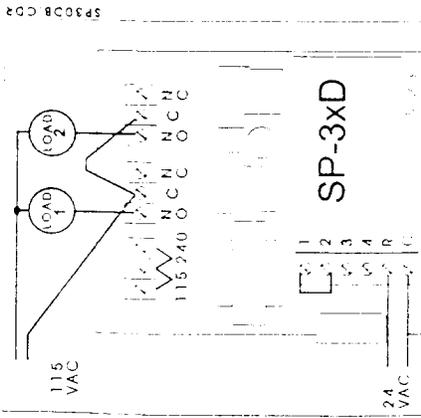
The test switch should normally be left in the "AUTO" position in which case operation is completely automatic with no operator intervention required. The "Power" indicator should always be on. The "Output" indicator will show the status of the control output relays. When the switches in the "OFF" position, the output is forced on (both relays energized) and when in the "OFF" position, the

output is forced off (both relays de-energized). The only exception to this is if the "R" and "W" feature is enabled. If so, the output 2 relay will be de-energized whenever continuity is broken across "R" and "W".

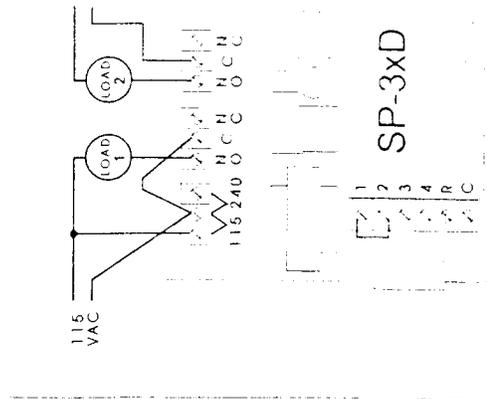
In "cool" mode the control output will turn on when the sensor temperature rises to the setpoint temperature.



115 VAC Applied to Loads When Output Is Off, Control Powered by 115 VAC



115 VAC Applied to Loads When Output Is Off, Control Powered by 24 VAC



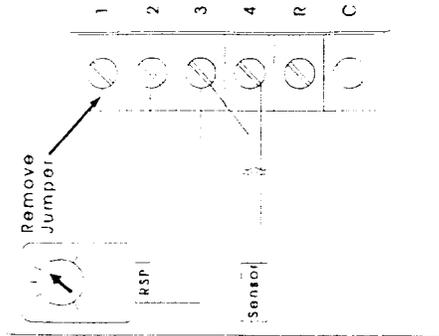
115 VAC Applied to Load 1, 24 VAC Applied to Load 2 When Output is Off, Control Powered by 115VAC

Operation (continued)

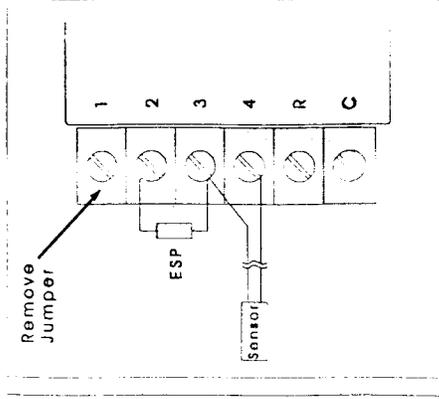
perature plus the differential. In "heat" mode the control output will turn on when the temperature falls to the setpoint temperature minus the differential.

Technical Assistance

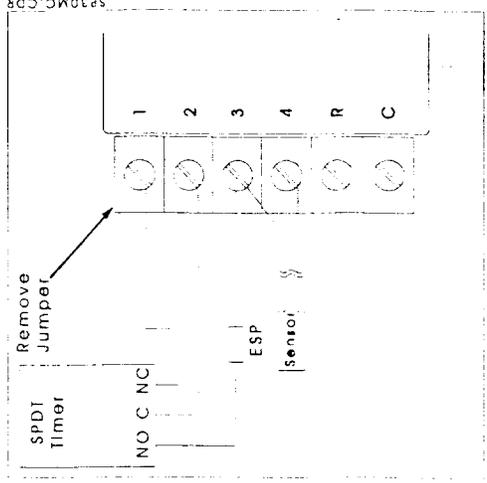
For help in installing, operating, or troubleshooting this control, you may call for technical assistance at 800-343-0826. Independent Energy's technicians are available from 8:00AM to 5:00PM Eastern Time, Monday through Friday. You may call at other times and leave a message, and a technician will call you back as soon as possible.



Remote Setpoint Using RSP



Fixed Setpoint Using ESP



Setback Using a Single Pole Double Throw Timer and ESP. Internal Setpoint Adjustment Used During "Normal" Hours and ESP Temperature is Setpoint During "Setback" Hours

Installation

1. Mounting
The SP-3x and SP-3xD series controls are designed for mounting indoors, protected from the weather and with non-condensing humidity. For outdoor use in moist environments use a Goldline Rain Tight Enclosure. Use the mounting screws supplied or optional mounting bracket (consult IF factory).

2. Sensor Mounting and Wiring

To maximize temperature measurement accuracy, securely mount the sensor and then insulate it to protect it from the effects of ambient temperature. 18 AWG twisted pair wire should be used for indoor and outdoor runs. Sensor wiring run outdoors must be rated for outdoor use and ensure that wire connections are protected from the weather. For

long runs or runs near other electrical wiring, use shielded cable (Belden 8760 for indoor use or Belden 8428 for outdoor use). Ground the shields to one of the control's cover screws. If the SW sensor supplied with the control does not meet your needs, contact your distributor for information on the wide range of interchangeable Goldline temperature sensors.

3. Power input

The SP-3x and SP-3xD controls require power to operate. You may connect either 24VAC to the "R" and "C" terminals, 24VDC to the "R" (+) and "C" (-), 115VAC to the terminals marked "115VAC" or 208/240VAC to the terminals marked "240VAC". Connect grounds to the green screw

provided or use grounding clips (eg Steel City "Gee clips" or Raco #975). Refer to wiring diagram on page 2.

4. Output wiring

SP-3x: The SP-3x provides one set of isolated SPDT relay outputs. If you are directly controlling a load (eg pump, blower, valve, etc), you must connect a source of power through this output relay. "NO" are normally open contacts which close when the control output is on. "NC" are normally closed contacts which open when the control output is on. Refer to the sample diagrams shown below.

SP-3xD: The SP-3xD provides two sets of isolated SPDT relay outputs. If you are directly controlling a load (eg pump, blower, valve, etc), you must connect a source of power through these output relays. "NO" are normally open contacts which close when the control output is on. "NC" are normally closed contacts which open when the control output is on. Refer to the sample diagrams shown on the following page.

The output 2 relay on the SP-3xD control will be disabled when the insulated wire jumper (located next to the "R" and "W" spade terminals) is cut

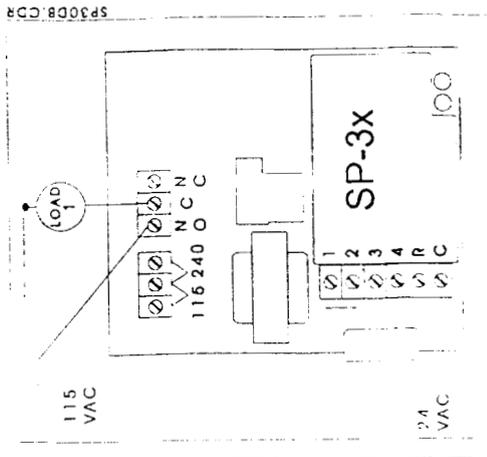
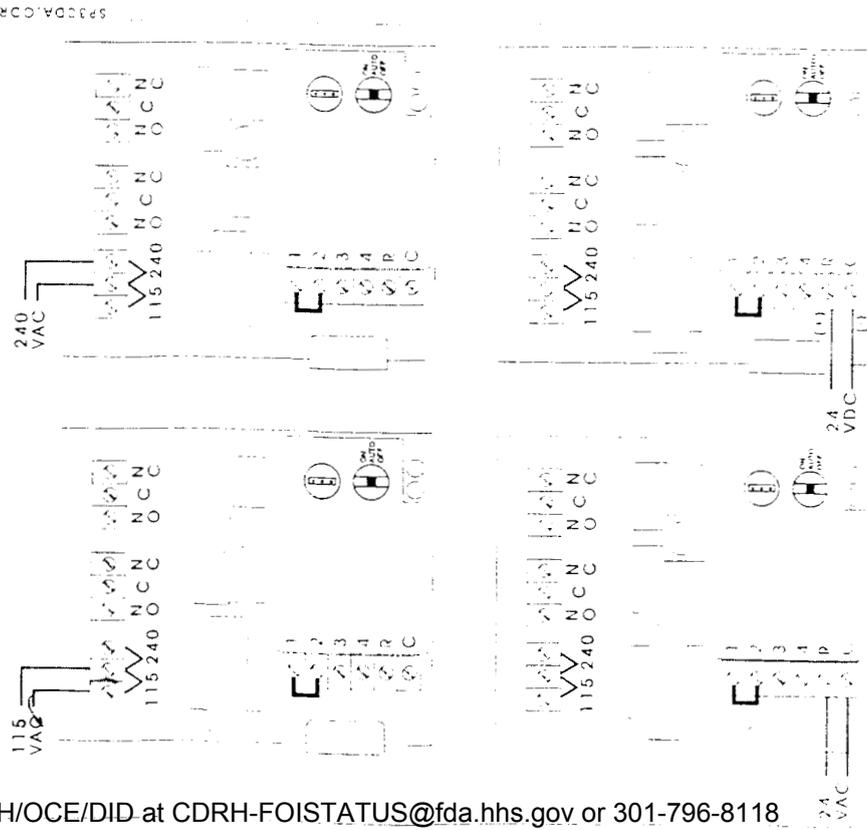
Shorting across "R" and "W" will again enable the output 2 relay. This feature allows for a switch (manual, temperature, etc.) to be wired across "R" and "W" to provide additional control of the output 2 relay (see diagram on page 6). A common application of this feature is a high or low limit override for the second relay. For normal operation, when this type of control is not needed, the wire jumper should remain untouched.

5. Setpoint

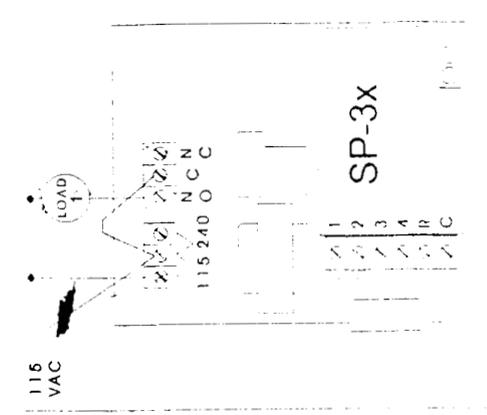
Controls are shipped from the factory set up to use the internal setpoint adjustment knob. If you would like to use a remote setpoint or a fixed setpoint, the internal setpoint adjustment can be disabled. To accomplish this, remove the jumper from terminals "1" and "2" and connect an RSP (potentiometer) or an ESP (fixed resistor) to terminals "2" and "3". RSPs and ESPs are available through your Goldline dealer. Setback can also be accomplished with the use of any SPDT timer. Refer to diagram on page 5.

6. Adjustments

Set the mode jumper into the "heat" or "cool" position. Adjust the setpoint and differential to the desired settings.



115 VAC Applied to Load When Output is ON, Control Powered by 24 VAC



115 VAC Applied to Load When Output is ON, Control Powered by 115 VAC

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Temperature vs. Resistance Chart

All Goldline controls use 10K thermistor sensors. When disconnected from the control, the sensor will read 10 K ohms at 25°C/77°F. Refer to the chart below for the resistance at other temperatures. For a given temperature, the resistance is accurate to $\pm 1\%$. For a given resistance the temperature is accurate to $\pm 0.5^\circ\text{F}$.

| °F | OHMS | °F | OHMS | °F | OHMS | °F | OHMS | °F | OHMS | °F | OHMS | °F | OHMS |
|-----|---------|----|--------|----|--------|-----|-------|-----|-------|-----|------|-----|------|
| -50 | 497,142 | 0 | 85,387 | 50 | 19,900 | 100 | 5,827 | 150 | 2,044 | 200 | 929 | 250 | 378 |
| -49 | 472,542 | 1 | 82,719 | 51 | 19,377 | 101 | 5,597 | 151 | 2,005 | 201 | 875 | 251 | 373 |
| -48 | 454,909 | 2 | 80,142 | 52 | 18,870 | 102 | 5,370 | 152 | 1,966 | 202 | 822 | 252 | 367 |
| -47 | 437,907 | 3 | 77,556 | 53 | 18,377 | 103 | 5,146 | 153 | 1,929 | 203 | 788 | 253 | 362 |
| -46 | 421,632 | 4 | 75,255 | 54 | 17,899 | 104 | 4,926 | 154 | 1,892 | 204 | 771 | 254 | 357 |
| -45 | 405,365 | 5 | 72,937 | 55 | 17,435 | 105 | 4,708 | 155 | 1,856 | 205 | 763 | 255 | 352 |
| -44 | 390,366 | 6 | 70,998 | 56 | 16,985 | 106 | 4,504 | 156 | 1,821 | 206 | 750 | 256 | 347 |
| -43 | 375,577 | 7 | 68,935 | 57 | 16,548 | 107 | 4,302 | 157 | 1,787 | 207 | 738 | 257 | 342 |
| -42 | 362,770 | 8 | 66,447 | 58 | 16,120 | 108 | 4,103 | 158 | 1,753 | 208 | 726 | 258 | 337 |
| -41 | 349,522 | 9 | 64,428 | 59 | 15,711 | 109 | 3,907 | 159 | 1,720 | 209 | 714 | 259 | 332 |
| -40 | 336,804 | 10 | 62,479 | 60 | 15,310 | 110 | 3,714 | 160 | 1,688 | 210 | 702 | 260 | 327 |
| -39 | 324,537 | 11 | 60,595 | 61 | 14,921 | 111 | 3,523 | 161 | 1,657 | 211 | 691 | 261 | 323 |
| -38 | 312,875 | 12 | 58,774 | 62 | 14,543 | 112 | 3,334 | 162 | 1,626 | 212 | 680 | 262 | 318 |
| -37 | 301,622 | 13 | 57,014 | 63 | 14,176 | 113 | 3,148 | 163 | 1,596 | 213 | 669 | 263 | 314 |
| -36 | 290,813 | 14 | 55,313 | 64 | 13,820 | 114 | 2,964 | 164 | 1,567 | 214 | 658 | 264 | 309 |
| -35 | 280,430 | 15 | 53,669 | 65 | 13,473 | 115 | 2,783 | 165 | 1,538 | 215 | 648 | 265 | 305 |
| -34 | 270,460 | 16 | 52,078 | 66 | 13,136 | 116 | 2,604 | 166 | 1,509 | 216 | 637 | 266 | 301 |
| -33 | 260,873 | 17 | 50,541 | 67 | 12,809 | 117 | 2,427 | 167 | 1,482 | 217 | 627 | 267 | 296 |
| -32 | 251,670 | 18 | 49,054 | 68 | 12,491 | 118 | 2,252 | 168 | 1,455 | 218 | 617 | 268 | 292 |
| -31 | 242,821 | 19 | 47,616 | 69 | 12,182 | 119 | 2,079 | 169 | 1,428 | 219 | 607 | 269 | 288 |
| -30 | 234,316 | 20 | 46,225 | 70 | 11,882 | 120 | 1,908 | 170 | 1,402 | 220 | 598 | 270 | 284 |
| -29 | 226,138 | 21 | 44,879 | 71 | 11,589 | 121 | 1,739 | 171 | 1,377 | 221 | 588 | 271 | 280 |
| -28 | 218,276 | 22 | 43,577 | 72 | 11,305 | 122 | 1,572 | 172 | 1,352 | 222 | 579 | 272 | 276 |
| -27 | 210,716 | 23 | 42,318 | 73 | 11,029 | 123 | 1,407 | 173 | 1,328 | 223 | 570 | 273 | 273 |
| -26 | 203,445 | 24 | 41,099 | 74 | 10,761 | 124 | 1,244 | 174 | 1,304 | 224 | 561 | 274 | 269 |
| -25 | 196,451 | 25 | 39,919 | 75 | 10,500 | 125 | 1,082 | 175 | 1,281 | 225 | 553 | 275 | 265 |
| -24 | 189,722 | 26 | 38,777 | 76 | 10,246 | 126 | 9,312 | 176 | 1,258 | 226 | 544 | 276 | 262 |
| -23 | 183,248 | 27 | 37,671 | 77 | 9,999 | 127 | 8,244 | 177 | 1,235 | 227 | 536 | 277 | 258 |
| -22 | 177,019 | 28 | 36,601 | 78 | 9,758 | 128 | 7,177 | 178 | 1,213 | 228 | 527 | 278 | 255 |
| -21 | 171,023 | 29 | 35,565 | 79 | 9,522 | 129 | 6,112 | 179 | 1,192 | 229 | 519 | 279 | 251 |
| -20 | 165,251 | 30 | 34,561 | 80 | 9,291 | 130 | 5,049 | 180 | 1,171 | 230 | 511 | 280 | 248 |
| -19 | 159,696 | 31 | 33,590 | 81 | 9,076 | 131 | 2,987 | 181 | 1,150 | 231 | 503 | 281 | 244 |
| -18 | 154,347 | 32 | 32,648 | 82 | 8,867 | 132 | 2,926 | 182 | 1,130 | 232 | 496 | 282 | 241 |
| -17 | 149,197 | 33 | 31,737 | 83 | 8,661 | 133 | 2,867 | 183 | 1,110 | 233 | 488 | 283 | 238 |
| -16 | 144,236 | 34 | 30,853 | 84 | 8,447 | 134 | 2,809 | 184 | 1,091 | 234 | 481 | 284 | 235 |
| -15 | 139,458 | 35 | 29,998 | 85 | 8,249 | 135 | 2,752 | 185 | 1,072 | 235 | 473 | 285 | 232 |
| -14 | 134,855 | 36 | 29,169 | 86 | 8,056 | 136 | 2,697 | 186 | 1,054 | 236 | 466 | 286 | 229 |
| -13 | 130,420 | 37 | 28,365 | 87 | 7,867 | 137 | 2,643 | 187 | 1,035 | 237 | 459 | 287 | 225 |
| -12 | 126,147 | 38 | 27,587 | 88 | 7,684 | 138 | 2,591 | 188 | 1,017 | 238 | 452 | 288 | 223 |
| -11 | 122,000 | 39 | 26,832 | 89 | 7,506 | 139 | 2,539 | 189 | 1,000 | 239 | 445 | 289 | 220 |
| -10 | 118,061 | 40 | 26,100 | 90 | 7,333 | 140 | 2,489 | 190 | 983 | 240 | 439 | 290 | 217 |
| -9 | 114,235 | 41 | 25,391 | 91 | 7,164 | 141 | 2,440 | 191 | 966 | 241 | 432 | 291 | 214 |
| -8 | 110,517 | 42 | 24,704 | 92 | 6,999 | 142 | 2,392 | 192 | 950 | 242 | 426 | 292 | 211 |
| -7 | 106,991 | 43 | 24,037 | 93 | 6,839 | 143 | 2,345 | 193 | 933 | 243 | 420 | 293 | 208 |
| -6 | 103,561 | 44 | 23,391 | 94 | 6,683 | 144 | 2,299 | 194 | 918 | 244 | 413 | 294 | 206 |
| -5 | 100,254 | 45 | 22,764 | 95 | 6,530 | 145 | 2,254 | 195 | 902 | 245 | 407 | 295 | 203 |
| -4 | 97,063 | 46 | 22,156 | 96 | 6,382 | 146 | 2,210 | 196 | 887 | 246 | 401 | 296 | 200 |
| -3 | 93,986 | 47 | 21,566 | 97 | 6,238 | 147 | 2,167 | 197 | 872 | 247 | 396 | 297 | 198 |
| -2 | 91,017 | 48 | 20,993 | 98 | 6,097 | 148 | 2,125 | 198 | 857 | 248 | 390 | 298 | 195 |
| -1 | 88,152 | 49 | 20,435 | 99 | 5,960 | 149 | 2,084 | 199 | 843 | 249 | 384 | 299 | 193 |
| | | | | | | | | | | | | 300 | 190 |

Tony
X 107

INDEPENDENT ENERGY INC.

42 Ladd Street, East Greenwich, RI 02818

(401) 884-6990 (800) 343-0826 (401) 885-1500 fax

P/N 116212(G)

SP34

204

IM-8

Direct immersion type,
304 stainless steel, 1/4" dia. x 8"
probe with 1/4" NPT brass fitting

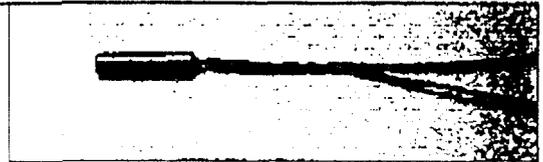
IM-4 - 44201

Direct immersion type,
304 stainless steel, 1/4" dia. x 4"
probe with 1/4" NPT brass fitting



SW

Brass thermowell type
(included with all SPcontrols)
5/16" diameter x 1-1/4"



SB

Bolt-on for flat surfaces/strap-on
for pipes or tubing. Copper, flat at
one end with hole for mounting

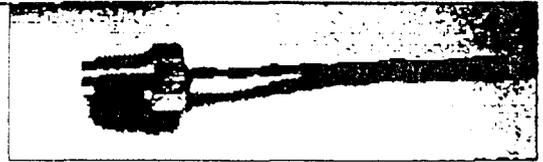


SC-1/2

Brass screw in type for 1/2" NPT

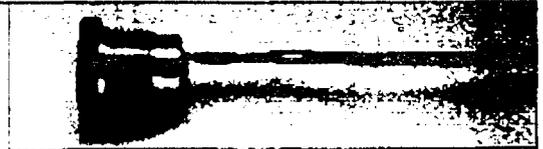
SC-1/4

Brass screw in type for 1/4" NPT



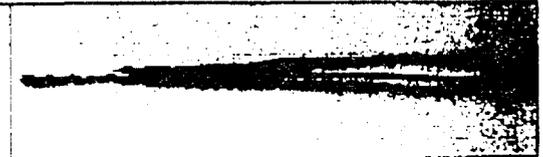
SCR-1/2

Brass reversed screw in type
for 1/2" NPT



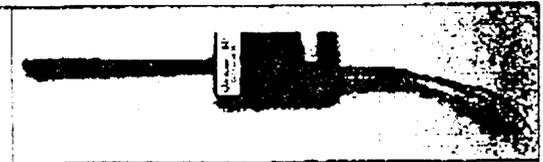
SX

Miniature bare thermistor
for fast response



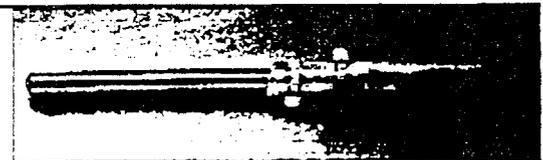
SD

Bare thermistor with plate
for duct mounting



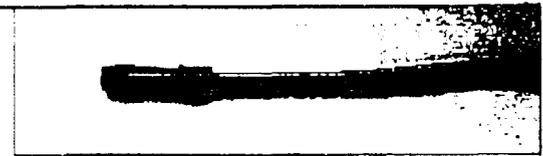
SMX-10

Direct immersion type,
304 stainless steel, 1/4" dia. x 4"
with 10 ft immersible cable



SWX-10 - 44202

Plastic molded type, 5/16" dia. with
10 ft leads. Ideal for refrigeration
and freezer applications



5
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Lifestream

Purification Systems, LLC

Operations Manual

for the

Angel of Water™

Purification System

DRAFT

2001 South Lamar, Suite G
Austin, Texas 78704

(512) 707-3773

Lifestream

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Lifestream Purification Systems, LLC

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and Colon Irrigation Session p.4

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Introduction

A Brief Description of the Angel of Water™ Purification System and Colon Irrigation Session

The Angel of Water™ Purification System is a very simple, safe, comfortable, and hygienic way to irrigate the colon for endoscopic and/or radiological purposes. The following sequence of events briefly describes the experience and how the person can control temperature, pressure, and flow of the System, once the System has been sanitized as specified in Chapter 1 of this manual.

The tank is filled with hot and cold water controlled by a water mixing valve on the basin right topside. The proper **temperature** of the water falls between 99 - 103 degrees Fahrenheit and is monitored by the temperature gauge visible on the front of the tower cabinet. If **at any time** the water rises above 103 degrees Fahrenheit, the temperature sensor control will shut off the flow valve, stopping water flow to the person.

After the person has comfortably positioned himself on the basin (with the pillow and cushioned backrest in place) and inserted the nozzle into the rectum, water **flow** can be activated by turning ON the FLOW switch. This is located on the wall-mounted control panel to the person's left. Water flow can be stopped **at any time** by simply turning the FLOW switch OFF. The tank line to the basin nipple has a backflow prevention valve as a permanent plumbing safety feature. It is located underneath the fiberglass basin and is connected directly to the basin nipple through an opening in the basin wall. It prevents water from flowing back into the line once it has passed through the basin nipple into the nozzle and into the person's rectum.

The System only has one **pressure** and that is the controlled pressure created by gravity as water exits the elevated tank in the tower cabinet as activated by the FLOW switch. The person experiencing the session has only to turn OFF the FLOW switch next to her on the wall-mounted control panel on her left to stop the water **at any time** and thus stop the pressure created by gravity (.7 psi).

In summary, **at any time**, the temperature, flow, and pressure of the Angel of Water™ Purification System can be controlled by simply turning OFF the FLOW switch at either control panel **or** by the person simply sliding back off the nozzle and resting on the basin.

Lifestream

A typical colon hydrotherapy session lasts approximately 30-40 minutes and uses approximately 12 gallons of water, which is the total volume capacity of the main tank. Therefore, typically, only one tank full of water is needed. At the end of the session, the person turns OFF all three switches (U.V., CYCLE, FLOW) and slides back off the nozzle so that it naturally drops away from his body. The person can now drain comfortably on the ergonomic basin, sitting up erect or leaning back in a lounge position to fully drain her colon. After this is done, the person can rinse himself using the personal shower sprayer and its control valve located on the basin left topside. Tempered water is delivered to the sprayer by the same water mixing valve on the right topside of the basin that also sends water to the System tank. The person can then towel herself dry before dressing and leaving the privacy of the colon irrigation room.

Lifestream

Indications for Use

This device is intended for colon irrigation before radiological or endoscopic examinations, or when otherwise medically indicated.

Patient Population

Colon irrigation can be administered in preparation for radiological or endoscopic examination (colonoscopy, protoscopy, lower Barium X-ray), or when otherwise medically indicated, such as before surgery and childbirth. Other conditions for which colon irrigation may provide assistance include, but may not be limited to:

- acute fecal impaction
- atonic colon
- bowel stimulation/training in para/quadruplegics
- constipation
- diarrhea
- flatulence or bloating
- intestinal toxemia
- mild hemorrhoids

Setting

The Angel of Water™ Purification System is intended for use in a clinical setting by a trained and certified health care practitioner under the order of a physician.

Lifestream

Contraindications for Use

The contraindications for the use of the Angel of Water Purification System include, but may not be limited to:

- congestive heart failure
- intestinal perforation
- carcinoma of the rectum
- fissures or fistula
- severe hemorrhoids
- abdominal hernia
- renal insufficiency
- recent colon or rectal surgery
- abdominal surgery
- first and last trimester of pregnancy
- cirrhosis

Chapter 1

Cleaning the Angel of Water™ Purification System

Safety First

Safety is your primary responsibility. **You must always assume the System is NOT ready until you prepare it immediately before use. Always clean your System immediately after use, and immediately before each use. This means that you disinfect and inspect the unit right before a session, even if you cleaned it the night before or hours before.**

If you clean the System and then leave the building where your System is located, and then you return to use the System, clean it again. You do not know what may have transpired in your absence.

This attitude assures that you ALWAYS begin each session hygienically. Plus, it gives you enormous peace of mind in serving others.

Tools and Procedures for Cleaning

The tools and procedures described below are considered the minimum requirements for proper disinfection and upkeep of your System.

REMEMBER, always clean your System immediately after use and immediately before each use!

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Tools For Sanitizing

- 1) **Zep Attack-A¹**- broad-spectrum disinfectant
- 2) **Chlorine bleach (sodium hypochlorite)** - deodorizer and stain remover
- 3) **Zep Air Fair Conquer** - deodorizer
- 4) **Degreaser and Tether Mop** - for periodic cleaning of Viewing Tube
- 5) **3 Buckets (one gallon size) / with Soft Mops** - two for Attack-A mixture, the third for chlorine bleach solution for deodorizing and stain removal
- 6) **Body Protection** - rubber gloves, eye or face shield, towel or respirator for lung protection
- 7) **Miscellaneous** - 2 spray containers (one for Attack-A mixture, one for Air Fair Conquer mixture), cotton balls, funnel for safe pouring, paper towels for used nozzle wrapping and disposal

Other items are needed for a successful session; the following items make a session more hygienic:

wastebasket with spring-open lid and plastic liners
petroleum jelly lubricant and tube dispenser
paper towels and/or toilet tissue
cotton balls (sterile)
facial tissues
towels for hand wiping and drying of System
floor rug of a non-slip type
disposable gloves

¹ *Attack-A* and *Air Fair Conquer* are products of Zep Manufacturing Company, Atlanta, GA

Procedure For Sanitizing

Regardless of whether the System was cleaned previously, clean the System again if you left the premises where it is located, even if only for a few hours.

Pre-Session Preparation -

1) Turn System LIGHTS Switch On

2) Protect Yourself

- a) Put on rubber gloves, eye shields, and protect respiratory channels with towel or respirator before next step.

3) Spray Attack-A on Basin, Rinse Lines, Towel Dry

- a) Allow a mixture of 1 oz. Attack-A to one gallon of water per manufacturer's instructions to contact basin surface for at least **10 minutes** for maximal disinfection.
- b) Run water from tank through nipple for a couple of minutes to wash out line.
- c) Towel dry System surfaces.

4) Connect New Flex Tube and Sterile Rectal Nozzle, Do Final Room Inspection

- a) Connect new flex tube and new sterile, disposable rectal nozzle to flex tube, then lubricate nozzle to conduct session.
- b) Inspect room for readiness before having person enter for session.

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Post-Session Cleaning -

1) Protect Yourself

- a) Put on rubber gloves, eye shields, and protect respiratory channels with towel or respirator before using chemicals.

2) Remove Soiled Linens from System Area

- a) Place soiled linens in laundry basket.

3) Spray Attack-A Disinfectant and Water Rinse, then Mop with Attack-A Disinfectant (Bucket #1), Water Rinse

- a) Spray entire basin area with Attack-A, then water rinse obvious waste material down drain. Turn on View Tube Flush valve as needed to clear drain line.
- b) Mop wash entire basin *and* used nozzle with Attack-A (Bucket #1)(1 oz. Attack-A to one gallon of water) before nozzle and flex tube removal. Water rinse everything down drain again.

4) Remove Used Nozzle and Flex Tube, Rinse Out Line

- a) With paper towel, grasp and pull out nozzle and flex tube from brass nipple together. Bend nozzle in half and wrap it and used flex tube in paper towel and dispose of both in wastebasket.
- b) Turn water flow on and rinse out line.

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5) Mop with Attack-A Disinfectant

(Bucket #2), Water Rinse

(Degrease View Tube as needed)

- a) Mop wash entire basin area again with Attack-A (Bucket #2)(1 oz. Attack-A to one gallon of water) after nozzle and flex tube removal.

Per manufacturer's instructions, make sure that the combined contact time of Buckets #1 and #2 (Zep Attack-A solution) on the basin surface is at least **10 minutes** for maximal disinfection

- b) Water rinse entire basin again well.
- c) Degrease Drain Pipe Viewing Tube in this step when build-up of petroleum jelly lubricant warrants this procedure. Use the tether mop and degreaser to scrub tube.

6) Mop with Chlorine Bleach Deodorizer

(Bucket #3), Water Rinse

- a) Mop wash entire basin area with diluted chlorine bleach solution (Bucket #3)(1 capful to one gallon of water for a 200ppm solution). Let solution contact surface for 1 minute. Chlorine bleach acts both as a deodorizer and stain remover.

7) Inspect Main Tank, Disinfect Main Tank and Recirculating (Small) Tank and Exit Line to Basin Nipple

At the end of every day, we recommend that you disinfect the main and recirculating (small) tank and the exit line of the Angel of Water™ Purification System.

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- a) Run water through the tank and lines to clear them of any debris that may have gotten into the main tank.
- b) Fill water in main tank to black disinfection mark (1 ½ gallons). Stop water filling. Turn on CYCLE switch and let small tank fill up until full (approximately 40 oz.). Turn off CYCLE switch.
- c) Add 1 oz. of Attack-A to main tank and ¼ oz. of Attack-A to small tank through their respective topside openings. Let disinfectant sit for **10 minutes**, according to manufacturer's instructions.
- d) To drain both tanks, close Valve #6 (U.V. Inlet) and open Valves #3, #4, and #5. Both tanks will now drain into basin. Refill main tank and small tank again and flush one more time. The System is now ready for use.

8) Spray Attack-A, Spray Air Fair Conquer, Towel Dry

- a) Spray a fine mist of Attack-A into the trough and on a linen hand towel to wipe the personal shower sprayer and all basin topside control knob handles.
- b) Spray a fine mist of Air Fair Conquer into the basin trough and splashguard to deodorize.
- c) Towel dry and wipe all surfaces of excess chemicals and water.

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9) Replace Linens, Do Final Inspection

- a) Put on a fresh pillowcase and supply a fresh cover cloth. Rotate and launder the pillow if it got wet for any reason. Have a number of linens/pillows to rotate and have them clean and ready as required.
- b) Wipe lavatory, glasses, and mirrors and inspect room for overall cleanliness before next session or before finishing for the day.

