K063876

p. 1 of 4

Medivators Reprocessing Systems Modular Disinfection System
for Endoscope Reprocessing

510(k) Summary of Safety and Effectiveness

JUN 14 2007

Manufacturer:	Medivators Reprocessing Systems, a Division of Minntech Corporation
Address:	14605 28th Avenue North Mpls., MN 55447 USA
Official Contact:	Lynn Lueders Director, Regulatory Affairs

Medivators has supplied the following information to the U.S. Food and Drug Administration to support substantial equivalence of the Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing to other endoscope reprocessors currently marketed in the U.S.

1. Device Description

The Modular Disinfection System (MDS) is an electro-mechanical system intended to test and high level disinfect heat sensitive semi-critical endoscopes. It is not intended for reprocessing rigid endoscopes. The machine can use any FDA cleared, reusable liquid germicide which is on the market that is labeled for high level endoscope disinfection. The testing provided to the FDA used both Medivators Rapicide® High Level Disinfectant and Cidex® OPA High Level Disinfectant.

The MDS does not replace manual cleaning of endoscopes, they must be precleaned and cleaned according to the endoscope manufacturer's instructions and professional guidelines prior to reprocessing them in the MDS.

During its software based reprocessing cycle, the machine tests the endoscopes for leaks and blockages. Before and during the machine cycles, connectivity with the machine through the connector blocks is evaluated. If the scopes pass these tests, they are flushed with water and detergent, disinfected and rinsed. The disinfection cycle takes approximately 30 minutes. The MDS is capable of asynchronously reprocessing two scopes at a time.

The machine has many built in safety features which stop the cycle and alarm when certain conditions exist which could indicate that disinfection might be compromised. These alarms and causes are defined in the directions for use for the product.

The machine also prints records by endoscope serial number indicating the results of testing, disinfection, number of disinfections, etc. which are required for permanent records.

2. Intended Use

Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing tests, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. The MDS is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes. It is indicated for use with FDA cleared, liquid high level disinfectants.

The MDS does not replace manual cleaning of endoscopes, they must be precleaned and cleaned according to the endoscope manufacturer's instructions and professional guidelines prior to reprocessing them in the MDS.

3. Comparison to Another Device in Commercial Distribution Within the United States

The MDS is equivalent in function and indications to the Medivators DSD-91E™ Endoscope Disinfector. This machine was found to be substantially equivalent in 1994 (K914145). Both machines have the same indications for use, the same methods of providing disinfection, can use the same reuseable disinfectants at the same temperatures and times. Both machines can reprocess two scopes asynchronously, one in each bay.

4. Summary of Testing

Medivators has provided testing to show that the MDS is safe and effective for its intended use following the requirements listed in the FDA's Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (dated August 1993).
This testing included:

Efficacy Testing

The MDS was tested using standard methods defined by the FDA guidance document. This testing included simulated use and in use testing.

The simulated use testing showed a >10^6 log reduction in the organism *Mycobacterium terrae* after the endoscopes were reprocessed in the MDS.

In use testing showed no viable organisms remained on the endoscopes following the disinfection cycle.

Additional in-use testing was performed to show that the MDS provided disinfected endoscopes when exposed to the entire endoscope cycle of disinfecting and rinsing.

Material Compatibility

The effect of disinfectants (Rapicide and Cidex OPA) on the materials used in the MDS was evaluated and showed that the materials had no significant deterioration over their use life. Studies were also presented to show that the filters used in the water filtration system were compatible with common disinfectants.

Biocompatibility

The amount of disinfectant residue left on endoscopes and in the MDS after the disinfection and rinsing cycles was evaluated and compared to determined safe levels. The results of the testing showed that any remaining residues would not have an effect on patients or users of the machine.

Performance Data

Data was provided to the FDA to show that the machine performs as required. This evaluation included testing to show that the leak check, blockage check, connectivity checks, disinfection cycle, rinse cycles, and drying cycles performed correctly. Any error messages were tested to ensure they function properly to notify users of any possible failure modes. Testing was performed to show that all critical parameters of the machine function correctly.

Testing was presented that showed that disinfectants which require heating remained at their required temperature for the length of time required in the labeling for the disinfectant.

Testing was completed that showed that the MDS self disinfection cycle works properly by disinfecting all areas of the machine, including the water filtration system.

Studies were performed to show that the water filtration system will function appropriately over time and that the machine will alarm if water filters are plugged to a point which will lower the water pressure below required input. This study also showed that the filters remained bacterial retentive even when plugged to a point that causes the machine to alarm.

5. Summary of Substantial Equivalence

Minntech Corporation has provided the above information in the form of a 510(k) to support the claim that the MDS is safe and effective when used in accordance with the device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medivators Reprocessing Systems
C/O Ms. Lynn Lueders
Director, Regulatory Affairs
A Minntech Corporation Business Group
14605 28th Avenue, North
Minneapolis, Minnesota 55447-4822

JUN 14 2007

Re: K063876
Trade/Device Name: Medivators Reprocessing Systems Modular Disinfection System for Endoscope Reprocessing
Regulation Number: 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEB
Dated: May 6, 2007
Received: June 7, 2007

Dear Ms. Lueders:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K063876

Device Name: Medivators Reprocessing Systems Modular Disinfection System for Endoscope Reprocessing

Indications for Use:

Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing tests, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. The MDS is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes. It is indicated for use with FDA cleared, liquid high level disinfectants.

The MDS does not replace manual cleaning of endoscopes, they must be precleaned and cleaned according to the endoscope manufacturer's instructions and professional guidelines prior to reprocessing them in the MDS.

Prescription Use ____ AND/OR Over-the Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Geetha Jayan - for Sheila Murphy

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K063876

MINNTECH®
A Cantel Medical Company

K063876/A1

June 13, 2007

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Control Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510(k) Number - K063876 - Amendment to the 510(k) for the Medivators Modular Disinfection System (MDS)

(b)(4) Trade Secret Process

[redacted]

Sincerely,

Lynn Lueders

Lynn Lueders

Director, Regulatory Affairs

Minntech Corporation

Indications for Use

510(k) Number (if Known): K063876

Device Name: Medivators Reprocessing Systems Modular Disinfection System for Endoscope Reprocessing

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Medivators Reprocessing Systems Modular Disinfection System
for Endoscope Reprocessing

510(k) Summary of Safety and Effectiveness

Manufacturer:	Medivators Reprocessing Systems, a Division of Minntech Corporation
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Official Contact:	Lynn Lueders Director, Regulatory Affairs

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medivators Reprocessing Systems
C/O Ms. Lynn Lueders
Director, Regulatory Affairs
A Minntech Corporation Business Group
14605 28th Avenue, North
Minneapolis, Minnesota 55447-4822

JUN 14 2007

Re: K063876
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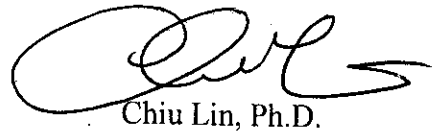
Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K063876

Device Name: Medivators Reprocessing Systems Modular Disinfection System for Endoscope Reprocessing

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Prescription Use ____ AND/OR Over-the Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Geetha Jayan -for Sheila Murphy

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K063876

MINNTECH

June 13, 2007

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Control Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510(k) Number - K063876 - Amendment to the 510(k) for the Medivators Modular Disinfection System (MDS)

(b)(4) Trade Secret Process

[redacted]

Sincerely,

Lynn Lueders

Lynn Lueders

Director, Regulatory Affairs

Minntech Corporation

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 29, 2007

MEDIVATORS REPROCESSING SYSTEMS
A MINNTECH CORPORATION BUSINESS GRO
14605 28TH AVE., NORTH
MINNEAPOLIS, MN 55447
ATTN: LYNN LUEDERS

510(k) Number: K063876
Product: MODULAR DISINFECTION SYSTEM (MDS) FOR ENDOSCOPE

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

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-40
9200 Corporate Blvd.
Rockville, Maryland 20850

February 28, 2007

MEDIVATORS REPROCESSING SYSTEMS
A MINNTECH CORPORATION BUSINESS GRO
14605 28TH AVE., NORTH
MINNEAPOLIS, MN 55447
ATTN: LYNN LUEDERS

510(k) Number: K063876
Device: MODULAR DISINFECTION SYSTEM (MDS) FOR ENDOSCOPE

Extended Until: 11-MAY-2007

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 (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

626

MEDIVATORS®
REPROCESSING SYSTEMS
A Minntech Corporation Business Group

February 27, 2007

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Control Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510(k) Number - K063876

(b)(4) Trade Secret Process

[redacted]

Yours truly,

Lynn Lueders

Director, Regulatory Affairs

K14

Minntech Corporation, 14605 28th Avenue North, Minneapolis, MN 55447-4822
763.553.3300, fax 763.553.3387, www.minntech.com

627

MEDIVATORS®
REPROCESSING SYSTEMS
A Minntech Corporation Business Group

February 27, 2007

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Control Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510(k) Number - K063876

(b)(4) Trade Secret Process

[redacted]

Yours truly,

Lynn Lueders

Director, Regulatory Affairs

FEB 28 2007

Minntech Corporation, 14605 28th Avenue North, Minneapolis, MN 55447-4822
763.553.3300, fax 763.553.3387, www.minntech.com

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 12, 2007

MEDIVATORS REPROCESSING SYSTEMS
A MINNTECH CORPORATION BUSINESS GRO
14605 28TH AVE., NORTH
MINNEAPOLIS, MN 55447
ATTN: LYNN LUEDERS

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We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 29, 2006

MEDIVATORS REPROCESSING SYSTEMS
A MINNTECH CORPORATION BUSINESS GRO
14605 28TH AVE., NORTH
MINNEAPOLIS, MN 55447
ATTN: LYNN LUEDERS

510(k) Number: K063876
Received: 29-DEC-2006
Product: MODULAR DISINFECTION SYSTEM (MDS) FOR ENDOSCOPE REPROCESSING

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(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 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (240)276-4040.

Sincerely yours,

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

K063876

MEDIVATORS®
REPROCESSING SYSTEMS
A Minntech Corporation Business Group

December 28, 2006

K27

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Control Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510(k) Premarket Notification for the Medivators® Reprocessing Systems' Modular Disinfection System (MDS) for Endoscope Reprocessing

Medivators Reprocessing is submitting this 510(k) Premarket Notification for the Medivators Reprocessing Systems (a Minntech Corporation Business Group) Modular Disinfection System (MDS) for Endoscope Reprocessing. We believe that the MDS is substantially equivalent to other endoscope disinfector/reprocessors currently on the market.

The MDS is intended to test, clean, and disinfect flexible endoscopes between uses. The system tests for blocks or leaks, then cleans the scopes (this cleaning step does not eliminate the manual cleaning performed by the user prior to placing the endoscope in the machine). If the scope passes the block and leak tests, the machine will fill the basin with the disinfectant and allow the endoscopes to be soaked in the disinfectant for the time required by the disinfectant manufacturer. After disinfection, the scopes are rinsed and dried by the machine.

As will be shown in the submission, the MDS has been tested to ensure that it performs all of its tasks in order to produce an endoscope that has been disinfected to clinical standards.

If there are comments or questions on this submission, please contact me by phone at 763-553-2475, by fax at 763-509-1601, or by email at llueders@minntech.com.

Regards,

Lynn Lueders
Director, Regulatory Affairs
Medivators Reprocessing Systems
Minntech Corporation

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Secret Process
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

HO II

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

MINNTECH CORP
14605 28TH AVENUE NORTH
MINNEAPOLIS MN 55447
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)

2. CONTACT NAME
Lynn Lueders

2.1 E-MAIL ADDRESS
llueders@minntech.com

2.2 TELEPHONE NUMBER (include Area code)
763-553-2475

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
null-null

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4)

21-Dec-2006

Form FDA 3601 (08/2003)

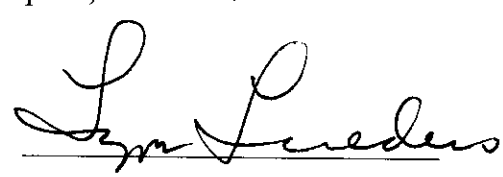
Close Window Print Cover Sheet

(b)(4) Trade Secret Process -Financial Specs

Premarket Notification for the Medivator Reprocessing Systems

Modular Disinfection System (MDS) Endoscope Reprocessor

Medivators Reprocessing Systems
A Minntech Corporation Business Group
14605 28th Avenue North
Minneapolis, MN 55447
USA



Lynn Lueders
Director, Regulatory Affairs

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Appendix S	Parameter Testing
Appendix T	Error Message Testing
Appendix U	Machine Functional Testing

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Premarket Notification [510(k)]
Modular Disinfection System (MDS) Endoscope Reprocessor

I. Identification

Applicant's Name and Address:

Medivators Reprocessing Systems
A Minntech Corporation Business Group
14605 28th Avenue North
Minneapolis, MN 55447
USA

Contact Person:

Lynn Lueders
Director, Regulatory Affairs

Telephone and Fax Number of Applicant:

Telephone:	763-553-2475
Fax:	763-509-1601
Email:	llueders@minntech.com

II. Truthful and Accurate Statement

A "Truthful and Accurate Statement" is provided in Appendix A.

III. Device Name:

Trade or proprietary name:	Medivators Modular Disinfection System for Endoscope Reprocessing
Common or usual name:	Endoscope washer/disinfector

IV. FDA Product Code: MED

V. FDA Review Panel Code: (b)(4)

VI. Establishment Registration Number: (b)(4)

VII. Classification name of the device:

Machine: Endoscope, accessories

Class of device: Class II

VIII. Standards

This submission is based upon the requirements listed in the FDA's Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (dated August 1993).

In addition, the FDA guidance documents Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff and General Principles of Software Validation; Final Guidance for Industry and FDA Staff were used to develop and test the software in the machine.

Electrical safety, compatibility and immunity of the machine was evaluated using the appropriate standards as discussed in Section XIV.B. of the submission.

IX. Device Description

The MDS machine was originally designed and built in The Netherlands by Dyped Corporation. The machine and its design were transferred to Medivators in 2001. The MDS being submitted here is essentially the same machine as was sold in the United Kingdom (UK) (it may also be identified in validation testing as a "Dyped" machine), but has been modified for U.S. conditions (i.e., from 230 volts to 120 volts). All design, development, and testing of the U.S. machine has followed the FDA and all applicable U.S. guidelines and standards.

A. Product Overview

The Modular Disinfection System (MDS) is an electro-mechanical system intended to test, clean, and high level disinfect flexible fiberoptic and video endoscopes between uses. It is not intended for reprocessing rigid endoscopes. The MDS is capable of asynchronously reprocessing two scopes at a time.

Prior to reprocessing in the MDS, users must perform manual cleaning of endoscope to remove debris from the outside and all lumens by following their clinic's internal guidelines and

procedures. The scopes are then connected to the MDS and the system tests the endoscopes for blockages in the channels and leaks in the outer skin, then proceeds to an optional cleaning step. The system also includes an optional channel connectivity test to verify proper connection of the fluid channels for reprocessing. If the endoscopes pass the blockage and leak tests and the cleaning cycle has been completed, the system proceeds to rinse the instruments and begins the disinfection cycle.

The system is designed to use currently marketed reusable high-level disinfectants containing glutaraldehyde such as Rapicide Disinfectant (manufactured by Medivators) or Ortho-phthalaldehyde (Cidex® OPA manufactured by Advanced Sterilization Products) packaged at use concentration. A detergent is used during the cleaning cycle. In order to show the machine effectiveness with both types of germicides, we used both Rapicide and Cidex OPA in our testing as shown later in this submission. Any non-enzymatic, neutral pH detergent may be used for the cleaning cycle according to its labeled instructions for use. During our testing, Intercept™ Detergent (distributed in the U.S. by Medivators) was used at a 0.5% final concentration. Labeling for Rapicide, Cidex OPA and Intercept are included in the labeling section of the submission. The machine also has the ability to perform an alcohol rinse to assist in drying. A 70% concentration of isopropyl alcohol is used.

Prior to the disinfection cycle, the disinfectant is heated (if required by the manufacturer's labeling) to the manufacturer's recommended use temperature. The disinfectant is then transferred to the reprocessing basin where it is recirculated through the lumens of the endoscope and fills the basin to fully immerse the endoscope in the disinfectant solution. The scope remains submersed for the chemical manufacturer's recommended contact time. The disinfectant is then drained from the basin into the onboard chemical reservoir. Following disinfection, the endoscopes are rinsed and dried by the machine, either by filtered air or an optional alcohol rinse, and are then removed from the machine for the next use.

Each machine must be properly set up at the user's facility by trained Medivator Service personnel. At that time, any setting specific to the germicide being used will be set. It is important for the customer to use the correct connections (hookups) for connecting the scope into the machine. Medivators provides a complete list of connectors which have been tested with all major

scope manufacturer's devices. Customers will be provided with this list during initial setup and through our website.

B. Detailed Machine Description

Included in Appendix B are reprocessing cycle diagrams showing each step of the reprocessing cycle.

The MDS CPU automatically controls the reprocessing cycle and monitors all process parameters. The operator interacts with the system through a computer interface and/or the control panel on the front of the machine, while the system displays prompts, messages, errors, and warnings through a graphical user interface on a computer monitor.

To initiate a reprocessing cycle, an operator connects an endoscope to a connector block hook-up compatible with the given endoscope. This may be pre-mounted in an optional cassette to hold the endoscope, or may be separate. The connector block is then mounted into a manifold connection inside the reprocessing basin as the endoscope is placed inside. The endoscope ID may be entered manually, by an optional i-dent system or by an optional bar code reader. The system requires operator log-in to start any new operation on the system, including a reprocessing cycle. The operator will then start a cycle by interacting with the computer menu screens using the control panel, an external keyboard, or an external mouse.

Preliminary checks of the endoscope then proceed. These checks include:

A leak test, during which the system pressurizes the endoscope with air and monitors the pressure decay rate. If the endoscope does not pass the leak test, the system will provide a warning message to the operator and will abort the reprocessing cycle to prevent damage to the endoscope.

A block test, during which the system pressurizes the endoscope with fluid and then allows the pressure to decay through the endoscope lumens. A low decay rate will indicate a blockage in one or more lumens. If a blockage is detected, the system will provide a warning message to the operator and will abort the reprocessing cycle. The operator will then need to remove the endoscope from the system and inspect and/or clean the endoscope lumens to remove the blockage.

An initial pre-rinse step pushes fluid through the channels of the endoscope, sprays the exterior of the endoscope and then drains the basin.

An optional secondary pre-rinse step allows the user to set a parameter to dose detergent into the water stream entering the basin to provide additional cleaning of the instrument during the reprocessing cycle. In the event that the user elects not to fill the soap dispenser and turn on the wash feature, the system will simply rinse with fresh incoming water. During this step, the system also checks for channel connectivity and interconnectivity.

The channel connectivity test is used to detect whether small volume fluid channels or large volume fluid channels, respectively, are properly connected to the system to ensure adequate perfusion during the reprocessing cycle. This check is performed twice during a cycle, once after the leak test and once again at the end of the disinfection to ensure that the endoscope has been properly reprocessed.

A final rinse step flushes the fluid channel of the endoscope and the exterior of the endoscope with fresh incoming water to remove any soap from the endoscope prior to continuing to the disinfection phase.

The disinfection phase includes several steps in which the chemical disinfectant is transferred from the reservoir to the reprocessing basin, is pumped through the fluid channels, and is sprayed over the surface of the endoscope simultaneously. It fills the basin to a level that allows the endoscope to be completely submerged, then recirculates the disinfectant through the fluid channels and spray head for the contact time required by the germicide manufacturer. It then drains the used disinfectant to the reservoir. During the disinfection phase, the system again checks for channel connectivity and interconnectivity.

The final rinses flush the basin, spray head, recirculation lines, and fluid channels of the endoscope with fresh incoming water to remove any residual chemistry to safe levels. The number of rinses performed will depend upon the disinfectant used and the user's preferences. A minimum of two rinses are required by the system. During the second rinse, the system checks again for channel connectivity and interconnectivity.

After the final rinses, the system purges the channels of the endoscope with filtered air to remove excess fluid. At the end of

the reprocessing cycle, the user will have the option to implement an optional alcohol purge to improve drying of the fluid channels of the endoscope.

The entire cycle time from initial tests through final rinses does not exceed 30 minutes when using two final rinses. Cycle times will be slightly longer if the customer is using a germicide with additional rinsing requirements. There are no significant chemical residues remaining after the final rinses, as shown in later testing sections of this submission. The used germicide is returned to a chemical reservoir following completion of the disinfection step of the reprocessing cycle where it is maintained and stored between reprocessing cycles.

Water used in the reprocessing cycle is passed through a 0.2 micron filter to produce bacteria free water. Likewise, air is filtered through a 0.2 micron air filter to prevent particles and airborne bacteria from entering the basin and contaminating the reprocessed endoscope

At the end of the cycle, the system displays a message indicating that the cycle is complete or any messages regarding failures that caused the system to abort the reprocessing cycle to a safe condition. A cycle log certificate is printed out that lists a summary of the key cycle parameters, cycle times, and any failures or errors encountered during the reprocessing cycle. If there were any errors leading to the system aborting the cycle, including user input, the system monitor and the cycle log will indicate this information and will also display a message that the endoscope is not properly reprocessed. Following successful completion of the reprocessing cycle, the user will open the reprocessing basin via a control panel button and remove the reprocessed endoscope.

As indicated earlier, the MDS is intended to be used with currently marketed reuseable disinfectants that are labeled for use with automatic endoscope reprocessors. The users of the MDS are required to check the active concentration of the reuseable disinfectant each day to ensure that the concentration stays above the Minimum Recommended Concentration (MRC). This testing is accomplished using the test strips indicated by the germicide manufacturer.

Medivators recommends that the MDS be self-disinfected on a daily basis. This self-disinfection procedure ensures that all filters, tubing, etc. not normally in contact with the germicide during the

scope disinfection are sanitized and will not contaminant the system.

The MDS is controlled through all of its functions by software contained in the computer. The PC proprietary software runs on the Microsoft XP Professional Operating System and all the critical steps of the PC operation is monitored by an independent and separate Programmable Logic Controller functioning as a Safety Control Unit (SCU). The SCU has the control authority to cancel a cycle and generate an error message should one of the operating parameters being monitored by the SCU exceeds its preset limit. All software written for the SCU is created in Function Block Diagram or Structured text languages. Further detail of the software control is provided later in this submission.

Included in the next pages are diagrams showing the major components of the system including the internal and external connection points and control panels.

C. Main MDS Components and Their Functions

The MDS machine consists of two independent reprocessing modules. Each has a basin, automatic cover, endoscope hookups, and the necessary pumps and valves to disinfect, rinse, and dry most models of flexible, submersible endoscopes.

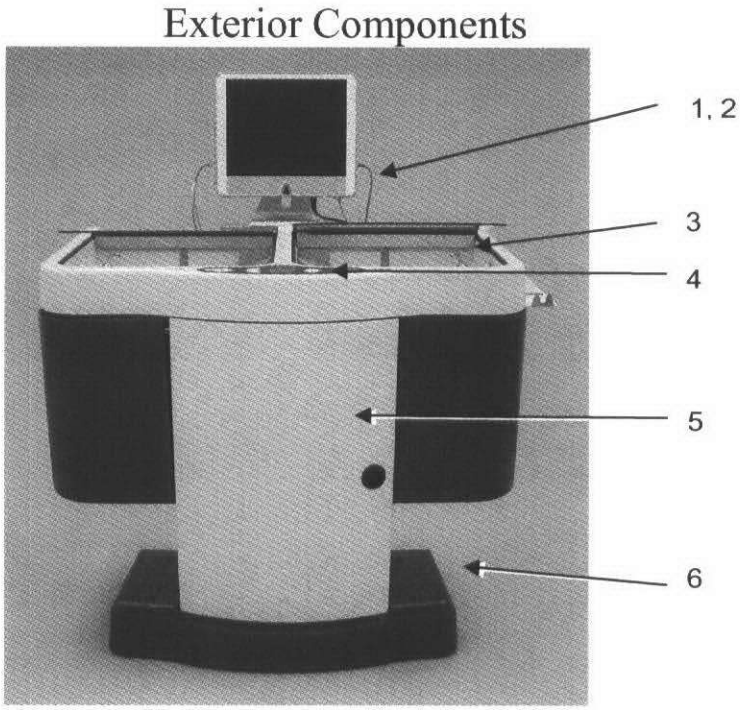

Figure 1 MDS Front View

1. **PC:** Runs the programs on the MDS
2. **PC Monitor:** Displays messages, menu selections, and the operation status.
3. **Basin Lid:** Cover for the left or right basin of the MDS. The lid opens to add or remove endoscopes.
4. **Control Panel:** Used to specify settings, operate the reprocessor, and view system Messages, errors and warnings.
5. **Access Door:** Opens to allow access to the reservoirs, filters, transfer valves, and pressure gauges.
6. **Foot Switch:** Pressing the right foot switch opens the right basin lid, and pressing the left foot switch opens the left basin lid.

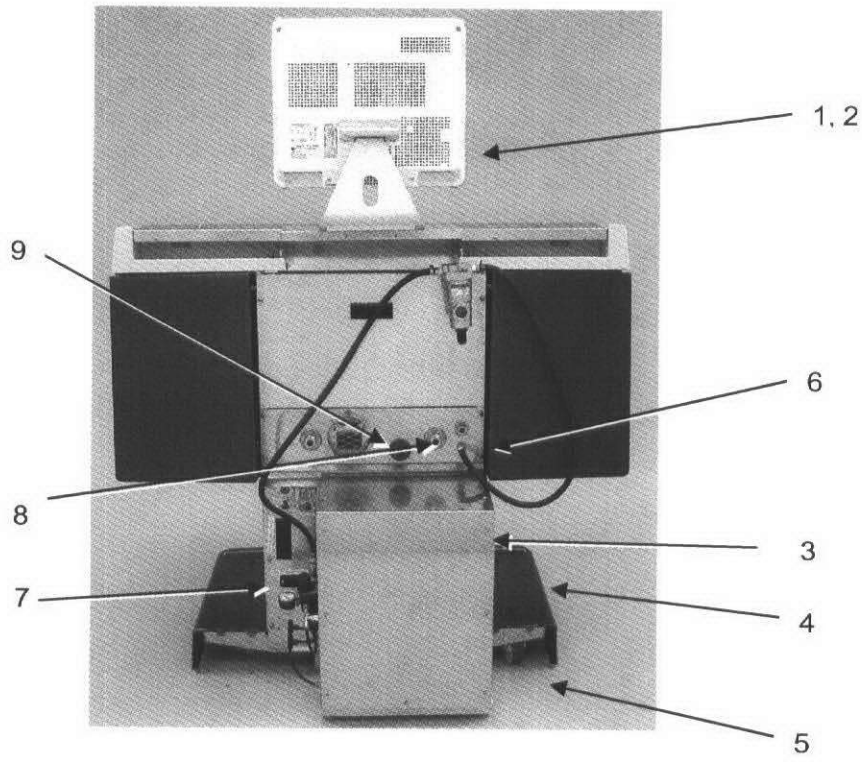

Figure 2 MDS Back View

1. **PC:** Runs the programs on the MDS that disinfect the machine and endoscopes.

2. **PC Monitor:** Displays Messages, menu selections, and the operation status.

3. **Electronic Module:** Contains electronic components, including fuses, which run the MDS.

4. **Foot Shroud:** Covers and protects the bottom of the MDS.

5. **Castors:** Small wheels to make the MDS easier to move.

6. **Water Supply Inputs:** Inlet for filtered water, one for each module.

7. **System Power:** Electrical power supply connection.

8. **Discharge:** Fluids output to the drain.

9. **Vapor Venting:** Exhausts fumes from the modules, preventing operator exposure.

Interior Components

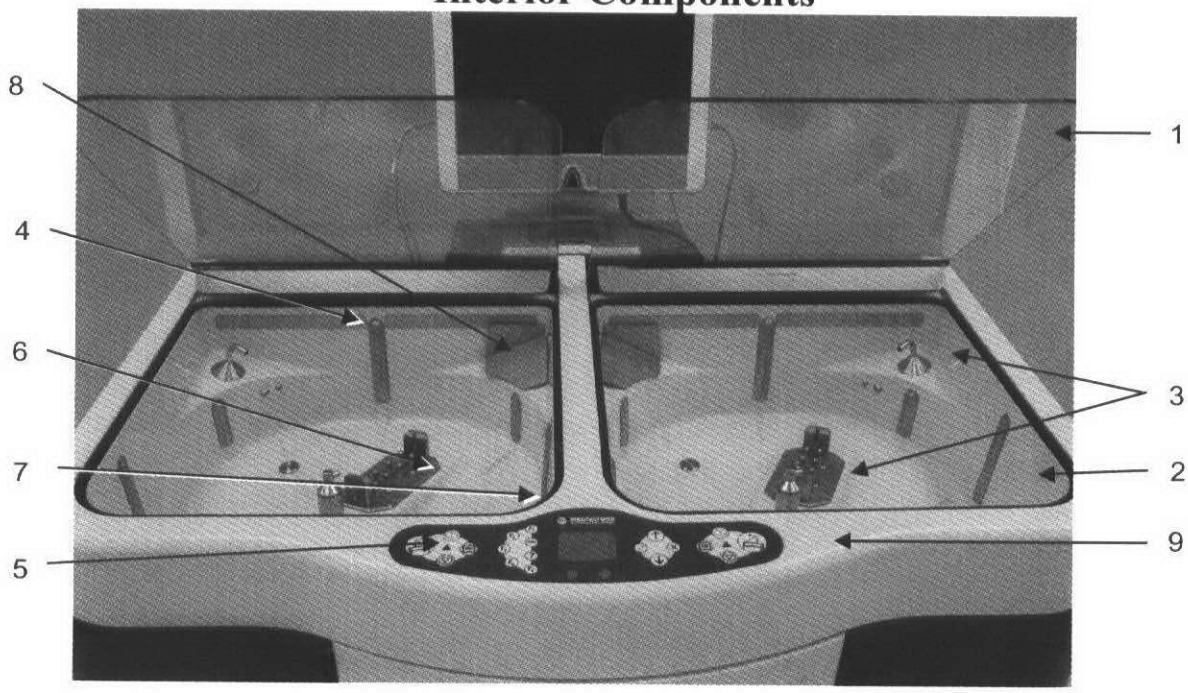

Figure 3 MDS Top View

1. **Basin Lid:** Cover for the left or right basin of the MDS. Open the cover to add or remove endoscopes.

2. **Basin:** Container where endoscopes are disinfected.

3. **Fluid Inlet:** Port where liquids are dispensed into the basin.

4. **Vapor Ports:** Draws fumes away from the module to prevent operator exposure

5. **Light Emitting Diode (LED):** Provides system and cycle status during endoscope disinfection.

6. **Cassette Dock:** Attaches a cassette to the basin.

7. **Drain:** Outlet port through which waste fluids are dispensed.

8. **Overflow:** Outlet used to drain off excess fluids.

9. **Control Panel:** Use to specify settings, operate the reprocessor, and view system Messages, errors and warnings.

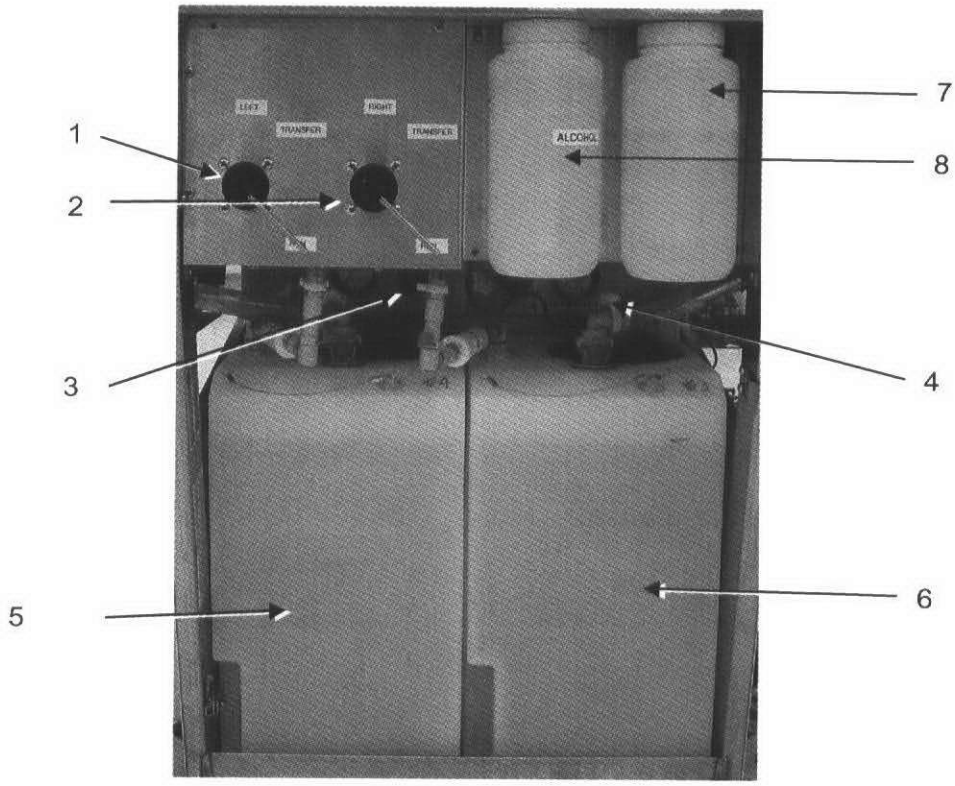

Figure 4 Chemical Reservoirs

1. **Left Transfer Valve:** Used to transfer fluid to the left reservoir.

2. **Right Transfer Valve:** Used to transfer fluid to the right reservoir.

3. **Main (High) Pressure Gauge (left):** Measures air pressure in the MDS system.

4. **Leak Test (Low) Pressure Gauge (right):** Measures air pressure in the endoscope and MDS system.

5. **Heated Disinfectant Reservoir (Optional):** Holds disinfectant solution at elevated temperature to be used in the disinfection process for left module.

6. **Heated Disinfectant Reservoir (Optional):** Holds disinfectant solution at elevated temperature to be used in the disinfection process for right module.

7. **Detergent Reservoir:** Holds detergent used in the disinfection process.

8. **Alcohol Reservoir:** Holds alcohol that may be used in the disinfection process.

PC and Connections

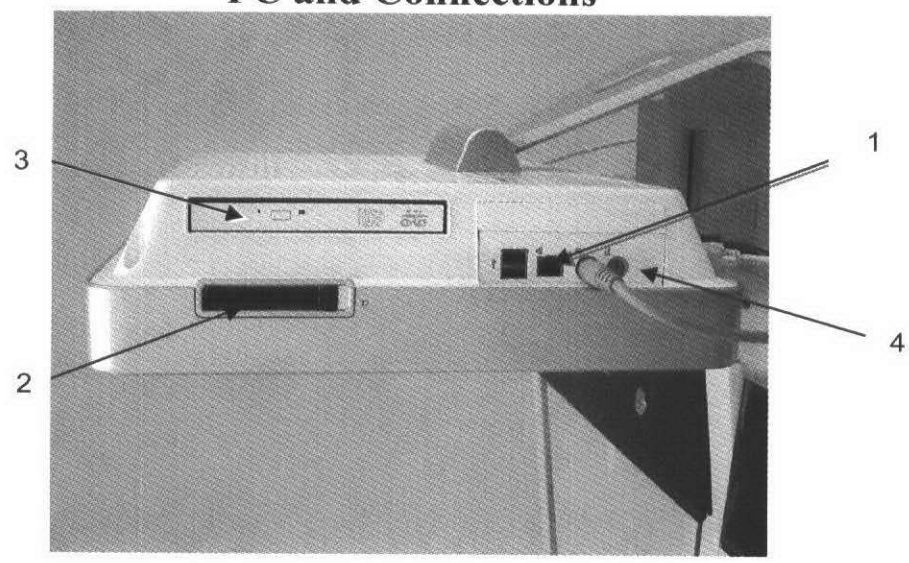

Figure 5 PC and Connections

1. **USB Port:** Connector between the PC and external peripherals.
2. **Serial Port:** Connector between the PC and external peripherals.
3. **CD Drive:** Reads and writes compact disks
4. **Mouse Connection:** Connection for an external mouse.

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Control Panel

The control panel allows the operator to specify settings, operate the reprocessor, and view system messages, errors and warnings. It consists of five main groups:

1. Left and right module control buttons
2. Function buttons
3. Touchpad and mouse buttons
4. Selection buttons

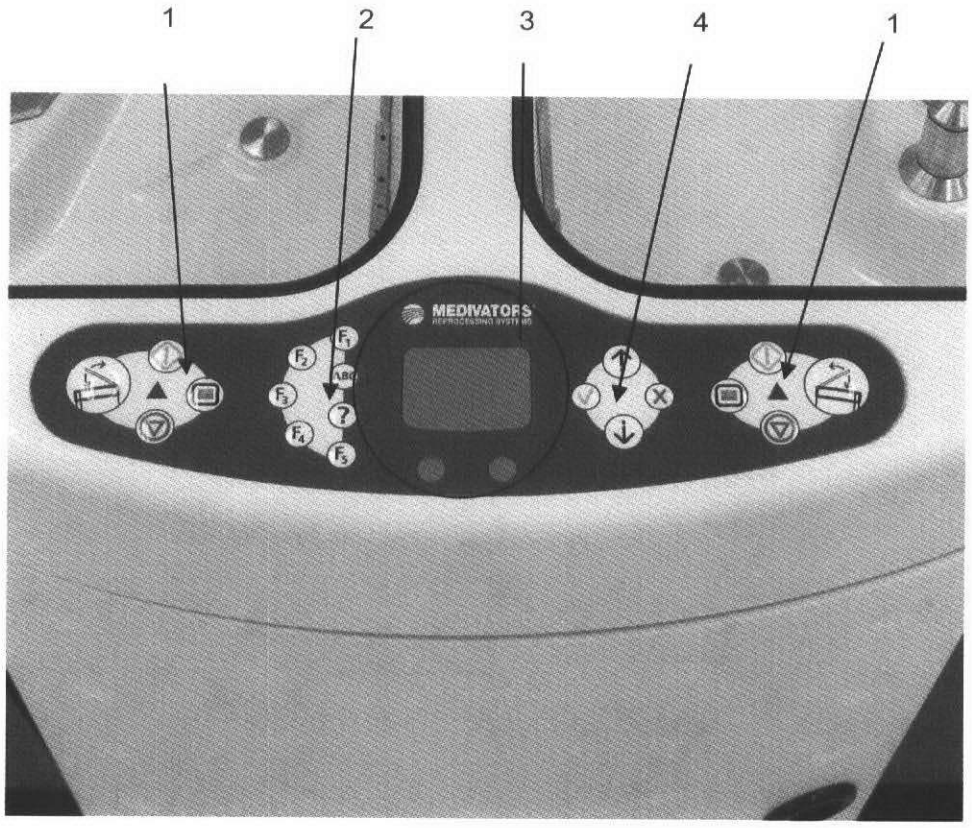

Figure 6 Control Panel

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Module Control Buttons

Each module is controlled by its own keypad grouping. The group shown in *Figure 7* is for the right module.

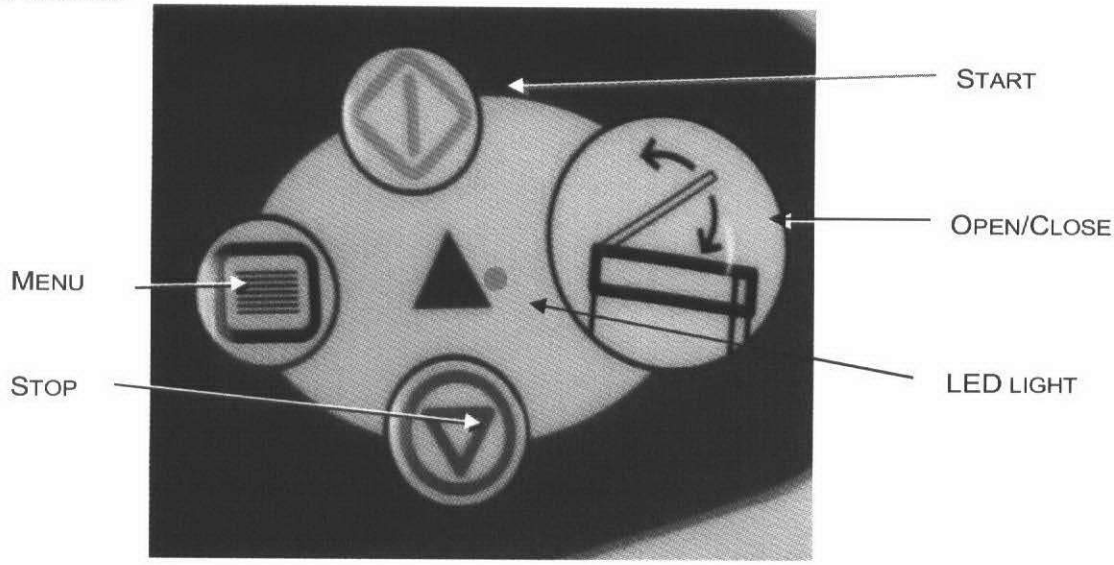

Figure 7 Module Control Buttons

- Press the **Open/Close** button to open or close the lid on the basin. Note that during disinfection, the lids will not open.
- Press the **Start** button to start a disinfection program. The button is also used to restart a program after an error.
- Press the **Stop** button whenever you have a reason to stop a disinfection program. If disinfectant is in contact with the endoscope when the button is pressed, the program will run until conditions are safe.
- Press the **Menu** button to log in, select programs, and enter data.
- The LED light will be extinguished when the MDS is in standby mode. When the MDS is reprocessing an endoscope properly, the LED will be a steady green light. When the MDS has successfully completed a reprocessing cycle, the LED will blink green. Should an error occur during reprocessing, the LED will be a steady red light.

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Touchpad and Mouse Buttons

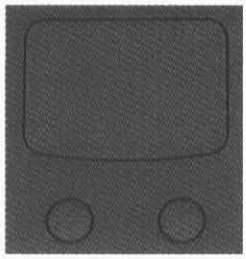

Figure 8 Touchpad and Buttons

The touchpad works as a mouse to enter information. Moving your finger on the pad causes the cursor to move on the monitor. Tapping the touchpad or pressing the left button has the same result as clicking the left button on a mouse. The two buttons correspond to the left and right buttons on a mouse.

Function Buttons

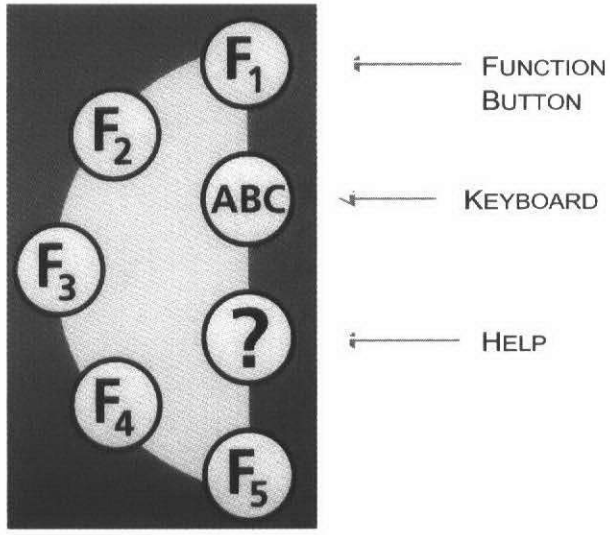

Figure 9 Function Buttons

- The **F1, F2, F3, F4,** and **F5** buttons have functions that can be designated by the MDS administrator.
- Press the **ABC** button to get a keyboard to appear on the monitor. By using the touchpad and mouse buttons, letters and numbers can be entered.
- Press the **Help** (?) button to obtain help and additional information.

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Table 1 Function Buttons

Function Key	Press Button (No. of times)	Result
F1	1	Signals and alarm overview, left basin
F1	2	Signals and alarm overview, right basin
F1	3	Signals and alarm overview, both basins
F1	4	Clears signals and alarm overviews, re-opens program window
F2	1	—
F3	1	Opens system parameters. Press again to close.
F4	1	History report for the current day. Press again to close.
F5	1	—

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Selection Buttons

- The **Stop/Cancel** ⊗ button corresponds to the Cancel button in the software.
- Pressing the **Scroll Up** ⓣ button allows you to scroll up through a list on the monitor.
- Pressing the **Scroll Down** ⓓ button allows you to scroll down through a list on the monitor.

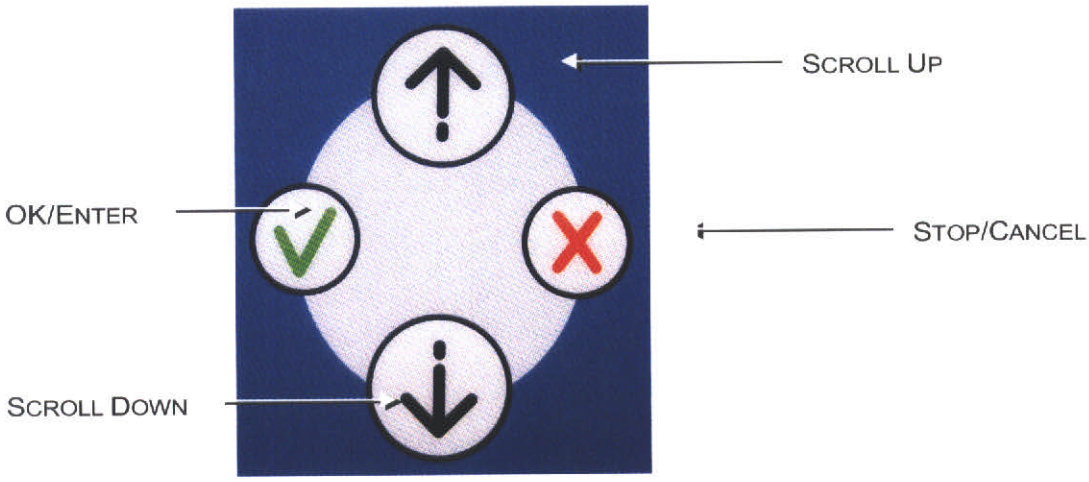

Figure 10 Selection Keys

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Dimensions and Weight of the MDS

(b)(4) Trade Secret Process - Product specs

D. Materials of Construction of the MDS Machine

(b)(4) Trade Secret Process - Product specs

Materials of Constructions of Major MDS Components

Component	Material of Construction	Rational for selection
(b)(4) Trade Secret Process - Product specs	[redacted]	

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Component	Material of Construction	Rational for selection
(b)(4) Trade Secret Process - Product specs		

E. Machine Packaging Description

(b)(4) Trade Secret Process - Product specs

F. Operating System Software Used in the MDS

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(b)(4) Trade Secret Process - Product specs

X. Labeling

Appendix E includes a (b)(4) Trade Secret Process - Product specs

A draft version of the labeling for the MDS machine is located in Appendix G.

Appendix H includes d(b)(4) Trade Secret Process - Product specs [redacted].

Appendix I contains (b)(4) Trade Secret Process - Product specs [redacted].

XI. Indications for Use

Appendix J includes an Indications for Use Statement for the MDS.

XII. Statement of Equivalence

(b)(4) Trade Secret Process - Product specs [redacted]

XIII. 510(k) Summary

A 510(k) Summary is located in Appendix M.

XIV. MDS Machine Evaluations

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(b)(4) Trade Secret Process - Product specs [redacted]

(b)(4) Trade Secret Process - Product specs

B. Electrical Safety Testing

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C. Performance Testing

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i. Simulated Use

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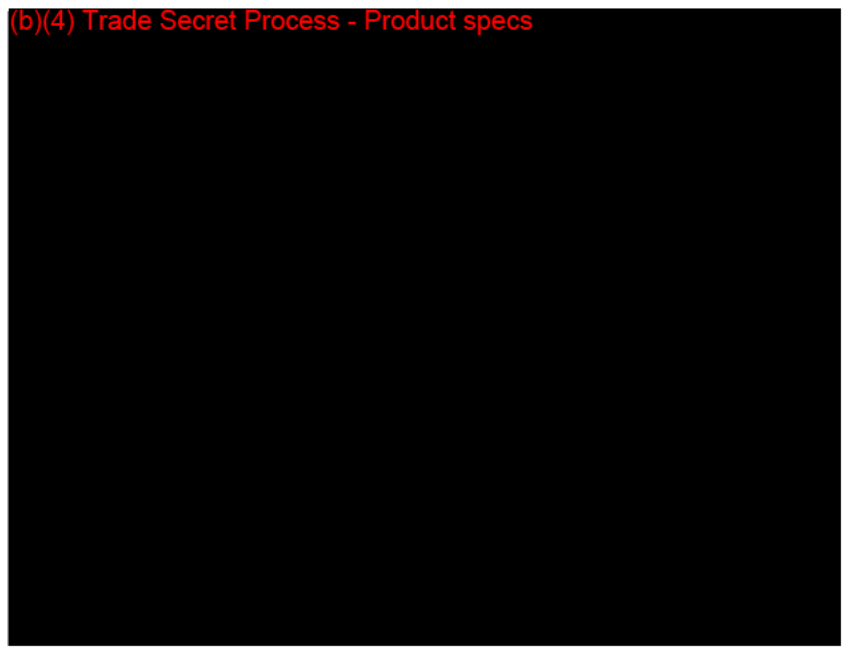

ii. In Use Testing of Clinically Used Scopes

(b)(4) Trade Secret Process - Product specs

D. Residue Evaluations

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ii. Endoscope Rinsing

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E. Machine Self-Disinfection

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F. Software Verification

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i. Software System Parameter Verification

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ii. Error Conditions

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(b)(4) Trade Secret Process - Product specs

[redacted]

G. Functional Testing

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[redacted]

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XV. Accessories

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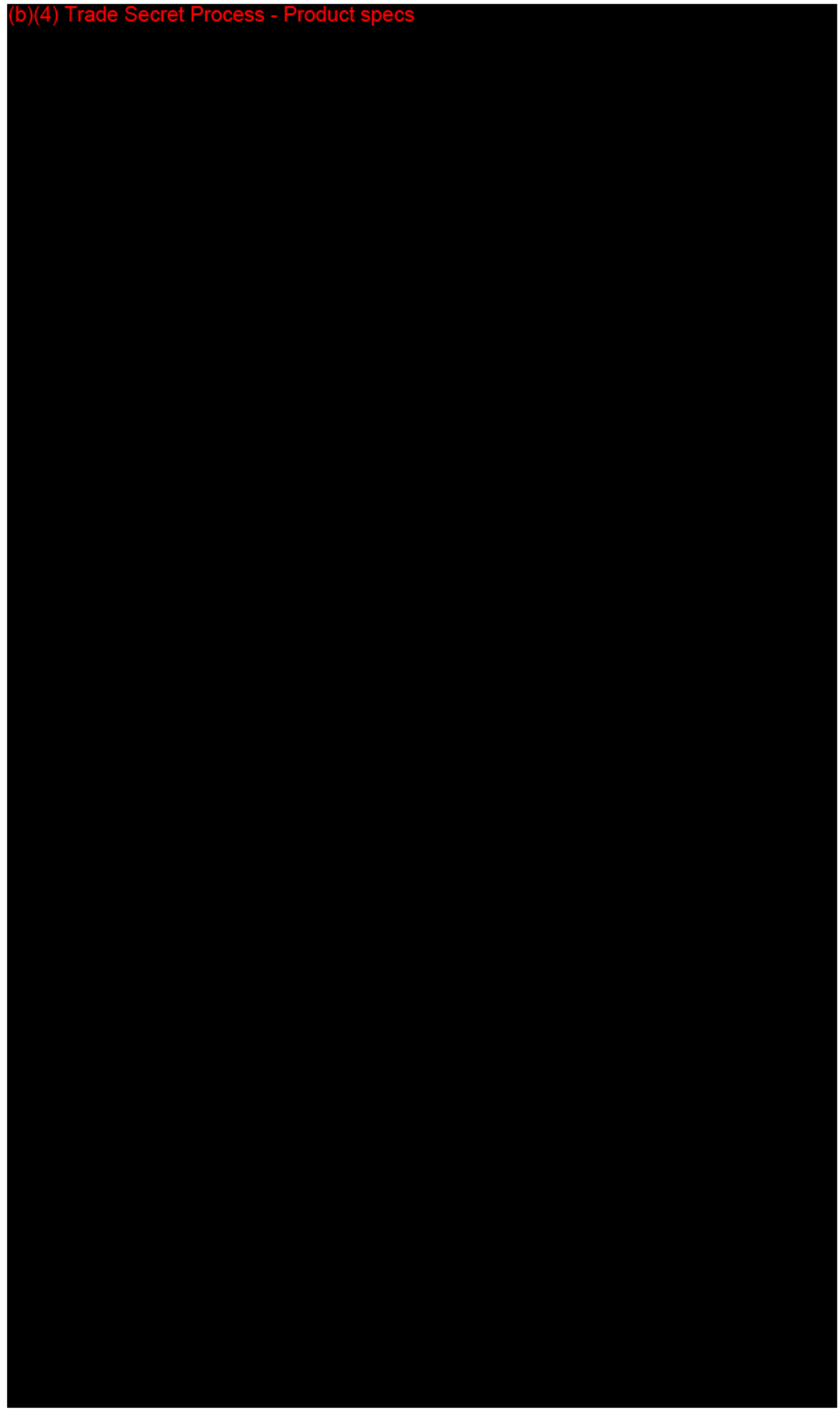
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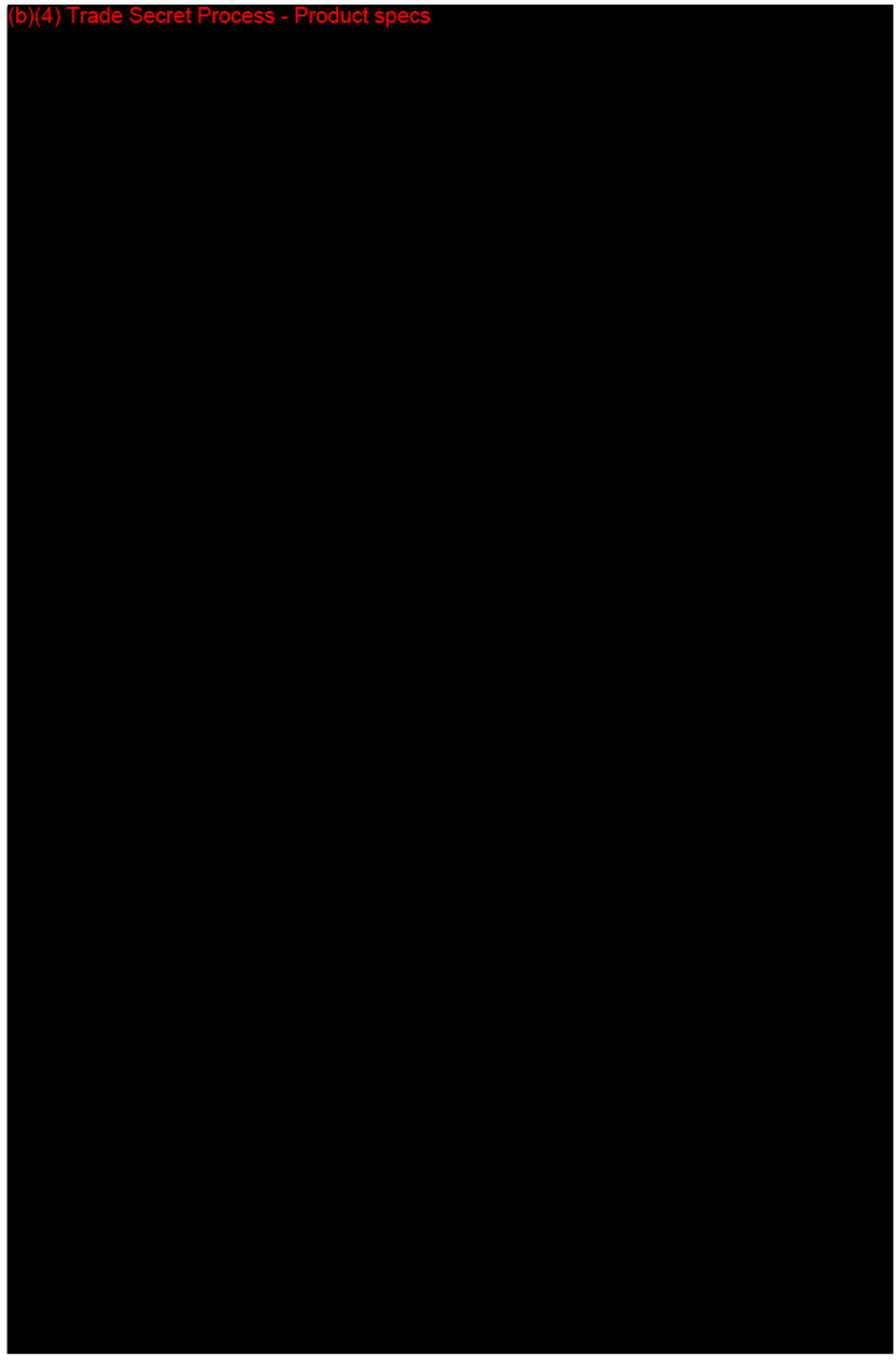
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Appendix A

Truthful and Accurate Statement

Medivators Reprocessing Systems
Modular Disinfection System for Endoscope Reprocessing
Premarket Notification
[As required under 21 CFR 807.87(j)]

I certify that in my capacity as Director, Regulatory Affairs of Minntech Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and no material fact has been omitted.

Lynn Lueders
Director, Regulatory Affairs

Dec. 28, 2006

Date

Appendix B

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Appendix C

Software Design Specification

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Appendix D

(b)(4) Trade Secret Process - Testing

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Appendix E

Medivators MDS

Endoscope Reprocessor

User Manual

DRAFT

Modular Disinfection System
For Multi-Use Chemistry

MEDIVATORS®
REPROCESSING SYSTEMS

50096-654 Rev. A

907

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Chapter 1

INTRODUCTION

This chapter describes the Medivators Modular Disinfection System (MDS) endoscope reprocessor.

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USING THIS MANUAL

This manual describes the features of the Medivators Modular Disinfection System (MDS) endoscope reprocessor, including the hardware, software, setup, operation, safety, maintenance, and troubleshooting procedures. It is important to follow the instructions provided to keep the MDS in good operating order and to ensure that endoscopes receive adequate disinfection.

This is not a service manual and does not provide detailed instructions for service beyond general maintenance. Contact your service representative for additional service information.

INTENDED USE

The Modular Disinfection System (MDS) is intended for the testing, washing, and high level disinfection of flexible video and fiber optic endoscopes.

WARNING *The MDS is not intended for the reprocessing of rigid endoscopes.*

MDS FEATURES

The Modular Disinfection System was designed for ease of use and maintenance in the disinfection of endoscopes. Features include:

- Soil removal to HTM 2030 and PrN 15883 (draft4) standards using water filtered to 0.2 µm, detergent solution, and a powerful spray.
- Asynchronous operation of two large independent basins with locking lids.
- A dedicated personal computer (PC) for cycle recording, powerful quality assurance reporting, easy backups, networking availability, and remote diagnostics.
- Easy-to-fill detergent and alcohol reservoirs and no separate water tank needed.
- Hook-up blocks dedicated to a family of endoscopes ensure correct connectivity and flow rates to meet manufacturers' specifications.
- Individual channel identification, blockage monitoring, alarming, cleaning, and rinsing.

- Remote diagnostics for operator assistance and troubleshooting.
- Ability to use heated disinfectant chemistry (if heated reservoir system is purchased).

MACHINE SPECIFICATIONS

General Specifications

The basic machine specifications required for installation and operation of the MDS are summarized in *Table 1*.

Table 1 Machine Specifications

Equipment Type	Laboratory Equipment
Electrical rating	120 VAC, 60 Hz, 1 PH
Power rating	1920 Watts
Maximum air pressure	10 Bar (145 psi)
Maximum water pressure	6 Bar (87 psi)
Humidity range for operation	20–80%, non-condensing
Temperature range for operation	17°C - 37°C
Environment	Indoor use only
Installation/Over voltage category	II
Pollution degree	2
Connection to power supply	Cord connection
Dimensions	107 cm x 112 cm x 148 cm (36 in x 46 in x 61 in)
Weight	~ 180 kg (400 lb)

Dimensions and Clearances

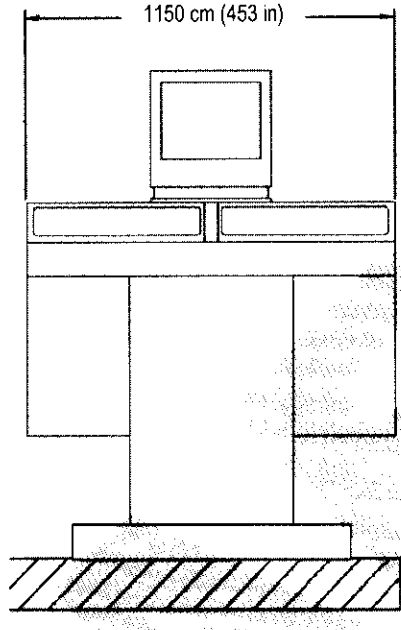

Figure 1 Front Dimensions

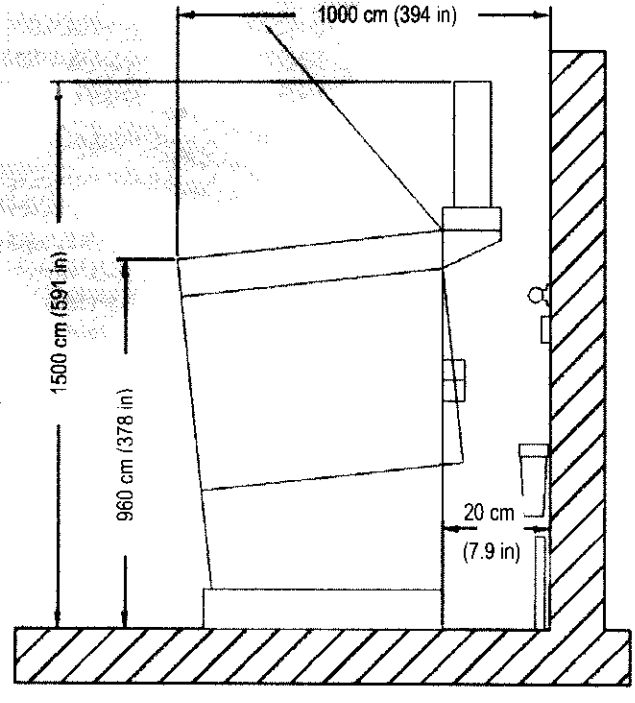

Figure 2 Side Dimensions and Clearance

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SAFETY

Intended Use

This section outlines general safety guidelines for proper operation and service of the reprocessor. Read and understand all procedures before operating or servicing the reprocessor. Never use the MDS for any purpose other than the manufacturer's specific intended purpose. Failure to follow these guidelines may result in severe injury or death to the patient and/or operator.

Regulatory Compliance

The MDS complies with standard UL61010-1: Safety Requirements for Electrical Equipment for measurement, control, and laboratory use.

Caution ***U.S. law restricts this device to sale by or on order of a physician.***

Notes, Cautions, and Warnings

Throughout the manual are notes, service notes, cautions, and warnings. These provide important information and you should pay special attention to them. Examples are shown below.

Note: A note refers to important information to which you should pay special attention.

Service: A service note refers to operations or repairs that only a trained service technician may perform.

Caution ***A caution describes actions or conditions that may cause damage to or destruction of the equipment.***

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WARNING A warning describes actions and conditions that may cause severe personal injury or death to the operator or patient.

Operator Safety

- Equipment must be operated solely by qualified personnel, and used for its intended use only.

WARNING: To avoid biological contamination and chemical burns, always wear appropriate personal protective clothing, gloves, and safety glasses when handling endoscopes or disinfectant solutions.

- Cleansing and disinfectant solutions must be used according to the manufacturer's labeling and instructions for their use, safety, and shelf life.
- Do not attempt to open the reprocessor lid during operation.
- Do not place heavy objects on the glass covers.
- For peracetic acid (PAA) disinfectant handling guidelines, refer to the American National Standard recommended practice titled, *Chemical Sterilants and High Level Disinfectants: A Guide to Selection and Use* (AAMI TIR7:1999) and/or *Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings* (AAMI/ANSI ST35:2003). The documents are available from the Association for the Advancement of Medical Instrumentation.
- For glutaraldehyde disinfectant handling guidelines refer to the American National Standard *Safe use and handling of glutaraldehyde-based products in health care facilities* (AAMI/ANSI ST 58:2005).
- In the event of a disinfectant or other chemical leak, use personal protective clothing, gloves & safety glasses & follow the disinfectant manufacturer's guidelines for spill clean-up procedures.
- Place guidelines for disinfectant clean-up in an easily visible area near the machine to ensure users will have access to the information when needed.

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Installation and Maintenance

Proper maintenance ensures effective disinfection and prolongs the life of the reprocessor.

- The MDS must be grounded in accordance with applicable regulations.
- The system default is factory-set for a specific disinfectant immersion period. This period may be changed in the custom program setting. Verify the program is appropriate for the disinfectant used.
- All pressure regulators are factory-preset. Do not adjust the settings. Contact your Technical Support representative for assistance.
- Do not allow the disinfectant solution to contact metal components.
- Do not use alcohol or alcohol-based products to clean the reprocessor cabinet.
- The hook-ups are not autoclavable and must be reprocessed by low temperature disinfection only.
- Do not remove covers, doors, or panels fastened with screws while the machine is in use.
- Replacement parts must be ordered from the manufacturer to maintain the warranty.
- Do not block ventilation openings.
- Regularly check all cables, piping, and drains for damage or leaks.
- Do not carry out any maintenance that is not described in this manual.
- Do not disable temperature sensors in heated reservoirs (optional equipment).
- Ensure that the power supply connection is accessible in the event that emergency disconnection is necessary.

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GUIDELINES FOR RELIABLE DISINFECTION

Water Quality

Potable water is the minimum standard. Medivators recommends the use of a high quality water pre -filtration system that filters incoming water to a minimum of 0.2 µm. A typical water pre-filtration system, such as the one offered by Medivators, filters incoming water through a 1 µm, .45 µm, .2 µm series of filters.

- The high performance 0.2 µm (absolute) water filter included with the reprocessor is a sterilizing grade bioretentive filter. The filter removes all microorganisms and particles larger than 0.2 µm.
- The routine maintenance schedule recommends replacing the 0.2 µm water filter every six months or sooner, depending on the pre-filtration system and the quality of the incoming water.

Detergent Solution

Medivators recommends the use of a non-enzymatic, low foam detergent solution that has bacteriostatic properties to inhibit bacterial growth in the detergent reservoir and detergent line. The low foam properties aid effective recirculation.

Alcohol

Medivators recommends the use of 70 isopropanol in the alcohol reservoir. The MDS will use this reservoir to draw solution during the final purge to facilitate drying of the endoscope channels.

Monitoring Disinfectant Concentration

The efficacy of a disinfection procedure is directly related to the disinfectant solution used and the amount of time the endoscope is exposed to that solution.

- Disinfectants must be monitored for concentration on a daily basis. Consult the disinfectant manufacturer recommendations for monitoring guidelines.
- Use the manufacturer's test strips to test the concentration of the solution on a daily basis. If the concentration of the solution is below its minimum recommended concentration (MRC), discard and replace it with fresh solution.
- Never use disinfectant beyond the manufacturer's labeling reuse life, even if the potency levels are acceptable.

Disinfectant Solution

Select a low-foaming, high level disinfectant specifically manufactured for high-level medical instrument disinfection. Consult the product label for the appropriate contact time and temperature when programming the disinfection cycle.

Endoscope Precleaning and Testing

General Disinfection Requirements

Endoscope disinfection is recommended if sterilization is not possible or is unnecessary. However, disinfection is a challenge because endoscopes have multiple internal valves and channels that have the potential to harbor microorganisms that could cross-contaminate patients. Reprocessing quality depends largely on a thorough flushing of those parts where contamination can occur.

The MDS may be used with all makes and sizes of flexible, submersible endoscopes that can be internally and externally disinfected. Different programs are available for the various channel configurations and sizes. Endoscope channels must be able to withstand the conditions shown in

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Table 2.

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Table 2 Endoscope Disinfection Requirements

Endoscope Requirement	Maximum Disinfection Conditions
Biopsy and extraction endoscope channels	14.5 psi
Jet, water, and air	21.8 psi
Lift channel	29 psi
Temperature stability	≤ 60°C
Leak test pressure	4 psi
Stability to cleansing and disinfection agents	Varies based on agents used

Preclean and leak test all endoscopes prior to disinfection. Follow manufacturer's instructions and established professional guidelines while cleaning and disinfecting endoscopes. Note that endoscopes with elevator wire channels require additional manual cleaning and disinfection steps.

PROFESSIONAL GUIDELINES

The following organizations have published recommended guidelines for cleaning and disinfecting endoscopes.

Society of Gastroenterology Nurses and Associates, Inc.
401 North Michigan Ave.
Chicago, IL 60611-4267
USA
Tel: 800-245-7462
Fax: 312-527-6658
www.sgna.org

Assoc. for Professionals in Infection Control and Epidemiology, Inc.
1275 K Street NW, Suite 1000
Washington, DC 20005-4006
USA
Tel: 202-789-1890
Fax: 202-789-1899
www.apic.org

American Society for Gastrointestinal Endoscopy
1520 Kensington Rd., Suite 202
Oak Brook, IL 60523-2141
USA
Tel: 630-573-0600
Fax: 630-573-0691
www.asge.org

American Society for Testing and Materials
100 Barr Harbor Dr.
West Conshohocken, PA 19428-2959
USA
Tel: 610-832-9585
Fax: 610-832-9555
www.astm.org

Association of periOperative Registered Nurses, Inc.
2170 S. Parker Rd., Suite 300
Denver, CO 80231-5711
USA
Tel: 800-755-2676
Fax: 303-750-3462
www.aorn.org

Canadian Society of Gastroenterology Nurses & Associates
27 Nicholson Dr.
Lakeside, NS B3T 1B3
CANADA
Fax: 902-473-4406
www.csgna.com

British Society of Gastroenterology
3 St. Andrews Place
Regents Park
London NW1 4LB
ENGLAND
Tel: (+44) (0)20 7387 3534
www.bsg.org.uk

Société Française d'Hygiène Hospitalière S.F.H.H.
Hôpital de la Croix-Rousse
Unité d'Hygiène Hospitalière-Épidémiologie
93 Grande Rue de la Croix-Rousse
69317 Lyon Cdx04
FRANCE
Tél: 04 72 07 19 83
Fax: 04 72 07 19 85
www.sfhh.net

MACHINE CONNECTIONS

Electrical

The MDS must be connected to a single electrical outlet capable of supplying 13 amps at 120 ± 10% volts AC. The outlet must be properly grounded.

Water

Potable water is the minimum standard. For optimum performance, water must be delivered at a minimum flow rate of 5 L/min at a dynamic pressure of 30 psi during the basin fill. A back syphonage prevention device must be purchased separately and installed between the water line & the machine to prevent contamination of the water supply in the event of a sudden drop in water pressure.

Drain

For optimum performance the MDS should be connected to a vented sanitary drain system capable of draining at a minimum rate of 6 L/min.

Room Ventilation

The MDS must be installed in a room with a ventilation system capable of delivering a minimum of 10 air exchanges per hour.

An optional ventilator fan may be factory installed for customer convenience. The fan can be connected to a duct system capable of handling an air flow of 60 m^3/hour. Connection of this fan does not change the requirement for adequate room ventilation.

Air

The MDS must be connected to an air supply for proper operation. The air supply must be capable of delivering medical grade air at a minimum of 40 L/min at 6 bar (87 psi).

An optional air compressor system is available for the Medivators MDS machine. The air compressor is factory installed and delivers proper air flows and pressures for correct system operation.

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STORAGE

If the MDS will be out of service for an extended period of time, the following steps must be followed:

- Remove the side covers, purge all liquids from the system, and then replace the covers.
- Place a covering over the unit to protect it from dust and moisture.
- The storage temperature must not go below 0°C (32°F), or exceed 60°C (140°F).
- The maximum relative humidity must not exceed 80% during storage.

TRANSPORT

The MDS may be safely moved on its casters on a smooth, level floor. However, if you will encounter any thresholds or floor level changes, the base cover must be removed to avoid damage. For all other moves, place the MDS on a pallet with a kraft liner.

ELECTROMAGNETIC COMPATIBILITY

This section covers the electromagnetic compatibility (EMC) aspects of the MDS Endoscope Reprocessor.

WARNING Portable and mobile communication devices can affect electrically-operated medical equipment.

Medical equipment requires special precautions regarding EMC. The MDS must be installed and put into service according to the EMC information in this section.

Symbols and Icons

Symbol	Symbol Meaning	Symbol	Symbol Meaning
	LIO software shortcut		Cancel
Management	Management software shortcut		Next
Server	Server software shortcut		Release All
	Expert Operation		Start
	Cancel		Stop
	Menu		Active report, filter applied.
	Open/Close		Edit
	OK/Enter		Expand
	Scroll Down		Export data
	Scroll Up		Filter data
	Start		Generate report
	Stop		Minimize report details
	Import data		New

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WARNING SUMMARY

WARNING Portable and mobile communication devices can affect electrically-operated medical equipment

WARNING Connecting a chemical container with the incorrect fluid may cause the endoscope to be improperly disinfected. Do not use the endoscope on a patient if this occurs.

WARNING Wear protective clothing, gloves and eyewear. The disinfectant and detergent manufacturers may recommend additional protection.

WARNING Do not insert hands into the disinfectant reservoir while it is connected to the system. This may result in injury due to contact with chemical or heater elements (optional equipment.)

WARNING Verify that the air pressure readings are within the acceptable ranges before every reprocessing cycle. Do not make air pressure adjustments during a disinfection process.

If the main air pressure regulator is not set correctly, the endoscope may not be properly disinfected.

If the leak test regulator cannot be set correctly, the endoscope may be damaged during the reprocessing cycle

WARNING All endoscope hookups must be periodically inspected for damage, and discarded if damaged, otherwise it could result in an endoscope that is not disinfected and therefore should not be used on a patient.

WARNING Verify all connections to the endoscope are secure. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.

WARNING Verify the connection tubing does not interfere with the spray head and confirm that the spray function is working during the cycle. Failure to do this could result in an endoscope that is not disinfected and therefore should not be used on a patient.

WARNING Before removing the endoscope, verify all connection to the endoscope are secure. If an adapter is loose or disconnected, the disinfection was not complete and must be repeated. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.

WARNING Report all system errors to your supervisor.

WARNING Wear clean gloves to prevent soiling of the disinfected endoscope.
If a run error was generated, a channel is blocked, or the endoscope is leaking, the endoscope must not be released for patient use. If there is any doubt as to whether an endoscope is correctly disinfected, it must be disinfected again before use. Contact your supervisor for further instructions.

Verify all connection to the endoscope are secure. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.

WARNING Avoid possible chemical burns. Always wear personal protective equipment (gloves, goggles) when handling disinfectant and/or detergent.

WARNING Use only cleaning and disinfectant fluids approved by Medivators Reprocessing Systems.

Check the expiration date of the disinfectant in the machine each day.

Never use disinfectant beyond the manufacturer's expiration date, even if the MRC level is acceptable.

Never use disinfectant that tests below the acceptable MRC level, even if it has not yet reached the expiration date.

If using heated reservoirs, always heat chemical to manufacturer's stated temperature.

Never use heated reservoirs with a disinfectant intended for use at room temperature.

When replacing disinfectant, always wear protective clothing, gloves and eyewear. The disinfectant manufacturer may recommend additional protection.

If leaking liquid is present and you suspect it is disinfectant, read and follow the manufacturer's instructions before attempting a cleanup.

WARNING Ensure that the machine is installed and maintained in a position that allows access to the power cord for emergency disconnection if necessary.

Never use the equipment in a manner inconsistent with the manufacturer's guidelines. Using the equipment in a manner inconsistent with the manufacturer's guidelines may impair the protections that are designed into the device and may cause injury to the user..

Chapter 2

OPERATOR CONTROLS

This chapter describes the MDS operator controls, and how to set up and program the reprocessor.

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MAIN COMPONENTS AND THEIR FUNCTIONS

Exterior Components

The MDS machine consists of two independent reprocessing modules. Each has a basin, automatic cover, endoscope hookups, and the necessary pumps and valves to disinfect, rinse, and dry most models of flexible, submersible endoscopes.

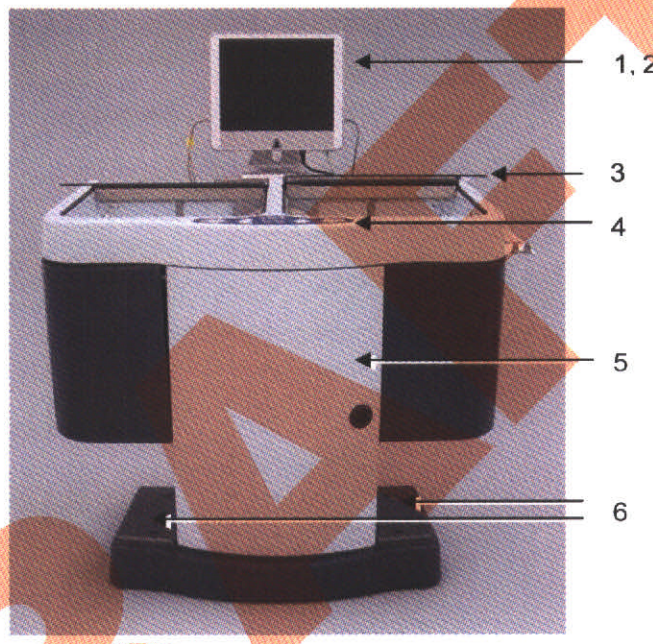

Figure 1 MDS Front View

1. **PC:** Runs the programs on the MDS that disinfect the machine and endoscopes.
2. **PC Monitor:** Displays messages, menu selections, and the operation status.
3. **Basin Lid:** Cover for the left or right basin of the MDS. Open the lid to add or remove endoscopes.
4. **Control Panel:** Use to specify settings, operate the reprocessor, and view system messages, errors and warnings.
5. **Access Door:** Opens to allow access to the reservoirs, filters, transfer valves, and pressure gauges.
6. **Foot Switch:** Pressing the right foot switch opens the right basin lid, and pressing the left foot switch opens the left basin lid.

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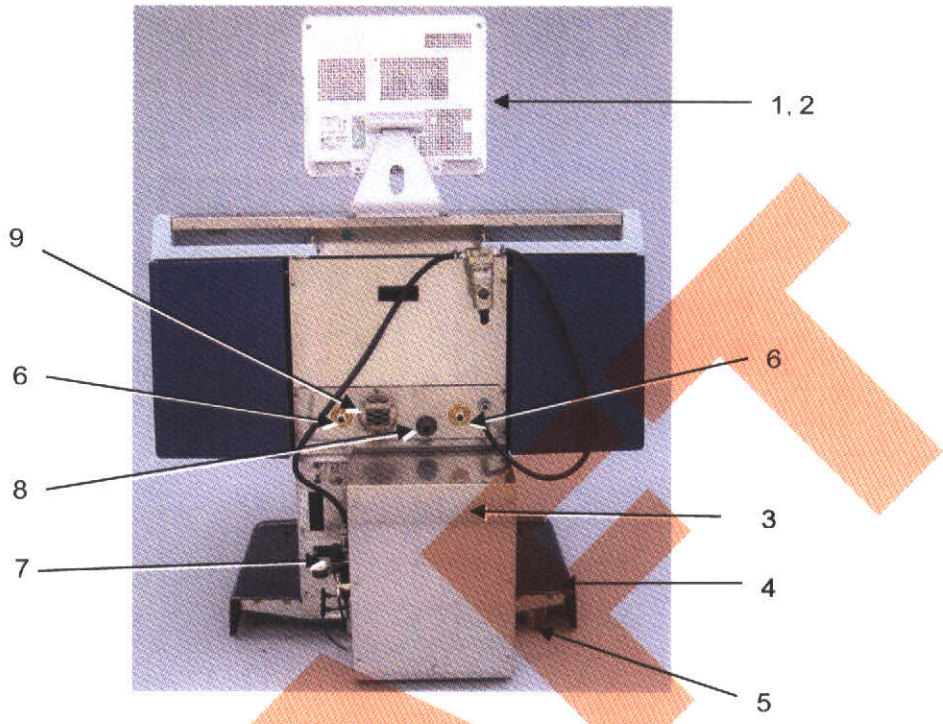

Figure 2 MDS Back View

1. **PC:** Runs the programs on the MDS that disinfect the machine and endoscopes.
2. **PC Monitor:** Displays messages, menu selections, and the operation status.
3. **Electronic Module:** Contains electronic components, including fuses, which run the MDS.
4. **Foot Shroud:** Covers and protects the bottom of the MDS.
5. **Castors:** Small wheels to make the MDS easier to move.
6. **Water Supply Inputs:** Inlet for filtered water, one for each module.
7. **System Power:** Electrical power supply connection.
8. **Discharge:** Fluids output to the drain.
9. **Vapor Venting:** Exhausts fumes from the modules, preventing operator exposure.
10. **Compressed Air:** Used to power different processes during disinfection.

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Interior Components

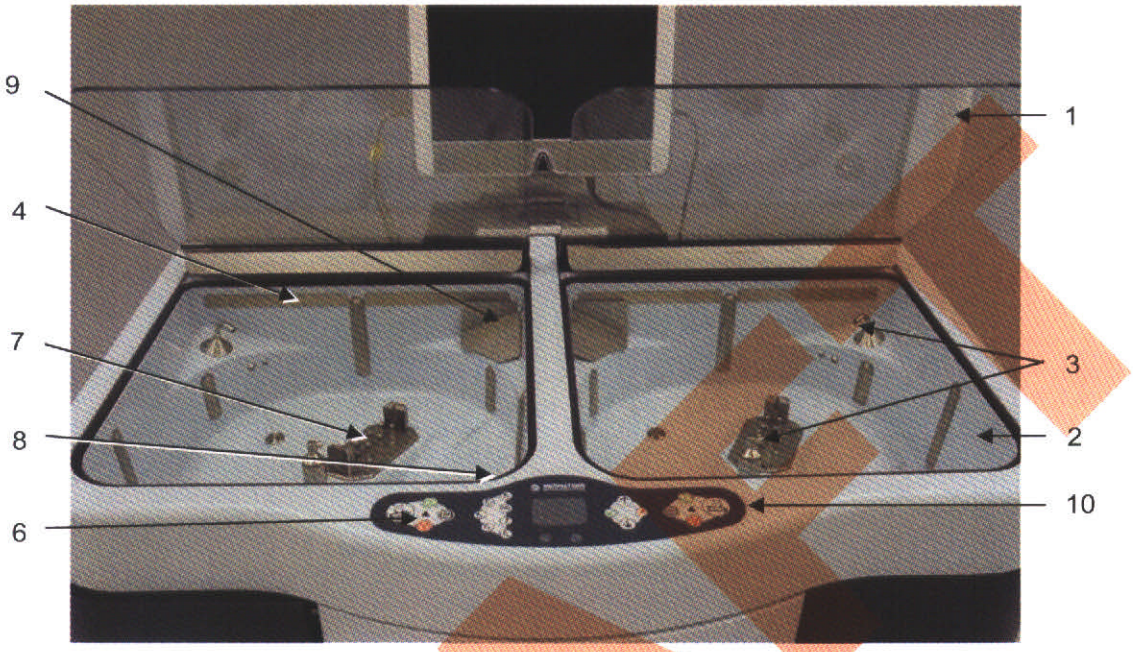

Figure 3 MDS Top View

1. **Basin Lid:** Cover for the left or right basin of the MDS. Open the cover to add or remove endoscopes.
2. **Basin:** Container where endoscopes are disinfected.
3. **Fluid Inlet:** Port where liquids are dispensed into the basin.
4. **Vapor Ports:** Draws fumes away from the module to prevent operator exposure
5. **Spray Head:** Disperses a fine jet of fluid into the basin.
6. **LED:** Provides system and cycle status during endoscope disinfection.
7. **Cassette Dock:** Attaches a cassette to the basin.
8. **Drain:** Outlet port through which waste fluids are dispensed.
9. **Overflow:** Outlet used to drain off excess fluids.

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10. **Control Panel:** Use to specify settings, operate the reprocessor, and view system messages, errors and warnings.

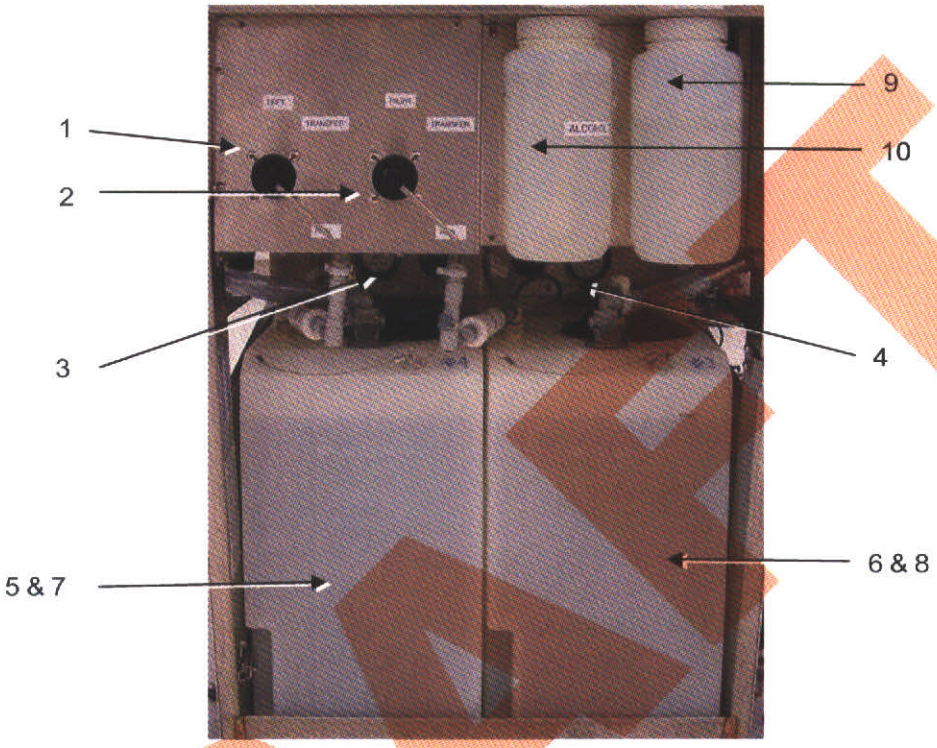

Figure 4 Chemical Reservoirs

1. **Left Transfer Valve:** Used to transfer fluid to the left reservoir.

2. **Right Transfer Valve:** Used to transfer fluid to the right reservoir.

3. **Main (High) Pressure Gauge (left):** Measures air pressure in the MDS system.

4. **Leak Test (Low) Pressure Gauge (right):** Measures air pressure in the endoscope and MDS system.

5. **Disinfectant Reservoir:** Holds disinfectant solution used in the disinfection process for left module

6. **Disinfectant Reservoir:** Holds disinfectant solution used in the disinfection process for the right module.

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7. **Heated Disinfectant Reservoir (Optional):** Holds disinfectant solution at elevated temperature to be used in the disinfection process for left module.

8. **Heated Disinfectant Reservoir (Optional):** Holds disinfectant solution at elevated temperature to be used in the disinfection process for right module.

9. **Detergent Reservoir:** Holds detergent used in the disinfection process.

10. **Alcohol Reservoir:** Holds alcohol that may be used in the disinfection process.

PC and Connections

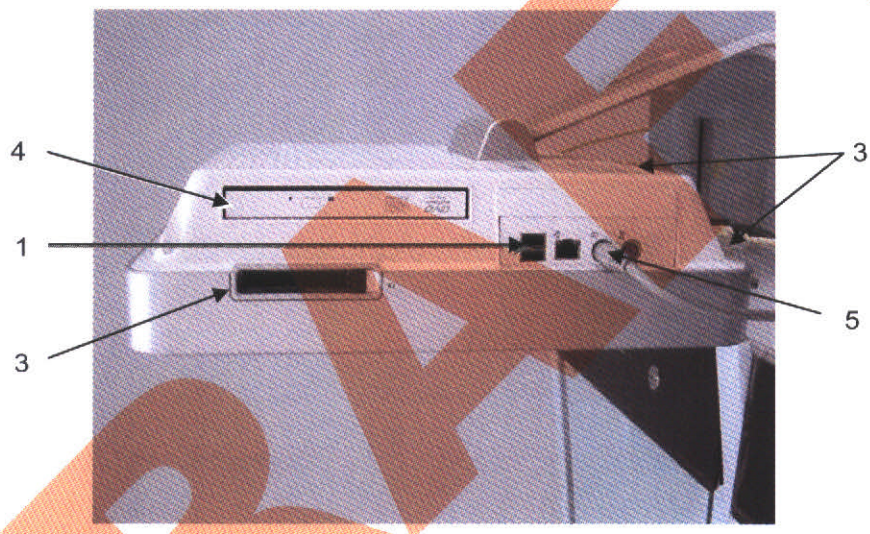

Figure 5 PC and Connections

1. **USB Port:** Connector between the PC and external peripherals.

2. **Power:** Electrical power supply connection (not shown).

3. **Serial Port:** Connector between the PC and external peripherals.

4. **CD Drive:** Reads and writes compact disks *(on front, not shown in photo)*.

5. **Mouse Connection:** Connection for an external mouse.

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Control Panel

The control panel allows the operator to specify settings, operate the reprocessor, and view system messages, errors and warnings. It consists of five main groups:

1. Left and right module control buttons
2. Function buttons
3. Touchpad and mouse buttons
4. Selection buttons
5. Left and right module LED lights

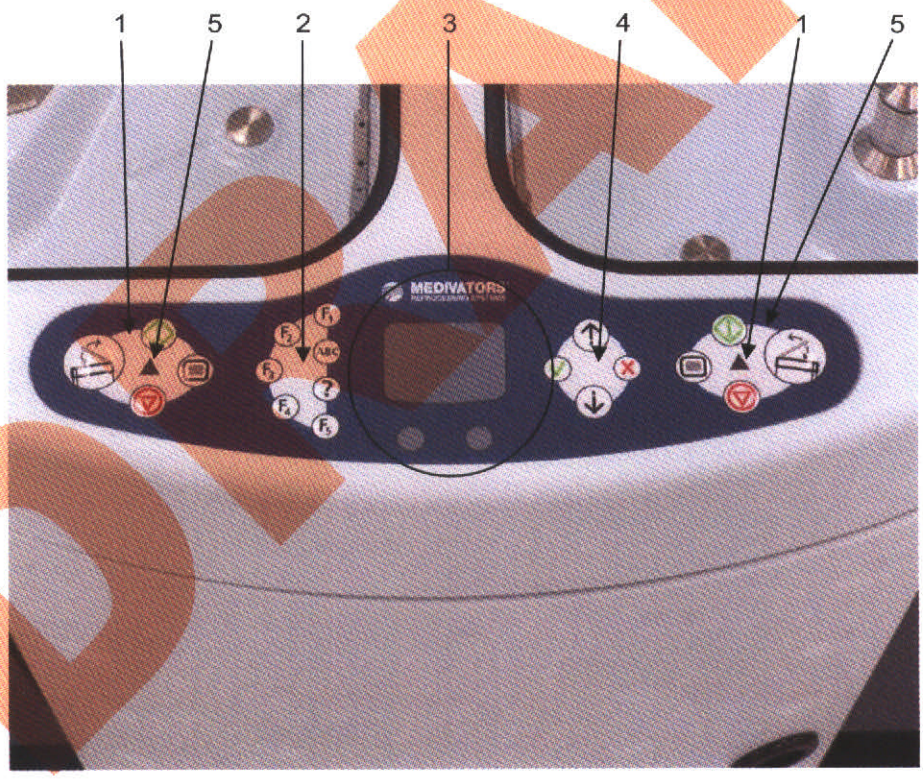

Figure 6 Control Panel

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MODULE CONTROL BUTTONS

Each module is controlled by its own keypad grouping. The group shown in *Figure 7* is for the right module.

