DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date: 5/20/97

From: Document Mail Center (HFZ-401)

Subject: Premarket Notification Number(s) K914145/A2

To: Division Director HO/DDIG

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) submission. 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. Feel free to note any additional comments below.

Thank you for your cooperation.

_____Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY 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 the company to submit a new 510(k). [THE DIVISION SHOULD PREPARE THE K30 LETTER ON THE LAN.]

_____Additional information requires a new 510(k); please process. [THIS INFORMATION WILL BE MADE INTO A NEW 510(K)].

X No response necessary ~~(e.g., hard copy of fax for the truthful and accuracy statement~~ or 510~~(k) statement)~~ at this time.

See July 9 1997 memo of telephone call - ~~may need~~ firm considering modification of proposal labeling for change that ~~make~~ may make new 510(k) unnecessary

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

Reviewed by SJB 7/10/97

Date July 9, 1997

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4)

(b) (4)

(b) (4)

(b)(4)

[redacted]

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date 2-25-94

From Mark Wright , Clerk-Typist, (CDRH, ODE, DMC) HFZ-401

Subject Premarket Notification Number(s) K914145/A1

To Division Director

The attached information has been received by the 510(K) Document Mail Center (DMC), on the above referenced 510(K) file(s). Since a final decision has been rendered, the record is officially closed.

Please review the documents(s) and return to DMC directed to my attention, with one of the statements checked below. Feel free to note any additional comments below. If there are any questions, please contact me on 594-3027.

X Information does not change status of 510(K); no other action required by DMC; please file. The Division should prepare a confirmation letter - example attached.

____ Additional information requires a new 510(K); please process.

____ Requests CLIA Categorization

Comments: This is my second copy of the faxed responses to our questions of 1/28/94 & 2/2/94. Please add to the file.

This information should be returned by 3-14-94.

Reviewed by: SFB

Panel: HO

Date: 2/28/94

Attachment

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Re: Device Name
Dated:
Received:

Dear _____:

We have reviewed the information dated _____, regarding the 510(k) notification (K_____) previously submitted for the device referenced above. Based solely on the information that you have provided, 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)). 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). The information you have supplied will be added to the file.

If you have any questions regarding the contents of this letter, please contact _____ at (301) 427-____.

Sincerely yours,

Division Director
Division of _____
Office of Device Evaluation
Center for Devices and
Radiological Health

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RESPONSE TO JANUARY 28, 1994 QUESTIONS

510(k) K914145

MEDIVATORS, INC.

MEDIVATORS, INC.

INNOVATIVE MEDICAL PRODUCTS

February 18, 1994

Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

Attention: Ms. Susanna Barrett
Division of General & Restorative Devices

RE: 510(k) Number K914145
Response to Questions

RECEIVED
FEB 18 1994
HFZ/DEPT/DMC

Provided herein are responses to your letter dated January 28, 1994 requesting additional information.

This response contains information that is confidential. The confidential information has been designated as such.

MediVators, Inc. will complete the testing described in your February 2, 1994 letter. As we agreed on February 17, 1994 the sampling will be taken prior to any cleaning and again after disinfection. The results will be kept on file at MediVators, Inc.

Thank you for your assistance with this process. If you have any questions please contact me at the number listed below.

Sincerely,

Michael S. Simmons
Director of Regulatory Affairs and Quality Assurance

MSS/ses

encls.

4

Cannon Plaza South • 6352 320 Street Way • P.O. Box 487 • Cannon Falls, MN 55009 • 507/263-4721 • 800/537-7324

CONFIDENTIAL

1. Provide data validating the recovery method. State the number of spore per channel which could be recovered prior to any cleaning or disinfection.

(b) (4) [redacted]

2. State the concentration of the germicides after stressing with horse serum for 40 cycle.

(b) (4) [redacted]

3. Clarify the following concerning the simulated-use testing reported in Attachment B:

a. (b) (4) [redacted]

See Geneva Lab Report Attached - Attachment 1

b. (b) (4) [redacted]

See Geneva Lab Report Attached - Attachment 1

c. (b) (4) [redacted]

See Geneva Lab Report Attached - Attachment 1

d. (b) (4) [redacted]

See Geneva Lab Report Attached - Attachment 1

e. (b) (4) [redacted]

See Geneva Lab Report Attached - Attachment 1

4. Provide clarification for the following from the manual:

a. all discussions about the heater; it is unclear whether the instructions are for the heater option not available in the USA or an optional manual heater;

(b) (4) [redacted]

Typically, the shutdown, minimum, and maximum temperatures will be set to within one degree of each other. for example, if the target temperature required for a disinfection protocol is 120° F, the shutdown temperature is set at 119° F, the minimum temperature is set at 120° F and the maximum temperature is set at 121° F.

The temperature sensors are accurate to within 1° F.

NOTE: If heaters are required MediVators will supply heaters that require manual temperature control. The user must set and monitor temperature. The on and off times can be controlled by the unit.

NOTE: Follow disinfectant manufacturer labeling when determining required temperature.

Page 3-5 will be changed to read:

Set Custom Temperature (Future Option)

This function is used to set the target disinfectant temperature to custom installation values. This function is effective only for those installations with the advanced heater control option.

NOTE: This feature not available.

NOTE: If heaters are required MediVators will supply heaters that require manual temperature control. The user must set and monitor temperature. The on and off times can be controlled by the unit.

NOTE: Follow disinfectant manufacturer labeling when determining required temperature.

b. temperature setting and monitoring of the heater;

Refer to 4. a.

c. identification and purpose of the 1 - 9 programs which can be altered;

Page 2-7 will be changed to read:

User Modifiable Program Cycles

There is one standard, and up to nine user modifiable programs. The user modified programs are stored in non volatile memory.
These programs are available so the user can change cycle times to accommodate different disinfectants or different desired protocols.
Each program has six cycles. Each of these cycles may have their length altered as described in the table on the next page.
As a result of the unique method used to record this information, all custom programs and other user defined settings are retained even if the computer mother board has to be repaired or replaced (except when the non volatile memory itself has failed).

Page 3-2 will be changed to read:

Operation using a selected protocol where logging of individual scopes is not required is accomplished by using the PROGRAM key to select the specific, user-defined disinfect protocol. The user must have pre-programmed a protocol prior to using this function. These programs are available so the user can change cycle times to accommodate different disinfectants or different desired protocols.
A program log is supplied so the user can have a ready reference to the custom program settings.
Program Log is Attached - Attachment 2

Page 3-6 will be changed to read:

This function allows custom alteration of cycle times to be set for an installation. These programs are available so the user can change cycle times to accommodate different disinfectants or different desired protocols.

The remainder of page 3-6 will remain unchanged.

d. explanation of how the maximum disinfection cycle count can be set according to disinfectant manufacturer's specification and the basis for 50 as the default maximum number of disinfection cycle;

Page 3-9 Warning will be changed to read:

WARNING
This function is not a replacement for daily monitoring of the Minimum Effective Concentration (M.E.C.) of the disinfectant. Refer to the labeling or the manufacturer of your disinfectant for the proper procedure.
The factory set default warning at 40 cycles and maximum of 50 cycles is based on 14 day reuse 2% Glutaraldehyde and approximately 3 cycles per day. The user must select the maximum disinfectant cycle warning based on the disinfectant being used and past experience with that disinfectants MEC testing.

The machine will also include a label that the user must monitor the disinfectant on a daily basis as a minimum. A draft is attached - Attachment 3

e. the disinfectant change warning as it is currently stated could imply that the disinfectant may be used beyond its recommended reuse life by inhibiting the warning stop for an additional ten cycle;

See 4. d.

f. the warnings against using the disinfectant past its reuse life even if it tests effective should also indicate that the disinfectant may lose its effectiveness before the end of its reuse life;

The warning notes will be changed to read:

All disinfectant must be monitored on a daily basis for effectiveness. The should not be used beyond the time period they are rated for in the manufacturers labeling (eg. a 14 day disinfectant should not be used beyond 14 days even if it does test effective). Also they may lose effectiveness before the end of the reuse life.

g. in the warning notes, the comment that pediatric endoscope air/water channels may be more difficult to clean should also include all small diameter endoscopes, for example, "Pediatric and small diameter endoscopes air/water channels";

The warning notes will be changed to read:

All endoscopes should be pre-cleaned following the manufacturers' instructions and recognized established society guidelines prior to being processed in an automatic washer/disinfector. Pediatric endoscope air/water channels and other small diameter channels may be more difficult to clean, additional cleaning should be performed on these instruments.

h. indication of whether the alcohol purge can be used at the end of every cycle if the user so desires;

Page 2-1 in the manual will be changed to read:
Alcohol Purge
Available to aid the end-of-day drying process after the last procedure of the day for the endoscope. This feature may be used at the end of each cycle if desired.

This same addition will also be included in the appropriate paragraphs on pages 2-5 and 2-6.

i. under standard operation on page 3-14, highlight "Precleaning of the scope should include brushing of the suction/biopsy channel in universal cord and insertion tube";

The manual will be changed to have this item hi-lighted.

j. page 3-15, note, indicate on the control panel, the MANUAL AIR button;

The manual will be changed to read:

NOTE: If additional purging with air is desired, press the ADD AIR button on control panel.

k. inclusion of any special instructions for bronchoscopes at the end of a disinfection cycle.

Faxed on February 7, 1994 - Attachment 4

5. Clarify or provide the following for the hook-up instructions:

a. flow diagram of the fluid through the upper and lower endoscopes based upon the hook-up instructions for in Attachment C; it is still unclear how fluid is moved from the disinfectant reservoir through all the channels based upon the instructions;

Faxed on February 7, 1994 - Attachment 4

b. clarify the status of part 4B, i.e., air inlet vent or air inlet plug;

Faxed on February 7, 1994 - Attachment 4

c. information on how 2 channel scopes and bronchoscopes are connected to the DSD-91.

Faxed on February 7, 1994 - Attachment 4

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Third Party Test Information and Results (b) (4)

Third Party Test Information and Results (b) (4)

Third Party Test Information and Results (b) (4)

17

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REF 4c

MEDIVATORS, INC.

INNOVATIVE MEDICAL PRODUCTS

CUSTOM PROGRAM REFERENCE CHART

STATION A

PROGRAM CYCLE TIME								
PROGRAM NUMBER	**FLUSH**	**DISINFECT 1**	**DISINFECT 2**	**RINSE 1**	**RINSE 2**	**ALCOHOL**	**AIR**	**MANUAL AIR**
PROGRAM 1								
PROGRAM 2								
PROGRAM 3								
PROGRAM 4								
PROGRAM 5								
PROGRAM 6								
PROGRAM 7								
PROGRAM 8								
PROGRAM 9								

STATION B

PROGRAM CYCLE TIME								
PROGRAM NUMBER	FLUSH	DISINFECT 1	DISINFECT 2	RINSE 1	RINSE 2	ALCOHOL	AIR	MANUAL AIR
PROGRAM 1								
PROGRAM 2								
PROGRAM 3								
PROGRAM 4								
PROGRAM 5								
PROGRAM 6								
PROGRAM 7								
PROGRAM 8								
PROGRAM 9								

17

3

18

REF 4d

WARNING
ALL DISINFECTANTS MUST BE MONITORED ON A DAILY BASIS TO ASSURE MINIMUM EFFECTIVE CONCENTRATION.

3/4"

6"

RADIUS CORNERS
DIM ARE LABEL SIZE
LABEL & ADHESIVE APPROVED MTL
COLOR CLEAR BACKGROUND
BLACK LETTERING

2 FEB 94

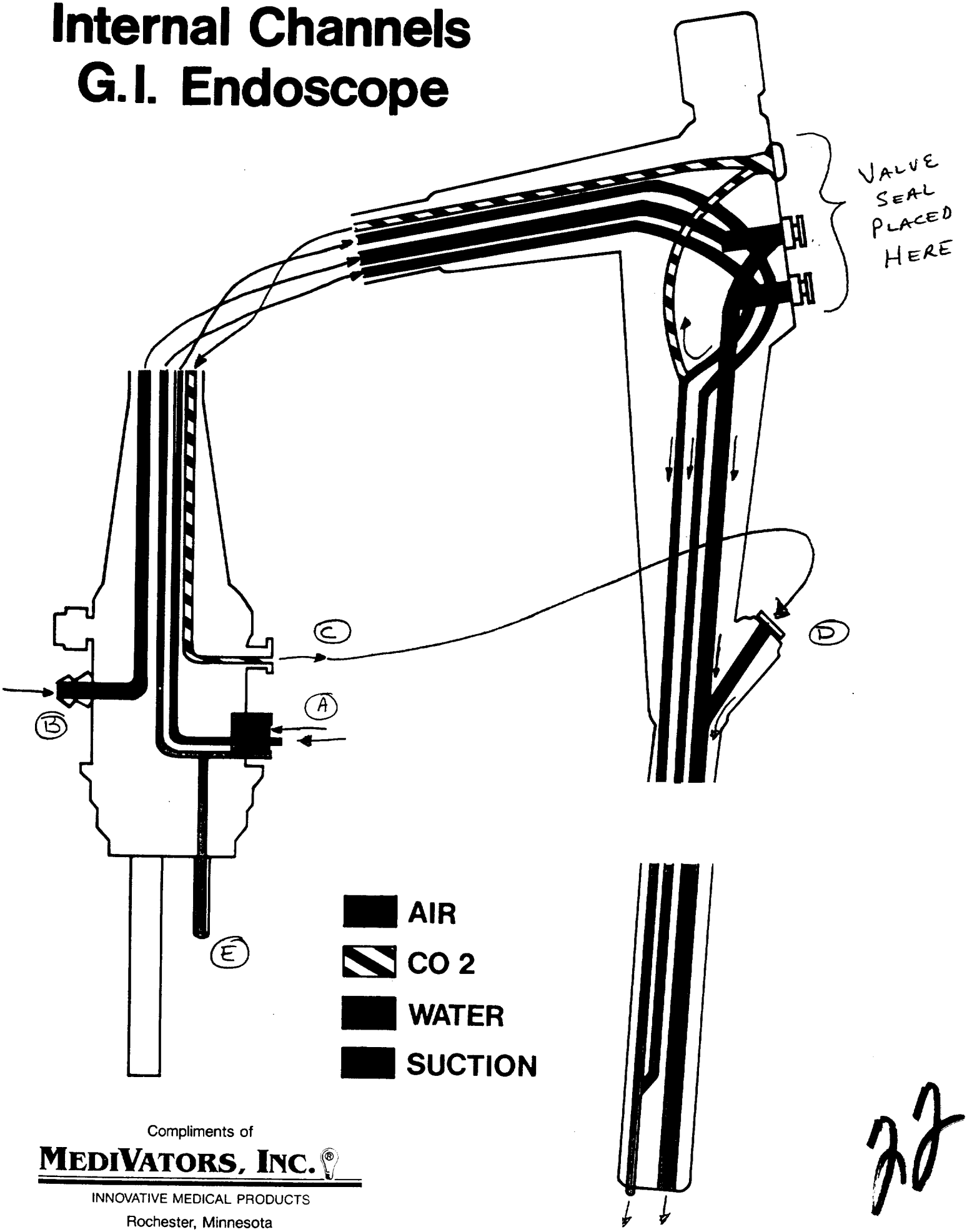
9

H

20

Third Party Test Information and Results (b) (4)

Internal Channels G.I. Endoscope



Compliments of

MEDIVATORS, INC.®

INNOVATIVE MEDICAL PRODUCTS

Rochester, Minnesota
800/537-7324

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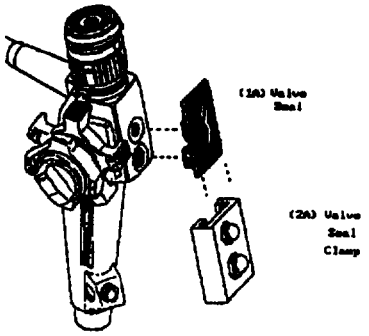
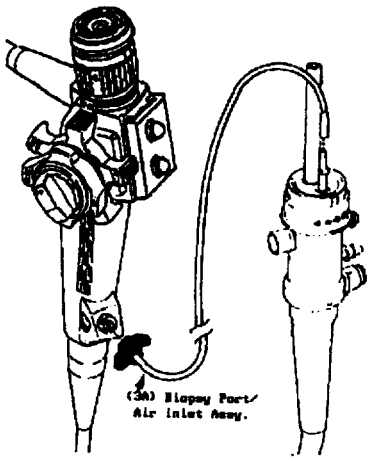
MEDIVATORS, INC.
1-800-537-7324

Olympus Upper OES And Video*

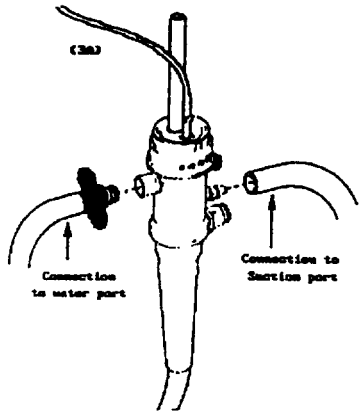
HU0042 (Consisting of HU0036 and HU0001)



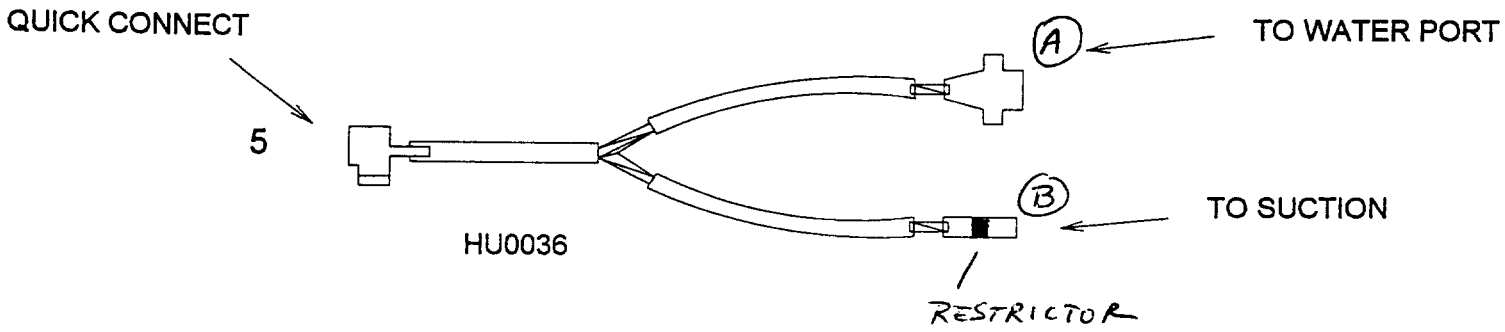
After removing air/water and suction caps from instrument, place the valve seal (1A) on the valve openings. Hold in place and slide seal clamp (2A) over seal. Finger tighten bottom screw, then finger tighten top screw.

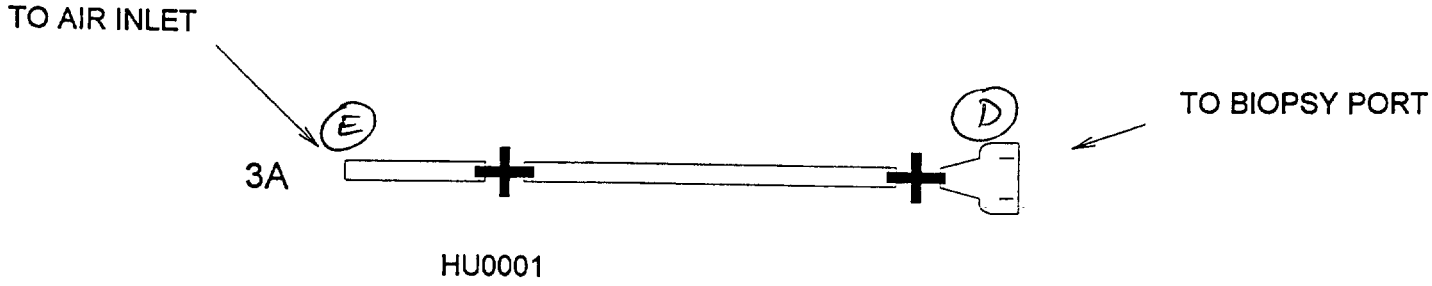


Connect the biopsy port/Air inlet tube assembly (3A) to biopsy port and inlet port.



Connect disinfector hook up to water port and suction port. The water port adapter must be firmly inserted and given a 1/4 turn to properly seat.





*Olympus and OES are trademarks of the Olympus Corp.

FORM: MF03-0012

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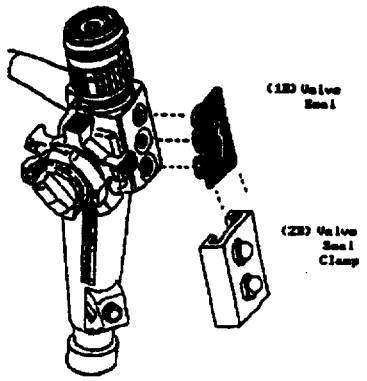
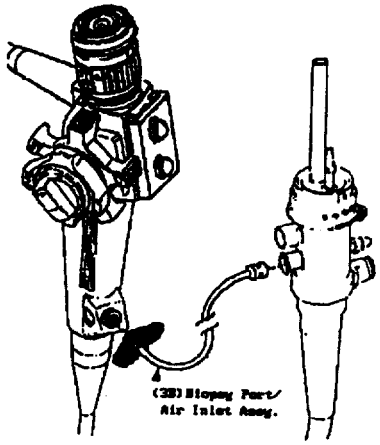
MEDIVATORS, INC.
1-800-537-7324

Olympus Lower OES And Video*

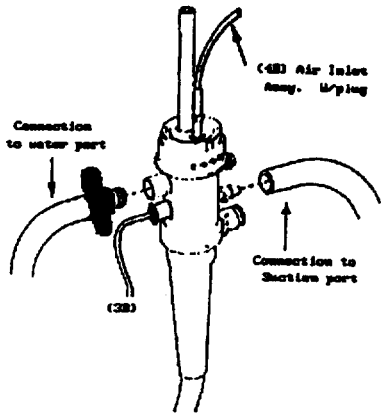
HU0043 (Consisting of HU0036 and HU0002)



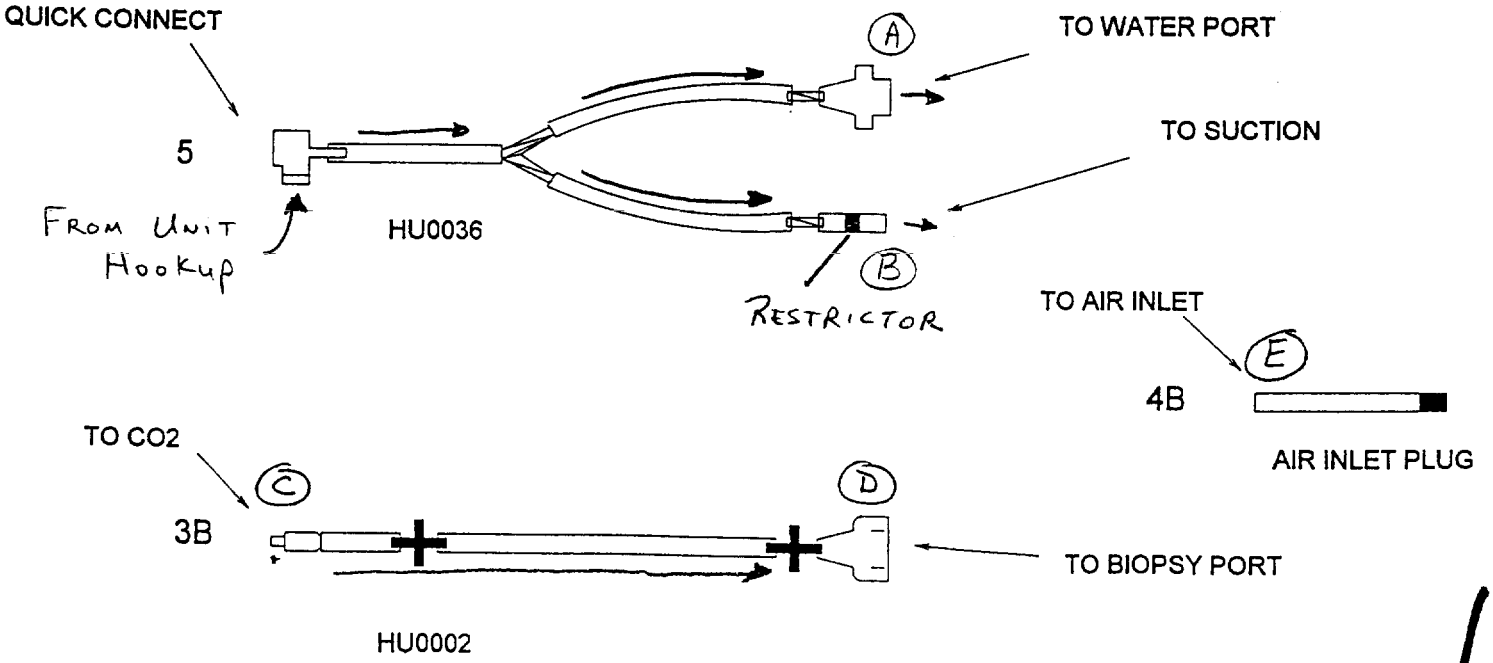
After removing air/water, suction and CO_2 valve caps from instrument, place the valve seal (1B) on the valve openings. Hold in place and slide seal clamp (2B) over seal. Finger tighten bottom screw, then finger tighten top screw.



Connect the biopsy port/CO_2 tube assembly (3B) to biopsy port and CO2 port.



Connect disinfector hook-up to water port and suction port. The water port adapter must be firmly inserted and given a 1/4 turn to properly seat. Connect air inlet tube assembly (4B) to air inlet.



*Olympus and OES are trademarks of the Olympus Corp.

FORM: MF03-0013

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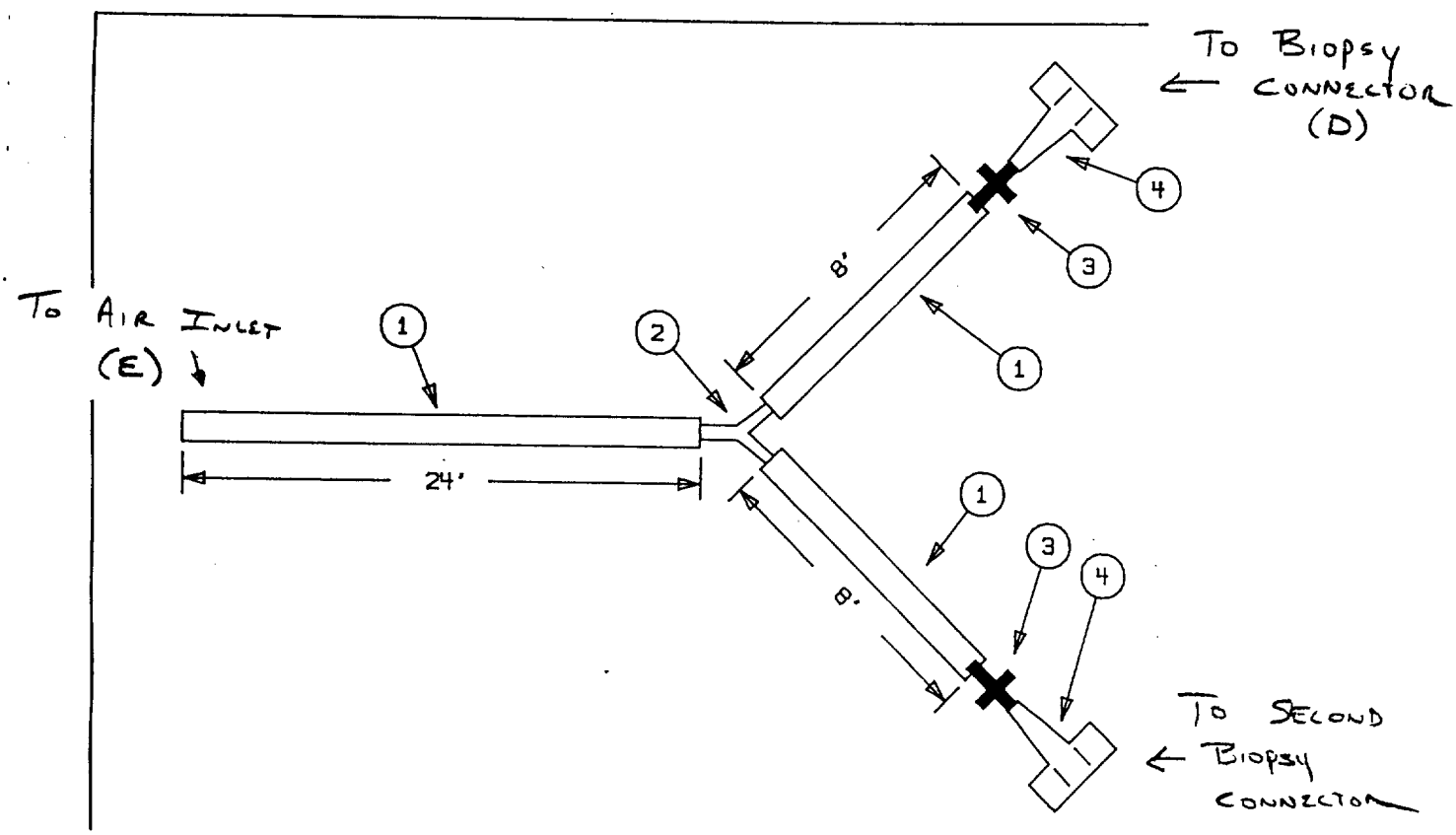
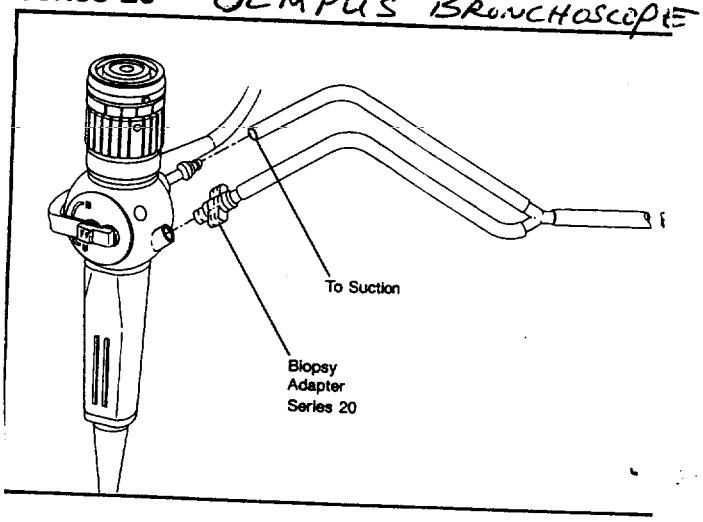
A DOUBLE CHANNEL SCOPE IS CONNECTED IN THE SAME WAY. THE TUBING CONNECTOR (3B) IS SPLIT TO ALLOW DISINFECTANT TO FLOW TO BOTH BIOPSY CONNECTORS.



ON A BRONCHOSCOPE, FLOW IS DELIVERED THROUGH TUBING TO EXISTING OUTLETS ON THE SCOPE HEAD. ON THE OLYMPUS SERIES 20 BRONCHOSCOPE ~~THE DISINFECTANT FLOW IS SPLIT TO ALLOW DISINFECTION OF THE BIOPSY PORT & THE SUCTION ARM~~ THE TUBING IS CONNECTED TO THE BIOPSY PORT & THE SUCTION ARM. THE DISINFECTANT FLOWS THROUGH SUCTION CHANNEL TO DISTAL TIP.

Series 20 OLMPUS BRONCHOSCOPE



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

FEB 22 1994

MediVators, Inc.
c/o Ms. Constance G. Bundy
Consultant
C. G. Bundy Associates
6470 Riverview Terrace
Minneapolis, Minnesota 55432

Re: K914145
DSD-91™ Disinfector for Flexible Endoscopes
Regulatory Class: II
Dated: May 14, 1993
Received: May 17, 1993

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. 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 on the labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) 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,

Philip J. Phillips
Acting Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

SFB

computer dated PRINT LTR

DO NOT REMOVE THIS ROUTE SLIP!!!!

VOLUME I of II

K-91-4145 7/22/92

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
MEDIVATORS, INC. ATTN: CONSTANCE G. BUNDY C/O C. G. BUNDY ASSOCIATES 6470 RIVERVIEW TERRACE MINNEAPOLIS, MN 55432	09/13/91	09/16/91	10/19/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K914145
	PHONE NO: 612-574-1976		
SHORT NAME: MEDIVATORS	ESTABLISHMENT NO: 2183640		

TO:	
ODE/DMC	CONT. CONF.: ? STATUS : R REV PANEL : SU/[redacted] ~~SU~~ HO PAN/PROD CODE(S): SU/[redacted] SU HO / /

SUBJECT:
DSD-91(TM) DISINFECTOR FOR FLEXIBLE ENDOSCOPES

DECISION:	RQST INFO DATE: 11/19/91	INFO DUE DATE: 01/17/92
DECISION DATE: / /	DATE: 03/23/92	DATE: 07/20/92
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /

DMC 3-8-93 HD

SUPPLEMENT: 01 LTR DATE: 911218 LOGIN DATE: 911224
SUPPLEMENT: 02 LTR DATE: 920720 LOGIN DATE: 920721

MAR - 8 1993

3

Sue

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-91-4145 1/2/92

TC

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
MEDIVATORS, INC. ATTN: CONSTANCE G. BUNDY C/O C. G. BUNDY ASSOCIATES 6470 RIVERVIEW TERRACE MINNEAPOLIS, MN 55432	09/13/91	09/16/91	03/23/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K914145
	PHONE NO: 612-574-1976		
SHORT NAME: MEDIVATORS	ESTABLISHMENT NO: 2183640		

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

1C 3·23·92 HD

SUBJECT:
DSD-91(TM) DISINFECTOR FOR FLEXIBLE ENDOSCOPES

DECISION:	RQST INFO DATE: 11/19/91	INFO DUE DATE: 01/17/92
DECISION DATE: / /	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /

SUPPLEMENT: 01 LTR DATE: 911218 LOGIN DATE: 911224

4

Sa

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-91-4145

9/19/91

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
MEDIVATORS, INC. ATTN: CONSTANCE G. BUNDY C/O C. G. BUNDY ASSOCIATES 6470 RIVERVIEW TERRACE MINNEAPOLIS, MN 55432	09/13/91	09/16/91	12/15/91
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K914145
SHORT NAME: MEDIVATORS	PHONE NO: 612-574-1976 ESTABLISHMENT NO: 2183640		

TO:
ODE/DMC
11/19/91-HD

CONT. CONF.: ?
STATUS : R
REV PANEL : SU
PAN/PROD CODE(S): SU/ / /

SUBJECT:
DSD-91(TM) DISINFECTOR FOR FLEXIBLE ENDOSCOPES

DECISION:
DECISION DATE: / /

RQST INFO DATE: / /
DATE: / /
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INFO DUE DATE: / /
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DATE: / /

INCB due 10/28/91

Assigned to ~~Sherry~~ 9/24
Due 10/24

Missouta → send to DGRD/INCB

5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date 2/17/94

From REVIEWER(S) - NAME(S) Barnett

Subject 510(k) NOTIFICATION K914145 | C

To THE RECORD

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

X (A) Is substantially equivalent to marketed devices.

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

____ (C) Requires more data.

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

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es)) Submitted before SMDA required CL

☑ A 510(k) summary of safety and effectiveness, or

N/A ☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

____ No Confidentiality

____ Confidentiality for 90 days

____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

78-FEB-II

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

REVIEW: Clem S. Lim (BRANCH CHIEF) FAC 2-17-94 (BRANCH CODE) (DATE)

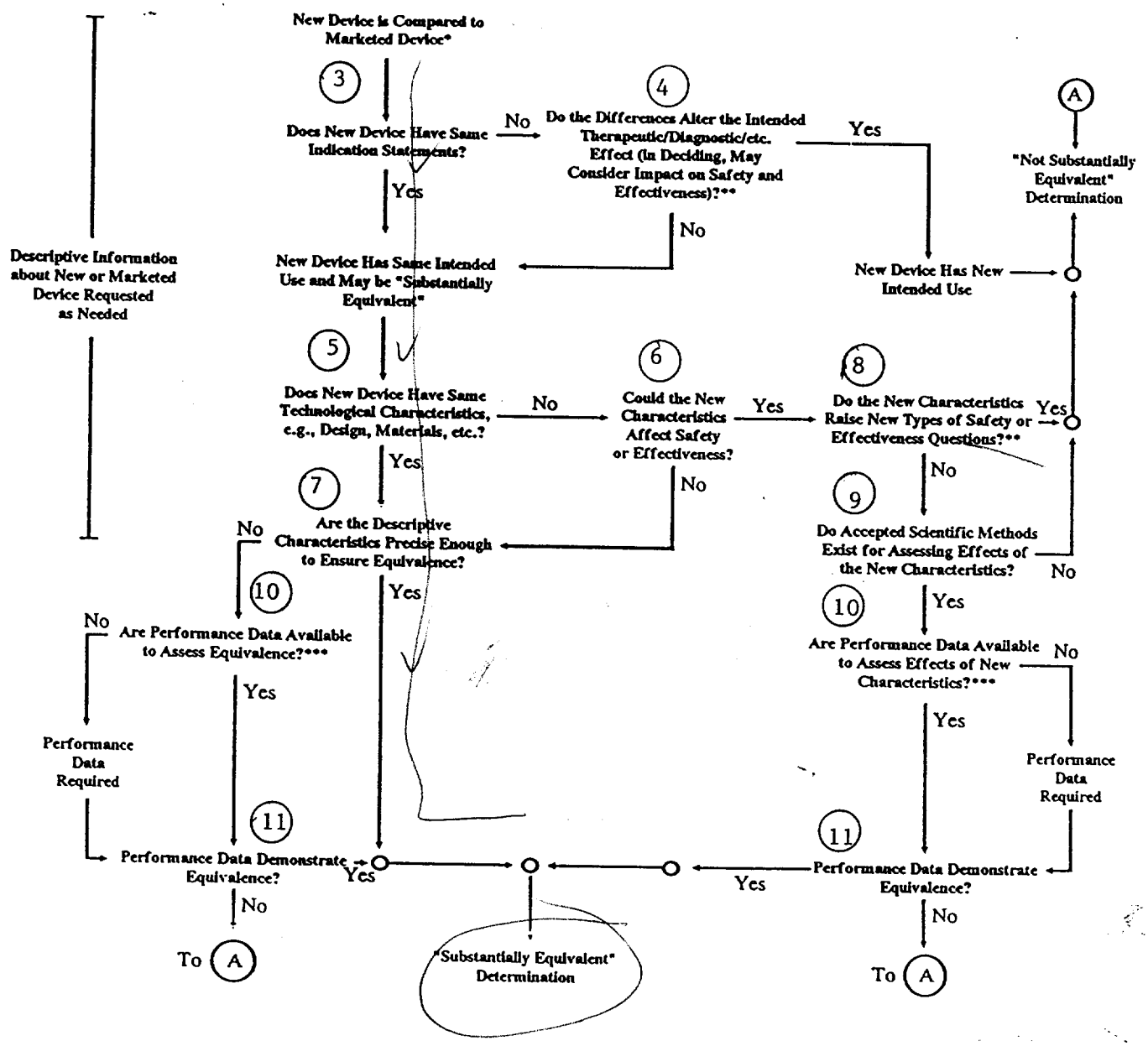
FINAL REVIEW: for DDP 2/18/94 (DIVISION DIRECTOR) (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

6

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.

K914145 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION
Reviewer: Susanna F. Barrett **Division/Branch:** DGRD/INCB
Trade Name: DSD-91
Common Name: endoscope disinfector
Panel: 78 **Product Code:** FEB **Class:** II
Product To Which Compared: K862402
510(k) Number: Medivator's Ott Scope Disinfector

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

* "yes" responses to 4, 6, 8, and 11, and every "no" response requires an explanation below

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: To disinfector flexible endoscopes

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.

   See memos dates 11/6/91, 3/4/92, 1/15/93, and 1/24/94

Susanna F. Barrett

DATE: February 17, 1994

FROM: Microbiologist, Infection Control Devices Branch, DGRD, (HFZ-413)

SUBJECT: K914145 DSD-91 Endoscope Disinfector
ProCode: 78-FEB-II
Contact: Mike Simmons
Phone #:

TO: To the record

I called Mr. Simmons today to discuss the 2/2/94 fax. I showed Mr. Simmons where we had gotten the 6-log reduction for an appropriate Mycobacterium species, such as M. terrae. The guidance for endoscope disinfectors refers to the guidance for liquid chemical germicides for the testing to support a high-level disinfection claim.

I also talked to him about the option which the firm had agreed to make as part of the device's specification. I tried to explain to Mr. Simmons that to be able to interpret data showing a reduction of organisms, one would have to compare the number of organisms that could be recovered from an inoculated untreated scopes with the number of organisms that could be recovered from a disinfected scope. he indicated that he understood what was needed. I told him to have the testing laboratory call me if there were any more questions.

I also stated that the testing should include the scopes used in the previous testing with the spores, but that it would not be necessary to test any cleaning, only after disinfection. DSD-91 does not make a cleaning claim. The instructions state that the scopes should be cleaned manually. Data showing a 6-log reduction of M. terrae from the channels of a scope without prior cleaning would be a worst case condition.

Susanna F. Barrett

2/22/94

DATE: February 17, 1994

FROM: Microbiologist, Infection Control Devices Branch, DGRD, (HFZ-413)

SUBJECT: K914145 DSD-91 Endoscope Disinfector
ProCode: 78-FEB-II
Contact:
Phone #:

TO: To the record

Medivator's has responded to the faxed request for clarification of the information contained in the supplement dated May 14, 1993. The firm has agreed to incorporate the labeling changes which were suggested for the manual and has satisfactorily clarified the testing data.

The firm will include in its specifications for the DSD-91 a certification that the machine, when operated according to the germicide and machine instructions will, demonstrate a 6-log reduction of a Mycobacterium species. The firm was given the option of using M. terrae as an appropriate Mycobacterium species.

Recommendation: SE

SFB
Susanna F. Barrett

2/22/94

11

MEDIVATORS, INC.

INNOVATIVE MEDICAL PRODUCTS

/

REFERENCE NUMBER:_____

FAX TRANSMISSION

FAX NUMBER: 301-594-2358

TO: SUSANNA BARRETT

COMPANY: _____

CITY & STATE: _____

SENDER: MICHAEL S SIMMONS

FAX NUMBER: (507) 263-0333 PHONE NUMBER: (507) 263-4721

NUMBER OF PAGES (including this page) 13

DATE: 16 FEB 94

SUSANNA:

FOLLOWING IS MEDIVATORS RESPONSE TO YOUR QUESTIONS SENT TO ME ON 28 JAN 94. THIS RESPONSE ALSO ADDRESSES THE CONCERNS EXPRESSED TO ME DURING OUR PHONE CONVERSATION ON 28 JAN 94. (IE MACHINE LABEL). THERE IS STILL MUCH CONFUSION WITH YOUR 2 FEB 94 FAX. TO ME PARTS OF THIS HAS ALREADY BEEN SUBMITTED. (b) (4) [redacted] I HAVE REVIEWED THE DRAFT GUIDANCE FOR DISINFECTORS DATED AUG 93 AND CAN NOT FIND THIS REQUIREMENT BUT AGAIN I AM NOT A BUG COUNTER. IF YOU COULD, PLEASE INFORM ME OF THE CORRECT PAGE IN THE DISINFECTOR GUIDANCE DOCUMENT AND I WILL FORWARD THIS TO THE TESTING LAB.

PLEASE CONTACT ME AT THE NUMBER BELOW WITH QUESTIONS.

Michael Simmons

2

CONFIDENTIAL

1. Provide data validating the recovery method. State the number of spore per channel which could be recovered prior to any cleaning or disinfection.

The following will be added to the specification section of the manual. MediVators, Inc. certifies that the DSD-91 Endoscope Disinfector will demonstrate at least a 6-log reduction of microbacterium species when the disinfection cycle of the machine is done according to the directions for high level disinfection as stated on the labeling for the germicide and the system is maintained and operated as described in this manual.

2. State the concentration of the germicides after stressing with horse serum for 40 cycle.

(b) (4)

[redacted]

3. Clarify the following concerning the simulated-use testing reported in Attachment B:

(b) (4)

[redacted]

(b) (4)

[redacted]

4. Provide clarification for the following from the manual:

a. all discussions about the heater; it is unclear whether the instructions are for the heater option not available in the USA or an optional manual heater;

Page 2-2 will be changed to read:
Temperature monitoring (Future Option)
This option is not available.

This option allows the disinfectant to be monitored for appropriate temperature levels. If the disinfectant in the reservoir fails to meet or exceed the specified minimum temperature, the disinfection cycle will be stopped and an error warning condition will be issued. A disinfection cycle that has been stopped must be manually restarted using the normal error restart procedure after the required temperature has been reached.

NOTE: If heaters are required MediVators will supply heaters that require manual temperature control. The user must set and monitor temperature. The on and off times can be controlled by the unit.

Page 2-7 will be changed to read:
Individual Temperature Control (Future Option)

Each station has its own heater and temperature sensor. The DSD-91 allows individual minimum, maximum, and shutdown temperature settings to be maintained for each disinfectant reservoir.

If the disinfectant temperature falls be low the minimum temperature settings for that station, the heater is turned on until the maximum temperature has been reached. If the reservoir falls below the shutdown temperature, operation is halted for that station until corrective action is taken.

Typically, the shutdown, minimum, and maximum temperatures will be set to within one degree of each other. for example, if the target temperature required for a disinfection protocol is 120° F, the shutdown temperature is set at 119° F, the minimum temperature is set at 120° F and the maximum temperature is set at 121° F.

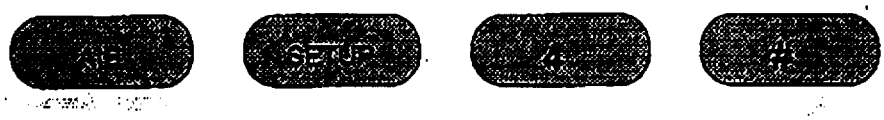
The temperature sensors are accurate to within 1° F.

NOTE: If heaters are required MediVators will supply heaters that require manual temperature control. The user must set and monitor temperature. The on and off times can be controlled by the unit.

NOTE: Follow disinfectant manufacturer labeling when determining required temperature.

Page 3-5 will be changed to read:

Set Custom Temperature (Future Option)



This function is used to set the target disinfectant temperature to custom installation values. This function is effective only for those installations with the advanced heater control option.

NOTE: This feature not available.

NOTE: If heaters are required MediVators will supply heaters that require manual temperature control. The user must set and monitor temperature. The on and off times can be controlled by the unit.

NOTE: Follow disinfectant manufacturer labeling when determining required temperature.

b. temperature setting and monitoring of the heater;

Refer to 4. a.

c. identification and purpose of the 1 - 9 programs which can be altered;

Page 2-7 will be changed to read:

User Modifiable Program Cycles

There is one standard, and up to nine user modifiable programs. The user modified programs are stored in non volatile memory.
These programs are available so the user can change cycle times to accommodate different disinfectants or different desired protocols.
Each program has six cycles. Each of these cycles may have their length altered as described in the table on the next page.
As a result of the unique method used to record this information, all custom programs and other user defined settings are retained even if the computer mother board has to be repaired or replaced (except when the non volatile memory itself has failed).

Page 3-2 will be changed to read:

Run Selected Disinfect Protocol

Operation using a selected protocol where logging of individual scopes is not required is accomplished by using the PROGRAM key to select the specific, user-defined disinfect protocol. The user must have pre-programmed a protocol prior to using this function. These programs are available so the user can change cycle times to accommodate different disinfectants or different desired protocols.
A program log is supplied so the user can have a ready reference to the custom program settings.
Program Log is Attached.

Page 3-6 will be changed to read:

Set Custom Program

This function allows custom alteration of cycle times to be set for an installation. These programs are available so the user can change cycle times to accommodate different disinfectants or different desired protocols.

The remainder of page 3-6 will remain unchanged.

d. explanation of how the maximum disinfection cycle count can be set according to disinfectant manufacturer's specification and the basis for 50 as the default maximum number of disinfection cycle;

Page 3-9 Warning will be changed to read:

WARNING
This function is not a replacement for daily monitoring of the Minimum Effective Concentration (M.E.C.) of the disinfectant. Refer to the labeling or the manufacturer of your disinfectant for the proper procedure.
The factory set default warning at 40 cycles and maximum of 50 cycles is based on 14 day reuse 2% Glutaraldehyde and approximately 3 cycles per day. The user must select the maximum disinfectant cycle warning based on the disinfectant being used and past experience with that disinfectants MEC testing.

The machine will also include a label that the user must monitor the disinfectant on a daily basis as a minimum. A draft is attached.

e. the disinfectant change warning as it is currently stated could imply that the disinfectant may be used beyond its recommended reuse life by inhibiting the warning stop for an additional ten cycle;

See 4. d.

f. the warnings against using the disinfectant past its reuse life even if it tests effective should also indicate that the disinfectant may lose its effectiveness before the end of its reuse life;

The warning notes will be changed to read:

All disinfectant must be monitored on a daily basis for effectiveness. The should not be used beyond the time period they are rated for in the manufacturers labeling (eg. a 14 day disinfectant should not be used beyond 14 days even if it does test effective). Also they may lose effectiveness before the end of the reuse life.

g. in the warning notes, the comment that pediatric endoscope air/water channels may be more difficult to clean should also include all small diameter endoscopes, for example, "Pediatric and small diameter endoscopes air/water channels";

The warning notes will be changed to read:

All endoscopes should be pre-cleaned following the manufacturers' instructions and recognized established society guidelines prior to being processed in an automatic washer/disinfector. Pediatric endoscope air/water channels and other small diameter channels may be more difficult to clean, additional cleaning should be performed on these instruments.

h. indication of whether the alcohol purge can be used at the end of every cycle if the user so desires;

Page 2-1 in the manual will be changed to read:
Alcohol Purge
Available to aid the end-of-day drying process after the last procedure of the day for the endoscope. This feature may be used at the end of each cycle if desired.

This same addition will also be included in the appropriate paragraphs on pages 2-5 and 2-6.

i. under standard operation on page 3-14, highlight "Precleaning of the scope should include brushing of the suction/biopsy channel in universal cord and insertion tube";

The manual will be changed to have this item hi-lighted.

j. page 3-15, note, indicate on the control panel, the MANUAL AIR button;

The manual will be changed to read:

NOTE: If additional purging with air is desired, press the ADD AIR button on control panel.

k. inclusion of any special instructions for bronchoscopes at the end of a disinfection cycle.

Faxed on February 7, 1994.

5. Clarify or provide the following for the hook-up instructions:

a. flow diagram of the fluid through the upper and lower endoscopes based upon the hook-up instructions for in Attachment C; it is still unclear how fluid is moved from the disinfectant reservoir through all the channels based upon the instructions;

Faxed on February 7, 1994.

b. clarify the status of part 4B, i.e., air inlet vent or air inlet plug;

Faxed on February 7, 1994.

c. information on how 2 channel scopes and bronchoscopes are connected to the DSD-91.

Faxed on February 7, 1994.

Third Party Laboratory and Testing Information (b) (4)

Third Party Laboratory and Testing Information (b) (4)

Third Party Laboratory and Testing Information (b) (4)

REF 4d

WARNING
ALL DISINFECTANTS MUST BE MONITORED ON A DAILY BASIS TO ASSURE MINIMUM EFFECTIVE CONCENTRATION.

3/4"

6"

RADIUS CORNERS
DIM ARE LABEL SIZE
LABEL & ADHESIVE APPROVED MTL
COLOR CLEAR BACKGROUND
BLACK LETTERING

2 FEB 94

REF 4c

13

MEDIVATORS, INC.

INNOVATIVE MEDICAL PRODUCTS

CUSTOM PROGRAM REFERENCE CHART

STATION A

PROGRAM CYCLE TIME								
PROGRAM NUMBER	FLUSH	DISINFECT 1	DISINFECT 2	RINSE 1	RINSE 2	ALCOHOL	AIR	MANUAL AIR
PROGRAM 1								
PROGRAM 2								
PROGRAM 3								
PROGRAM 4								
PROGRAM 5								
PROGRAM 6								
PROGRAM 7								
PROGRAM 8								
PROGRAM 9								

STATION B

PROGRAM CYCLE TIME								
PROGRAM NUMBER	FLUSH	DISINFECT 1	DISINFECT 2	RINSE 1	RINSE 2	ALCOHOL	AIR	MANUAL AIR
PROGRAM 1								
PROGRAM 2								
PROGRAM 3								
PROGRAM 4								
PROGRAM 5								
PROGRAM 6								
PROGRAM 7								
PROGRAM 8								
PROGRAM 9								

MEDIVATORS, INC.

INNOVATIVE MEDICAL PRODUCTS

REFERENCE NUMBER: _____

FAX TRANSMISSION

FAX NUMBER: 301-594-2358

TO: SUSANNA BARRETT

COMPANY: _____

CITY & STATE: _____

SENDER: MICHAEL S. SIMMONS

FAX NUMBER: (507) 263-0333 PHONE NUMBER: (507) 263-4721

NUMBER OF PAGES (including this page) 2

DATE: 7 FEB 94

SUSANNA: ATTACHED IS OUR RESPONSE TO YOUR QUESTIONS CONCERNING FLOWS AND HOOK-UPS FOR THE SCOPES. PLEASE REVIEW AND LET ME KNOW IF THIS CLARIFIES THIS PORTION OF THE SYSTEM. HOOK-UP KITS ARE ORDERED BASED ON THE TYPE OF SCOPE BEING USED. WE HAVE ABOUT 25 HOOK-UP KITS FOR THIS SYSTEM.

I WILL CALL YOU ON 8 FEB TO DISCUSS ANY QUESTIONS PLUS I NEED MORE INFO FROM YOU ON ITEM 4K.

THANK YOU

Michael Simmons

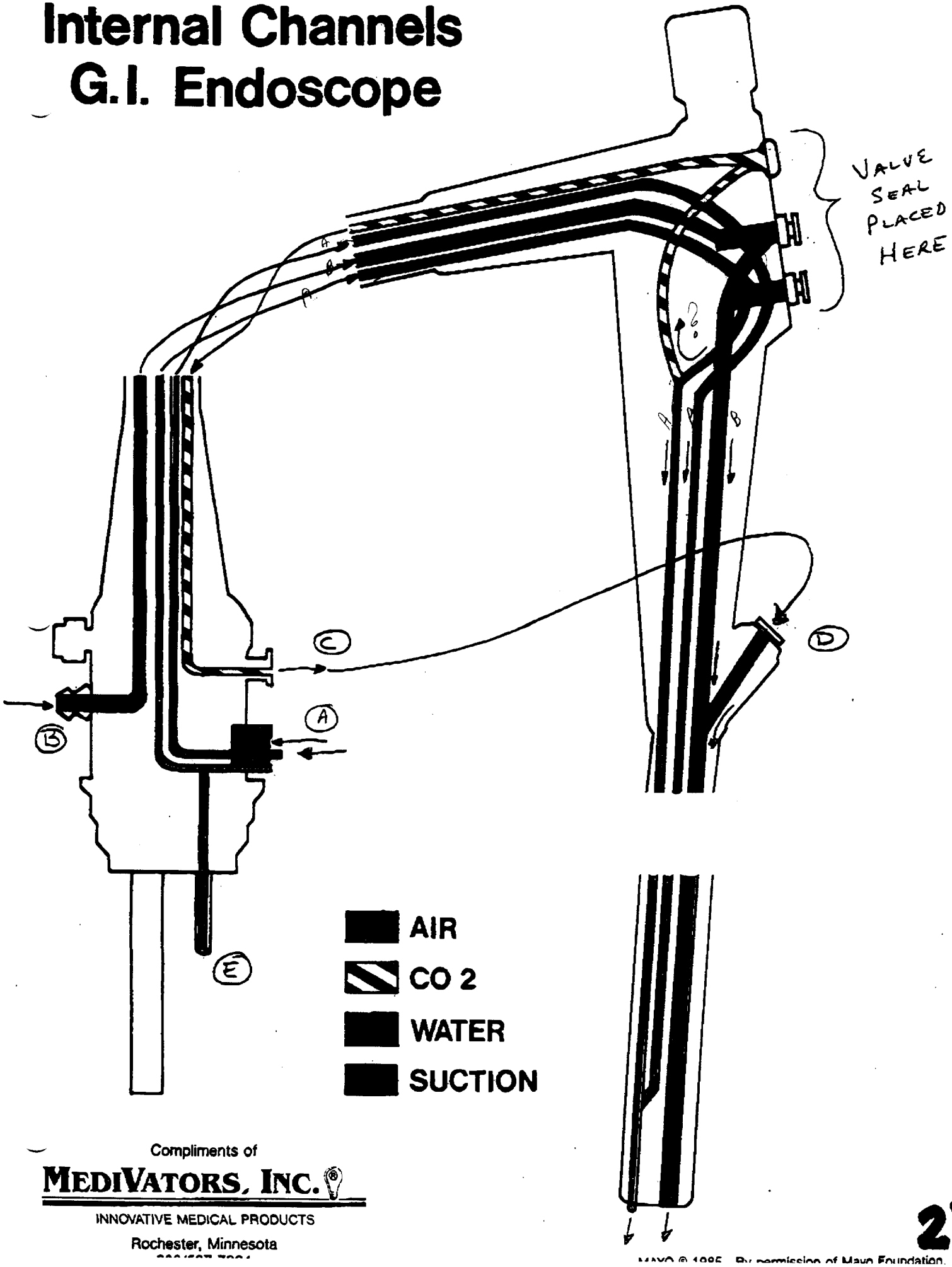
DISINFECTANT IS PUMPED FROM DISINFECTANT RESERVOIR TO UNIT HOOKUP LOCATED INSIDE UPPER RESERVOIR. DISINFECTANT FLOW IS SPLIT TO WATER PORT ADAPTER (A) & SUCTION ADAPTER (B). TUBING AT (B) IS FIT WITH A 1 MM RESTRICTER WHICH ASSURES THAT ALL DISINFECTANT FLOW IS NOT THROUGH THE LARGER SUCTION CHANNEL.

THE VALVE SEAL BLOCKS VALVE OPENINGS ON THE SCOPE HEAD. THIS ALLOWS DISINFECTANT FLOW TO CONTINUE FROM LIGHTSOURCE END, THROUGH THE SCOPE HEAD AND OUT THE DISTAL END OF SCOPE.

ON LOWER SCOPES THE TUBING CONNECTOR (3B) IS CONNECTED FROM THE CO_2 CONNECTION (C) TO THE BIOPSY CONNECTION (D). THIS ALLOWS THE DISINFECTANT FLOW TO TRAVEL THROUGH THE CO_2 CHANNEL AND ALSO DISINFECT THE BIOPSY OUTLET. A PLUG IS PLACED ON THE AIR INLET CONNECTION (E) WHICH FORCES FLOW THROUGH AIR & WATER CHANNELS

ON UPPER SCOPES, THE TUBING CONNECTOR (3A) IS CONNECTED FROM THE AIR INLET CONN. (E) TO THE BIOPSY OUTLET (D) FOR DISINFECTION OF THE BIOPSY OUTLET. THERE IS NO CO_2 CHANNEL IN UPPER SCOPES.

Internal Channels G.I. Endoscope



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INNOVATIVE MEDICAL PRODUCTS

Rochester, Minnesota

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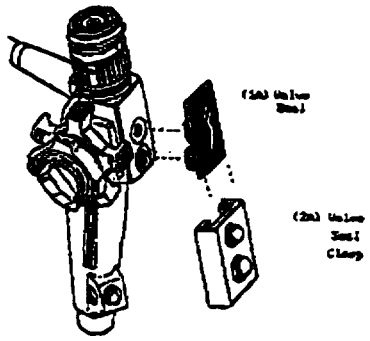
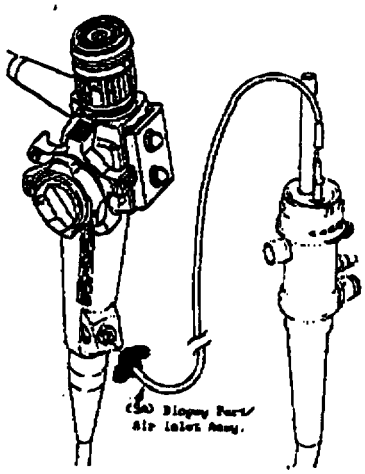
MEDIVATORS, INC.
1-800-537-7324

Olympus Upper OES And Video*

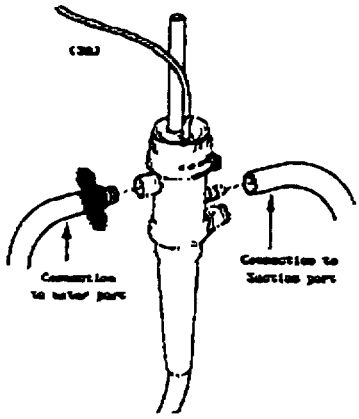
HU0042 (Consisting of HU0036 and HU0001)



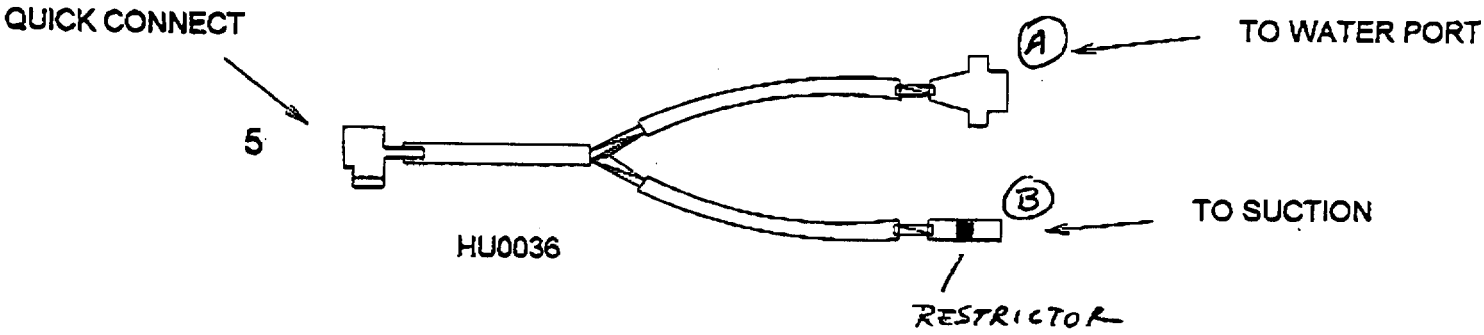
After removing air/water and suction caps from instrument, place the valve seal (1A) on the valve openings. Hold in place and slide seal clamp (2A) over seal. Finger tighten bottom screw, then finger tighten top screw.

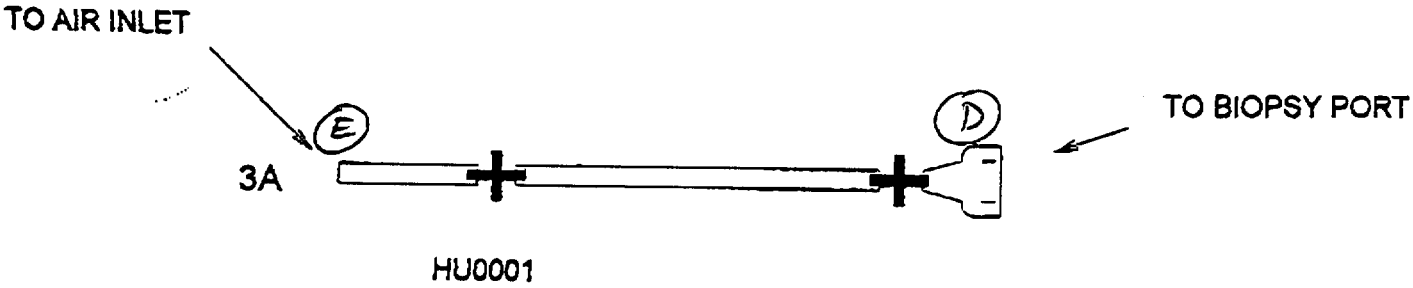


Connect the biopsy port/Air inlet tube assembly (3A) to biopsy port and inlet port.



Connect disinfector hook up to water port and suction port. The water port adapter must be firmly inserted and given a 1/4 turn to properly seat.





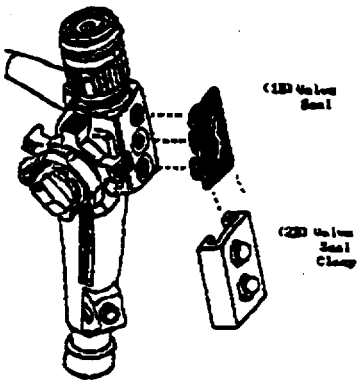
*Olympus and OES are trademarks of the Olympus Corp.

FORM: MF03-0012

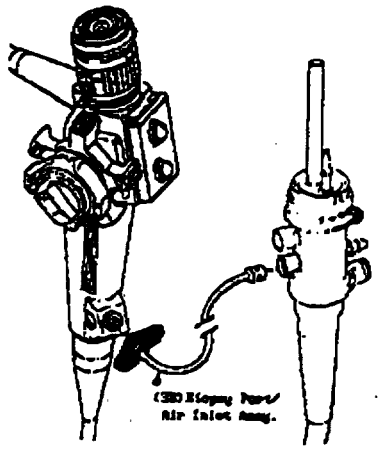
MEDIVATORS, INC.
1-800-537-7324

Olympus Lower OES And Video*

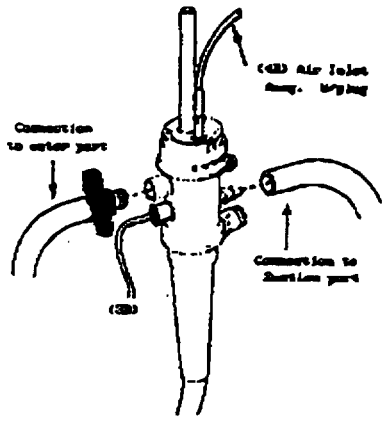
HU0043 (Consisting of HU0036 and HU0002)



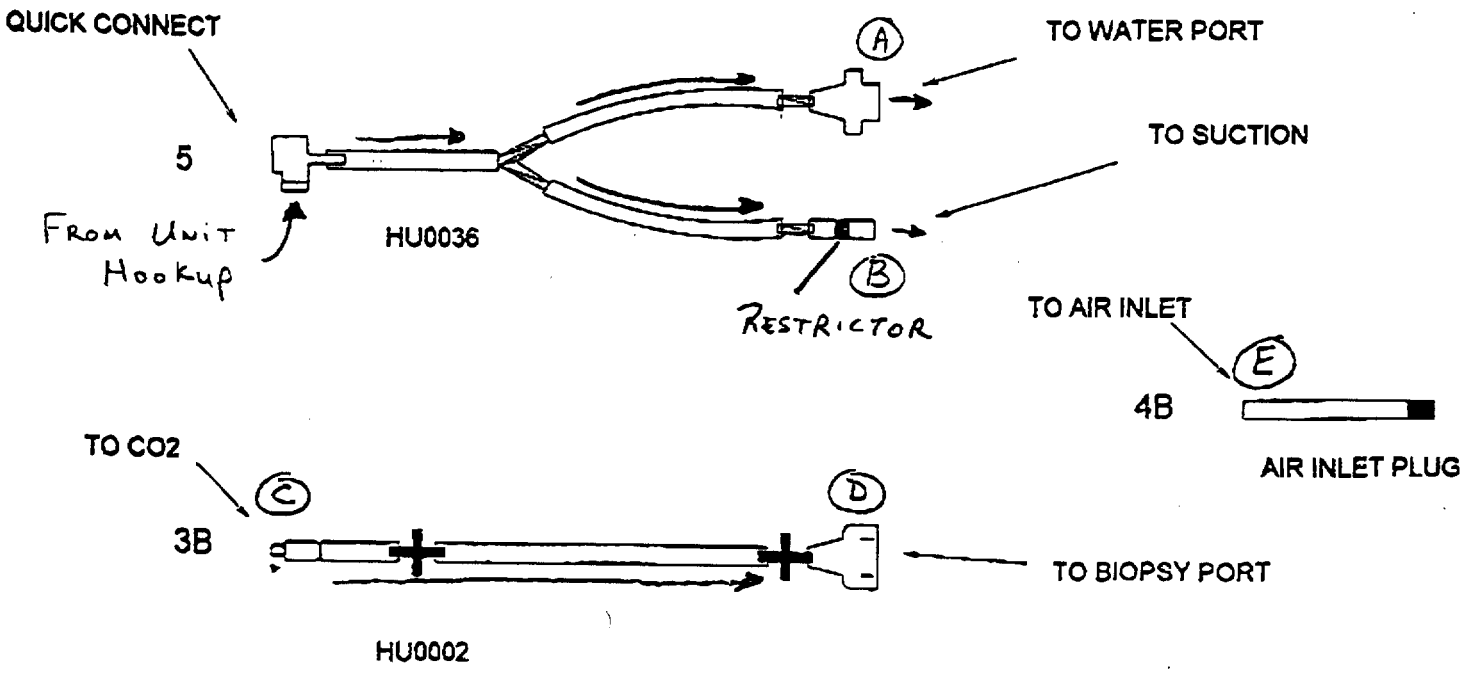
After removing air/water, suction and CO_2 valve caps from instrument, place the valve seal (1B) on the valve openings. Hold in place and slide seal clamp (2B) over seal. Finger tighten bottom screw, then finger tighten top screw.



Connect the biopsy port/CO_2 tube assembly (3B) to biopsy port and CO2 port.



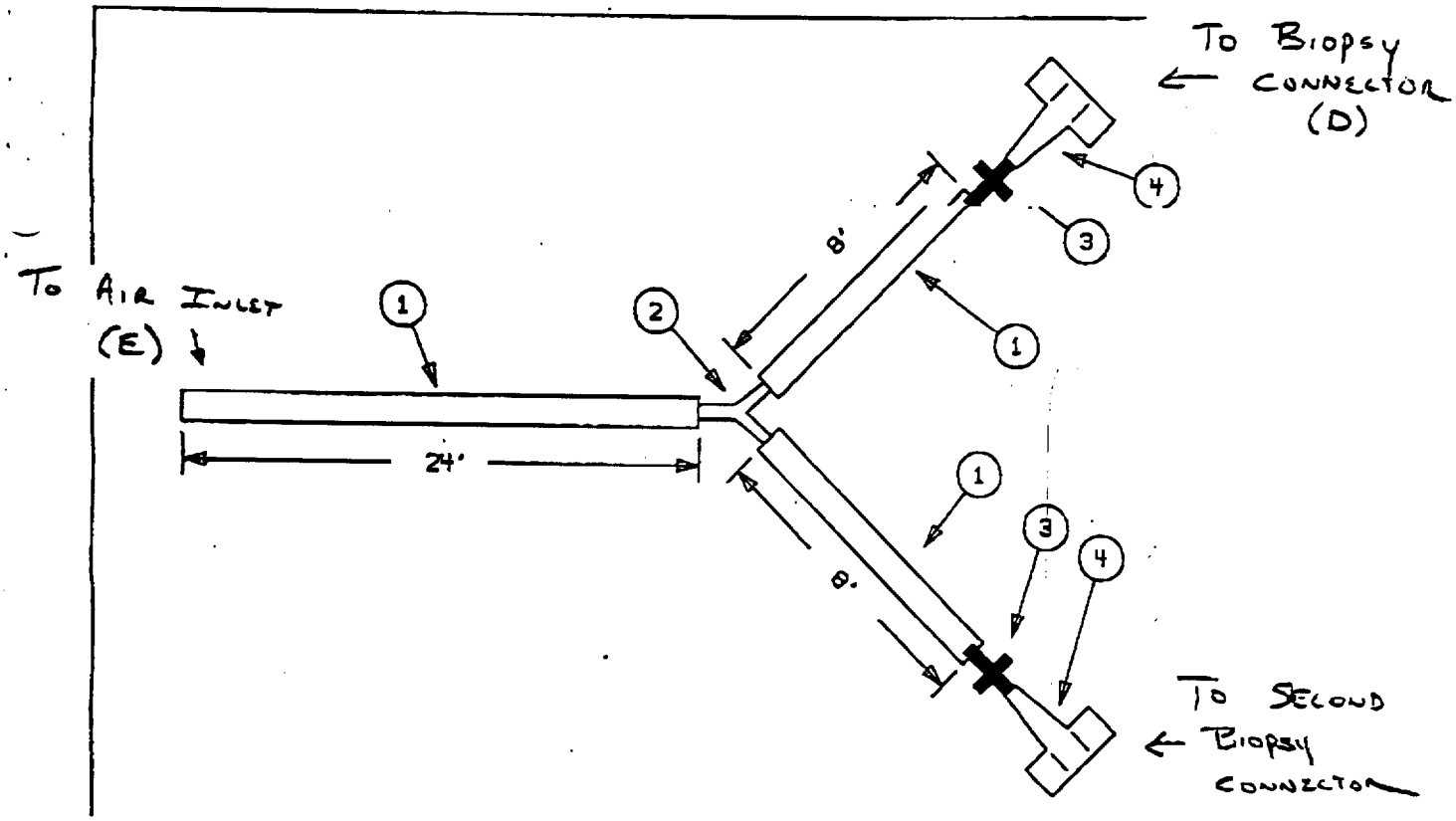
Connect disinfector hook-up to water port and suction port. The water port adapter must be firmly inserted and given a 1/4 turn to properly seat. Connect air inlet tube assembly (4B) to air inlet.



*Olympus and OES are trademarks of the Olympus Corp.

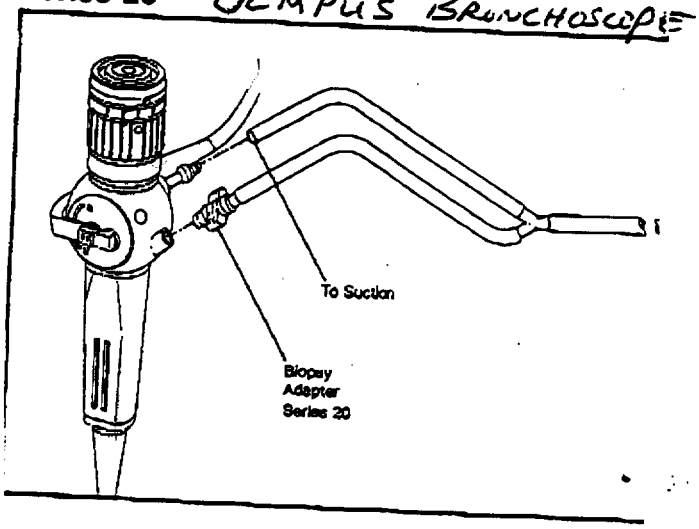
FORM: MF03-0013

A DOUBLE CHANNEL SCOPE IS CONNECTED IN THE SAME WAY. THE TUBING CONNECTOR (3B) IS SPLIT TO ALLOW DISINFECTANT TO FLOW TO BOTH BIOPSY CONNECTORS.

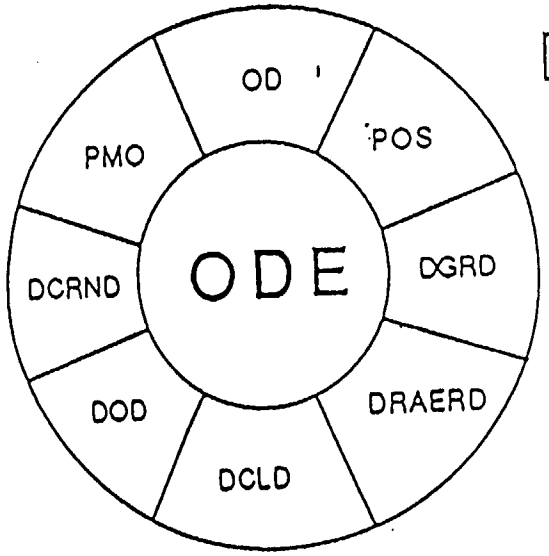


ON A BRONCHOSCOPE, FLOW IS DELIVERED THROUGH TUBING TO EXISTING OUTLETS ON THE SCOPE HEAD. ON THE OLYMPUS SERIES 20 BRONCHOSCOPE ~~THE DISINFECTANT FLOW IS SPLIT TO ALLOW DISINFECTION OF THE BIOPSY PORT & THE SUCTION ARM~~ THE TUBING IS CONNECTED TO THE BIOPSY PORT & THE SUCTION ARM. THE DISINFECTANT FLOWS THROUGH SUCTION CHANNEL TO DISTAL TIP.

Series 20 OLMPUS BRONCHOSCOPE



Division of General and Restorative Devices



DHHS/PHS/FDA/CDRH/ODE

1390 Piccard Drive
Rockville, MD 20850

Phone No.: (301) 594- 1207

Fax No.: (301) 594-2358

TO: Mike Simmons

FROM: S. Barr

Comments:

No. of Pages: 2
(including cover sheet)

Please advise if transmission is illegible.

February 2, 1994

To: Mike Simmons

From: Susanna Barrett

As discussed in our telephone conversation of January 28, 1994, you were provided an option if you did not have the data validating the recovery method as requested in question # 1. The option, which was proposed, was that you would include in the specifications that the DSD-91 Endoscope Disinfector will demonstrate at least a 6-log reduction of a mycobacterium species such as M. terrae when the disinfection cycle of the machine is done according to the directions for high level disinfection as stated on the labeling for the germicide.

The protocol for the testing should include the following specifications:

1. use of a stressed germicide at the end of its recommended reuse-life; concentration and the method used to determine the concentration of the germicide should be stated;

2. documentation of the number of organisms per channel prior to any cleaning and disinfection procedure to demonstrate % recovery; after cleaning to show the challenge to the germicide; and after disinfection; and

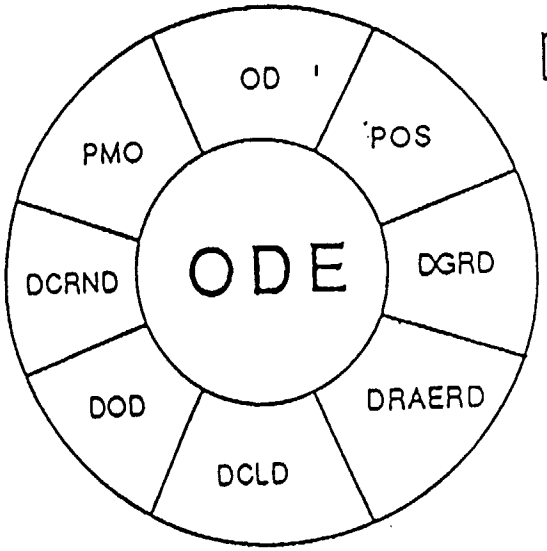
3. the contact conditions as stated in the germicide labeling for high level disinfection.

To finish the review of the 510(k) for the DSD-91, we will accept a certification that the DSD-91 will meet the specification; however, you will need to complete the testing before marketing the DSD-91. You will not need to submit the data to us for review, but you will need to keep the data on file. If the machine has to be redesigned to meet the specification, you will need to submit a new 510(k).

We will need a response to this and to the material faxed to you on January 28, 1994, by the end of February. If you can not respond by the end of February, then the submission will have to go back on hold.

faxed 2/4/94 to M. Simmons
fax # 507-263-0333

Division of General and Restorative Devices



DHHS/PHS/FDA/CDRH/ODE

1390 Piccard Drive
Rockville, MD 20850

Phone No.: (301) 594-1207

Fax No.: (301) 594-2358

TO: Mike Simmons

FROM: S Barrett

Comments:

No. of Pages: 3
(including cover sheet)

Please advise if transmission is illegible.

January 28, 1994

TO: Mike Simmons

From: Susanna Barrett SB

As per our our discussion today, I am sending you a copy of the items which were discussed in the conference call. I will be available to discuss the items after you have had a chance to review them. I can accept a fax of your responses, but you will need to submit a hard copy for inclusion into the 510(k) submission.

1. Provide data validating the recovery method. State the number of spore per channel which could be recovered prior to any cleaning or disinfection.

2. State the concentration of the germicides after stressing with horse serum for 40 cycles.

3. Clarify the following concerning the simulated-use testing reported in Attachment B:

(b) (4)

[redacted]

4. Provide clarification for the following from the manual:

   a. all discussions about the heater; it is unclear whether the instructions are for the heater option not available in the USA or an optional manual heater;

   b. temperature setting and monitoring of the heater;

   c. identification and purpose of the 1 - 9 programs which can be altered;

   d. explanation of how the maximum disinfection cycle count can be set according to disinfectant manufacturer's specification and the basis

for 50 as the default maximum number of disinfection cycles;

e. the disinfectant change warning as it is currently stated could imply that the disinfectant may be used beyond its recommended reuse life by inhibiting the warning stop for an additional ten cycles;

f. the warnings against using the disinfectant past its reuse life even if it tests effective should also indicate that the disinfectant may lose its effectiveness before the end of its reuse life;

g. in the warning notes, the comment that pediatric endoscope air/water channels may be more difficult to clean should also included all small diameter endoscopes, for example, "Pediatric and small diameter endoscopes air/water channels";

h. indication of whether the alcohol purge can be used at the end of every cycle if the user so desires;

i. under standard operation on page 3-14, highlight "Precleaning of the scope should include brushing of the suction/biopsy channel in universal cord and insertion tube";

j. page 3-15, Note, indicate on the control panel, the MANUAL AIR button; and

k. inclusion of any special instructions for bronchoscopes at the end of a disinfection cycle.

5. Clarify or provide the following for the hook-up instructions:

a. flow diagrams of the fluid through the upper and lower endoscopes based upon the hook-up instructions for in Attachment C; it is still unclear how fluid is moved from the disinfectant reservoir through all the channels based upon the instructions;

b. clarify the status of part 4B, i.e., air inlet vent or air inlet plug;

c. information on how 2 channel scopes and bronchoscopes are connected to the DSD-91.

faxed 1/28/94 to M. Simmons
Fax # 507-263-0333

DATE: January 24, 1994

FROM: Microbiologist, Infection Control Devices Branch, DGRD, (HFZ-413)

SUBJECT: K914145 DSD-91 Endoscope Disinfector
ProCode: 78-FEB-II
Contact: Constance G. Bundy
Phone #: 612-574-1976

TO: To the record

The firm has responded to the letter of 3/8/93 requesting additional information. CDRH has modified its position regarding the clearance of devices which require the use of a germicide. Devices can be cleared even though no germicides have received 510(k) clearance. The primary germicide used to validate the performance of DSD-91 Disinfector was Metrex 2% glutaraldehyde. The firm has contacted Metrex, Inc. and will receive written notification of any formulation or labeling changes.

The firm was reminded twice that it needed to submit in-use testing data. In-use testing data was submitted with this information. The data are in Attachment D.

(b) (4)

[redacted]

were presented to support the claims that the organisms were post-processing environmental contaminates.

The in-use testing is not as complete as one would expect. One would have hoped for an evaluation of the bioburden on the scopes prior to processing; an evaluation of the cleaning process; and validation of the recovery method. It may be possible to allow some leeway with the proviso that the firm monitor the performance of its machines. Most of the microorganisms, except for M. tuberculosis, that would contaminate a flexible endoscope are sensitive to 2% glutaraldehydes. Longer exposure times and slightly higher temperatures are required to kill M. tuberculosis.

The firm has used a total of 5 types of flexible endoscopes: gastroscope, colonoscope, sigmoidoscope, duodenoscope, and a pediatric gastroscope to validate the performance of the DSD-91.

The firm did additional simulated-use testing using B. subtilis spores. It evaluated the reduction after cleaning and after disinfection using 3 glutaraldehyde germicides: 2% Metricide, 2% Cidex, and 2% Omnicide and a 6% hydrogen peroxide, Endospore. None of these germicides have received 510(k) clearance at this time. Three types of flexible endoscopes were used in the testing: a gastroscope, a colonoscope, and a pediatric gastroscope. The data are in Attachment B. 2% Omnicide did not disinfect the scopes as well as Metricide, Cidex, or Endospore. The reason proposed by the firm was that the MEC of Omnicide dropped more rapidly than the other disinfectants. The firm did not provide any information concerning the effective concentration of any of the germicides during the testing. Therefore, there is no way to evaluate the claim.