(If another session is to be conducted continue to #10):

10) Run Properly Tempered Water through Line, Connect New Flex Tube and New Sterile, Disposable Rectal Nozzle

- a) Rinse out line with properly tempered water, 99 to 103 degrees Fahrenheit.
- b) Connect new flex tube and new sterile, disposable rectal nozzle to flex tube, then lubricate nozzle to conduct session.
- c) Inspect room for readiness before having person enter for session.

It is recommended that you always clean System directly after a session. Do not postpone for any reason. Clean it, and clean it properly NOW! Always give the first impression and guarantee of cleanliness and hygiene.

Chapter 2

Control Switch Panels

When setting up the Angel of Water™ Purification System, always connect the electrical power plug for the System into a hospital-grade receptacle wall outlet, such as the one included with your System. Consult with a qualified electrician if necessary.

The Angel of Water has two control switch panels: one is on the wall beside and for the use of the person experiencing the colon irrigation and the other is on the tower by the tank for the monitoring assistant or health care practitioner to use.

Switches on both panels must be in the ON position for the function to operate, which means that if one switch is turned OFF, such as the FLOW switch, then that function will not work.

The switches are described below:

LIGHTS - (on tower control panel only) - Turns on all lights for the inside and outside viewing tube areas and inside tower cabinet to illuminate tank water level and make it visible through tower cabinet side and front windows. This switch also activates all other switches. When this switch is ON, the other switch functions will work. When this switch is OFF, none of the other switches and their functions will work.

U.V. - activates ultraviolet light in U.V. Filter. This should only be turned ON just prior to water flowing to the person on the System. Turn OFF when session stops for more than a couple of minutes or when

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session is finished. Turn ON again as session resumes.

CYCLE - activates the water cycling device to move water from larger main tank to small recirculating tank. This keeps water temperature evenly mixed throughout the use of the entire contents of the water tank and maintains an even and constant stream of gravity-fed water to the person experiencing the colon irrigation.

The water cycling device should only be on when water is flowing through it. When water in large main tank runs out, turn **CYCLE** switch OFF until tank is filled with more water. Then resume session with **CYCLE** switch ON to maintain even and constant stream of gravity-fed water again.

FLOW - activates Solenoid valve that allows water flow from tank into the person who is on System. A small round indicator light next to the **FLOW** switch on the wall-mounted control panel lights up and is visible when water is flowing to person.

Temperature Gauge and Temperature Controller with Sensor

The Temperature Gauge on the Angel of Water™ Purification System is located on the front of the tower cabinet, visible to the person experiencing the colon irrigation or to a monitoring assistant or health care practitioner.

It shows the water temperature and, with the push of a button, the room temperature. This highly reliable and simple-to-use gauge is battery operated (AAA battery) and acts independently of any electrical supply. It therefore provides reliable

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readings during either Regular or Manual Modes of operation.

Consult the temperature gauge manual included in the **System Parts Packet** included with your System for information regarding functions.

The temperature controller with sensor senses water temperature and automatically closes Solenoid valve during Regular Mode of Operation should the temperature of the water exceed 104 degrees Fahrenheit.

Should the Solenoid valve shut off due to water temperature exceeding the acceptable range (99 – 103 degrees), the monitoring assistant should simply add cool water to the main tank by turning the mixing valve on the basin console (within reach on right top side of basin) to a cooler setting. The Solenoid valve will then automatically reactivate, allowing the FLOW function to deliver properly tempered water to the person experiencing colonic irrigation.

Chapter 3

Valves

Each of the valves on the Angel of Water™ Purification System is numbered and has a description label next to it. Turning valves ON or OFF achieves the following: directs certain flow patterns; allows water into the tank; allows tank to drain; allows bypassing of certain electrical components such as the Water cycling device or Solenoid valve so that the System may be operated with or without electricity; allows bypassing of certain electrical components (Water cycling device, Solenoid valve, U.V. Filter) so that the two tanks and exit line to user may be disinfected.

Be assured, the valves and their functions are easy to learn and can be mastered in a short period of time. Their descriptions are as follows:

Valves #1 and #2 are accessed through the small side door located on the tower cabinet:

#1 Tank Fill - allows water into tank

#2 Tank Drain - empties tank

Valves #3 - #9 are accessed through the back folding door located on the tower cabinet:

#3 Tank Exit - used for manual flow operation (without electricity)

#4 Manual Flow Inlet - allows water to flow to user (without electricity)

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#5 Solenoid Valve Bypass - allows water to flow without going into Solenoid valve

#6 U.V. Inlet - allows water into Ultraviolet filter

#7 Recirculating Tank Exit - allows water to leave small tank

#8 Recirculating Tank Bypass - keeps water from entering small tank

#9 Recirculating Tank Inlet - allows water into small tank

Valves #10 and #11 are accessed through the large door located on the basin cabinet:

#10 Cold Inlet - allows cold water source into System

#11 Hot Inlet - allows hot water source into System

The following three valves are located on the fiberglass basin topside:

Shower Sprayer Volume Control Valve (left side) - adjusts sprayer water volume

Viewing Tube Flush Valve (right side) - flushes waste matter through viewing tube line and down drain

Water Mixing Valve (right side) - mixes hot and cold water for tank fill and shower sprayer use

The following valve is located inside large main tank:

Tank Level Valve - automatically shuts off water fill into large main tank

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The following valve is the only electrical valve on the System and is located on the middle shelf of the tower cabinet. It is accessed by opening the back folding doors of the tower cabinet:

Solenoid Valve - activated by FLOW control panel switch

The following two valves are permanent plumbing safety features:

Basin Backflow Prevention (Ball Check) Valve - prevents water from flowing back into the line once it has passed from the basin nipple to the nozzle and into the person's rectum

This valve is located underneath the fiberglass basin and is connected directly to the basin nipple through the basin wall.

Viewing Tube Sprayer Backflow Prevention (Spring-loaded) Valve – prevents water flushed into viewing tube from backing into clean water line

This valve is located directly inside the basin cabinet large doors. It is reachable to the upper right of the door opening.

Chapter 4

Valve Sequences for System Operation

The Angel of Water™ Purification System has two modes of operation: **Regular Operation** functions by electricity and through electrical components and **Manual Operation** works with or without electricity and without the use of the electrical components.

Study the following valve sequences and actually go through each one on your System to see the operation of each.

1) Regular Operation (electrical)

This is the primary mode of operation. Regular Operation features water circulating from the large main tank via the water cycling device to the smaller tank. Then an even and constant stream of gravity-fed water flows through the U.V. Filter to the person experiencing the colon irrigation.

Follow this valve sequence:

a) Open valves #6, #7, #9, (#10 and #11 were set in OPEN position when System was set up and should be left OPEN always unless System plumbing maintenance requires otherwise.) All other valves are closed. Then open #1 and turn on and adjust Water Mixing valve to fill tank with water between 99 to 103 degrees Fahrenheit.

Close #1 or shut off Water Mixing valve to stop water to large main tank at any level. However, water level inside tank shuts off automatically by Tank Level valve once level

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has reached top (about 12 gallons). Once full, close #1 and/or turn off Water Mixing valve. As water is needed in tank, open #1 and/or turn on Water Mixing valve to refill tank.

b) Occasionally, the person experiencing the colon irrigation may feel as if no water is coming into their colon. This may indicate that the nozzle inserted into them is clogged at the tip with waste material. The monitoring assistant or health care practitioner can unclog nozzle in the following way *without* having the person on the System come off the nozzle in order to check it. To unclog nozzle with additional flow from large main tank, close #7 and #9. Then **slowly** open #8 **partially** until flow is felt again by person experiencing the irrigation. Then open #7 and #9 again, and close #8 completely.

2) Manual Operation (with or without electricity)

This mode and valve sequence allows a monitoring assistant or health care practitioner to send water to the person experiencing the colon irrigation directly from the large main tank with or without the activation of the FLOW control switch or with or without the use of electricity. (Of course, without electricity, the Water Cycling Device will not send water to the smaller recirculating tank, the Solenoid valve will not work by the FLOW control switch, nor will there be U.V. treatment of the water as it is flowing to the person.)

There are two manual modes:

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a) NO electricity and NO U.V. water treatment - open valve #1 and Water Mixing valve to fill tank to proper water temperature between 99 to 103 degrees Fahrenheit. When monitoring assistant or health care practitioner is ready to send water to the person experiencing the colon irrigation, open only valves #3 and #4. Close valve #4 when person on the System is finished with session or wants an intermission from session.

b) WITH electricity and WITH U.V. water treatment - open valve #1 and Water Mixing valve to fill tank to proper water temperature between 99 to 103 degrees Fahrenheit. When monitoring assistant or health care practitioner is ready to send water to the person experiencing the colon irrigation, open only valves #3 and #6. Close valve #6 when person on the System is finished with session or wants an intermission from session. If session stops longer than a couple of minutes, be sure to turn U.V. control switch to OFF temporarily during the intermission. Turn U.V. control switch ON when session resumes and valve #6 is opened again.

Chapter 5

Maintenance

Your Angel of Water™ Purification System is designed to be virtually maintenance free, aside from sanitizing the unit prior to and after each use.

However, some items will need to be replaced occasionally and can be ordered directly from Lifestream or found at most good hardware stores. The following items will need to be replaced due to normal usage and additional instructions can be found on each item listed in your **System Parts Packet**:

1) Filters

The **carbon cartridge** in the Standard Carbon Filter canister (for initial water filtration before water enters the large main tank) should be replaced every **15,000 gallons or 3 months**. The **sediment cartridge** in the U.V. Light Filter should be replaced every **16,000 gallons or 4 months**.

The practitioner should keep a log of carbon and sediment cartridge replacement dates to know when the manufacturer's recommended period of use has elapsed. The manufacturer states, however, that filter life will vary depending upon usage and water conditions—i.e., the amount of particulate in the water supply.

To change the filters:

- a) Turn off water supply to the System.
- b) Unscrew bottom of housing from cap.
- c) Locate and remove O-ring, wipe clean of lubricant, and put aside.

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d) Discard the used cartridge.

Relubricate O-ring with petroleum jelly, insert in groove, and press into place (important to ensure a proper seal on the housing).

e) Insert new cartridge, making sure it slips over the standpipe in the bottom of the housing.

f) Screw the bottom of housing onto the cap and hand-tighten it. Make sure cartridge slips over the standpipe.

g) Turn on the water supply slowly and allow System to fill with water. Flush cartridge for 15 minutes before using. Check for leaks before resuming regular use.

2) Batteries in Temperature Gauge

The Temperature Gauge on the front of the tower cabinet is battery operated. **Always pay close attention to the proper operation of the temperature gauge. When gauge display begins to fade, simply replace the old AAA battery with a new one by removing back panel of gauge. Always have spare batteries on hand and never operate System without a functioning temperature gauge.**

3) Diaphragm Plunger inside Solenoid Valve

The Solenoid valve has a diaphragm plunger inside the brass body that will begin to leak water slightly when it needs to be replaced. In other words, when the FLOW switch is OFF, water may leak slightly and be noticeable as it drips at the basin nipple or through sterilized nozzle prior to session beginning.

To replace, first unplug electrical power supply to System. Then simply

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unscrew four screws on valve housing, take old plunger out, and put in new plunger. Replace housing and screws. Reconnect to electrical power supply and test operation of Solenoid valve.

4) Light Bulbs

The Viewing Tube and Tank Tower light bulbs have been selected for their longevity and should last from 9,000 to 10,000 hours of use.

Simply replace bulbs when they go out by unscrewing or removing old bulb and replacing with new bulb.

5) U.V. Lamp

WARNING: Remember always to disconnect electrical power to the U.V. light when servicing it and remember NEVER to look at the lighted U.V. lamp.

The U.V. lamp is rated for **7,500 hours** of continuous use and not longer than **24 months** of intermittent use. If the UV lamp is not changed out after 7,500 hours of continuous use, its disinfection performance will be drastically reduced due to photochemical changes that lessen the water purifier's ability to kill bacteria. **The practitioner should keep a log of U.V. lamp replacement and servicing dates to know when the 7,500 hour (continuous use) or 24-month (intermittent use) period has elapsed.** The Service chapter in the Ultradynamics Manual contained within your **System Parts Packet** gives explicit directions on changing the U.V. lamp. When replacing

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the U.V. lamp, the quartz sleeve will need to be cleaned as well, since minerals and debris settle and deposit onto the quartz sleeve with use. The directions are as follows:

- a) Turn off the water and disconnect electrical power to the U.V. unit.
- b) Straighten the U.V. lamp wiring harness and carefully remove the old U.V. lamp from the quartz sleeve, and drain the U.V. chamber.
- c) Using hand pressure or an open-ended wrench, back off the compression nuts and carefully remove the quartz sleeve.
- d) Wash quartz sleeve with a mild soap and hot water solution and rinse clean with hot water.
- e) Slide new lamp carefully into clean quartz sleeve, pushing on the lamp all the way in.
- f) Be sure there are no marks or fingerprints on the U.V. lamp. (Clean with denatured alcohol and cotton if necessary).

Refer to the Ultradynamics Manual in your **System Parts Packet** to determine how often the quartz sleeve in the U.V. Unit needs to be cleaned.

Chapter 6

Trouble-Shooting Guide

| Description of Problem | Corrective Action | See Page...if Applicable |
|---|---|--------------------------|
| <p>1. System lights do not come on (from tower control panel light switch)</p> | <p>A. Make sure System power supply cord is plugged in correctly to wall AND into electrical source outlet on tower.</p> <p>B. Make sure circuit breaker that operates wall outlet is ON.</p> <p>C. Make sure GFCI reset switch in bottom of tower is in ON position.</p> <p>D. Check whether viewing tube light bulb and/or tower light bulb need to be replaced. Refer to component manufacturer information.**</p> | |

NOTE: In order for U.V., CYCLE, and FLOW functions to work, the wall-mounted supply cord must be properly connected to the coupling on the front of the tower AND both the tower and wall-mounted switches need to be in the ON position.

| Description of Problem | Corrective Action | See Page...if Applicable |
|---|--|--------------------------|
| <p>2. U.V. Filter light does not come on</p> | <p>A. See NOTE above.</p> <p>B. Make sure U.V. filter ballast is properly plugged into U.V. outlet in the bottom of tower.</p> <p>C. Make sure cord socket is properly plugged into U.V. bulb. Refer to installation instructions for UV filter.**</p> <p>D. If A. and B. don't work, the U.V. bulb may need to be replaced. Refer to bulb replacement instructions for U.V. filter.**</p> | |

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| | | |
|---|--|---|
| <p>3. CYCLE function does not work</p> | <p>A. See NOTE above.</p> | |
| <p>4. FLOW function does not work</p> | <p>A. See NOTE above. B. If no water flows into basin with Flow switch in ON position, the internal diaphragm of the Solenoid valve may need to be replaced. Refer to component manufacturer information.** C. Water may have exceeded 104 degrees Fahrenheit and Temperature controller has overridden FLOW function. Check water temperature and cool if necessary.</p> | |
| <p>5. Water does not flow into basin from main tank when both FLOW switches are on</p> | <p>A. Make sure valve sequence is configured for Regular Mode of Operation. B. Check the sediment filter in the U.V. filter and check your log to see whether it is time to replace it. C. Water may have exceeded 104 degrees Fahrenheit and Temperature controller has overridden FLOW function. Check water temperature and cool if necessary.</p> | <p>A. p.21 B. p.24</p> |
| <p>6. Water is not flowing into tank from water source at all or is flowing very slowly</p> | <p>A. Make sure valves #10 and #11 under basin cabinet are in OPEN position. B. Make sure Mixing valve on the basin cabinet is pulled to the OPEN position. C. Make sure Tank Fill valve (#1) located behind tower side door is in OPEN position. D. Check to see whether carbon filter in pre-filter canister installed before main tank is blocked with sediment. Check your log to see whether it is time to</p> | <p>D. p.24</p> |

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| | | |
|---|---|--|
| | replace it. E. If A., B., C., and D. don't work, the Tank Level valve (Delta Valve) inside main tank may need a new diaphragm kit. Refer to component manufacturer information.** | |
| 7. Personal Shower Sprayer does not work | A. Make sure shower volume control valve adjacent to sprayer head is in OPEN position. | |
| 8. Viewing Tube is clogged with waste matter | A. Turn on Viewing Tube Flush Valve to OPEN position and clear the tube. | |
| 9. Viewing Tube Drainpipe is clogged | A. Plunge over basin drain with small plunger provided with Angel of Water™ Purification System until drain clears. B. Contact a licensed plumber. WARNING: NEVER POUR DRAIN CLEANERS INTO YOUR ANGEL OF WATER™. | |
| 10. Water temperature is either too hot or too cold | A. Make sure valves #10 and #11 are completely in OPEN position. B. Make sure Mixing valve is pulled completely to OPEN position. Adjust toward hot or cold side to get properly tempered water (99 - 103 degrees Fahrenheit). | |
| 11. Temperature Controller is not stopping FLOW function when water temperature exceeds 104 degrees Fahrenheit | A. Remove face plate from temperature controller with small screwdriver. Make sure temperature setting knob is set at 104 degree mark. Refer to component manufacturer information.** | |

** Contained within the **System Parts Packet** that came with your Angel of Water™ Purification System.

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**For your maintenance questions please
contact our Maintenance Service Line at:**

**Lifestream Purification Systems, LLC
2001 South Lamar, Suite G
Austin, Texas 78704**

**(512) 707-3773
www.angelofwater.com**

Lifestream

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Test Item:

(b)(4) Testing

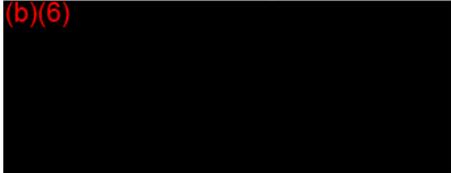
(b)(4) Testing

Testing Results Compiled By:



Amy Deilman
General Manager

(b)(6)



Research and Development

Date of Issue: June 27, 2001

Lifestream

Purification Systems, LLC

Installation Guide

for the

Angel of Water™

Purification System

DRAFT

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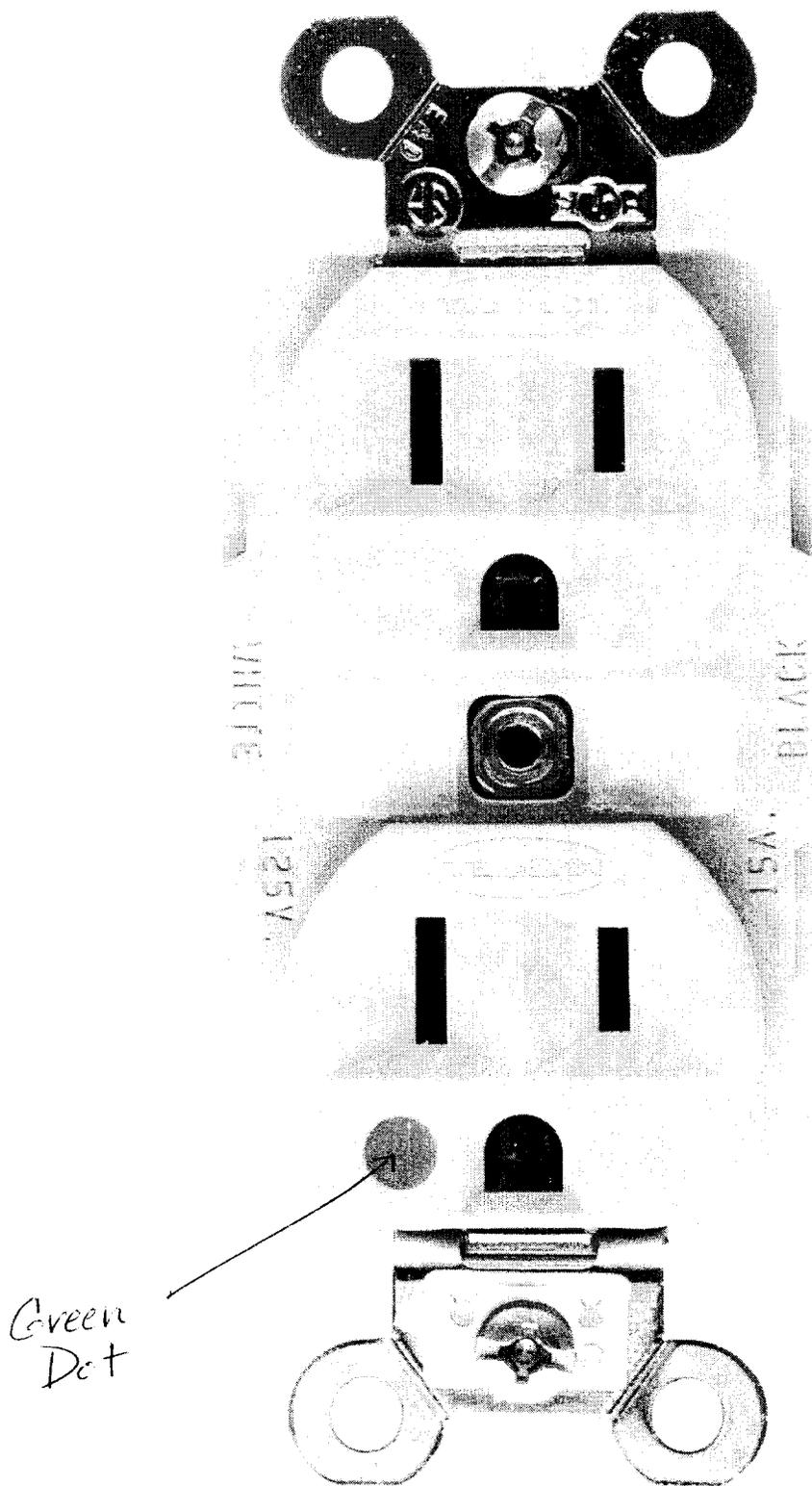


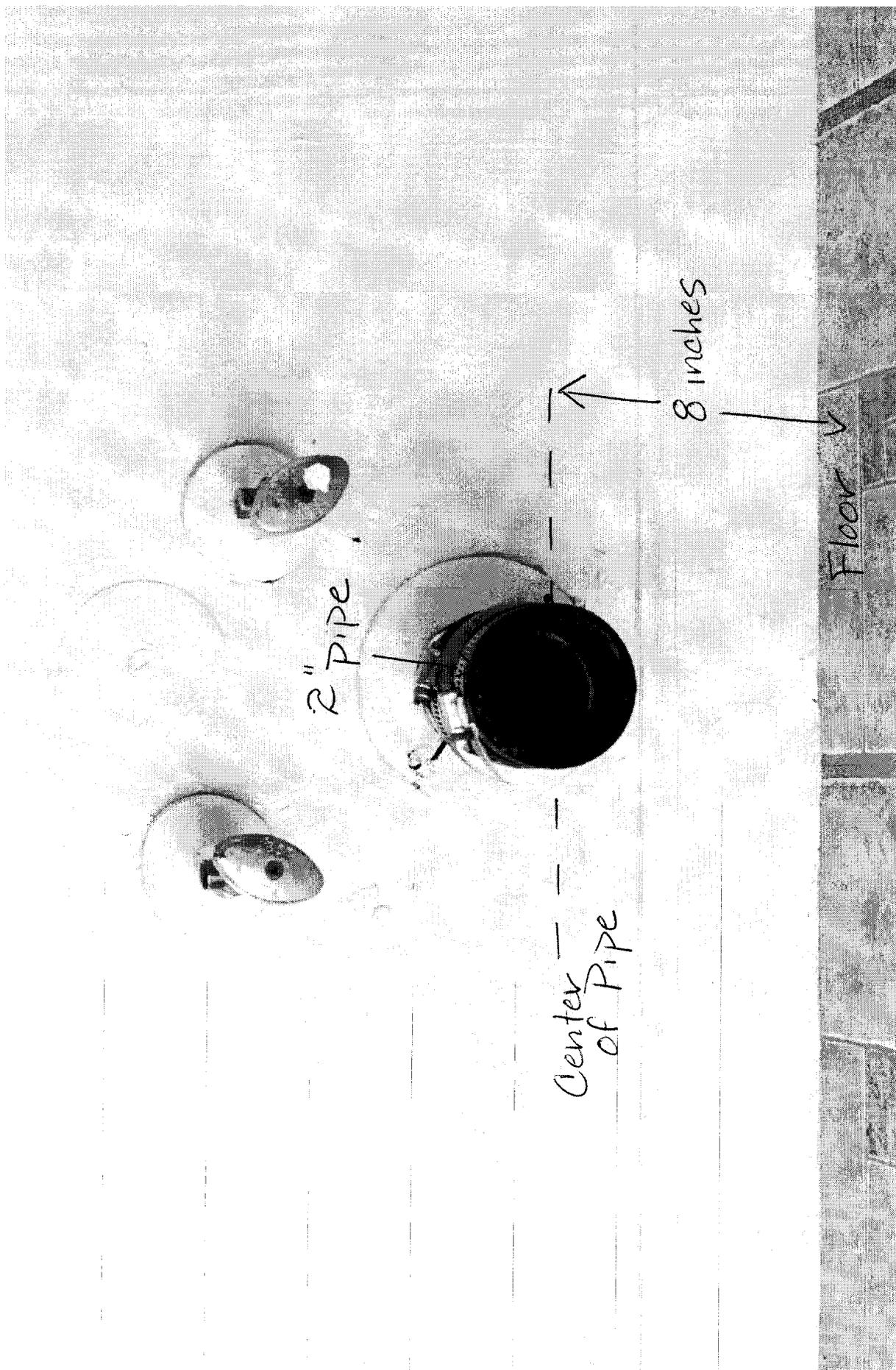
Figure 1
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Step 1. Hospital Grade Receptacle Installation

Install the hospital grade (green dot) duplex receptacle that is included with your Angel of Water™ Purification System in the wall outlet closest to the System according to electrical code (consult a licensed electrician). See figure 1.

Your room is now ready for preparation of the rough plumbing.

Figure 2

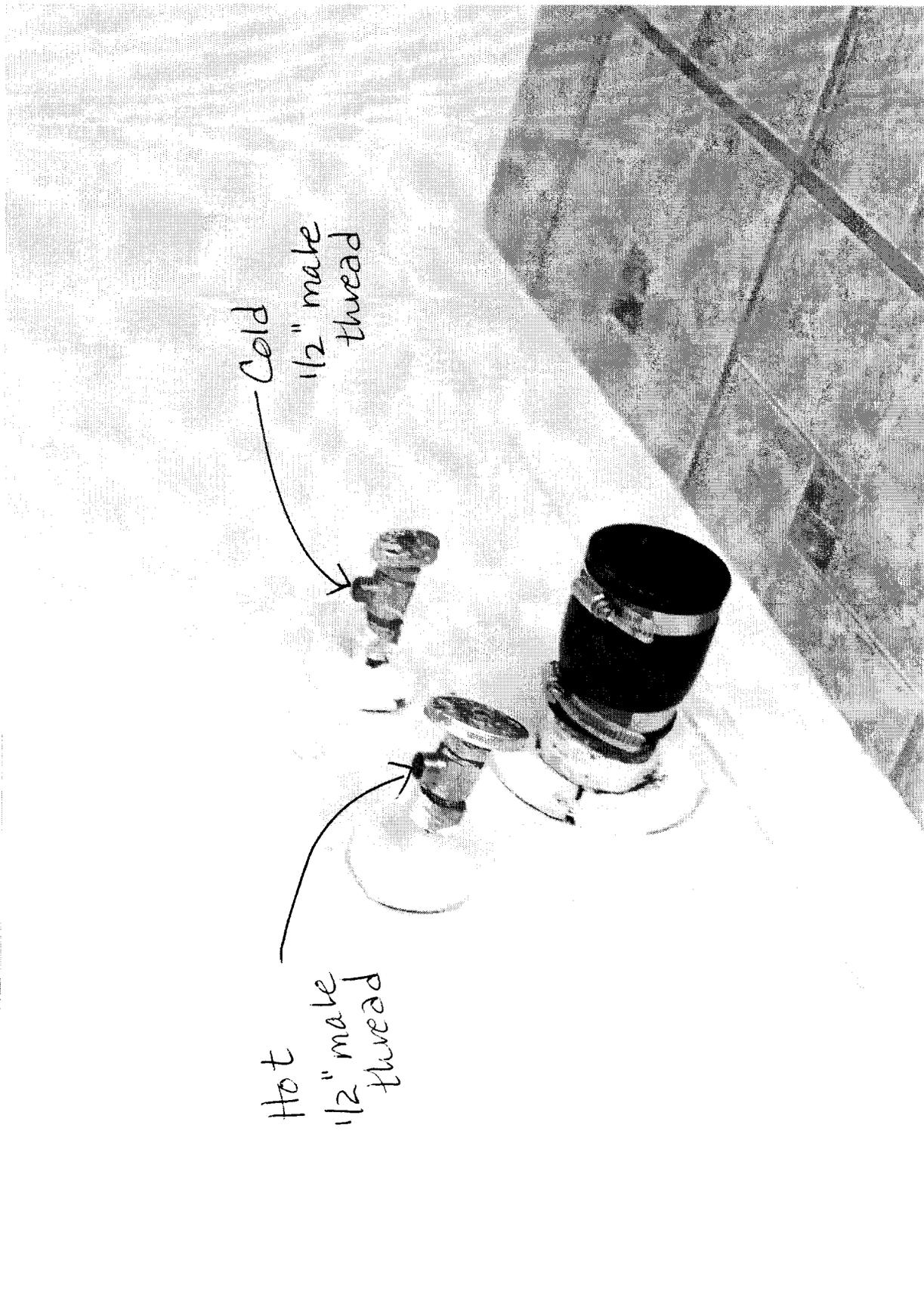


Step 2. Rough Plumbing Installation

Install rough plumbing connections (consult a licensed plumber).

Install the drain pipe so that it is 8 inches from the center of the pipe to the floor or less, **BUT NOT MORE THAN 8 INCHES**. See figure 2. A wall-mounted drain pipe is shown. However, a floor-mounted drain is also acceptable.

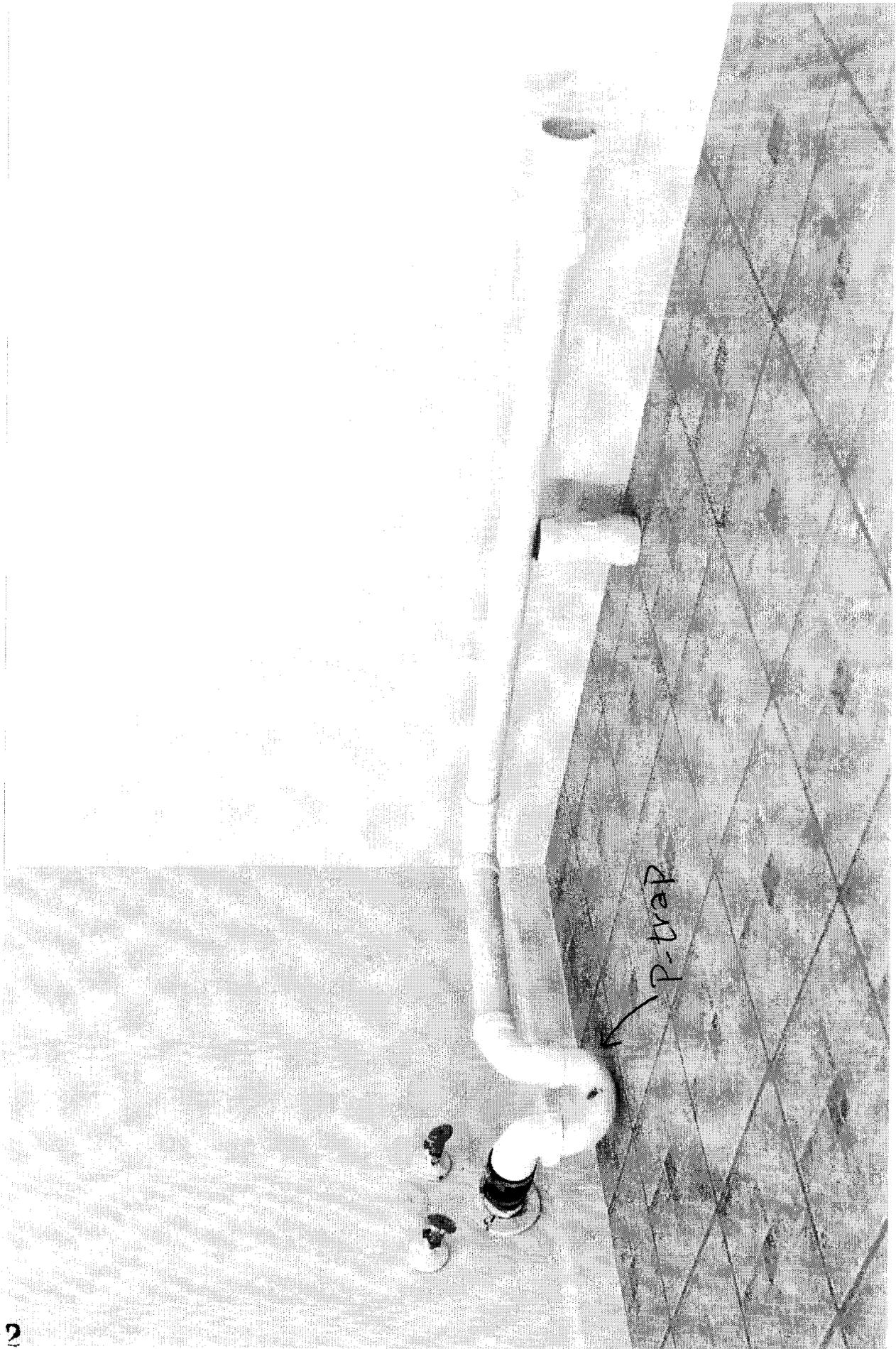
Figure 3



Step 3.