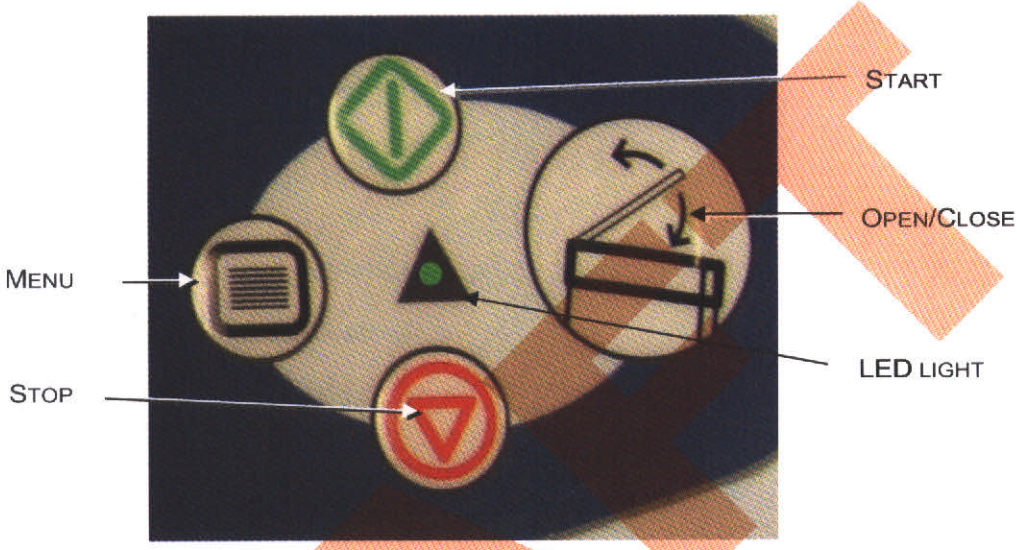

Figure 7 Module Control Buttons

- Press the **Open/Close** button to open or close the lid on the basin. Note that during disinfection, the lids will not open.
- Press the **Start** button to start a disinfection program. The button is also used to restart a program after an error.
- Press the **Stop** button whenever you have a reason to stop a disinfection program. If disinfectant is in contact with the endoscope when the button is pressed, the program will run until conditions are safe.
- Press the **Menu** button to log in, select programs, and enter data.
- The LED light will shine green when the system is operating normally.

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TOUCHPAD AND MOUSE BUTTONS

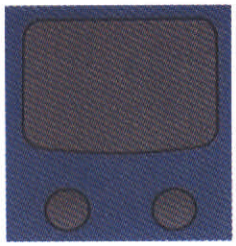

Figure 8 Touchpad and Buttons

The touchpad works as a mouse to enter information. Moving your finger on the pad causes the cursor to move on the monitor. Tapping the touchpad or pressing the left button has the same result as clicking the left button on a mouse. The two buttons correspond to the left and right buttons on a mouse.

FUNCTION BUTTONS

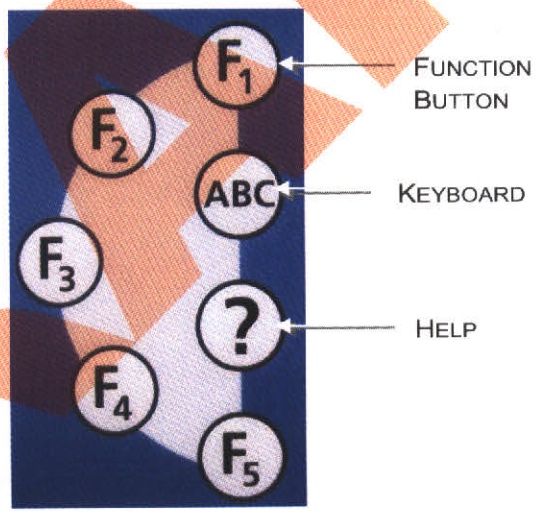

Figure 9 Function Buttons

- The **F1, F2, F3, F4,** and **F5** buttons have functions that can be designated by the MDS administrator.
- Press the **ABC** button to get a keyboard to appear on the monitor. By using the touchpad and mouse buttons, letters and numbers can be entered.
- Press the **Help** (?) button to obtain help and additional information.

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Table 1 Function Buttons

Function Key	Press Button (No. of times)	Result
F1	1	Signals and alarm overview, left basin
F1	2	Signals and alarm overview, right basin
F1	3	Signals and alarm overview, both basins
F1	4	Clears signals and alarm overviews, re-opens program window
F2	1	—
F3	1	Opens system parameters. Press again to close.
F4	1	History report for the current day. Press again to close.
F5	1	—

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SELECTION BUTTONS

- Pressing the **OK/ENTER** ✓ button is the same as clicking on the ✓ OK button in the software.
- The **Stop/Cancel** ⊗ button corresponds to the ✗ Cancel button in the software.
- Pressing the **Scroll Up** ⇧ button allows you to scroll up through a list on the monitor.
- Pressing the **Scroll Down** ⇩ button allows you to scroll down through a list on the monitor.

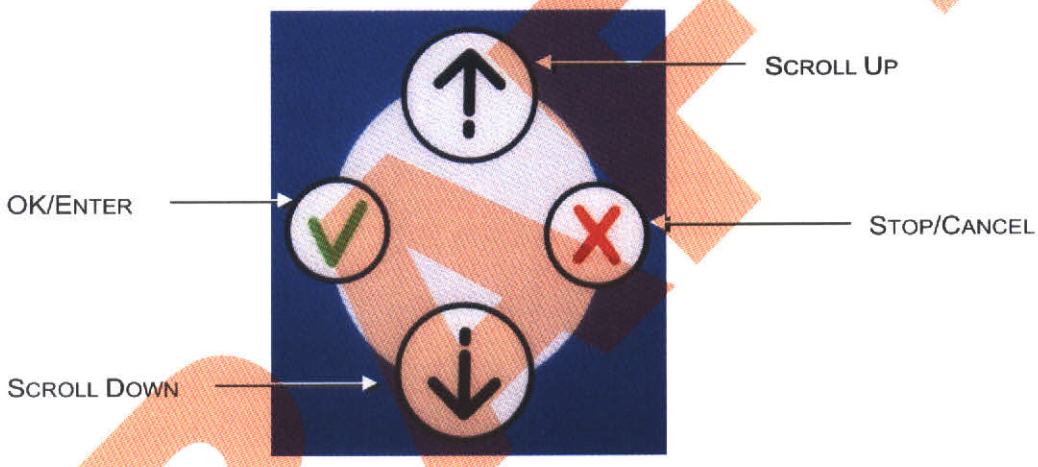

Figure 10 Selection Keys

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Connector Blocks

The endoscope channels are connected to the MDS via a connector block. Each endoscope style requires a unique connector block to ensure that proper disinfection can be achieved. Refer to the hookup application guide in provided with the MDS to identify the correct connector block to use for the endoscope to be disinfected.

The hookup application guide can also be found on the website (www.minntech.com/medivators/resource/index.html)

Note: Before a new type of endoscope is disinfected or if you have any questions about a connection block, contact your field service representative.

Accessories Pouch (Optional)

For instruments and accessories without an internal channel and not requiring a leak test, an accessories pouch may be placed as a fixed "set" in the basin. The set has one selection code and is inserted last. The extra instruments option must be activated by the MDS administrator.

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Transport Basket (Optional)

With the optional transport basket, the endoscope and connector block is integrated within the cassette to form a fixed set. This system allows for easy transportation through the entire disinfection process. From the examination room, to the pre-wash station, to the MDS, drying cabinet, and then back to the examination room, the endoscope is processed safely and hygienically.

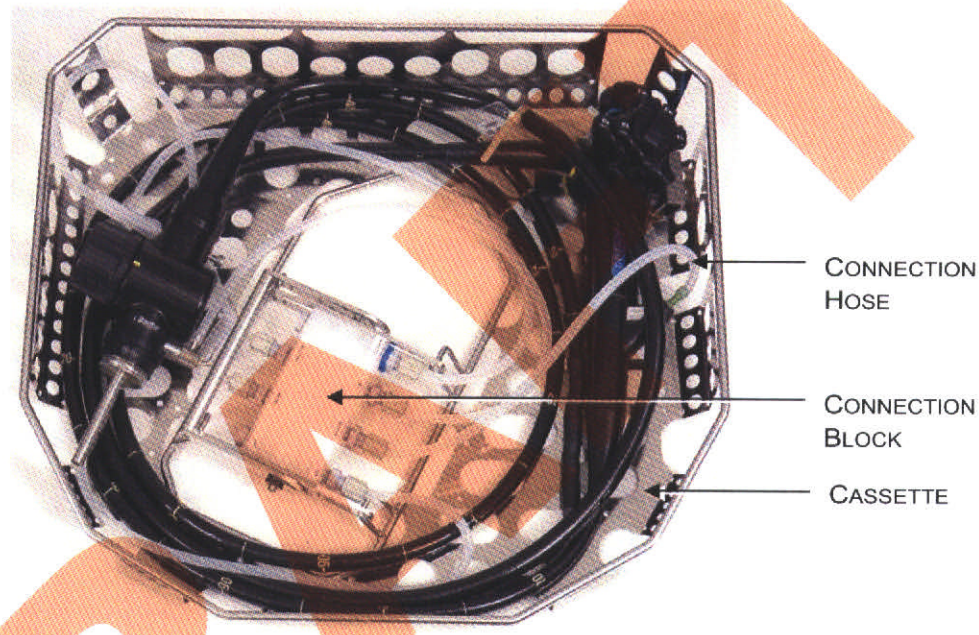

Figure 11 MDS Transport Basket

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Data Entry (Optional)

Bar Code Reader

An optional bar code scanner can be used to automatically enter data rather than manually entering it with the control panel. The system administrator may define a list for any of the following items:

- Operator login name
- Endoscope code
- Doctor/specialist ID
- Assistant ID
- Patient number

To correctly read the data, the point of the pen must move vertically (left to right) over the bar code.

Figure 12 Bar Code Reader for Operator Login and Endoscope ID

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I-DENT

An optional identification chip can be used to automatically enter codes rather than manually entering it with the control panel. The endoscope and operator both have I-Dent devices, as shown in *Figure 14*.

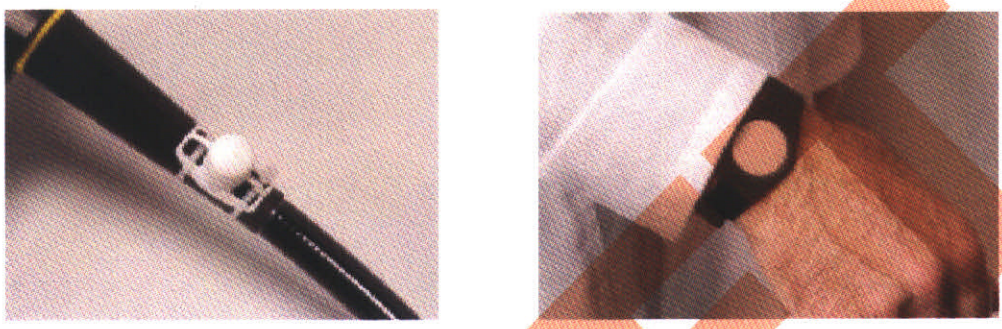

Figure 13 I-Dent Chip on Endoscope and Operator

To correctly read the data, the I-Dent chip on the endoscope and operator wrist band must be held in a specific position, as shown in *Figure 15* and *Figure 16*. If you are using the optional transport basket, the cassette has a notch where the chip on the endoscope must be positioned.

Figure 14 Reading the Operator I-Dent Chip

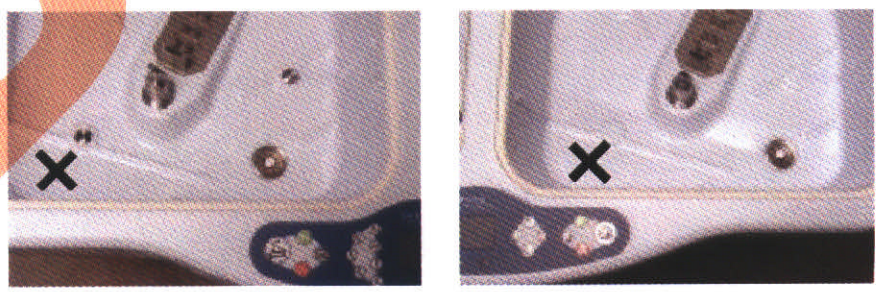

Figure 15 Reading Positions for the Endoscope

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HEATED DISINFECTANT RESERVOIRS (OPTIONAL)

Optional heated disinfectant reservoirs allow the machine to heat disinfectant to elevated temperatures per manufacturer's guidelines. The heated disinfectant can then be delivered to the reprocessing basin during an endoscope reprocessing cycle. The operator will have the option of setting the heater to a schedule which will automatically turn it on and off at preset times, or to turn it on and off manually.

SOFTWARE SYSTEM

Available Programs

Three separate programs control the MDS:

1. **LIO (Logic Input/Output)** is the main software program that MDS operators use to perform and run an endoscope cycle. This part of the software controls the MDS system and is what runs and displays on the PC monitor. This program is used most often by daily operators of the MDS system.

2. **Management** is the MDS database for user and run information. It allows an administrator access to input data, process reports, and manage multiple MDS machines. This program runs on one computer only, which is usually a server of the MDS system.

3. **Server** controls communication between LIO, Management, and MDS machines that may be on a network. This program runs in the background of the MDS system server and is available only to users with administrator access.

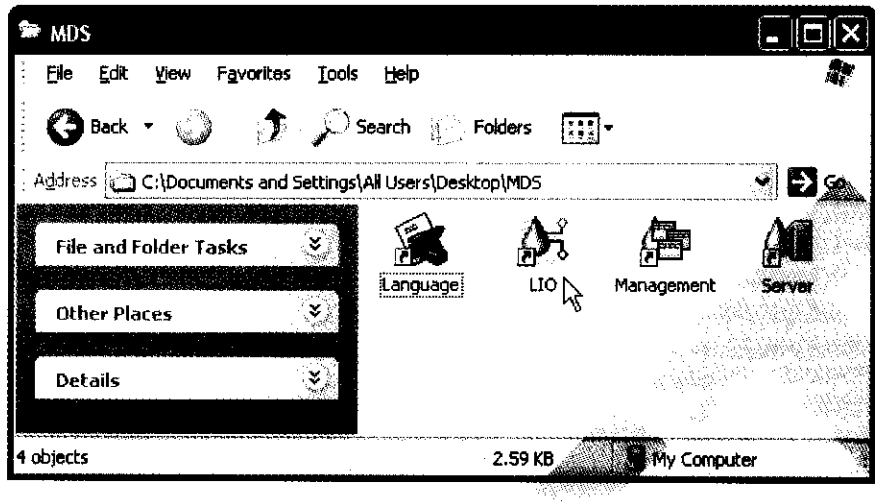

Figure 16 MDS Programs

Starting LIO

Before using the LIO software, you should have a working knowledge of PC computers and the Windows operating system. Make sure you know how to use the control panel, including the touchpad and its buttons. If you are uncertain how to proceed, contact your supervisor or the system administrator for assistance.

1. Verify that the PC is on, Windows is running, and you have a login name and password to run the MDS system.

2. Find the MDS folder on the Windows desktop and double click on it.

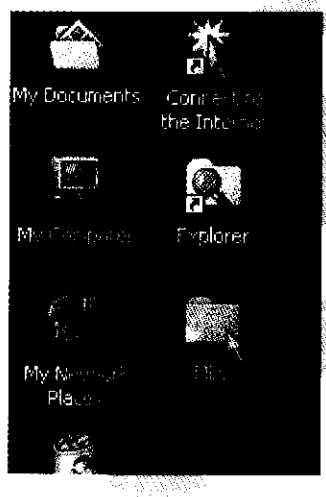

Figure 17 MDS Folder on the Desktop

3. In the MDS window that opens, locate the LIO icon and double click on it to launch the program.

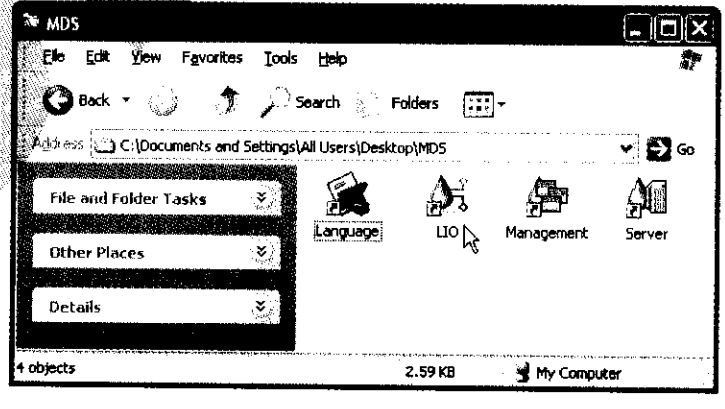

Figure 18 LIO in the MDS Window

The MDS Desktop

The monitor displays all necessary information for operating and maintaining the MDS. Use the buttons on the control panel, to access different screens, programs and functions.

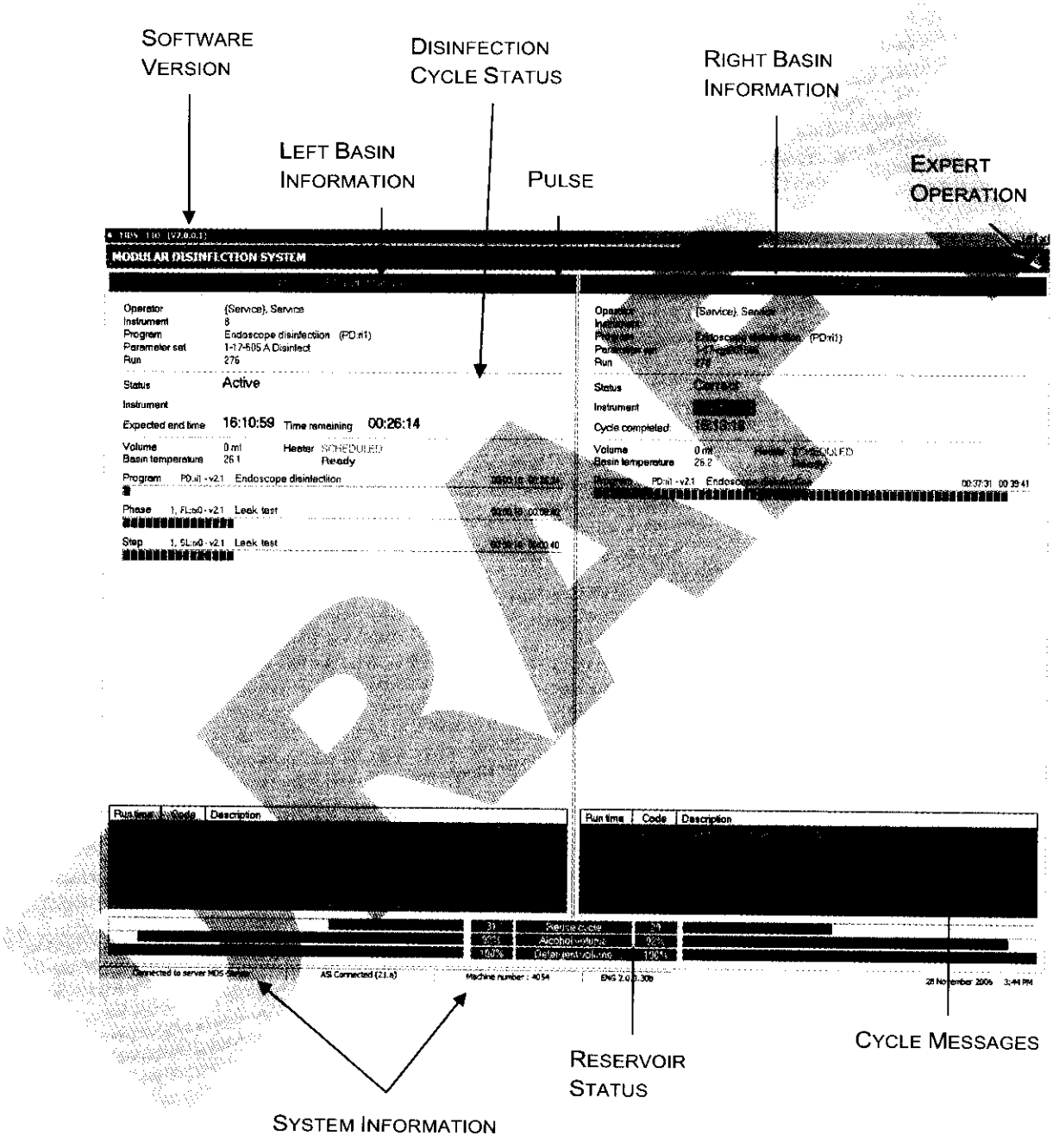

Figure 19 Typical Program Screen

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MENU BAR

Each program has a separate release version shown in the upper left corner of the screen. If a system error occurs, a red message bar appears here until the error is resolved.

The Expert Operation icon appears in the upper right of the menu bar. The Expert Operation is a special application that allows supplemental operations outside the normal use of the MDS. Double-clicking the icon launches the program. You must enter a login name and password to access this application.

MODULE AND PROGRAM STATUS

The status of each module is indicated in the main section of the screen. Program operations for the left module are on the left side of the screen; operations for the right module are on the right side of the screen.

Running program operations for each module are indicated in the section. The information provided includes:

- Operator name
- Endoscope ID
- Program name
- Parameter set
- Number of cycles
- Program status
- Expected run time
- Run time remaining
- Volume
- Temperature
- Program status bar
- Phase status bar
- Step status bar

PULSE

The red pulse indicator blinks on and off to show that the current program is active. Each module has a pulse indicator.

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PROGRAM MESSAGES

Program messages and operator instructions are shown in the lower section of the screen. The messages are presented with text and color. If an error occurs, an audible alarm also sounds.

The text shows the program time elapsed at which the message occurred, the message code, and a description of the message or instructions for the operator to follow. For troubleshooting purposes, the message codes and additional message details are listed in Chapter 5 of this manual. The meaning of each screen color is shown in *Table 2:*

Table 2 Screen Color and Program Status

Screen Color	Program
Orange	Standby, no program active
Gray	Program active
Red	Error
Blue	Program complete

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RESERVOIR STATUS

The reuse cycle and volume of alcohol and detergent in the reservoirs is provided at the bottom of the screen.

Note: The program does not stop at 0% volume. An error message appears and you must replace the fluids.

For heated reservoirs, the screen will also indicate when the heater is on and when it is ready.

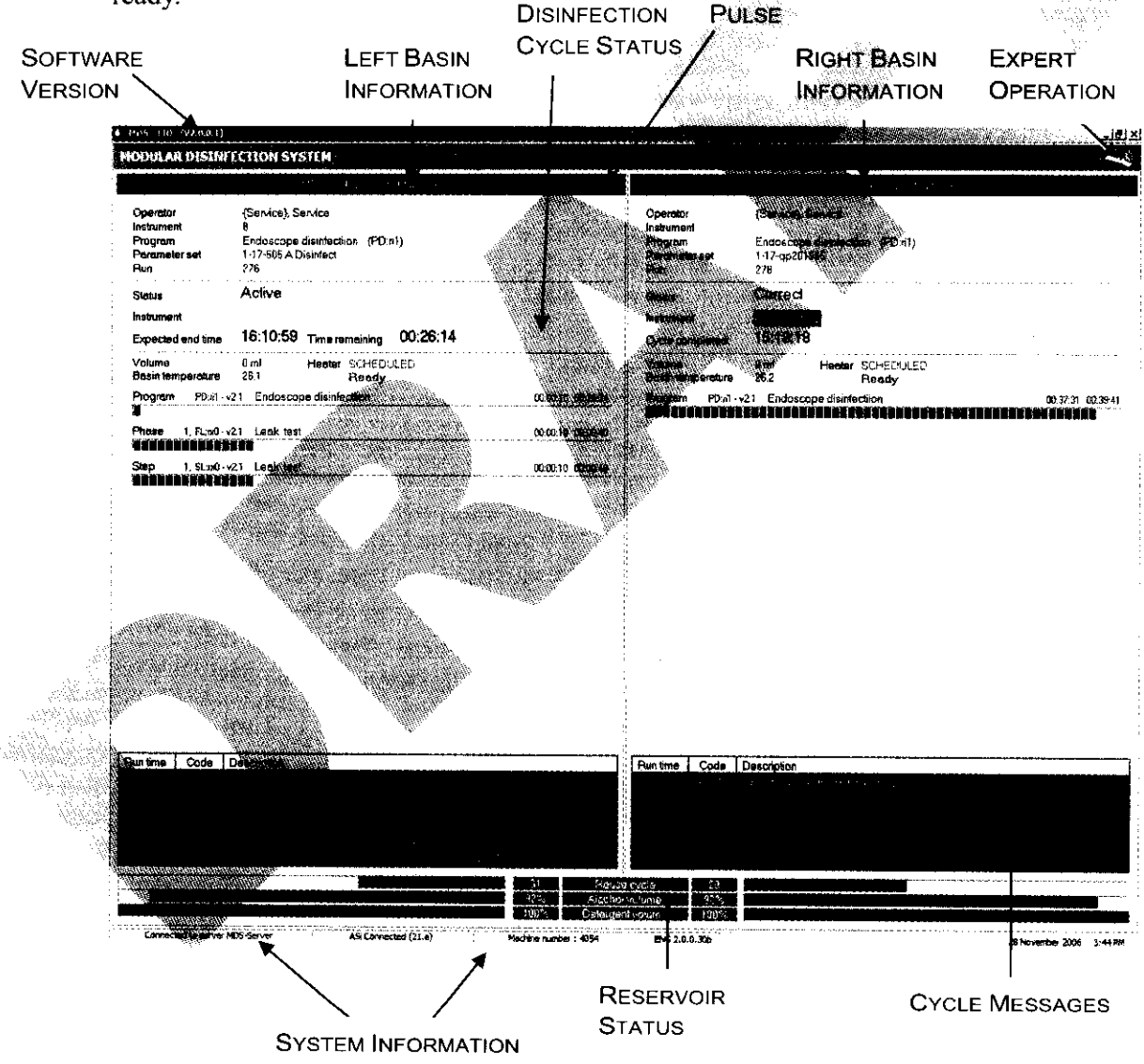

Figure 20 Screen shot showing heater status

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SYSTEM INFORMATION

The bar at the bottom of the screen provides system communication information, machine identification, and the software version for your selected language.

MDS software has two possible system connections:

1. MDS PC to the MDS (AS-i)

2. MDS PC to an external server (optional)

The left field on the bar indicates if the MDS is connected to a server. The next field to the right indicates if the PC is correctly connected to the MDS. If the PC is disconnected the field appears red.

Login Name and Password

Many processes on the MDS require you to supply a login name and password. This confirms that you have the proper authorization to run each program. Data gathered from each process, including the operator's name, is stored in the database and printed on reports.

To enter your login name, move the cursor to the window. Press the down arrow on the right side and scroll down until your login name is highlighted. Click on the name to select it.

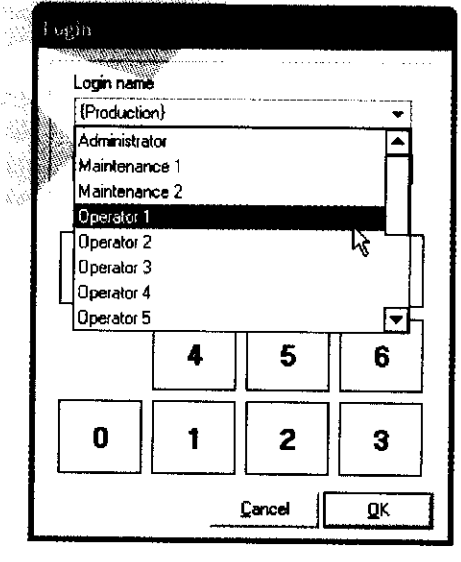

Figure 21 Login Name Selection

To enter your password, click on the appropriate number buttons in the window. If you enter an incorrect number, click the **CLR** button and enter the password again. Press the **OK/ENTER** ✓ button to continue.

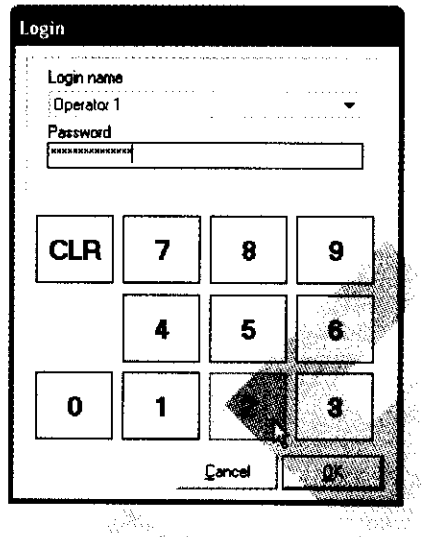

Figure 22 Password Entry

Printing

PRINT SERVICE UTILITY

1. Check for the printer icon in the system tray.

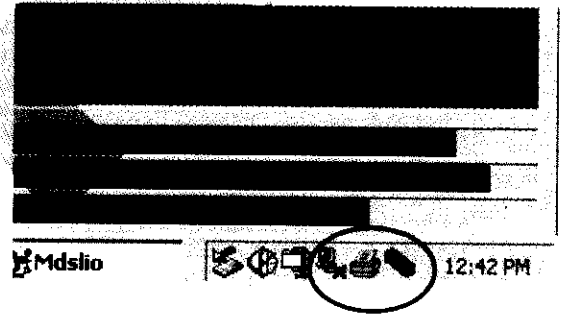

Figure 23 System Tray

2. If the icon is not present, display the Windows desktop by minimizing all open programs.

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3. Open the MDS folder by double-clicking the **MDS** icon.

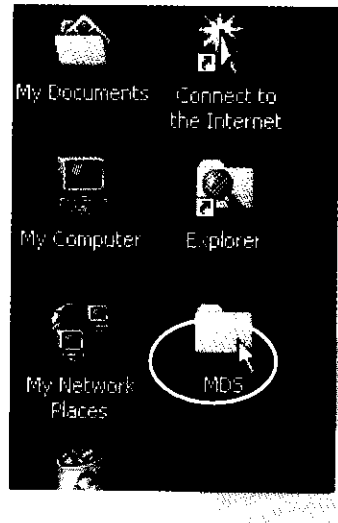

Figure 24 Desktop Detail

4. Double-click on the **Print Service** icon.

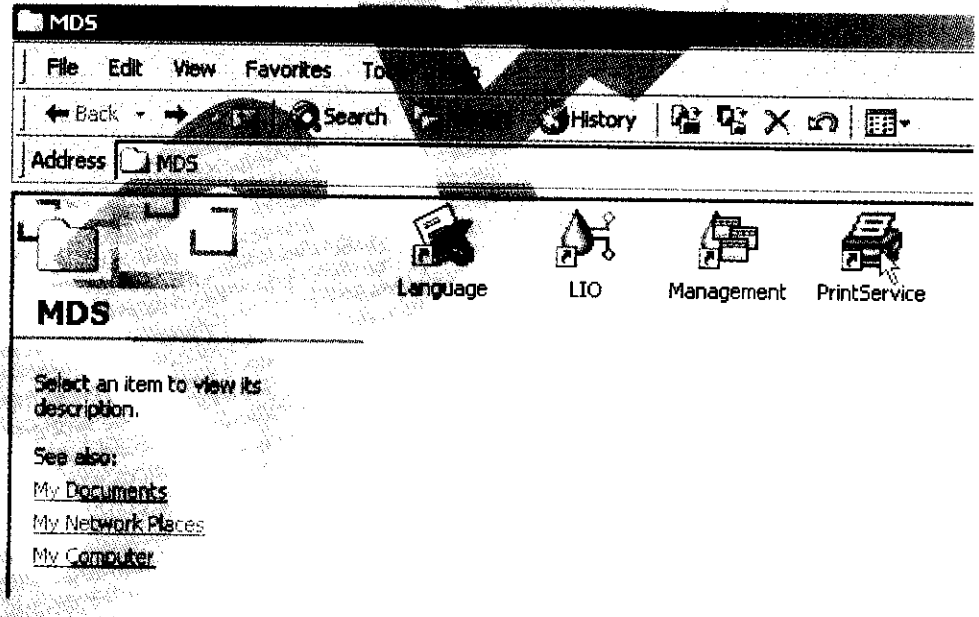

Figure 25 MDS Folder

5. The **Print Service** icon should now appear in the System Tray.

SET THE DEFAULT PRINTER

1. Click on `Start > Settings > Printers.`

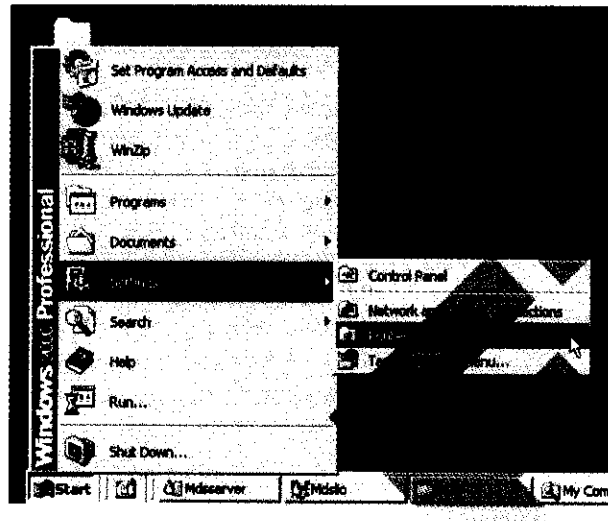

Figure 26 Printer Selection

2. Double-click the icon for your printer.

3. In the dialog box for the printer, double-click on **Set As Default Printer**. A checkmark appears above the printer icon and in the submenu the next time it is accessed.

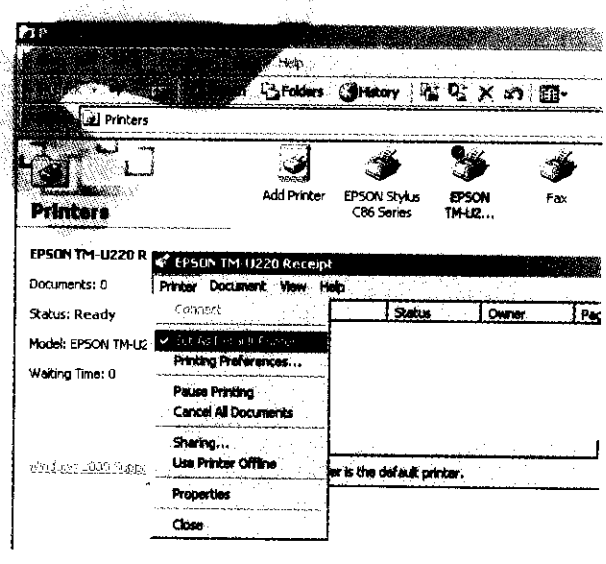

Figure 27 Set As Default Printer

MDS REPROCESSOR SET UP

All Fluids

The system monitors the use of disinfectant, alcohol, and detergent. The percentage of fluid remaining appears in the footer of all screens.

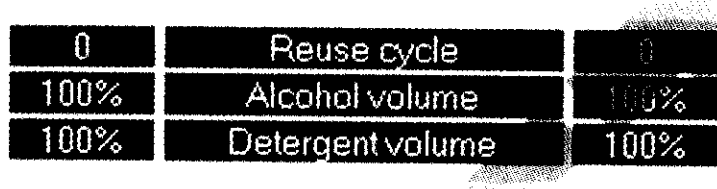

Figure 28 Reservoir Levels

WARNING Refilling the container with the incorrect fluid may cause the endoscope to be improperly disinfected. Do not use the endoscope on a patient if this occurs.

Wear protective clothing, gloves and eyewear. The disinfectant and detergent manufacturers may recommend additional protection.

Disinfectant

CONTACT TIME

Some disinfectant and cleaning agents may cause a change in the appearance of endoscopes and the MDS if used improperly. The disinfectant contact and rinse time is variable and should be set as needed. Before operating the MDS, set up the disinfectant temperature (if used), concentration, and contact time in accordance with the specifications provided by the manufacturer.

WARNING Use only cleaning and disinfectant fluids approved by Minntech Corporation.

DISINFECTANT CHANGE UTILITIES

The disinfectant change utilities are summarized in *Table 3*.

Table 3 Disinfectant Change Utilities

Utility	Function
Dump disinfectant from reservoir	Pumps the disinfectant from the reservoir to the drain
Fill disinfectant from basin	Module cover is opened and disinfectant is poured from container(s) into the basin
Fill disinfectant reservoir from bottle	Three-way valves pump disinfectant from the supply container(s) to the reservoir

WARNING When filling or draining disinfectant, Wear protective clothing, gloves and eyewear when filling or draining disinfectant. The disinfectant manufacturer may recommend additional protection.

If leaking liquid is present and you suspect it is disinfectant, read and follow the manufacturer's instructions before attempting a cleanup.

Service: If leaking fluids are present, contact a qualified service technician.

Dumping Disinfectant

1. Open the cover by pressing the **Open/Close** button.
2. If they are present, remove any endoscopes and/or cassette(s).
3. For each reservoir to be emptied (left and right), install a Machine Disinfection block on the corresponding basin connector block receptacle.

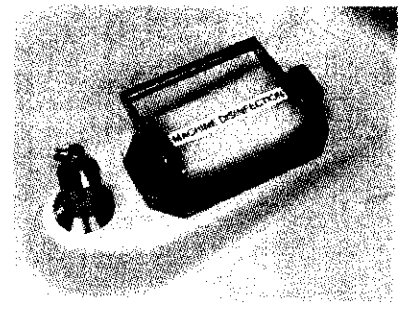

Figure 29 Machine Disinfection Block

4. Press the **Menu** ▣ button on the control panel.

5. Log in to the system.

6. When the **Program Selection** screen opens, select `Replace Fluids` and click the **OK/ENTER** ✓ button.

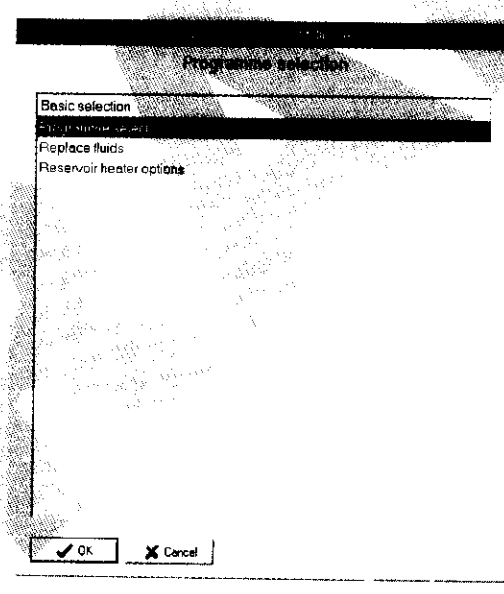

Figure 30 Program Selection Screen

7. When the Select Fluid Type screen opens, select `Disinfectant` and click the **OK/ENTER** ✓ button.

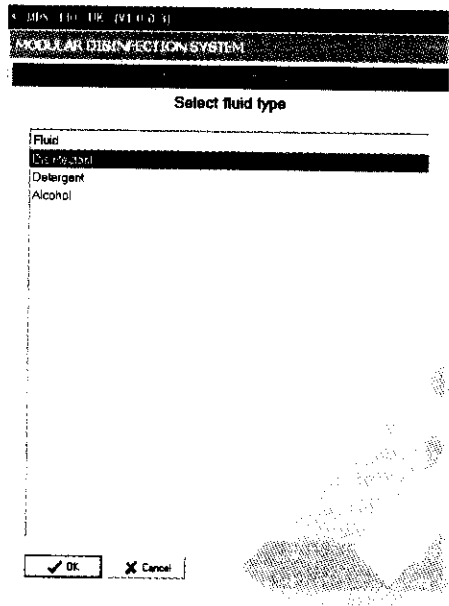

Figure 31 Select Fluid Type screen

8. From the **Disinfectant Transfer** screen, select `Dump disinfectant from reservoir` and click the **OK/ENTER** ✓ button.

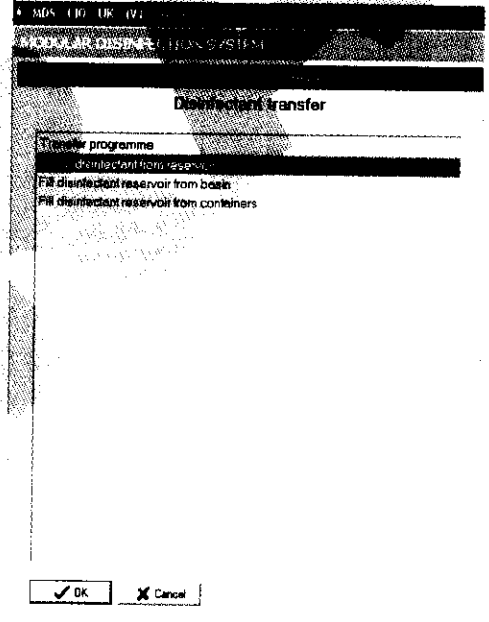

Figure 32 Dump Disinfectant from Reservoir

9. Press the **Start** ◈ button when prompted by the utility.

10. Disinfectant is pumped from the reservoir to the basin where it flows to the facility drain.

11. After a short rinse cycle, the utility ends.

Loading Disinfectant from the Basin

With this utility, disinfectant is poured directly into the basin and then pumped to the reservoir.

1. Open the cover by pressing the **Open/Close** button.

2. If they are present, remove any endoscope(s) and/or cassette(s).

3. For each reservoir to be emptied (left and right), install a machine disinfection block on the corresponding basin connector block receptacle.

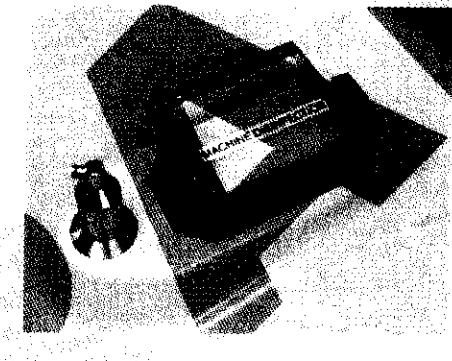

Figure 33 Machine Disinfection Block

4. Press the **Menu** button on the control panel.

5. Log in to the system.

6. When the **Program Selection** screen opens, select `Replace Fluids` and click the **OK/ENTER** ✓ button.

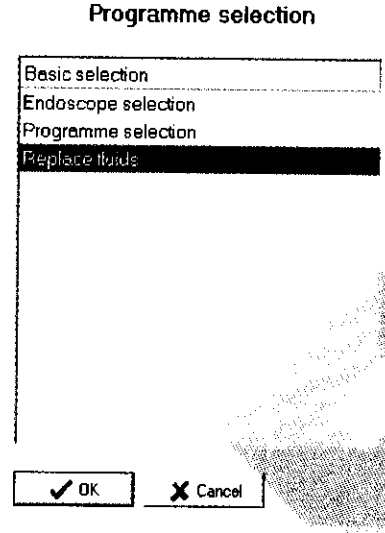

Figure 34 Program Selection Screen

7. When the **Select Fluid Type** screen opens, select `Disinfectant` and click the **OK/ENTER** ✓ button.

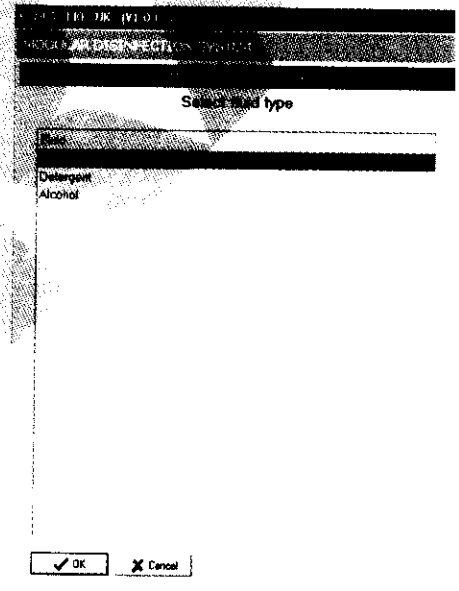

Figure 35 Select Fluid Type screen

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8. From the **Disinfectant Transfer** screen, select `Fill disinfectant reservoir from basin` and click the **OK/ENTER** ✓ button.

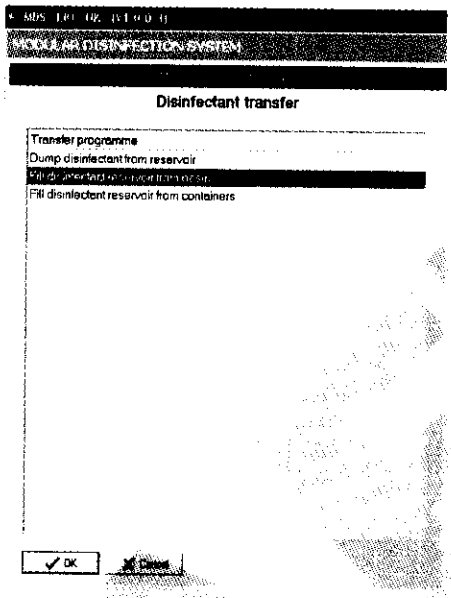

Figure 36 Fill Disinfectant Reservoir from Basin

9. Press the **Start** ⏻ button when prompted by the utility.

10. Open the basin cover by pressing the **Open/Close** ⏏ button.

11. Follow the disinfectant manufacturer's instructions to prepare the disinfectant for loading.

12. Pour 20 L disinfectant into the basin.

13. After all the disinfectant has drained from the basin to the reservoir, press the **Start** ⏻ button.

14. The cover closes, the basin rinses, and the utility ends.

Note: Pressing Start any time before all the disinfectant has drained into the reservoir terminates the utility. Any disinfectant left in the reservoir is directed to the drain.

If the reservoir overfills, the utility terminates and any disinfectant in the basin is directed to the drain.

Loading Disinfectant from the Supply Container

With this utility, the original disinfectant container is connected to the MDS with an uptake tube. The utility pumps the disinfectant from the container to the reservoir.

The disinfectant supply lines are located under the manual three-way valve panel above the left-side disinfectant reservoir.

1. Open the cover by pressing the **Open/Close** button.
2. If they are present, remove any endoscope(s) and/or cassette(s).
3. For each reservoir to be emptied (left and right), install a machine disinfection block on the corresponding basin connector block receptacle.

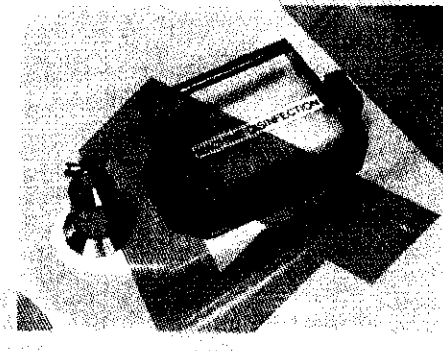

Figure 37 Machine Disinfection Block

4. Press the **Menu** button on the control panel.
5. Log in to the system.

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6. When the **Program Selection** screen opens, select `Replace Fluids` and click the **OK/ENTER** ✓ button.

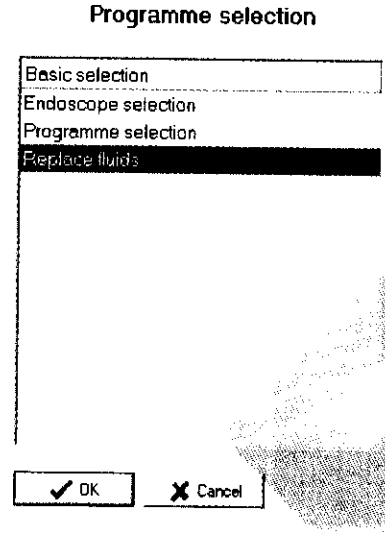

Figure 38 Program Selection Screen

7. When the **Select Fluid Type** screen opens, select `Disinfectant` and click the **OK/ENTER** ✓ button.

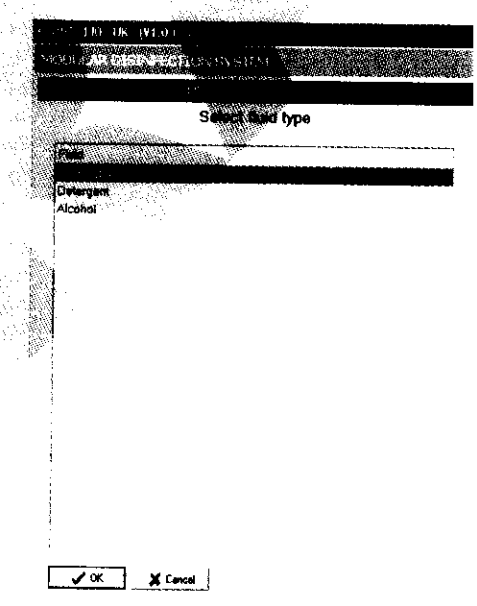

Figure 30 Select Fluid Type screen

8. From the **Disinfectant Transfer** screen, select `Fill disinfectant reservoir from containers` and click the **OK/ENTER** ✓ button.

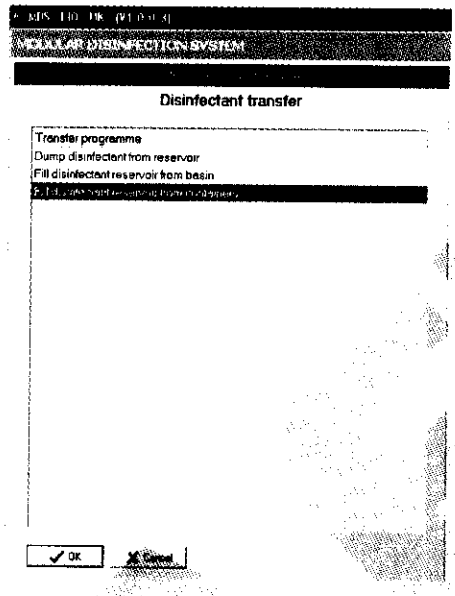

Figure 40 Fill Disinfection Reservoir from Containers

9. Attach the uptake tube to the disinfectant connection at the base of the three-way valve panel.

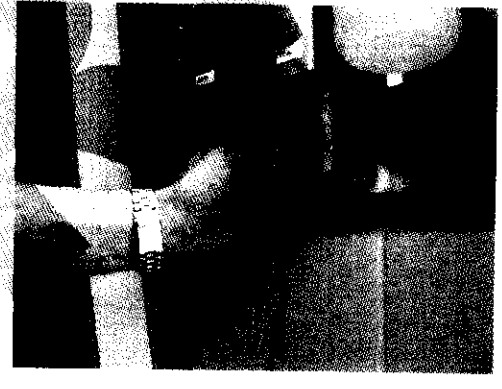

Figure 41 Uptake Tube Attached to Disinfectant Connection

10. Follow the disinfectant manufacturer's instructions to prepare the disinfectant for loading.

11. Turn the three-way valve to the transfer position.

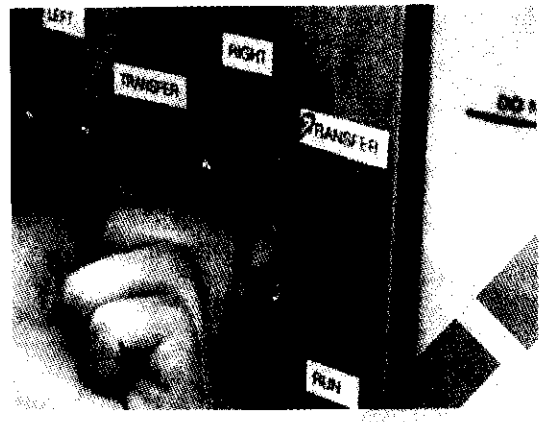

Figure 423 Transfer Position

12. Place the uptake tube in the disinfectant container.

Figure 43 Uptake Tube in Disinfectant Container

13. Press the **Start** ◈ button to start the utility and the transfer.

14. If necessary, press the **Start** ◈ button to pause the transfer when the container is empty and install the uptake tube in the next disinfectant container.

15. Press the **Start** ◈ button to continue the transfer.

16. After 20 L of disinfectant has transferred and the basin is empty, the utility terminates and rinses the basin.

17. Return the three-way valve to the Run position.

Figure 44 Valve Run Position

18. Disconnect and rinse the uptake tube.

Reservoir Heater Options

1. Press the **Menu** button on the control panel.
2. Log in to the system.
3. Select and Click **OK/ENTER** ✓ button.
4. When the **Program Selection** screen opens, select Reservoir Heater options and click **OK/ENTER** ✓ button.

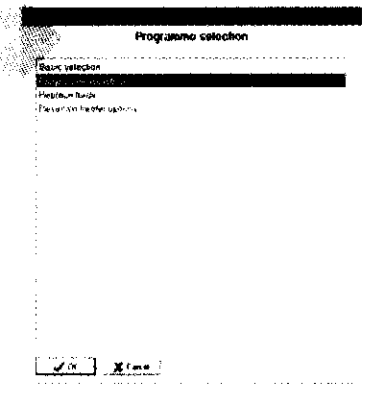

Figure 45 Screen shot of Program Selection

5. When the **Select Reservoir Heater State** screen opens, select the option from the menu that corresponds to the operation that you intend to do.

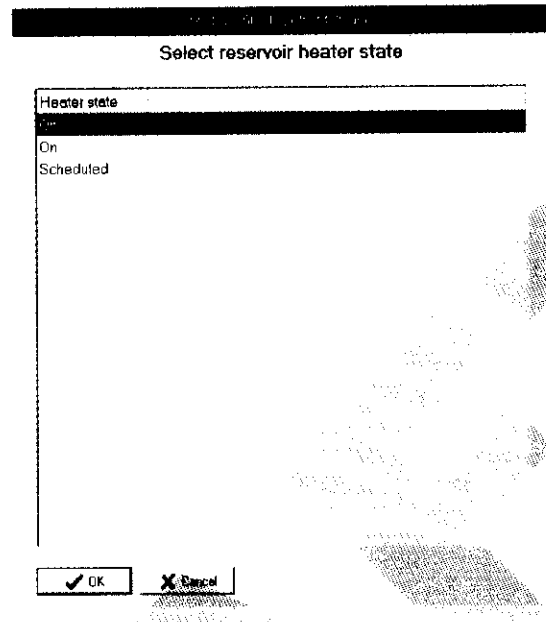

Figure 46 Screen shot of Select Reservoir Heater State

To Turn Off Reservoir Heater

1. From the **Select Reservoir Heater State** screen, select Off to turn the heater off manually.

Note: Turning the heater off manually will override any scheduled settings. The reservoir heater will remain off until the system is reset with scheduled settings or the On selection is made.

To Turn On Reservoir Heater

1. From the **Select Reservoir Heater State** screen, select On to turn the heater on manually.

Note: Turning the heater off manually will override any scheduled settings. The reservoir heater will remain off until the system is reset with scheduled settings or the On selection is made.

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Note: It will take some time to reach the correct temperature for the heated disinfectant. No cycles may be started until the correct temperature is reached.

To Schedule the Reservoir Heater

1. From the **Select Reservoir Heater State** screen, select Scheduled to set the heater to run on a defined schedule.

Note: The reservoir heater schedule is defined in the system parameters. To change the days and times that the heater is scheduled to turn on and off, see section Setting Heater Schedule on page 2-43.

2. The heater status can be viewed on the Status Operational screen. The following area examples of the Status Operational screen for several heater status conditions.

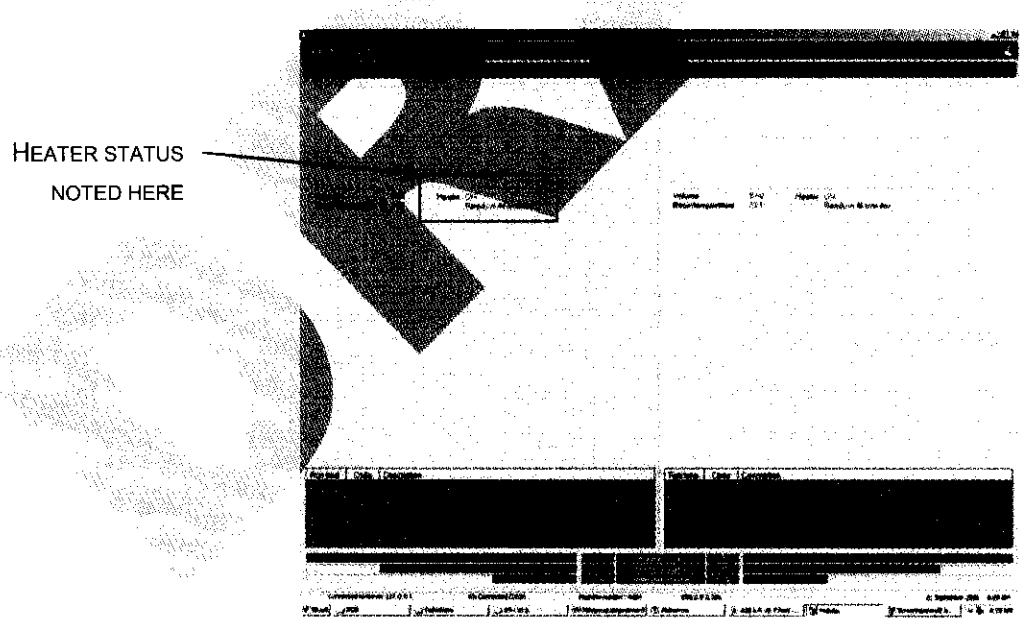

Figure 47 Heater is On, but not ready. Estimated ready time is given.

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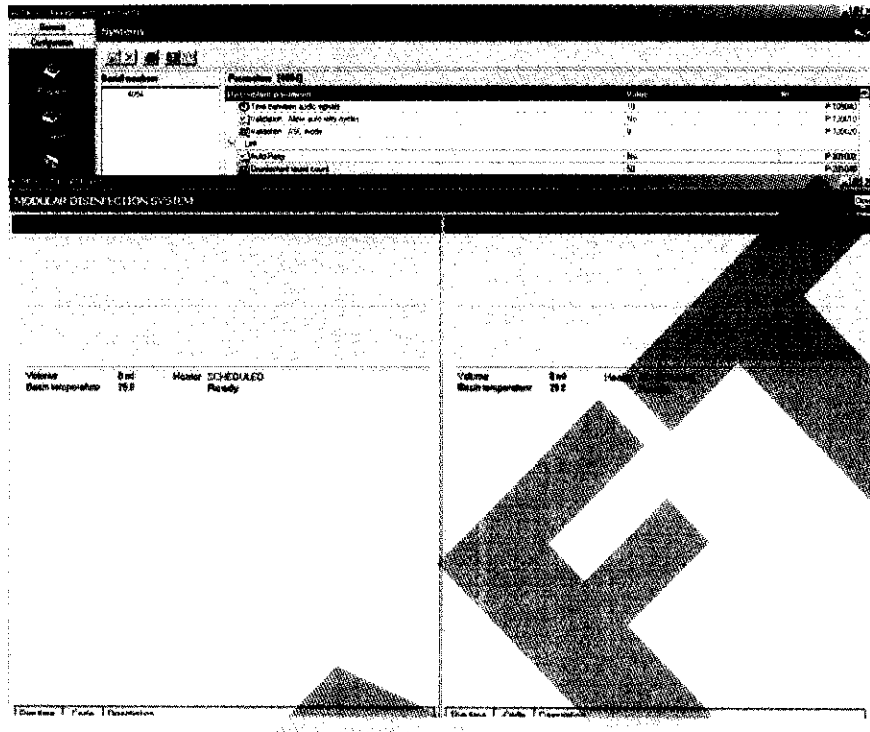

Figure 48 Heater is On, and ready

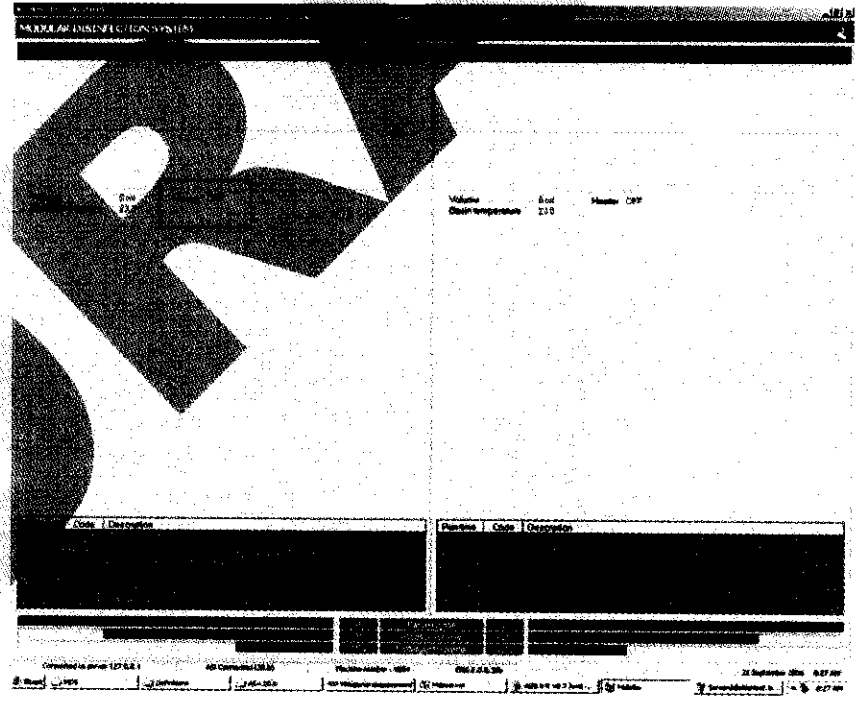

Figure 49 Heater is Off.

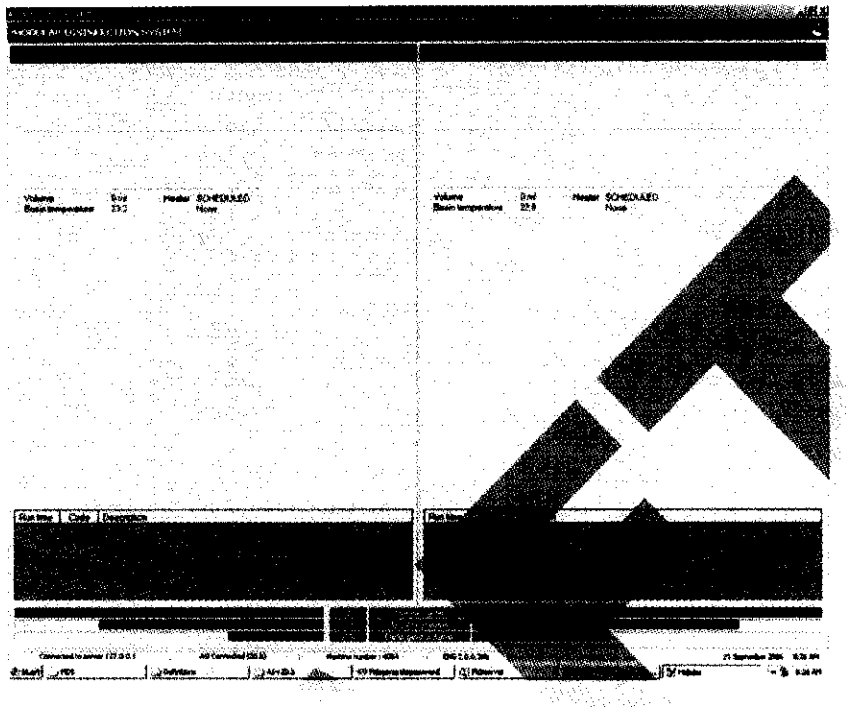

Figure 50 Heater is scheduled

Setting Heater Schedule

1. Load Management application and login using user name and password.

2. Select **Configuration** button in lower left corner of screen.

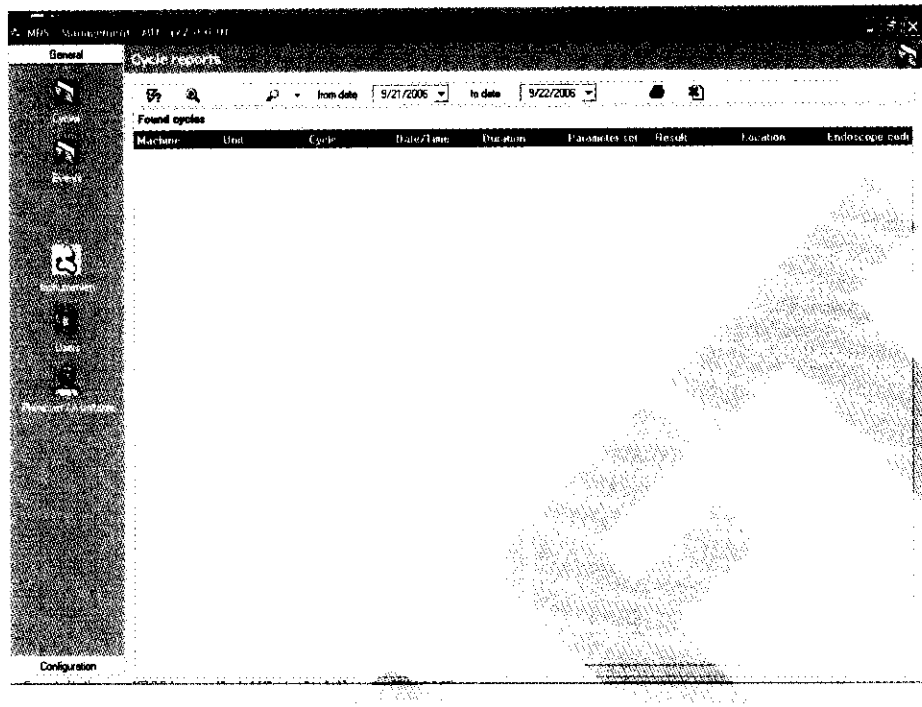

Figure 51 Screen Shot of Management

3. Selcct systems form upper left area.

4. Click on **Machine Serial #** to bring up parameter settings. Scroll down to left side settings and select **Yes** for any day that the machine should run on schedule.

5. Set the **Heater Start** and **Stop** times. Repeat for right side, save all changes using the **SAVE** icon and **EXIT OUT** of Management.

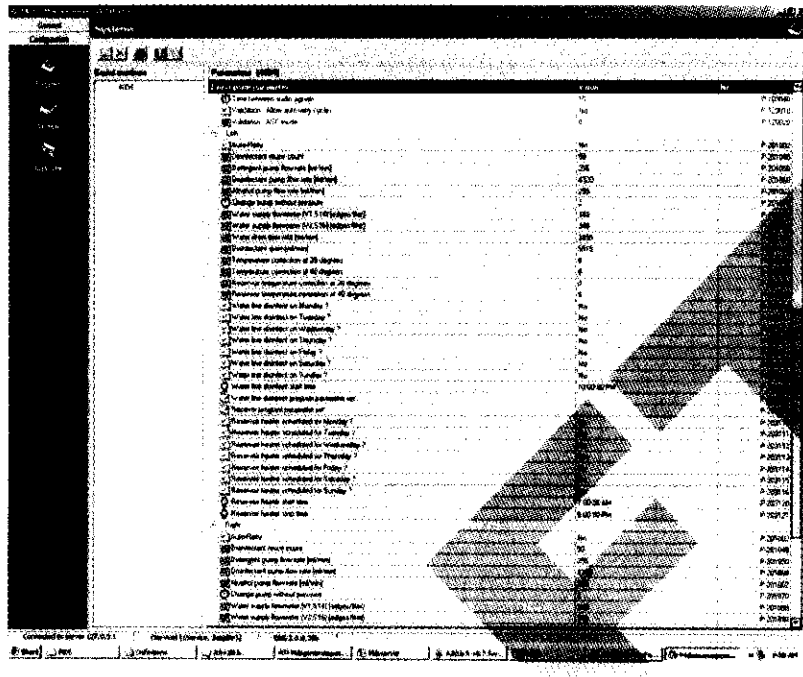

Figure 52 Screen Shot of Parameter Settings

Detergent and Alcohol

The detergent and alcohol reservoirs serve both the left and right modules. Each reservoir is threaded into a captive header and is removed by unscrewing the body.

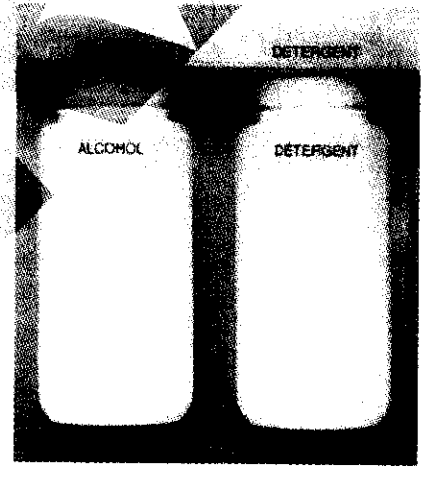

Figure 53 Alcohol and Detergent Reservoirs

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Because the two reservoirs are identical, you must pay attention to the labeling to ensure that the correct fluid is in each reservoir. To prevent errors, complete refilling one reservoir before removing the other.

> *WARNING* To prevent the accidental switching of the Alcohol and Detergent reservoirs always remove, refill and replace each reservoir bottle separately. Return the reservoir (bottle) to its original position by matching up the reservoir label to the label above the reservoir header.

Machine, Water Line, and Water Filter Disinfection

The Machine Self-Disinfection program or utility is used to disinfect the internal fluid lines of the MDS, the water line and the water filter. The utility fills the water line and water filter with disinfectant, and circulates it through the channels and the basin.

1. Verify that the concentration of disinfectant in both reservoirs exceeds the chemical manufacturer's minimum required concentration (MRC).
2. Ensure that the disinfectant reservoirs are filled and the water supply is turned on.
3. Ensure that the disinfectant is at the manufacturer's recommended temperature.
4. Open the cover by pressing the **Open/Close** button.
5. If they are present, remove any endoscope(s) and/or cassette(s).
6. Install a machine disinfection block on the each of the basin connector block receptacles.

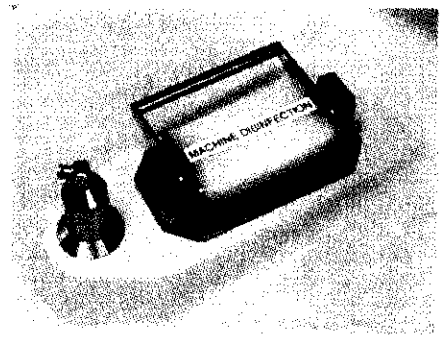

Figure 54 Machine Disinfection Block

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7. Press the **Menu** button for the left module on the control panel. The left side of the MDS controls this utility.

8. Log in to the system.

9. When the **Program Selection** screen opens, click on `Program Selection` and click the **OK/ENTER** ✓ button.

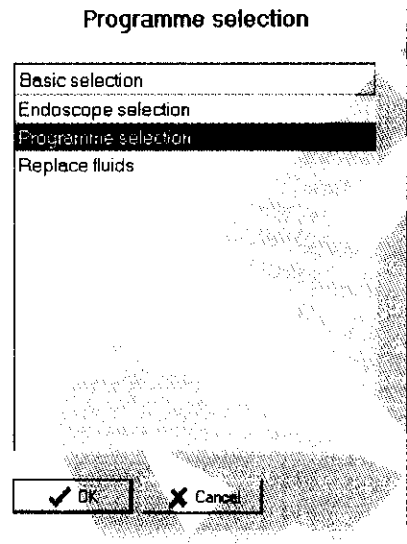

Figure 55 Program Selection

10. Select `Water Line Disinfect` from the **Select Program** screen.

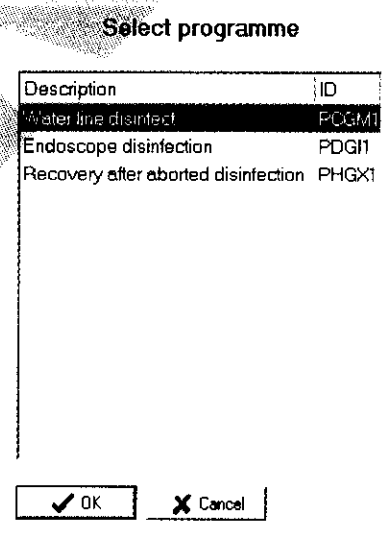

Figure 56 Water Line Disinfect

11. When the **Program Set Selection** screen opens, click on S-Sanitize.

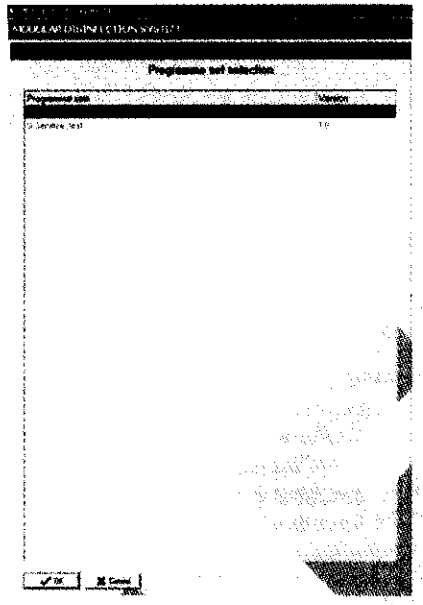

Figure 57 S-Sanitize

12. Select either Normal Start or Delayed Start.

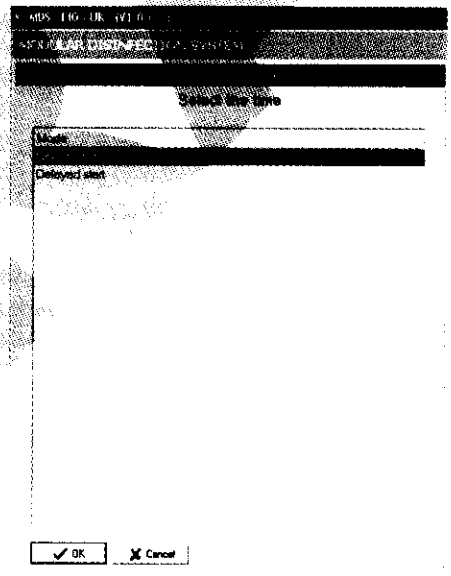

Figure 58 Normal Start

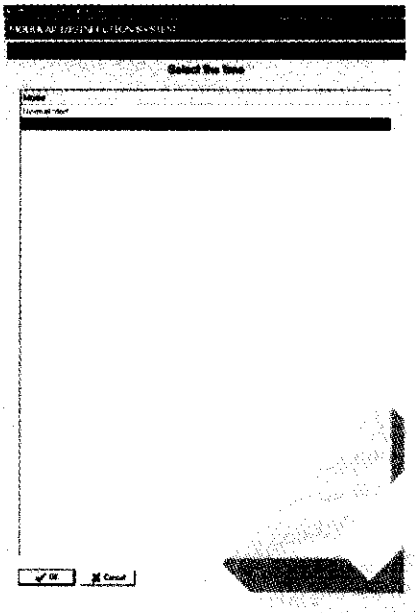

Figure 59 Delayed Start

13. If a delayed start is selected, a screen opens called Select the Time. It lists start times in 15 minute increments for the next 7 days. Note that the dates are listed in MM/DD/YYYY, where M = month, D = day, and Y = year. Scroll down to select the desired start time and click the **OK/ENTER** ✓ button.

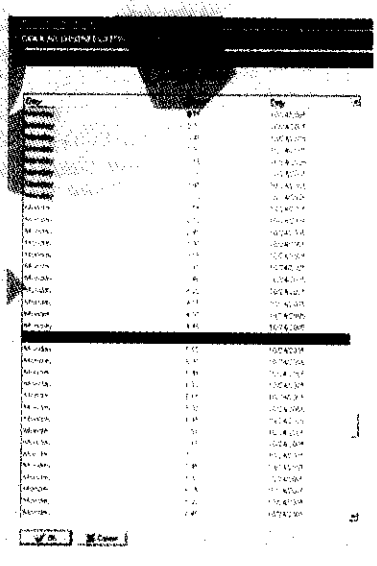

Figure 60 Select Delayed Start Time

14. An information screen is displayed to verify that the water line disinfection blocks are installed. Select the **OK/ENTER** ✓ button if the blocks are in place or select the **Stop/Cancel** × button to install the water line disinfect blocks.

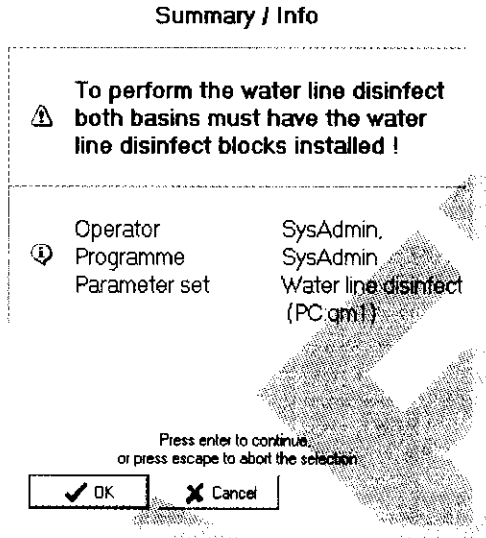

Figure 61 Summary/Information Screen

15. Press the **Start** ◈ button to initiate the water line disinfection.

16. When the dwell times for the water filter and the basin are satisfied, the disinfectant is returned to the reservoir. The water lines and filter are flushed, the basin is rinsed and the utility terminates.

17. Take a water sample (*see the following procedure*).

18. Replace the disinfectant.

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Taking a Water Sample

After running the Machine Disinfection utility, you should take a water sample. This sample can be tested to ensure that residual chemical levels in the water filter and line are at safe levels.

1. Place a container under the sample port or direct the flow from the sample port to a drain.

2. Activate the filtration system water valve by clicking on the Expert Control icon in the menu bar.

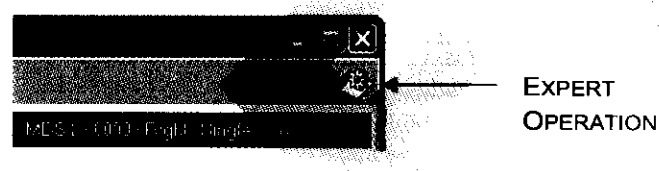

Figure 62 Expert Control Icon

3. Log in to the system.

4. Slowly turn the sample port three-way valve to the sample position (handle down).

5. Allow the water to run for ten minutes.

6. Take a water sample.

Figure 63 Taking a Water Sample

7. Turn the valve back to the normal position (handle horizontal)

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8. Test the water sample for residual disinfectant.

9. If disinfectant residuals are too high, open the valve to allow the line to flush with additional water.

Chapter 3

OPERATION

This chapter explains how to prepare and disinfect an endoscope in the MDS.

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DISINFECTION PROCESS SUMMARY

The complete reprocessing cycle in an MDS system is comprised of a number of specific steps designed to ensure proper endoscope disinfection. These steps include: startup, detergent wash, disinfectant, rinse, alcohol (optional), and air phases. All steps must be properly followed and should not be modified beyond manufacturer recommendations.

Startup Phase

During the start-up phase, the software reads and monitors all system sensors. If an error is detected, a message is displayed and the process is halted. The system operator then needs to resolve the error before the cycle can be continued.

Next the leak test is activated. The endoscope is pressurized and the pressure is monitored for a period of time. If the pressure drops below a set reading, an error message is displayed and the process is halted.

Refer to *Chapter 5: Troubleshooting* for appropriate instructions to resolve errors.

Detergent Wash Phase

During the wash phase, detergent and water enter the basin. This basin fluid is then flushed through the endoscope channels. At the completion of the wash phase, the basin is drained and the endoscope channels are flushed with fresh water. A rinse soak period without detergent then follows.

Disinfectant Phase

During the disinfectant phase, the endoscope channels are flushed with disinfectant. The basin is filled with disinfectant and the endoscope is submerged for the desired disinfectant soak time. After the soak, the disinfectant is drained from the basin.

Rinse Phase

During the rinse phase, the basin is partially filled with water and then drained to eliminate foam residue from inside the endoscope and from the basin. The basin is then filled with fresh water while the endoscope channels are being flushed. Once the basin fills up, water flushes through the endoscope channels. The basin is then drained while the channels are purged with fresh water.

Alcohol Phase (Optional)

During the alcohol phase, alcohol is injected through the endoscope channels. The alcohol is used to help purge any residual fluids from the endoscope.

Air Phase

The air phase is simply a programmed time during which air is purged through the endoscope channels. The air is used to aid in drying of the endoscope.

STARTUP

1. Verify that the MDS PC and main power source are on.

2. Open the shutoff valve to the incoming water line. For optimum performance the water supply must be capable of delivering a minimum of 5 L/min of flow at a dynamic pressure of 40 psi (2.8 bar) during the basin fill.

3. Turn the external air source on (if applicable). External air supply must be capable of delivering medical grade air at a minimum rate of 40 L/min at 6 bar (87 psi).

DAILY SERVICE

Checking the Disinfectant Concentration Level

Disinfectant concentration must be monitored for each module in accordance with the disinfectant manufacturer's instructions. Disinfectant that is below the minimum recommended concentration (MRC), or disinfectant with an expired reuse life date must be replaced.

WARNING Never use disinfectant beyond the manufacturer's expiration date, even if the MRC level is acceptable.

Never use disinfectant that tests below the acceptable MRC level, even if it has not yet reached the expiration date.

Always use the correct test strips for the disinfectant being used.

Ensure that the test strips are within their expiration date.

1. Locate the disinfectant test strips for the chemical being used in the system. Follow the test strip manufacturer's instructions to check for concentration levels.

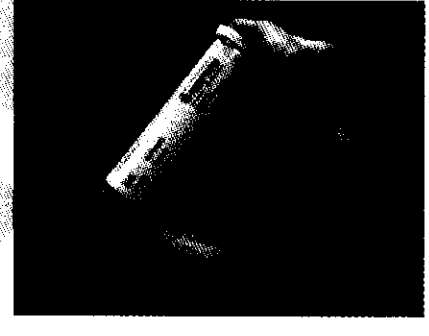

Figure 1 Typical Test Strip Containers

2. Place a test strip in a hemostat with the raised end away from the tool.

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Figure 2 Test Strip in Hemostat

3. Open the disinfectant container (*figure 3*).

Figure 3 Opening Container

4. Immerse the test strip into the disinfectant (*figure 4*).

Figure 4 Insert test strip into container

5. Remove the test strip from the disinfectant and replace the container cap.

6. Compare the strip to the chart on the test strip container.

7. If the concentration level is below the acceptable MRC level, do not use the disinfectant.

10. Repeat the procedure for each reservoir.

Air Pressure Adjustment

The main air pressure and leak test air pressure are maintained by regulators. The air pressure adjustment controls and corresponding gauges are located behind the front access door, just above the disinfectant reservoirs.

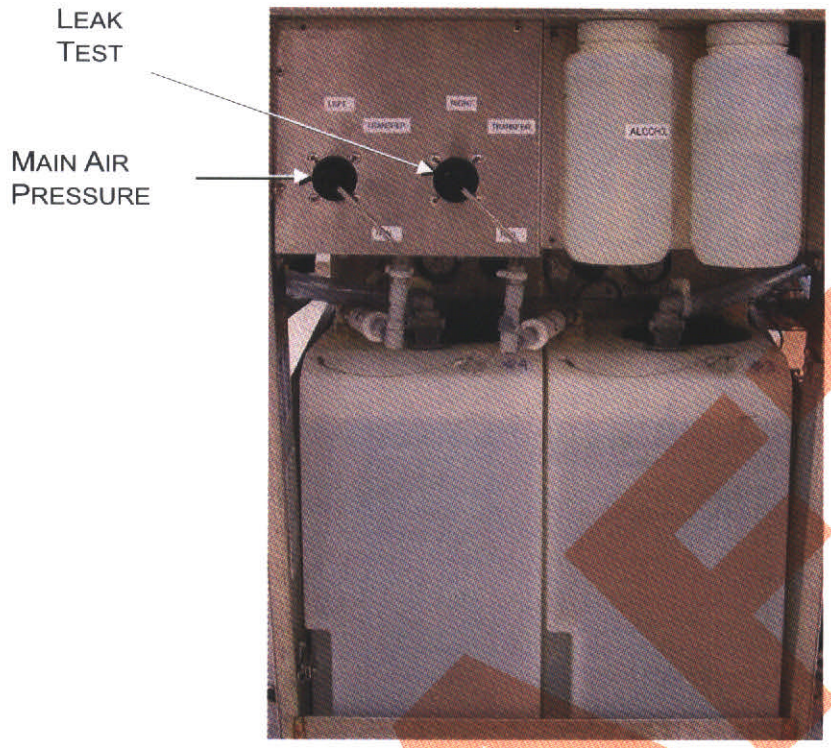

Figure 5 Air Pressure Controls

Proper operation of the MDS reprocessor requires that the air pressure be set and maintained at the values shown in the table below.

Table 1 Acceptable Pressure Ranges

Pressure Control	Acceptable Pressure Range
Main Air Pressure	2.8–3.0 bar (41-43.5 psi)
Leak Test Air Pressure	0.24–0.25 bar (3.5-3.6 psi)

If the pressure control readings do not fall within the acceptable ranges, contact technical service. Do not attempt to adjust the settings yourself as damage may occur to the MDS.

DRAFT

WARNING Verify that the air pressure readings are within the acceptable ranges before every reprocessing cycle. Do not make air pressure adjustments during a disinfection process.

If the main air pressure regulator is not set correctly, the endoscope may not be properly disinfected.

If the leak test regulator cannot be set correctly, the endoscope may be damaged during the reprocessing cycle.

O-Rings

Check the connection manifolds to verify that all the O-rings are present and undamaged. The manifolds are located in each basin and are the studs onto which the connector block slides down and seals.

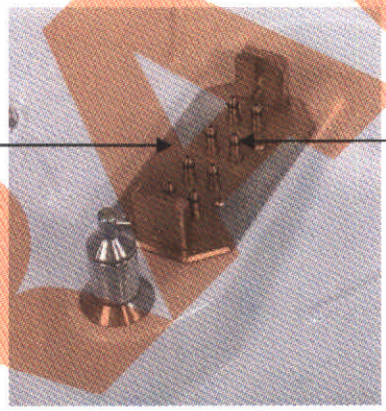

Figure 6 Check Manifold O-Rings

Screens

Replace the screens in the rinse basin if they are excessively soiled.

DRAFT

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Fluids

WARNING Refilling a reservoir with the incorrect fluid may cause the endoscope to be improperly disinfected. Do not use the endoscope on a patient if this occurs.

Wear protective clothing, gloves and eyewear. The detergent and disinfectant manufacturers may recommend additional protection.

LOADING DETERGENT

1. Press the **Menu** ▣ button on the control panel.
2. Log in to the system.
3. When the **Program Selection screen opens,** select `Replace Fluids` and click the **OK/ENTER** ✓ button.

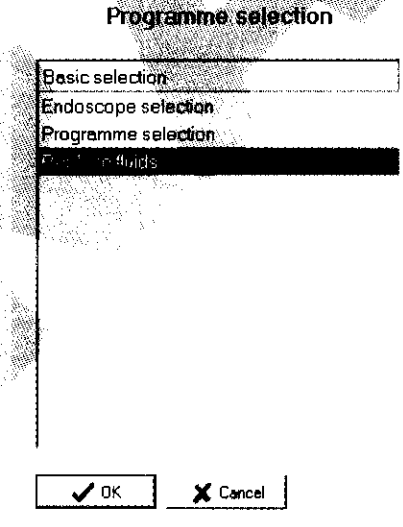

Figure 7 Program Selection Screen

4. When the **Select Fluid Type** screen opens, select `Detergent` and click the **OK/ENTER** ✓ button.

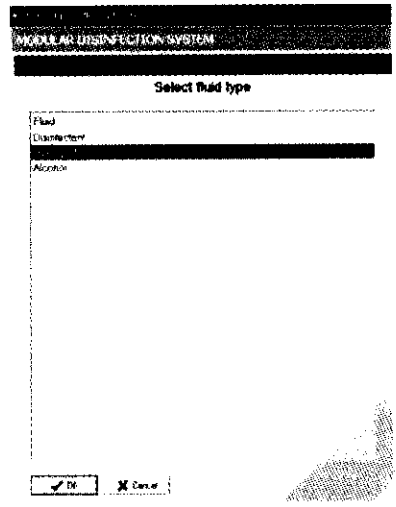

Figure 8 Select Fluid Type Screen

5. Enter the code found on the manufacturer's container and press the **OK/ENTER** ✓ button.

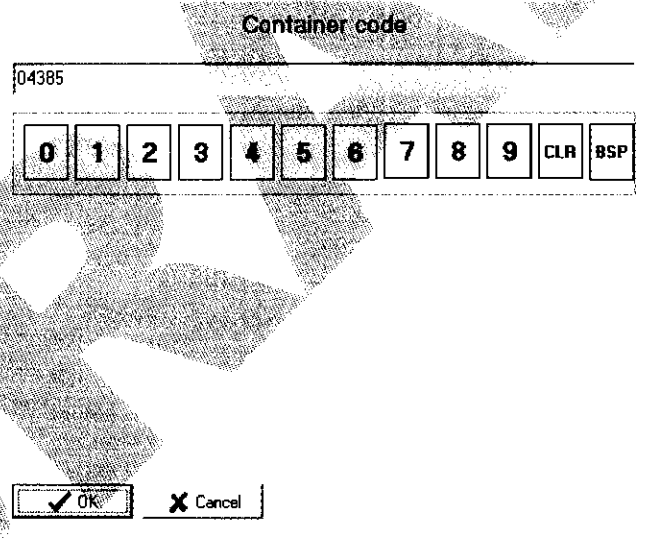

Figure 9 Container Code

6. Remove, refill and replace the reservoir.

LOADING ALCOHOL (OPTIONAL)

1. Press the **Menu** ▣ button on the control panel.

2. Log in to the system.

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3. When the **Program Selection** screen opens, select `Replace Fluids` and click the **OK/ENTER** ✓ button.

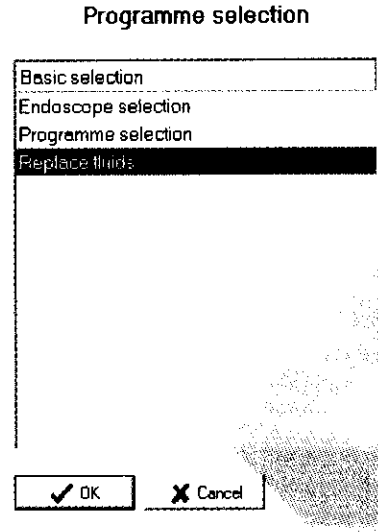

Figure 10 Program Selection Screen

4. When the **Select Fluid Type** screen opens, select `Alcohol` and click the **OK/ENTER** ✓ button.

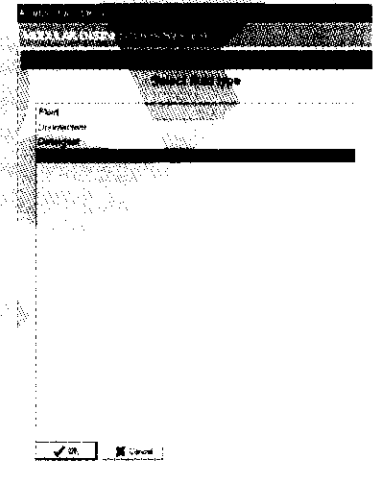

Figure 11 Select Fluid Type Screen

5. Enter the code found on the manufacturer's container and press **OK**.

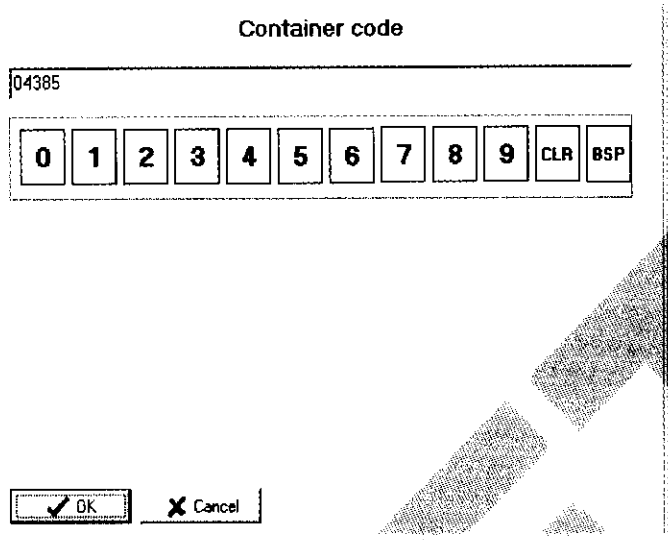

Figure 12 Container Code

6. Remove, refill and replace the reservoir.

1001

Disinfectant Change Utilities

WARNING Use only cleaning and disinfectant fluids approved by Minntech Corporation

Never use disinfectant beyond the manufacturer's expiration date, even if the MRC level is acceptable.