The firm has made an attempt to provide data validating the performance of its machine; however, there are still problems with the protocols.

1. lack of data validating the recovery method;

2. concentration of the germicides after stressing with horse serum for 40 cycles; and

3. number of spores per channel prior to treatment.

It also needs to clarify the following:

(b) (4)

1. [redacted]

2. [redacted]

3. [redacted]

4. [redacted]

5. [redacted]

All variations need to be explained in the discussion of the results.

The firm has included in the manual instructions that the Sterapore filter should be changed whenever the water pressure on the internal regulator drops by 5 psi. Testing showed that an 8 psi decrease in pressure reduced the water quantity and the flow. The firm stated that it tested the water flow and fill rates by reducing the

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(b) (4)

[redacted]

The firm has incorporated into the manual many of the suggestions that have been made in the memos for this 510(k). There are, however, several areas that need clarification or modification.

1. all discussions about the heater; it is unclear whether the instructions are for the heater option not available in the USA or an optional manual heater;

2. temperature setting and monitoring of the heater;

3. identification and purpose of the 1 - 9 programs which can be altered;

4. explanation of how the maximum disinfection cycle count can be set according to disinfectant manufacturer's specification and the basis for 50

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as the default maximum number of disinfection cycles;

5. the disinfectant change warning as it is currently stated could imply that the disinfectant may be used beyond its recommended reuse life by inhibiting the warning stop for an additional ten cycles;

6. the warnings against using the disinfectant past its reuse life even if it tests effective should also indicate that the disinfectant may lose its effectiveness before the end of its reuse life;

7. in the warning notes, the comment that pediatric endoscope air/water channels may be more difficult to clean should also included all small diameter endoscopes, for example, "Pediatric and small diameter endoscopes air/water channels";

8. indication of whether the alcohol purge can be used at the end of every cycle if the user so desires;

9. under standard operation on page 3-14, highlight "Precleaning of the scope should include brushing of the suction/biopsy channel in universal cord and insertion tube";

10. page 3-15, Note, indicate on the control panel, the MANUAL AIR button; and

11. inclusion of any special instructions for bronchoscopes at the end of a disinfection cycle.

The firm needs to provide and clarify the following information:

1. Provide data validating the recovery method.

2. State the concentration of the germicides after stressing with horse serum for 40 cycles.

3. State the number of spores per channel prior to treatment.

4. Clarify the following concerning the simulated-use testing reported in Attachment B:

(b) (4)

[redacted]

40

(b) (4)

[redacted]

5. Provide clarification for the following from the manual:

a. all discussions about the heater; it is unclear whether the instructions are for the heater option not available in the USA or an optional manual heater;

b. temperature setting and monitoring of the heater;

c. identification and purpose of the 1 - 9 programs which can be altered;

d. explanation of how the maximum disinfection cycle count can be set according to disinfectant manufacturer's specification and the basis for 50 as the default maximum number of disinfection cycles;

e. the disinfectant change warning as it is currently stated could imply that the disinfectant may be used beyond its recommended reuse life by inhibiting the warning stop for an additional ten cycles;

f. the warnings against using the disinfectant past its reuse life even if it tests effective should also indicate that the disinfectant may lose its effectiveness before the end of its reuse life;

g. in the warning notes, the comment that pediatric endoscope air/water channels may be more difficult to clean should also included all small diameter endoscopes, for example, "Pediatric and small diameter endoscopes air/water channels";

h. indication of whether the alcohol purge can be used at the end of every cycle if the user so desires;

i. under standard operation on page 3-14, highlight "Precleaning of the scope should include brushing of the suction/biopsy channel in universal cord and insertion tube";

j. page 3-15, Note, indicate on the control panel, the MANUAL AIR button; and

k. inclusion of any special instructions for bronchoscopes at the end of a

disinfection cycle.

6. Clarify or provide the following for the hook-up instructions:

   a. flow diagrams of the fluid through the upper and lower endoscopes based upon the hook-up instructions for in Attachment C; it is still unclear how fluid is moved from the disinfectant reservoir through all the channels based upon the instructions;

   b. clarify the status of part 4B, i.e., air inlet vent or air inlet plug;

   c. information on how 2 channel scopes and bronchoscopes are connected to the DSD-91.

Discussions were held 1/26/94 with Tim Ulatowski and Dr. Chiu Lin about options that we might have with the DSD-91 if the firm does not have the validation data for its recovery protocols. (b) (4) [redacted]

(b) (4) [redacted]

SFB
Susanna F. Barrett

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

MAY 18, 1993

MEDIVATORS, INC.
ATTN: CONSTANCE G. BUNDY
C/O C. G. BUNDY ASSOCIATES
6470 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432

510(k) Number: K914145
Received: 05-17-93
Product: DSD-91(TM) DISINFECTOR FOR FLEXIBLE ENDOSCOPES

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 within 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) 427-1190.

Sincerely yours,

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

MEDIVATORS, INC.

INNOVATIVE MEDICAL PRODUCTS

K914145/C

May 14, 1993

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Attention: Ms. Susanna Barrett
Division of General and Restorative Devices

RE: 510(k) Number K914145
Response to Questions

Provided herein are responses to your letter of March 8, 1993, requesting additional information. We believe we have fully addressed your concerns in this response.

This response contains information that is confidential. The confidential information has been designated as such on the appropriate pages or at the beginning of an appendix.

Thank you for your consideration and attention in this process. If you have questions, please contact me at the phone number noted below.

Sincerely,

Constance G. Bundy

Constance G. Bundy

Phone: 612-574-1976

Enclosures:

This Volume: Response 1 through 12
Appendices A through H

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Cannon Plaza South • 6352 320 Street Way • P.O. Box 487 • Cannon Falls, MN 55009 • 507/263-4721 • 800/537-7324

Response 1 through 12
Attachments A through H
510(k) K914145
MediVators, Inc.

1 a. FDA cannot find your device equivalent until at least one germicide is cleared by FDA for machine use, and your device is labeled for use with that germicide. How the germicide could be labeled is questionable. Whether it could be labeled with specifications for compatible machines or must be labeled for specific machines remains open. There must be performance data showing the germicide is effective when used according to labeling with the (type of?) machines indicated in labeling.

1 a. Our data demonstrates that the germicide manufactured by Metrex is effective when processed or used with the DSD-91. See attachment B.

1 b. FDA may find your device equivalent if you can justify that generic specifications for compatible germicides are feasible. You would have to consider not only the formulations of germicides now marketed but also the impact of formulation changes to those products, and new products that may legally enter the market. You would also have to consider how the user will be able to match your generic specifications to all germicide labeling. Current labeling lists only the active ingredients, but inactive ingredients may have just as much or more impact on effective use and compatibility with the machine.

Due to FDA's evaluation of germicides, the contact conditions of the germicides may be significantly revised. Your device must have features that allow for the revised contact conditions (e.g., contact times and temperature). Qualification of performance and compatibility still hinges on the use of a marketed germicide to confirm the labeling specifications. Given the flux of the germicide now under review this option is tenuous. Generally, germicide manufacturers are proposing to FDA longer contact times for disinfection than that registered under EPA.

1 b. MediVators, Inc. has tested endoscopes in accordance with the labeling specifications found on Metrex 2% glutaraldehyde. Because the system is programmed by the end user the system is compatible with and programmable for any germicide labeling requirements to include contact time and temperature. (Refer to page 2-8 in users manual attachment A). ?

The following statement has been added to the warning notes in the users manual: all testing was performed with 14 day reuse 2% glutaraldehyde. (See attachment A).

The DSD-91 has features which "allow for revised contact conditions". The system is programmable by the end user to accommodate germicide labeling specifications. (Refer to page 2-8 in users manual Attachment A).

1 c. FDA may consider data qualifying a specific legally marketed germicides in your machine even though they may be labeled for manual use only. We are evaluating the legality of this option. Under this scenario, labeling from the machine manufacturer will supplement the germicide labeling to ensure effective and safe use of the germicide in the machine. Data from the machine manufacturer must qualify the germicide for use in their machine. In this case the manual use contact cond
itions will probably have to be maintained in the machine (e.g., minimum concentrations, temperature, time).

1 c. The DSD-91 has been tested with Metrex 2% glutaraldehyde. The test results are in attachment B. The need to refer to manufacturers labeling is called out in the users manual pages labeled "IMPORTANT" and "WARNING NOTES" and 1-7, 2-7, 3-5, 3-9, 3-11 and 3-17.
The test results referred to in attachment B were obtained in the DSD-91 which was programmed to manual use conditions as specified on the germicide label (e.g. contact time, and MEC).

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1 d. A variation of option c. is for the germicide manufacturer to provide a finished legally marketed, manual use only germicide to the machine manufacturer as a "raw material" who in turn will relabel the germicide for use with the machine. As above, data from the machine manufacturer must qualify the germicide for machine use.

1 d. May be a future option.

1 e. The machine manufacturer may consider sole development and marketing of a germicide for their device. This would incur the need to submit a comprehensive 510(k) on the safety and effectiveness of the germicide.

1 e. May be a future option.

You will note that only option b. provides the opportunity to move to an equivalence decision before germicides are cleared. All the options probably require some form of communication between the germicide and machine manufacturers. As alluded to in option b, if the formulation of a germicide is modified the impact on the effectiveness in the machine must be addressed.

MediVators, Inc, has been in contact with Metrex , Inc. and we will receive in writing notification of any formulation or labeling changes.

2. FDA requires not only simulated testing but also in use testing, as noted in question #12 of our letter dated March 23, 1992. You did not fully respond to the deficiency. Provide the requested test data.

2. See ATTACHMENT D.

3 a. Without the proper control demonstrating the number of spores recovered from a scope after any "precleaning" procedure and prior to disinfection in the DSD-91, the disinfection efficiency data for the DSD-91 can not be evaluated. Provide efficacy testing data which include the proper controls.

3 a. Additional testing was performed, see ATTACHMENT B.

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3 b. Justify using a 2 ml inoculum for all channels considering the findings in the Vesley et. al., paper entitled "Significant Factors in the Disinfection and Sterilization of Flexible Endoscopes" that up to 15 ml can be contained in the suction channel.

3 b. 15 ml was tried. In our study we used a horse serum inoculum (Dr. Vesley did not). This dried into a hard plug in the channels after 24 hours. Using 2 ml and then slowly passing air through the channels and rotating the endoscope assures the coating of the channels and allows normal processing procedures to be completed. Subsequent testing was performed with 10cc of inoculum. This was injected into the suction channel and allowed to dry for 2 hours. Air/water channels were inoculated with 2cc. See ATTACHMENT B.

4. The minimum effective concentration (MEC) of the germicide must be maintained when using the DSD-91. The MEC is identified in the germicide labeling and may vary from product to product. Claiming a lower MEC than that in germicide labeling will not be permitted.

4. The requirements to follow the manufacturers labeling and to monitor for effectiveness is called out at the beginning of the manual in the section labeled "Important" and the section labeled "Warning Notes". This requirement is also called out on pages 1-8, 3-9, 3-11, 3-17. ATTACHMENT A.

5. It was noted that the air channel for the Olympus XQ10-3 was the most difficult to disinfect even following the SGNA guidelines. Please comment on the impact of this finding on the instructions for use. For example, should these scopes require special precleaning or processing?

5. Additional flushing and pre cleaning of the air/water channel in the XQ-10 and other pediatric endoscopes may be required. The XQ-10 has the water and air lines merging into a very small port at the distal tip of the endoscope, thus creating a more difficult cleaning and disinfection situation. This has been changed in models produced subsequent to the model we have. A warning has been added to the warning notes generically for pediatric endoscopes. See page labeled "WARNING NOTES" in ATTACHMENT A.

Identify the generic types of endoscopes used for the testing to make certain that the study contains representative samples of endoscopes. Note that in the absence of in-use data we cannot determine whether the reduction of contamination is clinically acceptable.

Five Types of Endoscopes Processed:

1. **Gastroscope**
2. **Colonoscope**
3. **Sigmoidoscope**
4. **Duodenoscope**
5. **Pediatric Gastroscope**

6. Anecdotal user information concerning the recommendation for changing the Sterapore filter is insufficient. Provide data to support the claim for changing the filter every 6 months. The testing should mirror maximum use conditions for the DSD-91 during the 6 month period such as significant water use, different qualities of water, etc. The data must show the safety factor associated with the recommendation for changing every 6 months.

6. The Sterapore filter change should occur when the water pressure on the internal regulator drops by 5 psi. Water flows were tested. Water pressure was reduced in increments of 1 psi. Flow and fill rates were measured. Between 0-8 psi drop there was no measurable difference in the water flow. At 8 psi drop, a decrease in water quantity and flow was was noticed. When this occurs the fill time during the rinse cycle increases. Flow through the channels did remain adequate. At a drop of 10 psi a significant decrese was observed. Our recommendation is that a change be made when a 5 psi drop is observed or at 6 months whichever comes first.
Under experimental conditions 91m^3 (24,039 gallons) of water was passed through the filter. See ATTCHMENT H.
Calculating water usage over a 6 month period, 8 cycles per day per side of DSD times 5 gallons per cycle times 180 days produces a usage of 14,400 gallons. A 40% margin of safty exists to compensate for water quality.

This has been added to the warning notes and page 3-20 of the users manual. ATTACHMENT A.

7. Provide the page number in the manual which clarifies the intent of the disinfectant filter (re answer to question 7). The information concerning disinfectant filtration (pg 2-1) contained in the manual submitted with the supplemental material dated 7/20/92 is identical to the information concerning disinfection filtration (pg 2-1) contained in the manual submitted with the original application dated 9/13/91. You have not satisfactorily demonstrated that the disinfectant filter keeps sediment out of the disinfectant reservoir.

7. The disinfectant filter is located between the pump and the reservoir. Disinfectant is drawn by the pump from the reservoir through the filter then to the scope in the upper tank and the upper tank. This prevents sediment from entering the endoscope or the upper tank. The manuals included with the previous submissions were in error stating that this filter "would keep the <u>reservoir</u> clean of sediment".

Page 2-2 has been updated. ATTACHMENT A.

8. The testing protocol for biofilm formation is not sufficiently rigorous to show that biofilms do not develop in units after extended use. Provide additional testing on units which have been in extended service. The testing should include the culturing of tubing, vents, etc.

8. The following additional tests were performed. (Test Unit #1 was placed into service May 1991)

A. The reservoir of a DSD-91 (Test Unit #1) was emptied of disinfectant and washed and rinsed. It was then filled with tap water, 30 ml of an inoculum of P. Aeruginosa 4.4 x 10^9 CFU/ml was then injected into the reservoir. After 24 hours three samples were taken, A01 from the reservoir tank, A02 from the endoscope hook up line, A03 from the tank fill line.
The DSD was then started and run for several cycles, allowing the inoculated water to circulate through out the machine. Samples were then taken at 24 and 48 hours from the hookups during the rinse cycle, A04 and A05.
The DSD then was emptied by using the disinfectant dump cycle. Normal cleaning and filter replacement was not performed. The reservoir was filled with 2% Glutaraldehyde and one standard cycle was run.
Sample A06 was taken from the rinse water of this cycle. Sample A07 was taken 24 hours later from the endoscope hookup during a rinse cycle. Sample A08 was taken at 48 hours from the endoscope hookup during a rinse cycle.

Results of P. Aeruginosa Test	
AO1	Positive for Pseudomonas
A02	Negative for Pseudomonas
A03	Negative for Pseudomonas
A04	Positive for Pseudomonas
A05	Positive for Pseudomonas
A06	Negative for Pseudomonas
A07	Negative for Pseudomonas
A08	Negative for Pseudomonas

See ATTACHMENT F.

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B. Swabbing of critical junctures was performed (Test Unit #1) . See next page for tested areas.

Sample A1, Incoming water supply line
Sample A2, Water line and incoming fitting of the Sterapore water filter.
Sample A3, Water line and check valve downstream of the Sterapore filter.
Sample B1, Chamber fill line and valve
Sample B2, Hookup fill line and valve
Sample B3 Water fill line and valve
Sample B4 Overflow line and valve
Sample B5 Air line and valve
Sample C1 Air compressor fan and housing
Sample D1 Inside a hookup used for 8 months

TOTAL AEROBES, COLONY FORMING UNITS/ML
Samples plated on three different media at Bio-Test Laboratories

Sample Number	TSA	EMB	R_2A
A-1	78	93	90
A-2	114	160	1
A-3	3	0	4
B-1	0	0	0
B-2	0	0	0
B-3	0	0	0
B-4	0	0	0
B-5	4	1	6
C-1	19	22	35
D-1	0	0	0

As can be seen from above chart there was no significant Biofilm formation.
See ATTACHMENT E.

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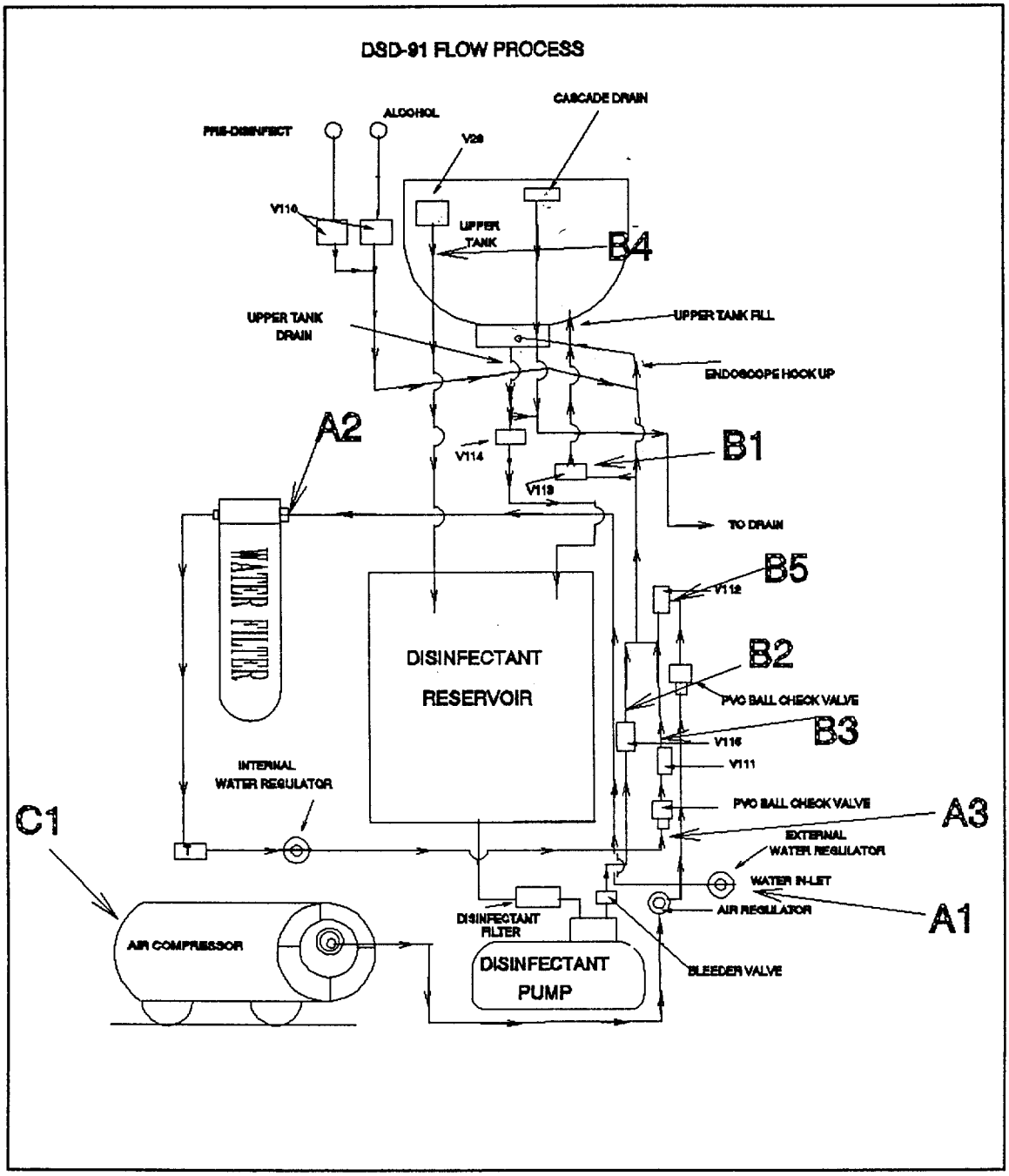
CHART OF TESTED AREAS



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9. Provide the method used to determine the level of glutaraldehyde residues which remained on the scopes after the rinse cycle. Identify the types of scopes used for the testing. Given that you refer only to glutaraldehyde generically in labeling, and given that you indicate that many different brands and types of scopes can be processed, justify with data how your rinsing step is adequate for all combinations of germicides and scopes. Alternatively, as the options in item 1 provide, you can specify brand name germicides and scopes in labeling and test the residues remaining on the scopes after processing with all combinations of stated germicides and scopes. Be advised that the residuals must be demonstrated to be at or below safe levels determined by relevant toxicity tests.

9. After consultation with Dr. Donald Vesley, School of Public Health University of Minnesota and Andrew Streifel, Department of Environmental Health and Safety, University of Minnesota, and the LaMott Co. (manufacturer of test kits for glutaraldehyde levels)[A], the following was performed:

To obtain residual glutaraldehyde levels, Deionized water was injected into the air/water and suction channels of listed endoscopes. The water was agitated in the channels by a back and forth action on the syringe plunger and then the water was withdrawn. The insertion tube of the endoscope with the channel ports blocked off was dipped in 2 gallons of water and a sample of this taken.
After the water was recovered and using a glutaraldehyde colorimeter test (LaMotte Chemical Products Co.), the samples were tested for residual glutaraldehyde.
The results from the colorimeter then are converted by formula from mg/m3 to ppm. Four germicides were tested:

2% 14 day Metricide
2% 14 day Cidex
2% 14 day Omnicide
3.2 % 14 Day Metricide

The channels and exterior of the following endoscopes were tested.

<u>OLYMPUS</u>
XQ-10 Pediatric Gastroscope
CF1TV10L Colonoscope
GIFV10 Gastroscope
GIF-D3 Gastroscope

<u>PENTAX</u>
FG-29X Gastroscope
FC-34FX Gastroscope

<u>FUJINON</u>
DUO-X Duodenoscope
UGI-F2 Gastroscope
SIG-EK Sigmoidoscope
SIG-E4 Sigmoidoscope

See attached table for results, Pages 15-18.
In addition, 9 samples on three endoscopes were sent for spectrographic analysis to verify a direct correlation with the LaMott method. There was a correlation. The results of this analysis are enclosed on Page 19. Also see ATTACHMENT G.

Literature reviews were performed by Medivators, Dr. Vesley and the Mayo clinic as to acceptable levels of glutaraldehyde residue on endoscopes. None specific to flexible endoscopes was found.
Cytotoxic levels of glutaraldehyde in the literature are stated as above 25 parts per million. Medivators position is that parts of the endoscope in direct contact with the patient (the insertion tube) are well below these limits. The suction channel is of limited import as fluid is suctioned out of this channel and there is little likelihood of residue entering the body from this channel.
Quoting McClellan "In reviewing the literature, no risk assessments or exposure standards for glutaraldehyde, other than the OSHA, PEL and ACGIH Threshold Limit Value, were identified." Instances where problems were identified were a result of user error in the rinsing process. Reports were all based on manual rinsing of the endoscopes.

Referencing Dr. Vesleys work, that with manual rinsing levels as high as 69 ppm were found on the endoscopes. Medivators position is that the DSD-91 reduces residue levels significantly more than manual rinse methods and is thus safer. Another significant finding was that the age and number of procedures performed with the endoscope had a direct relationship to the residue level. Endoscopes with high numbers of procedures had higher residue levels than less used endoscopes. Using a higher concentration product (3.2% glutaraldehyde) did not show an increase in residue levels. Residue level is effected by the age and porosity of material as the endoscope is used.

Based on literature and other sources it is Medivators conclusion the level of glutaraldehyde residual on endoscopes after processing in the DSD-91 are well within the limits of safety.[B]

A. 1. Boratynski J, Zal T, Colorimetric micromethods for glutaraldehyde determination, Anal Biochem (1990 Feb 1) 184(2):259-62

2. Millership JS, A report on an initial comparative study of two methods for the determination of glutaraldehyde., J Clin Pharm Ther (1987 Feb) 12(1):33-8.

B. 1. Power EG, Russell AD, Glutaraldehyde: its uptake by sporing and non-sporing bacteria, rubber, plastic and an endoscope., J Appl Bacteriology (1989 Sep) 67(3):329-42

2. Vesley D, Norlien KG, Nelson B, Streifel, Significant Factors In The Disinfection /Sterilization of Flexible Endoscopes or Disinfection Of Flexible Endoscopes, AJIC (1992 Dec) 20(6):291-300

3. Gerding, D. et al, Cleaning and Disinfection of Fiberoptic Endoscopes: Evaluation of Glutaraldehyde Exposure Time and Forced-Air Drying, Gastroenterology (1982);83:613-618.

4. Hess, J.A., Molinari J.A., Epidermal Toxicity of Disinfectants, AM J DENT (Feb 1991) 4(1):51-56.

5. St. Clair, M.B., et al, Evaluation of the Genotoxic Potential of Glutaraldehyde, Environ Mol Mutagen, (1991) 18(2):113-119.

6. Durante, L., Zulty, J.C., Investigation of an outbreak of Bloody Diarrhea, Am J Medicine, (May 1992) 92(5) :476-80.

7. Beauchamp, R.O., et al, A Critical Review of the Toxicology of Glutaraldehyde, Critical Reviews in Toxicology, Roger O. McClellan ed., (1992) 22(3-4):143-174.

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2% METRICIDE 14 DAY ALL RESULTS IN PARTS PER MILLION

OLYMPUS ENDOSCOPES	AIR/WATER CHANNELS	SUCTION CHANNELS	INSERTION TUBE
XQ-10 PED. GASTROSCOPE	2.93	7.10	.13
CF1TV10L COLONOSCOPE	3.27	5.83	.00
GIFV10 GASTROSCOPE	3.40	5.57	.03
GIF-D3 GASTROSCOPE	2.52	3.95	.00
PENTAX NEVER BEFORE USED			
FG-29X GASTROSCOPE	1.33	2.52	.00
FC-34FX COLONOSCOPE	1.37	2.80	.03
FUJINON			
DUO-X DUODENOSCOPE	3.07	8.90	.20
UGI-F2 GASTROSCOPE	2.87	4.33	.03
SIG-EK SIGMOIDOSCOPE	3.03	3.00	.10
SIG-E4 SIGMOIDOSCOPE	1.63	2.17	.00

CONFIDENTIAL

2% CIDEX 14 DAY ALL RESULTS IN PARTS PER MILLION

OLYMPUS	AIR/WATER CHANNELS	SUCTION CHANNEL	INSERTION TUBE
XQ-10 PED. GASTROSCOPE	2.83	6.50	.00
CF1TV10L COLONOSCOPE	3.27	5.33	.03
GIFV10 GASTROSCOPE	3.00	6.00	.03
GIF-D3 GASTROSCOPE	2.57	4.17	.07
PENTAX			
FG-29X GASTROSCOPE	1.53	2.47	.00
FC-34FX COLONOSCOPE	1.50	2.67	.07
FUJINON			
DUO-X DUODENOSCOPE	3.00	8.73	.00
UGI-F2 GASTROSCOPE	2.70	4.23	.00
SIG-EK SIGMOIDOSCOPE	3.13	3.50	.17
SIG-E4 SIGMOIDOSCOPE	1.60	2.20	.00

CONFIDENTIAL

2% OMNICIDE 14 DAY ALL RESULTS IN PARTS PER MILLION

OLYMPUS	AIR/WATER CHANNELS	SUCTION CHANNEL	INSERTION TUBE
XQ-10 PED. GASTROSCOPE	2.87	6.47	.00
CF1TV10L COLONOSCOPE	3.17	5.37	.00
GIFV10 GASTROSCOPE	3.07	5.97	.10
GIF-D3 GASTROSCOPE	2.70	4.17	.03
PENTAX			
FG-29X GASTROSCOPE	1.83	2.40	.10
FC-34FX COLONOSCOPE	1.73	2.43	.10
FUJINON			
DUO-X DUODENOSCOPE	3.00	8.33	.03
UGI-F2 GASTROSCOPE	2.73	4.00	.00
SIG-EK SIGMOIDOSCOPE	3.17	4.00	.17
SIG-E4 SIGMOIDOSCOPE	1.83	2.30	.10

CONFIDENTIAL

3.2 % METRICIDE 14 DAY ALL RESULTS IN PARTS PER MILLION

OLYMPUS	AIR/WATER CHANNELS	SUCTION CHANNEL	INSERTION TUBE
XQ-10 PED. GASTROSCOPE	3.00	6.90	.20
CF1TV10L COLONOSCOPE	3.50	5.90	.00
GIFV10 GASTROSCOPE	3.53	5.93	.27
GIF-D3 GASTROSCOPE	3.00	3.00	.00
PENTAX			
FG-29X GASTROSCOPE	1.53	2.17	.00
FC-34FX COLONOSCOPE	1.50	2.33	.20
FUJINON			
DUO-X DUODENOSCOPE	3.33	8.60	.20
UGI-F2 GASTROSCOPE	2.87	5.93	.00
SIG-EK SIGMOIDOSCOPE	3.17	3.17	.27
SIG-E4 SIGMOIDOSCOPE	1.80	2.13	.07

CONFIDENTIAL

ANALYTICAL RESULTS FROM TWIN CITY TESTING FOR GLUTARALDEHYDE RESIDUE LEVELS.
2% Metricide

	AIR/WATER CHANNELS	SUCTION CHANNEL	INSERTION TUBE
CF1TV10L COLONOSCOPE	.00	3.00	.00
GIFV10 GASTROSCOPE	3.60	5.90	.00
XQ-10 PED. GASTROSCOPE	2.90	7.50	.00

See ATTACHMENT G.

CONFIDENTIAL

10. Provide a more complete description of how an endoscope is connected to the DSD-91, of the Qwik-load insert, of all accessories and hook-ups, and of the fluid pathway through the scope. The instructions do not clearly describe how an endoscope is connected to the DSD-91.

10. The Qwik-load insert is a basket that is intended to hold and transport the endoscope. There are no hook-ups involved with the basket.

Medivators supplies hook-up kits ordered by the end user. The kit required depends on the scope to be disinfected.

To clarify ease of hook-up installation for the reviewer we have included our instructions of two hook-up kits and the drawings for the individual parts included with a hook-up kit. The designator to the left of the individual parts on the drawing are the same designator referenced in the instructions. ATTACHMENT C.

To connect the kit, start with the piece 3a. The tubing (item 2) is slid on to the air inlet tube. To connect piece 5 you slide the tubing (item 6) on to the suction port and the water port adapter (item 5) is pressed into the water port. The quick connection then is plugged into the DSD-91. Correct flows are maintained in the smaller channels by the use of restrictors (item 7) on the larger channels.

11. Clarify the following items:

a. Provide the page number in the manual where the recommendation for a 20 minute disinfection cycle with a 2 % glutaraldehyde is stated.

11. a. First item in warning notes.

11 b. Provide a statement in the manual describing the water quality required for the DSD-91. This is related to the issue on the filter.

11 b. Potable water is used. Manual has been updated. See ATTACHMENT A. Page labeled "WARNING NOTES" and Page 1-4.

11 c. There is an air purge after each of the cycles and for the end of day processing; however, there does not appear to be a requirement for an air filter. Provide information in the manual on how the user would prevent the endoscope from becoming contaminate with particulate matter from the air compressor or the house air line.

11 c. The air compressor supplied by MediVators, Inc. is an oil-less type which means there would not be any oil or contaminants generated by the compressor.

Our experience with the predicate device confirms the above and also indicates that house airlines do not contaminate the endoscope. There are no complaints on file indicating contamination due to air lines. Medivators, Inc. has not received any inquires concerning this issue.

Maintenance and inspection of compressed air lines is required by J.C.A.H. under the section on Medical Gas Systems.

11 d. The recommendation in the manual for the alcohol purge and air drying of the endoscopes at the end of the day should be clarified to state that this should be done after the last procedure of the day for the endoscope.

11 d. Manual updated. See pages 2-1, 2-5, 2-6, 2-7. ATTACHMENT A.

CONFIDENTIAL

11 e. State why the set custom temperature option for the disinfectant is not available in the U.S. (pgs 3-6) and how this feature is disabled for U.S. models.

11 e. The current level of software is not able to handle the function of setting temperature so there is no need to disable.
Note: In the event the user wishes to use a heated germicide, Medivators will provide a manually temperature controlled heating system.

11 f. Clarify in the manual the purpose of screens 3 & 4 in the "Set Custom Program", pages 3-6 & 3-7.

11 f. These are screens that the end user observes while performing those functions. Clarification has been added to the manual to eliminate the confusion between A & B stations and A & B cycles. ATTACHMENT A, Pages 3-6, 3-7 and 3-8 .

11 g. Explain why the fluid level sensors can be inhibited, pg 3-8.

11 g. This function is used only during service and disinfectant change. Unless the sensors are inhibited during the disinfectant change the warning beeper* keeps sounding. Manual has been changed to state that this function should only by used when changing disinfectant. See page 3-9.
ATTACHMENT A.

*** This is a audio warning system to inform the user of a high or low level of disinfectant.**

11 h. Explain how the user can set the maximum disinfection cycle count, since most disinfectant manufactures set the reuse life based upon a manual cycle (pgs 3-10). The information that the disinfection cycle is based upon a 14 day reuse life disinfectant should be repeated at this point.

11 h. Manual has been updated. This information is now listed in the section labeled "Important" and "Warning Notes". It is also on page 3-11. ATTACHMENT A.
Reuse in the DSD-91 is calculated on manual reuse life.

11 i. The information contained in the Section "Disinfectant Change", pg 3-16, is inadequate. The manual must clearly state that, at a minimum, the disinfectant must be monitored daily.

11 i. Manual has been updated. See pages 1-8, 3-17 and WARNING NOTES in ATTACHMENT A.

11 j. The manual should contain a statement that the user should monitor the DSD-91 to prevent the development of biofilm.

11 j. The following statement has been added to the manual: ATTACHMENT A, WARNING NOTES. Though testing has shown that there is a low probability for the development of biofilms in the DSD-91, it is Medivators position that testing for biofilm formation should be a part of a comprehensive Infection Control program. Two methods should be used, A: During a rinse cycle, take samples from the water at the endoscope hook-up, This should be performed at least weekly. B: Monthly, disconnect the fluid lines and swab the line and valve opening. These samples should then be tested for organism growth and identification.

11 k. The sections in the user's manual identified as "IMPORTANT" and USERS NOTES' must be reconsidered. The statements appear to be more appropriate as either precautions or instructions for use. Revise accordingly. The validity of the statement regarding contact conditions for the germicide are contingent upon the issue noted in item 1 above.

11 k. Manual has been changed. ATTACHMENT A.

12. Since some of the 3.2% glutaraldehyde contain surfactant which cause foaming and the manual contains a warning about foaming with certain brands of disinfectants, tell us what information is given to the user.

12. To our knowledge only 28 day Glutaraldehyds have surfactant in them, except for Cidex, which has such a small amount that excessive foaming has not been reported in any of our machines. In addition during in-house testing no adverse foaming condition was observed. We do not recommend use of a 28 day disinfectant in our equipment. Our response to customers is the above and that they should contact the disinfectant manufacturer if foaming occurs.

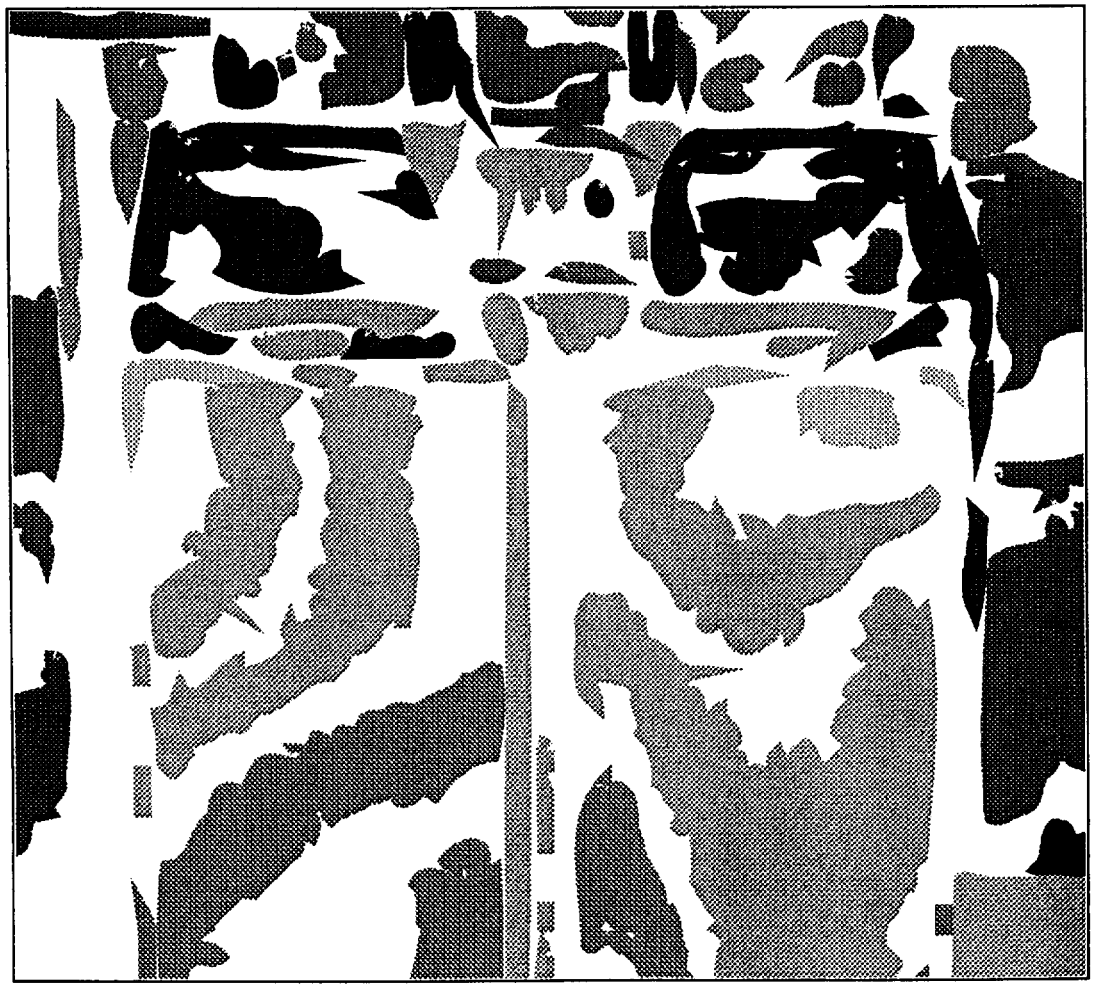
A

MEDIVATORS, INC.

INNOVATIVE MEDICAL PRODUCTS

Cannon Plaza South · Highway 52 South · Cannon Falls, MN 55009

DSD-91™ Disinfector for Flexible Endoscopes



USER'S MANUAL

Customer Service ·800/537-7324 · 507/263/4721

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MEDIVATORS, INC.

DSD-91 Disinfector for Flexible Endoscopes

USER'S MANUAL

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Manufactured in the United States of America

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IMPORTANT

- The level of disinfection is directly related to the disinfectant solution used and the amount of time the endoscope is exposed to the disinfectant solution. It is of importance that a disinfection protocol be established by the user of this equipment. These protocols must include systems to monitor their effectiveness.

- Pre-cleaning of the endoscope is essential.

- The labeling of the disinfectant solution must be rigidly adhered to. If labeling instructions are not strictly adhered to, the reuse life of the disinfectant could be significantly affected.

- The disinfect contact time cannot be set below 10 minutes.

- The 40 cycle warning light setting is based upon a 2% Glutaraldehyde disinfectant with a 14-day reuse life.

*WARNING NOTES

- **In laboratory studies, proper cleaning techniques in conjunction with a 20 minute disinfect cycle gave the best and most consistent results. All testing was performed with 14 day reuse 2% Glutaraldehyde.** The system as shipped is set at a 10 minute disinfect cycle. This cycle can be extended by the end user.

- ERCP endoscopes need additional cleaning and disinfection steps. Of particular importance is the elevator wire channel. This channel should be manually disinfected because it is uncertain whether it can be adequately disinfected in an automated unit.

- All endoscopes that are fully submersible and have facilities for leak/air tight testing should be leak tested prior to being submerged in any fluid.

- All endoscopes should be pre-cleaned following the manufacturers' instructions and recognized established society guidelines prior to being processed in an automatic washer/disinfector. Pediatric endoscope air/water channels may be more difficult to clean, Additional cleaning should be performed on these instruments.

- All disinfectants must be monitored on a daily basis for effectiveness. They should not be used beyond the time period they are rated for in the manufacturers labeling (eg. a 14 day disinfectant should not be used beyond 14 days even if it does test effective).

- All disinfectant and enzymatic detergent manufacturers' labeling must be followed.

- Operation of this equipment should be limited to those individuals trained in its proper use.

- The enzymatic dispenser should be removed, washed, and dried at the end of the day.

- After dumping used disinfectant, remove the lower reservoir, rinse, and wipe it with clean cloth. Wipe out the upper tank with a clean cloth. Paper towels should not be used.

WATER QUALITY

- **AT A MINIMUM, POTABLE WATER SHOULD BE USED.**

- **Due to differing water quality the water pressure regulators should be monitored frequently. If a drop of 5 p.s.i. in pressure occurs on the interior water pressure regulator during a rinse cycle, this is an indication that it is time to change the Sterapore filter. Otherwise a 6 month change is recommended. Call Medivators service if there are any questions.**

- All pressure regulators are factory pre-set. Do not attempt to adjust them without contacting Medivators Service Center first.

- If the enzymatic detergent or alcohol purge cycle are used, check the corresponding reservoir levels prior to starting

TESTING FOR BIOFILM

- **Testing has shown that there is a low probability for the development of biofilms in the DSD-91. However Medivators strongly recommends that testing for biofilm formation be a part of a comprehensive Infection Control program. On a weekly basis water samples should be taken from the endoscope hook-ups during a rinse cycle. A more comprehensive sampling should be done on a monthly basis. Disconnect the fluid lines at the valves and swab the line and valve opening. These samples should be tested for organism growth and identification.**

- Observe and compare the time of day as displayed by this device with the actual wall clock at the end of the programmed cycles to insure that there is no speed-up of the timing mechanism. Observe and compare the log for appropriate start and stop times to insure proper protocol timing. The colon (:) blink rate in the time display is timed to blink once per second.

If any questions arise regarding the use or servicing of the Medivators DSD-91 please contact our Service Department at:

1-800-537-7324

Professional established guidelines for cleaning and disinfection of endoscopes should be followed. A protocol should be developed by the user based on such guidelines. The following organizations have published recommended guidelines.

Society of Gastroenterology Nurses and Associates

1070 Sibley Tower

Rochester, NY 14604

(716) 546-7241

Association of Operating Room Nurses

10170 East Mississippi Avenue

Denver, Co 80231

(303) 755-6300

American Society for Gastrointestinal Endoscopy

13 Elm Street

P.O. Box 1565

Manchester, Ma 01944

(508) 562-8330

Association for Practitioners in Infection Control

505 E. Hawley Street

Mundelein, Il 60060

(708) 949 6052

Chapter 1
Specifications and Instrumentation

Chassis Dimensions

46" high, 36" wide, 21" deep

Weight

Approximately 350 pounds

Electrical Requirements

110 VA, 60 HZ, 15 amp
220 VA 50 HZ 8 amp

Water Requirements

Building water supply, Potable water (regulated for 17-20 p.s.i.)

Air Requirements

Compressed air at 40-100 p.s.i. (regulated at 10 p.s.i. inside machine)

Compressed air is required for operation and may be supplied externally, or by an optional air compressor.

Reservoir Capacity

Disinfectant reservoir (4 gallons each). Left and right upper tanks (2.4 gallons)

Rinse Water Consumption

Approximately 5 gallons per cycle

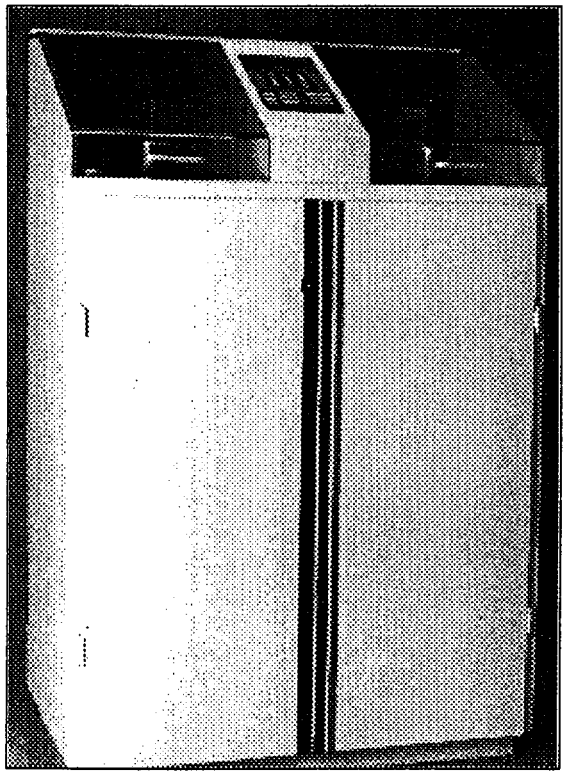

Illustration 1-1

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General

The MediVator DSD-91 disinfector comprises two disinfectant stations. These stations may operate independently (asynchronously) or in total synchrony with each other as desired by the user.

The station on the left-hand side of the device is referred to as "Station A" while the station on the right-hand side of the device is referred to as "Station B."

Each station is fully equipped with independent valves, disinfectant reservoirs, disinfectant pumps, and (optional) air compressors. The only common equipment is the power supply and the electronic circuitry. As a result of this design, the occurrence of a device failure for one of the stations is unlikely to affect the operation of the other station.

This design may be used to accommodate different disinfect chemistry and cycles for each of the stations.

Terms and Definitions

- **Cycle**
  A specific sequence of events comprising a major group of activities (e.g., the loading, soaking, and elimination of solution from the upper tank).

- **Default program**
  The disinfect program that is executed when no alternate program is selected by the operator.

- **Disinfecting chamber**
  See "upper tank."

- **Function**
  Any operation other than a disinfect program (e.g., a DISINFECTANT DUMP cycle).

- **Idle state**
  A standby state where no program cycles or other functions are in progress. Many setup and initialization functions require that the station be in the idle state prior to their operation.

- **Phase**
  A portion of a cycle that performs an auxiliary function within that cycle (e.g., compressed air purge phase at the end of a cycle).

- **Program**
  A series of cycles that perform a specified disinfect protocol.

- **Reservoir**
  The container used to hold the disinfecting solution between disinfect protocols.

- **Running**
  A state where a program is in progress, or some other function is occurring (i.e., any state other than IDLE or STOP).

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- **Station**
  The portion of the DSD-91 that is utilized to disinfect a single endoscope. This includes the upper tank, disinfectant reservoir, valves, hoses, pump, and (optional) air compressor.

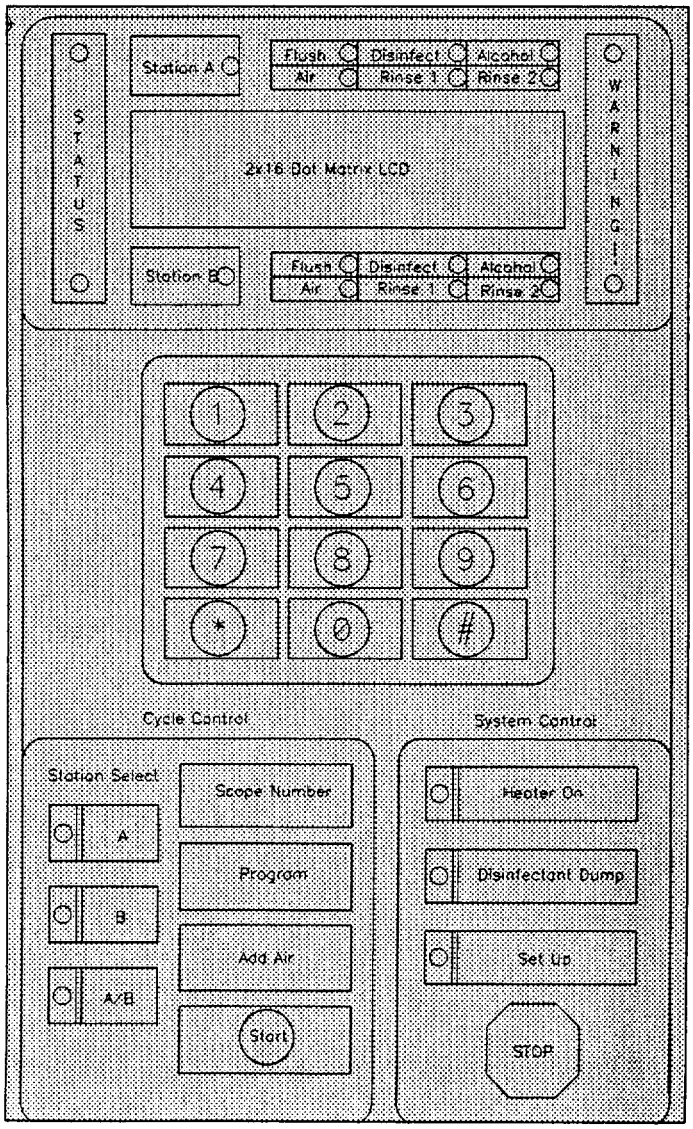
- **Stop state**
  A program state where a disinfect protocol is in progress, but the current cycle is suspended. A program may be suspended due to operator intervention, or due to the detection of an error condition.

- **Upper tank**
  The chamber into which the basket containing the endoscope is inserted prior to starting the disinfect program.

Control Panel Layout

Setup and operation of the DSD-91 disinfector is controlled by the membrane control panel located on the top and center of the device.

This control panel comprises three major operation sections. These sections are (1) the station status and warning indicators, (2) the numeric keypad, and (3) the station select and function keys.



Status and Warning

Numeric Keypad

Station Select and Functions

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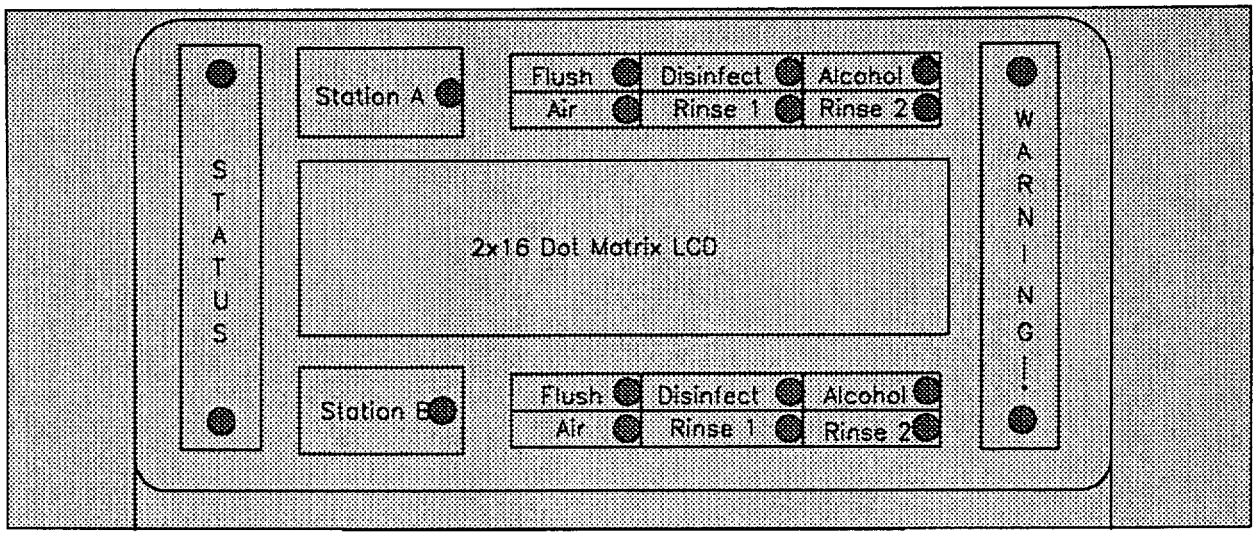
Status Area

The status area of the panel contains LED indicators and a dot matrix Liquid Crystal Display (LCD). The LED indicators are used to show current cycle status while the LCD is used to display detailed status/warning and other information as needed for the operation of this device.



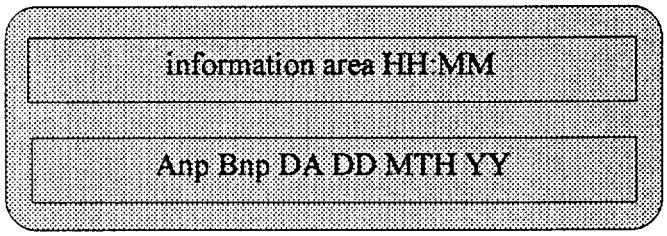
Status Indicator Area of Control Panel

The LCD has two lines of 20 characters. Normally the current time-of-day is displayed in the upper right-hand portion of the display, the day-of-week and date is displayed in the lower right half, and the current station program selection and operational status is displayed in the lower left half portion of the display.

The colon in the time-of-day portion of the display flashes on and off at one-second intervals to provide an indicator that the system is functioning.

The station status display provides an indication that operates when the corresponding station is running.

The STATUS BAR contains an upper and a lower LED indicator to show the STOPPED status for stations A and B, respectively. When either of these indicators are blinking, it shows that the



General LCD Information Layout

HH:MM indicates the current time of day.
Anp Bnp indicates the current operational status of the A and B stations, respectively. The "n" indicates the program selected ranging from 0 (default) to 1 through 9 (user defined programs). The "p" is the pacifier indication that operates when the station is running.
DA indicates the current day-of-week.
DD MTH YY indicates the current day, month, and year.

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associated station is in the STOPPED state, and is not yet idle. The stopped state is entered whenever a system error condition is detected that affects that station, or when the STOP key is pressed. The blinking status light is to remind the operator that the program for that station has not yet successfully terminated.

The CURRENT CYCLE STATUS indicators for station A are located above the LCD window, and the indicators for station B are located immediately below the LCD window.

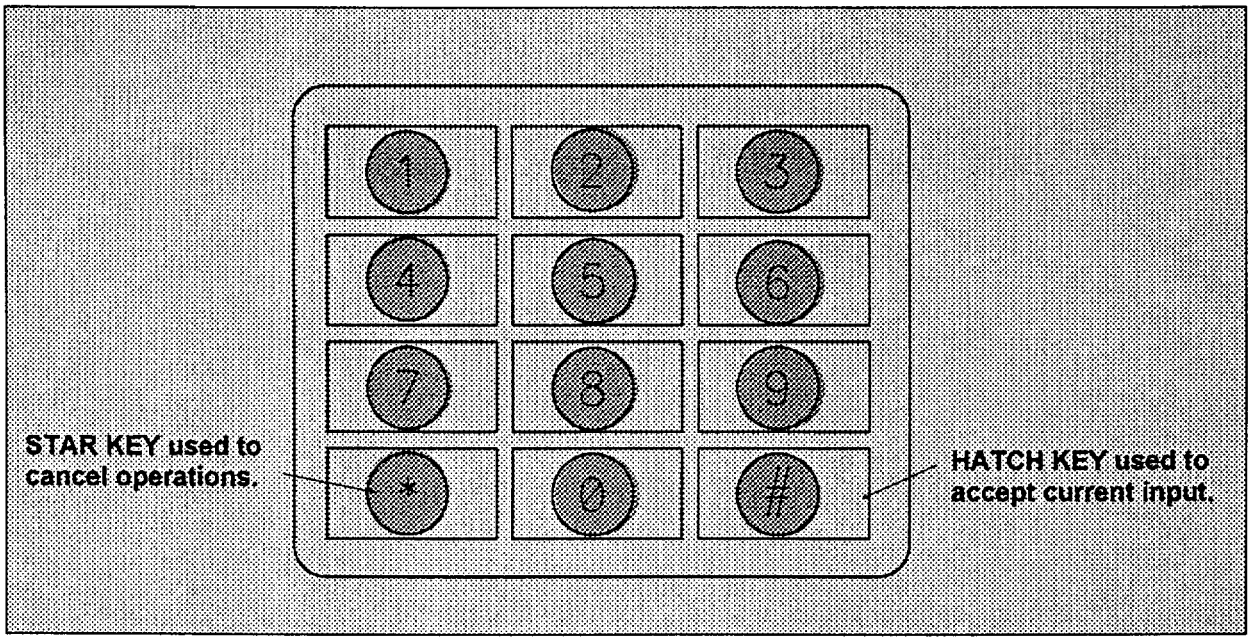
The STATION indicator is used to show that an operation is currently running for that station. This LED is extinguished if the station should enter the STOPPED state, or when the program has completed.

A steady state on any of the CYCLE STATUS indicators shows the specific disinfect cycle that is currently in progress for the associated station.

A blinking AIR indicator informs the operator that the current cycle (shown by the steady state indicator) is in the final air purge phase of that cycle.

The WARNING BAR also contains an upper and a lower LED indicator. This is the warning status for stations A and B, respectively. These indicators blink whenever any condition that may need operator attention occurs for the associated station. The LCD typically contains additional information regarding the warning status.

Keypad Area



Keypad Area of Control Panel

The keypad area of the control panel is used to enter numeric parameters. This is required for many functions performed by several other keys on the panel.

Generally, a specific function key will be depressed, followed by a number sequence on the keypad. The LCD will always prompt the operator to indicate the expected or required action.

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If the number string is correct as entered, it is accepted by depressing the HATCH (#) key.

If the last digit entered is incorrect and is to be CANCELED, the STAR (*) key is depressed to allow it to be re-entered.

The STAR key is also used in other contexts to cancel other operations.

Station Select and Function Area

The bottom portion of the membrane panel is dedicated to station selection and function control.

This area is subdivided into two general areas:

1) cycle control and

2) system control.

The left half is used for station selection and cycle control options. The right half is used for system-wide control and options.

Station Selection

Most functions apply only to the currently selected station or stations.

As a result the operator must insure that the appropriate station selection indicator is lit prior to executing the desired function. If the desired station(s) has not been selected, simply depress the corresponding station select key.

For example, assume that the station A indicator lamp is current lit. To start the current program for station B, the operator observes that station B is not currently selected. Since it is not, the station B select key must be depressed. Now the START key may be depressed to initiate the current program.

Depressing any station select keys while a station is idle clears the current scope number.

Cycle Control

The cycle control section of the panel contains keys that are used to alter current program cycles for the selected station(s). Most of these keys can be activated only when the selected station is in the idle state.

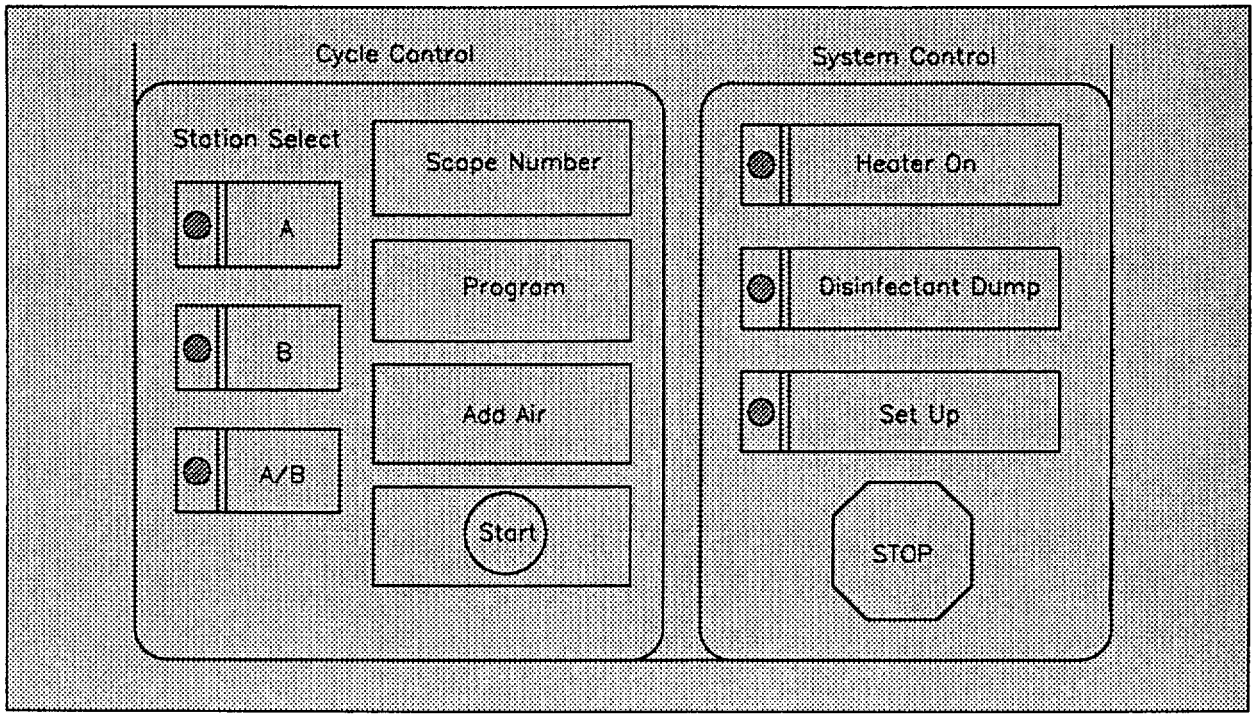
The keys that perform these functions are (1) the Scope Number key, (2) the Program key, and (3) the Add Air key.

The **SCOPE NUMBER** key is used to allow the serial number, or other reference number for the scope about to be disinfected to be recorded into the system operation log along with the date, time, program selected, and completion status information. This information remains in the operation log until it is off-loaded to a logging device (usually a personal computer) via the (optional) RS-232 serial interface port or it is explicitly cleared by one of the setup functions.

If the operation log is full, no additional logging will occur.

The **PROGRAM** key is used to select a special disinfect cycle that has been customized by the individual clinic to meet specific needs. The DSD-91 can have up to nine customized

programs retained in nonvolatile system memory. Any of these customized programs may be altered at any time by the operations staff.



Station Select and Function Area of Control Panel

The **ADD AIR** key is used to add an additional compressed air cycle at the end of the currently selected program. This is typically a 20 minute cycle used at the end of the day to insure that the endoscope is thoroughly dry prior to storage.

This key may be activated at any time.

Start key

The **START** key is the primary cycle control. It is used to initiate a program sequence, or is used to restart a program in progress that has been interrupted for any reason.

System Control

This portion of the control panel is used to set options and functions that affect all programs until they are altered again.

The **HEATER ON** key is a toggle that causes the reservoir heat option to be enabled or disabled for the selected station.

- **NOTE: Follow disinfectant manufacturers labeling when determining required temperature.**

If the heat option is on, the DSD-91 software enables power to the reservoir heating elements.

The **DISINFECTANT DUMP** key is used to cause the DSD-91 to eliminate the disinfectant from the selected reservoir. This is done after it has been determined that the disinfectant is no longer effective or has reached its expiration period.

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The **SET UP** key is used to initialize various system and station options. These options are described elsewhere in this manual.

The **STOP** key is used to temporarily halt the current program for the selected station. The

CAUTION : All disinfectants must be continually monitored on a daily basis for effectiveness.

START key may be used to resume the program where it was halted, or the **CANCEL** key (the star key on the keypad) may be used to terminate the program. A terminated program may have to go through a drain/purge cycle prior to going into the idle state.

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Chapter 2
Overview

This chapter provides an overview of the design, functional, and program features that have been built into the DSD-91 disinfector workstation.

Design Features

Synchronous and Asynchronous Operation

The DSD-91 disinfector stations may be run synchronously with each other if it is desired to disinfect two endoscopes using identical station timings and program cycles.

Synchronous operation is not required, however. This device has been equipped with separate reservoirs, pumps, motors and valves that allow complete asynchronous, on demand operation for each station. Any station may be put into use regardless of the status of the other station.

Quick-Connect Hookup

Minimizes the complexity of endoscope hookups to the disinfector.

Alcohol Purge

Available to aid the end-of-day drying process, after the last procedure of the day for the endoscope.

CAUTION

See endoscope manufacturer's comments regarding the use of alcohol.

Compressed Air

Programmed segment of the cycle that minimizes loss and dilution of disinfectant.

The ADD AIR button is for additional drying of the scope channels.

CAUTION

This cycle will not completely dry channels as required for end-of-day storage.

- **NOTE: The optional air compressor or a source of compressed air is required.**

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Disinfectant Filtration

Eliminates recycling of particulate matter through the scope channels. This filter is located between the reservoir and the pump. The pump draws disinfectant from the reservoir through the filter prior to going to the endoscope.

Maintenance

No daily maintenance is required. The operator should assure proper water pressure, disinfectant monitoring is complete. Enzymatic detergent and alcohol dispensers are filled if these options are selected. Check device clock.

All unit disinfector lines are disinfected while first scope of the day is put through a complete cycle.

Minimal Exposure to Disinfectant

The disinfectant reservoir inside the cabinet is tightly covered and virtually eliminates the escape of toxic vapors.

Unique, easy disinfectant loading procedure simplifies the reservoir replenishment.

Activating the DISINFECTANT DUMP button and pushing the start button on the control panel dumps disinfectant into the drain or receptacle.

Power Fail Restart

This equipment has been designed to tolerate line power brown-out and failure conditions.

The condition of the power supply is constantly monitored. If a brown-out condition is detected, the central processing unit is notified, the software checkpoints the current operational status in non volatile memory, all valves and motors are turned off to prevent stress damage to electromechanical components, and processing is suspended.

When proper power conditions are restored, the system resumes operation at the same point in the cycle that was interrupted, regardless of whether the power failure was a brown-out or a total black-out condition.

Temperature monitoring (Optional)

This option is not available in the U.S.A.

This option allows the disinfectant to be monitored for appropriate temperature levels. If the disinfectant in the reservoir fails to meet or exceed the specified minimum temperature, the disinfection cycle will be stopped and an error warning condition will be issued. A disinfection cycle that has been stopped must be manually restarted using the normal error restart procedure after the required temperature has been reached.

Watchdog Circuitry

A watchdog circuit has been implemented on this equipment to monitor its operational status. If the equipment fails to operate as expected, the watchdog circuit resets the processor and causes the program cycle to be reinitiated at the point that the failure occurred.

This circuit makes the device immune to failures that could be caused by the harsh electrical and magnetic impulse noise that is often present in the hospital/industrial environment.

Status Logging

The DSD-91 automatically logs the device usage history, error status, and other statistics as significant events occur.

This log can be manually examined through the use of the control panel function keys and LCD.

RS-232 Interface (Optional)

The DSD-91 offers an optional RS-232 interface that allows off-loading of the device log to other media (usually an IBM compatible personal computer).

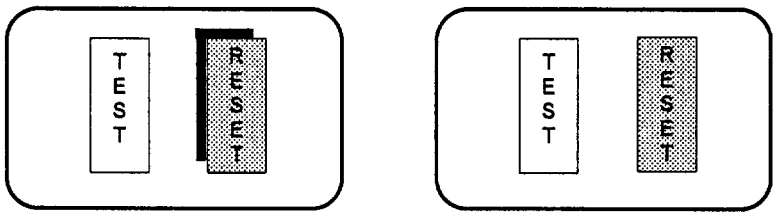
Non volatile Memory

The DSD-91 device log is maintained in non volatile memory. This means that under most circumstances, the device log will be retained even if the computer system requires repair or replacement.

100% Solid-State Electronics

The electronic control system for this device is completely solid state. This significantly increases reliability and aids in reducing electromagnetic interference and emissions caused by the switching of high-current equipment.

Special electronics have been included to insure that AC line-driven valves, motors, and heaters are switched on and off during the optimal portion of the AC line cycle.



If RESET button is out or tripped as shown above, simply push RESET button in.

Illustration 2–1

Circuitry

Designed to eliminate burnout. Automatic Ground Fault Interrupter (GFI) is included.

The GFI is a safety feature designed to protect the unit from power overloads. It is located inside the cabinet toward the bottom of the unit.

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Depot Maintenance

Repair of electronics are accomplished by swapping the entire computer mother board in order to minimize down time due to electronic failure.

The mother board has been designed to distribute line, control, and logic voltages to the entire system via an extremely efficient and reliable mechanism.

This distribution mechanism uses four wiring harnesses and one or two ribbon cables (depending on options selected) as illustrated in figure 2-2 below.

(1) The system line harness

This harness contains all cables necessary for the 110/220 VAC line voltage distribution system. It is attached to the mother board using a single 4-pin, locking, quick disconnect socket.

(2) The control and logic supply harness

This harness contains all cables necessary for providing the system with the 5-volt logic supply and the 24 VDC control supply. It is attached to the mother board using a single 6-pin, locking, quick disconnect socket.

(3) The station control harness

This harness contains all cables required for operating the valves, motors, pumps, and heaters for both of the stations. It is attached to the mother board using three 15-pin, locking, quick disconnect sockets.

(4) The station sensor and alarm harness

This harness contains all cables required to sense disinfectant levels, disinfectant temperatures, as well as the audible alarm. It is attached to the mother board using a 20-pin friction-fit socket.

(5) The control panel ribbon cable

This ribbon cable contains all of the power, ground, and logic signals required to interface with the control panel. This cable uses a standard 40S-40S-IDE ribbon cable.

(6) The optional RS-232 ribbon cable

This ribbon cable contains all of the standard RS-232 signals required to interface with most IBM compatible personal computers. One end of this cable 6-pin friction-fit socket, and the other end is connected to a 9-pin D-sub socket that is accessible via the front control panel of the DSD-91 system.

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Functional Features

Standard Delivered Cycle Time

The standard (nominal) cycle is preprogrammed at the factory and is approximately 20 minutes including a 10 minute disinfectant cycle. Cycle times may be easily reprogrammed by the user to meet specific installation needs.

Compressed Air Purge

Integrated into the disinfect and rinse cycles to minimize loss and dilution of the disinfectant.

Alcohol/Air Purge

Available to aid in end-of-day channel drying, after the last procedure of the day for the endoscope.

CAUTION

See endoscope manufacturer's comments regarding the use of alcohol.

Diagnostic aids

The DSD-91 has been designed to facilitate isolation and repair of faults in the field.

All valves, motors, and pumps can be individually exercised by field maintenance personnel using a special diagnostic port access mechanism. This allows rapid isolation of individual electromechanical parts.

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Programmed Features

The DSD-91 Disinfector is an integrated system designed to disinfect and rinse all flexible endoscopes without requiring the presence of an attendant during the entire disinfection process.

Cycles: Nominal

The first 30 seconds of flow for each cycle is directed through the scope channels only. This helps prevent air lock within the small scope channels. If air becomes trapped in a channel, it will block the flow of disinfectant and rinse water into that channel.

Flush Cycle

Detergent and water are flushed through the interior channels to insure that channels are not clogged. This water goes to the drain. This cycle should be observed by the operator.

Purge Cycle

After draining, the scope channels and unit lines are purged by compressed air.

Disinfect Cycle

Disinfectant is pumped through the scope channels and into the upper tank. This cycle has two phases. The "A" phase is used to fill the upper tank and circulate disinfectant around the entire scope. During the first 30 seconds of the "A" phase, and for the entire "B" phase, disinfectant flow is concentrated through the scope channels. At the end of this cycle, the disinfectant is drained from the upper tank and returned to the reservoir.

NOTE

Disinfectant is circulated through the biopsy/suction, air, water, and colonoscope CO_2 channels.

Rinse Cycle

Water is circulated around scope insertion tube and pumped through the interior channels. The first 30 seconds of flow is to the scope channels only. During and after the RINSE cycle, water is drained and discarded.

Alcohol Purge Cycle

An "on demand" ALCOHOL PURGE cycle is built into the system to aid with end-of-day drying, after the last procedure of the day.

CAUTION

See endoscope manufacturer's comments regarding the use of alcohol.

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Additional Air Purge Cycle

Allow additional air purging to aid in the end of day drying At completion of the total cycle time, the endoscope is ready for reuse. Note that 15-20 minutes of compressed air drying of channels should be done before end-of-day storage.

User Modifiable Program Cycles

There is one standard, and up to nine user modifiable programs. The user modified programs are stored in non volatile memory.

Each program has six cycles. Each of these cycles may have their length altered as described in the table on the next page.

As a result of the unique method used to record this information, all custom programs and other user defined settings are retained even if the computer mother board has to be repaired or replaced (except when the non volatile memory itself has failed).

Individual Temperature Control (Optional, not available in U.S.A.)

Each station has its own heater and temperature sensor. The DSD-91 allows individual minimum, maximum, and shutdown temperature settings to be maintained for each disinfectant reservoir.

If the disinfectant temperature falls below the minimum temperature setting for that station, the heater is turned on until the maximum temperature has been reached. If the reservoir falls below the shutdown temperature, operation is halted for that station until corrective action is taken.

Typically, the shutdown, minimum, and maximum temperatures will be set to within one degree of each other. For example, if the target temperature required for a disinfection protocol is 120° F, the shutdown temperature is set at 119° F, the minimum temperature is set at 120° F and the maximum temperature is set at 121° F.

The temperature sensors are accurate to within 1° F.

- **NOTE: Follow disinfectant manufacturer labeling when determining required temperature.**

Programmed Heater Startup and Shutdown

The DSD-91 has a unique feature that allows the optional reservoir heaters to automatically be turned on at the beginning, and to be shut off at the end of the normal work day.

This feature conserves the energy used by the heater to maintain the disinfectant temperature, while assuring that the reservoir temperature will be high enough at the time that the first disinfecting procedure of the day is started.

Optional manually controlled temperature heaters are available.

DSD-91 Standard Program				
Cycle	Time	Description	Min.	Max.
(1) Pre Disinfect	30 Sec	Flush detergent through scope channels with water	0 Sec	90 Min.
	5 Sec.	Compressor startup	factory set	factory set
	30 Sec.	Air purge of scope channels	factory set	factory set
(2) Disinfect	30 Sec.	Scope channel flush with disinfectant	factory set	factory set
	5 Min.	upper tank fill and circulation	5 Min.	90 Min.
	10 Min.	Scope channel disinfect	10 Min.	90 Min.
	65 Sec.	Disinfect drain	factory set	factory set
	5 Sec.	Compressor startup	factory set	factory set
	30 Sec.	Air purge of scope channels	factory set	factory set
(3) Rinse 1	30 Sec.	Scope channel flush with water	factory set	factory set
	4 Min.	Water rinse	4 Min.	90 Min.
	65 Sec.	Drain	factory set	factory set
	5 Sec.	Compressor startup	factory set	factory set
	30 Sec.	Air purge of scope channels	factory set	factory set
(4) Rinse 2	30 Sec.	Scope channel flush with water	factory set	factory set
	4 Min.	Water rinse	0 Min.	90 Min.
	65 Sec.	Drain	factory set	factory set
	5 Sec.	Compressor startup	factory set	factory set
	30 Sec.	Air purge of scope channels	factory set	factory set
(5) Alcohol	0 Sec.	Scope channel flush with alcohol	0 Sec.	120 Sec.
	5 Sec.	Compressor startup	factory set	factory set
	30 Sec.	Air purge of scope channels	factory set	factory set
(6) Air	5 Min.	Scope channel flush with compressed air	0 Min.	90 Min.

Chapter 3
Operation

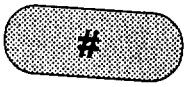
The operation of the DSD-91 has been designed to be simple for those installations that require only the standard disinfecting protocol, while retaining enough flexibility to meet the most demanding of protocol variations for complex installations.

Specific instructions for operating the equipment are described in this section. This section is organized by topic and specific keystroke sequences are specified.

Conventions for describing various keystrokes are as follows:

The selection of the A, B, or A/B stations by depressing one of the three station select keys.

The entry of a number by using one or more keystrokes on the numeric portion of the keypad.



The "enter" key generally used to indicate acceptance of a numeric data series.

The SCOPE NUMBER key used to allow the entry of an identifier denoting the endoscope.

The PROGRAM key used to allow the selection of a specific disinfecting protocol.

The ADD AIR key used to extend the air dry cycle for an endoscope.

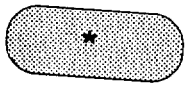
The START key used to start the selected disinfect protocol.

The HEATER ON key used to enable the optional disinfectant reservoir heaters.

The DISINFECTANT DUMP key used to unload disinfectant from the reservoir.

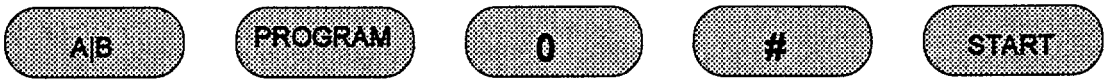
The STOP key used to suspend current station activity.

The SETUP key used for various auxiliary operations.



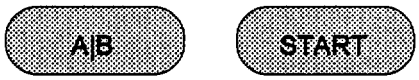
The CANCEL key used to erase numeric data that has been entered, or to cancel the currently running disinfect program protocol.

Run Default Disinfect Protocol



Operation using the default protocol where logging of individual scopes is not required is as simple as selecting the desired station, selecting factory default program 0, pressing the start key, and waiting for the cycle to complete.

Shortcut



If the program selected for that station is already 0, or if none of the programs have been user altered, then you may simply select the station and press the start key.

Run Selected Disinfect Protocol

Operation using a selected protocol where logging of individual scopes is not required is accomplished by using the PROGRAM key to select the specific, user-defined disinfect protocol. The user must have pre-programmed a protocol prior to using this function.

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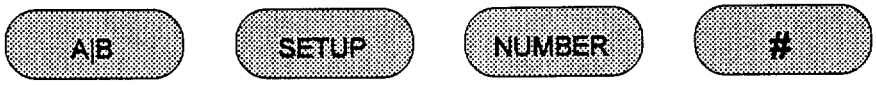
Log Endoscope With Selected Protocol

This sequence is used to log a specific endoscope with the following disinfecting procedure. The sequence following the # key is one of the protocol run selection sequences described above, starting AFTER the station selection key.

Depressing the A,B, or A/B station selection keys clears the endoscope number. This is to insure that an endoscope that has been logged for a previous procedure does not inadvertently become logged with the current procedure.

Set Up



This sequence is used to set options, read-out usage log, and load the disinfectant reservoir.

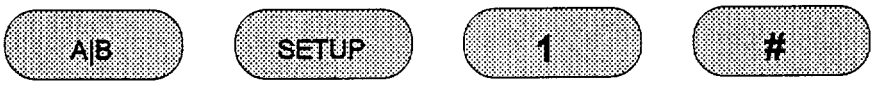
To enter the setup mode, both stations must be in the IDLE state. This is because most of the available setup functions (such as set date and time) affect the operational status of both of the system's station and could cause logging errors or other system failures if they were changed while a station was in operation.

Observe the setup LED when the SETUP key is depressed, and the LCD prompt.

Note that depressing the STAR key while in this mode will erase the numeric data entered, allowing it to be re-entered.

The following functions are all entered through the SETUP key as described above.

Load Disinfectant



This function is used to load fresh disinfectant into the selected station's reservoir.

Prior to starting this function, insure that the reservoir is empty.

To load disinfectant, load $2^1/_2$ gallons of fluid into the appropriate upper tank.

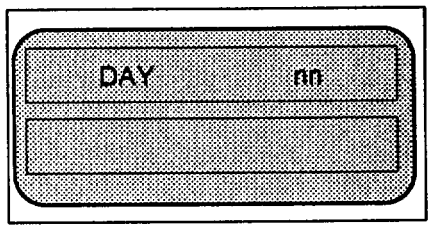
Start the load sequence adding the remaining fluid as the tank level drops.

Set Date

This function is used to set the date in the system clock/calendar. This function requires multiple screen interactions to complete.

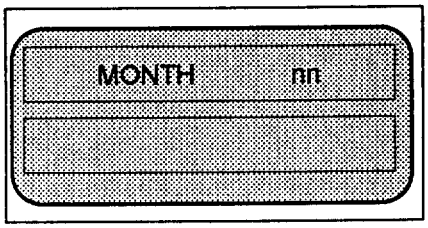
Screen 1, Set Day:

If the day displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct day. When the proper day has been entered, press the #-key.



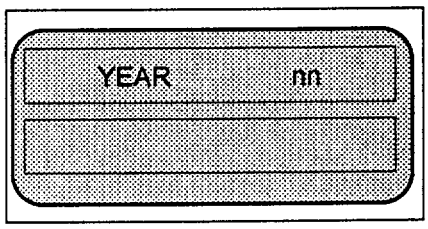
Screen 2, Set Month:

If the month displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct month. When the proper month has been entered, press the #-key. The valid numbers are 1-12.



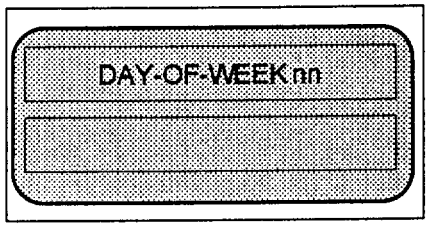
Screen 3, Set Year:

If the year displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct year. When the proper year has been entered, press the #-key. The valid numbers are 90-99 and 0-09.



Screen 4, Set Day-of-Week:

If the day-of-week displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct day-of-week. When the proper day-of-week has been entered, press the #-key. The valid numbers are 1-7 and Sunday is the first day of the week.



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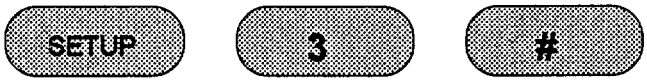
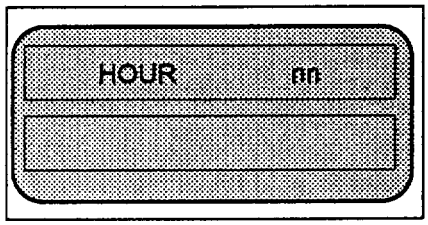
Set Time



This function is used to set the time on the system clock/calendar.

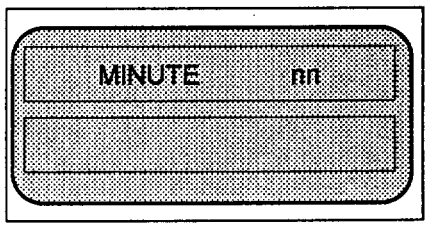
This function requires multiple screens to complete.

Screen 1, Set Hour:



If the hour displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct hour. When the proper hour has been entered, press the #-key. The valid numbers are 0-23.

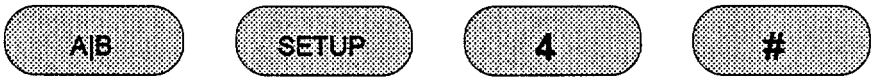
Screen 2, Set Minute:



If the minute displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct minute. When the proper minute has been entered, press the #-key. The valid numbers are 0-59.

The seconds portion of the time is automatically set to zero.

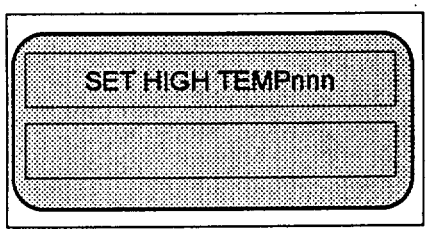
Set Custom Temperature



This function is used to set the target disinfectant temperature to custom installation values. This function is effective only for those installations with the advanced heater control option.

Note: This feature not available in the U.S.A. or its territories. Follow disinfectant manufacturers labeling for determining proper temperature settings.

Screen 1, Set High Temp:



This screen is used to set the target temperature for the selected station. When this temperature is reached, the heating element is turned off.