The Angel of Water™ Purification System requires both a hot and cold line connection. The hot and cold line coming from the wall should be in the side or back corner of the clinic room where System is to be placed. The connection valves must have 1/2-inch male threads. The drain must be a 2-inch PVC pipe or larger. See figure 3.

Figure 4



2

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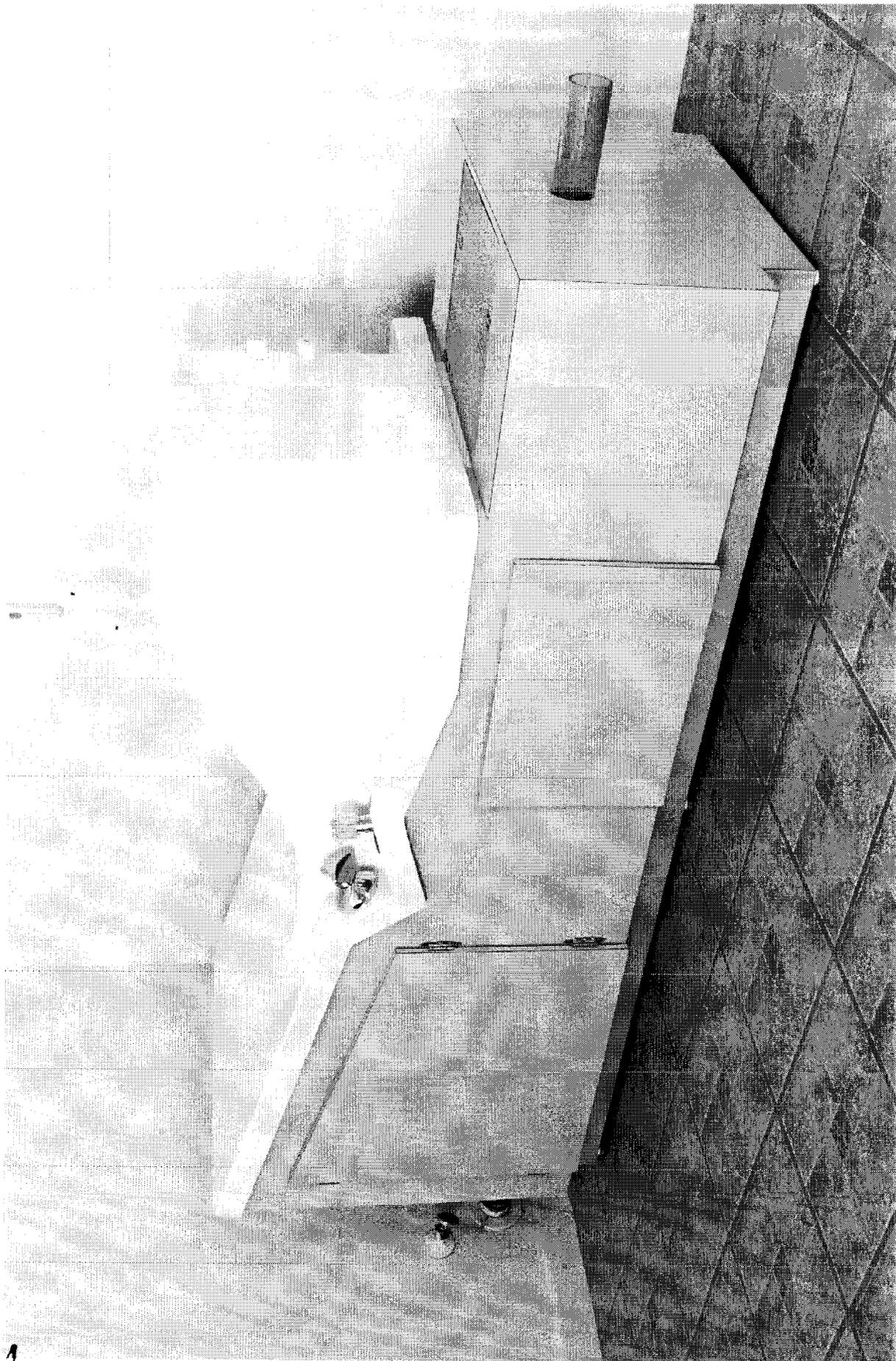
Step 4.

Estimate the length of 2-inch pipe needed to connect drain pipe to side viewing tube drain assembly. Put that length of pipe in place and support temporarily. This assembly will be finalized once the System is in place.

Install a P-trap in the 2-inch PVC drain pipe, either in the wall or in the drain line as shown in figure 4.

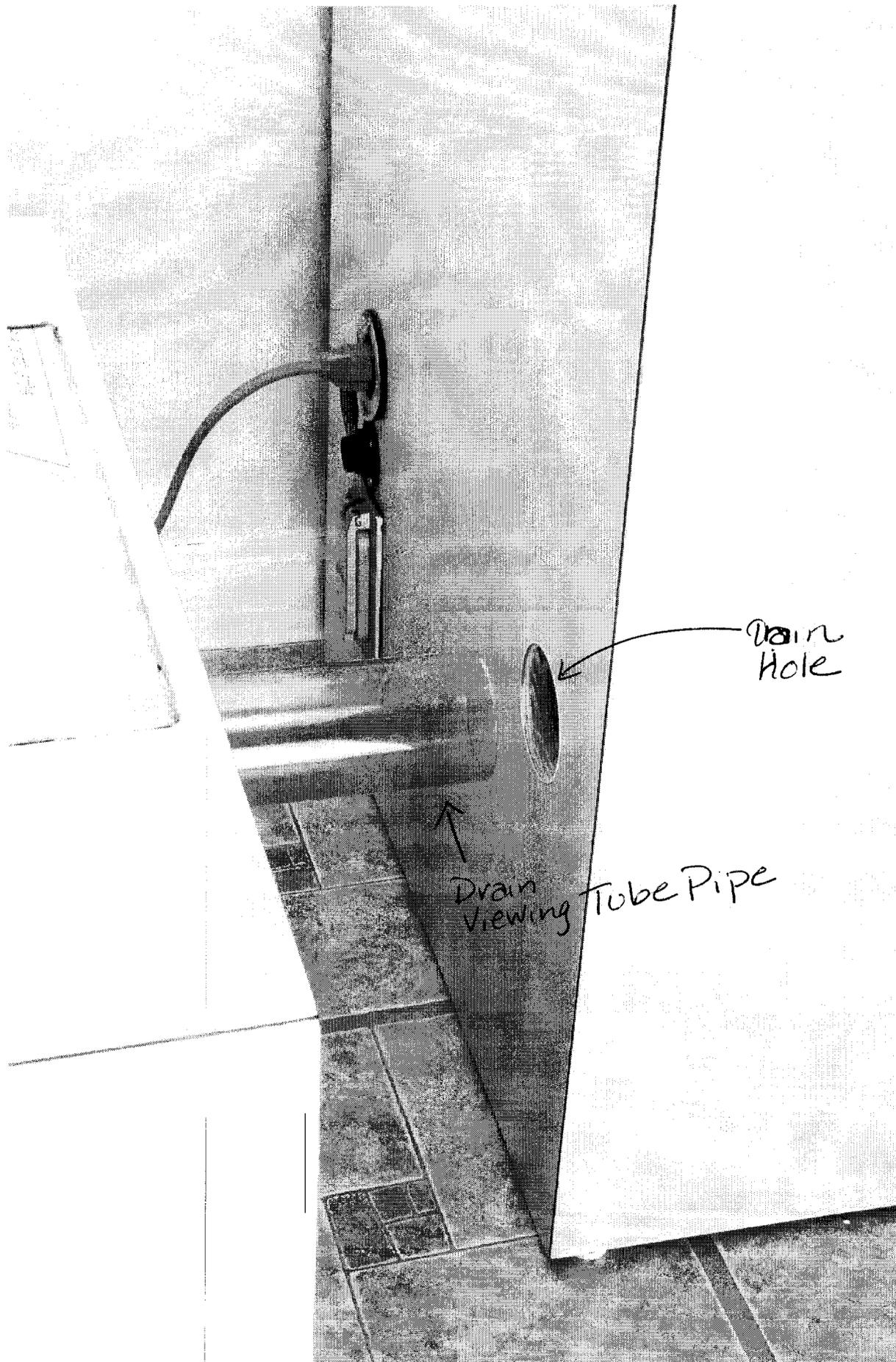
Your room is now ready for placement of the System.

Figure 5



Step 5. Basin Cabinet Placement

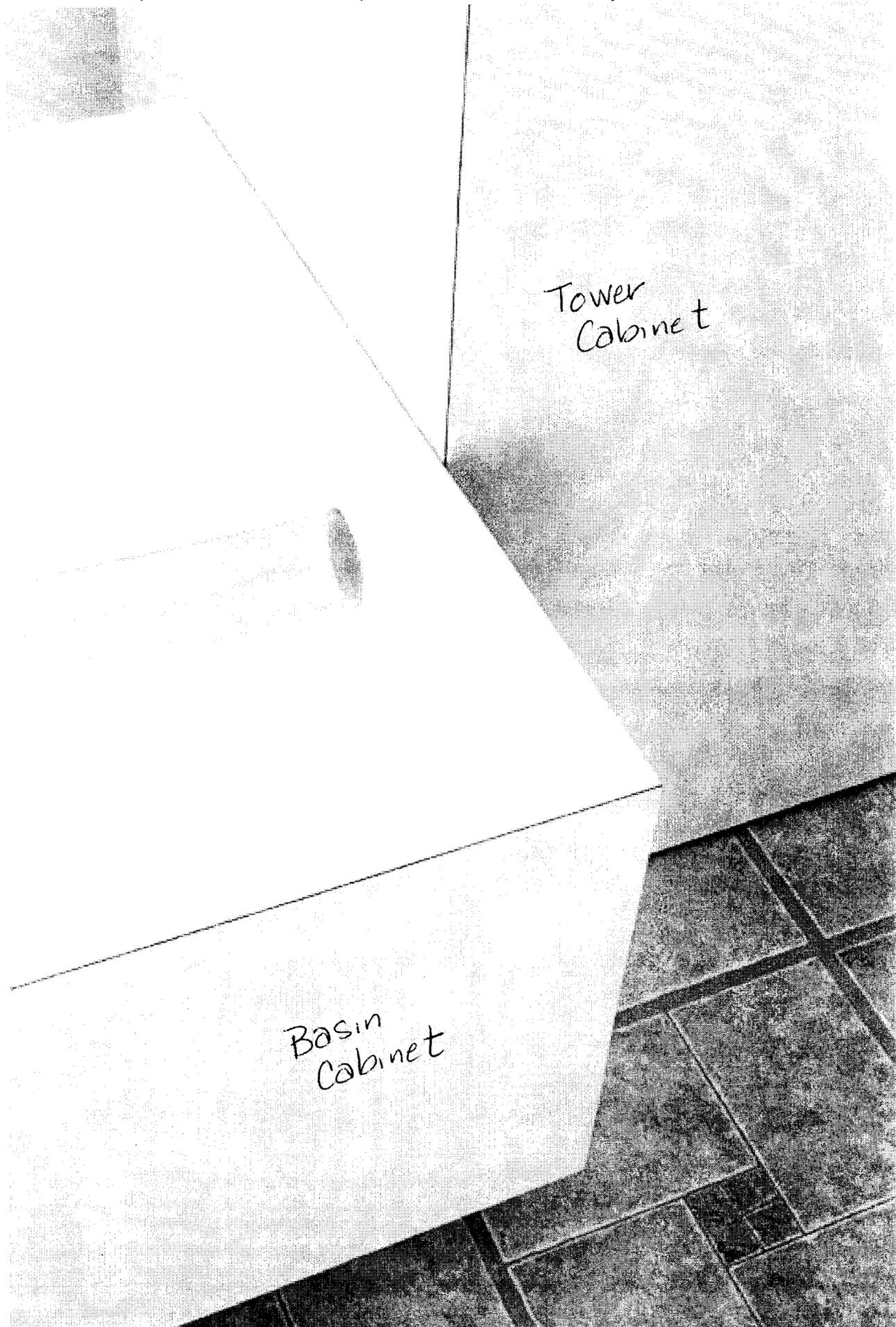
Place Angel of Water™ cabinet (backrest first) into the side or back corner of the room for making the plumbing and electrical connections. See figure 5.



Step 6. Tower Cabinet Placement

Align tower cabinet with drain viewing tube pipe of basin cabinet, as shown in figure 6.

300



Step 7.

Slide the two cabinets together until they meet, as shown in figure 7.



Step 8.

Take nut and bushing of compression fitting as shown in figure 8.

Slide the 2-inch connecting nut and bushing onto basin viewing tube pipe protruding from the lower left-hand part of the tower cabinet (figure 8).



2

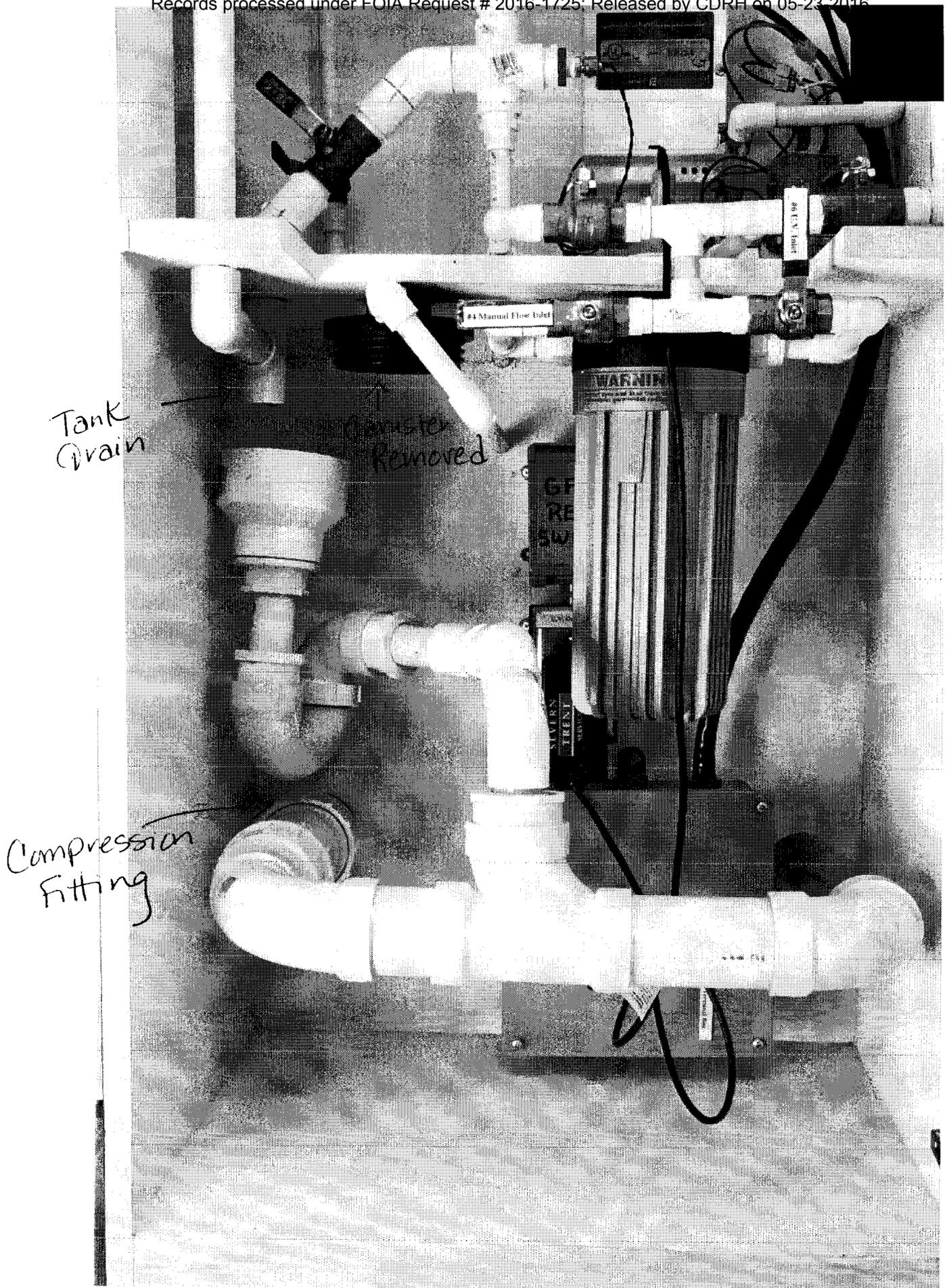
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI-STATUS@fda.hhs.gov or 301-796-8118

Figure 4

305

Step 9. Drain Assembly Installation

Take the drain assembly and place on the tower cabinet floor under 2-inch hole as shown in figure 9.



Step 10.

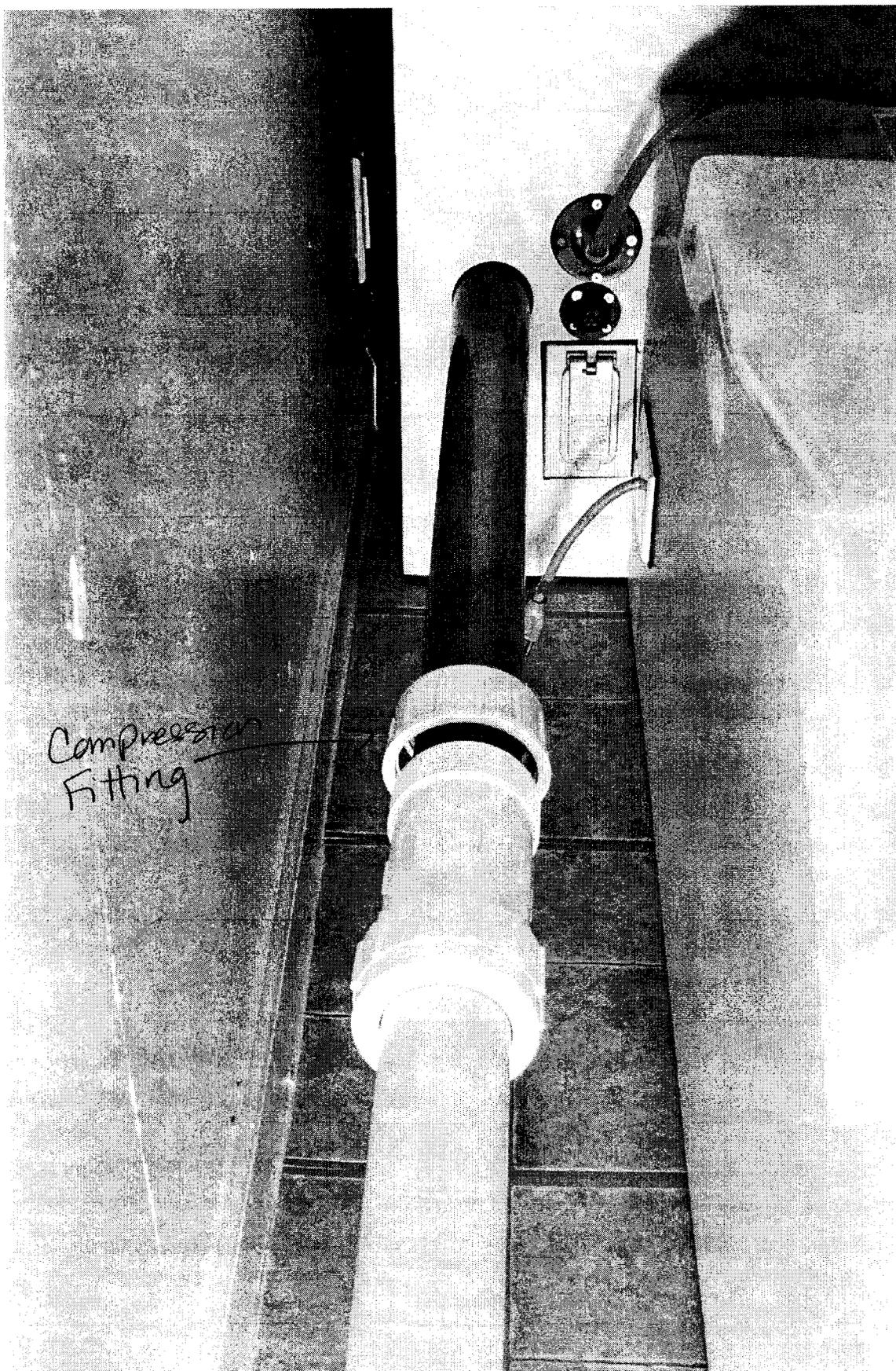
Remove carbon filter canister in tower cabinet temporarily, as shown in figure 10.

Slide clear tube on right-hand side of drain assembly into 2-inch hole.

Connect left-hand compression fitting on drain assembly to nut and bushing previously shown (figure 8).

BE SURE THAT THE TANK DRAIN IS DIRECTLY ABOVE THE DRAIN BOWL AT TOP OF DRAIN ASSEMBLY (THIS IS KNOWN AS AN AIR GAP). See figure 10.

Reinstall the carbon filter canister. Again, BE SURE THAT THE TANK DRAIN IS DIRECTLY ABOVE THE DRAIN BOWL AT TOP OF DRAIN ASSEMBLY ONCE CANISTER IS IN PLACE.



Step 11. Final Drain Connection

Make final adjustment to the drain pipe attached to the wall and to the clear viewing tube of drain assembly and connect them with compression fitting accordingly. See figure 11.

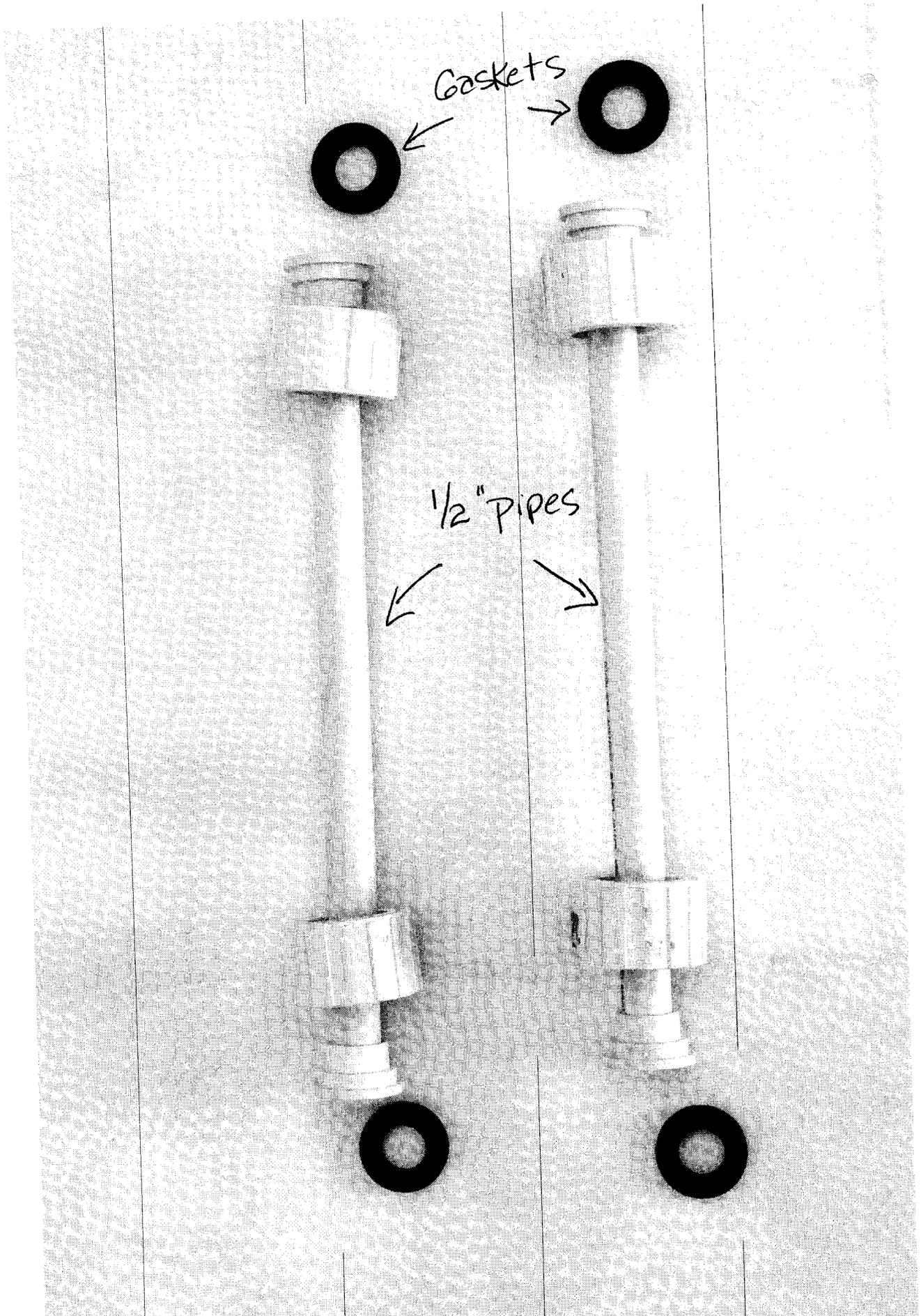


Figure 12

Step 12. Basin Cabinet to Tower Cabinet Connection

Locate tower and basin 1/2-inch connecting pipes with fittings as shown in figure 12.

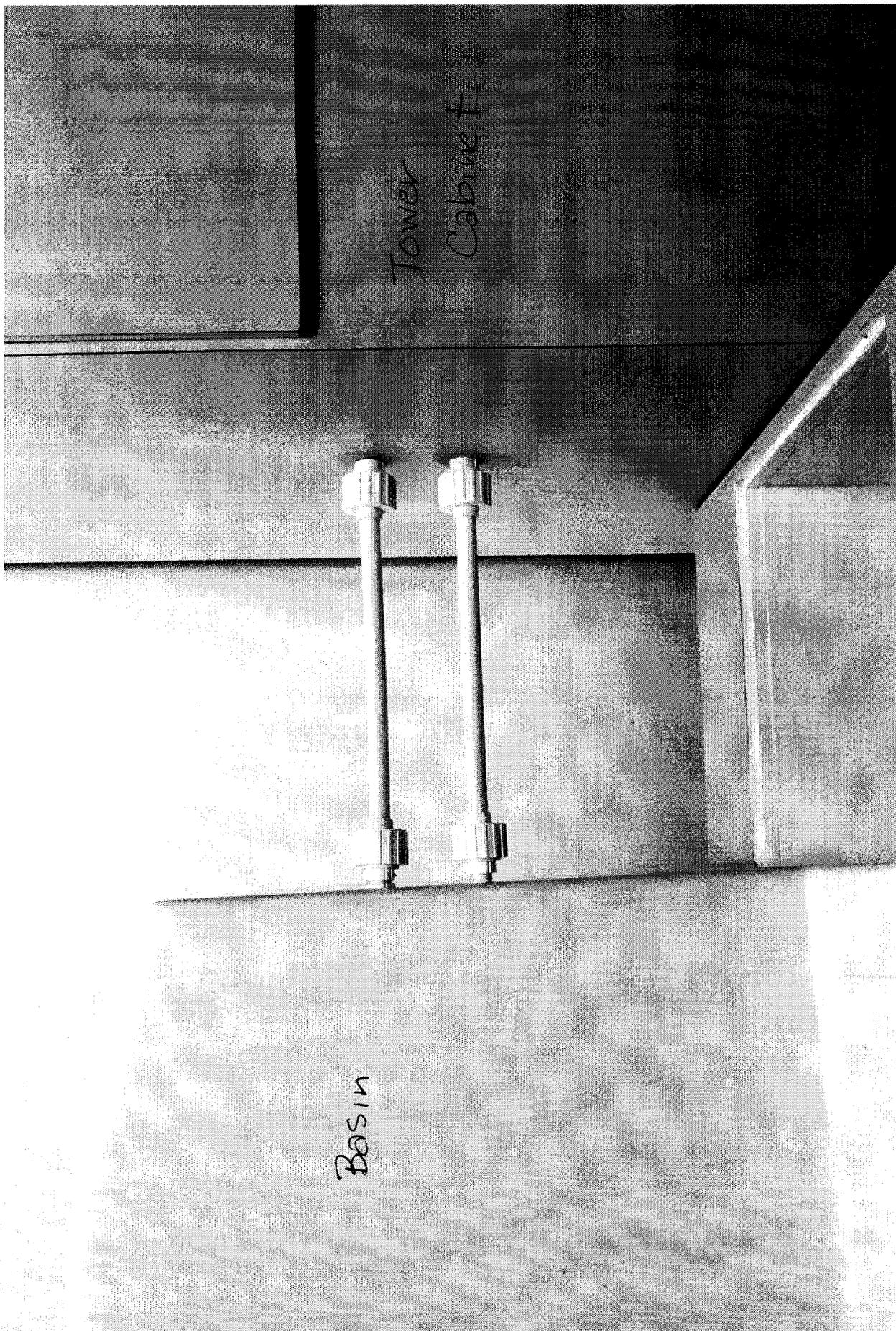


Figure 13

Step 13.

Connect those pipes by **HAND TIGHTENING** them **SECURELY** to front of basin and front of tower, as shown in figure 13.

Figure 14



2

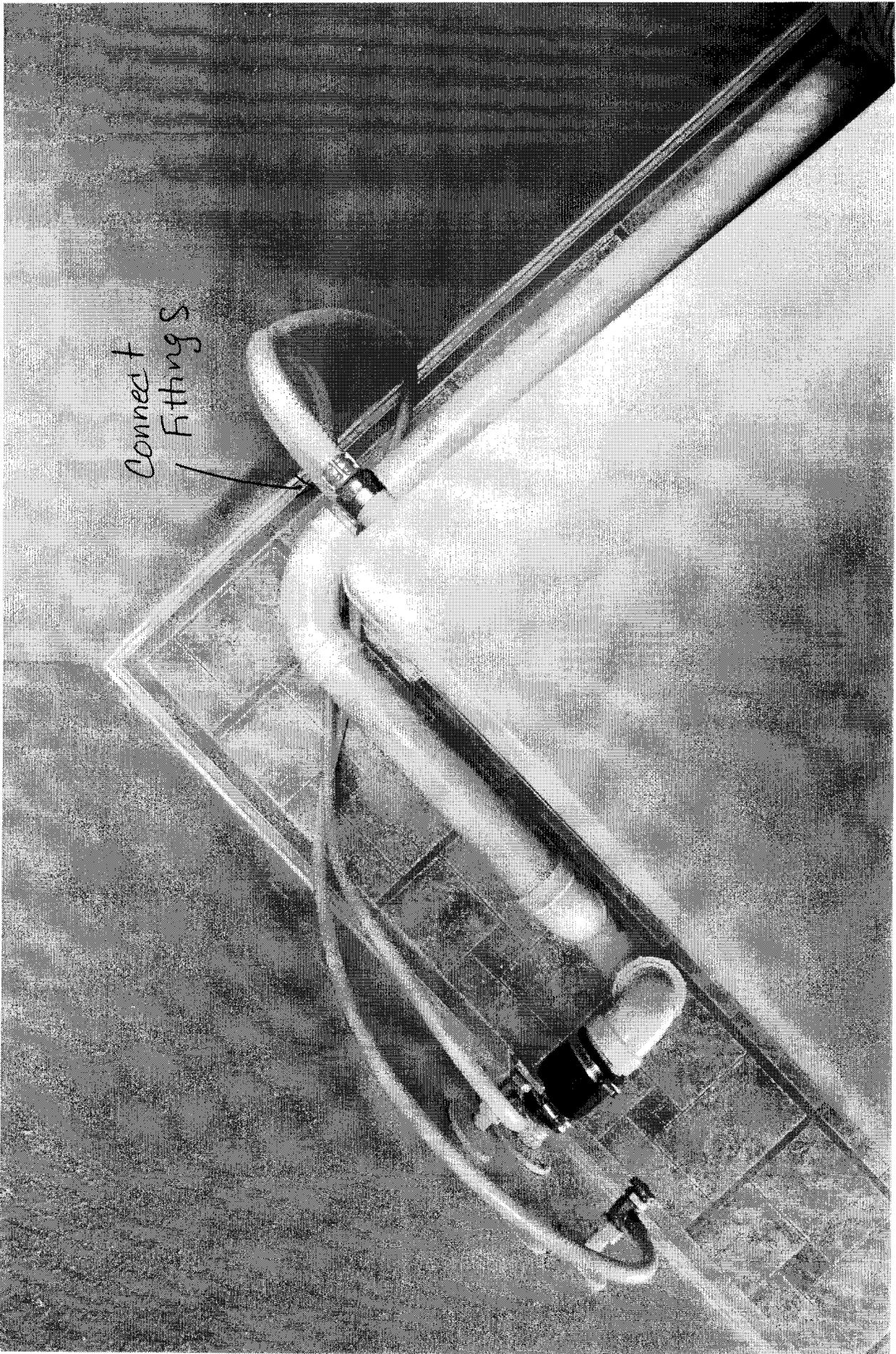
315

Step 14. Final Hot and Cold Connections from Basin Cabinet to Wall Plumbing

Locate hot and cold inlet 1/2-inch male threaded fittings on back left-hand side of basin cabinet. See figure 14.

THE TOP LINE IS THE COLD LINE; THE
BOTTOM LINE IS THE HOT LINE.

Figure 15



Step 15.