Never use disinfectant that tests below the acceptable MRC level, even if it has not yet reached the expiration date.

Always use the correct test strips for the disinfectant being used.

When filling disinfectant, wear protective clothing, gloves and eyewear when filling or draining disinfectant. The disinfectant manufacturer may recommend additional protection.

If leaking liquid is present and you suspect it is disinfectant, read and follow the manufacturer's instructions before attempting a cleanup.

Service: If leaking fluids are present, contact a qualified service technician.

The disinfectant change utilities are summarized in *Table 2*.

Table 2 Disinfectant Change Utilities

	Function
Dump disinfectant from reservoir	Pumps the disinfectant from the reservoir to the drain
Fill disinfectant from basin	Module cover is opened and disinfectant is poured from container(s) into the basin
Fill disinfectant reservoir from bottle	Three-way valves pump disinfectant from the supply container(s) to the reservoir
Reservoir Heater Options	Allows reservoir heater to be controlled by the operator

1002

WARNING When filling or draining disinfectant, Wear protective clothing, gloves and eyewear when filling or draining disinfectant. The disinfectant manufacturer may recommend additional protection.

If leaking liquid is present and you suspect it is disinfectant, read and follow the manufacturer's instructions before attempting a cleanup.

Service: If leaking fluids are present, contact a qualified service technician.

Dumping Disinfectant

1. Open the cover by pressing the **Open/Close** button.
2. If they are present, remove any endoscopes and/or cassette(s).
3. For each reservoir to be emptied (left and right), install a Machine Disinfection block on the corresponding basin connector block receptacle.

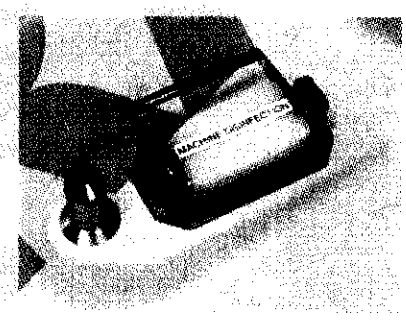

Figure 13 Machine Disinfection Block

4. Press the **Menu** button on the control panel.
5. Log in to the system.
6. When the **Program Selection** screen opens, select `Replace Fluids` and click the **OK/ENTER** ✓ button.

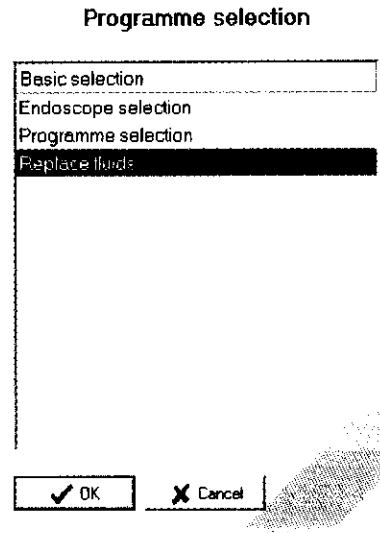

Figure 14 Program Selection Screen

7. When the Select Fluid Type screen opens, select `Disinfectant` and click the **OK/ENTER** ✓ button.

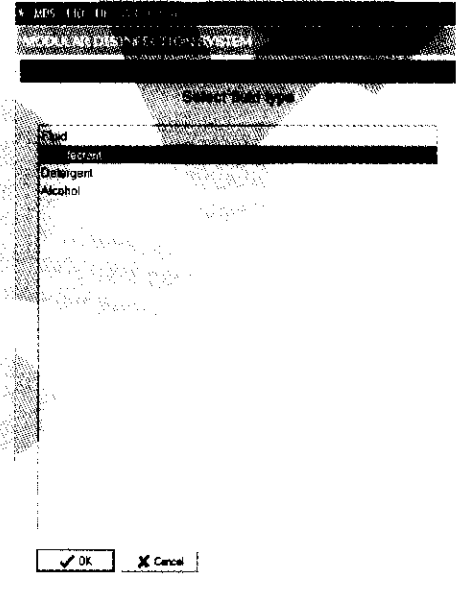

Figure 15 Select Fluid Type screen

8. From the **Disinfectant Transfer** screen, select `Dump disinfectant from reservoir` and click the **OK/ENTER** ✓ button.

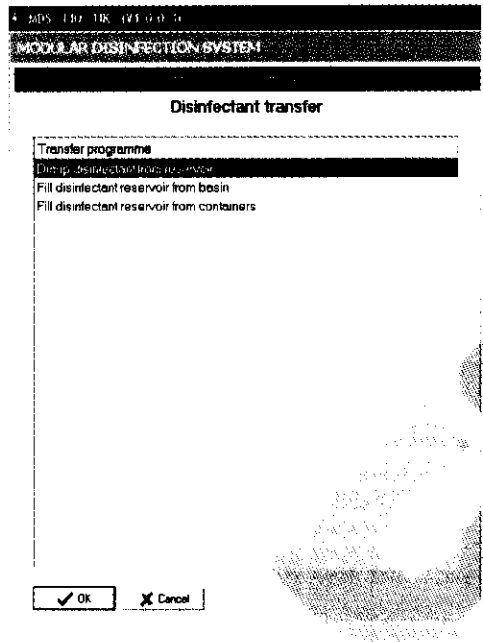

Figure 16 Dump Disinfectant from Reservoir

9. Press the **Start** ◈ button when prompted by the utility.

10. Disinfectant is pumped from the reservoir to the basin where it flows to the facility drain.

11. After a short rinse cycle, the utility ends.

Reservoir Heater Options

1. Press the **Menu** ▣ button on the control panel.

2. Log in to the system.

3. Select and Click **OK/ENTER** ✓ button.

4. When the **Program Selection** screen opens, select Reservoir Heater options and click **OK/ENTER** ✓ button.

1005

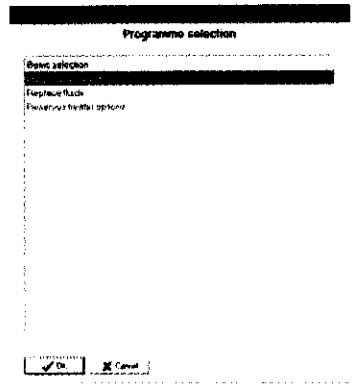

Figure 17 Screen shot of Program Selection

5. When the **Select Reservoir Heater State** screen opens, select the option from the menu that corresponds to the operation that you intend to do.

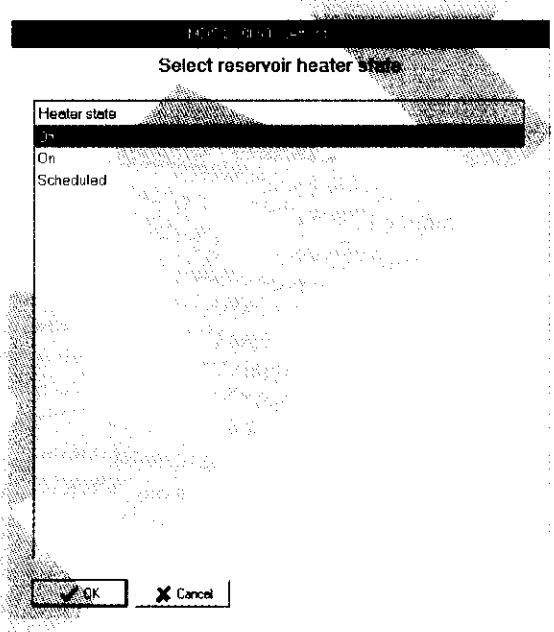

Figure 18 Screen shot of Select Reservoir Heater State

To Turn Off Reservoir Heater

1. From the **Select Reservoir Heater State** screen, select Off to turn the heater off manually.

Note: Turning the heater off manually will override any scheduled settings. The reservoir heater will remain off until the system is reset with scheduled settings or the On selection is made.

To Turn On Reservoir Heater

1. From the **Select Reservoir Heater State** screen, select On to turn the heater on manually.

Note: Turning the heater off manually will override any scheduled settings. The reservoir heater will remain off until the system is reset with scheduled settings or the On selection is made.

Note: It will take some time to reach the correct temperature for the heated disinfectant. No cycles may be started until the correct temperature is reached.

To Schedule the Reservoir Heater

1. From the **Select Reservoir Heater State** screen, select Scheduled to set the heater to run on a defined schedule.

Note: The reservoir heater schedule is defined in the system parameters. To change the days and times that the heater is scheduled to turn on and off, see section Setting Heater Schedule on page 2-43.

2. The heater status can be viewed on the Status Operational screen. The following area examples of the Status Operational screen for several heater status conditions.

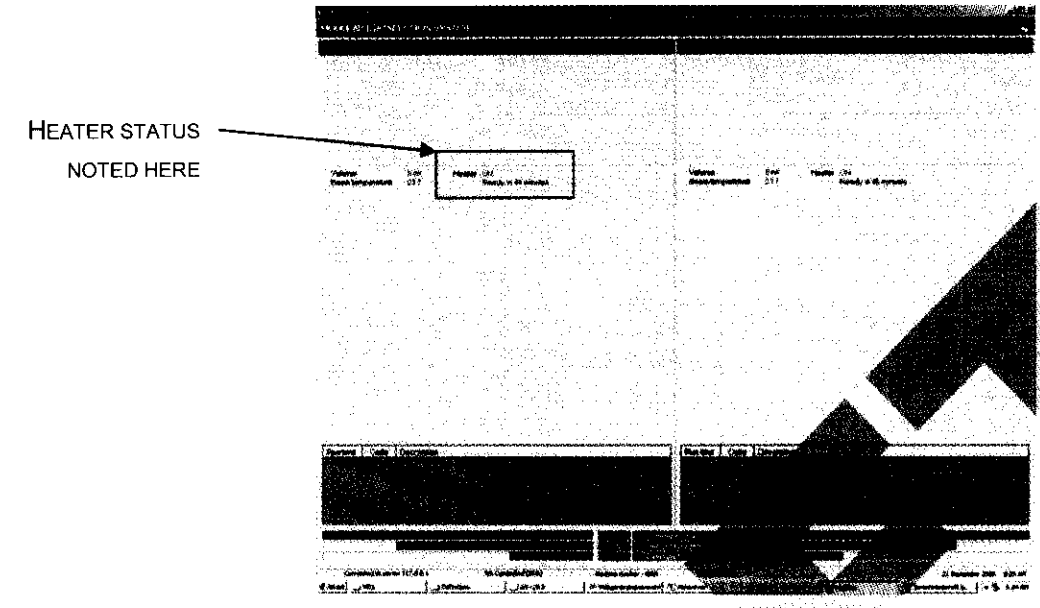

Figure 19 Heater is On, but not ready. Estimated ready time is given.

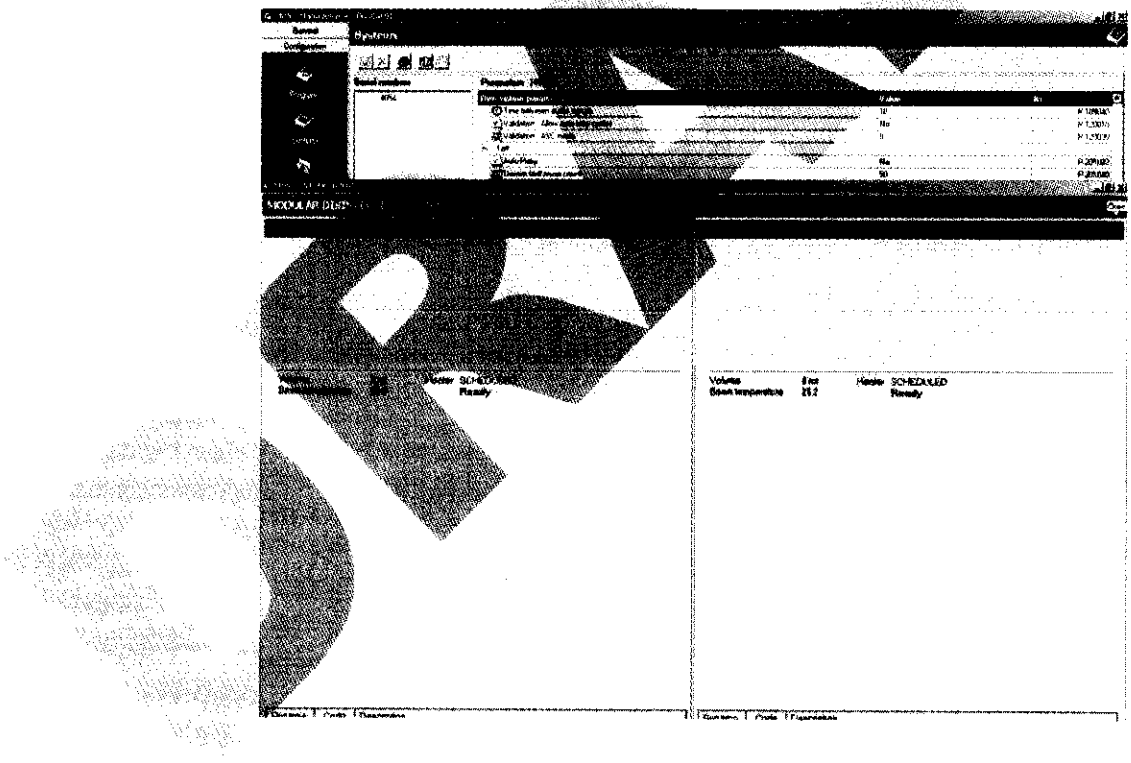

Figure 20 Heater is On, and ready

1008

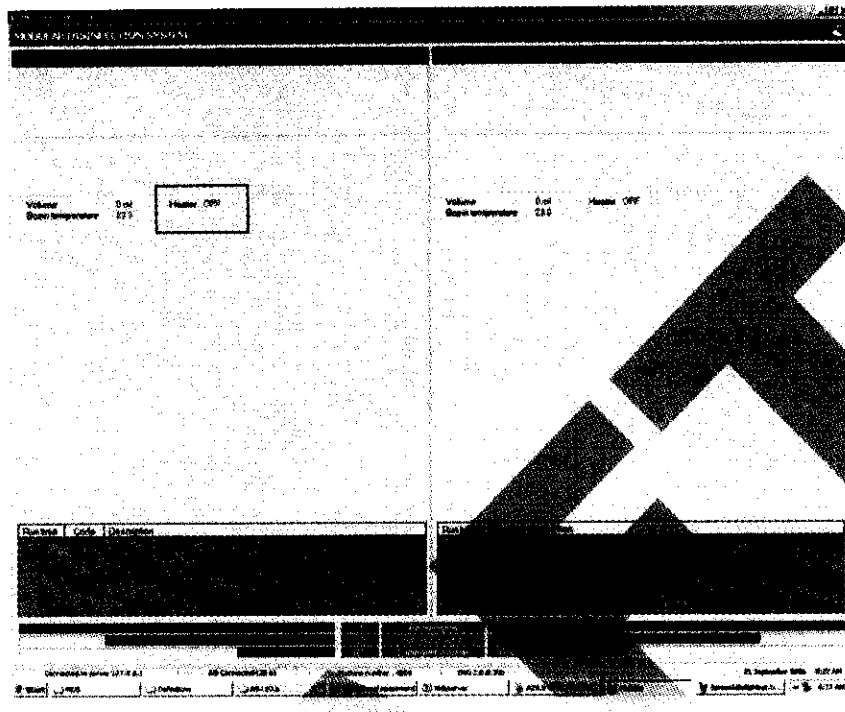

Figure 21 Heater is Off.

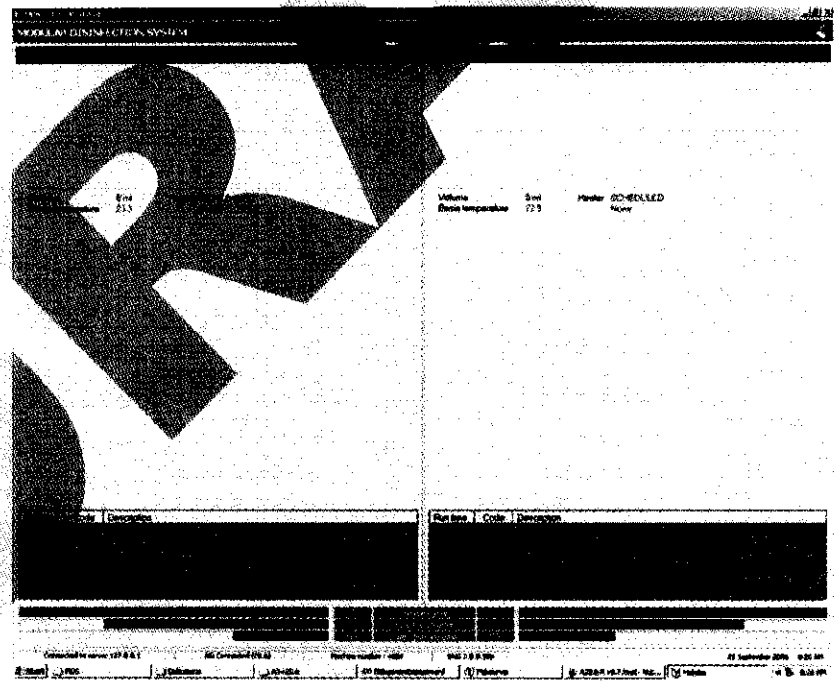

Figure 22 Heater is scheduled

1009

PREPARE THE ENDOSCOPE

Preclean

Preclean the endoscope to remove any organic debris. Follow the manufacturer's instructions for precleaning or refer to established professional guidelines.

Place the Endoscope in the Basin

1. Endoscopes fit best in the machine if they are installed in a particular fashion. The final position of the endoscope in the rinse basin depends primarily on the type of endoscope. To a lesser extent, the brand of endoscope may also affect the final position in the basin. Do not forcibly bend the endoscope to get it to fit. When positioned properly, the endoscope will fit appropriately in the basin.

2. Hold the control housing in your left hand and the two mantles in your right hand.

3. Place the control housing in the basin with the button upwards.

Figure 23 Place Control Housing in Basin

4. Set the image guide mantle in a circle in the basin.

1010

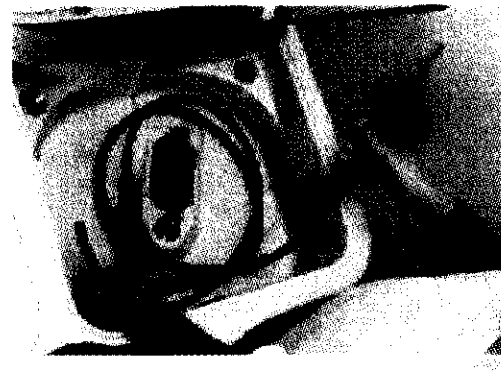

Figure 24 Set the Image Guide in Basin

5. Fit the light guide mantle.

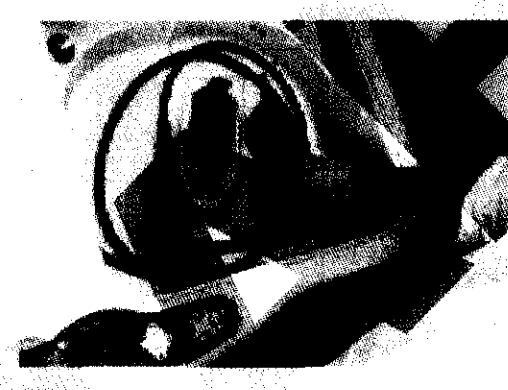

Figure 25 Fit the Light Guide Mantel

Fit the Separation Channel Adapter

Note: Only large endoscopes such as: gastroscopes, colonoscopes and duodenoscopes should have a separation channel fitted.

Select the correct separation adapter for the endoscope to be disinfected. Position the adapter in so that the stem with the o-ring fits properly in the water/air valve.

Because the valve design may vary depending on the brand and type of endoscope, fixing the adapters varies also.

Table 2 Fitting the Adapter

Brand	How to Fit the Adapter
Fujinon	Firmly push in the rubber caps.
Olympus	Press downward on the separation adapter housing to slide it under the flanged edge of the valve.
Pentax	Screw the separation adapter into the water/air valve. Close off the exhaust valve with a screw cap. Firmly press in the white cap on the two valve vents.
XION	Press downward on the separation adapter housing to slide it under the flanged edge of the valve.

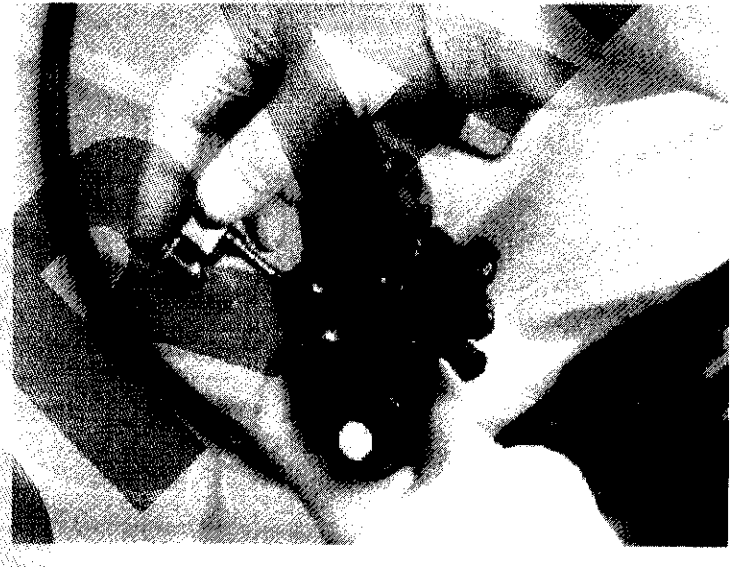

Figure 26 Fitting the Adapter

1012

Fit the Connector Block

1. Hold the connector block handle as shown below in *Figure 27*

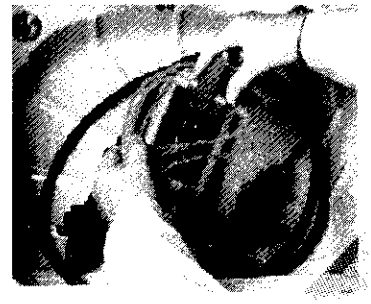

Figure 27 Fitting the Connector Block

2. Using your thumb and index finger, make certain the handle sits square on the block.

3. Hold the side with the four hose connections to the left.

4. Hold the hoses with your other hand, making certain that none of the hoses run under the block.

5. Press the block lightly over the manifold as shown in *Figure 28*.

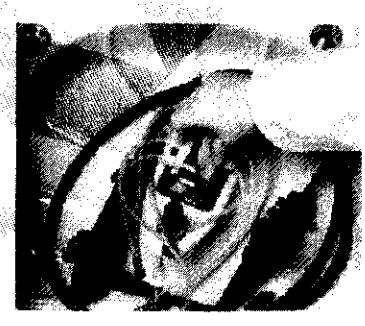

Figure 28 Press Block Over the Manifold

6. Close the handle as shown in *Figure 29*.

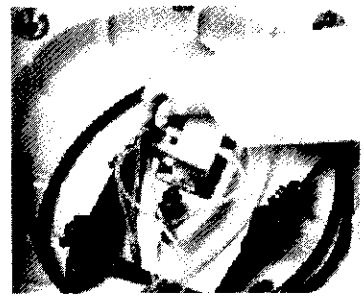

Figure 29 Close the Handle

WARNING Inspect the seating of the connector block to the manifold. Failure to achieve a proper connection could result in an endoscope that is not disinfected and therefore should not be used on a patient

Connect the Channels

1. Connect the endoscope channels as described in the endoscope hookup guide. The names of the connections of the different channels may be found in the endoscope user manual. See *Figure 30* for details on how to hookup the endoscope to the connectors.

WARNING: All endoscope hookups must be periodically inspected for damage, and replace if damaged, otherwise it could result in an endoscope that is not disinfected and therefore should not be used on a patient.

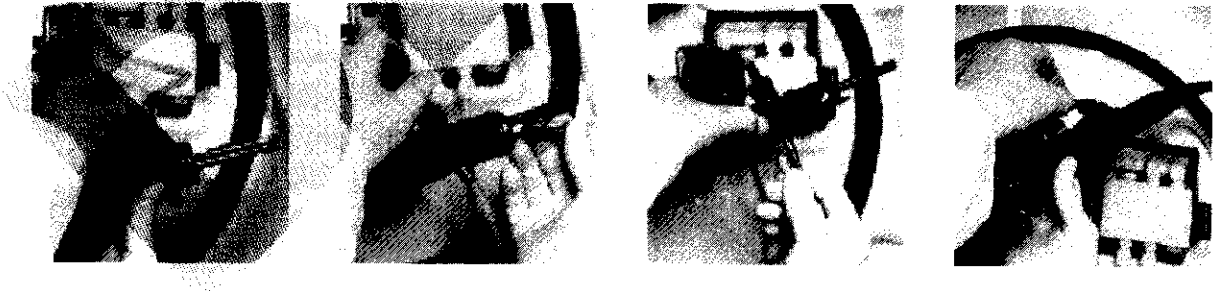

Figure 30 Connecting the Channels

2. Attach the leak test connection on the endoscope to the connector block with the red leak test connector. Secure the tubing under the endoscope so that it does not float during disinfection.

3. Make sure the hoses do not have any sharp bends or kinks.

4. Set the connection hoses down in such a way that they will be submersed in the liquid.

Verify the Connections

WARNING: Verify all connection to the endoscope are secure. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.

- Before closing the cover, inspect the hookup to ensure that all co made properly and the tubing does not interfere with the sprayer.
- The endoscope must be low enough in the basin to be completely sul
- All channels must be connected correctly.
- The channel separator must be fitted.
- The leak test tubing must be secured under the endoscope so that it does not float and interfere with the sprayer.
- The feed hoses must not be kinked.
- Move any hoses lying against the head of the sprayer so that it can turn freely.

WARNING: Verify the connection tubing does not interfere with the spray head and confirm that the spray function is working during the cycle. Failure to do this could result in an endoscope that is not disinfected and therefore should not be used on a patient.

1015

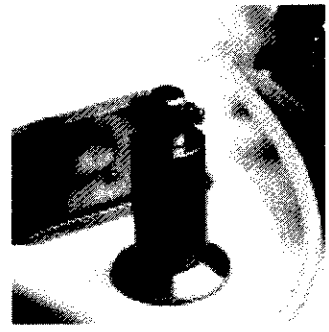

Figure 31 Sprayer Must Turn Freely

Note: Check the purge line before initiating a disinfection cycle. If air is continuously expelling out of the purge line, then contact your bio-medical department or call your manufacturer service line to have the air compressor checked.

PREPARE THE ENDOSCOPE (CASSETTE SYSTEM OPTION)

Note: When using the cassette system, the steps for placing the endoscope in the basin and making the connections differ from the standard procedure. Be careful to follow the directions described below.

Place the Endoscope in the Cassette

1. The endoscope is placed in the cassette in the examination room immediately after the patient procedure.

2. Hold the operating housing in your left hand and the two mantles in your right hand. Fit the operating housing into the cassette with the button facing up.

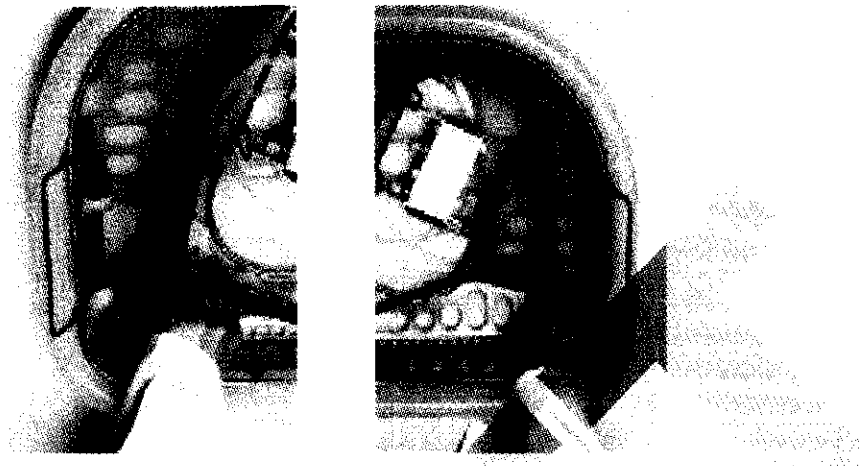

Figure 32 Large Endoscope (left) and Small Endoscope (right)

3. Set the image guide mantle into a circle in the cassette and place the tip through the plastic ring.

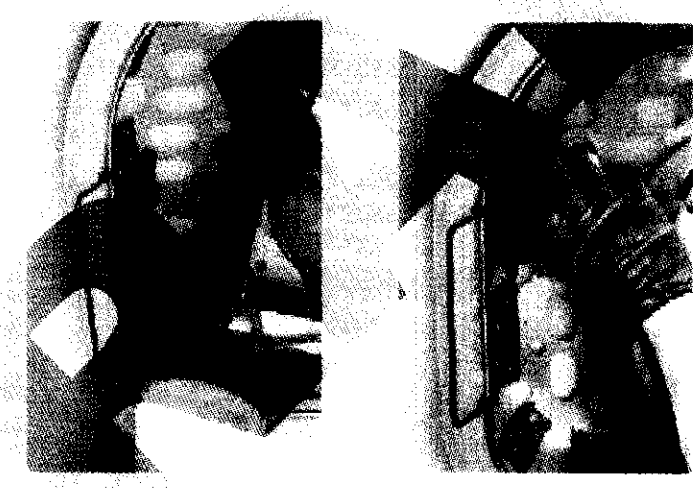

Figure 33 Large Endoscope (left) and Small Endoscope (right)

4. Fit the light guide mantle as shown in *Figure 34*.

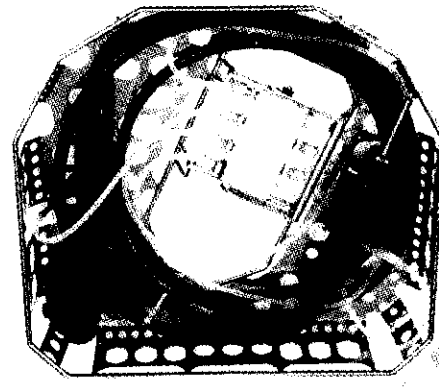

Figure 34 Large Endoscope in Cassette

Note: The endoscope mantles must be placed into the cassette as loosely as possible. For smaller endoscopes especially, the operating housing must be placed near the channel connections.

4. Place the cassette containing the endoscope into a transport basket to carry the system to a pre-wash station.

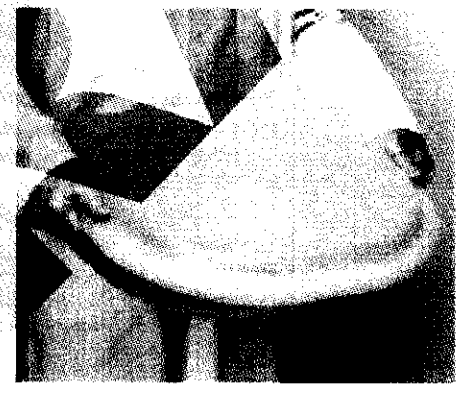

Figure 35 Transport Basket

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Preclean

The endoscope must be pre-washed following hospital protocol. The endoscope can stay in the cassette during pre-cleaning.

Fit the Separation Channel Adapter

Note: Only large endoscopes such as: gastroscopes, colonoscopes and duodenoscopes should have a separation channel fitted.

Select the correct separation adapter for the endoscope to be disinfected. Fit the adapter in so that the stem with the o-ring fits properly in the water/air valve.

Because the valve design may vary depending on the brand and type of endoscope, fixing the adapters varies.

Table 3 Fitting the Adapter

Brand	How to Fit the Adapter
Fujinon	Firmly push in the rubber caps.
Olympus	Press downward on the separation adapter housing to slide it under the flanged edge of the valve.
Pentax	Screw the separation adapter into the water/air valve. Close off the exhaust valve with a screw cap. Firmly press in the white cap on the two valve vents.
XION	Press downward on the separation adapter housing to slide it under the flanged edge of the valve.

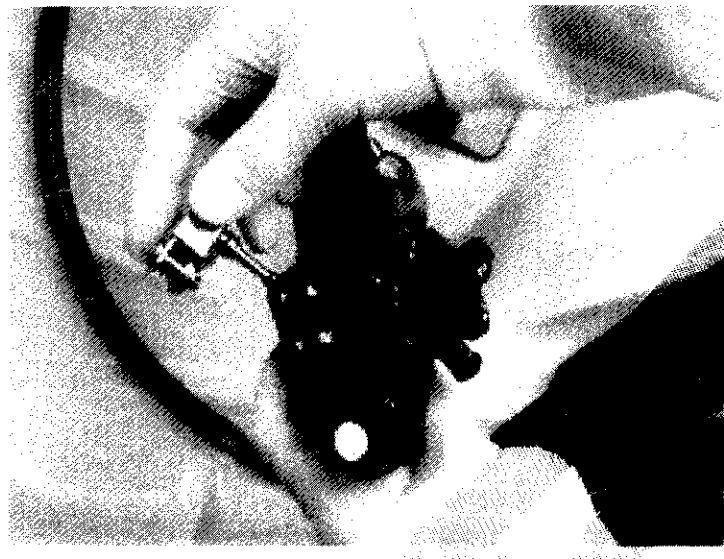

Figure 36 Fitting the Adapter

Connect the Channels

Connect the endoscope channels as described in the endoscope hookup guide. The names of the connections of the different channels may be found in the endoscope user manual.

WARNING: All endoscope hookups must be periodically inspected for damage, and discarded if damaged, otherwise it could result in an endoscope that is not disinfected and therefore should not be used on a patient.

1. Attach the leak test connection on the endoscope to the connector block with the red leak test connector. Secure the tubing under the endoscope so that it does not float during disinfection.

2. Make sure the hoses do not have any sharp bends or kinks.

3. Set the connection hoses down in such a way that they will be submersed in the liquid.

Fit the Cassette

1. Lift the cassette by the two side handles and carry to the MDS.

2. Open the basin lid by using the foot switch.

3. Fit the cassette by placing the white block over the manifold in the middle of the rinsing basin, making sure that the guiding pins fit into the grooves of the two side blocks.

Figure 37 Place the Cassette into the Basin

4. Turn the central handle fully forward, making sure that the block sits properly on the manifold. Then turn the handle to the back to make the correct connection with the machine.

Figure 38 Turn Handle Back

1021

Verify the Connections

WARNING: Verify all connection to the endoscope are secure. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.

Verify the connection tubing does not interfere with the spray head and confirm that the spray function is working during the cycle. Failure to do this could result in an endoscope that is not disinfected and therefore should not be used on a patient.

Inspect the seating of the connector block to the manifold. Failure to achieve a proper connection could result in an endoscope that is not disinfected and therefore should not be used on a patient.

- Before the closing the cover, inspect the hookup to ensure that all connections are made properly and the tubing does not interfere with the sprayer.
- The endoscope must be low enough in the basin to be completely submerged.
- All channels must be connected correctly.
- The channel separator must be fitted.
- The leak test tubing must be secured under the endoscope so that it does not float and interfere with the sprayer.
- The feed hoses must not be kinked.
- Move any hoses lying against the head of the sprayer so that it can turn freely.

Note: Check the purge line before initiating a disinfection cycle. If air is continuously expelling out of the purge line, then contact your bio-medical department or call your manufacturer service line to have the air compressor checked.

RUN THE DISINFECTION PROGRAM

Normal Start

Data entry must be carried out carefully. Each selection or input must be checked and confirmed by the operator. Entering erroneous information may lead to machine faults or inadequate disinfection of an endoscope channel.

1. Close the basin lid by pressing the **Open/Close** button or the foot switch.

2. Press the **Menu** button.

3. When the **Operator Selection** window opens, select your login name by using the **Scroll Down** ↓ button, or use the touchpad, bar code reader, or I-Dent chip. Then click the **OK/ENTER** ✓ button.

4. The **Authorization** window opens. Enter your password with the touchpad, bar code reader, or I-Dent chip and then click the **OK/ENTER** ✓ button.

5. When the **Program Selection** window opens, highlight `Endoscope Selection` and click the **OK/ENTER** ✓ button.

Note: With heated reservoir, "ENDOSCOPE SELECTION" option will not be available if the disinfectant is not at the correct temperature.

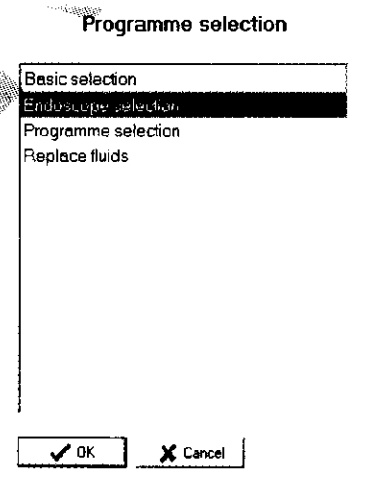

Figure 39 Endoscope Selection

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6. From the **Endoscope Selection** window, choose the instrument code or endoscope that you wish to disinfect by using the touchpad, bar code reader, or I-Dent chip. Click the **OK/ENTER** ✓ button.

Note: The endoscope code is required for the disinfection program to run. If pre-programmed endoscope codes have been entered by your system administrator, the specific disinfection program for that endoscope is selected automatically.

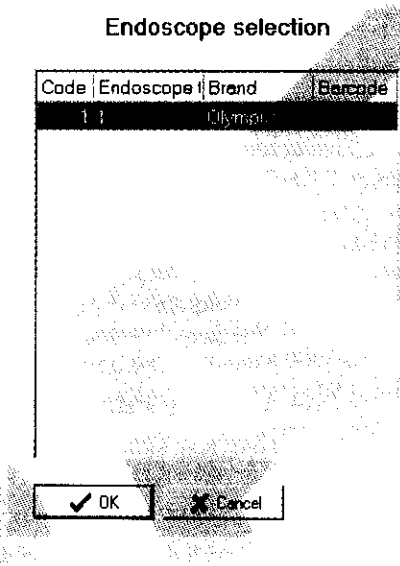

Figure 40 Endoscope Selection

7. Select the correct parameter set from the **Endoscope Type Parameter Set Selection window** by scrolling up or down with the **Scroll Down** ↓ button or **Scroll Up** ↑ button. Then click the **OK/ENTER** ✓ button.

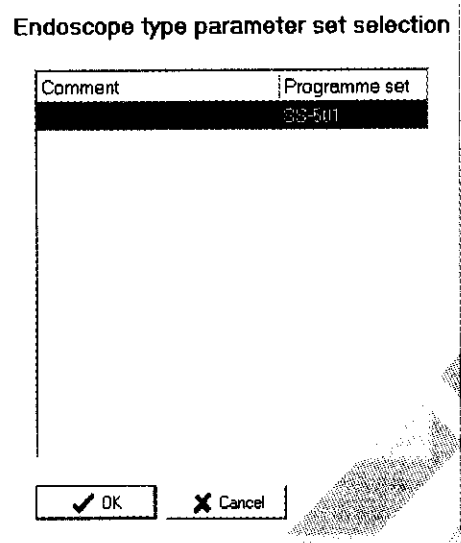

Figure 41 Parameter Set

WARNING Ensure the correct parameter set is selected for the type of endoscope to be processed. An endoscope is not disinfected and should not be used on a patient if the incorrect parameter set is used during a cycle.

Verify detergent rates and concentrates are properly set prior to initiating an endoscope cycle.

8. If the accessories pouch option is available, an extra window pops up when entering run data.

9. Select `Add Extra Instruments` and click the **OK/ENTER** ✓ button.

10. Add the extra instruments to the basin.

11. The **Patient Code** window opens. Enter the patient ID with the touchpad or bar code reader and click the **OK/ENTER** ✓ button.

1025

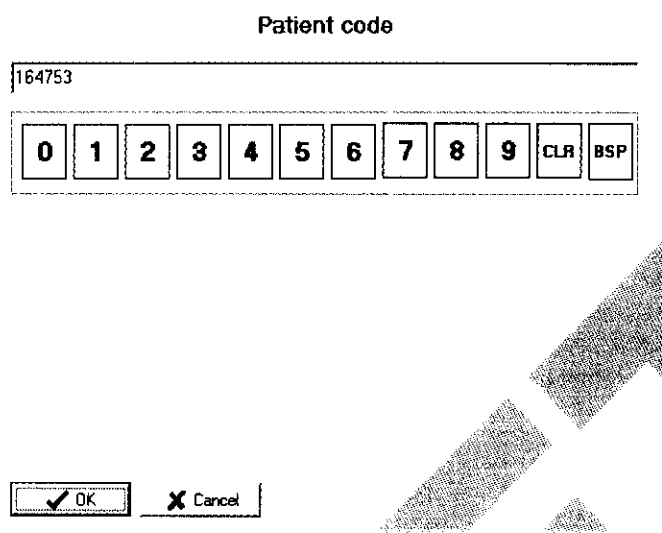

Figure 42 Patient Code

12. When the **Physician Selection** window opens, select the desired name by scrolling with the **Scroll Down** ⇩ button, or use the touchpad, bar code reader, or I-Dent chip. Then click the **OK/ENTER** ✓ button.

13. If the **Physician Assistant Selection** window opens, select the desired name by scrolling with the **Scroll Down** ⇩ button, or use the touchpad, bar code reader, or I-Dent chip. Then click the **OK/ENTER** ✓ button.

Note: The patient code, physician code, and assistant code may be optional fields on your MDS system. If your system administrator has determined that these items do not have to be tracked, the fields will not be shown.

14. The **Start Program** window opens. Verify that the data on the screen is all correct, and then click the **OK/ENTER** ✓ button.

15. A system check is carried out. If a yellow error report appears at the bottom of the screen, attempt to remove it by consulting *Chapter 5: Troubleshooting.*

16. The **Program Screen** opens and allows you to follow the progress of the disinfection process. The disinfection cycle will begin when the heater is ready. The heater status will be displayed on the screen.

1026

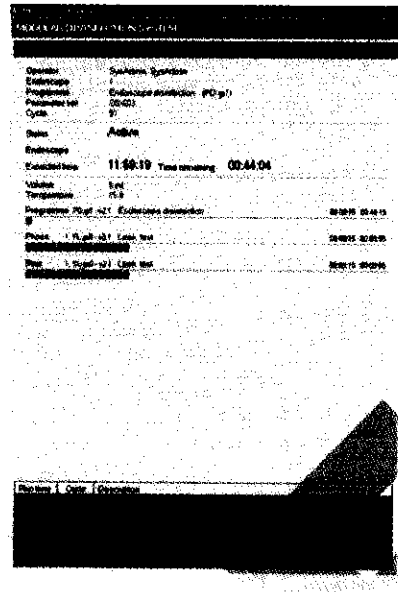

Figure 43 Process Window

Note: Heated reservoirs are optional equipment and may not be installed on all units.

Delayed Start

When selecting an automatic start, the endoscope is placed in the basin but the disinfection cycle will not begin until a pre-determined time. This is an administrative function and is available only during the time period as set up and allowed by the system administrator.

1. Prepare and connect the endoscope as described in steps 1-12 for the normal start above.

13. The **Select the Time** window opens. Select `Delayed Start` and press the **OK/ENTER** ✓ button. If the **Select the Time** window does *not* open, the delayed start is not available.

1027

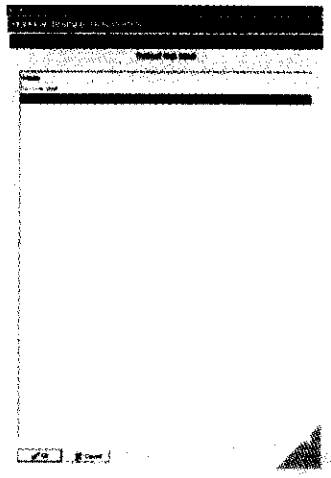

Figure 44 Delayed Start

14. When the **Select the Time** window opens, scroll down to select the desired start time and date. Click the **OK/ENTER** ✓ button.

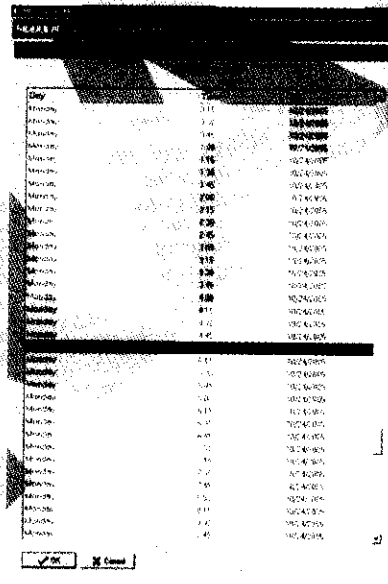

Figure 45 Select the Time

15. The **Delay Start** program window opens. Verify that the data on the screen is all correct, and then click the **Start** ⏻ button.

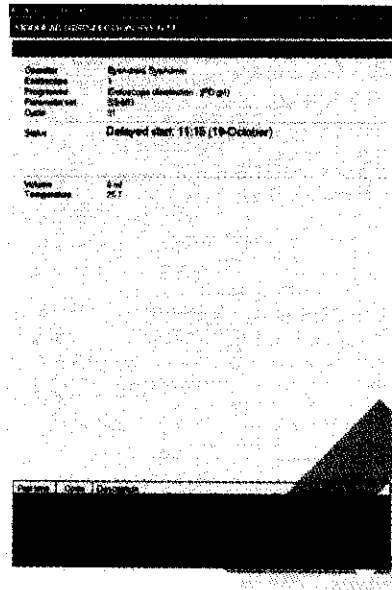

Figure 46 Delayed Start Progress

16. When the designated start time is reached, a system check is carried out. If a yellow error report appears at the bottom of the screen, attempt to remove it by consulting *Chapter 4: Maintenance and Troubleshooting.*

17. The Program screen opens and allows you to follow the progress of the disinfection process.

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PROCESS INTERRUPTIONS

Introduction

At startup and during the disinfection program cycle, the MDS monitors process parameters for the endoscope, machine, and software to ensure accurate disinfection of the endoscope. Reports, program errors, and system errors appear on the screen to communicate the cycle progress to you.

Operator messages and program errors appear at the bottom of the screen in the Reports field. A code number and short description of the report or error is shown. The elapsed time at which the message or error is generated is also provided.

System errors appear at the top of the screen in white letters on a red background.

Detailed error reports and troubleshooting steps are provided in *Chapter 5*.

WARNING *If system power is lost during a reprocessing cycle, the system will not complete the reprocessing cycle once the power is restored. The endoscope is not disinfected and should not be used on a patient. You must start the reprocessing cycle over so that the endoscope is properly disinfected.*

Program Errors

PROGRAM RESTART

In a few instances, an error disappears after restarting the program. You may attempt to restart the program if the following conditions are true:

- The basin lid is closed.
- The volume indicators on the screen show 0 mL.
- No error reports appear in the field program.
- No system errors appear at the top of the monitor.
- The LED is green.

If a program stop lasts longer than 60 minutes, the program can not be restarted, the LED turns red, and the program status is ASC (Reject). See *Table 4* for additional information.

To restart the program:

1. Press the **Start** button.
2. If the program restarts and progresses without any further errors, the disinfection cycle should be valid.
3. If the program does not restart, or one or more errors appear, press the **Stop** button. Follow the instructions below for the steps to take next.

PROGRAM STOP

If the **Stop** button is pressed, the program runs until a safe state is reached.

The alarm sounds and text appears in the Report section of the screen.

Every time the **Stop** button is pressed, the current program step is stopped and the next step is called up. By pressing the **Stop** button multiple times, the program can be forced to the end of the cycle. However, caution must be taken because the endoscope channels remain filled with fluid.

One of two status messages appears on the monitor. Follow the instructions below for the status message on your monitor.

Status: Broken Off

1. Press the **Stop** button.
2. Press the **Open/Close** button.
3. Select your login name and press the **OK/ENTER** ✓ button.
4. Enter your login name and password.
5. The basin lid opens.
6. Remove the endoscope or correct the cause of the error.
7. Re-start the disinfection program.

Status: Run Down Operator

The endoscope can not be removed from the machine. Continue the disinfection program.

After the incorrect program is completed, run the disinfection program again. Except for the operator login name, all entered data are automatically copied from the previous run if these steps are followed:

1. Press the **Open/Close** button.
2. Select your login name and press the **OK/ENTER** ✓ button.
3. Enter your login name and password.
4. The basin cover opens.
5. Within 30 seconds, press the **Menu** button.
6. Select your login name and press the **OK/ENTER** ✓ button.
7. Enter your login name and password.
8. Select "Repeat last run" and press the **OK/ENTER** ✓ button.

System Errors

If a system error occurs during standby mode, a warning message appears as the fault occurs but disappears as the situation is corrected.

If the error occurs during a disinfection cycle, the program ends and fluids are pumped out of the basin. A recovery program runs until a safe state is reached and the endoscope can be removed. The recovery program can not be stopped by the operator.

WARNING Report all system errors to your supervisor.

COMPLETE THE DISINFECTION PROCESS

When the disinfection process is complete, the process indicator light illuminates, the message "Completed" displays on the LCD screen, and the alarm sounds.

1. Press the **Stop** ⊽ button to silence the alarm.
2. The program status shows the state of the MDS machine.
3. The instrument status indicates the disinfection status of the endoscope.

Table 4 Post-Disinfection Program Status

Status	Description
ACTIVE	The program is progressing correctly.
CORRECT	The endoscope was disinfected without any faults or program interruptions.
CORRECT!!!	The endoscope was disinfected with one or more program interruptions.
STOP (fault)	The program is stopped due to an error.
STOP (ASC)	The safety control program stopped the program.
STOP (OPERATOR)	The operator stopped the program without a fault report
STOP (LIO)	The program stopped automatically after an error report or the maximum error time (50 minutes) was reached.
RUN DOWN (fault)	After an error, the endoscope is rinsed so that it can be safely removed.
RUN DOWN (OPERATOR)	The operator stopped the program. Run down program.
RUN DOWN (ASC)	The safety control program stopped the disinfection. Completion program.
ASC (REJECT)	The safety control program rejected the disinfection. Open the lid to close the program.
LIO (REJECT)	Disinfection was rejected due to an automatic program stop.

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Table 5 Post-Disinfection Instrument Status

Status	Description
DISINFECTED	The endoscope was run through a complete disinfection program.
NOT APPLICABLE	The program is not an endoscope disinfection program. **Warning: The endoscope can be used only if the connectors are correctly connected after the program.**
NOT SUITABLE FOR USE	The endoscope is insufficiently disinfected.

WARNING Wear clean gloves to prevent soiling of the disinfected endoscope.

If a run error was generated, a channel is blocked, or the endoscope is leaking, the endoscope must not be released for patient use. If there is any doubt as to whether an endoscope is correctly disinfected, it must be disinfected again before use. Contact your supervisor for further instructions.

4. Open the basin lid by pressing the **Open/Close** button or by using the foot switch. The run status report disappears and the Operator selection window opens.

5. Enter your login name and password.

6. Check that the basin lid is wet to verify that the sprayer worked correctly.

7. Verify that the endoscope has been properly rinsed and dried. Disinfectant residue left on the endoscope as a result of a loose hose can lead to serious complications in a patient.

8. Check that all adapters are still connected to the channel connections. If an adapter is loose or disconnected, the disinfection was not complete and must be repeated.

WARNING Before removing the endoscope, verify all connections to the endoscope are secure. If an adapter is loose or disconnected, the disinfection was not complete and must be repeated. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.

9. Disconnect the channel adapters

10. Remove the separation adapter(s).

11. Take the connector block out of the rinse basin and hang up the block.

12. Take the endoscope out of the rinse basin.

13. If appropriate, fit the valves.

14. The endoscope is now ready for a new examination. If it will not be used right away, the endoscope must be stored in an airing cupboard or on a suspension rack.

15. If automatic log printing is enabled, the log is printed.

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COMPLETE THE DISINFECTION PROCESS (CASSETTE SYSTEM OPTION)

When the disinfection process is complete, the process indicator light illuminates, the message "**Completed**" displays on the LCD screen, and the alarm sounds.

1. Press the **Stop/Cancel** × button to silence the alarm.
2. The program status shows the state of the MDS machine (*see Table 4*).
3. The instrument status indicates the disinfection status of the endoscope (*see Table 5*).

WARNING Always wear clean gloves to prevent soiling of the disinfected endoscope.

If a run error was generated, a channel is blocked, or the endoscope is leaking, the endoscope must not be released for patient use. If there is any doubt as to whether an endoscope is correctly disinfected, it must be disinfected again before use. Contact your supervisor for further instructions.

4. Open the basin lid by pressing the **Open/Close** button or by using the foot switch. The run status report disappears and the Operator selection window opens.
5. Enter your login name and password.
6. Check that the basin lid is wet to verify that the sprayer worked correctly.
7. Verify that the endoscope has been properly rinsed and dried. Disinfectant residue left on the endoscope as a result of a loose hose can lead to serious complications in a patient.
8. Check that all adapters are still connected to the channel connections. If an adapter is loose or disconnected, the disinfection was not complete and must be repeated.

9. Disconnect the cassette by rotating the connector block handle 1/2 turn (180 degrees).

10. With the two side handles, lift the cassette out of the basin.

11. The endoscope is now ready for a new examination. If it will be used right away, place the cassette in the transport basket and close the cover.

12. If it will not be used right away, the endoscope must be stored in drying cabinet or in a storage cabinet.

13. If automatic log printing is enabled, the log is printed.

REPORTS

Run Data Recorded

For each disinfection program run, the following data is recorded and stored on the PC hard drive:

- Machine ID
- Run number
- Date and time
- Endoscope Code
- Gydoscope ID
- Operator ID
- Patient ID
- Process step times
- Errors
- Additional information as set up by the system administrator

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Printing Reports

CURRENT REPORT

A cycle log prints automatically whenever the MDS module cover opens at the end of a disinfection cycle. To redisplay the current cycle log, double-click the printer icon in the system tray.

EARLIER REPORTS

All completed cycle logs may be viewed and reprinted at any time from the Management program.

1. Display the Windows desktop by minimizing all running programs.

2. Double click on the MDS icon to open the folder.

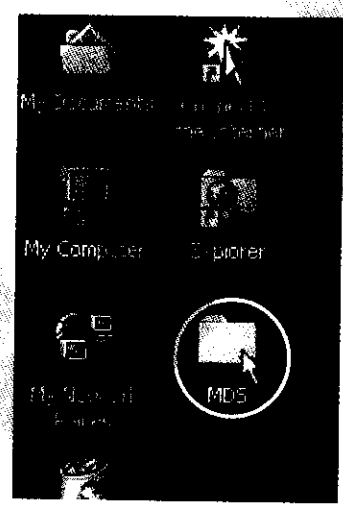

Figure 47 MDS Desktop Folder

3. Double-click on the **Management** icon.

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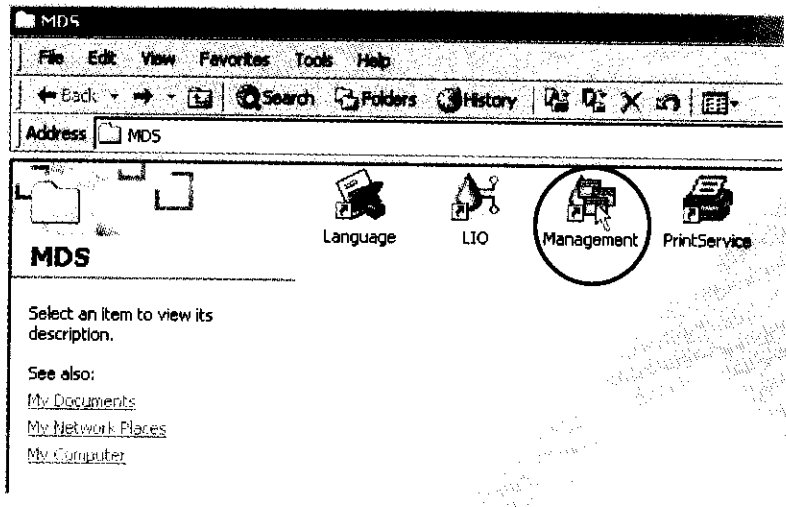

Figure 48 Management Icon

4. Log in to the Management system.

5. On the **Management** screen sidebar, click on the `General` tab.

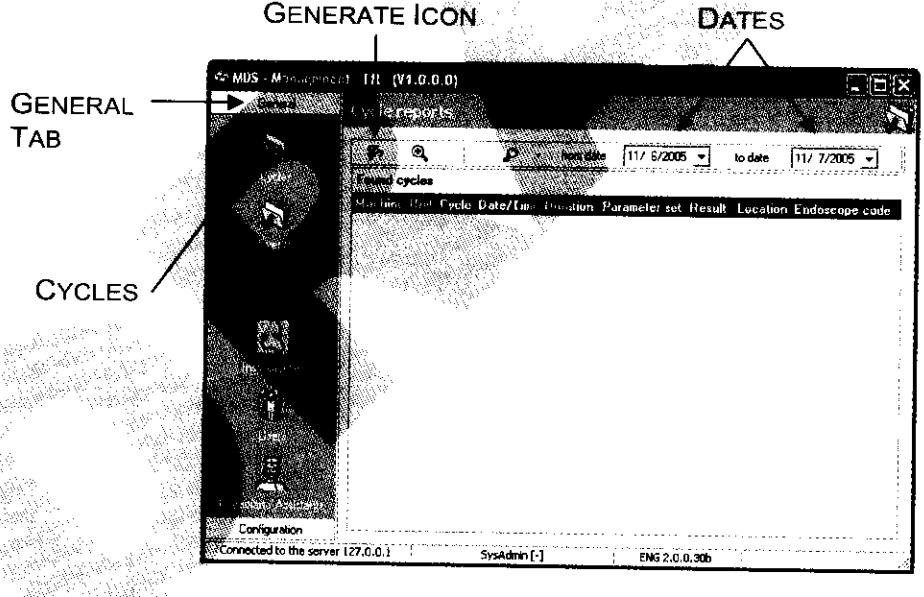

Figure 49 Management Screen

6. On the sidebar, click on the **`Cycles`** icon.

7. On the blank **Cycle Reports** screen, set the `From Date` and `To Date` parameters, and then click on the **`Generate`** icon in the toolbar.

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8. The **Cycle Reports** screen opens. Double-click on the desired cycle.

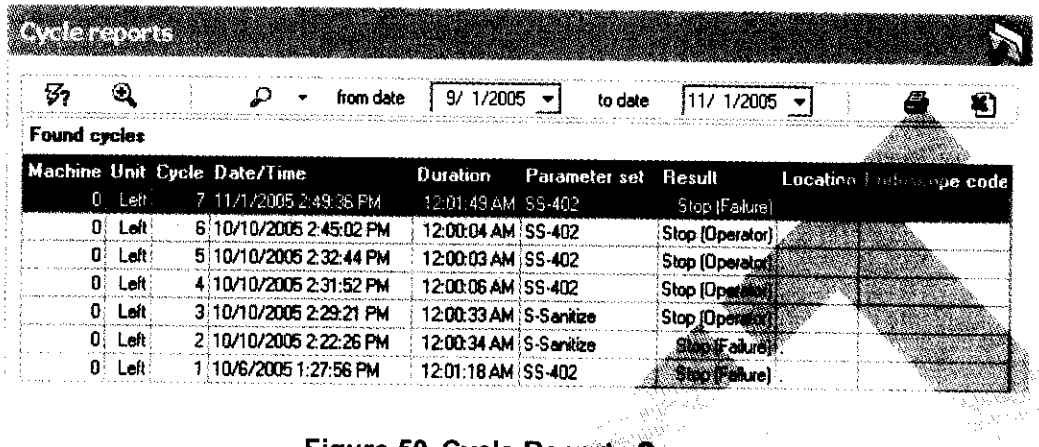

Figure 50 Cycle Reports Screen

9. The **Cycle Details** screen appears. Click on the plus sign to the left of each line to expand the report. Click on the printer icon to print a copy of the report.

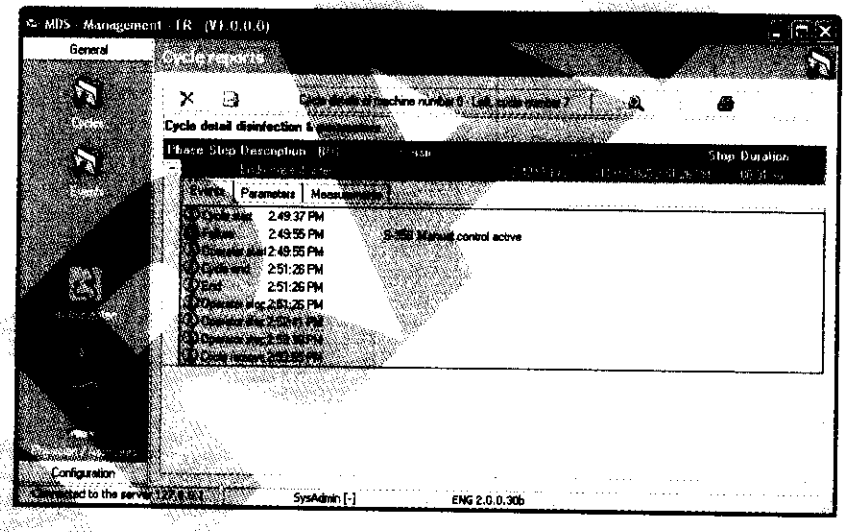

Figure 51 Cycle Details Screen

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SHUTDOWN

Use the following process to shutdown the reprocessor at the end of the day.

1. Clean the system by wiping down all surfaces with a non-scouring cleansing agent. Use a lime dissolving, non-scouring agent for the rinse basin and inside the lids. Use soap and water to clean the rubber covers.

WARNING Avoid possible chemical burns. Always wear personal protective equipment (gloves, goggles) when handling disinfectant and/or detergent.

2. Check the detergent and alcohol reservoirs for appropriate levels. Refill them if necessary.

3. Clean the detergent cap, bracket and reservoir. Flush the reservoir thoroughly with hot water. Refill the detergent reservoir, if necessary.

4. Close the incoming water line shutoff valve.

5. Turn the external air source to Off (if applicable).

PROCEDURE SUMMARY

1. Open the cover.

2. Connect the endoscope.

3. Close the cover.

4. Enter your login name and password, the endoscope ID, the patient number, the physician ID, and the assistant ID.

5. Start the program.

6. After disinfection, open the basin lid.

7. Enter your login name and password.
8. Check the sprayer and the connections.
9. Disconnect the connector block.
10. Remove the endoscope from the basin.
11. Print a report.

DOWNTIME

Brief Downtime

- If the MDS will be down for a brief period time—less than seven days—it should remain powered on.
- A screen saver may be installed on the PC to prevent damage to the monitor.
- To prevent moisture in the leak test system, fit disinfection blocks in the MDS when it is not is use.

Prolonged Downtime

- If the MDS will be down for more than seven days, it should be powered off.
- The pipes, blocks, filters and heaters in the machine contain a lot of water where bacterial growth may occur. After a long downtime, replace the bacterial filter and disinfect the MDS before running any endoscope disinfection procedures.
- To shut down the MDS, close all running programs first before pressing the main PC power switch. Failure to do this may result in software errors.

Chapter 4

MAINTENANCE

This chapter contains basic service procedures required for maintaining the MDS. Strict adherence to these requirements guarantees optimum continuous quality in endoscope reprocessing. Failure to perform required maintenance may result in injury or death to the operator or patient.

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- LUBRICATION 4-4
- DISCHARGE SCREEN 4-4
- MIXING TAP 4-4

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WATER FILTER REPLACEMENT 4-6

AIR COMPRESSOR SUBASSEMBLY INTAKE FILTER REPLACEMENT 4-13

INLINE AIR FILTER REPLACEMENT 4-16

FUSE INFORMATION 4-18

DISINFECTANT RESERVOIR REPLACEMENT 4-19

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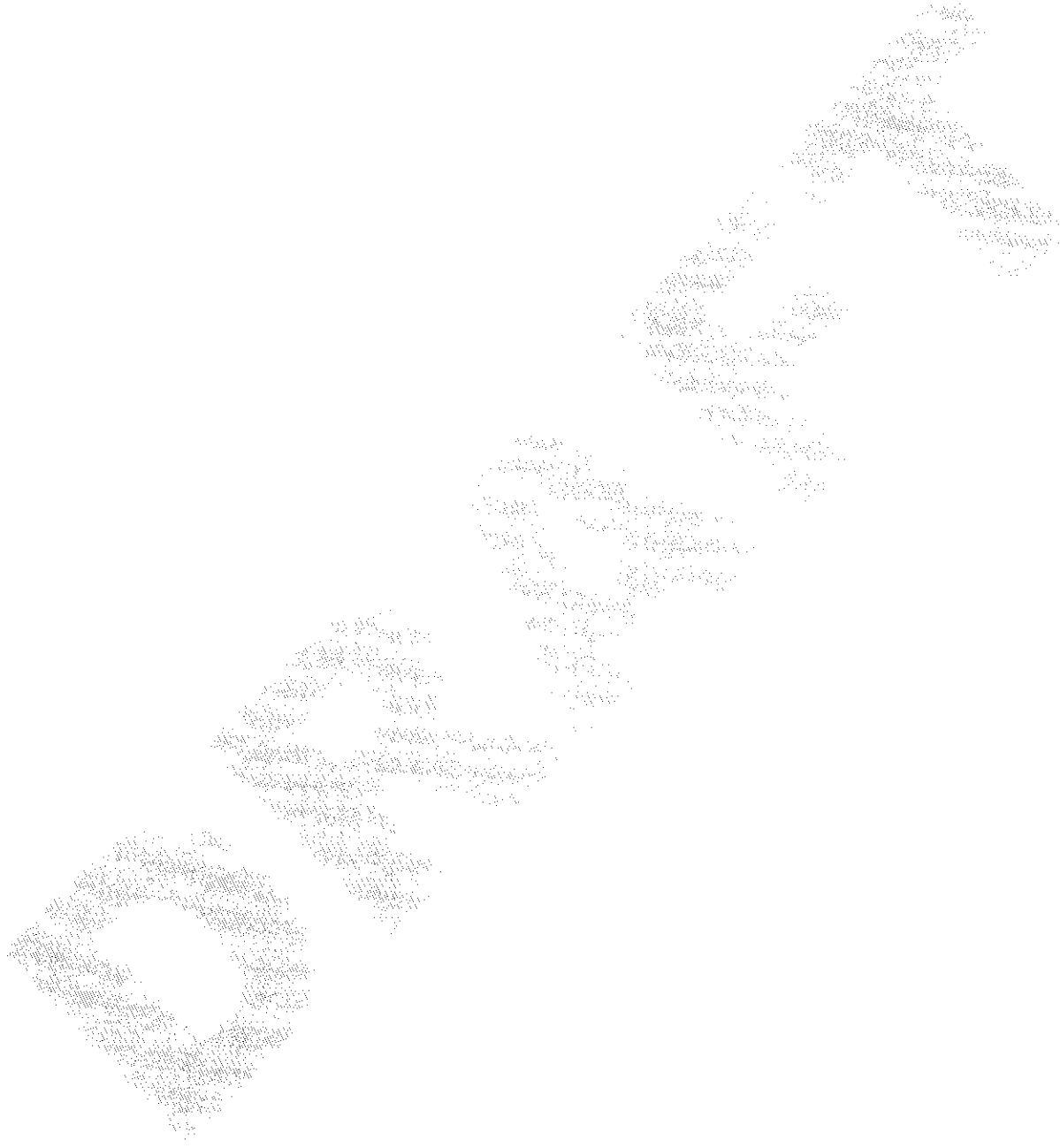

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DAILY MAINTENANCE

Details and instructions for the daily service requirements are included in *Chapter 3: Operation.*

The following daily maintenance procedures must be completed at the start of each day:

- Confirm that the main air pressure regulator is set between 2.8–3.0 bar.
- Confirm that the leak test air pressure regulator is set at 0.24–0.25 bar.
- Verify a sufficient flow of water into the basin or replace the system filters.
- Check that all O-rings on the connection columns are present and undamaged.
- Replace the screens in the rinse basin if they are excessively soiled.

At the end of each day, clean the MDS:

- For the top and outside covers, use a non-scouring cleansing agent.
- On the rinse basin and inside covers, use a non-scouring, lime-dissolving cleansing agent.
- Use soap and water to clean the cover gaskets and prevent them from sticking.

WEEKLY MAINTENANCE

Inspection

Inspect the following on a weekly basis. Adjustments or changes should be made by a qualified service technician.

- **Connector Blocks:** Check for cracks in the silicone hoses, especially at the connections to the connector block. If cracks have formed, the hose should be shortened or replaced.
- **Glass Covers:** The basin lids should open and close easily.
- **Door:** The front door should open and close easily.
- **MDS Tubing, Connections, Fittings, Hydraulics and Dosing System:** Check for wear and leakage and replace as needed.

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Lubrication

1. Using a cloth, dry the O-rings on the connection columns.
2. Take a small amount of O-ring grease between your thumb and index finger and spread it diagonally on the connector plate along the first two columns.
3. Repeat these two steps for the other three pairs of columns.
4. Spread the grease lengthwise along the O-rings with your thumb and index finger.

Discharge Screen

Using a screen hook, remove and clean the screen as it becomes soiled.

Mixing Tap

Open and close the mixing tap to keep the mechanism free.

DISINFECTANT FILTER REPLACEMENT

A disinfectant filter is connected above each of the disinfectant reservoirs. The filter assembly consists of a 65 µm fiber filter, tubing, and fittings that connect to the disinfectant lines. Replace the filter assembly every time the disinfectant is replaced. Use only Minntech-approved filters: US part no. 78399-377 (BV part no. 2-4-640).

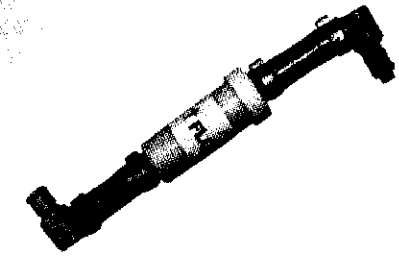

Figure 1 Disinfectant Filter Assembly

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1. Remove the disinfectant filter by depressing the thumb latches at each end and uncoupling the mating components.

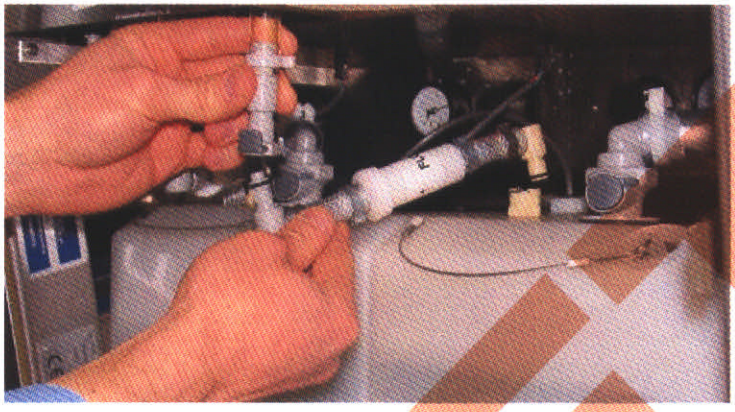

Figure 2 Uncoupling the Filter Assembly

2. Insert the disinfectant filter connector into the matching quick-connect coupling on the reservoir. Insert the other end into the matching coupling on the vertical tube. The couplings differ on each end of the filter to ensure proper orientation. Both connections will click when properly fit. The filter is installed correctly if the flow direction arrow on the filter label points away from the reservoir.

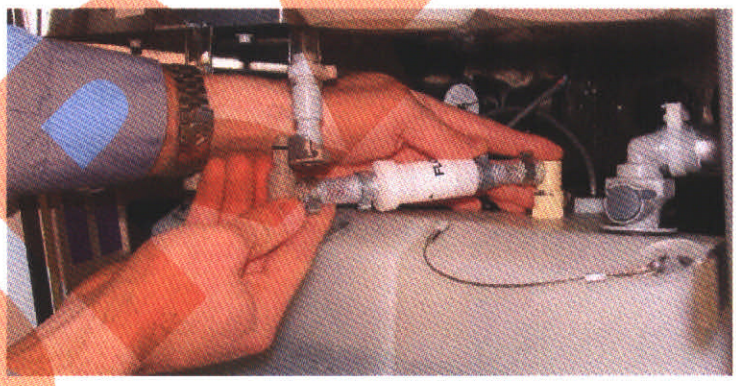

Figure 3 Installing New Filter Assembly

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WATER FILTER REPLACEMENT

WARNING: Only replace one water filter at a time. When replacing the water filter, make sure that the filter being removed is the same as the filter replacing it.

The water filtration system removes particulates down to 0.45 µm and biological contaminants as small as 0.2 µm from the supply water. During the water line disinfection procedure, the system disinfects the 0.2 µm filter and the incoming water line for the MDS.

Note: A water line and water filtration disinfection process must be performed whenever a water filter is replaced. *Refer to Section 2-31 in Chapter 2.*

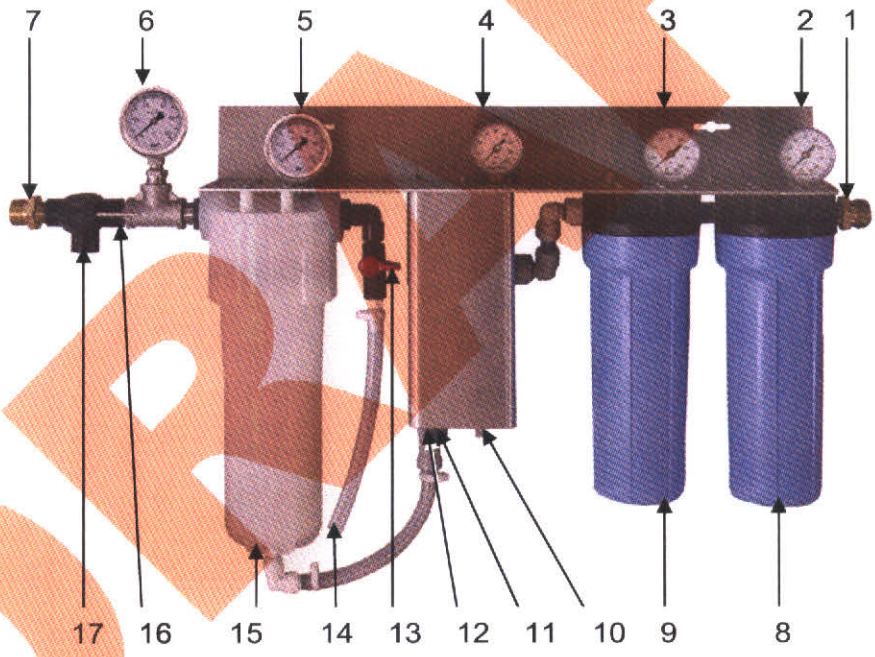

Figure 4 Water Filtration System

1. Water inlet
2. Inlet pressure gauge
3. 1 µm filter outlet pressure gauge
4. 0.45 µm filter outlet pressure gauge
5. 0.2 µm filter inlet pressure gauge
6. 0.2 µm filter outlet pressure gauge
7. Water outlet
8. 1 µm filter
9. 0.45 µm filter
10. Disinfectant inlet
11. 0.2 µm filter inlet/housing drain
12. Communication cable connector
13. Bleed valve
14. Bleed valve outlet
15. 0.2 µm filter
16. Sample port valve
17. Sample port

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The following conditions must be before changing a filter:

- No endoscope reprocessing cycles are running.
- No water line disinfection procedure is running.
- The inlet water supply is turned off.

You will need the following materials:

- A filter bowl wrench.
- The necessary filter cartridges (*see Table 1*).

Table 1 Filter Cartridges

Key	Filtration Porosity	Filter Type	Part Number
1	1 µm	Microfiber	MF01-0014
2	0.45 µm	Pleated	MF01-0015
3	0.2µm	Hollow fiber	MF01-0013

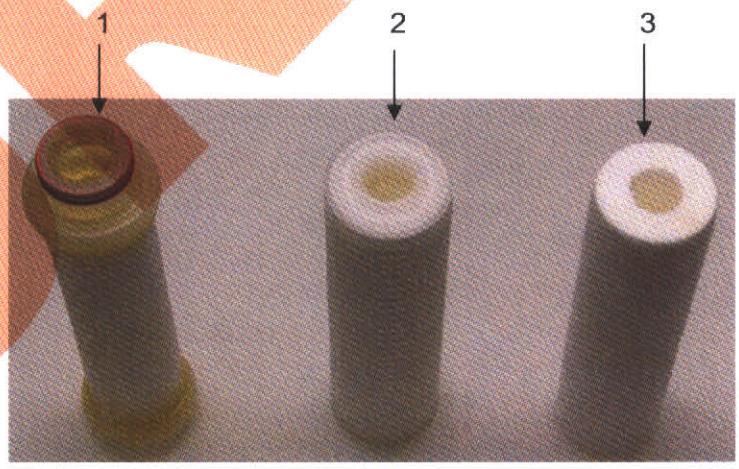

Figure 5 Filter Cartridges

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1. Open the **Expert Control** screen by clicking on the icon at the top of the screen. Enter your login name and password when prompted.

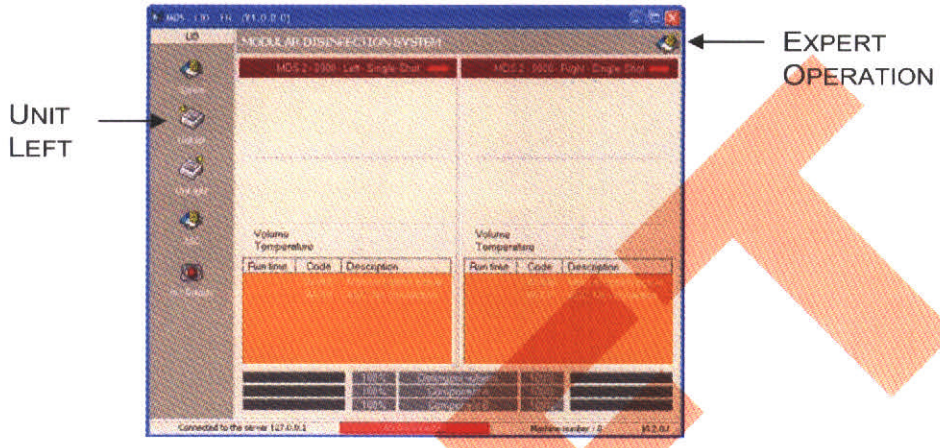

Figure 6 Expert Control and Unit Left

2. Click on the *Unit Left* icon on the left menu bar.

3. In the I/O screen that opens, scroll down in the Outputs column until `Y90-Filter Water` appears.

4. Double click on your selection to gain manual control.

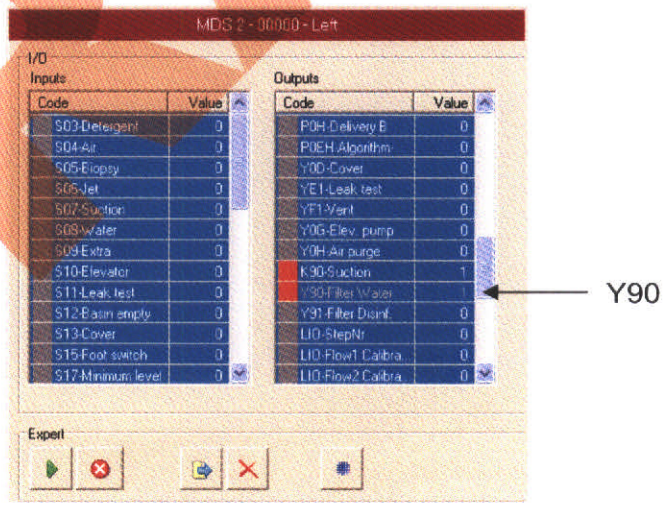

Figure 7 Y90 Filter Water

5. Relieve the pressure in the filtration system by opening the Y90 filter water valve.

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6. Check the inlet pressure gauge to ensure that the pressure is at zero.

7. Using a filter bowl wrench, remove the 1 µm filter housing and discard the used filter cartridge.

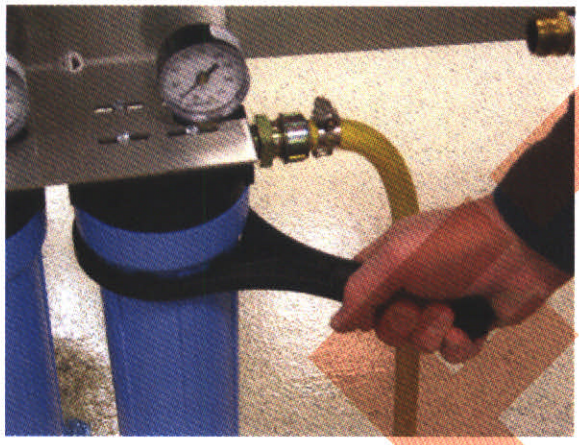

Figure 8 Loosen Filter Housing

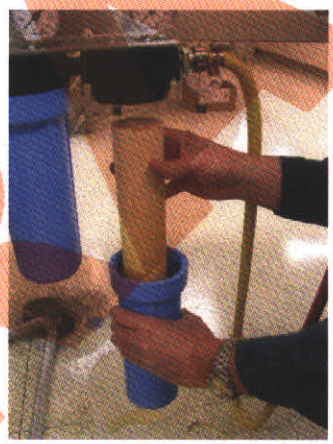

Figure 9 Remove Housing and Filter

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8. Place a new filter in the housing, ensuring that the O-ring is in place.

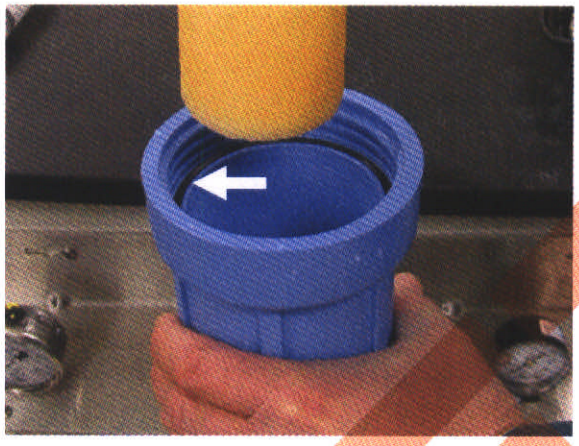

Figure 10 Check O-Ring

9. Thread the housing onto the header and tighten by hand.
10. Repeat the procedure to replace the 0.45 µm filter.
11. Check the 0.2 µm inlet and outlet pressure gauges to verify that both read zero.
12. Place a container under the filter housing.
13. Disconnect the drain tube and place the end in a container.

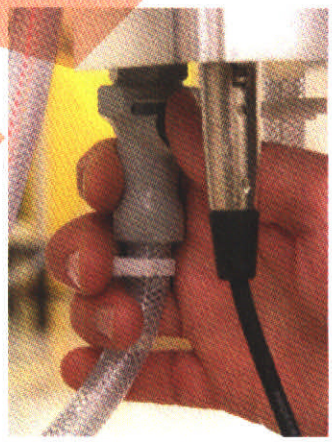

Figure 11 Release Drain Tube

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14. Open the bleed valve and drain the filter housing.

Figure 12 Open Bleed Valve

15. Return the bleed valve to the closed position.

16. Using a filter bowl wrench, remove the 0.2 µm filter housing.

17. Rotate the used filter cartridge counterclockwise, pull downward, and discard.

18. Insert a new filter cartridge into the housing header and rotate clockwise until the tabs snap into place.

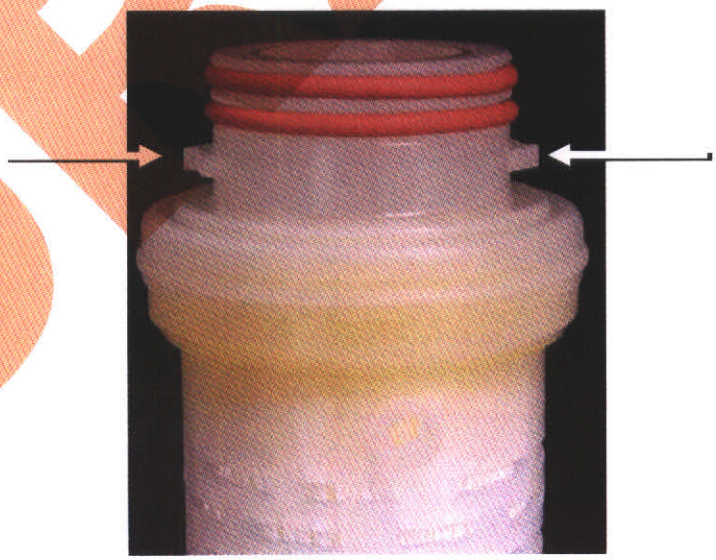

Figure 13 Filter Mounting Tabs

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19. Thread the housing into place on the header and tighten by hand.

20. Slowly open the main water supply valve and check for any leaks.

21. Bleed any air from the 0.2 µm filter housing and then close the valve.

22. Activate the filtration system water valve from the **Expert Control** screen.

23. Place a container under the bleed valve outlet tube and slowly open the bleed valve. Let the water run until it is a steady stream.

24. Close the bleed valve.

25. Activate the MDS water and drain valve, and the filtration system water valve from the Expert Control screen.

26. Allow the water to run for at least ten minutes to completely wet the filter.

27. Perform a water line and water filtration disinfection procedure. *Refer to Section 2-xx of Chapter 2.*

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AIR COMPRESSOR SUBASSEMBLY INTAKE FILTER REPLACEMENT

1. Acquire an Intake Filter service kit (Minntech BV part no. 3-9-452).
2. Remove the eleven screws and lift the cover off the compressor sub-assembly.

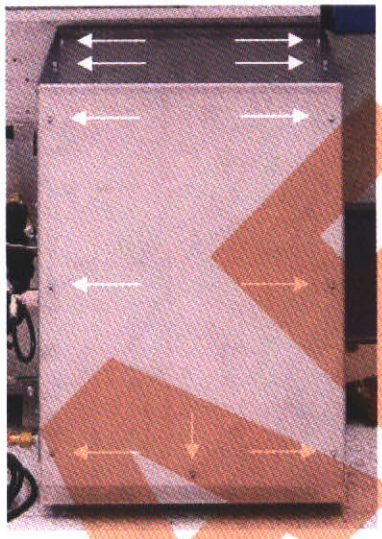

Figure 14 Access Cover Screw Locations

3. Pull downward on the safety valve pull-ring to bleed off pressure.

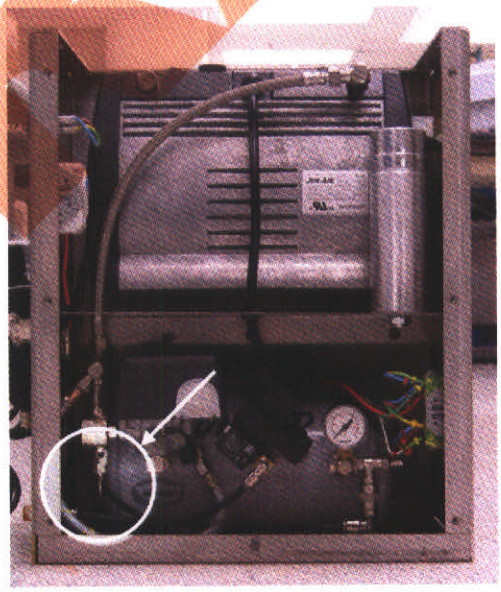

Figure 15 Safety Valve Pull Ring

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4. Locate the two filters on the compressor.

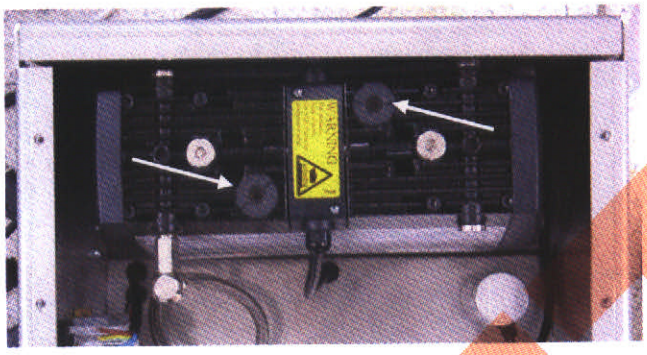

Figure 16 Filter Locations

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5. Loosen each filter with a medium size coin. Remove and discard the filters.

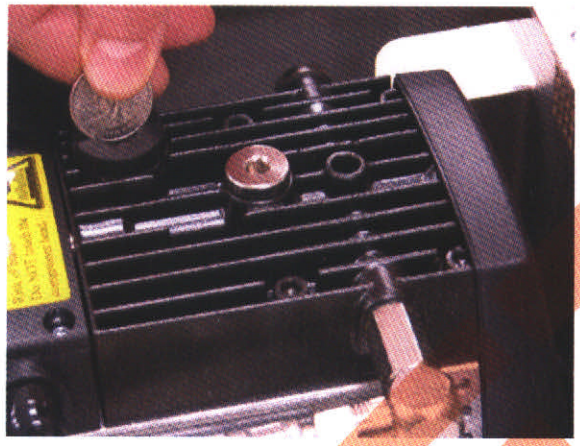

Figure 17 Loosen Filter

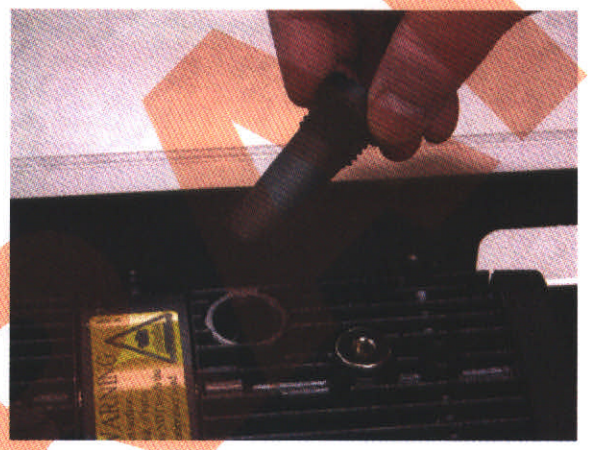

Figure 18 Remove Filter

6. Insert the new filters, tighten with a coin, and reattach the cover.

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INLINE AIR FILTER REPLACEMENT

1. Acquire two new inline filter assemblies (Minntech BV part no. 3-9-421).
2. Remove the shrouds and locate the filters.

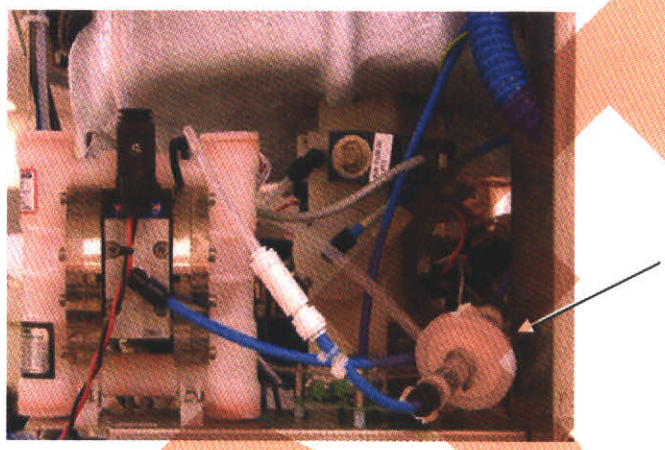

Figure 19 Right Side Filter Location

3. Move the filter away from the machine to allow access to the fittings.

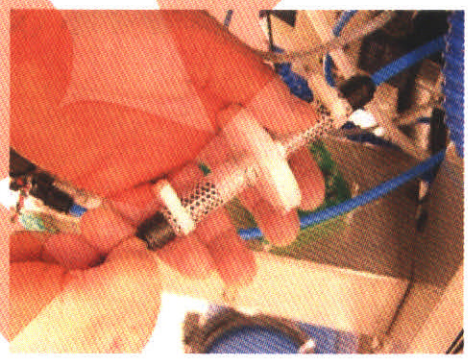

Figure 20 Tubing Removal

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4. Press on the push-in fitting to release the outlet tubing.