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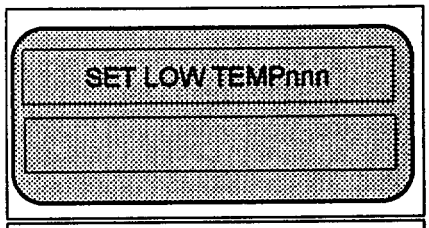
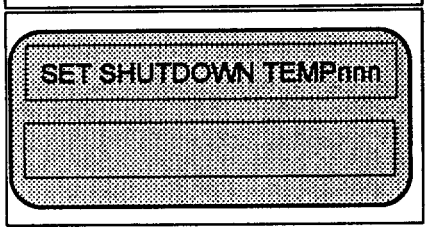
Screen 2, Set Low Temp:

This screen is used to set the minimum temperature for the selected station. When the reservoir temperature drops below this setting, the heating element is turned on.

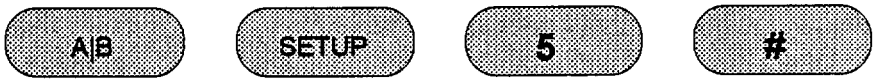


Screen 3, Set Shutdown Temp:

This screen is used to set the minimum acceptable temperature for this station. If the reservoir temperature falls below this setting, the station is forced to suspend its current operation and a warning alarm is sounded.



Set Custom Program



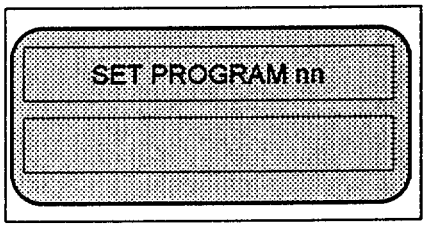
This function allows custom alteration of cycle times to be set for an installation.

All programs are set to the factory default when the system is shipped.

Creating a custom program protocol is a multi-screen operation.

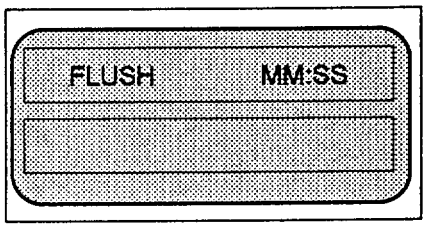
Screen 1, Set Program nn:

This screen is used to select the program that is to be altered. The valid programs that may be altered are 1-9. Program 0 cannot be altered and will always remain at the factory default setting.



Screen 2, Flush:

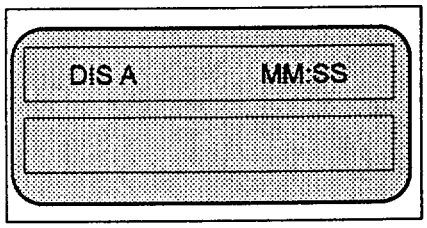
Set the FLUSH cycle time.



The following should <u>not</u> be confused with station A, B. They are components of the disinfection cycle. ***See illustration 3-A on page 3-8.***

Screen 3, Dis cycle A: (Disinfect cycle A)

Set the disinfect A cycle time. This cycle comprises disinfectant filling into the upper tank and tank circulation.



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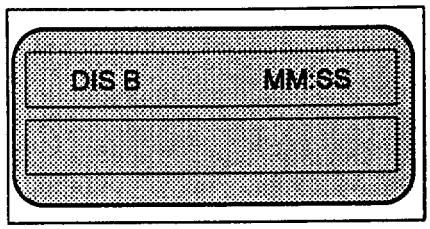
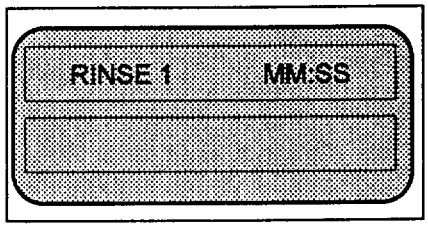
Screen 4, Dis B: (Disinfect cycle B)

Set the disinfect B cycle time. This cycle circulates disinfectant through the scope channels only.



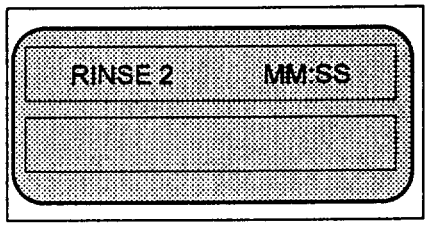
Screen 5, Rinse 1:

Set the RINSE 1 cycle time.



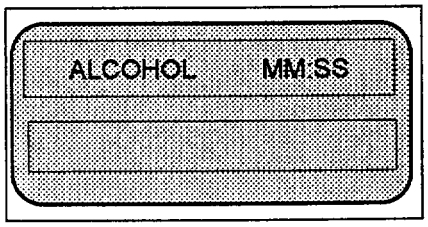
Screen 6, Rinse 2:

Set the RINSE 2 cycle time.



Screen 7, Set Alcohol:

This screen is used to enable or disable the alcohol dispensing prior to the AIR cycle.

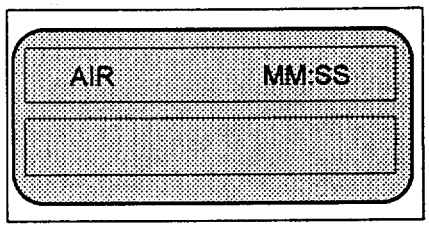


CAUTION

See endoscope manufacturer's comments regarding the use of alcohol.

Screen 8, Set Air:

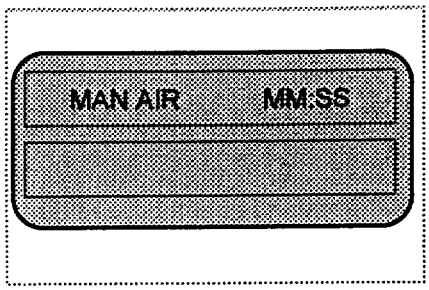
This screen is used to set the AIR cycle time.



Screen 9, Set Manual Air:

This screen is used to set the MANUAL AIR cycle time. The MANUAL AIR cycle is added whenever the ADD AIR key is depressed.

Note that if any cycle time is already correct, setting that program cycle may be skipped by pressing the #-key without entering any numbers.



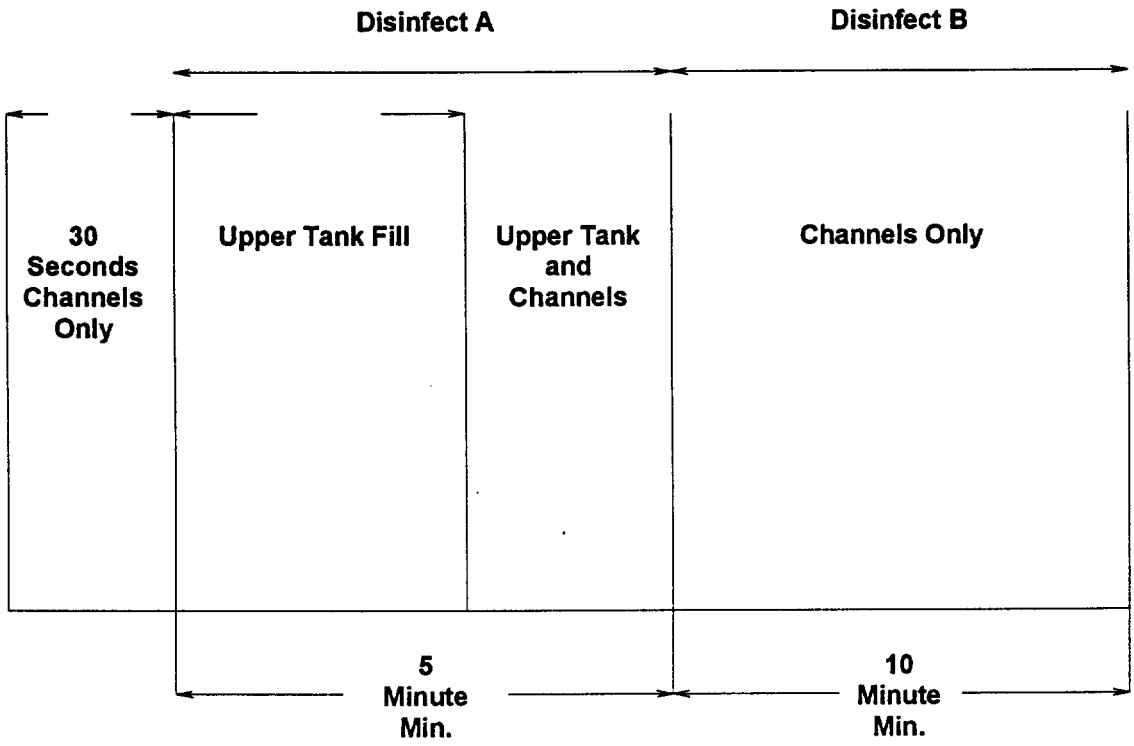
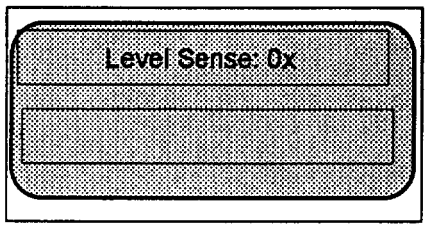


Illustration 3-A

Inhibit Fluid Level Sensors

SETUP 6 #

This function is used to disable the fluid level sensors. The disable mode should only be used when changing disinfectant.

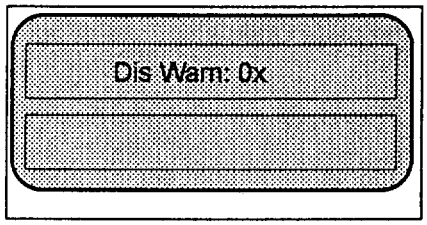


00: enable all level sensors
01: disable station A level sensors
02: disable station B level sensors
03: disable all level sensors

Disinfectant Cycle Warning Override

SETUP 7 #

This function is used to acknowledge the disinfectant cycle count warning. After the warning is acknowledged, 10 additional disinfection cycles will be allowed.



01: Station A warning ackknowledged
02: Station B warning acknowledged
03: Both station warnings acknowledged

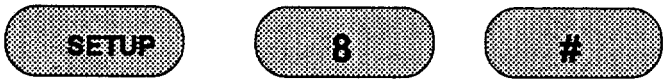
The DSD-91 is designed to prevent an excessive number of disinfection cycles from being run on a batch of disinfectant. The system will not be allowed to start a disinfection program when the number of disinfection cycles that has been run is ten less than the maximum number of cycles allowed until the warning is acknowledge using this function.

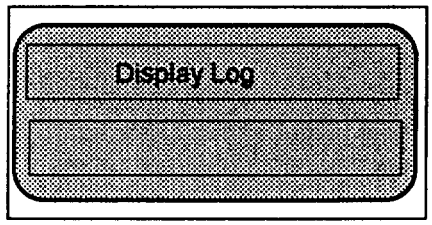
Note: This warning is valid only when the maximum disinfection cycle count has been set to an appropriate value. The default maximum number of disinfection cycles is 50, and the warning occurs at 40 cycles.

WARNING

¤ **This function is not a replacement for daily monitoring of the Minimum Effective Concentration (M.E.C.) of the disinfectant. Refer to the labeling or the manufacturer of your disinfectant for the proper procedure.**

Display Log





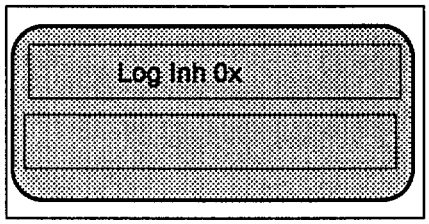
This function is used to review the log on the display. The entire log is displayed in most recent to least recent order, one entry at a time. As the ENTER key is pressed, the next oldest entry is displayed in order until all entries have been displayed, or until the SETUP key is pressed to exit the display function.

Log Inhibit

This function is used to disable the data logging function.

This function is used only in the unlikely event that the logging function causes the system to malfunction.

00: enable data logging
01: disable data logging



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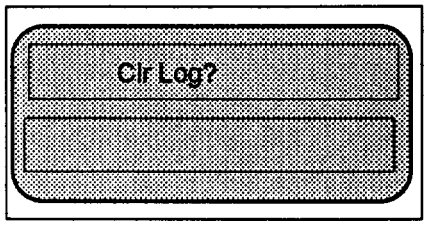
Clear Log

SETUP 10 #

This function is used to clear the data log. This must be done periodically to allow new data entries to be made.

To actually clear the log, press start when this screen appears. Any other key causes the operation to be canceled.



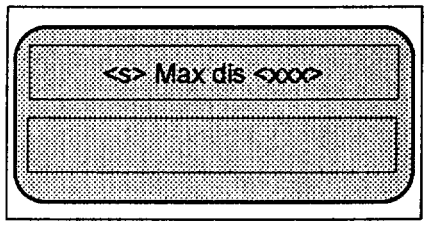
Set Maximum Disinfection Cycle Count

A or B SETUP 12 #

This function is used to set the maximum number of disinfection cycles that can be run by the selected station before a new batch of disinfectant must be loaded.

Note: The maximum disinfection cycle count must be set according to disinfectant manufacturer's specifications.

The symbol <s> is the selected station, and the symbol <xxx> is the current count.



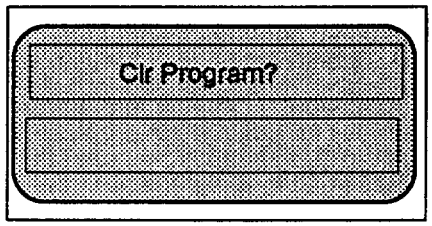
WARNING: Disinfectant should not be used beyond the number of days it is rated for, even if it tests effective.

Reset User Program

SETUP 13 #

This function is used to reset the user defined programs to the factory default settings.

To clear the user customized programs, press start when this screen appears. Otherwise, press any other key to cancel the request.



Set Heater On Time of Day

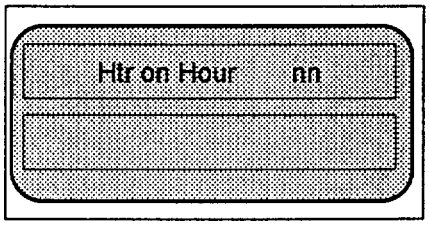
SETUP 14 #

This function is used to set the time of day to automatically turn on the optional reservoir heater elements.

This function requires multiple screens to complete.

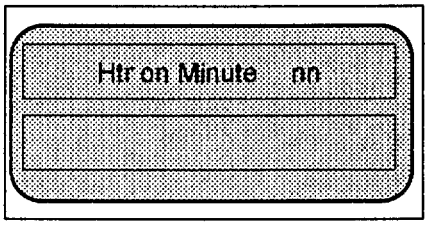
Screen 1, Set Hour:

If the hour displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct hour. When the proper hour has been entered, press the #-key. The valid numbers are 0-23.



Screen 2, Set Minute:

If the minute displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct minute. When the proper minute has been entered, press the #-key. The valid numbers are 0-59.



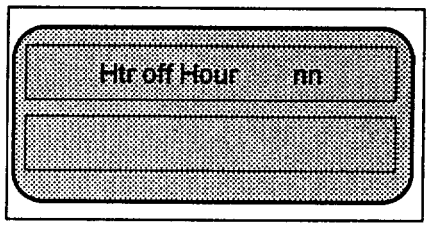
The seconds portion of the time is automatically set to zero.

Set Heater Off Time of Day

This function is used to set the time of day to automatically turn the optional reservoir heaters off

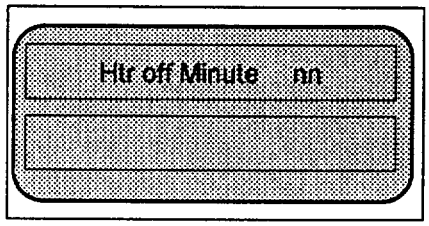
This function requires multiple screens to complete.

Screen 1, Set Hour:



If the hour displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct hour. When the proper hour has been entered, press the #-key. The valid numbers are 0-23.

Screen 2, Set Minute:



If the minute displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct minute. When the proper minute has been entered, press the #-key. The valid numbers are 0-59.

The seconds portion of the time is automatically set to zero.

Standard Operation

For endoscope hook up refer to the individual hook up instructions provided with your hook up.

The scope should be free of residual protein prior to disinfection. Pre-cleaning of the scope should include brushing of the suction/biopsy channel in universal cord and insertion tube.

Note: Proper placement and hook up of the endoscope is essential.

1. Remove all channel valves and block the ports with the appropriate fittings (see separate Hookup Instruction Sheet).
2. For non-immersible scopes, use lift stand for the head of the endoscope. Umbilical connector is to be placed in the concave receptacle located at the center of the insert (Illustration 3-1).
3. For immersible scopes, coil the entire instrument in the "Qwik-load" Basket.
4. Attach the channel connectors to fittings on umbilical connector. Place Qwik-load Basket into the DSD-91 (Illustration 3-2). Connect Qwik-load fitting to hook-up fill connector (Illustration 3-3).

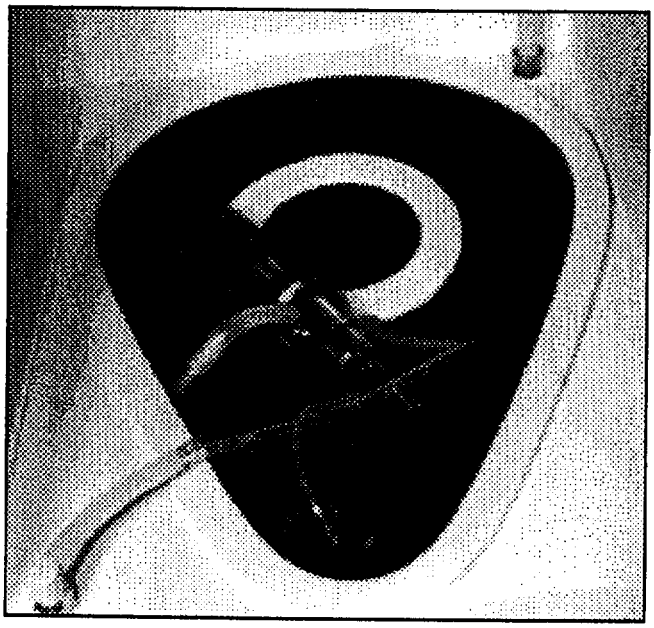


Illustration 3–2

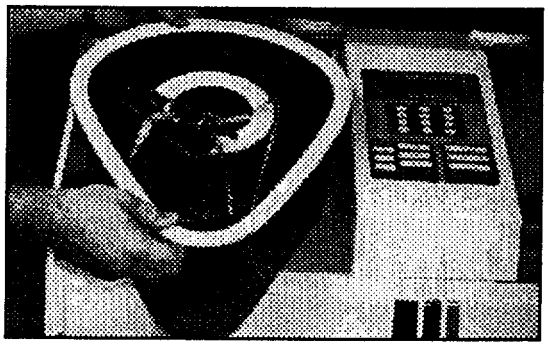


Illustration 3–1

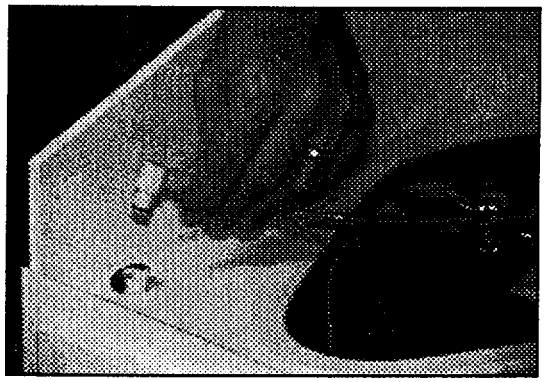


Illustration 3–3

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5. The distal end of the scope can be placed to observe channel exit while in the basket.
6. Select stations and protocols.
7. Press the START button on the control panel and observe initiation of program. Insure that a proper seal on scope connections and plugs has been made.
8. To insure that the scope channels are not blocked, observe the lines connected to them for movement of disinfectant into the scope channels. Watch the distal end of the scope until disinfectant is seen coming from the channel exits. Check the channel fittings and clamps for proper placement and seal by observing that there are no leaks in these areas.

   The disinfector will process the scope without any further attention from the operator.

   The status of the disinfecting process will be displayed on the control panel.

NOTE

If additional purging with air is desired, press the MANUAL AIR button on control panel.

9. Remove the channel connections from the universal cord.
10. Remove Qwik-load basket from the upper tanks.
11. Remove the endoscope from the Qwik-load basket.
12. Before use, seat valves and plug scope into a light source. Turn on light source to clear residual water from air channel. A spray of water should be seen exiting from the air/water valve at the distal end.

The endoscope should be cultured after the first cycle in DSD-91 Disinfector, to assure the unit is working properly and all channels are being disinfected.

IMPORTANT

Culture testing should be done on a regular basis thereafter as part of your quality assurance program.

Process Interruption

The disinfecting process will stop if:

1. The STOP button is pressed (e.g., activated by operator when an error in the scope hook-up has been observed).
2. The unit senses a high or low fluid level in reservoir. The appropriate reservoir HIGH or LOW indicator on the control panel will light, and an intermittent audible alarm will sound. Either condition must be corrected before the unit will restart. If this problem continues, call MediVators, Inc. (1-800-537-7324).

NOTE

Certain brands of disinfectants may foam. Foaming disinfectant may contact sensor prematurely causing an erroneous high level sensor. Call MediVators, Inc., for more information (1-800-537-7324).

3. The Hospital's circuit breaker or fuse for the unit's power has tripped. Reset circuit breaker or replace fuse. Call your maintenance department.
4. The unit's Ground Fault Interrupter (GFI) has tripped. Press the red RESET button located inside bottom of unit (see page 2-3, Illustration 2-1).

Recovery from Process Interruption

The interrupted program can either be resumed or terminated. To resume the program, press the START button. The program will resume at the point of interruption.

To terminate the program, press the RESET button. This will abort the cycle in process. Depending upon the phase of the cycle which has been interrupted, disinfectant will empty from the scope chamber to the reservoir or water will empty to the drain. When all fluid has drained from the scope chamber and the station is idle, the next operation may be started.

WARNING

If the process has been interrupted (power failure or brown out) it is advisable to reset and restart the operation to assure proper disinfection of the endoscope.

Disinfectant Change

A warning stop message indicates that the disinfectant has been used the maximum number of times allowed.

Note: this warning is effective only if SETUP OPTION 12 (SET MAX DIS CYCLES) has been set in accordance with the manufacturer's instructions for the disinfectant being used. Factory setting is 40 cycles.

¤ Medivators, Inc. recommends testing the disinfectant daily for effectiveness.

This message indicates that the disinfectant is reaching the end of its rated life which could make it ineffective for high level disinfection.

The disinfectant should be tested DAILY for dilution and effectiveness. Glutaraldehydes can be easily tested for dilution using available test kits. Contact your disinfectant manufacturer .

If the test results are satisfactory, SETUP OPTION 7 may be used to inhibit the warning stop for an additional 10 cycles.

The default disinfection cycle limit is 50 cycles, but may be altered as appropriate by using setup option 12 (SET MAX DIS CYCLES).

To Change Disinfectant

CAUTION

Follow instructions and heed all warnings on the chemical disinfectant. Disinfectant must not be used beyond its days usage rating, even if it tests effective

1. Depress the DISINFECTANT DUMP button, followed by the START button. Disinfectant will be pumped up into the scope chamber and flow out the drain. Total cycle time is approximately four minutes. Above process needs to be repeated a second time to assure total dumping. An audio alarm will sound at completion of the cycle.
2. Remove Qwik-load basket and wipe out with a damp cloth.*
3. Wipe out reservoir with a damp cloth.*
4. Replace disinfectant filter (see page 3-18, Illustration 3-4).
5. Fill the appropriate upper tank with the disinfectant. Activate the DISINFECTANT LOAD function from the top control panel.
6. The date and time of the disinfectant change is automatically recorded in the system log.
7. Prime the appropriate pump.

*Do not use paper towels. Gloves and goggles should be worn.

Disinfectant Filter Replacement

Replacement Procedure

CAUTION

The disinfectant filter should be changed at least twice a month (or more frequently in high use facilities) or when disinfectant is changed.

1. Remove quick connect (C1) from tank side first.
2. Remove other side quick connect .
3. Replace with new filter (arrow indicator as shown in Illustration 3-4).
4. Reattach pump side quick connect first.

CAUTION

Failure to install filter correctly (see arrow for direction of flow) will impair efficiency of operation in disinfectant cycle.

5. Reattach tank side C2.
6. Prime the pump.

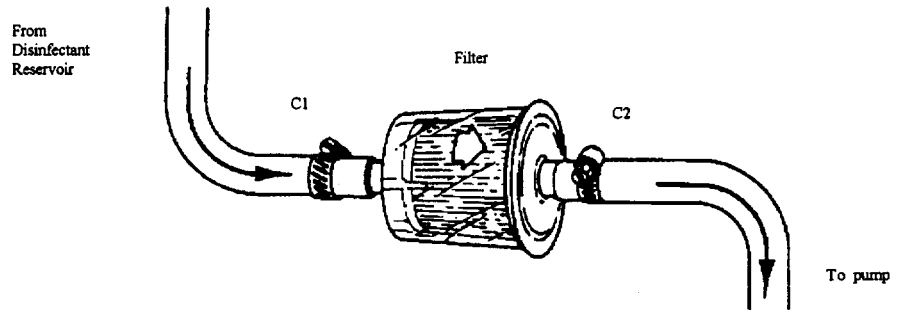

Illustration 3–4

NOTE

Additional disinfectant filters can be ordered from MediVators, Inc.

Part # DSD-115

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Sediment Water Filter Replacement

CAUTION

The sediment water filter must be checked periodically for particle saturation. It should be changed at least every 45 days. Saturation of filter will cause inadequate water pressure in the device.

Replacement Procedure

1. Shut off water supply to filter.
2. Place container under filter to catch excess water.
3. Loosen base of filter assembly slowly to relieve pressure.
4. Unscrew base, remove filter, and replace filter.
5. Tighten base of filter, turn on water supply.

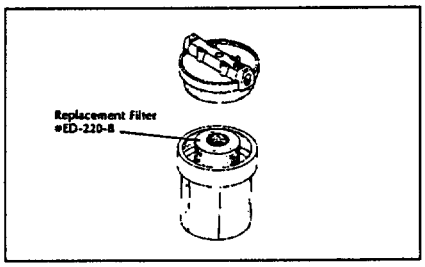

Illustration 3–5

NOTE

Additional water filters can be ordered from MediVators, Inc.

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Sterapore Filter Instructions

CAUTION

The Sterapore filter should be replaced every 6 months, or sooner if a diminished water flow is apparent. A 5 psi drop in the internal water regulator pressure is an indication to change the Sterapore filter.

1. Shut off water supply to system.
2. Locate filter in the bottom center of the system cabinet. Place container under filter to catch remaining water (Illustration 3-6).
3. Loosen bottom fitting to water distribution hose slowly to relieve pressure. Disconnect hose fitting and allow water to drain.
4. Disconnect top fitting to water supply.
5. Grasp filter assembly (Illustration 3-7) and remove from bracket.
6. Place new filter in bracket and reverse procedure to connect water supply and distribution lines.
7. Turn on water observing for leaks.

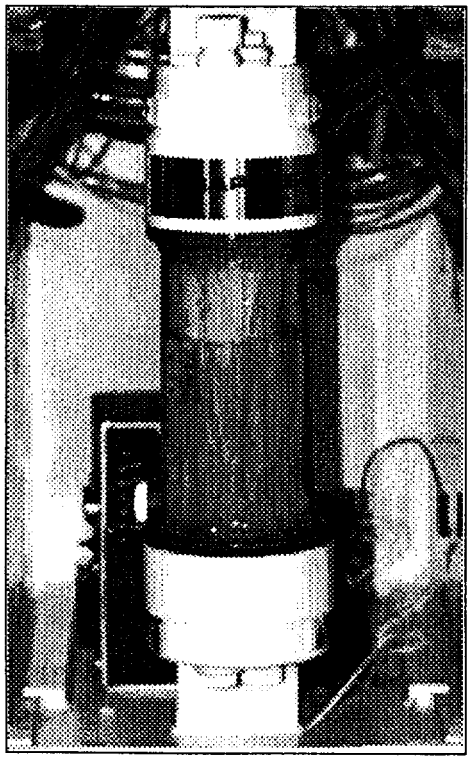

Illustration 3–6

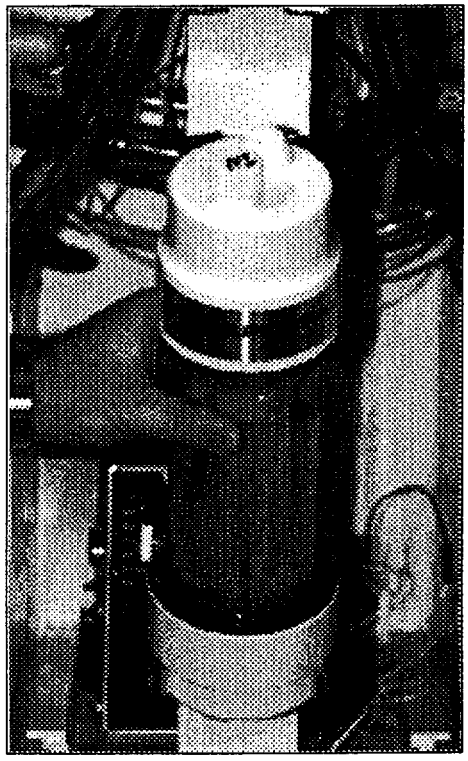

Illustration 3–7

Initial Break-In Procedure

Perform a trial run with water and tubing to simulate the endoscope to insure that the system is in functioning order. This initial break-in procedure should be repeated through several complete cycles to observe retained reservoir fluid level.

To perform a trial run:

1. Load the upper tank with water using the procedure described under "Load Disinfectant" on page 3-3.
2. The pump may need to be primed. To prime pump, the machine must be turned off. Use the bleeder valve located at the bottom of the unit directly above each pump. Open the bleeder valve by turning it counterclockwise. Water will come out of the valve when the pump is primed, so use a small container to catch this.

   The pump should be primed after changing the disinfectant and after changing the disinfectant filter.
3. Refer to standard operation instructions (page 3-13) and begin the break-in cycles.
4. Check and observe the flow through the scope during the DISINFECT, AIR, and RINSE cycles.
5. Check the water pressure gauge on the incoming water line. Pressure should be at 35-40 p.s.i. Pressure on the internal gauges should be set at 20-22 p.s.i. while in the flush cycle with scope in unit.

   6. Check the pressure gauges inside the DSD-91 cabinet while in the FLUSH cycle with scope attached. Pressure should be at 20-22 p.s.i.
7. Check for leaks to insure that all connections are intact.
8. Remove the scope and hold it vertically. Check to see if water has been removed from the channels (a few drops are acceptable).

Proceed to the DUMP cycle, and then proceed with standard operation by loading disinfectant.

B

PROCESS AND SUMMARY OF ENDOSCOPE DISINFECTION RESULTS FOR THE DSD-91

CONFIDENTIAL

Process And Summary Of Endoscope Disinfection Results For The DSD-91

Solution Stressing

CONFIDENTIAL

(b) (4)

[redacted]

Inoculum concentration

(b) (4)

[redacted]

Inoculation:

(b) (4)

[redacted]

(b) (4)

[redacted]

Cleaning procedure:

(b) (4)

[redacted]

(b) (4)

[redacted]

Post Wash Sampling

(b) (4)

[redacted]

Disinfection

(b) (4)

[redacted]

Post Disinfection

(b) (4)

[redacted]

Conclusion:

(b) (4)

[redacted]

(b) (4)

[redacted]

Results on following tables.

SUMMARY OF DISINFECTION RESULTS

(b) (4) [redacted]

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REF. # A AND B

(b) (4) [redacted]

SUMMARY OF DISINFECTION RESULTS

(b) (4) [redacted]

CONFIDENTIAL

REF. # H AND I

(b) (4) [redacted]

SUMMARY OF DISINFECTION RESULTS

(b) (4) [redacted]

REF. # C AND D

CONFIDENTIAL

(b) (4) [redacted]

CONFIDENTIAL

Disinfection With Endospore brand of 6% Hydrogen Peroxide.

Solution Stressing

(b) (4)

[redacted]

Inoculum concentration

(b) (4)

[redacted]

Inoculation:

(b) (4)

[redacted]

(b) (4)

[redacted]

Cleaning procedure:

(b) (4)

[redacted]

(b) (4)

[redacted]

CONFIDENTIAL

Post Wash Sampling

(b) (4)

[redacted]

Disinfection

(b) (4)

[redacted]

Post Disinfection

(b) (4)

[redacted]

SUMMARY OF DISINFECTION RESULTS

(b) (4) [redacted]

CONFIDENTIAL

REF. # P AND Q

(b) (4) [redacted]

THird Party Laboratory and Test Results (b) (4)

[redacted]

CONFIDENTIAL

MEDIVATORS, INC.

Endoscope Sanitization Evaluation
("On-Site" Inoculation and Recovery)

THird Party Laboratory and Test Results (b) (4)

[redacted]

Third Party Laboratory and Test Results (b) (4)

Third Party Laboratory and Test Results (b) (4)

Third Party Laboratory and Test Results (b) (4)

Third Party Laboratory and Test Results (b) (4)

Third Party Laboratory and Test Results (b) (4)

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Endoscope Sanitization Evaluation
("On-Site" Inoculation and Recovery)

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Endoscope Sanitization Evaluation
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MEDIVATORS, INC.

Endoscope Sanitization Evaluation
("On-Site" Inoculation and Recovery)

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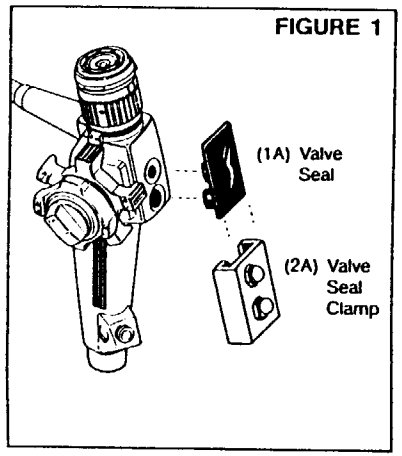
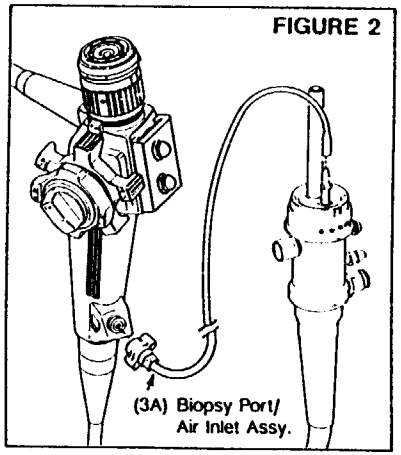
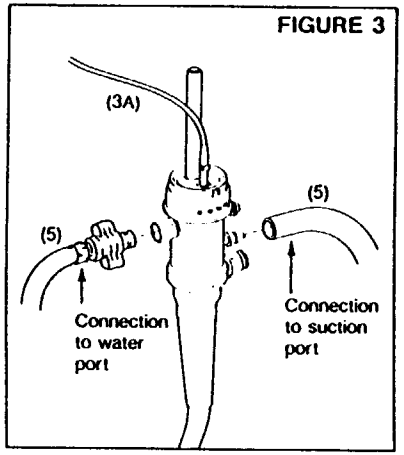
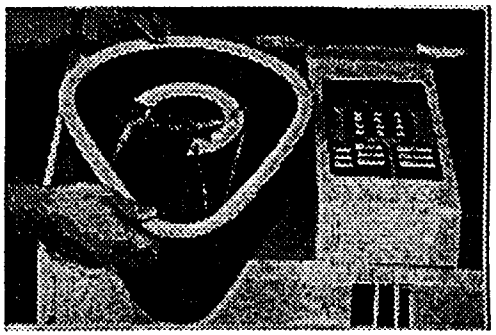
C

HOOK-UP INSTRUCTIONS FOR UPPER ENDOSCOPES









After making connection hook-ups, wrap the endoscope in the "quik-load" basket. Place basket in the DSD chamber.

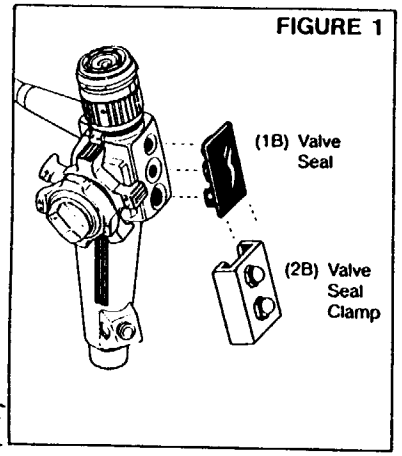
FIGURE 1: After removing air/water, suction valves from instrument, place the valve seal (1A) on valve openings. Hold in place and slide seal clamp (2A) over seal. Finger tighten bottom screw, then finger tighten top screw.

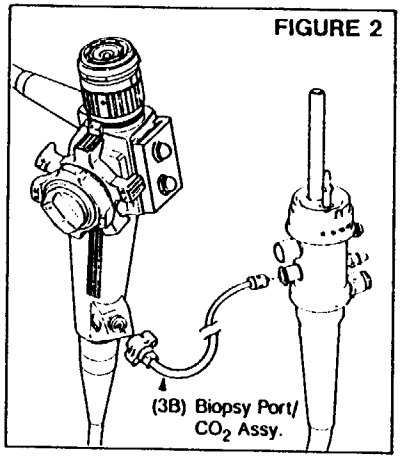
FIGURE 2: Connect the biopsy port/Air inlet tube assembly (3A) to biopsy port and air inlet port.

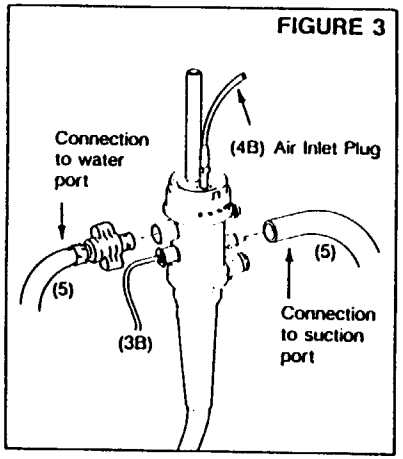
FIGURE 3: Connect disinfector hook-ups (5) to water port and suction port. The water port adapter must be firmly inserted.

Insert the quick connect fitting firmly into the opening located in the DSD.

HOOK-UP INSTRUCTIONS FOR LOWER ENDOSCOPES







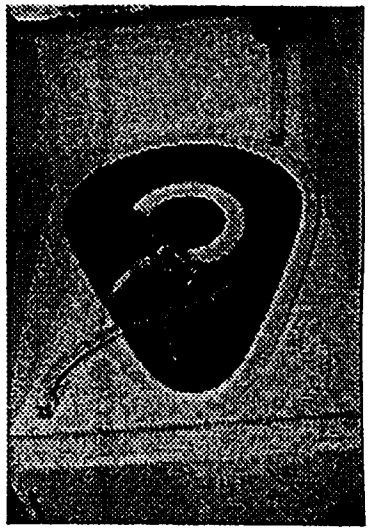


FIGURE 1: After removing air/water, suction valves and CO_2 valve cap from instrument, place the valve seal (1B) on valve openings. Hold in place and slide seal clamp (2B) over seal. Finger tighten bottom screw, then finger tighten top screw.

FIGURE 2: Connect the biopsy port/CO_2 tube assembly (3B) to biopsy port and CO_2 port.

FIGURE 3: Connect disinfector hook-ups (5) to water port and suction port. The water port adapter must be firmly inserted. Connect air inlet tube assembly (4B) to air inlet.

Engineering Drawings (b) (4)

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Engineering Drawings (b) (4)

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D

Third Party Correspondence Test Results (b) (4) (b) (6)

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April 8, 1993

Dear Jerry,

Enclosed in the results of the MediVator DSD Scope Disinfection Validation and Culture Study. The report includes scope selection and handling methods, culture techniques, microbiology methods, a table of culture results, comments and interpretation of reults.

I think you will be pleased with the results.

Third Party Correspondence Test Results (b) (4) (b) (6)

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MEDIVATORS DSD SCOPE DISINFECTION VALIDATION AND CULTURE STUDY

Third Party Validation Studies & Results (b) (4)

METHODS

Third Party Validation Studies & Results (b) (4)

RESULTS

Addendum 3

Third Party Validation Studies & Results (b) (4)

Third Party Validation Studies & Results (b) (4)

Third Party Validation Studies & Results (b) (4)

Third Party Validation Studies & Results (b) (4)

Third Party Validation Studies & Results (b) (4)

MEDIVATORS, INC.

INNOVATIVE MEDICAL PRODUCTS

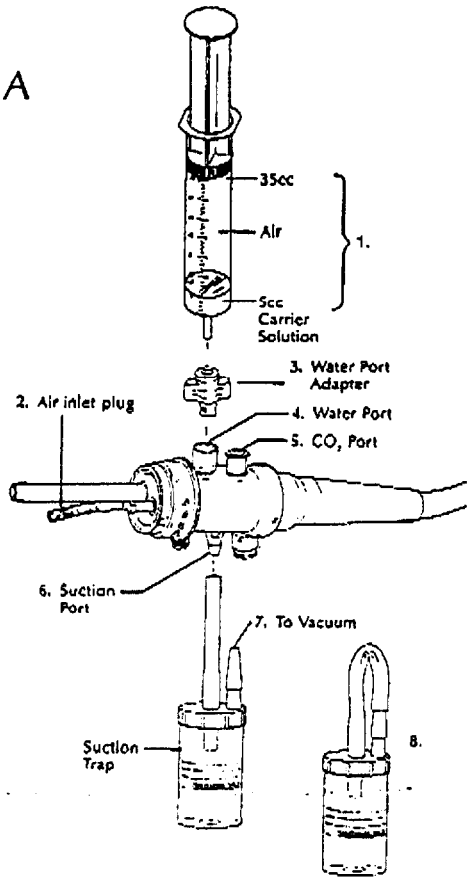
CANNON PLAZA SOUTH • HWY. 52 SOUTH • CANNON FALLS, MN 55009 • 507/263-4721 • 800-537-7324

OTT™ CHANNEL SAMPLING KIT

FOR FLEXIBLE ENDOSCOPES

- **Control valves (air/water & suction) must be left in place during sampling.**
- **When collecting samples for cultures:**
  - –Wear sterile gloves.
  - –Wipe distal end of insertion tube (not sheath) with alcohol prep (70%).
  - –Wipe water bottle port opening and suction opening on universal cord with alcohol prep (70%).

A



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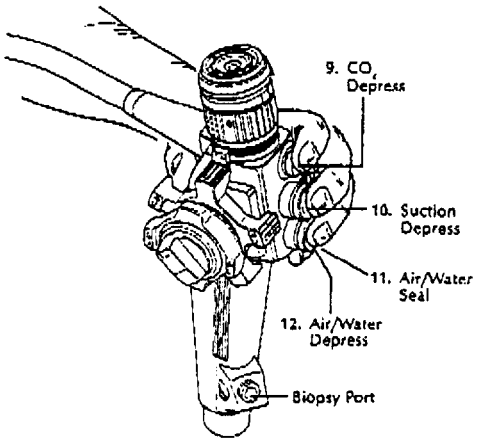

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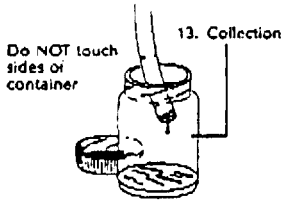

Steps

CHANNELS: Air	Water	CO_2*	Suction	To Sample Individual Channels, Follow Appropriate Steps Marked With Symbols.
Ⓐ	Ⓦ	Ⓒ	Ⓢ	1. Uncap and label collection container. Block air inlet on end of universal cord with plug provided. (A2)
Ⓐ	Ⓦ	Ⓒ		2. Put 5cc of carrier solution (ringers, saline or sterile water can be used for culturing) in syringe. Fill rest of syringe with air. (A1)
Ⓐ	Ⓦ			3. Place syringe on water port adapter (A3) and tightly attach to water bottle port on endoscope (A4). Hold syringe erect.
Ⓐ				4. Have assistant place finger over air/water valve without depressing. (B11) (Go to step 8.)
	Ⓦ			5. Have assistant depress air/water valve. (B12) (Go to step 8.)
		Ⓒ		6. Connect syringe to CO_2 port on universal cord (A5) and depress CO_2 valve at control head. (B9) (Go to step 8.)
			Ⓢ	7. SUCTION CHANNEL • **Biopsy port must be capped prior to sampling from suction channel.** a) Connect suction trap to suction port (A6) and vacuum supply. (A7) b) Position distal tip of instrument in sterile container with 10 cc of carrier solution. c) Have assistant depress suction valve at control head (B10). Vacuum source must be turned on for this step. d) Disconnect suction trap and cap. (A8)
Ⓐ	Ⓦ	Ⓒ		8. Slowly but firmly inject media through channel while collecting at distal tip of insertion tube (C13). *NOTE:* A second or third syringe of air will be needed to collect the majority of media in tube.

*Culture after air channel — not before.

NOTE WHEN CULTURING: Other channels may need to be sampled on special scopes, i.e., elevator channel, water-jet channel, second-biopsy channel, etc.

NOTE: Other volumes of carrier solution can be used, i.e., larger volumes are appropriate for residual chemical testing.

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Third Party Validation Studies & Results (b) (4)

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DSD SCOPE DISINFECTION VALIDATION CULTURE RESULTS

E

Third Party Validation Studies & Results (b) (4)

F

Third Party Laboratory & Results (b) (4)

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H

Steve,

FYI.

Any questions, please call.

DRCK

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Technical Data on STERAPORE® PKO

Comparisons among Various Methods of Water Purification

	Water Supply Capacity	Bacteria	Pyrogens	Inorganic Ion Removal	Organic Substance Removal	Micro-particle Removal	Methods of Regeneration	Energy Consumption	Equipment Cost	Uses
Distillation	Small Storage-in-tank type	Complete removal Recontamination	Removable, but ⊕ according to operating conditions	○	○	○	—	Great (e.g. 716 KWh/m³)	Great	Distilled water injection, etc.
Heat sterilization	Small Storage-in-tank type	Complete removal Recontamination	Not removable ⊕	×	×	×	—	Medium	Great	Hand-washing water for operation rooms etc.
Reverse osmosis (RO)	Small Storage-in-tank type	Leak occurs due to long-term use Recontamination	Removable, but ⊕ according to operating conditions	Removed to about 80∿95% level	Those of molecular weight 300 < are mostly removed	○	Reverse washing Renewal	Medium (1∿4 KWh/m³) High pressure pump required Very noisy and water loss is great	Great	Water for injection permitted in the United States
Ultrafiltration (UF)	Medium Continuous supply possible	Complete removal, if no leak	⊖ or ⊕ as the case may be	×	Macro-molecules ○ Medium to small molecules ×	○	Reverse washing Renewal	Small (0.4∿1 KWh/m³) Water loss occurs	Medium	Sterile, pyrogen-free water (specialized UF)
Microfilter (MF)	Great Continuous style	Leak may occur in the case of cartridge type	Not removable ⊕	×	×	○	Renewal	Small No water loss	Small	Bacterial removal, dust removal
Activated charcoal	Medium Continuous style	Bacterial growth considerable	Complete removal difficult	Cl_2 removal possible	○	×	Activation Renewal	Small	Small to medium	Pretreatment etc.
Ion exchange resin	Small to medium Continuous style	Bacterial growth considerable	Not removable except with special resins	○○	×	×	NaOH HCl Renewal	Small	Small to medium	Purified water
Ultraviolet (UV)	Medium Continuous or semicontinuous	Complete sterilization difficult	Not removable ⊕	×	×	×	Lamp renewal	Small	Small to medium	Hand-washing water for operation rooms
STERAPORE®	Medium to great Continuous style	Complete removal	Removable ⊖	×	Macro-molecules △∿○ Hydrophobic small molecules ○ Hydrophilic small molecules ×	◎	Renewal Alcohol regeneration	Small No water loss	Small	Sterile, pyrogen-free water

SP012	Features of the EHF Membrane	

1. Clean membrane
   Since being prepared from polyethylene fused spun yarn, EHF membrane contains no noxious substances such as solvents and plasticizers, so it is a very clean membrane.

2. Excellent chemical resistance
   Made of polyethylene as a base material, EHF membrane is stable against high concentrate acids and alkalis and a number of organic solvents.

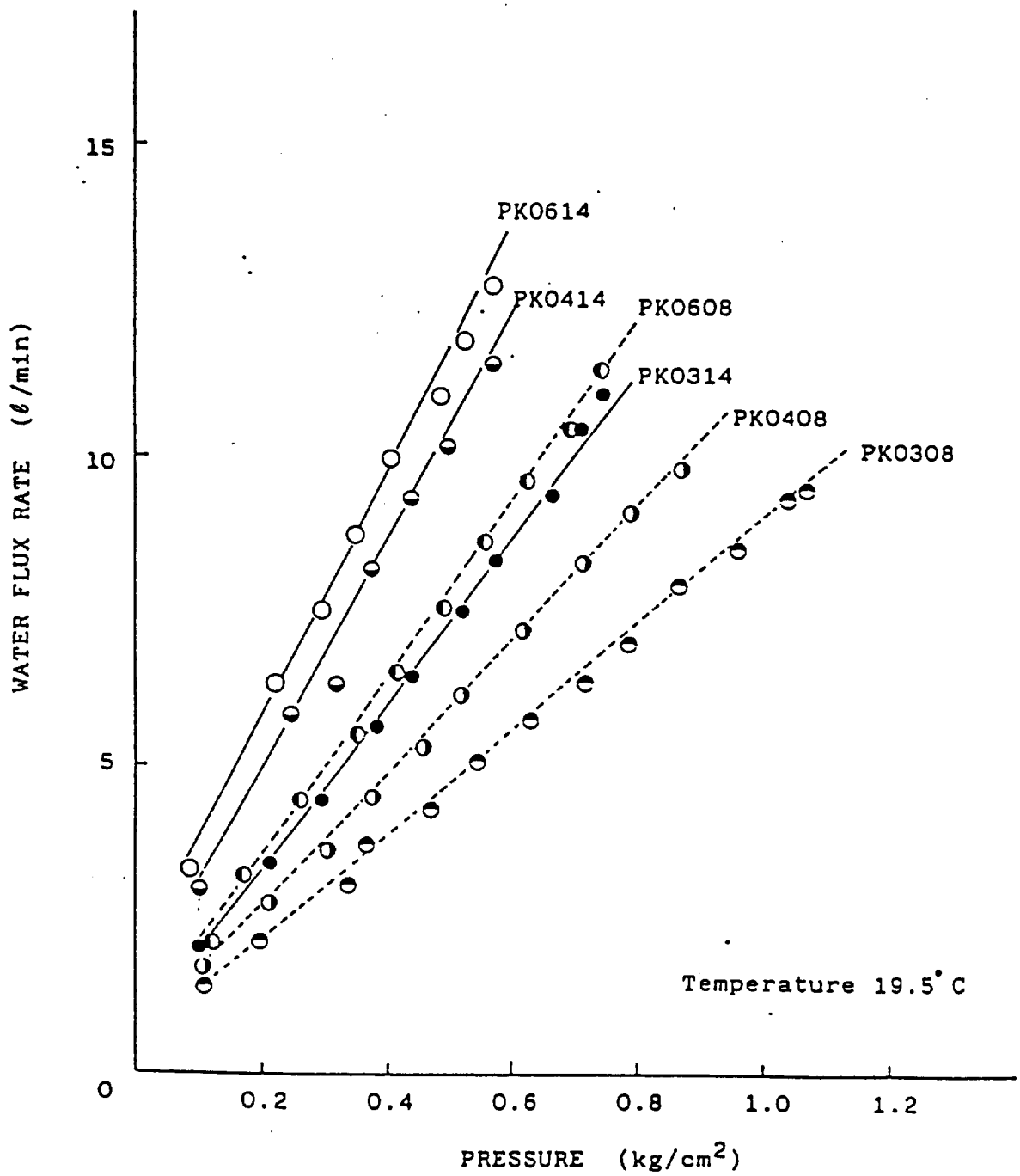
3. Excellent durability
   EHF membrane is made of polyethylene, so it is not subject to microbial deterioration. In addition, EHF membrane has excellent mechanical strength, due to longitudinal orientation of macromolecules in the fiber; therefore, it never breaks during use.

4. Very safe membrane
   With its membrane structure uniform in thickness (about 60u), EHF membrane is not an asymmetrical membrane, so it is less likely to be subject to pin hole formation.

5. Excellent separating performance
   Having a membrane structure in which numerous pectinate hollows formed in intermicrofibril spaces are piled in layers, EHF membrane shows great contaminant retention capacity as in depth-type membranes (i.e. filtering flow reduction is low), as well as solute removing performance as in ultrafilters.

6. EHF membrane ensures removal of trace amounts of low molecular organic substances in water
   Due to synergetic effects of the base material, polyethylene and the unique hollow structure, trace amounts of low molecular organic substances in water can be adsorbed and removed.

SP015	Flow Characteristics of STERAPORE PKO	



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SP016	Sterility and Pyrogen Tests of Water Treated with STERAPORE PKO (1)	

1. Testing organization

   Department of Microbiology

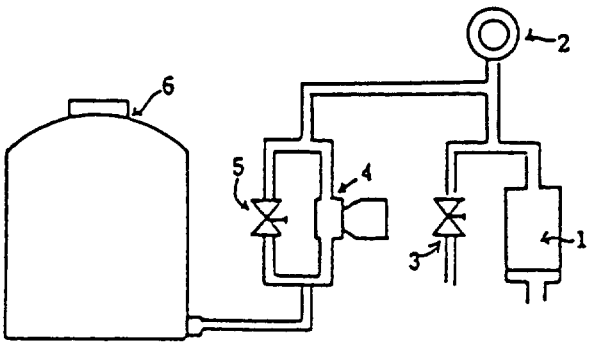
   City Health Research Institute, Nagoya

2. Materials and methods

2-1 Filter modules

PKO-408 and PKO-414 types

2-2 Test apparatus



1. Module
2. Pressure gauge
3. Water sampling valve
4. Pump
5. Pressure regulating valve
6. Polyethylene tank

2-3 Method of filtration

About 50ℓ of a bacterial suspension, prediluted with city water to 10^3- or 10^6-fold dilution was stored in the polyethylene tank of the above apparatus, and it was used as test water.

Flow rate was adjusted to 4ℓ/min.; filtrate samples were collected 1, 5, and 10 minutes after initiation of filtration.

2-4 Bacteria used in the tests

(1) Escherichia coli (0 ∿ 16 strain)

(2) Staphylococcus aureus (Terashima strain)

(3) Serratia marcescens (IDD620 strain)

3. Results

3-1 Inhibitory performance against *E. coli* passage

	Number of Bacterial Cells in Test Water (per 1.0 mℓ)	Number of Bacterial Cells in Filtrate (per 1.0 mℓ)			Filtrate Cultivation Test (per 50 mℓ)		
		Time after Initiation of Filtration			Time after Initiation of Filtration		
		1 min.	5 min.	10 min.	1 min.	5 min.	10 min.
STERAPORE®	1.6×10^4	0	0	0	Negative	Negative	Negative
PKO-408	2.8×10^6	0	0	0	Negative	Negative	Negative
STERAPORE®	1.0×10^3	0	0	0	Negative	Negative	Negative
PKO-414	2.1×10^6	0	0	0	Negative	Negative	Negative

(1) Bacterial cells were counted after pour culture (35°C, 24 hours) of 1 mℓ water sample using deoxycholate medium.

(2) Filtrate cultivation test was carried out by culturing 20 mℓ filtrate sample using lactose bouillon medium (35°C, 48 hours).

3-2 Inhibitory performance against Staphylococcus aureus passage

	Number of Bacterial Cells in Test Water (per 1.0 mℓ)	Number of Bacterial Cells in Filtrate (per 1.0 mℓ)			Filtrate Cultivation Test (per 50 mℓ)		
		Time after Initiation of Filtration			Time after Initiation of Filtration		
		1 min.	5 min.	10 min.	1 min.	5 min.	10 min.
STERAPORE®	4.4×10^3	0	0	0	Negative	Negative	Negative
PKO-40.8	1.0×10^6	0	0	0	Negative	Negative	Negative
STERAPORE®	3.0×10^3	0	0	0	Negative	Negative	Negative
PKO-414	1.0×10^6	0	0	0	Negative	Negative	Negative

(1) Bacterial cells were counted after cultivation (35°C, 24 hours) of 0.1 mℓ filtrate sample spread over heart infusion agar plate medium.

(2) Filtrate cultivation test was carried out by culturing 50 mℓ of the filtrate sample, adjusted to 2-fold concentration using ordinary bouillon (35°C, 48 hours).

3-3 Inhibitory performance against Serratia marcescence passage

	Number of Bacterial Cells in Test Water (per 1.0 mℓ)	Number of Bacterial Cells in Filtrate (per 1.0 mℓ)			Filtrate Cultivation Test (per 50 mℓ)		
		Time after Initiation of Filtration			Time after Initiation of Filtration		
		1 min.	5 min.	10 min.	1 min.	5 min.	10 min.
STERAPORE®	1.0×10^3	0	0	0	Negative	Negative	Negative
PKO-408	7.5×10^6	0	0	0	Negative	Negative	Negative
STERAPORE®	2.3×10^3	0	0	0	Negative	Negative	Negative
PKO-414	8.1×10^6	0	0	0	Negative	Negative	Negative

The methods of bacterial cell counting and filtrate cultivation test were the same as in the case of Staphylococcus aureus above.

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SP017	Sterility and Pyrogen Tests of Water Treated with STERAPORE PKO (2)	

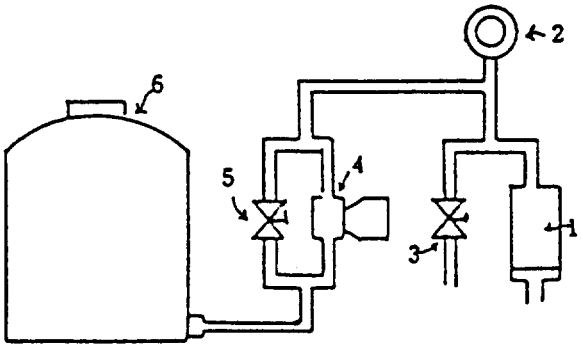
1. Testing organization
   Department of Clinical Tests
   National Hospital, Osaka

2. Materials and methods

2-1 Filter modules

PKO-414 and PKO-408 types

2-2 Test apparatus



1. Module
2. Pressure gauge
3. Water sampling valve
4. Pump
5. Pressure regulating valve
6. Polyethylene tank

2-3 Bacteria used in the tests

(1) Serratia marcescence
(2) Pseudomonas aeruginosa
(3) Escherichia coli
(4) Staphylococcus aureus

2-4 Test methods

2-4-1 Inhibition test against bacterial passage with various bacterial species

About 50ℓ of a bacterial suspension, diluted with city water was stored in the polyethylene tank and used as test water. Bacterial cells in the test water was counted, after which the test water was filtered at a flow rate of 4ℓ/min. using the above apparatus.

During about 10 minutes following the initiation of cultivation, filtrate samples were collected 5 times, and bacterial cells were counted in each sample. Bacterial cell counting was carried out after pour culture (37°C, 48 hours) using tryptic soy agar medium.
Cultivation test was also carried out at 37°C for 48 hours, in which filtrate samples were inoculated to tryptic soy bouillon.

2-4-2 Bacterial passage test by breaking hollow fiberous membrane

Hollow fiberous membranes in filter module were broken intentionally, and the relationship between the number of opened holes and the number of leaked bacterial cells were investigated using Serratia marcescence.

NB: The number of bacterial cells in the test water was adjusted to 10^5 to 10^6N/mℓ, and the methods of filtration and bacterial cell counting were the same as in 2-4-1 above.

3. Results

3-1 Inhibitory performance against bacterial passage by bacterial species

	Bacterial Species	Number of Bacterial Cells (N/mℓ)		Cultivation Test
		Test Water	Filtrate	
PKO408	Serratia marcescence	1.8×10^3	0	Negative
	Pseudomonas aeruginosa	1.6×10^3	0	Negative
	Escherichia coli	1.6×10^4	0	Negative
	Staphylococcus aureus	2.8×10^3	0	Negative
PKO414	Serratia marcescence	7.0×10^5	0	Negative
	Pseudomonas aeruginosa	6.0×10^5	0	Negative
	Escherichia coli	3.5×10^4	0	Negative
	Staphylococcus aureus	1.5×10^4	0	Negative

SP018	Sterility and Pyrogen Tests of Water Treated with STERAPORE PKO (3)	

1. Testing organization

Department of Drugs

National Hospital, Osaka

2. Materials and methods

2-1 Filter module

PKO 308-T type: 1 unit

2-2 Test methods

The above module was directly connected to a tap, and filtration of the tap water was carried out for a long period. The flow rate was about 20ℓ/day.

Bacteria test, fungus test and pyrogen test were carried out as follows:

Bacteria test

Medium:

Thioglycollate medium for sterility test I

(Control test was not carried out.)

Culturing conditions:

Test tubes	:	25mm × 200mm, 3 tubes
Sample volume	:	5mℓ (for each test tube)
Medium volume	:	40mℓ (for each test tube)
Culturing temperature	:	30 to 32°C
Culturing period	:	14 days

Judgement criterion:

Turbidity of the medium

Fungus test

Medium:

Glucose-peptone medium for sterility test

(Control test was not carried out.)

Culturing conditions:

Test tubes : 25mm × 200mm, 7 tubes
Sample volume : 2mℓ (for each test tube)
Medium volume : 15mℓ (for each test tube)
Culturing temperature: 25°C
Culturing period : 14 days

Judgement criterion:

Turbidity of the medium

Limulus test

Reagent:

PREGEL reagent, manufactured by Teikoku Hormone Mfg. Co., Ltd.

Test conditions:

Sample volume : 0.1mℓ
Reaction temperature: 37°C
Reaction time : 1 hour

Judgement criterion:

Degree of gelation

3. Results

Time after Initiation of Filtration	Test Water			Filtrate		
	Bacteria	Fungi	Pyrogens	Bacteria	Fungi	Pyrogens
2.5 months	Positive	Positive	(++)	Negative	Negative	(-)
6.0 months	Negative	Nagative	(++)	Negative	Negative	(-)

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* Reference data: Medium compositions (per 1ℓ purified water)

Thioglycollate medium for sterility test I

(pH after sterilization: 7.0 to 7.2)

Pancreatic juice digested casein	:	15.0g
L-cysteine	:	0.5g
Glucose (anhydrous)	:	5.0g
Yeast extract	:	5.0g
Sodium chloride	:	2.5g
Sodium thioglycolate	:	0.5g
Resazurin	:	0.001g
Agar	:	0.75g

Glucose-peptone medium for sterility test

Glucose (anhydrous)	:	40.0g
Katayama peptone	:	10.0g

SP019	Sterility and Pyrogen Tests of Water Treated with STERAPORE PKO (4)	

Results of Pyrogen Test of Water Treated Using PKO Modules

	Water before Treatment			Water after Treatment					
				PKO - 408			PKO - 414+614		
Rabbit No.	1	2	3	4	5	6	7	8	9
Body weight (kg)	1.90	1.55	1.51	1.80	1.65	1.80	1.75	1.90	2.20
Body temp. 1	39.5	39.7	39.5	39.5	39.7	39.7	39.6	39.8	39.3
2	39.6	39.6	39.6	39.6	39.6	39.6	39.7	39.8	39.4
3	40.5	40.8	40.2	39.6	39.5	39.7	39.8	39.8	39.5
4	40.6	40.8	40.5	39.4	39.5	39.7	39.7	39.6	39.5
5	40.4	40.6	40.2	39.7	39.6	39.7	39.8	39.7	39.4
Temperature gain	1.0	1.2	0.9	0.1		0.1	0.1		0.1
Temperature loss				0.2	0.1			0.2	
Judgement	Positive			Negative			Negative		
Limulus test	++			-			-		

(1) Water before treatment was prepared as a 0.1 μg/mℓ endotoxin-physiological saline solution. The endotoxin (E. coli 0111-B4) was produced by DIFCO Laboratories (Lot No. 3922-25).

(2) Treatment rate was 4.0 ℓ/min.

(3) Limulus test was conducted using PREGEL (reagent for endotoxin detection) produced by Teikoku Hormone Mfg. Co., Ltd.

NB: This experiment was carried out by the Aichi Prefectural Institute of Public Health (See next page). The filtrates from STERAPORE PKO passed the pyrogen tests using rabbits.

Evaluation of the Modules Following Long-term Test for Practical Application (Osaka City)

1) Bacterial challenge test

- Experimental conditions
  1) Subject bacterium : *Serratia marcescens*
  2) Bacterial cell density in test water : About 10^6 cells/mℓ
  3) Detection method : Qualitative test using lactose bouillon (Sample volume: 50mℓ, in total)

- Results

Type of Module	Number of Bacterial Cells in Test Water	Sampling Time after Initiation of Filtration		
		1 min.	5 min.	10 min.
414AP + 408AS	1.1×10^7	Negative	Negative	Negative
408AS	5.3×10^6	Negative	Negative	Negative

2) Pyrogen removing performance test

- Experimental conditions
  1) Test water : Underground water, collected in Nagoya
  2) Type of module : 414AP + 408AS
  3) Detection method: Limulus test

- Results

Subject Water	Limulus Test
Test water (untreated)	(++)
Filtrate (treated)	(-)

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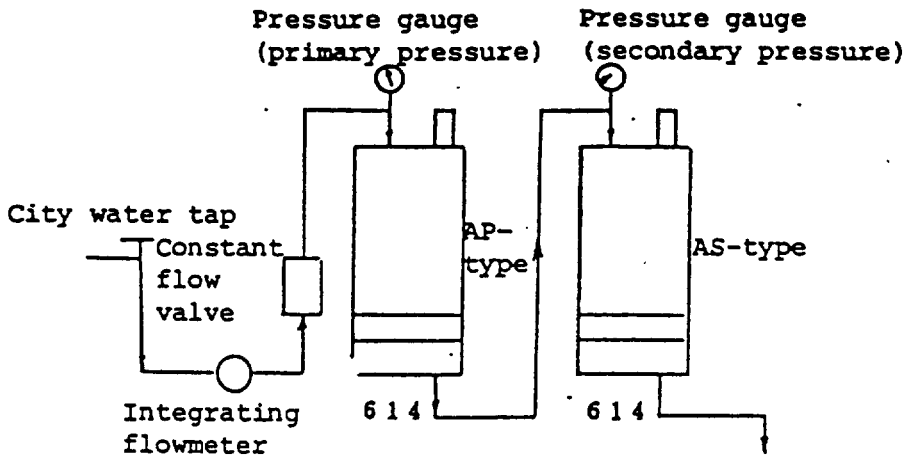
SP022	Test for Practical Application of STERAPORE Using City Water in Tokyo	

1. Experimental apparatus



2. Experimental conditions

Constant flow valve (3ℓ/min.) was set before AP filter; city water was supplied at constant flow rate; the state of membrane clogging was examined by monitoring the fluctuations of primary and secondary pressures.

3. Results

Refer to Figures 1 and 2.

i) Primary pressure was initially 0.8kg/cm^2, then increased to 1.15kg/cm^2 when about 40m^3 water had been supplied. It further increased up to 1.3kg/cm^2 when about 60m^3 water had been supplied, and up to 1.5kg/cm^2 with 70m^3. The increase in primary pressure was almost in proportion to the integrated amount of supplied water.
Clogging hardly occurred in the secondary filter, secondary pressure being nearly constant at 0.2 to 0.3kg/cm^2.

ii) Bacterium and pyrogen tests
Water quality tests were conducted of test water and filtrate at the time when about 30m^3 water had been supplied (March 30).

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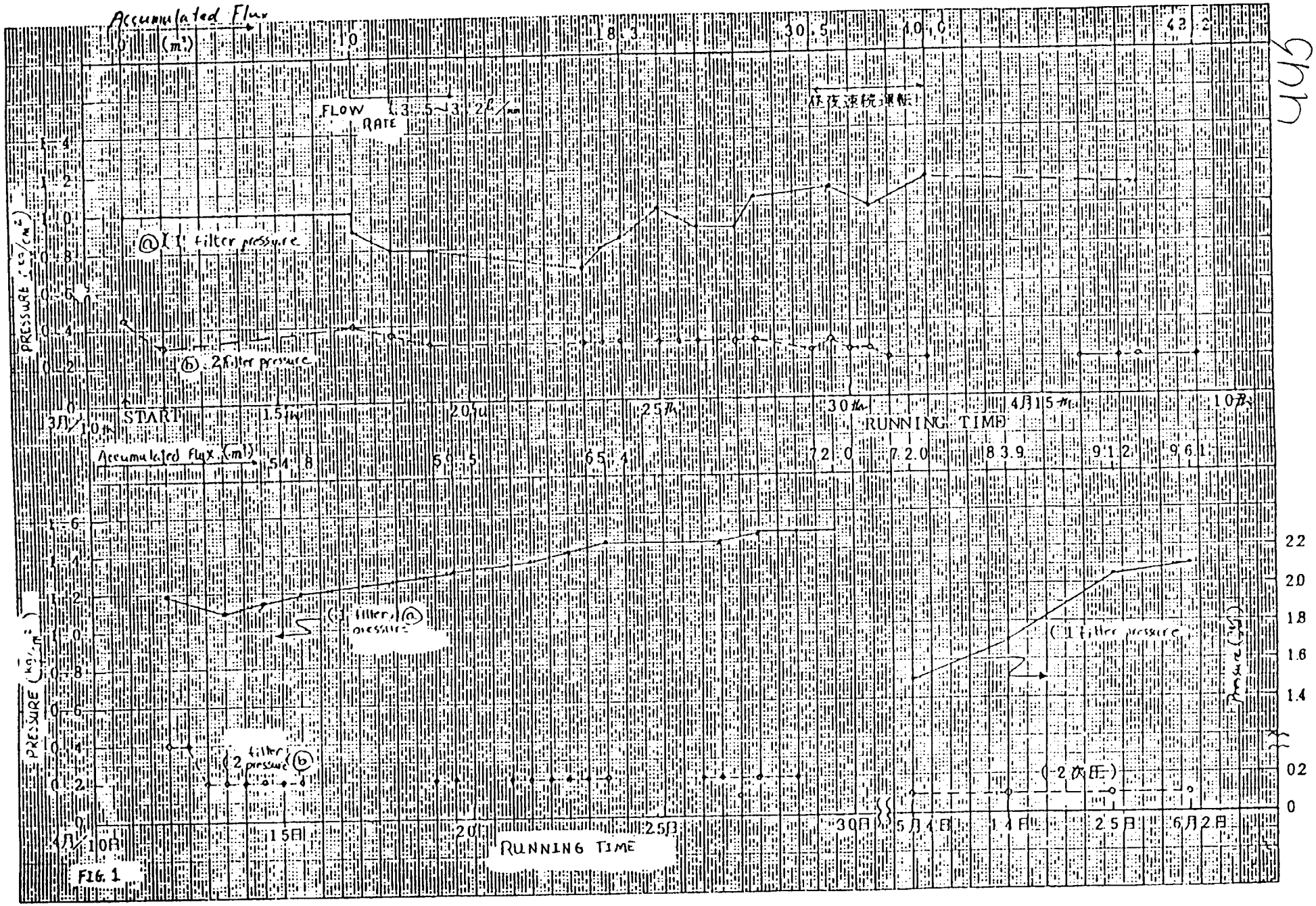
Ⓐ the pressure of the first filter (primary pressure)
Ⓑ the pressure of the second filter (secondary pressure)



	Bacteria	Pyrogens*
Test water	Negative	(++)
Filtrate	Negative	(-)

* Limulus test

Water quality tests were again conducted of filtrate at the time when about 91m^3 water had been supplied (May 25); the results were the same as above.

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Endotoxin removal from water using microporous polyethylene chopped fibres as a new adsorbent

BY YOSUKE SAWADA*, REIKO FUJII, IKUO IGAMI, ATSUSHI KAWAI,
Product and Development Centre, Mitsubishi Rayon Co., Ltd, Higashiku, Nagoya 461, Japan

TERUO KAMIKI
Public Health Research Institute of Kobe City, Chuoku, Kobe 650, Japan

AND MAKOTO NIWA†
Osaka City University Medical School, Department of Bacteriology, Abenoku, Osaka 545, Japan

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SUMMARY

A new adsorbent, microporous polyethylene chopped fibre, was produced from a high density polyethylene. This can adsorb lipopolysaccharides (LPS) linearly up to 2 h, and showed the highest capacity to adsorb LPS when compared with two other polyethylene-based adsorbents and a polystyrene-based adsorbent. More than twice as much orange II and 4-nitroquinoline N oxide were adsorbed in the new adsorbent as was LPS. The adsorption isotherm of the new adsorbent for LPS was of Ln type, the correlation between adsorption and concentration of solute was proportional; whereas orange II and 4-nitroquinoline N oxide were of L type (greater adsorption than Ln type); tetrachloroethylene adsorption was of S type, less than Ln type. Adsorption of LPS to the new adsorbent increased when temperature rose, whereas adsorption of orange II and 4-nitroquinoline N oxide decreased. These data suggest that the binding of LPS to the new adsorbent is a hydrophobic interaction, whereas the binding of both orange II and 4-nitroquinoline N oxide is not. The new adsorbent has a greater potential for the removal of endotoxin from tap water than other commercially available adsorbents such as charcoal and Amberlite XAD-2.

INTRODUCTION

A large portion of pyrogens are well-recognized endotoxins (lipopolysaccharides, LPS) which are produced by Gram-negative bacteria. Attempts have been made to remove endotoxins from aqueous samples by the following methods: (*a*) physical

* Present address: Bristol-Myers Research Institute, Shimomeguro, Meguroku, Tokyo 153, Japan.
† To whom all correspondence should be addressed.

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and chemical adsorbents such as charcoal (Pegues *et al.* 1979), ion exchange resin (Nolan, McDevitt & Goldman, 1975), polyolefine beads (Harris & Feinstein, 1976), asbestos (Kaden, 1975), bentonites (Ditter, Urbascheck & Urbascheck, 1983), immobilized polymyxin B (Niwa, Umeda & Ohashi, 1982) and immobilized histamine (Minobe *et al.* 1982); (*b*) chemical decomposition with alkali (Niwa *et al.* 1969) and oxidizing agents (Tsuji & Harrison, 1979); (*c*) filtration by ultramembrane filters (Sweadner, Forte & Nelsen, 1977; Cradock *et al.* 1978) as well as reverse osmosis membranes (Parkinson, 1983). Adsorbents must be evaluated for their specificity and capacity.

In initial studies the microporous polyethylene hollow fibre (EHF, Mitsubishi Rayon Co., Tokyo) with unique microfibrile structure, was found to remove an LPS isolated from *Escherichia coli* 0111: B4 when a water sample was permeated through the fibre's wall membrane (Kamiki *et al.* 1982). In order to eliminate the filtration process as the cause for the removal of endotoxin, the microporous EHF was chopped up (microporous polyethylene chopped fibre, PE-CF) and evaluated as an adsorbent for endotoxin removal. In this paper we report studies concerned primarily with the *in vitro* capacities of synthetic polymers, especially the contribution of the polymer's three-dimensional conformation to the binding of endotoxins in water. We also deal with the adsorption characteristics of PE-CF for various kinds of endotoxins. The removal levels of three potentially harmful organic compounds; a diazo dye orange II, a mutagen 4-nitroquinoline N oxide (4NQNO) and a carcinogen tetrachloroethylene, are compared to the endotoxin removal level.

MATERIALS AND METHODS

Preparation of PE-CF

The microporous EHF was produced from a high density polyethylene as described by Shindo *et al.* (1983). To make PE-CF, the hollow fibre (Code: EHF 390-C, Mitsubishi Rayon Co.) was chopped up by an automatic cutter (Type D-478, Onouchi Co., Kyoto) and pieces less than 1 mm in length were sifted and collected. Some properties of PE-CF are as follows; inner diameter, 270 μm; wall membrane thickness, 55 μm; porosity, 63%; and surface area determined by nitrogen adsorption method, 31·7 m^2/g. Scanning electron micrographs (Tyne JSM-25S and JSM-35C, Nihon Denshi Co., Tokyo) of PE-CF (Top picture) and the membrane surface (Bottom picture) are shown in Fig. 1. The mean size of the lattice-like structure on the membrane surface was 0·15 μm in width and 0·6 μm in length.

Other adsorbents

Nonporous polyethylene chopped fibres (NPE-CF, surface area, 0·1 m^2/g) were prepared by chopping nonporous polyethylene hollow fibres which are an intermediate product of microporous EHF (Mitsubishi Rayon Co.). Polyethylene microfibres (PE-MF, SWP E620, density; 0·96 g/cm^3; average length, 1·3 mm; surface area, 8 m^2/g) were obtained from Mitsui Petrochemical Co., Tokyo. Amberlite XAD-2 and charcoal (Shirasagi WH) were obtained from Organo Co., Tokyo, and Takeda Pharmaceutical Ind., Osaka, respectively.

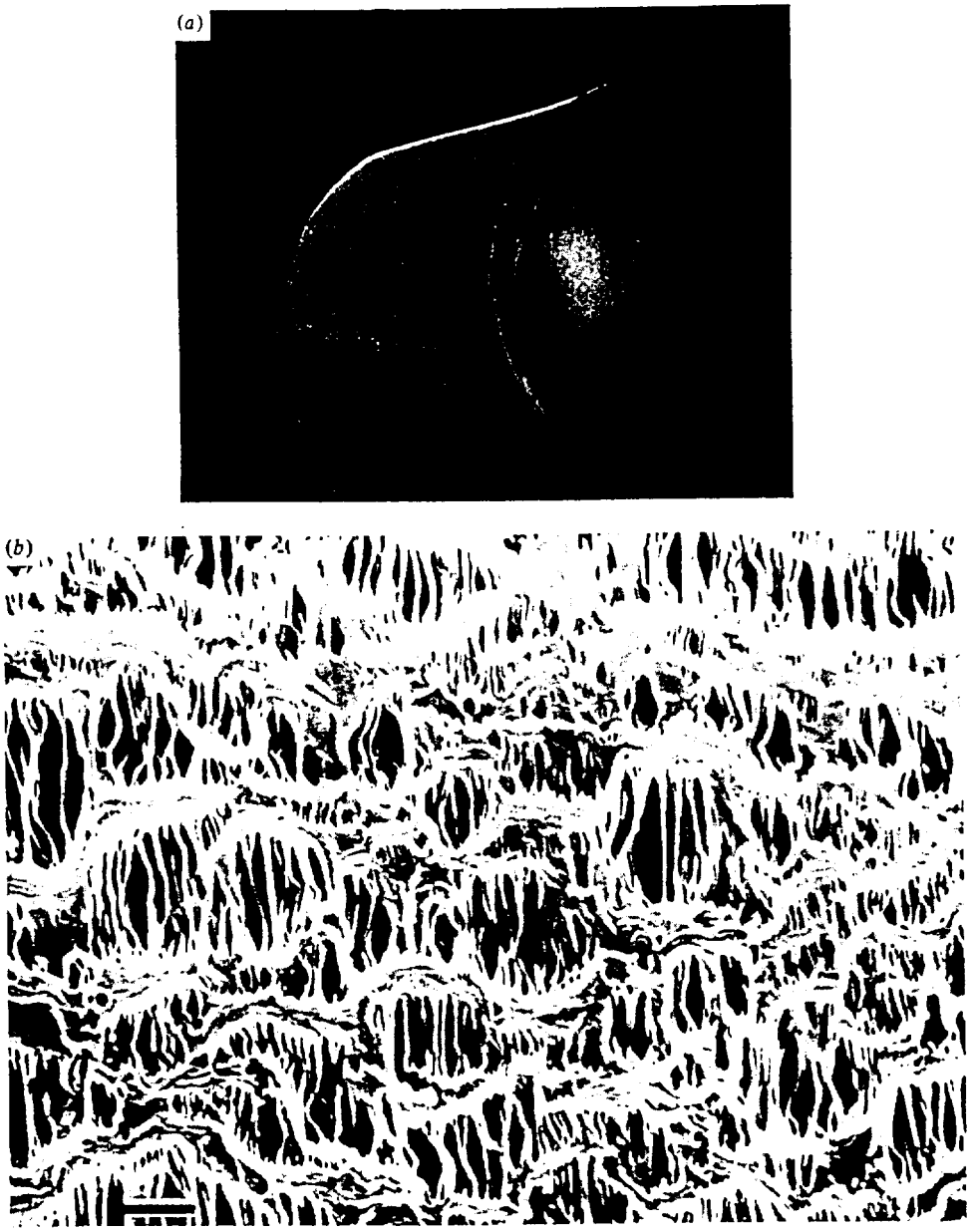

Fig. 1. Scanning electron micrographs of PE-CF, overall (*a*) and wall outer surface (*b*). Reference bars indicate 100 μm (*a*) and 1 μm (*b*).

Column chromatography

The PE-CF, PE-MF, NPE-CF and Amberlite XAD-2, 1 g, were individually packed into glass columns and were washed with 20 ml of 99 % ethanol and 40 ml of distilled water before use. The flow rate was set at 2 ml/min in all chromatographic experiments. A 2 ml fraction was collected for each. Concentrations of the compounds in the eluates were then determined.

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Determination of endotoxin at picogram levels

A synthetic substrate method of *Limulus* amoebocyte lysate (Iwanaga *et al.* 1978; Fujita & Nakahara, 1982) was employed to determine the concentration of endotoxin in the test water. The endotoxin assay kit, Pyrodick®, was purchased from Seikagaku Kogyo Co., Tokyo. The reaction mixture containing the Pyrodick reagent dissolved in 0·1 ml of the attached buffer solution pH 8·0 and 0·1 ml of an endotoxin solution was incubated for 30 min at 37 °C. The reaction was stopped by adding 1·0 ml of 0·6 N acetic acid. The optical density of the resultant solution was read at 405 nm with a spectrophotometer (Type UV-250 attached to a recording unit OPI-2, Shimadzu Co., Kyoto). Endotoxin concentration in the test water was estimated from the standard curve using an LPS of *E. coli* 0111: B4 (Difco Lab., Detroit, Michigan). Endotoxin was diluted with endotoxin-free water (Otsuka Pharmaceutical Co., Naruto). All glassware for pyrogen tests was heated at 250 °C for 2 h.

Determination of adsorption isotherm

The adsorbents to be used were bagged in polyethylene mesh fabric (80 mesh) in amounts of 50, 100, 200 and 400 mg by a heat-sealing technique. Each bag was dipped in 99% ethanol for 1 min, transferred into 70% ethanol (500 ml) and left for 1 min, transferred into distilled water (500 ml) and shaken for 1 min, and finally transferred to distilled water (500 ml). Each bag was put into a test tube containing 10 ml of the test solution. The test tube was shaken intermittantly for exactly 1 h and then the bagged adsorbent was removed. The polyethylene mesh fabric itself was tested as a control. The concentration of the compound was determined in the remaining solution. An adsorption isotherm was obtained using at least 12 points at different determinations by using Freundlich's equation (Freundlich, 1926);

$$\log (X/M) = \frac{1}{n} \log \mathrm{Ci} + \log \mathrm{K},$$

where X/M = adsorbed material, mg/100 ml/g of adsorbent; Ci = equilibrated concentration of solute, mg/100 ml; K = a constant; n = the adsorption coefficient.

Quantitative determination of adsorbing solutes

The concentrations of solutes were determined from the standard curves measured by a spectrophotometer at 214 nm for LPS, 225 nm for Orange II and 365 nm for 4NQNO. Tetrachloroethylene was determined by gas chromatography (Type G-1800 with FID detector at 120 °C, Yanagimoto Co., Kyoto).

Endotoxin removal from tap water by various adsorbents

Each individual adsorbent was packed into plastic columns of varying sizes as described in Table 3 and tap water of Nagoya City with temperature range of 15–20 °C was continuously passed through the column at a flow rate of 300 ml/min. When the cumulative flux of water reached 2 m^3 total for a column, the treated water sample was aseptically collected and the concentration of endotoxin was determined.