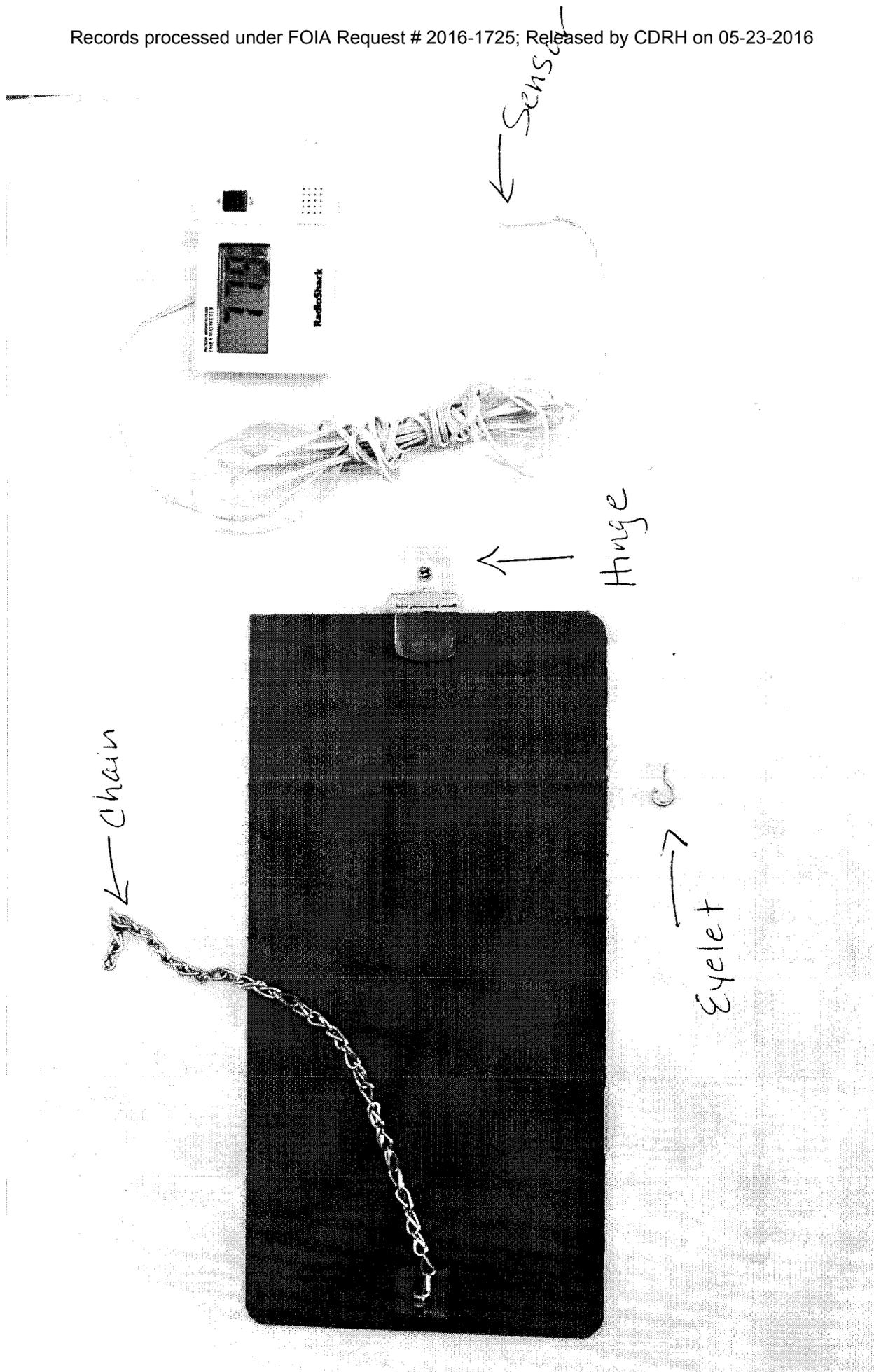
Connect hot and cold valves on the wall to hot and cold fittings with appropriate connectors (flex tube or CPVC), as shown in figure 15. These connectors are not included with your System. Consult your licensed plumber to decide on materials according to the needs of your space.

Your Angel of Water™ Purification System should now have:

- (1) complete drain assembly,
- (2) complete connection between tower and basin cabinets,
- (3) complete connection to the hot and cold water source.

HOWEVER, DO NOT TURN ON HOT AND COLD VALVES FROM WALL TO SYSTEM YET!

Figure 16



Step 16. Mirror and Temperature Gauge Installation

The mirror should have a bottom hinge to attach to tower cabinet, the eyelet to hold the chain, and the chain itself. See figure 16.

The temperature gauge has a sensor on a wire. Install AAA battery in the back of the temperature gauge now. (See your System Parts Packet for further instructions).

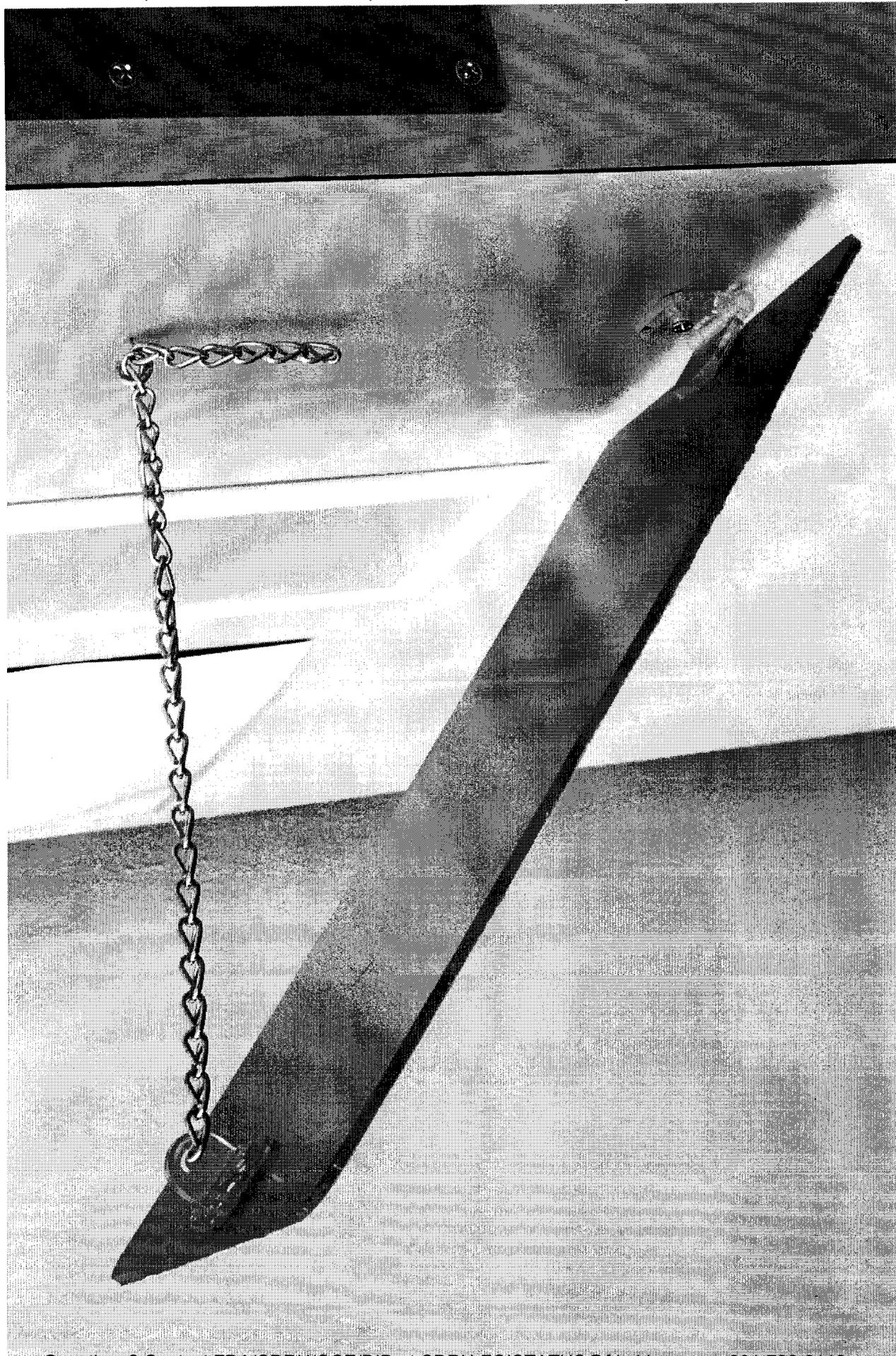


Figure 17

8

Step 17.

Install mirror on front of tower to right of viewing window in the pre-drilled holes provided.

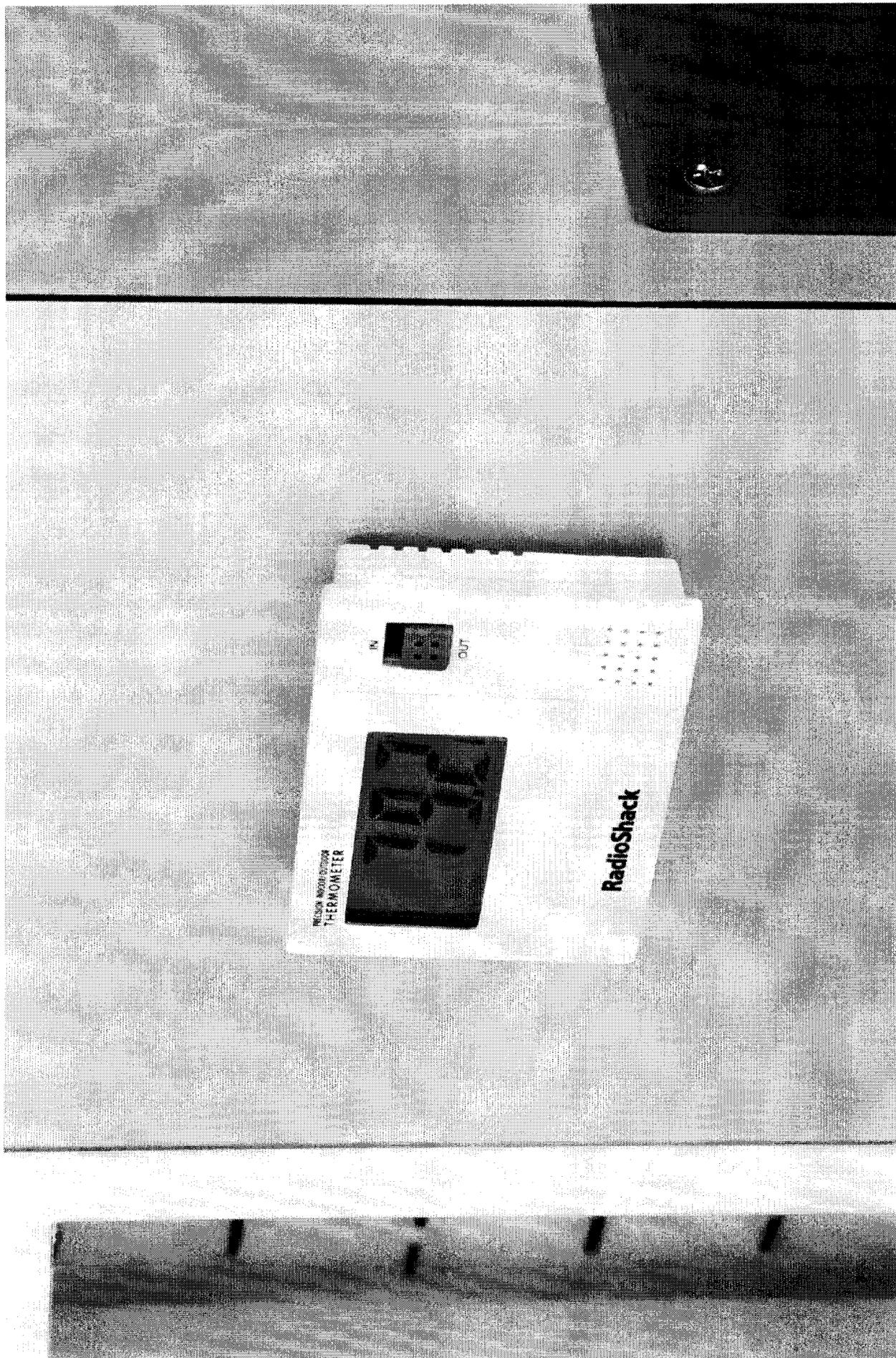
The lower hole is for the hinge at the base of the mirror.

Screw small eyelet into hole directly above hinge.

Connect chain as shown in figure 17.

Adjust for appropriate viewing angle of the viewing tube.

Figure 18

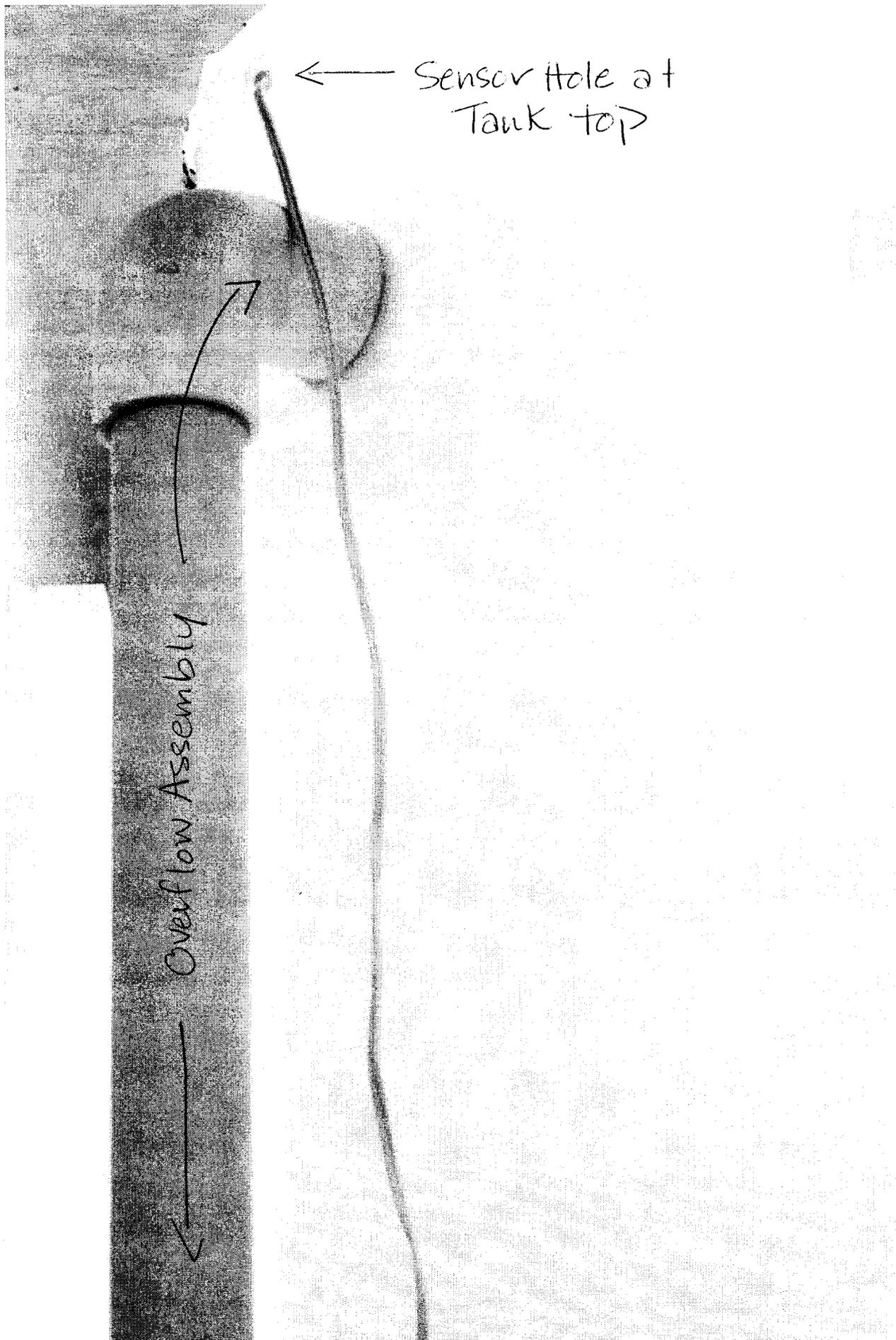


Step 18.

Take sensor on temperature gauge and insert into pre-drilled hole above mirror eyelet on tower cabinet.

Reach inside tower cabinet to pull sensor wire through.

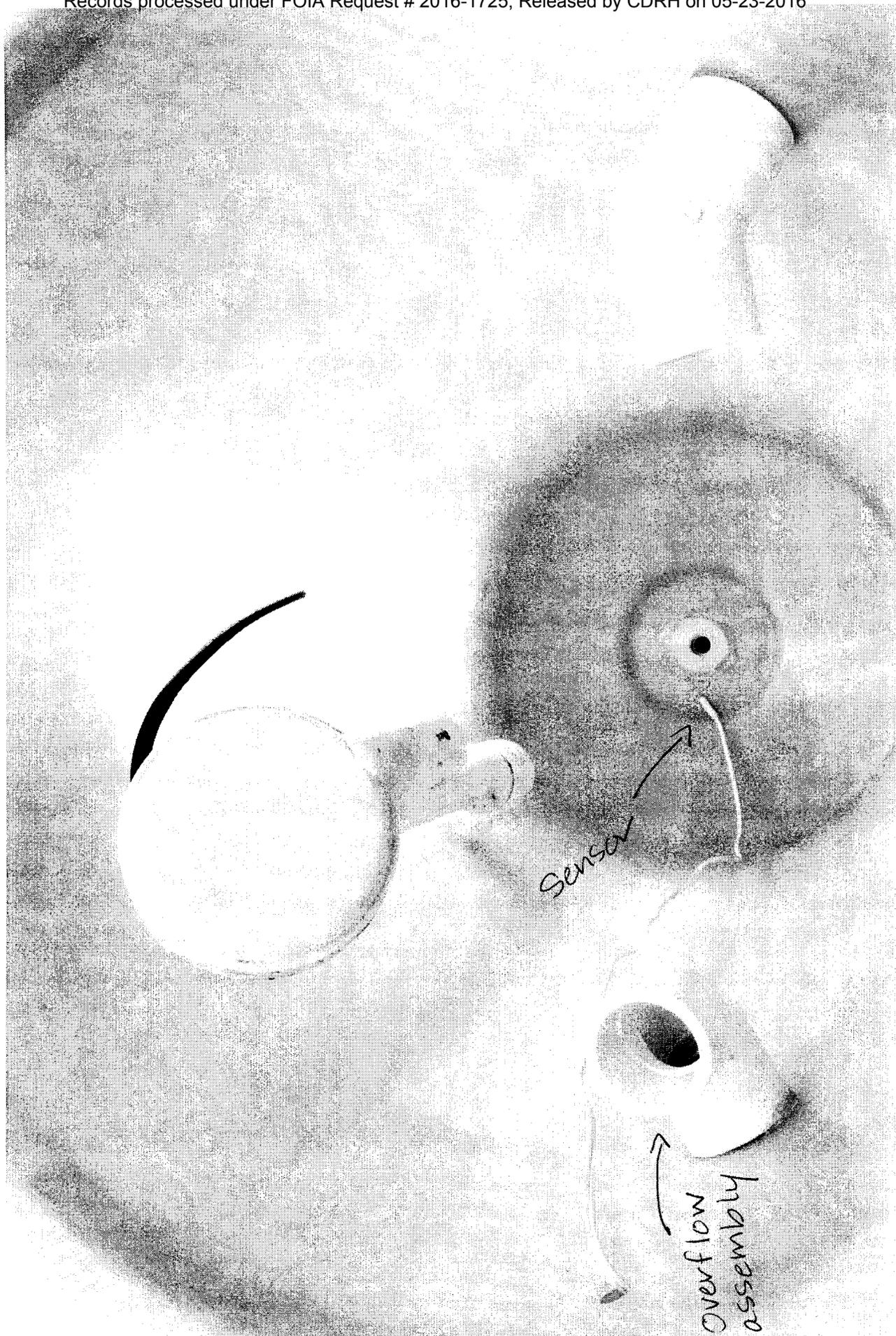
Attach temperature gauge to screw already in place on the face of tower cabinet above sensor hole. Your installed temperature gauge should look like the one shown figure 18.



Step 19.

Grasp sensor wire and send through the hole at the top of main tank above the overflow assembly. See figure 19.

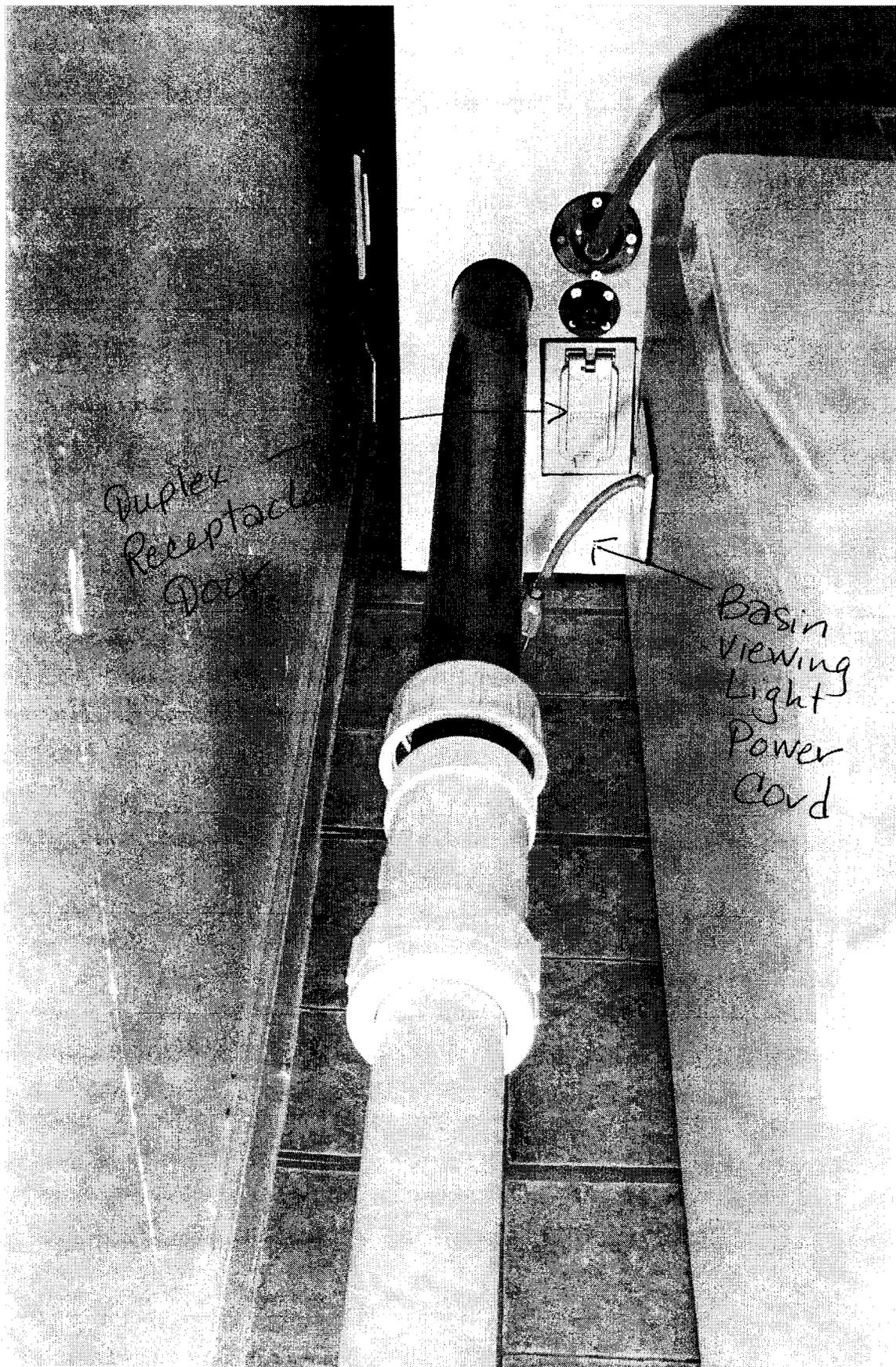
Figure 20



Step 20.

Allow only as much play or excess wire into tank as needed for sensor to touch the bottom of the main tank. See figure 20.

Gather excess wire, cinch it with the plastic tie included with your System, and bind it to the overflow drain pipe to insure that it is out of the way and not visible through the side viewing window of the tower cabinet.



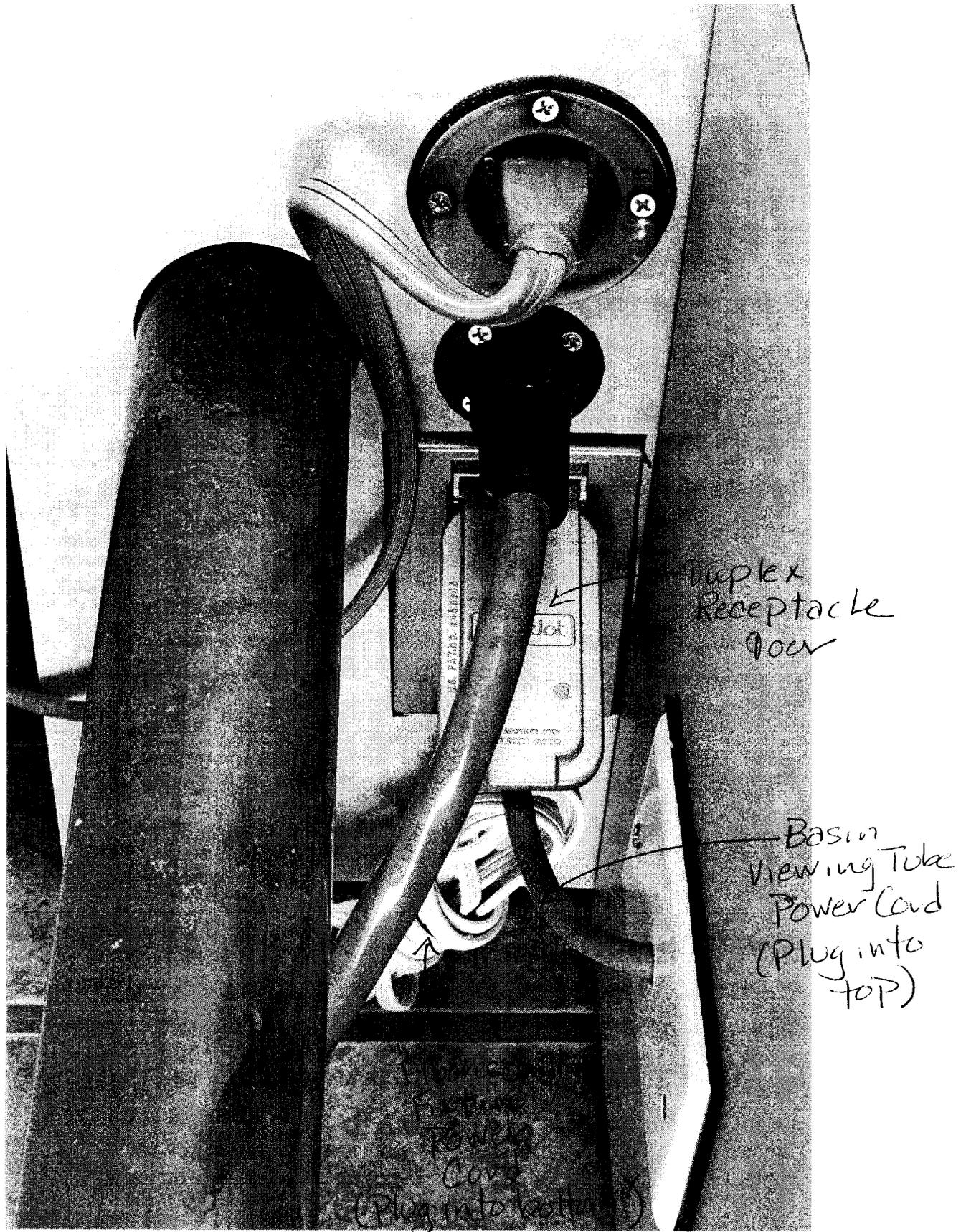
27

Figure 2.1

Step 21. Plugging in Basin Light Power Cord

Locate basin viewing light power cord on side of basin cabinet. See figure 21.

Lift door of duplex receptacle and plug cord into top inlet of duplex receptacle.



8

Figure 22

Step 22.

Plug fluorescent fixture for external viewing tube into same duplex receptacle, bottom inlet, as shown in figure 22.

← mate
end of
cord

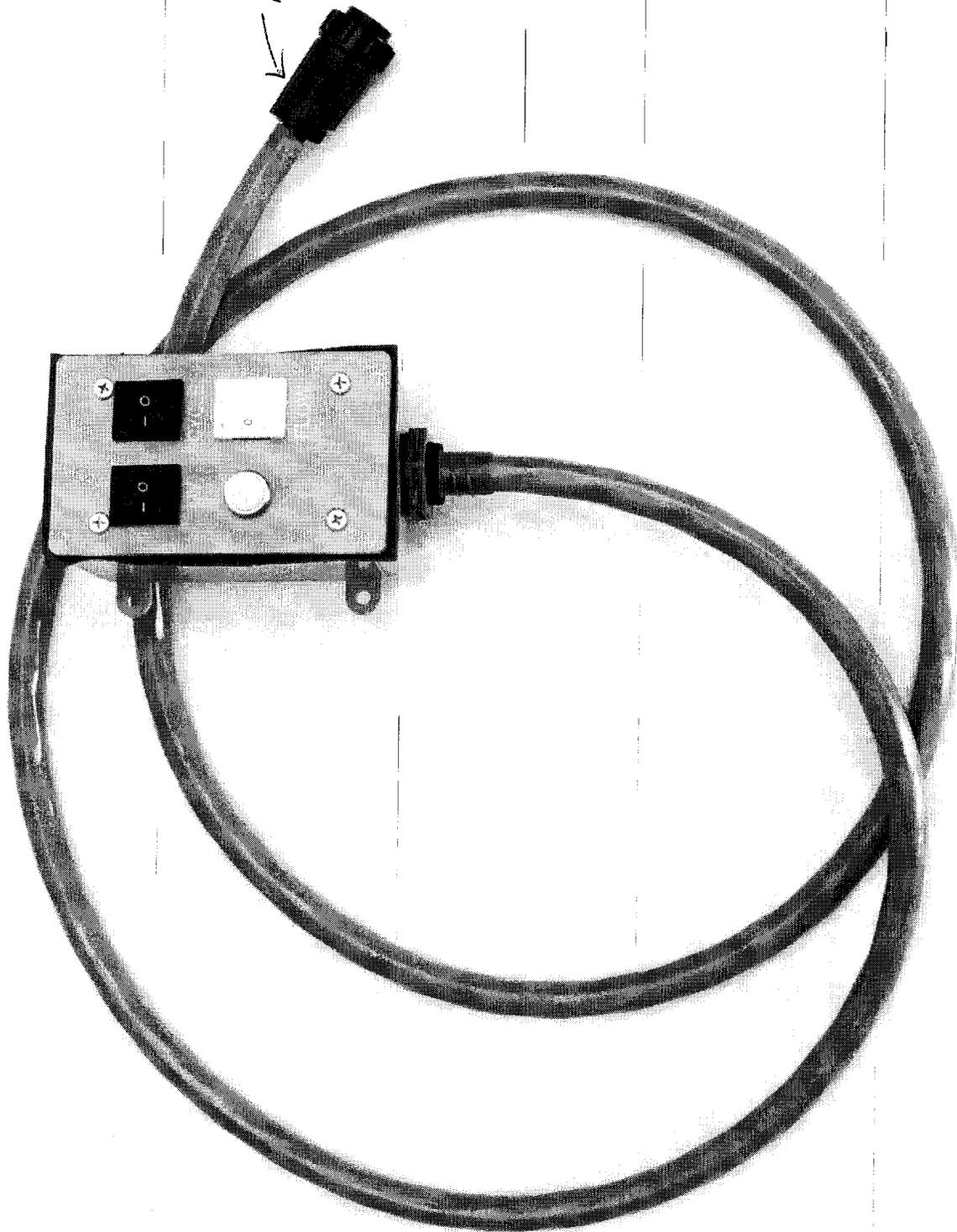
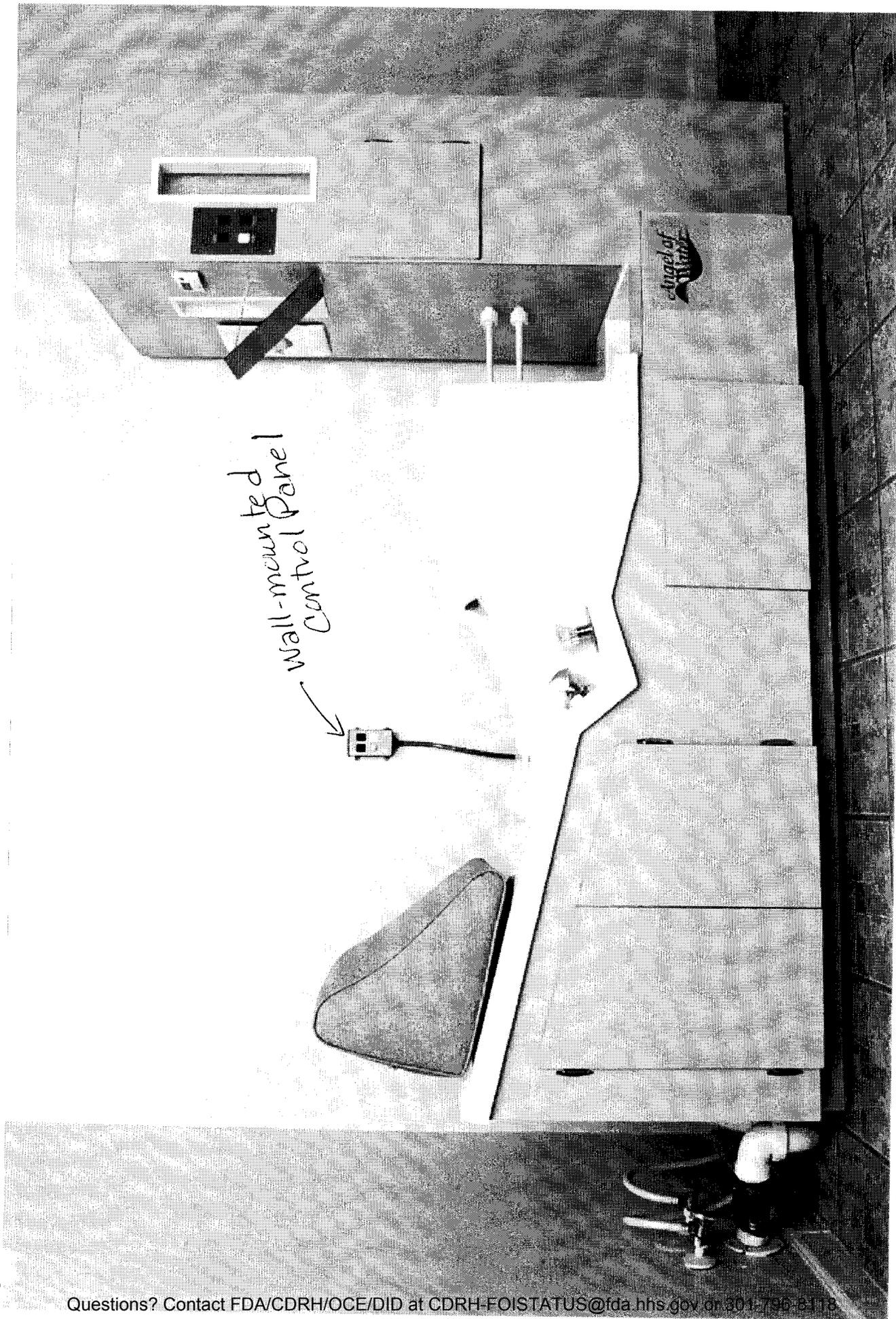


Figure 23

Step 23. Wall-mounted Control Panel Installation and Connection

Locate wall-mounted control panel, as shown in figure 23.