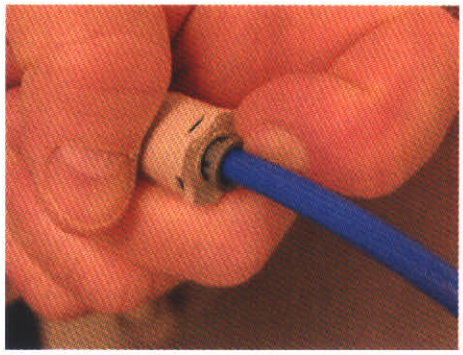

Figure 21 Push-In Fitting

Figure 22 Tubing Release

5. Release the inlet tubing in the same way as the outlet tubing. Remove and discard the filter assembly.

6. Replace the filter by attaching the inlet and outlet tubing. Ensure that the side of the filter marked "IN" is toward the center of the machine.

Figure 23 Filter Orientation

7. Replace the shrouds.

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FUSE INFORMATION

If your fuses needed to be replaced, seek qualified repair personnel. The fuses are located on the main control panel inside the machine, as shown in *Table 2*.

Table 2 Fuses

Key	Minntech P/N	Fuse Rating
F1	4-6-250	4.00A, 250V Fast Acting 5X20mm Fuse
F3	4-6-248	10.0A, 250V Fast Acting 5X20mm Fuse
F4	4-6-243	2.5A, 250V Time Lag 5X20mm Fuse
F5	31600-032	20A, 250V Time Lag 5X20mm Fuse
F6	4-6-254	12.5A, 250V time Lag 5X20mm Fuse
F10	4-6-250	4.00A, 250V Fast Acting 5X20mm Fuse

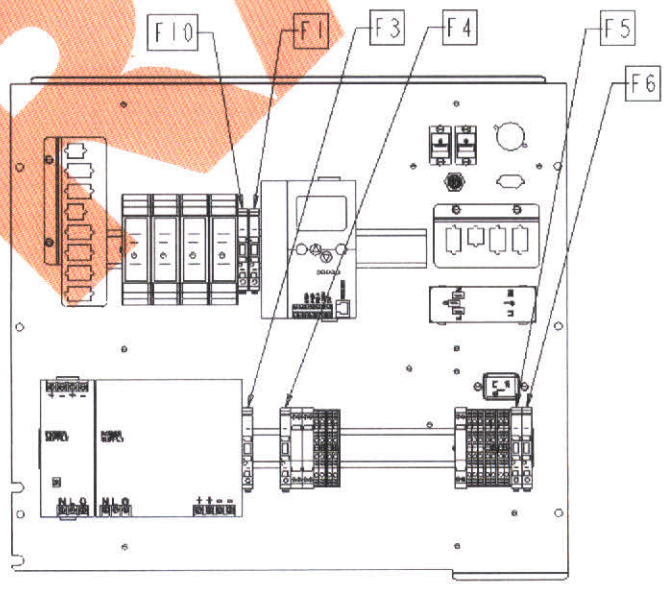

Figure 21 Fuse Location

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DISINFECTANT RESERVOIR REPLACEMENT

WARNING Wear appropriate protective clothing, gloves, and eyewear.

Drain all fluid from the reservoir prior to removal.

1. Use the appropriate disinfectant transfer utility to empty the reservoir. (*See Chapter 2.*)

2. Disconnect electrical connections. (Level sensor for non-heated version, Level sensor, temperature probe and heater for heated version).

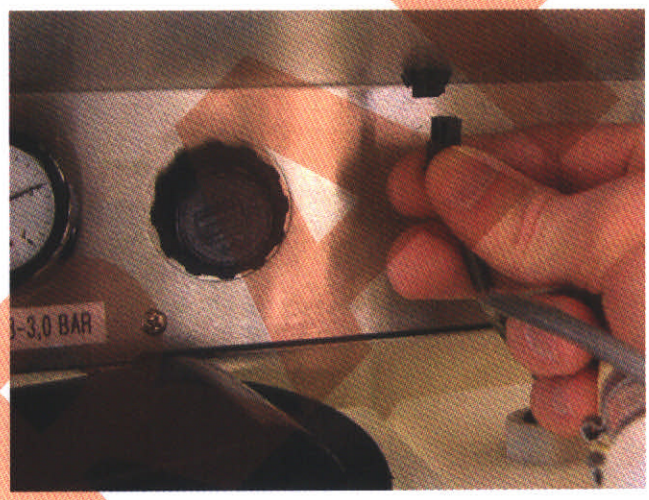

Figure 24 Level Sensor Connector (non-heated version)

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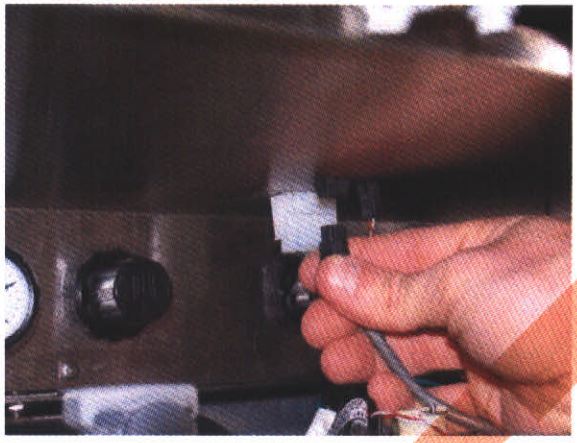

Figure 25 Level Sensor (heated version)

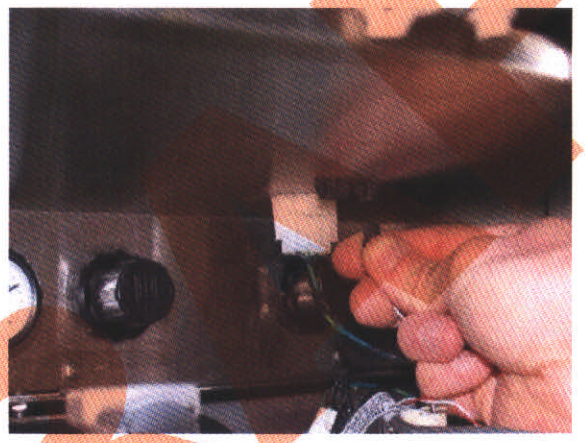

Figure 26 Temperature Probe (heated version)

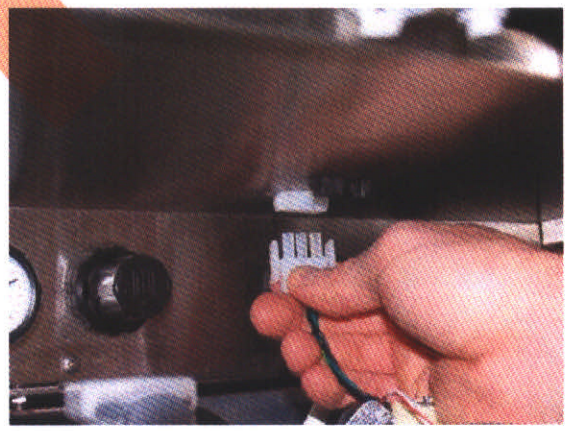

Figure 27 Heater (heated version)

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3. Disconnect the disinfectant filter outlet connector from the coupling on the vertical tube.

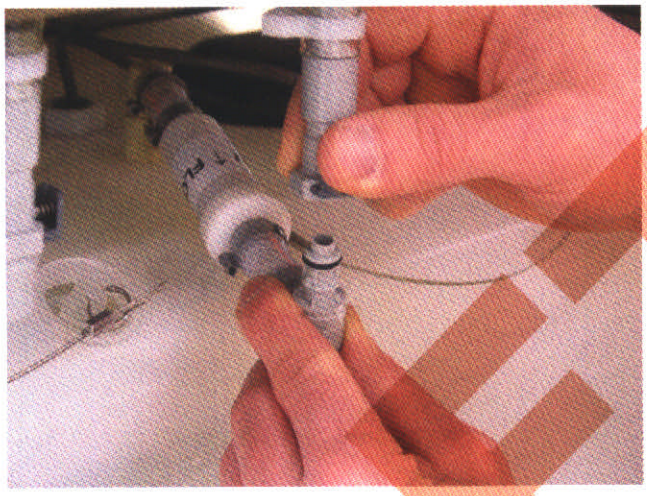

Figure 28 Tube Coupling

4. Disconnect the disinfectant filter inlet connector from the outlet coupling on the reservoir.

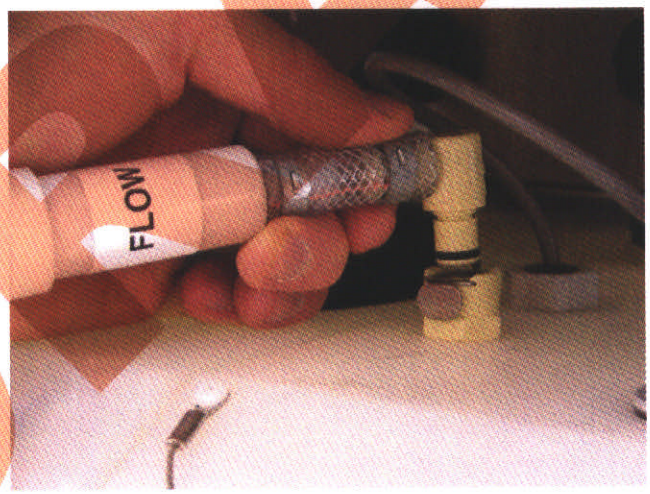

Figure 29 Reservoir Outlet Coupling

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5. Disconnect the disinfectant return line connector from the inlet coupling on the reservoir.

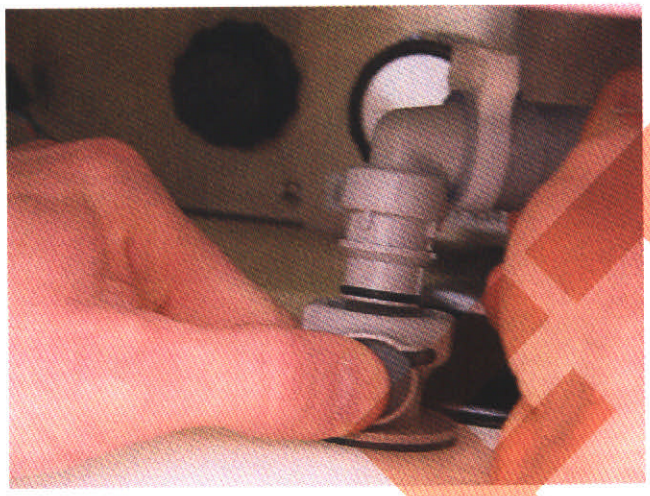

Figure 30 Reservoir Inlet Coupling

6. Lift out the reservoir.

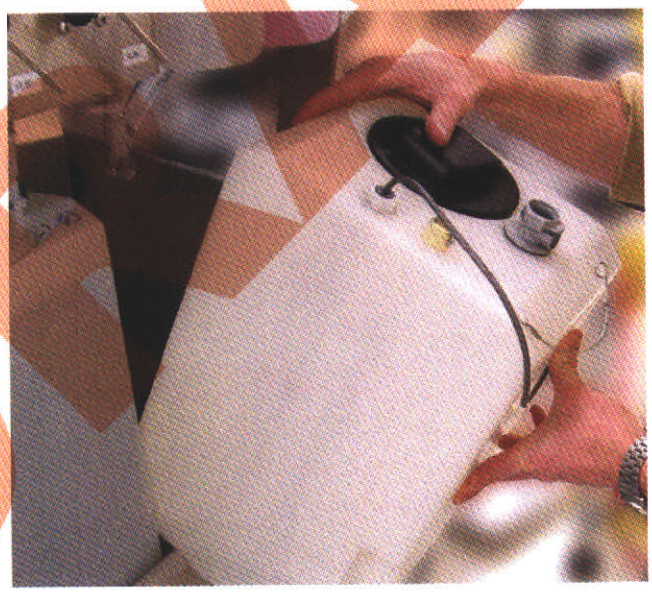

Figure 31 Remove Reservoir

7. Replace the reservoir by reversing the steps above.

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Chapter 5

TROUBLESHOOTING

This chapter lists error messages you may encounter while using the MDS. If the suggested action does not solve a problem or if the error recurs, contact your Technical Service representative.

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INTRODUCTION

Program Reports

The types of program reports are as follows:

- **Machine reports** list the test results that determine if the MDS is functioning correctly. These tests may be run during active or stand-by machine mode.
- **Safety control reports** list any deviations in the disinfection program as monitored by the ASi drive controller.
- **Status reports** list the program and instrument status. The program status report shows the progress of the working MDS. The instrument status report indicates the disinfection condition of the endoscope.

Communication errors (001–099) are not listed in the run report. Only those errors resulting from an endoscope or machine problem appear (execution errors 100–599 and ASi control errors 300–399).

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Onscreen Program Progress

The disinfection program consists of process steps called phases and sub-phases. For each disinfection cycle, the phase names, status, and run codes appear on the monitor. Information for the left module appears on the left side of the screen; information for the right module is on the right side.

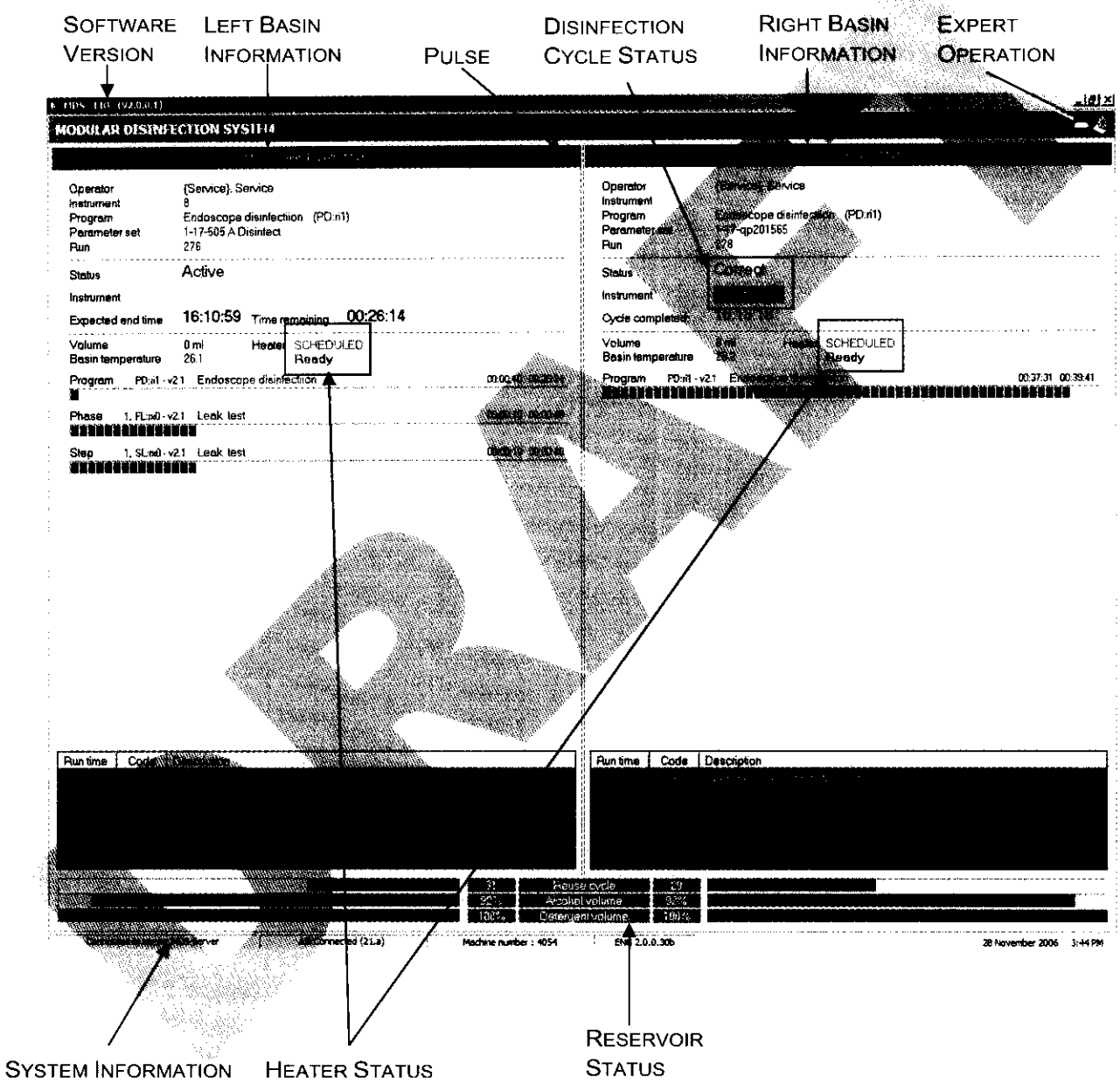

Figure 1 Disinfection Program in Process (Optional Heater Reservoir Equipment installed)

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Program Information

This field displays operator and endoscope information as well as the normal progress of the disinfection program. The pre-programmed run time, on the left in ***Error! Reference source not found.***, is fixed. Real time, on the right, is measured from the start of the cycle. This counter normally decreases as a normal cycle progresses, but may increase or become fixed if an error occurs. The progression of the sub-phases, below the timers, is illustrated with blue time bars. The real time is measured from the start of each step or phase.

Expert Information

This field is visible and active to operators and system administrators with valid passwords. It provides extra information for maintenance and troubleshooting.

Reports and Program Errors

Operator messages and errors appear in the Reports field to communicate the cycle progress to you. An audible alarm also sounds to communicate certain information.

A code number and short description of the report or error is shown, along with the elapsed time at which the message or error is generated. The most recent message is at the top of the field. The meaning of each screen color is shown in the table below:

Table 1 Screen Color and Program Status

Screen Color	Program Status
Orange	Standby, no program active
Gray	Program active
Red	Error
Blue	Program complete

System Errors

Current system errors appear at the top of the screen in white letters on a red background. The message disappears once the error is corrected.

If a system error occurs during standby mode, a warning message appears as the fault occurs but disappears as the situation is corrected.

If the error occurs during a disinfection cycle, the program ends and fluids are pumped out of the basin. A recovery program runs until a safe state is reached and the endoscope can be removed. The recovery program can not be stopped by the operator.

Reservoir Volume

The volume of the disinfectant, detergent, and alcohol reservoirs is indicated. You must monitor these volumes because if a reservoir is empty, an error message appears but the program will not stop.

System Information

The bar at the bottom of the screen provides system communication information, machine identification, and the software version for your selected language.

MDS software has two possible system connections:

1. MDS PC to the MDS (ASi)
2. MDS PC to an external server (optional)

The left field on the bar indicates if the MDS is connected to a server. The next field to the right indicates if the PC is correctly connected to the MDS. The bar is red if an error exists.

The **Operator Selection** Screen also displays messages in a yellow field near the top of the screen. This message informs the user of the current status after an error was made.

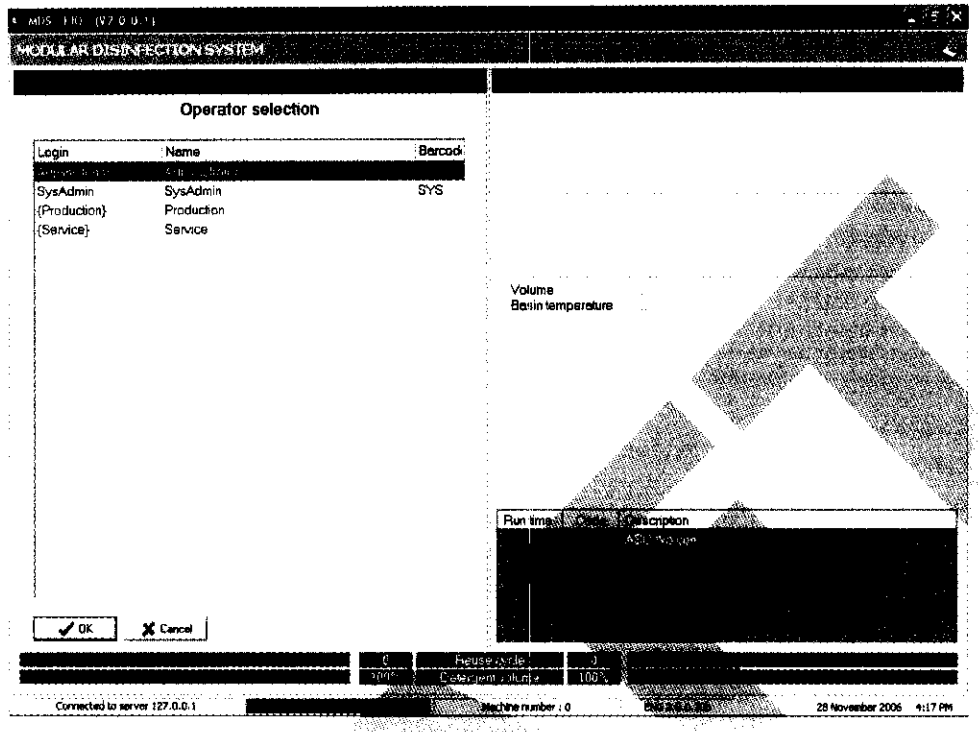

Figure 2 Operation Selection Screen

REPORTS OVERVIEW

Screen reports and errors are summarized by category and number in the following tables. In the following section of this chapter, more specific information is provided. Potential causes, solutions, and follow-up actions for each error are included. For complex problems, it is advisable to notify the maintenance department and/or your supervisor.

PC Communication Reports

Code	Description
C-001	AS-i error: %d: %S
C-011	Broken server connection: Run data will be buffered.
C-012	No hardware definition received. Hardware not initialized.
C-015	Server disconnected. Selection aborted.
C-019	The clock has been synchronized with the server computer (%S)
C-021	The expert control has been automatically closed, you have to log on again.
C-030	The previous run has ended incorrectly. Program aborted to a safe situation.

C-032	A failure occurred during the execution of a run. Program aborted to a safe state.
C-033	Program aborted to a safe situating but incorrect parameter set.
C-040	The hardware definition contains an invalid signal: %d.
C-042	Selected hardware definition not correct for "%S" type.
C-052	Automatic program start up is not possible the current state.
C-053	Another program is active.
C-060	Delayed start of program is not possible under current conditions.
C-080	Tag-reader not available.
C-099	Internal LIO failure: %S

Reports

Code	Description
M-910	An unknown code was read by the bar code reader.
M-912	The bar code function is not selected.
M-920	Unknown operator name.
M-922	Unknown instrument ID.
M-940	Incorrect tank code: %.

Endoscope Errors

Code	Description
S-102	Start not allowed: Leak test sensor high.
S-103	Endoscope leak or incorrectly connected.
S-104	Leak test pressure dropped after check.
S-105	Leak test vented but stays on pressure.
S-106	Block not pressurized or not connected.
S-112	Start not allowed: Air sensor high.
S-113	No flow: air channel.
S-114	Blocked air channel.
S-115	No pressure: air channel.
S-116	No connectivity air channel
S-117	Air channel not connected
S-122	Start not allowed: Biopsy sensor high.
S-123	No flow biopsy channel.

S-124 Blocked biopsy channel.
S-125 No pressure biopsy channel.
S-126 No connectivity biopsy channel
S-127 Biopsy channel not connected
S-132 Start not allowed: Jet sensor high.
S-133 No flow: jet channel.
S-134 Blocked jet channel.
S-135 No pressure: jet channel.
S-142 Start not allowed: Suction sensor high.
S-143 No flow: suction channel.
S-144 Blocked suction channel.
S-145 No pressure suction channel.
S-146 No connectivity suction channel
S-147 suction channel not connected
S-152 Start not allowed: Water sensor high.
S-153 No flow: water channel.
S-154 Blocked water channel.
S-156 No connectivity water channel
S-157 Water channel not connected
S-162 Start not allowed: Extra sensor high.
S-163 No flow: extra channel.
S-164 Blocked extra channel.
S-165 No pressure extra channel.
S-166 No connectivity extra channel
S-167 Extra channel not connected
S-172 Start not allowed: Lift sensor high.
S-173 No flow: lift channel.
S-174 Blocked lift channel.
S-175 No pressure lift channel.
S-176 No connectivity lift channel
S-177 No pressure lift channel
S-201 Fluid leak in the system
S-203 Wrong connector block
S-211 Cover open
S-222 Start not allowed: Detergent sensor high

S-223	No flow detergent
S-224	Start not allowed: Detergent level low
S-242	Start not allowed: Alcohol sensor high
S-243	No flow allowed
S-244	Start not allowed: Alcohol level low
S-271	Start not allowed: Insufficient disinfectant
S-272	Start not allowed: Basin not empty
S-273	Basin suddenly empty
S-274	Basin not emptying
S-275	Basin level dropped
S-276	Basin minimum level not reached
S-281	Volume measurement no pulses
S-282	Water inlet flow too high
S-283	Water inlet flow too low
S-285	No water supply
S-286	Volume measurement V1 > V2
S-287	Volume measurement V1 < V2
S-288	Unrequested inlet water detected
S-289	External water supply valve detected
S-292	Basin temperature sensor defective
S-293	Water temperature too high
S-294	Water temperature too low
S-297	Basin temperature too high
S-300	ASC
S-301	ASC in "OK" state
S-302	ASC: Wrong configuration
S-304	ASC: No connection
S-350	Manual control active
S-360	Stopped by operator

Machine Errors

Code	Description
S-102	Start not allowed: Leak test sensor high.
S-103	Endoscope leak or incorrectly connected.

S-104 Leak test pressure dropped after check.
S-105 Leak test vented but stays on pressure.
S-106 Block not pressurized or not connected.
S-112 Start not allowed: Air sensor high.
S-113 No flow: air channel.
S-114 Blocked air channel.
S-115 No pressure: air channel.
S-116 No connectivity air channel
S-117 Air channel not connected
S-122 Start not allowed: Biopsy sensor high.
S-123 No flow biopsy channel.
S-124 Blocked biopsy channel.
S-125 No pressure biopsy channel.
S-126 No connectivity biopsy channel
S-127 Biopsy channel not connected
S-132 Start not allowed: Jet sensor high.
S-133 No flow: jet channel.
S-134 Blocked jet channel.
S-135 No pressure: jet channel.
S-142 Start not allowed: Suction sensor high.
S-143 No flow: suction channel.
S-144 Blocked suction channel.
S-145 No pressure suction channel.
S-146 No connectivity suction channel
S-147 suction channel not connected
S-152 Start not allowed: Water sensor high.
S-153 No flow: water channel.
S-154 Blocked water channel.
S-156 No connectivity water channel
S-157 Water channel not connected
S-162 Start not allowed: Extra sensor high.
S-163 No flow: extra channel.
S-164 Blocked extra channel.
S-165 No pressure extra channel.
S-166 No connectivity extra channel

S-167 Extra channel not connected
S-172 Start not allowed: Lift sensor high.
S-201 Fluid leak in the system
S-203 Wrong connector block
S-211 Cover open
S-222 Start not allowed: Detergent sensor high
S-223 No flow detergent
S-224 Start not allowed: Detergent level low
S-242 Start not allowed: Alcohol sensor high
S-243 No flow allowed
S-244 Start not allowed: Alcohol level low
S-271 Start not allowed: Insufficient disinfectant
S-272 Start not allowed: Basin not empty
S-273 Basin suddenly empty
S-274 Basin not emptying
S-275 Basin level dropped
S-276 Basin minimum level not reached
S-281 Volume measurement no pulses
S-282 Water inlet flow too high
S-283 Water inlet flow too low
S-285 No water supply
S-286 Volume measurement V1 > V2
S-287 Volume measurement V1 < V2
S-288 Unrequested inlet water detected
S-289 External water supply valve detected
S-292 Basin temperature sensor defective
S-293 Water temperature too high
S-294 Water temperature too low
S-297 Basin temperature too high
S-300 ASC
S-301 ASC in "OK" state
S-302 ASC: Wrong configuration
S-304 ASC: No connection
S-350 Manual control active
S-360 Stopped by operator

Control Errors

Code	Description
S-300	ASC
S-301	ASC in "OK" state
S-302	ASC: Wrong Configuration
S-304	ASC no connection.
S-350	Manual control active
S-360	Stopped by the operator.

System Warnings

Code	Description
W-701	ASC: No connection.
W-702	ASC: Wrong configuration.
W-703	ASC: Incorrect status and cover inactive
W-704	ASC: Incorrect status
W-705	ASC: in "OK" state
W-711	Cover is open.
W-712	Cover will not open.
W-713	Cover will not close.
W-715	Basin not empty.
W-716	Fluid leak in system
W-720	Heater temperature sensor broken.
W-721	Water temperature sensor defective.
W-722	Heater temperature: too high
W-723	Heater inactive and the temperature is too high.
W 727	Reservoir temperature too high
W 728	Scheduled stop time incorrect, reset to midnight.
W-741	Sensor S01: external high.
W-742	Sensor S02: disinfectant high.
W-743	Sensor S03: detergent high.
W-744	Sensor S17: minimal level high.
W-746	Sensor S19: Disinfectant level low
W-747	Sensor S20: Disinfectant minimum level
W-749	Sensor S24: Alcohol high

Endoscope Warnings

Code	Description
W-751	Channel sensor S11: leak test-1 high.
W-753	Channel sensor S25: high
W-754	Channel sensor S26: high
W-757	Channel sensor S33: high
W-764	Channel sensor S04: air high.
W-765	Channel sensor S05: biopsy high.
W-766	Channel sensor S06: jet high.
W-767	Channel sensor S07: extraction high.
W-768	Channel sensor S08: water high.
W-769	Channel sensor S09: extra high.
W-770	Channel sensor S10: lift high.

Other Warnings

Code	Description
W-800	Manual operation active.
W-801	Purge active: Start is blocked.
W-802	Alcohol sensor venting, start blocked
W-803	Discharging air vessel, start blocked
W-805	Left side controls the water line disinfect
W-810	Open the cover to finished the cycle
W-820	Disinfectant in the basin (the cover is locked)
W-821	Disinfectant in the supply lines (the cover is locked)

Communication Errors

Asi error: No connection	**C-001**

Cause: There is a temporary interruption in the connection between the ASi and the MDS machine.

Action: Check the message at the lower left of the screen. If it says "ASi connected" then the connection has been restored. Press the **Open/Close** button or the **Start** button to continue. If the message says "ASi disconnected" then attempt the action listed below.

Cause: There is a power failure in the machine or the plug is loose.

Action: Check the plug. If it is not loose, report the failure to the maintenance department.

Broken server connection: Run data is being buffered.	**C-011**

Cause: The connection to the database has been interrupted.

- The LIO program cannot retrieve the overview lists and the selection screen is empty.
- The connection to the server is interrupted in stand-by mode.
- It is not possible to start a program.

Action: Report the error to the system manager. As long as "Disconnected from server" appears at the bottom of the screen, the program can not be restarted.

No hardware definition received. Hardware not initialized.	**C-012**

Cause: This error occurs if there is a problem with the ASi control software. This definition is the layout of the ASi control and is determined by the configuration of machine. Possible issues are in the following list:

- Installation of the ASi layout is not found.
- The LIO program was incorrectly installed.
- Software problem.
- Communication problem with the ASi interface.

Action: Report the error to the MDS system manager.

No server connection. Selection broken off. Start/ / close run impossible.	**C-015**

Causes: The connection to the database has been interrupted.

- The LIO program cannot retrieve the overview lists and the selection screen is empty.
- The connection to the server is interrupted in stand-by mode.
- It is not possible to start a program.

Action: Report the error to the system manager. As long as "Disconnected from server" appears at the bottom of the screen, the program can not be restarted.

No answer received from the server. Access not authorized.	**C-016**

Cause: The connection to the database has been interrupted.

- The LIO program cannot retrieve the overview lists and the selection screen is empty.
- The connection to the server is interrupted in stand-by mode.

- It is not possible to start a program.

Action: Report the error to the system manager. As long as "Disconnected from server" appears at the bottom of the screen, the program can not be restarted.

The clock is not keeping time with the server clock.	**C-019**

Cause: If the MDS clock and the server clock have a time difference of more than 30 seconds, a time variance occurs in the run report.

Action: Reset the clocks on the computer:

- Press the **Start** button.
- Press the Help button.
- Select change computer time.
- Open date/time.

The previous program run was not correctly shut down. Run down to a safe situation	**C-030**

If a system error occurs, then it is not possible to create a correct run report. If the error is repaired, then the error message disappears and the restoration program automatically runs to rinse the endoscope with water so that it can be safely removed of the machine. This program can not be stopped and the endoscope is not disinfected.

Cause: A black screen means the program is not visible. Possible causes are as follows:

- The PC was switched off.
- There is a PC defect.
- There was a power failure.

Action: Try pressing the **On/Off** switch on the PC. If this does not solve the error, contact the maintenance department.

Cause: There is a communication problem so the program cannot be run correctly. Possible causes are as follows:

- There is a cable fault.
- A cable is loose.
- There is a program error.
- The MDS control unit is defective.
- There is a blown or defective fuse.

Action: Contact the maintenance department and the system manager.

Cause: There is a communication problem with the ASi interface and message *W-701* is also on the screen. Possible causes are as follows:

- There is a fault with the ASi interface.
- A network cable is disconnected.
- A cable is faulty.
- There is a communication problem with the server.
- There is a server error.

Action: Check the cable connection between the network and the machine. Restore the connection if possible and start the machine program again. If you are unable to repair the connection, report the error to the system manager

Cause: The LIO program was interrupted. Message *W-703* also appears on the screen and the cover knob is blocked.

Action: Start the restore program.

An error occurred during the cycle. Run down to a safe situation.	**C-032**

If an ASi error occurs, then it is not possible to carry out a correct disinfection cycle. If the error is repaired, then this *C-032* message appears and the restoration program is automatically selected. The endoscope is rinsed with water so that it can be safely

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removed from the MDS but it will not be disinfected. The restoration program works automatically and can not be stopped.

The endoscope must be run through a complete disinfection program before use.

Cause: There is an internal communication problem with the PC. Possible causes are as follows:

- There is a cable fault.
- A cable is loose.
- There is a program error.
- The ASi interface in the MDS is defective.
- A fuse is blown or defective.

Action: Report the problem to the maintenance department.

Cause: A new program was started while another one was already active.

Action: Press the **Start** ⏀ button to start the restore program.

Run down to a safe situation but parameter set is incorrect.	**C-033**

Cause: An incorrect parameter set was selected for the machine disinfection or the restore program.

Action: Select the correct parameter set for the restore program.

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Cause: The LIO program was interrupted or shut down during a run. Message *W-703* also appears and the lid can not be opened.

Action: Start a restore program.

The hardware definition contains an unknown signal: nn..	**C-040**

Cause: An incorrect address is entering the controller from the ASi slaves or a slave has been incorrectly coded.

Action: Report the error to the maintenance department. Note the unknown signal number: nn.

The hardware definition contains an unknown data source for the signal: nn	**C-041**

Cause: An address was incorrectly set up in the AS-I software or a slave was incorrectly coded.

Action: Report the error to the MDS system manager. Note the signal number: nn.

The hardware definition is not correct for "unknown" type.	**C-042**

Cause: The system settings parameters for the left/right unit type have not been selected.

Action: Report the error to the MDS system manager.

Automatic program start up is not permitted under the current conditions.	**C-052**

Cause: There is warning text in the report field.

Action: Ensure that all error messages are resolved. Select a machine disinfection auto start. If necessary, consult the MDS system manager.

Cause: An auto start for endoscope disinfection is already set up.

Action: Cancel the auto start for the endoscope disinfection.

Automatic program start-up is not possible because another program is already active.	**C-053**

Cause: Machine disinfection should start but there is an active cycle running.

Action: Let the current program run to completion. When the MDS is ready and the basin cover is still open, insert the machine disinfection block and close the cover. The machine disinfection will start automatically.

Automatic program start-up program not possible, incorrect parameter set	**C-054**

Cause: In the management program a parameter set was incorrectly defined for thermal disinfection.

Action: Let the current program complete the cycle and report the error to the MDS system manager.

Delayed program start up is not permitted under current conditions.	C-060

Cause: Warning messages (numbers *W700-W799*) are present on the screen during automatic start up of a disinfection program.

Action: Ensure that the messages are resolved. Select the automatic restart. Consult the maintenance department if necessary.

Cause: Auto start for another program is already set up.

Action: For the delayed start, the other program must first be shut down.

The tag reader is not available.	C-080

Cause: The I-Dent system is defective.

Action: Report the error to the maintenance department and the MDS system manager to have the chip (=Tag) system disconnected. The program can be started after switching off I-Dent.

Unknown hardware definition for the tag reader.	C-081

Cause: The system configuration has an ASi setting error, or the com port is incorrectly selected.

Action: Contact the MDS system manager to change the settings via the hardware definition.

Internal LIO error: incorrect parameter set for this system	**C-099**

Cause: A wrong selection was executed when setting the machine system parameters.

Action: Report the error to the MDS system manager to correct the settings. Then restart the program.

REPORTS

An unknown code was read by the bar code reader.	**M-910**

If the system is set up to require the use of the bar code reader, manual selection with the cursor is not possible.

Cause: The bar code belongs to another item to be read.

Action: Check if the bar code type is the same as the selected input field on the screen. Scan the correct bar code again.

Cause: The bar code is not entered in the management system.

Action: Report the error to the MDS manager along with a request to add the bar code for the selected item.

The bar code function is not selected	**M-912**

The system is set up to require data entry via the cursor keys. The setting can be changed after a bar code error.

Cause: With this setting, bar codes are not accepted.

Action: Select the desired item with the cursor and operation panel.

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Cause: The bar code is correct but the system setting is wrong.

Action: Report the error to the MDS manager so that this setting can be corrected.

Unknown operator ID	M-920

The system is set up to require use of the automatic identification (I-Dent) system for operator identification.

Cause: The read tag is entered incorrectly or is not reported in the management database.

Action: Report the situation to the MDS manager along with a request to add the correct tag code to the operator list.

Unknown instrument ID	M-922

The system is set up to require use of the automatic identification (I-Dent) system for endoscope selection.

Cause: The read tag is entered incorrectly or is not reported in the management database.

Action: Report the situation to the MDS manager along with a request to add the correct tag code to the endoscope list.

Incorrect tank code: %	M-940

The system is set up to require scanning of the selected disinfectant, detergent or alcohol reservoir.

Cause: The incorrect reservoir was changed.

Action: Remove the reservoir and replace it with the correct one.

Cause: The wrong code was scanned.

Action: A reservoir may have several bar codes. Scan another code and confirm with the **OK/ENTER** ✓ button.

Cause: The wrong liquid reservoir was selected from the monitor.

Action: Abort the tank exchange by clicking on Abort. Restart the tank exchange: press by pressing the **Menu** ▣ button.

ENDOSCOPE ERRORS

Start not possible: leak test sensor high.	**S-102**

This message appears if no disinfection program is active and the leak test sensor is on. When this message occurs, no disinfection program can be started.

Cause: If the endoscope is vented too quickly, then it remains pressurized, causing the leak test sensor to be on.

Action: Stop the program and disengage the terminal block to reduce the pressure. This causes the message *W-751* to disappear. If the error message remains, see the next cause and action below.

Cause: A faulty sensor faulty continues to incorrectly read on.

Action: Report the situation to the maintenance department for repairs.

Cause: The air valve leaks.

Action: Report the error to the maintenance department.

Endoscope/instrument leaking or wrongly connected	S-103

Cause: The endoscope or connection hose is leaking seriously. The leak test connection is not in order.

Action: Use a manual leak tester (with a pressure gauge) to see if the endoscope leaks. If so, have the endoscope repaired. If there is no leak, check the endoscope connection and restart the program. If the report recurs, consult the maintenance department.

Cause: The block is out of alignment to the connection plate in the rinse basin.

Action: Stop the program, disconnect, and place the block anew. Restart the program.

Leak test pressure dropped after inspection.	S-104

Cause: Very tiny leak in the endoscope.

Action: Using the pressure gauge, pump the endoscope to pressurize and check to see if it is leaking. If there is a leak, report it to the maintenance department. If the endoscope is not leaking, see other causes of the error below.

Cause: Very tiny leak in the leak test system of the MDS, the terminal connector, or the connection block.

Action: Consult the maintenance department to repair the leakage.

Cause: A power failure vents the endoscope and the error message follows.

Action: If the machine automatically started up after the error, no further action is required. Otherwise, contact the maintenance department.

Cause: If the endoscope stays pressurized, a sensor is faulty.

Action: Report the situation to the maintenance department.

System vented but remains under pressure.	**S-105**

Cause: There may be an air valve defect if air does not vent from the endoscope during the ventilation process.

Action: Try to start the process again by pressing the **Start** ◈ button. If the message recurs, press the **Stop** ⊘ button. Remove the connection block and check to see if air is escaping (there is a hissing noise). If so, report it to the maintenance department. If air is not escaping, see other possible causes of the error below.

Cause: The leak test sensor is defective or out of alignment. This causes the signal to be maintained after the block is removed.

Action: Report to the maintenance department for repairs.

Cause: The flow control air valve is contaminated or out of alignment.

Action: Try to start the process step again by pressing the **Start** ◈ button. If the error recurs, ask the maintenance service to align the valve.

The block is not pressurizing or is not fitted.	**S-106**

Cause: The endoscope is not properly connected.

Action: Stop the machine and check if the leak test connections and the terminal block are properly placed. Connect the leak test and block again. Start the program.

Cause: Machine fault.

Action: Consult the maintenance department.

Start not possible: sensor high	**S-112, S-122, S-132, S-142, S-152, S-162**

This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Extraction
- Jet
- Water

These errors appear if a disinfection program is selected and the specific channel sensor is on. When this message occurs no disinfection program can be started.

Stop the program and open the lid. An endoscope warning (*W-764* through *W-769*) appears. This message must be cleared before a restart takes place.

Cause: The endoscope channel is blocked, causing the sensor to be on.

Action: Disconnect the connector from the channel in the endoscope. If the message disappears, report the blocked endoscope to the maintenance department. If the message remains, see other possible causes of the error below.

Cause: The connection block is blocked when the endoscope is not connected.

Action: Disconnect the connection block and replace it with another. If the message disappears, let the maintenance department unclog the block. If the message remains, see other possible causes of the error below.

Cause: The channel sensor is defective or out of alignment

Action: Report the faulty sensor to the maintenance department.

No flow: channel	**S-113, S-123, S-133, S-143, S-153, S-163**

This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Extraction
- Jet
- Water

Action: First try the process step again by pressing the **Start** ⏀ button. If the report recurs, press the **Stop** ▽ button.

Cause: Channel connector not connected.

Action: Press the **Stop** ▽ button and connect the endoscope. Start the program again.

Cause: The connector terminal block handle is not connected, or the block is out of alignment.

Action: Press the **Stop** ▽ button and open the cover. Place the terminal block and make sure that the handle is fastened in the lock pins on both sides. Start the program again.

Cause: An incorrect program choice was selected for the instrument.

Action: Check that the number of channel connections (excluding the leak test) agrees with the statement on the screen after "Parameter set." In the case of an anomaly or doubts, stop the program and report the error directly to the system manager.

Cause: Wrong block.

Action: Check that the number of hoses on the block (excluding the leak test) is the same as the number of channel connections on the endoscope. In the case of a deviation, replace the block with the correct implementation and start the program again.

Cause: Too little pump pressure or the channel sensor is faulty.

Action: Consult the maintenance department. After restart, the channel sensor does not become high. Press the **F1** or **F2** buttons to see the signal units.

Cause: The sprayer is worn, which causes too much pressure (flow) loss along the bearing.

Action: A horizontal spray pattern of the leaking water can be seen with a restart. Report the error to the maintenance department.

Cause: The channel sensor is out of alignment.

Action: After restart the signal blinks too much and is unstable. Press the F1 button to signal units. Report the situation to the maintenance department for carrying out calibration.

Blocked channel	**S-114, S-124, S-134, S-144, S-154, S-164**

This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Extraction
- Jet
- Water

Try to start the process again by pressing the **Start** ◈ button. This can be done once. If the message recurs, the **Stop** ▽ button must be pressed.

Cause: Connection hose(s) is kinked or pinched.

Action: Check all hoses. If kinked or pinched, straighten out hose(s) and start the program again. If none of the hoses is kinked or pinched, see other possible causes of the error below.

Cause: Channel blocked.

Action: If the channel is blocked, have the endoscope checked or repaired. If there is no blockage, try the endoscope in a different MDS system. If the error is repeated, check the connection block. See other possible causes of the error below.

Cause: Connection block obstructed.

Action: Press a properly fitting hose of a small bellows pump (manual leak test) in the holes on the underside of the terminal block. Squeeze the bellows. Air should come out of the channel connection. If there is a blockage, consult the instrument service manual to unclog the connection block. If the block is not obstructed, then a machine fault is probably the cause. Consult the maintenance department.

No pressure: channel	**S-115, S-125, S-135, S-145, S-155, S-165**

This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Extraction
- Jet
- Water

Cause: There is insufficient air pressure to blow the moisture out of the channels.

Action: Press the **Start** ◈ button to try the process step again. If the message recurs, press the **Stop** ▽ button.

Cause: A hose is detached.

Action: Verify all hoses are still connected to the endoscope then start the program again.

Cause: Incorrect parameter set.

Action: When in doubt or if the wrong parameter is set, report the problem to the MDS system manager.

No connection: channel	**S-116, S-126, S-136, S-146, S-156, S-166, S-176**

This control checks interconnected endoscope channels and the message is given per channel, i.e.:

- Air
- Biopsy
- Extra
- Extraction
- Jet
- Water

Cause: There is a connector loose from the endoscope.

Action: If you see a loose connection, press the **Stop** ⊽ button. Close the program, connect the loose connection, and restart the cycle.

Cause: It is not clear if all channels are connected.

Action: Try to start the process again by pressing the **Start** ◈ button. This may be tried once. If the message reoccurs, you must press the **Stop** ⊽ button and call Maintenance.

No connection: channel	**S-117, S-127, S-137, S-147, S-157, S-167, S-177**

This control checks small endoscope channels and the message is given per channel, i.e.:

- Air
- Biopsy
- Extra
- Extraction
- Jet
- Water

Cause: There is a connector loose from the endoscope.

Action: If you see a loose connection, press the **Stop** ▽ button. Close the program, connect the loose connection, and restart the cycle.

Cause: It is not clear if all channels are connected.

Action: Try to start the process again by pressing the **Start** ◁▷ button. This may be tried once. If the message reoccurs, you must press the **Stop** ▽ button and call Maintenance.

Start not possible: lift sensor high	**S-172**

This message appears if a disinfection program is selected and the lift channel sensor is on. When this message appears, no disinfection program can be started. Stop the program and open the cover. Then a message (*W-770*) appears. This message must be resolved before a restart can take place.

Cause: The endoscope channel is blocked, causing the sensor to turn on.

Action: Disconnect the connector from the lift channel on the endoscope. If the message disappears, report the blocked endoscope to the maintenance department. If the message remains, see other possible causes of the error below.

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Cause: The connection block is obstructed when the endoscope is not connected.

Action: Disconnect the connection block and replace it with another. If the message disappears, let the maintenance department unclog the block. If the message remains, see another possible cause of the error below.

Cause: The lift channel sensor is faulty.

Action: Report the faulty sensor to the maintenance department.

No flow: lift channel	**S-173**

Try the process step again by pressing the **Start** ◇ button. If the message recurs, press the **Stop** ▽ button.

Cause: The wrong program choice was selected, i.e.: for an endoscope without a tong lift channel.

Action: Check if the endoscope is equipped with a rinse connection for the servicing of the tong lift. If there is no tong lift, press the **Stop** ▽ button and report the situation to the system manager. If there is a tong lift, see other possible causes of the error below.

Cause: Incorrect block

Action: Press the **Stop** ▽ button and fit a block with a tong lift connection. Start the disinfection program again.

Cause: The rinse connection of the tong lift operation is not connected.

Action: Press the **Stop** ▽ button and connect the endoscope. Start the disinfection program again.

Cause: The sensor is defective, or there is too little or no pressure in the lift pump.

Action: Consult the instrument service manual.

Blocked lift channel	**S-174**

Try the process step again by pressing the **Start** ◈ button. If the message recurs, press the **Stop** ▽ button.

Cause: The lift channel is blocked.

Action: Manually check the lift channel. Using a 100 cc syringe, push liquid through the channel via the rinse lift connection. If the channel is open, the tip drips, see other possible causes of the error below. If the channel is blocked, have the endoscope repaired.

Cause: Restriction in connection block obstructed.

Action: Check that the block is not obstructed. If there is a blockage, have instrument service clear the block. If there is no blockage, there is a machine error: See the next possible cause and action.

Cause: The lift channel sensor is defective.

Action: Press the **Stop** ▽ button and report the situation to the maintenance department.

Lift channel: no pressure	**S-175**

Cause: There is insufficient air pressure to blow the moisture out of the lift channel.

Action: Try the process step again by pressing the **Start** ◈ button. If the report recurs, press the **Stop** ▽ button.

Cause: The lift channel sensor is defective or out of alignment.

Action: Press the **Stop** ▽ button and report the situation to the maintenance department.

MACHINE ERRORS

Liquid leakage in the machine	S-201

If the message report is visible, then the program can not be stopped. After drying out, it can take 5–10 minutes before the sensor message disappears. If the sensor is released, only the program can be stopped.

Cause: There is liquid in the front of the machine as result of a leak.

Action: If possible, close the water supply tap and consult the maintenance department

Cause: If the reservoir is dry, a sensor is out of alignment.

Action: Remove the two reservoirs and dry the green sensor with a cloth. If the message remains, report the error to the maintenance department to have the sensor aligned, or to have the program shut down for technical service.

Incorrect connection block	S-203

The machine disinfection automatically started and checked whether the hot water block is fitted.

Cause: No connection block is present:

Action: Place the machine disinfection connection block and then press the **Start** ◇ button.

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Cause: The endoscope connection block is present.

Action: Exchange this block for a machine disinfection connection block and press the **Start** ◈ button.

Cause: The machine disinfection connection block is present.

Action: Try pressing the **Start** ◈ button again. If the message recurs, then consult the maintenance department.

Cover is open	**S-211**

Cause: The cover is closed: During the program, the cover sensor has failed and now indicates that the cover is open.

Action: The program can be stopped only via the expert operation. Report the error to the maintenance department to adjust the sensor, if necessary.

Cause: During the program the cover was opened.

Action: Close the cover and press the **Start** ◈ button to continue the program.

Start not possible: detergent sensor high	**S-222**

Cause: The detergent sensor is out of alignment or faulty.

Action: Report the fault to the maintenance department.

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Tank empty or no detergent flow	S-223

Cause: The detergent reservoir is empty.

Action: Check if the detergent reservoir is empty. If so, fill the reservoir. If there is sufficient detergent in the reservoir, press the **Start** ◈ button. If the error repeats, see the alternate cause below.

Cause: The detergent sensor or pump is defective.

Action: Report the fault to instrument service.

Start not possible, detergent level low. Start not possible, alcohol level low.	S-224, S-244

Cause: The reservoir is empty.

Action: Check if the level of fluid in the reservoir. If it is empty, fill or replace the reservoir. If there is sufficient fluid in the reservoir, press the **Start** ◈ button. If the error repeats, see the alternate cause below.

Cause: The sensor in the reservoir is defective.

Action: Report the fault to Maintenance.

Start not possible: disinfectant sensor high	S-232

Cause: The disinfectant sensor is out of alignment or faulty.

Action: Report the fault to the maintenance department.

Tank empty or no flow disinfectant	**S-233**

Cause: The disinfectant reservoir is empty.

Action: Check if the disinfectant reservoir is empty. If so, fill the reservoir. If there is sufficient disinfectant in the reservoir, press the **Start** ◈ button. If the error repeats, see the alternate cause below.

Cause: The disinfectant sensor or pump is defective.

Action: Report the fault to instrument service.

Insufficient disinfectant dosage	**S-234**

Cause: The endoscope housing or accessories are blocking the disinfectant by the drainage sink. The sensor is not being reached.

Action: Press the **Start** ◈ button. Because the disinfectant has actually been dispensed, the program may go directly to the next step.

Cause: While dispensing disinfectant, an incorrect quantity entered the basin.

Action: Check if the reservoir is still filled. If there is sufficient disinfectant in the reservoir, press the **Start** ◈ button. If the reservoir is empty, add disinfectant and restart the program.

Cause: The basin empty sensor is out of alignment so the correct amount of liquid in the basin is not being sensed.

Action: Report the fault to the maintenance department.

Cause: The dosage pump is out of alignment, causing the yield to be inadequate.

Action: Report the fault to the maintenance department.

Excessive disinfectant dosage.	S-235

Cause: The basin empty sensor is out of alignment, causing an incorrect and inadequate amount of liquid to be sensed in the basin.

Action: Report the fault to the maintenance department.

Cause: The dosage pump is out of alignment, causing the yield to be too high and the sensor to react too quickly.

Action: Report the fault to the maintenance department.

Start not possible: Alcohol sensor high	S-242

Cause: The alcohol sensor is out of alignment or faulty.

Action: Report the fault to the maintenance department.

Tank empty or no alcohol flow	S-243

Cause: The alcohol reservoir is empty.

Action: Check if the alcohol reservoir is empty. If so, fill the reservoir. If there is sufficient alcohol in the reservoir, press the **Start** ⏻ button. If the error repeats, see the alternate cause below.

Cause: The alcohol sensor or pump is defective.

Action: Report the fault to instrument service.

Start not possible: External sensor high	**S-252**

Cause: Uncertain.

Action: Uncertain.

Heater system defect	**S-261**

Cause: Faulty fuse. The temperature in the rinse basin will not rise because the heater does not work.

Action: Report the situation to the maintenance department.

Cause: The liquid temperature and heater temperature remain constant with the defective heater.

Action: Report the machine fault to the maintenance department.

Heater temperature measurement is out of alignment	**S-262**

Cause: The heater is on and the temperature in the rinse basin rises while the heater temperature sensor does not rise.

Action: Report the machine fault to the maintenance department.

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The heater control is on and the temperature is too high.	S-263

This error occurs independently of the software and is an extreme situation. Pressing the **Stop** ⓥ button has no effect. Interrupting the program is only recommended after a technician has judged the situation. The program can be stopped via the expert operation. After resolving the fault, the program can be continued.

Cause: The heater is too hot due to an error in the temperature control.

Action: Report the fault to the maintenance department.

Heater temperature sensor defect	S-264

This error occurs independently of the software and is an extreme situation. Pressing the **Stop** ⓥ button has no effect. Interrupting the program is only recommended after a technician has judged the situation. The program can be stopped via the expert operation. After resolving the fault, the program can be continued.

Cause: The temperature measurement of the heater gives an incorrect value due to a component fault.

Action: Report the fault to the maintenance department.

The heater control is off and the temperature is too high.	S-265

This error occurs independently of the software and is an extreme situation. Pressing the **Stop** ⓥ button has no effect. Interrupting the program is only recommended after a technician has judged the situation. The program can be stopped via the expert operation. After resolving the fault, the program can be continued.

Cause: After stopping a machine disinfection program, the heater may be too hot (90°C).

Action: Open the cover and pour water in the rinse basin. Wait until the message has disappeared.

Cause: Due to an electronics error, the heater is still on.

Action: Press the **Stop** ⊽ button and report the fault to the maintenance department.

Start not possible: level sensor high	**S-271**

This message appears if no disinfection program is active and the level sensor is on. When this report occurs, a disinfection program can not be started.

Cause: Water in the rinse basin is causing the level sensor to report liquid.

Action: Wait until the basin is empty. Make sure that the cover is closed so that the basin can automatically run empty.

Cause: The basin level sensor is faulty, causing it to remain high even though the basin is empty.

Action: Report the fault to instrument service for repairs.

Start not possible: rinse basin not empty	**S-272**

This message appears if no disinfection program is active and the basin empty sensor is on. When this message occurs, a disinfection program can not be started.

Cause: Water in the rinse basin is causing the level sensor to report liquid.

Action: Wait until the basin is empty. Make sure that the cover is closed so that the basin can automatically run empty.

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Cause: The volume report on the screen is not 0, so the system is not released.

Action: Close the cover and wait until the message moves to zero. This may take a few minutes. If there is no effect, see the following cause below.

Cause: The basin empty sensor is faulty, causing it to read high when the basin is empty

Action: Report the fault to instrument service for repairs.

Rinse basin unexpectedly reported empty	S-273

Cause: The drain valve leaks due to contamination. The rinse basin empties during rinsing.

Action: Check if there is still any liquid in the basin. If the basin is empty, press the **Stop** ⓥ button and report the fault to the maintenance department. If the basin is filled see the cause below.

Cause: The basin empty sensor is faulty.

Action: Press the **Stop** ⓥ button and report the error to the maintenance department.

Rinse basin does not empty	S-274

Try the process again by pressing the **Start** ⓢ button. If the message recurs, press the **Stop** ⓥ button.

Cause: The drain is blocked.

Action: Check if the rinse basin runs empty properly. If it does not, contact the maintenance department. If is does, see the causes listed below.

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Cause: The drain valve is faulty if the volume level does not go down.

Action: If the level does not go down, report the error to the maintenance department. If the level goes down, see the causes listed below.

Cause: The drainage hose sags which causes the rinse basin to run empty too slowly.

Action: Check the drainage hose. If it is sagging, report the situation to the maintenance department. If the hose does not sag, see the cause listed below.

Cause: The basin empty sensor is faulty.

Action: Report the situation to instrument service.

Rinse basin level fell	**S-275**

Cause: Liquid ran out of the basin due to contamination on the valve seal.

Action: Report the fault to the maintenance department. If the tank is full, press the **Start** ⟲ button to try running the program. If the tank is empty, change the tank and restart the program.

Cause: The drainage valve opened due to an error control.

Action: Report the fault to the maintenance department.

Cause: The rinse basin level sensor is defective or contaminated.

Action: Report the fault to the maintenance department.

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Rinse basin minimum level not reached	S-276

Water must be present in the rinse basin to check for the correct connection block.

Cause: The drainage valve leaks.

Action: Press the **Start** ◈ button and to see if water drains from the basin. If it doesn't, contact the maintenance department. If water drains, see the cause below.

Cause: The basin empty sensor is defective so the control of the block is incorrectly carried out.

Action: Report the fault to the maintenance department.

Rinse basin minimal level not reached	S-277

Cause: The water level is below the basin sensor: The water pressure is too low, causing the basin to fill too slowly.

Action: Start the program again. Report the fault to the maintenance department to check the water reducer

Cause: The water level is below the basin sensor: The basin level sensor is defective or contaminated.

Action: Start the program again. Report the fault to the maintenance department.

Volume measurement: no pulse	S-281

Cause: There is water in the rinse basin but the volume is not measured.

Action: Press the **Stop** ⊽ button. Consult the maintenance department.

Water supply is excessive	**S-282**

Press the **Start** ◈ button to attempt to run the process step again. If the message recurs, press the **Stop** ▽ button.

Cause: - The rinse basin fills too quickly because the water supply pressure is too high.

Action: Press the **Stop** ▽ button and report the situation to the maintenance department.

Insufficient water supply	**S-283**

Press the **Start** ◈ button to attempt to run the process step again. If the message recurs, press the **Stop** ▽ button.

Cause: The basin fills too slowly because the water supply pressure is too low or the filter is contaminated.

Action: Press the **Start** ◈ button to continue the program and pay close attention to the water as it enters the basin. If the flow is weak, report it to the maintenance department. If the flow is normal, see the possible cause below.

Cause: The volume meter is contaminated or defective.

Action: Press the **Stop** ▽ button and report the situation to the maintenance department.

No water supply	**S-285**

Cause: The water tap is closed.

Action: Check the water tap. If it is open, see the possible cause below. If the tap is closed, open it and press the **Start** ◈ button.

Cause: The water supply valve is defective.

Action: Report the situation to the maintenance department.

Volume measurement V1 > V2	S-286, S-287

Cause: The volume measurement and volume control indicate deviating values

Action: Stop the program and report the error to the maintenance service.

Unrequested water inlet	S-288

Cause: The water supply valve is leaking and may dilute the disinfectant.

Action: Report the error to the maintenance department.

External water inlet valve defective	S-289

Cause: The water supply valve on the filter unit is leaking, so machine disinfection can not be performed.

Action: Report the error to the maintenance department.

Basin temperature sensor defect	**S-292**

This error occurs independently of the software and is an extreme situation. Pressing the **Stop** ⓥ button has no effect. Interrupting the program is only recommended after a technician has judged the situation. The program can be stopped via the expert operation. After resolving the fault, the program can be continued.

Cause: The temperature sensor is defective if the temperature message on the screen is higher than 100°C.

Action: Report the error to the maintenance department.

Cause: If the heater is switched on, the heater temperature sensor rises and the rinse basin temperature measurement does not.

Action: Report the fault to the maintenance department.

Water temperature is too high	**S-293**

Press the **Start** ⓟ button to start the process step again. If the message recurs, press the **Stop** ⓥ button.

Cause: The drainage block is too warm after a disinfection program.

Action: Wait five minutes, or pour cold water in the rinse basin to see if the temperature indicated on the screen drops.

Cause: The setting or mixing valve is out of order, causing the supplied water to be too hot.

Action: Press the **Stop** ⓥ button and check or adjust the setting of the mixing valve. Wait for a while until the water in the machine has cooled down. Then start the program again.

Water temperature is too low	**S-294**

Press the **Start** button to start the process step again. If the message recurs, press the **Stop** button.

Cause: The adjustment or mixing valve is out of order, causing the water supply to be too cold.

Action: Contact the maintenance department. Press the **Stop** button and check or adjust the mixing valve. Start the program and check if the temperature indicated on the screen is correct for the program.

Cause: The warm water supply is stagnated.

Action: Press the **Stop** button and consult the maintenance department.

Water temperature sensor out of alignment	**S-295**

The water temperature rises too slowly due to a badly working heater or circulation pump.

Cause: The sieve in the rinse basin extraction is clogged and impeding sufficient flow-through through the heater.

Action: Check the sieve. If it is clogged, replace it. If it is not clogged, see the possible causes below.

Cause: A faulty volume meter is causing too much water to flow into the basin

Action: Check the water level in the rinse basin. If it is too high, report the error to the maintenance department. If it is normal, see the possible causes below.

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Cause: The pump has a tear or is worn, or the compressed air pressure is too low.

Action: Report the fault to the maintenance department.

Cause: The heater is working poorly.

Action: Report the fault to the maintenance department.

Water temperature too high	**S-297**

This error occurs independently of the software and is an extreme situation. Pressing the **Stop** ⓥ button has no effect. Interrupting the program is only recommended after a technician has judged the situation. The program can be stopped via the expert operation. After resolving the fault, the program can be continued.

Cause: The water temperature in the rinse basin is too high:

- Instrument disinfection: >50°C.
- Machine disinfection: >90°C.

Action: Stop the program and report the fault to the maintenance service.

CONTROL ERRORS

ASC message F.../S.../T...	S-300

The report codes are as follows:

- F = error number
- S = step number where the error occurred in the program
- T = error text describing the undesired situation

After an error S-300, the phase is stopped and the program automatically goes to the post-rinse phase (a safe run down process).

The possible errors are listed in *Table 1* below.

Table 2 S-300 Control Error Details

Error Number	Description	Additional Details
F011	No step release	PC software error. The program runs through an incorrect step or closes the step before it is complete.
F012	Unknown step	PC software error. An active program step is not programmed into the ASC.
F013	Wrong step	The Stop ▽ button is pressed after a run failure. The program skipped over steps to finish the run. End the program via the Open/Close ⇔ button and operator selection.
F014	Setting flow #01	The volume measurement is out of alignment due to contamination, a defective meter, or incorrect calibration.
F015	Setting flow #02	
F021	Minimal time	LIO program step time duration deviates from ASC program control time; or an error report lasted too long before Start ◁▷ or Stop ▽ button was pressed.
F022	Maximum time	

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Error Number	Description	Additional Details
F031	Cover open detection	During a disinfection program, the cover sensor is off or the air valve is operated manually. A mechanical defect of either of the components can create an unsafe situation.
F032	Cover open drive	
F033	Heater driven	The heater is on due to a software or electrical error. The endoscope may become too hot.
F34	Safety Relay	Heater control safety relay has malfunctioned.
F041	Air channel or extra-1 channel	To control flow, the relevant channel sensor must read high or low for a minimal period of time. A "high" error occurs if a pump or valve is broken, or if the sensor is defective or blinks. A "low" error may be caused by a partially-blocked channel or terminal block.
F042	Biopsy channel or biopsy-1 channel	
F043	Jet channel or extraction-1 channel	
F044	Extraction channel or extraction-2 channel	
F045	Water channel or biopsy-2 channel	
F046	Extra channel	
F047	Lift channel: or extra-2 channel	
F051	Basin empty	The basin empty sensor does not detect the rinse basin draining. If there is water in the basin, the sensor is defective or the drainage hose is blocked. If when adding disinfectant, the basin empty sensor does not go on, the sensor is out of alignment, is defective, or the endoscope housing is blocking the flow of disinfectant.

Error Number	Description	Additional Details
F052	Minimal level	The basin full sensor is not activated when the basin fills. The sensor is contaminated or the water supply is too slow. During rinsing the basin full level sensor reads incorrectly due to a valve leak.
F061	Disinfectant	The relevant sensor is activated when it is not applicable in the step. When adding disinfectant or detergent, a message appears if the minimal dosage time is not achieved or the maximum dosage time was exceeded.
F062	Detergent	
F071	Pump disinfectant	The pump runs at the incorrect time due to a software or electronics error.
F072	Pump detergent	
F073	Pump channels	
F081	Drainage valve	The valve is open at the wrong step due to a software or electronics error.
F082	Water supply	
F091	Volume change	The volume meter counts pulses at the wrong step, possibly due to a leaking supply valve.
F092	Volume minimal	When filling the rinse basin, the measured volume is less than the minimum or more than the maximum setting.
F093	Volume maximum	
F094	V1 > V2	During filling the V2 meter verifies the amount measured by V1. The deviation between the two meters is greater than 10%.
F095	V1 < V2	
F101	Temperature high	The temperature of fluid in the basin is too high (45°C) or too low (33°C) if heater is installed.
F102	Temperature low	
F103	Unknown	(n/a)

Cause: The ASi Safety Control (ASC) program detects an error. A sensor or valve may have had an incorrect status for a short period of time so the program was rejected as unsafe. If the fault occurred at the end of a step, the message is in the run report of the next step.

Action: A correct description is important for a good analysis.

- Note the codes and the text.
- Report the fault and description to the maintenance department.
- Wait until the program has stopped.
- Press the **Open/Close** button.
- Start a restore program.
- Restart the endoscope disinfection.

Cause: A PC error disrupts the program. The ASC signals the unsafe situation and sends an error message.

Action: Note the code and description. Evaluate if the PC is working. Report the fault and description to the maintenance department.

ASC faulty configuration	**S-302**

The PC communicates with the ASi operation interface in the MDS. This interface transmits a signal every 20 msec to check the status of the signal in and out of the PC. If this communication stops or is interrupted the error appears.

Cause: The ASi safety control program found a fault in one of the electronic components or the controller is not running.

Action: Report the fault to the maintenance department.

ASC no connection	S-304

Cause: A communication error occurred between the PC and the electronics drive controller.

1. No USB connection with the PC
2. The power or plug is disconnected
3. The drive controller is defective.

Action: Make certain all cables are connected to the PC and the 230V plug. Report the fault to the maintenance department.

Manual operation is activated	S-350

Cause: Manual operation is active via the expert operation during a running program.

Action: Report to the maintenance department with a request to reset the option.

Stopped by the operator	S-360

Cause: During an active program, the **Stop** ▽ button was pressed.

Action: The message is automatically stored in the run report.

Measured contact time is too short	**S-511**

The prescribed contact time is a sum of the time for different steps
(SV + SS + SC + RS = option)

Cause: There was a change in the drain and fill time for the basin.

Action: Report the error to Maintenance so they can recalibrate.

Cause: The program parameters have been changed.

Action: Report the fault to the system administrator.

Disinfectant Reservoir Not Empty	**S-643**

Cause: The disinfectant reservoir is not emptying within acceptable time period.

Action: Low-level disinfectant sensor faulty or sticking.

Action: Disinfectant filter restricted – requires replacement.

Action: Disinfectant pump delivery system requires flow recalibration.

Disinfectant Reservoir Empty	**S-651**

Cause: No disinfectant in reservoir

Action: Fill reservoir with disinfectant

Cause: Low-level sensor faulty or sticking

Action: Report the error to the maintenance department.

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Unit control blocked by the other side	S-671

Cause: The machine disinfection program is active. It is not possible to use this side of the machine.

Action: Wait until the program has run completely.

Wrong system side	S-672

Cause: The machine disinfection program is started from the right side rather than the left side.

Action: Cancel the selection from the right side and restart it on the left side.

Air cylinder not pressurized	S-831

Cause: The cylinder is used to check connectivity from the endoscope to the MDS. The cylinder is not filled so the check can not be performed.

Action: This is the last step of the disinfection cycle. When all channels are still connected, the endoscope is properly disinfected. Visually check the connection and report the error to Maintenance.

Air cylinder remains pressurized	**S-832**

Cause: The cylinder is used to check connectivity from the endoscope to the MDS. The cylinder can not be vented after the check is performed.

Action: Report the error to Maintenance.

Start not possible: reservoir A-S25 (B-S26, A-S27, A-S28, B-S29, B-S30) high	**S-841, S-842, S-843, S-844, S-845, S-846**

This message appears after a warning is ignored and a program started. The warning must be cleared before a restart takes place.

Cause: The disinfectant reservoir in the MDS contains fluid or the sensor is defective.

Action: Press the **Stop** ⓥ button to end the program. Report the error to Maintenance.

Start not possible: air cylinder S33 high	**S-849**

This message appears after a warning is ignored and a program is started. The warning must be cleared before a program is restarted.

Cause: The air cylinder sensor is out of alignment or faulty.

Action: Press the **Stop** ⓥ button to end the program. Report the error to Maintenance.

SYSTEM WARNINGS

ASC: No connection	W-701

Cause: A communication error occurred between the PC and the electronics drive controller.

1. No USB connection with the PC
2. The power or plug is disconnected
3. The drive controller is defective.

Action: Make certain all cables are connected to the PC and the 230V plug. Report the fault to the maintenance department.

ASC: faulty configuration	W-702

Cause: The ASi Safety control program found a fault in one of the electronic components, or the controller is not in the run.

Action: Report the fault with number to the maintenance department.

ASC: rejection status. Start restore program	W-703

Cause: The ASi Safety control program rejected the previous run and blocked the cover. The LED is red. The cover remains closed under the following conditions:

- An error occurred during a restore program.
- There was a power outage.
- There is a software error.
- The LIO-program shut down.

- There is an electronics error.

Action: The maintenance department can access the expert service to shut down the process in order to make a repair.

- Run the disinfection program to a safe situation by starting a restore program.
- Press the **Start** button.
- Press the **Menu** button.
- Select your operator ID
- Select the program Restore after interrupted program.
- Press the **Start** button.
- If this program is ready, then the cover can be opened to safely remove the endoscope. After opening the cover, the message disappears and the red LED goes off. The status message "ASC (rejection)" is applicable to the program. The instrument status "not appropriate for use" is applicable to the endoscope.

ASC: Status reject	**W-704**

Cause: The ASC-i safety control program rejected the run and the LED is red.

Action: Open the cover so the message disappears and the red LED goes out. This takes 4 seconds. The control program is now on stand-by.

Cover is open	**W-711**

This message appears if no disinfection program is active and the cover sensor is on. No disinfection program can be started.

Cause: The cover is open.

Action: Press the **Open/Close** button and then the **Start** button.

Cause: There is a cover sensor defect, causing the message to appear even though the cover is closed.

Action: Report the situation to the maintenance department for repairs.

Cover will not close	**W-712**

Action: Press the **Start** button to close the cover or close the cover carefully by hand and test to see if it moves.

Cause: The cover is blocked.

Action: See if the blockage can be seen and attempt to remove it if possible. If no blockage can be seen, report the problem to the maintenance department.

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Cause: The cover sensor is defective or out of alignment.

Action: Consult the maintenance department.

Cause: The **Open/Close** button was pressed down too long.

Action: Press the button again but for a shorter time.

Cause: There is a defective air valve or the compressed air pressure is too low to open the cover.

Action: Report the situation to the maintenance department.

Cover will not open	**W-713**

Action: Try to open the cover by pressing the **Start** button.

Cause: The air pressure is too low to open the cover.

Action: Open the front cover and check the pressure gauges. Report any unusual readings to instrument service.

Cause: The cover is blocked.

Action: See if the blocking can be noticed visually, also on the rear side, and try if possible to remove this. If this does not work: report problem to the maintenance department.

Cause: A problem control valve is causing the cover cylinder to malfunction.

Action: Report the situation to the maintenance department.

Cause: The **Open/Close** button was pressed down too long.

Action: Press the button again but for a shorter time.

Rinse basin is not empty	W-715

Cause: The program was aborted and there is still fluid in the basin.

Action: Open the cover to shut down the program and automatically drain the basin.

Cause: There is liquid in the basin because the drain is blocked or the valve is defective.

Action: Check if the drain is used and report the problem to the maintenance department.

Cause: There is no liquid in the rinse basin. There is a basin sensor defect.

Action: Report the problem to the maintenance department.

Machine leak	W-716

Cause: Liquid was spilled while changing a reservoir.

Action: Remove the liquid and dry the sensor (the green plug) carefully. Resetting the sensor can take a few minutes.

Cause: While in stand-by, liquid is detected at the bottom of the machine. Possible causes are leaking or a sensor set at the wrong level

Action: Report the situation to the maintenance department.

Heater temperature sensor defect	**W-720**

Cause: The temperature measurement from the heater gives an incorrect value due to a component fault.

Action: Report the fault to the maintenance department

Water temperature sensor defect	**W-721**

Cause: There is a temperature sensor defect if the reading is >100°C.

Action: Report the problem to the maintenance department.

Cause: If the heater is switched on, the heater temperature sensor rises and the rinse basin temperature measurement does not.

Action: Report the problem to the maintenance department.

Heater temperature sensor: too high	**W-722**

Cause: The internal heater is overheated (>270°C).

Action: Report the warning to the maintenance department.

Heater off and temperature too high	**W-723**

Cause: After stopping a machine disinfection program, the heater is too hot. (>90°C)

Action: Open the cover and pour water in the rinse basin, or wait a bit until the message disappears.

Cause: The heater is on due to an electronic error.

Action: Press the **Stop** ⊽ button. Report the problem to the maintenance department.

Reservoir Temperature too High	**W-727**

Cause: Temperature of disinfectant in reservoir is greater than 42°C.

Action: Wait until disinfectant falls below 42°C, then start cycle.

Scheduled Stop Time Incorrect, Reset to Midnight	**W-728**

Cause: Reservoir heater scheduled stop time is earlier than the start time.

Action: Enter a new stop time in the System Parameter **"RESERVOIR HEATER STOP TIME"**. If no action is taken the system will automatically reset the stop time to midnight.

Sensor S01 high: external	**W-741**

Cause: A sensor placed outside the machine indicates an incorrect value.

Action: Report the warning to the maintenance department.

Sensor S02 high: disinfectant	**W-742**

Cause: A sensor is out of alignment or the dosage system is blocked.

Action: Report the warning to the maintenance department.

Sensor S03 high: detergent	**W-743**

Cause: A sensor is out of alignment or the detergent dosage system is clogged.

Action: Report the warning to the maintenance department.

Sensor S17 high: minimum level	**W-744**

Cause: There is water in the rinse basin or a sensor defect.

Action: Close the cover to allow the basin to run empty. Report the warning to the maintenance department.

Channel sensor high S11: leak test-1	**W-751**

Cause: Disinfection cycle fails or the user pushed the cancel button to end the cycle

Action: Open the basin lid and disconnect the channel block from the channel manifold. The pressure should now be released and the warning message should disappear. Reinstall the channel block, close the basin lid, and a new cycle can now be initiated

Sensor S33 high: air cylinder	**W-757**

This message appears if not disinfection program is active. The warning must be cleared before a program is restarted.

Cause: The air cylinder sensor is out of alignment or faulty.

Action: Report the error to Maintenance.

Sensor high	**W-764, W-765, W-766, W-767, W-768, W-769, W-770**

This message appears when the machine is in stand-by and one of the channel sensors is high. This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Water
- Extraction
- Jet
- Lift

Cause: The connection block is obstructed and the endoscope is not connected.

Action: Disengage the block. If the message disappears, report the obstructed block to the maintenance department. If the message remains see the next possible cause.

Cause: There is a channel sensor defect.

Action: Report the defective sensor to the maintenance department.

Manual operation is activated	**W-800**

Cause: One or more functions are manually set. This means a disinfection program can not be started.

Action: Contact the maintenance department with a request to cancel the setting.

Blow through active: Start is blocked	**W-801**

Cause: This message appears when the machine is in stand-by and the machine leak test system is blown through. This is an automatic routine that occurs every hour and lasts one minute.

Action: Wait until the message disappears and start the program.

Press the **Open/Close** button to shut down the program.	**W-810**

Cause: The program is finished. This report indicates how the program needs to be shut down.

Action: Press the **Open/Close** button and follow the instructions on the screen. After selecting the correct operator ID, the cover opens automatically and the program shuts down.

Reservoir A-full, sensor S25 (S27, S28) high Reservoir B full, sensor S26, (S 29, S30) high	**W-841, W-842, W-843, W-844, W-845, W-846**

This message appears if no disinfection program is active. The warning must be cleared before a restart takes place.

Cause: The disinfectant reservoir in the MDS contains fluid or the sensor is defective.

Action: Press the **Stop** ⓥ button to end the program. Report the error to Maintenance.

Chapter 6

SYSTEM ADMINISTRATION

Chapter Six is meant for *Administrative Use Only*. It shows the System Administrator how to setup and manage all process-specific data, along with the daily operations of the MDS machines, server and programs. The System Administrator must have a strong background in PC computers and Windows Operating Software. If you are uncertain of how to proceed, contact your Hospital Data Center or call Technical Support for assistance.

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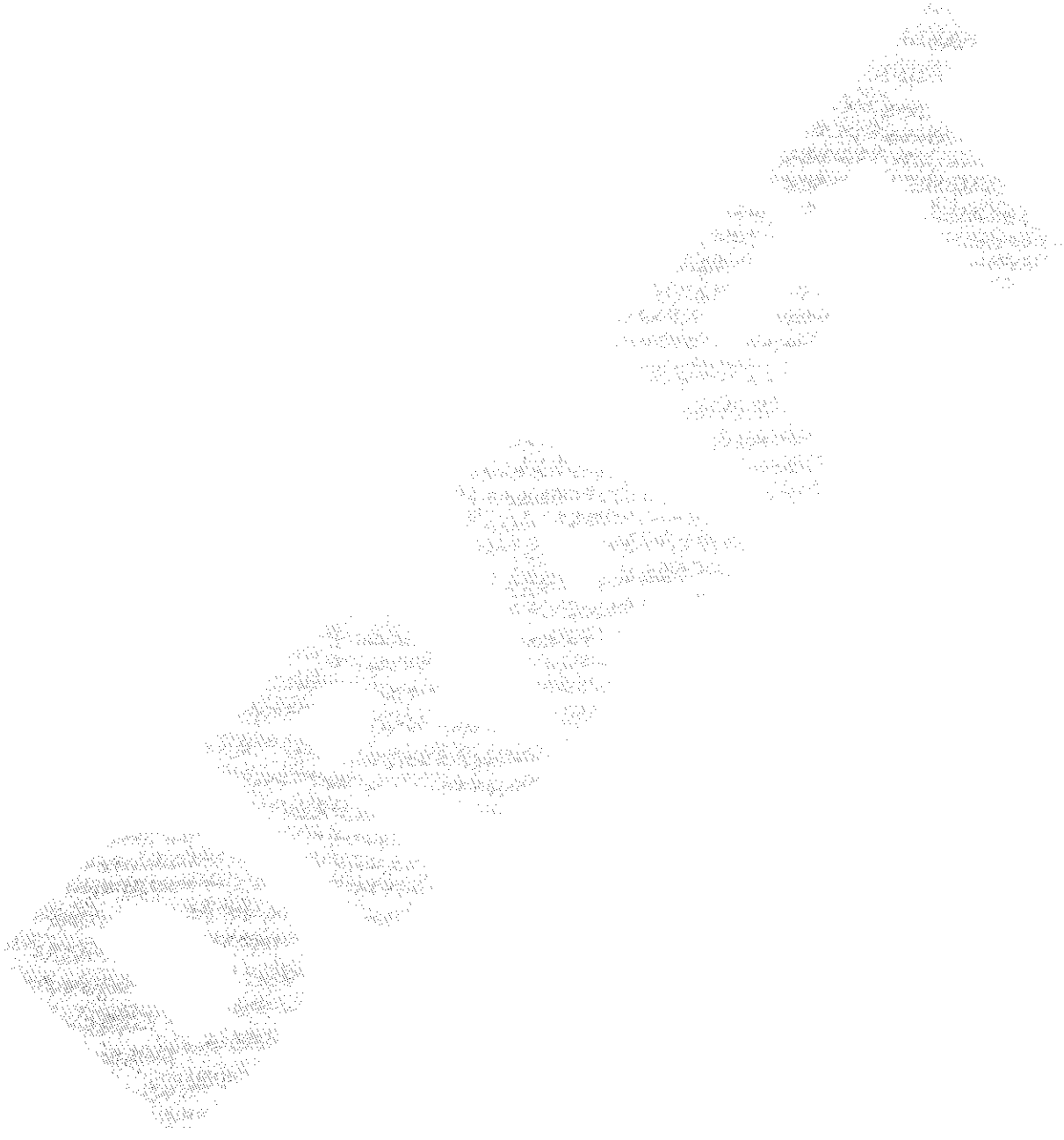

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MDS SYSTEM SOFTWARE

The MDS system software consists of three main programs:

1. **LIO (Logic Input/Output)** is the program operators use to communicate with the MDS. The software also controls the MDS machine and the disinfection processes. This program runs on every computer with an MDS machine connected.

2. **Management** is the MDS database for user and cycle run information. The system administrator has access to input data, process reports, and manage multiple MDS machines. This program runs on only one computer, usually a server of the MDS system.

3. **Server** controls communication between LIO, Management, and the MDS machines that may be on a network. This program runs in the background of the MDS system server and is available only to users with administrator access.

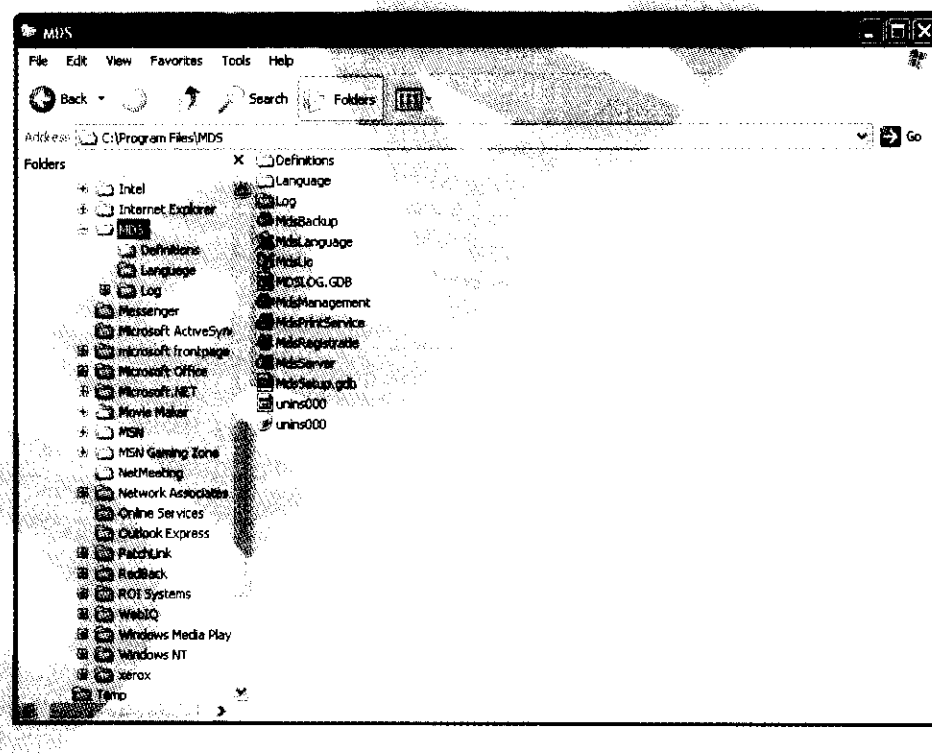

Figure 1 MDS Directory Structure

SERVER SOFTWARE

General Information

The server application is installed on the computer that acts as the server in the MDS network. It controls communication between the LIO applications on the MDS machines and the database on the server computer.

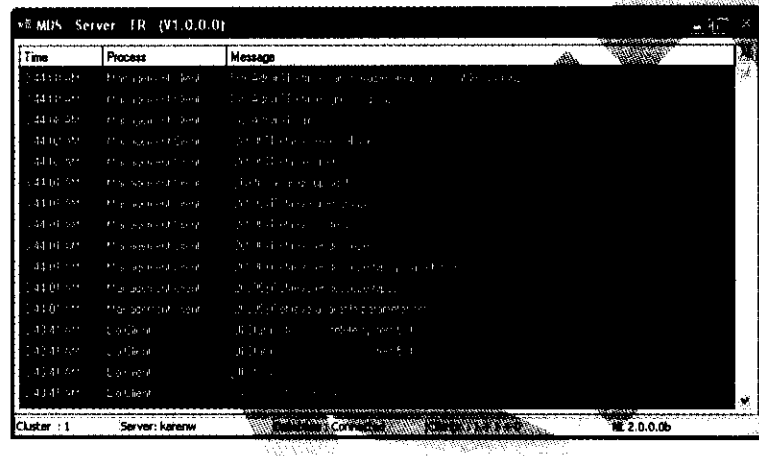

Figure 2 Server Window

The server Log Report shows each communication between the server PC and the linked machines. The machine number is in brackets. The application provides information if a communication problem arises.

Networks

The Management program can be used on a remote computer rather than the server PC. Because of variations in network configurations, instructions for establishing a network fall outside the scope of this manual. Contact your hospital IT department for assistance.

Finding the Server

The server program is installed on the server computers. It may be on the PC controlling the MDS machine, or on a separate PC in a network of machines. The program controls communication between LIO applications on one or more MDS machines and the database on the server computer.

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If the server program can not be found, a dialog box appears and you are asked for the IP address of the server computer.

1. In the serial number window, enter the MDS machine number which is found on the name plate inside the MDS cover.

2. In the server address window, enter the IP address of the PC that runs the Server program. To find the IP address, go to `Start > Run`. Enter `IPCONFIG` in the window and press the **OK/Enter** ✓ button. Contact the data center for further assistance.

3. Enter the IP address in the window and press the **OK/Enter** ✓ button.

System Administrator Password

The first time you open the Management program, you will create a password:

1. Launch the Server program if it is not already running.

2. Launch the Management program by going to `Start > All Programs > MDS > Management`, or by double clicking on the Management shortcut in the MDS folder on the computer desktop.

3. When the authorization window appears, click on the down arrow to select your Login name.

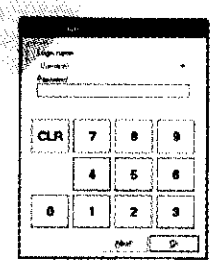

Figure 3 Authorization Window

4. Create a numeric password of nine digits or less and enter it using the keypad in the window. (The number keys on an external keyboard will not work for this field.) Press the **CLR** button if you make an entry error and want to re-enter the password. Press the **Cancel** button to close the Management Program without creating your password. Press the **OK** button to complete your password entry and continue on to the Management program.

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Note: To prevent unauthorized access to the Management program, close the program when you have finished your work.

Under special circumstances or if the system is frozen, a temporary password can be issued. Contact technical service to describe the problem. If you receive a password, it will be valid only for the date it was granted and only for specific applications.

MANAGEMENT PROGRAM

Structure

The Management program is subdivided into general and configuration applications. These are available as links on the management screen.

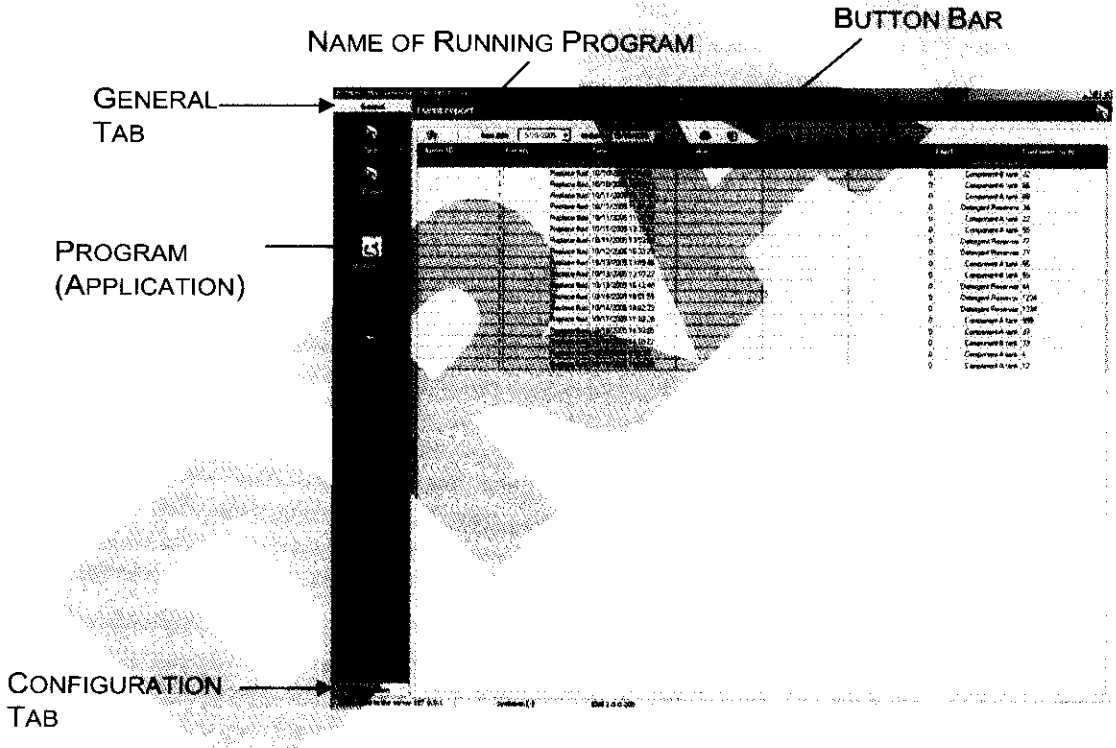

Figure 4 Management Screen

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General Applications

There are five general applications:

1. **Cycles** collects information from the disinfection programs. Specific data can be called up from the database with the sort and search options.

2. **Events** gathers data from non-program activities, such as reservoir changes.

3. **Instruments** stores data relating to instruments and endoscopes.

4. **Users** stores data on MDS operators and other authorized personnel who may work with the MDS or any peripheral hardware or software.

5. **Physician/Assistants** is a database used to identify physicians and other medical personnel who use endoscopes for patient examinations.

Configuration Applications

There are two configuration applications:

1. **Programs** provides an overview of the programs and the relevant settings.

2. **Systems** is where all machine settings are entered. These settings are mostly for maintenance and calibration.

Setup

The Management software is delivered with many base settings already established. However, before the MDS can be released for use, the system administrator must enter customer-specific data for the following:

- Instruments (if different from those already in the base settings)
- Users
- Physicians/Assistants

Network availability of the MDS management program is the responsibility of the hospital data center. The system administrator is the one who enters user login names, access options, and access rights. You also set the passwords which are distributed to

other users. It is your responsibility to keep the passwords confidential to protect the data and to meet all legal obligations. Forms are provided so that you can collect all the necessary information if the data is not available at a single location.

Note: File the forms in a safe location so that you maintain a record of the passwords that you assign. There is no other method available to retrieve passwords.

The following sections provide detailed instructions to assist you in entering data specific for your facility.

Navigation

The name of a button usually appears if you mouse over it. Information on the function of buttons unique to the program is described below. Buttons with a commonly understood function, such as **Save** are not covered.

Select: Press the arrow at the top right of a list to selection from a drop-down list.

Sort: Sort the information in any column by pressing the arrow at the top right of the column. By pressing the arrow again, the sequence is reversed. For example, sort alphabetically A to Z, or Z to A.

Export: Send a copy of the data to a CD or other external media.

Import: Retrieve stored data from another location.