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Chemicals

For the major examination an LPS from *E. coli* 0113 was chosen from our stock because this LPS has been well characterized (Niwa *et al.* 1969; Ribi *et al.* 1966) and has been used as the US Reference Endotoxin, EC-2. The other two LPSs were purchased from Wako Pure Chemical Ind., Osaka. In order to dissolve LPS, the LPS was suspended in 10 mM Tris-HCl, pH 7·1 and treated with a sonicator (Water-bath Type, Nippon Rikagaku Kikai Co., Tokyo) at maximum power for 10 min at 70 °C. Orange II, 4NQNO, tetrachloroethylene were purchased from Katayama Chemical Ind., Osaka. These compounds were dissolved in endotoxin-free water. All chemicals were of analytical-reagent grade.

RESULTS

PE-CF adsorption capacity of various compounds by column chromatographic technique

Three polyethylene-based adsorbents and a polystyrene-based adsorbent Amberlite XAD-2 were examined for their capacities to adsorb LPS (*E. coli* 0113), orange II and 4NQNO by the column chromatographic technique. The adsorption capacity of each adsorbent for each individual compound was calculated from the elution profiles in Fig. 2, and the result shown in Table 1. PE-CF had the highest capacity to adsorb LPS when compared with the other three adsorbents, PE-MF, NPE-CF and Amberlite XAD-2. Orange II was removed to the greatest extent with a column of PE-CF. On the other hand, PE-MF revealed little removal of LPS, orange II and 4NQNO. NPE-CF adsorbed the least amount of LPS when compared with the other three adsorbents. Amberlite XAD-2 was capable of binding less LPS, orange II, or 4NQNO than PE-CF. Interestingly, PE-CF showed an increase in the capacity to bind LPS when the temperature rose, for instance to 70 °C.

Adsorption capacity of PE-CF for LPS as a function of incubation time

The PE-CF was examined for its capacity to bind LPS as a function of incubation time. An adsorption curve was almost linear up to the first 2 h. At 1 h of incubation, approximately 10 mg of LPS was adsorbed per gram of PE-CF. Adsorption reached a plateau after 24 h (Fig. 3). Adsorption capacities of PE-CF for LPS (0113) in 10 mM Tris-HCl buffer at pH 5·1 and pH 9·1 under 1 h of incubation time were then compared to the control pH 7·1. Adsorption capacities were 95% at pH 5·1 and 91% at pH 9·1 as compared to the control, respectively (data not shown). For the later experiments for the adsorption isotherms, pH 7·1 and 1 h of incubation time were adopted.

Experimental adsorption isotherms

PE-CF was further studied for its adsorption isotherms for three kinds of LPS, orange II, 4NQNO and tetrachloroethylene (Fig. 4). Conditions of adsorption experiments in Fig. 4 were as described in Table 2. For LPS, the adsorption of PE-CF in the presence of 0·5 M NaCl (3) was obviously higher than that of the control without NaCl (1). Ethanol concentration at 5% (4) decreased adsorption. An

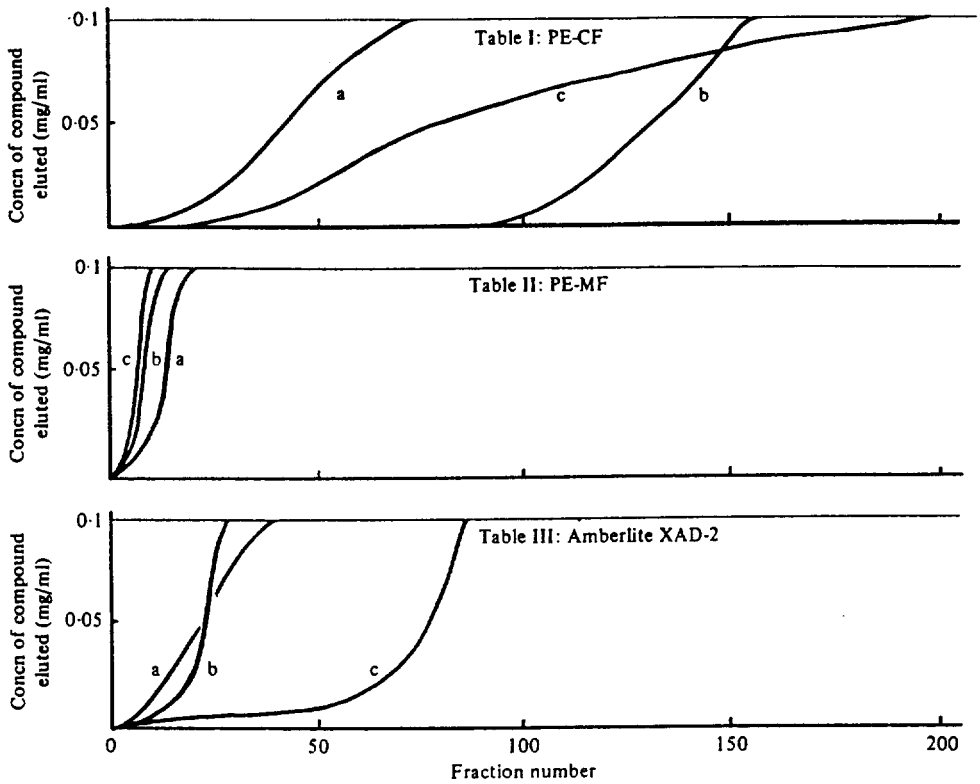

Fig. 2. Column chromatographic profiles of LPS, orange II and 4NQNO for three adsorbents. Table I: PE-CF, 1 g, column size: 0·9 × 8 cm. Table II: PE-MF, 1 g, column size: 0·9 × 10 cm (at beginning) to 0·9 × 6 cm. Table III: Amberlite XAD-2, 1 g, column size: 0·9 × 2·5 cm. All were done at 25 °C. (a) LPS (0113), (b) orange II, (c) 4NQNO. Axis: The concentration of the compound in the fraction was spectrophotometrically determined and calculated in reference to the unit of comparison (mg/ml).

Table 1. *Adsorption capacity of various adsorbents for LPS, orange II and 4NQNO using column chromatography*

	Amount adsorbed (mg/g) by			
Adsorbed solute	PE-CF	PE-MF	NPE-CF	Amberlite XAD-2
LPS (0113)	4·3 5·1*	1·3	0·4	2·2
Orange II	13·1	0·6	<0·1	2·1
4NQNO	9·5	0·8	<0·1	7·2

At 25 °C; * 70 °C.

elevated temperature (2) showed significantly stimulated binding as compared to the control temperature (1). Similar results were obtained for the three LPS. All adsorption isotherms except the condition 2 seemed linear and were quite similar to the Ln type of adsorption isotherm as demonstrated by Alligham, Giles & Neustadter in 1954. That is, the correlation between X/M and Ci is proportional. NPE-CF had less adsorption capacity of LPS (0113) in comparison to PE-CF. For

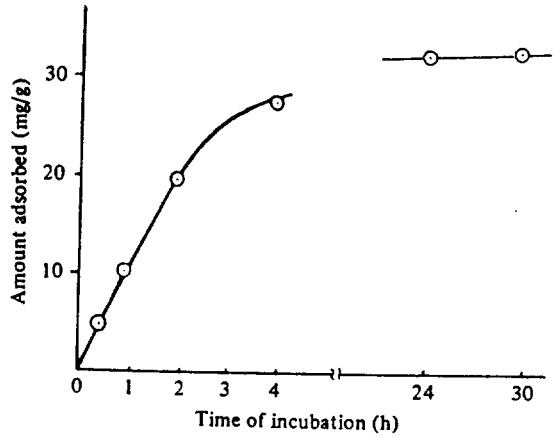

Fig. 3. Adsorption kinetic of PE-CF for LPS. LPS (0113) at initial concentration of 100 mg/100 ml, pH 7·1, was used. The adsorbent (300 mg/bag) was put into 10 ml of the solution and incubated for an indicated time at 25 °C and the LPS concentration remained was determined. Each point is a mean of duplicate determinations.

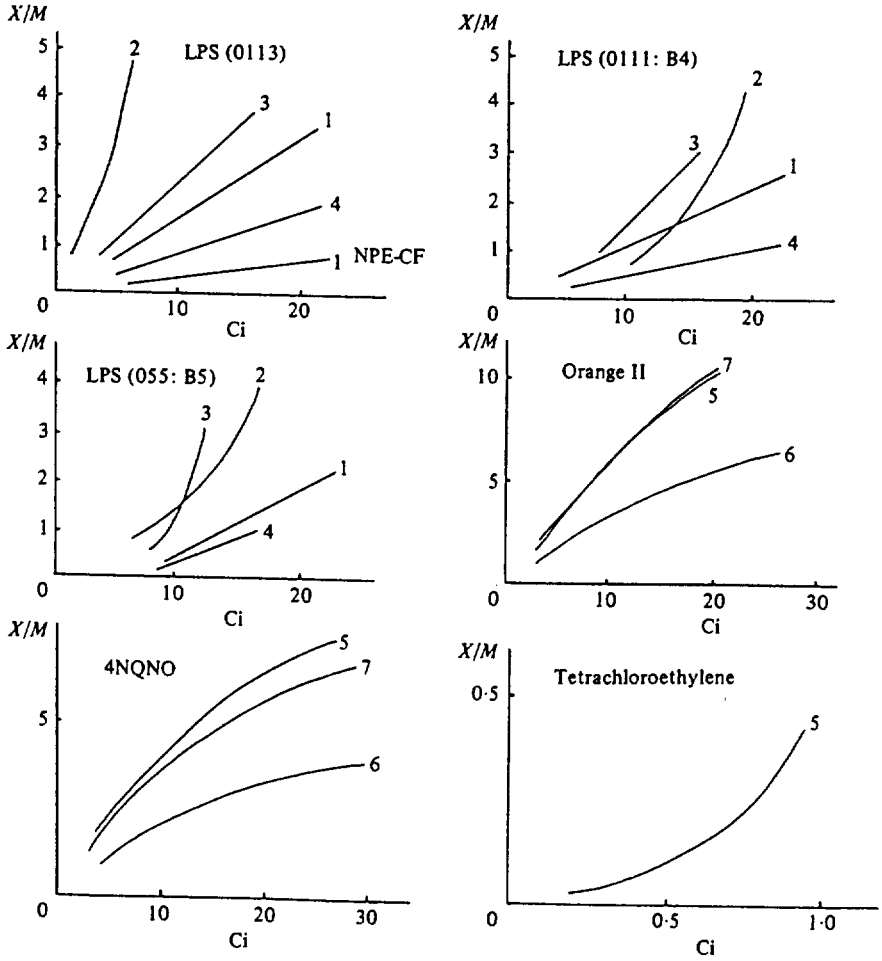

Fig. 4. Adsorption isotherms for PE-CF and NPE-CF of LPS, orange II and 4NQNO. Figures indicate conditions, see conditions in Table III. X/M, mg/g; Ci, mg/100 ml.

Table 2. *Experimental affinity values of PE-CF and NPE-CF for six compounds. Data were calculated by Freundlichs' equation*

Adsorbent condition	Solute: LPS (0113) 1/n	LPS (0113) log K	LPS (0111: B4) 1/n	LPS (0111: B4) log K	LPS (055: B5) 1/n	LPS (055: B5) log K	Orange II 1/n	Orange II log K	4NQNO 1/n	4NQNO log K	Tetrachloro-ethylene 1/n	Tetrachloro-ethylene log K
PE-CF												
1. pH 7·1* 25 °C	0·87	−0·55	1·09	−1·08	0·87	−0·55	—	—	—	—	—	—
2. pH 7·1 70 °C	1·37	−0·06	3·90	−3·98	2·54	−2·16	—	—	—	—	—	—
3. pH 7·1 25 °C 0·5 M NaCl	1·10	−0·42	2·48	−1·84	1·60	−1·17	—	—	—	—	—	—
4. pH 7·1 25 °C 5% EtOH	0·64	−0·41	3·57	−4·25	1·82	−1·63	—	—	—	—	—	—
5. In H_2O 25 °C	—	—	—	—	—	—	0·82	−0·04	0·81	−0·25	1·34	−0·55
6. In H_2O 70 °C	—	—	—	—	—	—	0·71	−0·09	1·06	−0·97	—	—
7. In H_2O 25 °C 0·5 M NaCl	—	—	—	—	—	—	0·92	−0·13	0·77	−0·31	—	—
NPE-CF												
1. pH 7·1 25 °C	0·98	−1·17	—	—	—	—	—	—	—	—	—	—

* 10 mM Tris-HCl buffer.

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Table 3. *Concentration of endotoxin in tap water following treatment with various adsorbents*

Treated with	Weight (g)	Column size (cm)	Concentration of endotoxin (ng/ml)
None	—	—	4·71
PE-CF	120	4·5 × 20	0·09
Charcoal	650	8·0 × 20	4·50
Amberlite XAD-2	120	4·5 × 20	2·17

other compounds, orange II and 4NQNO, the adsorption of PE-CF in the presence of 0·5 M NaCl (7) seemed to have very little effect as compared to the control (5). PE-CF revealed less adsorption capacity for both orange II and 4NQNO when the temperature rose (6). Adsorption isotherms of PE-CF for these organic compounds was of the L (Langmuir) type. The PE-CF had very little adsorption capacity for tetrachloroethylene and was of the S type, that is, affinity of the solute to the adsorbent is quite small.

Table 2 summarizes experimental affinity values of PE-CF and NPE-CF obtained by Freundlich's equation.

Endotoxin removal from tap water by various adsorbents

In order to compare the endotoxin removal efficiency, tap water which contains various natural sources of endotoxin was used. As a result, PE-CF treated water contained the lowest concentration of endotoxin activity when compared with the water samples treated with the other adsorbents, charcoal and Amberlite XAD-2 (Table 3).

DISCUSSION

Polyethylene, a hydrophobic material, can be wetted in the presence of some organic solvents or detergents, it is stable against acid, alkali, various organic solvents and detergents. This paper reports the following adsorption characteristics for endotoxin in water.

Adsorbents must have a large area of binding sites, and many modifications of three dimensional structure designed to increase the surface area can be considered. The most popular conformation is of microfibres like PE-MF but these have a low water flux during practical use. Therefore, to get sufficient water flux, a beady or granular shape is preferable. The PE-CF is beady and has approximately 63% surface porosity, giving it an approximately 300-fold larger surface area than that of NPE-CF and a 4-fold larger surface area than that of PE-MF. As shown in Table 1, PE-CF adsorbed 4·3 mg of LPS/g, whilst PE-MF adsorbed 1·3 mg/g. This result indicates that the polymer's surface area and its adsorption capacity are nearly proportional. However, this correlation between PE-CF and NPE-CF was in disagreement. The reasons for this contradiction are unclear at the present time.

In addition the pore size distribution of PE-CF is important. As shown in Fig. 1, PE-CF has a microfibril structure possessing various pore sizes on the surface. It has been reported that endotoxins in water have a size distribution from 10^4 Da

to 0·1 μm in size (Hannecart-Pokorni, Dekegel & Dupuydt, 1973). Therefore, it seems that the microfibrile structure of the PE-CF and its fine conformation of varying pore sizes contributes to the binding of various sizes of endotoxin molecules at a good rate of efficiency. This speculation is supported by the fact that the correlation of the adsorption capacities between PE-CF and PE-MF is contingent upon the polymer's surface areas.

Thirdly, the adsorption manner of LPS for PE-CF was studied, being quite similar to the Ln type of adsorption isotherms at 25 °C. When the temperature increased, the adsorption isotherm was bent and increased when compared to the control temperature. PE-CF pretreated by heating at 70 °C for 1 h and then allowed to cool had the same binding capacity for LPS as PE-CF with no treatment (data not shown). These results indicate that interaction between PE-CF and LPS at an increased temperature is not due to a change of the polymer's nature. In general, increased binding of solute to an adsorbent is recognized to be a hydrophobic interaction (Schneider, Kresheck & Scheraga, 1965). In contrast, both orange II and 4MQNO showed a decrease in their binding capacity to PE-CF when temperature rose, indicating that interactions other than a hydrophobic interaction were involved between PE-CF and these organic compounds. For PE-CF, these two organic compounds showed a typical Ln type of adsorption isotherm. Tetrachloroethylene showed an S type adsorption isotherm. The presence of salt in LPS solution resulted in a little increase in binding capacity of PE-CF as compared to the control without salt. We may speculate that addition of salt changes the LPS to a more fitting conformation for a hydrophobic binding. The binding capacity of PE-CF over a range of pH 5·1 to 9·1 did not change significantly. LPS between these pH ranges would not be altered in terms of its conformational features. Negative electrokinetic (zeta) potential of polyethylene is very close over a range of pH 5–9 (Beneš & Paulenová, 1973). The LPS molecule also has a negative charge (Nolan, McDewitt & Goldman, 1975; Hou *et al.* 1980). Therefore ionic interaction of endotoxin with PE-CF can be eliminated. Recently, immobilized histamine has been reported to have a binding affinity to LPS in hydrophobic and ionic interactions (Minobe *et al.* 1983). In aqueous solution millions of micells of amphipathic LPS molecules aggregate (Ribi *et al.* 1966). The LPS solution used in this paper seemed to be of the same nature, the LPS micells comprising hydrophilic group outside and hydrophobic group inside in aqueous solution. However, PE-CF binds efficiently to this type of LPS.

The adsorption profile of LPS was examined by a model experiment using a fluorescein isothiocyanate-LPS (*E. coli* 055: B5) conjugate (Skelly, Munkenbeck & Morrison, 1979). The fluorescein-LPS was passed through the membrane and observed under fluorescent microscopy. The EHF membrane was stained through the texture with fluorescein-LPS (Sawada *et al.* 1986).

Fourthly, an attempt was made to regenerate the used PE-CF. Approximately 60 % of the LPS (0113) and 95 % of both orange II and 4NQNO were removed from the adsorbent by a simple rinse with 70 (v/v) % ethanol (data not shown).

A number of commercially available adsorbents for endotoxin removal are available, polypropylene beads, Shell 5820 (Shell Chemical Co., Houston, Texas) and immobilized gel. Detoxi-gel™ (Pierce Chemical Co., Rockford, IL), in addition to conventional adsorbents such as charcoal and Amberlite XAD-2. The former

two are specifically for the removal of endotoxin from, for example protein solution, serum, and solutions containing pharmacologically important components. PE-CF is useful for treating large samples of water. The PE-CF has a better capability to bind endotoxin in tap water than other commercially available adsorbents such as charcoal and Amberlite XAD-2. PE-CF therefore has the potential to be utilized as an adsorbent for various fields; e.g. pharmaceutical, food, clinical, biotechnological, environmental and laboratory purposes.

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The adsorption of endotoxin molecule in a microporous polyethylene hollow fibre membrane

BY YOSUKE SAWADA*, REIKO FUJII, IKUO IGAMI, ATSUSHI KAWAI,

Product and Development Centre, Mitsubishi Rayon Co., Ltd, Higashiku, Nagoya 461, Japan

TERUO KAMIKI

Public Health Research Institute of Kobe City, Chuoku, Kobe 650, Japan

AND MAKOTO NIWA†

Osaka City University Medical School, Department of Bacteriology, Abenoku, Osaka 545, Japan

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SUMMARY

The microporous polyethylene hollow fibre membrane is capable of adsorbing small-sized lipopolysaccharides (LPS) prepared by sonication dispersion, column chromatography on Sephadex G-75 and filtration through a filter membrane with a nominal pore size of 0·025 μm. Small-sized LPS had a one-thousandth of endotoxin activity as compared to intact LPS, when determined by the Synthetic Chromogenic Substrate method of LAL with a specific endotoxin activity of 73·7 ng/μg LPS. Fluorescent microscopy of fluorescein conjugated LPS on a microporous polyethylene hollow fibre showed that fluorescein-LPS was adsorbed through the entire depth of the membrane texture. Accordingly the adsorption capacity of the filter for small-sized LPS was determined as 1·65 mg LPS/3·68 m^2 surface/116 mg fibre/module.

INTRODUCTION

The major pyrogenic substance in water is endotoxin (lipopolysaccharide, LPS). Gram-negative bacteria produce individual endotoxin on their cell surfaces and release it into the surrounding medium following cell lsyis. The amphipathic LPS molecule makes various aggregation forms (Weiser & Rothfield, 1968; Hannecart-Pokorni, Dekegel & Dupuydt, 1973). LPS in big forms can, in turn, be converted into smaller ones under various environmental conditions (Ribi *et al.* 1966; Leive, Schvlin & Mergenhagen, 1968; Shands & Chun, 1980) and smaller ones exist as free

* Present address: Bristol-Myers Research Institute, Shimomeguro, Meguroku, Tokyo 153, Japan.
† To whom all correspondence should be addressed.

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forms or combine to form hybrids (Rudbach, 1970; Seid & Sadoff, 1981). Such aggregation and disaggregation of LPS causes problems, e.g. in quality control during pharmaceutical manufacturing processes and the consequent clinical application. Recently, a microporous polyethylene hollow fiber (EHF, a commercial product of Mitsubishi Rayon Co., Tokyo) has been developed as a water-purifying medium which removes bacterial cells, fine particles and endotoxin from water (Kamiki *et al.* 1982; Kamiki *et al.* 1985). In the preceding paper (Sawada *et al.* 1986), an adsorbent produced from EHF membrane is reported to have the capability of adsorbing various kinds of endotoxin. To confirm the binding of endotoxin molecules on the surface of the EHF membrane in filtration process, we designed a model experiment using authentic LPS isolated from *Escherichia coli* 0113.

The characterization of the solubility or the dispersion degree of LPS is crucial for the evaluation of endotoxins and assessment of their removal. Sonication dispersion has been recently studied and recommended to solubilize or disperse LPS (Ogawa & Kanoh, 1984). The LPS molecules prepared by filtration through a membrane having a nominal pore size of 0·025 μm was designated here as the small-sized LPS. This paper describes (1) the preparation of small sized LPS and its characterization; (2) the removal capacity of EHF membrane for small sized LPS; and (3) the adsorption mode of LPS-fluorescein isothiocyanate conjugate in the EHF membrane texture.

MATERIALS AND METHODS

The EHF membrane and module

Characteristics of the EHF membrane (Code: EHF 390-C, Mitsubishi Rayon Co., Tokyo) were as described by Kamiki *et al.* (1982). A module for experiment was made by using 128 filaments of the EHF membrane as shown in Fig. 1. The total surface area as determined by the nitrogen adsorption method (Bohra, 1984) is approximately 31·7 m^2/g fibre. To permeabilize the EHF membrane in the module it was treated with 30 ml of 99 % ethanol and then 50 ml of endotoxin-free water (Otsuka Pharmaceutical Co., Naruto). Water flux through the membrane in the module was adjusted with a Mini-Pump (TMP 10H, Toyo Kagaku Sangyo Co., Tokyo) to 0·5 ml/min at 25 °C.

Determination of endotoxin activity

Determination of endotoxin in water samples was as described in the preceding paper (Sawada *et al.* 1986). A *Limulus* amoebocyte lysate (LAL) based kit, Pyrodick®, was purchased from Seikagaku Kogyo Co., Tokyo. An authentic LPS isolated from *E. coli* 0111:B4 (Difco Lab., Detroit, Michigan) was suspended in endotoxin-free water and treated with a sonicator (water-bath type, Nippon Rikagaku Kikai Co., Tokyo) at maximum power for 10 min at 70 °C. Endotoxin-free water was also used as a control sample. All glassware for pyrogen tests was heated at 250 °C for 2 h.

Carbocyanine dye reaction

A carbocyanine dye reaction was carried out by the method of Zey & Jackson (1973); briefly, 1·8 ml of acetate buffer (0·03 M, pH 4·0) and 0·9 ml of the dye

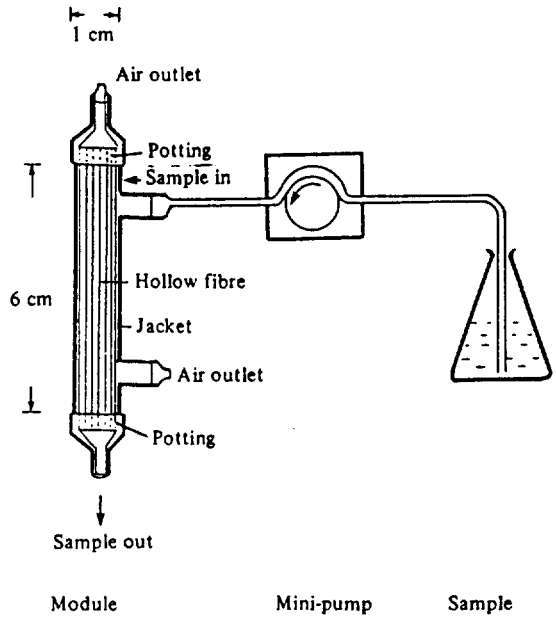

Fig. 1. A schematic diagram of filtration treatment.

reagent were added to a 0·3 ml sample, and the mixture was incubated at 30 °C for 15 min in the dark. Absorbance was determined by a spectrophotometer (Shimadzu UV-250 with attached recording unit OPI-2, Shimadzu Co., Kyoto).

Determination of the glucose concentration in LPS

The glucose concentration in LPS was estimated with anthrone (Spiro, 1966); briefly 2 ml of anthrone reagent was added to 1 ml of sample and the mixture heated at 95 °C for 15 min. The absorbance at 625 nm was measured. α-D-Glucose was used for the standard curve. LPS from *E. coli* 0113 contained 12 μg glucose/40 μg LPS.

LPS from E. coli 0113 *and sonication treatment*

LPS was extracted from a broth culture of *E. coli* 0113 by the hot-phenol method (Westphal & Lüderitz, 1954). In order to purify LPS, extraction was repeated three times and lyophilized to give a white powder. The LPS (2 mg) was suspended in 10 ml of buffer A (Tris-HCl, pH 7·1 containing 200 mM NaCl) and pulse-sonicated at 20 Kc, 20 W in a water-bath by a sonicator (Sonifier® Cell Disruptor 200, Branson Sonic Power Co., Dansbury, Conn.). At times indicated, 2 ml aliquots were removed and used for various assays.

Column chromatography of Sephadex G-75

Sephadex G-75 (Pharmacia Fine Chemicals AB, Uppsala, Sweden) was washed extensively with endotoxin-free water, and replaced with buffer A and a column (1·5 × 20 cm) was prepared. The LPS-containing sample was loaded onto the column and eluted with buffer A. The flow rate of chromatography was adjusted to 1 ml/min. The filtrate (2 ml) was collected in each tube.

Preparation of small sized LPS

A membrane filter (diameter 22 mm) with a nominal pore of 0·025 μm (Millipore Co., Bedford, MA) was rinsed with endotoxin-free water and set in an adaptor for syringe injection. The filtrate (approximately 1 ml) was collected and absorbance of the filtrate was determined. LPS which passed through the EHF membrane was defined as small-sized LPS in this paper. To prepare a large volume of small-sized LPS, LPS sonicated for 1 min was filtered through a membrane (0·025 μm) in a filtration unit, Lab Cassett (Millipore Co.). The sonicated LPS and the small sized LPS were used on the day without freezing.

Removal capacity of EHF membrane for small sized LPS

Small-sized LPS at an optical density of 0·21 at 214 nm, which is equivalent to 100 μg/ml, was prepared by adjusting the concentration with buffer A. The LPS solution was continuously applied onto the EHF membrane in a module at a flow rate of 0·5 ml/min at 25 °C. The filtrate (1·5 ml) was collected in each fraction.

Observation of FITC-LPS adsorbed EHF membrane

Fluorescein isothiocyanate conjugate (LPS-FITC; Skelly, Munkenbeck & Morrison, 1979) was purchased from List Biological Lab. (Campbell, CA). An LPS isolated from *E. coli* 055:B5 was used for the preparation (23·3 moles of FITC per mole of LPS, List Biological Lab. Technological Data). The FITC-LPS (0·5 mg) dissolved in 50 ml of buffer A was divided into two parts. One part, 20 ml of the solution, was applied to one module, and the other part, 30 ml, to another module. Each module was broken and the EHF membrane was taken out and left in the dark for a few days. The FITC-LPS adsorbed EHF was fixed in paraffin and sliced by a microtome to 100 μm length. The cut end of EHF was observed under fluorescence microscopy (Olympus BH with a filter of 515 nm, Olympus Co., Tokyo).

Chemicals

Carbocyanine dye and anthrone were purchased from Eastman Kodak Co. (Rochester, New York) and Ishidzu Pharmaceutical Co. (Osaka), respectively. Other chemicals were of analytical reagent trade.

RESULTS

Sonication effect on the characteristics of LPS

The LPS isolated from *E. coli* 0113 was chosen because it is well-characterized (Ribi *et al.* 1966; Niwa *et al.* 1969) and is used as the US Standard (EC-2). The LPS suspended in buffer A was sonication-dispersed. At the indicated time sonicated samples were incubated with carbocyanine dye solution. The dominant moiety of LPS which reacts with the dye was lipid A (Ogawa & Kanoh, 1984). Accordingly, the absorption maximum of the LPS (0113) and dye conjugate was set at 470 nm. The absorbance at 470 nm increased during the first 30 sec of sonication and then levelled off to a slight increase. This indicates that the LPS molecules were fairly dispersed in the first 30 sec of sonication. Endotoxin activity was determined by the Synthetic Chromogenic Substrate method (Iwanaga *et al.*

Table 1. *Reactivities of LPS with carbocyanine and LAL following sonication*

Sample	Sonication period (min)	Carbocyanine dye reaction* (470 nm)	Endotoxin activity†		Absorbance at 214 nm	
			unfiltered (mg/ml)	filtered‡ (μg/ml)	unfiltered	filtered
Blank control	0	0·076	0·00	0·00	0·00	0·00
LPS	0	0·168	0·15	0·16	1·28	0·15
LPS	0·5	0·631	0·61	4·3	0·51	0·26
LPS	1	0·653	0·73	5·2	0·51	0·32
LPS	2	0·660	0·84	5·2	0·46	0·35
LPS	5	0·656	0·91	5·5	0·46	0·38

* A 100 μl aliquot (20 μg LPS) is used for the assay.
† Concentration of LPS was 0·2 mg/ml. For assay, the sample was diluted with endotoxin-free water. Data are a mean of duplicate determinations.
‡ Sample was filtered by a membrane with a nominal pore size of 0·025 μm.

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1978; Harada-Suzuki *et al.* 1982) of LAL. This method has an advantage of quantitative determination with a fairly good accuracy and reproducibility (Usami & Shimohira, 1981; Fujita & Nakahara, 1982). Endotoxin activity resulted in an increase after 30 sec of sonication and a gradual increase by further treatment (Table 1). The endotoxin activity of the sonicated LPS filtered through a membrane with a nominal pore size of 0·025 μm was 6–7 % of the unfiltered LPS. Absorption at 214 nm in the filtrate increased with prolonged periods of sonication, while absorbance at 214 nm, where almost all organic compounds have an absorbance in aqueous solution, decreased gradually following sonication in unfiltered material. This suggests that the LPS suspension was dispersed.

Gel-filtration of sonicated LPS and size estimation

In order to estimate the molecular size of the sonicated LPS, Kanoh, Kohlage & Siegert (1968) used a pyrogen-free column of Bio-Gel P-100. Similarly gel-filtration through a column of Sephadex G-75 was carried out in this paper. The elution profile was followed by reading the absorbance at 214 nm. Recovery of LPS from the column was over 85 in absorption base. Two ml of LPS dispersed for 1 min showed a major peak, Peak I, and a minor peak, Peak II (Fig. 2). A 1·5 ml aliquot of each fraction was next filtered by a filter membrane with a nominal pore size of 0·025 μm. Two peaks of absorbance in the filtrate were obtained as indicated by bars. Each of the peak fractions were combined and endotoxin activity was determined. As shown in Table 2, the Peak I filtrate had a poor activity in the LPS test, and Peak II had much less activity than the Peak I filtrate in absorption base. Endotoxin in Peak I had the highest activity. Since Peak II seemed to contain something like a by-product of LPS, e.g. an oxidized product (Ogawa & Kanoh, 1986), endotoxin in the Peak I filtrate was used in this study as a small-sized LPS.

Determination of the specific activity of small-sized LPS

The LPS concentration of the Peak I filtrate was determined from the glucose concentration by an anthrone reaction. Intact LPS contained 12 μg of glucose in 40 μg LPS (30 % glucose/LPS). The Peak I filtrate at A 214 nm: 0·1 contained 14·25 μg glucose/ml. Therefore, Peak I filtrate at A 214 nm:0·1 contains 47·5 μg LPS/ml. From the endotoxin activity in Table 2, the specific endotoxin activity of the Peak I filtrate was obtained, being 73·7 ng activity/μg LPS.

Removing capacity of EHF membrane for small-sized LPS

Small-sized LPS in the Peak I filtrate was passed through the EHF membrane in a module as shown in Fig. 1 and the LPS concentration in the filtrate was measured (Fig. 3). From an elution profile indicated by oblique lines, the amount of small-sized LPS adsorbed on the EHF membrane was estimated, resulting in 1·65 mg/116 mg fibre/3·68 m^2/module.

To confirm that molecular size distribution of LPS in the filtrate is the same size as the small sized LPS, a filtrate fraction number 10 in Fig. 3, 2 ml aliquot, was analysed on a column of Sephadex G-75. The retention fraction of LPS in the fraction number 10 appeared in fraction 13 (Fig. 4). Peak I filtrate was also analysed. Although small-sized LPS was prepared from Peak I fraction (a main

Table 2. *Correlation between LPS concentration and the endotoxin activity*

Peak fraction	Endotoxin concentration (μg/ml/A 214 nm:0·1)
I	1150·0
II	0·4
I Filtrate	3·5

Calculation based on A 214 nm:0·1.

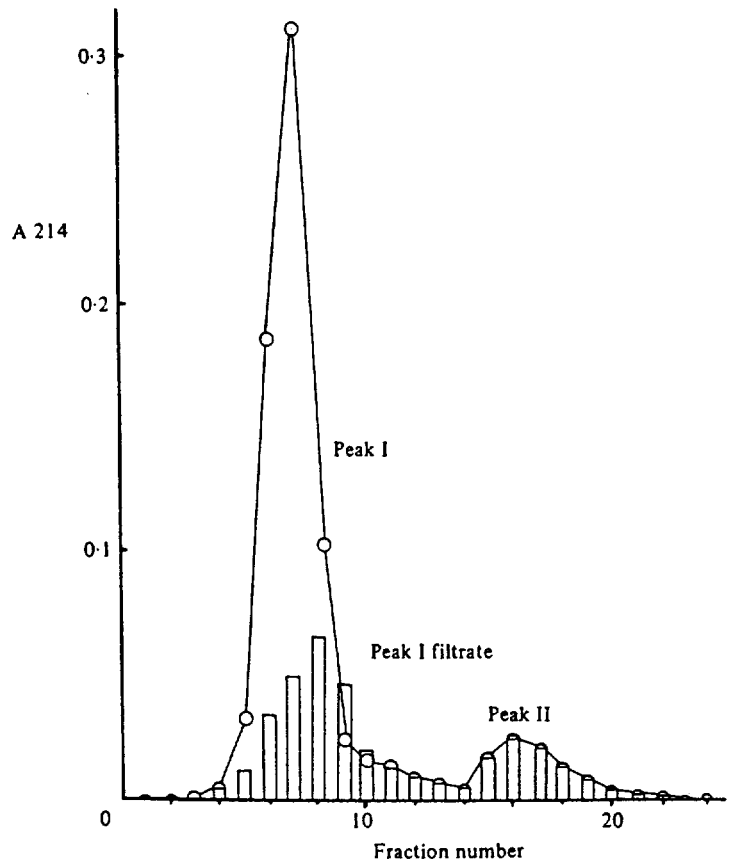

Fig. 2. Chromatographic profile of LPS sonicated on a column of Sephadex G-75 and filtration profile with a membrane. -O-, Sonicated for 1 min; ▭, filtered with a membrane.

peak fraction 8) in Fig. 2, it was eluted in fraction number 13. Recovery of the small-sized LPS through the gel filtration was approximately 85 % in absorption base. Specific endotoxin activity of the fractions 12–14 (Fig. 4) obtained from the filtrate 10 (Fig. 3) was 3·0 μg/ A 214 nm:0·1/ml.

Recovery of small-sized LPS adsorbed on the EHF membrane

To confirm whether adsorbed small-sized LPS can be released, LPS adsorbed EHF membrane was rinsed with 20 ml of 70 (v/v)% ethanol and 2 ml aliquots were analysed on a column of Sephadex G-75. From peak intensity, an approxi-

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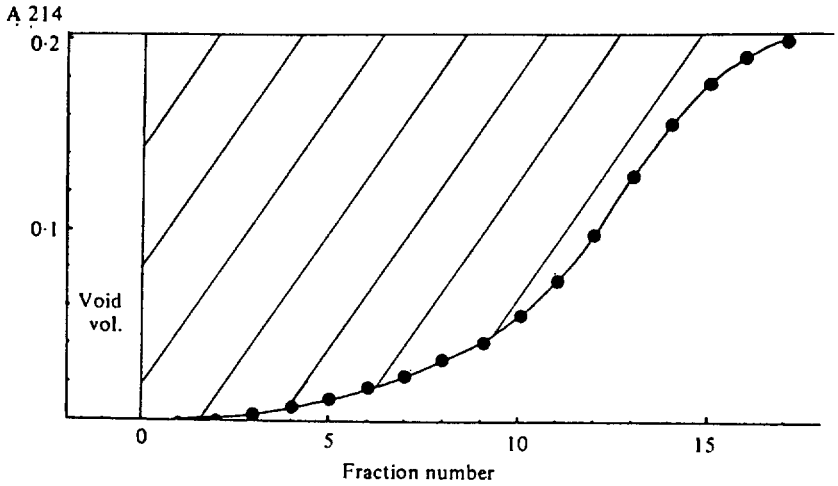

Fig. 3. Removing capacity of EHF membrane for small-sized LPS.

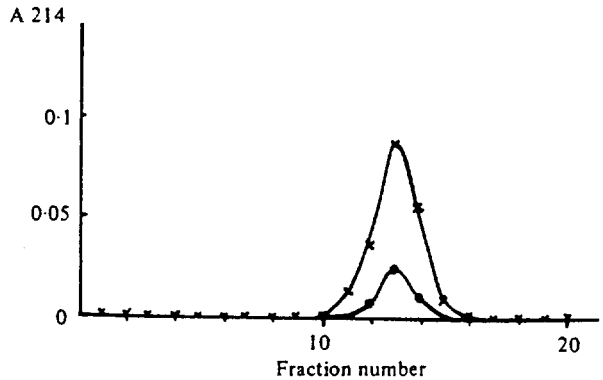

Fig. 4. Chromatographic pattern of the Peak I filtrate and the peak fraction 10 in Fig. 2. -✳-, Filtrate with a membrane; -●-, Fraction 10 in Fig. 2.

mately 92 % recovery of LPS, identical with small-sized LPS, from EHF membrane was obtained (data not shown).

Adsorption mode of the EHF membrane for FITC-LPS

The fluorescein conjugated LPS was passed through the EHF membrane and the adsorption mode of FITC-LPS was observed under a fluorescence microscopy. The membrane texture was stained all over with fluorescein. The intensity of fluorescein seemed to depend on the concentration of FITC-LPS loaded (Fig. 5).

Formation of large-sized LPS from the small-sized LPS

To see whether the small-sized LPS forms large-sized LPS under certain conditions, a solution of the small-sized LPS was left at 4 °C for 7 days. The solution was then analysed on a column of Sephadex G-75. Recovery of LPS from the column was 93 % in absorption base at 214 nm. Approximately 7 % of total absorption eluted was in fraction numbers 7–9. A specific endotoxin activity of the large-sized LPS was 1063 μg/ml/A214 nm:0·1.

466

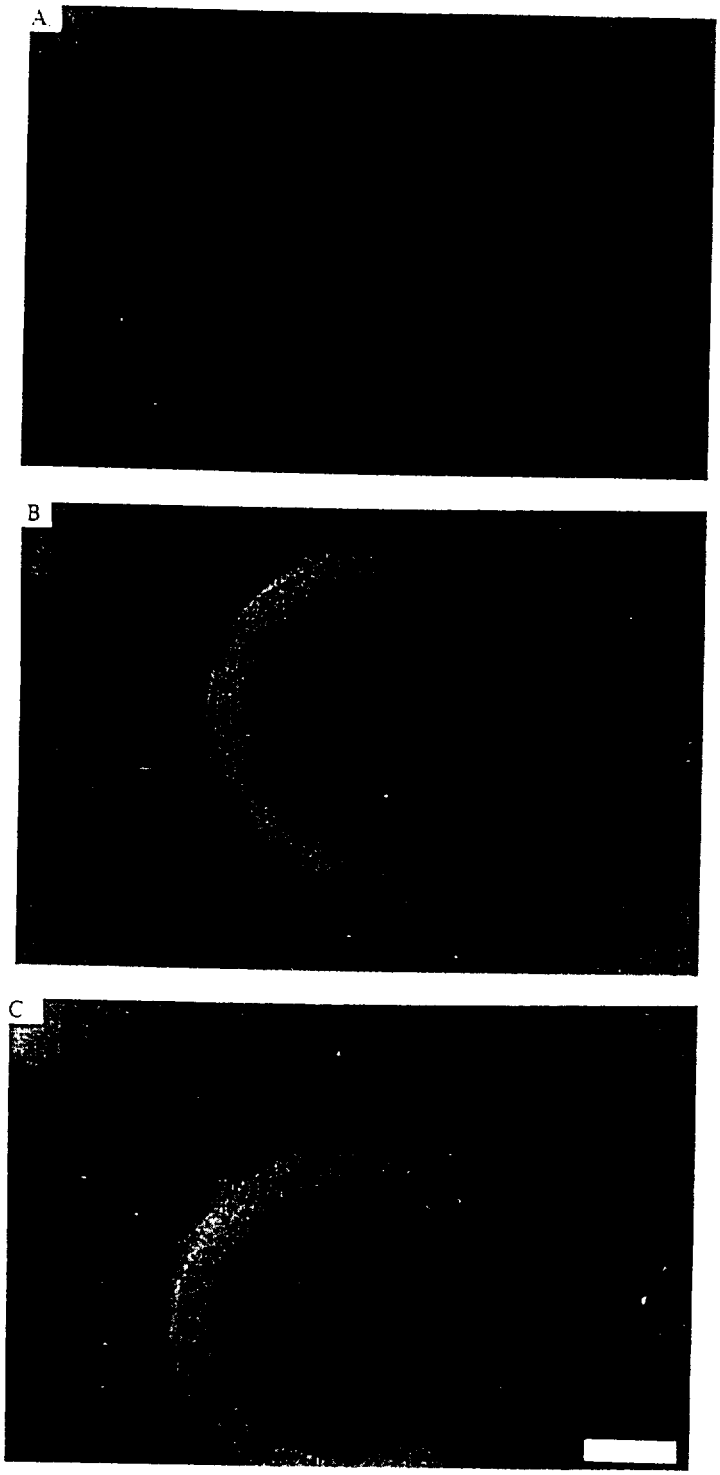

Fig. 5. Microscopic feature of FITC-LPS adsorbed EHF membrane. A, untreated control; B, FITC-LPS (20 ml) loaded, C, FITC-LPS (30 mL) loaded. A bar indicates 100 μm.

DISCUSSION

The solubility or dispersion degree of LPS in an aqueous solution is directly responsible for the difference of endotoxicity. That is, LPS molecules with a small size have less reactivity to LAL test and less pyrogenicity in rabbits (Marx *et al.* 1968; Sweadner, Forte & Nelsen, 1977; Kanoh & Kawasaki, 1980). Likewise, small sized LPS prepared from *E. coli* 0113 by sonication dispersion and membrane filtration (0·025 μm in pore size) showed very poor reactivity to the LAL test (Table 2). Kanoh also observed that, following either sonication treatment or Triton X-100 treatment, LPS exists as small-sized LPS with a range of 0·01–0·02 μm as determined by electron microscopy by staining with uranyl acetate as well as sucrose gradient centrifugation (unpublished data). The small-sized LPS prepared seemed to have a similar size as observed above. The small-sized LPS may, therefore, be the short rodlets, not long string and spherical forms. A problem of small-sized LPS is that it forms large-sized LPS under various conditions which give high pyrogenicity. Indeed, we observed the formation of large-sized LPS from the small-sized LPS at a low temperature; this was determined by specific endotoxin activity of LAL test for LPS eluted from a column of Sephadex G-75. This observation is consistent with the report that deoxycholate-treated LPS could be reaggregated to the large LPS following dialysis against deoxycholate-free water (Ribi *et al.* 1966).

The EHF 390C membrane was found to have a maximum pore size of 0·04 μm as determined by several kinds of spherical, uniform particles and various viruses (Sawada, unpublished data). If endotoxin molecules are of larger size than this pore size, it would be removed by a filtration mechanism. The small-sized LPS was initially removed from the filtrates and was leaked out gradually in successive feedings (Fig. 3). This result clearly indicates that small-sized LPS was adsorbed and leaked out because of the reduction of binding sites on the EHF membrane. The adsorption mode of LPS was visualized by staining the EHF membrane with fluorescein. Not only the membrane surface, but also the entire depth of the membrane texture had been stained (Fig. 5).

It is well known that an ultrafiltration (below 0·02 μm, Porter, 1975) technique can provide endotoxin-free water (Sweadner, Forte, & Nelsen, 1977; Cradock *et al.* 1978). Because current ultrafiltration membranes have no specificity to bind endotoxin, contaminating particles are also removed from water. Therefore, the membrane soon faces fouling. EHF membrane has a relatively high water flux because of microfiltration in pore range (Porter, 1975). EHF membrane can simply be rinsed with organic solvents such as ethanol or acetone to simultaneously rejuvenate and sterilize the membrane. It was also found that removal efficiency of endotoxin from water at a high temperature, e.g. 70 °C, was greater than that of low temperature (data not shown). This result is in good agreement with our preceding observation (Sawada *et al.* 1986). Thus, EHF membrane is unique medium for water purification and is shown to have the capacity of adsorbing a kind of LPS in water by the filtration process.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

MAR - 8 1993

Constance G. Bundy
C/O C. G. Bundy Associates
Medivators, Inc.
6470 Riverview Terrace
Minneapolis, MN 55432

Re: K914145
DSD-91™ Disinfector
Dated: July 20, 1992
Received: July 21, 1992

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following information:

1. Because of the increasing public health concern about the transmission of diseases such as AIDS, hepatitis, and tuberculosis, FDA is now actively regulating general purpose germicides and other products used in reprocessing medical devices, e.g., detergents, enzyme agents, lubricants, etc. As a result, even though there are general purpose germicides on the market registered by the Environmental Protection Agency (EPA), none are considered legal under the laws administered by FDA.

   You are aware that FDA has been testing and evaluating these germicides, has removed one product from the market due to lack of effectiveness, and is pursuing legal action against others. FDA has cleared certain germicides used in dialysis and one machine, the Steris System, with a dedicated germicide that is labeled for general use.

   The FDA compliance initiative creates a regulatory dilemma for those products that are labeled for use with the violative germicides. The affected products include test strips and automatic washer/disinfectors. It is agency policy not to render a decision of equivalence for accessories until the primary device (in this case the germicide) is legal.

   FDA is not aware of any legally marketed germicide indicated for machine use. Even under the EPA registration virtually all germicides used in reprocessing endoscopes are labeled for manual use only. Those that are labeled for machine use have either been removed from the market or may be compelled to be removed by FDA. The upshot is that health care users may be using germicides that are ineffective when used in machines. Such factors as foaming and dilution may adversely impact some germicides more than others. Information provided by accessory manufacturers to supplement germicide labeling in order to facilitate machine use may not be adequate.

   We have considered our approach to evaluation of disinfecting machines. There are aspects of performance that can be considered from an engineering basis. Still, data must show that the machine operates as intended using machine compatible germicide(s) indicated in labeling. Data must show that reprocessed devices are high level disinfected when the machine is used according to labeling. The variable of germicide performance is a confounding factor.

   FDA is receptive to your opinions regarding its regulatory options. At the present time we believe there are 5 options:

a. FDA cannot find your device equivalent until at least one germicide is cleared by FDA for machine use, and your device is labeled for use with that germicide. How the germicide could be labeled is questionable. Whether it could be labeled with specifications for compatible machines or must be labeled for specific machines remains open. There must be performance data showing the germicide is effective when used according to labeling with the (type of?) machines indicated in labeling.

b. FDA may find your device equivalent if you can justify that generic specifications for compatible germicides are feasible. You would have to consider not only the formulations of germicides now marketed but also the impact of formulation changes to those products, and new products that may legally enter the market. You would also have to consider how the user will be able to match your generic specifications to all germicide labeling. Current labeling lists only the active ingredients, but inactive ingredients may have just as much or more impact on effective use and compatibility with the machine.

   Due to FDA's evaluation of germicides, the contact conditions of the germicides may be significantly revised. Your device must have features that allow for the revised contact conditions (e.g., contact times and temperature). Qualification of performance and compatibility still hinges on the use of a marketed germicide to confirm the labeling specifications. Given the flux of the germicide labeling now under review this option is tenuous. Generally, germicide manufacturers are proposing to FDA longer contact times for disinfection than that registered under EPA.

c. FDA may consider data qualifying a specific legally marketed germicides in your machine even though they may be labeled for manual use only. We are evaluating the legality of this option. Under this scenario, labeling from the machine manufacturer will supplement the germicide labeling to ensure effective and safe use of the germicide in the machine. Data from the machine manufacturer must qualify the germicide for use in their machine. In this case the manual use contact conditions will probably have to be maintained in the machine (e.g., minimum concentrations, temperature, time).

d. A variation of option c. is for the germicide manufacturer to provide a finished legally marketed, manual use only germicide to the machine manufacturer as a "raw material" who in turn will relabel the germicide for use with the machine. As above, data from the machine manufacturer must qualify the germicide for machine use.

e. The machine manufacturer may consider sole development and marketing of a germicide for their device. This would incur the need to submit a comprehensive 510(k) on the safety and effectiveness of the germicide.

You will note that only option b. provides the opportunity to move to an equivalence decision before germicides are cleared. All the options probably require some form of communication between the germicide and machine manufacturers. As alluded to in option b, if the formulation of a germicide is modified the impact on the effectiveness in the machine must be addressed.

We understand that you are concerned about fairness in regulation and will want to know how FDA intends on dealing with other machines now marketed or that may be in the review process. Applicants of machines in process will be presented the same options. For those machines now marketed FDA is taking appropriate action to respond to this public health issue.

This is potentially what FDA calls an "outstanding device issue" that prevents FDA from completing its review of this submission. We'll consider your comments before rendering a final determination. Nevertheless, in order to ultimately expedite matters, we have identified other deficiencies below which must be answered in order to establish whether the device is substantially equivalent. Some of the questions assume satisfactory resolution of deficiency 1. Depending on the outcome of deficiency 1, some of the recommendations below for labeling and data may need modification or may be moot. As a result, deficiency 1 must be resolved first. FDA is amenable to meeting with you to discuss the options and other options that you may wish us to consider.

2. FDA requires not only simulated testing but also in use testing, as noted in question #12 of our letter dated March 23, 1992. You did not fully respond to the deficiency. Provide the requested test data.

3. Without the proper control demonstrating the number of spores recovered from a scope after any "precleaning" procedure and prior to disinfection in the DSD-91, the disinfection efficacy data for the DSD-91 can not be evaluated. Provide efficacy testing data which include the proper controls.

   Justify using a 2 ml inoculum for all channels considering the findings in the Vesley et.al, paper entitled "Significant Factors in the Disinfection and Sterilization of Flexible Endoscopes" that up to 15 ml can be contained in the suction channel.

4. The minimum effective concentration (MEC) of the germicide must be maintained when using the DSD-91. The MEC is identified in the germicide labeling and may vary from product to product. Claiming a lower MEC than that in germicide labeling will not be permitted.

5. It was noted that the air channel for the Olympus XQ10-3 was the most difficult to disinfect even following the SGNA guidelines. Please comment on the impact of this finding on the instructions for use. For example, should these scopes require special precleaning or processing? Identify the generic types of endoscopes used for the testing to make certain that the study contains representative samples of endoscopes. Note that in the absence in-use data we cannot determine whether the reduction of contamination is clinically acceptable.

6. Anecdotal user information concerning the recommendation for changing the Stearopore filter is insufficient. Provide data to support the claim for changing the filter every 6 months. The testing should mirror maximum use conditions for the DSD-91 during the 6 month period such as significant water use, different qualities of water, etc. The data must show the safety factor associated with the recommendation for changing every 6 months.

7. Provide the page number in the manual which clarifies the intent of the disinfectant filter (re answer to question 7). The information concerning disinfectant filtration (pg 2-1) contained in the manual submitted with the supplemental material dated 7/20/92 is identical to the information concerning disinfectant filtration (pg 2-1) contained in the manual submitted with the original application dated 9/13/91. You have not satisfactorily demonstrated that the disinfectant filter keeps sediment out of the disinfectant reservoir.

8. The testing protocol for biofilm formation is not sufficiently rigorous to show that biofilms do not develop in units after extended use. Provide additional testing on units which have been in extended service. The testing should include the culturing of tubing, vents, etc.

9. Provide the method used to determine the level of glutaraldehyde residues which remained on the scopes after the rinse cycle. Identify the types of scopes used for the testing. Given that you refer only to glutaraldehydes generically in labeling, and given that you indicate that many different brands and types of scopes can be processed, justify with data how your rinsing step is adequate for all combinations of germicides and scopes. Alternatively, as the options in item 1 provide, you can specify brand name germicides and scopes in labeling and test the residues remaining on the scopes after processing with all combinations of stated germicides and scopes. Be advised that the residuals must be demonstrated to be at or below safe levels determined by relevant toxicity tests.

10. Provide a more complete description of how an endoscope is connected the DSD-91, of the Qwik-load insert, of all accessories and hook-ups, and of the fluid pathway through the scope. The instructions do not clearly describe how an endoscope is connected to the DSD-91.

11. Clarify the following items:

    a. Provide the page number in the manual where the recommendation for a 20 minute disinfection cycle with a 2% glutaraldehyde is stated.

    b. Provide a statement in the manual describing the water quality required for the DSD-91. This is related to the issue on the filter.

    c. There is an air purge after each of the cycles and for the end of day processing; however, there does not appear to be a requirement for an air filter. Provide information in the manual on how the user would prevent the endoscope from becoming contaminated with particulate matter from the air compressor or the house air line.

    d. The recommendation in the manual for the alcohol purge and air drying of the endoscopes at the end of the day should be clarified to state that this should be done after the last procedure of the day for the endoscope.

    e. State why the set custom temperature option for the disinfectant is not available in the U.S. (pgs. 3-6) and how this feature is disabled for U.S. models.

    f. Clarify in the manual the purpose of screens 3 & 4 in the "Set Custom Program", pages 3-6 & 3-7.

    g. Explain why the fluid level sensors can be inhibited, pg 3-8.

h. Explain how the user can set the maximum disinfection cycle count, since most disinfectant manufactures set the reuse life based upon a manual cycle (pgs 3-10). The information that the disinfection cycle is based upon a 14 day reuse life disinfectant should be repeated at this point.

i. The information contained in the Section "Disinfectant Change", pg 3-16, is inadequate. The manual must clearly state that, at a minimum, the disinfectant must be monitored daily.

j. The manual should contain a statement that the user should monitor the DSD-91 to prevent the development of biofilms.

k. The sections in the user's manual identified as "IMPORTANT" and "USERS NOTES" must be reconsidered. The statements appear to be more appropriate as either Precautions or instructions for use. Revise accordingly. The validity of the statement regarding contact conditions for the germicide are contingent upon the issue noted in item 1 above.

12. Since some of the 3.2% glutaraldehydes contain surfactants which cause foaming and the manual contains a warning about foaming with certain brands of disinfectants, tell us what information is given to the user.

The additional information should be submitted in duplicate, referencing the 510(k) number, to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 80 7.87(f) and (h), 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 requested information 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 re-submitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Susanna F. Barrett at (301) 427-1307. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for

Paul R. Beninger, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

MAR - 8 1993

Constance G. Bundy
C/O C. G. Bundy Associates
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This is potentially what FDA calls an "outstanding device issue" that prevents FDA from completing its review of this submission. We'll consider your comments before rendering a final determination. Nevertheless, in order to ultimately expedite matters, we have identified other deficiencies below which must be answered in order to establish whether the device is substantially equivalent. Some of the questions assume satisfactory resolution of deficiency 1. Depending on the outcome of deficiency 1, some of the recommendations below for labeling and data may need modification or may be moot. As a result, deficiency 1 must be resolved first. FDA is amenable to meeting with you to discuss the options and other options that you may wish us to consider.

2. FDA requires not only simulated testing but also in use testing, as noted in question #12 of our letter dated March 23, 1992. You did not fully respond to the deficiency. Provide the requested test data.

3. Without the proper control demonstrating the number of spores recovered from a scope after any "precleaning" procedure and prior to disinfection in the DSD-91, the disinfection efficacy data for the DSD-91 can not be evaluated. Provide efficacy testing data which include the proper controls.

   Justify using a 2 ml inoculum for all channels considering the findings in the Vesley et.al, paper entitled "Significant Factors in the Disinfection and Sterilization of Flexible Endoscopes" that up to 15 ml can be contained in the suction channel.

4. The minimum effective concentration (MEC) of the germicide must be maintained when using the DSD-91. The MEC is identified in the germicide labeling and may vary from product to product. Claiming a lower MEC than that in germicide labeling will not be permitted.

5. It was noted that the air channel for the Olympus XQ10-3 was the most difficult to disinfect even following the SGNA guidelines. Please comment on the impact of this finding on the instructions for use. For example, should these scopes require special precleaning or processing? Identify the generic types of endoscopes used for the testing to make certain that the study contains representative samples of endoscopes. Note that in the absence in-use data we cannot determine whether the reduction of contamination is clinically acceptable.

6. Anecdotal user information concerning the recommendation for changing the Stearopore filter is insufficient. Provide data to support the claim for changing the filter every 6 months. The testing should mirror maximum use conditions for the DSD-91 during the 6 month period such as significant water use, different qualities of water, etc. The data must show the safety factor associated with the recommendation for changing every 6 months.

7. Provide the page number in the manual which clarifies the intent of the disinfectant filter (re answer to question 7). The information concerning disinfectant filtration (pg 2-1) contained in the manual submitted with the supplemental material dated 7/20/92 is identical to the information concerning disinfectant filtration (pg 2-1) contained in the manual submitted with the original application dated 9/13/91. You have not satisfactorily demonstrated that the disinfectant filter keeps sediment out of the disinfectant reservoir.

8. The testing protocol for biofilm formation is not sufficiently rigorous to show that biofilms do not develop in units after extended use. Provide additional testing on units which have been in extended service. The testing should include the culturing of tubing, vents, etc.

9. Provide the method used to determine the level of glutaraldehyde residues which remained on the scopes after the rinse cycle. Identify the types of scopes used for the testing. Given that you refer only to glutaraldehydes generically in labeling, and given that you indicate that many different brands and types of scopes can be processed, justify with data how your rinsing step is adequate for all combinations of germicides and scopes. Alternatively, as the options in item 1 provide, you can specify brand name germicides and scopes in labeling and test the residues remaining on the scopes after processing with all combinations of stated germicides and scopes. Be advised that the residuals must be demonstrated to be at or below safe levels determined by relevant toxicity tests.

10. Provide a more complete description of how an endoscope is connected the DSD-91, of the Qwik-load insert, of all accessories and hook-ups, and of the fluid pathway through the scope. The instructions do not clearly describe how an endoscope is connected to the DSD-91.

11. Clarify the following items:

    a. Provide the page number in the manual where the recommendation for a 20 minute disinfection cycle with a 2% glutaraldehyde is stated.

    b. Provide a statement in the manual describing the water quality required for the DSD-91. This is related to the issue on the filter.

    c. There is an air purge after each of the cycles and for the end of day processing; however, there does not appear to be a requirement for an air filter. Provide information in the manual on how the user would prevent the endoscope from becoming contaminated with particulate matter from the air compressor or the house air line.

    d. The recommendation in the manual for the alcohol purge and air drying of the endoscopes at the end of the day should be clarified to state that this should be done after the last procedure of the day for the endoscope.

    e. State why the set custom temperature option for the disinfectant is not available in the U.S. (pgs. 3-6) and how this feature is disabled for U.S. models.

    f. Clarify in the manual the purpose of screens 3 & 4 in the "Set Custom Program", pages 3-6 & 3-7.

    g. Explain why the fluid level sensors can be inhibited, pg 3-8.

h. Explain how the user can set the maximum disinfection cycle count, since most disinfectant manufactures set the reuse life based upon a manual cycle (pgs 3-10). The information that the disinfection cycle is based upon a 14 day reuse life disinfectant should be repeated at this point.

i. The information contained in the Section "Disinfectant Change", pg 3-16, is inadequate. The manual must clearly state that, at a minimum, the disinfectant must be monitored daily.

j. The manual should contain a statement that the user should monitor the DSD-91 to prevent the development of biofilms.

k. The sections in the user's manual identified as "IMPORTANT" and "USERS NOTES" must be reconsidered. The statements appear to be more appropriate as either Precautions or instructions for use. Revise accordingly. The validity of the statement regarding contact conditions for the germicide are contingent upon the issue noted in item 1 above.

12. Since some of the 3.2% glutaraldehydes contain surfactants which cause foaming and the manual contains a warning about foaming with certain brands of disinfectants, tell us what information is given to the user.

The additional information should be submitted in duplicate, referencing the 510(k) number, to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 80 7.87(f) and (h), 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 requested information 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 re-submitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Susanna F. Barrett at (301) 427-1307. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for 3/3/93

Paul R. Beninger, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
413	Barrett	3/4/93	410		3593			
413		3/3/93						
40		3/3/93						

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cc: HFZ-401
HFZ-403
HFZ-410 DGRD

HFZ/410/SBarrett/lw/3/3/93

DATE: January 15, 1993

FROM: Microbiologist, Infection Control Devices Branch, DGRD, (HFZ-413)

SUBJECT: K914145 DSD-91 Disinfector
ProCode: 78-FEB-II
Contact: Constance Bundy
Phone #: 612-574-1976

TO: To the record

The firm has replied to the request for information dated March 23, 1992.

The firm provided some additional information about its testing protocol. (b) (4)

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

does not believe that a self-disinfection protocol for the DSD-91 is necessary, I still believe that the manual should instruct the users to monitor the DSD-91 for the development of biofilms.

The firm claims that it will not make a claim for sterile water rinse. The firm also claims that glutaraldehyde disinfectants are the only germicide recommended for use with the DSD-91 and that if it recommends some other disinfectant for use within the DSD-91, it will submit a new 510(k).

The firm claims that the disinfectant filter is to prevent solid material from returning to the endoscope and that the manual has been changed to reflect this change. However, the firm will have to state where that change has been made because there is no difference between the manual submitted with the supplemental material dated 7/20/92 and the manual submitted with the original material dated 9/13/91. Both versions of the manual state that "disinfectant filtration keeps the reservoir clean of sediment" (page 2-1). If the referenced reservoir is the disinfectant reservoir, then the statement is misleading and needs to be clarified.

The firm states that water and detergent are prevented from draining to the disinfectant reservoir by a valve. The valve to the disinfectant reservoir is closed during the wash and rinse cycles. If the valve fails, the firm claims that the system will shut down.

A revised copy of the manual has been included in this submission. Many of the suggestions have been incorporated in the manual (see sections labeled "IMPORTANT" and "USER NOTES"). The sections labeled as "IMPORTANT" and "USER NOTES" should be identified as warnings and precautions. One additional feature of the manual is the inclusion of the addresses and telephone numbers of several societies which have developed guidelines for the cleaning and disinfection of endoscopes.

The manual does not appear to have been changed significantly from the draft submitted with the 9/13/91 material. In general the manual does not appear to have been written for users who are not familiar with the Ott's Disinfector. The hook-up requirements for the DSD-91 appear to differ from those for other endoscope washers; there appears to be only one line used to direct fluid flow from the DSD-91 to the internal channels of the endoscopes. Based upon the instructions, I can not trace the fluid flows through the endoscope. The hook-up instructions do refer to Qwik-load fittings that connect to the DSD-91 and to a scope shut-off valve (re pg 3-13); however, these are not adequately described or shown in the instructions. The firm will need to provide a more complete description of how an endoscope is connected to the DSD-91, of the Qwik-load insert, all accessories and hook-ups, and the fluid pathway through the scope. It should also provide better photographs of the connections. In addition, there are several other items in the manual that need clarification.

a. The water requirements do not describe water quality.

b. There is an air purge after each of the cycles and for the end of day processing; however, there does not appear to be a requirement for an air filter. The firm should comment upon this.

c. The recommendation in the manual for the alcohol purge and air drying of the endoscopes at the end of the day should be clarified to state that this should be done after the last procedure of the day for the scope.

d. The firm should comment on why the set custom temperature option for the disinfectant is not available in the U.S.A. (re pg 2-2 & 3-6). Some disinfectants do require elevated temperatures. The firm should also comment upon how the temperature is maintained through the lines and through the scopes. It also needs to comment upon how cyclic temperature variations of the disinfectant will affect the reuse life of the disinfectant (re pg 3-11). The firm must be aware that the reuse life of disinfectants are validated at set temperature conditions and that temperature changes could affect adversely the reuse life of the disinfectant. It should also convey this information to the user.

e. The firm needs to clarify screens 3 & 4 in the "Set Custom Program", pages 3-6 & 3-7. The instructions do not convey the purpose of these.

f. It needs to explain why the fluid level sensors can be inhibited, pg 3-8.

g. The firm will need to explain how the user can set the maximum disinfection cycle count, since most disinfectant manufactures set the reuse life based upon a manual cycle (re pg 3-10). It should probably repeat the warning that the cycle count is based upon a disinfectant with a 14 day reuse life and that the disinfectant should be monitored daily for efficacy.

h. The manual contains a warning about foaming with certain brands of disinfectants and that the user should call MediVators for more information. The firm needs to state what information it is distributing to the user.

i. The information contained in the Section "Disinfectant Change" , pg 3-16, is inadequate. The firm must clearly state in its manual that at a minimum the disinfectant must be monitored daily.

j. The flow diagram shows that if the air purge cycle at the end of day does not dry the lines completely, there is the potential for contamination of the units.

In reviewing all the documentation submitted with this 510(k), it was noted that the firm did not describe the method used to determine the glutaraldehyde residues remaining on the endoscopes. These results are based upon the scopes being rinsed twice; however, the second rinse is

optional. The firm should include in its manual information about glutaraldehyde residues.

The firm was asked to provide not only data from simulated testing but also data from clinical testing (question #12 of letter dated 3/23/92). The firm did not provide data based upon clinical testing. It claims that the fluid flow of the DSD-91 is the same as the Otts and that no problems have been reported for the Otts during its 5 year history. FDA policy now is to require both simulated and clinical data for all automated endoscope washers.

The firm has several issues which will need to be resolved. First, there currently are no FDA cleared disinfectants with an indication for machine use. Those disinfectants that are under review specifically state manual use. Second, the firm appears to have tested the DSD-91 with a disinfectant manufactured by Metrex. Metrex does not have, at this time, ~~have~~ any 510(k)s for its disinfectants "in house" for review. Third, the Medivators used a Metrex test kit, either MX-200 MEtriTEST Kit or MX-5000 ColdTest Kit, to monitor the effectiveness of the disinfectant. These test kits have not been reviewed under the 510(k) process. A policy decision will have to be made upon how to handle these issues. Once these issues have been resolved, the firm will need to provide the following:

1. Because of the increasing public health concern about the transmission of diseases, such as AIDS, hepatitis, and tuberculosis, FDA is requiring not only simulated testing but also clinical testing, as noted in question #12 of our letter dated March 23, 1992. Provide clinical testing data demonstrating the efficacy of the DSD-91.

2. Without the proper control demonstrating the number of spores recovered from a scope after any "precleaning" procedure and prior to disinfection in the DSD-91, the disinfection efficacy data for the DSD-91 can not be evaluated. The testing must include the proper controls.

3. Identify the disinfectants used during the testing of the DSD-91. State the minimum effective concentration, as identified in the germicide labeling, for the disinfectants used during the testing for the DSD-91.

4. The promotion of an off-labeled use for a disinfectant, that is, the use of a disinfectant in a automated endoscope washer machine which is labeled for manual use only may raise an outstanding device issue. You should be working in consort with a germicide manufacturer to validate the use of a germicide labeled for machine use.

5. Since there are no legally marketed disinfectants which are indicated for use with machines, state how the user can follow the disinfectant manufacture's labeling if the disinfectant is not

labeled for use with machines.

6. It was noted that the Olympus XQ10-3 was the most difficult to disinfect even following the SGNA guidelines. Please comment. Identify the types of endoscopes used for the testing.

7. Anecdotal user information concerning the recommendation for changing the Stearopore filter is insufficient. Provide data to support the claim for changing the filter every 6 months. The testing should mirror maximum use conditions for the DSD-91 during the 6 month period such as significant water use, different qualities of water, etc. The data must show the safety factor associated with the recommendation for changing every 6 months.

8. Provide the page number in the manual which clarifies the intent of the disinfectant filter (re answer to question 7). The information concerning disinfectant filtration (pg 2-1) contained in the manual submitted with the supplemental material dated 7/20/92 is identical to the information concerning disinfectant filtration (pg 2-1) contained in the manual submitted with the original application dated 9/13/91. The disinfectant filter does not appear to keep sediment out of the disinfectant reservoir.

9. The testing protocol for biofilm formation does not appear to be sufficiently rigorous to show that biofilms do not develop in units after extended use. Provide additional testing on units which have been in extended service. The testing should include the culturing of tubing, vents, etc.

10. Provide the method used to determine the level of glutaraldehyde residues which remained on the scopes after the rinse cycle. Identify the types of scopes used for the testing. The manual will need to describe for the user the level of glutaraldehyde residues which remain on the scopes after processing.

11. Provide a more complete description of how an endoscope is connected the DSD-91, of the Qwik-load insert, of all accessories and hook-ups, and of the fluid pathway through the scope. The instructions do not clearly describe how an endoscope is connected to the DSD-91.

12. Clarify the following items in the manual:

    a. Provide a statement in the manual describing the water quality required for the DSD-91.

    b. There is an air purge after each of the cycles and for the end of day processing; however, there does not appear to be a requirement for an air filter. Provide information on how the user would prevent the endoscope from becoming contaminated with particulate matter from the air compressor or the house air line.

c. The recommendation in the manual for the alcohol purge and air drying of the endoscopes at the end of the day should be clarified to state that this should be done after the last procedure of the day for the endoscope.

d. State why the set custom temperature option for the disinfectant is not available in the U.S.A. (re pg 3-6). Some disinfectants do require elevated temperatures. Indicate how the temperature is maintained through the lines and through the endoscopes. State how cyclic temperature variations of the disinfectant will affect the reuse life of the disinfectant (re pg 3-11). The reuse life of disinfectants are validated at set temperature conditions; temperature changes could affect the reuse life of the disinfectant. The manual should convey this information to the user.

e. Clarify screens 3 & 4 in the "Set Custom Program", pages 3-6 & 3-7.

f. Explain why the fluid level sensors can be inhibited, pg 3-8.

g. Explain how the user can set the maximum disinfection cycle count, since most disinfectant manufactures set the reuse life based upon a manual cycle (re pg 3-10). The information that the disinfection cycle is based upon a 14 day reuse life disinfectant should be repeated at this point.

h. The information contained in the Section "Disinfectant Change" , pg 3-16, is inadequate. The manual must clearly state that, at a minimum, the disinfectant must be monitored daily.

i. The manual should contain a statement that the user should monitor the DSD-91 to prevent the development of biofilms.

j. The sections in the user's manual identified as "IMPORTANT" and "USERS NOTES" must be identified as Warnings and Precautions.

13. Since some of the 3.2% glutaraldehydes contain surfactants which cause foaming and the manual contains a warning about foaming with certain brands of disinfectants, state what information it is given to the user.

CL 1/31/93

F Barrell

491

ROUTING AND TRANSMITTAL SLIP

3/3/93 CJ

Document K914145

Date MAR - 3 1993 Orig. Div. DGRD

China - Suk - DB 3/4/93

	Name	Initials	Date
1.	Tim	RU	3/3
2.	Paul		
3.	~~I SIGNED BUT YOU WILL HAVE TO~~		
4.			
5.			
6.			
7.			

File _____ For Correction _____ Signature ✓

FROM: HFZ-410 Rm. 240 Phone: 427-1090

due 10/19

Tim has ~~this~~ volume 2

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-91-4145 3/8/93

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
MEDIVATORS, INC. ATTN: CONSTANCE C. BUNDY C/O C. G. BUNDY ASSOCIATES 6470 RIVERVIEW TERRACE MINNEAPOLIS, MN 55432	09/13/91	09/16/91	10/19/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K914145
	PHONE NO: 612-574-1976		
SHORT NAME: MEDIVATORS	ESTABLISHMENT NO: 2183640		

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

SUBJECT:
DSD-91(TM) DISINFECTOR FOR FLEXIBLE ENDOSCOPES

DECISION:	RQST INFO DATE: 11/19/91	INFO DUE DATE: 01/17/92
DECISION DATE: / /	DATE: 03/23/92	DATE: 07/20/92
	DATE: 03/08/93	DATE: 04/07/93
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /

SUPPLEMENT: 01 LTR DATE: 911218 LOGIN DATE: 911224
SUPPLEMENT: 02 LTR DATE: 920720 LOGIN DATE: 920721

Memorandum

Date 3/3/93

REVIEWER(S) - NAME(S) Barrett

Subject 510(k) NOTIFICATION K914145/B

To THE RECORD

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

_____ (A) Is substantially equivalent to marketed devices.

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

✓ (C) Requires more data.

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

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

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

_____

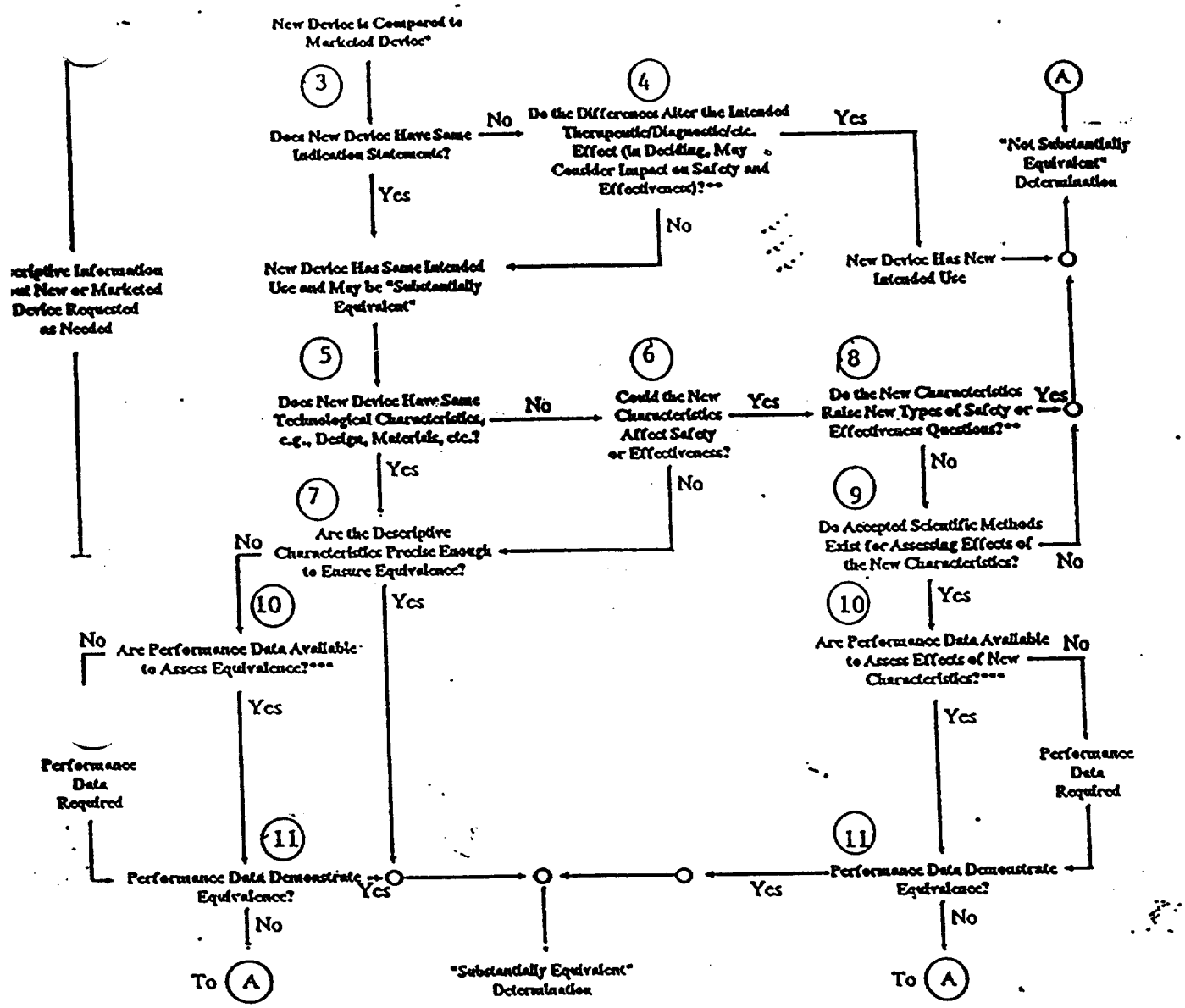
REVIEW: [signature] (BRANCH CHIEF) | IN UR | BRANCH CODE | 3/3/93 (DATE)

FINAL REVIEW: [signature] for PRB 3/3/93 (DIVISION DIRECTOR) (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

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.

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

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

MAY 21, 1992

MEDIVATORS, INC.
ATTN: CONSTANCE G. BUNDY
C/O C. G. BUNDY ASSOCIATES
6470 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432

510(k) Number: K914145
Product: DSD-91(TM)
DISINFECTOR FOR
FLEXIBLE ENDOSCOPES

Extended Until: 07/20/92

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 Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

MAR 23 1992

MediVators, Inc.
c/o C. G. Bundy Associates
Ms. Constance G. Bundy
Consultant
6470 Riverview Terrace
Minneapolis, MN 55432

Re: K914145
DSD-91™ Disinfector for Flexible Endoscopes
Dated: December 18, 1991
Received: December 24, 1991

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following information.

1. Clarify the following concerning the testing protocols for the DSD-91.

   a. (b) (4) [redacted]

   b.

   c.

   d.

   e.

2. Provide data supporting the claimed yearly replacement schedule of the Sterapore filter since you have identified it as a critical component. Provide data supporting the claim that a self-disinfection protocol for the DSD-91 is unnecessary and that the instructions in the manual are adequate. For example, show that 100% of all the lines contact the disinfectant and/or biological testing does not indicate contamination.

3. Comment upon the statement in the paper by Vesley, et.al. that the Ott's Disinfector provides a "sterile water rinse" (page 19). If you are planning to make such a claim for the DSD-91 Disinfector, then you must supply data supporting a "sterile water rinse" claim.

4. The paper by Vesley, et.al. also indicates that a different type of liquid chemical germicide can be used in the Ott's Disinfector, i.e., 6% H_2O_2. State what types of liquid chemical germicides can be used with the DSD-91 Disinfector. If you claim that different types of liquid chemical germicides can be used with the DSD-91, then provide the instructions for use in the manual which indicate all the germicides.

Provide data showing all the liquid germicides indicated in the labeling are compatible with the DSD-91. Provide data to show that all the germicides are within the a range of physical characteristics to ensure that microbiological testing with one of the germicides will suffice for all in terms of fluid flow (e.g., one is not significantly more viscous than the one tested).

5. The statements in the manual simply referring to precleaning of the endoscopes according to manufacturer's instructions or SGNA guidelines should be modified to include those guidelines since everyone may not have access to the SGNA guidelines.

6. Provide a description of the hookup including the "Qwik-load" insert (see page 3-9). The information submitted in the amendment does not adequately describe how this is accomplished and the corresponding pictures are of poor quality. The Hook-up sheet should also correspond to the DSD-91.

7. Provide an explanation of how the disinfectant filter keeps the reservoir clean of sediment since the filter appears to be in-line from the disinfectant reservoir to the upper chamber (see page 5.5 - material flow diagram). Clarify the information concerning the disinfectant filter replacement schedule, specifically the statement to change monthly or when the disinfectant is changed since the basis for the indicator light is a disinfectant with a 14-day reuse life. Indicate what prevents the detergent and the water from being drained into the disinfectant reservoir.

8. The manual should contain the following information.

   a. the basis upon which the 40 cycle warning light was set, that is, that it is based upon a disinfectant with a 14-day reuse life;

   b. warning that if the disinfectant's labeling is not rigidly followed then the reuse life of the disinfectant could be significantly affected;

   c. that the user can not set disinfectant contact time below 10 minutes; and

   d. the replacement schedule for the Sterapore should be on the same page as the installation instructions in addition to in the parts list;

9. On page 5-4 reference is made to wall-mount. Clarify to what this refers.

10. The materials flow diagram provided with the supplement is not very readable. Provide a block diagram clearly showing the flow of all fluids and air.

11. Since the potential for serious harm to patients from improperly processed endoscopes exists, the Major Level of Concern is the appropriate software documentation level as noted in our letter to you of 11/19/91. Our analysis of the software documentation indicates that it is incomplete and lacks many of the details needed to finish our review. Provide information for the following.

a. Provide a diagram showing the organization of software and its interaction with the functional components of the DSD-91. Provide a narrative description of the diagrammed functions or processes and how they interact. Include the relevant function or performance requirements in each description.

b. The hazard analysis failed to address completely the issue of temperature range of the disinfectant as set by the operator. Specify the range of and the tolerances for selectable disinfectant temperatures, both upper and lower limits. Describe the means for assuring that the upper limit setting is always greater than the lower limit setting. State the software requirements for meeting this system requirement. Describe the procedures(s) for verifying that the software or system meets these requirements. Provide records of the verification procedure, such as, test results.

c. Specify the disinfection protocols possible with this device. State the software requirements for encoding and executing these protocols. Describe the procedures used to verify that the device and the software faithfully performs these protocols. Provide records of this verification procedure, such as test results.

d. State the numeric requirement for reliability of the device, that is expected working life and mean time between failures over the working life. Describe the analysis used to confirm this requirements. Describe the software analysis (or analyses) used to detect and remove software errors that would affect this requirement. Compare the working life and reliability of the DSD-91 to the predicate device, the Ott's Disinfector.

e. Identify the numeric design requirement for the throughput of the device and compare it to the numeric design requirement for the throughput of the predicate device. State the software requirements for meeting the required throughput. Describe the procedure used to verify this requirement. Provide records of the verification procedure, such as, test results.

f. Specify the interruptions that the device is required to accommodate, that is type(s) of interruption(s) and duration(s) if applicable. State the recovery time requirement(s) for each type of interruption, if applicable. State the software requirements for executing this function. Describe the procedures used to verify that the device performs this function. Provide records of the procedures such as test results.

g. Describe the software requirements for recording the status data as specified in Appendix H, pages 9-10, that is, how often or under what conditions to record, how often or under what conditions to delete and what action must occur if the required data were accidentally deleted. Describe the procedures used to verify the execution of this function. proved the records of these procedures.

12. You tested only one type of endoscope, the Olympus GIF Type Q10, #2401765. Other types of scopes are indicated for use in this device. Either justify that the data submitted are adequate to establish effectiveness with all scopes or provide additional data. The additional data should be comprised of simulated and clinical tests with representative types of scopes claimed in labeling and a sufficient

number of replicates of each to achieve statistical confidence in the data. Include a pediatric endoscope if your labeling may encompass this scope. The protocol should establish the actual challenge and the log reduction after processing.

The additional information should be submitted in duplicate, referencing the 510(k) number, to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 80 7.87(f) and (h), 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 requested information 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 re-submitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Susanna F. Barrett at (301) 427-1090. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Philip J. Phillips
Interim Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

C.G. BUNDY ASSOCIATES

Consultants to the medical products industry.