Figure 24



Step 24.

Mount wall(-mounted) control panel in a position that will be central to the basin console and in easy reach of the person reclining on the System. See figure 24. Use appropriate anchors, screws, or moly-bolts (not included) for your wall structure.

336

Tower Cabinet

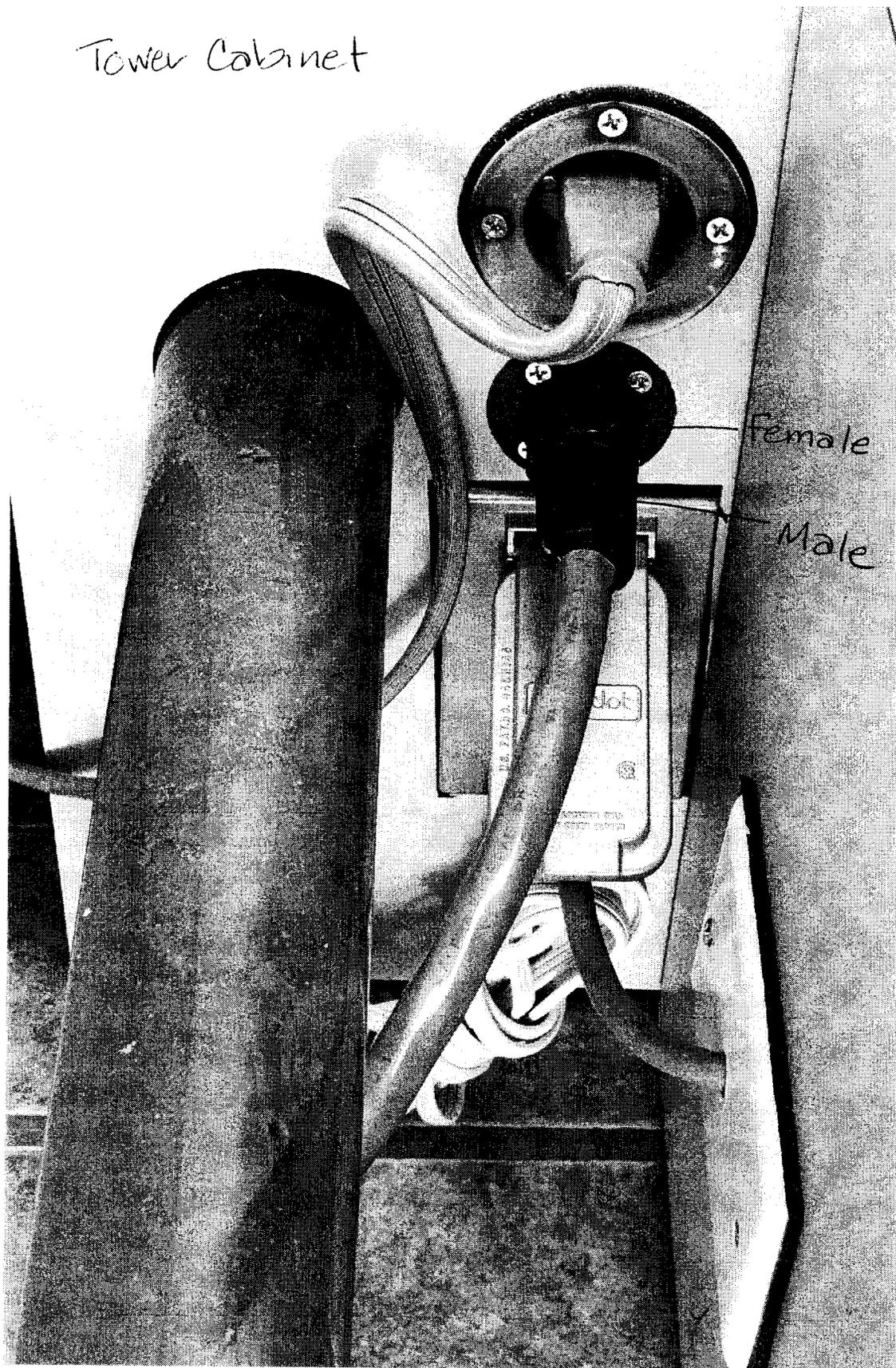


Figure 25

Step 25.

Connect the male end of the wall-mounted control panel cord to the female end (tower side) at the lower left-hand corner of the tower next to the drain pipe.

Line up the connection pins carefully, push them in firmly, and twist the connecting lock. See figure 25.

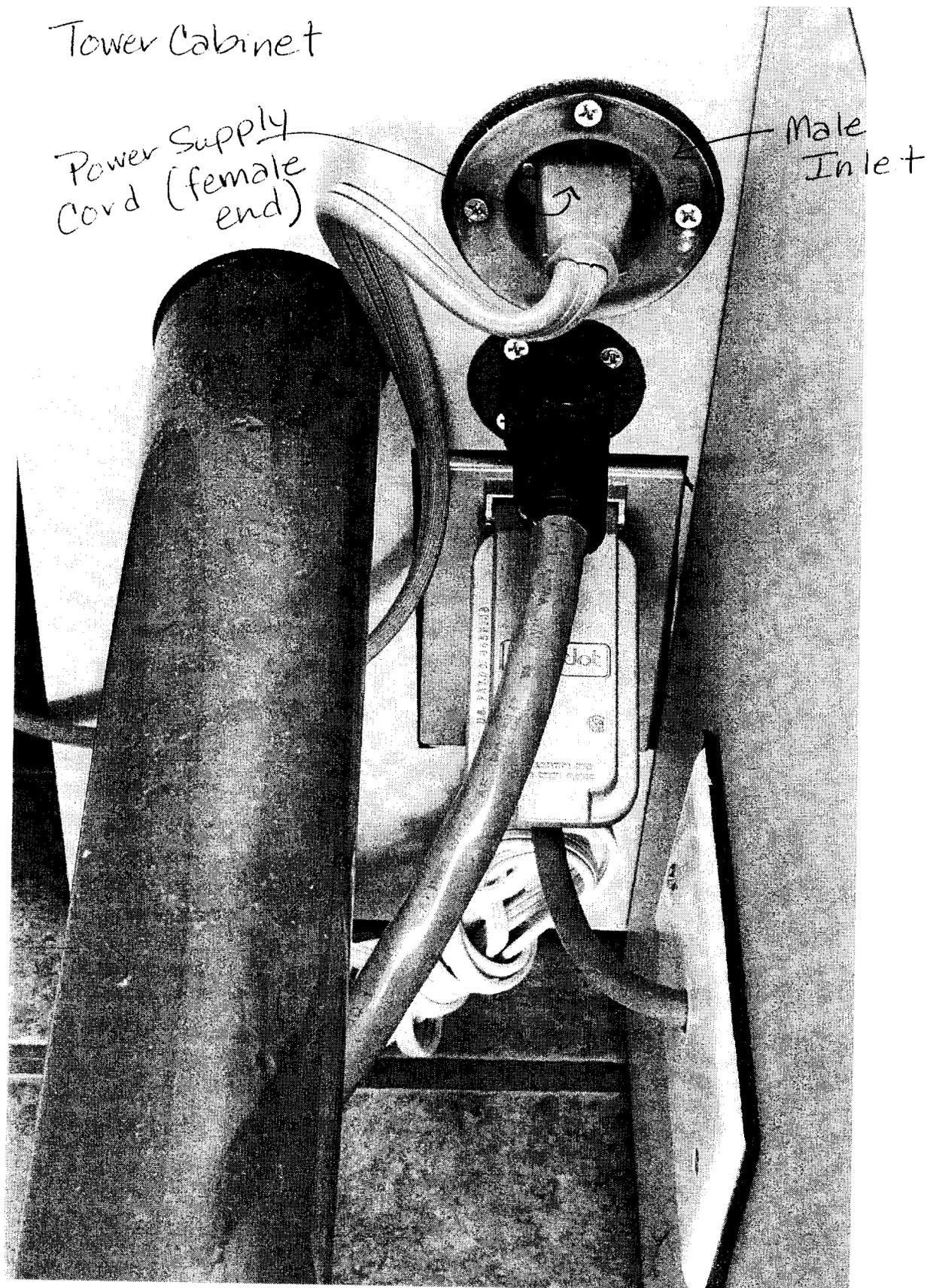


Figure 26
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118

Step 26. Power Supply Cord Connection

Connect female end of power supply cord to the male inlet on lower left-hand corner of the tower. See figure 26.

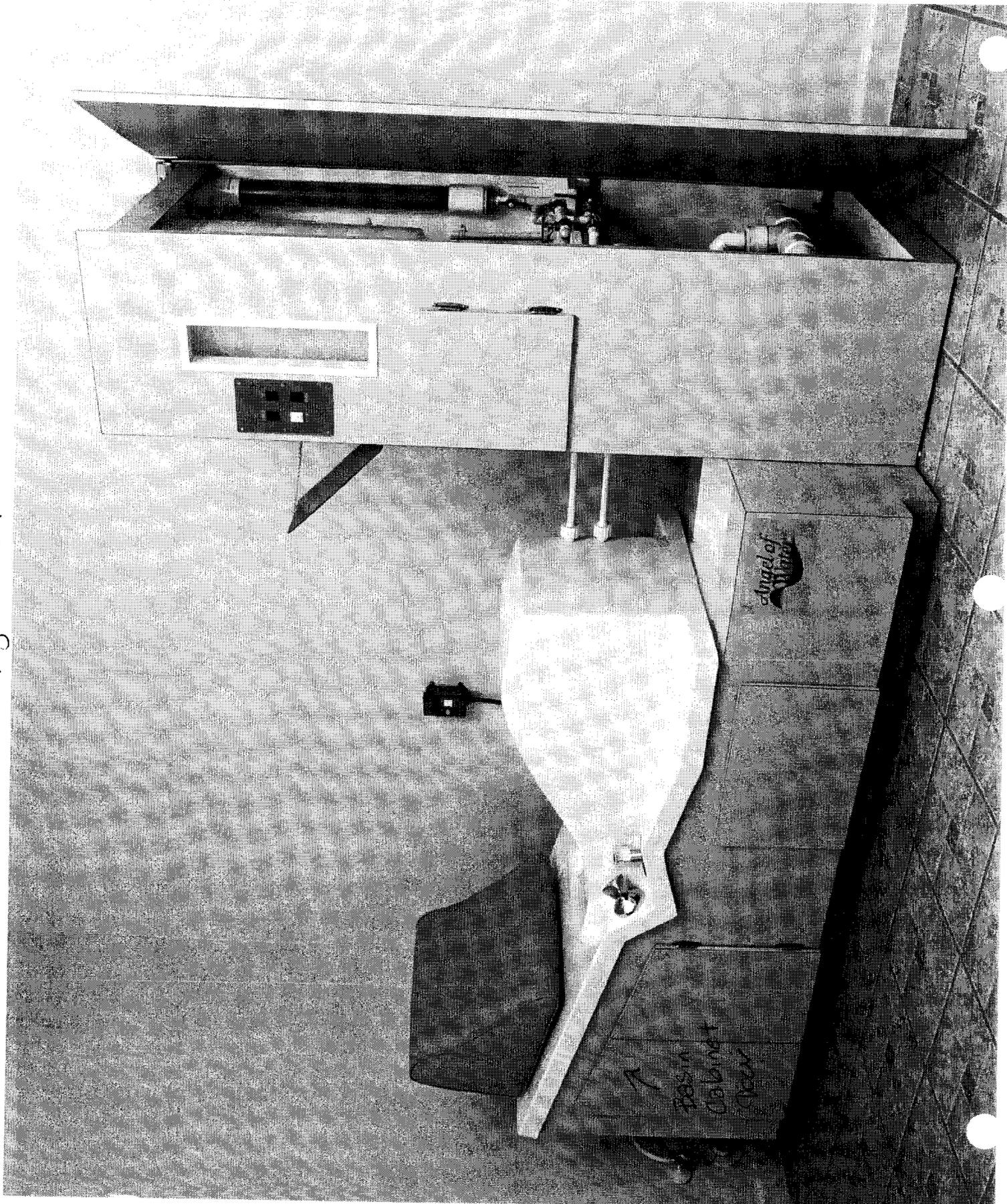
Now, plug male end of the power supply cord into wall outlet installed previously (Step 1).

Your Angel of Water™ Purification System should now have installed/connected:

- (1) mirror
- (2) temperature gauge with sensor
- (3) basin viewing tube light
- (4) external viewing tube fixture
- (5) wall-mounted control panel
- (6) power supply cord

YOUR ANGEL OF WATER™ PURIFICATION SYSTEM IS NOW INSTALLED.

Figure 27

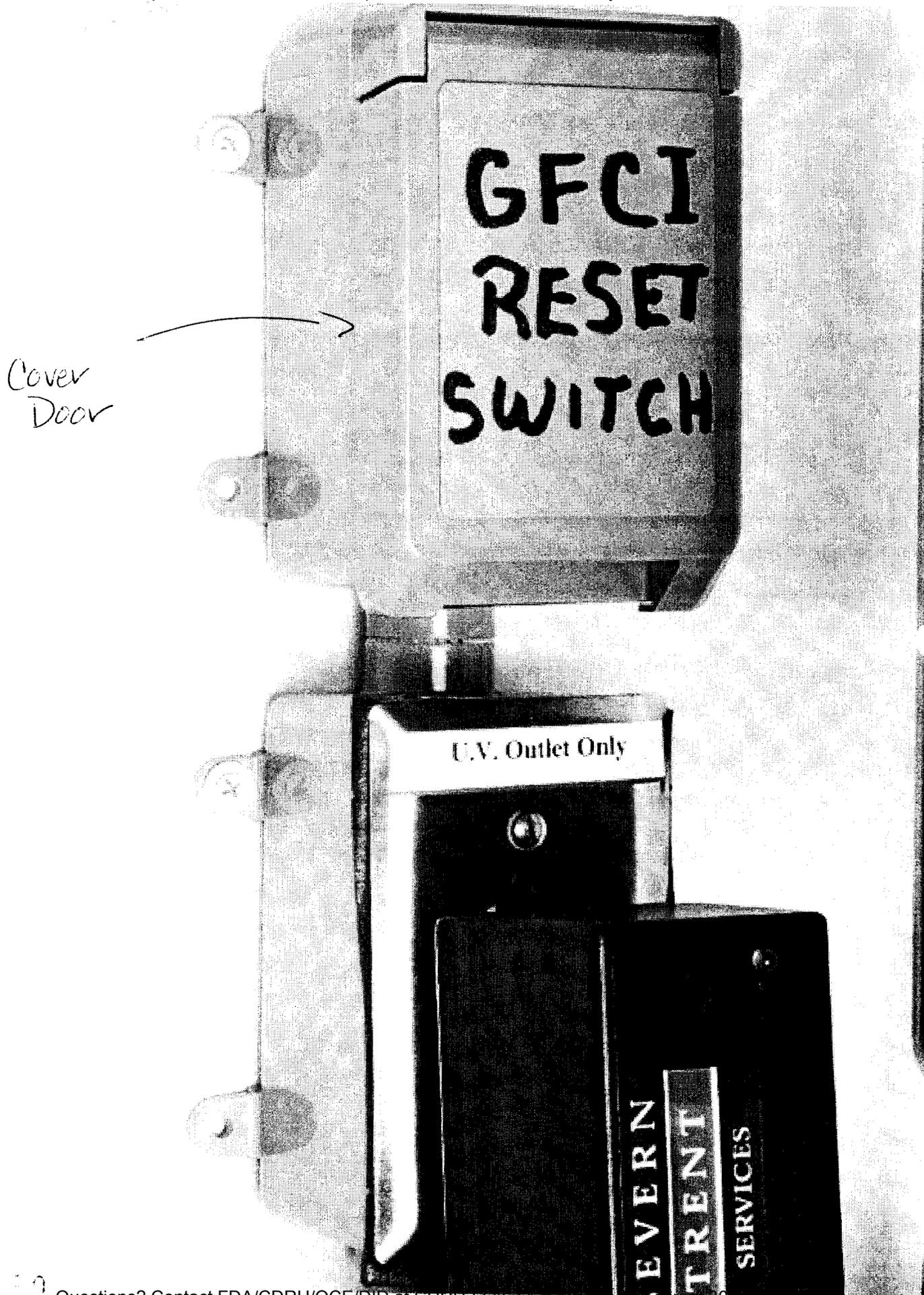


Step 27. Preparation of System for Use

OPEN hot and cold valves at the wall.

OPEN basin cabinet large door as shown in figure 27.

Reach inside basin cabinet large door to OPEN valves #10 and #11. They are located directly inside the left-hand door and are reachable along the upper, underside portion of the door opening.



Cover Door

**GFCI
RESET
SWITCH**

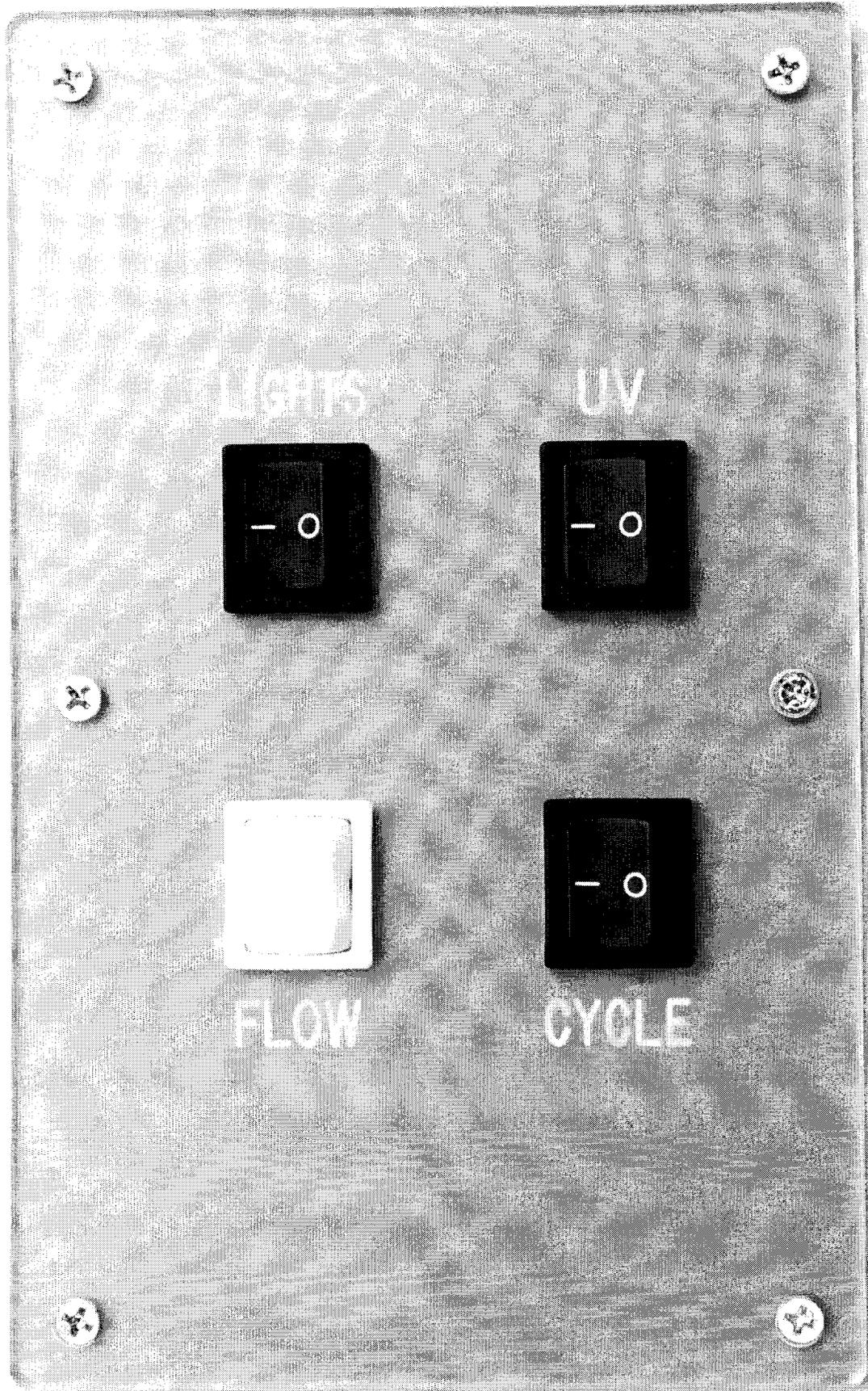
U.V. Outlet Only

**EVERN
TRENT
SERVICES**

Step 28.

Locate GFCI Reset switch in lower tower cabinet, lift cover, and make sure that the red button is depressed for activation of GFCI. See figure 28.

ALL SYSTEM FUNCTIONS SHOULD NOW WORK.



Step 29.

Locate LIGHTS switch on tower control panel.

Turn on LIGHTS switch and make sure that tower, basin, and external viewing tube lights come on. See figure 29.

Your Angel of Water™ Purification System comes with valve settings for Regular Operation Mode. Refer to the Operations Manual, Chapter 4.

If you experience any problems with the operation of your System, refer to the Trouble-Shooting Guide in the Operations Manual, Chapter 7.

Once your System is operational and has been cleaned and sanitized according to the Operations Manual, Chapter 5 AND ACCORDING TO YOUR TRAINING, the Angel of Water™ Purification System is ready for use.

For questions regarding the installation of the Angel of Water™ Purification System, contact our Technician Service Line at :

(512) 707-3773

(b)(4) Manufacturing Information

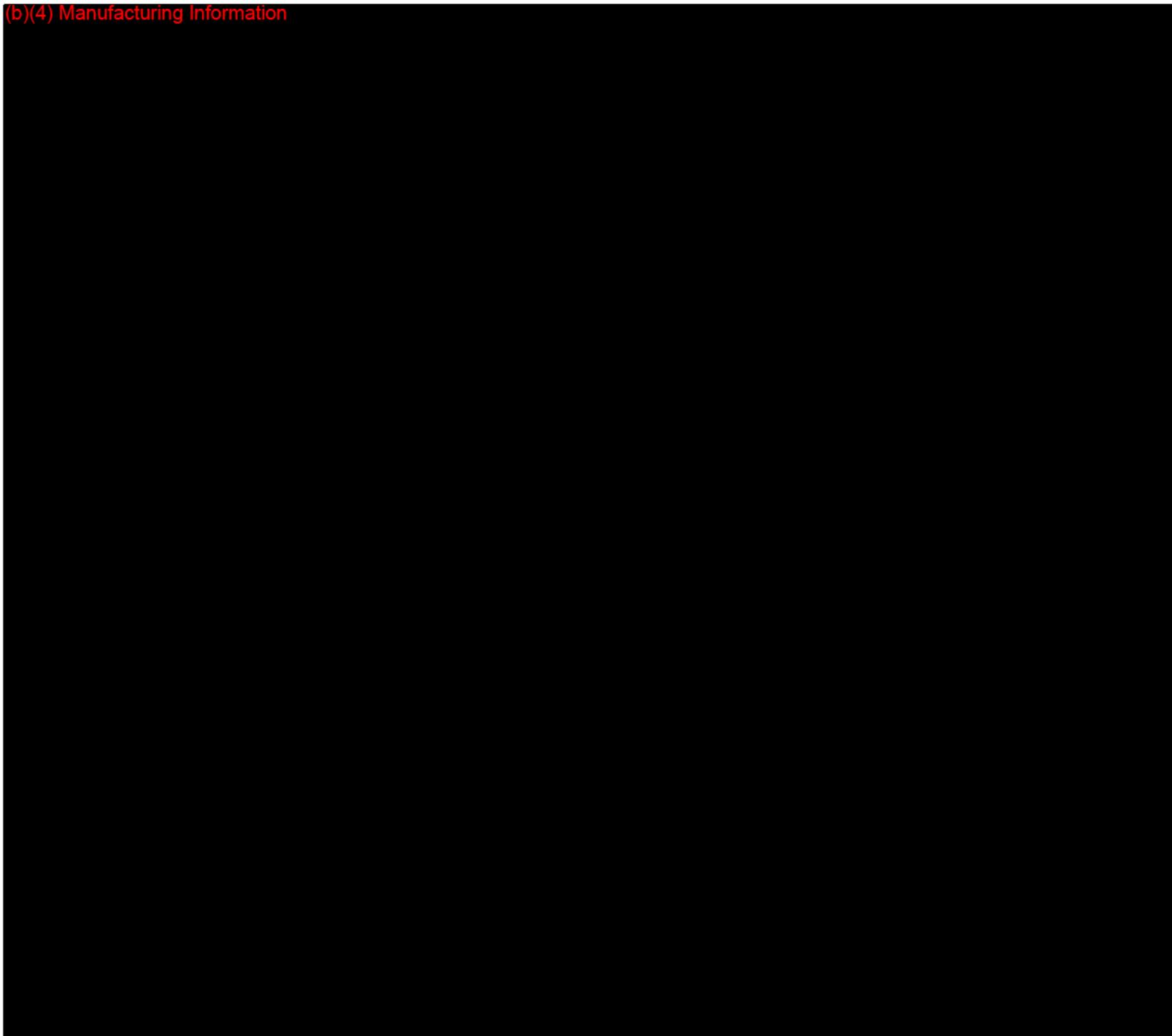


June 14, 2001

Ms. Amy Heilman
General Manager
Lifestream Purification Systems, LLC
2001 South Lamar, Suite G
Austin, TX 78704

Ms. Heilman,

(b)(4) Manufacturing Information



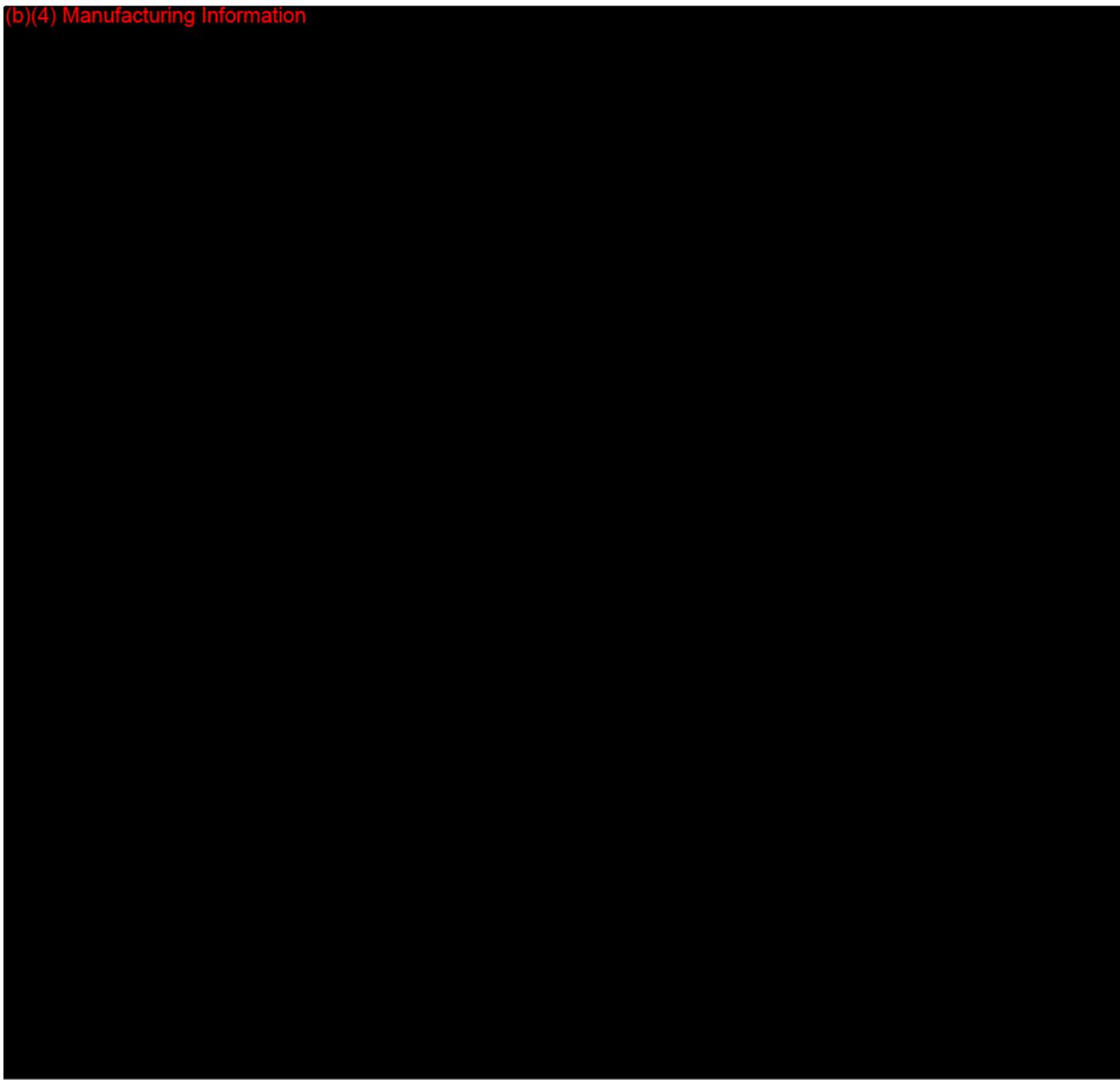
A

(b)(4)

Manufacturing

LIFESTREAM

(b)(4) Manufacturing Information



5

348

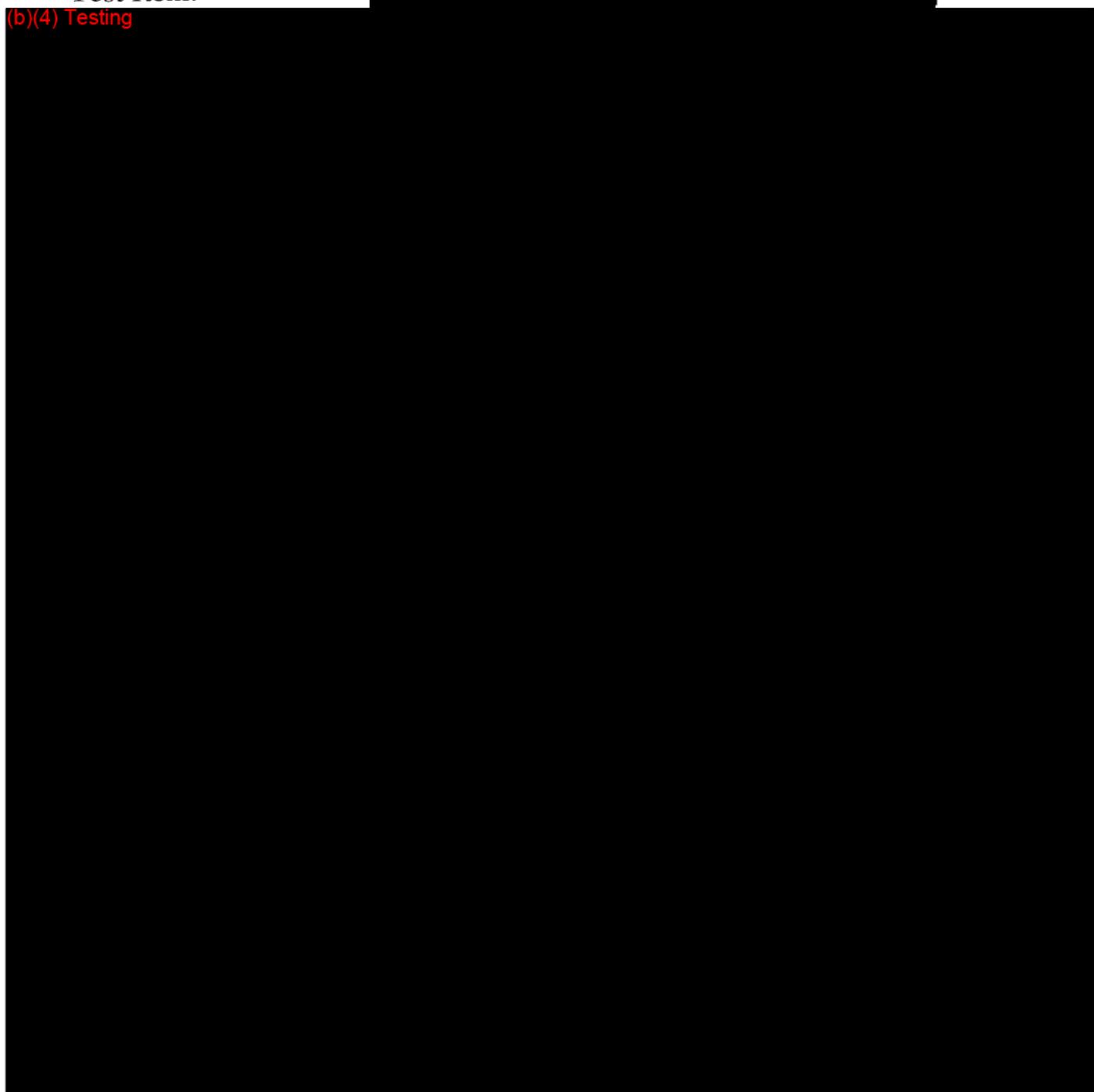
Lifestream

Purification Systems, LLC
2001 South Lamar, Suite G
Austin, Texas 78704
Phone 512-707-3773

Test Item:

(b)(4) Testing

(b)(4) Testing



Testing Results Compiled By:



Amy Deilman
General Manager

(b)(6)



Research and Development

Date of Issue: June 14, 2001

352
5

Lifestream

Purification Systems, LLC
2001 South Lamar, Suite G
Austin, Texas 78704
Phone 512-707-3773

Test Item:

(b)
(4)

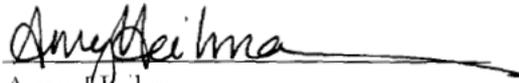
(b)(4)



353

10

Testing Results Compiled By:



Amy Heilman
General Manager

(b)(6)



Date of Issue: June 27, 2001

354

.1

Directions for Use of Zep Attack-A:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

ZEP ATTACK-A is a proven "one-step" disinfectant-cleaner-sanitizer-fungicide-mildewstat-virucide which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination.