Printing

To print specific lists from various applications, press the **Print** button. Properties and settings are specific for your printer. See your printer user manual for additional information.

Data Management

Caution ***Importing or modifying data may result in its loss. Backup your data regularly and verify that only one management application is active when data is modified.***

BACKUPS

All data should be backed up on a regular basis. Follow the procedures established by your facility for scheduling and storing backups.

MDS data is stored on the PC hard drive. Backups may be saved to a CD, diskette, memory stick, or an external server: Depending on the application, backups are created by the following steps:

1. Click the **Save** or **Save As** button
2. Copy the file(s) to the desired location via Windows Explorer®.

IMPORTING DATA

Only MDS-specific files such as program parameter sets, endoscope codes, and user information can be imported. Two file formats are available:

- XLS = Microsoft Excel files
- TXT = Comma Separated Values (CSV) text files

1. Click on the **Import Data** button .
2. When the Import Data Wizard screen appears, select the file format of the original application. For example, to reset the edited list, the original destination file should be given as source file:
    - For Excel: Data file-1-MDS.xls
    - For Word: Data file–1-MDS.txt
3. If the system parameters have changed, all LIO applications must be restarted.

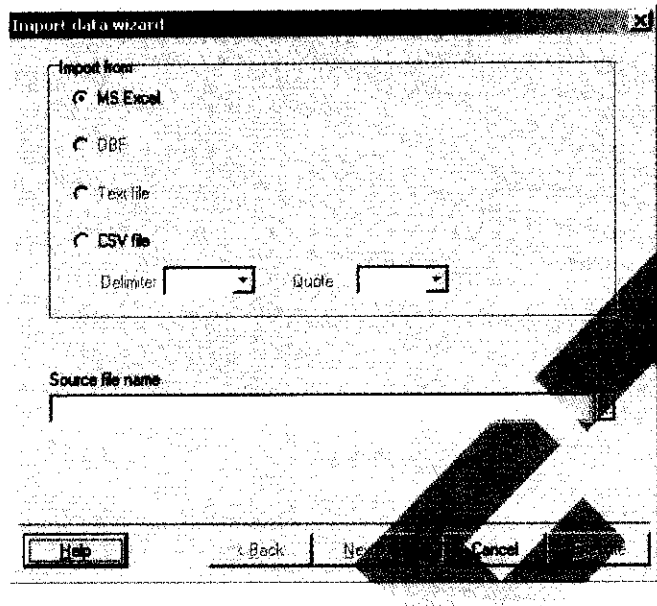

Figure 5 Import Data Wizard

IMPORTING DATA REMOTELY

The following procedure should be followed for changing and managing data from a remote computer:

1. Close the Management application on all PCs in the MDS network.
2. Open the Management application on the PC where data will be imported.
3. Import the data as described in the section above.
4. Close the Management application.
5. If the system parameters have changed, all LIO applications must be restarted.

EXPORTING DATA

Data can be exported only if the **Export Data** button is present in the button bar.

1. Click the **Export Data** button so the Export Dialog screen appears.
2. Using the menu, select the formats appropriate for the application (program) to which the file will be transferred. The file name is entered in the input line under

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Destination File. For example, to process a data file which may be re-imported later, the file name can be used as the destination file name:

- For Excel: Data file-1-MDS.xls
- For Word: Data file–1-MDS.txt

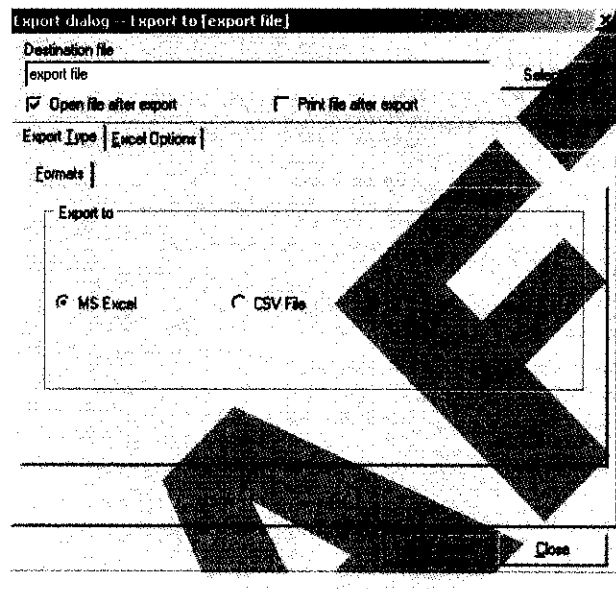

Figure 6 Export Dialog Window

STANDARD CODING

Developing a System

When assigning ID codes to operators, physicians, and instruments, it is best to develop a system for assigning numbers. For example, you may wish to start each ID with a letter that signifies the type of code:

A = Assistant

E = Endoscope code

O = Operator

P = Patient (if applicable)

R = Reservoir (if applicable)

S = Specialist (physician)

It is also advisable create a system that leaves several open numbered positions for each category, so that new IDs can be added in the future.

Endoscopes should have watertight, adhesive labels printed with their ID code. Affix the labels so that the ID can be read while the endoscope is lying in the MDS rinse basin.

Bar Codes (Optional)

With the optional bar code reader, IDs can be quickly and easily entered into the system. After establishing a coding system, create bar code labels for the endoscopes and operators. For ease of use, a human-readable code or name should be printed along with each bar code.

Endoscope bar codes should be attached to the instrument with watertight, adhesive labels. Operators may wear their bar code on a badge or wrist band.

You may also create bar codes for physicians and assistants. Print the codes on a piece of paper for easy reading by the operator and the bar code reader.

I-Dent System (Optional)

The I-Dent system is another optional method to quickly and easily enter endoscope and operator IDs. To prepare the system, assign the appropriate ID codes, print labels, and assemble the tags. Be careful to document the information so that the correct tag and label are placed on the correct endoscope or operator wrist band. The tag holder on the endoscopes must be placed so it can be read by the sensor while the instrument is in the MDS rinse basin. If you don't know a particular tag code, it can be read at the MDS machine. Proceed as follows:

1. Launch the LIO software.
2. Double click on the Expert Operation icon in the top right of the screen.
3. Enter your login name and password.
4. Click on the Tag icon to cause the Read screen to appear.
5. Hold the tag in front of the reader.
6. After the tag number appears on the monitor, add it to your documentation.

INSTRUMENT REGISTRATION

Categorizing Endoscopes

WARNING Incorrectly categorizing an endoscope may result in incomplete disinfection. If you have questions about an endoscope, contact the endoscope manufacturer or technical service for advice.

The MDS has different programs for different types of endoscopes. The objective is to monitor only those channels that are connected, preventing the generation of incorrect failure messages. Each endoscope requires a specific connector block and a specific parameter set. Reference the Endoscope Hook-up guide to identify the endoscope that you are using and the appropriate connector block and parameter set to use. Failure to sue the correct connector block and parameter set can result in an endoscope that is not disinfected properly and therefore should not be used on a patient. If you are uncertain about the correct channel setup of an endoscope, call technical support for assistance.

Entering Data

WARNING Endoscope codes are unique, and can be assigned once only. If a single endoscope must be registered under two different programs, then it must be done under different codes.

DATA FIELDS

Endoscopes, instruments, and accessories can be registered as single units or defined sets. The following data is entered:

- **Code** is a short ID number used for quick recognition. It is applied to the operating housing.
- **Endoscope Type** provides a reference to a defined parameter set.

- **Connection Block** is the assembly code for the connection block.
- **Brand** is the name of the endoscope manufacturer.
- **Bar Code** (optional) is the human-readable information in the endoscope bar code.
- **Type Number** is the model of endoscope.
- **Serial Number** is the manufacturer-assigned identification number on the endoscope.
- **Internal ID** is the hospital identification number for the endoscope.
- **Tag** (optional) is the human-readable information encoded in the identification chip.
- **Memo** is a field where extra information can be entered as text.

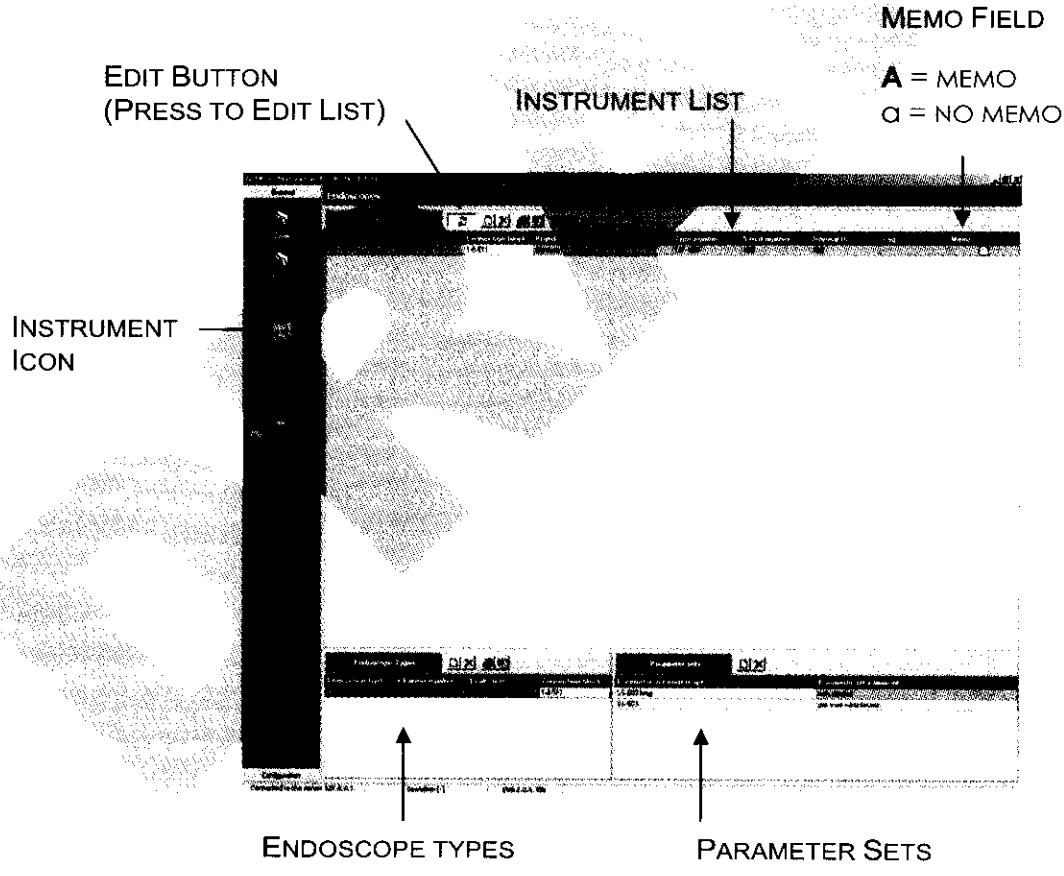

Figure 7 Instrument Fields

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ADDING ENDOSCOPE TYPES

Before entering data for specific endoscopes, the endoscope types must be entered:

1. Click on the **New** button at the top of the Endoscopes Type window at the lower left of the screen. An empty input line appears.
2. Place the cursor in the Endoscope Type field and enter the appropriate data.
3. Move the cursor to the next field and continue entering data in all applicable fields.

Note: There is no **Save** button. Data is saved only if you click or move the cursor to another field in the list.

ADDING PARAMETER SETS

Different types of endoscopes can be linked to a parameter set in the disinfection program. A standard disinfection program is then provided. These are the most common types of endoscopes:

- Bronchoscope
- Colonoscope
- Cystoscope
- Duodenoscope
- Gastroscope

The difference between parameter sets is the number of channels that are monitored during the program:

2K = Two channels

3K = Three channels

4K = Four channels

4K+jet = Four channels and jet channel

4K+lift = Four channels and lift channel

6K = Four channels and jet- and lift channel

ADDING A NEW INSTRUMENT

Information for a new endoscope is entered as follows:

1. Click on the **New** button at the top of the instrument field. An empty input line appears.

2. Place the cursor in the Code field and enter the data.

3. Move the cursor to the next field. Click on the arrow on the right side to select the appropriate endoscope type.

4. Continue entering data in all applicable fields.

5. If you wish to add a memo, click on the arrow key to open a small notepad. Type in your memo and click the **OK** button to save.

ADDING A LOAN ENDOSCOPE

The registration system allows you to enter information for loan endoscopes. Registration of loan instruments can be set up as follows:

1. When defining endoscope types in the lower left of the screen, allow for a minimum of one loan endoscope per instrument type. For example: 4K-loan, 4K+jet-loan, etc.

2. The Code field in the Endoscopes section of the window can be filled in as you choose. This code is used for each loan endoscope

3. In the Brand field, enter `Loan Endoscope`. This information appears on the monitor when disinfecting the endoscope.

4. In the Memo field, enter the registration loan period.

INSTRUMENT SETS

It is possible to disinfect a registered set of instruments. The entire set has one endoscope code. A description of the set can be entered in the Memo field.

There are two possible disinfection procedures for instrument sets:

1. **Individual:** The set is selected as a normal endoscope and runs with the special instrument program. The set must be selected first and any additional selection is not possible.

2. **Combined:**. The set is added to an endoscope already placed in the basin and is disinfected along with the endoscope. In this case, the set must be selected last.

Registration is set up as follows:

1. Define the set on the Endoscope Types section of the window.

2. Enter the following data:

   a. Code = "`10`" followed by the serial number.

   b. Endoscope Type = "`Set-individual`"

   c. Connection Block = (blank)

   d. Brand = Manufacturer's name

   c. Bar code = "`10`" followed by the serial number

   f. Type number = Type number

   g. Serial number = Serial number on the endoscope

   h. Internal ID = Internal ID for the endoscope

   i. TAG code can not be entered

   j. Memo = a description of the set

ENDOSCOPE REPLACEMENT

If an endoscope is replaced by a new one, data traceability may be lost. There are two solutions:

1. **Consecutively number the endoscope codes.** Although the old endoscope is no longer used, the code and data remain stored in the system.

2. **Create a Memo report.** The information for the replaced endoscope is noted in the memo field along with the replacement date.

New endoscope data are entered via the endoscope registration.

ABBREVIATED PROGRAMS

In addition to the standard disinfection programs, abbreviated programs may be set up. With this type of program, the pre-rinse with water and detergent is not executed.

WARNING With an abbreviated program, the endoscope must be carefully cleaned in conformance with a protocol approved by the hospital.

An abbreviated program is indicated by the short appendage after the parameter set. A separate endoscope code must be entered for the abbreviated program. This is done by placing "20" or some other significant number before the existing code.

EDITING DATA

To change any information already entered, do the following:

1. Click on the field to be modified and enter the new information.

2. Press **Enter** to save the data.

DELETING DATA

To completely remove an endoscope and all the information entered for it, follow these steps:

1. Click on the line to be deleted in the overview list.
2. Click on the **Delete** button.
3. A window opens asking for confirmation. Click **OK** to delete the information. Click **Cancel** to go back without deleting any data.

USER (OPERATOR) REGISTRATION

Users/Operators

Users are the people who have access to the system data and operate the MDS machine. For security and data protection, operator access is limited to specific programs and functions. A system administrator should ensure that all users are properly trained in safe use of the equipment before allowing access to the system for operation or maintenance. The system administrator should ensure that training on equipment, safe use and handling is regularly offered and keeps records of user training to ensure safe operation.

For each operator the following data can be entered:

- Name
- Login
- Group
- Bar Code
- Tag
- Personal Code or Employee Number
- Password

Note: Passwords consist of numbers only.

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User Groups

User groups are set up to establish access rights for different types of operators. A user may actually operate the MDS to disinfect endoscopes, or may use the data stored. The following groups are standard:

- Hospital operator = Daily operator
- Hospital maintenance = Hospital technicians and maintenance
- Hospital management = Data manager
- Supplier R&D = Supplier system management
- Supplier maintenance = Field technician
- Supplier production = Manufacturer production personnel

The software is supplied with a number of base settings for these groups. They can be changed by the system administrator and new groups may be added.

Entering Data

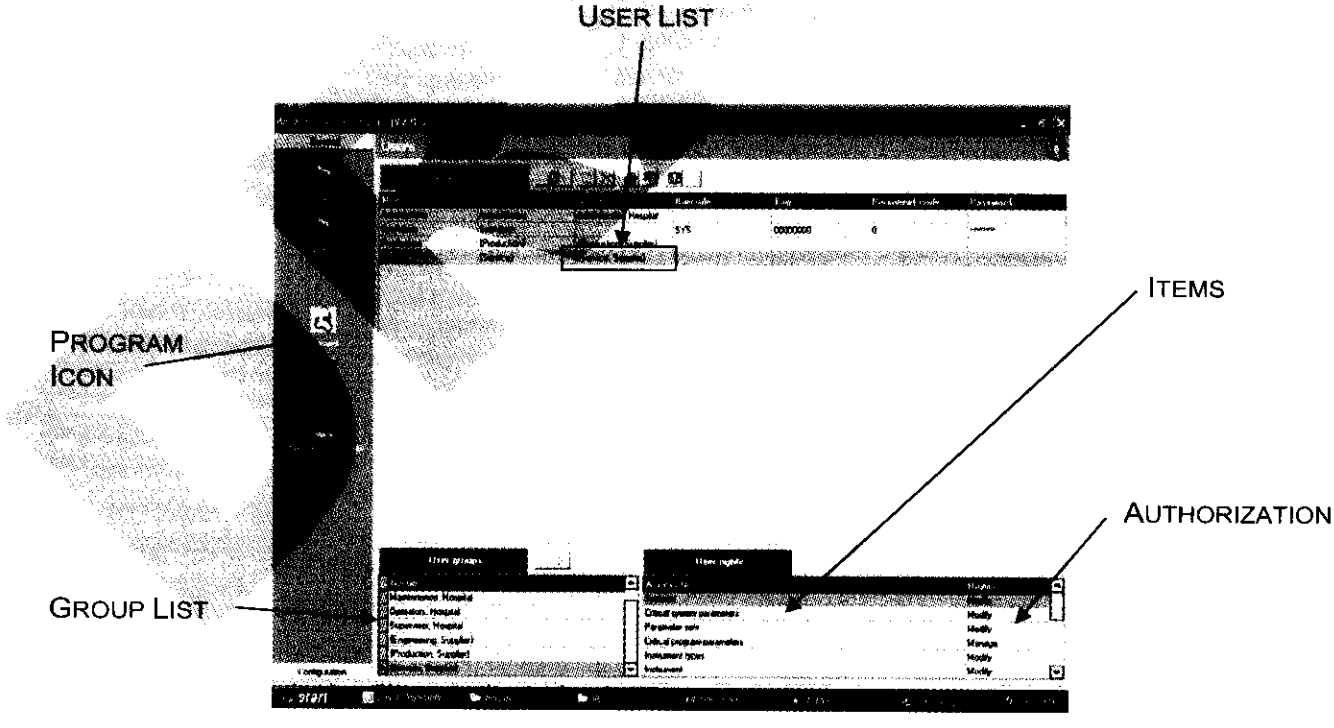

Figure 8 Users Screen

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ADDING A GROUP

To add a User Group, follow these steps:

1. Select the **Input** field under Group.
2. Type in the name of the new group.
3. Click the **Add** key.
4. Select the Group's rights.

ADDING A NEW USER

To add a new user, follow these steps:

1. Click on the **Add** button to add an empty record at the top of the list.
2. Position the cursor in the first field and enter the appropriate information.
3. **Name:** Complete user name.
4. **Login:** Login in name
5. **Group:** Select the appropriate group for this user.
6. **Tag:** Chip number for I-Dent system.
7. **Personal Code:** Employee number, bar code number, or other ID.
8. **Password:** Personal access code.
9. Click on another line to save the data and sort the list.

CHANGING USER DATA

To modify user data, follow these steps:

1. Select the field to be changed and enter the new information.
2. Press the **Enter** button to save the data.

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DELETING USER DATA

To delete a user profile, follow these steps:

1. Select the line to be deleted in the overview list.
2. Click on the **Delete** button.
3. When a confirmation window opens, click **OK** to delete the user, or click **Cancel** to go back without deleting the information.

User Rights

ACCESS

In the User Rights fields in the lower right of the screen, the following may be entered:

- **Critical System Parameters** are important for the proper functioning of the machine.
- **Non-Critical System Parameters** are user settings that apply to the whole MDS.

Critical Program Parameters can influence the disinfection result. Examples are concentrations and rinse times.

- **Non-Critical Program Parameters** are general variables such as fill volume.
- **Critical Errors** are system errors that influence the disinfection process.
- **Non-Critical Errors** are warnings that draw the user's attention to a specific situation.
- **Parameter Sets** are programs designated for specific instruments.
- **Systems** are settings specific to the left or right half of the system.

Instrument Types establishes the connection to a specific program parameter set.

- **Instruments** are data describing the endoscopes and instruments, type, coding, etc.
- **Users** are the machine operators with data such as name and codes.

- **Reporting** provides messages and errors.
- **LIO-Run Management** allows for operation of the machine and data entry.
- **LIO-Removing Instruments** allows the user to operate the basin cover and remove the endoscope.
- **LIO-Expert Operations** is for maintenance operations.
- **LIO-Changing Tank** allows a reservoir change.

Rights Field

In the Rights field, you may choose among the following:

- **None.** This user can not see this information.
- **View.** The user may see data but not edit it.
- **Process.** The user can edit data but not delete it.
- **Management.** Data can be edited and deleted.

Changing Group Rights

To change a user's rights, do the following:

1. Select the desired group in the Group field.
2. Scroll to the desired information that you wish to change.
3. Select the area in the Rights column and double click to change the setting.

Note: If the rights of a group are changed, then the rights for all individual operators in the group are automatically changed.

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PHYSICIAN/ASSISTANTS REGISTRATION

General Information

Under Doctors are listed the people who have a connection to the patient and endoscope, but who are not actively involved in the disinfection process. Because they do not operate the MDS, they have no user rights on the system.

For the doctor or assistant the following data can be entered:

- Internal ID such as employee number
- Name
- Bar Code
- Type (Physician or Assistant)

Note: If an MDS operator assists in a patient examination, then the operator's name must be registered as an operator *and* as an assistant.

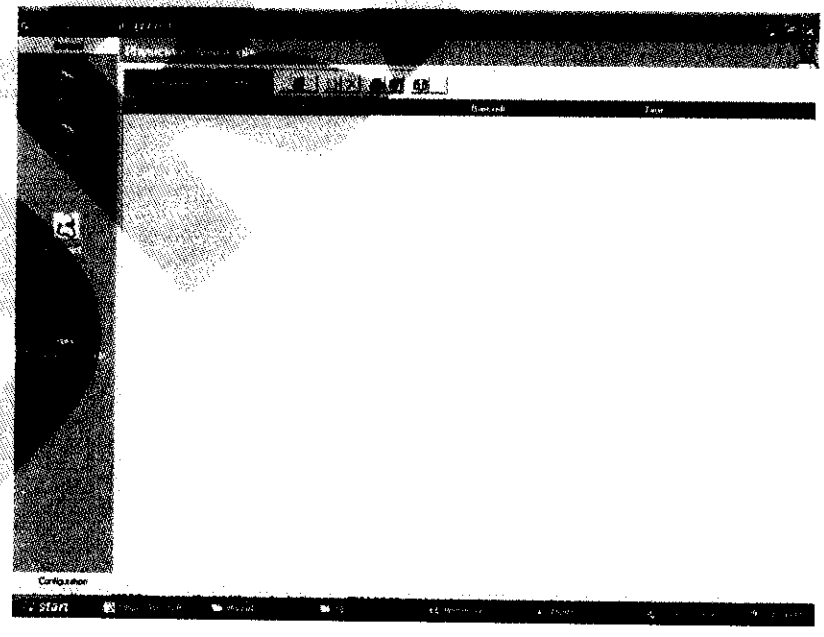

Figure 9 Physician and Assistant Window

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Adding Physician Information

Doctor and Assistant information is entered by doing the following:

1. Click on the **Physician/Assistants** icon on the left side of the screen.
2. Click on the **Edit** button at the top of the window if editing is turned off.
3. Click on the **New** button at the top of the window. A new, empty input line appears.
4. Place the cursor in the Internal ID field and enter the appropriate information.
5. Continue to enter data in the fields.
6. In the Type field, click on the arrow mark and select **Specialist** (physician) or **Assistant** (other medical personnel present at the patient examination).

Changing Physician Information

To change existing information, do the following:

1. Click on the field to be modified and enter the new information.
2. Press **Enter** to save the data.

Deleting Physician Information

To completely delete a physician ID, follow these steps:

1. Select the line to be deleted and press the **Delete** button.
2. When a confirmation window opens, press **OK** to delete the information or **Cancel** to go back without deleting.

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REPORTS

Introduction

By clicking on the **Cycles** icon on the left side of the Management General window, program data can be called up. The information is based on the cycles run and data entered.

If the database is large, searching specific items may be time consuming. Non-applicable criteria can be excluded. A selection can be made from:

- Date or time period
- Machine number
- Operator
- Patient
- Program level

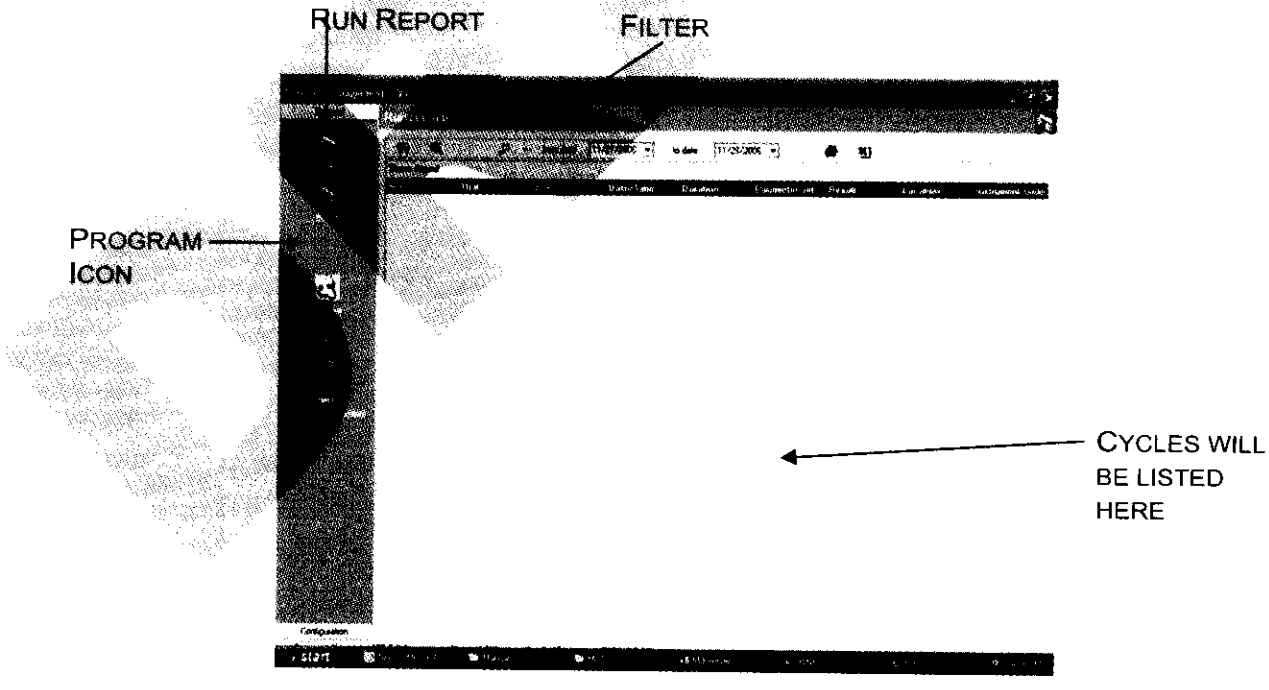

Figure 10 Report Screen

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Selecting Report Criteria

TIME PERIOD SELECTION

1. Narrow down your search criteria by gathering data from a specific time period.
2. With buttons "from date" and "to date" select the dates for your report.
3. Click on the arrow key to the right of each date window.
4. Select the desired start and end dates from the calendars that pop up.
5. Press the **Run** button to run the report.

NARROW CRITERIA

1. The overview report is easier to read if it is shorter and more concise. To narrow or filter your search criteria, press the arrow key beside the **Filter** button, and chose the desired selection in the menu.

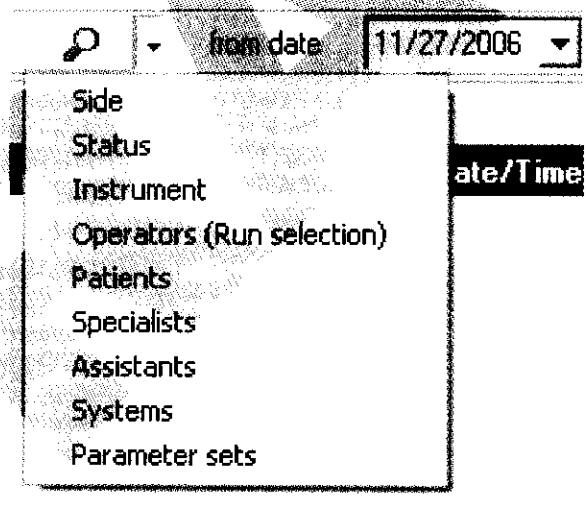

Figure 11 Narrow Criteria

2. In the window that opens, chose the selections which you want displayed.

3. For the status selection, for example, you can choose the following items.

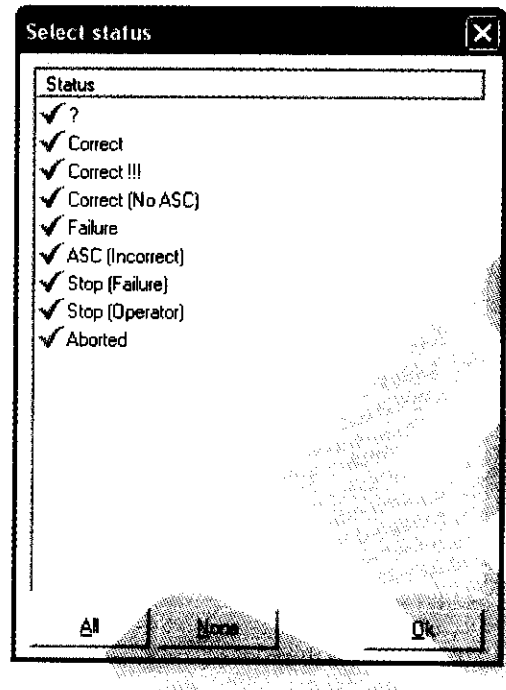

Figure 12 Status Selection

4. Double click on an item to select it or to cancel the selection.

5. Press **OK** and **Run** to run the report.

6. If a selection is active, then the icon changes to to indicate that a selection has been implemented.

7. A selection can be made from:

- Assistants
- Endoscope code
- Operators
- Parameters
- Left or right side of the MDS
- Patients
- Physicians
- Run status
- Systems

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Run Report

By pressing the **Run Report** button, the report overview is set up and the report is shown on the screen.

1. Click on the upper blue bar to sort the list in the appropriate column. Click again to reverse the selection.

2. The data of each run goes horizontally by line.

3. Double click on a line if more information is desired. The screen run details are displayed.

Run Details

In the Run Details field, a number of columns are included with specific run data.

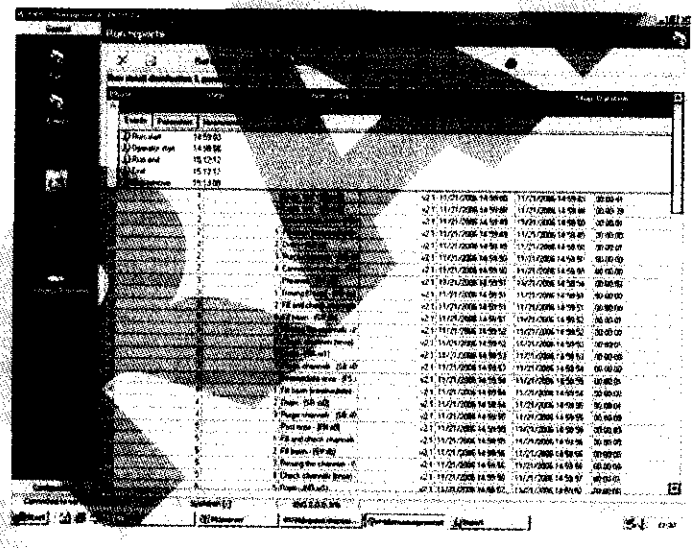

Figure 13 Run Details

- The button displays the details for all steps. While the button minimizes all details.

- Press the plus sign ⊞ to the left of each step to see more information, or press the minus sign ⊟ to close the step overview.

- Errors are indicated with the ⊗ symbol.

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EVENTS

The Events overview is accessed from the icon on the left side of the Management General screen.

1. The selected time period is set from the buttons "from date" and "to date."
2. Pressing the **Selection** button retrieves the overview.
3. To simplify the selection, click on any column to sort the data.

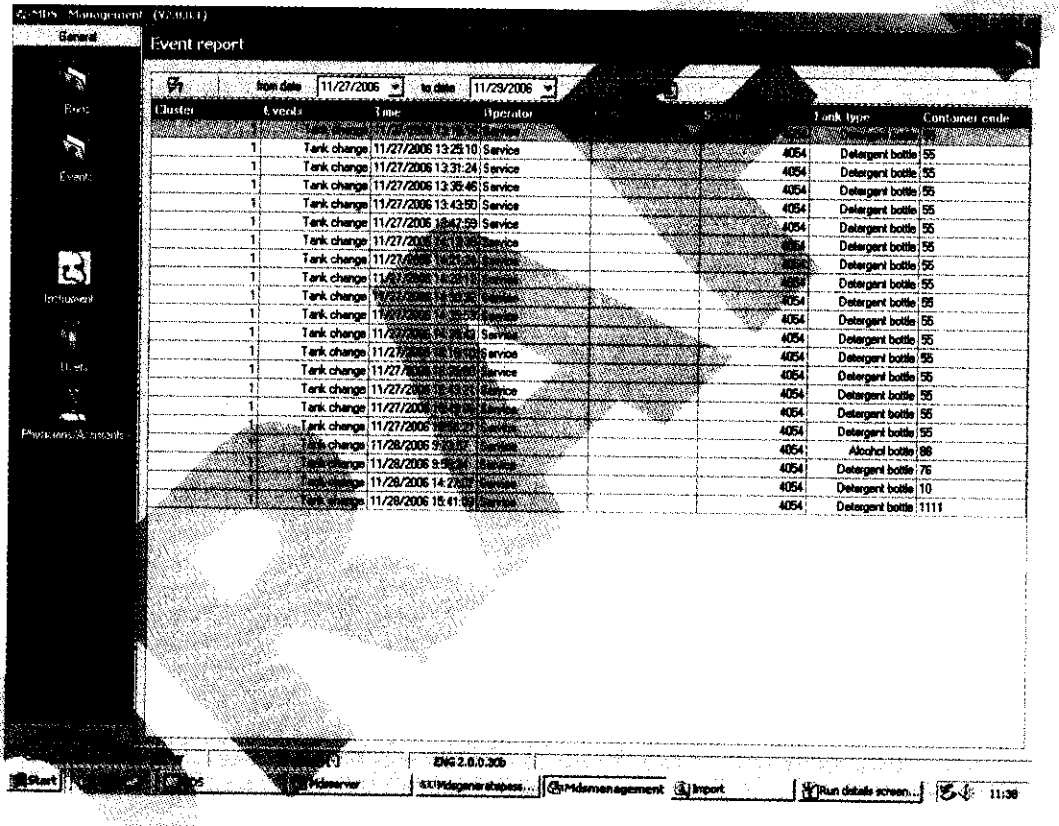

Figure 14 Events Overview

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CYCLES

Program Parameter Sets

An endoscope parameter set is an optimized program for the disinfection of a particular type of endoscope. Non-applicable channel controls are switched off, reducing the possibility of errors.

Here the non-applicable (channel) controls are switched off, except in the step SK. The chance for incorrect error reports is reduced as result.

A program parameter set is based on the following variables:

- Endoscope channel diagram
  - Number of channels
  - Leak test connection
  - Endoscope size
- Combined channels in the endoscope are alternately rinsed during channel selection
- Chemicals used
  - Concentration
  - Contact Time
  - Possible Foaming
- System configuration
  - E = Single endoscope per rinse basin
  - R = Disinfectant recirculation

Instrument disinfection is coded as Letter–Type–Description, where:

- Letter = E (single endoscope) or R (disinfectant recirculation)
- Type = Channel diagram number for the endoscope
- Description = Specific features of the endoscope

Program Selection

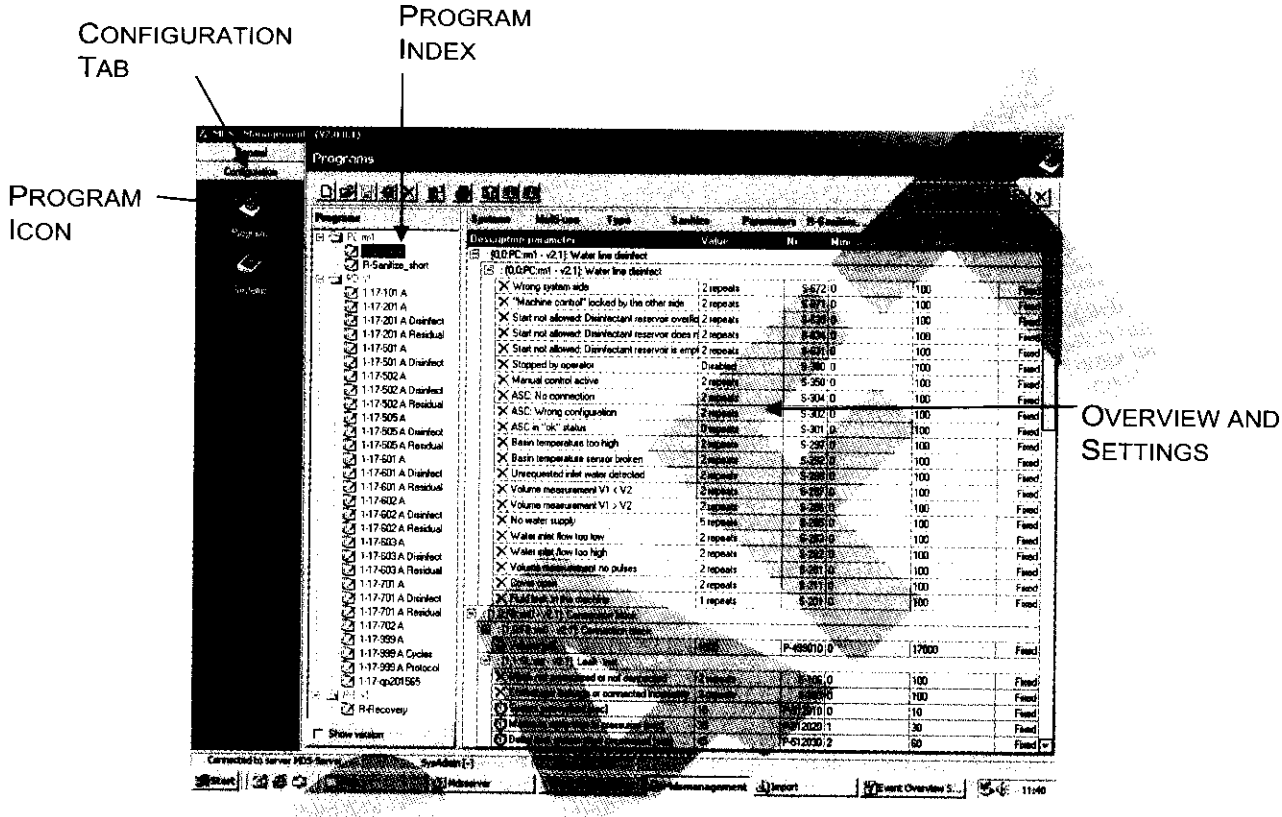

Figure 15 Programs Screen

The program window shows a list of program folders. The folders are labeled with the following codes:

PD Instrument disinfection programs

PR MDS machine cleaning programs

PT MDS machine thermal disinfection

PV Validation program for the process and the MDS machine

PX Extra MDS machine programs

PH Restore program after an interrupted disinfection

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Most programs are available for different machine configurations indicated with a prefix:

E Single scope per rinse basin

R Disinfectant recirculation

To select a specific program, follow these steps:

1. Click the plus sign in front of a folder to view the programs inside.
2. Select the program you want by clicking on the name.
3. Click on the **Open File** button.
4. The parameter overview and settings for the program appears in the next window to the right.

Changing Parameter Sets

Modifying program parameter sets is not allowed. You may request a unique password from the manufacturer to change standard settings. This request may be granted if:

- Repeated errors are incorrectly generated.
- An endoscope does not appear on the standard list of instruments.
- The channel diagram for an endoscope is in question.

Note: When in doubt, use the most extensive disinfection program, and select a universal instrument type..

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SYSTEMS

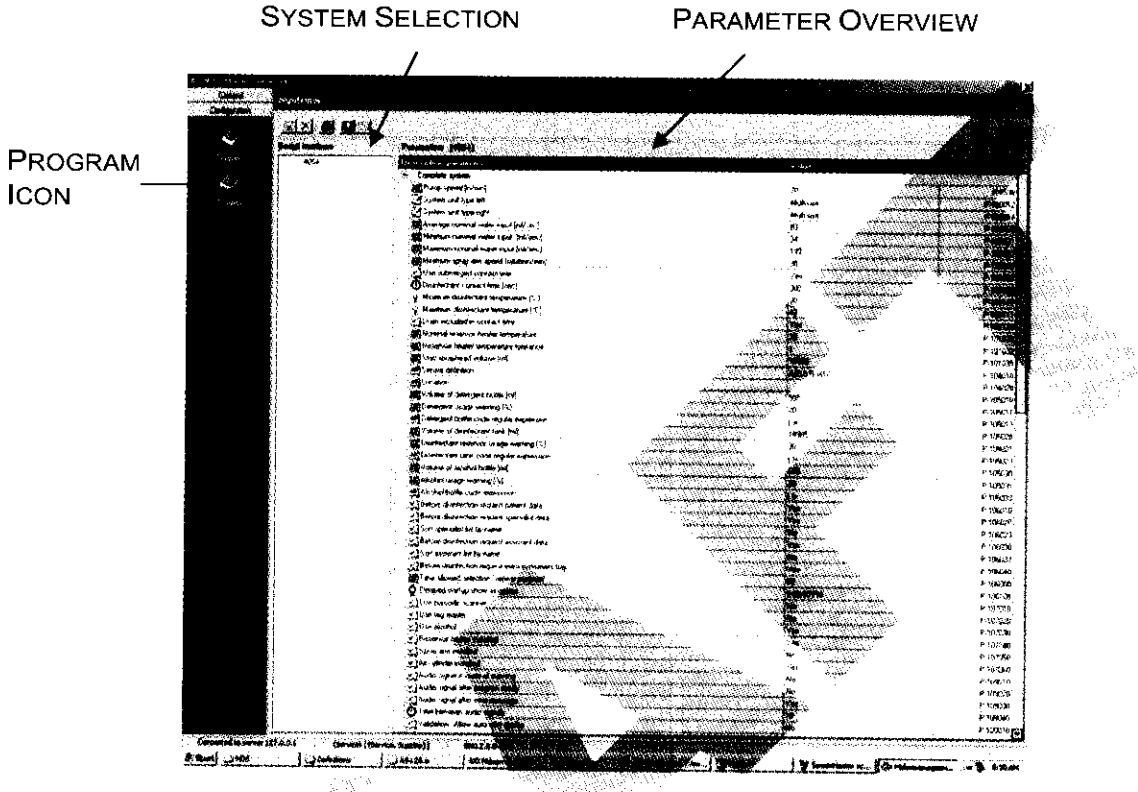

Figure 16 System Window

System settings may be adjusted as desired with the Server application. Some settings may require calibration before use.

The system overview gives one or more machine numbers, which via the server application are connected to the central management database.

MDS machines are selected by their serial number. This can be found on the name plate inside the front door. To select a machine and its parameters, follow these steps:

1. Select the machine by clicking on the serial number in the **System Overview** window.
2. Click on the **Open** button on the icon bar.
3. The parameter overview appears in the **Parameter Overview** window.
4. A description of each parameter function appears in the tables below.

Table 1 System Parameters

Parameter	Function
Nominal water supply (min.-max.)	Average filling speed of the rinse basin. The machine gives an error report (S-282 or S-283) when the given value is exceeded.
Pump speed	For tests and manual operation, sets a standard strokes/minute for the channel circulation pump. The speed varies during the disinfection program.
Pump speed rinse basin pump	Optional circulation pump for the rinse basin.
System left	Checks for machine modules for the left unit.
System right	Checks for machine modules for the right unit.
Sensor definition	I/O configuration for the ASi control system. Dependent on the modules and built in options.
Location	Department where the MDS resides. This is reported in the run report.
Content full tank (mL)	Onscreen display of the tank level for detergent, disinfectants, and alcohol.
Tank code expression	Unique product code for detergent, disinfectant, and alcohol. Value is manually entered within the parentheses. Allows the system to detect reservoir changes. Report M-940 appears if there are errors.
For patient disinfection data call-ups	If set to "Yes," the requirement to enter patient data is activated and appears on the screen.
Specialist/assistant	If set to "Yes," the requirement to enter physician or assistant data is activated and appears on the screen.
Sort list by name	If set to "Yes," overviews for physicians and assistants are sorted alphabetically by name in the selection screen. If set to "No," the overview is sorted by number.
Extra rack for disinfection call-ups	If set to "Yes," an extra instrument set can be added to the selected endoscope. The extra set is registered separately in the run report. This is possible only for instruments with channel diagram 00 (no leak test, no channel). If "No," the extra rack is not called up.

Parameter	Function
Time allowed for selection (seconds) (Repeat Program)	If a run did not proceed correctly, then the program can be restarted. If this occurs within the time input, then all input data is automatically re-entered, except the operator login and password.
Using the bar code scanner	If set to "Yes," data is entered via the bar code scanner only. Selection with the cursor key is not possible. If "No," data may be entered by either method.
Using Tag reader	If set to "Yes," the operator and instrument selection is entered via the I-Dent chip only. If "No," data entry is via the operation panel. This option is set to "Yes" if an automatic identification system is built in.
Print disinfection label	If set to "Yes," a label prints automatically after every program run with the result and a data overview. With "No," no label is printed.
Audio signal	If set to "Yes," an audible signal sounds for a warning, error, and when the program is done.

Table 2 Left/Right Parameters

Parameter	Function
Unit type	Differences in execution can be selected.
Auto retry	If set to "Yes," before a report is created, the program automatically restarts. (Not yet available.)
Delivery (mL/min)	Adjustable rate of delivery for the detergent, disinfectant, and alcohol.
Switching pump without pressure	During circulation, the channels are alternately rinsed. To connect the valves, the pump does not run during the switch, for the specified time.
Water yield	Flow meter yield determined during machine adjustment. (Flow meters S14 and S16)
Water discharge:	Speed at which the rinse basin drains. Used to calculate the time duration of the program.
Temperature correction	Compensates for the temperature deviation of the rinse basin sensor.
Machine program	Choose the machine disinfection program from the parameter sets: E (single) or R (recirculation).
Restore program	The program to implement after a system failure. Choose from the restore parameter sets: E (single),or R (recirculation).
Machine program (Monday through Sunday)	Select the day to automatically execute the machine cleaning program.
Machine program (time period)	Start time for the automatic start. Either basin may have a delayed start of up to two hours.

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The system parameters are set to standard values prior to delivery. At installation, process-specific values are calibrated, such as:

- Detergent and disinfection yield
- Water supply
- Temperature correction

Many settings are based on the machine configuration and can not be changed. Contact your technical service representative if you believe a parameter setting should change. Instructions and a unique password will be issued to you if the change is appropriate.

LIO EXPERT OPERATION

Introduction

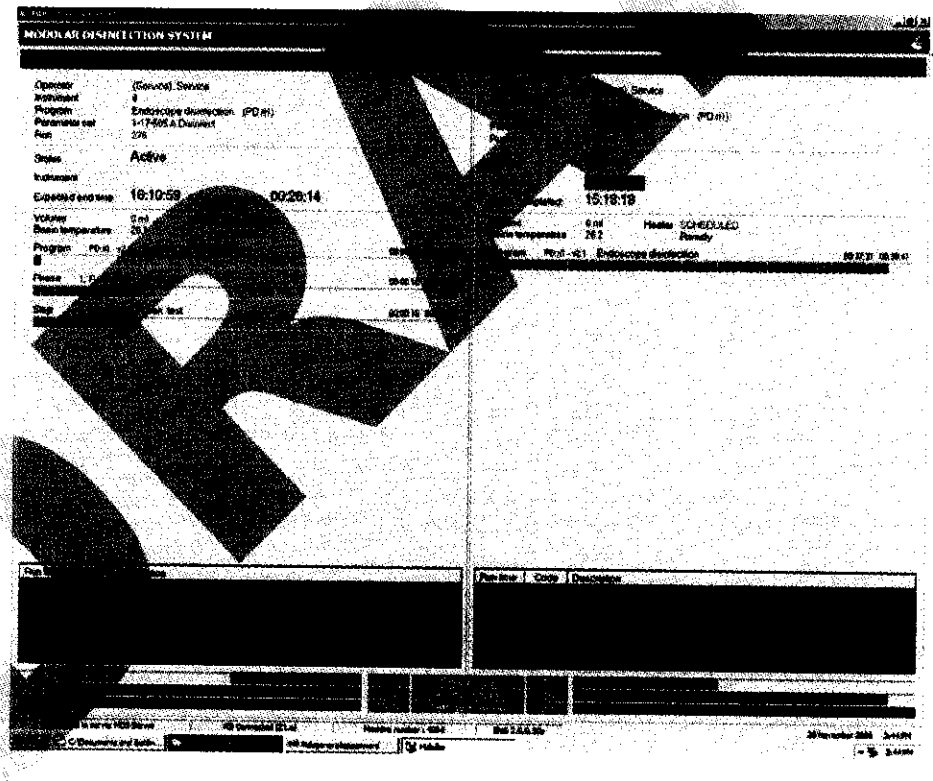

Figure 17 MDS LIO Window

Expert Operation is a special application of the LIO program. It is used to carry out operations that fall outside the normal use of the MDS.

Expert Operation is launched by double clicking on the icon in the upper right of the window. A login window appears and shows the names of the operators who have access rights to the program.

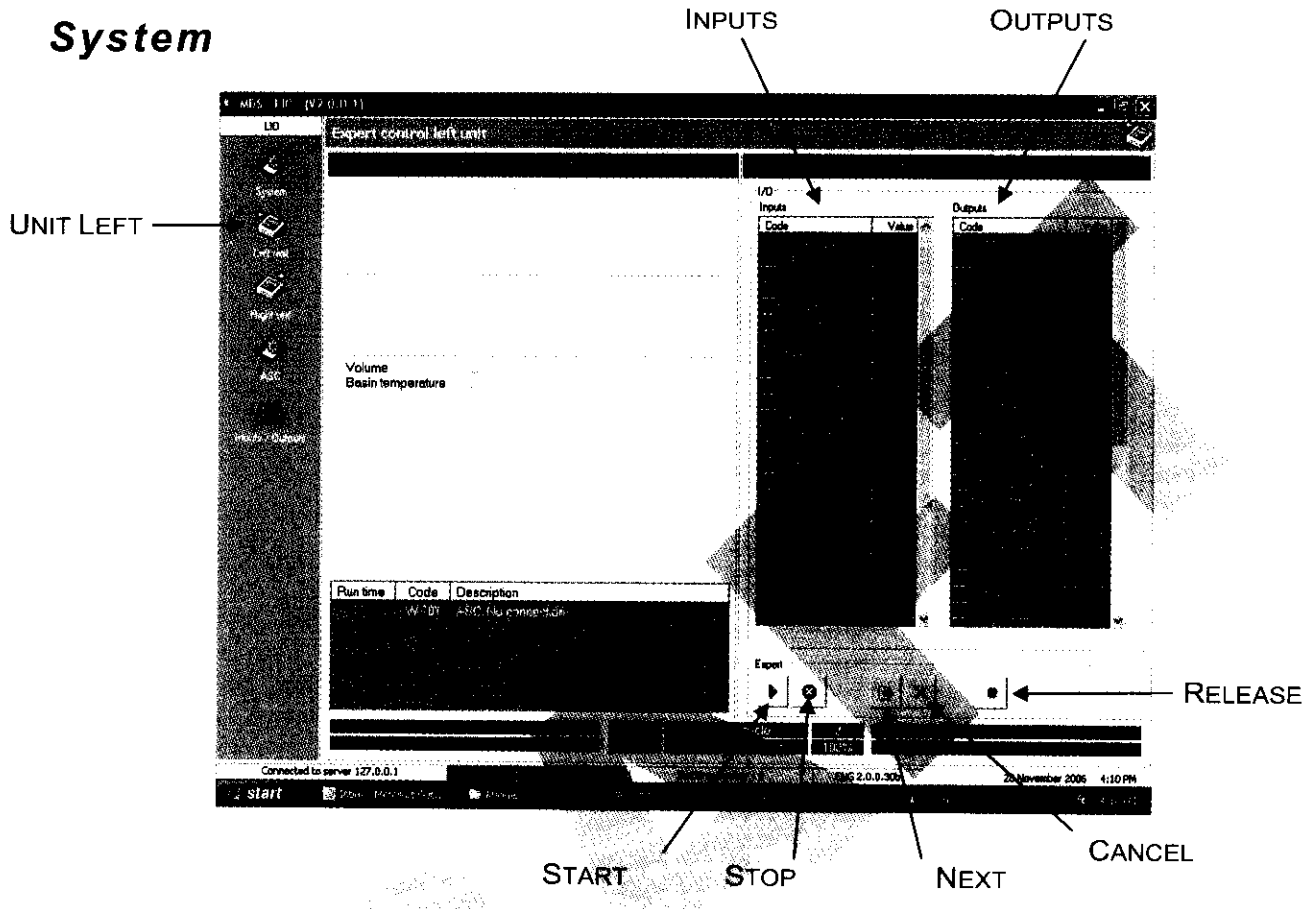

Figure 18 Unit Left Expert Operation

- Selecting either the **Unit Left** or **Unit Right** icons allows that half of the system to be monitored and manually operated:
- If a sensor sends a signal to an input, the indicator turns green.
- Double clicking on an output allows it to be manually driven. The indicator turns red when the output is activated and report *W-800* appears in the status field.
- Pressing the **Start** or **Stop** button affects an already active program. Clicking the **Stop** button sends the program to the final step in the process.
- Pressing the **Next** Step button sends the program to the following step in the process. This is useful when simulating an error report or testing a component after a repair.
- **Release All *(Reset)*** must be pressed to undo all manual operations. You may also need to double click on the output.

WARNING The Reset button must be pressed before another program can be started.

ASi Master (ASC)

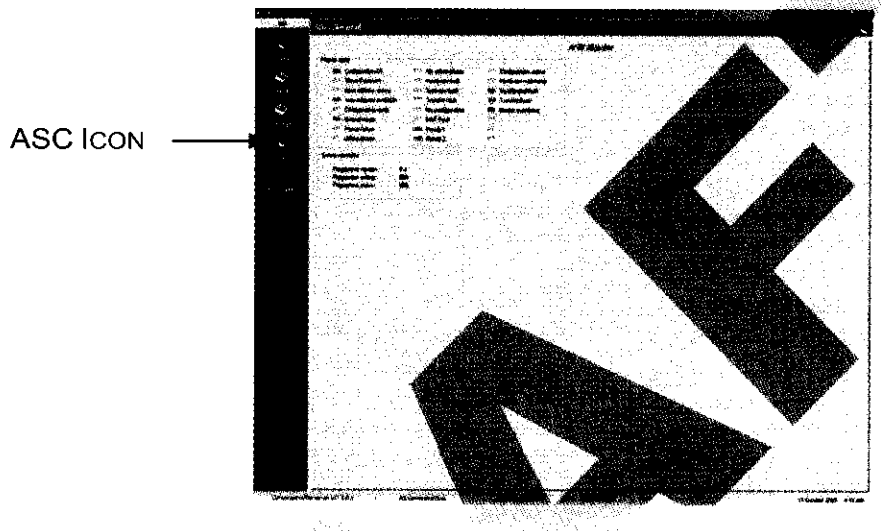

Figure 19 ASC Window

Clicking the ASC icon opens the status overview for the ASi master and safety controller.

In the overview, master states are marked gray, green, or red. A state that is gray is inactive, a green state is running OK, and deviations are red.

In the safety controller field, the version number of the safety controller software is reported.

Inputs/Outputs

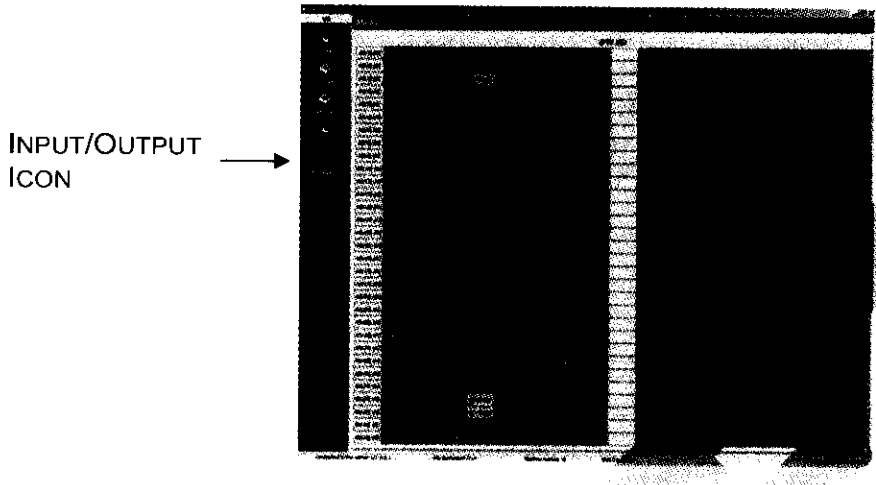

Figure 20 Input/Output Window

You can see input and output status onscreen by clicking the In/Outputs icon. The data comes from the IFM-ASi controller in the MDS machine. The controller communicates between the MDS machine and the PC.

Tag

The Tag window allows you to find the number of a tag chip or to check the operation of a tag reader.

1. Click on the **Tag** button.
2. Move the chip across the reader.
3. Read the number on the monitor.

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Appendix A

REGISTRATION FORMS

Sample registration forms are provided for system administration functions.

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INSTRUMENT REGISTRATION FORM A-3

OPERATOR REGISTRATION FORM A-5

PHYSICIAN REGISTRATION FORM A-7

NOTES

MODULAR DISINFECTION SYSTEM
INSTRUMENT REGISTRATION FORM

Endoscope code .....

Instrument type .....

Brand .....

Bar code .....

Type code .....

Serial number .....

Internal ID .....

Tag code .....

Date .....

Endoscope code .....

Instrument type .....

Brand .....

Bar code .....

Type code .....

Serial number .....

Internal ID .....

Tag code .....

Date .....

Endoscope code .....

Instrument type .....

Brand .....

Bar code .....

Type code .....

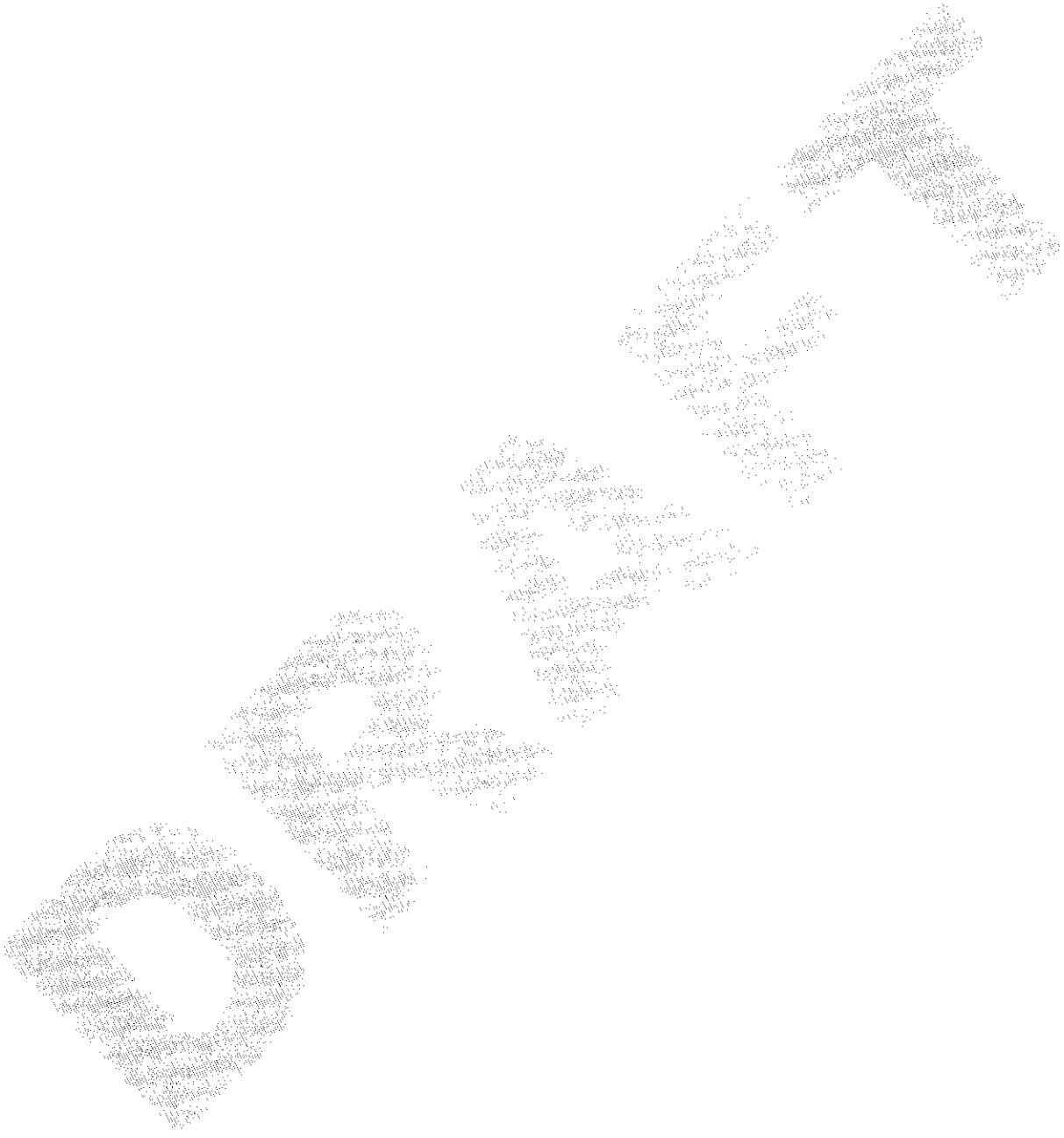
Serial number .....

Internal ID .....

Tag code .....

Date .....

NOTES



MODULAR DISINFECTION SYSTEM

OPERATOR REGISTRATION FORM

Name .....

Login Name .....

Group .....

Bar code .....

Tag code .....

Staff code .....

Password .....

Date .....

Name .....

Login Name .....

Group .....

Bar code .....

Tag code .....

Staff code .....

Password .....

Date .....

Name .....

Login Name .....

Group .....

Bar code .....

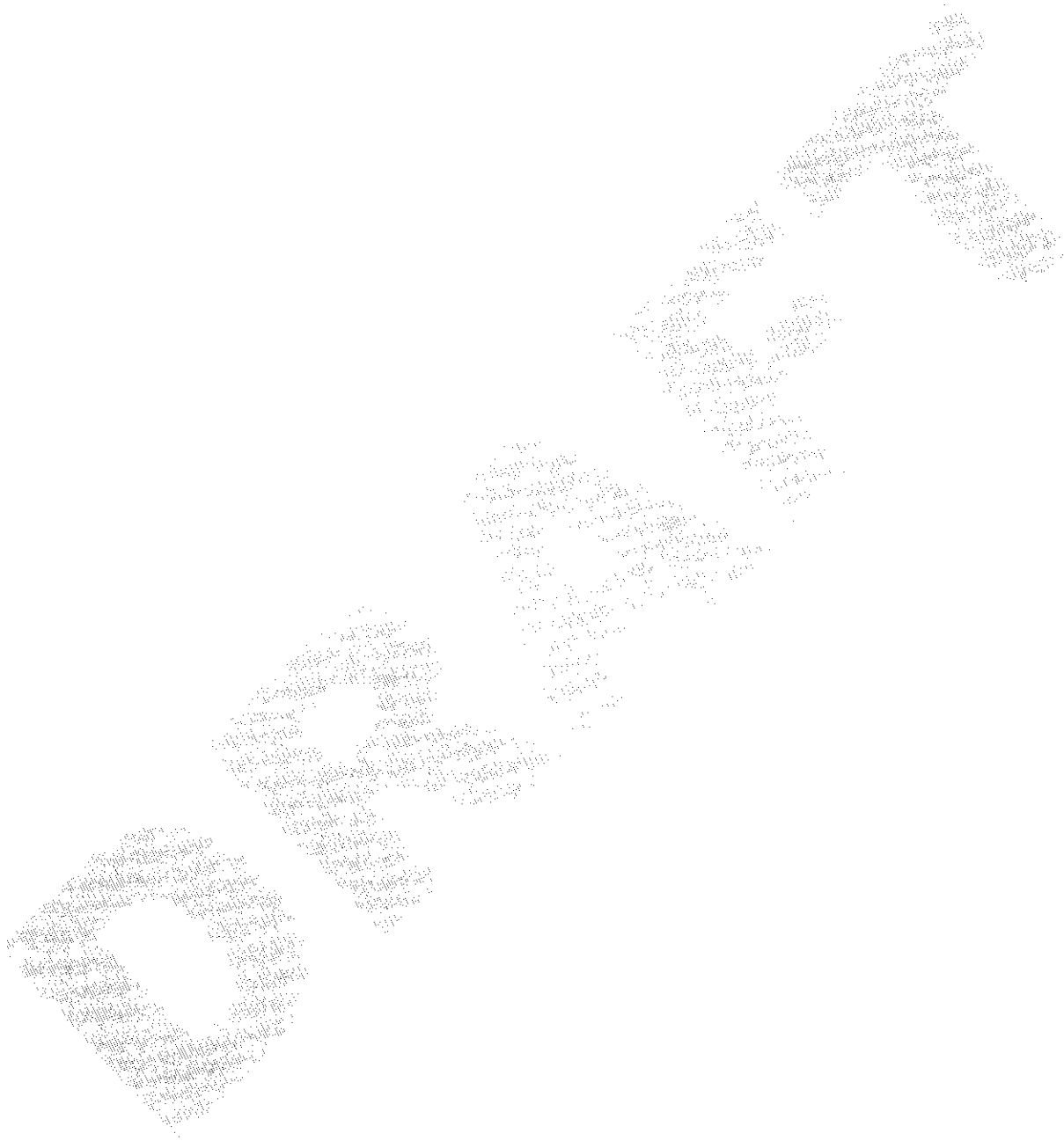
Tag code .....

Staff code .....

Password .....

Date .....

NOTES



MODULAR DISINFECTION SYSTEM

PHYSICIAN REGISTRATION FORM

Name .....

Staff code .....

Bar code .....

Specialist or Assistant .....

Date .....

Name .....

Staff code .....

Bar code .....

Specialist or Assistant .....

Date .....

Name .....

Staff code .....

Bar code .....

Specialist or Assistant .....

Date .....

Name .....

Staff code .....

Bar code .....

Specialist or Assistant .....

Date .....

Name .....

Staff code .....

Bar code .....

Specialist or Assistant .....

Date .....

NOTES

DRAFT

Appendix B

WARRANTIES

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II. LIMITATION OF REMEDY B-2

III. WARRANTY DISCLAIMER B-2

DRAFT

NEW EQUIPMENT LIMITED WARRANTY

Limited Warranty

Medivators Reprocessing Systems, a division of Minntech Corporation ("Medivators"), warrants that the endoscope reprocessor it manufactures (the "Product") will conform to Medivators' written specifications and will be free from defects in material and workmanship under normal use and service for a period (the "Warranty Period") of fifteen (15) months from date of shipment from Medivators or one (1) year from the date of installation, whichever occurs first.

Notwithstanding anything herein to the contrary, the Warranty Period for consumables and accessories supplied by Medivators, including, but not limited to, endoscope hook-ups, filters, printers, printer supplies, test strips, and accessory bags, is ninety (90) days from the date of installation.

The warranty does not cover, and Medivators will have no warranty obligation whatsoever with respect to, any damage to the Product caused by or associated with: (i) external causes, including without limitation, accident, vandalism, acts-of-God, power failure or electric power surges, (ii) abuse, misuse or neglect of the Product by the customer or use of unauthorized third party filters or other consumables and accessories, (iii) usage not in accordance with product instructions, (iv) the customer's failure to perform required preventive maintenance, or (iv) servicing or repair not authorized by Medivators.

Limitation of Remedy

The warranty obligation of Medivators hereunder is limited to the repair or replacement (at its option) of the Product or any parts it deems defective. This will be customer's exclusive remedy for a covered defect.

In order to recover under the warranty, the customer must notify Medivators or a Medivators Authorized Distributor in the state (if in the U.S.A.) or country of installation of the defect (describing the problem in reasonable detail) prior to the expiration of the warranty period and within thirty (30) days of discovery of the defect. Upon receiving Medivators' official "return goods authorization" (RGA), the customer must promptly return the defective part or Product to Medivators (or the service center indicated on the RGA), freight and insurance prepaid. Medivators will not be responsible for any damage during shipment.

Warranty Disclaimer

THE WARRANTY ABOVE IS MEDIVATORS' ENTIRE WARRANTY OBLIGATION TO PURCHASERS OF THE PRODUCT. IT IN LIEU OF ALL OTHER WARRANTIES OF MEDIVATORS, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION,

WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND MEDIVATORS DOES NOT REPRESENT OR WARRANT THAT THE PRODUCT WILL MEET CUSTOMER'S REQUIREMENTS. MEDIVATORS' RESPONSIBILITY FOR DEFECTS IN THE PRODUCT IS LIMITED SOLELY TO REPAIR AND REPLACEMENT AS SET FORTH IN THIS WARRANTY STATEMENT.

TO THE EXTENT PERMITTED BY LAW, MEDIVATORS SHALL NOT, UNDER ANY CIRCUMSTANCES, BE LIABLE TO CUSTOMER FOR CONSEQUENTIAL, INCIDENTAL, INDIRECT OR SPECIAL DAMAGES OR LOSSES, INCLUDING WITHOUT LIMITATION, DAMAGES ARISING OUT OF OR IN CONNECTION WITH ANY MALFUNCTIONS, DELAYS, LOSS OF PROFIT, INTERRUPTION OF SERVICE, OR LOSS OF BUSINESS OR ANTICIPATORY PROFITS, EVEN IF MEDIVATORS HAS BEEN APPRISED OF THE LIKELIHOOD OF SUCH DAMAGES OCCURRING.

This Warranty gives customer of the Product specific legal rights, and customers may also have other rights which vary from jurisdiction to jurisdiction.

In no event shall Medivators' liability exceed the original purchase price of the covered Product.

No representative or agent of Medivators has any authority to bind Medivators to any other representation or warranty with respect to the Product, and the customer accepts the Product subject to all of the terms above.

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Appendix F

Medivators MDS

Endoscope Reprocessor

Service Manual

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Modular Disinfection System
For Multi-Use Chemistry

MEDIVATORS®
REPROCESSING SYSTEMS

50096-653 Rev A

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Chapter 1

OVERVIEW MDS

There are images of the processes, connections, sensors and alignment

The following images are available:

1. process diagram
2. floor-plan rinsing tank
3. channel position connecting plate channels block
4. channels block sensors / valves / slaves
5. machine outputs and sensors
6. machine maintenance points.

Sensor type abbreviations

SET	=	Adjustment necessary
RU	=	MDS – Re-use
P.S	=	Pressure switch
C.B	=	=Conductivity board
O.S	=	Optical switch
S	=	Switch (pulse)
R.S	=	Reed switch
P.C	=	Pulse counter
C.S	=	Capacity sensor

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OUTPUT / INPUT CODES

Table 1 Outputs

Code	Description	
Y01	Rinsing tank disposal drain	
Y02	Water supply	
Y03	Spray supply	
Y04	Channel valve:	air
Y05		biopsy
Y06		jet
Y07		extraction
Y08		water
Y09		extra
Y10		lift
Y11		purges
Y12	Disinfectant:	return
Y13	Loads	
Y14	Disinfectant supply	
P0A	Pump channels	
P0C	Alcohol pump	
P0D	Disinfectant pump	
P0Z	Soap pump	
Y0D	Air valve	Cover
Y0E		leak test 1
Y0F		vent
Y0G		lift pump
Y0H		purges
K90	Ventilator	
K01	Heater	

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Table 2 Inputs

Code	Description		Type	Set
U01a	Temperature rinsing tank		PT-100	X
U01b	Temperature heater		PT-100	X
S02	Disinfectant quantity		P.S.	X
S03	Soap quantity		P.S.	X
S04	Channels	air	P.S.	X
S05		biopsy	P.S.	X
S06		jet	P.S.	X
S07		extraction	P.S.	X
S08		water	P.S.	X
S09		extra	P.S.	X
S10		lift	P.S.	X
S11	Leak test-1		P.S.	X
S12	Tank empty		P.S.	X
S13	Cover		P.S.	X
S14	Tank volume -1		P.C.	X
S15	Foot switch		S	-
S16	Tank volume – 2		P.C.	X
S17	Minimum level		O.S.	-
S19	Disinfectant tank empty		R.S.	-
S20	Disinfectant tank minimum		R.S.	-
S21	Disinfectant tank maximum		R.S.	-
S22	Soap tank empty		R.S.	-
S23	Alcohol tank empty		R.S.	-
S24	Alcohol quantity		P.S.	X
S90	Leakage sensor		C.S.	X

Table 3 Overview Diagram Codes - Filters

Code	Description		#
F1	Internal bacteria retentive water filter	0.2 µ	1
F2		0.45 µ	1
F3		1.0 µ	1
F4	Rinsing tank sieve		2
F5	Air flow		2
F6			
F7	Disinfectant		2
F11	Compressor – first		1
F12	Compressor – middle		1
F13	Compressor – final		1
F14	Compressor – air		1

Table 4 Overview Diagram Codes - Regulators

Code	Description	Type	Set
R1	Water supply	Liquid regulator	X
R2	Liquid channels	Liquid regulator	X
R3	Air leakage test	Air regulator	X
R4	Air general	Air regulator	X
R6	Air compressor	Air regulator	X
R7	Leakage test flow	Flow regulator	X
R8	Cover cylinder	Flow regulator	X
R9	Rinsing tank ventilation	Air regulator	X
R10	Water source valve	Liquid regulator	X

Table 5 Overview Diagram Codes – Other Components

Code	Description		#
CV1	Flow return stroke		4
CV3	Filter return stroke		2
PR1	Purge restrictor		2
PH	Metering pump head valve		4
V1	Over pressure valve channel block		2
MV1	Supply tap	(manual valve)	1
MV2	Conversion tap		1
MV3	Vent valve		1
MD1	Speed coupling filter	(manual disconnect)	1
MD2	Speed coupling disinfectant	(manual disconnect)	1
SH	Spray head		2
PR	Pillar o-ring		16
CS	Cover seal		2
LM	Lift diaphragm		2

Table 6 Overview Maintenance Articles

Part Number	Description
MF01-0013	F1 – Bacteria filter
MF01-0015	F2 – Pre filter 1 0.45µ
MF01-0014	F3 – Pre filter 2 1.0µ
3-9-420	F4 – Rinsing tank sieve
3-9-421	F5 – Air purge filter 0.2µ
2-4-640	F7 – Disinfectant filter
3-9-520	F11 – Regulator filter 0.01µ
3-9-510	F12 – Air pre filter 5µ
3-9-522	F13 – Machine air filter
3-9-500	F14 – Compressor air inlet filter
3-4-261	CV4 – Compressor return stroke valve
3-6-224	PR1 – Purge restriction
	PH – Metering pump hose coupling
3-2-280	SL – Hose water supply
3-8-110	O1 – O-ring pillar
3-4-411	LM – Lift diaphragm (VITON)
6-8-300	CS – Cover seal
2-3-222	SH – Spray head (exchange)
37590-205	- RVS hose clamp in aid of filters
Maintenance Sets	
Part Number	**Description**
3-9-452	PO – Air compressor De-Air

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Table 7 Tools

Description
Torque screwdriver
Screwdriver: Cross PH 1x 35
Screwdriver: Cross PH 1x 80
Screwdriver: Cross PH 2x 35
Screwdriver: Cross PH 2x 100
Screwdriver: Cross PH 2x 300
Screwdriver: Flat 4.0 x 35
Screwdriver: Flat 4.0 x 75
Screwdriver: Flat 5.5 x 100
Screwdriver: Flat 7.0 x 150
Screwdriver: Right-angled flat: 5.5 x 125
Screwdriver: Right-angled cross : 6 x 100
Hollow-head screw wrench set 1.5-2-2, 5-3-4-5-6-8-10
Open-ended ring spanner set 19-17-14-13-12-11-10-9-8-7-55-5
Box spanner: 5.5 x 7
Box spanner: 14 x 15
Drill set: Ø6.8, Ø5.1- Ø5.0- Ø4.9- Ø4.2- Ø2.0- Ø2.7- Ø2.5- Ø2.4- Ø2.3
Water pump pliers
Small point pliers
Small side-cutting pliers
Grip pliers
Amp pliers
Tie wrap installation tool
Tel plug pliers
Hose-cutter
Hammer
Scissors
Ballpoint pen
Tweezers
"Steel" brush
Automatic center point
Leveling spatula
Junior saw

Description *(continued)*
Hand pump 0-300 mmHg
Multimeter + temperature recorder
Kocher clamp 2x
Tap holder with tap set: M3/M4/M5/M6
Small knife and large knife
Soldering iron and solder

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Table 8 Consumer Goods

Part Number	Description	
--	Loctite 5331	
--	Loctite 577	
--	Silicone kit / transparent	
--	Silicone spray	
--	O-ring filter housing	
--	Hose clips	- Ø 30
		- Ø 100
--	Drainage	- coupling PVC
		- bends PVC
		- valve pieces PVC
--	Curve	- ¾ - ½ EXT-INT
		- ½-1/4 EXT-INT
		- ¼ - 1/8 EXT-INT
--	Silicone kit	-transparent
		-black
--	Paint	-grey
		-green
--	Filler	-glass
		-polyester
--	Tape	-painters
		-linen
		-teflon
		-aluminium
--	Dry-cleaning naphta	
3-1-640	Silicone grease	
--	Citric acid	
--	Teflon tape	
--	PVC glue	
3-1-611	2 K glue (Permabond)	

Table 9 Overview Reserve Components – Spare Parts

Part Number	Description
1-4-112	Assy. Hot-water block double
1-4-114	Assy. Hot-water single
1-4-123	Assy. Connecting block – double
1-4-124	Assy. Connecting block – single
1-4-404	Barcode Scanner USB
2-2-305	Main pump 80gr
2-2-810	Foot switch
2-2-920	Module Software Server
2-3-222	Assy. Sprayer-2
2-3-310	Assy. Metering pump
2-3-530	Assy. Air cylinder
2-4-510	Assy. Reducing MDS
2-4-533	Assy. Over-pressure valve
2-4-611	Assy. Heater MDS
2-4-830	Keyboard MDS-2
2-5-431	Assy. PT-100 Cable-B
2-5-432	Assy. PT-100 Cable-H
2-5-481	Assy. Led Red/Grn MDS
2-5-600	Assy. Transformer
3-2-310	Screw-in coupling 1/8" 4/6"
3-2-330	Full Screw-in coupling ¼"
3-4-210	Sirai component set D144
3-4-211	Sirai component set D344
3-4-220	Valve Sirai L-180
3-4-260	Component set drainage valve
3-4-410	Pressure switch 25-220mBar
3-4-411	Diaphragm Viton
3-4-412	Pressure switch 80-2000mBar
3-4-414	Pressure switch 12.5-200mBar
3-4-415	Pressure switch 6-75mBar
3-4-416	Pressure switch coupling 12.5-200mBar
3-4-417	Tank empty sensor 2-8mBar
3-4-420	Spring for 6-75mBar

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3-5-140	ASF Thomas pump 24V DC
3-5-232	Extraction ventilator EBM G2S085-AA-03-01
3-6-223	Reducer
3-6-321	Manometer 0-1 Bar
3-6-323	Manometer 0-4 Bar
3-6-410	Bimba Cylinder EM 25-80-U
3-8-110	O-ring 008 Viton
4-1-114	ASi on/off plug (small)
4-1-115	ASi slave off
4-1-116	ASi slave ASi on/off
4-1-118	Connector M12 right-angle Steck
4-1-119	ASi cable distributor
4-1-450	Controller Cable
4-3-120	Clicks on 280C
4-3-213	Solid State Relay 845160
4-3-222	Relay EMG10REL/KSR-G24/1-10
4-3-310	Reed switch Fek-110-Aox
4-3-510	ASi interface PT-100
4-3-511	ASi slave PT-100
4-3-600	Capacity sensor
4-3-640	Optical sensor
4-3-650	Water meter fl mtr 0.2-10l/min
4-4-130	ASi supply +24V
4-4-140	ASi-interface supply
4-4-142	ASi supply 230V
4-5-301	Asi controller with 1 RS232
4-5-304	ASi slave 41/40
4-6-242	Fuse 250V-1 6A
4-6-245	Fuse 250V-5A
4-6-248	Fuse 250V-10A
4-6-249	Heater fuse
4-6-320	Heater element Heater band
7-3-212	Shut-down LIP
3-2-252.1	Hose – silicone: 3.2 x 1.6
3-2-254.1	Hose – silicone: 4.8 x 1.6
3-2-250.1	Hose – silicone: 1.6 x 1.6
3-2-220.1	Hose – PVS: 4 x 1

3-2-240.1	Hose – PU: 4 x 1
3-2-210.1	Hose – PVDF: 6 x 1
3-2-222.1	Hose – drainage drain
4-6-248.1	Screw – sensor M3x12
3-0-432.1	Screw – block M3x30
3-0-461.1	Screw – valve M6x10
3-2-330.1	MDS coupling for block ¼"
3-2-332.1	MDS coupling for pump ¼"
3-2-311.1	Coupling for block 1/8"
3-2-500.1	Coupling for plug 1/8"
3-9-420.1	Rinsing tank filters
3-9-310.1	Leakage test pump + pillar
3-3-100	Compressor condensation drainage timer
6-8-225	O-ring drainage block 23x28

Images MDS

Contents:

1. process diagram
2. plan rinsing tank
3. channel positions connecting plate channel block
4. channel block sensors / valves / slaves
5. machine outputs + sensors
6. machine maintenance points

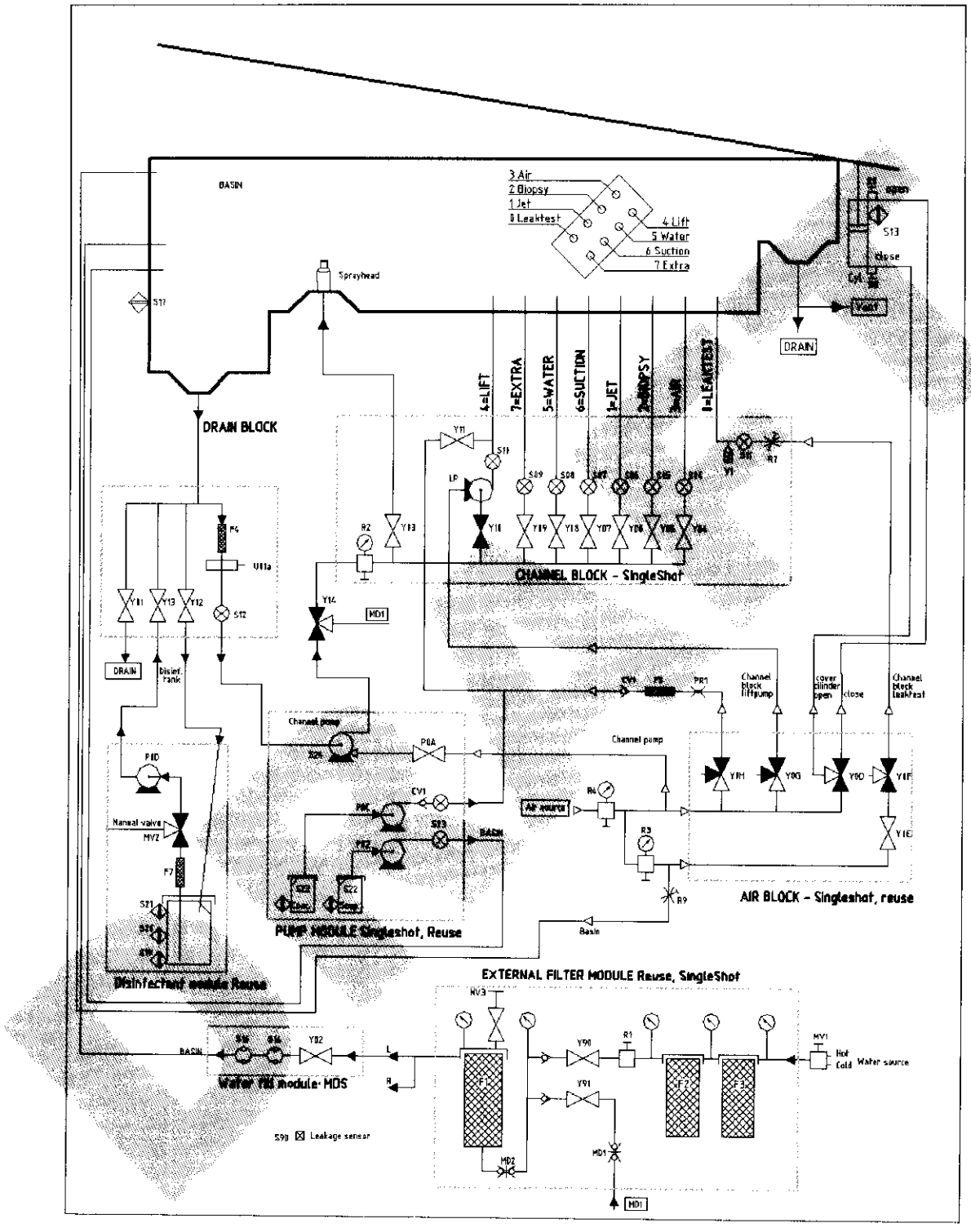

Figure 1. Process diagram

1208

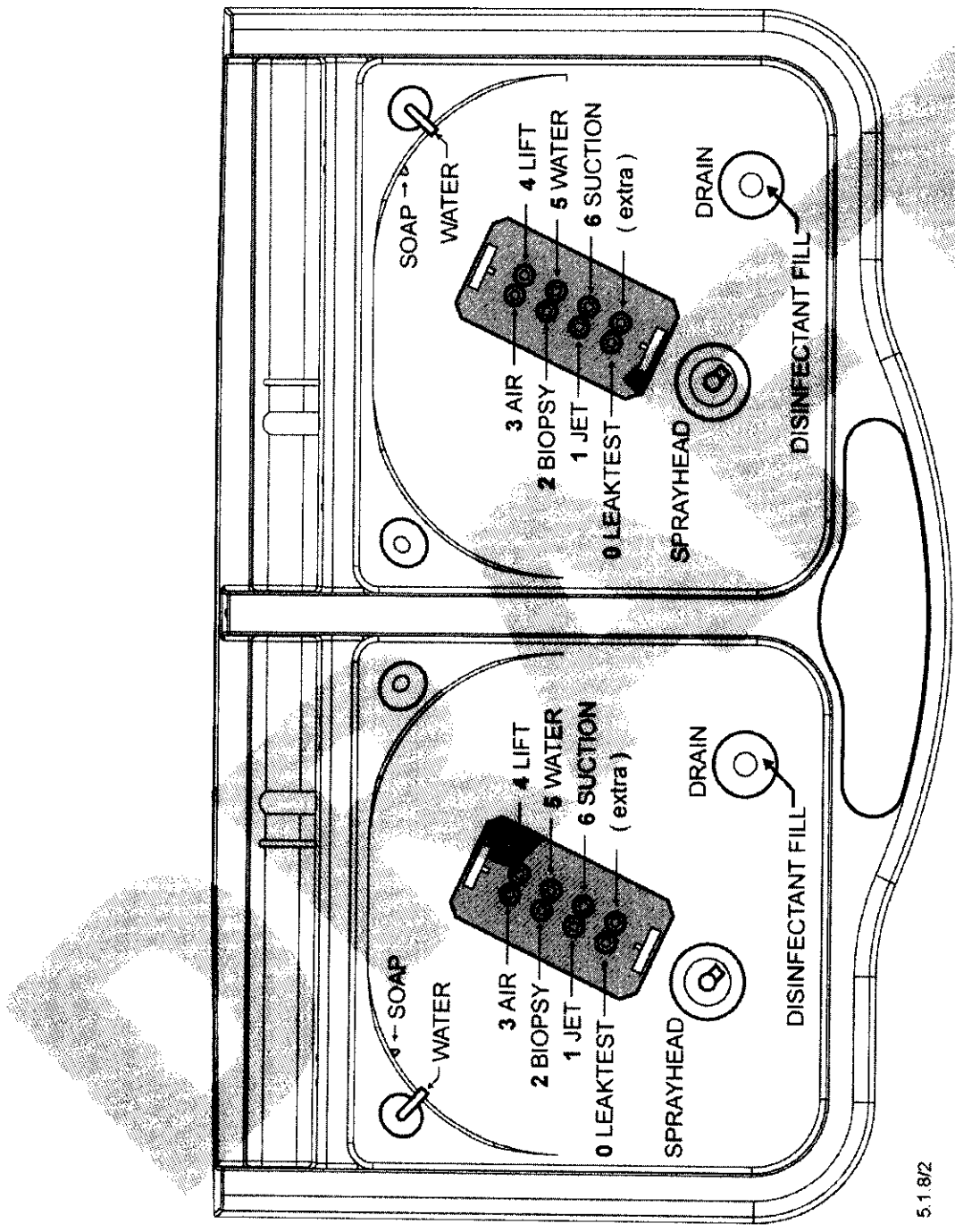

Figure 2. Plan rinsing tank

1209

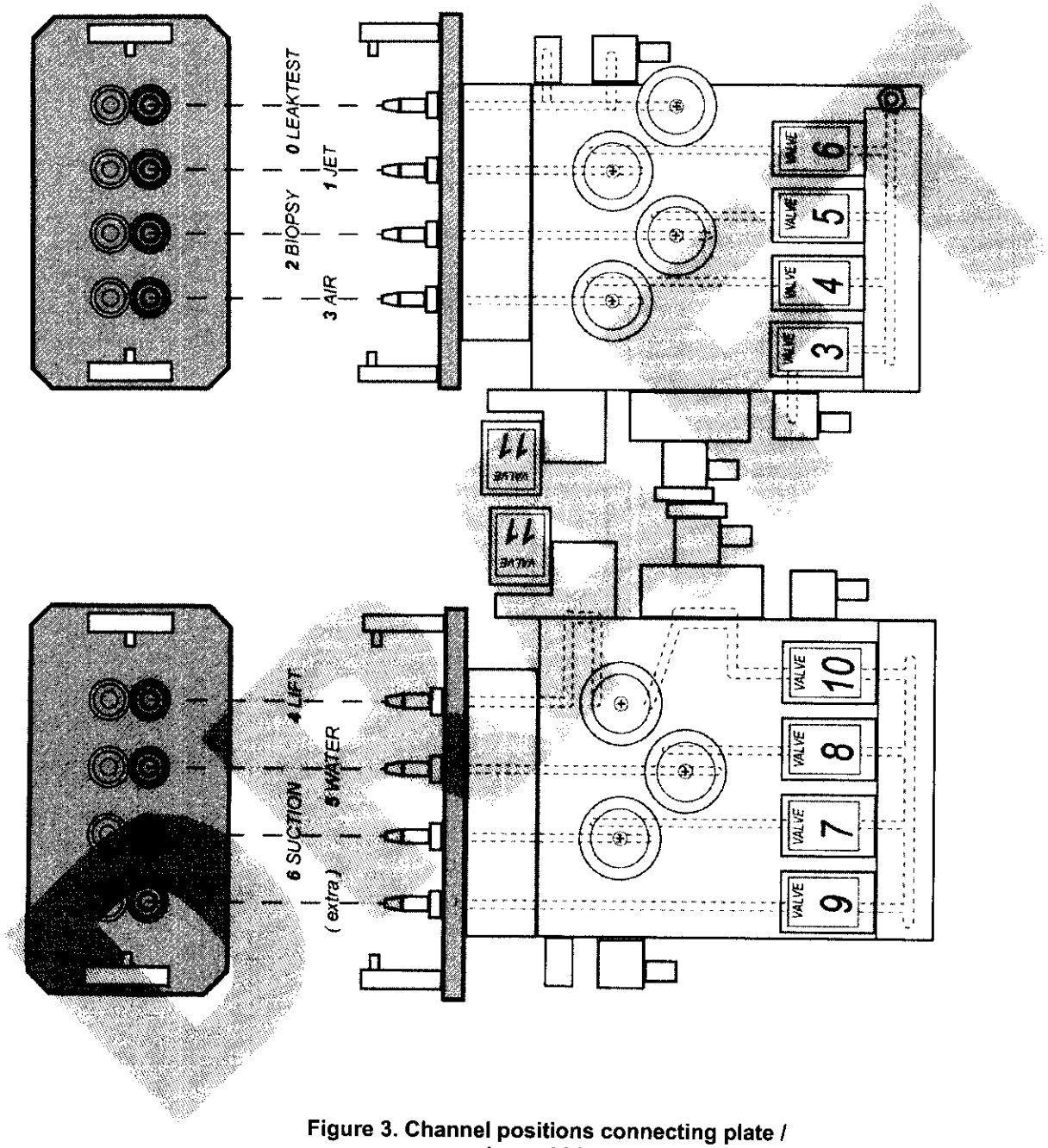

Figure 3. Channel positions connecting plate / channel block

1210

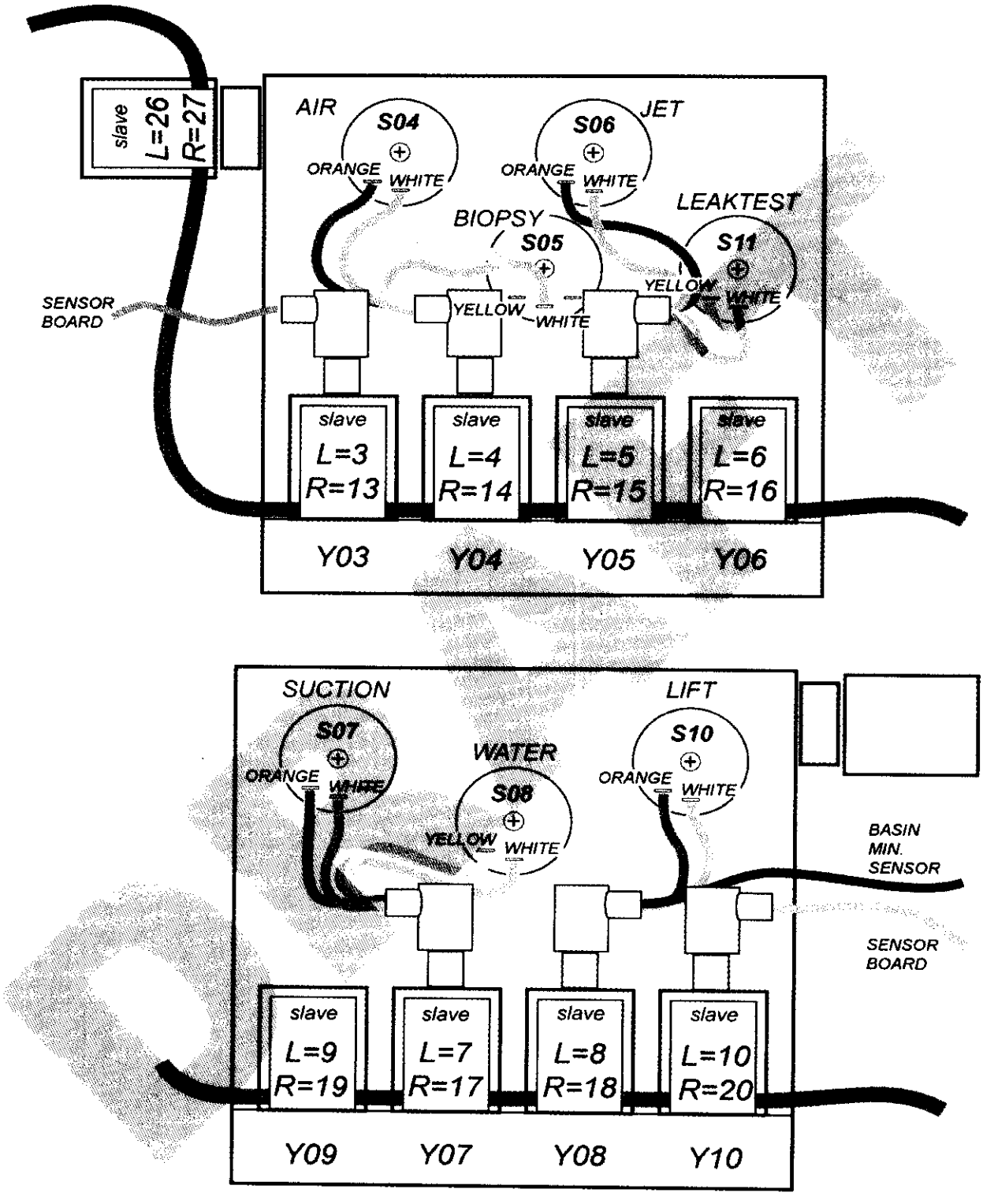

Figure 4. Channel block sensors / valves / slaves

1211

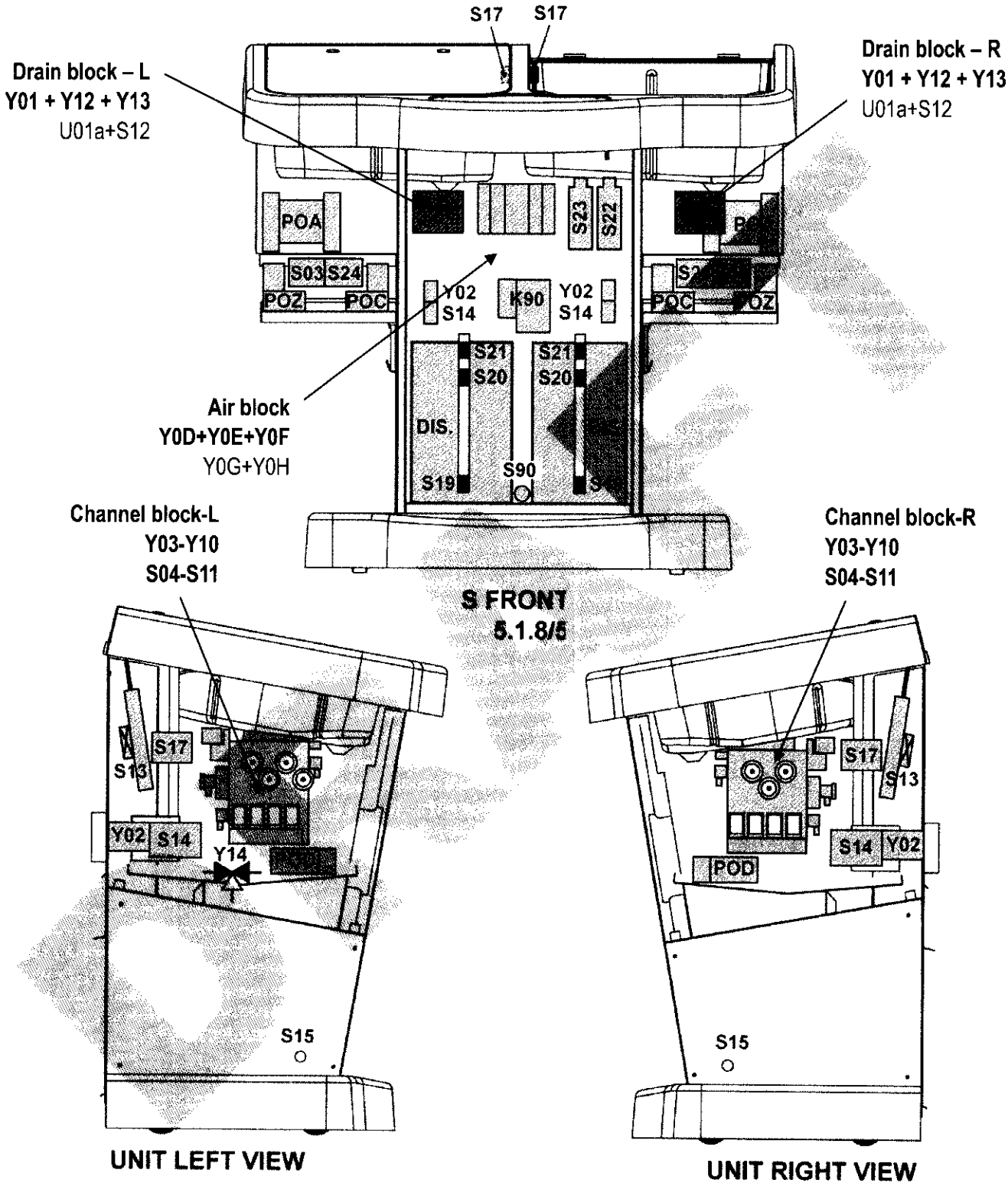

Figure 5. Machine outputs + sensors

1212

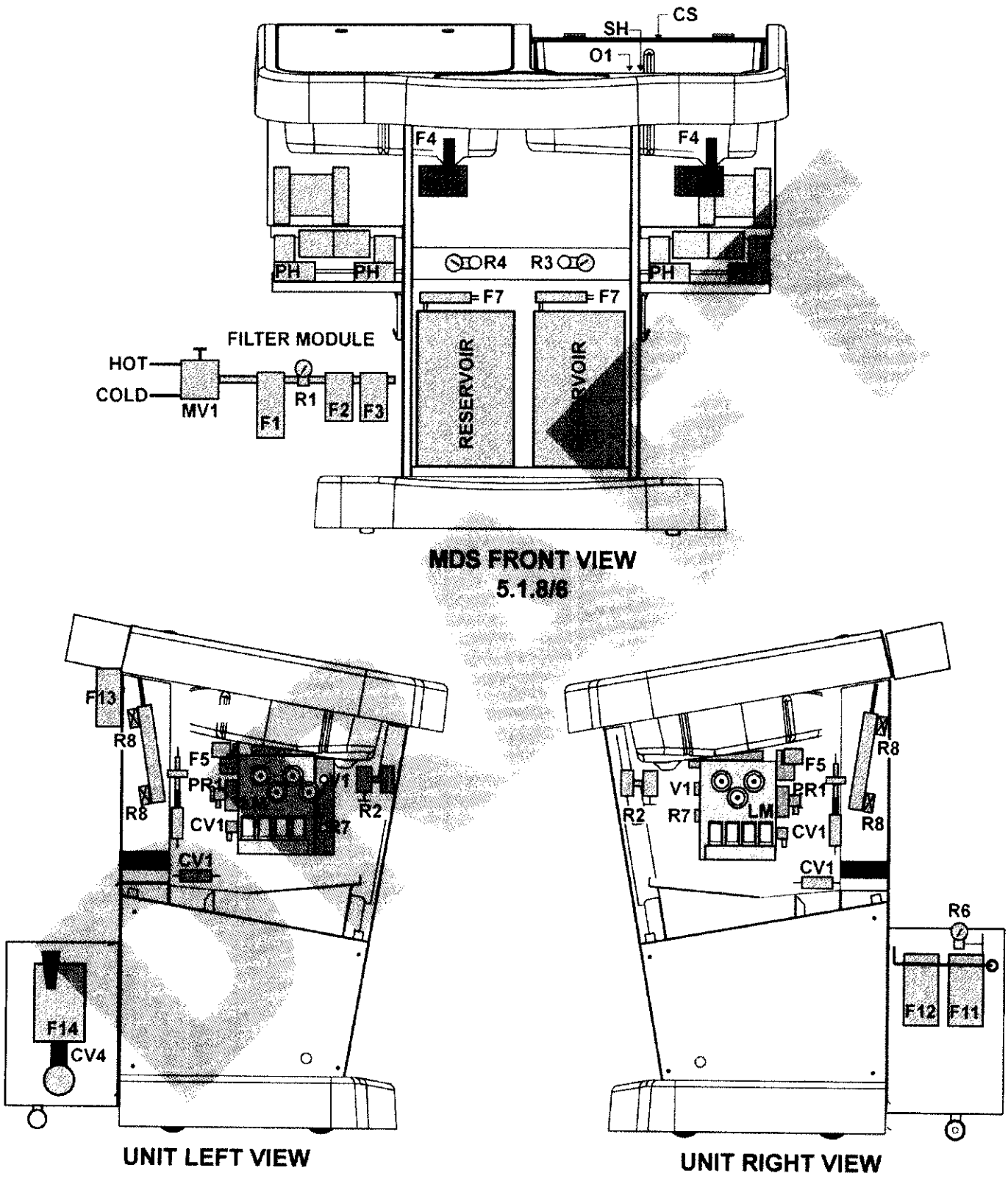

Figure 6. Machine maintenance points

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FORMS

CONTENTS

1. service report
2. installation report MDS
3. maintenance report MDS
4. system check MDS

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SERVICE REPORT

SERVICE REPORT

CUSTOMER:

Hospital _____ State: _____

Street Address: _____ Date: _____

Contact Person: _____ Department: _____

Inventory code: _____

MACHINE DATA **Visit Data**

Machine location: _____ Date: _____

Machine Type: _____ Time in: _____

Machine S/N: _____ Time out: _____

Software Version: _____ Technician: _____

ACTIVITIES:

Report: _____

Analysis: _____

Action Taken: _____

PARTS USED

Part No.	Description	Number	Lot No.