6470 Riverview Terrace
Minneapolis, Minnesota 55432
(612) 574-1976

May 12, 1992

RECEIVED
20 MAY 92 11 56
FDA/CDRH/ODE/DMC

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

RE: 510(k) #K914145, MediVators, Inc.
DSD-91^{tm} Disinfector for Flexible Endoscopes
Extension of Time

Gentlemen:

We request a time extension of 60 days from May 20, 1992, on the above referenced 510(k) notification.

Please notify me when the extension is granted. If there are any questions, please call me.

Yours truly,

Constance G. Bundy

Constance G. Bundy
Consultant to MediVators, Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

APRIL 22, 1992

MEDIVATORS, INC.
ATTN: CONSTANCE G. BUNDY
C/O C. G. BUNDY ASSOCIATES
6470 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432

510(k) Number: K914145
Product: DSD-91(TM) DISINFECTOR FOR FLEXIBLE ENDOSCOPES

Extended Until: 05/22/92

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 Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

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

C.G. BUNDY ASSOCIATES

Consultants to the medical products industry.

6470 Riverview Terrace
Minneapolis, Minnesota 55432
(612) 574-1976

April 20, 1992

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

RE: 510(k) #K914145, MediVators, Inc.
DSD-91tm Disinfector for Flexible Endoscopes
Extension of Time

Gentlemen:

We request a time extension of 30 days from the date of this letter on the above referenced 510(k) notification.

Please notify me when the extension is granted. If there are any questions, please call me.

Yours truly,

Constance G. Bundy

Constance G. Bundy
Consultant to MediVators, Inc.

RECEIVED
21 APR 92 10 33
FDA/CDRH/ODE/DMC

503

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-91-4145

3/23/92

FROM: MEDIVATORS, INC. ATTN: CONSTANCE G. BUNDY C/O C. G. BUNDY ASSOCIATES 6470 RIVERVIEW TERRACE MINNEAPOLIS, MN 55432 SHORT NAME: MEDIVATORS	LETTER DATE 09/13/91 LOGIN DATE 09/16/91 TYPE OF DOCUMENT: 510 (k) PHONE NO: 612-574-1976 ESTABLISHMENT NO: 2183640	DUE DATE 03/23/92 CONTROL # K914145
TO: ODE/DMC	CONT. CONF.: ? STATUS : H REV PANEL : SU PAN/PROD CODE(S): SU/ / /	

SUBJECT:
DSD-91(TM) DISINFECTOR FOR FLEXIBLE ENDOSCOPES

DECISION: DECISION DATE: / /	RQST INFO DATE: 11/19/91 DATE: 03/23/92 DATE: / / DATE: / / DATE: / / DATE: / /	INFO DUE DATE: 01/17/92 DATE: 04/22/92 DATE: / / DATE: / / DATE: / / DATE: / /

SUPPLEMENT: 01 LTR DATE: 911218 LOGIN DATE: 911224

504

MAR 23 1992

MediVators, Inc.
c/o C. G. Bundy Associates
Ms. Constance G. Bundy
Consultant
6470 Riverview Terrace
Minneapolis, MN 55432

Re: K914145
DSD-91™ Disinfector for Flexible Endoscopes
Dated: December 18, 1991
Received: December 24, 1991

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following information.

1. Clarify the following concerning the testing protocols for the DSD-91.

(b) (4)

[redacted]

2. Provide data supporting the claimed yearly replacement schedule of the Sterapore filter since you have identified it as a critical component. Provide data supporting the claim that a self-disinfection protocol for the DSD-91 is unnecessary and that the instructions in the manual are adequate. For example, show that 100% of all the lines contact the disinfectant and/or biological testing does not indicate contamination.

3. Comment upon the statement in the paper by Vesley, et.al. that the Ott's Disinfector provides a "sterile water rinse" (page 19). If you are planning to make such a claim for the DSD-91 Disinfector, then you must supply data supporting a "sterile water rinse" claim.

4. The paper by Vesley, et.al. also indicates that a different type of liquid chemical germicide can be used in the Ott's Disinfector, i.e., 6% H_2O_2. State what types of liquid chemical germicides can be used with the DSD-91 Disinfector. If you claim that different types of liquid chemical germicides can be used with the DSD-91, then provide the instructions for use in the manual which indicate all the germicides.

Provide data showing all the liquid germicides indicated in the labeling are compatible with the DSD-91. Provide data to show that all the germicides are within the a range of physical characteristics to ensure that microbiological testing with one of the germicides will suffice for all in terms of fluid flow (e.g., one is not significantly more viscous than the one tested).

5. The statements in the manual simply referring to precleaning of the endoscopes according to manufacturer's instructions or SGNA guidelines should be modified to include those guidelines since everyone may not have access to the SGNA guidelines.

6. Provide a description of the hookup including the "Qwik-load" insert (see page 3-9). The information submitted in the amendment does not adequately describe how this is accomplished and the corresponding pictures are of poor quality. The Hook-up sheet should also correspond to the DSD-91.

7. Provide an explanation of how the disinfectant filter keeps the reservoir clean of sediment since the filter appears to be in-line from the disinfectant reservoir to the upper chamber (see page 5.5 - material flow diagram). Clarify the information concerning the disinfectant filter replacement schedule, specifically the statement to change monthly or when the disinfectant is changed since the basis for the indicator light is a disinfectant with a 14-day reuse life. Indicate what prevents the detergent and the water from being drained into the disinfectant reservoir.

8. The manual should contain the following information.

   a. the basis upon which the 40 cycle warning light was set, that is, that it is based upon a disinfectant with a 14-day reuse life;

   b. warning that if the disinfectant's labeling is not rigidly followed then the reuse life of the disinfectant could be significantly affected;

   c. that the user can not set disinfectant contact time below 10 minutes; and

   d. the replacement schedule for the Sterapore should be on the same page as the installation instructions in addition to in the parts list;

9. On page 5-4 reference is made to wall-mount. Clarify to what this refers.

10. The materials flow diagram provided with the supplement is not very readable. Provide a block diagram clearly showing the flow of all fluids and air.

11. Since the potential for serious harm to patients from improperly processed endoscopes exists, the Major Level of Concern is the appropriate software documentation level as noted in our letter to you of 11/19/91. Our analysis of the software documentation indicates that it is incomplete and lacks many of the details needed to finish our review. Provide information for the following.

a. Provide a diagram showing the organization of software and its interaction with the functional components of the DSD-91. Provide a narrative description of the diagrammed functions or processes and how they interact. Include the relevant function or performance requirements in each description.

b. The hazard analysis failed to address completely the issue of temperature range of the disinfectant as set by the operator. Specify the range of and the tolerances for selectable disinfectant temperatures, both upper and lower limits. Describe the means for assuring that the upper limit setting is always greater than the lower limit setting. State the software requirements for meeting this system requirement. Describe the procedures(s) for verifying that the software or system meets these requirements. Provide records of the verification procedure, such as, test results.

c. Specify the disinfection protocols possible with this device. State the software requirements for encoding and executing these protocols. Describe the procedures used to verify that the device and the software faithfully performs these protocols. Provide records of this verification procedure, such as test results.

d. State the numeric requirement for reliability of the device, that is expected working life and mean time between failures over the working life. Describe the analysis used to confirm this requirements. Describe the software analysis (or analyses) used to detect and remove software errors that would affect this requirement. Compare the working life and reliability of the DSD-91 to the predicate device, the Ott's Disinfector.

e. Identify the numeric design requirement for the throughput of the device and compare it to the numeric design requirement for the throughput of the predicate device. State the software requirements for meeting the required throughput. Describe the procedure used to verify this requirement. Provide records of the verification procedure, such as, test results.

f. Specify the interruptions that the device is required to accommodate, that is type(s) of interruption(s) and duration(s) if applicable. State the recovery time requirement(s) for each type of interruption, if applicable. State the software requirements for executing this function. Describe the procedures used to verify that the device performs this function. Provide records of the procedures such as test results.

g. Describe the software requirements for recording the status data as specified in Appendix H, pages 9-10, that is, how often or under what conditions to record, how often or under what conditions to delete and what action must occur if the required data were accidentally deleted. Describe the procedures used to verify the execution of this function. proved the records of these procedures.

12. You tested only one type of endoscope, the Olympus GIF Type Q10, #2401765. Other types of scopes are indicated for use in this device. Either justify that the data submitted are adequate to establish effectiveness with all scopes or provide additional data. The additional data should be comprised of simulated and clinical tests with representative types of scopes claimed in labeling and a sufficient

number of replicates of each to achieve statistical confidence in the data. Include a pediatric endoscope if your labeling may encompass this scope. The protocol should establish the actual challenge and the log reduction after processing.

The additional information should be submitted in duplicate, referencing the 510(k) number, to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 80 7.87(f) and (h), 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 requested information 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 re-submitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Susanna F. Barrett at (301) 427-1090. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Philip J. Phillips
Interim Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
413	Barrett	3/23/92						
413	Fine	3/26/92						
410	Ostrid	3/28/92						

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date 3/6/92

From REVIEWER(S) - NAME(S) Sharre D

Subject 510(k) NOTIFICATION K914145 /A

To THE RECORD

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

_____ (A) Is substantially equivalent to marketed devices.

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

__Y__ (C) Requires more data.

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

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

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

_____

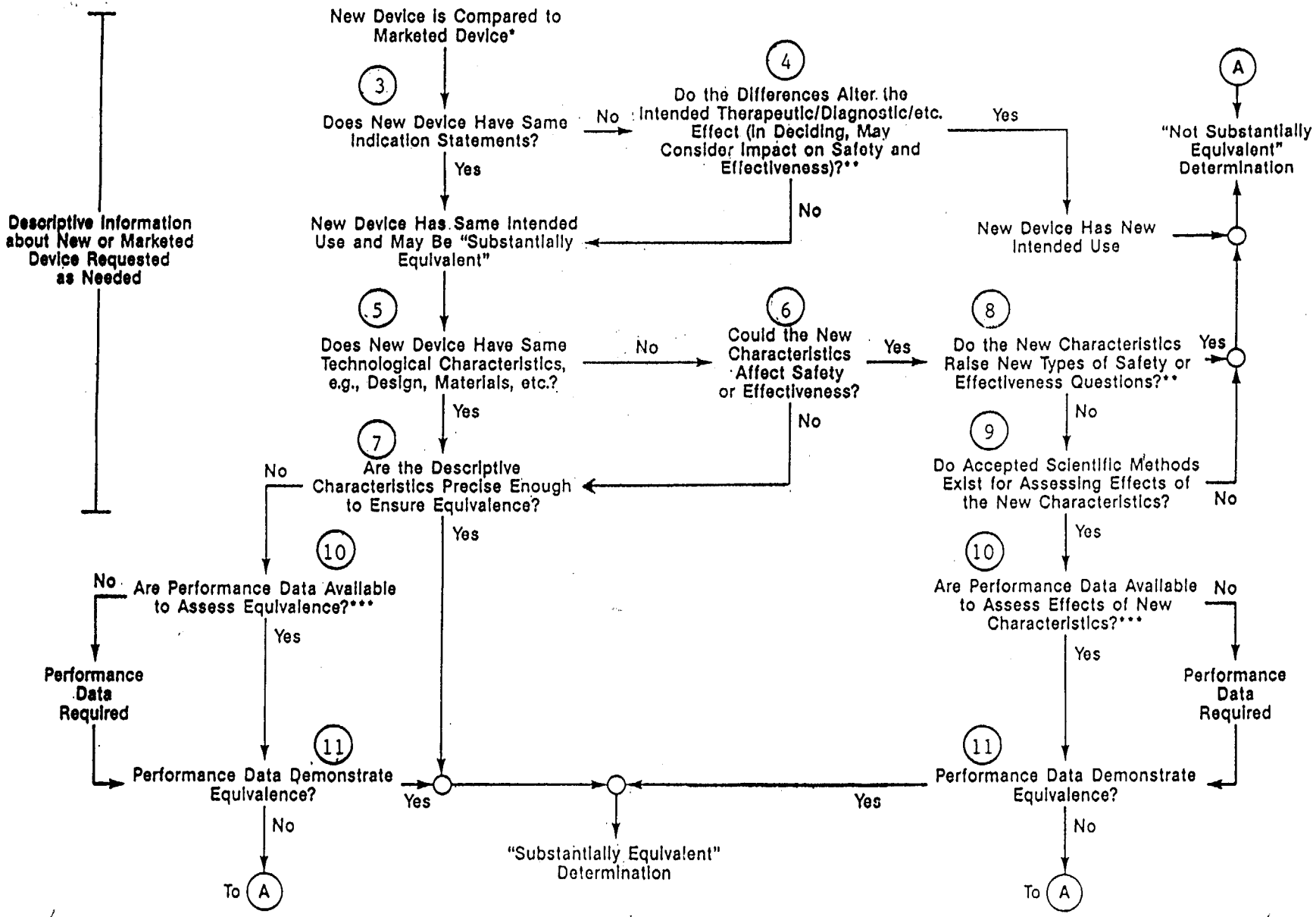
REVIEW: Chris Lin (SFB) (BRANCH CHIEF) 413 (BRANCH CODE) 3/18/92 (DATE)

FINAL REVIEW: for PP (DIVISION DIRECTOR) 3/23/92 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS 509

Revised 11/18/91

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



* ...bmissions 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.

DATE: March 4, 1992

FROM: Microbiologist, Infection Control Devices Branch, DGRD, (HFZ-413)

SUBJECT: K914145 DSD-91 Disinfector
ProCode: 78-FEB-II
Contact: Constance Bundy
Phone #: 612-574-1976

TO: To the record

The firm has responded to the questions asked in the letter dated 11/19/91. The firm provided a description of the protocol used to evaluate the DSD-91 which was included in the original submission. The

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

8. The manual should contain the following information.

   a. the basis upon which the 40 cycle warning light was set, that is, that it is based upon a disinfectant with a 14-day reuse life;

   b. warning that if the disinfectant's labeling is not rigidly followed then the reuse life of the disinfectant could be significantly affected;

   c. that the user can not set disinfectant contact time below 10 minutes; and

   d. the replacement schedule for the Sterapore should be on the same page as the installation instructions in addition to in the parts list;

9. On page 5-4 reference is made to wall-mount. State to what this refers.

10. The materials flow diagram provided with the supplement is not very readable. Provide a blocked diagram clearly showing the flow of all fluids and air.

11. Since the potential for serious harm to patients from improperly processed endoscopes exists, the Major Level of Concern is the appropriate software documentation level as noted in our letter to you of 11/19/91. Our analysis of the software documentation indicates that it is incomplete and lacks many of the details needed to finish our review. Provide information for the following.

    a. Provide a diagram showing the organization of software and its interaction with the functional components of the DSD-91. Provide a narrative description of the diagrammed functions or processes and how they interact. Include the

1. Clarify the following concerning the testing protocols for the DSD-91.

(b) (4)

[redacted]

2. Provide data supporting the claimed yearly replacement schedule of the Sterapore filter since you have identified it as a critical component. Provide data supporting the claim that a self-disinfection protocol for the DSD-91 is unnecessary and that the instructions in the manual are adequate.

3. Comment upon the statement in the paper by Vesley, et.al. that the Ott's Disinfector provides a "sterile water rinse" (page 19). If you are planning to make such a claim for the DSD-91 Disinfector, then you must supply data supporting a "sterile water rinse" claim.

4. The paper by Vesley, et.al. also indicates that a different type of liquid chemical germicide can be used in the Ott's Disinfector, i.e., 6% H_2O_2. State what types of liquid chemical germicides can be used with the DSD-91 Disinfector. If different types of liquid chemical germicides can be used with the DSD-91, then the manual should indicate that and contain instructions for use with the different types of germicides. If other liquid germicides can be used with the DSD-91, provide data showing the efficacy of the disinfection cycle of the DSD-91 with these different types liquid chemical germicides.

5. The statements in the manual referring to precleaning of the endoscopes according to manufacturer's instructions or SGNA guidelines should be modified to established guidelines since everyone may not have access to the SGNA guidelines.

relevant function or performance requirements in each description.

b. The hazard analysis failed to address completely the issue of temperature range of the disinfectant as set by the operator. Specify the range of and the tolerances for selectable disinfectant temperatures, both upper and lower limits. Describe the means for assuring that the upper limit setting is always greater than the lower limit setting. State the software requirements for meeting this system requirement. Describe the procedures(s) for verifying that the software or system meets these requirements. Provide records of the verification procedure, such as, test results.

c. Specify the disinfection protocols possible with this device. State the software requirements for encoding and executing these protocols. Describe the procedures used to verify that the device and the software faithfully performs these protocols. Provide records of this verification procedure, such as test results.

d. State the numeric requirement for reliability of the device, that is expected working life and mean time between failures over the working life. Describe the analysis used to confirm this requirements. Describe the software analysis (or analyses) used to detect and remove software errors that would affect this requirement. Compare the working life and reliability of the DSD-91 to the predicate device, the Ott's Disinfector.

e. Identify the numeric design requirement for the throughput of the device and compare it to the numeric design requirement for the throughput of the predicate device. State the software requirements for meeting the required throughput. Describe the procedure used to verify this requirement. Provide records of the verification procedure, such as, test results.

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required data were accidentally deleted. Describe the procedures used to verify the execution of this function. proved the records of these procedures.

Since the firm had contested the requirement of Major level of concern for the software validation, a copy of the firm's software validation was sent to Frank Houston in OST for his comments on whether Major level of concern is appropriate for these types of devices. See memo dated 3/11/92. He agreed with us that Major level of concern was appropriate but he felt that we could get the necessary information for an equivalence determination using the Moderate level (see attached memo from Frank Houston). His software suggestions have been incorporated as noted above in question 11.

Susanna F. Barrett

Susanna F. Barrett

MEMO TO THE RECORD

From: Biomedical Engineer
DGRD/GHDB

Date: March 6, 1992

Subject: K914145, Medivators, Inc.
DSD-91(TM) Disinfector for Flexible Endoscopes

The sponsor was informed that ODE believes these devices to be a Major level of concern as per the Reviewer's Guidance for computer Controlled Medical Devices. The sponsor does not agree with this position, as is stated on Page 8 of Appendix H, and has submitted only the information in accordance with a Moderate level of concern device.

I discussed this issue with Susanna Barret, ICDB, the lead reviewer for this 510(k). Because of reports of deaths and serious injuries occurring as a directly related to inadequately disinfected flexible endoscopes, ODE's position that the status of endoscope washers as Major concern devices in not negotiable.

The sponsor must readdress the requirements outlined in the Reviewer's Guidance focusing on the major concern guidelines.

Consult
K914145

Christine M. Harris

Christine M. Harris

Third Party Correspondence (b) (4)

Third Party Correspondence (b) (4)

Third Party Correspondence (b) (4)

Third Party Correspondence (b) (4)

Third Party Correspondence (b) (4)

DATE: MAR 11 1992

FROM: Microbiologist, Infection Control Devices Branch, DGRD, HFZ-410

Through: Acting Chief, Infection Control Devices Branch, DGRD, HFZ-410 CL 3/11/92
Through: ADGD TL/for CL

SUBJECT: K914145 Concern Level for Software Review of DSD-91 Automated Endoscope Washer

TO: Frank Houston, HFZ-142

Enclosed is the material on which Tim has asked you to comment. We asked the firm to analyze the software at the Major Level of Concern because there have been reported cases of patient injury and death from the use of endoscopes which were contaminated as a direct result of being processed in automated endoscope washers.

The firm has objected to this requirement and has included in its software documentation its own analysis.

Please advise if the Major Level of Concern is appropriate based on the Software Guidance Document. The 90 day due date for this document is March 23, 1992.

Susanna F. Barrett
Susanna F. Barrett
427-1090

MEMO TO THE RECORD

From: Biomedical Engineer
DGRD/GHDB

Date: March 6, 1992

Subject: K914145, Medivators, Inc.
DSD-91(TM) Disinfector for Flexible Endoscopes

The sponsor was informed that ODE believes these devices to be a Major level of concern as per the Reviewer's Guidance for computer Controlled Medical Devices. The sponsor does not agree with this position, as is stated on Page 8 of Appendix H, and has submitted only the information in accordance with a Moderate level of concern device.

I discussed this issue with Susanna Barret, ICDB, the lead reviewer for this 510(k). Because of reports of deaths and serious injuries occurring as a directly related to inadequately disinfected flexible endoscopes, ODE's position that the status of endoscope washers as Major concern devices in not negotiable.

The sponsor must readdress the requirements outlined in the Reviewer's Guidance focusing on the major concern guidelines.

Consult
K914145

Christine M. Harris

Christine M. Harris

APPENDIX H

FDA Reviewer Internal Correspondence Predecisional (b) (4)

FDA Reviewer Internal Correspondence Predecisional (b) (4)

FDA Reviewer Internal Correspondence Predecisional (b) (4)

FDA Reviewer Internal Correspondence Predecisional (b) (4)

FDA Reviewer Internal Correspondence Predecisional (b) (4)

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FDA Reviewer Internal Correspondence Predecisional (b) (4)

FDA Reviewer Internal Correspondence Predecisional (b) (4)

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

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

JANUARY 3, 1992

MEDIVATORS, INC.
ATTN: CONSTANCE G. BUNDY
C/O C. G. BUNDY ASSOCIATES
6470 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432

510(k) Number: K914145
Product: DSD-91(TM) DISINFECTOR FOR FLEXIBLE ENDOSCOPES

Extended Until: 01/17/92

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 Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

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

C.G. BUNDY ASSOCIATES

Consultants to the medical products industry.

6470 Riverview Terrace
Minneapolis, Minnesota 55432
(612) 574-1976

December 17, 1991

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FDA/CDRH/ODE/DMC

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

RE: 510(k) #K914145, DSD-91 Disinfector
MediVators, Inc.
Extension of Time

Gentlemen:

We request a time extension of 30 days from the date of this letter on the above referenced 510(k) notification.

Please notify me when the extension is granted. If there are any questions, please call me.

Yours truly,

Constance G. Bundy

Constance G. Bundy
Consultant to MediVators, Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

JANUARY 2, 1992

MEDIVATORS, INC.
ATTN: CONSTANCE G. BUNDY
C/O C. G. BUNDY ASSOCIATES
6470 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432

510(k) Number: K914145
Received: 12-24-91
Product: DSD-91(TM) DISINFECTOR FOR FLEXIBLE ENDOSCOPES

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 within 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) 427-1190.

Sincerely yours,

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

MEDIVATORS, INC.®

INNOVATIVE MEDICAL PRODUCTS

K914145/A

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December 18, 1991

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

RE: K914145
Additional Information

Attached please find the additional information requested in the letter of November 19, 1991. Note also a revised summary availability statement is included.

MediVators would appreciated expeditious review of this information. If further information is necessary, contact the undersigned at (612) 574-1976.

Sincerely,

Constance G. Bundy

Constance G. Bundy
Consultant to: MediVators, Inc,

347

P.O. BOX 6431 • ROCHESTER, MN 55903 • 507/263-4721 • 800/537-7324

Third Party Test & Methodology (b) (4)

Third Party Test & Methodology (b) (4)

Third Party Test & Methodology (b) (4)

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Third Party Test & Methodology (b) (4)

Third Party Test & Methodology (b) (4)

Third Party Test & Methodology (b) (4)

[redacted]

AVAILABILITY OF SAFETY AND EFFECTIVENESS
INFORMATION PURSUANT TO 513(F) OF
THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

RE: MediVators DSD-91 Disinfector

Information supporting a substantial equivalence determination will be made available to any interested persons upon request.

Signature: _____

Name of Individual Signing: Michael S. Simmons

Title: Operations Manager

Company Name: MediVators, Inc.

Address: Cannon Plaza South
Cannon Falls, Minnesota 55009

Phone Number: 507-263-4721

Date: December 18, 1991

APPENDIX A

Third Party Laboratory Reports (b) (4)

[redacted]

November 8, 1991

Mr. Jerry Blonsky
MediVators, Inc.
Cannon Plaza South
Hwy 52 South
Cannon Falls, MN 55009

Dear Mr. Blonsky:

Third Party Laboratory Reports (b) (4)

Please find enclosed the [redacted] second Sanitization Study of the GI Endoscope spanning the test period September 6 through September 27, 1991.

You will note that the data are quite a bit better this time as regard to sanitization efficacy.

Please let me know if you have any questions or comments.

Sincerely,

(b) (4), (b) (6)

[redacted]

Enclosure

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LIST OF ATTACHMENTS

1. Inoculum Recovery Study (Population Check)
2. Certification of Inoculation
3. Endoscope Channel Diagram
4. Incubation Record (30-35°C)
5. Membrane Recovery Results - Air Channel
6. Membrane Recovery Results - Water Channel
7. Membrane Recovery Results - Suction Channel

Third Party Laboratory Evaluation of Sanitization Process (b) (4)

[redacted]

MediVators, Inc.

Evaluation of GI Endoscope
Sanitization Process (II)

November 6, 1991

Third Party Laboratory Evaluation of Sanitization Process (b) (4)

Third Party Laboratory Evaluation of Sanitization Process (b) (4)

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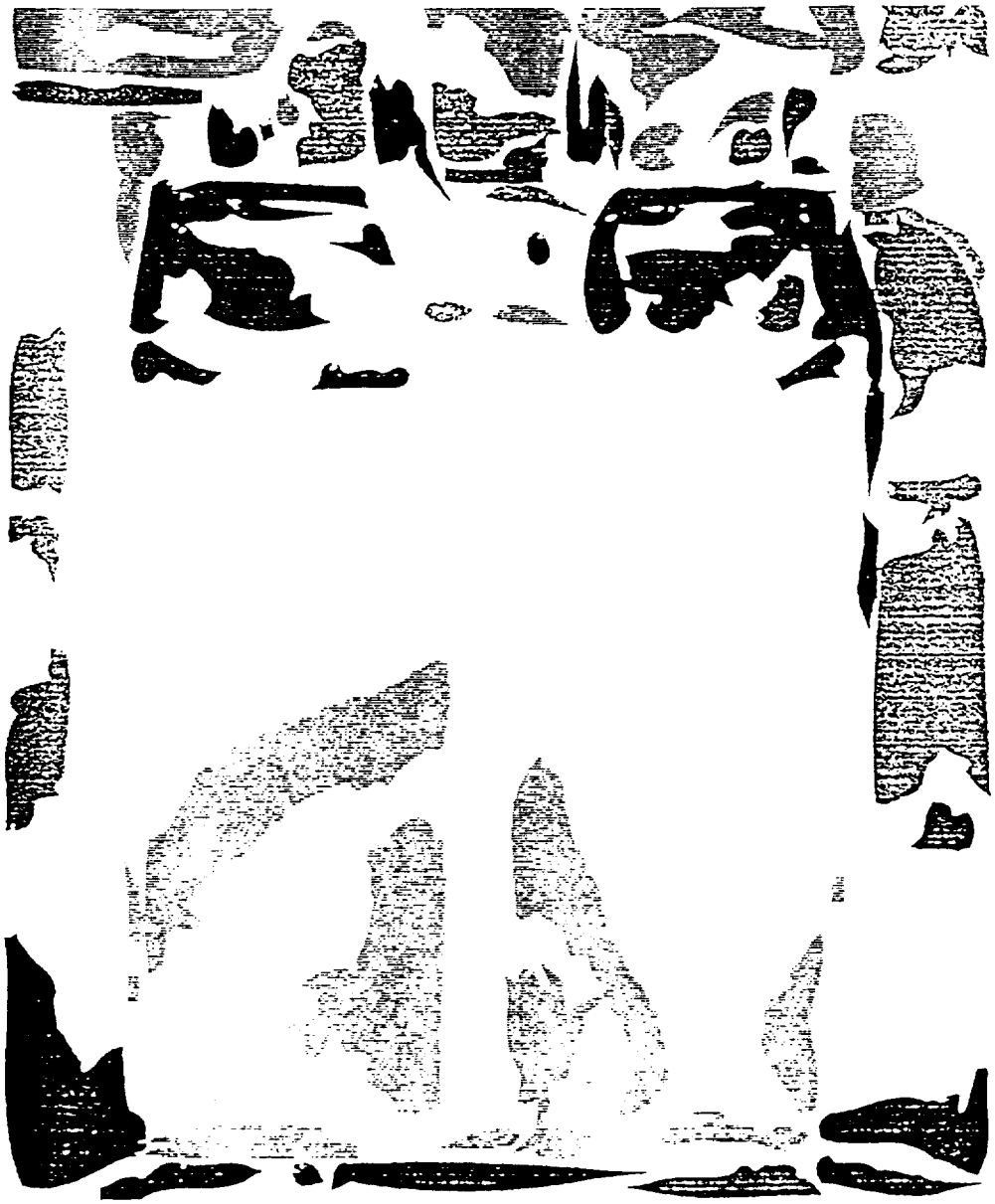
DSD-91™ Disinfector for Flexible Endoscopes



SERVICE MANUAL

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APPENDIX D

Third Party Laboratory Test Reports (b) (4)

[redacted]

MediVators, Inc.

Efficacy of the Sterapore Ultramicrofilter in Preventing Bacterial Cell Passage

October 16, 1987

Third Party Laboratory Test Reports (b) (4)

Third Party Laboratory Test Reports (b) (4)

Third Party Laboratory Test Reports (b) (4)

Third Party Laboratory Test Reports (b) (4)

Third Party Laboratory Test Reports (b) (4)

APPENDIX E

SIGNIFICANT FACTORS IN THE DISINFECTION/STERILIZATION OF FLEXIBLE ENDOSCOPES

OR

DISINFECTION OF FLEXIBLE ENDOSCOPES

Donald Vesley, Ph.D.[1]; Kathy G. Norlien[1], Barbara Nelson, LPN, GIA[2]; and Andrew J. Streifel, MPH[3]

(1) School of Public Health, University of Minnesota, Minneapolis, Minnesota;
(2) Mayo Clinic, Rochester, Minnesota;
(3) Department of Environmental Health and Safety, University of Minnesota, Minneapolis, Minnesota

CONFIDENTIAL
NOT YET PUBLISHED

Send correspondence to: Donald Vesley, Ph.D.
Division of Environmental and Occupational Health
University of Minnesota
Box 197 Mayo, 420 Delaware Street SE
Minneapolis, MN 55455

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ABSTRACT

Many nosocomial infection outbreaks have been linked to improper disinfection of flexible endoscopes used in hospitals and clinics. The objective of this study was to evaluate the efficacy of scope disinfection using glutaraldehyde and hydrogen peroxide in manual and mechanical protocols. *Bacillus subtilis* and *Pseudomonas cepacia* were the test organisms. Each channel of two different endoscopes ~~were~~ was seeded and evaluated separately. Residual chemical germicide levels in the channels and in the work environment were also measured.

Parametric analyses were carried out on log-transformations of number of colony forming units (cfu) recovered. Using repeated measures analysis it was demonstrated that both the type of disinfectant (hydrogen peroxide better than glutaraldehyde) and the method of washing (machine better than manual) were significant factors for disinfection. The channel to be disinfected also proved to be a significant factor with carbon dioxide and elevator channels being the most difficult to disinfect consistently.

INTRODUCTION

Cases of bacteremia caused by the use of contaminated endoscopes during endoscopic retrograde cholangio-pancreatography (ERCP) and sigmoidoscopy procedures are well documented in infection control literature.[1] Species of Salmonella and Pseudomonas have been implicated in many of these nosocomial infections.[2-5] The increase of tuberculosis and HIV cases has further increased the concern over proper disinfection or sterilization techniques used for these endoscopes.[5]

The use of flexible endoscope procedures in hospitals and clinics throughout the U.S. is rapidly increasing. Due to the high cost of these instruments there is a vital need for cleaning and high level disinfection or sterilization procedures which require minimum turn-around time. This process is complicated by an array of extremely small diameter tubing associated with these instruments which makes cleaning difficult. Procedures which have been used include ethylene oxide sterilization, with a relatively high turnover time of 12-24 hours, and a 2% activated glutaraldehyde solution for high level disinfection. Reports of worker sensitivity to glutaraldehyde[7-9] and recent lowering of ~~its~~ the OSHA permissible exposure limit for glutaraldehyde to 0.2 ppm[10] has further complicated this option. As a result, current attention has been focused on high level disinfection procedures using 6% hydrogen peroxide at both room temperature and elevated temperatures (50°C).

Additionally, septicemia after ERCP has been linked to the

use of automatic endoscope disinfecting machines.[11] This calls for the need to evaluate critically mechanical endoscope disinfecting machines. The availability of the Ott mechanical disinfector with high pressure penetration of the disinfectant into the narrow cannulas provided an opportunity for comparative testing of the various treatment modes in a standard manner against appropriate microorganisms.

MATERIALS AND PROCEDURES

Pseudomonas cepacia (kingii) American Type Culture Collection (ATCC) 25609 and *Bacillus subtilis* ATCC 6633 were obtained from ATCC (Rockville Maryland). The freeze-dried culture of *P. cepacia* was aseptically rehydrated with trypticase soy broth (TSB) and this rehydrated mixture added to 50 mL of TSB which was then incubated for 24 hours at 35°C. After incubation, *P. cepacia* was washed, vortexed and spun down at 40 RPM two times before the pellet was placed in 1.5 L of sterile buffered distilled water (SBDW). This mixture was placed in a dark cabinet for 48 hours to stabilize the population. For each day in which trials were run, bacterial counts were obtained by serial dilution followed by enumeration of the bacteria on duplicate pour plates using standard methods agar (SMA). Between trials the bacterial solution was stored in a dark cabinet at room temperature. Stock cultures were maintained on SMA at 4°C.

Bacillus subtilis ATCC 6633 freeze-dried culture was aseptically rehydrated with trypticase soy broth (TSB) and this

rehydrated mixture was added to 50 mL TSB which was then incubated for 24 hours at 35°C along with SMA prepared plates. Cultures were maintained on SMA at 4°C.

Rapid Disk Assay Method[12] was used to enumerate the *B. subtilis* and to obtain sufficient spore counts within the 10^6-10^8 cfu/mL range. Verification of spore content within this prepared mixture was completed using phase contrast microscopy.

The two endoscopes utilized in this study included an end-viewing sigmoidoscope (P-10-S) and a side-viewing endoscope used for endoscopic retrograde colangio-pancreatography (ERCP/ JF-10 or colonoscope), both manufactured by Olympus Optical Co., LTD. Tokyo, Japan. The 60 cm sigmoidoscope had air, water, suction and carbon dioxide (CO_2) channels while the 120 cm ERCP had air, water, suction and elevator channels. Reflux from the patient may occur in any of the channels and it is therefore of utmost importance to clean and disinfect all channels of the endoscope thoroughly between patient use. Both endoscopes were approximately the same age and both were in excellent condition as their previous use had been as trade show demonstration units.

The amount of inoculum needed to fill each channel was determined by trial and error using tap water. It was found that the suction channel could hold 15 mL, the air and water channels could hold 5 mL each, the CO_2 channel could hold 3 mL and the elevator channel 1 mL. For consistency, these same volumes were used for inocula in each trial as well as for sterile buffered distilled rinse water utilized for recovery after each individual

treatment. Volumes of the inoculum and the sterile rinse solutions were measured using a pipette. Delivery into the air, water, and special channels (CO_2 and elevator) was accomplished using a syringe. The suction channel was inoculated using a syringe but recovery was accomplished by connecting the endoscope to a vacuum pump and drawing the sample through in the manner described in the Ott Sampling Kit.[13] All trials were carried out in the same manner. The order in which the channels were inoculated were as follows: 1-air, 2-water, 3-suction, 4-elevator or CO_2 channel. The order for recovery was the same as with the inoculum.

After the endoscope was seeded (inoculated) with the appropriate bacteria to be tested (*B. subtilis* or *P. cepacia*), it was manually washed and put through the disinfection or sterilization process to be tested. Endoscopes were mechanically disinfected between each trial.

INOCULATION OF THE ENDOSCOPE

Two individuals, an experimenter and assistant were required to carry out the inoculation for each endoscope trial.

To inoculate the scope, the air inlet at the end of the universal cord was blocked with the plug provided in the kit. A 35cc syringe was placed on the water port adapter and tightly attached to the water bottle port on the endoscope. For the air channel, 5 mL of inoculum was placed in the syringe while the assistant placed her finger over the air/water valve. The 5 mL

were then injected into the scope. Another five mL of inoculum were placed in the same syringe and injected into the endoscope while the assistant depressed the air/water valve. Fifteen mL were then placed in the 50cc syringe which was connected to the suction port of the endoscope with a rubber tubing adaptor. The assistant then depressed the suction valve at the control head while the experimenter injected the inoculum into the scope. For the elevator channel of the colonoscope, 1 mL of inoculum was placed in a 5cc syringe which had been firmly attached to the elevator port of the endoscope with an adaptor. This inoculum was then injected into the endoscope. To inoculate the CO_2 channel, 3 mL were pipetted into the 35cc syringe which had been connected to the CO_2 port in the universal cord. The CO_2 valve was depressed at the control head while the inoculum was slowly injected into the scope. Once inoculation of the scope had been completed the inoculum was either directly recovered for the control trials or the scope was put through the manual cleaning process followed by scope disinfection.

MANUAL CLEANING PROCEDURES

After seeding with the test organism, the endoscope was placed in a laboratory sink. Liquid enzymatic cleaning solution (Endozyme, Ruhof Corp., Valley Stream, N.Y.) was then added to the wash water in accordance with manufacturers recommendations. Exterior surfaces of the endoscope were washed in this enzymatic solution using a clean cloth. The scope was then connected to

the light source and the air/water valve was activated to ensure unblocked channels. Air/water valve was replaced with the air/water cleaning adaptor provided by the manufacturer for cleaning the endoscope. All accessible channels, in particular the suction channel and umbilical cord of the scope were thoroughly brushed. A small hand-held cytology brush was then used in the suction channel valve opening, biopsy port opening, and the suction tubing connection on the umbilical cord. When cleaning the colonoscope, the special cleaning hose was attached at the head of the scope for washing and rinsing the elevator channel. A 3cc syringe was used to deliver 9cc for each washing and rinsing of this elevator channel. The all-channel irrigator was then attached and the scope was completely submerged in the cleaning solution and water. A 60cc syringe was used to infuse cleaning solution through the scope. 250cc each were used for the wash and for the tap water rinses.

DISINFECTION/STERILIZATION PROCEDURES

After the manual washing was completed, the endoscope was put through a test disinfectant treatment. The test treatments included: 1) manual disinfection using a 2.0% activated Glutaraldehyde solution (MetriCide MX-1400 Metrex Research Corp., Parker, CO); 2) a mechanical disinfection (Ott Disinfector, MediVators Inc, Rochester, MN) using 2.0% Metricide at room temperature; 3) manual disinfection using a 6% hydrogen peroxide/0.85% phosphoric acid solution (EndoSpore, Globe Medical

Instruments Inc., Clearwater, FL); 4) a machine disinfection using 6% hydrogen peroxide/0.85% phosphoric acid solution at room temperature; 5) a machine disinfection using 6% hydrogen peroxide/0.85% phosphoric acid at 50°C; 6) ethylene oxide sterilization (ETO) in a standard hospital cycle; and 7) manual wash followed by no disinfection. Each treatment was repeated three times for each of the two types of endoscopes. Between each trial, scopes were manually washed and mechanically disinfected. *B. subtilis* and *P. cepacia* were always utilized in separate tests.

If the endoscope was to be manually disinfected after the manual wash described above, the all-channel irrigator remained attached to the scope and the scope was then submerged in the appropriate disinfectant. The 60cc syringe was used to infuse 180cc of disinfectant through the scope. If the colonoscope was being disinfected, 9cc of disinfectant were infused separately into the elevator channel using the 3cc syringe. The scope was then left to soak in the disinfectant for 10 minutes. A total of 500cc of tap water was used as a final rinse to flush out the disinfectant. Scopes were dried only at the end of the day, for 10 minutes with the caps on and 10 minutes with the caps off.

Manufacturer's directions were always followed for scope hook-up when mechanical disinfection was used.

Before ETO sterilization, the scope was placed in a foam nest for safe transport and handling after all valves had been removed and the gas cap had been placed on the scope to allow for

gas flow so as to avoid damage to the distal end of the scope. The foam nest was then wrapped and ETO indicator tape was used for verification of ETO cycling. Endoscopes were processed through the standard ETO hospital cycling which consisted of a 2 hour exposure at 54°C with a standard 1288 Freon/ETO mix in a Castle ETO sterilization unit. Sterilization was followed by a 30 minute aeration within the sterilizer at 54°C and a final 12 hour aeration at room temperature outside the sterilization unit.

RECOVERY PROCEDURES

Recovery from each channel paralleled the procedures used to inoculate the endoscopes. SBDW was substituted for inoculum and air allowed through until no more of this SBDW "carrier" could be collected in the sterile plastic collection bottles from the distal end of the scope. The exception was from the suction channel. For this channel the suction trap was connected to the suction port and vacuum supply. The distal tip of the scope was placed in a sterile container with 15 mL of SBDW. The assistant depressed the suction valve at the control head as the vacuum source was slowly turned on and until the entire 15 mL rinse had passed through the endoscope and was collected in the sterile suction trap.

Additionally, direct recovery trials were completed for each test bacterium and each endoscope. These trials consisted of using a syringe of inoculum followed by a syringe full of air.

Once collected, serial dilutions were made and the samples

were plated in 100x15 mm petri plates using Standard Methods Agar (SMA). Plates were then incubated for 24 hours (*B. subtilis*) or 48 hours (*P. cepacia*) at 35°C. Plates with counts between 25 and 250 cfu were read and the average was calculated for duplicate plates. Plates with cfu counts below 25 were also recorded but were used only when no dilution yielded plate counts within the 25-250 range.

RESIDUAL DISINFECTANT/STERILANT TESTING FROM ENDOSCOPE

Samples of residual levels of chemical disinfectant within each separate channel of the endoscope were collected after disinfection. To obtain residual chemical levels, sterile buffered distilled water in the same volumes as used for recovery of bacterial samples was inoculated and directly recovered from the endoscope to be tested. For hydrogen peroxide residuals these samples were analyzed along with a blank using CHEMet (0-1 and 1-10 ppm) and VACUette (0-25 and 25-250 ppm) colorimetric kits (FeSCN by CHEMetrics, Inc. Calverton, VA). This test kit is based on hydrogen peroxide oxidation of ferrous iron to the ferric state, resulting in the formation of a red thiocyanate complex.

Glutaraldehyde residuals were obtained in the same manner as hydrogen peroxide samples except that analysis was completed using a glutaraldehyde colorimeter test (LaMotte Chemical Products Co., Chestertown, MD.). Scopes were tested for glutaraldehyde residuals after disinfection followed by rinses

with a series of different rinse temperatures. Four trials were run after a tepid rinse, 2 after hot water rinses (44°C), and 2 after cold water rinses (13°C).

Ethylene oxide residuals were obtained by injecting air through the sterilized/ventilated endoscope while measuring the expelled air via a Miran 1A Portable Gas Analyzer (spectrophotometer) which was connected to a plotter.

WORKER EXPOSURE TO 2.0% ACTIVATED GLUTARALDEHYDE

The spectrophotometer was also used in a separate series of manual disinfection schemes using hot and cold water rinses, as well as during machine disinfection to measure exposure levels of personnel working with disinfection of these scopes.

RESULTS

B. subtilis was far more resistant to all disinfection methods and disinfectants than was *P. Cepacia*. *P. Cepacia* was so readily killed and/or flushed from the scopes by all cleaning and disinfection methods that no statistically significant differences between products/methods could be ascertained. Due to its hardiness, *B. Subtilis* was chosen as the bacterium for which comparisons of various disinfection procedures were made.

Parametric analyses were carried out on the log-transforms of the bacterial recovery rates. Each different channel of the endoscope was treated as an independent experimental unit. Tables 1 & 2 show the averaged log reductions for the ERCP and

sigmoidoscope trials respectively. All bacterial recovery rates in the log reduction tables (1 & 2) are recorded in cfu/mL of inoculum recovered. Log reductions denoted as "greater than" in these two tables represent an average recovery of $\leq$ 0.5 cfu/mL. It is evident from Tables 1 & 2 that ETO sterilization proved to be more efficacious than high level disinfection procedures, although a few *B. Subtilis* did survive in the elevator channel of the ERCP scope. Plates which were "too numerous to count" (TNTC) as shown in Table 2 occurred during cleaning and manual disinfection procedures, and only from the carbon dioxide channel of the sigmoidoscope. Several of these TNTC events also occurred with manual disinfection trials using *P. Cepacia*.

The type of scope tested did not make a difference in the efficacy of the disinfection method (Table 3). Because the within channel variances were different, separate analyses were carried out for the air and CO_2 or elevator channels (1 and 4 respectively). The water and suction channels (2 and 3) had similar variances and thus were calculated together. Both the type of disinfectant and the channel were important in the efficacy of high level disinfection achieved for the water and suction channels ($p<0.001$) and the type of disinfectant was statistically significant at $p=0.001$ for the air channel.

Pair-wise comparisons with the Wilcoxon Sign Test (Table 4) show Ott mechanical disinfection as significantly more efficacious than manual disinfection, and hydrogen peroxide as more efficacious than glutaraldehyde for high level disinfection.

This test took the amount of the difference into account and therefore was more sensitive than utilization of a test ignoring these numerical differences. Although the ratios may be the same, the p values can differ as they reflect the numerical amount of difference between trials.

When comparing manual disinfection using glutaraldehyde or hydrogen peroxide and Ott disinfection using glutaraldehyde or hydrogen peroxide with the control (manual wash with no disinfection), it was found that all four treatments were statistically significant at $p < 0.0001$. Ott mechanical disinfection was shown to be more effective than manual disinfection ($p < 0.004$) and hydrogen peroxide found to be more effective than glutaraldehyde ($p < 0.0001$) for disinfection. No advantage was found in using heated hydrogen peroxide for disinfection in conjunction with Ott mechanical disinfection ($p= 0.4$). During manual disinfection, the hydrogen peroxide performed better than the glutaraldehyde in 23 out of 24 trials. (Table 4)

When the non-parametric Friedman test was employed to compare the four groups, Ott mechanical disinfection with hydrogen peroxide proved most effective, followed by manual disinfection with hydrogen peroxide, Ott mechanical disinfection with glutaraldehyde, and finally manual disinfection using glutaraldehyde.

Residual levels of glutaraldehyde in the endoscopes after

manual disinfection and final rinses using hot (44°C), cold (13°C) and tepid (33°C) water were inconsistent and somewhat dependent upon the channel tested. Dependence on the channel is consistent with results of bacteriological testing which show that the channel tested was a significant factor in the disinfection procedure (Table 3). Residuals in the air channel regardless of rinse temperature were consistently $\leq$ 5 ppm. Water channel concentrations averaged 12 ppm although one value after a cold water rinse was as high as 35 ppm. The suction channel appears to be most difficult to rinse with an average residual glutaraldehyde concentration of 48 ppm. The large lumen in this channel may contribute to difficulty in rinsing out the residual chemicals. The carbon dioxide and elevator channels had average residual levels of 10 ppm with a range from <5ppm to 20ppm. More sampling pertaining to the residual levels found in the endoscopes after various temperature rinses needs to be completed in the future.

Residual levels of disinfectant/sterilant were also obtained for endoscopes after each type of disinfecting regimen. These average residual chemical disinfectant levels are shown in Figure I. Glutaraldehyde residuals (Glu) after machine disinfection (Mach.) with a 4 minute 8 second rinse cycle averaged 8.4 ppm. as compared with the 69 ppm. residual after manual disinfection (Man).

Residual levels of hydrogen peroxide (HP) after Ott disinfection (Mach.) averaged 77.4 ppm as compared with 88.3 ppm

following manual disinfection using H_2O_2. In both cases, machine disinfection resulted in lower residual levels than after manual disinfection. (Fig. 1)

High levels of ETO residual were found in the endoscopes despite a standard 12.5 hour aeration period following sterilization. ETO residuals averaged 66.2 ppm. The suction channel proved to have the highest residuals with levels of 190 ppm, 105 ppm, >200 ppm, and 105 ppm.

Figure 2 shows that personnel glutaraldehyde exposure monitoring during a simulation of manual disinfection of an endoscope exceeded the 0.2 ppm OSHA ceiling limit (TWA) in five out of six trials using a 4.3°C cold water rinse (μ=0.5 ppm / s.d.=0.205). In all trials using a 43.3°C hot water rinse, the 0.2 ppm TWA was exceeded (μ=3.1 ppm / s.d.=0.6 ppm). The average breathing zone glutaraldehyde exposure was approximately six times higher when using hot water for rinsing of the flexible endoscope as compared to use of a cold water rinse.

DISCUSSION

In this study, Ott mechanical disinfection proved to be more efficacious and consistent in reducing *B. Subtilis* counts than manual disinfection. Additionally the pressure in the channels created by the Ott mechanical disinfection machine apparently prevented air blocks from occurring in the CO_2 channel as this failure was not detected after any of the mechanical disinfection

protocols while it occurred in 3 out of 18 manual trials with the sigmoidoscope. This 17% failure rate could cause contamination between patients resulting in nosocomial infections. The endoscope used for ERCP was not associated with the air block problem yet this particular scope has an elevator channel which needs separate cleaning even when mechanically disinfected. Unfortunately the air-block problem or simply forgetting to clean and disinfect the elevator channel would be detectable only after infection resulted from this cross contamination. Thus, it is obvious that a clear understanding as to how the scopes work is necessary to ensure both consistency and improved cleaning and disinfection methods.[14]

Hydrogen peroxide was significantly more effective in the high level disinfection of the flexible endoscopes than the 2% glutaraldehyde solution used in these trials. However, H_2O_2 is usually not recommended by the manufacturers of flexible endoscopes as it is thought to be harmful to both the interior and exterior surfaces of the endoscopes. There continues to be some doubt as to the compatibility of hydrogen peroxide with endoscopes and the probability that its oxidizing properties may be harmful to the scope surfaces. Many infection control experts are calling for manufacturers to redesign flexible endoscopes utilizing durable materials tough enough to withstand chemical disinfection and with removable parts which allow for ease in high level disinfection procedures.[15,16] The apparent advantages of H_2O_2 over glutaraldehyde as a high level disinfectant, which we

have demonstrated, gives added credence to that recommendation. Heated H_2O_2 is particularly efficacious in destroying heat sensitive microorganisms, however, in these trials there was no advantage to heating the H_2O_2 to 50^0C for destruction of *B. Subtilis*, a result which was unexpected and which has no obvious explanation.

Ethylene oxide (ETO) sterilant was also tested. ETO is not routinely used for endoscope sterilization due to the lengthy turn around time and the high cost of endoscopes which prohibits medical facilities from owning multiple scopes. Although ETO sterilization proved highly effective in our study, a mere 2% of the respondents in a recent questionnaire on disinfection practices for endoscopes and other semicritical items, reported that ETO was the method they utilize in the disinfection of gastrointestinal endoscopes. 59% used a 2% glutaraldehyde solution for this purpose.[6] The number of bacteria recovered after ETO sterilization in our trials were extremely low. However, some viable spores were recovered from the elevator channel of the ERCP scope suggesting that even this time consuming process cannot always guarantee sterility. The residual levels of ETO averaging 66.2 ppm and ranging from 0 to >200 ppm even after a standard 12.5 hour degassing time, are of greater concern. These test results provide evidence that scopes should be manually aired out by inoculating each channel with air to eliminate high ETO residuals before being used on patients.

High level disinfection is defined as "a procedure that inactivates all fungi, viruses, and vegetative microorganisms, but not necessarily all bacterial spores"[17] and thus glutaraldehyde is appropriate for this purpose. Despite the fact that many institutions use a glutaraldehyde or glutaraldehyde-phenol-phenate mixture in the high level disinfection of flexible endoscopes, debate continues as to which type of glutaraldehyde product is best.[18] With this wide use, glutaraldehyde has been implicated frequently in worker chemical sensitization[7,8,19]. The fact that the Ott disinfection machine reduces employee exposure to glutaraldehyde, may maximize personnel time, and supplies offices and hopitals with a consistent method of disinfection, provides convincing evidence of its advantages over manual processes.[6,20] More importantly, the machine disinfection provides a standardized disinfection cycle complete with a sterile water rinse. Additionally, flow of disinfectant was more reliable and no air blocks were observed during these trials as compared to the air blockages which occurred during manual disinfection.

Drawbacks of mechanical disinfection include the cost of the equipment, and the fact that manual cleaning of the endoscope must first be completed before the endoscope undergoes the disinfection process. This cleaning process may be subject to human error. Special channels such as the elevator channel on the JF-10 (ERCP) must still be disinfected manually. Record keeping and other errors must be guarded against regardless of the treatment methods. Finally, some automatic disinfecting

machines have had problems with bacterial growth within reservoirs in the machinery, exacerbating transmission of disease through this disinfection process.[21] The Ott disinfecting machine has a unique "sterile water" filtered rinse and is designed to guard against providing a reservoir for bacterial growth. Periodic sampling of the reservoir during these trials did not detect any contamination. This is likely to be superior to the reported 54% who rinse their G.I. endoscopes with unfiltered tap water.[6]

The responsibilities of endoscopic personnel should not be taken lightly. It is of utmost importance to have specially trained personnel and a system of checks and balances to maintain high level disinfection of the scopes regardless of methods or products used. Walter Bond of CDC has pointed out that, "In virtually every reported instance of disease transmission associated with endoscopes, there has been a major error in either the cleaning, disinfecting or sterilizing of the instrument."[22] Trained personnel are needed to inspect scopes for damage, manual cleaning, disinfection, rinsing, drying, and proper storage to prevent damage to the endoscopes and for prevention of disease transmission between patients.

Our trials were limited by a lack of organic material buildup within the various channels. Such a buildup could compromise disinfection of flexible endoscopes.[23] In hospital settings there are other factors besides the efficacy of high level disinfection procedures which may increase the risk of

nosocomial infections, including the degree of debilitation of the patient. All the risks and benefits of using various chemical germicides as well as methods and procedures used for the disinfection of flexible endoscopes must be considered in institutional decisions.

Acknowledgments

A special thanks to Beverly Ott who provided technical advice for this research project and to Dorothy Aeppli PhD, from the Department of Biostatistics at the University of Minnesota, who performed the statistical analysis on our data.

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TABLE 1. LOG REDUCTION- *Bacillus subtilis*

Endoscopic Retrograde Cholangio-Pancreatography Scope

CHANNEL	WASH ONLY	HYDROGEN PEROXIDE MANUAL	HYDROGEN PEROXIDE MACH. 50°C	HYDROGEN PEROXIDE MACH. 21°C	GLUTARALDEHYDE MANUAL	GLUTARALDEHYDE MACH.	ETO
AIR	4.85	6.53	8.05	6.64	4.23	5.06	>6.96
	4.38	6.06	8.27	6.94	6.03	5.41	>6.95
	4.37	6.31	6.96	7.11	5.10	5.89	>7.92
WATER	4.37	5.71	8.48	5.77	4.95	4.99	>6.96
	4.27	5.91	7.90	7.11	5.03	5.41	>6.95
	4.35	4.51	6.22	>7.11	5.13	5.70	>7.92
SUCTION	5.23	>7.64	>8.48	7.11	5.46	5.65	>6.96
	4.96	7.47	8.05	>7.11	5.63	6.14	>6.95
	5.04	6.49	>6.96	>7.11	5.95	6.48	>7.92
ELEVATOR	3.88	5.71	5.17	4.39	4.10	4.87	5.70
	3.37	6.11	6.27	4.77	4.35	4.93	>6.95
	2.84	5.27	5.75	6.81	4.95	5.02	7.02

TABLE 2. LOG REDUCTION– *Bacillus subtilis*

Sigmoidoscope

CHANNEL	WASH ONLY	HYDROGEN PEROXIDE MANUAL	HYDROGEN PEROXIDE MACH. 50°C	HYDROGEN PEROXIDE MACH. 21°C	GLUTARALDEHYDE MANUAL	GLUTARALDEHYDE MACH.	ETO
AIR	4.46	5.96	5.88	6.57	4.81	4.77	>6.96
	4.38	6.17	5.71	7.11	4.42	4.98	>6.95
	3.81	5.88	6.56	>6.73	4.42	5.48	>7.92
WATER	4.46	6.03	6.60	6.81	4.57	4.99	>6.96
	4.25	6.06	6.58	6.64	4.92	5.18	>6.95
	4.15	5.25	>6.96	>6.73	4.27	5.44	>7.92
SUCTION	4.81	>7.64	>8.48	>7.11	6.49	5.97	>6.96
	4.56	5.41	8.48	>7.11	5.85	6.34	>6.95
	4.93	>7.92	>6.96	>6.73	5.88	6.93	>7.92
CO_2	4.18	6.39	6.97	6.81	5.24	5.23	>6.96
	4.52	5.69	6.81	6.72	4.88	5.44	>6.95
	TNTC‡	5.95	6.96	6.73	TNTC‡	5.53	>7.92

TABLE 3. ANOVA using Bacillus Subtilis as the test microorganism.

BACILLUS SUBTILIS

AIR CHANNEL

	SS	df	MS	F	P
Disinfectant	71.96	1	71.96	56.69	0.001
within	6.35	5	1.27		
Device	12.55	1	12.55	9.95	0.025
within	6.3	5	1.26		
Disinfectant x Device	1.17	1	1.17	1.74	0.25
within	3.38	5	0.68		

WATER AND SUCTION CHANNELS

	SS	df	MS	F	P
Channel	2507.25	1	2507.25	808.14	<0.001
within	31.03	10	3.1		
Disinfectant	111.18	1	111.18	146	<0.001
within	7.62	10	0.76		
Device	27.49	1	27.49	10.53	0.009
within	26.1	10	2.61		
Channel x disinfectant	0.28	1	0.28	0.36	0.56
Channel x device	6.27	1	6.27	2.4	0.15
Disinfectant x device	3.13	1	3.13	2.69	0.13
Channel x disinfect x device	4.61	1	4.61	3.96	0.075

ELEVATOR OR CO2 CHANNEL

	SS	df	MS	F	P
Disinfectant	49.88	1	49.88	15.67	0.011
within	15.92	5	3.18		
Device	10.69	1	10.69	2.05	0.21
within	26.09	5	5.22		
Disinfectant x device	2.26	1	2.26	0.78	0.42
within	14.45	5	2.89		

TABLE 4. Pair-wise comparisons using the Wilcoxon Sign Test on disinfectant regimens for *B. Subtilis*. The difference in P values despite like ratios is a reflection of the Wilcoxon test accounting for the numerical differences between trials.

COMPARISONS	RATIO	p value
Glutaraldehyde Mechanical > Manual	20/24	<0.001
Hydrogen Peroxide Mechanical > Manual	19/24	0.004
Manual Disinfection Hydrogen perox. > Glutarald.	23/24	<0.0001
Mechaniacal Disinfection Hydrogen perox. > Glutarald.	22/24	<0.0001
Mechanical disinfect H_2O_2 $21^0C > 50^0C$	10/24	0.4
Mechanical > Manual	20/24	0.0004
Hydrogen perox.> Glutarald.	24/24	<0.0001
Interaction	16/24	>0.3

AVERAGE RESIDUAL CHEMICAL LEVELS
WITHIN CHANNELS / POST RINSE

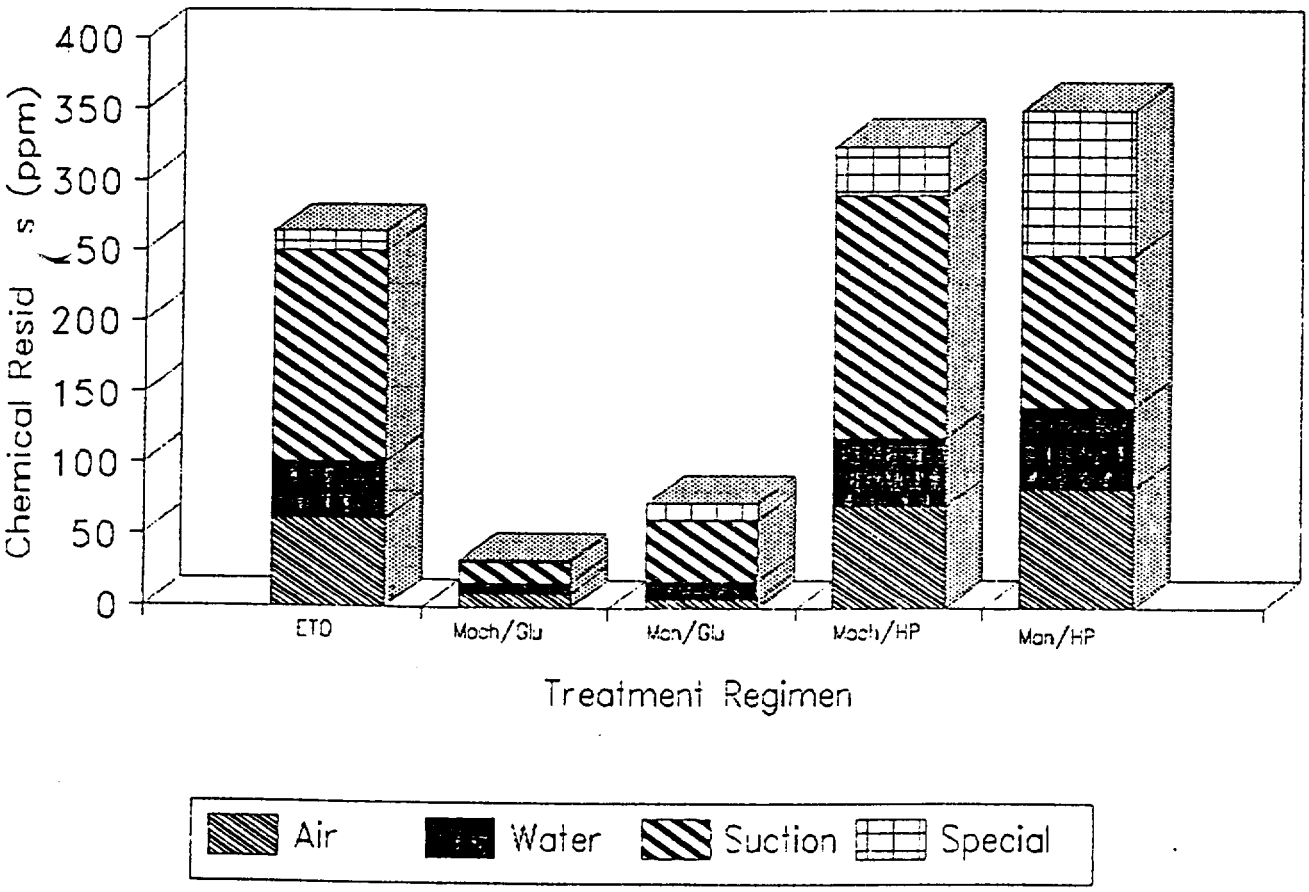
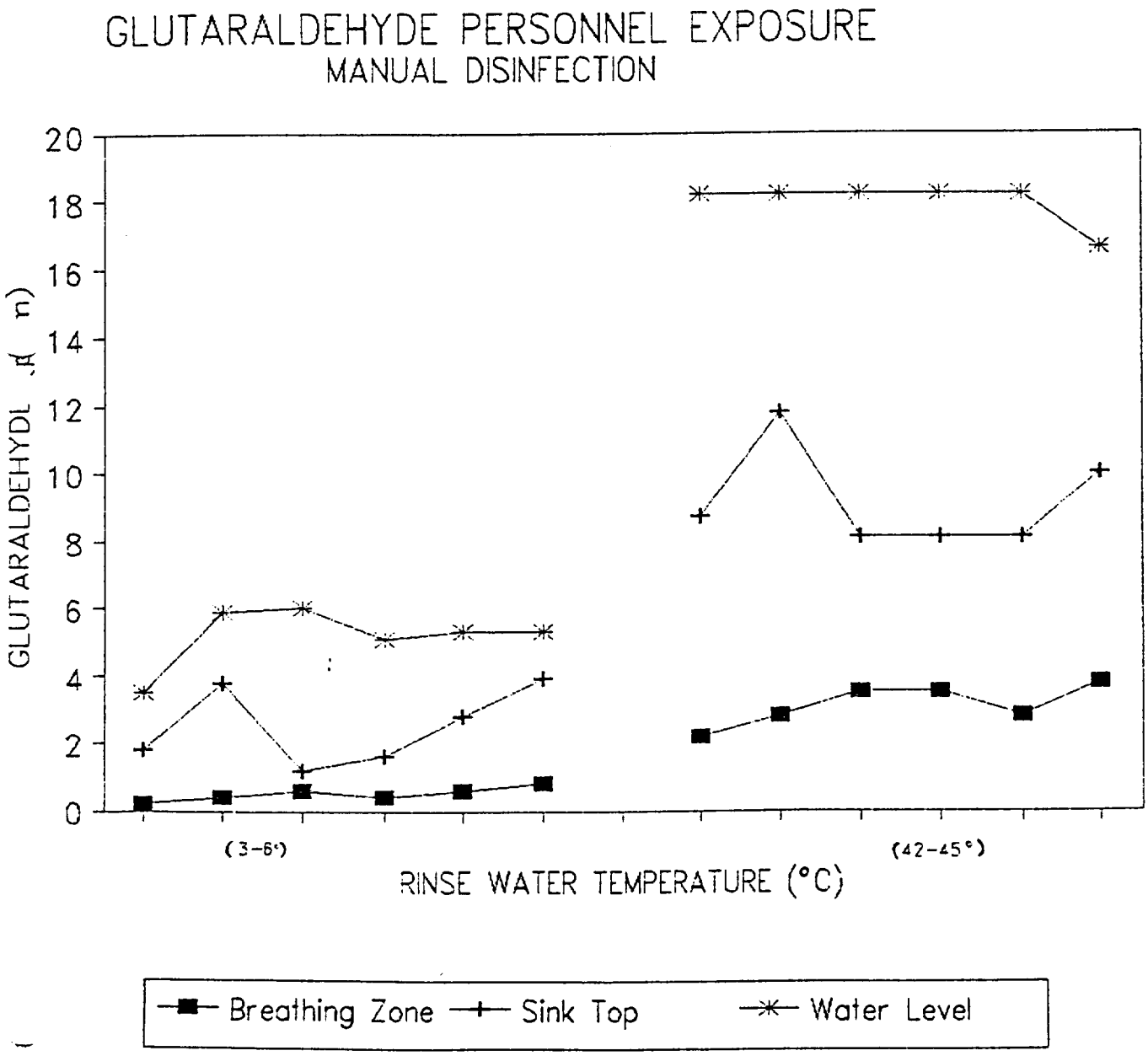


Fig. 2


GLUTARALDEHYDE PERSONNEL EXPOSURE
MANUAL DISINFECTION
GLUTARALDEHYDE (µg/m³)
20
18
16
14
12
10
8
6
4
2
0
(3-6°)
(42-45°)
RINSE WATER TEMPERATURE (°C)
Breathing Zone
Sink Top
Water Level

APPENDIX F

OTT™
DISINFECTOR

INSTRUCTION SUPPLEMENT

CONNECTIONS FOR:

UPPER AND LOWER
OLYMPUS
GI ENDOSCOPES

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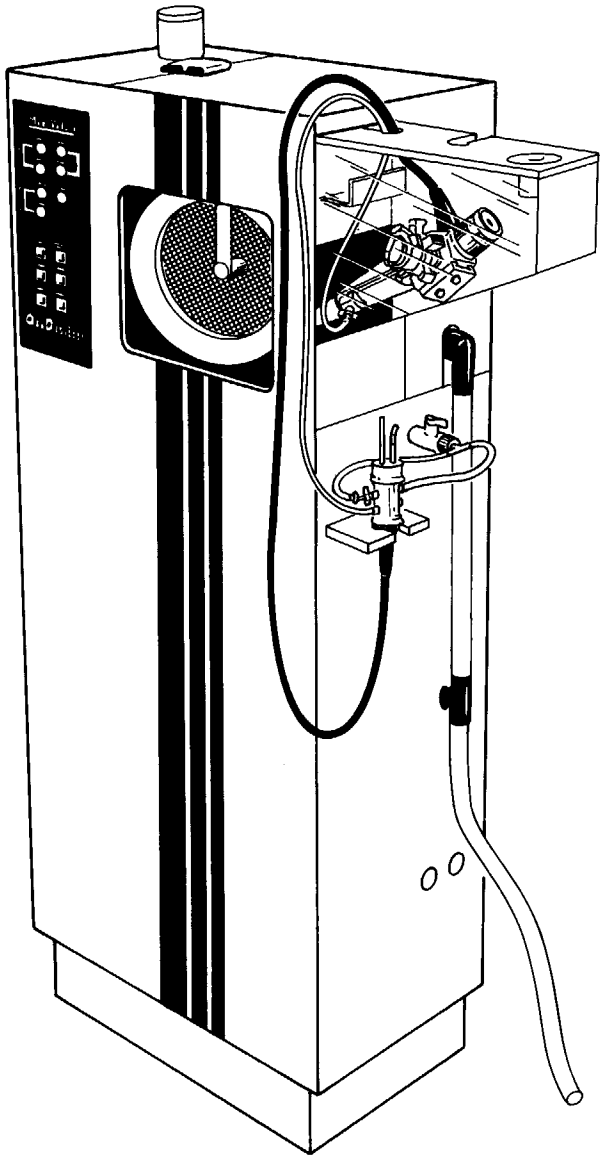
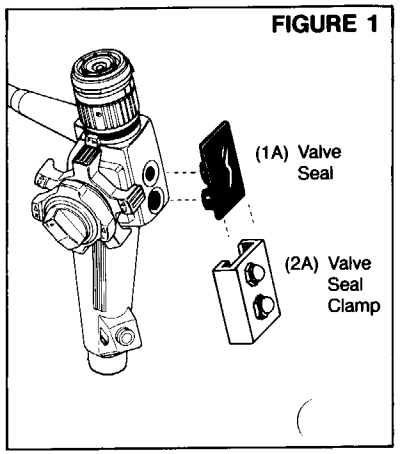
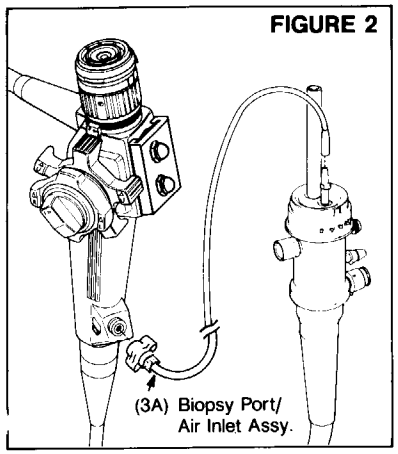


HOOK-UP INSTRUCTIONS FOR UPPER ENDOSCOPES





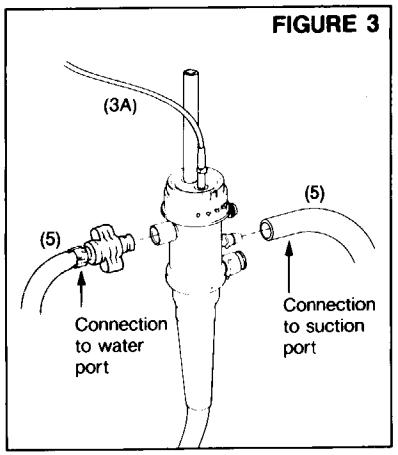
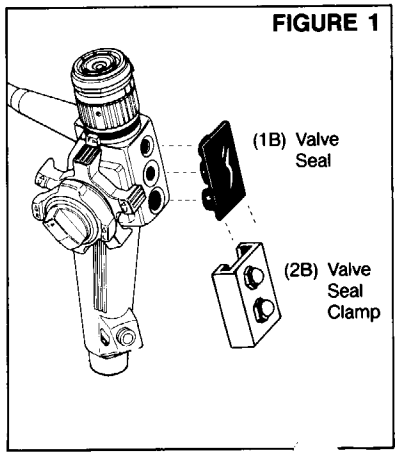


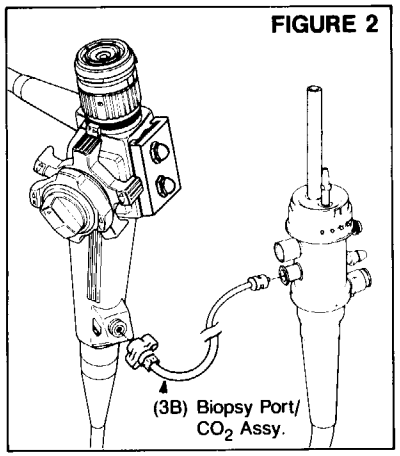
FIGURE 1: After removing air/water, suction valves from instrument, place the valve seal (1A) on valve openings. Hold in place and slide seal clamp (2A) over seal. Finger tighten bottom screw, then finger tighten top screw.

FIGURE 2: Connect the biopsy port/Air inlet tube assembly (3A) to biopsy port and air inlet port.

FIGURE 3: Connect disinfector hook-ups (5) to water port and suction port. The water port adapter must be firmly inserted.

HOOK-UP INSTRUCTIONS FOR LOWER ENDOSCOPES





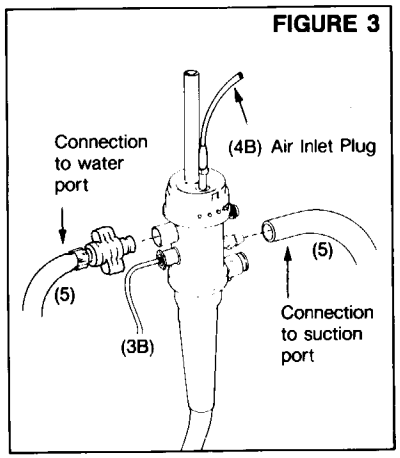


FIGURE 1: After removing air/water, suction valves and CO_2 valve cap from instrument, place the valve seal (1B) on valve openings. Hold in place and slide seal clamp (2B) over seal. Finger tighten bottom screw, then finger tighten top screw.

FIGURE 2: Connect the biopsy port/CO_2 tube assembly (3B) to biopsy port and CO_2 port.

FIGURE 3: Connect disinfector hook-ups (5) to water port and suction port. The water port adapter must be firmly inserted. Connect air inlet tube assembly (4B) to air inlet.

PARTS LIST & REORDER INFORMATION

Olympus OES Upper Hook-up Set
reorder #ED110-OU

ITEM #	PART #	DESCRIPTION
2A	105H04-2	**Upper Olympus OES Valve Clamp;** Delron w/turn screws, (includes 105H02 valve seal, item 1A)
5	105H09-1	**Olympus Water Port Adapter/Suction Tubing;** amber butterfly connector w/tubing
3A	105H10	**Olympus Upper Biopsy Port/Air Inlet Assembly;** 24" clear tubing w/amber connector and clear 1/8" tubing for air inlet

Olympus OES Lower Hook-up Set
reorder #ED110-OL

ITEM #	PART #	DESCRIPTION
2B	105H03-1	**Lower Olympus OES Valve Clamp;** Delron w/turn screws, (includes 105H01 valve seal, item 1B)
5	105H09-1	**Olympus Water Port Adapter/Suction Tubing;** amber butterfly connector w/tubing
3B	105H11	**Olympus Lower Biopsy Port/CO_2 Tube Assembly;** 24" clear PVC tubing w/amber connector for biopsy port and luer lock for CO_2
4B	105H12	**Air Inlet Plug;** 4" clear PVC tubing with white plug

PARTS LISTED MAY BE ORDERED SEPARATELY
CONTACT MEDIVATORS FOR MORE INFORMATION

MEDIVATORS, INC.®

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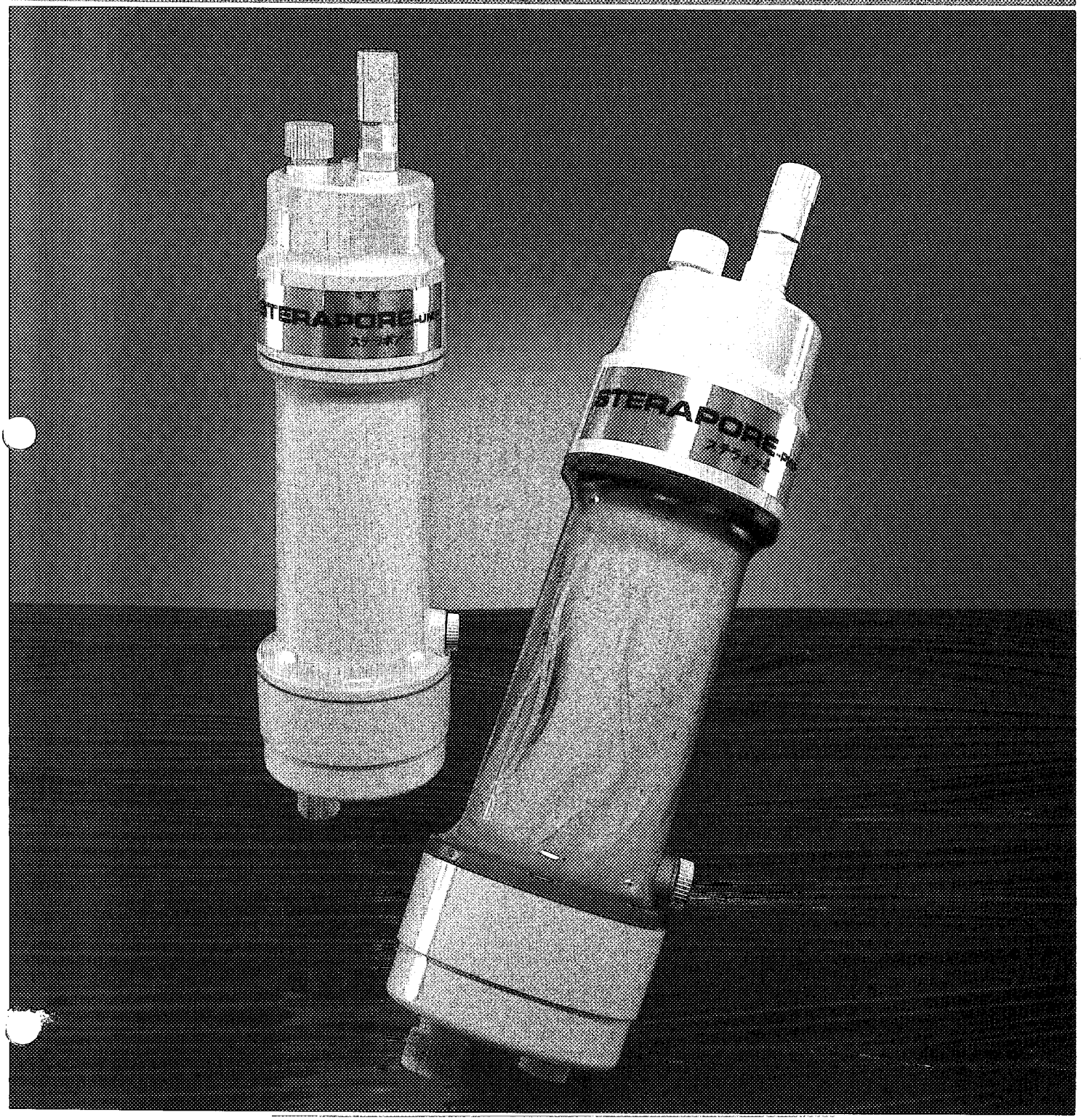
APPENDIX G

STERAPORE™

Disposable Ultramicrofilter

PKO/UMF module

ULTRAMICROFILTER MODULE
TO MEET A WIDE RANGE OF HIGH-TECH NEEDS



MEDIVATORS, INC.®

INNOVATIVE MEDICAL PRODUCTS

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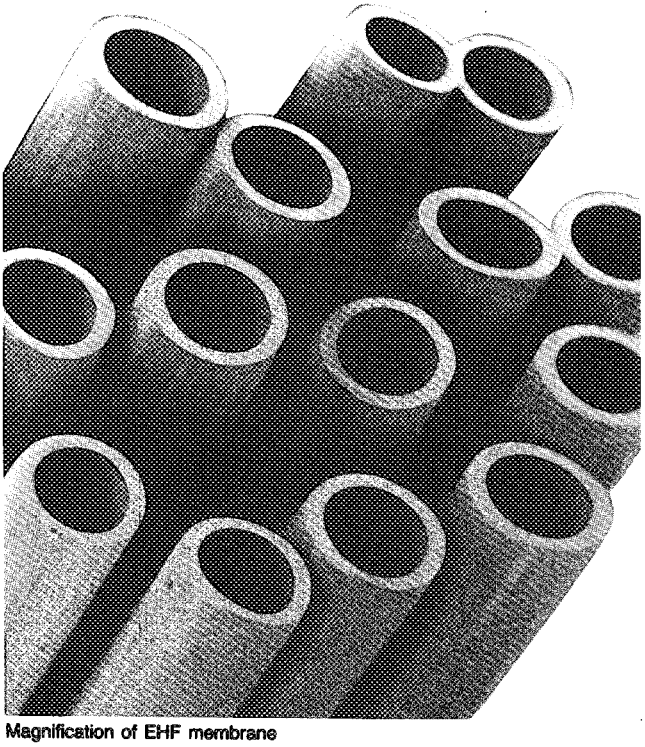
STERAPORE™ offers many features beyond the conventional filter.

Polyethylene porous hollow fiber membrane

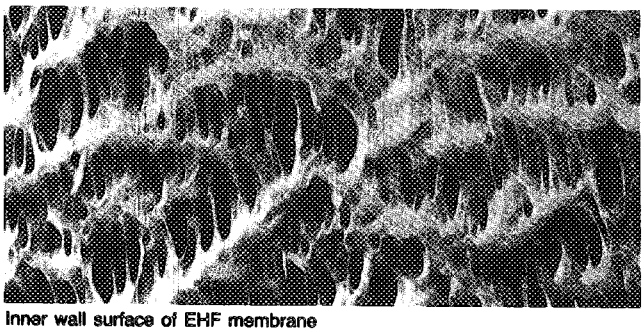
Water is the source of life and is indispensable to the progress of high-tech science. In modern medical technology a large volume of safe water free from pyrogen is required in areas such as cancer and brain surgery, heart surgery and internal organ transplants. In electronics, removal of fine particles, less than 0.1 μ, is necessary for very large scale integration (VLSI) areas above 256 Kbits. And in biotechnology, pure water is a must. Mitsubishi Rayon Co. has developed a new epoch-making ultramicrofilter system, STERAPORE,™ featuring an EHF membrane, the fruit of advanced synthetic fiber manufacturing technology, to meet a wide variety of needs from high-tech areas to potable water.

Applications

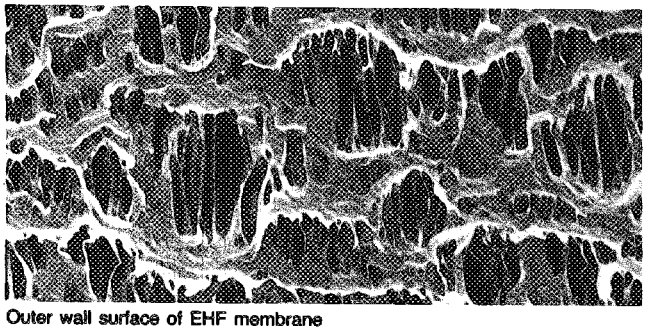
Medical • Water for surgical hand washing, pharmacy installment washing water, water to dilute drugs • Combined with ion exchange resins and reverse osmosis, purified water for testing and dialysis, washing affected parts, etc. Industrial • The final filter in super pure water production for very large scale integration (256 Kbits) and other semiconductor applications • Sterile water and pyrogen-reduced water for pharmaceutical applications • Sterile water for food processing • Other concentration, separation and bioreactor applications. Household • Potable water for home use, areas damaged by natural disasters, and employees stationed in remote foreign countries • Commercial water clarifier for hotels and restaurants.



Magnification of EHF membrane



Inner wall surface of EHF membrane



Outer wall surface of EHF membrane

EHF Porous Hollow Fiber Membrane—Epoch-Making Material for Ultramicrofilter

Outstanding Separation Performance

The special hollow fiber structure, having slit-like ultramicropores between the microfibril, catches bacteria and submicron fine particles (greater than 400 angstrom) and effectively removes endotoxin (pyrogen) and hydrophobic toxic organic substances due to the characteristics of the polyethylene base material.