Apply ZEP ATTACK-A to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, sinks, tile, porcelain, and bed frames with a cloth, mop, or mechanical spray device so as to thoroughly wet surfaces. For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution daily or when use solution becomes visibly dirty.

Disinfection - to disinfect hard, non-porous surfaces, add 1 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. The activity of ZEP ATTACK-A has been evaluated in the presence of 5% serum and 400 ppm hard water by the AOAC use dilution test and found to be effective against a broad spectrum of gram negative and gram positive organisms as represented by:

| | |
|-------------------------|-----------------------------|
| Pseudomonas aeruginosa | Salmonella schottmuelleri |
| Staphylococcus aureus | Streptococcus faecalis |
| Salmonella choleraesuis | Shigella dysenteriae |
| Escherichia coli | Brevibacterium ammoniagenes |
| Streptococcus pyogenes | Salmonella typhi |
| Klebsiella pneumoniae | Serratia marcescens |
| Enterobacter aerogenes | Pseudomonas cepacia |

Virucidal Performance - At 1 oz. per gallon use-level, ZEP ATTACK-A was evaluated in the presence of 5% serum and 400 ppm hard water for a contact time of 10 minutes at room temperature (20-25°C) against the following viruses found on inanimate, hard, non-porous surfaces:

| | |
|--------------------|-----------------------|
| HIV-1 (AIDS virus) | Herpes Simplex Type 1 |
| Influenza A/Brazil | Vaccinia |

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

**Zep Manufacturing Company
Division of National Service Industries, Inc.
Atlanta, Georgia 30301**

Directions for Use of Zep Air Fair Conquer

Ready to use. Simply spray as a fine air mist, using the hand sprayer provided, or squirt on the odor source using the handy flip-spout cap.

Excellent for odor control in floor and carpet cleaning solutions. Squirt an ounce or two into the mop bucket or carpet shampoo solution tank.

Spray In: Restrooms, lobbies, closets, locker rooms, storage areas, hospital rooms, motel and hotel rooms, air conditioning filters and ducts, elevators, kitchens, dining areas, and meeting rooms.

Squirt In: Garbage compactors, cigarette urns, disposals, garbage cans, dirty linens, toilets and urinals, bed pans, cabinets, sink traps, floor drains, and mopping solutions. Care should be exercised in applying solution to fabric and color-sensitive surfaces. Test on small inconspicuous area before general use. Chemically neutralizes the source of malodors. Imparts a pleasant, fresh fragrance to all areas.

Concentrated effectiveness provides for long-lasting odor control.

Quickly and conveniently eliminates all types of odors produced by cigars and cigarettes, body wastes, food and cooking odors, garbage, pets and zoo animals, fire produced odors.

**Zep Manufacturing Company
Division of National Service Industries, Inc.
Atlanta, Georgia 30301**

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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 18, 2002

LIFESTREAM PURIFICATION SYSTEMS, LLC 510(k) Number: K003720
C/O RICHARD HAMER ASSOCIATES, INC Product: ANGEL OF WATER
6401 MEADOWS WEST DR. COLON
FORT WORTH, TX 76132 HYDROTHERAPY
ATTN: RICHARD A. HAMER 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. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K003720-52



RICHARD HAMER ASSOCIATES, INC.
REGULATORY CONSULTANTS

VIA FEDERAL EXPRESS

January 15, 2002

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Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RECEIVED
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OFFICE OF DEVICE EVALUATION
CENTRAL MAIL ROOM

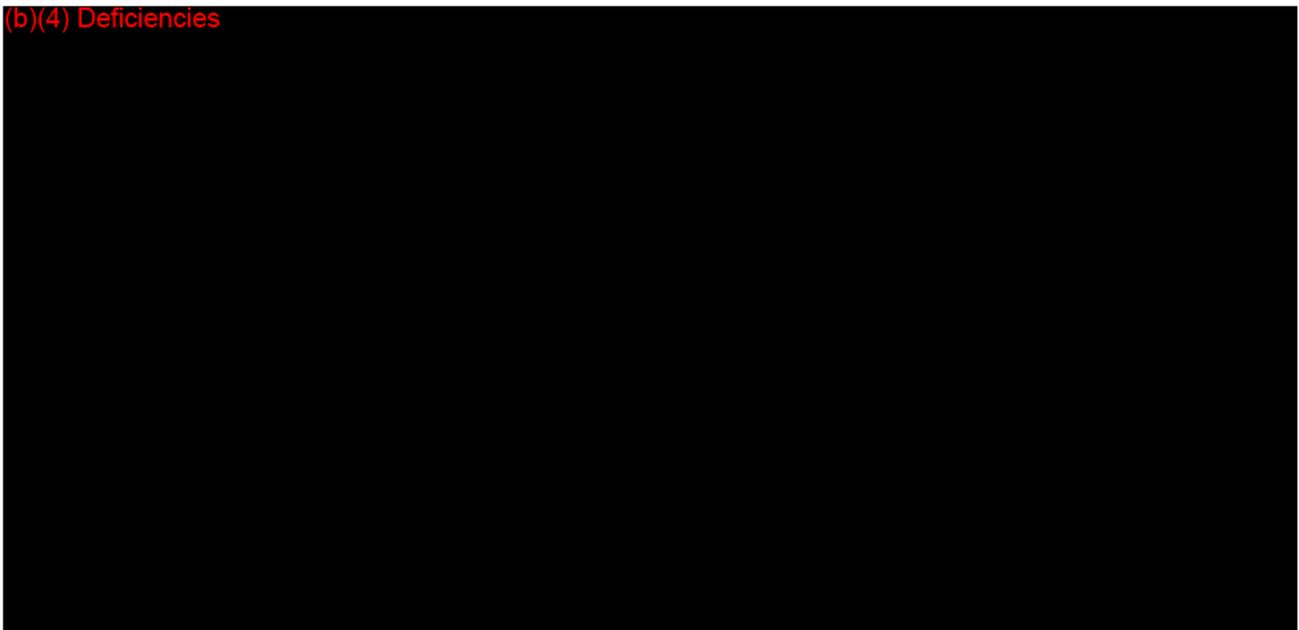
Re: K003720 Angel of Water™ Colon Hydrotherapy System
Amendment #2
Lifestream Purification Systems, LLC Austin, Texas

Dear Dr. Neuland:

Reference is made to the subject 510(k) premarket notification submitted on behalf of Lifestream Purification Systems, LLC on November 30, 2000 as amended on July 31, 2001. Please also refer to your letter of October 30, 2001 requesting additional information, and to our letter of December 6th requesting an extension of the 510(k) review period until January 15, 2002.

We are pleased to submit herewith, on behalf of Lifestream Purification Systems, LLC, duplicate copies of an amendment to K003720 addressing each of the questions raised in your October 30th letter. For convenience, each of the questions is listed below, followed by our response:

(b)(4) Deficiencies



(817) 294-3644 • Fax (817) 294-3761 • E-mail: rhamer@hamerassoc.com

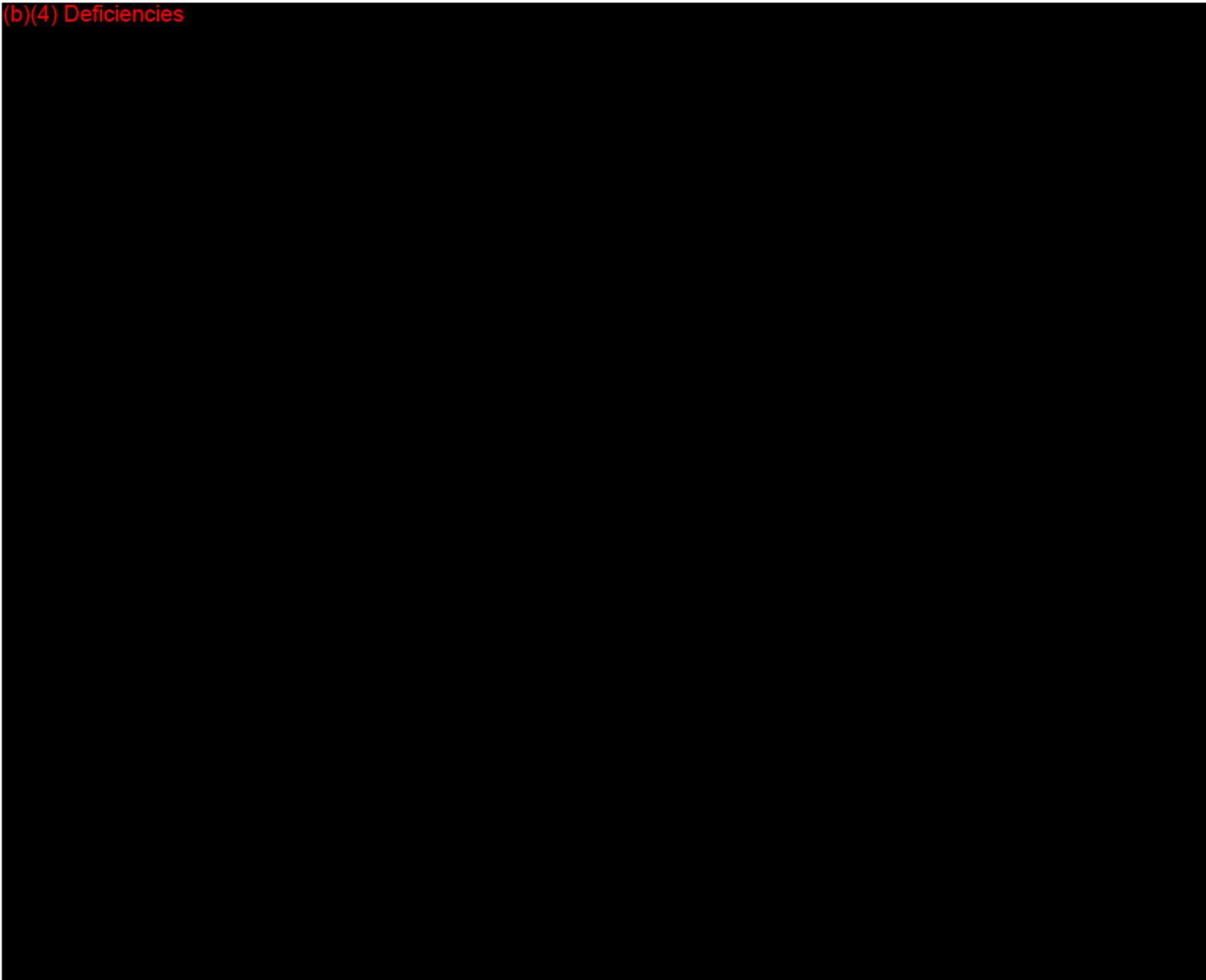
Questions? Contact Office: 6400 Meadowcreek West Dr, Ft Worth, TX 76162 or 301-796-8118
Mailing address: P.O. Box 16598, Ft. Worth, TX 76162-0598

SK51

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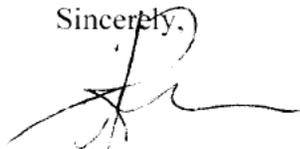
FDA/CRDH/ODE
K003720
Page Seven

(b)(4) Deficiencies



We trust that the information provided herewith will permit you to complete a satisfactory review of this 510(k) premarket notification. Should you have any questions concerning these issues or require additional information, please do not hesitate to call me.

Sincerely,



Richard A. Hamer
Consultant to Lifestream Purification Systems, LLC

Chapter 1

Cleaning and Disinfecting the Angel of Water™ Colon Hydrotherapy System

Safety First

Safety is your primary responsibility. **You must always assume the System is NOT ready until you prepare it immediately before use. Always clean and disinfect your System immediately after use, and immediately before each use. This means that you disinfect and inspect the unit right before a session, even if you cleaned and disinfected it the night before or hours before.**

If you clean and disinfect the System and then leave the building where your System is located, and then you return to use the System, clean and disinfect it again. You do not know what may have transpired in your absence.

This attitude assures that you ALWAYS begin each session hygienically. Plus, it gives you enormous peace of mind in serving others.

Disinfectants, Sanitizers, and Tools and Procedures for Cleaning and Disinfection

The disinfectants, sanitizers, and tools and procedures described below are to be used in exact accordance with the instructions provided below for the care and upkeep of your System. Only the disinfectants given here may be used with the Angel of Water™ Colon Hydrotherapy System.

Lifestream

WARNING: No other disinfectant, sanitizer, tool, or procedure may be substituted for those given here in the cleaning and disinfection protocols for your System.

REMEMBER: Always clean and disinfect your System immediately after use and immediately before each use!

Disinfectants and Sanitizers for use on the Angel of Water™ Colon Hydrotherapy System

- 1) **Zep Attack-A¹** - broad-spectrum hospital grade disinfectant with label claim for virucidal activity against HIV used for the pre-session preparation and the post-session cleaning and disinfection of the System.
- 2) **Chlorine bleach (sodium hypochlorite)** - deodorizer and stain remover used during the post-session cleaning and disinfection of the System.
- 3) **Zep Air Fair Conquer¹** - deodorizer used during the post-session cleaning and disinfection of the System.
- 4) **BioBLUE²** - antimicrobial for System water lines used during the monthly disinfection of the tanks and exit line of the System.

¹ *Attack-A* and *Air Fair Conquer* are products of Zep Manufacturing Company and are available through Lifestream Purification Systems, LLC.

² *BioBLUE* is a product of Micrylium and is available through Lifestream Purification Systems, LLC.

Tools

- 1) **Degreaser and Tether Mop** - for periodic cleaning of Viewing Tube
- 2) **3 Buckets (one gallon size) / with Soft Mops** - two for Attack-A mixture, the third for chlorine bleach solution for deodorizing and stain removal
- 3) **Body Protection** - rubber gloves, eye or face shield, towel or respirator for lung protection
- 4) **Miscellaneous** - 3 spray containers (one for Attack-A mixture, one for Air Fair Conquer mixture, one for BioBLUE); cotton balls; funnel for safe pouring; paper towels for used nozzle and flex tube wrapping and disposal; flex tube line stopper for performing monthly disinfection protocol for tanks and exit line.

The following items are needed also for a successful, hygienic session:

wastebasket with spring-open lid and plastic liners
petroleum jelly lubricant and tube dispenser
paper towels and/or toilet tissue
cotton balls (sterile)
facial tissues
towels for hand wiping and drying of System
floor rug of a non-slip type
disposable gloves

Procedures For Sanitizing and Disinfection

Regardless of whether the System was cleaned and disinfected previously, clean and disinfect the System again if you left the premises where it is located, even if only for a few hours.

A. Pre-Session Preparation:

1) Turn System LIGHTS Switch On

2) Protect Yourself

- a) Put on rubber gloves, eye shields, and protect respiratory channels with towel or respirator before next step.

3) Spray Attack-A on Basin, Rinse Lines, Towel Dry

- a) Allow a mixture of 1 oz. Attack-A to one gallon of water per manufacturer's instructions to contact basin surface for at least **10 minutes** for maximal disinfection.
- b) Run water from tank through nipple for a couple of minutes to wash out line.
- c) Towel dry System surfaces.

4) Visually Inspect Main Tank

- a) Visually inspect main tank. In the event that tank needs rinsing, do so and drain before filling with water for first session.

5) Connect New Flex Tube and Sterile

Cifestream

Rectal Nozzle, Do Final Room Inspection

- a) Connect new flex tube and new sterile, disposable rectal nozzle to flex tube, then lubricate nozzle to conduct session.
- b) Inspect room for readiness before having person enter for session.

B. Post-Session Cleaning and Disinfection:

1) Protect Yourself

- a) Put on rubber gloves, eye shields, and protect respiratory channels with towel or respirator before using chemicals.

2) Remove Soiled Linens from System Area

- a) Place soiled linens in laundry basket.

3) Spray Attack-A Disinfectant and Water Rinse, then Mop with Attack-A Disinfectant (Bucket #1), Water Rinse

- a) Spray entire basin area with Attack-A, then water rinse obvious waste material down drain. Turn on View Tube Flush Valve as needed to clear drain line.
- b) Mop wash entire basin *and* used nozzle with Attack-A (Bucket #1)(1 oz. Attack-A to one gallon of water) before nozzle and flex tube removal. Water rinse everything down drain again.

**4) Remove Used Nozzle and Flex Tube,
Rinse Out Line**

- a) With paper towel, grasp and pull out nozzle and flex tube from brass nipple together. Bend nozzle in half and wrap it and used flex tube in paper towel and dispose of both in wastebasket.
- b) Turn water flow on and rinse out line.

**5) Mop with Attack-A Disinfectant
(Bucket #2), Water Rinse
(Degrease View Tube as needed)**

- a) Mop wash entire basin area again with Attack-A (Bucket #2)(1 oz. Attack-A to one gallon of water) after nozzle and flex tube removal.

Per manufacturer's instructions, make sure that the combined contact time of Buckets #1 and #2 (Zep Attack-A solution) on the basin surface is at least **10 minutes** for maximal disinfection

- b) Water rinse entire basin again well.
- c) Degrease Drain Pipe Viewing Tube in this step when build-up of petroleum jelly lubricant warrants this procedure. Use the tether mop and degreaser to scrub tube.

**6) Mop with Chlorine Bleach Deodorizer
(Bucket #3), Water Rinse**

- a) Mop wash entire basin area with diluted chlorine bleach solution (Bucket #3)(1 capful to one gallon of water for a 200ppm solution). Let solution contact surface for 1

minute. Chlorine bleach acts both as a deodorizer and stain remover.

7) Spray Attack-A, Spray Air Fair Conquer, Towel Dry

- a) Spray a fine mist of Attack-A into the trough and on a linen hand towel to wipe the personal shower sprayer and all basin topside control knob handles.
- b) Spray a fine mist of Air Fair Conquer into the basin trough and splashguard to deodorize.
- c) Towel dry and wipe all surfaces of excess chemicals and water.

8) At the conclusion of the treatment day, drain all water from the main tank, the recirculating (small) tank, and the lines by. If another session is to be conducted continue to #9. If the treatment day is concluded, however, you must drain all water from the system. Do this by opening Valves #2, #3, #4, and #5. **Remember to reset valve sequence to that of Regular Operation mode at the beginning of the next treatment day.**

9) Replace Linens, Do Final Inspection

- a) Put on a fresh pillowcase and supply a fresh cover cloth. Rotate and launder the pillow if it got wet for any reason. Have a number of linens/pillows to rotate and have them clean and ready as required.
- b) Wipe lavatory, glasses, and mirrors and inspect room for overall cleanliness before next session or before finishing for the day.

10) Run Properly Tempered Water through Line, Connect New Flex Tube and New Sterile, Disposable Rectal Nozzle

- a) Rinse out line with properly tempered water, 99 to 103 degrees Fahrenheit.
- b) Connect new flex tube and new sterile, disposable rectal nozzle to flex tube, then lubricate nozzle to conduct session.
- c) Inspect room for readiness before having person enter for session.

It is recommended that you always clean and disinfect the System directly after a session. Do not postpone for any reason. Clean and disinfect the System properly NOW! Always give the first impression and guarantee of cleanliness and hygiene.

C. Disinfect Tanks and Exit Line Once a Month:

1) Disinfect Main Tank and Recirculating (Small) Tank and Exit Line to Basin Nipple

At the end of every month, you must disinfect the main tank and recirculating (small) tank and the exit line of the Angel of Water™ Colon Hydrotherapy System. This prevents the type of microbial contamination characteristic of water lines. **By draining the tanks and exit line of**

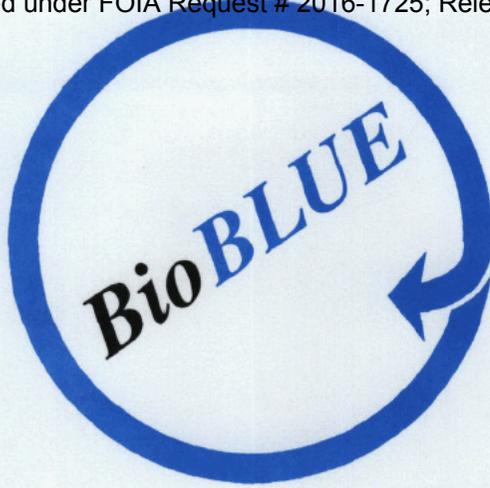
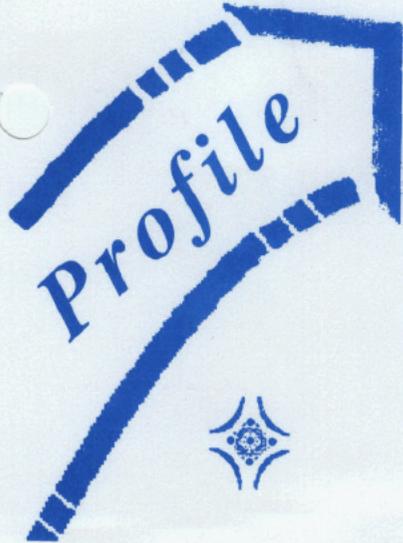
the Angel of Water™ Colon Hydrotherapy System at the end of every treatment day, you are ensuring that microbial buildup is negligible. However, once a month, you must perform the following protocol for the disinfection of the tanks and water line

- a) Run water through the tank and lines to clear them of any debris that may have gotten into the main tank. Drain main tank completely and then close Valve #2.
- b) Place the **flex tube line stopper** (provided with your System) onto the end of the brass nipple in the basin trough in order to block the exit line.
- c) Close Valve #6 (U.V. Inlet) (Valve #2 should already be closed) and open Valves #3, #4, and #5.
- d) Using your spray bottle of **BioBLUE**, apply **BioBLUE**, a ready-to-use, full-strength formulation, to the sides of the main tank and the recirculating (small) tank making sure you have a good, strong stream of disinfectant to cover the sides and bottom of each tank. Let the excess flow down into the line.
- e) Pour one bottle of BioBLUE (500 ml) into the bottom of the main tank so that it can flow into

Lifestream

and fill the entire exit line. Allow BioBLUE to stand overnight in the line (a minimum of 10 hours).

- f) In the morning, remove **the flex tube line stopper** and allow the exit line to drain. Fill the main tank and small tank with water and drain them to flush the line. The System is now ready for use.



Waterlines

Bio BLUE is a fresh mint, full strength antimicrobial multi-purpose dental fluid.

Usage: 1: Use to clean the dental unit water lines overnight or
2: Use continuously as a coolant/lubricant to increase cutting efficiency, reduce aerosols, bad odours and tastes during dental procedures with high speed handpieces and ultrasonic scalers.

Availability: Bottles, each 500mL (17oz)
Case of 10 Bottles or Bulk 6 L Bag in Box

Registration: FDA, HPB

May be used for continuous oral usage such as cutting or scaling. Contains no designated toxic substances.

Protects **patients** and staff from **cross-contamination** and eliminates *Pseudomonas aeruginosa* in lines

One 500mL bottle will fill approximately 166 metres of 1/16" dental tubing or 63 metres of 1/8" tubing.

* **will not** corrode metals, clog valves, stain or stick as do water-based Chlorhexidine mouthwashes

A 30 second water purge will reduce the **Bio BLUE** content to 18 ppm.

• **protects staff** from bacterial **aerosols** generated by the cutting or scaling of teeth.

Safe

Antimicrobial

**Economical
Weekend Use**

**Non-Corrosive
Non-Staining**

**Purges
completely**

**Chlorhexidine
Base**

*Regular use of **Bio BLUE** will ensure that water counts will begin near 0 CFU and the Total Heterotrophic Plate Counts should stay below 200 CFU (Colony Forming Units) by day's end provided quality water is used. Complete studies and reference materials about Dental Unit Waterlines are available by contacting our Customer Service.*



Micrylium is a proud supporter of WWF Canada

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Micrylium

ISO 9001

Resources

Customer Service

(800) 489-8868

FAX (800) 871-6506

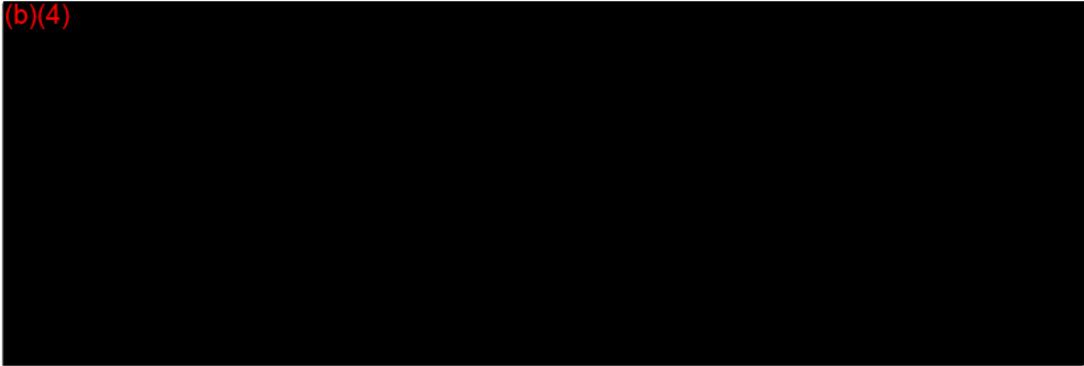
eMAIL greenteam@micrylium.com

www.micrylium.com

120



(b)(4)



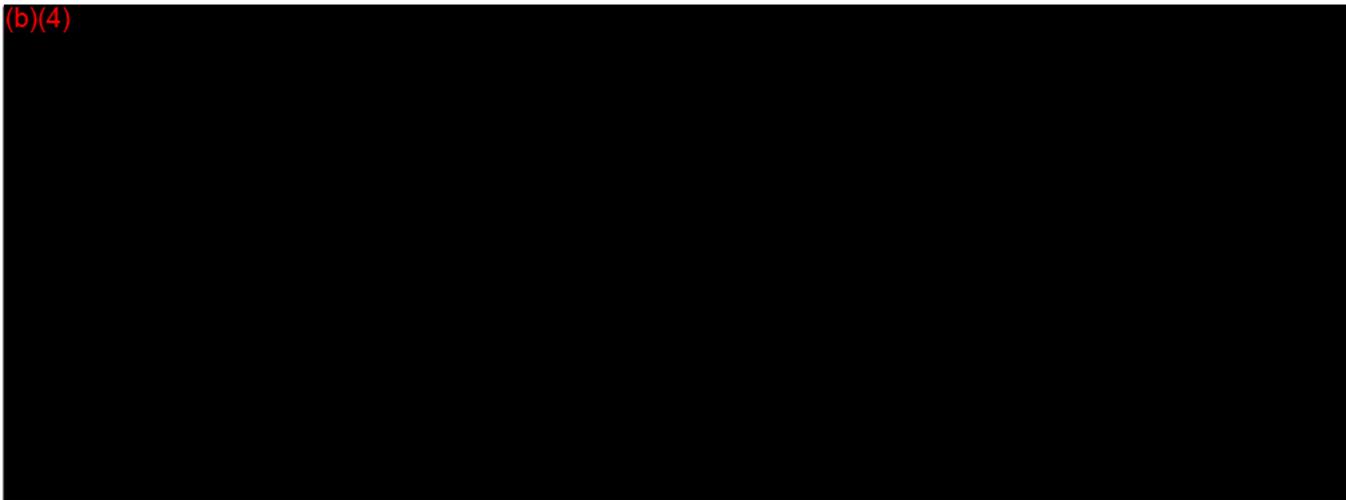
Colon Hydrotherapy Equipment

(b)(4)



Protocol

(b)(4)



(b)(6)

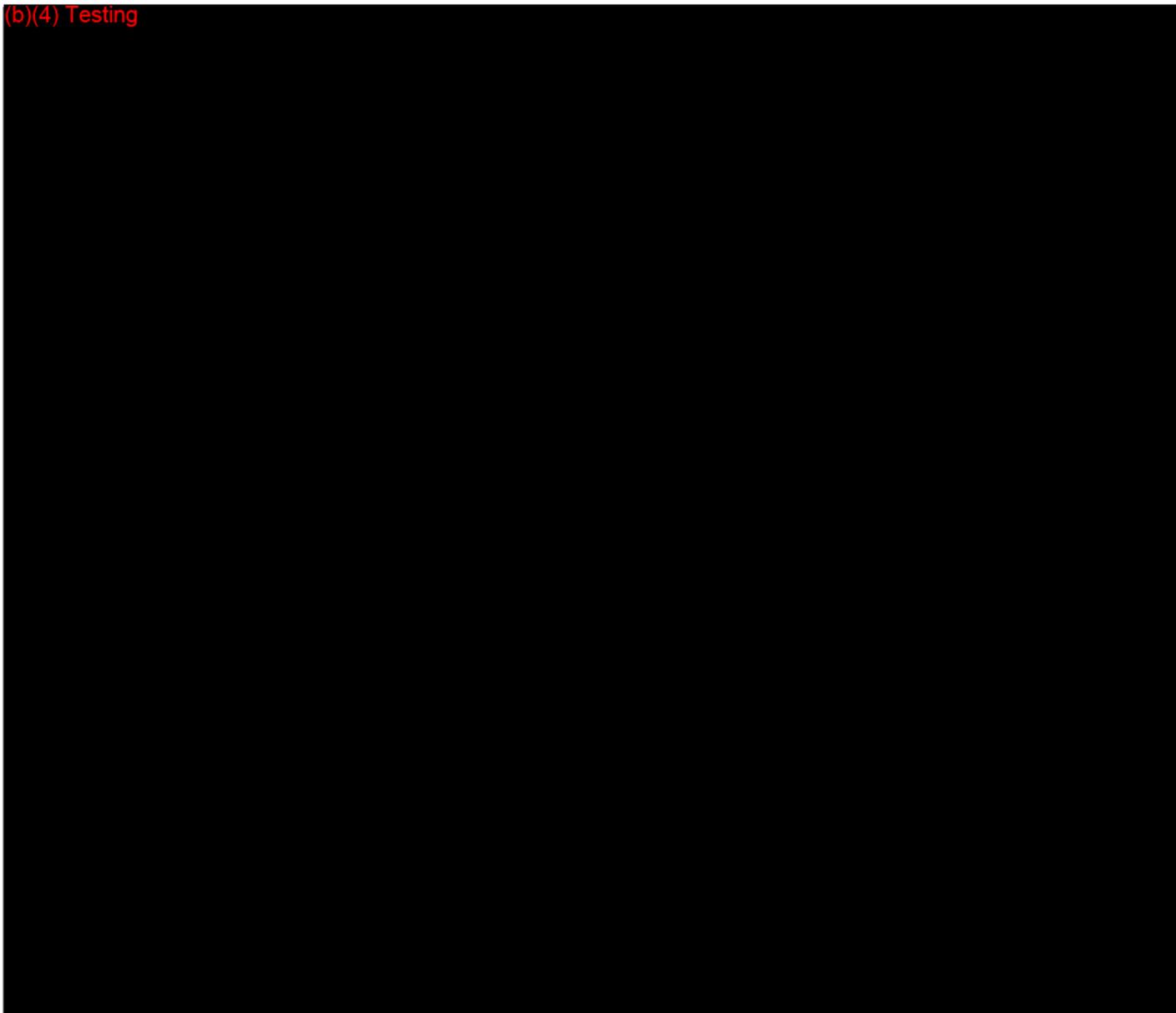


December 1, 2001

Results for (b)(4)

December 19, 2001

(b)(4) Testing

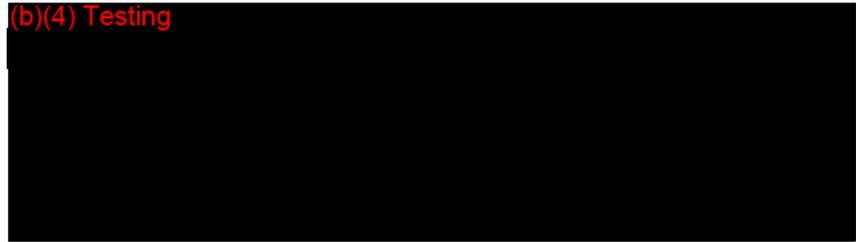


Lifestream

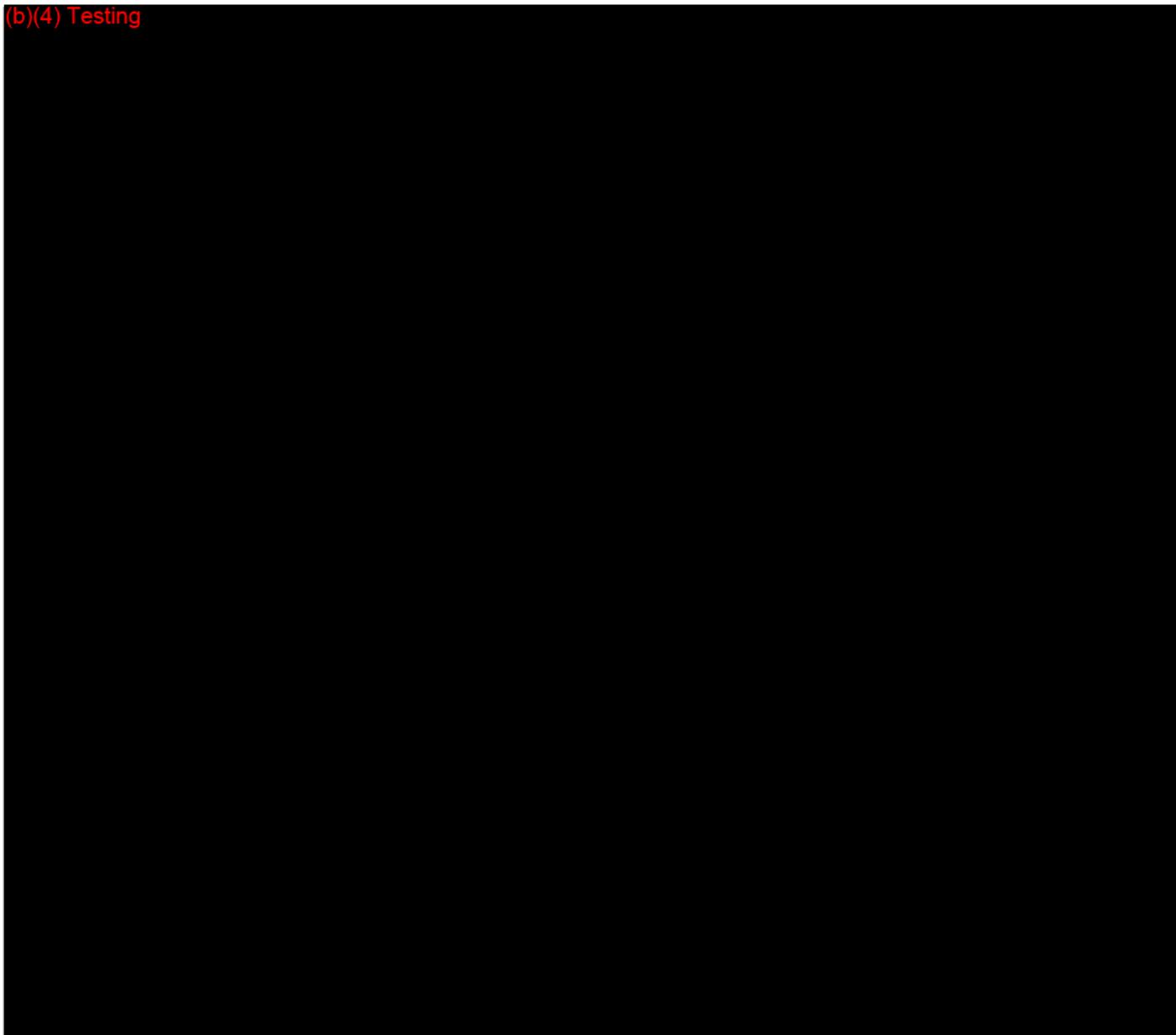
Purification Systems, LLC
2001 South Lamar, Suite G
Austin, Texas 78704
Phone 512-707-3773

Test Item:

(b)(4) Testing

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(b)(4) Testing

A large rectangular black redaction box covering the majority of the page content.