SYSTEM DATA

	Side 1	Side 2	Results:
Test Run			
Machine Disinfection			

☐ Data Copy _____ (File Name)

Signature Hospital Contact Signature Minntech Technician

☐ Warranty ☐ Contract ☐ Invoice

Minntech Contact Information: (763) 553-3300, 14605 28th Avenue North, Mpls, MN 55447

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INSTALLATION REPORT MDS

INSTALLATION REPORT MDS

Data

MACHINE TYPE:		**S/N:**	
LOCATION:		**Date:**	

Installation

Electrical 220V:		Compressed Air:		Modem:		Network:	
Filters:		Extraction:		Water:		Drainage:	
System Setup:				Alignment:			
I-Dent System:				Barcode:			

Block Connections:

Activities

Disinfectant Codes:		Barcodes:	
Operator Codes:		I-Dent Code:	

Note:

Logbook:		Operating Instructions:		Product Info:	

Name DYPED:		Name Client:	
Signature:		Signature:	

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MAINTENANCE REPORT MDS

Maintenance Report MDS

Machine Type:		**Serial Number:**	
Location:		**Date:**	

Sensor	L	R
U01a – Temp. Tank		
U01b – Temp. Heater		
S03 – Soap metering		
S04 – Channel 3 = Air		
S05 – Channel 2 = Biopsy		
S06 – Channel 1 = Jet		
S07 – Channel 6 = Extraction		
S08 – Channel 5 = Water		
S10 – Channel 4 = Lift		
S11 – Leakage test – 1		
S12 – Tank P.S.		
S13 – Cover		
S14 – Flow – 1		
S16 – Flow – 2		
S24 – Alcohol Metering		
S90 – Leakage		
Y01 – Drain		

Replaced Items	L	R
CS – Cover Seal		
LB – Lift Diaphragm		
CV1 – Flow Check Valve		
PH – Tube pump Head		
PR – O-ring set of 8 pieces		
SH – Sprayhead		

Regulators	L	R
R1 – Water source		
R2 – Channels (2x)		
R3 – Leakage test		
R4 – General		
R6 – Compressor		
R7 – Leakage test flow		
R8 – Cover Flow		

Pumps	L	R
POZ - Detergent		
POD – Disinfectant		
POC – Alcohol		

Replaced Filters	L	R
F1 – Bacterial		
F2 – RRE - 1		
F3 – PRE – 2		
F4 – Beam		
F5 – Air Flow		
F7 – Disinfectant		
F11 – Compressor – 1		
F12 – Compressor – 2		
F13 – Compressor – 3		
F14 – Compressed - Air		

Name Technician:	Name Customer:
Signature:	Signature:

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SYSTEM CHECK MDS

System Check MDS

Machine Type:		Serial Number:
Location:		Date:
LIO Version:	Man. Version:	Server Version:

R	Check	Type	L	R
X	1. Supply	Y01 + S12 + S17 / Y90 + Y02 + S14 + S16		
X	2. Channels	POA – Y04 + S04 + - Y05 + S05 – Y06 + S06 / Y07 + S07 – Y08 + S08 – Y09 + S09 – Y10 + S10 – Y03		
X	3. Air	YOH – YOD + S13 – YOE + S11 – YOF / Y01 + S18 – YOJ – YOG		
X	4. Air Tank	Y15 + S33 – Y16		
X	5. Melering	POD + S02 – S22 + POZ + S03 / S23 + POC + S24		
X	7. DES. SS	POF + S28 + S27 + S25 + POE / POG + S03 + S29 + S26 = POH		
X	8. OTHERS	S90 – U01a – U01b – K01		
X	9. LED	RED + GREEN		

Appearance:	
Doors Panels:	
Wiring:	
Drains:	
Others:	

Conclusion / Deviation

Disinfection:	L	R	Cleaning:	L	R

Name Technician:	Name Customer:
Signature:	Signature:

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LOGBOOK

The logbook should always be present in the department where the machine is placed.

The following pages describe the contents of the logbook.

The service engineer should also be aware of the use of it and release the written sheets , procedure and use of the forms.

WARNING: The described adjustment data is indicative and consequently does not provide current values. Refer to the machine logbook.

LOGBOOK CONTENTS

Machine Number:	Type:
Location:	Place:
System Administrator (Automation):	Tel:
MDS Administrator (DATA):	Tel:

Logbook usage

1. Release procedure
2. Changes procedure
3. Use of forms
4. Notes

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Master cards

Installation

1. Installation report
2. Dimensions / connections
3. Connection conditions (per machine)
4. Connection block (per program)

Specifications

1. Process diagram
2. Adjustment data
3. Software version: changes after installation
4. PC settings: changes after installation
5. Parameter sets: changes after installation

Failure reports

Maintenance reports

1. Master card: Metering calibration
2. Master card: Filter replacement
3. Installation report
4. Maintenance report
5. System check
6. Validation / calibration

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LOGBOOK USE

Introduction

The Logbook contains machine-bound registrations of:
- software set-ups
- process parameters
- failure reports
- service/maintenance registrations
- adjustments

Master card

Failures-, remarks- and maintenance activities are described on this by the user and supplier

Installation

Gives an overview of the installation data of the machines.

Specifications

There are standard settings and adjustment data for each design form of the machine.
There can be deviations as a result of users' wishes and conditions of use.
The change should be noted in the corresponding registration table.
Applies to supplier and user.

There are change tables for:
- software updates
- adjustment data
- program times

Failures / maintenance reports

These are filed..
The relevant data is noted on the master card, as well as the number of the (failure) report.

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RELEASE PROCEDURE

A test program, without endoscope, should be run after repair/maintenance activities. For this proceed as follows:

Machine run-down:

- fit all caps on the machine
- place the machine back in its usage position
- place tanks in the machine

Reducer:

Check whether the manometers of the value conform to those indicated in the logbook. This is indicated on the failure form.

Check:

After each maintenance the service menu checks if the "fixed" program times still correspond to the values mentioned in the logbook. Possible deviations are mentioned on the master card and corrected.

Registrations via scope code:

- name operator	=	name of executor of maintenance / repairs
- Scope code:		"MDS test" : for the supplier
		"Maintenance test" : for the client

Registration in logbook:

Note in the logbook the description:

- name, date
- release run with run number

Release

Release follows when the program runs without fault. Any fault should be rectified and the release procedure must be repeated until a normal run has been carried out.

Reporting (by client or technician)

After each periodic maintenance a report of the test run process, see above, is printed on paper.
The fixed program times are checked by the employee of the client. If the document is correct, then it is completed with the name and initials of the technical employee of the client.

CHANGE PROCEDURE

The changes of the parameters in the program and sensor settings should be carried out as follows:

1. The client submits a written request to the quality manager at Minntech with a statement of:
   - current settings of the machine or program.
   - motivation of the change proposal.
2. Minntech evaluates the request and responds in writing with a statement of the reasons for the decisions and/or advice taken.

Warning: The fixed program times are validated and tested. Changing the settings without written permission of the supplier is strongly discouraged because machine failures can occur after changes!

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MASTER CARD

Run no.:	Unit:	Description:
Date:		
Name:		

Run no.:	Unit:	Description:
Date:		
Name:		

Run no.:	Unit:	Description:
Date:		
Name:		

Run no.:	Unit:	Description:
Date:		
Name:		

Run no.:	Unit:	Description:
Date:		
Name:		

Run no.:	Unit:	Description:
Date:		
Name:		

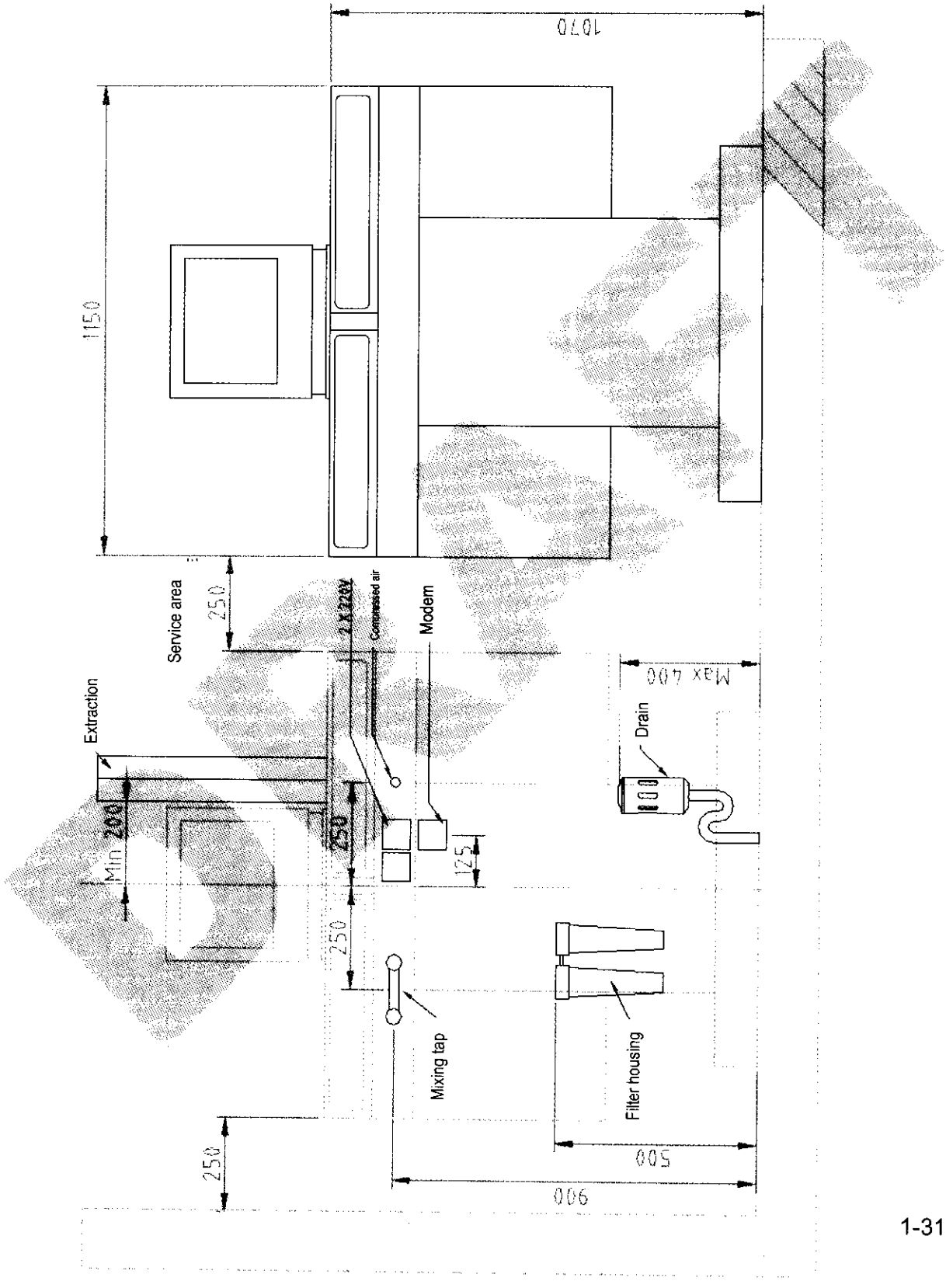
Use :

Each operation that is carried out on the machine is mentioned, in a short description, on the master card, including:

- when each periodic maintenance has been carried out.
- interim calibrations are carried out by the client or the service technicians.
- interim filter exchanges.
- repair of faults by the client or the fault technicians.

With this, the progress status of the machine is determined. The master card is also used when there has been a problem and the data is no longer known.

DIMENSIONS / CONNECTIONS



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CONNECTION CONDITIONS (PER MACHINE)

Electric connection

Current		:120V - 60 Hz
Tolerance	:	3 KW
Fuse	:	16 Amp. (slow)
Contact		:Wall socket, 2-pin with rim earth, 2 pieces
Placing in room		:(according to NEN-3134)
Direct	:	class S0 and S1
Not permitted	:	class S2 and S3

Water connection

Pressure	:	20-87 psi
Supply	:	Single line for hot and cold
Coupling	:	Mixing valve
Setting	:	± 30°C
Connection	:	¾ " G outer thread
Quality	:	Drinking water
Consumption	:	Max. 10 ltr./min. at 1 Bar

Air connection

Pressure	:	5-10 Bar
Connection	:	Ø 6 mm (internal)
Quality	:	Medicinal
Consumption	:	Max. 100 ltr./min. at 1 Bar
		10 ltr./min. at 10 Bar
		5 ltr./min. at 5 Bar

Water drainage

Connection	:	Ø 40 mm
Height	:	Max. 25 cm
Type	:	Free-fall with odorous extraction

Moisture extraction

Low pressure	:	± 100 Pascal (minimal)
Take-off	:	50 m^3/hour
Connection	:	Ø 100 mm
Circuit	:	Adjustable by means of time clock

Warning: The adjustment data provided is indicative and consequently does not represent the current values. For this, one should refer to the machine logbook.

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CONNECTING BLOCK (PER PROGRAM)

The machine cannot function without a connecting block. By placing the connecting block the following channel connections can be achieved:

0. Leakage test.
1. Jet.
2. Biopsy.
3. Air
4. Lift channel.
5. Water.
6. Extraction.
7. Extra.

Depending on the number of channels the corresponding silicone hoses are connected to the block. There are eight connection possibilities. See images below.

- When a channel is not connected to the scope, then the connection in question should be equipped with a plug with a hole.
- The hose couplings on the connection block are 'fixed volume free'.
- The connection block is carried out in PVDF and RVS.
- A flow restriction is installed in the connection blocks :
- The function is the realisation of a specific pre-pressure in the system on which pressure switches react and a flow in the scope channels can be detected.
- In addition, the liquid pressure in the endoscope channels limit the occurrence of overloading.

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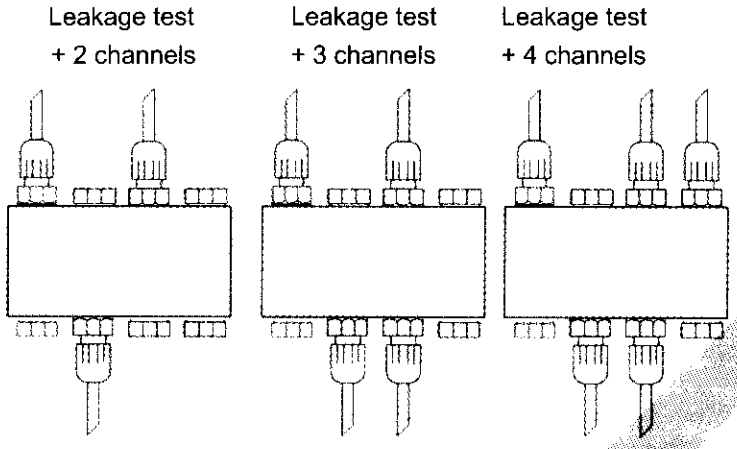

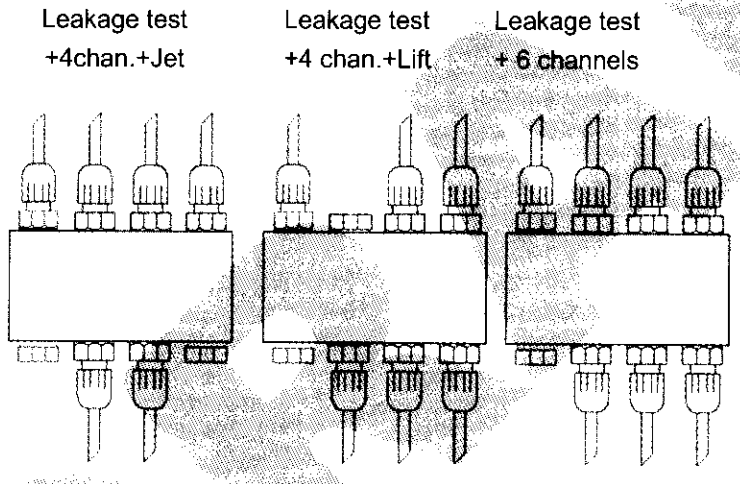

Use :

At installation the data is entered in the top most frame.
After this the client can change an adjustment provided that the change procedure is followed.
When the supplier has carried out the change then it is filled in by the service technician.
This provides an overview of the user settings of the machine.

Warning: The adjustment data provided is indicative and consequently does not represent the current values. For this, one should refer to the machine logbook.

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FORMS:

Machine Type:	Serial Number:
Location:	Date:

CALIBRATION:

AIR REGUL.: - Leakage		[bar]	(0.25)		WATER REGULATOR DYNAMIC		[bar]	(2.0)	
	- general	[bar]	(2.8-3.0)		LEAKAGE SENSOR		[bar]	(3.0)	
LEFT TANK			Valve		**RIGHT TANK**			Valve/statu	
SENSOR cover open		[cm]	(1.5)		SENSOR cover open		[cm]	(1.5)	
SENSOR tank empty		[ml]	(60)		SENSOR tank empty		[cm]	(1.5)	
Temp. correction 30° C		[°C]	Max. ± x		Temp. correction 30° C		[°C]	Max. ± x	
SENSOR : - Leakage Test		[mmHg]	(60-50)		SENSOR : - Leakage Test		[mmHg]	(60-50)	
	- jet	[mmHg]	(80-70)			- jet	[mmHg]	(80-70)	
	- biopsy	[mmHg]	(50-40)			- biopsy	[mmHg]	(50-40)	
	- air	[mmHg]	(50-40)			- air	[mmHg]	(50-40)	
	- water	[mmHg]	(50-40)			- water	[mmHg]	(50-40)	
	- suction	[mmHg]	(50-40)			- suction	[mmHg]	(50-40)	
	- elevator (lift)	[mmHg]	(280-220)			- elevator (lift)	[mmHg]	(280-220)	
	- alcohol	[mmHg]	(50-40)			- alcohol	[mmHg]	(50-40)	
	- soap	[mmHg]	(50-40)			- soap	[mmHg]	(50-40)	
PUMP alcohol		[ml/min]	Min 200		PUMP alcohol		[ml/min]	Min 200	
PUMP soap		[ml/min]	Min 200		PUMP soap		[ml/min]	Min 200	
FLOWMETER 1		[fl/hr]	(261-391)		FLOWMETER 1		[fl/hr]	(261-391)	
FLOWMETER 2		[fl/hr]	(261-391)		FLOWMETER 2		[fl/hr]	(261-391)	
LEAKAGE TEST -		[mmHg]	Min 180		LEAKAGE TEST -		[mmHg]	Min 180	
	- flow	[sec]	(2)			- flow	[sec]	(2)	
DISINFECTANT SUPPLY		[ml/min]	Min 3000		DISINFECTANT SUPPLY		[ml/min]	Min 3000	
DISINFECTANT DRAIN		[ml/min]	Min 3000		DISINFECTANT DRAIN		[ml/min]	Min 3000	
WATER DRAIN		[ml/min]	Min 3000		WATER DRAIN		[ml/min]	Min 3000	

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Software Version: Changes After Installation

DATA

MDS Type:		Serial Number:		Year of Manufacture:	
Process Diagram Version:		Location:		Date:	
Details:					

SOFTWARE

Date:	LIO: Version No.	MANAGEMENT Version No.	SERVER Version No.	Name:
Installation:				
Update:				

Use :

At installation the data is entered in the top most frame.
After this the client should keep the version changes of the MDS programs up-to-date.
When the supplier has carried out the change it is filled in by the service technician.
Importing new versions is the responsibility of the MDS administration.

PC Sets: Changes after Installation

Set-up	Value	Date	Name	Remarks

Use :

Here the client should keep the user settings which the management program has changed up-to-date. This provides an overview of the user positions of the machine.

DRAFT

Parameter Sets: Changes after Installation

Set-up	Version	Name	Remarks

Use:

Here the client should keep versions of the disinfectant parameter program up-to-date. Importing new versions is the responsibility of the MDS administration.

DRAFT

METERING CALIBRATION

Execution		Unit Left				Unit Right			
Name	Date	Water: FL/Ltr.		Soap	Disinf.	Water: FL./Ltr.		Soap	Disinf.
		S14	S16	ml/min	ml/min	S14	S16	ml/min	ml/min

Use:

At each periodic maintenance the values which are carried out in the management program are noted with the system.
Also the interim calibrations that are carried out by the client or the service technician are entered here.
With this the values are fixed when there has been a PC problem and the adjustments are no longer known.

DRAFT

FILTER REPLACEMENT

Filter:		Filter:		Filter	
Frequency:		Frequency:		Frequency:	
Name	Date	Name	Date	Name	Date

Use :

At installation it is noted which filters have been placed in the water supply of the machine.
Depending on the water quality the exchange frequency per filter must be entered.
With each periodic maintenance it is noted which filters have been replaced.
With bad water quality the interim replacement, which has been carried out by the client or the service technician is also entered.
With this, the replacements are fixed and the next one can be planned.

DRAFT

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Chapter 2

INSTALLATION

PREPARATION

Filling in forms

Installation report MDS

Maintenance report MDS

Service report (if it concerns a re-installation)

Logbook Various, see development

Tools

Standard tool-box for maintenance

Empty tank: 5 liters

Printer

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Material

Connection components.

- hose clip Ø 20/ Ø 40 / Ø 100 (2x)
- drainage hose Ø 20 (int) – 2 mtr
- 90°/45° knee Ø 20 (ext)
- extraction hose Ø 100
- water supply hose (2x)
- various reducing nipples pipe thread
- air hose Ø 7 (inw) – 3 mtr
- file: product information (for client)
- file: operating instructions (for client)
- file: logbook (for client)

Precaution:

1. Contact the technical service of the client 2 weeks before delivery to inquire whether all provisions on which the machine must be connected have been applied. If in doubt, carry out an on-site inspection.
2. Hand over MDS users manual with the request to review entire document and the data for the database for the preparation of:
   - endoscope
   - specialist
   - operator
   - assistant

   Let the client complete the relevant forms.
3. Hand over the product information file so that the client can check whether all connectors and accessories for the endoscopes are present.

PROCEDURE

Introduction

The machine is aligned and tested in the production workshop. The installation at the client must ensure that the machine also functions well in the new surroundings and different circumstances.

The installation is divided into 11 steps.

When a step has been completed then it is signed off on the installation report.

PROCEDURE POSITION :

1 filling in report
2 monitor - PC
3 drainage
4 water supply
5 air supply
6 extraction
7 turning on machine
8 ventilate filter
9 placing liquid tanks
10 system settings
11 introduce scope codes

Filling in report

At installation the form: Installation report is filled in.

Depending on completion or when it concerns a replacement (after a repair) some steps are not applicable.

When a step has been completed, it is signed off on the installation report:
"OK" if the item is correct.

"NA" : when it is not applicable.

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Monitor

The PC-monitor can be installed in two ways.

1. Coupled to the machine.

   The monitor foot is suspended on the machine by means of two keyholes on the protruding bolt. First place the nut. Then the two nuts are screwed tight. Finally the feeder cable and other cables are connected.

   Tie up the cables and hang the cylinder on the turntable with tie-wraps.

2. Free-standing.

   A board should then be placed above the machine.

!! In the open position the covers must not touch this board!!

The board must be provided with holes in order to put the cables through. After placing the monitor the signal cable is lengthened with a standard cable.

This simplifies the placing of the machine.

Drainage

There is a divisible coupling with a PVC-out feed on the machine. The drainage hose is clipped onto this by means of a hose clip.

Allow the hose to run in a bend so that the machine can still be equipped at the front.

The drain hose may not be clipped on the drainage.

The hose should hang freely to flow into the drain. (This is to prevent backflow from the drain).

Water supply

The water hose is first screwed onto the mixing valve (side with sieve).

Then the opening of the hose is laid in the rinsing tank and the tap is opened, so that air is removed from the hose. Each unit has a separate water supply.

Compressed air supply

The air hose is clipped to the grommet with hose clips. For this a reinforced hose is used.

Extraction

The elastic air drain hose slides over the round tube-piece and sealed with a clip.

Turning on machine

Put the plug in the wall socket and press the main switch of the PC.

In connection with the nightly machine disinfection the machine should not be switched off if it is not necessary.

Ventilating filters

Connect the hot water blocks in the two rinsing tanks!!

Valve 13 is turned "on" via the "manual control".

Open the tap a little so that the air can be filtered out slowly by the water.

Placing liquid tanks

Wear gloves!! These are the tanks with cleaning soap and disinfectant.

Reset the option: Change disinfectant. The starting position for the shelf life of the disinfection agent.

- put the disinfectant connector in the tank
- place the tank in the machine, with the opening at the front
- do the same with the other tank

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System settings

These are adjusted once at installation in consultation with the machine administrator of the client.

The parameters to be adjusted are below.

NOMINAL DRAINAGE:

- go to expert operation
- set the drain to stop by click on the right mouse button
- fill the rinsing tank with 5 liter
- open the drain and measure the time that the tank runs completely empty
- fill in the value = 5000 ml / x sec. on the screen

NOMINAL WATER SUPPLY :

- let water run in the tank via the expert operation and valve 2
- measure the time to fill the tank with 5000 ml, see screen
- fill in the value = 5000 ml / x sec. on the screen

Tank soap content: check / adjust

Tank disinfectant content: check / adjust

DRAFT

ENTER THE FOLLOWING DATA IN CONSULTATION WITH THE MACHINE ADMINISTRATOR:

- Import obligatory: patient code
- Import obligatory: specialist code
- Import obligatory: assistant code
- Barcode use obligatory
- Tag-reader use obligatory
- Audio signal warning
- Audio signal end program
- Audio signal failure
- Machine disinfection: day of the week

OTHER DATA

- Import on the basis of the calibration

SAVING

- Save all imported data on the server by regularly clicking the diskette icon (above in the bar).

- Store the data in the machine by closing the LIO program and subsequently starting it up again.

Importing management data

It is recommended to carry out imports on the basis of the forms as mentioned in the users manual. This is divided by the separate management applications, instruments, users and medical staff.

The data files can then be copied onto a USB stick and be read by several machines.

Note: The import of scope codes and users codes is described in the *users manual* under chapter 5.

Note: Out of practical considerations it is recommended to provide the scopes with a number. Thus when importing, the scope code can go before this number. Then with the daily procedure only the number on the scope has to be keyed in. The complete scope code is then automatically registered. Loaned scopes can also be registered.

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DEVELOPMENT

Development Procedure:

1. check codes
2. check connection blocks
3. alignment
4. concentrations
5. test run
6. print lists
7. administration

Check codes

- check with the system administrator of the client whether all correct scope codes and types, are imported and coupled to the right program 2K, 3K, 4K etc.
- check also whether all user codes have been imported correctly
- with barcode application the strips must be made so that they can be checked.
- check whether all read in i-dent system chips have been given the correct code

When all this data is correct then this it is signed off per item on the installation form.

Check connection blocks

Check whether the hoses on the delivered connection blocks are mounted in accordance with the diagrams.

These are recorded in the connection block catalog.

Note on the installation form, after the check, the number of each type that have been delivered.

Adjustment

The installation circumstances with the client can be different from the adjustment circumstances.

- therefore the machine should be adjusted again
- note in the activities square: "Installation" of calibration form
- the procedure is described in the Calibration Section

Concentrations

Check / correct whether the set cleansing agent and disinfectant is of the concentration indicated by the supplier of these agents.

Check whether this applies to all program parameter sets.

The setting of the machine can be found via the management program.

Note the concentration on the installation form.

Test run

Put the machine through a test run:

- import as scope code: MDS test 1
- import your own initials as operator
- start up unit left and right one minute after each other
- write the run numbers on the installation form

Print lists

Print lists of the data which is entered in the management:

- instruments
- users
- doctor

Date the lists and have them signed by the client as confirmation of the installation data. When it is not possible to print then a copy must be made on the USB. This should be printed and sent to the client for signature.

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Note: The signature is important to enable subsequent discussions concerning the correct import and coupling of scope data to the parameter sets.

Administration

- print the system settings twice, write down the date and machine number
- check whether the form: Installation MDS is filled in completely
- let the form be signed by an authorised employee of the hospital (system administration)
- add a print of the form and the system settings in the logbook
- put the following forms in the logbook:
  - master card: installation + date
  - filter replacement: date
  - metering calibration: date + value
  - software: version
- check whether the three files are present
- submit another example to the office staff employee

Note: The logbook, operating instructions and product info are left with the machine. The administration is now the responsibility of the client. With a replacement after maintenance or overhaul the form. Service report is also filled in.

DRAFT

Chapter 3
PREVENTIVE MAINTENANCE

PREPARATION

Filling in forms

- Service report
- Maintenance report MDS
- System check MDS
- Note form

Tools

- standard maintenance box
- windows external keyboard

Documentation and software:

- operating manual MDS
- MDS software

Material, maintenance set MDS

See annex 1, component list for small material and reserve components.

Precaution

Wear gloves when removing tanks and cleaning machine parts.

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PROCEDURE

Executer: technical employee

Explanation

The maintenance is divided into a standard- and major maintenance. For major maintenance such as revisions there are separate instructions.

The overview list indicates the minimum that must be carried out at a service. This also corresponds with what must be filled in on the form.

The procedures contain a complete description of each individual activity. It is sometimes more practical to divide a procedure by first doing other activities in between.

Machine Layout

In Chapter 1 of the MDS Service Manual figures 5 and 6 show the location of the components.

DRAFT

Standard maintenance service

All activities mentioned in this procedure.

Overview activities:

1 Filling in report
2 Complaints / noting remarks
3 Dismantling hoods
4 General inspection
5 Activities:
   - dismantling components
   - cleaning
   - carrying out activities/repairs
   - components
6 System check
7 Check / Calibration
8 Dismantlement

Filling in report:

The activities carried out are kept up-to-date on the maintenance report MDS and service report by noting the items. When a specific action, component or check is not present then " - " is filled in behind the item.

After performing the "inspection" the most important items that deviate are mentioned.

The used materials, with part number, are mentioned on the service report.

Activities which are necessary in order to make the machine optimal again but that deviate from the general activities are mentioned on the service report.

For the alignment the maintenance form is filled in. All existing alignments are entered here. With a correct alignment the measured setting value of the sensor is stated.

Note on the form the number of items which are replaced. Note a " - " at the items if:
- they are not applicable
- are not aligned
- are not replaced

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Complaints / noting remarks:

The client can have remarks about the functioning of:

- the machine
- the supplier

- Complaints about the supplier should be mentioned on the note form, and submitted to the service manager.
- General remarks, advices and complaints about the machine which are not directly rectifiable by repair, are mentioned on the note form under Fault and submitted to the service manager.
- Complaints which can be rectified should be carried out as much as possible during the P.O.

When an extra form is filled in then it is indicated on the maintenance report under: "Activities".

Dismantling caps :

For an attainability for the maintenance the following plate parts are removed:

- left and right side cap
- left and right receiving plate
- inside screening cap
- upper and lower back panel

General inspection:

The inspection points below should be checked one by one. When a point is not correct, this is noted on the form under Inspection, so that it can be rectified later.

The working of the apparatus is also determined by the status of the wiring, the connections and the mechanical components.

The aim of the inspection involves carrying out all the attention points below. Established deviations are noted as much as possible in the maintenance report.

The faults are rectified during the maintenance activities.

Points of attention:

- Wiring in electronics unit.
- Wiring in the apparatus and the slaves
- External connections for leakages.
- Contamination
  - rinsing tank and kit flange
  - inside the apparatus, e.g. as a result of leakage
  - covers
  - filter unit
- Dismantability of the side tanks.
- Appearance status (damages and/or contamination).
- Position of the leak tanks.
- Cover status
  - position/start
  - working
  - contamination
- Status front door
  - closure/hinges
  - insulating edge
- Pump
  - couplings
  - mounting nuts
- Extraction, rinsing tank
  - remove extraction hose and check whether ventilator still works
- Status connection blocks
  - handle
  - hinge points
  - pillar bores
- Status adhesive seams rinsing tank
  - seams rinsing tank inserts

DRAFT

- Discharge
  - connector plate
  - leakage traces
  - underside block 3 on rinsing tank
  - drainage block on rinsing tank
  - couplings general
  - main pump
  - mixing valve
  - hot and cold working button
  - status flow blocks
  - condition liquid couplings
  - status / leakage pressure sensors
  - contamination by leakage

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MAINTENANCE ACTIVITIES

This section describes activities that could be carried out during a maintenance service.

Decalcifying

The decalcification is separated by means of a machine disinfection program in which citric acid is added:

- place the hot-water blocks
- deposit in each rinsing tank 50 gram = 1 graduated beaker, citric acid
- start the program machine disinfection (in the middle on the upper side)

Note: During this decalcification the PT-100 calibration can also be carried out. Note on form.

Cleaning:

Note: Cleaning the apparatus is the only visible proof that maintenance has been implemented. For the user the alignments are just as important as justifying the need for the preventive maintenance.

- Covers:
  Non-abrasive cleaning agent. Remove lime with a sponge.
  Remove light contamination with screen cleaner.
- Receiving plates:
  Rinse off with warm water. Dissolve with hot water
  Disinfectant: (thickened)
- Rinsing tank:
  Remove scale with a non-abrasive agent.
  Remove lime scale on the RVS parts with citric acid.
- Housing external sides:
  With non-abrasive agent.
  Remove stains and dust from side- and foot-cap
- Sieves: Replace in rinsing tank.
- Leakage receiving tank:
  Fill with some warm water. Let de-contamination take effect.
  Remove damp and dirt.

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Replace cover sealing:

- Close the drain off with adhesive tape or a paper wad
- Remove the rubber and scrape the edge clean
- Remove adhesive remnants with dry-cleaning naphta.
- Apply drops of transparent silicone adhesive (small Ø 3mm) to the edge, around 10cm.
- Grease the adhesive around the edge with an old piece of seal.
- Apply rubber, do not extract but lightly press.
- Close covers
- Check sealing by sticking a double-folded piece of paper between the cover and around the seal
- Remove the adhesive remnants from the rinsing tank

Rework top (if damaged):

- Seal damage all round with painter's tape ± 5 mm area
- Fill hole with filler, a large hole first with fibreglass, after filler has hardened, sand the filled areas, file, and remove excess filler
- Fill 2nd time with only polyester filler
- Remove the tape
- Sand so that the surface of the hole is exactly flush with the surface
- Paint filler with green varnish, use a cotton swab to roll over the surface
- Swab on thin layers ± 5 minutes after each other
- Roll the cotton swab over the last layer when the paint is almost dry, in order to create texture.

Locking socket screws:

- The bolts of the flow blocks can be made loose
- Check each bolt, tightening them with a hexagon (2.5 mm), 0.65 N/cm by using a torque key

Adhesive seals rinsing tank inserts:

The fixing nuts of drain, sprayer, water inlet and supply can be loose because the adhesive is loose. Tighten nuts and/or renew the adhesive by removing the complete unit and mounting again.

Install new silicone kit as follows:

- clean unit and rinsing tank glue surface with dry-cleaning naphta.
- apply adhesive bead on the glue surface of the unit.
- place unit and tighten nut.
- remove excess adhesive immediately.

Decalcify heater:

- For this turn the thermal disinfection
- Meter citric acid beforchand

F1, F2, F3 / F9, F10 = Replace water filters:

- Close water supply tap
- For the applicable filters use the maintenance articles overview table 60
- Work as follows:
  - Get the pressure of the filter housing
  - Turn the filter case loose. Pay attention to water in the filter
  - Let the case drop slightly
  - Pull filter down
  - Remove filter and case together
  - Grease O-ring of the case
  - Place new filter
  - Place case and tighten until ready
- Filling with water
  - Place hot-water block on the connector plate
  - Open via the manual control valve 2: Supply :
  - Turn the water tap open halfway.

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Note: Filling must occur slowly in order to force air out of the filter

- Fill until no more air flows from the vent. ± 10 min.

When the water flows, the reducer is adjusted to the required value according to MDS adjustment. Adjust after the compressed air is reduced to the correct value.

Other filters :

-F4 : RINSING TANK FILTER

--Drain the filter in the rinsing tank with the strainer hook pulled high.

--Push the new filter over the metal case.

-F5 : AIR FLOW FILTER

--Push the ring round the hose on the filter connector and pull onto the hose.

--Replace complete filter with connector.

-F7 : DISINFECTANT FILTER

--Press the grey button of the quick-connect coupling, both sides.

--Replace the complete filter unit with a new one.

-F8 : CONCENTRATION FILTER

--With the help of a screwdriver push the hose back from the filter pillar.

--Push the new filter over the two hose ends.

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Air compressor (option):

-F11 : REGULATOR FILTER

--Remove the tank cap.
--Unscrew the filter holder.
--Replace the white filter.
--Place the components back.

-F12 : AIR PRE-FILTER

--Remove the tank cap.
--Unscrew the filter holder.
--Replace the green filter.
--Place the components back.

-F13 : MACHINE AIR FILTER

--Dismantle the holder re 3 mm socket.
--Remove the metal filter,
--Place a new filter in the holder with hole at the top.
--Re-mount the holder.

-F14 : AIR INTAKE FILTER

--Remove the metal cap from the compressor unit.
--Unscrew the filter with a penny coin and remove.
--Place a new filter and screw it tight.

-CV 4 : NON-RETURN VALVE

--Remove the valve placed between the compressor and the tank.
--Place a new valve.

Flow components :

Flow components are the restrictions and the non-return valves. When these are jammed, serious damage to the machine can occur. See overview other components.

-CV1 : FLOW RECOIL

--Set the ring round the hose pressed on the recoil and pull the hose.

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--Ensure with replacement in the direction of the current, pipe on recoil.

-CV2 : METERING RECOIL

--Place a rag above the two slaves in connection with moisture leakage.

--Turn the two holder parts round one quarter turn.

--Remove the recoil and the two o-rings and replace them.

--Ensure with replacement in the direction of the current, open direction rinsing tank.

Metering pump house coupling:

- Dismantle the two leakage collection plates by unscrewing the two cross screws 2 turns.
- Replace the complete hose coupling of the soap and alcohol metering pump.
- Turn the knurled ring of the connecting coupling from the hose and pull the supply hose loose.
- The head is fixed with two click connections. Cut these and pull the complete head of the motor housing.
- Place the new head until it clicks in.
- Connect the two hoses with the tubes.
- The metering unit part A and B must first be dismantled separately.
- Dismantle the door.
- Unscrew the two uppermost screws of the metering frame.
- Tilt the metering unit forward in order to reach the metering pump.

Grease covers:

The lower points of the covers are spotted with silicone oil.

Connecting block

- Open curved side-plate, latching can be bent back with water pump pliers
- When bending in the breadth it must be dismantled with the handle
  - Unscrew the adjusting screw (underneath block)
  - Remove centering pin
  - Dismantle handle
  - Bend handle back
  - Mount handle (without bearing brush)
  - Place bearing brushes
  - Mount the pin
  - Screw adjusting screw on again
  - Fit block onto the connector plate
- Check the hoses for wear, cracks and holes
- With cracks in the connector the hose can be shortened a little
- Mount hose on block:
  - Slide union on hose
  - Slide clamping sleeve on hose
  - Slide hose with clamping sleeve over the pillar of the connector
  - Tighten union

Lift pump diaphragm (not for double scope version):

- Dismantle the housing of the lift pump
- Remove old diaphragm
- Check block for damages and/or contamination
- Place new diaphragm
- Mount the housing of the lift pump

Pillar o-rings:

- With two fingers press the O-ring on the pillar in one direction and remove the loosened ring with a small screwdriver.
- Remove all 16 O-rings.
- Press the new O-rings over the pillar.
- Grease thumb and forefinger lightly with silicone oil.
- Grease the O-rings by moving along the pillars in a diagonal and lengthwise direction.

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Spray head:

- Unscrew the two sprayers and replace them with the exchange sprayers.
- Place a red reject sticker on the sprayer and after the maintenance place the sprayer in revision department for re-working.

System check

In order to guarantee that all in- and out-puts still function correctly a system check should be carried out. Fill in the form:
System Check-MDS.

Check / Calibration

Check whether all adjustments are regulated in accordance with the data in the logbook. Adjust the machine in accordance with the calibration procedure.

Fill in the values on form: Maintenance report MDS.

Tests

Align the machine in accordance with the work description in Calibration section.

PROCEDURE TESTS

GENERAL

During the test run there must be regular checks for leakages. The particular points of attention for this are the:

- canning-in in the flow-blocks
- water volume in the rinsing tank
- couplings
- system unit

DISINFECTION PROGRAM

- Place two test connection blocks and start unit L and R around the same time, program 4K + jet.
- Note the run number with result on the form under "disinf. L/R".
- If a normal run, see administration procedure.

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- If failure: note down the problem, rectify and repeat test procedure.

MACHINE DISINFECTION

- Place two hot water connection blocks and start up a machine disinfection.
- Note the run number with result on the form under "disinf. L/R".
- If a normal run, see administration procedure.
- If failure: note down the problem, rectify and repeat test procedure.

COMPLETION

- All plate parts are placed back.
- The machine is placed in its original position.

Administration

1. Check whether the form is completely filled in.
2. Let the machine turn a normal program on system 1 and 2, preferably program with lift.
   - Connect two endoscopes to the machine
   - Select scope number
   - Enter your own name in as operator
   - Start program left system
   - Repeat for right system
   - Fill in run number on the form
3. Initial the form when the test run has progressed normally.
4. Completion
   - Add a print-out of the filled-in form to the logbook
   - Fill in the master card of the logbook
   - Submit the original example of the form to the office staff employee of Minntech.

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Chapter 4
MAJOR MAINTENANCE

PREPARATION

FILLING IN FORMS

fault report
calibration report MDS
system check MDS

TOOLS

Standard tools vehicle for the maintenance activities at the client.

MATERIAL

Type definition

On the basis of the order or machine number, define which process diagram the machine to be revised has. This defines the sub modules to be replaced.

Replace / exchange components	#
Screw countersunk M5	8
O-ring 008-pillar	16
O-ring drain	2
Block channels	2
Block drain	2
Heater	2
Alcohol / Soap / Disinfectant metering unit	2
Channel pump	2
Disinfectant pump	2
Water supply unit	2
Regulator R2 channels	2
Extraction ventilator (new)	1
Preventive maintenance set (new)	1

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Precaution

Make an appointment around 4 weeks beforehand so that the machine is available for 2 days:

one day for the maintenance activities

one day for the end check, adjustment and validation

Two technical employees are planned for the implementation unless contractually agreed that the client assists.

Check beforehand the type and operation form of the machine to be revised (see process diagram). Correspond the sub-assemblies to be taken for this.

PREPARATION ON-SITE:

Rinse through the blocks and the pumps with the expert control: fill unit L and R tank

- valve 1 = off
- valve 2 = on
- until tank is filled with water = 2 liter
- pump = on
- 2 minutes circulation
- reset manual control

Rinse pipe and pumps of the metering unit (type dependent)

- remove tanks
- place tank with water
- set "on" via manual control:
  -soap + concentration pump unit left
- after 30 seconds: reset
- set "on" via manual control:
  -soap + concentration pump right
- after 30 seconds: reset
- wear gloves for pulling the hoses loose from the metering unit

Disconnect the machine

- water
- air
- extraction
- 120V
- monitor

Take the machine to the workshop.

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Procedure

To keep an overview of the activities carried out the assembled parts per system are replaced one by one.

It is possible to work on two systems at the same time.

The sequence is indicated in the procedure.

Plating

DISMANTLE / REMOVE:

fluid tanks (2x)

side covers (2x)

door

inner screen

hoses of the adaptors

Dismantling metering unit (if applicable)

DISMANTLING:

- connections to metering nipples in the rinsing tank L and R
- AS-i cable of the metering unit
- metering unit (2x crossheads)

ASSEMBLY:

- assemble metering unit with the 2 cross screws
- connect the AS-i cables. Attention wire colours!
  BLACK: - blue on : aux – and - brown on : aux +
  YELLOW: - blue on : as-i – and - brown on : as-i +
- place the metering hoses (via metering unit sides) on the nipples of the tank
- attention soap = black on the tank, disinfectant = re the drainage block
- bind the hoses to the nipples with tie-wraps
- connect the hoses (via upper side of metering unit) to the tank adaptors

Block channels

DISMANTLING:

- mark wiring on the sensors, leakage test, lift, etc.
- mark hoses, lift pump, lift blows
- *remove:*

  --hoses (5x)

  --connectors (9x)

  --wiring sensors (7x)

  --silicone plugs in connection plate (4x)
- unscrew the 4 countersunk screws in the connection plate out the block (block supports)
- *remove:*

  --block by levering it lightly and pulling it down

  --moisture from screw holes

  --o-rings on the pillars

  --potential silicone remains in the screw-plates and on the underside of the connection plate

  --let the water run out of the blocks, rinsing by pressing with the hand = valve open.

ASSEMBLY:

- assembly new O-rings (008)
- grease the O-rings with: Silubrin grease
- push the channel block on the pillars and screw it tightly with 2 screws, diagonal
- prior to assembling the other 2 screws, first put a groove of silicone adhesive on the underside of the screw head
- remove the first 2 screws and also put silicone adhesive under the screw head here
- fill the first 4 screw holes in the connecting plate with silicone adhesive and then wipe smooth with a spatula
- *assemble:*

  --AS-i connectors

  --pressure switch contacts

  --water hose

  --air hose

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Block drain

DISMANTLE:

- *remove*:
  --hoses (3x)
  --connectors (2x)
- screw the socket screws loose in the block under the mounting
- undo the drainage hose

ASSEMBLY:

- slide the socket screws through the block and slide an O-ring over the screw thread screw block 1 tight on the ring
- *assemble*:
  --hoses
  --connectors
- check whether everything is fastened

Heater

DISMANTLE / REMOVE:

- hoses (2x)
- wiring
- PT- 100 decouple

ASSEMBLY:

- check per heater whether the assembly brackets are on the right side.
- connect the hoses to the coupling
- tighten the coupling with special ring spanner 17
- *assemble*:
  --hoses
  --wiring and PT-100
  --connectors
- check whether everything is fastened

Main pump

DISMANTLING:

- *remove:*
  --hoses (3x)
  --connector
- screw the 4 screws loose under the mounting bracket
- let the pump run empty by holding it on the hood

ASSEMBLY:

- screw the pump tight with 4 screws
- *assemble:*
  --hoses
  --connector

Water reducer unit

DISMANTLE:

- *remove:*
  --supply hoses
  --turn the nut loose from the coupling on the filter unit, (open-ended spanner 30)
- remove the reducer
- remove the old sealing ring

ASSEMBLY:

- fit a new sealing ring on the coupling
- place new reducer
- tighten the nut
- set nut tight with the open-ended spanner

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Ventilators

DISMANTLING:

- disconnect plug next to the pneumatic unit
- make suction hoses loose
- unscrew the 4 socket screws on the rear side

ASSEMBLY:

- place the new ventilator
- tighten the 4 screws
- place the hoses and the plug back

Water supply

DISMANTLING:

- disengage water supply hoses
- loosen slave plug of the valve coil
- screw the nut on the underside loose

ASSEMBLY:

- place the replaced water supply
- place the plug back
- tighten the nut
- connect the hoses again

MAINTENANCE

After all modules and components of the major maintenance are replaced, the preventive maintenance procedure, Check/Calibration still has to be carried out, including the components.

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COMPLETION

System check

This check is intended to verify whether all connectors and connections have been placed back correctly.

Carry out this check according to the system check: see System.

Alignment

The alignment of the machine is carried out in accordance with the definition in Calibration Section.

Tests

- test the working of the pumps of the metering unit via the manual control
- place a tank with water in the machine and put the adaptor in
- set the soap or disinfectant pump "on" via the manual control
- one by one
- take the adaptor out of the tank, statement on screen (disinfectant or soap sensor high or defective) must now be omitted, repeat a few times
- reset the manual control

Note: When a pump runs well but does not prime, injecting a few drops of water from a syringe into the suction hose can help a "dry" pump to flow.

Validation

The machine is validated according to the validation procedure.

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Administration

Check whether the forms have been correctly signed, also by the client, in accordance with the instructions.

After signing the machine is officially released for use.

- attach a print-out of the 4 forms to the logbook
- fill in the master card of the logbook
- submit the original examples to the office employee

DRAFT

Chapter 5
CALIBRATION

PREPARATION

Filling in forms

MDS Maintenance report:
MDS Logbook: Master card:

LOGBOOK:

- Master card: enter the nature of the maintenance, date, name
- Filter replacement: name, date
- Metering calibration: take over values of the calibration report, name, date

Each item to be adjusted is mentioned on the maintenance form.

- For each item that is adjusted L and R, note the adjusted value on the form. This should fall within the tolerance value of the adjustment data.
- Note the value of the measured items which are also entered into the system settings of the management program. Do this for Left and Right.
- Note the number of items that are replaced on the form.
- Note an "_" at the items when:
  --this is not applicable.
  --is not adjusted.
  --is not replaced.

MDS SERVICE REPORT:

- Fill in the usual data as described in part 6 of the workshop manual.
- On this note the replaced components which are not mentioned on the forms:
  --maintenance set number.
  --number of the extra replaced components.

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Tools

- standard maintenance tool box.
- blood pressure meter 0-300 mmHg.
- scales to min. 2 Kg.
- graduating beaker of 2 liter.
- stopwatch.
- connector cable for sensor board.
- multimeter.
- temperature gauge.

Material

Precaution

Look for the following data of the apparatus to be adjusted:

- machine type
- serial number
- process diagram
- adjustment data

The data can be found in the logbook of the machine.

OVERVIEWS

This regulation describes the primary settings of the MDS. These should be checked and/or restored during the periodic maintenance and, when applicable, after a repair.

Operation overview

The settings of the machine include the activities below:
The procedure is described in the next procedure.

1. PS = Pressure switch
   - S11, S18 : leakage test
   - S10 : lift channel
   - S04, S09 : other channels
   - S02,S03,S24 : metering system
   - S12 : tank empty
2. R7 = Leakage test flow regulator
3. V1 = Leakage test overpressure regulator
4. AR = Compressed air reducer
   - R3 : leakage test
   - R4 : general
   - R5 : air tank
   - R6 : compressor
5. LR = Fluid reducer
6. RS = Reed switch
7. R8 = Cover flow regulator
8. PC = Pulse counter:
9. POC, POD, POZ = Disinfectant / soap / alcohol metering
10. PT 100 = Temperature calibration
11. CB = Guiding pins
    - S12 en S17 : tank sensors
12. CS = Leakage sensor
13. Draining
14. R2 = Channel regulator
15. LIO = Calibrations
    POE t/m POH = Single-Shot
16. S33 = air tank sensor

Sensors Diagram

Most MDS sensors must be calibrated. An overview of all sensor codes of the process diagrams, the type of sensor and the application with the MDS performance.

Based on the type of sensor the corresponding calibration description can be followed.

Figure 5 of the images gives the location of the sensors.

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Regulator overview

The regulators should be adjusted. Figure 6 of the images gives an overview of all regulators from the process diagrams and the application with the MDS performance.

Adjustment overview

A logbook is attached to each MDS.

It is possible that for an individual machine an adjustment deviates from the general setting. This deviating value and the reason for it is mentioned in the logbook.

Warning: Always use the calibration values as they are mentioned in the logbook of MDS.

Machine layout

In layout sketches are recorded with regard to the calibration, section:

MDS - Re-Use

Endoscope channel connections

The connections on the connector plate in the rinsing tank all have a specific function. The correct operation is essential for the functioning of the machine.

Figure 2 shows the plan of the rinsing tank. The number indicates the pillar position:

0 = leakage test of the endoscope

1 - 7 = endoscope channels

Figures 3 and 4 show the structure with the corresponding number of the access valve, and shows the corresponding access valves on the channel blocks.

Channel block sensors / slaves

On the channel blocks, the corresponding sensors, valves and slaves of the endoscope connections are confirmed. See chapter 1 and the corresponding figures 3 and 4.

Other adjustment points

These are spread throughout the machine.

The coding is in accordance with the overviews indicated in chapter 1 and the corresponding figures 5 and 6.

PROCEDURE

When there are several user applications for one sensor type, then a separate description for this is made.

PS = S12, & S24 Pressure switches

The pressure switches are mounted on the channel block and the metering unit. They are tested with the aid of a calibrated hand pump. During operation two switch points are important:
on switch point (higher value)
off switch point (lower value)

The status of the leakage test, - channels, - soap- and disinfectant sensor can be made visible in the "Signal Overview".
This screen can be reached via menu:

F1 for left unit
F2 for right unit

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ALIGNMENT (GENERAL)

Adjustment switch point

- the switch point is the value whereby when switching on the signal "1" is given. the switch is represented in the figure below.
- Connect middle and left contacts of the pressure switch.
- the relevant signal must stand at "0".If necessary unscrew the central screw.
- bring the switch to the desired pressure by using the bellow-pump.
- turn the central screw in (1) until the switch switches on:
- audible click sound
- on the screen is the signal overview: "1"

with this the highest (change up) switch-on point is set

ADJUSTMENT HYSTERESIS

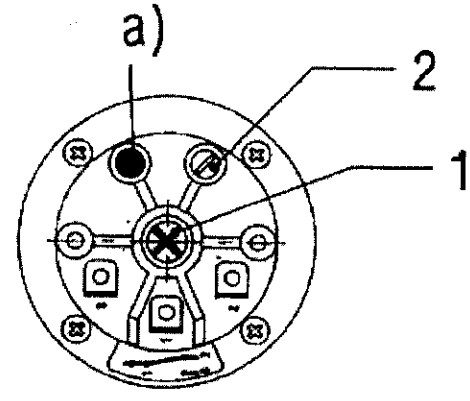
Hysteresis is the pressure difference between switching on and switching off points.

- apply pressure to the sensor
- let the pressure fall slowly to check the lowest (switch down) switching off point
- too low (pressure difference too big) then adjusting screw 2 should be turned more clockwise
- if necessary turn the central screw a little until the higher value is reached
- too high (pressure difference too small) then the adjusting screw should be turned counter-clockwise

TIP

Pump a few times to remove moisture from the hose.
Pump the bellow in stages just before the pressure to be adjusted is reached, stages of ± 10mm Mg, and wait 3 seconds each time to see whether you have changed the signal. This gives a better indication of the correct adjustment.

Note: Adjust screws 1 and 2 :
Don't fix with a sealing agent!



Note: Ventilations and blow-throughs of the bellow-pump occur because moisture via the leakage test system ends up in the endoscope !

Machine adjustment

The connections in the rinsing tank are connected to pressure switches on the flow blocks, see figures. The image also indicates which pillar must be used for the various settings.

S04 = Channel sensor

The switches are mounted on the channel block, right under the corresponding channel pillar.
By sliding a bellow-pump with manometer over a channel pillar, pressure on the system can be set in order to measure them.
- Slide the hose over the pillar
- Slowly pump up the bellow-pump

Also look at the screen signal: "channel sensor"
When the switch point is reached the signal is "green"
Check the switch value on the manometer of the bellow-pump
- ventilate the bellow-pump and check the fall-off point

When the value is not correct, then this should be corrected by turning the central screw (1), see figure on page 80.

S11 = Leakage test

To avoid moisture coming into the leakage test system the bellow-pump should be pumped through a few times.
Proceed further in accordance with the procedure of the channel sensor.

S10 = Lift channel

Adjustment lower than 300 mmHg:
- set valve 10 "on" with the manual control L or R Unit
- slide the hose of the bellow-pump over the pillar of the lift control
- adjust the sensor lift channel according to specification

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ADJUSTMENT HIGHER THAN 0.5 BAR.

The bellow-pump can not be used for this. Proceed as follows:
- place a connecting block with lift channel hose on the connector plate with pillars
- close off the lift channel hose with a bung
- set valves 10, 11 and valve H "on", L or R unit, via the manual control
- turn the "general" compressed air reducer down
- slowly turn the reducer up until the lift channel signal is "1"

- the value on the meter gives the switch-on value of the lift sensor. This must be the same as the adjustment data in the logbook. Adapt adjusting screw 1 of the pressure switch if the value deviates
- by turning the reducer slowly the switch-off point is visible on the screen: signal is "0" and on the pressure meter
  - repeat the on- and off-switches to check

S03, S24 = Metering system

See figures for the position of the disinfectant (d) and soap (s) pumps and sensors.

S03 = Soap sensor

IMPLEMENTATION

- place hose of the pressure meter on the metering nipple in the rinsing tank
- pump the bellows up slowly until the correct value is reached
- at the correct value the soap sensor signal is: "green"

S24 = Alcohol sensor

- set valves Y10 (lift) and Y11 (blowers) "on" via the expert control
- slide the hose of the bellow-pump over the pillar of lift channel 4.
- pump the bellow-pump up slowly, when the switch point is reached the signal S24 "green"
- check the switch value and re-adjust sensor
- repeat until the correct setting
- reset the expert control

R7 = Leakage test flow regulator

This regulator protects the endoscope against overpressure and is screwed in the channel block.

SETTING:

- screw in the flow regulator until ready + quarter turn back

TESTS:

- set the Y0F valve via the expert control: leakage test de-ventilate "on"
- slide the hose of the bellow-pump over the leakage test pillar
  - bellow-pump on pressure to 250mmHg
  - drop-off time to 50mmHg ± 4 sec : adjust by means of the central screw of the flow regulator.

V1 = Leakage test overpressure regulator

This regulator protects the endoscope against overpressure and is screwed in the channel block. There are two situations:

ADJUSTABLE MODEL:

- place hot-water block
- via expert control valve Y0E: leakage test "on"
- set reducer leakage test at 0.6 bar
- unscrew overpressure vent until it begins to blow off
- tighten lock nut

FIXED SETTING MODEL:

- place hot-water block
- via expert control valve Y0E: leakage test "on"
- turn the leakage test reducer slowly from 0 to 1 bar
  - at 0.5 bar the overpressure vent must blow off
  - when turning back from 1 to 0 the overpressure must close at 0.5 bar

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TESTS LEAKAGE DENSITY V1 :

Is applicable for both models.
- reset the valves and remove the block.
- slide the hose of the bellow-pump over the leakage test pillar
  - bellow-pump on pressure to 250mmHg
  - meter of the pump may not run back.

A.R. = Compressed air reducer

The meter values of the adjustment data are statistic values; no program active.

SETTINGS:

By turning the knob on the reducer, the settings change. The position of reducer and meter is represented in figure 6 of chapter 1.

CHECK:

When a meter is re-adjusted, then the system valves must first be opened, because after that the exact statistic value is read only when the valves are closed again.

R3 = ALIGNMENT LEAKAGE TEST

- set the valve E "on" via the expert control
- close off the leakage test pillar in the rinsing tank with a finger
- turn the meter if this deviates
- allow air to escape with the finger and check the new meter position
- repeat until the set value is reached

R4 = GENERAL ADJUSTMENT

- set valve H and H "on" via the expert control
- close valve H: "off" and check the new meter position
- turn the meter if this deviates
- repeat until set value is reached

R6 = ADJUST AIR COMPRESSOR

- turn off the tap of the air tank
- set the compressor on
- check whether the manometer of the tank increases. When tank is full:
- turn the reducer open
- turn off the reducer R6 until the manometer indicates the logbook value

L.R. = Liquid reducer

R1 = ADJUST WATER SUPPLY

- the water reducer is dynamically set
- place connecting blocks in each rinsing tank for the machine disinfection
- via the manual control valves 2 are: set to water supply "on":
- do this for the left and right units at the same time
- when the water flows, the reducer is set to the required value. See machine logbook

R2 = ADJUSTMENT CHANNEL PUMP REGULATOR

- adjust left and right separately
- via the expert control, set the drainage valve to "stop"
- fill the rinsing tank via valve 2 with 2 liters water
- place a connecting block in the rinsing tank, close cover
- "open" valve 5 and 6, set pump channels "on"
- turn reducer until the manometer R2 indicates the logbook value
- adjust other side
- reset the expert control

S13 = R.S. = Reed switch (cover working)

This is determined by the signaling position and open / closed movement.

COVER POSITION

The position of the cover sensor is signaled by a reed contact. The contact is activated by a magnet on the piston rod of the compressed air cylinder.

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ADJUSTMENT:

Message: "cover is open" must disappear in the closed movement when the cover is ± 1.5 cm above the closed position.

- place a block of ± 1.5 cm under the cover
- undo the reed contact bracket
- move the reed contact to the R: "cover is open" disappears from the screen
- check this for the closed movement
- re-adjust contact if necessary
- tighten bracket again

R8 = Cover flow

The movement of the covers is adjusted by means of two speed-control vents on the air cylinders. The covers should open and close easily.
When the covers close or open too slowly or not at all, then there are two possibilities:

1. Grease the lower points with silicone spray.
2. Adjust the control valve.

IMPLEMENTATION

Only carry out when the working of the cover demands it.

- adjust compressed air on system and pressure regulator according to the specification of the corresponding process diagram.
- close cover: adjust with lowest adjusting valve, first turn off completely and then unscrew 2 and a half turns.
- open cover: adjust with topmost shock-absorber, first turn off completely and then unscrew 1 turn.
- Tests:
  close cover: cover must be closed smoothly and not slammed, last piece cushioned.
  Open cover: cover must be opened smoothly and last piece cushioned.
- adjust pressure regulator to the value according to the specification (logbook). Covers must always be opened and closed well.
- adjust pressure regulator to 0.3 Bar lower. Covers close either good or not good. Covers must open well.
- reset pressure regulator to the correct value. Test the working of the covers again.

1280

COVER LOCK

With a locked cover the lock must prevent the cover being opened from the back.
Split front side of cover to max. 15 mm settings via movement of the adjusting plate on the back of the machine at the height of the cylinder.

Note: In a locked position the lock must not touch the adjusting plate.
Split clearance + 0.5 mm.

S14, S16 = pulse counter (metering calibration)

WATER METERING

The volume of the two flow meters can be calibrated at the same time.
Flow meter 1 = S14
Flow meter 2 = S16

Used for calculating the screen volume signal and old flank/liter value as they are mentioned in the S14 and S16 management application: Configuration, system parameters.

- start up the expert manual control
- select the left of right system unit
- block the working of the drainage valve
  - press right mouse button
  - click on drain
  - select "stop "
- activate water supply. This must be adjusted according to point 4.
- let the water in the tank flow.
- stop supply with the reset button as soon as the minimum sensor level S17 is high, see screen.
- note down immediately, before the rinsing tank is empty, the flank values of S14 and S16.
- find the volume-to-S17, left or right, in the logbook of the machine.
- The new flank value for the flow meter S14 and S16 is calculated as follows:

$$\frac{\text{(OLD FLANK VALUE) X (SCREEN VOLUME ml)}}{\text{(VOLUME-tos17 ml)}} = \text{NEW FLANK VALUE}$$

- note the new flank values of S14 and S16 on the maintenance form.

- A: POC, POZ = soap / alcohol metering:

With the help of the access code select the manual control screen of left unit.

- place the reservoir filled with alcohol on the scales.
- reset the scales to 0.
- screw the reservoir to the correct position in the machine.
- meter alcohol for 1 minute via the expert manual control.
- weight reduction is the metering per minute.
- calculate the weight reduction for the pump and note this in the maintenance report as follows.

(WEIGHT BEFORE) – (WEIGHT AFTER) = METERING (ml/min)

Repeat this procedure for:

- soap

Now select the manual control of right unit and repeat the procedure for:

- alcohol
- soap

Note the volume outputs in the maintenance report.

PT-100 = Temperature sensor

Using the access code select the expert manual control of left unit

- block the working of the drainage valve
  - press the right mouse button
  - click on drainage
  - select stop
- place a temperature gauge in the drainage pit.
- pour water of ~ 30 degrees in the tank. Let it stand for a few minutes.
- note the temperature deviation on the screen with regard to the meter on the form
- let the tank run empty.
- pour 200 ml water of ~ 80 degrees in the rinsing tank. Let it stand for a few minutes.
- note the temperature deviation on the screen with regard to the meter on the form.

Repeat the procedure for right unit.

Import the values of the maintenance report in the database of the machine.

Do this separately for left and right unit.

Note: TAKE CARE!! : values not imported well can result in incomplete disinfection.

- modify value in "management" program under:
  - systems
  - left or right
  - temperature correction:
- save setting
- close off "LI0" and start "LI0" again
- check by repeating the metering

S17 = Tank sensors

The tank full conduction sensor is specifically for the correct concentration of the disinfectant. The conduction sensor is adjusted to a fixed volume and proportion.
The tank empty pressure sensor is to check the idle times of the rinsing tank.

Note: TAKE CARE!! : This sensor is only used when the machine is connected to RO-water. When RO water is not used, an input contact of the sensor is disconnected.

CB = Conduction Pins

When the tank empty S12 and the tank minimum level S17 are performed as conduction pins then they must be adjusted to the sensor board. Use the measuring cable on J6 (tank empty) and J8 (minimum level) as represented in the figure below.

RED = Output
BLUE = Adjusted voltage
BLACK = Mass

Note: Take care with the settings of the sensor to the orientation of the sensor board !

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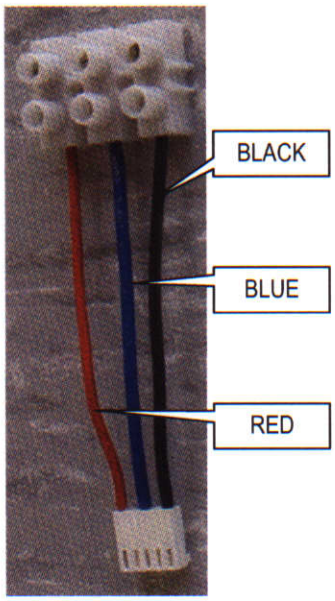
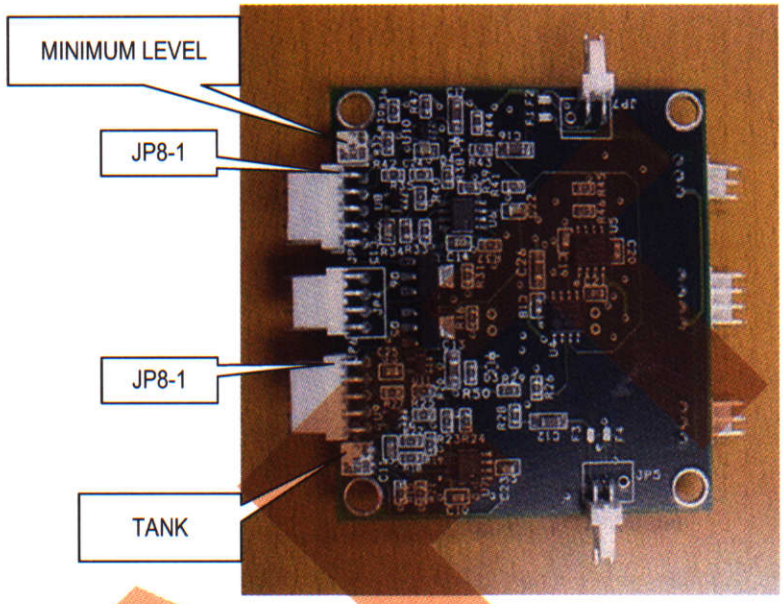


Test cable



Sensor board

A volt meter measures the voltage on the mass and the output (pin 5 and 1).
When the measuring pins are dry the voltage will be +/- 12V. When the pins are completely immersed under water then the voltage will be around 9V.

The voltage where the board must be switched on must then be (12+9)/2 = 10.5V
Now connect the voltage meter to the pin 5 and pin 3 and turn on the potentiometer until you measure 10.5V.

This measurement must be carried out for J6 and J8.Immediately next to the connector for the plug of the measuring cable, a small potentiometer can be found on the print. With this the set value is set.

If the switch voltage is on the high side, for example more than 11V, then look whether the screws stick out at least one millimeter. The more the screw makes contact with the water, the lower the voltage will be.

DRAFT

PROCEDURE:

All values can be measured during a full cycle. Proceed as follows:
- remove the cap from the sensor board and place two nuts back.
- connect the plug of the measuring cable to the J6=tank empty S12 connector.
- note the voltage if the sensor is empty.
- set the drain to <STOP> and let the tank fill via valve 2.
- when the voltage meter is steady again, then note the sensor is high value.
- move the plug to the JP8 = minimum level S17 connector on the sensor board.
- note the minimum level sensor is low voltage.
- when the voltage meter is steady again, then note the sensor is high value.
- do a general reset of the expert control.
- calculate the average value of both sensors.
- move the + measuring pin (red) of the voltage meter to pin 3 on the measuring cable (middle).
- screw tight the potentiometer of sensor JP8 = S17 until you measure the calculated voltage value.
- move the plug of the measuring cable to the other sensor connector.
- screw tight the potentiometer of sensor JP6 = S15 until you measure the calculated voltage value.
- after this the print must be well aligned. Check the working with a test-run.

IMPORTANT !! :
Note the adjusted voltage values on the maintenance report of the left and right units:
JP6 = S12 = tank empty.
JP8 = S17 = tank minimum.

S90 = CS = Leakage sensor

On the back of the capacitive sensor there is a small adjusting screw. Use a Micro screwdriver.
Sensor is high when the LED is lit.

ADJUSTMENT:

sensor high, by pressing finger on green sensor face.
sensor drops off with releasing sensor.

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Y01 = Drainage discharge

- ensure that the machine is connected to the drain.
- fill the rinsing tank with 5 liters water, set to "stop" via valve 1 and "on" via valve 2 of the expert control.
- press the "release all" button and measure the time until the tank empty sensor drops.
- divide the time by 5 and mention this in the maintenance report.

R2 = Channel regulator

- place machine cleaning block.
- set valve 1 to "stop" via the expert control.
- let 3500 ml water run into the tank via valve Y02 and Y90 (supply).
- pull the button of the regulator up and turn this completely open.
- close the lift valve Y10.
- set the channel pump POA "on" and spray valve Y03.
- turn the regulator tight until the manometer result lies between 15 and 18 psi.
- set channel air Y04 "on" and lift Y10 "off".
- set channel Y04 "off" and Y10 "on" channel block is filled with water.
- close the sprayer valve Y03.
- open the sprayer and close again after 10 sec.
- pump pressure against fixed volume.
- adjust regulator higher or lower to 24 ± 1 psi.
- open and close sprayer valve to check.

Lock the button of the regulator and press on "Release All" button of the expert control.

DRAFT

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ADMINISTRATION

End check

Check whether all data on the master card and maintenance report has been filled in and corresponds with the system settings in the management program.

System settings

All settings on the applicable MDS type must now be imported via the management program. The values should taken up from the maintenance report.

Warning: The program can no longer be changed. Access is only obtainable via a code!!!! Changing the program settings can cause system faults.
All settings which are filled in on the check list should be signed for approval.

- Activate "Management" in the program via the maintenance access code.
- Select the: "Configuration" application.
- Change the applicable data from the maintenance report:
  - systems
  - left or right
  - disinfectant yield (ml/min)
  - soap yield (ml/min)
  - alcohol yield (ml/min)
  - water supply (ml/min)
  - water yield S14 (fl/min)
  - water yield S16 (fl/min)
  - save setting
  - close "LI0" and start "LI0" again
  - check by repeating the measurement

Completion

- let the maintenance report be signed by the client to release the machine.
- fill in the logbook.

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Chapter 6

SYSTEM CHECK

PREPARATION

Filling in forms

System check MDS
Logbook MDS: master card

On the system check form, each item to be adjusted is mentioned.
Note "OK" on the form for each item that is checked and found to be good.
Do this for left and right.

Tools

1/2/4-8-001: instruments connecting block

Material

Precaution

Couple the machine completely to:
- 120V
- supply water
- drain water
- compressed air

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PROCEDURE

Mechanical procedure

The inspection actions to be carried out are below.
The results of all check points are noted on form: System check

In addition there is still the possibility to note remarks/criticisms.

EXTERIOR INSPECTION

- connections of the various housing parts to each other
- finishing of adhesive seams of glass plates and rinsing tanks
- dirt on or in the machine

INSPECTION OF DOORS AND PANELS

Working and relcasability of :
- foot-caps and side-caps
- back panels
- door and cover

These must be moved gently or be removed with little effort.

WIRING INSPECTION

The convenient arrangement, safety and reach ability of components is determined by the positioning of the wiring.
- bundled as much as possible
- concealed as much as possible
- no sharp edges

INSPECTION OF HOSES

- couplings not to tightly screwed (2 mm leeway)
- no sharp edges

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OTHER INSPECTIONS

- check whether the nuts of inserts in the rinsing tank are firmly screwed in
- check whether all connectors on the air and fluid valves are screwed tight.

Procedure control

All in- and outputs should be checked one by one for good operation. The check can be carried out visually or audibly.
Carry out procedure first for left unit and then for right unit.

The tests of the outputs contain the activities below:

FILLING IN FORM

Each step should be signed on the check form immediately after implementation.

CHECK OUTPUTS

The outputs can be guided via the expert control of the LIO program.
For this click on the icon in the upper right-hand. After login and selection the expert screen appears.
Note: De-activate the output after each test handling and before starting the next.

First do the guidings of left unit and then right unit. The reaction of the outputs are described in the checks below.

Proceed as follows:
- set the output to be inspected to "on = red ", by double-clicking the track pad
- check whether the reaction is according to the description
- note: - "OK" when component reaction conforms to the description
  - "N.A." when the component is not applicable to the machine operation
  - "ERROR" when component reaction is wrong or does not take place
- set the output to "off" (double-click)
- set the next output to be inspected to "on"
- repeat this until all outputs have been inspected.

CHECK INPUTS

The inputs can be read via the keyboard-option:
F1 for left unit
F2 for right unit
First carry out the check of left unit and then the right unit
Proceed as follows:
- carry out the signal handling
- check whether the correct system signal changes from "0" to "1 = green"
- note reaction on inspection form
- repeat this until all inputs have been inspected

Note: an "ERROR" reaction in the "conclusion / deviations" field:
- check number, relevant component code and description

CONNECTION BLOCK

The check can better be carried out with a test block with closed leakage test connection or instruments block. Place this block in the rinsing tank of both units.

CHECKS

At each check a number of in- and outputs are tested in a small circuit. After the part test, these can be signed as "OK".

LIQUID VALVES: CHECK 1 + 2

These valves have a connector which is equipped with two LED's. When the valve is addressed these LED's light up. It can also be seen that the plunger is pulled into the solenoid. A click is then audible. The position of the connection to the blocks is essential for the functioning of the machine. Pay attention to this at the inspection. Figures 2, 3 and 4 show the valve numbers and their positions.

SUPPLY CHECK 1

- set valves Y90 and Y02 "on", water flows into the rinsing tank. Volume sensor S14 and S16 indicate an increasing value.
- when sensor S12 is "high" then the drain opens.
- set valve Y01-drain to "stop" via the right mouse button.
- valve 2 closes itself and tank proceeds to fill.

- let tank run full to the min. Sensor S17 is "high".
- set valves Y90 and Y02 "off".
- go to channel check 2.

CHANNEL CHECK 2

- set valves Y04 and Y10 and pump POA "on", water flows via the block connection.
  - air and sensor S04 air is "high".
- set valve Y05 "on" and Y04 "off". Water flows via the block connection.
  - biopsy and sensor S05 biopsy is "high".
- set valve Y06 "on" and Y05 "off", water flows via the block connection.
  - jet and sensor S06 jet is "high".
- set valve Y07 "on" and Y06 "off", water flows via the block connection.
  - extract and sensor S07 extract is "high"
- set valve Y08 "on" and Y07 "off", water flows via the block connection.
  - water and sensor S08 water is "high"
- set valve Y09 "on" and Y08 "off", water flows via the block connection.
  - extra and sensor S09 extra is "high"
- set valve Y10 "off" and Y09 "off", water flows via the block connection.
  - lift and sensor S10 lift is "high"
- set valve Y10 "on" and Y03 "on", water flows via sprayer.
- press the "Release all" button in the expert control. Rinsing tank runs empty and all outputs are "empty".
- go to air valves check 3 and 4.

LIQUID SENSORS

As an alternative for check 2, the working can be checked by putting the system under pressure with a bellow-pump. In the signal overview the relevant input must then be high = "green". Putting it under pressure is carried out by sliding the hose of the pump on the relevant "metering nipple" or "pillar" on the connecting plate. See figure 2, 3 and 4 for the position of the pillars and nipples. Proceed as follows:

LEAKAGE TEST: S11 + S18

- slide the hose on the pillar in the rinsing tank
- pump bellow: leakage test signal is "green"

CHANNELS: S04-S05-S06-S07-S08-S09

- place the hose on the pillar in the rinsing tank jet, biopsy, air, water, extract

- pump bellow: channel sensor signal is "green"

LIFT: S10

- set valve 10 "on" via the manual control
- slide the hose on the pillar: lift control
- pump bellow (to 300 mmHg): lift sensor signal is "green"
- when this is not the case: unscrew the central knob until signal is "green"

SOAP: S03

- place hose on dosering nipple in the rinsing tank
- pump bellow: soap sensor signal is "green"

AIR VALVES: CHECK 3 + 4

When an air valve is activated then it is visible through a mechanical indicator on the underside of the valve block. A soft 'tick' is also audible. Repeat this a few times

Inspection occurs through checking the system reaction
Make sure: set air reducer:

- GENERAL 2.5 bar
- leakage test : 0.5 bar
- air tank: 2.5 bar

Air block check 3:

- set valve blowers Y0H + Y10 + Y11 "on" air blows out the lift connection.
- set valve cover Y0D "on" cover opens and cover sensor S13 is "low".
- set valve Y0D "off" cover closes and sensor S13 is "low".
- set valve leakage test Y0E "on" after some time the leakage test sensor S11 is "high".
- set valve Y0E "off".
- set valve ventilate Y0F "on" sensor S11 is "low".
- set valve leakage test: 2 Y0I "on" after some time leakage test sensor S18 is "high".
- set valve Y0I "off".
- set valve Y0J "on" sensor S18 is "low".
- remove the air hose of the lift pump.
- set valve lift pump Y0G "on" air flows from the hose.
- press "Release all" button.

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Dosering check 5:

- place disinfectant tank at red socket.
- set disinfectant pump POD "on". Pump turns "on" and after ± 30 sec. the tank empty sensor is "high", disinfectant sensor S02 is "high".
- set pump P0D "off".
- remove the soap container and place full container back. Soap empty sensor S22 is "high".
- set soap pump P0Z "on" sensor soap S03 is "high", liquid flows in the tank.
- set pump P0Z "off".
- remove the alcohol container and place back full. Alcohol sensor S23 is "high".
- set alcohol pump P0C and valves Y11 and Y10 "on: sensor alcohol S24 is "high", liquid flows in the tank via the lift connection.