High Water Permeability

The fine hollow fiber structure (390 μ O.D. and 270 μ I.D.) provides large filtering surfaces. In addition, more than 60% of these membrane walls consist of slit-like ultramicropores, thus resulting in high water permeability. Due to the deep uniform membrane structure formed by microfibril, the STERAPORE™ ultramicrofilter is characterized by a large fouling retention capacity and a long filtering life.

Clean EHF Membrane

Unlike conventional wet and dry manufacturing methods, a melt spinning of polyethylene polymer is used to make the EHF membrane. Therefore, the EHF membrane is clean, sanitary and safe, and contains no solvent or plastilizer.

Tough EHF Membrane

Breaking strength, breaking elongation and bursting strength are over 300g/F, 90% and 10kg/cm^2, respectively. Since the EHF membrane is also very tough against flexing fatigue, it allows easy module fabrication and handling.

Outstanding Durability

In addition to excellent physical strength, the EHF membrane is resistant to microbial attack, chemicals and radiation. Its excellent resistance to concentrated acids and bases and its stability in many organic solvents make the STERAPORE™ ultramicrofilter suitable for removal of fine particles from those chemicals.

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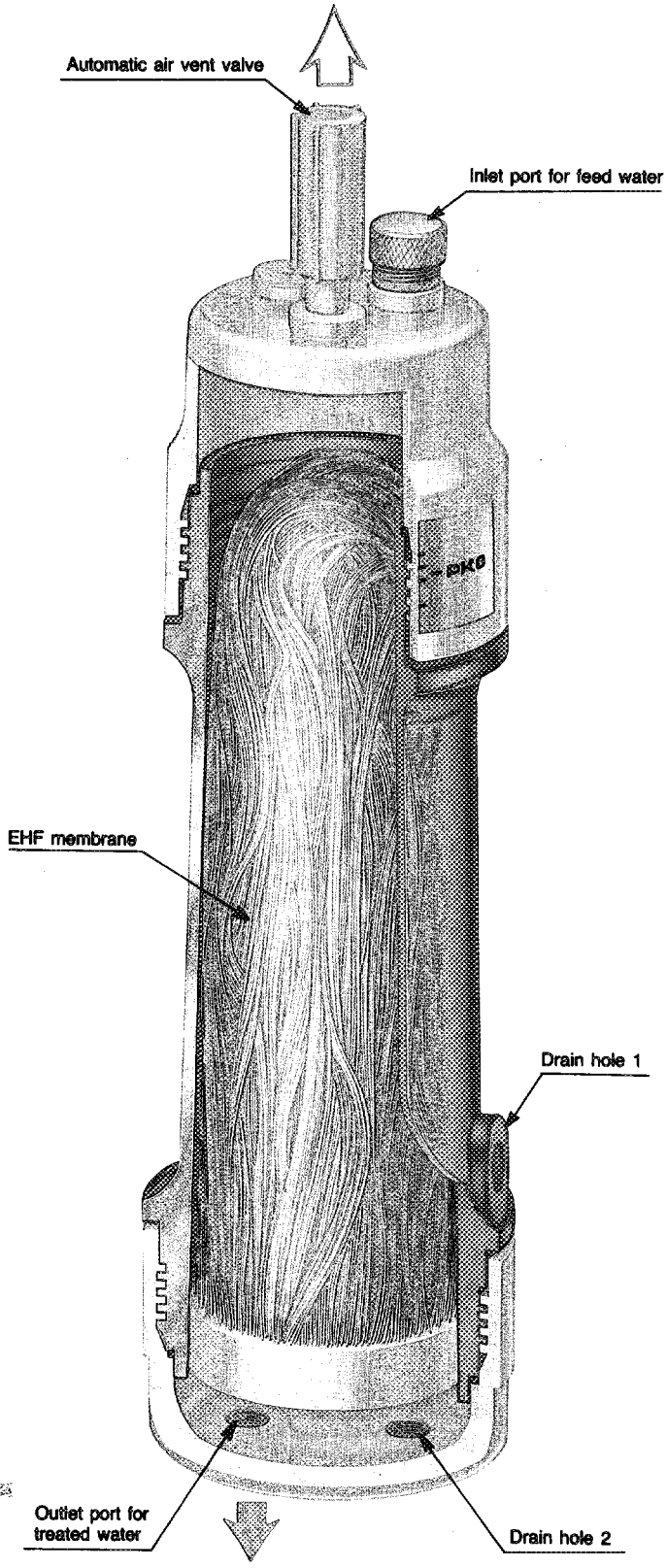
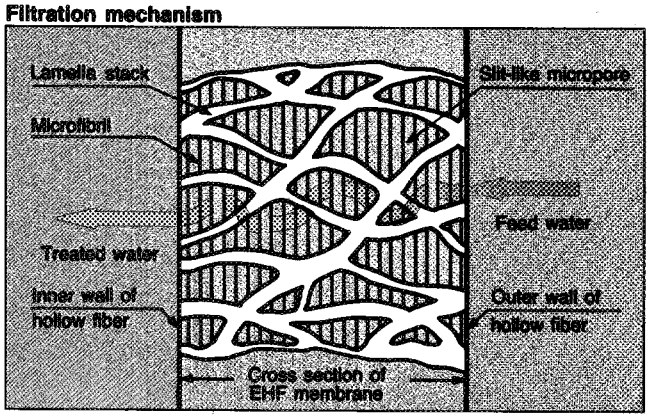
(EHF membrane) and unique module structure



Filtration mechanism



Unique Module Structure — The filter module has made the ideal treatment method "USE POINT TREATMENT" possible.

Total Filtration Method
The excellent anticlogging property of the EHF membrane has enabled a total filtration system which allows no feed loss and makes easy piping possible.

High Productivity
The large surface area, $6m^2$, and high permeability of the EHF membrane offer high productivity at low pressure with a long filter life.

Compact Size
Due to its compact size, a module can easily be installed in a faucet or just before the use point.

No Leakage
The tight seal on a small sealing area, due to the adoption of a hollow fiber configuration, assures no leakage to the product water side.

New Innovative Automatic Air Vent Valve
The automatic air vent valve, which uses an EHF membrane, is installed at the top of the module. This valve has made it possible to keep the inside of the module sterile from outside contamination while still maintaining smooth air venting.

Easy Maintenance
The module structure allows the user to sterilize the inside of the module. The disposable module offers handy replacement.

Minimum Reverse Contamination
A minimum of reverse contamination is expected due to 1) use point application and 2) the compact and simple structure of the product water side where the product water flows.

* A faucet which prevents reverse contamination with sterilizing beads is available.

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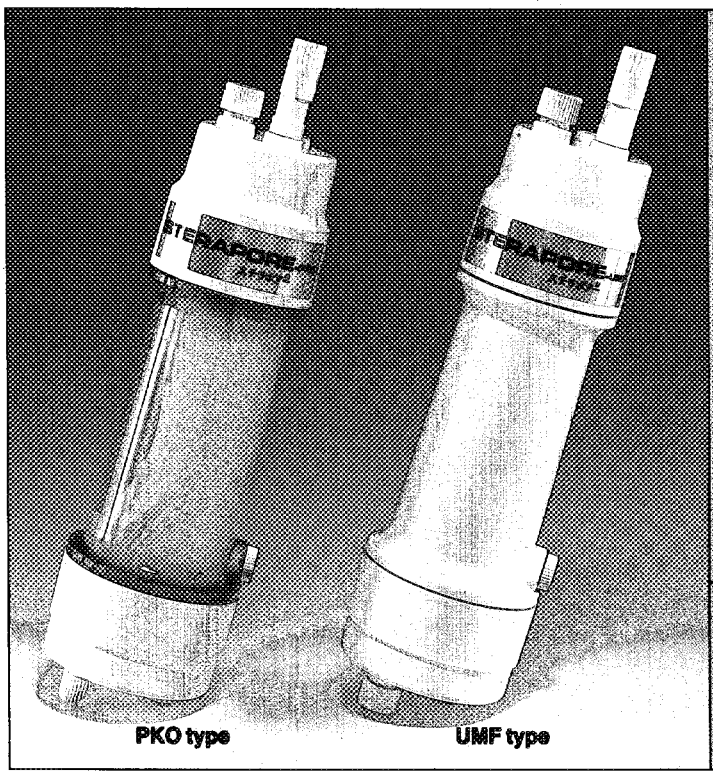

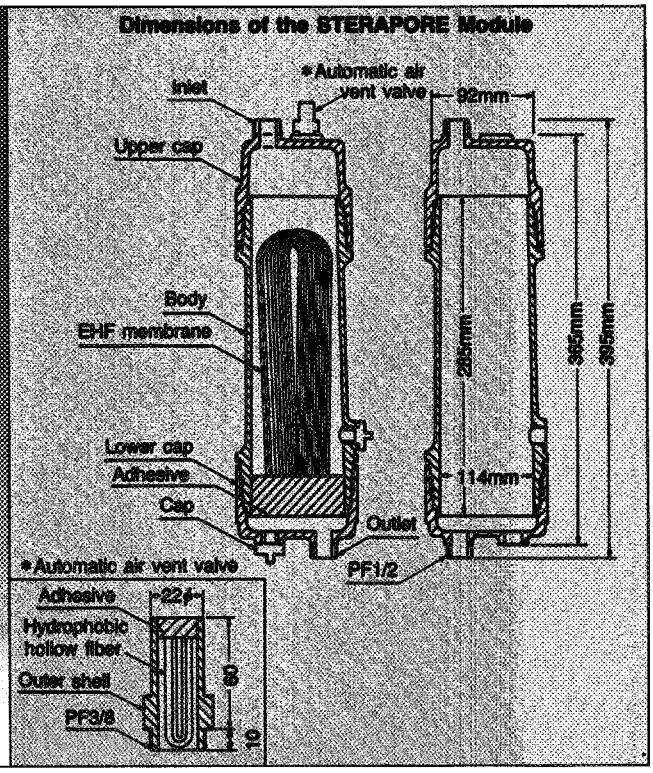

STERAPORE MODULE SPECIFICATIONS			
Module Type		PKO 614	UMF 614
Application		Medical	Industrial
Material		Polyethylene Porous Hollow Fiber (EHF)	
Effective Membrane Area		6.0m² (64.6feet²)	
Housing	Material	Acrylonitrile-Styrene Resin	Polycarbonate
	Length	395mm (15.6inch)	
	Upper Diameter	92mm (3.6inch)	
	Lower Diameter	114mm (4.5inch)	
	Connection	PF 1/2	
Normal Operating Pressure		less than 3kg/cm² (42.6psi)	
Normal Operating Temperature		less than 45°C (113°F)	
Initial Productivity		11ℓ/min (0.5kg/cm² pressure difference, 20°C water) [2.9gal/min (7.1psi, 68°F)]	
Containment Solution		Formaldehyde Aqueous Solution (0.5%)	Hydrogen Peroxide Aqueous Solution (0.2%) [Electronic Grade]

* Specifications are subject to change.
* A higher productivity module can be built according to your needs. (ex. 70m² effective membrane area)

Distributed by

MEDIVATORS, INC.®
INNOVATIVE MEDICAL PRODUCTS

1652 Greenview Drive Southwest
Rochester, Minnesota 55902

800-537-7324

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APPENDIX H

Third Party Laboratory Test Reports (b) (4)

Third Party Laboratory Test Reports (b) (4)

Third Party Laboratory Test Reports (b) (4)

Third Party Laboratory Test Reports (b) (4)

Third Party Laboratory Test Reports (b) (4)

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Third Party Laboratory Test Reports (b) (4)

Third Party Laboratory Test Reports (b) (4)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date 11/6/91

From REVIEWER(S) - NAME(S) Sparrow

Subject 510(k) NOTIFICATION K914145

To THE RECORD

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

_____ (A) Is substantially equivalent to marketed devices.

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

__X__ (C) Requires more data.

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

Additional Comments:

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

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

_____

PU 11/18

REVIEW: Chin S Lin (BRANCH CHIEF) | INCB (BRANCH CODE) | 11/18/91 (DATE)

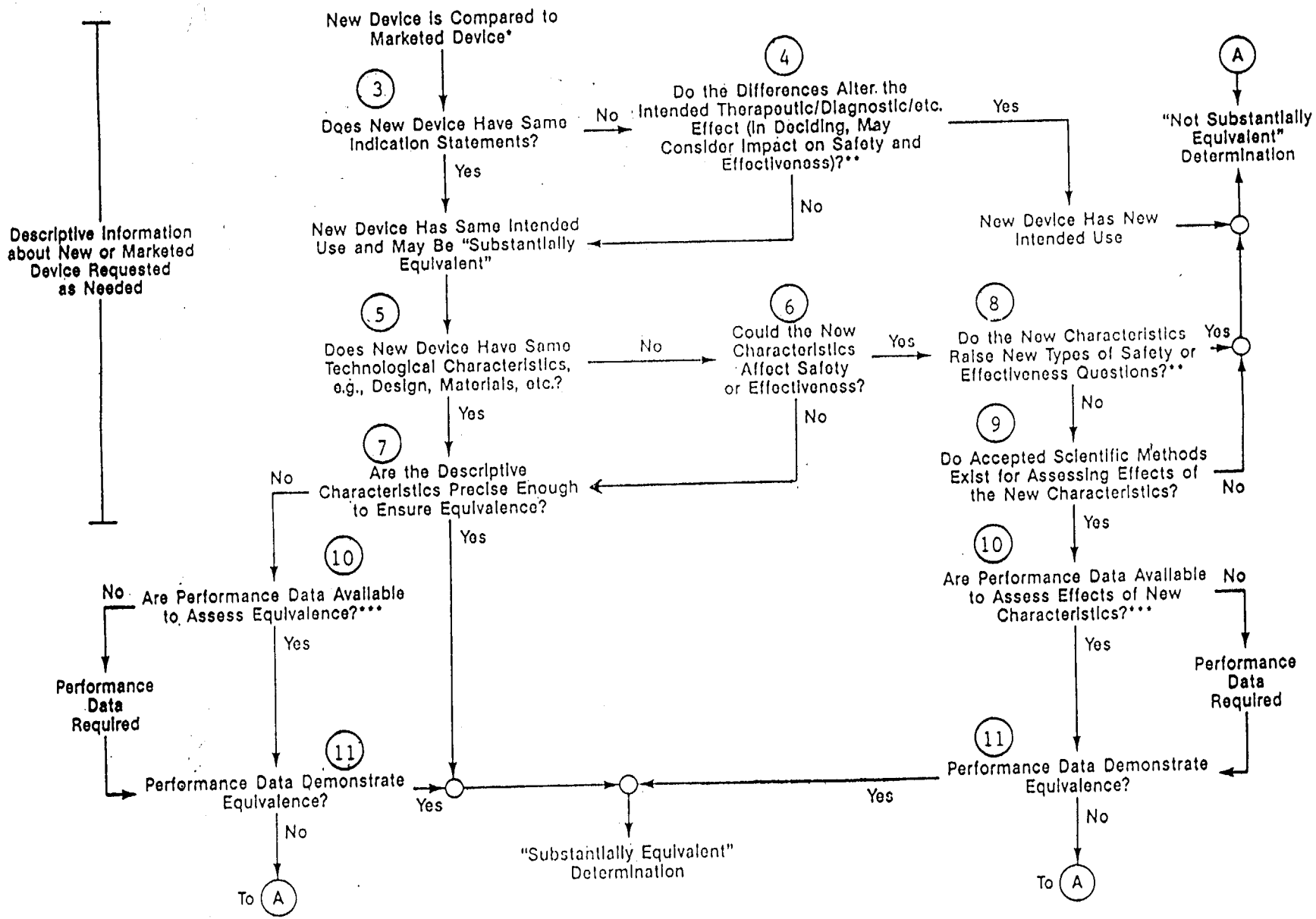
FINAL REVIEW: Carl A. Larson (DIVISION DIRECTOR) 11/19/91 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 5/31/91

716

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

NOV 19 1991

Medivators, Inc.
c/o C. G. Bundy Associates
Ms. Constance G. Bundy
Consultant
6470 Riverview Terrace
Minneapolis, MN 55432

Re: K914145
DSD-91™ Disinfector
Dated: September 13, 1991
Received: September 16, 1991

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following information.

1. Provide a detailed description of the method used to disinfect the endoscope used in the evaluation of the DSD-91™ including disinfectant used, cycle times, alcohol purge, air drying, etc.

2. Indicate if DSD-91™ was tested under simulated-use and worst case conditions; for example, 40-cycle stressed disinfectant, use of serum in the inoculum, etc. If the DSD-91™ was not tested under simulated or worst case conditions, justify not doing so.

3. Describe the methodology (dilution or bioburden) used to set the disinfectant change warning light at 40-cycles. Indicate whether the setpoint is appropriate for all brands of disinfectants indicated for use in automated endoscope washers/disinfectors or for only one brand of disinfectant. If the 40-cycle limit is based upon only one brand of disinfectant then that information must be included in the labeling.

4. Explain the conclusion that the SLR for the device as a whole was 5.41 log10. Since flexible endoscopes are considered as critical devices requiring high level disinfection, if sterilization is not feasible, justify not achieving the 6-log reduction of the indicator organism expected by FDA.

5. Include in the manual instructions on how the user should disinfect the DSD-91™ or justify why a disinfection protocol for the DSD-91™ is not required. The disinfection protocol should include the frequency and identification of critical areas in the machine which could be colonized by heterotrophic microorganisms. Please refer to the report in the MMWR 40, pp 675 - 678, 1991. Submit data validating the protocol.

6. The promotional literature and the manual for the DSD-91™ lists a pre-disinfectant enzyme or detergent wash cycle, indicate the location of this reservoir. Indicate if the pre-disinfectant enzyme wash is the same as the detergent wash cycle. If they are not the same, explain the difference. Also identify the types of enzymes used for this purpose.

7. Submit data showing the effect of the detergent, if any, upon the effectiveness of the disinfectant and how the device minimizes such interaction.

8. State the residue levels of the detergent and the disinfectant remaining in the channels and on the device at the end of the cycle and submit data showing that these residue levels are nontoxic.

9. State the purpose of the disinfectant reservoir heater and justify the set temperature of 120^0 F. Indicate the effect of the elevated temperature on the use-life of the disinfectant. If the disinfectant does not require an elevated temperature, indicate if the heater can be turned off and the washer still function.

10. Clarify the actual contact time of the disinfectant in the endoscope. The promotional material states a 12 1/2 minutes hold time, but the standard program indicates a shorter hold time.

11. From the information provided, it appears that the user could omit the flush cycle, the air purges at the end cycle, and the second rinse and that the user could shorten the disinfectant hold time to less than the 10 minutes. Clarify the standard program and justify the rationale for letting the user set the disinfectant hold time to less than 10 minutes.

12. State whether the air purges at the end of each cycle can be omitted from the disinfection process. If the air purges are omitted, indicate the effect on the use-life of the disinfectant. The promotional material lists an air compressor as a component of the unit; however, the air compressor is not listed on the parts list. State whether the air compressor is standard or optional component of the DSD-91™. If the air compressor is an optional component and the user facility does not have access to a compressed air line, identify other gases which could be substituted and how the user would program the progress.

13. The labeling should contain a statement about the special characteristics of certain types of endoscopes that may require special handling and that may not be adequately disinfected by the DSD-91™. The labeling could contain, as a courtesy to the user, a reminder that the endoscopes should be leak-tested before processing in an automatic washer/disinfector. The labeling should also <u>emphasize</u> the necessity of precleaning the endoscope before being processed in an automatic washer/disinfector.

14. Submit a copy of the Hook-up Instruction Sheet referred to in the manual and a copy of the manual which includes all figures. Several of the figures referenced in the manual are not included. Provide more information on the Sterapore filter and the universal hook up.

15. The software validation for your device must be documented. Since the process efficacy of endoscope washers/disinfectors can not be monitored by traditional methods such as biological indicators and the potential of significant harm to patients from improperly processed endoscopes, these devices are considered to be in the major level of concern category. For information concerning the requirements of validation of the software, refer to the FDA document, "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review". This guidance is available from the Division of Small Manufacturers' Assistance (800-638-2041).

The additional information should be submitted in duplicate, referencing the 510(k) number, to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 80 7.87(f) and (h), 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 requested information 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 re-submitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Susanna F. Barrett at (301) 427-1225. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Carl A Larson

Carl A. Larson, Ph.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DATE: ~~October 9, 1991~~ Nov 6, 1991

FROM: Microbiologist, Infection Control Devices Branch, DGRD, (HFZ-410)

SUBJECT: K914145 DSD-91™ Disinfector for Flexible Endoscopes
ProCode: 78-FEB-II
Contact: Constance G. Bundy
612-574-1976

TO: To the record

Medivators, Inc. plans to introduce the DSD-91™ Disinfector which is an updated version of its OTT Disinfector, K862402. Both disinfectors have a computerized control panel, immersion chamber(s), and disinfectant reservoir(s). The main difference between the two, according to the firm, is that the OTT can only process one endoscope at a time and the DSD-91 can process two endoscopes simultaneously.

The firm has listed the similarities and differences between the two disinfectors. Both have the same specifications, indications for use, major components, and function. The differences are that the entire endoscope is immersed in the DSD-91 whereas only the control head and distal end are immerse in the OTT. The DSD-91 has an updated programmable control system; the OTT needs a special programming device. The DSD-91 has a double seal to inhibit fumes; the OTT has a single seal. The DSD-91 has an alcohol purge cycle to assist in the drying of the endoscopes at the end of the day; the OTT does not. The specifications for the machines are the same except that the DSD-91 is larger 46x36x21" compared to 18x10x53" for the OTT and it weighs approximately twice as much as the OTT.

The firm has included a draft of its service manual for the DSD-91 Disinfector. The device requires hook up to building water supply (17-20 psi) and to compressed air at 40-100 psi regulated to 10 psi inside the machine. The two disinfectant reservoirs hold 4 gallons each. The left and right endoscope chambers hold 2.4 gallons of liquid. The rinse water consumption is approximately 5 gallons per cycle. The electrical requirements are 110 VAC, 60 HZ, 15 amp.

The equipment has been designed to tolerate line power brown-out and failure conditions. The condition of the power supply is constantly monitored so that if proper power conditions are interrupted, the device can go into an idle mode until power conditions are restored. If the power failure results in the temperature of the disinfectant reservoir dropping below the shutdown temperature, then the machine will turn itself off; it must be restarted using the error restart procedure.

Other features of the DSD-91 include a watchdog circuitry which monitors the operational status of the machine; status logging of the device usage history such as error status, etc; RS-232 Interface (optional) so that the device log can be offloaded to other media (usually IBM compatible PC); nonvolatile memory; 100% solid-state electronics, error detection of any valve electrical failures; and depot maintenance, that is, repair of any electronic failure can be accomplished by replacing

the motherboard.

According to the service manual the operation of the two disinfectant stations are independent of one another; each station can have its own programmed disinfectant cycle and disinfectant. Each station has its own valves, tanks, disinfectant pumps, and air compressors. The firm states that the only common equipment is the power supply and the electronic circuitry.

The manual is divided into 5 major sections which detail specifications and instrumentation, overview, operation, trouble shooting, and installation. The information contained in each of the sections appears to be sufficient.

The machine has a default factory installed disinfectant program of approximately 20 minutes consisting of 6 cycles. According to the manual the default disinfectant cycle is 12 1/2 minutes. The times of cycles can be modified as defined by the table on page 2-9 to meet specific user requirements. The machine can store up to 9 user modified programs in nonvolatile memory.

The default program consists of a flush cycle where detergent and water are flushed through the interior channels (first 30 seconds of the flow is directed through the scope channels only); a disinfectant cycle where a disinfectant is pumped through the major channels (biopsy/suction, air, water, and colonscope CO_2 channels (first 30 seconds of flow is directed through the channels); and two rinse cycles where water is circulated around the scope insertion tube and pumped through the interior channels. Air is forced through the channels for 30 seconds at the end of each cycle to remove excess fluid from the lines. At the completion of the process, the endoscope is ready for reuse. The default program also has an end-of day alcohol purge (if compatible with the endoscope manufacturer's recommendations) and a 5 minutes of compressed air drying of channels. The manual, however, recommends a 15 - 20 minute compressed air drying of the channels as part of the end-of day routine. The manual recommends that if compressed air is not available, the scope should be disinfected before use after overnight or weekend storage.

The parts list contains available hookup parts for different brands of endoscopes.

Each station has its own heater and temperature sensor. Each disinfectant reservoir can be set with its own minimum, maximum, and shutdown temperature setting. If the disinfectant reservoir falls below the shutdown temperature, operation for that station is halted until corrective action is taken. Usually shutdown, minimum, and maximum temperatures are set to within 1^0 of each other. The temperature for the disinfectant reservoir is defined by the disinfection protocol. The heater temperature is set at the factory to 120^0 F. The firm states that the temperature sensors are accurate to within 1^0 F.

Reviewer Correspondence Pre Decisional With Sponsor(b) (4), (b) (5)

[redacted]

The firm has submitted a 510(k) statement.

The report in the MMWR 40(39), pp 675 - 678, 1991, indicates that automatic endoscope washers/disinfectors have been implicated in nosocomial infections because of their potential to become colonized with heterotrophic organisms. Therefore automatic endoscope washers/disinfectors must not only demonstrate that they can achieve a high level disinfection (defined as a 6-log reduction of the indicator organism) but that they should demonstrate an ability to be adequately cleaned and disinfected to prevent colonization of heterotrophic organisms. Because of this potential problem, the firm needs to provide instructions on how the user should disinfect the DSD-91™ or a justification of why a machine disinfection protocol is not necessary.

Based on the memo from Chris Harris, dated 11/5/91, the firm needs to provide software documentation for the device.

The firm needs to provide additional information.

1. Provide a detailed description of the method used to disinfect the endoscope used in the evaluation of the DSD-91™ including disinfectant, cycle times, alcohol purge, air drying, etc.

2. Indicate if DSD-91™ was tested under simulated-use and worst case conditions; for example, 40-cycle stressed disinfectant, use of serum in the inoculum, etc. If the DSD-91 was not tested under simulated or worst case conditions, justify not doing so.

3. Describe the methodology (dilution or bioburden) used to set the disinfectant change warning light at 40-cycles. Indicate ~~whether~~ whether the setpoint is appropriate for all brands of disinfectants indicated for use in automated endoscope washers/disinfectors or for only one brand of disinfectant. If the 40-cycle limit is based upon only one brand of disinfectant then that information must be included in the labeling.

4. Explain the conclusion that the SLR for the device as a whole was 5.41 log10. Since endoscopes are defined as critical devices requiring high level disinfection, if sterilization is not feasible, justify not achieving a 6-log reduction of the indicator organism.

5. Include in the manual instructions on how the user should disinfect the DSD-91™ or justify why a disinfection protocol for the DSD-91™ is not required. The disinfection protocol should include the frequency and identification of critical areas in the machine which could be colonized by heterotrophic microorganisms. Please refer to the report in the MMWR 40, pp 675 - 678, 1991. Submit data validating the protocol.

6. The promotional literature and the manual for the DSD-91™ lists a pre-disinfectant enzyme or detergent wash cycle, indicate the location of this reservoir. Indicate if the pre-disinfectant enzyme wash is the same as the detergent wash cycle. If they are not the same, explain the difference. Also identify the types of enzymes used for this purpose.

7. Submit data showing the effect of the detergent, if any, upon the effectiveness of the disinfectant.

8. State the residue levels of the detergent and the disinfectant remaining in the channels and on the device at the end of the cycle and submit data showing that these residue levels are nontoxic.

9. State the purpose of the disinfectant reservoir heater and justify

the set temperature of 120° F. Indicate the effect of the elevated temperature on the use-life of the disinfectant. If the disinfectant does not require an elevated temperature, indicate if the heater can be turned off and the washer still function.

10. Clarify the actual contact time that the endoscope including the channels has with the disinfectant. The promotional material states a 12 1/2 minutes hold time, but the standard program indicates a shorter hold time.

11. From the information provided, it appears that the user could omit the flush cycle, the air purges at the end of each ~~of each~~ cycle, and the second rinse and could shorten the disinfectant hold time to less than the 10 minutes. Clarify the standard program and justify the rationale for letting the user set the disinfectant hold time to less than 10 minutes.

12. State whether the air purges at the end of each cycle can be omitted from the disinfection process. The promotional material lists an air compressor as a component of the unit; however, the air compressor is not listed on the parts list. State whether the air compressor is standard or optional component of the DSD-91™. If the air compressor is an optional component and the user facility does not have access to a compressed air line, identify other gases which could be substituted and how the user would program the progress. If the air purges are omitted, indicate the effect on the use-life of the disinfectant.

13. The labeling should contain a statement about the special characteristics of certain types of endoscopes that may require special handling and that may not be adequately disinfected by the DSD-91™. The labeling could contain, as a courtesy to the user, a reminder that the endoscopes should be leak-tested before processing in an automatic washer/disinfector. The labeling should also <u>emphasize</u> the necessity of precleaning the endoscope before being processed in an automatic washer/disinfector.

14. Submit a copy of the Hook-up Instruction Sheet referred to in the manual and a copy of the manual which includes all figures. Several of the figures referenced in the manual are not included. Provide more information on the Sterapore filter and the universal hook up.

15. The software validation for your device must be documented. Since the process efficacy of endoscope washers/disinfectors can not be monitored by traditional methods such as biological indicators and the potential of significant harm to patients from improperly processed endoscopes, these devices are considered to be in the major level of concern category. For information concerning the requirements of validation of the software, refer to the FDA document, "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review". This guidance is available

from the Division of Small Manufacturers' Assistance (800-638-2041).

Susanna F. Barrett

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MEMO TO THE RECORD

From: Biomedical Engineer
DGRD/GHDB

Date: November 5, 1991

Subject: K914145, Medivators, Inc.
DSD-91 Disinfector for Flexible Endoscopes

Consultation for Susanna Barrett

The summary information regarding the software procedures followed by the manufacturer is not in accordance with the Reviewer's Guidance for Computer Controlled Medical Devices of MAJOR concern. I have provided the chart from p. 16 of that document outlining the necessary information.

If the manufacturer is not familiar with this document, it can be obtained from DSMA.

Christine M. Harris

Christine M. Harris

K914145

510(K) SOFTWARE DOCUMENTATION MATRIX

(b) (4)

[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

SEPTEMBER 19, 1991

MEDIVATORS, INC.
ATTN: CONSTANCE G. BUNDY
C/O C. G. BUNDY ASSOCIATES
6470 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432

510(k) Number: K914145
Received: 09-16-91
Product: DSD-91(TM) DISINFECTOR FOR FLEXIBLE ENDOSCOPES

We have 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.

The Safe Medical Devices Act of 1990 (SMDA), 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 within 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.

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages manufacturers to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law

requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

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.

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

Sincerely yours,

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

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K914145

RECEIVED
16 SEP 91 10 56
FDA/CDRH/CDE/DMO

September 13, 1991

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

Re: 510(k) Notification

Att: Document Control Clerk

This is to notify you of the intention of MediVators, Inc. to market the following device:

MANUFACTURER: MediVators, Inc.

ESTABLISHMENT REGISTRATION NUMBER: 2183640

PRODUCT:

Trade Name: DSD-91tm Disinfector for Flexible Endoscopes

Descriptive Name: Endoscope Disinfector

CLASSIFICATION: Class II

PERFORMANCE STANDARDS: None

LABELING:

A draft of the Service Manual including operation instructions and proposed promotional material is enclosed in Appendix A. Information concerning the OTTtm Disinfector is enclosed in Appendix B.

Statement of Availability of Substantial Equivalence Information is enclosed in Appendix C.

CONTACT: Constance G. Bundy
C. G. Bundy Associates
6470 Riverview Terrace
Minneapolis, MN 55432 Phone/Fax: 612-574-1976

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PRODUCT DESCRIPTION

The use of flexible endoscopes in hospitals and clinics has increased dramatically in the last decade due to their cost effectiveness as an alternative to exploratory surgery. As endoscopes have become more widely used, increased attention has been given to procedures for cleaning and disinfecting between uses. MediVators, Inc. currently markets the OTT™Disinfector which is used for cleaning and disinfecting flexible endoscopes. The OTT Disinfector was judged substantially equivalent February 3, 1987, #K862402.

MediVators, Inc. intends to market an updated disinfector. This updated device, called the DSD-91™, is simply a repackaging of the previous device to allow multiple endoscope disinfection and make the unit easier to use.

Both products consist basically of a computerized control panel, immersion chamber(s) and disinfectant reservoir(s) contained in a cabinet. The major difference between the two products is that the DSD-91 comprises two disinfectant stations whereas the OTT is a single disinfectant station. Please refer to respective Installation/Service Manuals for product diagrams. A chart comparing specifications is on the following page.

SUBSTANTIAL EQUIVALENCE

The DSD-91 is substantially equivalent to the OTT regarding specifications, indications for use, major components and function. The difference is the ability of the DSD-91 to disinfect two endoscopes at once. Minor differences include:

1. The ability to immerse the entire endoscope with the DSD-91. With the OTT, only the control head and distal end are immersed.

2. The DSD-91 has an updated programmable control system. The OTT requires a special programming device. Please refer to the DSD-91 Service Manual for a discussion of software controls and function. Descriptions of the software development and verification/validation processes are enclosed in Appendix D.

3. The DSD-91 is double sealed to inhibit fumes, whereas the OTT has a single seal.

4. The DSD-91 has added an alcohol purge cycle to assist in the drying of endoscopes at the end of a day.

MediVators, Inc. believes these differences do not affect the safe and effective functioning of the DSD-91 and that the DSD-91 is substantially equivalent to the OTT.

COMPARISON SPECIFICATIONS

	OTT	DSD-91
Chassis Dimensions	18x10x53 in.	46x36x21 in
Weight	150 lbs.	300 lbs (aprx)
Electrical Requirements	110 VAC, 60 Hz, 12 amp	110 VAC, 60 Hz, 15 amp
Water Requirements	Building water supply regulated 17-20 psi	SAME
Air Requirements	Compressed air at 40-100 psi (regulated at 10 psi inside machine)	SAME
Reservoir Capacity	Disinfectant Chamber 4 gallons	Disinfectant Reservoir 4 gallons each
Rinse Water Consumption	5 gallons/cycle (aprx)	SAME
Cycle Time	20 Minutes (aprx)	SAME
Pump Motor	110V, 1/4hp, 50/60 cycle, 7.5 gpm, max head 16 feet	SAME
Power Supply Cord	Hospital grade	SAME
Circuitry	Automatic Fault Interrupter	SAME

To support a determination of substantial equivalence, MediVators has evaluated the efficacy of the endoscope sanitation process of the DSD-91. Results of the evaluation are enclosed in Appendix E.

This submission and its attachments are submitted in duplicate as required by regulation. If further information is required, please contact the undersigned as shown on page one of this submission.

Yours truly,

Constance G. Bundy

Constance G. Bundy
Consultant to: MediVators, Inc.

APPENDIX A

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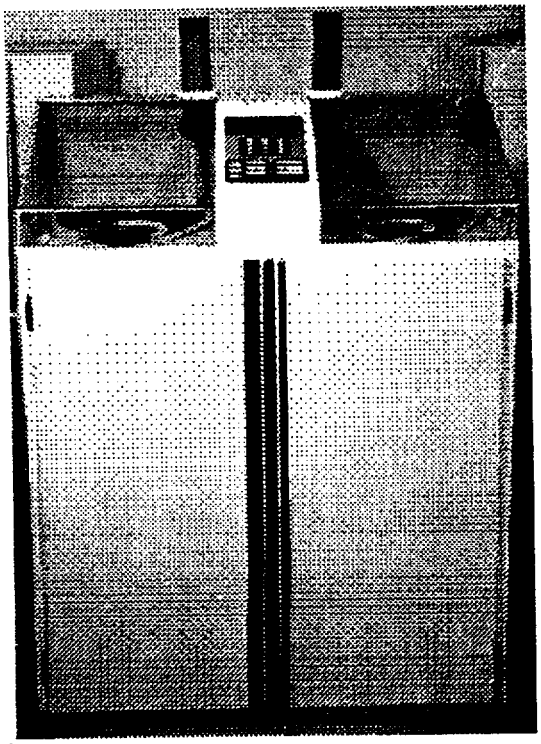
MEDIVATORS, INC.

INNOVATIVE MEDICAL PRODUCTS

Cannon Plaza South • Highway 52 South • Cannon Falls, MN 55009

DSD-91™ Disinfector for Flexible Endoscopes



SERVICE MANUAL

Includes Operation Instructions and Trouble Shooting Guide

Customer Service • 800/537-7324 • 507/263/4721

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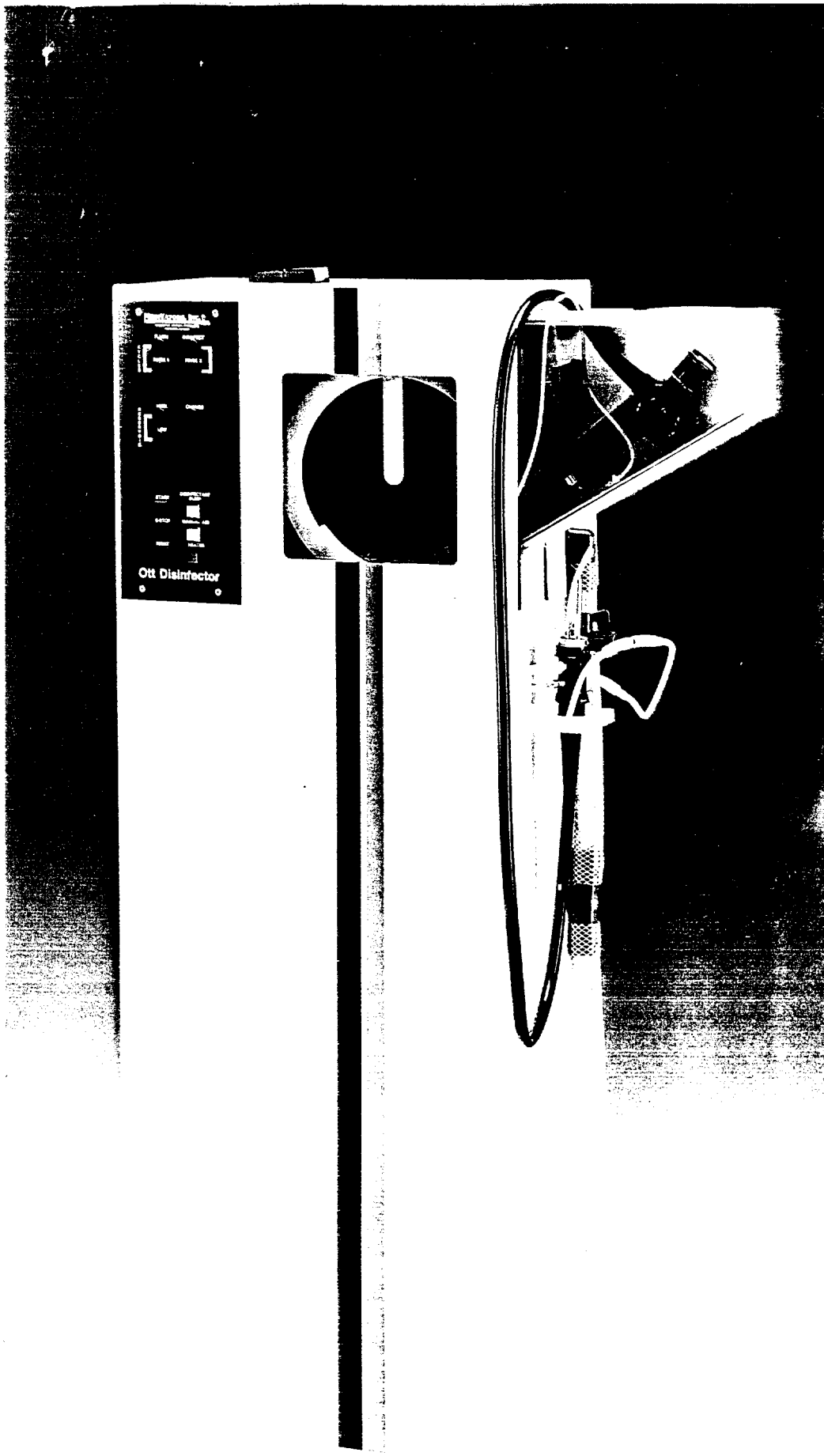
APPENDIX B

Performance and reliability that set the industry standard

OTT™ Disinfector
for Flexible Endoscopes



Designed, developed and clinically tested in cooperation with the Mayo Clinic to meet OC guidelines and your most critical requirements for infection control.

MEDIVATORS, INC.®

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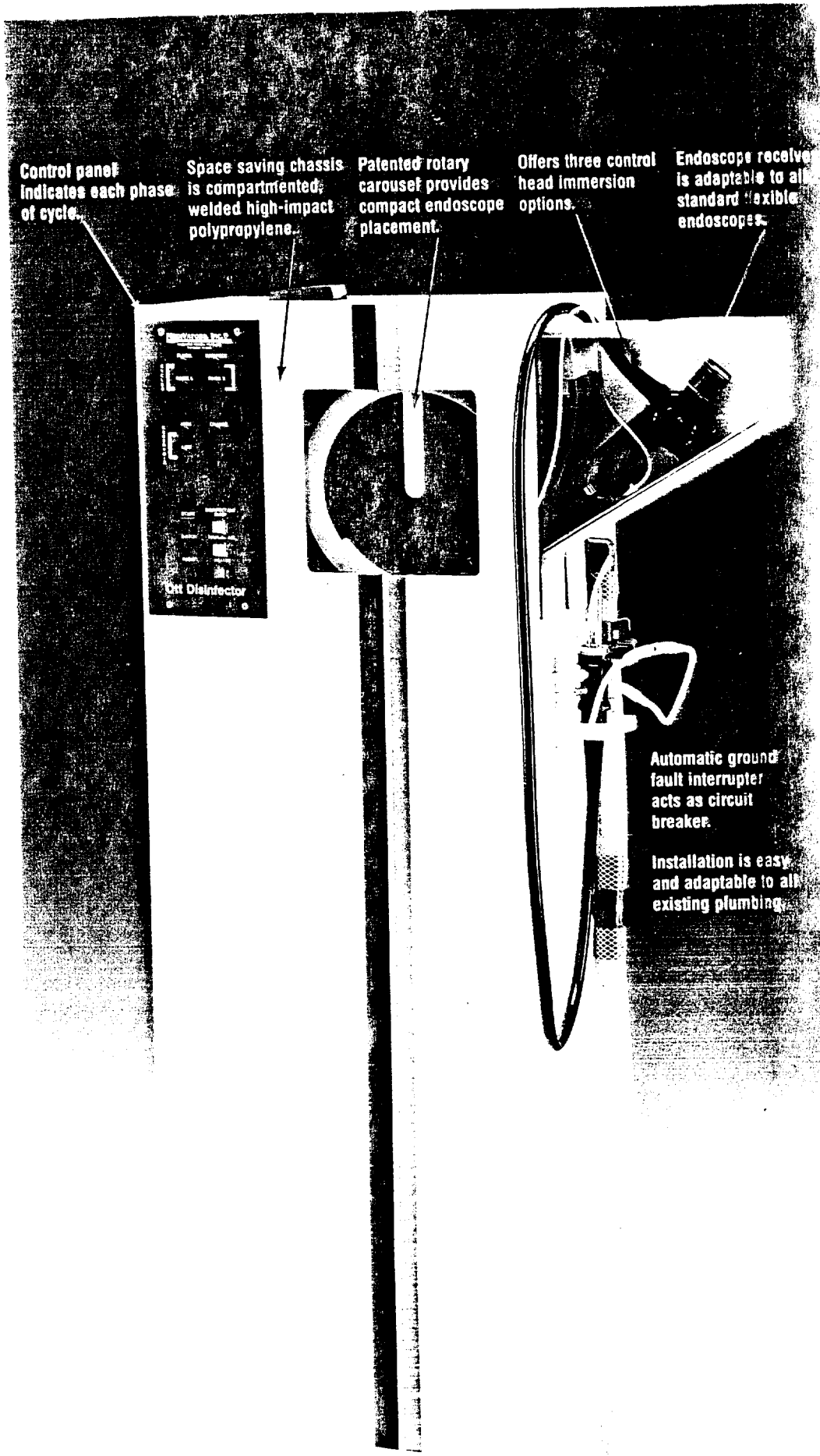
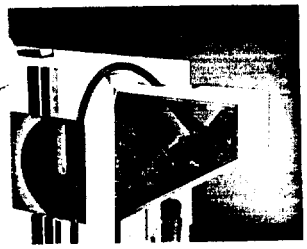
Hospitals across the U.S. report nsistent high level disinfection and reduced channel blockage after upgrading their disinfection protocol to include the OTT Disinfector.

The OTT Disinfector for flexible endoscopes was designed to maximize valuable physician and personnel time while providing the most effective disinfection and rinsing of endoscopes without exposing personnel or patients to harmful disinfectants. Efficient, cost-effective and easy to use, the OTT Disinfector features:

- **Compact design to fit any procedure room or cleaning area**
- **Virtual elimination of clogged air and water channels because channels are constantly flushed during disinfect and rinse cycles**
- **Patented carousel accepts all standard brands of flexible endoscopes**
- **Warning light signals when to hange disinfectant**
- **Ability to disinfect up to three scopes per hour, tying up only one scope at a time**
- **Compressed air after every phase of the cycle to help minimize dilution and loss of disinfectant**
- **Filtering of disinfectant to prevent recycling of proteinaceous material through scope channels, making reservoir maintenance easier**
- **Three control head immersion options for maximum flexibility**
- **Optional sterile water rinse, disinfectant heater and enzyme detergent flush**
- **Eliminates the risk of cross infection via standard channels**
- **No daily maintenance required**
- **Programmable**

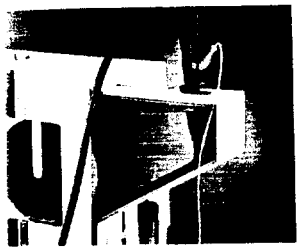
The OTT Disinfector is a reliable method to ensure high level isinfection consistently, together with adequate rinsing of residual disinfectant from the scope.



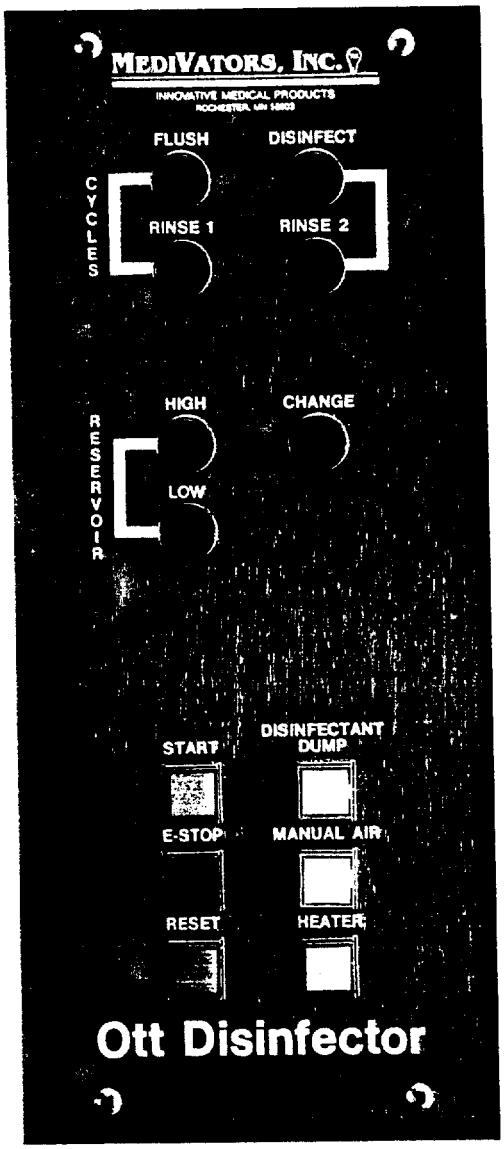


Full Immersion

Partial Immersion



Non-Immersion



Three control head immersion options; full, partial, and non-immersion, offer maximum user flexibility, while eliminating the inconsistencies of manual disinfection and exposure to glutaraldehyde fumes. Choose the method that best suits your requirements and preferences.

All functions are driven by an industrial programmable computer designed to meet the exacting specifications of the Mayo Clinic.

Indicator Lights

Lights mark current phase of cycle.

Warning Lights

Change light alerts user that a preprogrammed number of cycles have been completed with current batch of disinfectant. The disinfectant should be changed before next endoscopy day.

High and low warning lights alert user that reservoir fluid is too high or low. Unit stops and sounds an intermittent warning until problem is corrected.

Operator Buttons

Start button begins standard cycle.

Disinfectant dump empties disinfectant to drain.

E-stop halts unit during any cycle phase. Can also be used to extend disinfect soak time. To resume cycle, simply push start.

Manual air button is used for additional purging of disinfector lines and scope channels.

Heater button is operational only with optional heater installed.

Reset button allows the user to abort cycle in progress in order to start over.

Specifications and Features

Chassis Dimensions:	18″ w × 10″ d × 53″ h, "Space Saver" 28″ w at upper tank
Weight:	150 pounds (68 kilograms)
Power Supply:	110V, 60Hz
Pump Motor:	110V, 1/4 hp, 50/60 cycle, 7.5 gpm, max head 16 feet
Power Supply Cord:	Hospital grade

Other Specifications Available Upon Request

Circuitry:	Designed to eliminate burn-out, automatic fault interrupter included.
Reservoir Capacity:	Disinfectant chamber (lower) 4 gallons (15 liters) max. Carousel chamber (upper) approximately 2.4 gallons (9 liters).
Rinse Water Consumption:	Approximately 5 gallons (19 liters) per cycle.
Precise Cycle Time:	Standard programmed, approximately 20 minutes. Includes 12.5 minutes disinfectant contact with endoscope channels. 10 minute contact with insertion tube. Cycle time may be reprogrammed on request or after installation.
Compressed Air:	Integrated into each cycle to minimize loss of disinfectant and dilution of disinfectant with rinse water.

Policy • Conditions • Terms

The OTT™ Disinfector is designed, engineered, and manufactured with precision and care under strict quality control. Only the finest of materials and components are utilized assuring long-term, efficient, maintenance-free operation. MediVators recommends the OTT Disinfector should be used under the authority and guidance of a physician.

Warranty: One (1) year. MediVators warrants to the original purchaser the device will be free from defects in materials and workmanship for a period of 12 consecutive months from date of purchase, when under normal use and service. MediVators hereby disclaims any other warranties whether expressed or implied, including, but not limited to, any warranty or merchantability or fitness for a particular purpose. MediVators shall not be responsible for any incidental or consequential damages, and the customer's sole remedy will be repair or replacement of any defective components.

Delivery: Shipments are FOB Cannon Falls, Minnesota. Considering inventory and production schedules, delivery is six to eight weeks or sooner. Upon receipt of order, customer is notified of estimated delivery date. However, MediVators disclaims any liability for delays or non-delivery resulting from any cause whatsoever beyond our control.

Terms of Payment: Standard terms are net within 30 days from date of invoice. An additional charge of 1½% per month — but not to exceed the lawful maximum may be added to any amount that is 30 days in arrears of payment.

Prices: MediVators reserves the right to price adjustments without prior notice. Prices quoted on orders placed 30 days prior to a price change will be honored.

MEDIVATORS, INC.®

800/537-7324

Corporate Office:
1652 Greenview Drive
P.O. Box 6431
Rochester, MN 55903-6431
1-800-537-7324

Administration/Customer Service:
Cannon Plaza South
Hwy. 52 South
Cannon Falls, MN 55009
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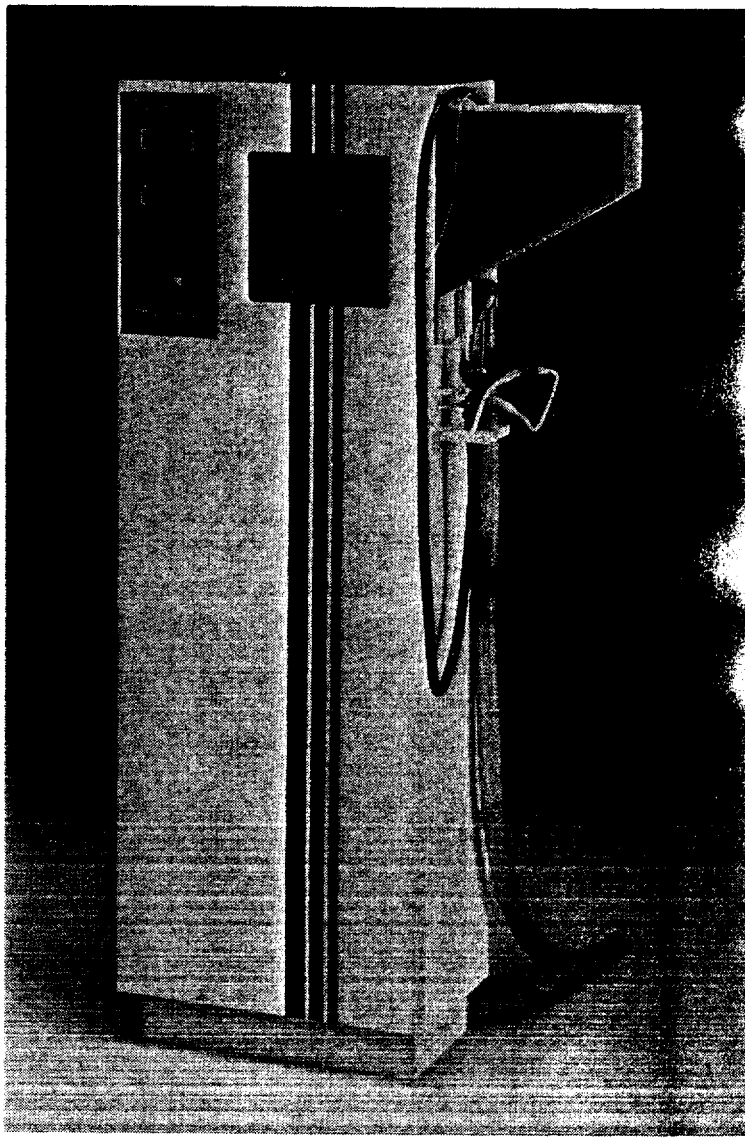
CANNON PLAZA SOUTH • HWY 52 SOUTH • CANNON FALLS, MN 55009

OTT™ Disinfector for Flexible Endoscopes
Installation Manual



Designed, developed and clinically tested in cooperation with the Mayo Clinic to meet CDC guidelines and the most critical requirements for infection control.

CUSTOMER SERVICE

800/537-7324 or **507/263-4721**

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INSTALLATION

Installation of the Ott Disinfector is relatively simple and can be accomplished by the hospital plumbing department or licensed plumbing contractor in less than three hours. Reference Illustration 2.

1. DRAIN: Drain relies on gravity flow. There should be no low spots in the drain line. Fluid trapped in drain line will interfere with drain and machine function. The drain is a 1" tube (#8) which is to be connected to sink drain, above the trap. Because of varied sink drain configurations, the "T" fitting required for this connection is not furnished by MediVators, Inc. (see illustration 2)

2. WATER: USE COLD WATER LINE. The water connection (#4) requires a water filter (A) and regulator (B) between the unit's water connection (#1) and the building's water supply. The regulator should be set during rinse cycle to provide a water pressure to the unit of 17 (minimum) to 20 (maximum) pounds per square inch (psi). Sediment water filter mounts to wall and should be checked periodically for particle saturation (illustration 1). Saturation of sediment water filter will lead to an inability to maintain 17-20 psi of water pressure. It is suggested that the sediment water filter be changed every 90 days. The regulator and sediment water filter are provided by MediVators, Inc. Replacement filters are available from MediVators, Inc.

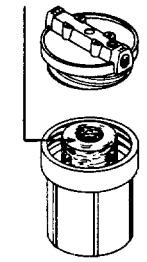


ILLUSTRATION 1

3. AIR: Air connection is made to any source of compressed air capable of furnishing 40 (minimum) to 100 (maximum) P.S.I. If cylinder air is used, use a K type cylinder or larger.

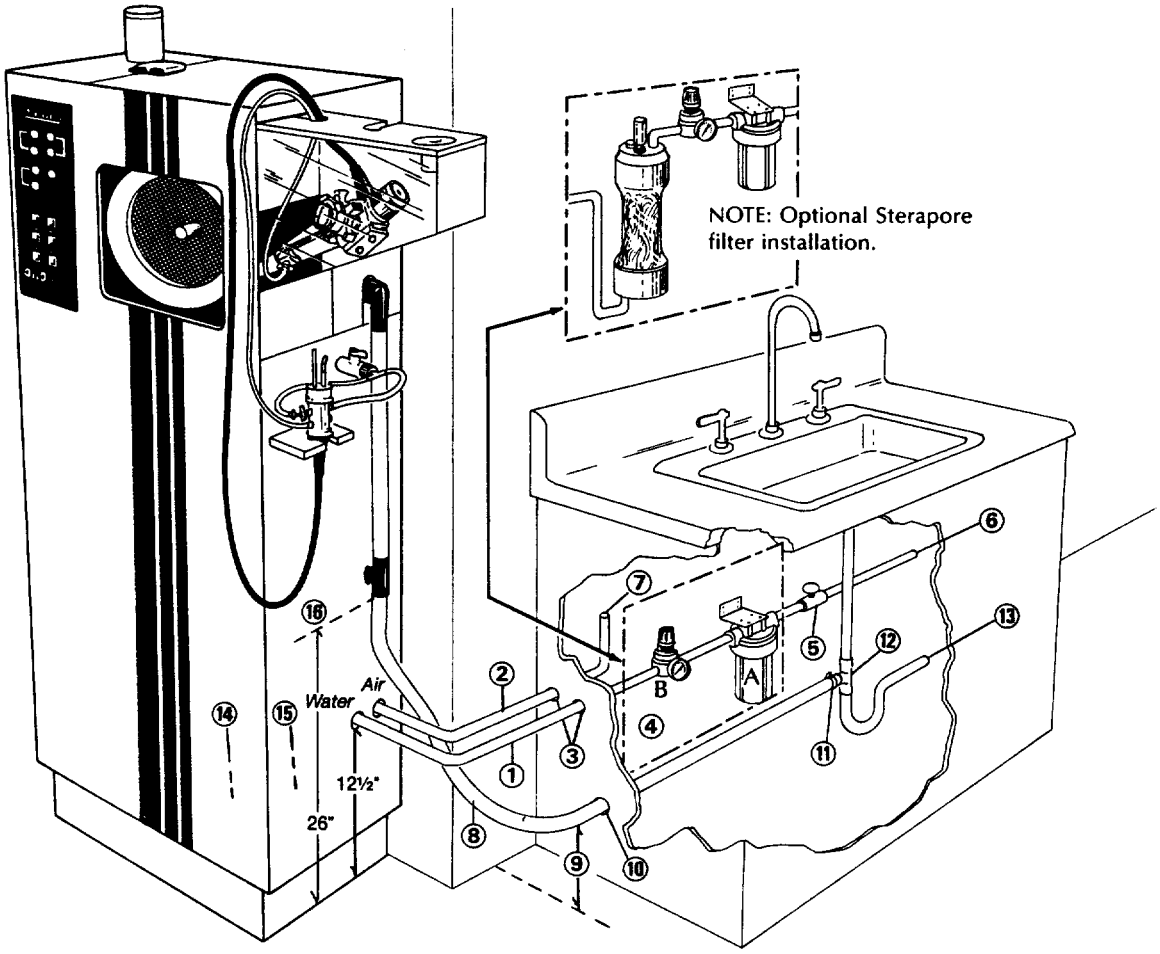
4. ELECTRICAL (U.S.): The unit is supplied with a standard, hospital grade plug that can be connected to any standard 110-120 VAC wall outlet.

INSTALLATION INSTRUCTIONS FOR (NEW STYLE) UPPER TANK ON THE OTT™ DISINFECTOR

1. Remove top cover from OTT Disinfector body and set aside (release latch and lift off).
2. Remove carousel and cover from the upper tank you have just received before installing.
3. Remove clamp from valve shaft on upper tank.
4. Set upper tank in place (upper right hand corner of OTT Disinfector).
5. Put solenoid in place on valve shaft and snugly secure with the clamp you removed in Step 3.
6. Put drain hose (braided 1") on gray manifold attached to upper tank.
7. Attach clear 1" hose to gray 90° fitting from valve body and clamp.
8. Attach 1" hose to 1" fitting located at bottom of tank. Clamp tightly with clamp.
9. Attach ⅜" braided hose to ⅜" fitting at bottom of tank. Clamp tightly with clamp.
10. Check all fittings; there should be four hoses and one solenoid that you connected.
11. When everything is in place, install carousel and cover to the upper tank.
12. Replace top cover for OTT Disinfector body (line up pin with hole in bottom of cover and when in place secure with latch).
13. If water line, drain line and air line (air only applicable if compressor is not present in unit) are hooked up, your machine is now ready for inservice and operation.

If you have any questions, contact MediVators at 800-537-7324. 803

Disinfector Installation Diagram



① Tap water line – 1/4" NPT copper tube (2-3 ft. est.) ⅜" water line preferred

② Compressed air line – flexible low pressure tygon tubing (2-3 ft. est.) - **No hook-up necessary if air compressor option is already in unit.**

③ Drill holes (2) 3/4"-1" dia.

④ Water regulating assembly (17-20 PSI)
Water filter A 105D70
Regulator B 105D22

⑤ Shut off valve (not provided)

⑥ Tap water supply

⑦ Air supply

⑧ 1" clear drain tube (provided) 36 inches in length

⑨ Distance from floor should be equal to or above ⑫ and below ⑯. Maximum 26" (Disinfectant drain is gravity fed - 3" drop or more)

⑩ Drill hole (1) 1½" dia. (drain hose)

⑪ Hose clamp (not provided)

⑫ Copper 1"x1"x1" tee fitting (not provided)

⑬ To sewer. Must be lower than center line of ⑫

⑭ Disinfectant filter (inside cabinet) Factory Installed. Change every 30 days

⑮ Air regulator (inside cabinet) Factory set

NOTE: When bringing water (and/or air supply) from left-side of unit, install pipe along back-side base of unit. This will allow the OTT Disinfector to sit flush against the wall. If you have any questions regarding installation, please call MediVators at 1-800-537-7324.

CAUTION: When performing a wall-mounted installation, assure reservoir cover is in place to prevent drill shavings/chips from entering reservoir. Holes are pre-drilled for securing unit to wall.

Allow 3 hours for complete hook-up.

ILLUSTRATION 2

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FLOW PROCESS

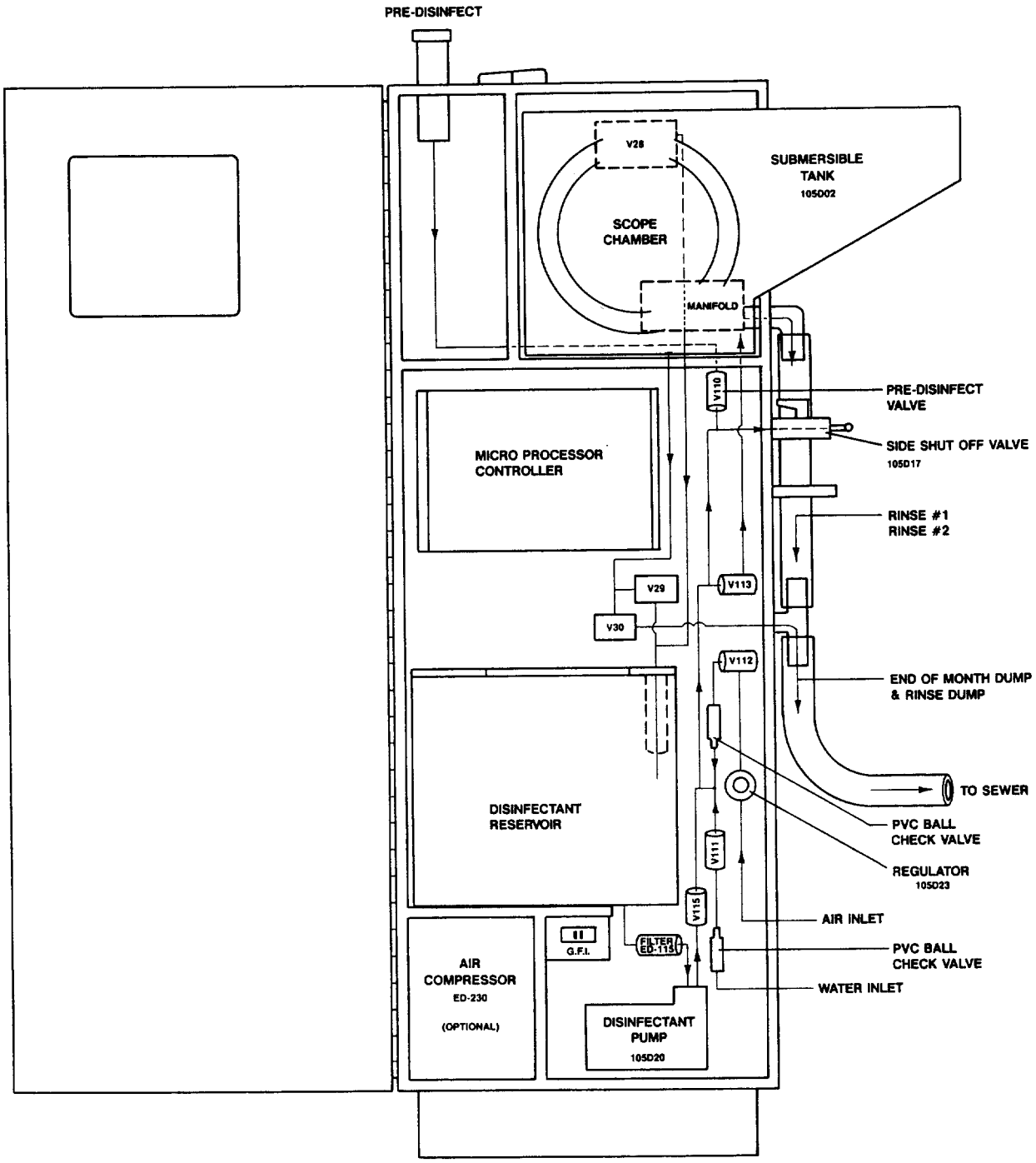

ILLUSTRATION 3

VALVE NUMBER	RE-ORDER PART NUMBER	VALVE NUMBER	RE-ORDER PART NUMBER
V 28, V 29, V 30	105D13 BRASS or 105D15 STAINLESS STEEL	V111, V112, V113, V115	105D14
V110	105D16		

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Front cabinet view

Side cabinet view

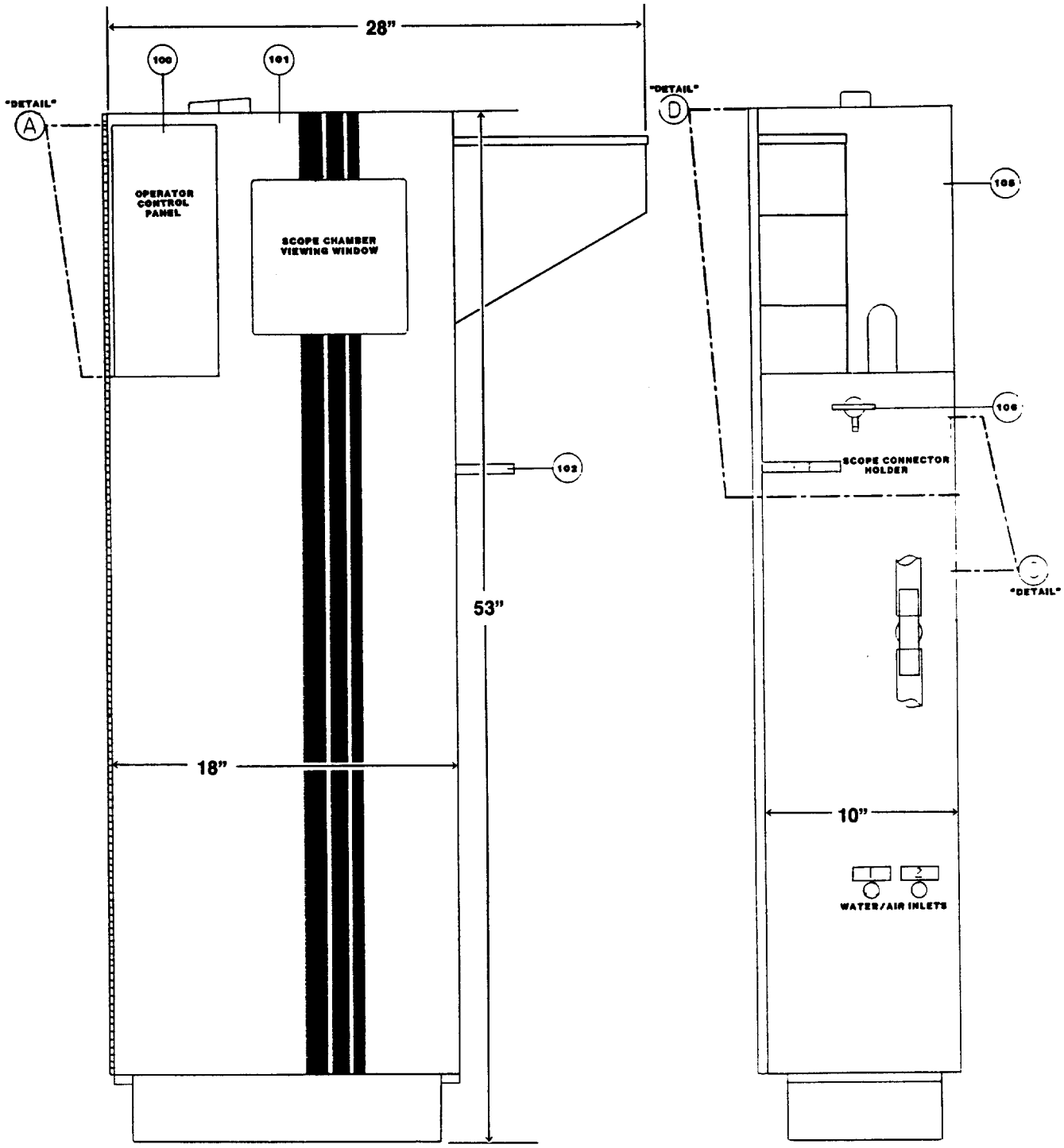

ILLUSTRATION 4

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Interior cabinet view

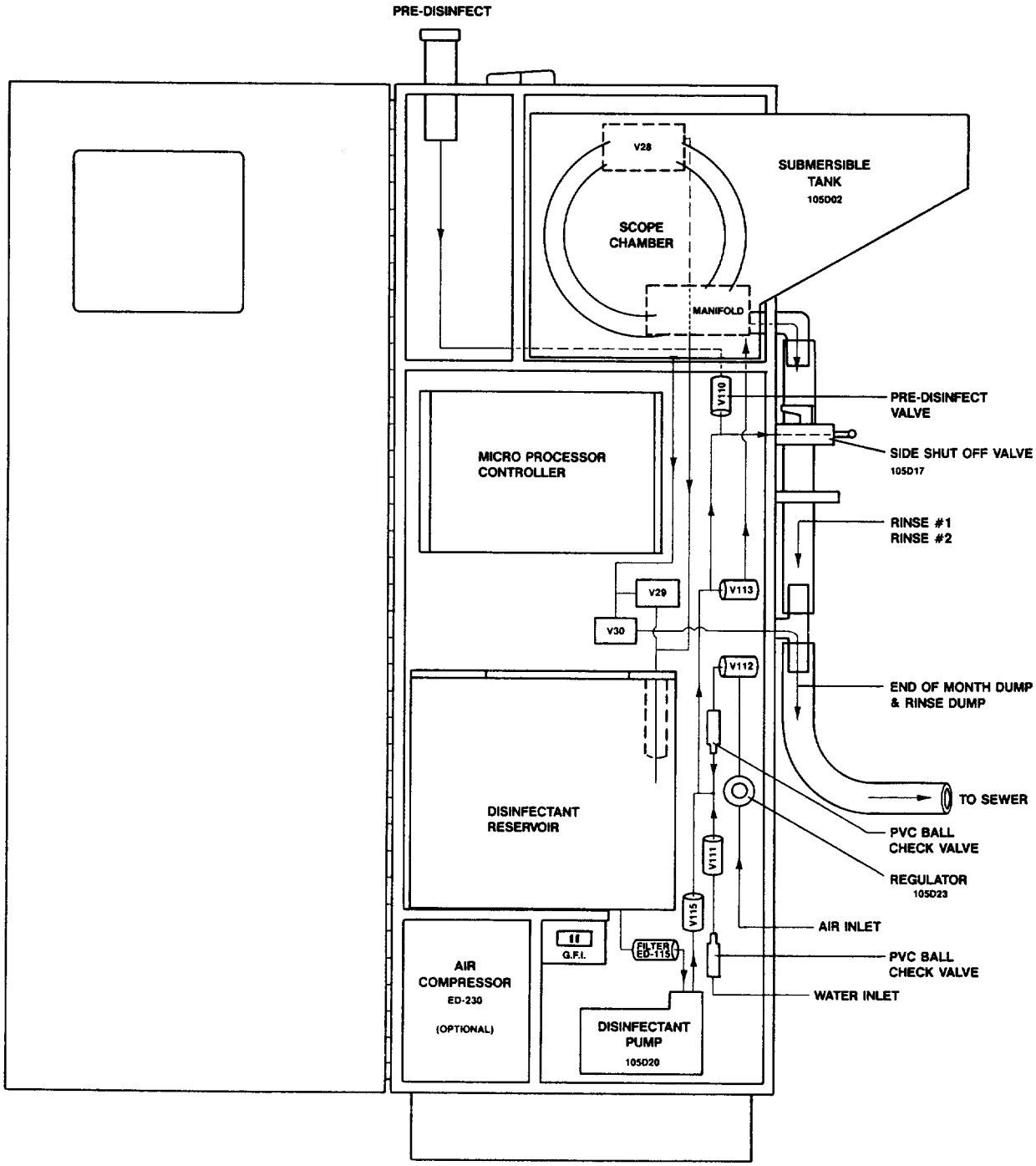

ILLUSTRATION 5

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Electrical controls sub panel

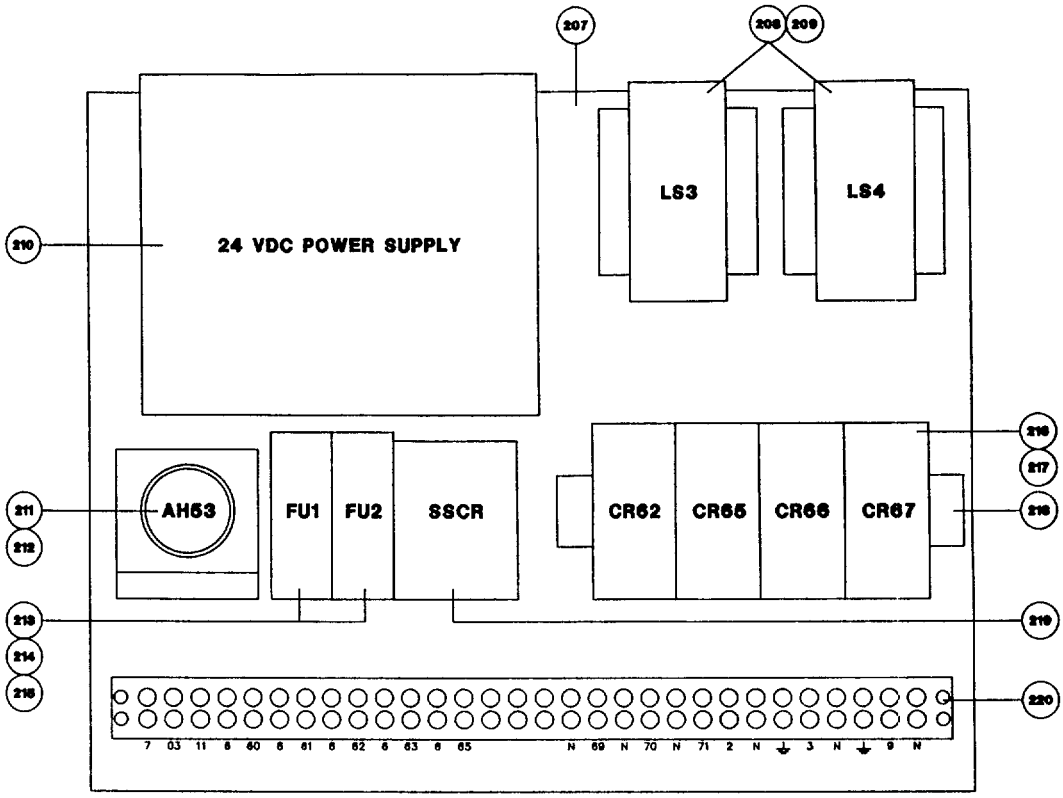

ILLUSTRATION 6

Control panel

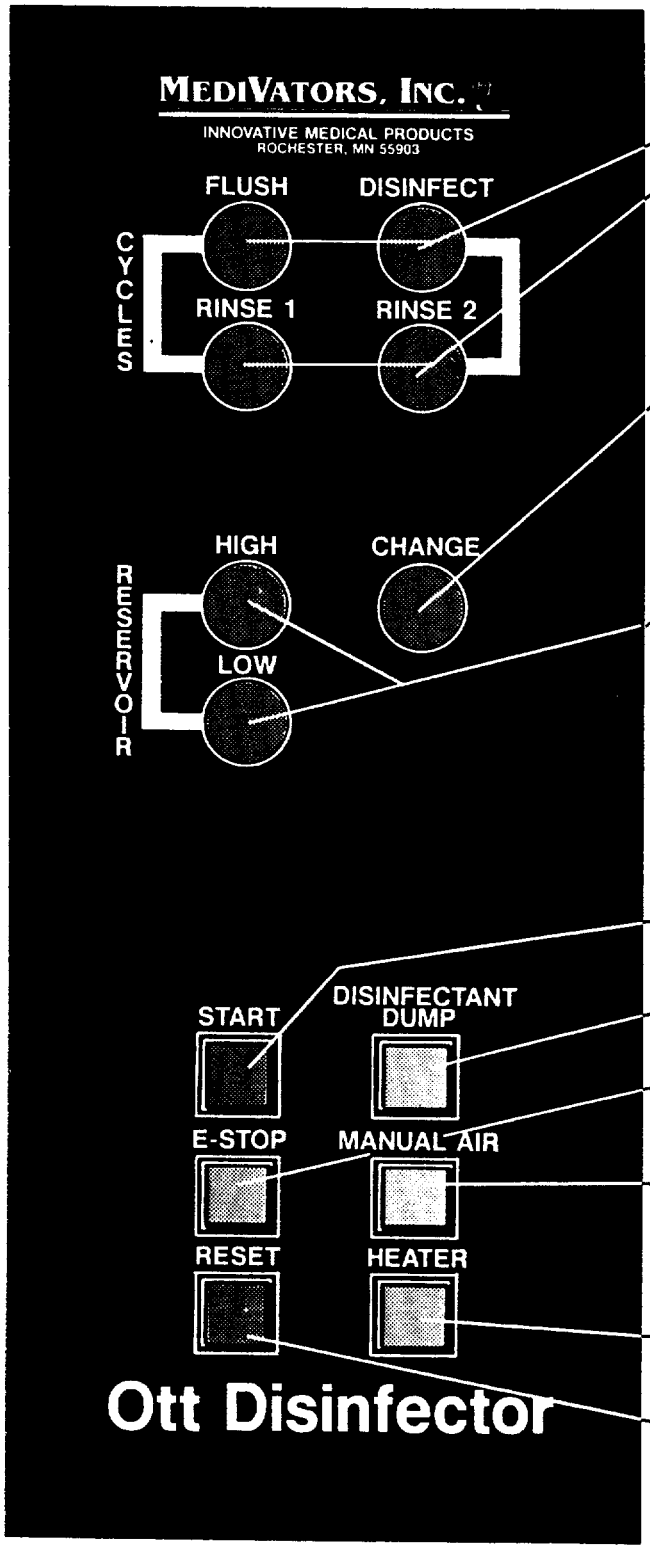

ILLUSTRATION 7

INDICATOR LIGHTS

Lights to indicate current phase of cycle.

WARNING LIGHTS

The change light alerts the user that 40 cycles have been completed with the current batch of disinfectant.
The warning after 40 cycles allows a safety margin to complete the day's endoscopy schedule. Disinfectant should be changed before the next endoscopy day. (Testing of glutaraldehydes demonstrated significant dilution after 40 - 50 cycles.)

High and low warning lights alert user that fluid in reservoir is too high or too low. When lights are lit, the unit stops and sounds an intermittent warning until problem is corrected.

OPERATOR BUTTONS

The Start button is used to begin standard cycle.

Disinfectant Dump is used to dump disinfectant to drain.

Activation of E-Stop will stop unit during any phase of cycle. To resume cycle simply push start. This button can also be used to extend disinfect soak time.

The Manual Air button is used for additional purging of disinfector lines and scope channels.

The Heater button is not operational unless a heater (optional) is installed in the unit.

A Reset button allows user to abort cycle in progress in order to start over.

CAUTION: Review operation manual to operate buttons.