How to be Certified by I-ACT

Exams and their requirements

The Foundation Level

- Requirements:**
1. Provide proof of completing a 100 hour course of Colon Hydrotherapy training from an I-ACT approved School and/or an I-ACT Certified Instructor, or proof of a minimum of one year of practice with at least 100 colon hydrotherapy sessions.
 2. Must be a Full I-ACT Member in good standing.
 3. Must send your resume and proof of all related education; Seminars completed, degrees and experience in both practice and theory. (Copies Please).
 4. Must send pictures of your facility showing waiting area, Colon Hydrotherapy room, bathroom, etc...
 5. Must send documentation of 25 different client colon hydrotherapy sessions you have given during your 100 hour course internship program.
 6. Send a blank) copy of your Health Questionnaire. (Intake Form)
 7. Must carry Liability Insurance and give insurance policy number.
 8. Must take and pass an I-ACT Level 1 written exam .

The Intermediate Level

- Requirements:**
1. Minimum 500 hours of Colon Hydrotherapy training approved by I-ACT, or have proof of a minimum of 2 years of practice.
 2. Must be certified, by I-ACT, at Foundation Level and be a Full I-ACT Member.
 3. Make any corrections on your resume - update continuing education, recent seminars, etc...
 4. Share 15 to 25 minutes, choose A, B, or C: *
 - A: Take us on a video journey with your client as you teach them how they may assist themselves during a session.
 - B: Read your essay of 1000 words in personal experience.
 - C: Demonstrate the expertise you have developed through your work in Colon Hydrotherapy.
 5. Must take and pass the I-ACT Intermediate Level 2. Exam.

*Above presentations may be at an I-ACT approved school, a regional seminar, or an I-ACT Convention - eight people in attendance desired. .

The Advanced Level

- Requirements:**
1. Minimum 1,000 hours of Colon Hydrotherapy training approved by I-ACT, or have proof of a minimum of 3 years of practice.
 2. Must be certified, by I-ACT, at the Intermediate Level and be a Full I-ACT Member.
 3. Must take and pass the I-ACT Advanced Level 3. Exam.

The Instructor Level

- Requirements:**
1. Must be certified, by I-ACT, at the Advanced Level and be a Full I-ACT Member.
 3. Demonstrate 4 hours of teaching at an I-ACT approved school, Regional Meeting, or I-ACT Convention meeting (at least one hour must be at an I-ACT Convention) - eight people in attendance desired.
 4. Submit outline of teaching to headquarters 1 month prior to seminar.
 5. Write a test of 50 questions on Colon Hydrotherapy -multiple choice- with answers (provide answers on separate pages and also provide source documentation for each question). Submit this test to I-ACT.

I-ACT • P. O. Box 461285, San Antonio, TX 78246-1285 • (210) 366-2888 • Fax (210) 366-299

Records processed under FOIA Request # 2016-1725, Released by CDRH on 05-23-2016

COLON HYDROTHERAPY SCHOOLS - I-FACT APPROVED

Alpha Natural Therapeutics
3227 Independence @ Parker
Plano, TX 75075
(972) 769-1474

American Institute of Massage Therapy, Inc.
416 E. Atlantic Blvd.
Pompano beach, FL 33060
(800) 752-2793

Christian Wellness & Treatment Center
1413 Crescent, Suite B
Tyler, TX 75702
(903) 592-3900

Circle of Life School of Colon Hydrotherapy
P.O. Box 22088
Sante Fe, NM 87502-2088
(505) 986-0775 / (800) 793-7513

Colon Therapeutics Research Institute
2909 Main Ave
Groves, Texas 77619
409-963-0300

Dotolo Institute & ReNew Life School
1007 N. MacDill
Tampa, FL 33607
(800) 690-9988 / (813) 871-3200

Internal Environment Institute
11739 Washington Blvd.
Los Angeles, CA 90066
(310) 572-6223

International School of Colon Hydrtherapy
*13878 Oleander Avenue
Juno Beach, FL 33408
(800) 717-7432 or 561-627-3560
*IMI-Lientalerhof, 3723 Kiental-CH
Switzerland
011-41-33-676-2676 / US (800) 717-7432

Joyce Long's Wellness Institute
2301 Yorktown, #201 A
Houston, TX 77056
(713) 623-0866

Long Island School of Colon Hydrotherapy
At ABC Wellness Center
105 West Hoffman Ave
Lindenhurst, NY 11757
631-956-7152

Michigan School of Colon Hydrotherapy
2386 East Buchanan Rd.
Ithaca, MI 48847
(517) 875-8634

Mind Body Colon Cleansing Centre
3/Floor Lin Fook House, 3 Jardine's Crescent
Causeway Bay, Hong Kong
(852) 2805-7535

MIND BODY Naturopathic Institute
10911 West Avenue
San Antonio, TX 78213-1537
(210) 308-8888 / 800-939-1110

New England School of Colon Hydrotherapy
214 Market Street
Brighton, MA 02135
617-787-5040

Oriental School of Colon Hydrotherapy
10, Loke Yew Street
Singapore, Hong Kong 179229
011-65-235-6311

You may take the Anatomy and Physiology (A&P) at a college level, the Dotolo Research correspondence course, the MIND BODY correspondence course, or the Caitlyn Mayfair correspondence course thru A.R.E.*

COLON HYDROTHERAPY MANUFACTURERS

The following manufacturers provide FDA registered colon hydrotherapy equipment.

Colon Therapeutics, Inc.

Jim Girouard
2909 Main Ave
Groves, Texas 77619
409-963-0300
Fax 409-962-2251

Specialty Health

Maury Solomon
21636 N. 14th Ave., Suite A1
Phoenix, Arizona 85027
623-582-4950
Fax 623-581-8724

Clearwater Colon Hydrotherapy

MaryRuth Baker
4451-A South Pine Avenue
Ocala, Florida 34480
352-401-0303 / 888-869-6191
Fax 352-401-9197

Tiller MIND BODY, Inc.

Jeri C. Tiller
10911 West Avenue
San Antonio, Texas 78213-1537
210-308-8888 / 800-939-1110
Fax 210-349-5679

Dotolo Research

Raymond Dotolo
2875 MCI Drive
Pinellas Park, Florida 33782
800-237-8458
Fax 727-217-9500

TRANSCOM S.L.

Raymond Echevarria Ruiz
Sangroniz, 6, Edificio Beaz -
Pabellon 15
48150 Sondika (Vizcaya), SPAIN
011 (34-4) 4531033 / (34-4) 4710116
Fax 011 (34-9)44531034

Chapter 4

Valve Sequences for System Operation

The Angel of Water™ Colon Hydrotherapy System's primary mode of operation is called **Regular Operation mode**. **All colon hydrotherapy sessions are to be conducted in Regular Operation mode**. The System is shipped with Valves preset for Regular Operation mode. For operational familiarity, double check that the Valves are opened and closed as described below for Regular Operation mode before beginning your first session.

There is a backup mode of operation for the Angel of Water™ Colon Hydrotherapy System called the **Manual Operation mode**. Manual Operation mode provides for the completion of a session already in progress in the unlikely event of a waterflow component malfunction or a power outage to the system. Familiarize yourself with the Valve sequences for Manual Operation mode should you ever need to use it.

1) Regular Operation (used for all colon hydrotherapy sessions)

This is the primary mode of operation for all colon hydrotherapy sessions. Regular Operation features water circulating from the large main tank via the water cycling device to the smaller tank. Then an even and constant stream of gravity-fed water flows through the

Lifestream

U.V. Filter to the person experiencing the colon irrigation.

Follow this Valve sequence:

a) Open Valves #6, #7, #9, (#10 and #11 were set in OPEN position when System was set up and should be left OPEN always unless System plumbing maintenance requires otherwise.) All other Valves are closed. Then open #1 and turn on and adjust Water Mixing Valve to fill tank with water between 99 to 103 degrees Fahrenheit.

Close #1 or shut off Water Mixing Valve to *stop* water to large main tank at any level.

However, water level inside tank shuts off automatically by Tank Level Valve once level has reached top (about 12 gallons). Once full, close #1 and/or turn off Water Mixing Valve. As water is needed in tank, open #1 and/or turn on Water Mixing Valve to refill tank.

b) Occasionally, the person experiencing the colon irrigation may feel as if no water is coming into their colon. This may indicate that the nozzle inserted into them is clogged at the tip with waste material. The monitoring assistant or health care practitioner can unclog nozzle in the following way *without* having the person on the System come off the nozzle in order to check it. To unclog nozzle with additional flow from large main tank, close #7 and #9. Then **slowly** open #8 **partially** until flow is felt again by person experiencing the irrigation. Then open #7 and #9 again, and close #8 completely.

2) Manual Operation (backup mode)

Manual Operation mode allows the practitioner to assist the patient to complete a

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session already in progress in the unlikely event of a malfunction of one of the waterflow components (the FLOW rocker switch or the Solenoid Valve) or a power outage to the system. Manual Operation mode allows the health care practitioner to send water to the person experiencing the colon irrigation directly from the large main tank with or without the activation of the FLOW control switch or with or without the use of electricity.

There are two Valve sequences you need to know:

a) If either the FLOW rocker switch or the Solenoid Valve malfunctions, continue the session in the following way:

Open Valve #1 and Water Mixing Valve to fill tank to proper water temperature between 99 to 103 degrees Fahrenheit. When monitoring assistant or health care practitioner is ready to send water to the person experiencing the colon irrigation, open only Valves #3 and #6. Close Valve #6 when person on the System is finished with session or wants an intermission from session. If session stops longer than a couple of minutes, be sure to turn U.V. control switch to OFF temporarily during the intermission. Turn U.V. control switch ON when session resumes and Valve #6 is opened again.

b) If there is a power outage to the equipment, continue session in the following way:

Open Valve #1 and Water Mixing Valve to fill tank to proper water temperature between 99 to 103 degrees

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Fahrenheit. When monitoring assistant or health care practitioner is ready to send water to the person experiencing the colon irrigation, open only Valves #3 and #4. Close Valve #4 when person on the System is finished with session or wants an intermission from session.

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 20, 2002

LIFESTREAM PURIFICATION SYSTEMS, LLC 510(k) Number: K003720
C/O RICHARD HAMER ASSOCIATES, INC Product: ANGEL OF WATER
6401 MEADOWS WEST DR. COLON
FORT WORTH, TX 76132 HYDROTHERAPY
ATTN: RICHARD A. HAMER 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. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh.ode/A02-01.html.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

40

K003720/SS

Lifestream

Purification Systems, LLC
2001 South Lamar, Suite G
Austin, Texas 78704
Phone 512-707-3773

VIA EXPRESS MAIL

18 May 2002

Office of Device Evaluation
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Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

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FDA/CDRH/OCE/DMC

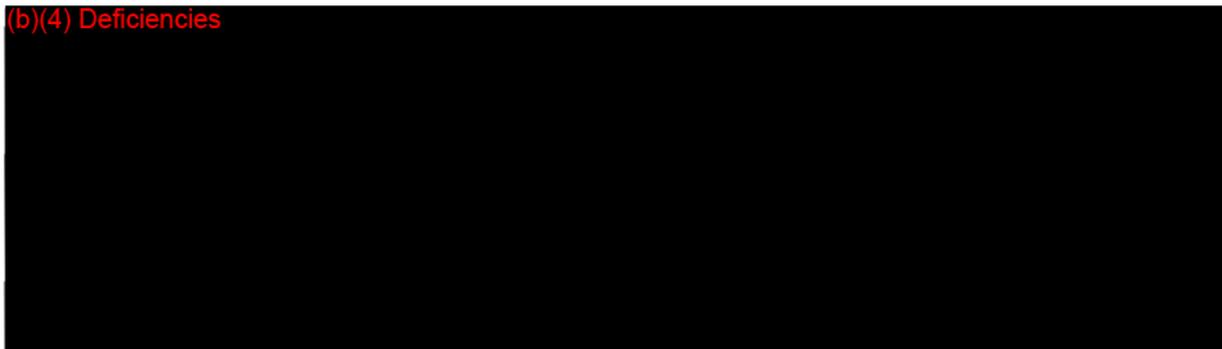
Re: K003720 Angel of Water™ Colon Hydrotherapy System
Amendment #3
Lifestream Purification Systems, LLC, Austin, Texas

Dear Dr. Neuland,

Reference is made to the subject 510(k) premarket notification submitted on behalf of Lifestream Purification Systems, LLC on November 30, 2000 as amended on July 31, 2001 and again on January 15, 2002.

We are pleased to submit herewith, on behalf of Lifestream, duplicate copies of an amendment to K003720 addressing each of the four questions raised in your April 17, 2002 letter. For convenience, each of the questions is listed below, followed by our response:

(b)(4) Deficiencies



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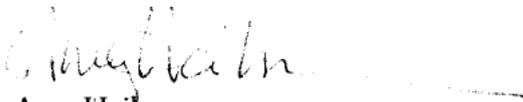
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(b)(4) Deficiencies



We certainly hope that the information provided herewith will permit you to complete a satisfactory review of this 510(k) premarket notification. We very much appreciate the assistance of Ms. Kathleen Olvey via telephone in the last two weeks in spelling out for us precisely what information was still lacking and what would allow your satisfactory review of this notification. Should you have any questions concerning these issues, please call me as soon as possible.

Sincerely,



Amy Heilman
General Manager
Lifestream Purification Systems, LLC

CaviCide

®

Ready-To-Use

Contains Biodegradable Detergent

- Bactericidal
- Virucidal*
- Fungicidal
- Tuberculocidal**

ACTIVE INGREDIENTS:

Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride0.28%

Isopropanol17.20%

INERT INGREDIENTS:.....82.52%

TOTAL:.....100.00%

CAUTION KEEP OUT OF REACH OF CHILDREN

EPA REG. NO.: 46781-6 EPA EST. NO.: 46781-MI-1

INSTRUMENTS: (Where appropriate, follow Universal Precautions.)

For use as an immersion precleaning instrument decontaminant solution:

Fill appropriate size container with a sufficient amount of undiluted **Cavicide** so as to allow for complete submersion of instruments. Place instruments into **Cavicide** solution, cover and allow to soak for 10 minutes. Remove and rinse. Follow with appropriate cleaning and disinfection process. Change solution as needed when the solution becomes diluted or visibly soiled. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

For use as an instrument preclean decontamination spray: Place

instruments into a suitable container. Thoroughly spray **Cavicide** solution onto instruments so as to thoroughly drench all surfaces. Cover instruments and transport to appropriate cleaning area. Rinse instruments, follow with appropriate cleaning and disinfection process. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

For use as an instrument ultrasonic cleaning solution: Thoroughly pre-rinse

instruments under running water to remove visible gross debris. Using 1 ounce **Cavicide** per liter of water in ultrasonic unit, immerse instruments into mixed solution and activate unit for 5 minutes or longer if necessary. Remove instruments and rinse thoroughly. Change solution as needed. Follow with appropriate disinfection process.

(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)

For use as a manual instrument cleaner: Thoroughly pre-rinse dirty instruments under running tap water to remove visible gross debris. Place pre-rinsed instruments into a solution of 1 ounce **Cavicide** per liter of water. Scrub instruments using a stiff bristle brush until visibly clean. (Instruments should be submerged as scrubbed.) Rinse instruments thoroughly. Change solution as needed. Follow with appropriate disinfection process. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

For disinfection of NON-CRITICAL precleaned instruments: Instruments must be thoroughly precleaned to remove excess organic debris, rinsed and then rough dried. (Clean and rinse lumens of hollow instruments before filling with solution or before immersion.) Using either a soaking tray or ultrasonic unit, immerse instruments into undiluted **Cavicide** solution and allow to remain submerged for 3 minutes. For tuberculocidal activity, allow 10 minutes at room temperature (69°F/20°C). Remove and rinse or wipe dry prior to use. Change solution daily or more often as needed if the solution becomes diluted or visibly soiled. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

***This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. **This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection.**

STORAGE AND DISPOSAL - STORAGE: Store in a cool place. **PESTICIDE DISPOSAL:** Dilute with water. Dispose of in ordinary sanitary sewer. **CONTAINER DISPOSAL:** Triple rinse. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, keep out of smoke.

Manufactured By:

METREX RESEARCH CORPORATION
28210 Wick Road

Romulus, Michigan 48174 **Reorder No. 13-1000 3101-10**

For product or technical information, contact Metrex at **800-841-1428** or visit our web site at **www.metrex.com**.

EFFECTIVE AGAINST: • Staphylococcus aureus • Pseudomonas aeruginosa • Salmonella choleraesuis
• Mycobacterium tuberculosis var: bovis (BCG)** • Methicillin Resistant Staphylococcus aureus (MRSA)

• Vancomycin Resistant Enterococcus faecalis (VRE) • Trichophyton mentagrophytes • Herpes simplex virus types 1 and 2* • Human Immunodeficiency Virus (HIV-1)* (*On inanimate surfaces.) (**In 10 minutes at room temperature - 20°C.)

DIRECTIONS FOR USE:

It is a violation of U.S. Federal law to use this product in a manner inconsistent with its labeling.

DESCRIPTION: CaviCide

®

is a multi-purpose, broad spectrum, ready to use, highly effective cleaner and disinfectant for use on the surfaces of inanimate objects. It is especially useful in hospital operating rooms, isolation areas, neonatal units, and other critical care areas where environmental control of cross contamination is important.

Cavicide will effectively clean and disinfect, when used as directed, such items as: infant incubators and bassinets, anesthesia machines and respiratory therapy equipment surfaces, operating room tables and lights, and other inanimate surfaces, including those made of plastics (such as: polycarbonate, polyvinylchloride, polypropylene and polystyrene), non-porous vinyl and upholstery, stainless steel, painted surfaces, Plexiglas®, glass, and other hard non-porous surfaces.

APPLICATIONS:

SURFACES: (Where appropriate, follow Universal Precautions.)

For disinfecting non-critical devices/medical equipment and surfaces:

Apply **Cavicide** directly to precleaned surface, thoroughly wetting area to be disinfected. Allow surface to remain wet for 3 minutes at room temperature (69°F/20°C). **(For Tuberculocidal Activity: allow 10 minutes.) Follow by wiping surface using a clean paper or cloth towel; **or** rinse and either allow surface to air dry or wipe rinsed surface dry using a clean paper or cloth towel.

Discard towel.

For precleaning medical equipment and other surfaces prior to

disinfection: Apply directly to surface. Allow to remain wet for 30 seconds. Wipe surface clean using a paper or cloth towel **or** rinse surface and either wipe dry or allow to air dry. Discard dirty towel.

CAVICIDE EFFECTIVELY KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUS-LY

SOILED WITH BLOOD/BODY FLUIDS IN HEALTHCARE SETTINGS OR OTHER SETTINGS IN WHICH THERE IS AN EXPECTED LIKELIHOOD OF SOILING OF INANIMATE SURFACES/OBJECTS WITH

BLOOD/BODY FLUIDS, AND IN WHICH THE SURFACES/OBJECTS CAN BE ASSOCIATED WITH THE POTENTIAL FOR TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE-1 (HIV-1).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUID: •

Personal Protection: Wear

appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. • **Cleaning Procedure:** Blood

and other bodily fluids must be thoroughly cleaned from surfaces and objects before disinfection with **Cavicide**. •

Contact Time: While the HIV-1 virus is inactivated in 2 minutes, use the recommended contact time for the disinfection

of other organisms listed on this label. • **Infectious Materials Disposal:**

Cleaning materials used that may

contain blood or other bodily fluids should be autoclaved and/or disposed of in accordance with local regulations for

infectious materials disposal. **Contents: 1 Gallon (128 fluid oz.) (3.8L)**

PRECAUTIONARY STATEMENTS: Hazards to Humans and

Domestic Animals. Causes moderate eye irritation. Avoid contact

with eyes or clothing. Wash hands thoroughly with soap and water

after handling. In case of direct eye contact, immediately flush

eyes with plenty of water for at least 15 minutes. If irritation

persists, seek medical attention.

5

CAVICIDE

Technical Bulletin

Cavicide is a general purpose disinfectant intended for use in cleaning, decontaminating and disinfecting equipment surfaces and non-critical instruments in hospitals, laboratories, and other critical care areas where environmental control of cross contamination is important.

Cavicide has biocidal effectiveness against the following microorganisms:

Mycobacterium bovis BCG
Staphylococcus aureus
Pseudomonas aeruginosa
Salmonella choleraesuis
Trichophyton mentagrophytes
Methicillin Resistant Staphylococcus aureus (MRSA)
Vancomycin Resistant Enterococcus faecalis (VRE)
Herpes Simplex Virus Type 1
Herpes Simplex Virus Type 2
Human Immunodeficiency Virus (HIV-1)
Canine parvovirus

Tuberculocidal Efficacy Studies:

Mycobacterium bovis BCG

"A Quantitative Suspension Test For Determining Tuberculocidal Activity of Cavicide"
Southern Research Institute. June 19, 1991. Lab ID# 7363-91-1.
Conclusion: The results of the study indicate that Cavicide may be considered an effective tuberculocidal agent when in contact with inanimate surfaces for at least 10 minutes at 20°C.

"AOAC Tuberculocidal Test"

Shaladra Biotest, Inc. September 21, 1985.

Conclusion: Three lots of Cavicide exhibited no growth of *Mycobacterium bovis BCG* when tested for 10 minutes at 20°C.

"AOAC Confirmative Tuberculocidal Activity of Cavicide"

MicroChem Laboratory. July 19, 1994. Lab ID# 940412-2.

Conclusion: Cavicide killed 100% of the *Mycobacterium bovis BCG* labeled cylinders within 5 minutes at 20°C. Cavicide can pass the AOAC Confirmative Tuberculocidal Test within 5, 10, 20, 30 and 45 minutes at 20°C.

"Cavicide vs. *Mycobacterium bovis BCG* in a Rate of Kill Suspension Test"

MicroChem Laboratory. May 4, 1994. Lab ID# 940222-2, 940301-3; 940329-2

Conclusion: In suspension over a period of three separate tests, Cavicide consistently killed 100% *Mycobacterium bovis BCG* within 10 minutes at 20±1°C.

(6)

Bactericidal Efficacy Studies:

Staphylococcus aureus
Pseudomonas aeruginosa
Salmonella choleraesuis
Trichophyton mentagrophytes
Methicillin Resistant *Staphylococcus aureus* (MRSA)
Vancomycin Resistant *Enterococcus faecalis* (VRE)

"Cavicide versus *Staphylococcus aureus* in the AOAC Germicidal Spray Products Test"
MicroChem Laboratory. January 9, 1995. Lab ID# 914201-1; 941208-1; 941209-1; 941229-1;
950103-1; 950105-1.

Conclusion: Diluted Cavicide (worst case solution with minimum manufacturing concentrations of Isopropanol and Hyamine 1622) passed the AOAC Germicidal Spray Products Test 961.02 at 2, 5 and 10 minutes when tested against *S. aureus* at 20±1°C.

"AOAC Use-Dilution Test: Evaluation of the Efficacy of Cavicide against *Staphylococcus aureus*" (confirmatory)

ViroMed Laboratories, Inc. May 27, 1993. Amended Report November 2, 1993.

Lab ID# 391-SA

Conclusion: Two lots of Cavicide, used undiluted, demonstrated no growth on any of the carriers in the primary subculture when tested against *S. aureus*. Under the conditions of this study, Cavicide was germicidal against *S. aureus*.

"Cavicide versus *Pseudomonas aeruginosa* in the AOAC Germicidal Spray Products Test"
MicroChem Laboratory. January 3, 1995. Lab ID# 914201-1; 941208-1; 941209-1; 941216-1;
941221-1; 941227-1.

Conclusion: Diluted Cavicide (worst case solution with minimum manufacturing concentrations of Isopropanol and Hyamine 1622) passed the AOAC Germicidal Spray Products Test at 2, 5 and 10 minutes when tested against *P. aeruginosa* at 20±2°C.

"AOAC Use-Dilution Test: Evaluation of the Efficacy of Cavicide against *Pseudomonas aeruginosa* (confirmatory)

ViroMed Laboratories, Inc. November 9, 1993. Lab ID# 533-PA

Conclusion: Two lots of Cavicide, used undiluted, demonstrated no growth on any of the carriers in the primary subculture when tested against *P. aeruginosa*. Under the conditions of this study, Cavicide was germicidal against *P. aeruginosa*.

"Cavicide versus *Salmonella choleraesuis* in the AOAC Germicidal Spray Products Test"
MicroChem Laboratory. January 18, 1995. Lab ID# 914201-1; 941208-1; 941209-1; 950111-1;
950116-1.

Conclusion: Diluted Cavicide (worst case solution with minimum manufacturing concentrations of Isopropanol and Hyamine 1622) passed the AOAC Germicidal Spray Products Test at 2, 5 and 10 minutes when tested against *S. choleraesuis* at 20±1°C.

"AOAC Use-Dilution Test: Evaluation of the Efficacy of Cavicide against *Salmonella choleraesuis* (confirmatory)

ViroMed Laboratories, Inc. November 9, 1993. Lab ID# 533-PA

Conclusion: Two lots of Cavicide, used undiluted, demonstrated no growth on any of the carriers in the primary subculture when tested against *S. choleraesuis*. Under the conditions of this study, Cavicide was germicidal against *S. choleraesuis*.

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"AOAC Use-Dilution Test: Cavicide versus *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella choleraesuis*"

Shaladra Biotest, Inc. August 22, 1986.

Conclusion: Three lots of Cavicide showed no growth of *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella choleraesuis* when tested for 10 minutes at 20°C.

"Bactericidal Activity of Cavicide in a Stainless Steel Cylinder Test and in Suspension"

MicroChem Laboratory. January 18, 1994. Amended Report November 10, 1994.

Lab ID# 931203-1; 931206-3; 931208-1; 931213-2; 931217-1; 931222-1; 931228-3; 931229-1; 940105-1; 940113-3.

Conclusion: In these studies, tests were designed to determine how quickly bacteria were killed on stainless steel surfaces, and in suspension by Cavicide at 20±1°C. Several procedures were used to eliminate any questions that Cavicide might inhibit rather than kill the bacteria. Cavicide was found to kill *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella choleraesuis* in suspension within 15 seconds at 20±1°C. Cavicide also killed these bacteria on stainless steel surfaces within 10 minutes at 20±1°C.

"Quantitative Analysis of the Kill or Removal of Bacteria in Heavy Organic Soil from Surfaces by Cavicide" (custom-designed test)

MicroChem Laboratory. April 18, 1995. Lab ID# 950327-1; 950329-1; 950331-1; 950412-1.

Conclusion: The study was designed to measure the extent to which Cavicide could kill *S. aureus*, *P. aeruginosa* and *S. choleraesuis* dried in concentrations up to 20% calf serum on glass slide surfaces. A 10 minute exposure to Cavicide at 20±2°C. killed more than or equal to 10⁴ bacteria dried in 5%, 10% or 20% calf serum on glass cover slips. No surviving bacteria were found in the Cavicide drained from the glass slips. These data indicate that the health hazard to personnel from bacteria, and by comparison to other microbes, on contaminated medical instruments could be reduced by decontaminating the instruments with Cavicide prior to further process.

"Fungicidal Activity of Cavicide in a Stainless Steel Cylinder Use-Dilution Test and in Suspension"

MicroChem Laboratory. January 24, 1994. Lab ID# 931230-1; 940104-1; 940106-1; 940110-2; 940112-4; 940114-2.

Conclusion: Cavicide killed *Trichophyton mentagrophytes* and *Candida albicans* in suspension within 30 seconds at 20±1°C. Cavicide also killed these fungi on stainless steel surfaces within 1 minute at 20±1°C.

"AOAC Fungicidal Test: Cavicide"

Shaladra Biotest, Inc. June 29, 1985.

Conclusion: Three lots of Cavicide exhibited no growth of *Trichophyton mentagrophytes* when tested for 10 minutes at 20°C.

"Cavicide versus *Methicillin Resistant Staphylococcus aureus* (MRSA) in the AOAC Germicidal Spray Products Test"

MicroChem Laboratory. April 19, 1995. Lab ID# 950406-1.

Conclusion: Two lots of Cavicide diluted to the minimum manufacturing concentrations of Isopropanol and Hyamine 1622 passed the AOAC Germicidal Spray Products Test against MRSA in 2 minutes at 20±1°C.

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"Cavicide versus Vancomycin Resistant Enterococcus faecalis (VRE) in the AOAC Germicidal Spray Products Test"

MicroChem Laboratory. April 19, 1995. Lab ID# 950406-1.

Conclusion: Two lots of Cavicide diluted to the minimum manufacturing concentrations of Isopropanol and Hyamine 1622 passed the AOAC Germicidal Spray Products Test against VRE in 2 minutes at 20±1°C.

Virucidal Studies

Herpes Simplex Virus Type 1

Herpes Simplex Virus Type 2

Human Immunodeficiency Virus (HIV-1)

Canine parvovirus

"Cavicide v. Herpes Simplex Virus Type 1" (Spray)

Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 278-161-1053.

Conclusion: Cavicide inactivated Herpes Simplex Virus Type 1 at 30 seconds.

"Cavicide v. Herpes Simplex Virus Type 1" (Liquid)

Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 279-161-1056.

Conclusion: Cavicide inactivated Herpes Simplex Virus Type 1 at 30 seconds.

"Cavicide v. Herpes Simplex Virus Type 2" (Spray)

Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 275-161-1040.

Conclusion: Cavicide inactivated Herpes Simplex Virus Type 2 at 30 seconds.

"Cavicide v. Herpes Simplex Virus Type 2" (Liquid)

Gibraltar Biological Laboratories, Inc. July 31, 1984. Lab ID# 276-161-1044.

Conclusion: Cavicide inactivated Herpes Simplex Virus Type 2 at 30 seconds.

"Virucidal Efficacy of Cavicide Against the Human Immunodeficiency Virus (HIV-1)"

Southern Research Institute. July 14, 1992. Lab ID# 0051.