Disinfectant check 6:

- tank is empty: stock tank. Sensors S19 + S20 + S21 are "low".
- remove the sensor unit from the tank.
- move the 3 drivers one by one over the holder so that tank sensors S19 + S20 + S21 are "high".
- place the sensor unit back.
- set valves Y90 + Y02 + Y12 "on".
- set valve Y01 via mouse button to "stop". Water flows in the stock tank, sensor S19 is "high".
- after 30 sec. press "Release all" button.
- set disinfectant pump P0D and supply valve Y13 "on", liquid flows in the rinsing tray.
- when air is lightly pumped, press the "Release all" button.

Other sensor check 8:

- hold a wet cloth against the leakage sensor S90. Sensor S90 is "high".
- fill the tank with 1 liter water via valve Y90 and Y02 valve drain to "stop".
- set the heater "on" temperature sensor U01a and U01b run on.
- pressure after 1 min. on the "Release all" button.
- operate the foot-switch S15. Cover opens and sensor S13 is "high".

LED working:

- remove the comm. cable from the AS-i master on the back of the PC
- the two LED's must be red
- place the cable back
- start up left program 00-instr
- LED left is "green"
- stop the program
- LED left is "red"
- repeat process for right unit

DEVIATIONS

When an output does not function or an input does not react then the relevant component must be repaired or replaced.

After the repair the relevant system check should be repeated.

COMPLETION

Approved:

- note this as conclusion
- initial the form and attach it to the machine logbook

Rejected:

- note this as conclusion
- machine is provided with a "REJECTED" label

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Chapter 7
TECHNICAL VALIDATION (CONCEPT)

PREPARATION

Filling in forms

- Calibration report
- Validation report

Tools

- Standard maintenance tool box
- Pressure meter with bellow to 300mmHg.
- Printer
- Validation cassette

Precaution

Make an appointment around 4 weeks beforehand so that the machine is available from day 1.

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PROCEDURE

Regular validation is necessary in order to guarantee a reproducible disinfection result.
The disinfecting capability of the machine is determined by the rinsing principle, in combination with the disinfection program and the checks on the process parameters. The disinfection process is validated with a working machine with the correct settings.

The technical validation of the MDS provides for the checking of these parameters by means of external measuring aids. With deviations the setting should be corrected. Afterwards the system checks are tested.

Warning: All adjustment values and alignment procedures should be accurately followed up. Some adjustments are set in relation to each other. One incorrect adjustment can dislocate various control functions.

Note: This manual describes the system reactions as they must be according to the specification. When a setting does not conform to the adjustment data then this should first be adapted before the physical tests are carried out.

Note: The settings of the software, regulators, sensors and switches are described in separate instructions.

The validation / calibration includes the following activities:

DATA

The machine details necessary for this instruction are:

VERSION NUMBER :

A. machine
B. Software

SETTING DETAILS SEE:

A. logbook machine
B. service handbook

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PROCESS DIAGRAM SEE:

A. logbook
B. service handbook

ACTIVITIES

Below is an overview of the activities to be carried out:

1 Filling in report
2 General settings
  - alignment
  - valve working
3 Physical tests
  - normal test run / release
4 Print-out details
5 End check
6 Completion
7 Archiving

FILLING IN REPORT

At the validation / calibration, two forms are filled in.
The first part is: MDS maintenance report.
The second part is: MDS system check.
These are general forms. Depending on the implementation of the apparatus some settings or tests are not applicable.

GENERAL SETTINGS

1 ADJUSTMENT

AIM: Bringing the sensors and adjustment points of the machine within the specifications.
Implementation: Carry out the adjustment of the machine according to instruction manual:
Calibration

2 SYSTEM CHECK

AIM: Check all inputs and outputs are working properly.
Implementation: Carry out the check of the machine according to the instruction manual:
System check

PHYSICAL TESTS

AIM: The physical tests concern the process flow of the apparatus. During these tests the process steps and the sensor working are checked for correct operation. Disinfectant is applicable with all tests.

Note: Use should be made of the standard program times

NORMAL TEST RUN / RELEASE

AIM: Check the working of the apparatus with an arbitrary scope.
Release by showing that the machine works without error.

IMPLEMENTATION:

Let the machine run a normal program on left and right units.
- connect the validation cassette to the machine
- supply scope code in MDS test
- enter at 'operator' your own name
- start left unit
- repeat for right unit
- fill in run numbers on the form at "normal run"

RESULT:

- system should complete the rinsing process normally without disturbances
- statement on screen: disinfection finished

PRINTING OUT DETAILS

AIM: recording the test details

IMPLEMENTATION:

- select the printer option via the report menu
- print report of all tests carried out
- attach print report to the validation report

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END CHECK

Check whether:
- all data has been filled in on the form
- all reports are printed out

COMPLETION

The form : Validation report signed by the client. With this, the machine is officially released for used. Attach the print-out of the form to the enclosures and put these in the logbook of the machine.

- attach a print-out of the forms in the logbook.
- fill in the master card of the logbook.
- submit the original examples of the form and the enclosures to the office employee of Minntech.

ARCHIVING

Executor: employee internal service

DRAFT

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DRAFT

DRAFT

Manufactured in the USA by:
MEDIVATORS®
REPROCESSING SYSTEMS
A Minntech Corporation Business Group

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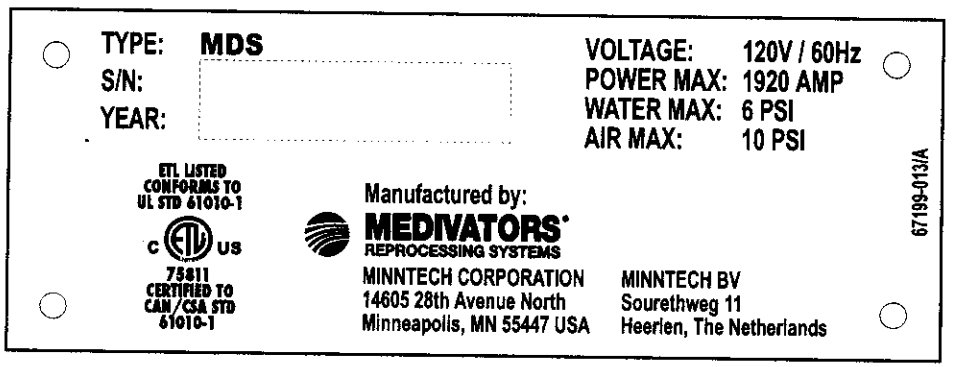
Appendix G


TYPE: MDS
S/N:
YEAR:
VOLTAGE: 120V / 60Hz
POWER MAX: 1920 AMP
WATER MAX: 6 PSI
AIR MAX: 10 PSI
ETL LISTED
CONFORMS TO
UL STD 61010-1
c ETL us
75811
CERTIFIED TO
CAN/CSA STD
61010-1
Manufactured by:
MEDIVATORS
REPROCESSING SYSTEMS
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14605 28th Avenue North
Minneapolis, MN 55447 USA
MINNTECH BV
Sourethweg 11
Heerlen, The Netherlands
67199-013/A

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Appendix H

REVISIONS					
REV.	DESCRIPTION	ECO	DRW BY	APPR	DATE
	SEE SHEET 1				

DIRECTIONS FOR USE: It is a violation of Federal (U.S.A.) Law to use this product in a manner inconsistent with its labeling. Read the package insert for more detailed information.

CLEANING/DECONTAMINATION: Medical devices must be thoroughly cleaned of blood and other body fluids before sterilization or high-level disinfection with Rapicide. See labeling of the reusable device for additional cleaning and decontamination. Select an enzymatic detergent that is low foaming, neutral in pH, and is easily rinsable. Improper rinsing may affect Rapicide efficacy.

STERILIZATION: Rapicide is intended to be used for the automated sterilization of heat sensitive critical medical equipment for which alternative sterilization methods are not suitable. Placed devices into an Automated Endoscope Reprocessor (AER) in accordance with the manufacturer's instructions. Select a validated sterilization cycle that provides for a minimum sterilant contact or immersion time of 7 hours and 40 minutes at 35°C (95°F) at a minimum concentration of 1.5% Glutaraldehyde. Select an adequate rinse cycle with bacterial-retentive filtered, potable water.

HIGH LEVEL DISINFECTION: Rapicide is intended to be used for the automated high level disinfection of heat sensitive semi-critical medical devices for which sterilization is not practical. Place devices into an AER in accordance with the manufacturer's instructions. Select a validated high-level disinfection cycle that provides for a minimum disinfectant contact or immersion time of 5 minutes at 35°C (95°F) at a minimum concentration of 1.5% Glutaraldehyde. Select an adequate rinse cycle with bacterial-retentive filtered, potable water.

REUSE PERIOD: Rapicide may be used and reused for 28 days provided the glutaraldehyde concentration remains above 1.5%. Always monitor the glutaraldehyde concentration prior to use. **Do not use beyond the expiration date on the product label or the 28 day reuse period even if the concentration is above the minimum concentration.** Maintain the solution at 35°C over the 28-day reuse period.

⚠ READ CASE INSERT FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

Rapicide®

HIGH-LEVEL DISINFECTANT AND STERILANT

- **Ready to Use**
- **No Activation Required**
- **28-Day Maximum Use Life**

FOR USE IN REPROCESSING FLEXIBLE FIBEROPTIC AND VIDEO ENDOSCOPES IN LEGALLY MARKETED AUTOMATED REPROCESSORS ONLY

PRECAUTIONARY STATEMENTS:

HAZARD TO HUMANS AND DOMESTIC ANIMALS

Direct contact is corrosive to exposed tissue, causing eye and skin damage. Do not get in eyes, on skin or clothing, and avoid breathing the fumes. Avoid contamination of food. Wear protective eye covers and Nitrile gloves when handling or pouring.

STATEMENT OF PRACTICAL TREATMENT:

In case of contact, immediately flush eyes or skin with copious amounts of water for a least fifteen (15) minutes. Get medical attention for eye contact. Harmful if swallowed. Drink large quantities of water and call a physician immediately. *Note to Physician:* Probable mucosal damage may contraindicate gastric lavage.

ACTIVE INGREDIENTS:

Glutaraldehyde	2.5%
Inert Ingredients	97.5%
Total	100.0%

NET CONTENT:
1 U.S. Gallon
(3.8 Liters)

KEEP OUT OF REACH OF CHILDREN

DANGER

Manufactured in U.S.A. for:
MEDIVATORS® REPROCESSING SYSTEMS
A Minntech Corporation Business Group

14605 28th Avenue North
Minneapolis, MN 55447
Phone: (763) 553-3300
Toll Free: (800) 328-3342
Fax: (763) 553-2496
Website:www.minntech.com

CE 0050

4 X 1 Gallon bottles per case
Product Code: ML02-0059
© Minntech Corporation, 2002

U.S. Pat. Reg. No. 4,748,279

USER PROFICIENCY: The user should be adequately trained in the decontamination and disinfection or sterilization of medical devices and handling of toxic substances such as liquid chemical germicides.

STORAGE AND DISPOSAL: Store at controlled room temperature 15°C-25°C (59°F-77°F). Once opened, the contents of container should be immediately used, with any unused portion being discarded. Discard residual solution according to local, state, and federal regulations. Do not reuse empty container. Triple rinse with water and dispose in an incinerator or landfill approved for pesticide containers. For additional information regarding the safety and effectiveness of Rapicide call 1-800-328-3340.

PRECAUTIONS:

1. *Sterilant Usage:* Routine biological monitoring is not feasible with Rapicide and therefore Rapicide should NOT be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g. heat, ethylene oxide, or gas plasma.
2. *High-Level Disinfectant Usage:* Rapicide should NOT be used to high-level disinfect a semi-critical device when sterilization is practical.
3. *Endoscope Usage.* Rapicide is not the method of choice for sterilization of rigid endoscopes that the reusable device manufacturer indicates is compatible with steam sterilization. Rapicide may be used for flexible endoscope reprocessing if a validated protocol for automated rinsing and leak testing is employed. Contact the instrument manufacturer if there are doubts about the compatibility of Rapicide and the instrument.
4. Nitrile gloves, eye protection, face masks and liquid proof gowns should be worn when cleaning and sterilizing/ disinfecting soiled devices.
5. The user is cautioned to minimize exposure to vapors at elevated temperature by using Rapicide in an AER with an effective vapor containment system and placed in a well-ventilated area.
6. Contaminated reusable devices MUST BE THOROUGHLY CLEANED prior to disinfection or sterilization, since residual contamination will decrease effectiveness of the germicide.
7. The user MUST adhere to the Direction for Use since any modification will affect the safety and effectiveness of the germicide.
8. The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using Rapicide.
9. The use of Rapicide in Automated Endoscope Reprocessors must be part of a validated reprocessing procedure supplied by the AER manufacturer to ensure that a minimum contact or immersion time is achieved per the directions on this label and the package insert.
10. Use 3M Comply, Cold Sterilog 1.5% Glutaraldehyde Monitor, Cat. No. 3983MM, chemical indicator strips to monitor glutaraldehyde concentration prior to reprocessing in order to detect unexpected dilution.

67198-525/C

WORD DOCUMENT CONFIDENTIAL AND PROPRIETARY DISCLOSURE OR REPRODUCTION PROHIBITED RETURN REQUIRED UPON DEMAND	THIRD ANGLE PROJECTION	TITLE LABEL, BOT RAPICIDE 1 GAL CE	
MINNTECH 14605 28th AVENUE NO. MINNEAPOLIS, MINNESOTA 55447-4822	UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES X ± .XX ± .XXX ± ANGLES ±	SIZE B 11X17	SCALE = DRAWING SCALE DO NOT SCALE DRAWING SHT 2 OF 2
		DOC. NO. 67198-525	REV. C

1306

Cidex® OPA

ortho-Phthalaldehyde Solution

high level disinfectant for semi-critical medical devices

Active Ingredient	
ortho-Phthalaldehyde	0.55%
Inert Ingredients	99.45%
Dipotassium hydrogen phosphate	
Potassium dihydrogen phosphate	
Benzotriazole	
Citric acid	
D&C Green Dye #5	
N-(hydroxyethyl)-ethylenediaminetriacetic acid (HEDTA)	
Total	100.00%

Does not require activation before use.

INSTRUCTIONS FOR USE

Intended Use: CIDEX® OPA Solution is a high level disinfectant for reprocessing heat sensitive reusable semi-critical medical devices, for which sterilization is not feasible, and when used according to the Directions for Use. CIDEX OPA Solution is intended for use in manual (bucket and tray) systems made from polypropylene, acrylonitrile-butadiene-styrene (ABS), polyethylene, glass-filled polypropylene and/or polycarbonate plastics. CIDEX OPA Solution may also be used in automated endoscope reprocessors according to the manufacturer's instructions and should be monitored with CIDEX OPA Solution Test Strips. See DIRECTIONS FOR USE – Reusage for Disinfection.

The semi-critical medical devices reprocessed in CIDEX OPA Solution must first be cleaned according to a validated cleaning protocol or standard, such as the ASTM F 1518 "US Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera."

Indications for Use: CIDEX OPA Solution is a high level disinfectant for reprocessing heat sensitive semi-critical medical devices, for which sterilization is not suitable, and when used according to the Directions for Use.

Manual Processing: High Level Disinfectant at a minimum of 20°C (68°F). CIDEX OPA Solution is a high level disinfectant when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by CIDEX OPA Solution Test Strips, with an immersion time of at least 12 minutes for a reuse period not to exceed 14 days.

Automatic Endoscope Reprocessors that can be set to a minimum of 25°C: High Level Disinfectant at a minimum of 25°C (77°F). CIDEX OPA Solution is a high level disinfectant when used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum of 25°C) according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by CIDEX OPA Solution Test Strips, with an immersion time of at least 5 minutes for a reuse period not to exceed 14 days.

Note: If your AER cannot be set to a minimum of 25°C please follow the time and temperature stated in Indications for Use, Manual Processing.

Minimum Effective Concentration (MEC): 0.3%.

Reuse Period for Disinfection: CIDEX OPA Solution has demonstrated disinfection efficacy in the presence of 5% organic soil contamination and microbiological burden during reuse. CIDEX OPA Solution may be reused for up to a maximum of 14 days provided the required conditions of *ortho*-phthalaldehyde concentration and temperature exist based upon monitoring described in the Directions for Use. DO NOT rely solely on days in use. Concentration of this product during its reuse life must be verified by the CIDEX OPA Solution Test Strip prior to each use to determine that the concentration of *ortho*-phthalaldehyde is above the MEC of 0.3%. The product must be discarded after 14 days, even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC.

General Information on Selection and Use of Germicides for Medical Device Reprocessing: Choose a germicide with the level of antimicrobial activity that is appropriate for the reusable device. Follow the reusable device labeling and standard institutional practices. In the absence of complete instructions, use the following process:

First, for patient contacting devices, determine whether the reusable device to be reprocessed is a critical or semi-critical device.

***Critical device:** Presents a high risk of infection if not sterile. Routinely penetrates the skin or mucous membranes during use or are otherwise used in normally sterile tissue of the body.*

***Semi-critical device:** Makes contact with mucous membranes but does not ordinarily penetrate normally sterile areas of the body.*

Second, determine if sterilization or high level disinfection is required.

***Critical device (e.g., cardiac catheters, scalpels, surgical instruments):** Sterilization is required.*

***Semi-critical reusable device (e.g., endoscopes):** Sterilization is required whenever feasible; where not feasible, high level disinfection is the minimum acceptable process.*

Third, select a germicide that is labeled for the appropriate germicidal level and is compatible with the reusable device. Follow directions for the germicide.

Microbicidal Activity: The following table indicates the spectrum of activity as demonstrated by testing of CIDEX OPA Solution using prescribed test methods.

MICROORGANISM
VEGETATIVE ORGANISMS
Staphylococcus aureus
Salmonella choleraesuis
Pseudomonas aeruginosa
Mycobacterium bovis
FUNGI
Trichophyton mentagrophytes
VIRUSES
NON-ENVELOPED
Poliovirus Type 1
Rhinovirus Type 42
Adenovirus Type 2
Vaccinia (Wyeth)
Coxsackievirus Type B-3
ENVELOPED
Coronavirus
Cytomegalovirus
Influenza Virus [Hong Kong]
HIV-1
Herpes simplex Types 1,2

To qualify CIDEX OPA Solution as a high level disinfectant, the reused solution passed the AOAC Sporicidal Activity Test in 32 hours at 20°C and in 32 hours at 25°C.

Material Compatibility: CIDEX OPA Solution has been tested and found to be compatible with the materials shown below.

METALS[1]	PLASTICS[4]
Aluminum	Polymethylmethacrylate (Acrylic)
Anodized aluminum[2]	Nylon
Brass	Polyethylene terephthalate (Polyester)
Carbon steel	Polystyrene
Chrome plated brass[2]	Polyvinylchloride (PVC)[6]
Chrome plated steel[2]	Acrylonitrile/butadiene/styrene (ABS)
Copper	Polysulfone
Nickel plated brass[2]	Polycarbonate[7]
Nickel silver alloy[2]	Polyethylene
Stainless steel[3]	Polypropylene
Titanium	Acetal
Tungsten carbide[2]	PTFE
Vanadium steel[2]	Polyamide

ELASTOMERS[4]
Polychloroprene (Neoprene)
Kraton G
Polyurethane
Silicone rubber[8]
Natural Rubber Latex

ADHESIVES[5]
Cyanoacrylate[6]
EPO-TEK 301 Epoxy[5]
EPO-TEK 353 Epoxy

1. Exposed to 31 days (744 hours) of continuous contact with CIDEX OPA Solution with no effect unless otherwise noted.
2. Shows signs of surface discoloration at 7 days or greater.
3. Most grades tested show no effect. Others may exhibit slight discoloration at 7 days or greater. Stainless steel 440 shows rust at 14 days immersion.
4. Treated with 500 cycles of CIDEX OPA Solution. Surface breakdown noted after 150 cycles (25 hour total contact).
5. Exposed 7 days of continuous contact with CIDEX OPA Solution with no effect unless otherwise noted.
6. Some grades or applications exhibit discoloration.
7. Some sonic welded parts may exhibit crazing.
8. Some loss in shear strength but show no signs of severe degradation.

Olympus, Pentax, and Fujinon endoscopes are compatible with CIDEX OPA Solution.

If questions arise regarding the compatibility of a device with CIDEX OPA Solution, contact the device manufacturer.

Cleaning Agent Compatibility: CIDEX OPA Solution is compatible with enzymatic detergents which are mild in pH, low foaming, and easily rinsed from equipment (e.g., ENZOL® Enzymatic Detergent). Detergents that are either highly acidic or alkaline are not recommended as cleaning agents.

CONTRAINDICATIONS

1. CIDEX OPA Solution should not be utilized to process any urological instrumentation used to treat patients with a history of bladder cancer. In rare instances CIDEX OPA Solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.
2. CIDEX OPA Solution should not be utilized to process instrumentation for patients with known sensitivity to CIDEX OPA Solution or any of its components.
3. CIDEX OPA Solution should not be used to sterilize heat sensitive medical devices. When sterilization by a biologically monitorable process is not feasible, high level disinfection of rigid endoscopes is recommended by the Centers for Disease Control and Prevention (CDC) and the Association for Professionals in Infection Control and Epidemiology (APIC).

WARNINGS

1. May elicit an allergic reaction. Possible allergic reactions have been reported in rare instances. In the majority of these instances health care workers were not using the product in a well-ventilated room or not wearing proper personal protective equipment. (See PRECAUTIONS).
2. Avoid contact with eyes, skin, or clothing. (See PRECAUTIONS – for important information on how to protect eyes, skin and clothing.) Direct contact with eyes may cause irritation. Direct contact with skin may cause temporary staining. Repeated contact with skin may cause skin sensitization. In case of eye contact, immediately flush eyes with large quantities of water for at least 15 minutes. Seek medical attention. In case of skin contact, immediately wash with water. Refer to the MSDS for additional information. Do not form sprays, mists or aerosols of this product.
3. Avoid contamination of food. Ingestion may cause irritation or chemical burns of the mouth, throat, esophagus and stomach. If swallowed, DO NOT INDUCE VOMITING. Drink large quantities of water and call a physician immediately. Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.
4. Avoid exposure to *ortho*-phthalaldehyde vapors, as they may be irritating to the respiratory tract and eyes. May cause stinging sensation in the nose and throat, discharge, coughing, chest discomfort and tightness, difficulty with breathing, wheezing, tightening of throat, urticaria (hives), rash, loss of smell, tingling of mouth or lips, dry mouth or headache. May aggravate a pre-existing asthma or bronchitis condition. In case of adverse reactions from inhalation of vapor, move to fresh air. If breathing is difficult, oxygen may be given by qualified personnel. If symptoms persist, seek medical attention.
5. The use of CIDEX OPA Solution with semi-critical devices must be part of a validated rinsing procedure as provided by the device manufacturer. See DIRECTIONS FOR USE Rinsing Instructions – for important information on rinsing.
6. ALWAYS follow the Directions For Use Rinsing Instructions (Part B) and the SPECIAL INSTRUCTIONS for transesophageal echocardiography (TEE) probes in Part C EXACTLY or residues of CIDEX OPA Solution may remain on the device. Failure to follow rinsing instructions exactly has resulted in reports of chemical burns, irritation, and staining of the mouth, throat, esophagus and stomach.

PRECAUTIONS

Follow OSHA Bloodborne Pathogens Universal Precautions when handling and cleaning soiled devices.

1. When disinfecting devices, use gloves of appropriate type and length, eye protection and fluid-resistant gowns. When using latex rubber gloves, the user should double glove and/or change single gloves frequently, e.g., after 12 minutes of exposure. For those individuals who are sensitive to latex or other components in latex gloves, 100% synthetic copolymer gloves, nitrile rubber gloves, or butyl rubber gloves may be used.

   Note: Contact with CIDEX OPA Solution may stain exposed skin or clothing.

2. Use CIDEX OPA Solution in a well-ventilated area and in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air conditioning system, use in local exhaust hoods, or in ductless fume hoods/portable ventilation devices which contain filter media which absorb *ortho*-phthalaldehyde from the air.
3. Contaminated reusable devices MUST BE THOROUGHLY CLEANED prior to disinfection, since residual contamination with soil or lubricants will decrease the effectiveness of the germicide.
4. The user MUST adhere to the Directions for Use, as modification to the Directions for Use may affect the safety and effectiveness of the germicide.
5. Do not use CIDEX OPA Solution on critical medical devices that are intended for use in a sterile area of the body (e.g. cataract surgical instruments).
6. The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using CIDEX OPA Solution.

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7. The use of CIDEX OPA Solution in automated endoscope reprocessors must be part of a validated reprocessing procedure. The contact conditions must be 25°C for 5 minutes. (See note following the Indications for Use section).

8. Use CIDEX OPA Solution Test Strips to detect *ortho*-phthalaldehyde concentration before each cycle to detect the MEC. Follow the Directions For Use provided with the CIDEX OPA Solution Test Strips.

DIRECTIONS FOR USE

Cleaning/Decontamination: Blood, other body fluids, and lubricants must be thoroughly cleaned from the surfaces and lumens of semi-critical medical devices before reprocessing in the disinfectant. Blood and other body fluids should be disposed of according to all applicable regulations for infectious waste disposal.

Refer to the reusable device manufacturer's labeling for instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

Before immersion in CIDEX OPA Solution, thoroughly clean devices, including all lumens, using a cleaning protocol or standard, such as the ASTM F 1518 "Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera."

Thoroughly rinse and rough dry all surfaces and lumens of cleaned devices.

Usage: NO ACTIVATION IS REQUIRED.

Record the date the container was opened on the container label, or in a log book. After opening, the solution remaining in the container may be stored for up to 75 days (providing the 75 days does not extend past the expiration date on the container) until used.

Record the date the solution was poured out of the original container into a secondary container in a log book (separate from the one mentioned above), or on a label affixed to the secondary container. The solution in the secondary container can be used for a period up to 14 days. The product must be discarded after 14 days even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC.

A. High Level Disinfection

1. **Manual Processing:** Immerse device completely, filling all lumens and eliminating air pockets, in CIDEX OPA Solution for a minimum of 12 minutes at 20°C (68°F) or higher to destroy all pathogenic microorganisms. Remove device from the solution and rinse thoroughly following the rinsing instructions below.

2. **Automatic Endoscope Reprocessor that can be set to a minimum of 25°C** (See note following the Indications for Use section): High Level Disinfectant at a minimum of 25°C (77°F). For use in a legally marketed AER (that can be set to a minimum of 25°C) with a minimum immersion time of 5 minutes. As with all high level disinfectants, it is critical that temperature is monitored when using CIDEX OPA Solution in an AER at 25°C. See section D. 1 "Monitoring of Germicide."

B. Rinsing Instructions

1. **RINSING PROCEDURE**

a) Manual Processing:

- Following removal from CIDEX OPA Solution, thoroughly rinse the semi-critical medical device by immersing it completely in a large volume (e.g. 2 gallons) of water. Use sterile water unless potable water is acceptable. See item 2 or 3 below.
- Keep the device totally immersed for a minimum of 1 minute in duration, unless a longer time is specified by the reusable device manufacturer.
- Manually flush all lumens with large volumes (not less than 100 mL) of rinse water unless otherwise noted by the device manufacturer.
- Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.
- Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water to remove CIDEX OPA Solution residues. Residues may cause serious side effects. SEE WARNINGS. THREE (3) SEPARATE, LARGE VOLUME WATER IMMERSION RINSES ARE REQUIRED.
- Refer to the reusable semi-critical medical device manufacturer's labeling for additional rinsing instructions.

b) Automated Processing:

- Select a rinse cycle on an automatic endoscope reprocessor that has been validated for use with this product.
- Ensure that the automated rinse cycle selected will thoroughly rinse the semi-critical medical device including all lumens with large volumes of sterile or potable water equivalent to the reusable device manufacturer's recommendations.
- Verify that each rinse is a minimum of 1 minute in duration unless the reusable device manufacturer specifies a longer time. Ensure that a fresh volume of water is used for each rinse. Do not reuse the water for rinsing or any other purpose.
- Refer to the reusable device manufacturer's labeling for additional rinsing instructions.

2. **STERILE WATER RINSE:** The following devices should be rinsed with sterile water, using sterile technique when rinsing and handling:

Devices intended for use in normally sterile areas of the body.

Devices intended for use in known immuno-compromised patients, or potentially immuno-compromised patients based on institutional procedures (e.g., high risk population served).

When practical, bronchoscopes, due to a risk of contamination from potable water supply. Although microorganisms in this type of water system are not normally pathogenic in patients with healthy immune systems, AIDS patients or other immuno-compromised individuals may be placed at high risk of infection by these opportunistic microorganisms.

3. **POTABLE WATER RINSE:** For all other devices, a sterile water rinse is recommended when practical. Otherwise, potable tap water rinse is acceptable.

When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with microorganisms which may be present in potable water supplies.

Water treatment systems, such as softeners or deionizers, may add microorganisms to the treated water to the extent that microbial content of the water at the point of use could exceed that of the pretreated drinking water. To ensure proper water quality, adherence to maintenance of the water treatment system(s) is recommended.

The use of a bacterial retentive (0.2 micron) filter system may eliminate or greatly reduce the amount of these waterborne bacteria from the potable water source. Contact the manufacturer of the filter or UV system for instructions on preventative maintenance and periodic replacement of the filter to avoid colonization or formation of biofilms in the filter.

A device that is not completely dried provides an ideal situation for rapid colonization of bacteria. As these waterborne bacteria are highly resistant to drying, rapid drying will avoid possible colonization but may not result in a device free from these bacteria. A final rinse using a 70% isopropyl alcohol solution can be used to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.

C. Special Instructions for Transesophageal Echocardiography (TEE) probe reprocessing: As with all devices, carefully follow all probe manufacturer recommendations such as use of a sterile protective sheath when performing TEE. Soaking for a minimum of 12 minutes in CIDEX OPA Solution is required for high level disinfection (HLD). Excessive soaking of the probes (e.g., longer than an hour) during HLD and/or not rinsing three times with a fresh quantity of water each time as described in Part B, may result in residual CIDEX OPA Solution remaining on the device, the use of which may cause staining, irritation or chemical burns of the mouth, throat, esophagus and stomach.

D. Reusage for Disinfection: CIDEX OPA Solution has demonstrated efficacy in the presence of organic soil contamination and microbiological burden during reuse. The *ortho*-phthalaldehyde concentration of CIDEX OPA Solution during its use-life must be verified by the CIDEX OPA Solution Test Strips prior to each use, to determine that the MEC of 0.3% is present. CIDEX OPA Solution may be used and reused within the limitations indicated above for up to a maximum of 14 days. CIDEX OPA Solution must be discarded after 14 days, even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC.

1. **MONITORING OF GERMICIDE:** During reuse, it is recommended that the CIDEX OPA Solution be tested with CIDEX OPA Solution Test Strips prior to each use. This is to ensure that the Minimum Effective Concentration (MEC) of *ortho*-phthalaldehyde is present.

During the usage of CIDEX OPA Solution as a high level disinfectant, it is recommended that a thermometer and timer be utilized to ensure that the optimum conditions are met.

Monitoring Temperature in Automatic Endoscope Reprocessor that can be set to a minimum of 25°C: As with all high level disinfectants, temperature monitoring is critical for use of CIDEX OPA Solution at a minimum of 25°C for 5 minutes in an AER. If you cannot monitor temperature appropriately in your machine, contact ASP at (888) 783-7723 for further instructions.

Visually inspect the solution during the reuse life for the presence of precipitates which may result from the use of hard water. Discard solution if precipitation occurs.

POST-PROCESSING HANDLING AND STORAGE OF REUSABLE DEVICES: Disinfected reusable devices are either to be immediately used, or stored in a manner to minimize recontamination. Refer to the reusable device manufacturer's labeling for additional storage and/or handling instructions.

STORAGE CONDITIONS AND EXPIRATION DATE

1. CIDEX OPA Solution should be stored in its original sealed container at controlled room temperature 15 - 30°C (59 - 86°F) in a well-ventilated, low-traffic area.

2. Once opened, the unused portion of the solution may be stored in the original container for up to 75 days until used.

3. The expiration date of the CIDEX OPA Solution is found on the immediate container.

EMERGENCY AND TECHNICAL PRODUCT INFORMATION

For further hazard information please refer to the Material Safety Data Sheet. Emergency, safety, or technical information about CIDEX OPA Solution can be obtained from Advanced Sterilization Products at (888) 783-7723, or by contacting your local Advanced Sterilization Products sales representative.

USER TRAINING

The user should be adequately trained in the decontamination and disinfection of semi-critical medical devices and the handling of liquid chemical germicides. Additional information about CIDEX OPA Solution can be obtained by contacting your local Advanced Sterilization Products sales representative.

DISINFECTANT/CONTAINER DISPOSAL INFORMATION

Disinfectant Disposal: Check state and local disposal regulations. Glycine (free base) may be used as a neutralizer for CIDEX OPA Solution prior to disposal, if required. A minimum of 25 grams of glycine (free base) should be used to neutralize one gallon of CIDEX OPA Solution. The minimum recommended neutralization time is one hour. Discard residual solution into drain. Flush drain thoroughly with water.

Container Disposal: Do not reuse empty container. Rinse and dispose per hospital policy.

HOW SUPPLIED

Reorder	Description	Case Contains
20390	One Gallon (3.785L) Container	4 gals (4 x 3.785L)/case
20392	CIDEX OPA Solution Test Strips	60 strips/btl; 2 btls/case
20393	CIDEX OPA Solution Test Strips	15 strips/btl; 2 btls/case

MARKETED BY:

ASP ADVANCED STERILIZATION PRODUCTS®

a Johnson & Johnson company

Division of Ethicon, Inc.

33 TECHNOLOGY DRIVE, IRVINE, CA 92618-9824

For technical information and/or information regarding safety and effectiveness, call 1-888-783-7723

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LC-20390-008 Rev. D (FAX)

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Appendix I

6.00"

9.50"

CAT NO. SAMPLE USE ONLY. NOT FOR RESALE

ACTIVE INGREDIENTS:

Alkyl dimethyl benzyl ammonium chloride	10.00%
Glycol monoethyl ether	5.00%
Alkyl polysaccharide	2.00%
Ethylenediamine tetraacetic acid (sodium salt)	1.00%
Inert Ingredients & Water	82.00%
Total	100.00%

DIRECTIONS FOR USE

MANUAL CLEANING:
For cleaning of fully immersible instruments and related accessories or other instruments, use INTERCEPT at 0.25% - 0.5%, based on soil load. For instrument cleaning at normal soil load, dilute INTERCEPT at 0.33 oz./gal of water (0.25% use concentration). For worst case cleaning of heavily soiled instruments with dried surgical soils, dilute INTERCEPT at .64 oz./gal of water (0.5% use concentration). For best results, mix INTERCEPT with warm water (25°C - 35°C). Follow device or instrument manufacturer's recommendation for proper cleaning procedures.

Intercept™

Next-generation detergent for use as an aid in the manual or automated pre-cleaning of various fully immersible medical instruments and accessories.

READ MSDS FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

KEEP OUT OF REACH OF CHILDREN
CAUTION

FEATURES
- Non-enzymatic, neutral pH detergent
- Laboratory proven to effectively remove biological and organic residues from a wide variety of medical instruments and surfaces.
- Effective cleaning of medical instrument is the critical first step in a validated reprocessing program, and INTERCEPT can help to enhance that process.

NET CONTENTS
1 U.S. Quart
(.95 Liters)

AUTOMATED CLEANING:
Use INTERCEPT at 0.25% - 0.5%, based on soil load. Follow endoscope reprocessors manufacturer's recommendation for proper AER detergent use.

PRECAUTIONARY STATEMENTS:
Use of nitrile gloves or equivalent is recommended for all cleaning involving re-usable medical devices and accessories. Please refer to the Material Safety Data Sheet (MSDS) for additional information.

FIRST AID:
In case of contact with eyes, flush with copious quantities of water for 15 minutes. In case of ingestion, DO NOT induce vomiting. Contact Chemtrec for emergency medical treatment at 1-800-424-9300.

STORAGE & DISPOSAL:
Store at room temperature 15°C-25°C (59°F-77°F). Discard unused solution according to local, state, and federal regulations. Do not reuse container.

Manufactured in the U.S.A. and Distributed by:
MEDIVATORS®
REPROCESSING SYSTEMS
A MINNTECH CORPORATION BUSINESS GROUP

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Appendix J

Indications for Use

510(k) Number (if Known): _____

Device Name: Medivators Reprocessing Systems Modular Disinfection System for Endoscope Reprocessing

Indications for Use:

Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing tests, cleans, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109) OR Over-the Counter Use _____ (Optional Format 1-1-96)

Appendix K

MEDIVATORS™
REPROCESSING SYSTEMS

DSD-91E™ Endoscope Disinfector

User's Manual

CE 0123

ETL LISTED

MM03-0011Rev.G 12/03

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Pentax

Sporox

DSD-91E™ Endoscope Disinfector User's Manual Revised
Part Number MM03-0011, Rev. G — December, 2003

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Medivators Reprocessing Systems
14605 28th Avenue North
Minneapolis, MN USA 55447
Telephone - (763) 553-3300
Telephone - (800) 328-3340
FAX – (763) 553-3387

Explanation of Symbols

Note: This information adds additional insight and/or instructions for a specific topic.

Caution: This information is an alert to the possibility of a problem with the device associated with its use or misuse.

Warning: This information is an alert to the possible injury or other serious adverse reaction associated with the use or misuse of the device.

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1 SAFETY

1.1 Warning Notes

Warning: Before operating the DSD-91E Endoscope Disinfector, read and understand this instruction manual - especially the following warning notes:

- If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
- Allow operation of the Disinfector only by those individuals trained in its proper use.
- Failure to properly clean and disinfect an endoscope after each examination can compromise patient safety.
- Patient debris and disinfectants are hazardous. Wear the appropriate personal protective equipment.
- In laboratory studies, the best and most consistent disinfection resulted from using proper cleaning techniques and a 20-minute disinfect cycle. All testing was done with a 14-day-reuse glutaraldehyde.
- The system is factory-set for a 20-minute disinfectant immersion period. This period can be extended in custom programs, but it cannot be set below 10 minutes without special instructions from the manufacturer. Be sure to program disinfectant immersion time appropriate for the disinfectant selected.
- All disinfectants must be monitored daily for effectiveness. Strictly follow the disinfectant manufacturer's labeling, or the reuse life could be significantly affected. Do not use disinfectants beyond the time period specified on the manufacturer's label (e.g., do not use a 14-day disinfectant beyond 14 days — **even** if potency test results are favorable). Disinfectants may lose effectiveness before the end of the reuse life.
- If enzymatic detergent or alcohol purge cycles will be used, check the corresponding cylinder levels before starting. If required, dilute the enzymatic detergent according to the manufacturer's labeling.
- The air/water channels and other small-diameter channels of pediatric endoscopes may be more difficult to clean, and extra precleaning should be done for these instruments.
- Duodenoscopes with elevator wire channels require additional cleaning and disinfection steps. It is particularly important that the elevator wire channel be manually reprocessed.
- Endoscopes should be leakage tested before submersion as part of the overall reprocessing protocol.
- Remove, wash, and dry the enzymatic detergent dispenser at the end of the day.
- After discarding used disinfectant, remove the basin cover. Rinse and wipe dry the cover, basin, and reservoir with a clean cloth. **Do not use** paper towels: use of paper towels may generate particulate matter that may interfere with the system's function.
- All pressure regulators are factory-preset. Do not try to adjust them without first contacting your local distributor *Medivators* Customer Service.
- Do not open the lid or remove the basin cover during operation.
- Factory-supplied replacement parts and filters must be used to assure proper operation and efficacy of the DSD-91E Disinfector.
- Do not use alcohol containing products to clean disinfection lids. Alcohol may cause crazing of the acrylic windows.

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1.2 Precautions

- We recommend use of a detergent such as *Medivators* Enzymatic Detergent and Pre-soak with:
  - — Bacteriostatic properties to inhibit bacterial growth in the detergent reservoir and the detergent line
  - — Dual enzymes to rapidly attack soils
  - — Low foam properties for effective recirculation
  - — Color coding to enhance worker safety.

- Do not use regular kitchen detergent for the following reasons:
  - — Kitchen detergent may contain bacteria.
  - — Kitchen detergent is not capable of inhibiting bacterial growth in the detergent cylinder.
  - — Kitchen detergent cannot be easily diluted with water and may lead to clogging the detergent line and valves.

- Select a high level disinfectant whose label indicates that it may be used to achieve high-level disinfection (see Section 5, Glossary, for definition) of medical instruments. The product should be capable of killing *Mycobacterium tuberculosis* at 20-25° C. Consult the product's label for the appropriate high level disinfectant contact time for the disinfection cycle.
- *Medivators* certifies that the DSD-91E Endoscope Disinfector will demonstrate at least a 6-log reduction of *Mycobacterium* 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.
- High-level disinfectants: Agents used to achieve high-level disinfection and liquid chemical germicides are registered with a national authority (e.g., U.S. FDA) as "high level disinfectants" that are used according to the time, temperature, and dilution recommended by the disinfectant manufacturer for achieving high-level disinfection. These conditions usually coincide with those recommended by the disinfectant manufacturer for 100% kill of *Mycobacterium tuberculosis*.
- Choose a non-foaming high level disinfectant. Some high level disinfectants contain surfactants. Such products will produce unacceptable amounts of foam when used in an automatic disinfector. Use the manufacturer's test strips to test the potency of the solution on a daily basis. If the potency of the solution is below its minimum effective concentration, discard and replace with fresh solution.
- The efficacy of a disinfection procedure is directly related to the disinfectant solution used and the amount of time the endoscope is exposed to that solution. It is important to establish a disinfection protocol that includes systems to monitor the protocol's effectiveness.
- All endoscopes must be precleaned. Follow the manufacturer's instructions and established professional guidelines (see Section 1.4, Guidelines for Cleaning and Disinfection) for guidance concerning those reprocessing steps that must be performed prior to placing an endoscope into an automated disinfector.
- The 40-cycle warning light setting on the unit is based on the use of a glutaraldehyde with a 14-day reuse life. See Section 2.7, Setup Functions.

This manual covers the DSD-91E Disinfector for Flexible Endoscopes, and is intended for use by qualified and trained personnel who operate and maintain the unit.

If you need additional information, please contact your local distributor or *Medivators* Customer Service at 1-800-444-4729 or 763-553-3300.

Before attempting to service the DSD-91E, you should review and understand the Service Manual for complete familiarization of system operation.

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1.3 Water Quality

You should use potable water as a *minimum* standard. Since water quality varies, check the water pressure regulators frequently. If the pressure at the internal water pressure regulator drops by 5 psi from its original setting during an initial flush cycle, replace either the sediment water filter or the 0.2-micron air filter (see "Maintenance").

Note: The normal routine maintenance schedule recommends that you replace the 0.2-micron water filter every 6 months or sooner depending on water quality.

The high performance 0.2-micron water filter included with this device is a sterilizing grade filter. It removes micro-organisms and all particles greater than 0.2-microns diameter from the liquid stream. When the incoming water has not been pretreated by clarification, deionization, and filtration, the volume of liquid that passes the filter before it blocks is severely limited. Incoming water should be prefiltered to at least 0.45-microns.

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1.4 Guidelines for Cleaning and Disinfection

Always follow established professional guidelines for cleaning and disinfection of endoscopes. Develop a protocol based on such guidelines.

The following organizations have published recommended guidelines:

Society of Gastroenterology Nurses and Associates
401 North Michigan Av.
Chicago, IL 60611-4267
TEL: (800) 245-7462
FAX: (312) 321-5194
http://www.sgna.org/

American Society for Gastrointestinal Endoscopy
13 Elm Street
P. O. Box 1565
Manchester, MA 09144-1314
TEL: (978) 526-8330
FAX: (978) 526-4018
http://www.asge.org/

Association of Operating Room Nurses
2170 So. Parker Rd., Suite 300
Denver, CO 80231-5711
TEL: (303) 755-6304
FAX: (303) 750-3462
http://www.aorn.org/

British Society of Gastroenterology
3 St. Andrews Place
Regents Park, London NW1 4LB
01144-171-387-3534
BSG@mailbox.u2cc.ac.uk.

Association for Professionals in Infection Control and Epidemiology, Inc
1016 - 16th St., NW., 6th floor
Washington, DC 20036-5703
TEL: (202) 296-2742
FAX: (202) 296-5645
http://www.apic.org/

American Society for Testing and Materials
100 Barr Harbor Drive
West Conshohocken, PA 19428-2959
TEL: (610) 832-9585
FAX: (610) 832-9555
http://www.astm.org/
"Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes used in the Examination of the Hollow Viscera," F 1518-94

Canadian Society of Gastroenterology Nurses & Associates
P.O. Box 366
36 Adelaide Street East
Toronto, Ontario M5C 2J5
www.webray.com/csgna
(No telephone numbers available. The executives work from hospitals.)

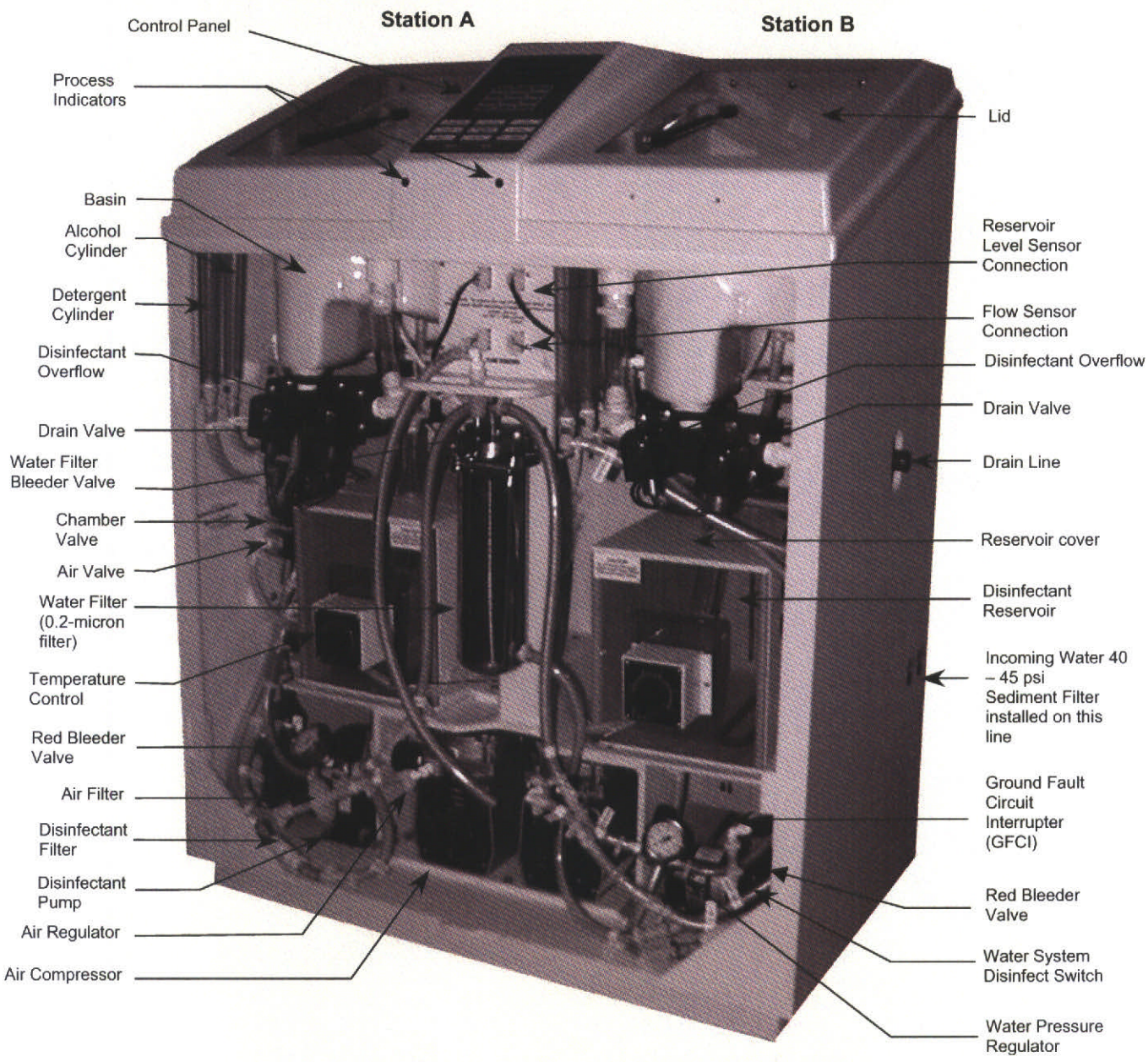

Figure 1. *Medivators* DSD-91E Endoscope Disinfector (doors omitted to show interior).

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2 FEATURES AND FUNCTIONS

2.1 General Information

All DSD-91E disinfectors meet requirements for year 2000 compliance.

The DSD-91E Endoscope Disinfector is designed for high-level disinfection of flexible endoscopes. The unit contains two stations A and B (see Figure 1). Either station can be operated by itself, or both can be operated at the same time. The stations may operate either:

- Synchronously, for disinfection of two endoscopes using identical program cycles; or
- Asynchronously, using different program cycles.

Each station has its own independent fluid lines, valves, disinfectant reservoir, disinfectant pump, and air compressor. The only common equipment is the power supply, water supply, filter and the electronic circuitry. As a result, a device failure in one of the stations is unlikely to affect the operation of the other station.

2.2 Programmed Cycle Features

Note: Refer also to Section 2.4, Disinfection Cycle Chart.

General. During the disinfection and rinse phase of a cycle, the first 30 seconds of flow is directed through the endoscope channels only. This helps prevent an air lock within endoscope channels that could block the flow of disinfectant and rinse water into a channel.

Flush Phase. Detergent and water are flushed through the endoscope channels to remove any fluids carried over from the manual precleaning procedure and to insure that the channels are not obstructed. The effluent from this cycle goes to the drain. After draining, the endoscope channels and Disinfector hoses are purged by compressed air.

Disinfect Phase. At the beginning of this phase, disinfectant is pumped through the endoscope channels. Then the disinfectant is directed to filling the basin and circulates around the entire endoscope. Once the basin is filled, the flow is directed back to the channels. At the end of this phase, the disinfectant is drained from the basin and returned to the reservoir.

Rinse Phase. Water is circulated around the endoscope and through the interior channels. During this phase, water is continually drained and discarded.

Alcohol Rinse / Air Dry Phase. An alcohol rinse / air dry phase, although not part of the default program, can be added to custom programs. This phase should be programmed into a disinfection cycle to facilitate the drying of endoscope channels.

Warning: Alcohol is flammable and should be used with care. Refer to the endoscope manufacturer's comments regarding the use of alcohol

Additional Air Purge Phase. After each phase, endoscope channels are purged with compressed air to reduce carryover from phase to phase. Additional air purging may be manually added to a cycle for more thorough channel drying, if desired.

Caution: This extra air cycle assists in drying, but may not completely dry the endoscope channels.
Consult the endoscope manufacturer's instructions for directions regarding proper storage of reprocessed endoscopes.

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2.3 Other System Features

Power Fail Restart. If the system detects an electrical power interruption, it shuts off all valves and motors to prevent damage and suspends reprocessing. When power conditions are restored, the system resumes operation at the same point in the cycle where it was interrupted.

Watchdog Circuit. A watchdog circuit constantly monitors the operational status of the Disinfector. If the unit fails to operate as expected at any point in the program, this circuit resets the processor and causes the program cycle to be reinitiated at the point at which the failure occurred. This feature may be activated as a result of harsh electrical and magnetic impulse noise.

Ground Fault Circuit Interrupter. A ground fault interrupter (GFCI), located inside the cabinet, protects the unit from possible electrical problems resulting from contact with fluids.

Status Log. The system automatically logs the unit's usage history, error status, endoscope number (if entered), and other information. The log can be manually examined using one of the system's Setup Functions (see Section 2.7, Setup Functions). Under normal circumstances, the log is retained in memory even if the computer system must be serviced.

Printer. A dot-matrix printer allows printing of a paper copy of individual cycle parameters and/or the status log.

Protection from Disinfectant Fumes. The lid gasket and basin cover minimize the dispersal of disinfectant fumes from the unit.

Reservoir Heaters. The disinfectant reservoirs each contain a heater. If the manufacturer recommends heating the disinfectant, the heater thermostat may be set from room temperature to 125° F (52° C). The thermostat should be adjusted to the desired temperature upon installation. The system can be programmed to automatically turn the heaters on before the beginning of the normal workday and off at the end of the workday. The heaters may be left on, if desired.

Disinfectant Filtration. To eliminate recycling of particulate matter through the Disinfector and endoscope channels, a disinfectant filter is installed between the reservoir and the pump. See Figure 1.

Water Filtration. The Disinfector is supplied with a sediment filter, and an internal 0.2-micron water filter. See Figure 1.

Air Filtration. The Disinfector is supplied with a 0.2-micron air filter for each station. See Figure 1.

Process Indicator Lights: The Disinfector is supplied with two process indicator lights, corresponding to the two stations, located just above the panel doors (See Figure 1). These indicators will:

- Remain off throughout the disinfection process.
- Light when a disinfection process has been successfully completed.
- Blink if the cycle has been stopped or interrupted.

Vapor Management System. Optional Feature that aids in the reduction of vapors

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2.4 Disinfection Cycle Chart

Phase	Description	Duration		
		Program Default	Minimum Limit	Maximum Limit
Flush	Endoscope channel flush with detergent and water	30 sec	0 sec	89:59 min
	Compressor startup[1]	5 sec	factory set	factory set
	Endoscope channel air purge[1]	30 sec	factory set	factory set
Disinfect	Endoscope channel flush with disinfectant	30 sec	factory set	factory set
	Basin Fill and circulation	5 min	5 min	89:59 min
	Endoscope and channel disinfection	20 min	9 min	89:59 min
	Disinfectant drain	90 sec	factory set	factory set
	Compressor startup	5 sec	factory set	factory set
	Endoscope channel air purge	30 sec	factory set	factory set
Rinse 1	Endoscope channel flush with water	30 sec	factory set	factory set
	Water rinse	4:10 min	4:10 min	89:59 min
	Drain	90 sec	factory set	factory set
	Compressor startup	5 sec	factory set	factory set
	Endoscope channel air purge	30 sec	factory set	factory set
Rinse 2	Endoscope channel flush with water	30 sec	factory set	factory set
	Water rinse	4:10 min	0 min [4]	89:59 min
	Drain	90 sec	factory set	factory set
	Compressor startup	5 sec	factory set	factory set
	Endoscope channel air purge	30 sec	factory set	factory set
Alcohol	Endoscope channel flush with alcohol followed by air purge.	0 sec	0 sec OR 15 sec	89:59 min [3]
	Compressor startup[2]	5 sec	factory set	factory set
	Endoscope channel air purge[2]	30 sec	factory set	factory set
Air	Endoscope channel flush with compressed air	5 min	0 min	89:59 min
Add Air	Additional endoscope channel flush with compressed air	10 min	0 min	89:59 min
	Total Cycle Time	47:61		

[1]Not included if Flush Phase is set to zero (0).
[2]Not included if Alcohol Phase is set to zero (0).
[3]This indicates length of time for air purge.
[4] If under 4:10 you will experience a low CBR.

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2.5 Control Panel

Use the membrane control panel (on top of the Disinfector) to control setup and operation. The control panel has three main sections as indicated in Figure 2.

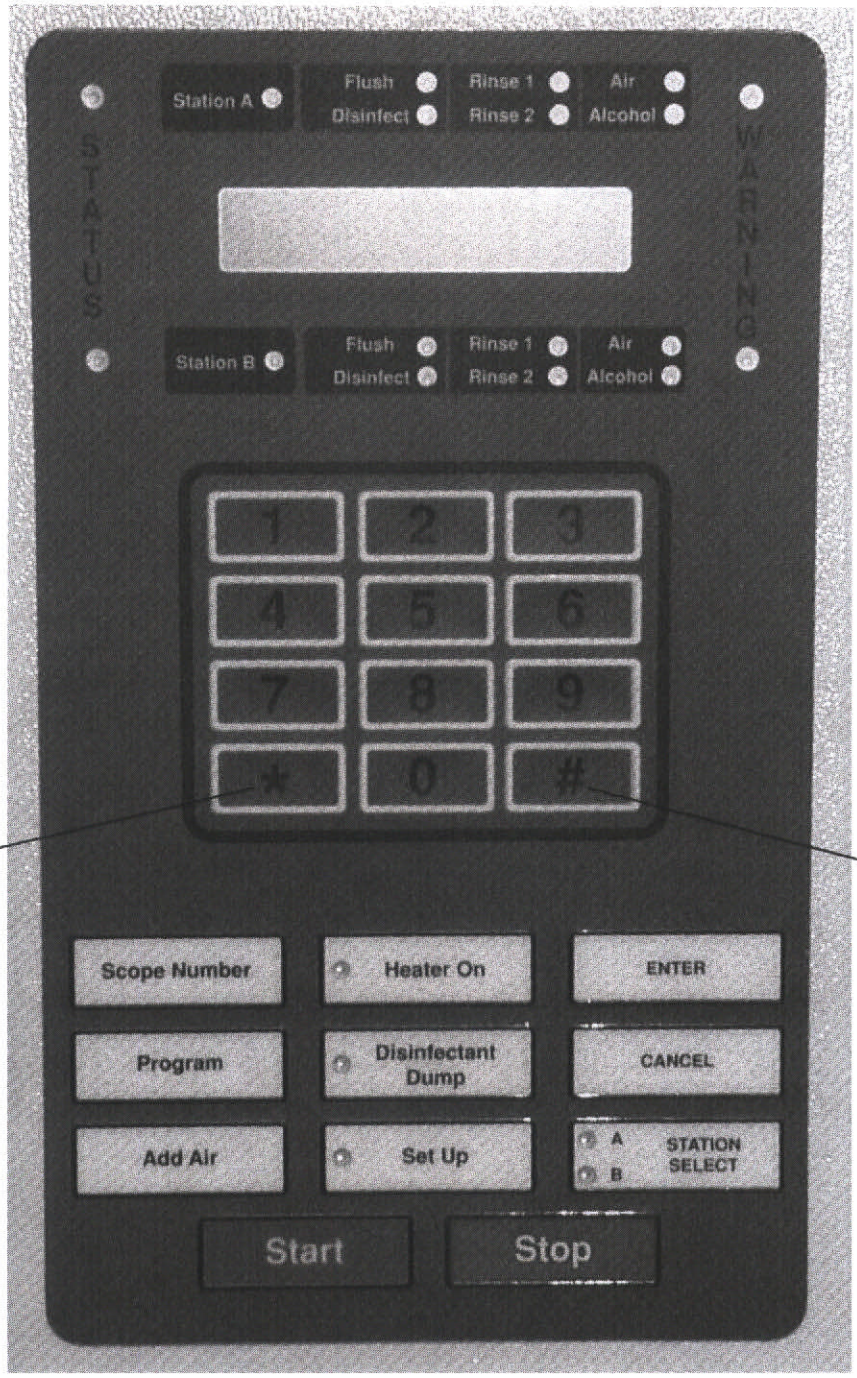

Figure 2. Control Panel

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Station Status and Warning Section

The station status and warning section of the control panel contains LED indicators and a liquid-crystal display (LCD) screen. The LED indicators display warning conditions and the status of the current cycle. The LCD screen shows detailed status, warning, or other information as needed to operate the unit.

LCD Screen

The LCD screen has two lines and displays the following:

Upper Left: User prompts.

Upper Right: Current time of day (HH:MM, based on a 24-hour clock):

HH	=	Hour
MM	=	Minute

The colon flashes on and off at one-second intervals to indicate that the system is functioning.

Lower Left: Current station selected, and its operational status (ANS BNS):

A	=	Station A
B	=	Station B
N	=	The program number selected (0-9) for the station
S	=	The "LCD status symbol" indicator, which appears when the selected station is running. It changes appearance according to the station's operating state, and disappears only when a complete disinfection program has been successfully completed.

Press	LCD Status Symbol appears as
[Start]	a repeatedly descending horizontal line
[Stop]	a vertical line
[Reset]	starburst

Lower Right: Current day of the week, and date (Da DD Mth YY — e.g., Mo 07 Apr 96)

Da	=	Current day of the week
DD	=	Current day
Mth	=	Current month
YY	=	Current year

Status Indicator

The vertical STATUS area has an upper and a lower LED indicator that blink to show when Station A (upper) or B (lower) respectively is stopped but not yet idle. The stopped state is entered whenever a system error is detected that affects that station, or whenever the [**Stop**] key is pressed. The blinking status light indicates that the station program is not completed.

Current-Cycle Status Indicators

The current-cycle status indicators for Station A are located above the LCD screen, and the corresponding indicators for Station B are located immediately below the LCD screen. The Station A or B indicator is lit when a program is currently running on the station. The LED goes out if the station enters the stopped state, and when the program has completed.

The six phase indicators (Flush, Disinfect, Rinse 1, Rinse 2, Air, Alcohol) to the right of the station indicator are lit when the indicated disinfection activity is currently in progress for that station. The air indicator **blinks** when the current cycle is in the air purge phase. The air indicator remains lit during the final air purge phase.

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Warning Indicator

The vertical WARNING area also contains an upper and a lower LED indicator. These indicators blink whenever any condition occurs that may need operator attention (upper indicator for Station A and lower indicator for Station B). When indicators are activated, the LCD screen typically contains additional information about the warning status.

Keypad Section

Use the keypad section of the control panel (Figure 2) to enter numbers that are required for many setup and operation functions.

Generally, a specific function key is pressed, followed by a number sequence on the keypad. The LCD screen will prompt the user by indicating the expected or required action.

If the number string is correct as entered, accept it by pressing either **[Enter]** or the **[#]** key. If a digit is entered incorrectly, cancel by pressing either **[Cancel]** or the [*] key and then enter the correct digit(s).

Station Select and Function Section

The station select and function section of the control panel (Figure 2) is used to select a station (A or B) and to control various functions.

Station Select

Most functions apply only to the currently selected station or stations. Ensure that the appropriate station selection indicator is lit before calling for the desired function. If the desired station(s) has not been selected, press **[Station Select]** until the corresponding indicator(s) are lit (A, B, or both).

Scope Number

Press **[Scope Number]**, followed by up to 10 numbers from the numeric keypad, to enter into the system operation log the serial number or other reference number for the endoscope about to be disinfected. See Section 2.6, Protocol Selection Functions. The Scope Number key can be activated only when the selected station is in the idle state. Changing the station **clears** the current endoscope number from the system's memory.

Program

Press **[Program]**, followed by a number (0-9) from the numeric keypad, to select either the default disinfection protocol (program 0) or a custom protocol (programs 1-9) for the selected station(s). See Section 2.6, Protocol Selection Functions, for the complete selection procedures, or Section 2.7, Setup Functions, for the procedure to set up a custom protocol. The Program key can be activated only when the selected station is in the idle state.

Add Air

Press **[Add Air]** to add a second compressed air cycle at the end of the currently selected program on the selected station(s). The Add Air key can be activated at any time during the cycle. The duration can be set by specifying a custom program setup function.

Caution: This extra air cycle assists in drying, but may not dry the endoscope channels completely. It is recommended that the endoscope be stored in such a manner as to encourage continued draining of residual water from the channels (e.g. by hanging vertically in a cabinet).

Heater On

Press **[Heater On]** to either turn on or off the reservoir heater for the selected station(s). The heater thermostat is not set at the factory, but can be set from room temperature to 125°F (52° C). If the heater is on, the system software controls the on and off times of the heater to maintain the temperature set on the thermostat. If the heater is turned off, it will be off the entire cycle. The setting of the Heater On key affects all programs (default and custom).

Note: Follow the disinfectant manufacturer's labeling to determine whether or not to heat the disinfectant and, if heating is required, the desired temperature. Do not exceed the maximum temperature recommended by the manufacturer of the endoscope.

Disinfectant Dump

Select the appropriate Station (A or B), then press **[Disinfectant Dump]** (The display must read "Dis Dump?"), then **[Start]**, to direct the system to drain the disinfectant from the selected station's reservoir, when a determination has been made that it is no longer effective or has reached its expiration. Refer to Section 3.5 for the complete procedure.

Note: If scope connectors are not in basin, dump will not complete.

Caution: Check the effectiveness of the disinfectant every day, using test strips recommended by the disinfectant manufacturer. Disinfectant may lose effectiveness before the end of its reuse life.

Set Up

Press **[Set Up]**, followed by a number from the numeric keypad, to initialize various system and station options. See Section 2.7, Setup Functions, for the complete procedures.

Enter

Press **[Enter]**, or the **[#]** key on the numeric keypad, to accept the number just entered.

Cancel

Press **[Cancel]**, or the **[*]** key on the numeric keypad, to erase the number just entered or to terminate the currently running disinfection program. A terminated program may have to go through a drain/purge cycle before going into the idle state.

Caution: Any endoscope that has not gone through a complete cycle is not patient-ready. If the cycle is terminated prior to completion, subject the endoscope to another complete disinfection cycle.

Start

Press **[Start]** to start a program sequence for the selected station(s), or to restart a program in progress that has been interrupted for any reason.

Stop

Press **[Stop]** to temporarily stop the current program for the station(s) selected. When ready to resume disinfection, press **[Start]** to resume the program where it was halted, or press **[Cancel]** to terminate the program. A terminated program may have to go through a drain/purge cycle before going into the idle state.

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2.6 Protocol Selection Functions

TO RUN A DISINFECTION PROTOCOL

This function starts a disinfection cycle. Refer to Section 3.4, Disinfecting an Endoscope, for the complete disinfection procedure. To run the default program, enter zero as indicated below. A **custom** disinfection cycle can be started by using one of the custom protocols set up in Function 5 (see Section 2.7, Setup Functions): enter 1-9 (instead of zero) as indicated below. To indicate a specific endoscope number in the log and the printout, enter the endoscope number (a 10-digit maximum number) as indicated below.

Caution: The default program parameters may not be appropriate for the disinfectant being used. If so, create a custom program to meet the label requirements of the disinfectant manufacturer, or to meet local hospital policies or professional guidelines.

A Station B Select	Select the Station (A or B) to be used. This keystroke also clears the endoscope number from a previous procedure.
Program	The display now shows the last Program Number that was selected.
0	Press the desired custom program number (0-9) on the numeric keypad. If this Number is correct for the new cycle, it need not be reentered.
Enter	
Scope Number	Enter the endoscope's number (up to 10 digits) on the numeric keypad. This keystroke is optional.
Start	Wait for the cycle to complete.

SHORTCUT: If you are not going to log an endoscope number, and the correct program is already displayed, you may simply select the station and press [**Start**].

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2.7 Setup Functions

Whenever in a setup mode, [**Cancel**] or [*] can be pressed to erase the numeric data entered, allowing corrected numbers to be entered.

Entry	Function	Referenced Page Number (User's Manual)
1	To load disinfectant into reservoir of the **selected station**.	2-11
2	To set date in the system's clock/calendar (date shown on display).	2-16
3	To set time in the system's clock/calendar (time shown on display).	2-17
5	To set up a custom program (9 available) to match different disinfectants or different desired protocols.	2-13
6	To disable the fluid level sensors.	Refer to Service Manual
7	To override the disinfectant cycle warning.	2-12
8	To review the status log on the display.	2-14
9	To disable the data logging function so no additional entries are made.	2-15
10	To clear all entries from the data log.	2-15
[1]11	To clear disinfectant cycle count. [1]	2-18
12	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.	2-12
13	To clear all custom programs that have been entered using Setup 5.	2-14
14	To set the time of day that the optional reservoir heater elements are automatically turned on.	2-17
15	To set the time of day that the optional reservoir heater elements are automatically turned off.	2-18
16	To display the number of **disinfection** cycles run on each station since the disinfectant was loaded.	2-19
17	To display the time remaining in the current disinfection cycle.	2-18
18	To adjust the contrast level of the display screen for optimal viewing.	2-19
19	To disable the basin level sensors. [1]	Refer to Service Manual
20	To display miscellaneous information.	2-20
21	To print a copy of the disinfection cycle log.	2-15

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Setup Functions (cont)

Entry	Function	Referenced Page Number (User's Manual)
22	To set the country code. [1]	Refer to Service Manual
23	To disable the flow sensors for fluid. [1] Setup 26 must be off if you turn setup 23 off.	Refer to Service Manual
24	To disable the lid interlock sensors. [1]	Refer to Service Manual
25	To print a copy of the last disinfection cycle run.	20
26	To disable the flow sensors for air. [1,3]	Refer to Service Manual

[1]Functions 6, 19, 22, 23, 24, and 26 are SERVICE ACCESSIBLE ONLY.

[2]This function returns the disinfection cycle count to zero (Setup Function 16 shows "00"). REFERENCE ONLY:

Call your local distributor or *Medivators* customer service 1-800-444-4729 or 1-763-553-3300.

Caution: Clearing the cycle count occurs automatically during disinfectant dump. This function should be manually activated only under special circumstances, as it would allow running more than the maximum number of cycles with the current disinfectant.

[3]This function is available on version 5.23 software and higher versions.

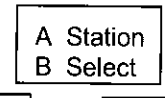
DISINFECTION FUNCTIONS

To Load Disinfectant (Setup Function 1)

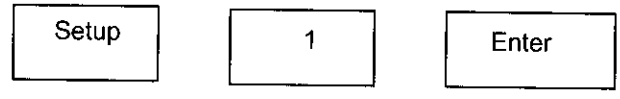
This function allows loading of fresh disinfectant into the reservoir of the **selected station**. This function can be entered on one station while the other station is operating.

Caution: The following procedure requires access to the interior of the cabinet and should be done by qualified personnel, trained and familiar with use of the unit.

1. Select the appropriate Station (A or B).



2. Press [Setup], [1], [Enter].



The display shows: **Load Dis?**

If **Load Dis?** Does not show on the display:

a. Do not put fluid in the machine.

b. Press **[Cancel]**.

c. Wait for station indicator light to turn ON without blinking. This indicates that the unit has reset.

d. If Cancel was pressed go back to Step 2. If not proceed to next step.

3. Press [**Start**] on the control panel.
4. Add approx. 1 gallon of disinfectant to verify that it is going to the bottom reservoir
5. Add the remaining 3 gallons of disinfectant.

   Use the *Medivators* AVAP manual transfer device or *Medivators* Automatic Chemical Transfer Pump for easy loading. Refer to the AVAP's package insert for more details.

6. Prime the pump for that station. Refer to Figure 1 for location of pumps A and B and bleeder valves.

   Place a container under the pump bleeder valves at the outlet of the Station B pump. When the disinfectant have drained into the reservoir, bleed the air from the pump until disinfectant flows from the bleed valve, then close the valve.

Note: The date and time of the disinfectant change are automatically recorded in the system log. To check, the log can be displayed at any time by running Setup Function 8.

To Override the Disinfectant Cycle Warning (Setup Function 7)

This function allows acknowledgment of the warning that the disinfectant is nearing its maximum number of cycles (in Setup Function 12), and to proceed with up to 10 additional disinfection cycles. This function can be done on one station while the other station is operating.

Warning: This function is not a replacement for daily monitoring of the Minimum Effective Concentration (M.E.C.) of the disinfectant. Refer to the product label or to the disinfectant manufacturer for the proper procedure. The factory-set default warning at 40 cycles and maximum of 50 cycles is based on 14-day-reuse of 2% high level disinfectant (without surfactant) and about 3 cycles per day. Set the maximum disinfectant cycles warning based on the disinfectant being used and past experience with that disinfectant's M.E.C. testing. A disinfectant may lose effectiveness before the end of reuse life.

Once the machine has run 10 less than the maximum number of cycles allowed, the system will not permit additional cycles to be run until this warning is acknowledged.

A Station B Select	Setup	7	Enter

The display shows:

Dis Warn Ack 0

On the numeric keypad, enter the appropriate number following the initial 0:

0 = Disable warning
1 = Acknowledge warning for the station(s) selected

To Set the Maximum Disinfection Cycle Count (Setup Function 12)

This function sets the maximum number of disinfection cycles that can be run by the selected station before a new batch of disinfectant must be loaded. The default setting is 50, but it must be set according to the disinfectant manufacturer's specifications.

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

Warning: The disinfectant should not be used beyond the number of days it is rated for, even if it tests effective. The disinfectant may lose its effectiveness before the end of the reuse life.

A Station B Select	Select the appropriate station (A or B).

Setup	1	2	Enter

The display shows:

S Max Dis XXX

S is the selected station (A or B).
XXX is the current maximum.
Enter the desired maximum number of disinfection cycles.

CUSTOM PROGRAM FUNCTIONS

To Set Up a Custom Program (Setup Function 5)

This function allows changing cycle times to match different disinfectants or different desired protocols. Up to **nine** custom programs can be set up. If desired, separate custom programs can be set up for the two stations (A and B). The default cycle (Program 0) cannot be changed. This function can be done only when both stations are idle.

After pressing the initial keys to enter this function, a sequence of screens appears on the display in order to enter a custom program number and the desired time for each portion of the program cycle.

Note: An existing custom program can be modified by following the same procedure. If the information on a particular screen is correct, simply press **[Enter]** to accept it without change and bring up the next screen.

A Station B Select

Select the appropriate Station (A or B).

Setup	5	Enter

The display shows:		Range	Default Value
SET PROGRAM XX	To create a new program or to modify an existing program, enter the digit on the numeric keypad that corresponds to the desired custom program and press **[Enter]**.	1-9	N/A
FLUSH MM:SS	On the numeric keypad enter the desired detergent flush time. Enter two digits for the minutes, then press **[Enter]**. Enter two digits for the seconds, then press **[Enter]**.	00:00-89:59	00:30
DISINFECT FILL MM:SS	On the numeric keypad enter the desired cycle time for disinfectant to fill and circulate in the basin. Enter two digits for the minutes, then press **[Enter]**. Enter two digits for the seconds, then press **[Enter]**.	05:00-89:59	05:00
DISINFECT SOAK MM:SS	On the numeric keypad enter the desired cycle time to soak the endoscope and circulate disinfectant through the endoscope channels. Enter two digits for the minutes, then press **[Enter]**. Enter two digits for the seconds, then press **[Enter]**.	10:00-89:59	20:00
RINSE 1 MM:SS	On the numeric keypad enter the desired cycle time the first rinse. Enter two digits for the minutes, then press **[Enter]**. Enter two digits for the seconds, then press **[Enter]**.	04:00-89:59	04:00

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RINSE 2 MM:SS	On the numeric keypad enter the desired cycle time for the second rinse. Enter two digits for the minutes, then press **[Enter]**. Enter two digits for the seconds, then press **[Enter]**. If under 4:10 you will experience a low CBR.	00:00- 89:59	04:00
ALCOHOL MM:SS	On the numeric keypad enter the desired cycle time alcohol is to be dispensed before the air cycle. Enter two digits for the minutes, then press **[Enter]**. Enter two digits for the seconds, then press **[Enter]**. To suppress an alcohol cycle, enter 0000, then press **[Enter]**.	00:00- 89:59	00:00

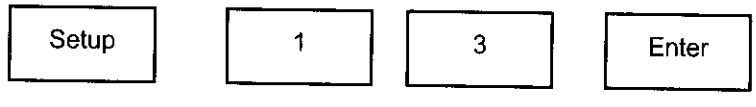
Caution: Refer to the endoscope manufacturer's recommendations regarding the use of alcohol.

SET AIR MM:SS	On the numeric keypad enter the desired air cycle time. Enter two digits for the minutes, then press **[Enter]**. Enter two digits for the seconds, then press **[Enter]**.	00:00- 89:59	05:00
MAN AIR MM:SS	On the numeric keypad enter the desired **manual** air cycle time. Enter two digits for the minutes, then press **[Enter]**. Enter two digits for the seconds, then press **[Enter]**. This is the air cycle that will be added whenever **[Add Air]** is pressed.	00:00- 89:59	10:00

Make a copy of the Custom Program Reference Chart at the end of this section, for keeping a record of the above settings.

To Clear the Custom Programs (Setup Function 13)

This function erases all the custom (user-defined) protocols that have been entered using Setup Function 5, and replaces them with the factory default settings.



The display shows:

Reset Program? To clear the current protocols, press **[Start]**.
To retain the current protocols, press any other key.

LOG FUNCTIONS

To Display the Log (Setup Function 8)

This function allows review of the status log on the display. The entire log can be displayed one entry at a time, starting with the most recent entry.

A Station B Select	Setup	8	Enter	The most recent log entry will appear on the screen.

Continue pressing **[Enter]** to display the next oldest log entry until all entries have been displayed. Or press **[Setup]** at any time to exit this function.

To Inhibit the Log (Setup Function 9)

This function allows disabling of the data logging function so that no additional entries are made.

Setup	9	Enter

The display shows:

Log Inh 0 — On the numeric keypad, enter the appropriate digit following the initial 0:

0 = Allows data logging
1 = Disable (turn off) data logging

To Clear the Log (Setup Function 10)

This function clears all entries from the data log. Once the log is full, no additional entries will be made in the log if additional cycles are run. It is recommended that the log be printed and cleared on a regular basis — e.g., once a week, or when the disinfectant is dumped.

Setup	1	0	Enter

The display shows:

Clr Log? — To clear the log, press **[Start]**.
To retain the log, press any other key.

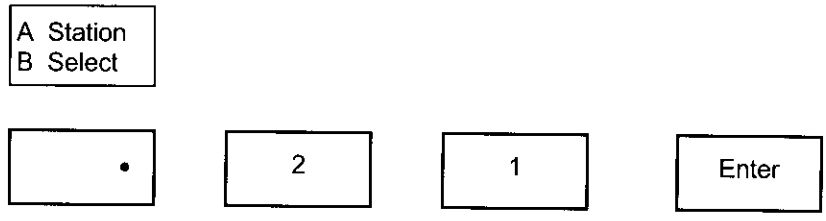
To Print the Log (Setup Function 21)

- Station must be at idle.

  This function allows printing of a paper copy of the disinfection cycle log.

- Ensure the printer is on (press the printer's on-off switch momentarily toward ON).
- Check that there is enough paper on the roll, and that the end of the paper is fed through the top of the printer and then through the slot in the top panel of the Disinfector.

Select the station(s) for which a log printout is desired -- A, B, or both.

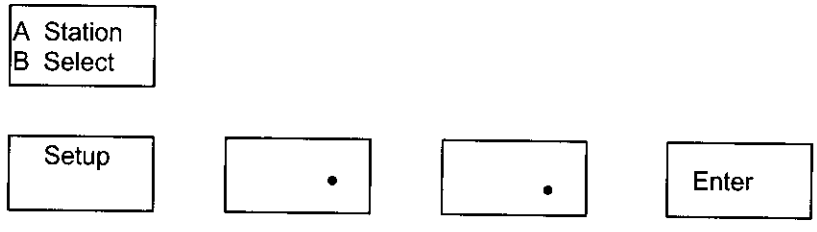


To Print the Last Disinfection Cycle (Setup Function 25)

- Station must be at idle.

  This function allows printing of a paper copy of the last disinfection cycle run.
- Ensure the printer is on (press the printer's on-off switch momentarily toward ON).
- Check that there is enough paper on the roll, and that the end of the paper is fed through the top of the printer and then through the slot in the top panel of the Disinfector.

Select the station(s) for which a log printout is desired — A, B, or both.



DATE TIME FUNCTIONS/TIME FUNCTIONS

To Set the Date (Setup Function 2)

This function allows resetting the date in the system's clock/calendar (the date that is shown on the display). This function can be done only when both stations are idle.

Setup | 2 | Enter

The display shows:

DAY XX

If the day on the display is correct, press [**Enter**]. To change it, enter the correct day (1 through 31) on the numeric keypad, then press [**Enter**].

MONTH XXX

If the month on the display is correct, press [**Enter**]. To change it, enter the correct month (1 through 12) on the numeric keypad, then press [**Enter**].

Note: Although entered as a numeral, on the display the month appears as 3 alpha characters (Jan, Feb, etc.)

YEAR XX

If the year on the display is correct, press [**Enter**]. To change it, enter the correct year (last two digits only) on the numeric keypad, then press [**Enter**].

DAY OF WEEK XX

If the day-of-week on the display is correct, press [**Enter**]. To change it, enter the correct day (1 through 7, with 1 being Sunday) on the numeric keypad, then press [**Enter**].

Note: Although entered as a numeral, on the display the day of the week appears as 2 alpha characters (Su, Mo, etc.)

To Set the Time (Setup Function 3)

This function allows resetting the time in the system's clock/calendar (the time that is shown on the display). This function can be done only when both stations are idle. Check the time shown on the display daily to verify its accuracy.

Setup | 3 | Enter

The display shows:

HOUR XX

If the hour on the display is correct, press [**Enter**]. To change it, enter the correct hour (0 through 23) on the numeric keypad, then press [**Enter**].

Note: The system uses a 24-hour clock. Hours 00 through 11 are **12 midnight through 11 a.m.**, and hours 12 through 23 are **12 noon through 11 p.m.**

MINUTE XX

If the minute on the display is correct, press [**Enter**]. To change it, enter the correct minute (00 through 59) on the numeric keypad, then press [**Enter**].

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To Set the Heater-On Time (Setup Function 14)

This function sets the time of day that the optional reservoir heater elements are automatically turned on. It is recommended that the heater-on time be set approximately 1-1/2 hours before the first endoscope will be processed. Check the temperature of the disinfectant in the reservoir with an accurate thermometer before running the first disinfection cycle of the day.

Setup	1	4	Enter

The display shows:

Htr on Hour XX — If the hour on the display is correct, press [**Enter**]. To change the hour, enter the correct hour (00 through 23) on the numeric keypad, then press [**Enter**].

Htr on Minute XX — If the minutes on the display are correct, press [**Enter**]. To change the minutes, enter the correct minute (00 through 59) on the numeric keypad, then press [**Enter**].

To Set the Heater-Off Time (Setup Function 15)

This function sets the time of day that the optional reservoir heater elements are automatically turned off.

Setup	1	5	Enter

The display shows:

Htr off Hour XX — If the hour on the display is correct, press [**Enter**]. To change it, enter the correct hour (00 through 23) on the numeric keypad, then press [**Enter**].

Htr off Minute XX — If the minutes on the display are correct, press [**Enter**]. To change it, enter the correct minutes (00 through 59) on the numeric keypad, then press [**Enter**].

To Display the Time Remaining in the Cycle (Setup Function 17)

This function displays the time remaining in the current disinfection cycle.

Setup	1	7	Enter

The display shows:

Time Remaining A: XX:XX B: XX:XX

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MISCELLANEOUS FUNCTIONS

To Clear the Disinfectant Cycle Count (Setup Function 11)

This function clears the disinfectant cycle count. This function will not operate in the middle of a cycle.

REFERENCE ONLY: CALL SERVICE TECHNICIAN.

Setup	1	1	Enter

This function returns the disinfection cycle count to zero (Setup Function 16 shows "00").

Caution: Clearing the cycle count occurs automatically during disinfectant dump. This function should be manually activated only under special circumstances, as it would allow running more than the maximum number of cycles with the current disinfectant.

To Display the Current Cycle Count (Setup Function 16)

This function displays the number of **disinfection** cycles run on each station since the disinfectant was loaded.

Note: The count automatically resets to 00 for a station when the Disinfectant Dump or Setup Function 1 are run.

Setup	1	6	Enter

The display shows:

Dis cycle count A: XX B: XX.

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To Adjust the Display Contrast (Setup Function 18)

This function adjusts the contrast level of the display screen for optimal viewing.

Setup	1	8	Enter

The display shows:

Contrast adj. The text on the display screen will fade in and out:

To stop the cycling when the contrast is at the desired level, press [**Enter**] again.

To change to a fine-tuning procedure, press [**Stop**]. Each additional press of [**Stop**] will then increase or decrease the adjustment another step. If there is less than a one-second interval between presses, the adjustment occurs in the same direction as the previous key press. If there is an interval longer than one second, the adjustment occurs in the opposite direction.

To discontinue the contrast adjustment (i.e., to return the contrast level to its previous setting), press [**Cancel**].

The display shows:

Print Log? Press [**Start**] to print the log, or [**Cancel**] to not print.

Clr Log? To clear the log, press [**Start**].
To retain the log, press any other key.

To Display Miscellaneous Information [Function 20]

This function displays miscellaneous information.

Setup	2	0	Enter

INOPERATIVE FUNCTIONS

[Function 4]

This function is not accessible to the user, as it is inoperative at this time.

Note: Setup Functions 6, 19, 22, 23 and 24, which are listed in the DSD-91E Service Manual, are SERVICE ACCESSIBLE ONLY.

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2.8 Specifications

Chassis Dimensions (height - width - depth) Height with lid open	46 X 36 X 21 inches (117 X 91 X 53 cm) 64 inches (162.5 cm)
Power Cord	Hospital grade – 8 feet
Weight (approx.)	350 lb. (160 kg)
Designed Use	Indoor
Environmental Rating	Standard
Pollution Degree	2
Mode of Operation	Continuous
Degree of Mobility	Stationary
Altitude	<15,000 feet (4,572 meters)
Humidity	<80%, non-condensing
Temperature	80° F (27° C) ± 20°
Mains Supply Voltage Fluctuations	Not to exceed ±10% of the nominal voltage
Installation Overvoltage Category	II
Classification	I, Ordinary Protection
Electrical Requirements	220 VAC 50 Hz, 8 amp, 1ϕ 110 VAC 60 Hz, 12 amp, 1ϕ
Water Requirements	Potable water from building (cold water supply) Minimum of 65 psi (4.5 bar) to prefilter,minimum of 40 – 45 psi (2.75 – 3.1 bar) after prefilter. Water temperature maximum: 110° F (43° C)
Waste Drain	The unit's drain is 26-inches above the floor. Because the unit uses a gravity system there must be at least a 3-inch drop over 36-inches for proper draining.
Reservoir Capacity	Disinfectant reservoirs: 4 gal (15 liters) each Basins: 2.4 gal (9 liters) each Alcohol and detergent reservoirs: 2 oz. (60 ml) each
Rinse Water Consumption	Approx. 5 gal (19 liters) per cycle
Disinfectant	Tested for use with 14-day-reuse 2% glutaraldehyde. Consult your local distributor or contact your local distributor or *Medivators* customer service 1-444-4729 to discuss alternative reprocessing chemicals.
Internal Heaters	Room temperature to 125° F (52° C)

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Fuses on Valve/Motor Board

Fuse	Circuitry Fused	Fuse Size
F201	All other electrical components	1.0A / 230VAC
F202	Disinfectant pump, air compressor	5.0A / 230VAC or 8.0A / 110VAC
F203	Heaters	5.0A / 230VAC
F1	Power Supply	1.0A / 230VAC

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								

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3 OPERATION

3.1 Daily Startup

At the Beginning of Each Work Day

1. If off, turn on the electrical power to the Disinfector.

Note: If the power to the unit was turned off, and the disinfectant needs to be used at other than room temperature, it may take an hour or more before the disinfectant in the reservoirs is fully heated and the unit is ready for use.

2. Open the shutoff valve in the incoming water line. The unit will not operate without water pressure.
3. Turn on the air supply (if an external source is used).
4. Check the external sediment water filter, and replace the cartridge if necessary. The cartridge must be replaced at least every 30 - 45 days.

Note: The pressure reading on the external water regulator during a flush cycle should be 40-45 psi (2.7 – 3.1 bar).

5. Check the record of when the disinfectant filter cartridges were last replaced. The cartridges must be replaced at least twice a month (or more often if usage is high), and whenever the disinfectant is changed.
6. If an alcohol purge will be used, check the supply in the alcohol dispenser.

   Check the supply of bacteriostatic enzymatic detergent in the detergent dispenser. We recommend use of a detergent such as *Medivators* Enzymatic Detergent and Pre-soak with:
   — Bacteriostatic properties to inhibit bacterial growth in the detergent reservoir and the detergent line
   — Dual enzymes to rapidly attack soils
   — Low foam properties for effective recirculation
7. Color coding to enhance worker safety.

Note: The alcohol and detergent dispensers hold a maximum of 2-oz (60 cc). Maintain at least 1-inch head space when refilling to allow for replacement of the cylinder cap.

8. Test the disinfectant (every day) for potency.

Caution: The disinfectant must not be used beyond its recommended useful life even if it tests favorably. Disinfectants may lose effectiveness before the end of their reuse life.

9. Check temperature of the disinfectant in the reservoirs with a thermometer.
10. Check the time shown on the display screen for accuracy.

To Disinfect an Endoscope

Refer to "Disinfecting an Endoscope," Refer to Section 3.4.

During the First Disinfection Cycle of the Day

Check the water pressure at the internal regulator during a flush cycle. Pressure should be 18 to 20 psi (1.25 to 1.4 bar). If it drops 5 psi (0.35 bar) or more from the original setting, replace the cartridge in the internal water filter. The cartridge must be replaced at least every 6 months.

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3.2 Process Interruption

During a disinfection cycle, the process will stop if:

- The **[Stop]** key is pressed.
- The lid has been opened while the cycle was in progress. Close the lid, select the station and press the start button to restart the cycle.
- The hospital's circuit breaker, or the fuse for the unit's power, has tripped. Have a service technician reset the circuit breaker or replace the fuse.
- The unit's ground fault circuit interrupter (GFCI) has tripped. Have a service technician press the red RESET button on the front of the GFCI.
- The unit senses either a high or low fluid level in the disinfectant reservoir. The WARNING indicator on control panel will blink, display screen will say "**High Dis Res**" or "**Low Dis Res**," and an intermittent alarm will sound. The condition must be corrected before the unit will restart.
- The unit loses water pressure. The WARNING indicator on the control panel will blink. The display will show **No Flow** and an intermittent alarm will sound.

Note: If the problem persists, call your local distributor or *Medivators* Customer Service 1-800-444-4729 or 1-763-553-3300.

Caution: Some disinfectant brands may foam. Foaming disinfectant may contact the high-level sensor and prematurely cause an erroneous message. For more information, call your local distributor or *Medivators* Customer Service 1-800-444-4729.

To Recover from a Process Interruption

After correcting the cause of the interruption (as noted above), either resume or terminate the interrupted program:

- To resume the program, press **[Start]**. The program will resume at the point of interruption.
- To terminate the program, press **[Cancel]**. This will abort the cycle in process. Depending on the phase of the cycle that has been interrupted, disinfectant will empty from the basin to the reservoir or water will empty to the drain. When all fluid has drained from the basin and the station is idle, start the next operation. Observe the unit to ensure the problem is not repeated.

Note: If scope hookup is not connected to basin, cancel cycle will not complete.

Warning: If the process has been interrupted by a power failure or brownout, reset the Disinfector and restart the program from the beginning to ensure that the endoscope has been properly disinfected.

If the cycle is interrupted, the station's status symbol on the display screen will not go blank until the entire program is successfully completed. The endoscope should not be used until the LCD status symbol disappears, indicating a complete disinfection cycle.

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3.3 Daily Shutdown

At the End of Each Work Day

1. Turn off the air supply (if an external source is used).
2. Close the shutoff valve in the incoming water line.

Caution: *Do not* allow the sanitizing solution to come in contact with any metal parts.

3. Sanitize the upper basin area and the basin lid. A chlorine based EPA registered sanitizer should be used following manufacturer's directions, to wipe the exposed areas of the basin and lid.

4. Sanitize both detergent and alcohol cylinders.
   a) Uncouple the quick-connect and lift the cylinder out of the Disinfector.
   b) Remove the cylinder cap.
   c) Attach the accessory hose to the quick-connect.
   d) Rinse with hot water.
   e) Rinse with sanitizing solution (same as step 3 above).
   f) Rinse again with hot water.
   g) Remove the accessory hose, dry it, and reinstall the cylinder in the Disinfector.
   h) Attach the quick-connect and reinstall the cylinder cap.

Once a Week, Day, or Cycle

Print a copy of the disinfection status log (Setup Function 21, **[Enter]**, **[Start]**, then clear the log (Setup Function 10, **[Enter]**, **[Start]**). Print this log, as required, according to the institution's documentation guidelines. (Setup Function 21 allows you to print the entire log. Setup Function 25 allows you to print the last cycle only.)

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3.4 Disinfecting an Endoscope

Caution: Only trained personnel following approved institution protocols should attempt these procedures.

Caution: Prior to operating the Disinfector, put on personal protective equipment for protection against contact with reprocessing chemicals and infectious material. Personal protective equipment should include proper gloves, gowns, and protective eyewear.

Preparing the Endoscope

IMPORTANT: The endoscope must be free of residual organic debris prior to disinfection. Always preclean the endoscope prior to placement into the DSD-91E.

IMPORTANT: For disinfection, the endoscope must be properly positioned and connected.

1. The endoscope must be free of organic debris prior to disinfection. Preclean it, including brushing the suction/biopsy channel in the universal cord and insertion tube. Follow the manufacturer's instructions and recognized established society guidelines (see "Guidelines for Cleaning and Disinfection").