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Universal hook-up

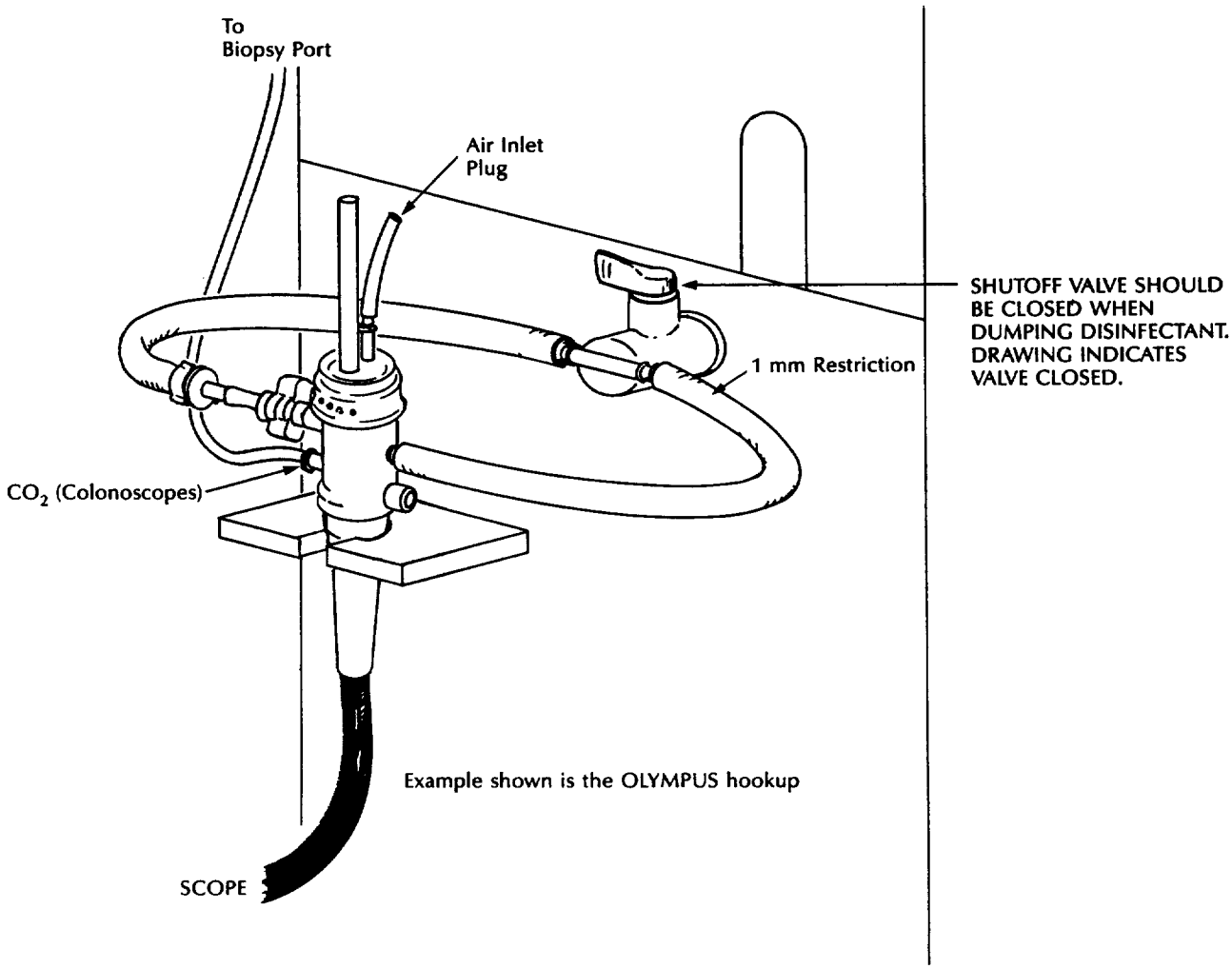

ILLUSTRATION 8

ELECTRICAL DIAGRAMS

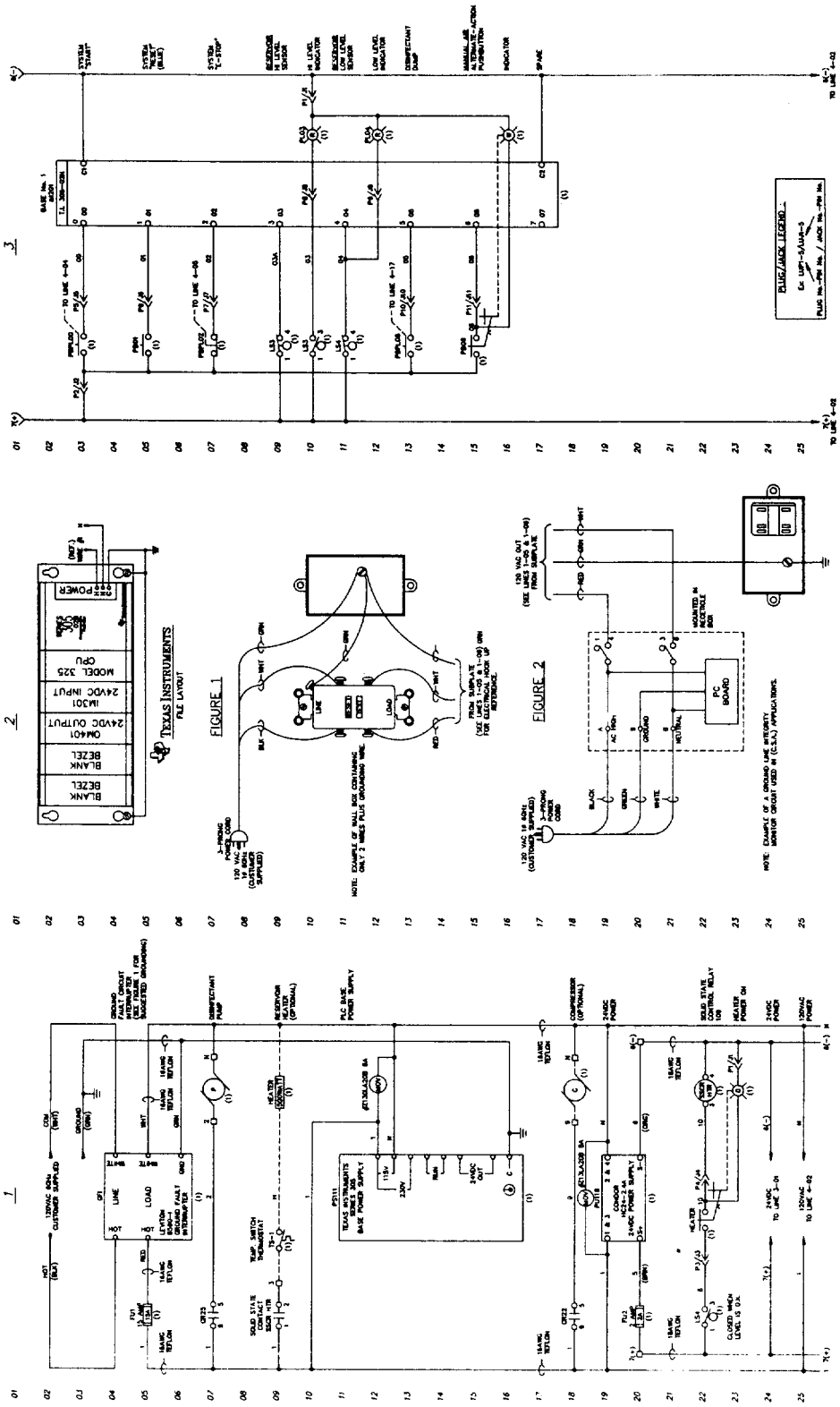

ILLUSTRATION 9

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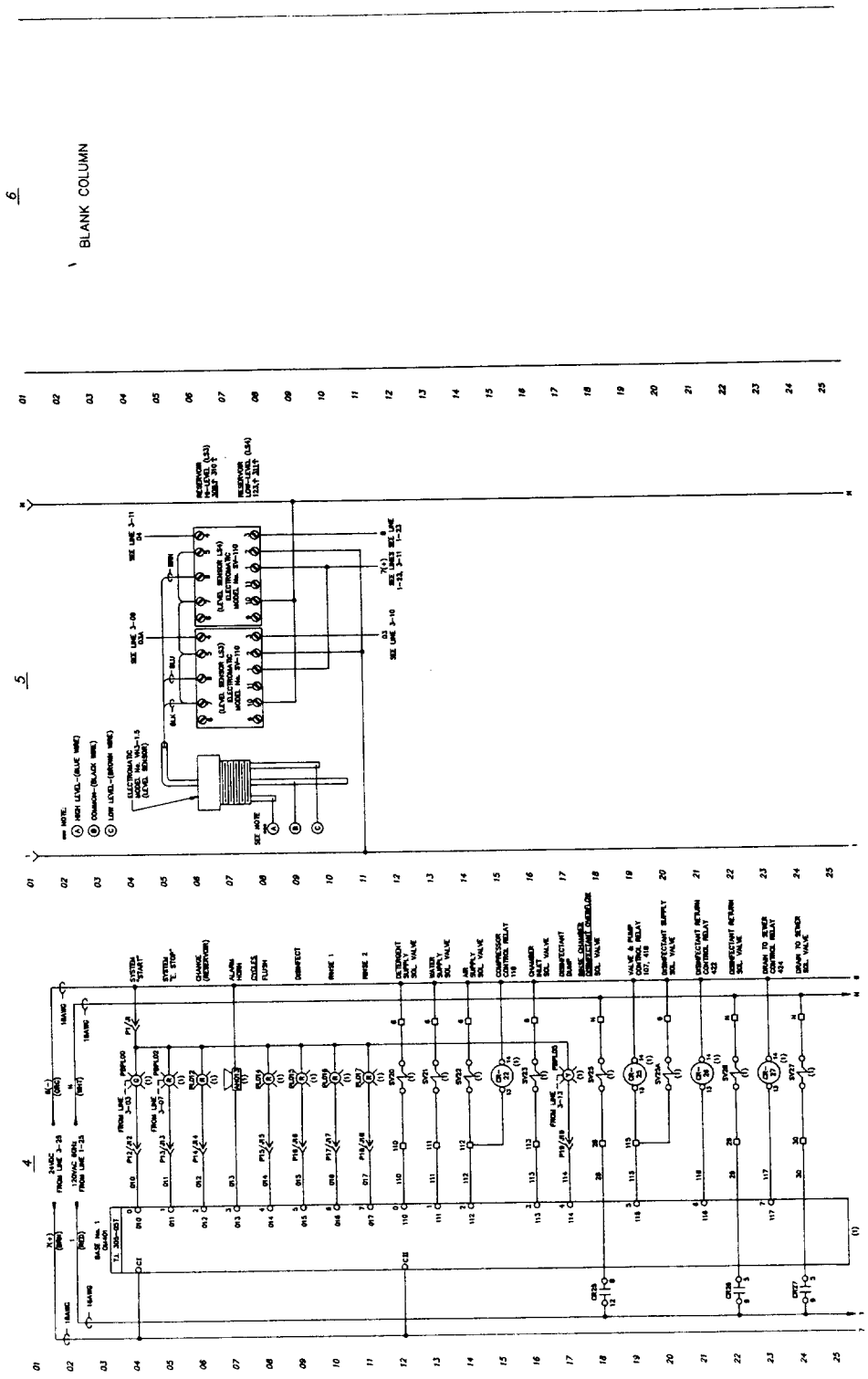

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MEDIVATORS, INC. INNOVATIVE MEDICAL PRODUCTS

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INTERNATIONAL INC.

ort™ Disinfector for Flexible Endoscopes

Service Manual

Developed in conjunction
with the Mayo Clinic to meet
the guidelines and the most
critical requirements for
infection control

CUSTOMER SERVICE

800/537-7394

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SPECIFICATIONS and INSTRUMENTATION

Chassis Dimensions:
28 in. wide at upper tank
53 in. High*, 18 in. Wide*, 10 in. Deep

Weight:
Approximately 150 Pounds

Electrical Requirements:
110 VAC, 60 HZ, 15 amp

Water Requirements:
Building water supply, regulated for 17-20 PSI

Air Requirements:
Compressed Air at 40-100 PSI (regulated at 10 PSI inside machine)

Reservoir Capacity:
Disinfectant Reservoir ..... 3 gallons (4 with heater option)
Carousel Scope Chamber ..... 2.4 gallons

Rinse Water Consumption:
Approximately 5 gallons per cycle

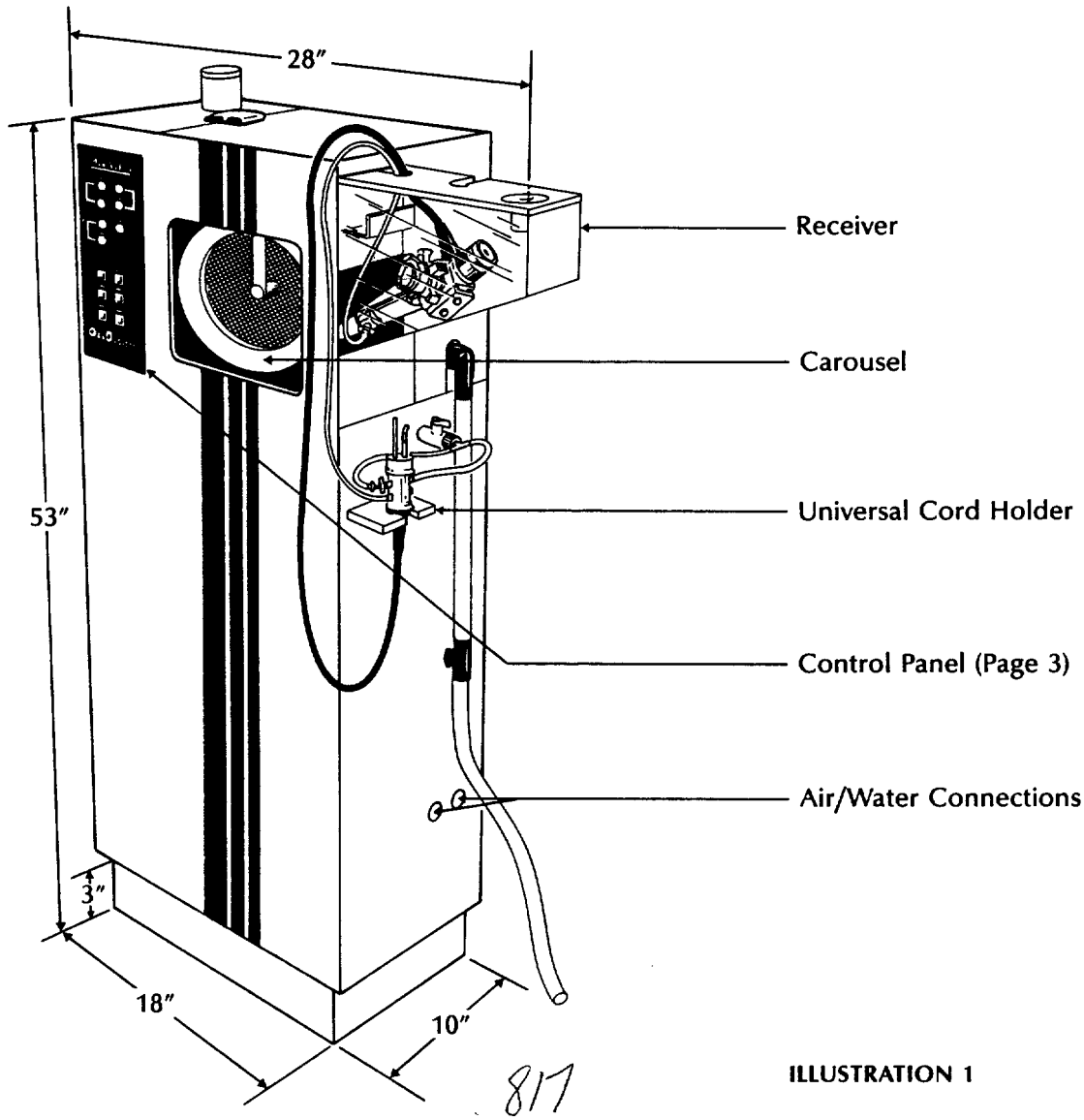

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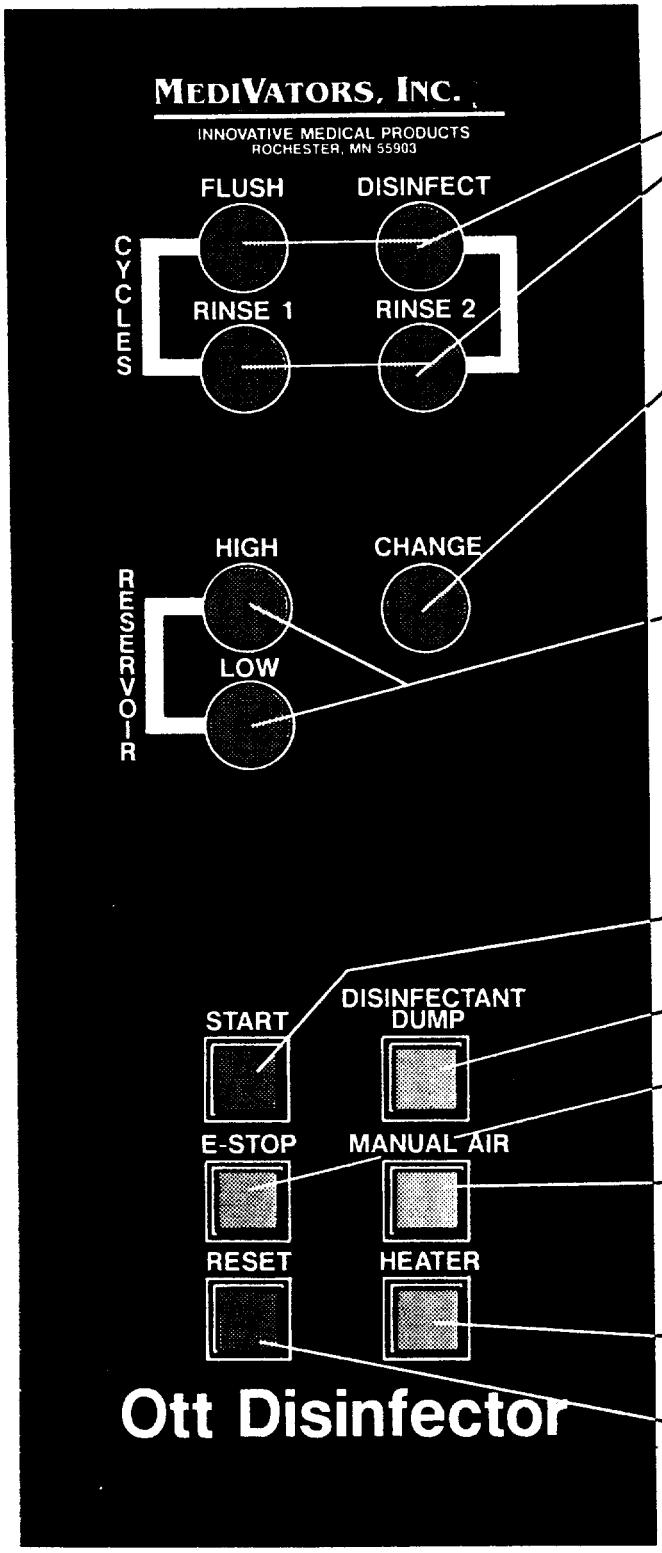
ILLUSTRATION 1

Control Panel



INDICATOR LIGHTS

Lights to indicate current phase of cycle.

WARNING LIGHTS

The change light alerts the user that 40 cycles have been completed with the current batch of disinfectant.
The warning after 40 cycles allows a safety margin to complete the day's endoscopy schedule. Disinfectant should be changed before the next endoscopy day. (Testing of glutaraldehydes demonstrated significant dilution after 40 - 50 cycles.)

High and low warning lights alert user that fluid in reservoir is too high or too low. When lights are lit, the unit stops and sounds an intermittent warning until problem is corrected.

OPERATOR BUTTONS

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Activation of E-Stop will stop unit during any phase of cycle. To resume cycle simply push start. This button can also be used to extend disinfect soak time.

The Manual Air button is used for additional purging of disinfector lines and scope channels.

The Heater button is not operational unless a heater (optional) is installed in the unit.

A Reset button allows user to abort cycle in progress in order to start over.

ILLUSTRATION 2

OVERVIEW

Design Features

One at a time scope disinfection:

1. Provides reliable flow of disinfectant and rinse water to all standard channels in the scope. A flow of 4-5 pounds per square inch (PSI) through the small channels virtually eliminates blockage of air/water channels.
2. Ties up only one scope at a time, allowing for three full cycle scope disinfecting in little over one hour.
3. Minimizes complexity of hookups.

Compressed Air:

1. Is a programmed segment of the cycle to minimize loss of and dilution of disinfectant.
2. Manual Air button for additional drying of scope channels.

NOTE: Will not completely dry channels for end of day storage.

Filtering Disinfectant:

1. Keeps reservoir clean of sediment.
2. Eliminates recycling of particulate matter through scope channels.

Maintenance:

1. No daily maintenance required.
2. All unit disinfector lines are disinfected while first scope of the day is put through complete cycle.

Minimal Exposure to Disinfectant:

1. Disinfectant reservoir inside the cabinet is tightly covered and virtually eliminates toxic vapors in room air.
2. Activating disinfectant dump button on control panel dumps disinfectant to drain.

Compact:

1. Compact design allows for convenient upright installation in existing procedure room space or central cleaning room facility.

Functional Features

Circuitry:

Fully programmable solid state, designed to eliminate burnout. Automatic ground fault interrupter (GFI) included. (see below)

Standard Delivered Cycle Time:

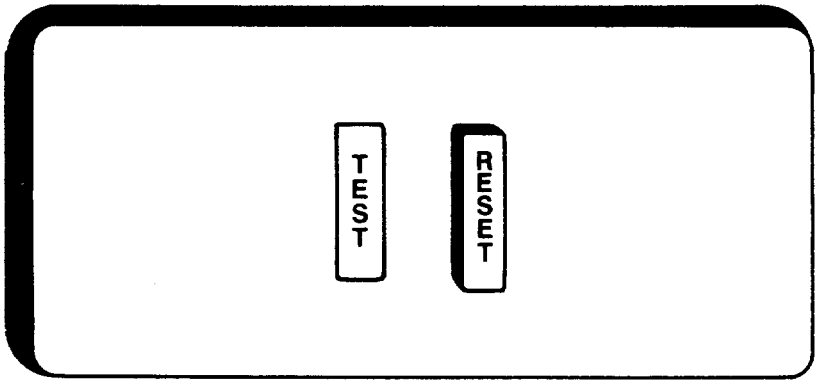
Approximately 20 minutes, including 12½ minutes disinfectant cycle. Preprogrammed at the factory. Cycle times may be reprogrammed to meet specific needs BEFORE installation.

Compressed Air Purge:

Integrated into the disinfect and rinse cycles to minimize loss and dilution of the disinfectant.

(GFI) GROUND FAULT INTERRUPTER

The GFI is a safety feature to protect the unit from power overloads. It is located inside the cabinet toward the bottom of the unit.



A: IF RESET BUTTON IS OUT (OR TRIPPED) SEE ILLUS. B

B: TO RESET GFI SIMPLY PUSH RESET BUTTON IN

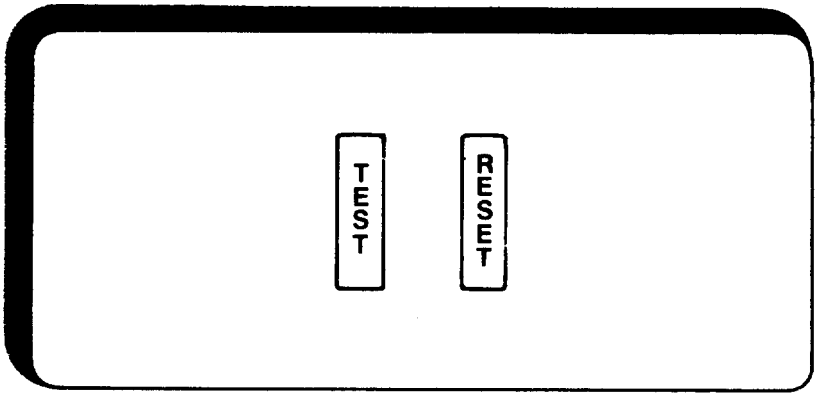


ILLUSTRATION 3

820

Programmed Features

The Ott Disinfector is an integrated System designed to disinfect and rinse all flexible endoscopes without requiring the presence of an attendant during the disinfection process.

CYCLES:

1. Flush Cycle
   Water is flushed (90 seconds) through the interior channels to ensure channels are not clogged. This water goes to the drain.

2. Purge Cycle
   After draining, scope channels and unit lines are purged by compressed air. (35 seconds)

3. Disinfect Cycle
   Disinfectant is pumped through scope channels and into scope chamber (containing scope insertion tube) for a total of 12½ minutes*. During first 30 seconds** and last 5 minutes flow is concentrated through scope channels only. At the end of this cycle the disinfectant is drained from the scope chamber and returned to the reservoir.

   NOTE: Disinfectant is circulated through the biopsy/suction, air, water, and colonoscope CO_2 channels.

4. Purge Cycle
   (Cycle 2 is repeated)

5. Rinse Cycle
   Water is circulated around scope insertion tube and pumped through the interior channels. The first 30 seconds** of flow is to scope channels only. During and after the rinse cycle, water is drained and discarded. (3 minutes)

6. Purge Cycle
   (Cycle 2 is repeated)

7. Rinse Cycle
   (Cycle 5 is repeated)

8. Purge Cycle
   (Cycle 2 is repeated)

At completion of the total cycle time, the endoscope is ready for reuse. 15-20 minutes of compressed air drying of channels should be done before end of day storage. If compressed air is not available, scope should be disinfected before use after overnight or weekend storage.

* Because 2½ minutes are required to fill upper chamber, a total cycle time of 12½ minutes is necessary to achieve a 10 minute soak of the external insertion tube. Cycle times are preprogrammed at the factory. If alternate disinfect time is desired, contact MediVators, Inc. (1-800-537-7324).

** The first 30 seconds of flow of all cycles is directed to scope channels only–to ensure against an air lock in small channels. Air trapped (locked) in a channel will block the flow of disinfectant and rinse water into that channel.

Initial Break-in Procedure

NOTE: It is RECOMMENDED to do a trial run (with tubing, not a scope) with water to ensure proper overall cycles are in functioning order:

1. Pour 3 gallons (4 with heater option) of water into disinfectant reservoir.
2. Refer to standard operation instructions (page 8) and begin cycles. (*Before starting, pump may need to be primed.)
3. Check and observe flow through scope during disinfect, air and rinse cycles.
4. Check water pressure gauge on incoming water line. Pressure should be 17-20 PSI while in flush cycle with scope in unit.
5. Check for leaks to ensure all connections are intact. Damage could have occurred in shipment or installation.
6. Remove scope and hold vertically to check and observe if all water has been removed from the channels. (A few drops are to be expected.)

NOTE: This initial break-in procedure should be repeated through several complete cycles to observe retained reservoir fluid level.

Proceed to Dump Cycle, and then to Standard Operation using 3 gallons (4 with heater option) of disinfectant.

*To prime pump, use bleeder valve located at bottom right side of unit directly above pump. Open bleeder valve by turning counterclockwise. Disinfectant will come out of valve when pump is primed. (A small container may be used to catch disinfectant by valve.)

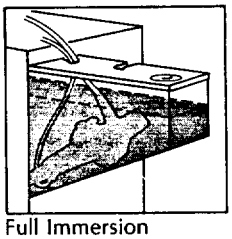
Pump should be primed after changing disinfectant and after changing disinfectant filter.

Standard Operation

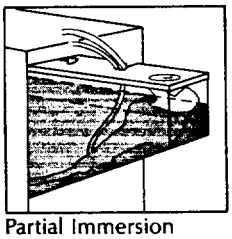
Scope should be free of residual protein prior to disinfection. Pre-cleaning of scope should include brushing of the suction/biopsy channel in universal cord and insertion tube.

1. Remove all channel valves and block the ports with the appropriate fittings. (see separate hookup instruction sheet)
2. For non-immersible scopes; gently feed the endoscope insertion tube through the receiver farthest to the right on the top of the unit until the head of the instrument rests on opening. DO NOT FORCE.
3. For immersible scopes; remove lid on upper tank and feed distal end into carousel. Put on lid with the universal cord and tubings coming out of opening to the left for full immersion or middle opening for partial immersion. (see illustration 4A)
4. Hang scope universal cord in the holder at the right side of the unit.
5. Attach the channel connectors to fittings on universal cord. (see illustration 4)
6. Open the scope Shutoff valve at the right side of the unit.

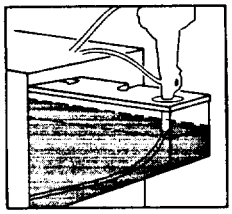
Control Head Immersibility Options



Full Immersion



Partial Immersion



Non-Immersion

ILLUSTRATION 4A

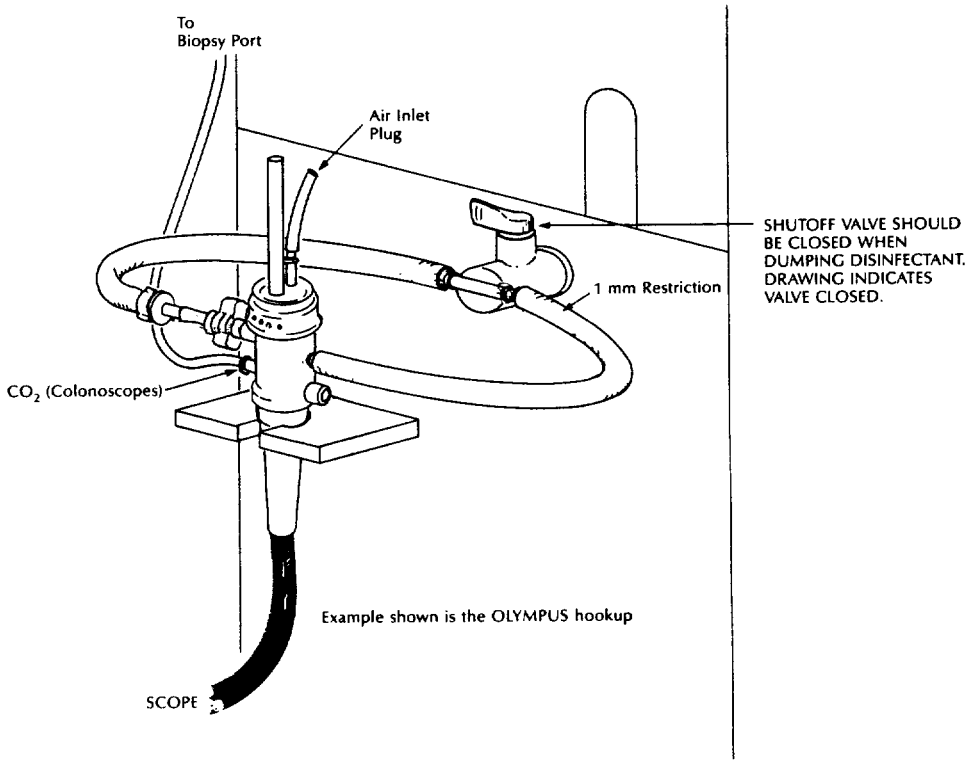


ILLUSTRATION 4

CAUTION

IF THE SCOPE SHUTOFF VALVE IS NOT OPEN, THE INTERIOR SCOPE CHANNELS WILL NOT BE DISINFECTED.

7. The distal end of the scope can be turned to observe channel exit while in scope chamber.

8. Press START button on control panel and observe initiation of cycles for proper seal on scope connections and plugs.

9. To be sure that the channels are not blocked, observe the lines connected in step 4 for movement of disinfectant into the scope channels. Watch the distal end of the scope until disinfectant is seen coming from the channel exits. Check the channel fittings and clamps for proper placement and seal.

10. If not immersing control head, damp wipe with 70% alcohol or disinfectant. Avoid contact of disinfectant with eye piece.

The disinfector will now disinfect, rinse, and purge without any further attention from the operator.

The status of the disinfecting process will be displayed on the control panel. When all lights are out, the process is finished and the operator may proceed to step 10:

NOTE: If further purging with air is desired, press the MANUAL AIR button on control panel. After 15 minutes, the E-STOP light will come on if no further purging is desired, press the MANUAL AIR button and then the RESET button to shut off all panel lights. (If longer than 15 minutes is desired, press RESET button only to restart the process.)

11. Straighten the distal end of scope to prevent damage during removal.

12. Remove the channel connections from the universal cord.

13. Remove the endoscope from disinfector.

NOTE: Before use, plug scope (with valves in place) into light source. Then turn light source on to clear residual water from air channel. A spray of water will be seen exiting from the air/water valve at the control head.

NOTE: It is recommended that the endoscope be cultured after the first cycle in the OTT Disinfector, to be assured that the unit is working properly and all channels are being disinfected.

Culture testing should be done on a regular basis as a part of your quality assurance program.

Process Interruption

The disinfecting process will stop if:

1. The "E-Stop" button is pressed. Example: Operator activated when error in scope hookup has occurred.

2. The unit senses a high or low fluid level in reservoir. Then the appropriate reservoir "High" or "Low" indicator, on the control panel, will light and an intermittent audible alarm will sound. Either condition must be corrected before the unit will restart. If problem continues, call MediVators, Inc., 1-800-537-7324.

   NOTE: Certain brands of disinfectants may foam. Foaming disinfectant may contact sensor. (Call Medivators for more information, 1-800-537-7324.)

3. The Hospital's circuit breaker or fuse for the unit's power has tripped. Reset circuit breaker or replace fuse. This is required before restart. Call your Electrical Maintenance Department.

4. The unit's ground fault interrupter (GFI) has tripped. Press the red reset button located inside bottom of unit. (see page 5, illustration 3)

Recovery from Process Interruption

1. Press the START button. The process will now resume from the point of interruption.

OR

2. Press the RESET button. This will abort the cycle in process. (Depending upon phase of cycle which has been interrupted, disinfectant will empty from scope chamber to reservoir or water will empty to drain.) When all fluid has drained from the scope chamber and all monitor lights are out, proceed from step 1 of the operating instructions.

   To ensure completion of reset cycle, DO NOT press start until all monitor lights are out.

Disinfectant Change

A warning light indicates the disinfectant may be reaching a level of dilution and could be ineffective for high level disinfection. Disinfectant should be changed before the next day. MediVators recommends testing the disinfectant for dilution* and changing before the next cycle if indicated by test.

*2% Glutaraldehydes can be easily tested for dilution using available test kits.

The Change indicator light on the control panel is computer programmed to light after 40 cycles. The disinfectant should then be tested.

NOTE: The Change indicator light will stay on until the disinfectant is changed, but does not interfere with unit operation.

TO CHANGE DISINFECTANT:

1. Close the scope shutoff valve. (see page 8, illustration 4)
2. Depress DISINFECTANT DUMP button until pump is activated. Disinfectant will be pumped up into the scope chamber and flow out the drain.
3. Total cycle time is approximately 2½ minutes.

DO NOT press operator buttons until cycle is complete and the unit shuts itself off. An audio alarm will sound at completion of the cycle. In addition, the low level sensor light and the E-Stop button on control panel should be lit. If the operator buttons are activated before completion of the dump cycle, the change light on the control panel will continue to flash.

4. Unplug the unit.
5. Wipe out reservoir with a damp cloth, not paper towels. (Wear gloves.)
6. Replace disinfectant filter. (see page 13, illustration 5)
7. Refill the reservoir with 3 (4 gallons with heater) gallons of disinfectant. DO NOT OVERFILL.
8. Remove carousel and clean. (see page 14, illustration 7)
9. Record the date of the disinfectant change on the log sheet provided. (see page 12)
10. Plug in unit.
11. Prime pump. (see page 7)

NOTE: ALL INSTRUCTIONS, WARNINGS, ETC. ON THE CHEMICAL DISINFECTANT LABEL SHOULD BE FOLLOWED.

DISINFECTANT SERVICE LOG

TEST DATE	DISINFECTANT CHANGE DATE	DISIN-FECTANT	FILTER CHANGE DATE	TEST RESULTS	INITIALS	REMARKS

NOTE: Photocopy this chart, then place the photocopy on the inside of the disinfector's door.

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Disinfectant Filter Replacement

NOTE: It is suggested that the disinfectant filter be changed once a month, or more frequently in high use facilities. The filter should be changed after disinfectant dump and before refilling reservoir.

REPLACEMENT PROCEDURE:

1. Remove clamp (C1) from end of filter. (use ¼" nut driver)
2. Remove hose from end of filter.
3. Replace with new filter (arrow indicator as shown in illustration 5).
4. Reattach hose and clamp per illustration.
5. Repeat steps 1-4 for clamp C2.
6. Prime pump. (see page 7)

NOTE: Call MediVators to purchase additional disinfectant filters, 1-800-537-7324. Order #ED-115

WARNING

FAILURE TO INSTALL FILTER CORRECTLY (ARROW FOR DIRECTION OF FLOW) WILL IMPAIR EFFICIENCY OF OPERATION IN DISINFECTANT CYCLE.

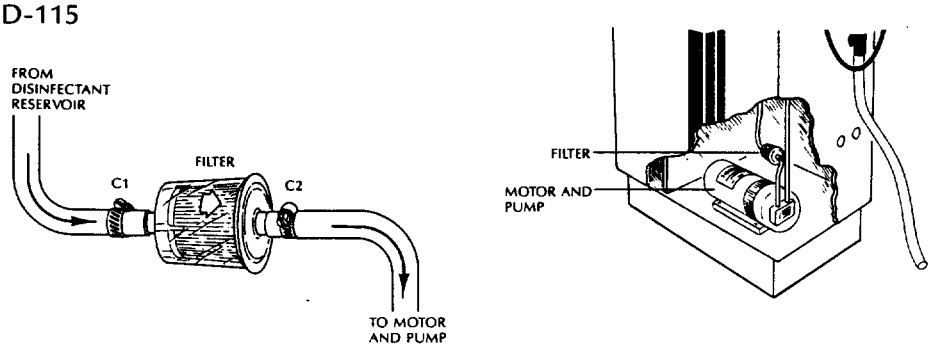

ILLUSTRATION 5

Sediment Water Filter Replacement

NOTE: It is suggested that the sediment water filter be checked periodically for particle saturation. It should be changed every 90 days. Saturation of filter will lead to an inability to maintain 17-20 psi of water pressure.

REPLACEMENT PROCEDURE:

1. Shut off water supply to filter.
2. Place container under filter to catch excess water.
3. Loosen base of filter assembly slowly to relieve pressure.
4. Remove base, remove filter and replace.
5. Replace base of filter, turn on water supply.

NOTE: Call MediVators to purchase additional water filters, 1-800-537-7324.

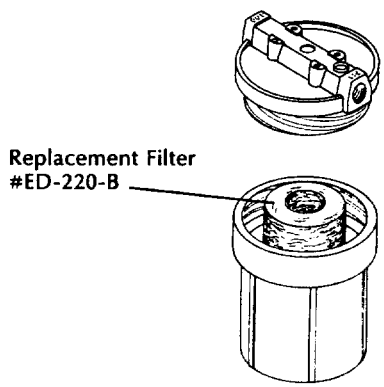

ILLUSTRATION 6

828

Carousel Removal and Cleaning Procedure

1. Illustration 7A: Note normal shroud assembly position.
2. Illustration 7B: Unlatch shroud assembly and lift off pin as shown.
3. Illustration 7C: Lift carousel out by pulling straight up.
4. Illustration 7D: Once removed, carousel assembly and scope chamber can be cleaned.
5. Reverse procedure to replace carousel and shroud assembly. (Note: Shroud assembly has pinhole for the alignment on the cabinet.)

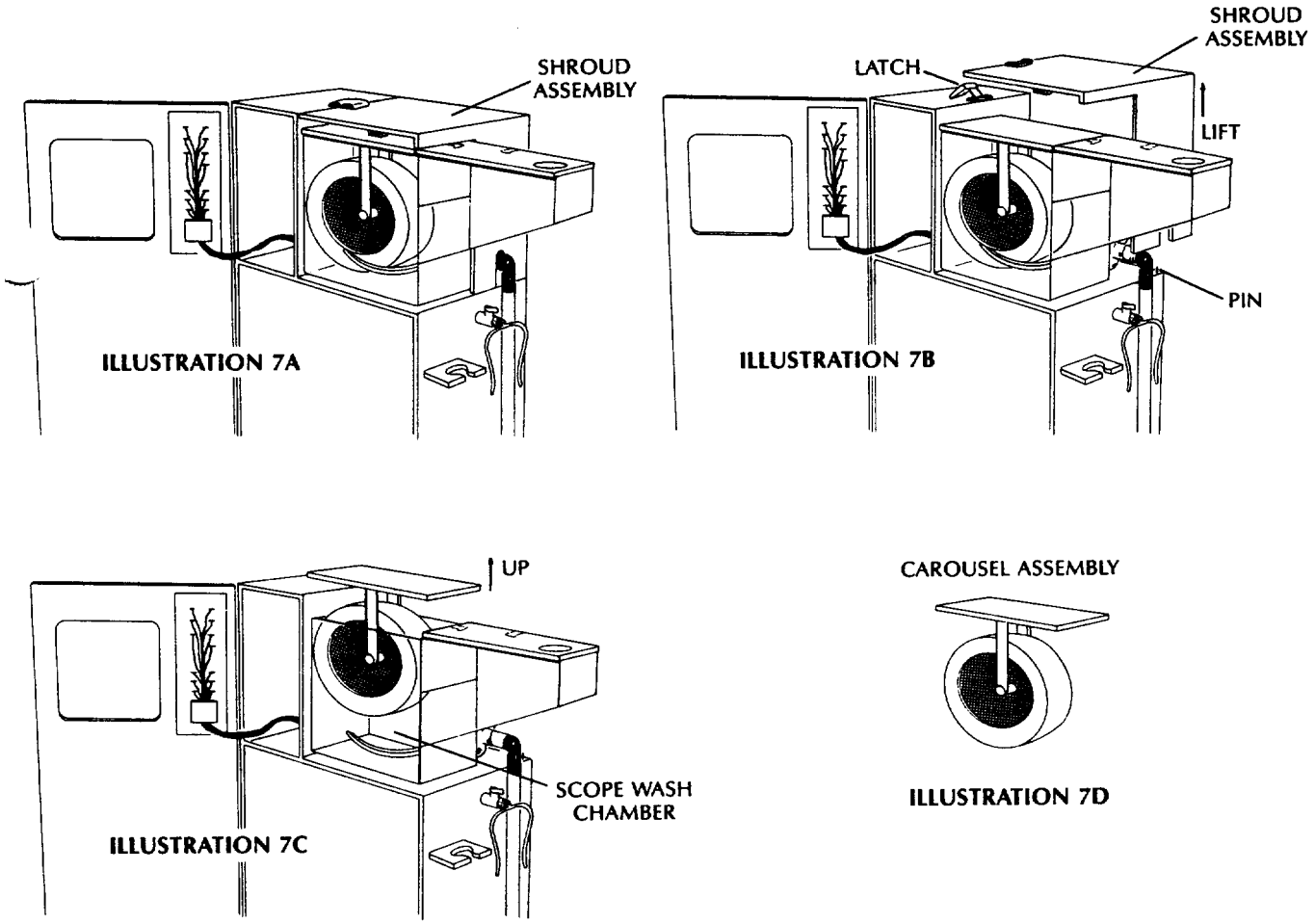

ILLUSTRATION 7

TROUBLE SHOOTING GUIDE

Set forth below are some of the most commonly experienced problems with the OTT Disinfector and the solution for each. This troubleshooting guide is intended as a guide only, and should you have a problem not described below, or if you are unable to solve it, please call factory service at 1-800-537-7324.

1. PROBLEM - LOW LIGHT ON AND LOSING DISINFECTANT.

A. Foreign material caught in ¾" drain valve.
(Location) - directly below black computer control unit ("P.C.") on right side of cabinet.
(Description) - valve is either brass or stainless steel in color with coil attached to it (coil will be underside of valve).
(Solution) - locate valve, disconnect hose from 90° fitting on left side of valve. Next rotate valve ¼ turn toward you exposing the four screws and the coil. Remove the four screws, valve will then come apart exposing the rubber diaphragm. Remove foreign material from diaphragm. Wipe diaphragm, be sure o-ring stays in place. Put diaphragm back in place, replace screws, rotate valve back into position, replace hose and reclamp.

2. PROBLEM - HIGH LIGHT ON AND WATER GETTING INTO DISINFECTANT.

A. Foreign material in one of two disinfectant dump valves.
(Location) - first valve, directly to right side of P.C.; second valve, directly behind upper tank.
(Description) - valves are either brass or stainless steel in color with coil attached (lower valve has coil on top side, upper valve has coil on bottom side).
(Solution) - to determine which valve is causing the problem remove some solution from lower tank so high light will go off (you may dip solution out by hand). Once high light is off, put a scope into unit and be sure all hookups are in place. Start unit. Let unit go through flush cycle and into disinfectant cycle. Once upper tank is three-fourths full, push E-stop. Remove cover on lower tank and look at hose in right rear corner. If disinfectant is dripping or flowing back into lower tank, the lower disinfectant valve is the problem. If there is no dripping from the hose, push start button and let tank fill completely until disinfectant cascades back to lower tank. When disinfectant is cascading to lower tank, push E-stop. Disinfectant should hold its level in middle of one inch outlet, which is located in upper left hand corner of the upper tank. If solution continues to cascade to lower tank until disinfectant is at bottom of the one inch outlet, the problem is with the valve at the back side of upper tank.

1. Remove safety shield from P.C. and unplug machine.
2. To remove lower valve, insert the ⅜" and 1" hose from upper tank loosening the ⅜" hose first. Loosen 1" hose from front valve located directly below P.C. unit. Remove 1" hose from T fitting where it goes directly to lower tank. Now valve assembly will pull forward allowing you to remove the four screws. After removing four screws valve will come apart, exposing the rubber diaphragm. Clean diaphragm and remove foreign material. Replace diaphragm (be sure 0-ring is in place) and replace screws. Slide valve assembly back into place. Replace rear hose to lower tank and reclamp. Replace hose to front valve. Replace hoses to upper tank and reclamp (put 1" hose on first).
3. To access the valve at rear of upper tank, remove cover from top of unit by releasing the catch on top of cabinet. Remove hose from 90° fitting at end of valve, slide hose off of straight fitting at tank (located between two 90° fittings on tank, upper right hand corner). With pliers or screw driver remove clamp on bottom side of coil (this will allow you to slide coil off of the valve and rotate whole valve assembly up to access the four screws at bottom of the valve. Remove screws exposing diaphragm. Clean out foreign material and wipe diaphragm. Put valve back together and reattach coil. Rotate valve back into position. Replace and reclamp hoses.

3. PROBLEM - WATER NOT COMING INTO UPPER TANK DURING FLUSH OR RINSE CYCLE OR COMING IN VERY SLOWLY.

A. Water turned off.
(Solution) - turn on water.

B. Sediment water filter is plugged.
(Solution) - replace filter cartridge. (part # ED-220B)
(Location) - directly on incoming water line before water regulator.

C. Water regulator has been changed causing a drop in water pressure. (It is very important to maintain proper water pressure to effectively rinse scopes.)
(Solution) - reset water regulator. (Check filter first).
(Location) - directly inline after sediment water filter.

D. ¼" water valve is not opening.
(Location) - lower right side of cabinet directly below ¼" disinfectant valve. Water valve is facing down with coil on bottom and ball check valve attached directly to it.
(Solution) - A. Take valve apart and check for foreign material. Or - B. Replace valve (order directly from factory, part # 105D14).

4. PROBLEM - DISINFECTANT NOT FILLING UPPER TANK OR GOING THROUGH SCOPE.

A. Disinfectant filters plugged (causing slow fill of upper tank).
(Solution) - replace filter. (part # ED-115)
(Location) - directly inline from lower tank to pump.

B. Disinfectant is going through scope only and not filling upper tank.
(Solution) - replace ¼" valve.
(Location) - directly below upper tank with ⅜" braided hose attached to valve and upper tank (call factory to order, part # 105D14).

C. Disinfectant not coming through scope or to upper tank.
(Solution) - replace ¼" disinfectant valve.
(Location) - directly above pump at bottom of cabinet (call factory to order, part # 105D14).

5. PROBLEM - DISINFECTANT NOT DRAINING OUT OF UPPER TANK TO LOWER RESERVOIR.

A. ¾" disinfectant valve not opening.
(Location) - right side of P.C. unit.
(Solution) - A. Diaphragm is stuck closed, remove valve and clean diaphragm following steps in Problem 2. (This is the same valve as described in problem 2.)

6. PROBLEM - WATER NOT DRAINING OUT OF UPPER TANK DURING FLUSH OR RINSE CYCLE.

A. Kink in drain line outside of unit.
(Solution) - find kink and straighten it out.

B. Drain line is plugged.
(Solution) - unplug.

C. ¾" valve is not opening.
(Location) - directly below P. C. unit at right side.
(Solution) - Diaphragm is stuck closed, take valve apart and clean diaphragm. (Follow steps in problem 1.)

7. PROBLEM - AIR DOES NOT PURGE SCOPE AFTER EACH CYCLE OR MANUAL AIR DOES NOT COME ON.

   A. Air is turned off.
   (Location) - air comes in at outside of unit next to water line.
   (Solution) - turn air on.

   B. Air is getting to machine, still no air. Air regulator has failed.
   (Location) - directly in line of air line coming from bottom right side of unit. Air regulator is one-third of the way up on right side of unit.
   (Description) - air regulator has black bonnet with metal body or all metal with set screw in front (factory set).
   (Solution) - replace air regulator (order from factory, part # 105D23.

   C. Factory equipped air compressor has failed.
   (Location) - lower left side of unit.
   (Solution) - replace air compressor (order from factory, part # ED-230).

8. PROBLEM - HOOKUP CONNECTIONS BLOWING OFF OF SCOPE WHEN IN FLUSH CYCLE OR RINSE.

   A. Water pressure too high.
   (Solution) - reset water regulator when in flush cycle 17 to 20 PSI.

   B. Hookup tubing is worn out.
   (Solution) - replace tubing (order from factory, see hook-up instruction sheet).

9. PROBLEM - HOOKUP CONNECTIONS BLOWING OFF SCOPE DURING AIR PURGE.

   A. Air regulator is clogged with foreign material.
   (Location) - directly in line of air line coming from lower right hand side of unit one-third of the way up on right side of unit (same description as in problem 7).
   Air regulator is in same location on units equipped with factory air compressor).
   (Solution) - take air regulator apart by removing bonnet on front side of air regulator. You may want to take air regulator out of the line to work on it easier. Remove foreign material, replace bonnet, put air regulator back into line. (Caution - shut air off on incoming line before taking air regulator apart. Units equipped with factory air compressor unplug unit.

10. PROBLEM - WATER OR DISINFECTANT NOT FLOWING THROUGH SUCTION TUBING.

   A. Restrictor plugged.
   (Description)- small gray plastic material with ½mm hole in center.
   (Location) - restrictor is in one end of suction tubing (should be end that is on T at side shut off valve).
   (Solution) - take small needle and clean 1mm hole or replace (order from factory, part # 105H13).

11. PROBLEM - WATER OR DISINFECTANT NOT FLOWING THROUGH BIOPSY TUBING.

   A. Biopsy connector plugged (½mm hole).
   (Location) - end of biopsy tubing where biopsy adapter is connected to tubing.
   (Solution) - clean out with small needle or replace (order from factory, part # 105H93).

12. PROBLEM - MACHINE WILL NOT START.

A. Check to see if lights on P.C. unit are on. If lights are off -

1. Machine is unplugged.
   (Solution) - plug in machine.
2. Ground fault interrupter (GFI) is tripped.
   (Location) - at bottom of unit in front of pedestal or under lower reservoir tank.
   (Solution) - reset GFI by pushing the red button; if GFI will not stay reset there is an electrical short somewhere (call maintenance or call factory).

13. PROBLEM - CHANGE LIGHT COMES ON SHORTLY AFTER DUMPING DISINFECTANT.

(Location) - front panel.
(Solution) - you must let machine run until E-stop comes on, low light will flash and unit will beep when cycle is completed after dumping disinfectant. Failure to let cycle finish will result in 40 cycle timer not being reset and change light will come on prematurely. To correct: Ignore change light and manually count cycles until next dump, or press disinfectant dump button again and let the unit finish out the cycle. (Disinfectant will dump.)

Factory Customer Service 1-800-537-7324

Parts List

PART #	PARTS LIST
105D02	Submersible Tank
105D13	¾" B.ass Solenoid Valve
105D14	¼" Stainless Solenoid Valve
105D15	¾" Stainless Solenoid Valve
105D16	Pre-disinfect Valve
105D17	Shut-off Valve; gray w/black "T"
105D20	March Pump
105D22	Water Regulator w/Pressure Gauge
105D23	Air Regulator
105D34	Bleeder Valve
105D35	Front Panel Light Bulbs (pkg/5)
105D40	Small Snap Clamps (pkg/20)
105D41	Large Snap Clamps (pkg/20)
105D42	Hose Clamps (pkg/2)
105D70	Water Filter Housing (blue) w/Bracket
105A28	Sound Mat for Air Compressor

PART #	FILTER REPLACEMENTS
ED-115	Disinfectant Filters (pkg/12) Suggested change monthly
ED-220B	Replacement Water Filter Cartridge Suggested change quarterly
ED-250	Sterapore Sterile Water Filter Suggested change yearly

PART #	HOOK-UPS PARTS LIST
105H01	Lower Olympus OES Valve Seal, stainless steel & silicone rubber
105H02	Upper Olympus OES Valve Seal, stainless steel & silicone rubber
105H03-1	Lower Olympus OES Valve Clamp; Delron w/turn screws, (includes valve seal - 105H01)
105H04-2	Upper Olympus OES Valve Clamp; Delron w/turn screws, (includes valve seal - 105H02)
105H12	Air Inlet Plug 4" clear PVC tubing with white plug (pkg 5)
105H11	Olympus Lower Biopsy Port/CO_2 Tube Assembly; 24" clear PVC tubing w/amber connector for biopsy port and luer lock for CO_2
105H10	Olympus Upper Biopsy Port/Air Inlet Assembly; 24" clear tubing w/amber connector and clear ⅛" tubing for air inlet
105H09-1	Olympus Water Port Adapter/Suction Tubing; amber butterfly connector w/tubing
105H44	Fujinon Water Port Adapter/Suction Tubing
105H46	Fujinon Upper Biopsy/Air Inlet Assembly
105H47	Fujinon Lower Biopsy/J Channel Assembly
105H15	#1 Plug (Olympus pre-OES)
105H16	#2 Plug (Olympus pre-OES)
105H40	#3 Plug (Fujinon)
105H41	#4 Plug (Fujinon)
105H42	#5 Plug (Fujinon)
105H43	#6 Plug (Fujinon)
105H17	#7 Plug (Olympus pre-OES)
105H18	#8 Plug (Olympus OSF)
105H19	#9 Plug (Olympus pre-OES)
105H71	#10 Plug (Pentax)
105H72	#11 Plug (Pentax)
105H73	#12 Plug (Pentax-FC Series)
105H20	1 Line Biopsy (Olympus pre-OES)
105H21	2 Line Biopsy (Olympus pre-OES)
105H22	4 Line Biopsy (Olympus pre-OES)
105H23	6 Line Biopsy (Olympus pre-OES)

PREPARING ENDOSCOPE FOR STORAGE

Recommended Procedure

To avoid organism growth during storage, endoscope channels must be thoroughly dried. Drying may require the use of 10-15 PSI of air to all channels for 15 minutes or more. The use of 30-45% alcohol will:

1. Enhance the drying process
2. Inhibit organism growth

* An end-of-day drying hookup is available from Medivators. For more information, call 1-800-537-7324.

* Custom built storage cabinets for endoscopes are available from Medivators. For more information, call 1-800-537-7324.

OPTIONS

1. Heating Element: (ED-200)

   Should not exceed temperature recommendations on disinfectant label.

   An optional heating element may be directly installed into the disinfectant chamber. The heating element includes a thermostat and probe. This option may be purchased with the unit or at a later date, however, the hospital is responsible for the cost and proper installation if purchased separately. Heater may be used to heat certain chemicals to a sterilizing ability. There is a 12% variance with the heater. Please use a thermometer to determine actual temperature.

2. Air Compressor: (ED-230)

   An optional air compressor may be purchased with the unit or at a later date. This compact air compressor is installed directly in the unit and fulfills the air pressure requirement of 10 PSI.

3. Sterile Water Filter: (ED-250)

   Provides a sterile water rinse in cycle. Compact, suggested change annually.

4. Stainless Steel Valve Assembly: (ED-210)

   Needed for use with hydrogen peroxide based disinfectants or sterilants.

TEST RESULTS

Test results show a greater than 5-log reduction in Bacillus Subtilis spores after inoculation of an endoscope with approximately 4.7×10^8 CFU/6ml, followed by disinfection with the Ott Disinfector, using a 6% hydrogen peroxide-based solution with an exposure time of 11½ minutes.

FOR INFORMATION ON OTHER MEDIVATORS PRODUCTS, CALL 1-800-537-7324

1. Ott Channel Sampling Kit for flexible endoscopes (for cultures and residual chemical testing)
2. "Sterapore" Sterile Water Filter
3. Ott Storage Cabinet for flexible endoscopes and accessories
4. End-of-Day Drying hook-up for endoscopes
5. Wall Storage Rack for esophageal dilators (Savary or Malorey)

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APPENDIX C

AVAILABILITY OF SAFETY AND EFFECTIVENESS
INFORMATION PURSUANT TO 513(F) OF
THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

RE: MediVators DSD-91 Disinfector

Information supporting a substantial equivalence determination will be made available to any interested persons upon request.

Signature: Constance G. Bundy

Name of Individual Signing: Constance G. Bundy

Title: Consultant to MediVators, Inc.

Company Name: C. G. Bundy Associates

Address: 6470 Riverview Terrace N.E.
Minneapolis, Mn 55432

Phone Number: 612-574-1976

Date: September 13, 1991

APPENDIX D

DEVELOPMENT PROCESS FOR
DSD-91

SPECIFICATIONS

The specifications for this device were generated by carefully reviewing the technical and service manuals for the existing OTT device; interviewing MediVators, Inc. management, sales, and technical staff; and reverse engineering relay ladder diagrams for the existing device.

This information was then embodied in PASCAL-like structured code and an updated USER/SERVICE manual.

SYSTEM DESIGN

A TOP-DOWN design philosophy combined with a BOTTOM-UP implementation philosophy was used.

What this means is that the overall specifications are reviewed in their totality to determine what the system is to do, and decisions are made as to the architecture and strategy that is to be emplyed to perform these functions. Trade-offs are made as to what functions should be performed in hardware, and what functions should be performed in software.

Actual development of the system is then accomplished using a building block approach, implementing the primitive functions and circuits first.

FAILSAFE CONSIDERATIONS

The system has been designed such that it is immune to software loop failures, hardware latchup and lockup conditions by implementing certain features in hardware. These features are:

1. System watchdog timer: This requires that the main control loop and certain other major control loops inform the hardware that it is still operational by issuing a strobe command to the hardware. If this command is not received within a certain period of time, the hardware will force a reset condition to cause the system to re-initialize itself.

   Under most conditions a reset is capable of clearing failures caused by both hardware and software failure modes.

2. System power monitor: This allows the software to monitor the stability of the system power supply. This is used to inhibit certain operations under unstable conditions.

3. Non-volatile RAM: This is used to retain the current state of the system. This allows the system state to be restored in the event of a total power failure.

SOFTWARE IMPLEMENTATION

After design decisions are made, code is written for the smallest, most primitive service routines. Each service routine is tested as an independent module to insure that it performs as expected. For each service routine, a process of successive refinement is used to improve upon its functionality and reliability until the module is accepted as a building-block for the next layer of software to use.

As each layer is built, tested, and accepted, it becomes a collection of VERBS (functions) for use by the next layer. This means that the invocation of a function (i.e., the use of a VERB) can be assumed to produce a known, predictable result and is not explicitly tested for correctness. This follows the principle that the "ADD" verb in a COBOL program is assumed to produce correct results and is not explicitly tested every time it is used.

Once again, as each module is built using the functions from the preceding lower layer, it is tested and validated and the process repeats itself.

Finally, all layers are completed and the outer control loop is put into place. At this time the functionality of the software has been well tested and verified. All that remains is final verification and validation to insure that all functionality plays well together.

VERIFICATION AND VALIDATION

Final verification and validation is accomplished on two levels.

The first level is exhaustive testing to insure that the system functions as specified. This involves manually exercising the software in the actual mechanical device, observing for correct action, and insuring the timing of various phases is correct.

The second level of testing is three-fold.

1. Re-verify operation by utilizing technical staff to observe for expected action and timing.

2. Insure failure immunity by utilizing non-technical staff to perform the "1000 monkeys" testing procedure. This testing simulates the use of the device by non-experienced, non-engineering staff that may exist in the actual operational environment. This testing occurs over several weeks and requires hundreds of operational hours on the actual device.

3. Insure system effectiveness in actual use. This is accomplished by submitting a scope that has been innoculated under a controlled procedure to the sterilization cycle and subsequently culturing that scope and examining the results in a laboratory environment.

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VERSION CONTROL

Version control of released software will be accomplished by utilizing a unique revision number that is embedded within the system ROMs and is displayed during the system power up selftest (POST) routines.

Each production version of the software that is released to the field will be archived and retained until all boards using that particular release are either updated or have been taken out of service.

This archived software will be kept in an appropriate, safe place.

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APPENDIX E

Third Party Laboratory Tests and Results (b) (4)

[redacted]

September 11, 1991

Mr. Jerry Blonsky
MediVators, Inc.
Cannon Plaza South
Hwy 52 South
Cannon Falls, MN 55009

Third Party Laboratory Tests and Results (b) (4)

Dear Mr. Blonsky:

Please find enclosed the [redacted] Evaluation of Sanitization Process of a GI Endoscope.

Please note that the log reduction resulting from the sanitization is reported for each of the channels individually, and for the endoscope as a whole.

If you have any questions after reviewing the study, please don't hesitate to call me.

Sincerely,

(b) (4), (b) (6)

[redacted]

Enclosure

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Third Party Laboratory Tests and Results (b) (4)

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Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

JULY 22, 1992

MEDIVATORS, INC.
ATTN: CONSTANCE G. BUNDY
C/O C. G. BUNDY ASSOCIATES
6470 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432

510(k) Number: K914145
Received: 07-21-92
Product: DSD-91(TM) DISINFECTOR FOR FLEXIBLE ENDOSCOPES

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 within 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) 427-1190.

Sincerely yours,

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

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Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

RESPONSE # 1 THROUGH 10 AND 12

APPENDICES A THROUGH J

510(K) K914145

MEDIVATORS, INC.

Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

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Summary of Results:

Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

[redacted]

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Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

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Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

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Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

[redacted]

For response to the following questions refer to Appendix K

Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

[redacted]

Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

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Reviewer /Sponsor Correspondence Pre Decisional (b) (4), (b) (5)

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App. A

CONFIDENTIAL

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App. B

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App. C

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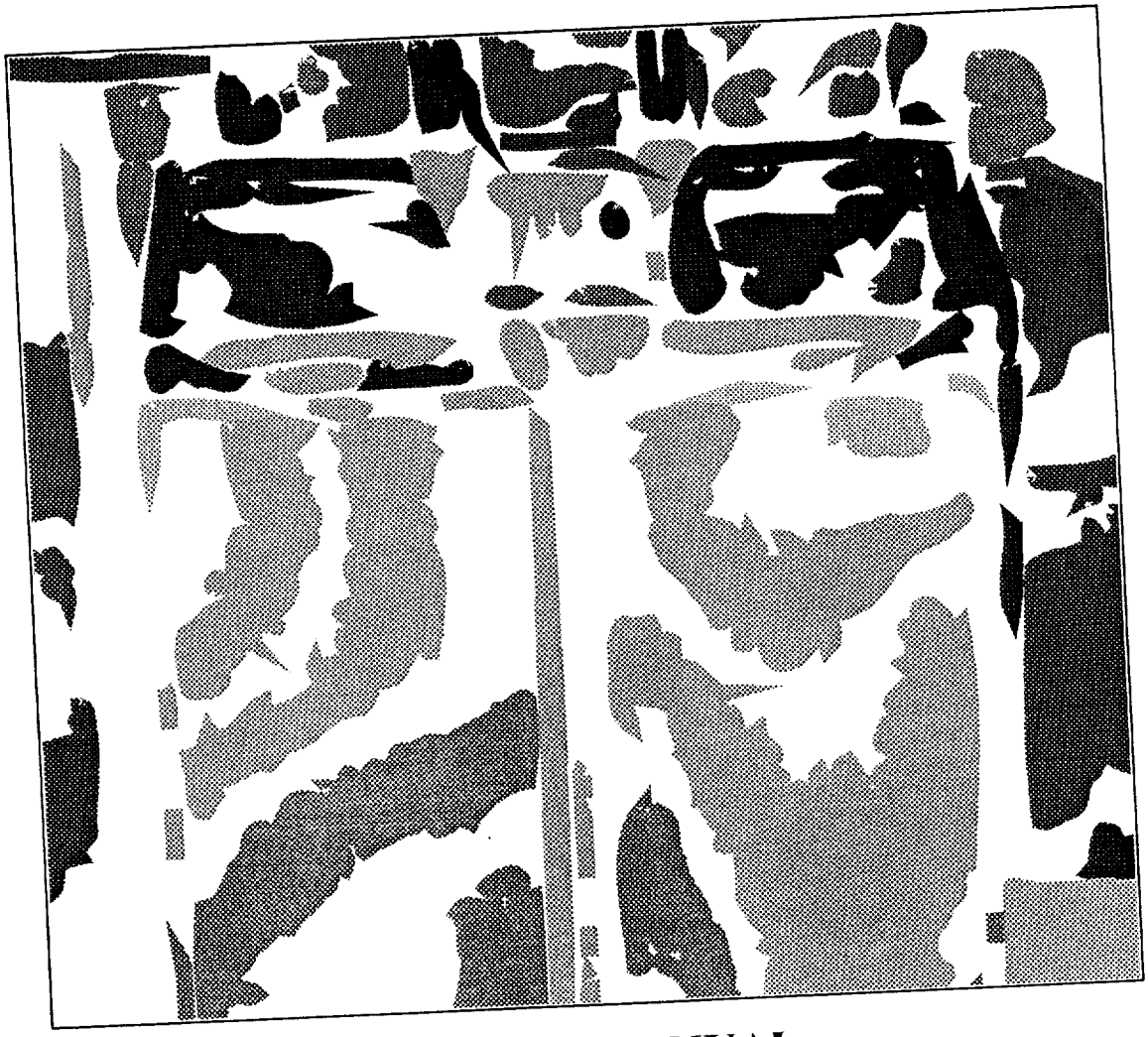
App. D

MEDIVATORS, INC.

INNOVATIVE MEDICAL PRODUCTS

Cannon Plaza South • Highway 52 South • Cannon Falls, MN 55009

DSD-91™ Disinfector for Flexible Endoscopes



USER'S MANUAL

Customer Service • 800/537-7324 • 507/263/4721

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MEDIVATORS, INC.

DSD-91™ Disinfector for Flexible Endoscopes

USER'S MANUAL

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Copyright protection claimed includes all forms and matters of copyrightable material and information now allowed by statutory or judicial law or hereinafter granted.

(b) (4)

[redacted]

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IMPORTANT

- The level of disinfection is directly related to the disinfectant solution used and the amount of time the endoscope is exposed to the disinfectant solution. It is of importance that a disinfection protocol be established by the user of this equipment. These protocols must include systems to monitor their effectiveness.

- Pre-cleaning of the endoscope is essential.

- The labeling of the disinfectant solution must be rigidly adhered to. If labeling instructions are not strictly adhered to, the reuse life of the disinfectant could be significantly affected.

- The disinfect contact time cannot be set below 10 minutes.

- The 40 cycle warning light setting is based upon a disinfectant with a 14-day reuse life.

USER NOTES

- **In laboratory studies, proper cleaning techniques in conjunction with a 20 minute disinfect cycle gave the best and most consistent results. All testing was performed with 14 day reuse Glutaraldehyde.**

- ERCP endoscopes need additional cleaning and disinfection steps. Of particular importance is the elevator wire channel. This channel should be manually disinfected because it is uncertain whether it can be adequately disinfected in an automated unit.

- All endoscopes that are fully submersible and have facilities for leak/air tight testing should be leak tested prior to being submerged in any fluid.

- All endoscopes should be pre-cleaned following the manufacturers' instructions and recognized established society guidelines prior to being processed in an automatic washer/disinfector.

- All disinfectants must be continually monitored for effectiveness.

- All disinfectant and enzymatic detergent manufacturers' labeling must be followed.

- Operation of this equipment should be limited to those individuals trained in its proper use.

- The enzymatic dispenser should be removed, washed, and dried at the end of the day.

- After dumping used disinfectant, remove the lower reservoir, rinse, and wipe it with clean cloth. Wipe out the upper tank with a clean cloth. Paper towels should not be used.

- All pressure regulators are factory pre-set. Do not attempt to adjust them without contacting Medivators Service Center first.

- The water pressure regulators should be monitored frequently. If a drop in pressure occurs on the interior water pressure regulator, this could be an indication that it is time to change the Sterapore filter. Call Medivators service if there are any questions.

- If the enzymatic detergent or alcohol purge cycle are used, check the corresponding reservoir levels prior to starting

- Observe and compare the time of day as displayed by this device with the actual wall clock at the end of the programmed cycles to insure that there is no speed-up of the timing mechanism. Observe and compare the log for appropriate start and stop times to insure proper protocol timing. The colon (:) blink rate in the time display is timed to blink once per second.

If any questions arise regarding the use or servicing of the Medivators DSD-91 please contact our Service Department at:

1-800-537-7324

Professional established guidelines for cleaning and disinfection of endoscopes should be followed. A protocol should be developed by the user based on such guidelines. The following organizations have published recommended guidelines.

Society of Gastroenterology Nurses and Associates

1070 Sibley Tower

Rochester, NY 14604

(716) 546-7241

Association of Operating Room Nurses

10170 East Mississippi Avenue

Denver, Co 80231

(303) 755-6300

American society for Gastrointestinal Endoscopy

13 Elm Street

P.O. Box 1565

Manchester, Ma 01944

(508) 562-8330

Association for Practitioners in Infection Control

505 E. Hawley Street

Mundelein, Il 60060

(708) 949 6052

Chapter 1
Specifications and Instrumentation

Chassis Dimensions
46" high, 36" wide, 21" deep

Weight
Approximately 350 pounds

Electrical Requirements
110 VA, 60 HZ, 15 amp

Water Requirements
Building water supply (regulated for 17-20 p.s.i.)

Air Requirements
Compressed air at 40-100 p.s.i. (regulated at 10 p.s.i. inside machine)

Compressed air is required for operation and may be supplied externally, or by an optional air compressor.

Reservoir Capacity
Disinfectant reservoir (4 gallons each)

Left and right chambers (2.4 gallons)

Rinse Water Consumption
Approximately 5 gallons per cycle

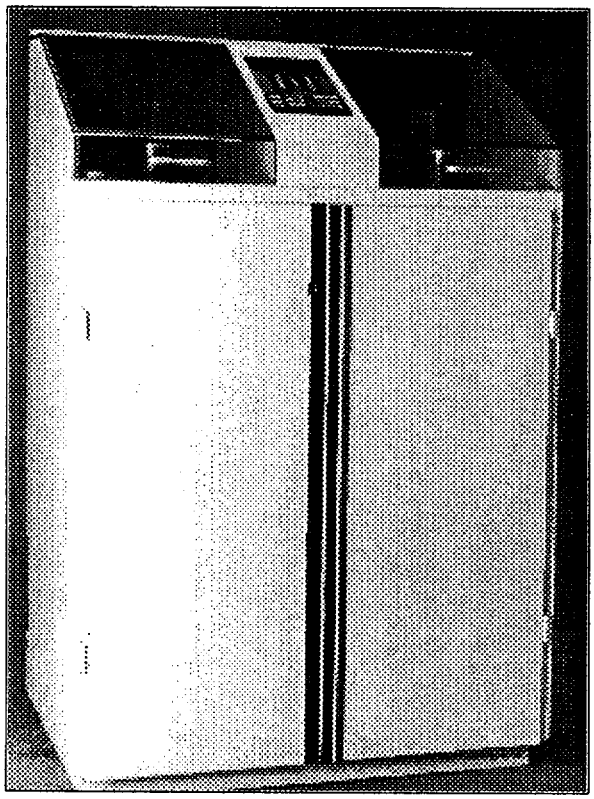

Illustration 1-1

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General

The MediVator DSD-91™ disinfector comprises two disinfectant stations. These stations may operate independently (asynchronously) or in total synchrony with each other as desired by the user.

The station on the left-hand side of the device is referred to as " Station A" while the station on the right-hand side of the device is referred to as " Station B."

Each station is fully equipped with independent valves, disinfectant tanks, disinfectant pumps, and (optional) air compressors. The only common equipment is the power supply and the electronic circuitry. As a result of this design, the occurrence of a device failure for one of the stations is unlikely to affect the operation of the other station.

This design may be used to accommodate different disinfect chemistry and cycles for each of the stations.

Terms and Definitions

- **Cycle**
  A specific sequence of events comprising a major group of activities (e.g., the loading, soaking, and elimination of solution from the chamber).

- **Default program**
  The disinfect program that is executed when no alternate program is selected by the operator.

- **Disinfecting chamber**
  See "upper chamber."

- **Function**
  Any operation other than a disinfect program (e.g., a DISINFECTANT DUMP cycle).

- **Idle state**
  A standby state where no program cycles or other functions are in progress. Many setup and initialization functions require that the station be in the idle state prior to their operation.

- **Phase**
  A portion of a cycle that performs an auxiliary function within that cycle (e.g., compressed air purge phase at the end of a cycle).

- **Program**
  A series of cycles that perform a specified disinfect protocol.

- **Reservoir**
  The container used to hold the disinfecting solution between disinfect protocols.

- **Running**
  A state where a program is in progress, or some other function is occurring (i.e., any state other than IDLE or STOP).

- **Station**
  The portion of the DSD-91™ that is utilized to disinfect a single endoscope. This includes the upper chamber, disinfectant reservoir, valves, hoses, pump, and (optional) air compressor.

- **Stop state**
  A program state where a disinfect protocol is in progress, but the current cycle is suspended. A program may be suspended due to operator intervention, or due to the detection of an error condition.

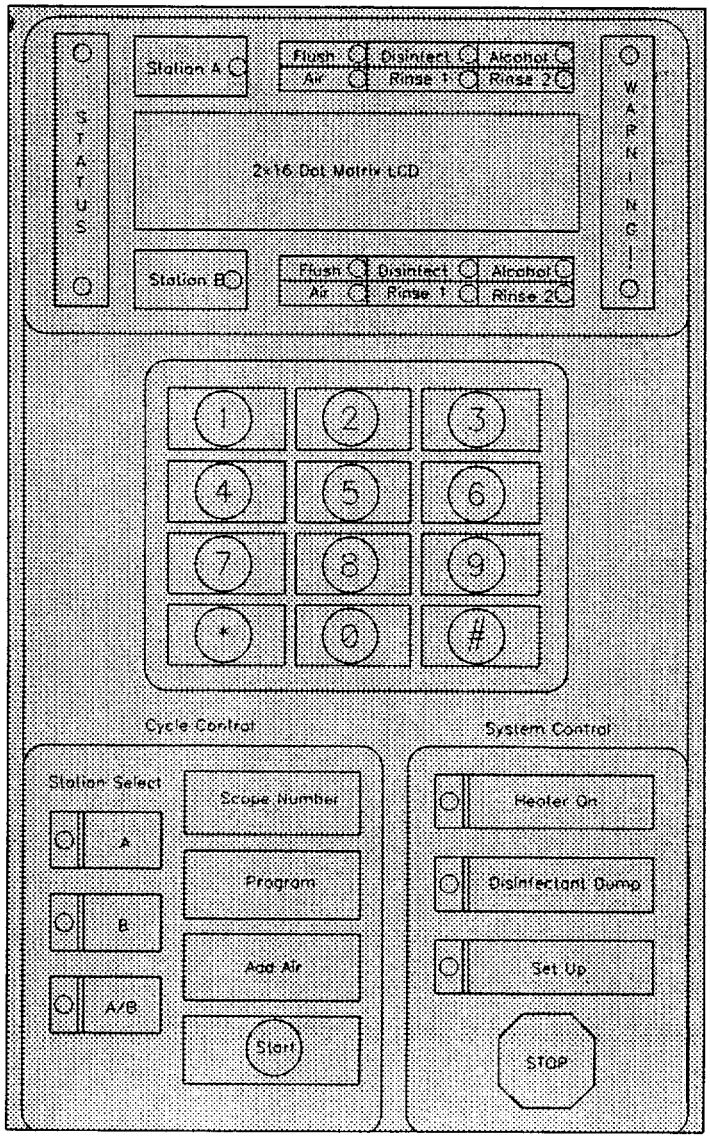
- **Upper chamber**
  The chamber into which the Qwik-load container is inserted prior to starting the disinfect program.

Control Panel

Layout

Setup and operation of the DSD-91™ disinfector is controlled by the membrane control panel located on the top and center of the device.

This control panel comprises three major operation sections. These sections are (1) the station status and warning indicators, (2) the numeric keypad, and (3) the station select and function keys.



Status and Warning

Numeric Keypad

Station Select and Functions

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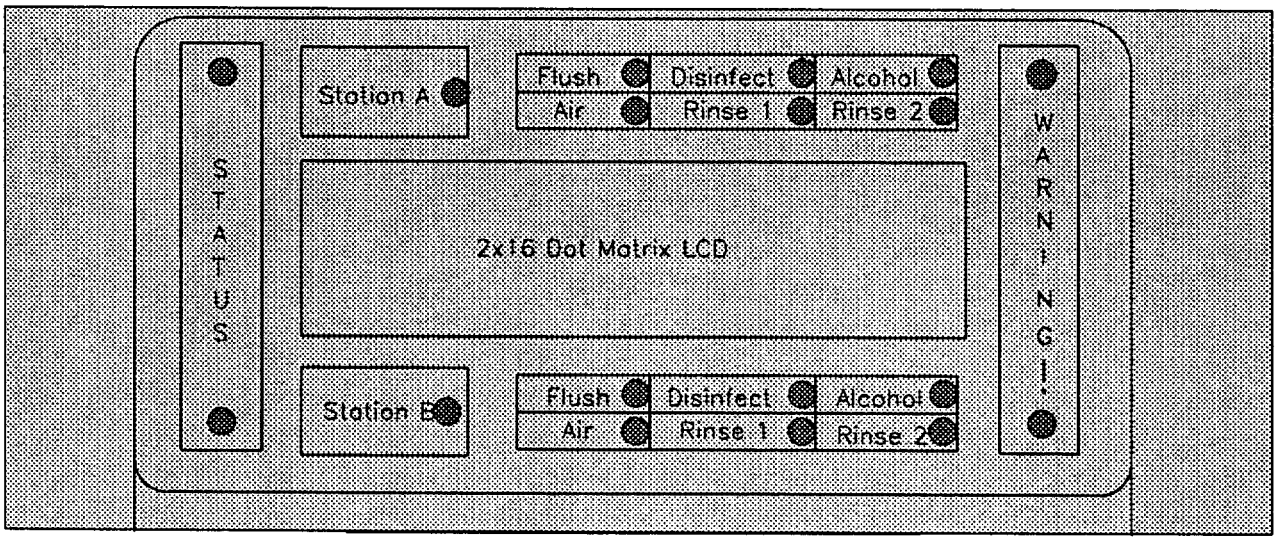
Status Area

The status area of the panel contains LED indicators and a dot matrix Liquid Crystal Display (LCD). The LED indicators are used to show current cycle status while the LCD is used to display detailed status/warning and other information as needed for the operation of this device.



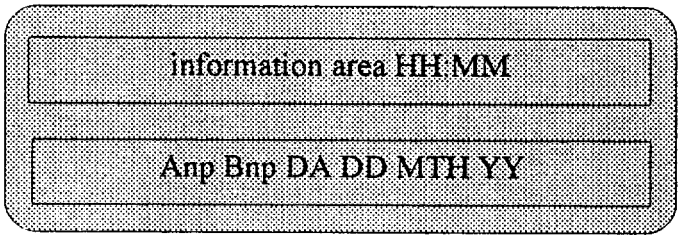
Status Indicator Area of Control Panel

The LCD has two lines of 20 characters. Normally the current time-of-day is displayed in the upper right-hand portion of the display, the day-of-week and date is displayed in the lower right half, and the current station program selection and operational status is displayed in the lower left half portion of the display.

The colon in the time-of-day portion of the display flashes on and off at one-second intervals to provide an indicator that the system is functioning.

The station status display provides an indication that operates when the corresponding station is running.

The STATUS BAR contains an upper and a lower LED indicator to show the STOPPED status for stations A and B, respectively. When either of these indicators are blinking, it shows that the



General LCD Information Layout

HH:MM indicates the current time of day.
Anp Bnp indicates the current operational status of the A and B stations, respectively. The "n" indicates the program selected ranging from 0 (default) to 1 through 9 (user defined programs). The "p" is the pacifier indication that operates when the station is running.
DA indicates the current day-of-week.
DD MTH YY indicates the current day, month, and year.

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associated station is in the STOPPED state, and is not yet idle. The stopped state is entered whenever a system error condition is detected that affects that station, or when the STOP key is pressed. The blinking status light is to remind the operator that the program for that station has not yet successfully terminated.

The CURRENT CYCLE STATUS indicators for station A are located above the LCD window, and the indicators for station B are located immediately below the LCD window.

The STATION indicator is used to show that an operation is currently running for that station. This LED is extinguished if the station should enter the STOPPED state, or when the program has completed.

A steady state on any of the CYCLE STATUS indicators shows the specific disinfect cycle that is currently in progress for the associated station.

A blinking AIR indicator informs the operator that the current cycle (shown by the steady state indicator) is in the final air purge phase of that cycle.

The WARNING BAR also contains an upper and a lower LED indicator. This is the warning status for stations A and B, respectively. These indicators blink whenever any condition that may need operator attention occurs for the associated station. The LCD typically contains additional information regarding the warning status.

Keypad Area

The keypad area of the control panel is used to enter numeric parameters. This is required for many functions performed by several other keys on the panel.

Generally, a specific function key will be depressed, followed by a number sequence on the keypad. The LCD will always prompt the operator to indicate the expected or required action.

If the number string is correct as entered, it is accepted by depressing the HATCH (#) key.

If the last digit entered is incorrect and is to be CANCELED, the STAR (*) key is depressed to allow it to be re-entered.

The STAR key is also used in other contexts to cancel other operations.

Station Select and Function Area

The bottom portion of the membrane panel is dedicated to station selection and function control.

This area is subdivided into two general areas:

1) cycle control and

2) system control.

The left half is used for station selection and cycle control options. The right half is used for system-wide control and options.

Station Selection

Most functions apply only to the currently selected station or stations.

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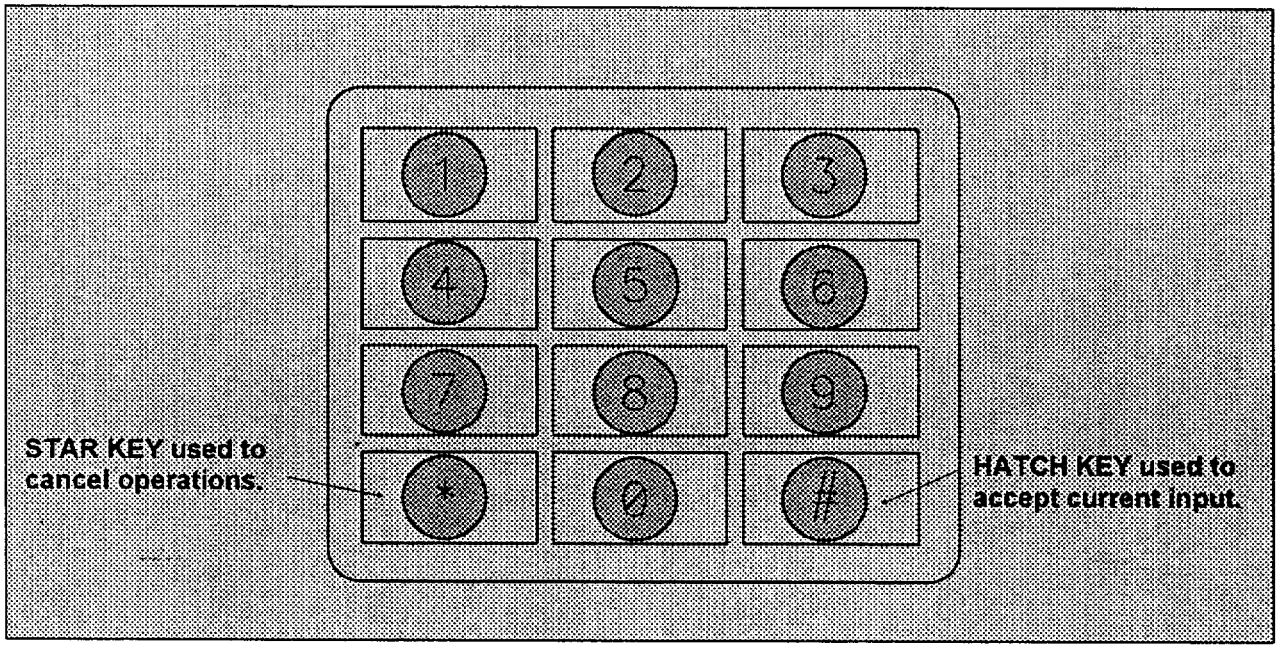


Keypad Area of Control Panel

As a result the operator must insure that the appropriate station selection indicator is lit prior to executing the desired function. If the desired station(s) has not been selected, simply depress the corresponding station select key.

For example, assume that the station A indicator lamp is current lit. To start the current program for station B, the operator observes that station B is not currently selected. Since it is not, the station B select key must be depressed. Now the START key may be depressed to initiate the current program.

Depressing any station select keys while a station is idle clears the current scope number.

Cycle Control

The cycle control section of the panel contains keys that are used to alter current program cycles for the selected station(s). Most of these keys can be activated only when the selected station is in the idle state.