Conclusion: Cavicide demonstrated virucidal activity against HIV-1 in a CPE assay with MT-2 cells during a 2 minute exposure period.

"Virucidal Effectiveness Test of Cavicide Against the Canine parvovirus"

Conclusion: Cavicide was effective against the *Canine parvovirus* in a screen test conducted in 10 minutes at 20±1°C.

Toxicity Studies

Oral Toxicity

Inhalation Toxicity

Dermal Toxicity/Irritation/Sensitization

Ocular Irritation

"Acute Oral Toxicity Study of Cavicide in Sprague-Dawley Rats"

American Standards Biosciences Corporation. May 23, 1986. Lab ID# 86-367.

Conclusion: Cavicide was tested for potential acute oral toxicity in accordance with the procedure outlined in the Pesticide Assessment Guidelines. No signs of toxicity were exhibited at any time during the 14-day observation period of this study. Based on the results obtained in this study, the acute oral toxicity LD₅₀ of Cavicide is greater than 5g/kg of body weight.

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APR 25 1995

Food and Drug Administration
5200 Corporate Boulevard
Rockville MD 20850

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Mr. Gregory F. Steil
Manager, Regulatory Affairs/Quality Control
Micro-Aseptic Products, Incorporated
987 East Wilmette Road
Palatine, Illinois 60067

Re: K951123
Trade Name: Cavicide[®] Surface Disinfectant/Decontaminant
Cleaner
Regulatory Class: Unclassified
Product Code: LRJ
Dated: February 10, 1995
Received: February 24, 1995

Dear Mr. Steil:

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 or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market 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. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

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Page 2 - Mr. Steil

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate 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 for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. 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,



Timothy A. Ulatowski
Acting Director
Pilot Division
Office of Device Evaluation
Center for Devices and
Radiological Health

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CAVICIDE®



SALON DISINFECTANT/DECONTAMINANT CLEANER
BARBER DISINFECTANT/DECONTAMINANT CLEANER
VETERINARY DISINFECTANT/DECONTAMINANT CLEANER
CLIPPER BLADE DISINFECTANT/ DECONTAMINANT CLEANER
DISINFECTANT/ DECONTAMINANT CLEANER
SURFACE DISINFECTANT/ DECONTAMINANT CLEANER

Bactericidal • Virucidal* • Fungicidal • Tuberculocidal**

Ready-To-Use

Contains Biodegradable Detergent

For Professional Use Only

ACTIVE INGREDIENTS:

| | |
|---|----------------|
| Dilcobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride..... | 0.28% |
| Isopropanol..... | 17.20% |
| INERT INGREDIENTS..... | 82.52% |
| TOTAL..... | 100.00% |

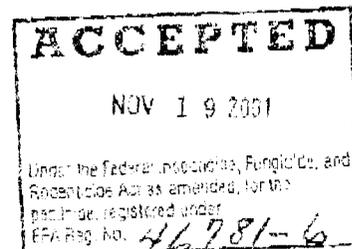
**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Precautionary Statements: Hazards to Humans and Domestic Animals.
Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse. See side panel for additional precautionary statements.

EPA Reg. No. 46781-6 EPA Est. No. 46781-MI-1 Reorder No: 00-0000

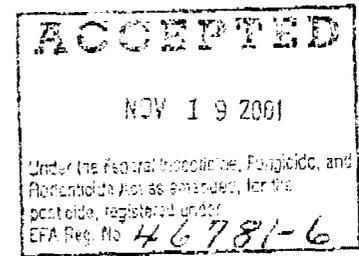
Net Contents: 1 U.S. Gallon / 3.785 Liters (Net Weight 8.22 lbs. / 3.73 kg.)

Manufactured By: Metrex Research Corporation
28210 Wick Road
Romulus, MI 48174



EFFECTIVE AGAINST:

Mycobacterium tuberculosis var: bovis (BCG)**
 Staphylococcus aureus
 Pseudomonas aeruginosa
 Salmonella choleraesuis
 Trichophyton mentagrophytes
 Methicillin Resistant Staphylococcus aureus (MRSA)
 Vancomycin Resistant Enterococcus faecalis (VRE)
 Hepatitis B Virus (HBV)*
 Adenovirus type 8*
 Herpes simplex virus types 1 and 2*
 Human Immunodeficiency Virus (HIV-1)*
 Canine parvovirus*



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DIRECTIONS FOR USE:

It is a violation of U.S. Federal law to use this product in a manner inconsistent with its labeling.

DESCRIPTION:

Cavicide is a multi-purpose disinfectant/decontaminant cleaner for use on inanimate surfaces. It is useful in hospital operating rooms, emergency departments, isolation areas, neonatal units, ophthalmic and optometric facilities, eye surgical centers, dental operatories, surgical suites, animal care facilities, beauty salons, salon settings, manicure salons, skin care salons, barber shops, bathrooms, tanning salons, out-patient surgical centers, daycare centers, schools, ambulances, police and fire vehicles, prisoner detention facilities, jails, prisons, morgues, cadaver processing areas, funeral homes, patient care areas, laboratories, non-food contact surfaces in food preparation areas, storage areas, health club facilities, and other critical care areas where environmental control of cross contamination is important. Safe for cleaning/decontamination of delicate medical/ dental/ surgical/ optical/ salon/ barber/ veterinary/ environmental/ equipment/ implements and instrumentation. Cavicide will effectively clean and disinfect, when used as directed, such items as: infant incubators and bassinets, infant care cribs and warmers, infant/child care equipment surfaces, oxygen hoods, anesthesia machines and respiratory therapy equipment surfaces, operating room tables and lights, laboratory equipment and surfaces, physical therapy (PT) equipment surfaces, neck brace appliances and cervical collars, drained whirlpool tank surfaces, stretchers, spine back boards, ambulance equipment surfaces, slit lamps, external lenses for vision correction***, countertops, exterior toilet surfaces, sinks, refrigerator units, floors, walls, handrails, door knobs, bed railings, bathing units, bathtubs, shower stalls, cabinets, shampoo bowls, manicure tables, chairs, workstations, nail/ hair care implements, tanning beds, hair dryers, telephones, diaper changing stations, baby cribs, hair clippers, shears, razors, hair cutting implements, clipper blades, salon surfaces, scissors, combs, brushes, manicure implements, washable nail files, hair rollers, animal cages, veterinary care surfaces, dental operator surfaces, dental countertops, dental chairs, unit stools, light lens covers, curing lights, and other inanimate surfaces, including those made of plastics (such as: polycarbonate, polyvinylchloride, polypropylene and polystyrene), weight lifting surfaces, non-porous vinyl, stainless steel, painted surfaces, Plexiglas®, glass, and other hard non-porous surfaces.

***Not for use on contact lenses.

APPLICATIONS:

SURFACES: (Where appropriate, follow Universal Precautions.)

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For PRECLEANING instruments, equipment and surfaces prior to disinfection:

- Apply Cavicide directly to surface. Allow to remain wet for 30 seconds. Wipe surface using a paper or cloth towel. Discard towel.

ACCEPTED

For DISINFECTING non-critical instruments and equipment surfaces:

NOV 19 2001

- Apply Cavicide directly to precleaned surface, thoroughly wetting area to be disinfected. Allow surface to remain wet for 3 minutes at room temperature (69°F/20°C).

Under the Federal Insecticide, Fungicide, and
 Rodenticide Act as amended, for the
 pesticide, registered under
 EPA Reg. No. 46781-6
 Inactivation of

- **For Tuberculocidal Activity: allow 10 minutes at room temperature. For Adenovirus type 8: allow 20 minutes at room temperature. Wipe surface using a paper or cloth towel, or allow to air dry. Discard towel.

tank surface

INSTRUMENTS: (Where appropriate, follow Universal Precautions.)

For use as a precleaning immersion decontaminant solution:

- Fill appropriate size container with a sufficient amount of Cavicide as to allow for complete submersion of instruments. Place instruments into Cavicide solution, cover and allow to soak for 10 minutes at room temperature (69°F/20°C). Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Change solution as needed when the solution becomes diluted or visibly soiled. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

lines

For use as a precleaning decontamination spray:

- Place instruments into a suitable container. Spray Cavicide onto instruments so as to thoroughly drench all surfaces. Allow surface to remain wet for 30 seconds. Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

For use as an ultrasonic cleaning solution:

- Thoroughly pre-rinse instruments under running water to remove visible gross debris. Using 1 ounce Cavicide per liter of water in ultrasonic unit, immerse instruments into mixed solution and activate ultrasonic unit for 5 minutes or longer if necessary. Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Change solution as needed when the solution becomes diluted or visibly soiled. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

For use as a manual cleaner:

- Thoroughly pre-rinse instruments under running water to remove visible gross debris. Place rinsed instruments into a solution of 1-ounce Cavicide per liter of water. Scrub instruments for 30 seconds using a stiff bristle brush until visibly clean. (instruments should be submerged as scrubbed.) Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Change solution as needed when the solution becomes diluted or visibly soiled. **(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)**

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For cleaning hair clippers, electric shears:

While clipper/shear is running, hold it in the downward position and spray Cavicide directly onto the blades two or three times so as to thoroughly wet the blades. (Avoid spraying on the clipper case or dripping into the clipper housing.) Allow to remain wet for 3 minutes. Wipe dry with a clean, soft cloth. Lubricate as per clipper/shear manufacturer's instructions.

For cleaning salon implements, shears and barber implements:

• Spray implement/shear to thoroughly wet with Cavicide solution. Wipe away visible debris using a soft bristle brush or cloth. Immerse precleaned implement/shear into a container of Cavicide for 3 minutes. Remove implement/shear and wipe dry. No rinsing is necessary. Change solution as needed when the solution becomes diluted or visibly soiled.

For disinfection of NON-CRITICAL, precleaned instruments:

• Instruments must be thoroughly precleaned to remove excess organic debris, rinsed and rough dried. (Clean and rinse lumens of hollow instruments before filling with solution or before immersion.) Using either a soaking tray or an ultrasonic unit, immerse instruments into Cavicide solution for 3 minutes. **For Tuberculocidal activity, allow 10 minutes at room temperature (69°F/20°C). For inactivation of Adenovirus type 8, allow 20 minutes at room temperature. Remove and rinse instruments. Wipe dry prior to use. Change solution as needed when the solution becomes diluted or visibly soiled.

(Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)

This product is not to be used as a terminal sterilant/ high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection.

ACCEPTED
NOV 19 2001
This is the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the purpose of registration under FIFRA Section 4615-1-6

CAVICIDE EFFECTIVELY KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS IN HEALTHCARE SETTINGS OR OTHER SETTINGS IN WHICH THERE IS AN EXPECTED LIKELIHOOD OF SOILING OF INANIMATE SURFACES/OBJECTS WITH BLOOD/BODY FLUIDS, AND IN WHICH THE SURFACES/OBJECTS CAN BE ASSOCIATED WITH THE POTENTIAL FOR TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUID:

Personal Protection: Wear appropriate barrier protection such as protective gloves, gowns, masks or eye coverings.

Cleaning Procedure: Blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before disinfection with Cavicide.

Contact Time: While the HIV-1 virus is inactivated in 2 minutes, use the recommended contact time for the disinfection of other organisms listed on this label.

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Infectious Materials Disposal: Cleaning materials used that may contain blood or other bodily fluids should be autoclaved and/or disposed of in accordance with local regulations for infectious materials disposal.

| FIRST AID | |
|--|--|
| If in eyes | <ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice. |
| If on skin or clothing | <ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for further treatment advice. |
| If swallowed | <ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person. |
| If inhaled | <ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice. |
| <p>For emergency information on product, call Metrex at 1-800-841-1428, Monday through Friday, between 6 a.m. and 4 p.m. Pacific Time. After 4 p.m., call Chemtrec 24-Hour Emergency Service at 1-800-424-9300.</p> | |
| <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> | |

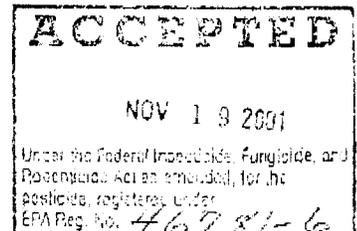
STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a cool place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of according to applicable Federal, State, or local procedures.

Container Disposal: Triple rinse. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration or, if allowed by state and local authorities, by burning. If burned, keep out of smoke.

For product or technical information, contact Metrex at 800-841-1428 or visit our website at www.metrex.com.



Written protocol for Angel of Water™ Colon Hydrotherapy System tank and lines disinfection with directions for use according to Metrex Cavicide label

At the end of every session, you must disinfect the main tank and the exit lines of the Angel of Water™ Colon Hydrotherapy System. These components are considered indirect patient-contacting components and must therefore undergo the following protocol after each session:

- 1) Drain main tank completely and then close Valves #2 and #6. Open Valves #3 and #4.
- 2) Place the **flex tube line stopper** (provided with your System) onto the end of the brass nipple in the basin trough in order to block the exit line.
- 3) Using your spray bottle of **Cavicide**, apply **Cavicide**, a ready-to-use, full-strength formulation, to the sides of the main tank, making sure you have a good, strong spray of disinfectant to thoroughly wet the sides and bottom of the tank. Let the excess flow down into the line.
- 4) Pour 8 oz. of Cavicide into the bottom of the main tank so that it can flow into and fill the entire exit line. Go back and temporarily remove flex tube line stopper to release excess air from the line. Once air escapes, replace stopper onto brass nipple. Cavicide can now fill entire line for disinfection.
- 5) Allow Cavicide to stand in the line for **10 minutes at room temperature** while cleaning and disinfecting the basin, using the personal shower sprayer as your rinse water source.
- 6) After cleaning and disinfecting the basin and at the end of **10 minutes**, again using the shower sprayer as your rinse water source, remove the flex tube line stopper and thoroughly rinse the main tank for 30 seconds of full-force spray. (This will exceed 1 gallon of water). Allow rinse water to flow out through the brass nipple in the basin trough. This is **Rinse #1**.
- 7) Close Valve #4 (Valve #2 is still closed) and allow water in tank to fill up to 1-gallon rinse water mark on main tank for **Rinse #2**. Drain water by opening Valve #4 so that water comes out through basin nipple again.
- 8) Close Valve #4 **AGAIN** and allow water in tank to fill up to 1-gallon rinse water mark on main tank for **Rinse #3**. Drain water **AGAIN** by opening Valve #4 **AGAIN**.
- 9) Now close Valves #3 and #4 and open Valve #6.

You are now ready for your next colon hydrotherapy session.

5) Connect New Flex Tube and Sterile Rectal Nozzle, Do Final Room Inspection

- a) Connect new flex tube and new sterile, disposable rectal nozzle to flex tube, then lubricate nozzle to conduct session.
- b) Inspect room for readiness before having person enter for session.

B. Post-Session Cleaning and Disinfection:

1) Protect Yourself

- a) Put on rubber gloves, eye shields, and protect respiratory channels with towel or respirator before using chemicals.

2) Remove Soiled Linens from System Area

- a) Place soiled linens in laundry basket.

3) Spray Attack-A Disinfectant into Basin and Water Rinse, then Mop with Attack-A Disinfectant (Bucket #1), Water Rinse

- a) Spray a fine mist of Attack-A into the basin trough, including used nozzle and flex tube, personal shower sprayer, and all basin topside control knob handles.
- b) Water rinse obvious waste material down drain. Turn on View Tube Flush Valve as needed to clear drain line.

Cifestream

- c) Mop wash entire basin *and* used nozzle and flex tube with Attack-A (Bucket #1)(1 oz. Attack-A to one gallon of water). Water rinse everything down drain again.

4) Remove Used Nozzle and Flex Tube, Rinse Out Line

- a) With paper towel, grasp and pull out nozzle and flex tube from brass nipple together. Bend nozzle in half and wrap it and used flex tube in paper towel and dispose of both in wastebasket.
- b) Turn water flow on and rinse out line.

5) Disinfect Main Tank and Exit Line to Basin Nipple

At the end of every session, you must disinfect the main tank and the exit line of the Angel of Water™ Colon Hydrotherapy System. These components are considered indirect patient-contacting components and must therefore undergo the following protocol after each session:

- a) Drain main tank completely and then close Valves #2 and #6. Open Valves #3 and #4.
- b) Place the **flex tube line stopper** (provided with your System) onto the end of the brass nipple in the basin trough in order to block the exit line.
- c) Using your spray bottle of **Cavicide**, apply **Cavicide**, a ready-to-use, full-strength

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formulation, to the sides of the main tank, making sure you have a good, strong spray of disinfectant to thoroughly wet the sides and bottom of the tank. Let the excess flow down into the line.

- d) Pour 8 oz. of Cavicide into the bottom of the main tank so that it can flow into and fill the entire exit line. Go back and temporarily remove flex tube line stopper to release excess air from the line. Once air escapes, replace stopper onto brass nipple. Cavicide can now fill entire line for disinfection.
- e) Allow Cavicide to stand in the line for **10 minutes at room temperature** while continuing to clean and disinfect the basin, using the personal shower sprayer as your rinse water source.

6) Mop with Attack-A Disinfectant (Bucket #2), Water Rinse (Degrease View Tube as needed)

- a) Mop wash entire basin area again with Attack-A (Bucket #2)(1 oz. Attack-A to one gallon of water).

Per manufacturer's instructions, make sure that the combined contact time of Buckets #1 and #2 (Zep Attack-A solution) on the basin surface is at least **10 minutes** for maximal disinfection.

- b) Water rinse entire basin again well.
- c) Degrease Drain Pipe Viewing Tube in this step when build-up of petroleum jelly lubricant warrants

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this procedure. Use the tether mop and degreaser to scrub tube.

7) Mop with Chlorine Bleach Deodorizer (Bucket #3), Water Rinse

- a) Mop wash entire basin area with diluted chlorine bleach solution (Bucket #3)(1 capful to one gallon of water for a 200ppm solution). Let solution contact surface for 1 minute. Chlorine bleach acts both as a deodorizer and stain remover.

8) Spray Air Fair Conquer, Towel Dry

- a) Spray a fine mist of Air Fair Conquer into the basin trough and splashguard to deodorize.
- b) Towel dry and wipe all surfaces of excess chemicals and water.

9) Finish Disinfection of Main Tank and Line

- a) After cleaning and disinfecting the basin and at the end of **10 minutes**, again using the shower sprayer as your rinse water source, remove the flex tube line stopper and thoroughly rinse the main tank for 30 seconds of full-force spray. (This will exceed 1 gallon of water). Allow rinse water to flow out through the brass nipple in the basin trough. This is **Rinse #1**.
- b) Close Valve #4 (Valve #2 is still closed) and allow water in tank to fill up to 1-gallon rinse water mark on main tank for **Rinse #2**. Drain water by opening Valve #4 so that water comes out through basin nipple again.

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- c) Close Valve #4 AGAIN and allow water in tank to fill up to 1-gallon rinse water mark on main tank for **Rinse #3**. Drain water AGAIN by opening Valve #4 AGAIN.
- d) Now close Valves #3 and #4 and open Valve #6.

10) At the conclusion of the treatment day, drain all water from the main tank, the recirculating (small) tank, and the lines. If another session is to be conducted continue to Step 11. If the treatment day is concluded, however, you must drain all water from the system. Do this by opening Valves #2, #3, and #4. **Remember to reset valve sequence to that of Regular Operation Mode (Close #2, #3, and #4, and Open #6) at the beginning of the next treatment day.**

11) Replace Linens, Do Final Inspection

- a) Put on a fresh pillowcase and supply a fresh cover cloth. Rotate and launder the pillow if it got wet for any reason. Have a number of linens/pillows to rotate and have them clean and ready as required.
- b) Wipe lavatory, glasses, and mirrors and inspect room for overall cleanliness before next session or before finishing for the day.

12) Run Properly Tempered Water through Line, Connect New Flex Tube and New Sterile, Disposable Rectal Nozzle

- a) Rinse out line with properly tempered water, 99 to 103 degrees Fahrenheit.

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- b) Connect new flex tube and new sterile, disposable rectal nozzle to flex tube, then lubricate nozzle to conduct session.
- c) Inspect room for readiness before having next person enter for session.

Always clean and disinfect the System directly after a session. Do not postpone for any reason. Clean and disinfect the System properly NOW! Always give the first impression and guarantee of cleanliness and hygiene.

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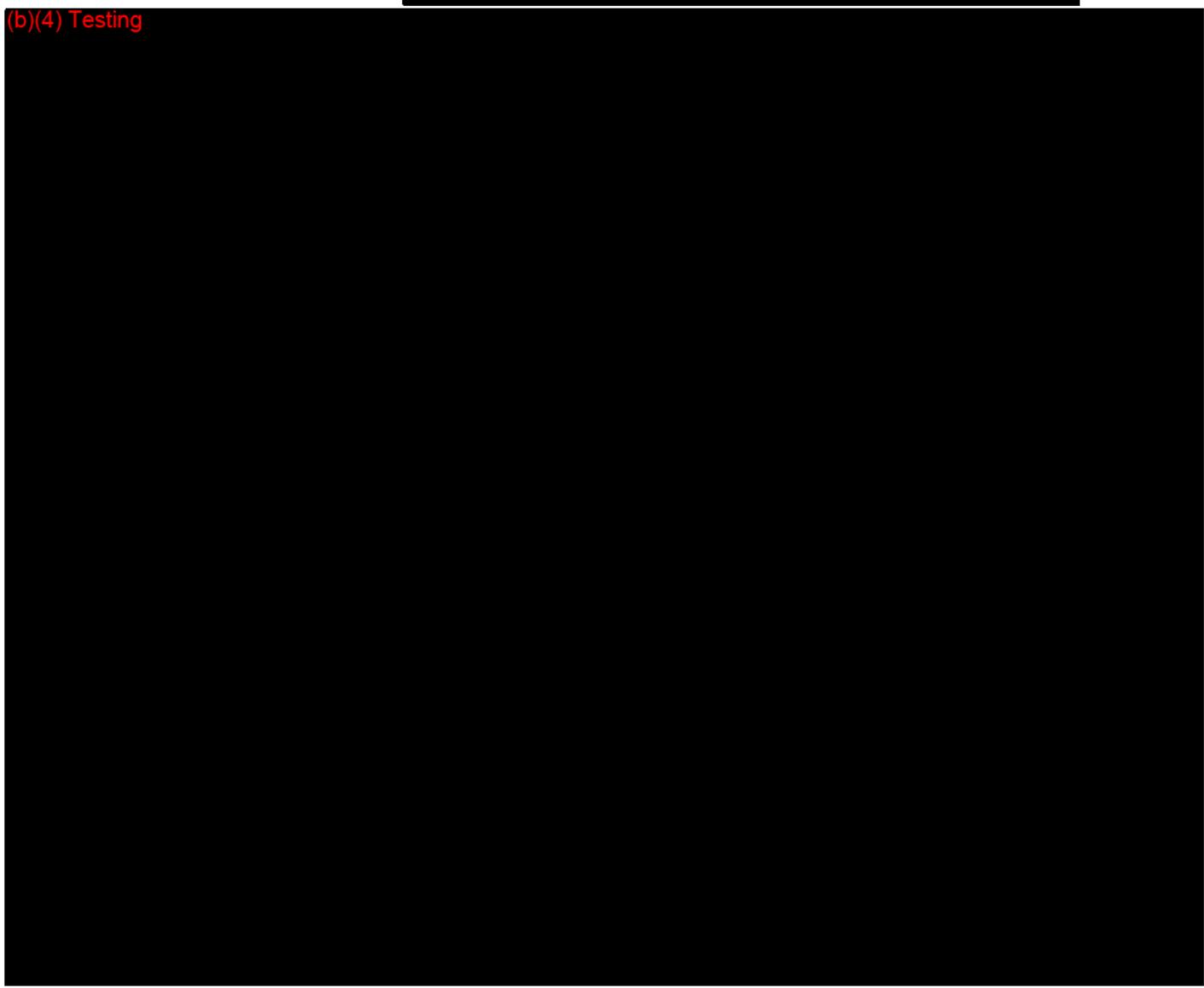
Purification Systems, LLC
2001 South Lamar, Suite G
Austin, Texas 78704
Phone 512-707-3773

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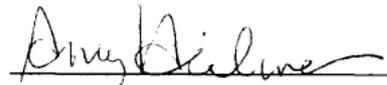
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Testing Results Compiled By:



Amy Heilman
General Manager

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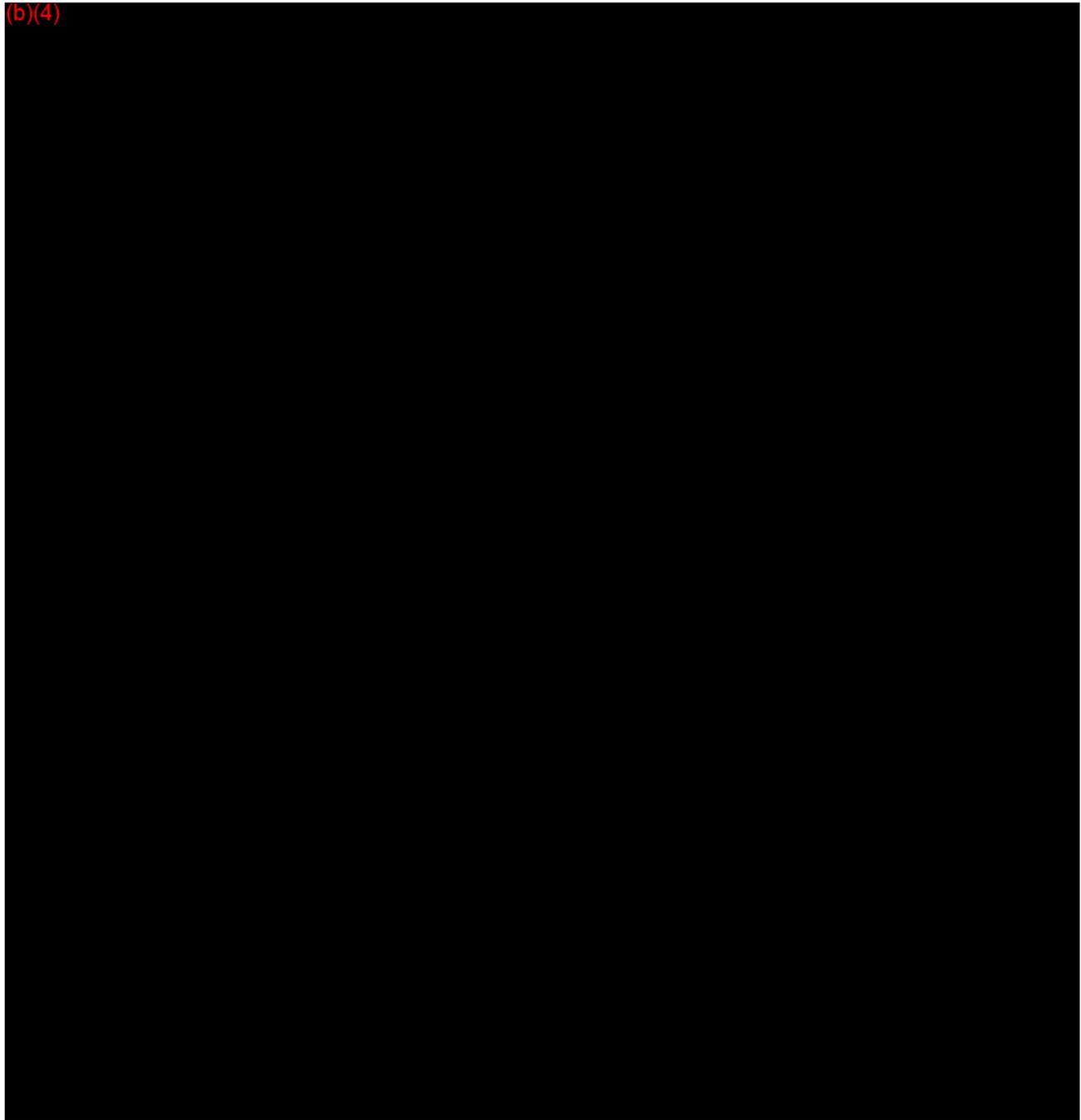


Date of Issue: May 16, 2002

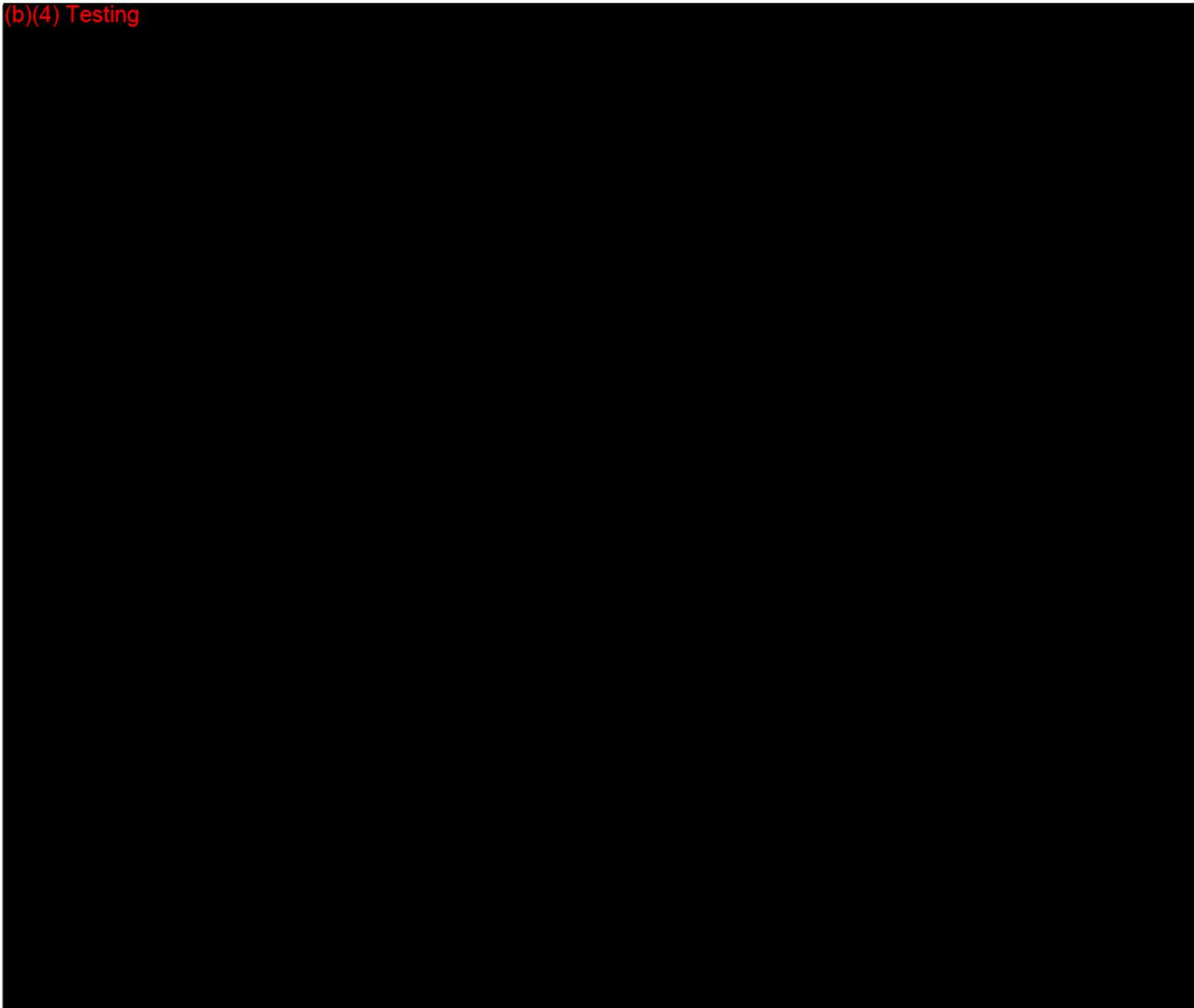
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Phone 512-707-3773

TEST METHOD

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Chapter 4

Valve Sequences for System Operation

The Angel of Water™ Colon Hydrotherapy System's mode of operation is called **Regular Operation mode**. **All colon hydrotherapy sessions are to be conducted in Regular Operation mode**. The System is shipped with Valves preset for Regular Operation mode. For operational familiarity, double check that the Valves are opened and closed as described below for Regular Operation mode before beginning your first session.

Regular Operation (used for all colon hydrotherapy sessions)

This is the mode of operation for all colon hydrotherapy sessions. Regular Operation features water circulating from the large main tank via the water cycling device to the smaller tank. Then an even and constant stream of gravity-fed water flows through the U.V. Filter to the person experiencing the colon irrigation.

Valve sequence a:

Open Valves #6, #7, #9, (#10 and #11 were set in OPEN position when System was set up and should be left OPEN always unless System plumbing maintenance requires otherwise.) All other Valves are closed. Then open #1 and turn on and adjust Water Mixing

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Valve to fill tank with water between 99 to 103 degrees Fahrenheit.

Close #1 or shut off Water Mixing Valve to *stop* water to large main tank at any level.

However, water level inside tank shuts off automatically by Tank Level Valve once level has reached top (about 12 gallons). Once full, close #1 and/or turn off Water Mixing Valve. As water is needed in tank, open #1 and/or turn on Water Mixing Valve to refill tank.

Valve sequence b:

Occasionally, the person experiencing the colon irrigation may feel as if no water is coming into their colon. This may indicate that the nozzle inserted into them is clogged at the tip with waste material. The monitoring assistant or health care practitioner can unclog nozzle in the following way *without* having the person on the System come off the nozzle in order to check it. To unclog nozzle with additional flow from large main tank, close Valve #9. Then **gradually** open Valve #8 until flow is felt again by person experiencing the irrigation. Once person feels water flowing, open Valve #9 again and close #8 completely.

In the unlikely event of a power outage to the System, have the patient slide off the rectal nozzle and stop the session. You may resume session once the power to the System has come back on.