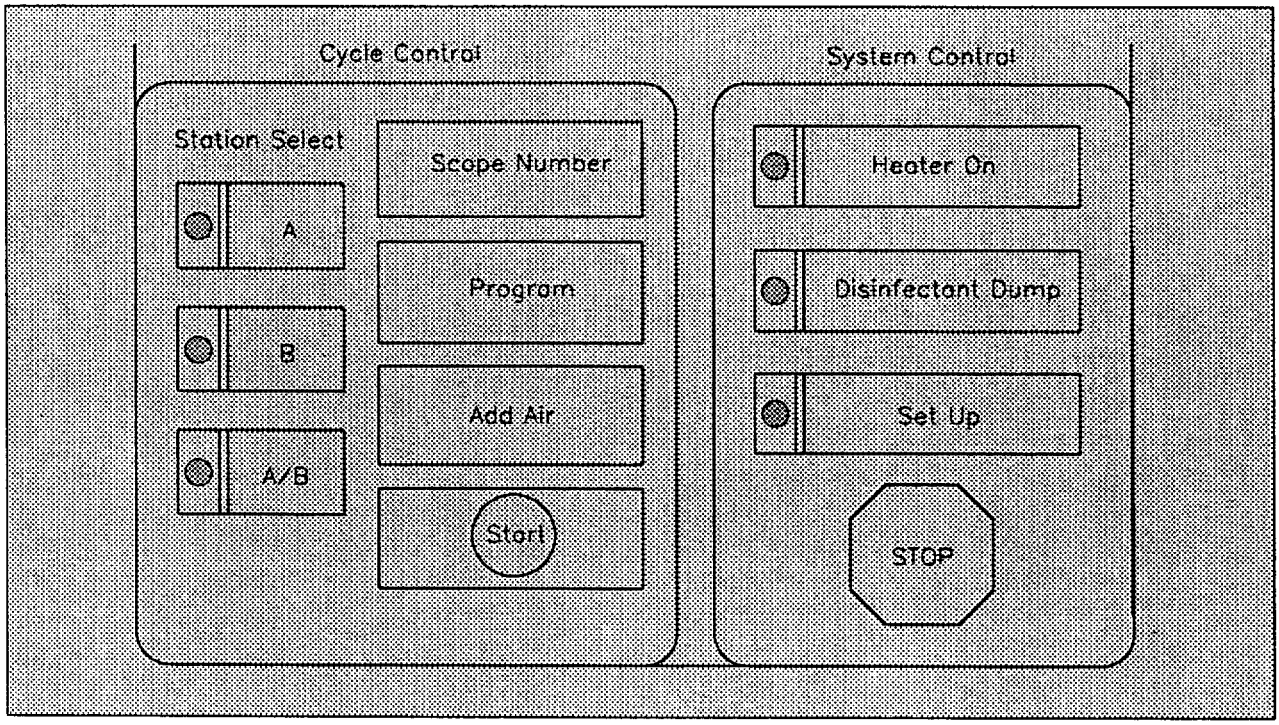
The keys that perform these functions are (1) the Scope Number key, (2) the Program key, and (3) the Add Air key.

The **SCOPE NUMBER** key is used to allow the serial number, or other reference number for the scope about to be disinfected to be recorded into the system operation log along with the date, time, program selected, and completion status information. This information remains in the operation log until it is off-loaded to a logging device (usually a personal computer) via the (optional) RS-232 serial interface port or it is explicitly cleared by one of the setup functions.

If the operation log is full, no additional logging will occur.

The **PROGRAM** key is used to select a special disinfect cycle that has been customized by the individual clinic to meet specific needs. The DSD-91™ can have up to nine customized

programs retained in nonvolatile system memory. Any of these customized programs may be altered at any time by the operations staff.



Station Select and Function Area of Control Panel

The **ADD AIR** key is used to add an additional compressed air cycle at the end of the currently selected program. This is typically a 20 minute cycle used at the end of the day to insure that the endoscope is thoroughly dry prior to storage.

This key may be activated at any time.

Start key

The **START** key is the primary cycle control. It is used to initiate a program sequence, or is used to restart a program in progress that has been interrupted for any reason.

System Control

This portion of the control panel is used to set options and functions that affect all programs until they are altered again.

The **HEATER ON** key is a toggle that causes the reservoir heat option to be enabled or disabled for the selected station.

- **NOTE: Follow disinfectant manufacturers labeling when determining required temperature.**

If the heat option is on, the DSD-91™ software enables power to the reservoir heating elements.

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The **DISINFECTANT DUMP** key is used to cause the DSD-91™ to eliminate the disinfectant from the selected reservoir. This is typically done after 40 to 50 endoscopes have been disinfected by that station.

- **NOTE: All disinfectants must be continually monitored for effectiveness.**

The **SET UP** key is used to initialize various system and station options. These options are described elsewhere in this manual.

The **STOP** key is used to temporarily halt the current program for the selected station. The **START** key may be used to resume the program where it was halted, or the **CANCEL** key (the star key on the keypad) may be used to terminate the program. A terminated program may have to go through a drain/purge cycle prior to going into the idle state.

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Chapter 2
Overview

This chapter provides an overview of the design, functional, and program features that have been built into the DSD-91™ disinfector workstation.

Design Features

Synchronous and Asynchronous Operation

The DSD-91™ disinfector stations may be run synchronously with each other if it is desired to disinfect two endoscopes using identical station timings and program cycles.

Synchronous operation is not required, however. This device has been equipped with separate reservoirs, pumps, motors and valves that allow complete asynchronous, on demand operation for each station. Any station may be put into use regardless of the status of the other station.

Quick-Connect Hookup

Minimizes the complexity of endoscope hookup.

Alcohol Purge

Available to aid the end-of-day drying process.

CAUTION

See endoscope manufacturer's comments regarding the use of alcohol.

Compressed Air

Programmed segment of the cycle that minimizes loss and dilution of disinfectant.

The ADD AIR button is for additional drying of the scope channels.

- **NOTE: The optional air compressor or a source of compressed air is required.**

CAUTION

This cycle will not completely dry channels as required for end-of-day storage.

Disinfectant Filtration

Keeps the reservoir clean of sediment.

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Eliminates recycling of particulate matter through the scope channels.

Maintenance

No daily maintenance is required.

All unit disinfector lines are disinfected while first scope of the day is put through a complete cycle.

Minimal Exposure to Disinfectant

The disinfectant reservoir inside the cabinet is tightly covered and virtually eliminates the escape of toxic vapors.

Unique, easy disinfectant loading procedure simplifies the reservoir replenishment.

Activating the DISINFECTANT DUMP button and pushing the start button on the control panel dumps disinfectant into the drain or receptacle.

Power Fail Restart

This equipment has been designed to tolerate line power brown-out and failure conditions.

The condition of the power supply is constantly monitored. If a brown-out condition is detected, the central processing unit is notified, the software checkpoints the current operational status in nonvolatile memory, all valves and motors are turned off to prevent stress damage to electromechanical components, and processing is suspended.

When proper power conditions are restored, the system resumes operation at the same point in the cycle that was interrupted, regardless of whether the power failure was a brown-out or a total black-out condition.

Temperature monitoring (Optional)

This option is not available in the U.S.A.

This option allows the disinfectant to be monitored for appropriate temperature levels. If the disinfectant in the reservoir fails to meet or exceed the specified minimum temperature, the disinfection cycle will be stopped and an error warning condition will be issued. A disinfection cycle that has been stopped must be manually restarted using the normal error restart procedure after the required temperature has been reached.

Watchdog Circuitry

A watchdog circuit has been implemented on this equipment to monitor its operational status. If the equipment fails to operate as expected, the watchdog circuit resets the processor and causes the program cycle to be reinitiated at the point that the failure occurred.

This circuit makes the device immune to failures that could be caused by the harsh electrical and magnetic impulse noise that is often present in the hospital/industrial environment.

Status Logging

The DSD-91™ automatically logs the device usage history, error status, and other statistics as significant events occur.

This log can be manually examined through the use of the control panel function keys and LCD.

RS-232 Interface (Optional)

The DSD-91™ offers an optional RS-232 interface that allows off-loading of the device log to other media (usually an IBM compatible personal computer).

Nonvolatile Memory

The DSD-91™ device log is maintained in nonvolatile memory. This means that under most circumstances, the device log will be retained even if the computer system requires repair or replacement.

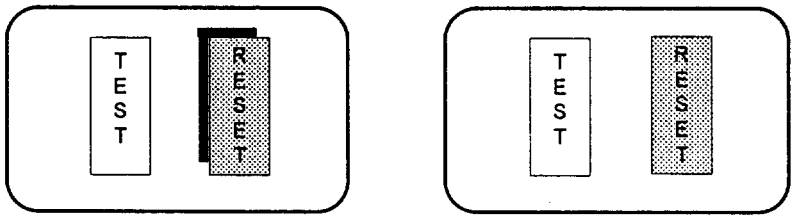
100% Solid-State Electronics

The electronic control system for this device is completely solid state. This significantly increases reliability and aids in reducing electromagnetic interference and emissions caused by the switching of high-current equipment.

Special electronics have been included to insure that AC line-driven valves, motors, and heaters are switched on and off during the optimal portion of the AC line cycle.

Circuitry

Designed to eliminate burnout. Automatic Ground Fault Interrupter (GFI) is included.



If RESET button is out or tripped as shown above, simply push RESET button in.

Illustration 2–1

The GFI is a safety feature designed to protect the unit from power overloads. It is located inside the cabinet toward the bottom of the unit.

Depot Maintenance

Repair of electronics are accomplished by swapping the entire computer motherboard in order to minimize down time due to electronic failure.

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The motherboard has been designed to distribute line, control, and logic voltages to the entire system via an extremely efficient and reliable mechanism.

This distribution mechanism uses four wiring harnesses and one or two ribbon cables (depending on options selected) as illustrated in figure 2-2 below.

(1) The system line harness

This harness contains all cables necessary for the 110/220 VAC line voltage distribution system. It is attached to the mother board using a single 4-pin, locking, quick disconnect socket.

(2) The control and logic supply harness

This harness contains all cables necessary for providing the system with the 5-volt logic supply and the 24 VDC control supply. It is attached to the mother board using a single 6-pin, locking, quick disconnect socket.

(3) The station control harness

This harness contains all cables required for operating the valves, motors, pumps, and heaters for both of the stations. It is attached to the mother board using three 15-pin, locking, quick disconnect sockets.

(4) The station sensor and alarm harness

This harness contains all cables required to sense disinfectant levels, disinfectant temperatures, as well as the audible alarm. It is attached to the mother board using a 20-pin friction-fit socket.

(5) The control panel ribbon cable

This ribbon cable contains all of the power, ground, and logic signals required to interface with the control panel. This cable uses a standard 40S-40S-IDE ribbon cable.

(6) The optional RS-232 ribbon cable

This ribbon cable contains all of the standard RS-232 signals required to interface with most IBM compatible personal computers. One end of this cable 6-pin friction-fit socket, and the other end is connected to a 9-pin D-sub socket that is accessible via the front control panel of the DSD-91™ system.

Functional Features

Standard Delivered Cycle Time

The standard (nominal) cycle is preprogrammed at the factory and is approximately 20 minutes including a 10 minute disinfectant cycle. Cycle times may be easily reprogrammed by the user to meet specific installation needs.

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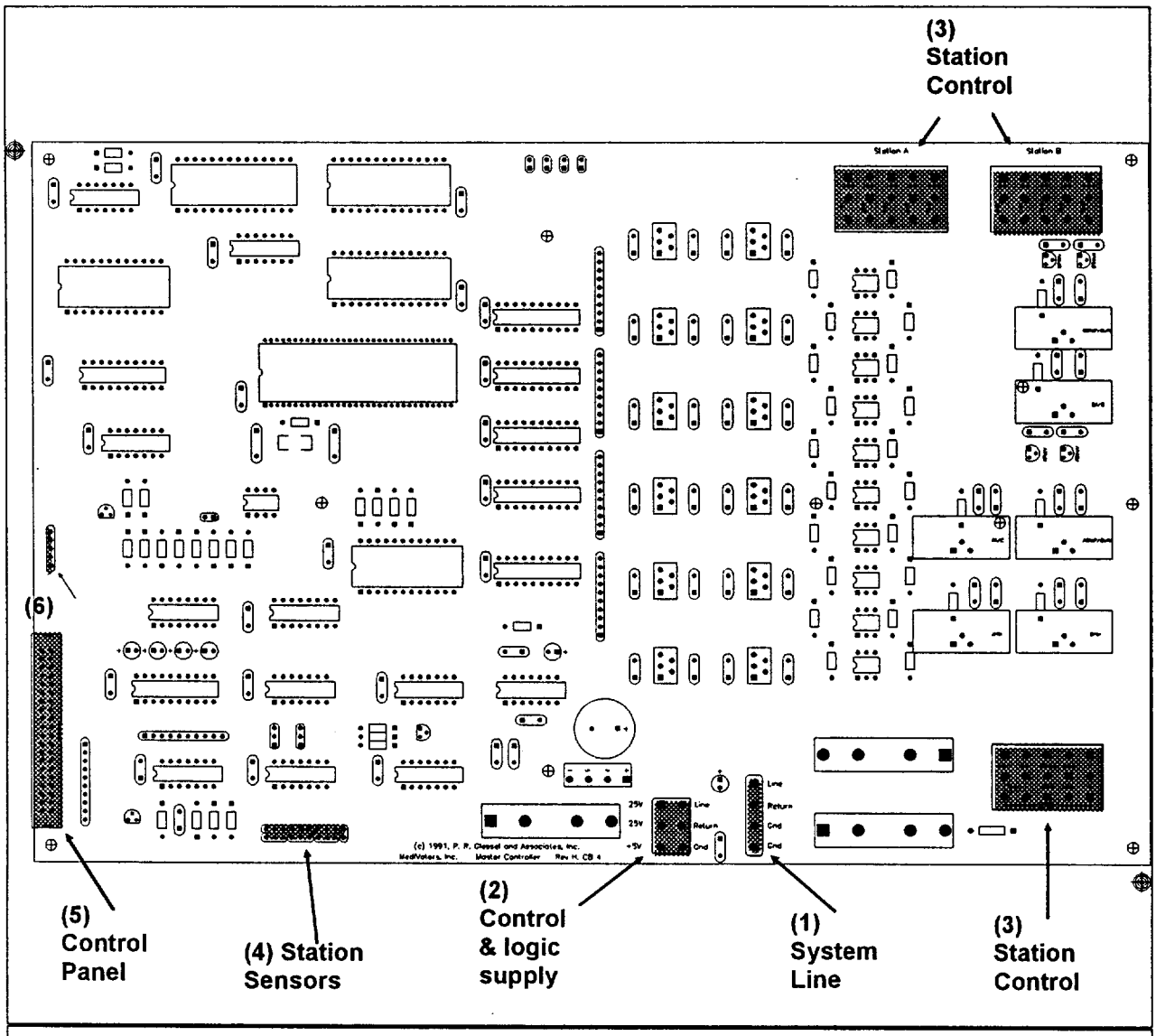

Illustration 2—2

Compressed Air Purge

Integrated into the disinfect and rinse cycles to minimize loss and dilution of the disinfectant.

Alcohol/Air Purge

Available to aid in end-of-day channel drying.

CAUTION

See endoscope manufacturer's comments regarding the use of alcohol.

Diagnostic aids

The DSD-91™ has been designed to facilitate isolation and repair of faults in the field.

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All valves, motors, and pumps can be individually exercised by field maintenance personnel using a special diagnostic port access mechanism. This allows rapid isolation of individual electromechanical parts.

Programmed Features

The DSD-91™ Disinfector is an integrated system designed to disinfect and rinse all flexible endoscopes without requiring the presence of an attendant during the disinfection process.

Cycles: Nominal

The first 30 seconds of flow for each cycle is directed through the scope channels only. This helps prevent air lock within the small scope channels. If air becomes trapped in a channel, it will block the flow of disinfectant and rinse water into that channel.

NOTE

Disinfectant is circulated through the biopsy/suction, air, water, and colonoscope CO_2 channels.

Flush Cycle

Detergent and water are flushed through the interior channels to insure that channels are not clogged. This water goes to the drain.

Purge Cycle

After draining, the scope channels and unit lines are purged by compressed air.

Disinfect Cycle

Disinfectant is pumped through the scope channels and into the scope chamber. This cycle has two phases. The " A" phase is used to fill the upper chamber and circulate disinfectant around the entire scope. During the first 30 seconds of the " A" phase, and for the entire " B" phase, disinfectant flow is concentrated through the scope channels. At the end of this cycle, the disinfectant is drained from the scope chamber and returned to the reservoir.

Rinse Cycle

Water is circulated around scope insertion tube and pumped through the interior channels. The first 30 seconds of flow is to the scope channels only. During and after the RINSE cycle, water is drained and discarded.

At completion of the total cycle time, the endoscope is ready for reuse. Note that 15-20 minutes of compressed air drying of channels should be done before end-of-day storage.

Alcohol Purge Cycle

An " on demand" ALCOHOL PURGE cycle is built into the system to aid with end-of-day drying.

CAUTION

See endoscope manufacturer's comments regarding the use of alcohol.

User Modifiable Program Cycles

There is one standard, and up to nine user modifiable programs. The user modified programs are stored in nonvolatile memory.

Each program has six cycles. Each of these cycles may have their length altered as described in the table on the next page.

As a result of the unique method used to record this information, all custom programs and other user defined settings are retained even if the computer motherboard has to be repaired or replaced (except when the nonvolatile memory itself has failed).

Individual Temperature Control (Optional, not available in U.S.A.)

Each station has its own heater and temperature sensor. The DSD-91™ allows individual minimum, maximum, and shutdown temperature settings to be maintained for each disinfectant reservoir.

If the disinfectant temperature falls below the minimum temperature setting for that station, the heater is turned on until the maximum temperature has been reached. If the reservoir falls below the shutdown temperature, operation is halted for that station until corrective action is taken.

Typically, the shutdown, minimum, and maximum temperatures will be set to within one degree of each other. For example, if the target temperature required for a disinfection protocol is 120° F, the shutdown temperature is set at 119° F, the minimum temperature is set at 120° F and the maximum temperature is set at 121° F.

The temperature sensors are accurate to within 1° F.

- **NOTE: Follow disinfectant manufacturer labeling when determining required temperature.**

Programmed Heater Startup and Shutdown

The DSD-91™ has a unique feature that allows the optional reservoir heaters to automatically be turned on at the beginning, and to be shut off at the end of the normal work day.

This feature conserves the energy used by the heater to maintain the disinfectant temperature, while assuring that the reservoir temperature will be high enough at the time that the first disinfecting procedure of the day is started.

DSD-91™ Standard Program				
Cycle	Time	Description	Min	Max
(1) Pre Disinfect	30 Sec	Flush detergent through scope channels with water	0 Sec	90 Min
	5 Sec	Compressor startup	factory set	factory set
	30 Sec	Air purge of scope channels	factory set	factory set
(2) Disinfect	30 Sec	Scope channel flush with disinfectant	factory set	factory set
	5 Min	Scope chamber fill and circulation	5 Min	90 Min
	10 Min	Scope channel disinfect	10 Min	90 Min
	65 Sec	Disinfect drain	factory set	factory set
	5 Sec	Compressor startup	factory set	factory set
	30 Sec	Air purge of scope channels	factory set	factory set
(3) Rinse 1	30 Sec	Scope channel flush with water	factory set	factory set
	4 Min	Water rinse	4 Min	90 Min
	65 Sec	Drain	factory set	factory set
	5 Sec	Compressor startup	factory set	factory set
	30 Sec	Air purge of scope channels	factory set	factory set
(4) Rinse 2	30 Sec	Scope channel flush with water	factory set	factory set
	4 Min	Water rinse	0 Min	90 Min
	65 Sec	Drain	factory set	factory set
	5 Sec	Compressor startup	factory set	factory set
	30 Sec	Air purge of scope channels	factory set	factory set
(5) Alcohol	0 Sec	Scope channel flush with alcohol	0 Sec	120 Sec
	5 Sec	Compressor startup	factory set	factory set
	30 Sec	Air purge of scope channels	factory set	factory set
(6) Air	5 Min	Scope channel flush with compressed air	0 Min	90 Min

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Chapter 3
Operation

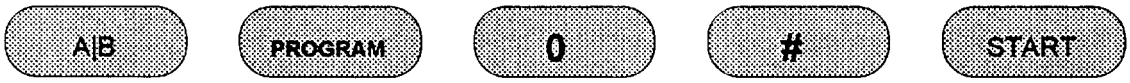
The operation of the DSD-91™ has been designed to be simple for those installations that require only the standard disinfecting protocol, while retaining enough flexibility to meet the most demanding of protocol variations for complex installations.

Specific instructions for operating the equipment are described in this section. This section is organized by topic and specific keystroke sequences are specified.

Conventions for describing various keystrokes are as follows:

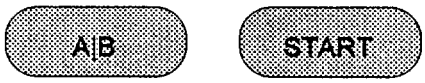
A|B	The selection of the A, B, or A/B stations by depressing one of the three station select keys.
Number	The entry of a number by using one or more keystrokes on the numeric portion of the keypad.
#	The " enter" key generally used to indicate acceptance of a numeric data series.
SCOPE	The SCOPE NUMBER key used to allow the entry of an identifier denoting the endoscope.
PROGRAM	The PROGRAM key used to allow the selection of a specific disinfecting protocol.
ADD AIR	The ADD AIR key used to extend the air dry cycle for an endoscope.
START	The START key used to start the selected disinfect protocol.
HEATER	The HEATER ON key used to enable the optional disinfectant reservoir heaters.
DUMP	The DISINFECTANT DUMP key used to unload disinfectant from the reservoir.
STOP	The STOP key used to suspend current station activity.
SETUP	The SETUP key used for various auxiliary operations.
*	The CANCEL key used to erase numeric data that has been entered, or to cancel the currently running disinfect program protocol.

Run Default Disinfect Protocol



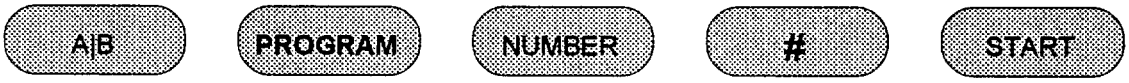
Operation using the default protocol where logging of individual scopes is not required is as simple as selecting the desired station, selecting factory default program 0, pressing the start key, and waiting for the cycle to complete.

Shortcut



If the program selected for that station is already 0, or if none of the programs have been user altered, then you may simply select the station and press the start key.

Run Selected Disinfect Protocol



Operation using a selected protocol where logging of individual scopes is not required is accomplished by using the PROGRAM key to select the specific, user-defined disinfect protocol.

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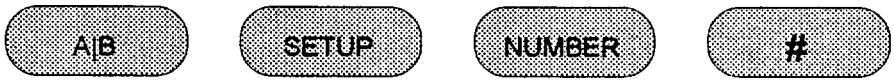
Log Endoscope With Selected Protocol

This sequence is used to log a specific endoscope with the following disinfecting procedure. The sequence following the # key is one of the protocol run selection sequences described above, starting AFTER the station selection key.

Depressing the A,B, or A/B station selection keys clears the endoscope number. This is to insure that an endoscope that has been logged for a previous procedure does not inadvertently become logged with the current procedure.

Set Up



This sequence is used to set permanent options, read-out usage log, and load the disinfectant reservoir.

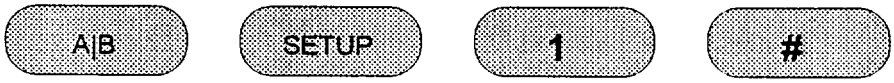
To enter the setup mode, both stations must be in the IDLE state. This is because most of the available setup functions (such as set date and time) affect the operational status of both of the system's station and could cause logging errors or other system failures if they were changed while a station was in operation.

Observe the setup LED when the SETUP key is depressed, and the LCD prompt.

Note that depressing the STAR key while in this mode will erase the numeric data entered, allowing it to be re-entered.

The following functions are all entered through the SETUP key as described above.

Load Disinfectant



This function is used to load fresh disinfectant into the selected station's reservoir.

Prior to starting this function, insure that the reservoir is empty.

To load disinfectant, load 2½ gallons of fluid into the appropriate upper chamber.

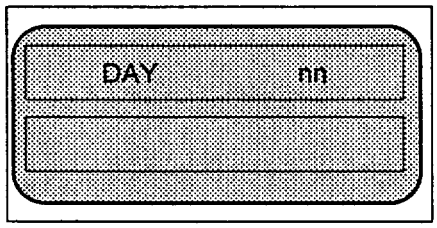
Start the load sequence adding the remaining fluid as the chamber level drops.

Set Date

This function is used to set the date in the system clock/calendar. This function requires multiple screen interactions to complete.

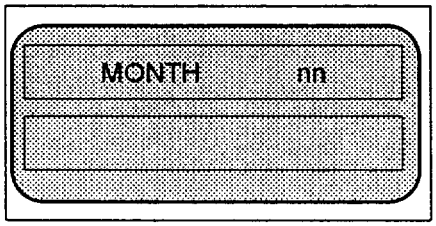
Screen 1, Set Day:

If the day displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct day. When the proper day has been entered, press the #-key.



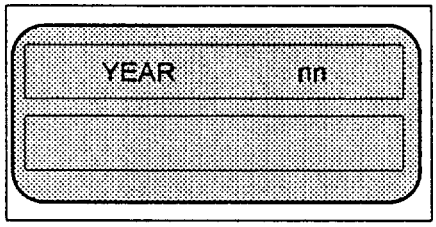
Screen 2, Set Month:

If the month displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct month. When the proper month has been entered, press the #-key. The valid numbers are 1-12.



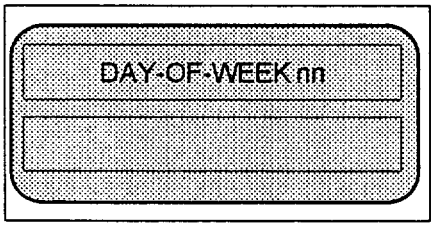
Screen 3, Set Year:

If the year displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct year. When the proper year has been entered, press the #-key. The valid numbers are 90-99 and 0-09.



Screen 4, Set Day-of-Week:

If the day-of-week displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct day-of-week. When the proper day-of-week has been entered, press the #-key. The valid numbers are 1-7 and Sunday is the first day of the week.



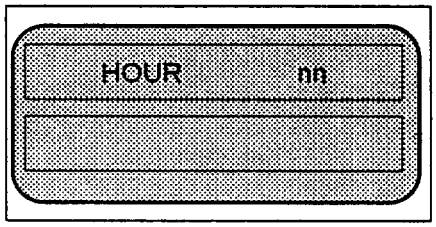
Set Time

SETUP 3 #

This function is used to set the time on the system clock/calendar.

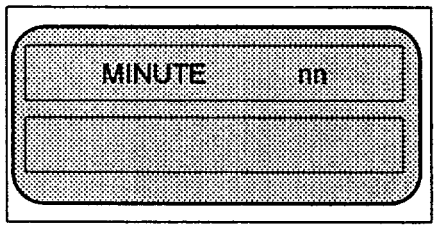
This function requires multiple screens to complete.

Screen 1, Set Hour:



If the hour displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct hour. When the proper hour has been entered, press the #-key. The valid numbers are 0-23.

Screen 2, Set Minute:



If the minute displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct minute. When the proper minute has been entered, press the #-key. The valid numbers are 0-59.

The seconds portion of the time is automatically set to zero.

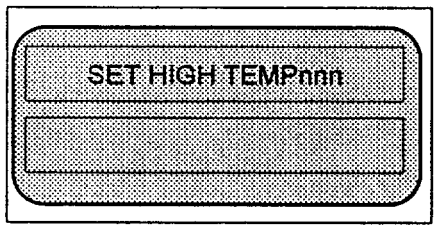
Set Custom Temperature

A|B SETUP 4 #

This function is used to set the target disinfectant temperature to custom installation values. This function is effective only for those installations with the advanced heater control option.

Note: This feature not available in the U.S.A. or its territories. Follow disinfectant manufacturers labeling for determining proper temperature settings.

Screen 1, Set High Temp:



This screen is used to set the target temperature for the selected station. When this temperature is reached, the heating element is turned off.

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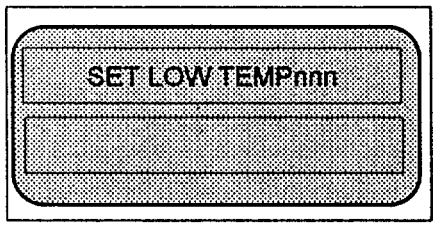
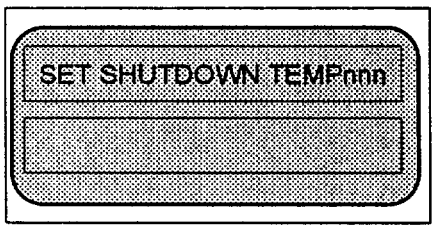
Screen 2, Set Low Temp:

This screen is used to set the minimum temperature for the selected station. When the reservoir temperature drops below this setting, the heating element is turned on.

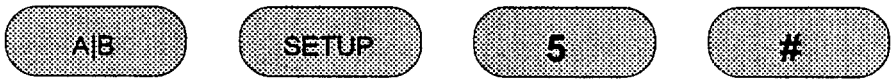


Screen 3, Set Shutdown Temp:

This screen is used to set the minimum acceptable temperature for this station. If the reservoir temperature falls below this setting, the station is forced to suspend its current operation and a warning alarm is sounded.



Set Custom Program



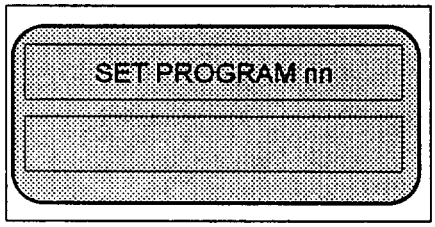
This function allows custom alteration of cycle times to be set for an installation.

All programs are set to the factory default when the system is shipped.

Creating a custom program protocol is a multi-screen operation.

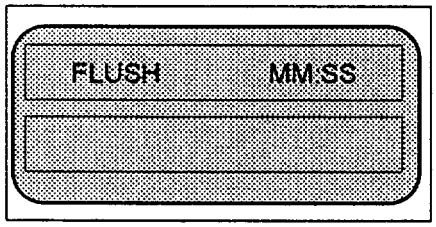
Screen 1, Set Program nn:

This screen is used to select the program that is to be altered. The valid programs that may be altered are 1-9. Program 0 cannot be altered and will always remain at the factory default setting.



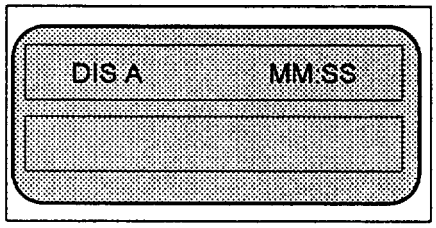
Screen 2, Flush:

Set the FLUSH cycle time.



Screen 3, Dis A:

Set the disinfect A cycle time. This cycle comprises disinfectant loading into the upper chamber and chamber circulation.



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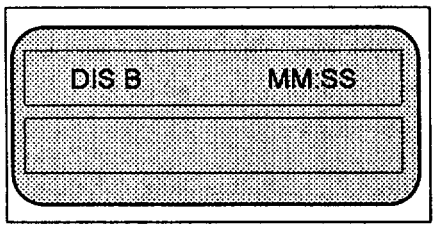
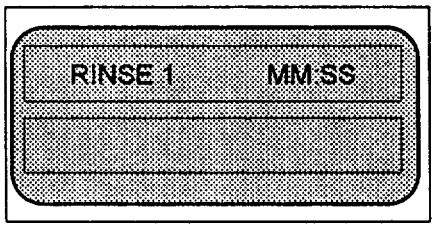
Screen 4, Dis B:

Set the disinfect B cycle time. This cycle circulates disinfectant through the scope channels only.



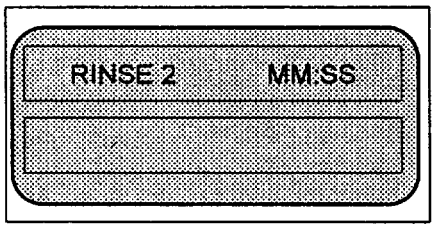
Screen 5, Rinse 1:

Set the RINSE 1 cycle time.



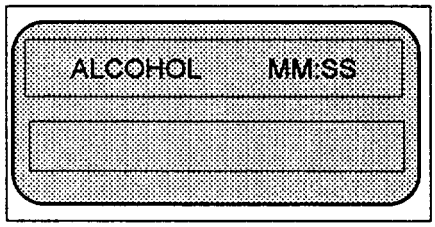
Screen 6, Rinse 2:

Set the RINSE 2 cycle time.



Screen 7, Set Alcohol:

This screen is used to enable or disable the alcohol dispensing prior to the AIR cycle.

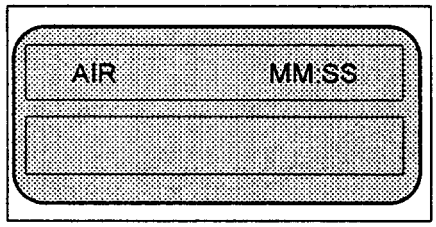


CAUTION

See endoscope manufacturer's comments regarding the use of alcohol.

Screen 8, Set Air:

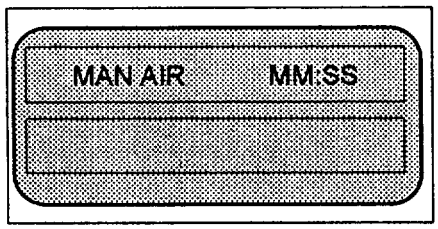
This screen is used to set the AIR cycle time.



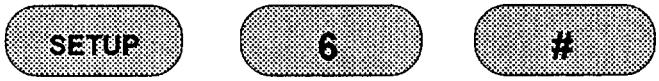
Screen 9, Set Manual Air:

This screen is used to set the MANUAL AIR cycle time. The MANUAL AIR cycle is added whenever the ADD AIR key is depressed.

Note that if any cycle time is already correct, setting that program cycle may be skipped by pressing the #-key without entering any numbers.

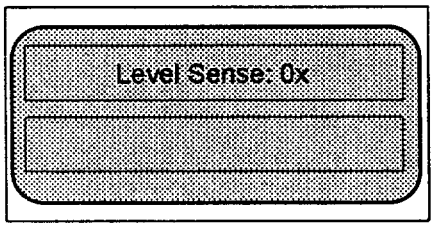


Inhibit Fluid Level Sensors



This function is used to disable the fluid level sensors.

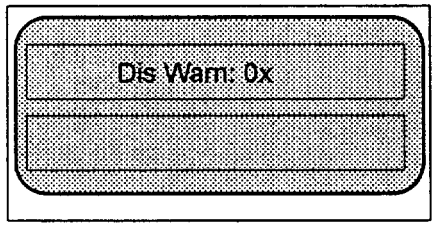
00: enable all level sensors
01: disable station A level sensors
02: disable station B level sensors
03: disable all level sensors



Disinfectant Cycle Warning Override

This function is used to acknowledge the disinfectant cycle count warning. After the warning is acknowledged, 10 additional disinfection cycles will be allowed.

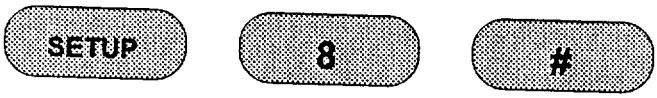
00: No disinfection cycle warning acknowledged
01: Station A warning acknowledged
02: Station B warning acknowledged
03: Both station warnings acknowledged



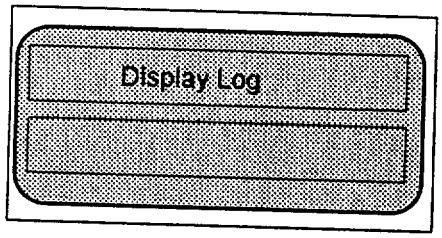
The DSD-91 is designed to prevent an excessive number of disinfection cycles from being run on a batch of disinfectant. The system will not be allowed to start a disinfection program when the number of disinfection cycles that has been run is ten less than the maximum number of cycles allowed until the warning is acknowledge using this function.

Note: This warning is valid only when the maximum disinfection cycle count has been set to an appropriate value. The default maximum number of disinfection cycles is 50, and the warning occurs at 40 cycles.

Display Log



This function is used to review the log on the display. The entire log is displayed in most recent to least recent order, one entry at a time. As the ENTER key is pressed, the next oldest entry is displayed in order until all entries have been displayed, or until the SETUP key is pressed to exit the display function.

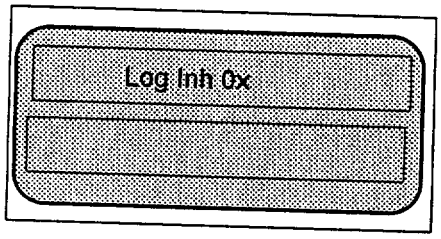


Log Inhibit

This function is used to disable the data logging function.

This function is used only in the unlikely event that the logging function causes the system to malfunction.

00: enable data logging
01: disable data logging

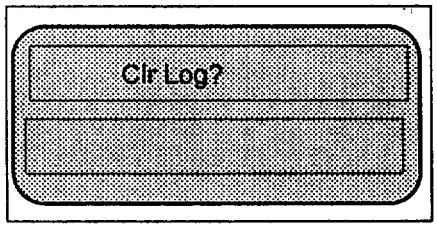


Clear Log

SETUP | 10 | #

This function is used to clear the data log. This must be done periodically to allow new data entries to be made.

To actually clear the log, press start when this screen appears. Any other key causes the operation to be canceled.

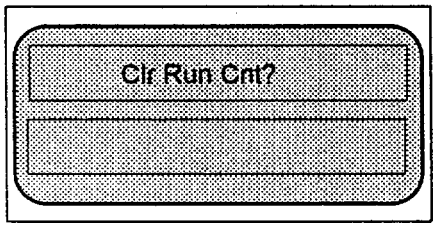


Clear Run Count

A|B | SETUP | 11 | #

This function is used to clear the disinfection cycle count for the selected station. Under normal circumstances, this is used only when the disinfectant has been loaded manually.

Note: Improper use of this function will invalidate the disinfection cycle count warning feature.



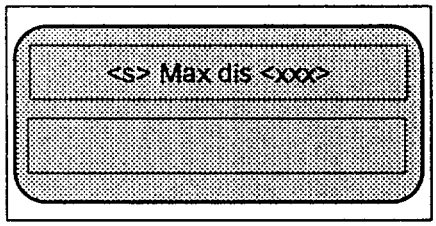
Set Maximum Disinfection Cycle Count

A or B | SETUP | 12 | #

This function is used to set the maximum number of disinfection cycles that can be run by the selected station before a new batch of disinfectant must be loaded.

Note: The maximum disinfection cycle count must be set according to disinfectant manufacturer's specifications.

The symbol <s> is the selected station, and the symbol <xxx> is the current count.



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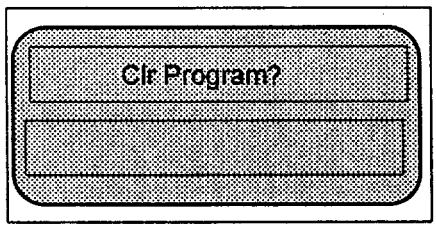
Reset User Program

SETUP 13 #

This function is used to reset the user defined programs to the factory default settings.

To clear the user customized programs, press start when this screen appears. Otherwise, press any other key to cancel the request.



Set Heater On Time of Day

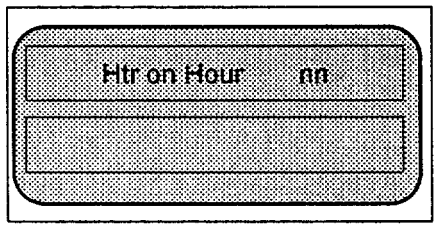
SETUP 14 #

This function is used to set the time of day to automatically turn on the optional reservoir heater elements.

This function requires multiple screens to complete.

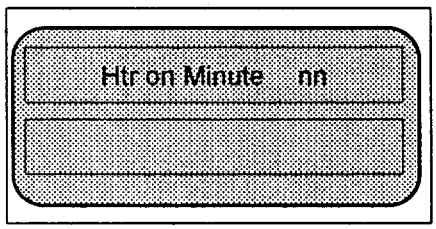
Screen 1, Set Hour:

If the hour displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct hour. When the proper hour has been entered, press the #-key. The valid numbers are 0-23.



Screen 2, Set Minute:

If the minute displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct minute. When the proper minute has been entered, press the #-key. The valid numbers are 0-59.



The seconds portion of the time is automatically set to zero.

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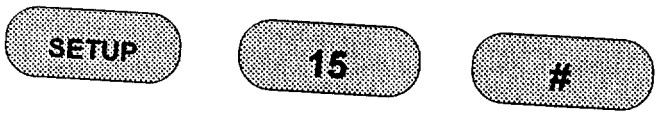
Set Heater Off Time of Day

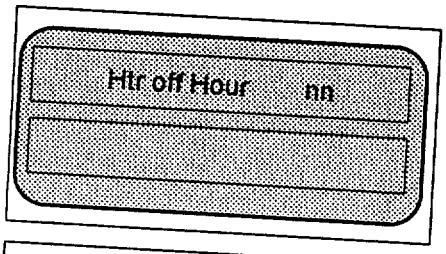


This function is used to set the time of day to automatically turn the optional reservoir heaters off

This function requires multiple screens to complete.

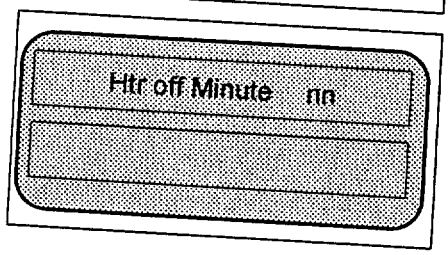
Screen 1, Set Hour:

If the hour displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct hour. When the proper hour has been entered, press the #-key. The valid numbers are 0-23.



Screen 2, Set Minute:

If the minute displayed is correct, depress the #-key, otherwise, use the numeric keypad to enter the correct minute. When the proper minute has been entered, press the #-key. The valid numbers are 0-59.



The seconds portion of the time is automatically set to zero.

Standard Operation

The scope should be free of residual protein prior to disinfection. Pre-cleaning of the scope should include brushing of the suction/biopsy channel in universal cord and insertion tube.

Note: Proper placement and hook up of the endoscope is essential.

1. Remove all channel valves and block the ports with the appropriate fittings (see separate Hookup Instruction Sheet).
2. For non-immersible scopes, use lift stand for the head of the endoscope. Umbilical connector is to be placed in the concave receptacle located at the center of the insert (Illustration 3-1).
3. For immersible scopes, coil the entire instrument in the " Qwik-load" insert.
4. Attach the channel connectors to fittings on umbilical connector. Open the scope shutoff valves. Place Qwik-load insert into the DSD-91™ (Illustration 3-2). Connect Qwik-load fitting to disinfecting chamber (Illustration 3-3).

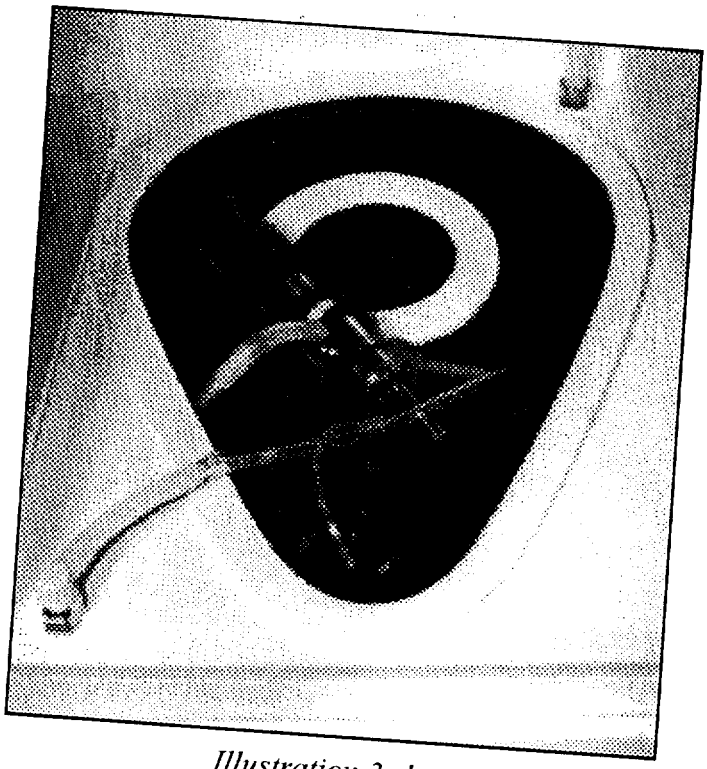


Illustration 3–1

Illustration 3–2

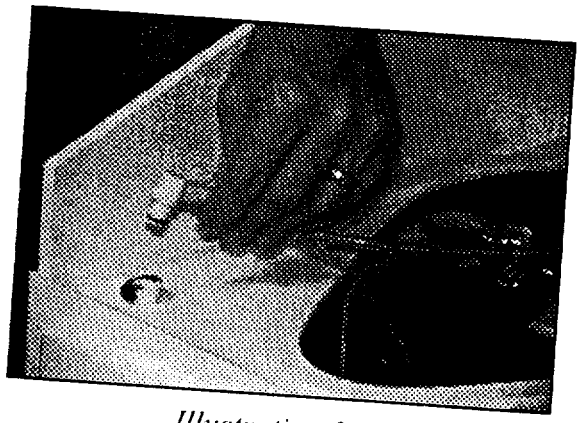


Illustration 3–3

CAUTION

If the scope shutoff valve is not open, the interior scope channels will not be disinfected.

5. The distal end of the scope can be turned to observe channel exit while in the scope chamber.
6. Select stations.
7. Press the START button on the control panel and observe initiation of program. Insure that a proper seal on scope connections and plugs has been made.
8. To insure that the scope channels are not blocked, observe the lines connected to them for movement of disinfectant into the scope channels. Watch the distal end of the scope until disinfectant is seen coming from the channel exits. Check the channel fittings and clamps for proper placement and seal.

   The disinfector will process the scope without any further attention from the operator.

   The status of the disinfecting process will be displayed on the control panel. When the program is finished, the operator may proceed.

NOTE

If additional purging with air is desired, press the MANUAL AIR button on control panel.

9. Remove the channel connections from the universal cord.
10. Remove Qwik-load insert from the upper tanks.
11. Remove the endoscope from the Qwik-load insert.
12. Before use, seat valves and plug scope into a light source. Turn on light source to clear residual water from air channel. A spray of water should be seen exiting from the air/water valve at the control head.

The endoscope should be cultured after the first cycle in DSD-91™ Disinfector, to assure the unit is working properly and all channels are being disinfected.

IMPORTANT

Culture testing should be done on a regular basis thereafter as part of your quality assurance program.

Process Interruption

The disinfecting process will stop if:

1. The STOP button is pressed (e.g., activated by operator when an error in the scope hook-up has been observed).
2. The unit senses a high or low fluid level in reservoir. The appropriate reservoir HIGH or LOW indicator on the control panel will light, and an intermittent audible alarm will sound. Either condition must be corrected before the unit will restart. If this problem continues, call MediVators, Inc. (1-800-537-7324).

NOTE

Certain brands of disinfectants may foam. Foaming disinfectant may contact sensor prematurely causing an erroneous high level sensor. Call MediVators, Inc., for more information (1-800-537-7324).

3. The Hospital' s circuit breaker or fuse for the unit' s power has tripped. Reset circuit breaker or replace fuse. Call your maintenance department.
4. The unit' s Ground Fault Interrupter (GFI) has tripped. Press the red RESET button located inside bottom of unit (see page 2-3, Illustration 2-1).

Recovery from Process Interruption

The interrupted program can either be resumed or terminated. To resume the program, press the START button. The program will resume at the point of interruption.

To terminate the program, press the RESET button. This will abort the cycle in process. Depending upon the phase of the cycle which has been interrupted, disinfectant will empty from the scope chamber to the reservoir or water will empty to the drain. When all fluid has drained from the scope chamber and the station is idle, the next operation may be started.

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Disinfectant Change

A warning stop message indicates that the disinfectant has been used the maximum number of times allowed.

Note: this warning is effective only if SETUP OPTION 12 (SET MAX DIS CYCLES) has been set in accordance with the manufacturer's instructions for the disinfectant being used.

This message indicates that the disinfectant is reaching the end of its rated life which could make it ineffective for high level disinfection.

The disinfectant should be tested at this time for dilution and effectiveness. Glutaraldehydes can be easily tested for dilution using available test kits.

If the test results are satisfactory, SETUP OPTION 7 may be used to inhibit the warning stop for an additional 10 cycles.

The default disinfection cycle limit is 50 cycles, but may be altered as appropriate by using setup option 12 (SET MAX DIS CYCLES).

To Change Disinfectant

CAUTION

Follow instructions and heed all warnings on the chemical disinfectant.

1. Depress the DISINFECTANT DUMP button, followed by the START button. Disinfectant will be pumped up into the scope chamber and flow out the drain. Total cycle time is approximately four minutes. An audio alarm will sound at completion of the cycle.
2. Remove Qwik-load insert and wipe out with a damp cloth.*
3. Wipe out reservoir with a damp cloth.*
4. Replace disinfectant filter (see page 3-17, Illustration 3-4).
5. Fill the appropriate chamber with the disinfectant. Activate the DISINFECTANT LOAD function from the top control panel.
6. The date and time of the disinfectant change is automatically recorded in the system log.
7. Prime the appropriate pump.

---

* Do not use paper towels. Gloves should be worn.

Disinfectant Filter Replacement

CAUTION

The disinfectant filter should be changed at least twice a month (or more frequently in high use facilities) or when disinfectant is changed.

Replacement Procedure

1. Remove clamp (C1) from end of filter. Use ¼" nut driver.
2. Remove hose from end of filter.
3. Replace with new filter (arrow indicator as shown in Illustration 3-4).

CAUTION

Failure to install filter correctly (see arrow for direction of flow) will impair efficiency of operation in disinfectant cycle.

4. Reattach the hose and clamp per Illustration.
5. Repeat steps 1-4 for clamp C2.
6. Prime the pump.

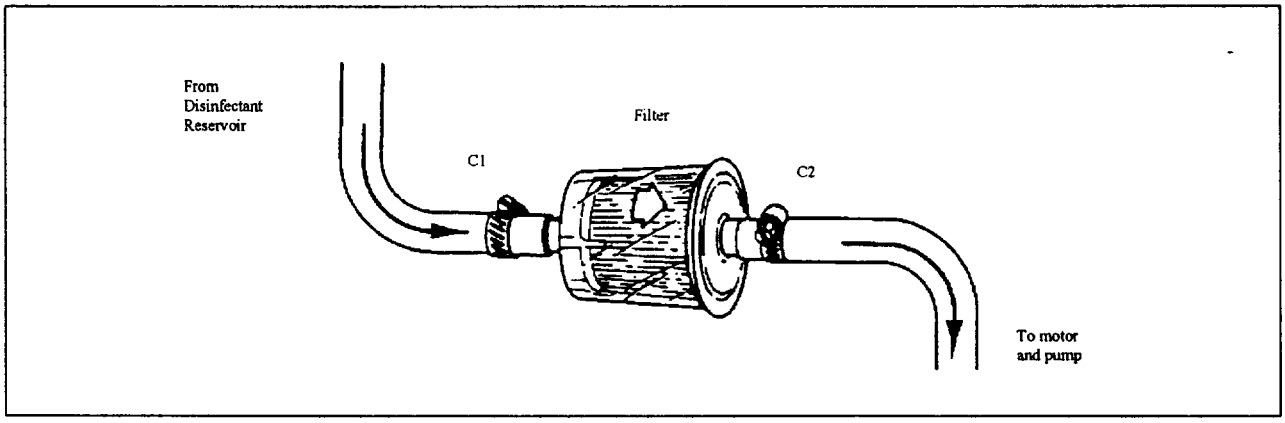

Illustration 3–4

NOTE

Additional disinfectant filters can be ordered from MediVators, Inc.

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Sediment Water Filter Replacement

CAUTION

The sediment water filter must be checked periodically for particle saturation. It should be changed at least every 45 days. Saturation of filter will cause inadequate water pressure in the device.

Replacement Procedure

1. Shut off water supply to filter.
2. Place container under filter to catch excess water.
3. Loosen base of filter assembly slowly to relieve pressure.
4. Unscrew base, remove filter, and replace filter.
5. Tighten base of filter, turn on water supply.

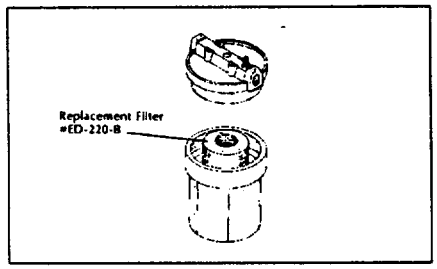

Illustration 3–5

NOTE

Additional water filters can be ordered from MediVators, Inc.

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Sterapore Filter Instructions

CAUTION

The Sterapore filter should be replaced every 6 months, or sooner if a diminished water flow is apparent.

1. Shut off water supply to system.
2. Locate filter in the bottom center of the system cabinet. Place container under filter to catch remaining water (Illustration 3-6).

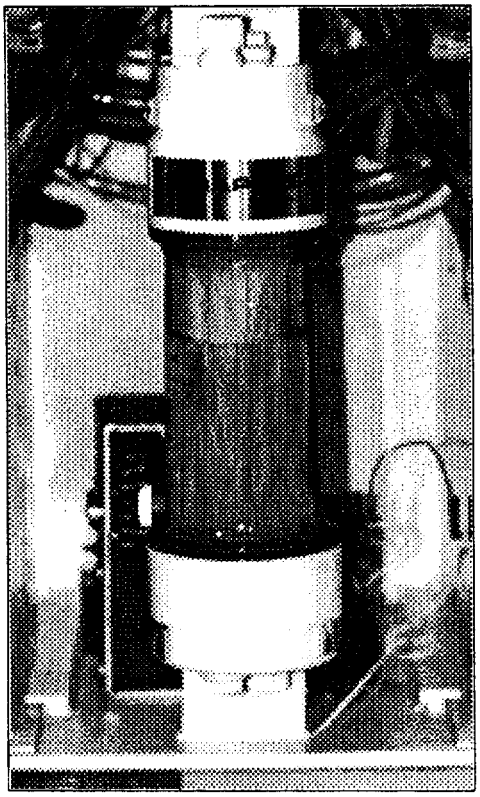

Illustration 3–6

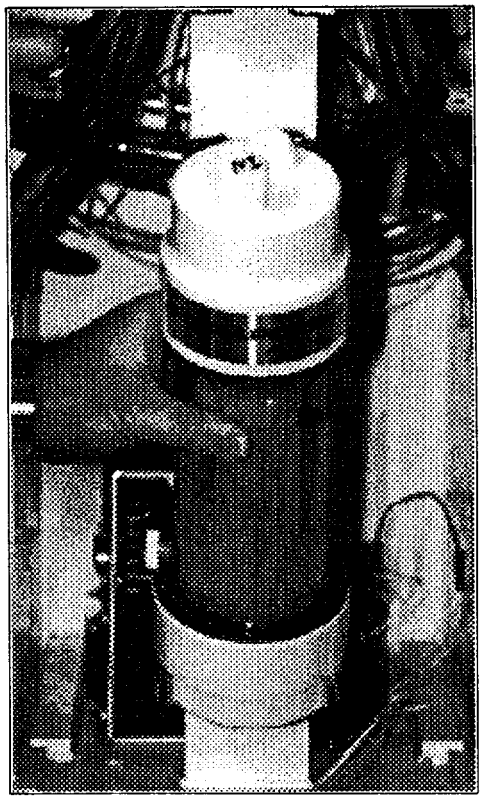

Illustration 3–7

3. Loosen bottom fitting to water distribution hose slowly to relieve pressure. Disconnect hose fitting and allow water to drain.
4. Disconnect top fitting to water supply.
5. Grasp filter assembly (Illustration 3-7) and remove from bracket.
6. Place new filter in bracket and reverse procedure to connect water supply and distribution lines.
7. Turn on water observing for leaks.

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Initial Break-In Procedure

Perform a trial run with water and tubing to simulate the endoscope to insure that the system is in functioning order. This initial break-in procedure should be repeated through several complete cycles to observe retained reservoir fluid level.

To perform a trial run:

1. Load the reservoir with water using the procedure described under " Load Disinfectant" on page 3-3.
2. The pump may need to be primed. To prime pump, the machine must be turned off. Use the bleeder valve located at the bottom of the unit directly above each pump. Open the bleeder valve by turning it counterclockwise. Disinfectant will come out of the valve when the pump is primed, so use a small container to catch this.

   The pump should be primed after changing the disinfectant and after changing the disinfectant filter.
3. Refer to standard operation instructions (page 3-13) and begin the break-in cycles.
4. Check and observe the flow through the scope during the DISINFECT, AIR, and RINSE cycles.
5. Check the water pressure gauge on the incoming water line. Pressure should be at 35-40 p.s.i.

   6. Check the pressure gauges inside the DSD-91 cabinet while in the FLUSH cycle with scope attached. Pressure should be at 17-20 p.s.i.
7. Check for leaks to insure that all connections are intact.
8. Remove the scope and hold it vertically. Check to see if water has been removed from the channels (a few drops are acceptable).

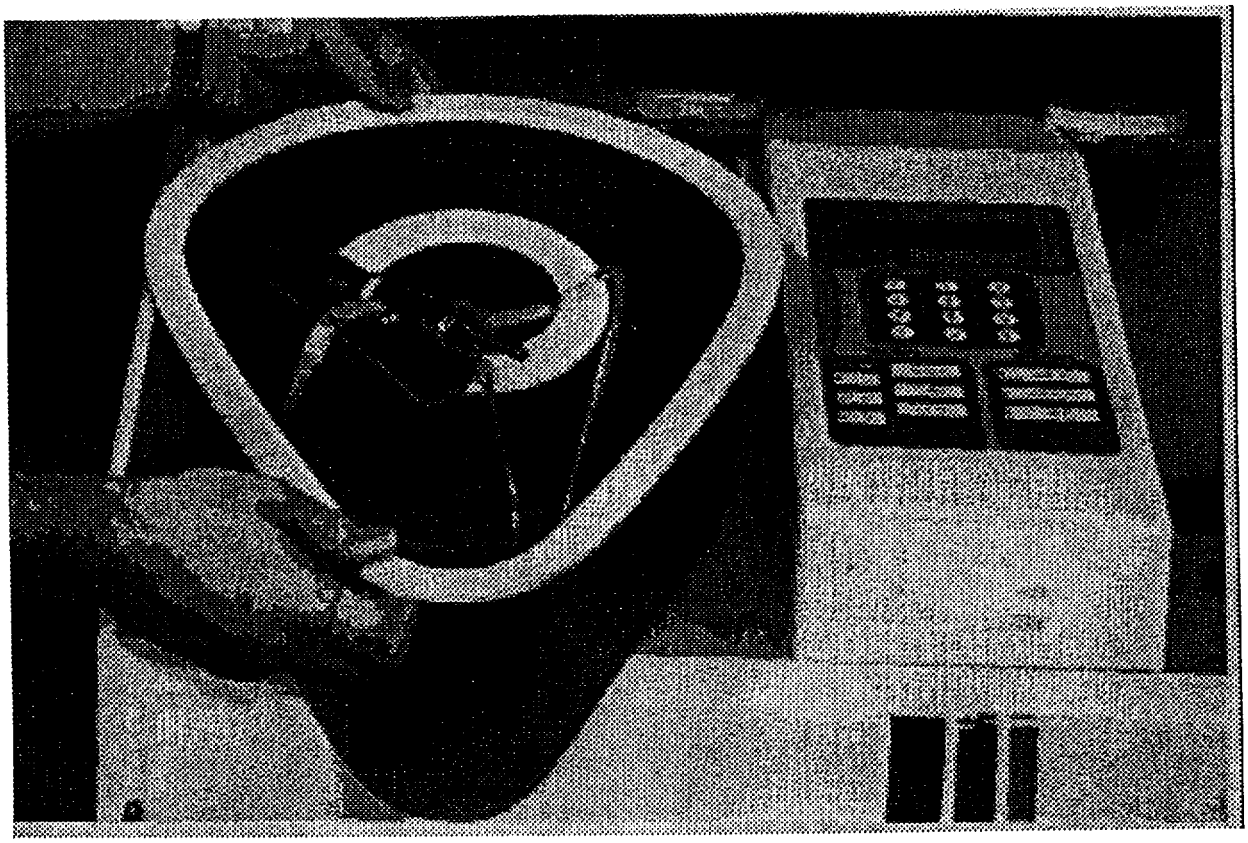
Proceed to the DUMP cycle, and then proceed with standard operation by loading disinfectant.

App. E

Third Party BioBurden Reports (b) (4)

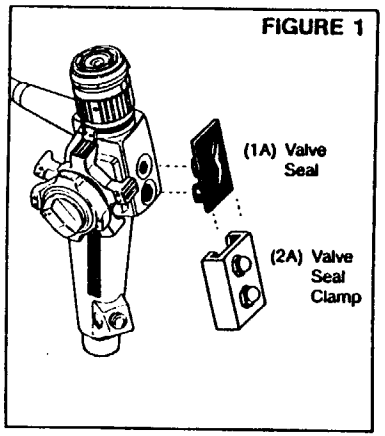
Third Party BioBurden Reports (b) (4)

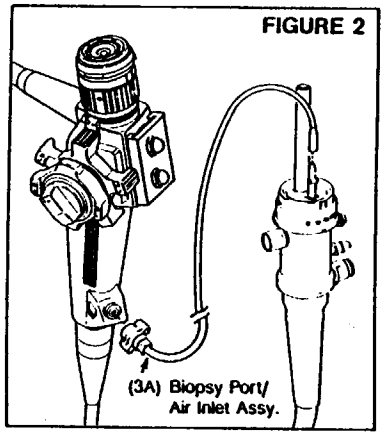
App. F



This is the "Quik-Load" Insert

HOOK-UP INSTRUCTIONS FOR UPPER ENDOSCOPES





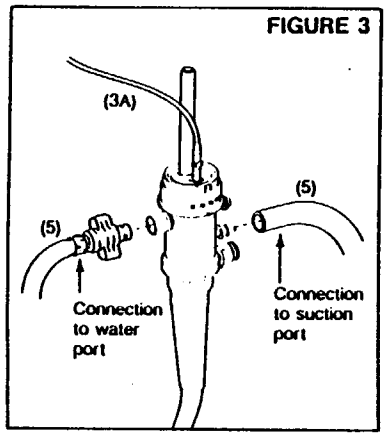
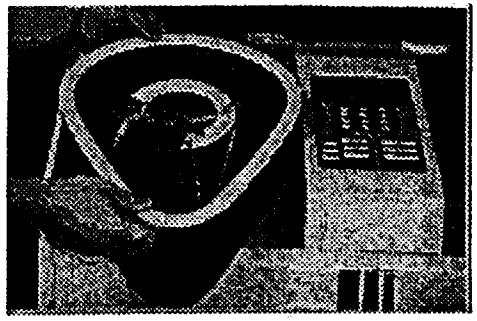


FIGURE 1: After removing air/water, suction valves from instrument, place the valve seal (1A) on valve openings. Hold in place and slide seal clamp (2A) over seal. Finger tighten bottom screw, then finger tighten top screw.

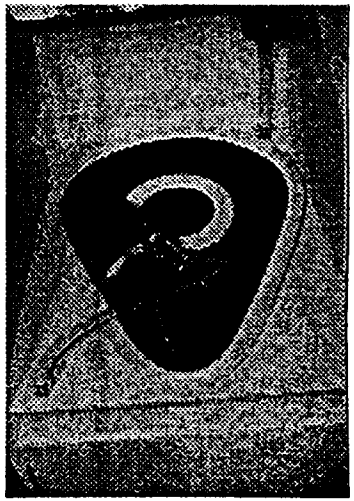
FIGURE 2: Connect the biopsy port/Air inlet tube assembly (3A) to biopsy port and air inlet port.

FIGURE 3: Connect disinfector hook-ups (5) to water port and suction port. The water port adapter must be firmly inserted.

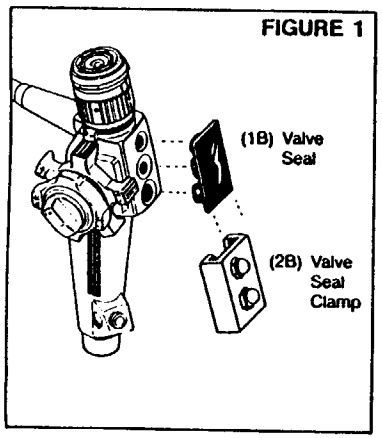


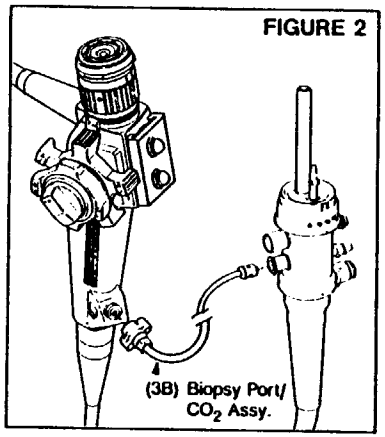
After making connection hook-ups, wrap the endoscope in the "quik-load" basket. Place basket in the DSD chamber.

Insert the quick connect fitting firmly into the opening located in the DSD.



HOOK-UP INSTRUCTIONS FOR LOWER ENDOSCOPES





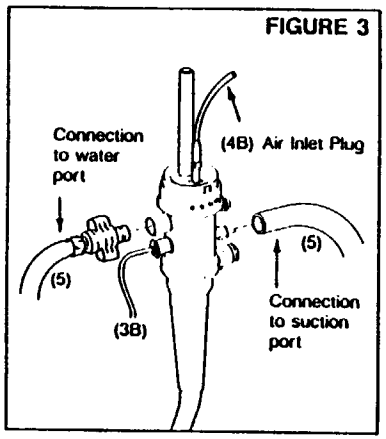


FIGURE 1: After removing air/water, suction valves and CO_2 valve cap from instrument, place the valve seal (1B) on valve openings. Hold in place and slide seal clamp (2B) over seal. Finger tighten bottom screw, then finger tighten top screw.

FIGURE 2: Connect the biopsy port/CO_2 tube assembly (3B) to biopsy port and CO_2 port.

FIGURE 3: Connect disinfector hook-ups (5) to water port and suction port. The water port adapter must be firmly inserted. Connect air inlet tube assembly (4B) to air inlet.

App G

(b) (4)

[redacted]

FLOW PROCESS

(b) (4)

[redacted]

(b) (4)

(b) (4)

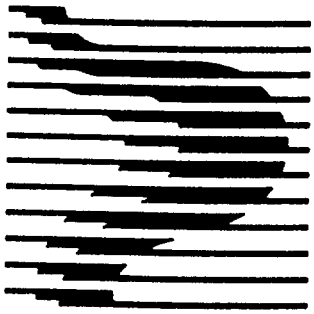
App H

THird Party Summary of Disenfectant Results (b) (4)

THird Party Summary of Disenfectant Results (b) (4)

App I

Recommended Guidelines for Infection Control in Gastrointestinal Endoscopy Settings



Society of Gastroenterology Nurses and Associates, Inc.

SGNA Monograph Series

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Preface

In 1978, the Association for Practitioners in Infection Control (APIC) organized a multidisciplinary committee that developed and published a set of guidelines to minimize risks of infection transmission in the endoscopy setting.

The Society of Gastrointestinal Assistants (SGA) adopted the guidelines, which met the general requirements for gastrointestinal (GI) endoscopy infection control in both hospital-based and private practice settings.

In 1988, SGA incorporated the guidelines into a monograph, restating the original principles and providing its members with the most current information regarding infection control in the GI practice setting. In addition to minimizing the potential for transmitting infectious agents from patient to patient, the updated guidelines addressed the safety and health concerns of the GI nurse and related health care workers.

In this 1990 revision of the monograph, the Society of Gastroenterology Nurses and Associates (SGNA) addresses supplemental topics not contained in the previous edition and provides a concise, up-to-date reference source for infection control information relating to the specialty of endoscopy.

Disclaimer

This monograph is based on current understanding and practice in the field. The leadership of each endoscopy unit is responsible for establishing the best procedures for that particular setting. Different settings may call for different procedures. This monograph suggests only guidelines that are meant to provoke thought and cause each unit to create the best possible program for infection control, given that unit's particular organization, layout, equipment and personnel.

The Society of Gastroenterology Nurses & Associates, Inc. assumes no responsibility for the practices or recommendations of any member or other practitioner, or for the policies and practices of any endoscopy unit.

First edition, 1988, prepared and written by the SGA Task Force for Disinfection/Sterilization Policy: Phyllis McGregor, RN MBA and Patricia Connell, RN CGC. Second edition revised and edited by Marjorie Beck, RN, with assistance from Patricia Connell, RN CGC, Patricia Holland RN CGC and Melanie Swartz, RN CGC, and adopted by the SGNA Board of Directors, May 1990. Published as a service to members by the Society of Gastroenterology Nurses and Associates, Inc.

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716/546-7241

Introduction

Within the specialty of endoscopy, much attention must be given to the implementation of infection control standards. Contaminated endoscopes and accessories are potential sources of infection for both patients and personnel.

Endoscopes differ in use, type and design. Their complex and fragile structure presents problems in cleaning/disinfecting/sterilizing. "In virtually every reported instance of disease transmission associated with endoscopes, there has been a major error in either the cleaning, disinfecting or sterilizing of the instrument." (Bond, W., 1989, 63-64) To prevent such transmission of disease, the processing of contaminated equipment must be performed by specially trained personnel who strictly adhere to established protocol.

In certain circumstances, the use of disposable accessory equipment may be the optimal choice and may be safer and more economical than reprocessing nondisposable items.

Other potential sources of infection transmission include waste products and direct contact of patients and contaminated equipment with environmental surfaces. Waste products generated during the procedure and the cleaning/disinfecting process must be handled and treated according to the institution's policies. Environmental surfaces must be thoroughly cleaned.

The use of chemical germicides for disinfecting and sterilizing endoscopic equipment must be closely monitored to ensure that the proper chemical agent is used and that it is used according to the manufacturer's instructions.

The GI practitioner must assume a personal, professional responsibility for reporting equipment or chemical problems to the appropriate agencies and manufacturers.

Collaboration with the institution's infection control practitioners is essential when implementing new infection control practices that affect the specialty of endoscopy and when monitoring current practice.

SGNA recognizes that strict guidelines are needed to standardize the cleaning/disinfecting/sterilizing processes and to protect patients and personnel. This monograph provides recommended guidelines to assist institutions and endoscopy units in the development of policies for their specific needs.

Recommendations for Endoscopes

Endoscopes are used with patients who may harbor both recognized and unrecognized infections. To prevent the spread of infection, all endoscopes must be thoroughly cleaned and disinfected after each patient use. Refer to the manufacturer's instructions for cleaning and disinfecting each particular endoscope.

Inspection

- Inspect the endoscope for damage at all stages of handling.
- Leak testing, if available, should be performed prior to the cleaning process.
- If damage is detected, do not soak the endoscope. Soaking may cause further damage. Consult the manufacturer for guidance.

Cleaning

- Scrupulous mechanical cleaning of all immersible parts of the endoscope, including all channels and removable parts, is imperative.
- Special water irrigators may be an aid in the cleaning process.
- Immediately after removal of the endoscope from the patient, flush the air/water channel with water to eject any refluxed patient material.
- Immediate cleaning with a detergent and a channel brush will effectively prevent drying of secretions, remove organic material and decrease the number of microorganisms present. All gross material must be removed to ensure the effectiveness of the disinfection or sterilization process.
- Assure that access to the air/water/CO_2 channels is attained. These channels are exceptionally difficult to clean.
- If necessary, the endoscope may be flushed, then soaked with solutions (e.g., enzymatic detergents or 3% hydrogen peroxide) for a short time until personnel are able to initiate the mechanical cleaning process.
- Rinse the endoscope and all its channels thoroughly with water following the cleaning process.
- Remove all excess water from the channels to lessen dilution of the disinfectant during the subsequent disinfection process.
- After removal of gross contaminants, clean all non-immersible parts of the endoscope with 70% alcohol-moistened pads.
- Non-immersible endoscopes should be replaced because they are extraordinarily difficult to clean and disinfect.

Disinfection

- High level disinfection of the endoscope and all channels must be performed after each use.
- When used according to the manufacturer's instructions, a high level disinfectant destroys all microorganisms but not necessarily all bacterial spores. The chemical agent should be sporicidal when used in recommended concentrations and at specified temperatures. Chemical agents registered with the EPA as sterilant/disinfectants are appropriate for high level disinfection.
- Chemical germicide agents for disinfection or sterilization of endoscopic equipment must be chosen carefully. These agents must be used according to the manufacturer's instructions including monitoring chemical concentration if possible. Effective use-life of a germicide is dependent on use patterns rather than on time.
- Disinfectants can become diluted with water retained in endoscopes and accessories or by wash/rinse water in machines. The disinfectant concentration should be tested at intervals determined by institutional policy using products and guidelines recommended by the manufacturer of each specific disinfectant.

Rinsing

- Adequate rinsing must follow disinfection to remove all traces of the disinfectant. Any residual chemical can cause toxic effects in a patient if it is transmitted during the next endoscopic procedure.
- The use of sterile water for rinsing is ideal. In most G.I. settings, however, this practice is impractical or impossible.
- If tap water is used, follow with a 70% alcohol rinse and dry with compressed air.

Drying

- Dry the insertion tube and inner channels thoroughly using forced air after cleaning/disinfection and prior to storage. Bacteria and fungi multiply in a moist environment.
- Air drying by suctioning, injecting air through the channels or by use of the air drying cycle of a scope washer/disinfector are acceptable drying methods for use between procedures. However, these methods may not completely remove all moisture and are not acceptable drying methods for use prior to storage.
- Prior to storage, flush the channels with 70%-90% ethyl or isopropyl alcohol to facilitate drying of the channel and discourage growth of residual bacteria and fungi.

- The alcohol rinse and air drying procedure must be performed prior to endoscope storage. Use of this procedure may be considered necessary between cases depending on the type of patient (e.g., immunosuppressed), the procedure (e.g., ERCP) or the endoscope used (e.g., a side-viewing scope with hard-to-dry areas).

Sterilization

- Conventional heat sterilizing methods will destroy flexible endoscopes. Current methods of sterilization are:
  - Ethylene oxide (EtO) gas sterilization is not always practical because of the extended time needed to complete the sterilizing and aeration process. Thorough cleaning and drying of the endoscope and all its channels prior to EtO use is necessary because organic materials and moisture render the cycle ineffective. Thorough aeration must follow the sterilization process. Manufacturer's instructions must be followed for each specific endoscope.
  - Sterilization using EPA-registered sterilant/disinfectants requires prolonged immersion of the instrument and presents a high probability of endoscope damage. If this method of sterilization is used, follow label directions for use of the selected product. The endoscope manufacturer should also be consulted to determine if the product can be safely used for that particular endoscope.
  - A peracetic acid-based automated system sterilizes immersible medical instruments and rinses them with sterile water. Effectiveness of the sterilizing process is dependent on proper mechanical cleaning prior to processing and contact of all external and internal surfaces of the instrument with the sterilant.

Storage

- Endoscopes must be stored in a way that prevents recontamination or damage between uses. They should be hung vertically in a well-ventilated cabinet.

Documentation

- Documentation of disinfection cycles and disinfecting solution testing should be performed if required by institutional policy (see example form).

Culturing

- Routine culturing of endoscopes is not recommended. If performed, culturing requires very precise techniques done in close consultation with an infection control committee.

Automated Washer/Disinfectors

- Scope washer/disinfectors may standardize an endoscopy unit's cleaning/disinfecting process and decrease exposure of personnel to contaminated equipment and disinfectants. Current data is insufficient to support the safety and efficacy of scope washer/disinfectors. This equipment may be useful in circulating germicides and containing germicidal vapors.
- Meticulous cleaning as previously described in the Cleaning section must precede the use of any automated washer/disinfector.
- After removal of gross contaminants, clean all non-immersible parts of the endoscope with 70% alcohol-moistened pads.
- The washer/disinfector must have the following capabilities:
  - The machine should circulate the detergent and/or disinfectant through all channels at an equal pressure without trapping air.
  - The washing and disinfection cycles should be followed by thorough rinse cycles with forced air to remove the used solution.
  - The disinfectant should not be diluted with wash or rinse water.
  - No residual water should remain in the water hoses and reservoirs; this could promote colonization of bacteria and cause contamination during subsequent processing of instruments.
  - The machine should have a forced air drying cycle or forced air drying should be completed by hand.
  - All mechanical washer/disinfectors must be routinely disinfected according to the manufacturer's instructions and institutional policy.

Special Considerations

- Diagnosed or suspected infection, including hepatitis B or human immunodeficiency virus (HIV), is not a contraindication for endoscopy. Instruments dedicated for use with infected patients are not recommended.
- Sterilization or high level disinfection should be used as directed by institutional policy.
- Deviation from routine processing of equipment may need to be considered on an individual clinical basis (e.g., immunosuppressed patients).
- Endoscope manufacturers must supply an effective, verifiable cleaning method. Little, if any, data is available at present on the efficacy of cleaning procedures.

Recommendations for Accessories

Nondisposable accessories require meticulous cleaning and disinfection or sterilization after each use according to manufacturer's guidelines as directed by institutional policy.

Biopsy Forceps

- As soon as possible after the procedure, clean the forceps with detergent and rinse thoroughly.
- An ultrasonic cleaner is recommended to remove debris that hand cleaning cannot achieve.
- Biopsy forceps require sterilization because they are classified as critical instruments that break the mucosal barrier.
  - Chemical sterilization is ineffective because it cannot completely penetrate the metal coils of the spring-like structure.
  - The only method that will effectively penetrate the coils and any residual organic material employs steam under pressure. Therefore, full cycle steam sterilization is the only recommended method for sterilizing biopsy forceps.

Water Bottle

- Sterilize the water bottle and its connecting tubing daily according to the manufacturer's instructions.
- Use sterile water to fill the bottle for endoscopic irrigation.
- A fresh sterile bottle and sterile water should be used for each ERCP procedure. A close connection exists between *Pseudomonas aeruginosa* colonization of equipment and patient infection following ERCP.

Other Accessories

- Meticulously clean all nondisposable accessories using a detergent followed by thorough rinsing with water.
- Steam autoclave if possible.
- The manufacturer should be consulted if steam sterilization is not applicable.

Medical Equipment

- Noncritical equipment (e.g., cameras, teaching scopes, light sources) should be kept visibly clean with soap and water.
- If significantly soiled, use an intermediate level disinfectant.

Recommendations for Environment

Confinement and removal of organic material are essential aspects in any infection control program.

General Cleaning

- The use of an EPA-registered housekeeping product is recommended for general wipe-down of equipment such as procedure carts, stretchers, sinks, etc., after each use.

Spills

- Spills of blood or body fluid are blotted with disposable towels.
- The spill area is then wiped with clean, disposable towels soaked in freshly prepared household bleach (1:100 dilution) or an EPA-registered tuberculocidal "hospital disinfectant" and allowed to dry.

Waste

- Medical waste should be minimally handled.
- Storage and disposal of waste should be handled according to institutional policy in accordance with directives and recommendations from regulatory agencies.

Processing Area

- Cleaning/disinfection areas should be separated from patient care areas.
- Proper ventilation to remove toxic chemical vapors is essential.
- Supporting space should contain at least proper plumbing, drains, "clean" and "dirty" areas and adequate storage space.

Recommendations for Protection of Personnel

Protection of endoscopy unit personnel can best be accomplished by applying consistent practices whenever and wherever the potential for spread of infectious agents and risk of danger from chemicals exists.

- Gloves must be worn for touching blood, body fluids, mucous membranes or nonintact skin of patients, for handling items or surfaces soiled with blood or body fluids, for all clean-up procedures and for performing vascular access procedures.
- Masks and eye protection must be worn when danger of splashing from blood, body fluids or disinfectant is present.
- Moisture-resistant gowns or aprons must be worn when danger of soiling clothing from blood or body fluids is present.
- Needles and all sharps must be discarded in designated disposal containers. Do not bend, cut or break needles by hand before disposal. Because of demonstrated potential for environmental contamination, needle cutters are not recommended. Used needles must not be recapped by hand.
- Personnel with open skin lesions should not perform or assist with any endoscopy procedures or handle equipment used for procedures.
- Jewelry, watches, glue-on nails and fingernail polish should not be worn because they harbor microorganisms and make effective handwashing difficult. Fingernails should be kept short to avoid puncturing gloves.
- Thorough handwashing with soap and water is essential when entering and leaving the endoscopy area, after glove removal and between each procedure and patient contact.
- All GI personnel, if not sero-positive for anti-HBs, should be immunized with the hepatitis B vaccine.

Agencies and Organizations Involved with Infection Control Practices

APIC (Association for Practitioners in Infection Control) - A professional association involved in healthcare infection control practices.

APIC National Office
505 E. Hawley Street
Mundelein, IL 60060
Phone: (312) 949-6052

CDC (Centers for Disease Control) - A federal agency that investigates specific disease outbreaks and formulates general guidelines for disease control.

U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control
Atlanta, GA 30333

EPA (Environmental Protection Agency) - A federal agency that approves products for disinfectant registration by review of labeling and supporting data submitted by the registrants.

Office of Pesticides and Toxic Substances
EPA
401 M Street, SW
Washington, DC 20460

FDA (Food and Drug Administration) - A federal regulatory agency for controlling the safety and effectiveness of drugs, devices and instrumentation.

U.S. Food and Drug Administration
Centers for Devices and Radiological Health
8757 Georgia Avenue
Silver Springs, MD 29010

JCAHO (Joint Commission on Accreditation of Healthcare Organizations) - An independent credentialing agency which grants voluntary approval to healthcare facilities which comply with applicable standards for public and patient health and safety.

JCAHO
875 North Michigan Avenue
Chicago, IL 60611

USP (United States Pharmacopeial Convention) Medical Device and Laboratory Product Problem Reporting Program - A national program established in 1973 to report problems with medical devices and/or laboratory equipment used in health care.

United States Pharmacopeial Convention, Inc.
Medical Device and Product Problem Reporting
12601 Twinbrook Parkway
Rockville, MD 20852
Phone: (800) 638-6725
(301) 881-0256

OSHA (Occupational Safety and Health Administration) - A federal regulatory agency responsible for enforcing safety and health regulations in the workplace.

U.S. Department of Labor
OSHA
200 Constitution Avenue, NW
Washington, DC 20210

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Classification Schemes for Sterilants, Disinfectants and Sanitizers

ENVIRONMENTAL PROTECTION AGENCY (EPA) PRODUCT CLASSIFICATIONS	CENTERS FOR DISEASE CONTROL (CDC) PROCESS CLASSIFICATIONS
Sterilant/Disinfectant	*Sterilization* (sporicidal chemical – prolonged contact time) *High Level Disinfection* (sporicidal chemical – short contact time)
Hospital Disinfectant (with label claim for TB activity)	*Intermediate Level Disinfection*
Hospital Disinfectant Sanitizer	*Low Level Disinfection*

EXAMPLES OF COMMON DISINFECTANTS USED IN ENDOSCOPY SETTINGS

High Level Disinfectants
(used on instruments, *not* on environment surfaces)

- glutaraldehyde
- hydrogen peroxide-based chemicals

Intermediate Level Disinfectants
(*not* used on instruments)

- iodophors
- chlorine compounds
- phenolics

Low Level Disinfectants
(*not* used on instruments)

- quaternary ammonium compounds

— Modified from Favero and Bond, 1990

430

Daily Disinfection/Sterilization Control Form

This form may be photocopied.

431

Today's Date: _____ **Solution Type:** _____

Location: _____ **Solution Strength:** _____

Room Temperature: _____ **Activation Date:** _____

Solution Temperature: _____ **Expiration Date:** _____

Load #	Load Contents:	Cleaned by:	Immersion Required:	Before patient:	After patient:	Start time:	Start by:	Stop time:	Stop by:

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(716) 546-7241

App I

THERE IS NO APPENDIX J

THE ENTIRE CONTENTS OF THIS BOOK ARE CONFIDENTIAL

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App K.

APPENDIX K

RESPONSE #11

510(K) K914145

BOOK 1 OF 2

MEDIVATORS, INC.

APPENDIX K

NOTE: This appendix contains responses to question #11 regarding FDA letter of March 23, 1992, 510(k) Number K94145.

This appendix has its own appendices, i.e. A through G. Medivators has also included additional software information such as source listing, call free, etc. This information is included in two separate books and designated as Book 1 and Book 2.

CONFIDENTIAL

Response to FDA reviewer Questions of March 1992 Regarding Software Issues Prepared for: MediVators, Inc.

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