   The air/water channels and other small-diameter channels of pediatric endoscopes may be more difficult to clean, and extra precleaning should be done for these instruments.

   Duodenoscopes with elevator wire channels require additional cleaning and disinfection steps. It is particularly important that the elevator wire channel be manually reprocessed.

2. Remove all channel valves from the endoscope. Block the endoscope ports with the appropriate fittings.
3. Coil the entire instrument inside the basin. See Figure 3 for a typical example.

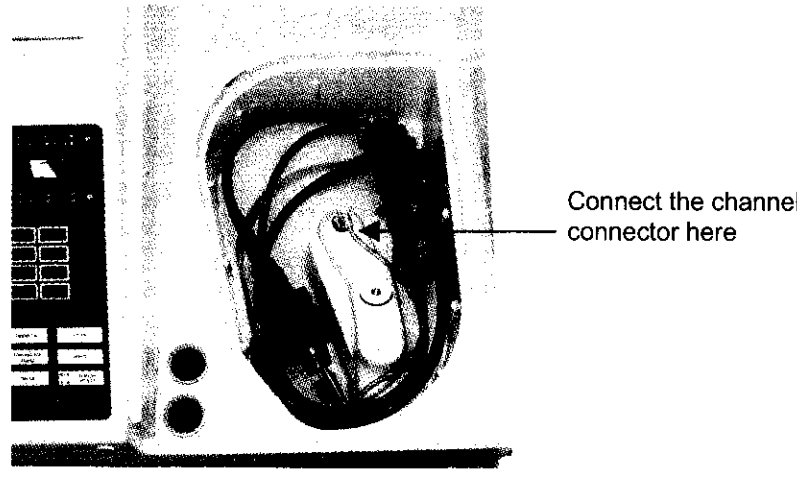

Figure 3. Positioning the Endoscope in the Basin (viewed from top front of unit)

For most endoscope models, the control section should be positioned at the right rear of the basin and the light guide connector at the left front. As the endoscope is coiled in the basin, the distal end will naturally fall into place.

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Caution: The endoscope must be positioned so that the basin cover can fully rest on its ledge, and so that the entire endoscope will be covered when the basin fills with disinfectant. The endoscope should not contact the underside of the basin cover.

4. Attach the endoscope channel connectors to the fittings on the endoscope's light guide connector. Refer to the instruction accompanying the channel connector.
5. Attach the inflow end of the channel connector to the basin fitting. See Figure 3.
6. Position the distal end of the endoscope so that fluid can be observed exiting the channel into the basin. Ensure that the hookup is not kinked.

Starting the Disinfecting Process

1. Place the cover on the basin. Confirm that the endoscope is not protruding from the basin or preventing the cover from completely seating.
2. Select the Station (A or B) where the endoscope is located.
3. Close lid.
4. Select the appropriate disinfection protocol: either the default program (0) or the desired custom program (1-9). Refer to "Run Default Disinfect Protocol" or "Run Selected Disinfect Protocol."
5. Press **[Start]**. During the detergent flush cycle:
   a. Ensure that the endoscope connections and plugs have been properly attached.
   b. Observe the components of the endoscope hookup connected to the channels to see if liquid moves into the channels and to confirm that the endoscope channels are not blocked.
   c. Observe the distal end of the endoscope until liquid is seen coming from the channel.
   d. Look for any leaks at the channel fittings and adapters.
   e. Observe the internal regulator for the station(s) being used to ensure that the pressure is between 18 and 20 psi (1.25 and 1.4 bar). Adjust the pressure only during the initial flush cycle.
6. The Disinfector will process the endoscope without any further attention from the user. The indicators at the top of the control panel will show the status of the disinfecting process.

Note:
- To interrupt the process at any point, or if the machine stops of its own accord, refer to "Process Interruption."
- If additional purging with air is desired at the end of the program, press **[Add Air]**.

When the Disinfecting Program is Completed

The indicator lights will come on, indicating a full, complete cycle.

1. Remove the channel connectors from the endoscope.
2. Remove the endoscope from the basin.
3. If the endoscope channels were not completely dried because the endoscope is to be used immediately in a procedure, reattach the valves and plug the endoscope into a light source. Turn on the light source to clear any residual water from the air channel. A spray of water should be visible exiting from the air/water nozzle at the distal end.

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3.5 Dumping the Disinfectant

Ensure that endoscope hookups are connected to station A & B quick connect fittings in upper basins.

Warning: The leak test adapter must be disconnected and removed from the basin(s) before commencing a disinfectant dump cycle.

Warning: If the leak test hardware is disabled, the leak test adapter must not be left connected to the basin, to avoid the potential for fluid ingress during operating cycles.

Select the appropriate Station (A or B), then press **[Disinfectant Dump]** (display reads "Dis Dump?), then **[Start]**, to direct the system to drain the disinfectant from the selected station's reservoir, when a determination has been made that it is no longer effective or has reached its expiration.

The disinfectant is pumped out of that station's reservoir, into the basin, and out of the drain. The basin then fills up with water for the rinse cycle. Total cycle time is approximately 14 minutes. (An indicator light will turn on at the end of the cycle.)

Once the reservoir is empty, remove the hose and the reservoir retaining pin, then pull out the reservoir. Wipe out the reservoir with a damp cloth. **Do not use** paper towels. **Wear appropriate personal protective equipment (e.g., gloves and goggles)**.

Remove the basin cover. Rinse and wipe the cover and basin with a clean cloth.

Replace the disinfectant filter cartridge. Refer to the Service Manual for the replacement procedure.

If a different brand or type of disinfectant is used, the disinfection cycle limit may have to be reset (Setup Function 12).

Note: If the dump cycle is interrupted and not completed, cycle counter will not reset.

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3.6 Operator Maintenance

The operator should assure proper water pressure and that disinfectant monitoring is complete. The operator should also insure that the enzymatic detergent and alcohol dispensers are filled, if these options are selected in the program. Follow all manufacturers' labeling.

Microbiologic Monitoring of Fluid and Air Pathways

The DSD-91E is designed such that an endoscope being disinfected is contacted only by bacteriostatic detergent, high level disinfectant, alcohol, and water or air that has passed through a 0.2-micron filter. If your institution's infection control program includes periodic monitoring of the DSD-91E, the surface of the endoscope basin may be aseptically swabbed and cultured at specified intervals immediately at the conclusion of a full disinfection cycle.

Maximum Cycle Count

Setup Function 12 sets the maximum number of disinfection cycles that can be run by the selected station before a new batch of disinfectant must be loaded. This maximum disinfection cycle count must be set according to the disinfectant manufacturer's specifications. The default cycle limit, if not changed by Function 12, is 50 cycles.

Once the number of cycles run is 10 less than the maximum number of cycles programmed by Setup Function 12, the system displays a warning that the disinfectant is nearing its maximum number of cycles. This message indicates that the disinfectant is reaching the end of its rated life, which could make it ineffective for high-level disinfection. Setup Function 7 may now be performed, acknowledging the warning and allowing up to 10 additional cycles.

The system will not permit the additional cycles until the warning has been acknowledged. Once 10 additional cycles have been run, the system will not permit **any** additional cycles until the disinfectant is changed. The 10-cycle warning feature allows you to schedule a technician to change the disinfectant in the reservoir at a convenient future time.

Disinfectant Testing

Test disinfectant potency **daily**. High level disinfectant can be easily tested for dilution using available test kits: contact the disinfectant manufacturer for the specific test to use.

Caution: Follow instructions and heed all warnings on the chemical disinfectant. The disinfectant must not be used beyond its expiration date, even if it tests favorably. Disinfectants may lose effectiveness before the end of their reuse life.

Changing Disinfectant

Refer to Section 2.7 Setup Function 1, "To Load Disinfectant".

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Disinfecting the Internal Water Filter (Refer to Quick Guide)

Caution: The 0.2-micron water filter (MF01-0007) is not compatible with hydrogen peroxide chemicals, i.e. SPOROX™ sterilizing and disinfecting solution. A glutaraldehyde solution should be used to sterilize filters of this type. Use 0.2-micron filter, part number MF01-0012 with approved hydrogen peroxide disinfecting/sterilizing solutions.

Caution: The internal water filter *must* be sterilized with disinfectant before use:

Note:
- Station A must have disinfectant in its disinfectant reservoir.
- Station B must have effective disinfectant in its disinfectant reservoir since you will be utilizing the disinfectant from station B in order to disinfect the internal water filter housing and associated tubing.

1. The DSD must be in the idle state. Place an endoscope hookup connector into station A and B's endoscope basin without an endoscope attached. Place the floating lids onto the endoscope basins and close the station covers.

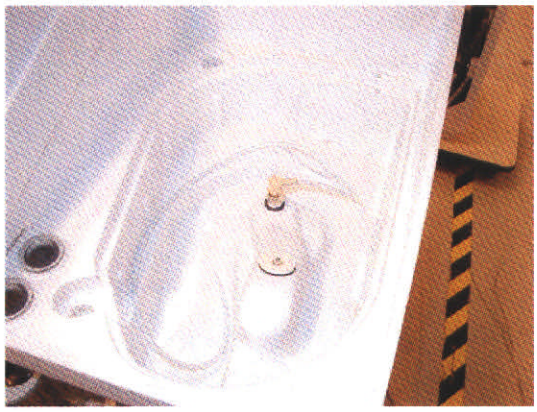

Figure 4. Hookup connected to Station "B"

2. Close the incoming water supply valve external to the DSD.

3. Open the front panel doors to the DSD and disconnect the internal water filter, inlet connector from the incoming water supply line. (This connector is located on the bottom tubing line coming from the internal water filter).

4. Place a container underneath the internal water filter's, bleeder valve line. Open the bleeder valve to relieve the water pressure. Refer to Figure 5.

5. Unscrew the internal water filter clamp and remove the canister housing in order to expose the internal water filter.

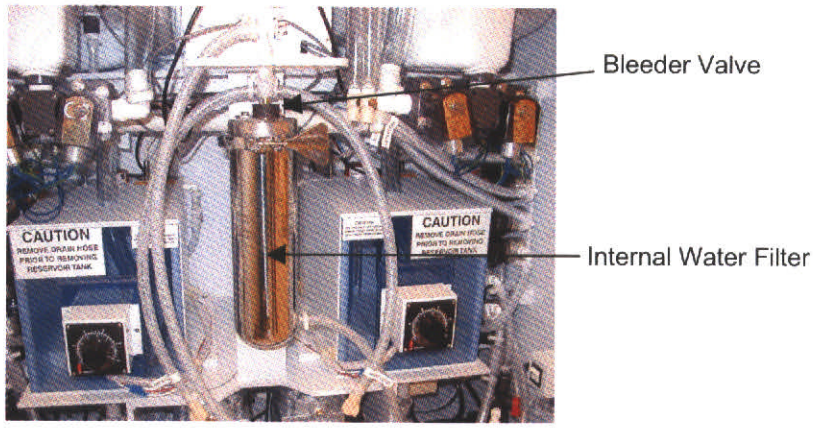

Figure 5. Internal Filter Canister

6. Turn the internal water filter ½-inch in the -clockwise position in order to unlock the filter from the mounting posts. Then pull the filter downwards, in order to release and discard the filter.

7. Place the new filter into the internal water filter housing by pushing the filter upwards with the locking tabs of the filter away from the locking posts. Turn the internal water filter counter clockwise until the filter locks into the posts.

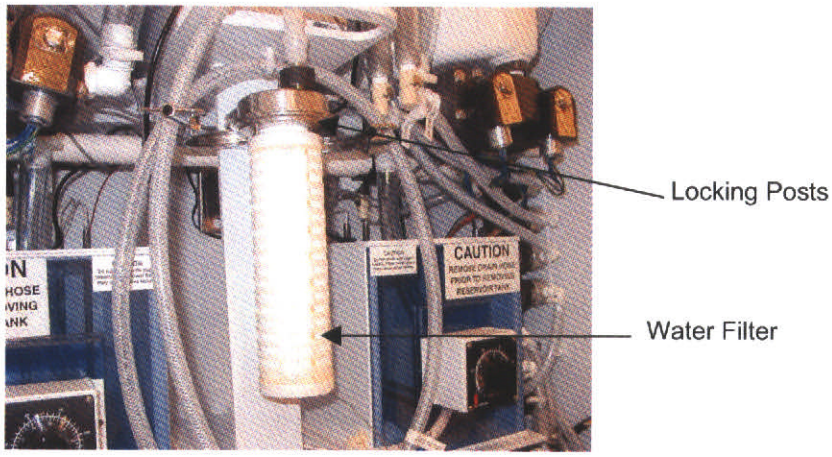

Figure 6. Internal Water Filter

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8. Wipe the internal water filter canister clean with a lint-free cloth.

9. Re-attach the internal water filter canister ensuring that the o-ring is in place. Lock the filter down using the screw-clamp.

10. Attach the bottom, internal water filter line to station B's disinfectant pump's bleeder valve line. Open the disinfectant pump, bleeder valve. Refer to Figure 7.

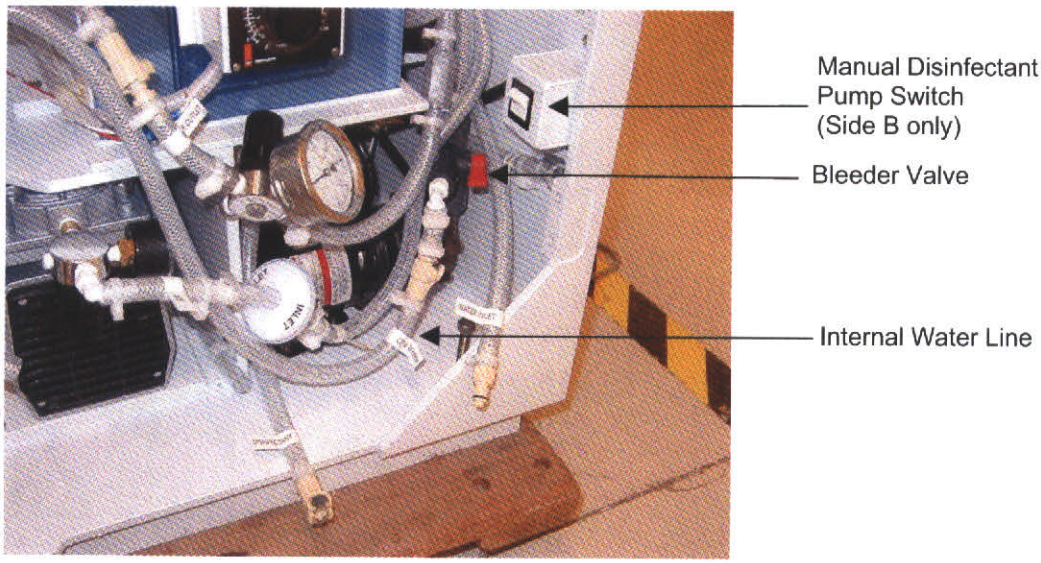


Figure 7. Internal Water Filter Line

11. Ensure that the bleeder valve on the internal water filter housing is open and has a container underneath the bleed valve line.

12. Turn on the disinfectant pump on station B by depressing the manual pump switch located on the right-hand, side of the DSD cabinet.

13. Once the disinfectant flows out the internal water filter housing's bleed line, let go of the manual pump switch. Close the bleeder valve on the internal water filter housing.

14. On the DSD front panel, press Station Select and choose both stations A and B.

15. Ensure that program 9 is set for a flush time of 10:00. Press Program, 9, and Enter. Refer to Section 2, Custom Program Functions.

16. Press Start and immediately depress the manual pump switch on the right-hand side of the cabinet in order to energize station B's disinfectant pump.

17. Once the disinfectant flows from the endoscope hookups in the endoscope basins, release the manual pump switch and press the Stop key on the front panel. (If the DSD is alarming with the No Flow error, ignore the error).

18. Close the disinfectant pump, bleed valve on station B.

19. Leave the DSD in the Stop state with the disinfectant in the internal water filter housing and associated tubing for a minimum of ten hours (not exceeding 24 hours) for sterilization.

Note: You may leave the disinfectant for only 20 minutes if you only desire to achieve a high-level disinfection, not sterilization. Please refer to the manufacturer's label of your disinfectant for the exact time periods in order to achieve either high-level disinfection or sterilization.

20. After the required time period has passed, disconnect the internal water filter's incoming line from the disinfectant pump's bleeder valve on side B and reconnect the this line to the water inlet line.

21. Open the external incoming water supply valve to the DSD.

22. Ensuring that both stations A and B are still selected, press the Start key to resume the ten-minute flush cycle. At the end of the Flush cycle, press the Cancel key in order to abort the program.

23. Press the Station Select key to enable both stations, Program, X (where (x) represents the number of the normal disinfection program used, 0-8), and the Enter keys.

24. Depending upon the life left in your disinfectant on side B, you can either:
    - Dump the remaining disinfectant on side B.
    - Add additional disinfectant into station B (Station Select B only, Setup, 1, and the Enter key).

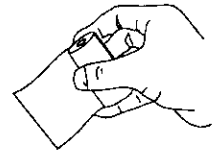
    This will bring the disinfectant level up to the bottom of the caution sticker (approximately 1 1/4" from the top of the disinfectant reservoir).

Replacing the Printer Paper

Caution: Use printer paper Part No. MP10-0502.

To change the paper roll:

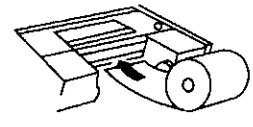
1. Raise the cover that is over the printer compartment (on top of the Disinfector).
2. Press the rocker switch to the left. The light will go off.

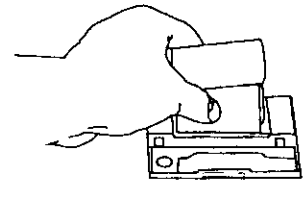


3. Remove the used paper roll and any remaining paper by pressing on the paper feed button on the printer:

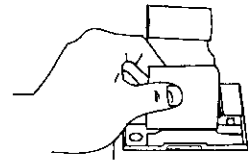
Caution: Never pull the paper out of the back of the printer, as this will damage the print mechanism.

4. Advance the paper about 1-inch beyond the paper cutter by using the Paper Feed switch.
5. Cut off any remaining paper on the roll from the printer.
6. Pull the remaining paper through the printer mechanism. **Be sure to pull the paper from the top** (paper cutter side).
7. Unroll several inches of the paper from a new roll.
8. Cut the leading edge of paper roll if uneven. This will facilitate the entry of the paper into the printer.
9. Slide the paper through the slot connecting the paper compartment and the printer compartment. You can slide it in about ¼-inch before it stops.

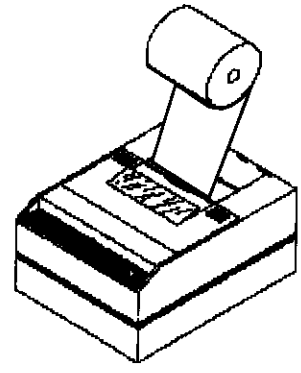




10. While holding the paper in place, press the rocker switch to the Paper Feed position. The printer will activate, and a rubber roller will pull the paper into the printer compartment. Hold the switch in the Paper Feed position until the paper emerges from the top of the printer mechanism.
11. When a 1-inch of paper has emerged from the top of the printer, release the Paper Feed button.
12. Now pull the paper through the printer, until several inches are exposed.



13. Place the paper roll in the back of the printer. Turn the paper roll so as to take up any slack in the paper feeding to the printer. Make sure the roll of paper turns freely. If it does not turn freely, the paper will jam and will possibly damage the printer mechanism.



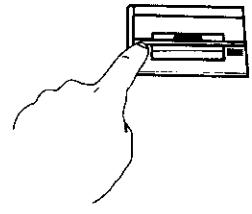
14. Reinstall the printer's clear rear cover. Lower the machine cover that is over the printer compartment.
15. Pull the excess paper through the slot on the Disinfector's printer cover.
16. Lower the machine cover that is over the printer compartment.

Replacing the Printer Ribbon

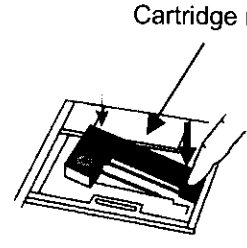
Note: Use printer ribbon Part No. MP10-0500.

Replace the ribbon when the printing becomes difficult to read:

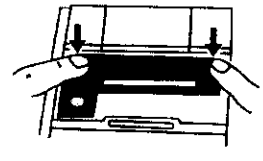
1. Turn the printer switch OFF.
2. Four small grooves are embossed on each side of the printer's front cover. Push down on one or both of these areas until the cover tilts.



3. When the printer cover is tilted up, lift it completely off.
4. Push down on the right side of the ribbon cartridge where it is marked "PUSH".



5. Remove the cartridge.
6. Install a new cartridge in its place. (If there is paper in the printer, slide the cartridge over the paper be sure the paper goes between the ribbon cartridge and the ink ribbon.)
7. Ensure that the ink cartridge is properly sealed and aligned. (Weak or irregular printing is a sign that the ink cartridge is not inserted firmly.)



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8. Turn the cartridge "knob" (marked by an arrow) clockwise to stretch the ribbon.

9. Reinstall the cover.

Caution: If you get ribbon ink on the printer case, wipe it off immediately. Once it dries, it is difficult to remove.

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3.7 Replace Fuses

1. Unplug the unit from the AC power receptacle.
2. Remove the access screw at the front of the control panel lid.
3. Disconnect the wiring harnesses and remove the board.
4. Remove the fuse from the board.
5. Inspect visually or electrically to determine if fuse is damaged.
6. Replace damaged fuses.
7. Reconnect the harness.
8. Reinstall the cover over the motherboard.
9. Replace the access screw.
10. Plug the power cord into the power receptacle.

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3.8 Leak Tester Operation and Testing

Description:

If your *Medivators* DSD-91E reprocessor is fitted with the leak tester option, continue reading the following information. The function of this option is controlled from the set-up menu via SET-UP 27. SETUP 27 is a service accessible only setup. Refer to Service Manual, Section 5.3, Steps 1 through 6 to place the DSD-91E into diagnostics mode.

Note: The DSD warning indicators will blink whenever any condition occurs that may need operator attention (upper indicator for Station A and lower indicator for Station B). When indicators are activated, the LCD screen typically contains additional information about the warning status.

When enabled, the interior of the endoscope will be pressurized each time a cycle is started. If a gross leak is detected within the first minute, the DSD-91E will stop and alert the operator. The pressure is also maintained throughout the disinfection process to monitor for the presence of any small leaks. If a pressure drop is noticed, the DSD-91E will continue the disinfection process and alert the operator at the end of the cycle.

The endoscope is automatically deflated at the end of the disinfection process.

The leak tester is compatible with Olympus, Pentax and Fujinon endoscopes. Adapters are available to enable any of these scopes to be connected to the DSD-91E.

Caution: The leak test adapter should be disconnected and removed from the basin(s) during extended periods of non-use to avoid the potential for fluid ingress.

Note: The use of automated leak testing is not a substitute for manual leak testing as per the instructions of the endoscope manufacturer.

Note: Connection of the leak test adapter to the scope and to the basin connector is simplified if the adapter is connected to the scope prior to loading in the basin.

Instructions for Use.

1. Ensure that the waterproof caps/leak test adapters are fitted to the endoscope.
2. Load the endoscope, making normal channel connections.
3. Connect the leak test adapter to the connector on the endoscope.
4. Connect the small CPC fitting to the leak test outlet in the center of the upper chamber.
5. Select the cycle required as normal and press start.
6. There will be a one-minute delay before the normal disinfection cycle starts:
   - 30 seconds to inflate the scope.
   - 30 seconds to monitor the pressure.
7. The DSD-91E will only indicate a leak test failure. If no indication is shown, the endoscope has passed the test.
8. The log printout, SET UP 21 will indicate if the leak test option is enabled. It will also indicate a leak test failure.

3.9 Delayed Start Option

Description:

Many G.I. units are faced with increased workloads causing a longer working day and earlier starts.

In response to this dilemma, *Medivators* has developed a further option to the DSD-91E endoscope reprocessor. The delayed start option will allow staff to load endoscopes at the end of the operating list, set a disinfection program and remote start time and leave the unit. At the pre-programmed time, the DSD-91E will automatically start and carry out the disinfection cycle.

This function will allow staff to process two endoscopes before they arrive for duty, thus easing the subsequent day's workload.

The delayed start option is enabled or disabled via the set-up menu and can be run either synchronously or asynchronously. If required, different program selections can be made for either station.

Instructions for Use:

1. To initiate the delayed start option:
   a. Select 'A', 'A/B' or 'B' station.
   b. Press SET UP.
   c. Press 29.
   d. Press ENTER.
      - Press "1 ENTER" to enable.
      - Press "0 ENTER" to disable.
2. To set the remote start time:
   a. Select 'A', 'A/B' or 'B' station.
   b. Press SET UP.
   c. Press 28.
   d. Press ENTER.
   e. Program the hour that you wish the cycle to start and press ENTER.
   f. Program the minutes that you wish the cycle to start and press ENTER. The DSD-91E will now carry out the disinfection process that is selected and displayed on the screen.

Note:

- The delayed start facility will only carry out the disinfection program that is selected.
- When this option is enabled you cannot enter endoscope serial numbers for hard copy printout.
- The DSD-91E will carry out a delayed start every 24 hours at the pre-set time unless the option is disabled.

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3.10 Chemical Loading System.

Description:

This *Medivators* DSD-91E has been fitted with the Chemical Loading System. A diaphragm pump is mounted behind the compressor assembly and is operated by a spring loaded switch which is located on the left hand side of the machine just above the lower door hinge.
The inlet and outlet for the pump are located either side of the compressors just below A & B reservoirs.

Instructions for Use:

To Load Disinfectant:

1. Locate and disconnect the disinfectant outlet from the bottom of the reservoir to be filled (large gray CPC fitting).

2. Connect the elbow end of filling tube set to the bottom of the reservoir.

3. Connect the other end of this tube to the fitting marked OUTLET, which is located to the right of the compressors.

4. Connect the end of the remaining tube set which has the CPC fitting to the INLET located to the left of the compressors.

5. Insert the end of this tube into the container of activated solution. Press and hold the switch until the solution container is empty. Repeat this operation for the remaining containers.

6. Repeat this operation for the other side of the machine.

Note: Ensure that the cycle count is reset by using SETUP 11.

To Unload Disinfectant:

1. Locate and disconnect the disinfectant outlet from the bottom of the reservoir to be emptied (large gray CPC fitting).

2. Connect the elbow end of filling tube set to the bottom of the reservoir.

3. Connect the other end of this tube to the fitting marked INLET, which is located to the left of the compressors.

4. Connect the end of the remaining tube set which has the CPC fitting to the OUTLET located to the right of the compressors.

5. Insert the end of this tube into the empty container to be used for unloading. Press and hold the switch until the container is full. Repeat this operation for the remaining containers.

Note: When unloading disinfectant ENSURE that the container being used is the correct size for the amount of solution being dumped. If dumping into one-gallon containers, release the switch before the container is full.

6. Ensure that the cycle count is reset by using SETUP 11. Refer page 2-19 user manual.

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4 TROUBLESHOOTING

4.1 Process Interruption

During a disinfection cycle, the process stops if:

- The **[Stop]** key is pressed.
- The hospital's circuit breaker has tripped or the fuse for the unit's power has blown. (Only trained personnel should reset the circuit breaker or replace the fuse.)
- The unit's ground fault circuit interrupter (GFCI) or current limiting device has tripped. (Only trained service personnel should press the red RESET button on the front of the GFCI.)
- If any of the unit sensors finds a fault:

1. The unit senses either a high or low fluid level in the disinfectant reservoir. The WARNING indicator on the control panel blinks, the display screen indicates "High Dis Res" or "Low Dis Res," and an intermittent alarm sounds. The condition *must* be corrected before the unit will restart.
2. Lid ajar – This message indicates that the lid has been opened while the cycle was in progress. Simply close the lid, select the station and press the start button to restart the cycle.
3. No Flow – This message indicates that fluid flow has dropped to an unacceptable level at some time during a scope irrigation portion of the cycle. This could happen during the flush, disinfect, rinse, and air purge portions of the cycle. Select the station that has stopped and press start to restart the cycle. If the error is still present, some of the possible causes are as follows:
   a. Scope hookup not connected to the disinfector or kink in tubing (connector).
   b. Insufficient water pressure due to supply pressure drop, Blockage of sediment filter, blockage of internal water filter, or improper adjustment of the water pressure regulator.
   c. Low disinfectant flow due to disinfectant filter blockage or failure to prime disinfectant pump.
   d. Low air flow during air purge due to filter blockage, or misalignment of air pressure regulator.
4. Low Cbr – (low chamber) This message indicates that fluid has not filled the chamber in the disinfection or rinse portions of the cycle. This could be caused by any of the items listed above which cause low flow in the water rinse and disinfect portions if the cycle. Select the station that has stopped. Press start to restart the cycle. This will result in an additional 10 seconds for the chamber to fill. Repeat this process to force a cycle to complete.
5. Flow error – This message is generated at the start of the cycle if the flow sensor indicates flow when no flow is present. Press the Add Air key to attempt to free the flow sensor. If the error persists the flow sensor will need to be cleaned or replaced.
6. Basin error – This message is generated at the start of the cycle if the basin sensor indicates fluid is in the basin when fluid should not be present. This condition could be caused by contamination on the basin level sensor or a defective sensor. Clean the sensor with a soft cloth, if this does not correct the problem the sensor will need to be replaced.
   - Other problems may also cause process interruption. See Section 4.1.

Note: If the problem persists, call your local distributor or *Medivators* Customer Service 1-800-4444-4729 or 1-763-553-3300.

Caution: Some disinfectant brands may foam. Foaming disinfectant may contact the high-level sensor and prematurely cause an erroneous message.

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To Recover from a Process Interruption

After correcting the cause of the interruption (as noted above), either resume or terminate the interrupted program:

- To resume the program, press **[Start]**. The program resumes at the point of interruption.
- To terminate the program, press **[Cancel]**. This aborts the cycle in process. Depending on the phase of the cycle interrupted, disinfectant empties from the basin to the reservoir or water empties to the drain. When all fluid has drained from the basin and the station is idle, start the next operation. Observe the unit to ensure that the problem is not repeated.

Warning: If the process has been interrupted by a power failure or brownout, reset the Disinfector and restart the program from the beginning to ensure that the endoscope has been properly disinfected.

If the cycle is interrupted, the station's status symbol on the display screen does not go blank until the entire program is successfully completed. The endoscope should not be used until the LCD status symbol disappears, indicating a complete disinfection cycle.

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4.2 Troubleshooting Guide

The following table lists the most common problems experienced while working with the Disinfector. If you need additional information, contact your local distributor or the *Medivators* Customer Service at 1-800-444-4729 or (763) 553-3300.

Problem/Message	Cause	Corrective Action
Machine won't start.	Electrical power is not being supplied to the system.	Be sure the unit power cord is plugged into a proper receptacle.
	Warning: *Do not* proceed further until the system has been unplugged from line power. Continuing while the system is attached to line power presents a serious shock hazard! The system board and various connectors have high voltage present whenever the system is plugged into the wall socket.	
	System fuse has blown.	Contact Service Technician
	Note: To remove the entire electronic package from the unit, remove the lid shocks and fully open the lids and center console.	
Low level warning (disinfectant is being lost).	Drain valve not closing	Check drain valve for foreign material.
	Unit is not level.	Contact Service Technician
	No disinfectant in lower tank	Add disinfectant
	Return valve blockage	Contact Service Technician
High level warning (water is getting into disinfectant reservoir).	Disinfectant overflow valve not closed (foreign matter caught in one of the valves).	Contact Service Technician
	Disinfectant valve, due to improper seal or foreign matter in valve.	Check and clean the disinfectant valve or contact Service Technician
	Excessive foaming	Contact Service Technician
Water entering sink slowly.	Sediment water filter is plugged.	Contact Service Technician
	0.2-micron filter plugged	Contact Service Technician
	Water regulator setting has been changed, causing a drop in water pressure.	Contact Service Technician
	Debris in water valve	Contact Service Technician
	Supply pressure too low	Call hospital maintenance.

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Disinfectant not filling properly.	Disinfectant filter is plugged (causing slow fill of basin).	Contact Service Technician
	Disinfectant valve seal is worn.	Contact Service Technician
	Chamber valve seal is worn.	Contact Service Technician
	Quick connector on lower tank tubing is plugged with lint.	Contact Service Technician toweling causes lint buildup in quick connector.)
	Disinfectant pump is not bled.	Contact Service Technician
Disinfectant not draining to lower tank.	Disinfectant return valve and/or disinfectant overflow valve is failing to open or is not opening completely.	Contact Service Technician
	Obstruction in the drain manifold.	Contact Service Technician
Constant flow of water out of hookups	Water valve not sealing	Contact Service Technician
Water is not draining out of basin during flush or rinse cycle.	Kink in drain line outside of the machine.	Find the kink and straighten it out.
	Drain line is plugged.	Unplug.
	Drain valve is not opening or is plugged.	Contact Service Technician
Air doesn't purge scope after each cycle, or manual air doesn't come on.	Air compressor not working.	Contact Service Technician
	Air is getting to the machine, but not to the scope (air regulator has failed).	Contact Service Technician
	Air valve not opening	Contact Service Technician
Disinfectant pump and air compressor do not work.	F202 fuse	Contact Service Technician
		Contact Service Technician
Valves not working.	Fuses blown because of power surge.	Contact Service Technician
LCD screen shows a black bar	Bad ribbon cable.	Contact Service Technician
Printing is faint.	Ribbon worn out.	Replace the ribbon.
	Infrequent use.	Advance the ribbon by holding down the paper feed switch for a few seconds.
Printer will not operate.	Printer is disconnected.	Reconnect the printer.
	Transformer is unplugged.	Contact Service Technician
	Printer is broken.	Contact Service Technician
	Rocker switch has been turned OFF.	Press the rocker switch to ON LINE.
	Ribbon is stuck	Move or replace the printer ribbon.
Water is entering the air line.	Bad air check valve.	Contact Service Technician
Function occurs that is not	Inadvertent function entry.	Press the asterisk * key or the cancel key to reset

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intended.		the unit. Indicator lights will be lit when resetting is complete.
RTC Fail	Motherboard is faulty	Press SETUP to reinitialize if problem persists, contact Service Technician
Lid ajar	The lid has been opened while the cycle was in progress	Close the lid, select the station and press the start button to restart the cycle.
No flow	indicates that fluid flow has dropped to an unacceptable level at some time during a scope irrigation portion of the cycle	Select the station that has stopped and press start to restart. If error is still present, check these possible causes. Determine if cycle is in the disinfectant portion or rinse portion.
	• For no disinfectant flow check.	
	a) Lint build up in quick connector.	a) Clean quick disconnect.
	b) Disinfectant pump not bled properly.	b) Contact Service Technician
	c) Faulty disinfectant pump.	c) Contact Service Technician
	d) Faulty disinfectant valve.	d) Contact Service Technician
	• For no rinse flow check:	
	a) Scope hookup not connected to disinfector.	a) Connect scope
	b) Incoming water not connected or shut off.	b) Connect or turn on water.
	c) Water sediment filter plugged.	c) Clean water sediment filter.
	d) 0.2-micron filter plugged.	d) Contact Service Technician
	e) Faulty water valve	e) Contact Service Technician
No air flow	a) Low air pressure in air purge due to blockage of air filter.	a) Contact Service Technician
	b) Faulty air compressor.	b) Contact Service Technician
	c) Blown F202 fuse.	c) Contact Service Technician
	d) Scope hookup not connected to upper basin	d) Connect the scope.
	e) Kink in scope connector	e) Find kink and straighten
Low Cbr - (low chamber)	Fluid has not filled the chamber in the disinfection or rinse portions of the cycle in the allotted amount of time.	Select the station that has stopped. Press start to restart the cycle Determine disinfectant or rinse cycle.
	• If disinfectant:	
	a) Check for lint in quick connect.	a) Clean quick connect.
	b) Faulty disinfectant valve	b) Contact Service Technician
	c) Faulty chamber valve.	c) Contact Service Technician
	d) Clogged disinfectant filter.	d) Contact Service Technician
	• If rinse:	
	a) Clogged 0.2-micron filter.	a) Contact Service Technician
	b) Clogged water sediment filter.	b) Contact Service Technician
	c) Faulty water valve.	c) Contact Service Technician
	d) Low water supply pressure	d) Call building maintenance.
Flow error	Faulty flow sensor	Press "Add Air" key to attempt to free flow sensor. If problem persists Contact Service Technician
Basin error	Drop of water on sensor.	Clean the sensor with a soft cloth.
	Defective sensor.	Contact Service Technician
	Defective sensor board.	Contact Service Technician

5 Glossary

5.1 Term Definition

Term	Definition
'Add air'	Adds 10 minutes to air cycle
'Air'	Air dry the endoscope
'Alcohol'	Drying inside of endoscope channels
AVAP	Anti vapor Manual Chemical Transfer Device
'Basin Error'	No fluid in basin
'Bsn Soak'	Detergent soak cycle
'Cancel'	Starts the existing cycle over
'Disinfect'	Disinfecting the endoscope
'Dump disinfectant'	Empty basin
'End of log'	Indicates the end of log
'End of program'	End of program'
'Expired dis'	Disinfectant must be changed
'Flow Error'	Faulty or jammed flow sensor
'Flush'	Cleaning endoscope channels
'High reservoir'	Water is mixing with disinfectant
'Invalid record'	Invalid record'
'Lid ajar'	Lids are open
'Load disinfectant'	Fill basins
'Low Chamber'	Fluid level is low
'Low reservoir'	Disinfectant has been lost
'Manual air'	Manual air'
'No flow'	No fluid flow
'Power on'	Power is on
'Reseting'	Starts the existing cycle over
'Resume'	Ends the pause and continues cycle
'Rinse 1'	Rinsing the endoscope
'Rinse 2'	Rinsing the endoscope
RTC Fail	Real time clock failure
'RTC chk err'	Real time clock checksum error
'Scp Soak'	Scope is soaking
'Start'	Starts the machine

Term	Definition
'State Err'	State error
'Stop'	Temporary pause
basin	The chamber into which the endoscope is placed for disinfection.
cleaning	Physical removal of organic debris.
control panel.	The keys, LED indicators, and LCD screen that allow the user to set up and operate the unit and that provide information about the disinfection cycle. Located in the center of the unit, between the two stations. Refer to Figure 2.
custom program	A disinfection program that can be entered and selected by the operator using Setup Function 5. See Section 2.7, Setup Functions.
cycle	A sequence of phases that collectively constitute the disinfection process: Detergent flush, basin fill, disinfection, rinse, alcohol purge, air purge, additional air. See Section 2.4, Disinfection Cycle Chart.
cylinder	The container that holds detergent or alcohol.
default program	The disinfection cycle program provided with the Disinfector that will be executed if the operator selects no alternative program.
function	Any operation other than a disinfection program (e.g., a *disinfectant discard* cycle). See Section 2.6, Protocol Selection Functions and Section 2.7, Setup Function.
high-level disinfection	Defined by the Centers for Disease Control and Prevention as a process that destroys all vegetative bacteria, viruses, and fungi, but not necessarily all bacterial endospores.
idle state	A standby operating state during which no program cycles or other functions are in progress. Some setup and initialization functions require that the stations be in the idle state prior to their operation.
LCD status symbol	A signal on the control panel display screen that indicates the unit's current operating state. Each station has a separate LCD status display. Refer to Figure 2.
phase	A particular portion of a disinfection cycle (e.g., the *air purge* phase at the end of a cycle).
disinfection procedure	A preprogrammed series of phases that collectively constitute a specified disinfection protocol. See also "default program" and "custom program."
reservoir	The container that holds disinfectant.
running state	An operating state during which a program is in progress, or some other function is occurring (i.e., any state other than idle or stop).
station	The part of the system used to disinfect a single endoscope. A station includes a basin, fluid reservoirs, valves, hoses, pump, and compressor. Refer to Figure 1.
status log	A record of the recent disinfection cycles run in the unit, maintained in the computer's memory. It contains the unit's usage history, error status, and endoscope numbers (if entered). The unit's printer can print the contents of the log.
stop state	An operating state during which a disinfection protocol is in progress, but the current cycle is suspended. A program may be suspended by operator intervention or by the system if an error condition is detected.

6 WARRANTY

1. **Limited Warranty.**

   a. **Warranty.** *MEDIVATORS* warrants to the Distributor (and to no other person) that the Products (as such term is defined in the Distributor Agreement), with the exclusion of accessories as defined in B below, and the component parts thereof, distributed or manufactured by *MEDIVATORS*, shall be free from defects in workmanship and materials (the "Warranty") for a period of 15 months from the date of delivery to the distributor, or one year from the date of installation, whichever comes first (the "Warranty Period").

   b. **Accessories.** Accessories including, but not limited to, printer and hookups have a 90 day warranty.

2. **Limitations of Liabilities and Disclaimer of Warranties.**

   a. ***MEDIVATORS'* Obligation.** *MEDIVATORS'* sole obligation in the case of any breach of the Warranty, shall be, at *MEDIVATORS'* option, to repair or replace the Product without charge to Distributor or to refund the Distributor's purchase price of the Product. In order to recover under the Warranty, Distributor must send *MEDIVATORS* written notice of the defect (describing the problem in reasonable detail) prior to the expiration of the Warranty Period and within thirty (30) days of discovery of the defect.

   b. **Return Procedure.** Upon receiving *MEDIVATORS'* official "return goods authorization" (RGA), Distributor shall return the Product to *MEDIVATORS*, freight and insurance prepaid, for inspection. In the case of international shipment, contact *MEDIVATORS* international customer service representative for shipping and customs broker instructions. *MEDIVATORS* will not be responsible for damage due to improper packaging or shipment.

   c. **Refund, Repair or Replacement.** If *MEDIVATORS* determines in its sole reasonable discretion that the Product contains defective workmanship or materials, *MEDIVATORS* will refund to Distributor the purchase price for the defective Product or return the repaired Product or a replacement Product to Distributor, freight and insurance prepaid, as soon as reasonably possible following receipt and inspection of the Product by *MEDIVATORS*. If *MEDIVATORS* determines in its sole reasonable discretion that the Product does not contain defective workmanship or materials, *MEDIVATORS* will return the Product to Distributor, freight and insurance billed to Distributor.

   d. **Voiding Warranty.** This Warranty is voided immediately as to any Product which has been repaired or modified by any person other than authorized employees or agents of *MEDIVATORS* or which has been subjected to misuse, abuse, negligence, damage in transit, accident or neglect. Any and all modifications must be approved by the Company.

   e. **Disclaimer of Warranty.** Except as provided in Paragraph I(A), all Products and accessories are being sold to Distributor on an "AS IS" basis. THE WARRANTY PROVIDED IN PARAGRAPH I(A) IS INTENDED SOLELY FOR THE BENEFIT OF DISTRIBUTOR AND *MEDIVATORS* DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND WARRANTIES ARISING FROM COURSE OF DEALING AND USAGE OF TRADE. Notwithstanding the foregoing sentence, in the event an implied warranty is determined to exist, the period of performance by *MEDIVATORS* thereunder shall be limited to one (1) year after the date of shipment of the Product to Distributor. No employee, representative or agent of *MEDIVATORS* has any authority to bind *MEDIVATORS* to any affirmation, representation or warranty except as stated in this written warranty policy.

   f. **Limitation of Remedy.** *MEDIVATORS* SHALL NOT BE LIABLE TO ANY PERSON FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, LOST PROFITS OR MEDICAL EXPENSES, CAUSED BY THE USE OR SALE OF THE PRODUCTS, WHETHER ARISING UNDER WARRANTY OR OTHER CONTRACT, NEGLIGENCE OR OTHER TORT OR OTHER THEORY, THE REMEDY PROVIDED IN PARAGRAPH II(A) HEREOF SHALL CONSTITUTE DISTRIBUTOR'S SOLE REMEDY FOR BREACH OF WARRANTY.

   g. *MEDIVATORS* disinfectors were tested and validated with approved *MEDIVATORS*™ filters. *MEDIVATORS* is not responsible for cost of repairs associated with use of non *MEDIVATORS* approved filters.

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Manufactured in the USA by:

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REPROCESSING SYSTEMS
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Appendix L

Predicate Comparison Table

Item	Medivators MDS for use with Reuseable Disinfectants	Medivators DSD-91E for use with Reuseable Disinfectants (K914145)
Indicated Use	To test, flush, and high level disinfect flexible endoscopes	To test, flush, and high level disinfect flexible endoscopes
Type of Endoscopes Reprocessed	Flexible video and fiberoptic endoscopes	Flexible video and fiberoptic endoscopes
Type of Machine Function	Electro-mechanical	Electro-mechanical
Software-based operation	Proprietary software written for use with Microsoft Windows XP Professional Operating System and Safety Control Software written for the Programmable Logic Controller	Proprietary software
Disinfection Time	Dependent on labeling for germicide used	Dependent on labeling for germicide used
Disinfection Temperature	Dependent on germicide used	Dependent on germicide used
Disinfectants Used	System designed to use full strength, undiluted, FDA-cleared chemical high level disinfectants and sterilants	System designed to use full strength, undiluted, FDA-cleared chemical high level disinfectants and sterilants
Disinfection efficacy	$> 10^6$ log reduction of *Mycobacterium*	$> 10^6$ log reduction of *Mycobacterium*
Capable of using reusable disinfectants?	Yes	Yes
Germicide handling by user	Germicide may be pumped into the chemical reservoirs or poured into the basins to load into the system.	Germicide may be pumped into the chemical reservoirs or poured into the basins to load into the system.

Item	Medivators MDS for use with Reuseable Disinfectants	Medivators DSD-91E for use with Reuseable Disinfectants (K914145)
Manual Cleaning Required Prior to Reprocessing?	Yes	Yes
Performs Leak Tests?	Yes	Yes
Performs Block Tests?	Yes	No
Number of endoscopes processed at one time	Up to two endoscopes, one in each of two independent reprocessing basins	Up to two endoscopes, one in each of two independent reprocessing basins
Asynchronous reprocessing in each basin?	Yes, each basin can run different cycles	Yes, each basin can run different cycles
Spray arm used during basin filling?	Yes	No
Filters Used	0.2 micron water filter 0.2 micron air filter 0.65 micron disinfectant filter	0.2 micron water filter 0.2 micron air filter 0.65 micron disinfectant filter
Printer Communications	Certificate of cycle printed at completion of successfully cycle or completion of aborted cycle indicating parameters and error messages (if applicable)	Certificate of cycle printed at completion of successfully cycle or completion of aborted cycle indicating parameters and error messages (if applicable)
Post-disinfection treatment	Optional alcohol purge followed by air purge of channels	Optional alcohol purge followed by air purge of channels

Appendix M

Medivators Reprocessing Systems Modular Disinfection System
for Endoscope Reprocessing

510(k) Summary of Safety and Effectiveness

Manufacturer:	Medivators Reprocessing Systems, a Division of Minntech Corporation
Address:	14605 28th Avenue North Mpls., MN 55447 USA
Official Contact:	Lynn Lueders Director, Regulatory Affairs

Medivators has supplied the following information to the U.S. Food and Drug Administration to support substantial equivalence of the Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing to other endoscope reprocessors currently marketed in the U.S.

1. Device Description

The Modular Disinfection System (MDS) is an electro-mechanical system intended to test, clean, and high level disinfect flexible fiberoptic and video endoscopes between uses. It is not intended for reprocessing rigid endoscopes. The machine can use any reusable germicide which is on the market that is labeled for high level endoscope disinfection. The testing provided to the FDA used both Medivators Rapicide® High Level Disinfectant and Cidex® OPA High Level Disinfectant.

During its software based reprocessing cycle, the machine tests the endoscopes for leaks and blockages. Before and during the machine cycles, connectivity with the machine through the connector blocks is evaluated. If the scopes pass these tests, they are flushed with water and detergent, disinfected and rinsed. The disinfection cycle takes approximately 30 minutes. The MDS is capable of asynchronously reprocessing two scopes at a time.

The machine has many built in safety features which stop the cycle and alarm when certain conditions exist which could indicate that disinfection might be compromised. These alarms and causes are defined in the directions for use for the product.

The machine also prints records by endoscope serial number indicating the results of testing, disinfection, number of disinfections, etc. which are required for permanent records.

2. Intended Use

Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing tests, cleans, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses.

3. Comparison to Another Device in Commercial Distribution Within the United States

The MDS is equivalent in function and indications to the Medivators DSD-91E™ Endoscope Disinfector. This machine was found to be substantially equivalent in 1994 (K914145). Both machines have the same indications for use, the same methods of providing disinfection, can use the same reuseable disinfectants at the same temperatures and times. Both machines can reprocess two scopes asynchronously, one in each bay.

4. Summary of Testing

Medivators has provided testing to show that the MDS is safe and effective for its intended use following the requirements listed in the FDA's Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (dated August 1993).
This testing included:

Efficacy Testing

The MDS was tested using standard methods defined by the FDA guidance document. This testing included simulated use and in use testing.

The simulated use testing showed a $>10^6$ log reduction in the organism *Mycobacterium terrae* after the endoscopes were reprocessed in the MDS.

In use testing showed no viable organisms remained on the endoscopes following the disinfection cycle.

Material Compatibility

The effect of disinfectants (Rapicide and Cidex OPA) on the materials used in the MDS was evaluated and showed no that the materials had no significant deterioration over their its use life.

Biocompatibility

The amount of disinfectant residue left on endoscopes and in the MDS after the disinfection and rinsing cycles was evaluated and compared to determined safe levels. The results of the testing showed that any remaining residues would not have an effect on patients or users of the machine.

Performance Data

Data was provided to the FDA to show that the machine performs as required. This evaluation included testing to show that the leak check, blockage check, connectivity checks, disinfection cycle, rinse cycles, and drying cycles performed correctly. Any error messages were tested to ensure they function properly to notify users of any possible failure modes.

5. Summary of Substantial Equivalence

Minntech Corporation has provided the above information in the form of a 510(k) to support the claim that the MDS is safe and effective when used in accordance with the device labeling.

Appendix N

(b)(4) Trade Secret Process - Testing

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Elaine Schalk Mayhall

Subject: 510(k) Number K063876/S2

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Is clinical data necessary to support the review of this 510(k)?			✓
Does this device include an Animal Tissue Source?			✓
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	Class*	Product Code
876.1500	Class II	FEB

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Leslie Taylor - for Sheila Murphy
(Branch Chief) (Branch Code) (Date)

Final Review: [signature]
(Division Director) 6/14/07 (Date)

Rev. 5/30/07

XI. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?		X	If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

Note: Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

MEMORANDUM

DATE: June 13, 2007

FROM: Elaine Schalk Mayhall, Chemist, Infection Control Devices Branch, DAGID, HFZ-480

Jeanette Joyce
- for
Julie Murphy

SUBJECT: K063876 S2
Modular Disinfection System (MDS) for Endoscope Reprocesser ing
Medivators Reprocessing Systems
Minntech Corporation Business Group

CONTACT: Lynn Leuders
763-553-2475 (MN)
763-509-1601 fax

TO: The Record

Document date: 5/6/07 (received 6/7/07)

BACKGROUND

The firm also has submitted a response to a FDA letter requesting additional information, dated 5/28/07.

INTENDED USE/INDICATIONS FOR USE

The Medivators Modular Disinfection System (MDS) for Endoscope Reprocessing tests, disinfects, and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. The MDS is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes. It is indicated for use with FDA cleared, liquid high level disinfectants.

The MDS does not replace manual cleaning of endoscopes, they must be precleaned and cleaned according to the endoscope manufacturer's instructions and professional guidelines prior to reprocessing them in the MDS.

DEVICE DESCRIPTION

The MDS is an electro-mechanical system intended to test, clean, disinfect, and rinse flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. It is capable of asynchronously reprocessing two scopes at time.

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

Specifications: (b)(4) Trade Secret Process - Product Specs

MDS dimensions:

(b)(4) Trade Secret Process - Product Specs

Materials of Construction: (b)(4) Trade Secret Process - Product

(b)(4) Trade Secret Process - Product Specs

Disinfectant: (b)(4) Trade Secret Process - Product Specs

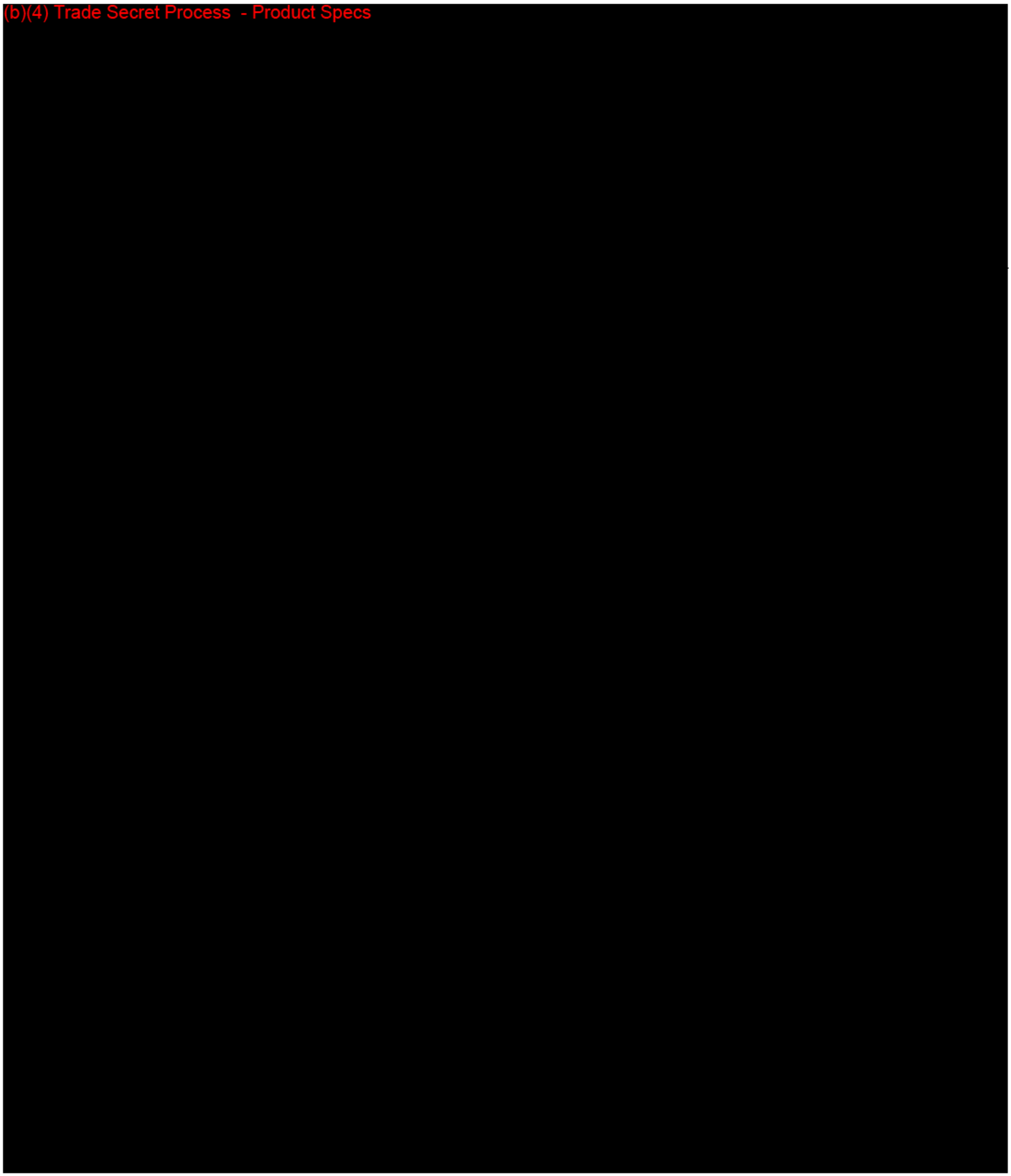
Detergent: (b)(4) Trade Secret Process - Product Specs

Alcoho(b)

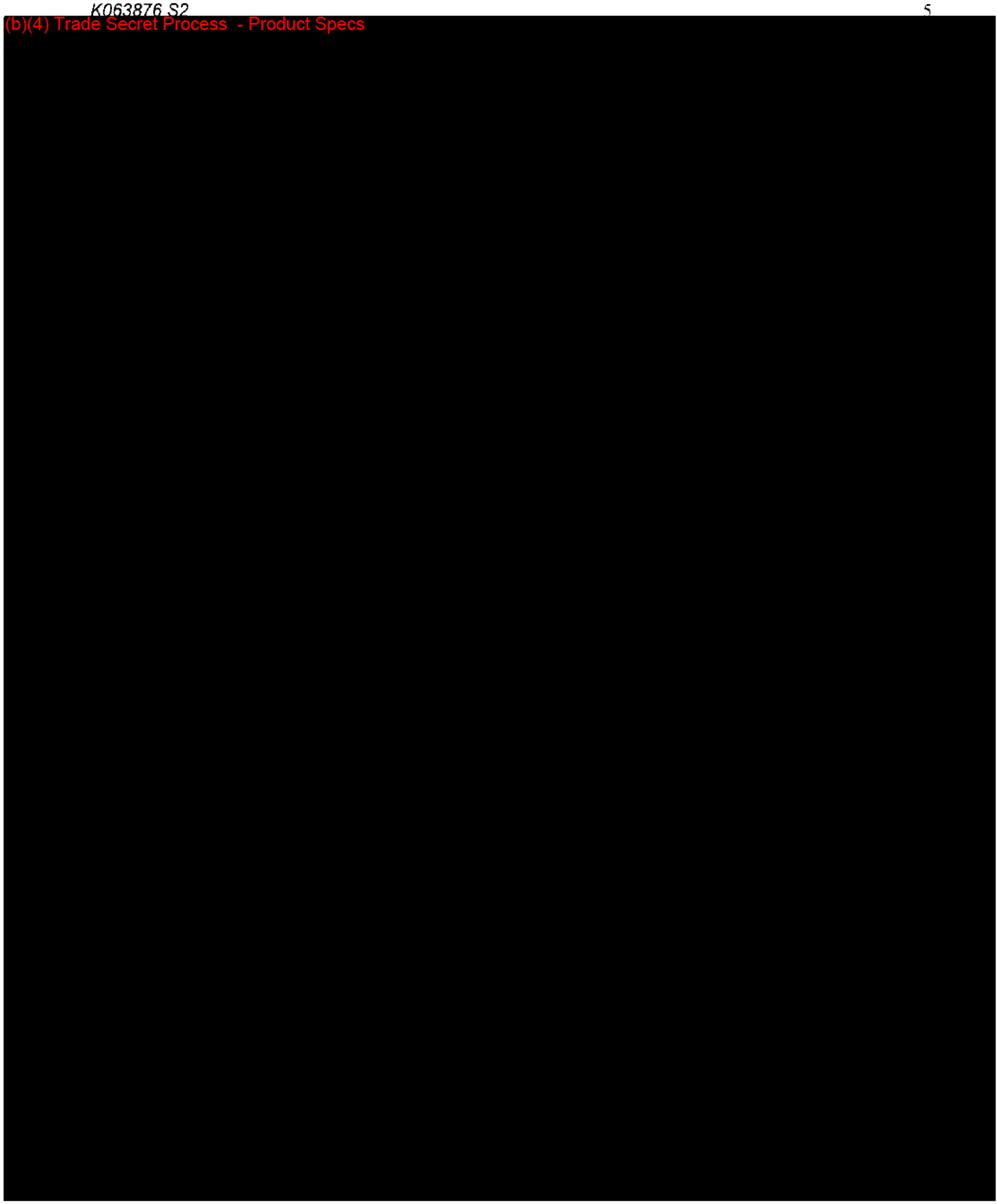
(b)(4) Trade Secret Process - Product Specs

[redacted]

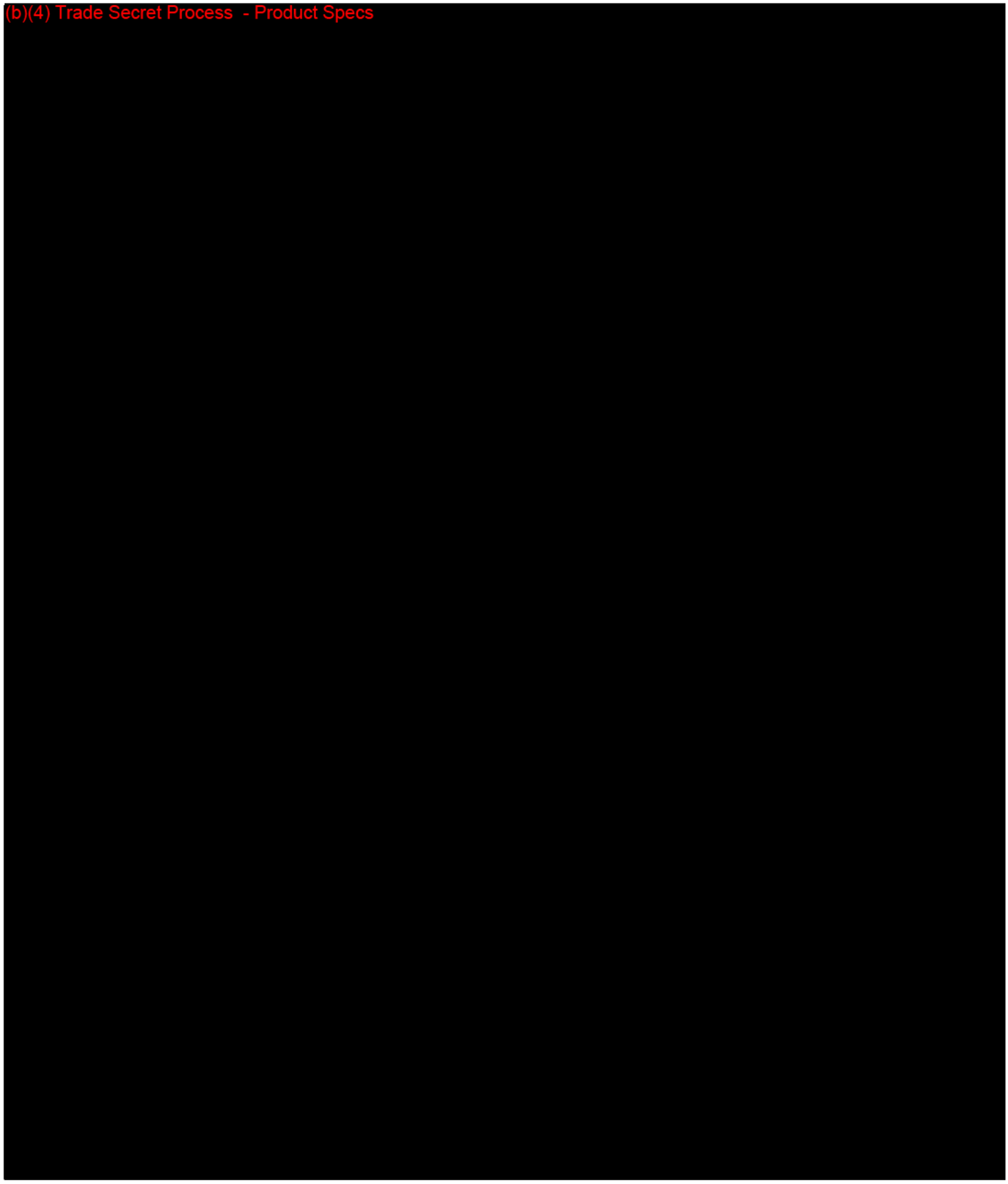
(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs

[redacted]

Reviewed by: Elaine S. Mayhall

Elaine Schalk Mayhall, Ph.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

May 28, 2007

From: Reviewer(s) - Name(s) Elaine Schalk Mayhall

Subject: 510(k) Number K063876/S1

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

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

see memo dated 5/28/07 TH

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☐ YES	☑ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

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

☐ The required certification and summary for class III devices

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

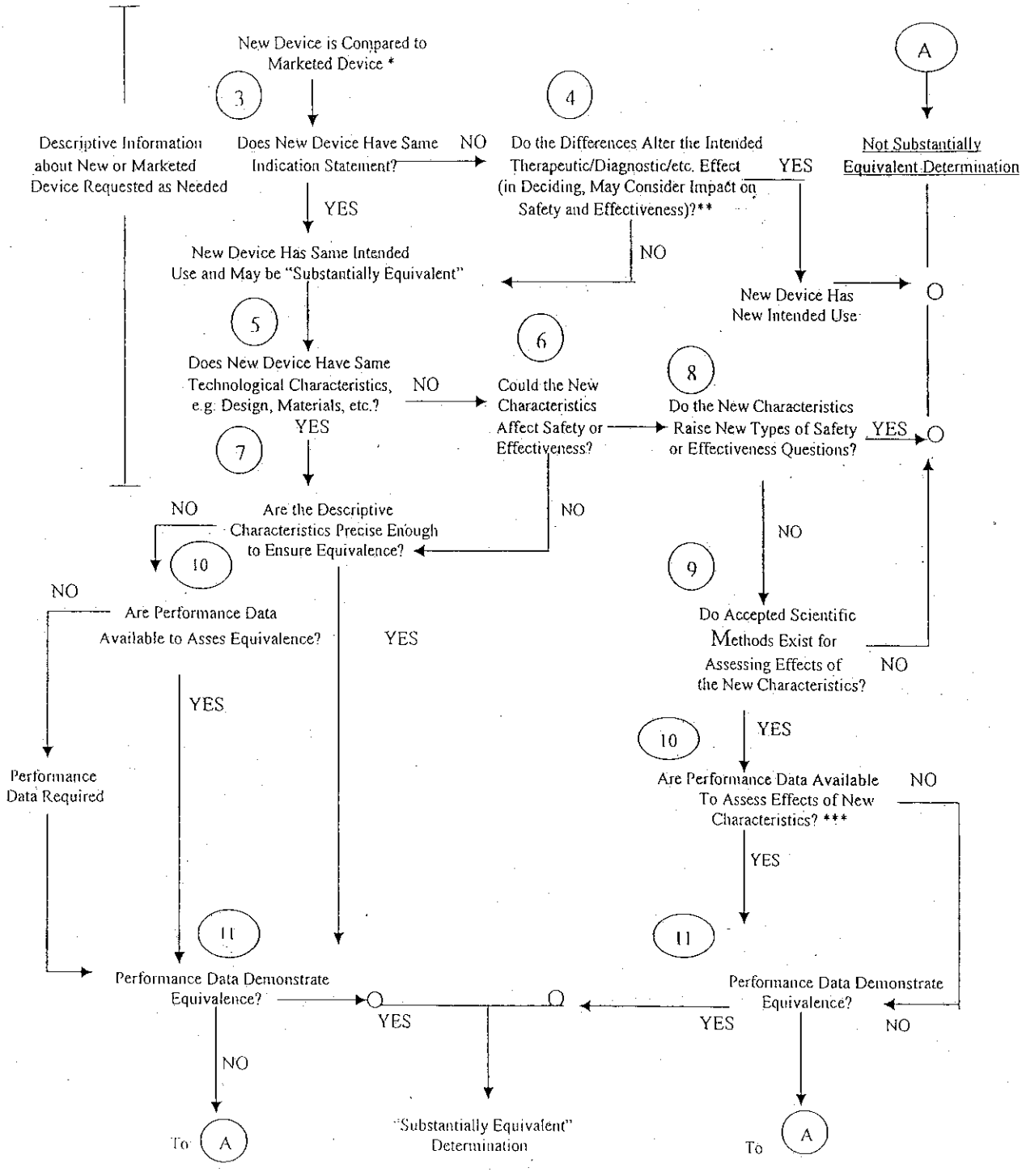
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Review: Sheila A Murphy MD 1 MCB 5/29/07
(Branch Chief) (Branch Code) (Date)

Final Review:
(Division Director) (Date)

Revised:4/2/03

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



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

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

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

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

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

1. Intended Use:

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

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Mayhall, Elaine

From: Mayhall, Elaine
Sent: Tuesday, May 29, 2007 12:33 PM
To: [redacted] (b)(4) Trade Secret Process - Product
Subject: K063876

Attachments: K063876 S1 Medivators MDS Letter.doc

[redacted] (b)(4) Trade Secret Process - Product Specs

Sincerely,

Elaine Schalk Mayhall, Ph.D.
Chemist/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Blvd.
HFZ-480
Rockville, MD 20850
(240) 276-3747
(240)276-3789 fax

40

May 28, 2007

Dear (b)(4) Trade:

(b)(4) Trade Secret Process - Product Specs

[redacted]

Sincerely,

Elaine Schalk Mayhall, Ph.D.
Chemist/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

MEMORANDUM

DATE: May 28, 2007

FROM: Elaine Schalk Mayhall, Chemist, Infection Control Devices Branch, DAGID, HFZ-480

SUBJECT: K063876 S1
Modular Disinfection System (MDS) for Endoscope Reprocessor
Medivators Reprocessing Systems
Minntech Corporation Business Group

CONTACT: (b)(4) Trade Secret Process - Product

TO: The Record

Document date: 5/9/07

BACKGROUND

(b)(4) Trade Secret Process - Product Specs

INTENDED USE/INDICATIONS FOR USE

The Medivators Modular Disinfection System (MDS) for Endoscope Reprocessing is intended for the high level disinfection of flexible endoscopes. Only use high level disinfectants that are labeled to provide high level disinfection when used according to the manufacturer's specified conditions and contact times.

(b)(4) Trade Secret Process - Product Specs

DEVICE DESCRIPTION

The MDS is an electro-mechanical system intended to test, clean, disinfect, and rinse flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. It is capable of asynchronously reprocessing two scopes at time.

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

Specifications: (b)(4) Trade Secret Process - Product Specs

MDS dimensions:

(b)(4) Trade Secret Process - Product Specs

Materials of Construction: (b)(4) Trade Secret Process - Product Specs

Disinfectant: (b)(4) Trade Secret Process - Product Specs

Detergent: (b)(4) Trade Secret Process - Product Specs

Alcoho[redacted]

(b)(4) Trade Secret Process - Product Specs

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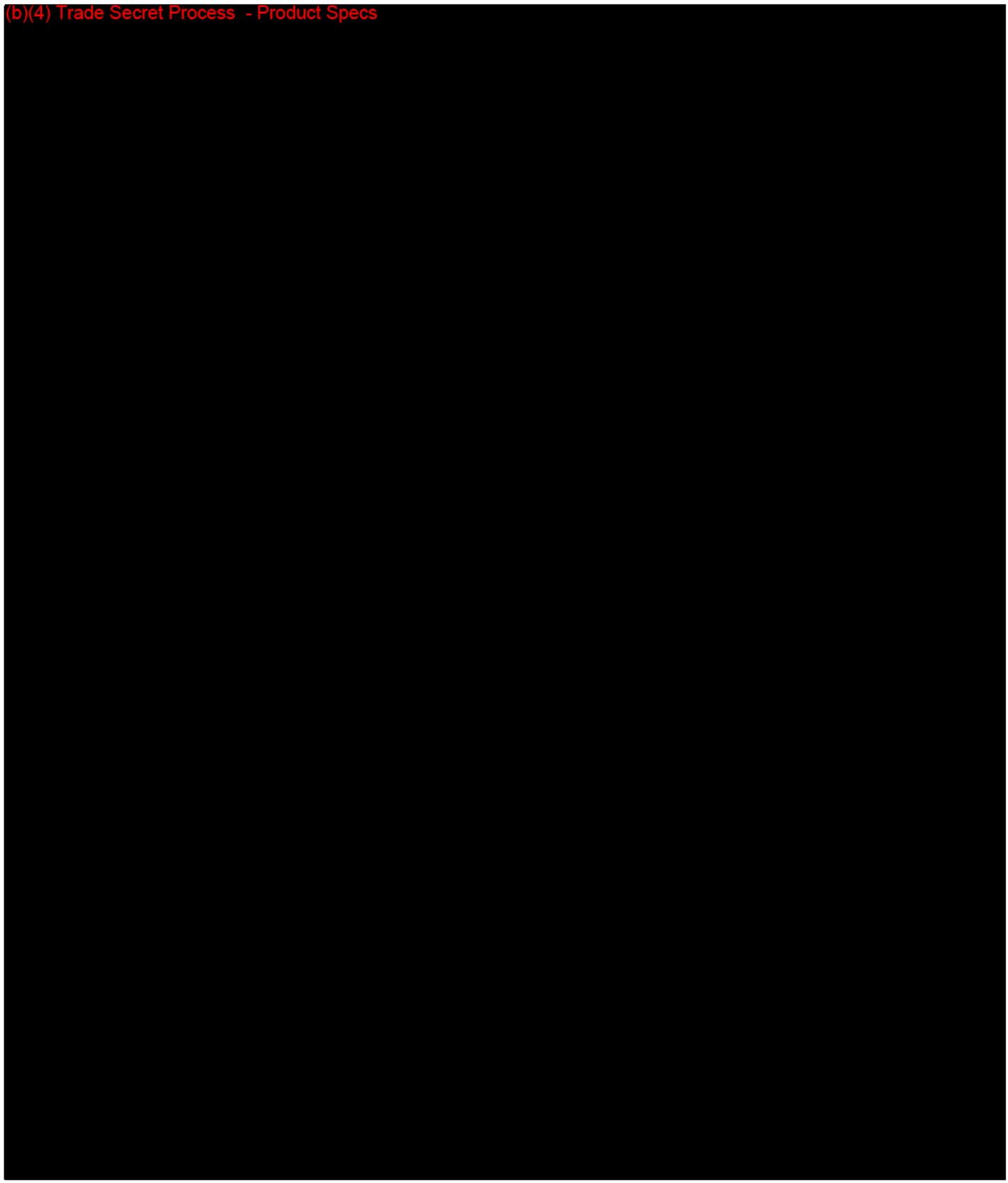
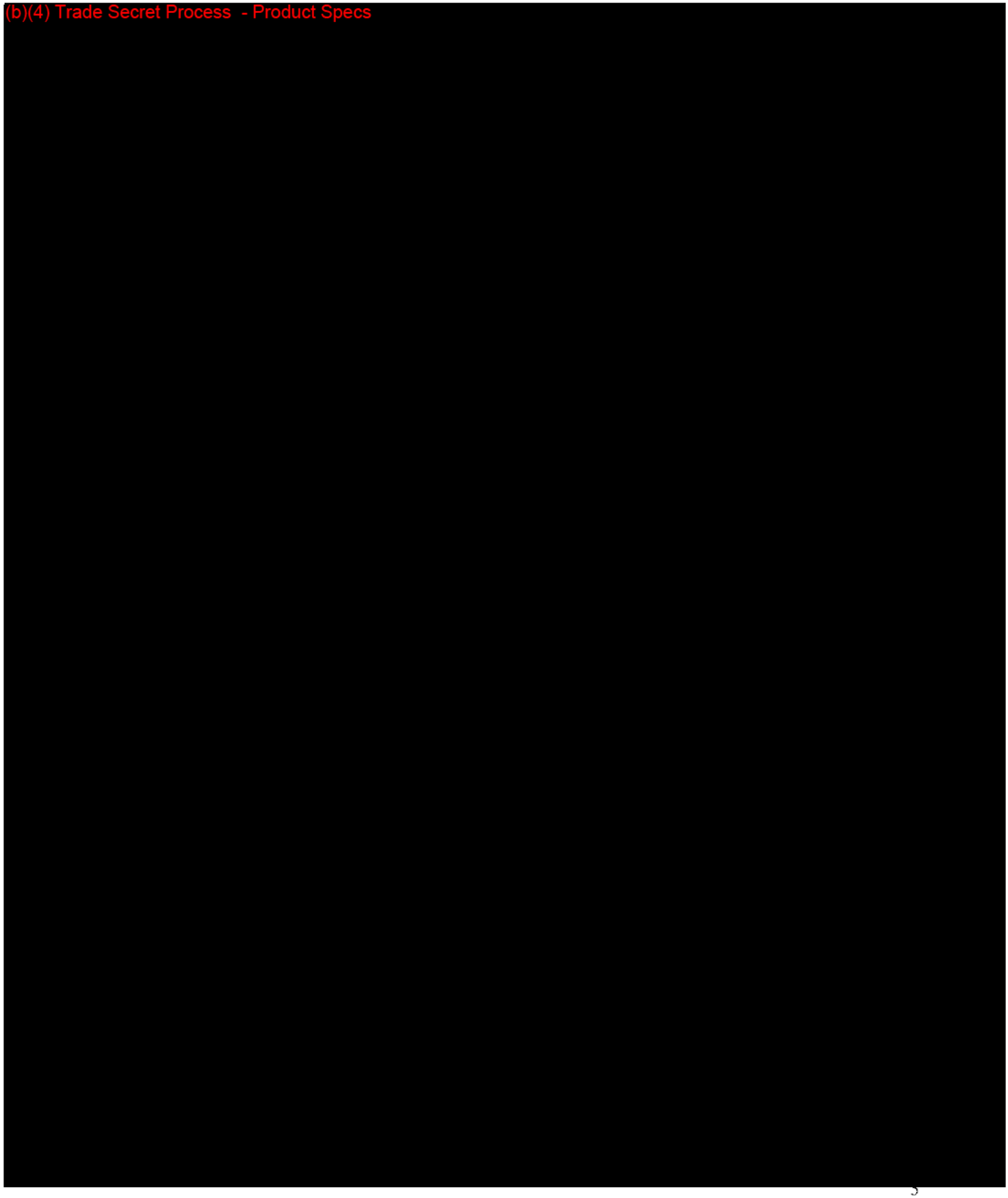
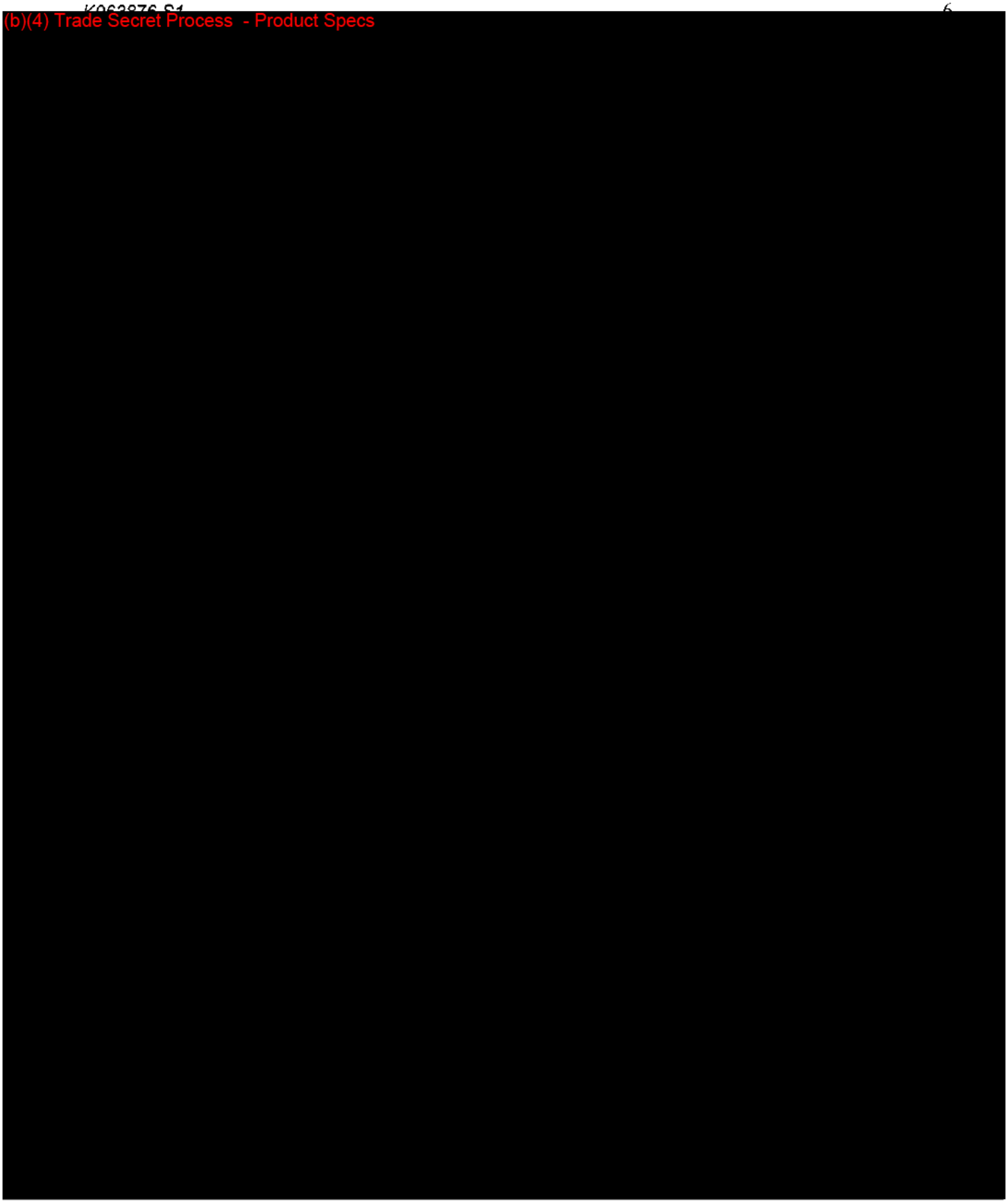
(b)(4) Trade Secret Process - Product Specs



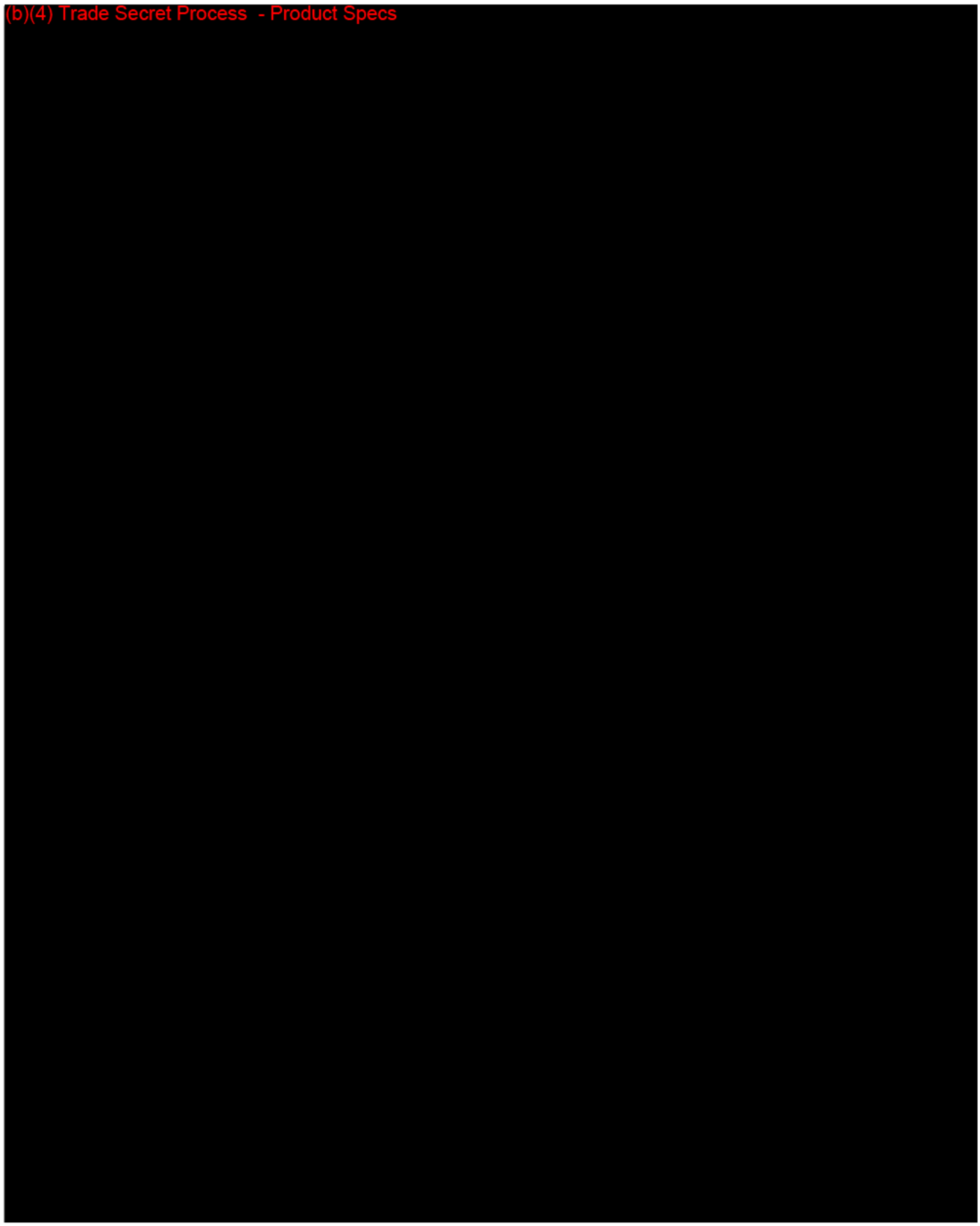
(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs

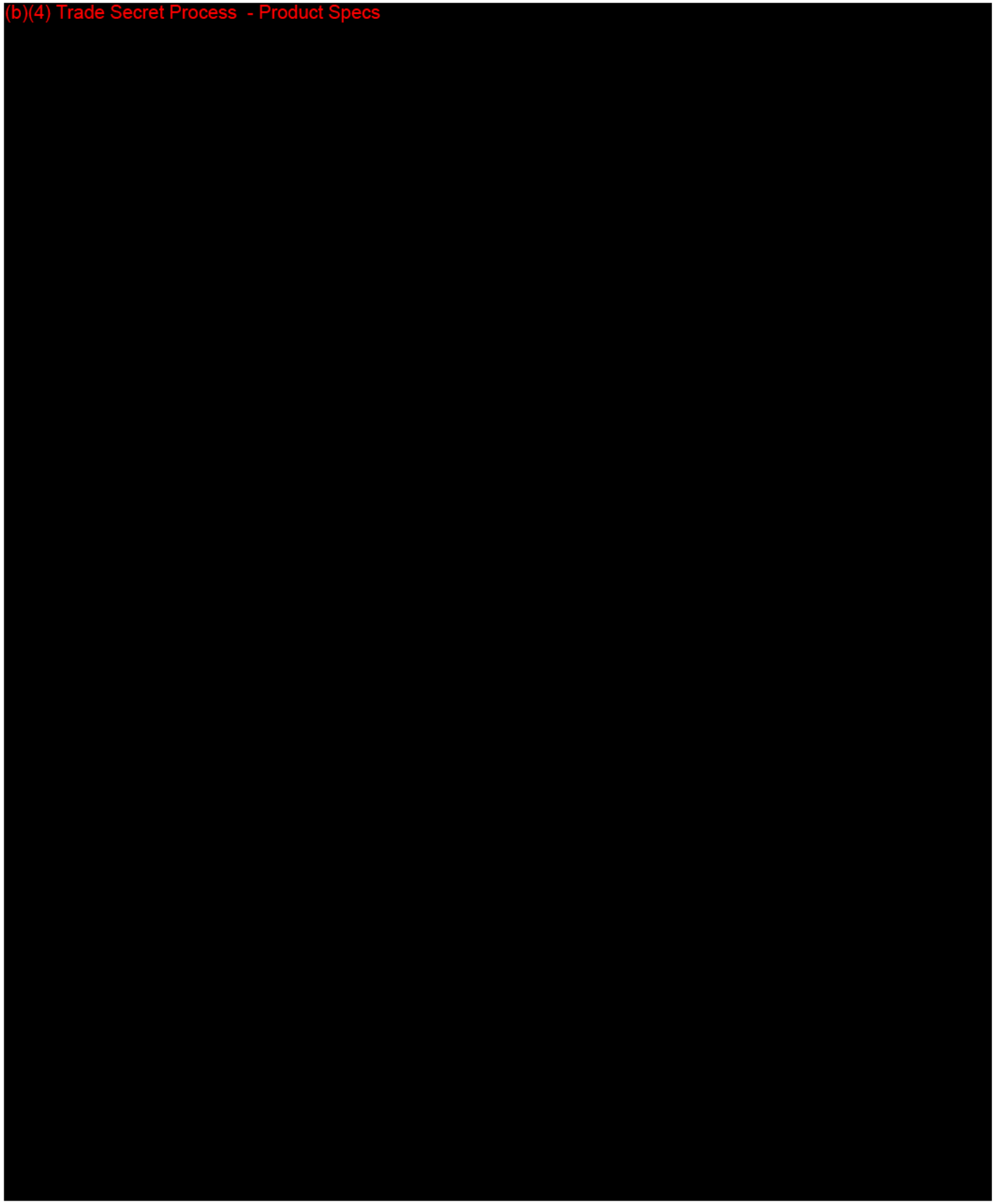


(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs



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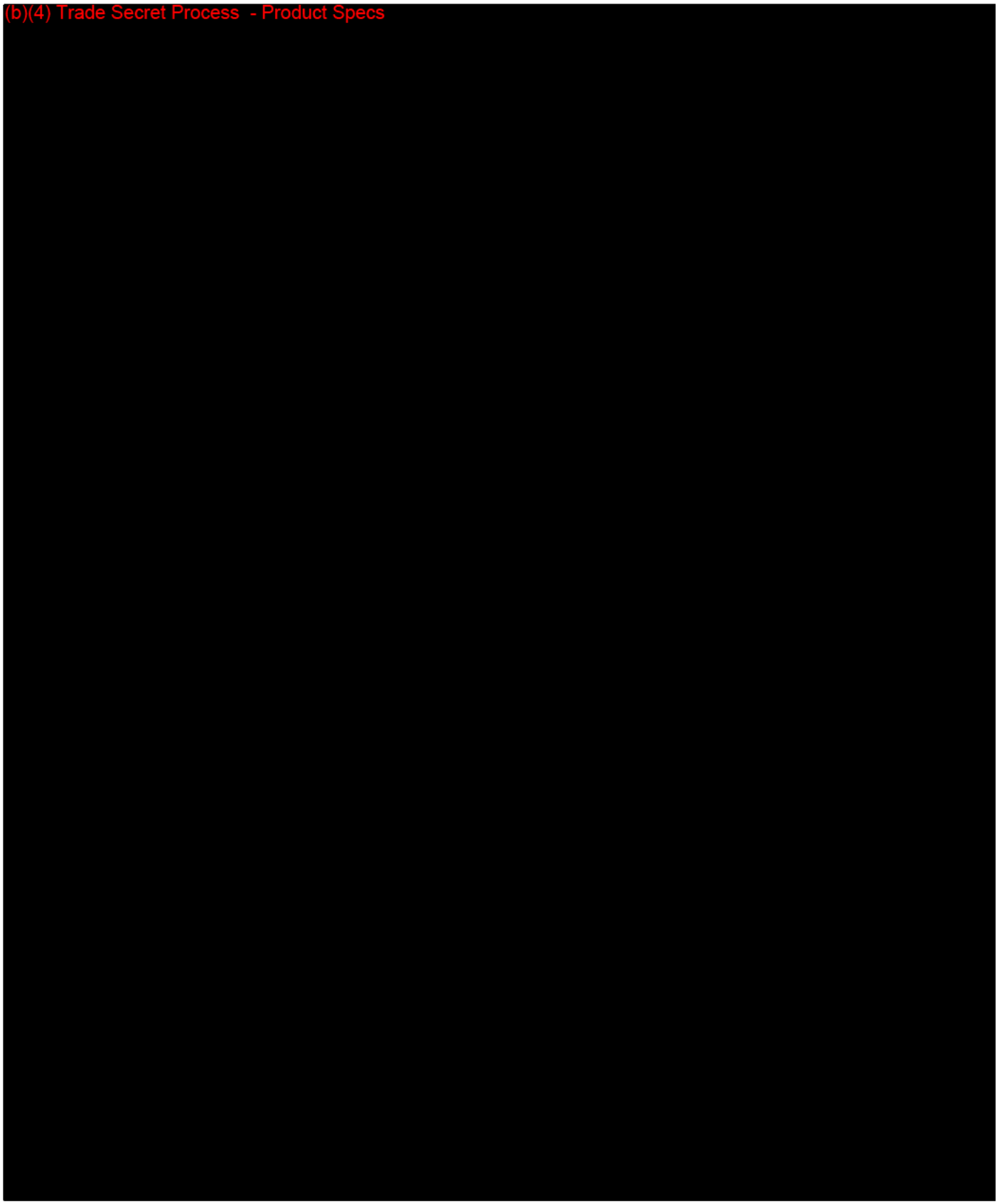
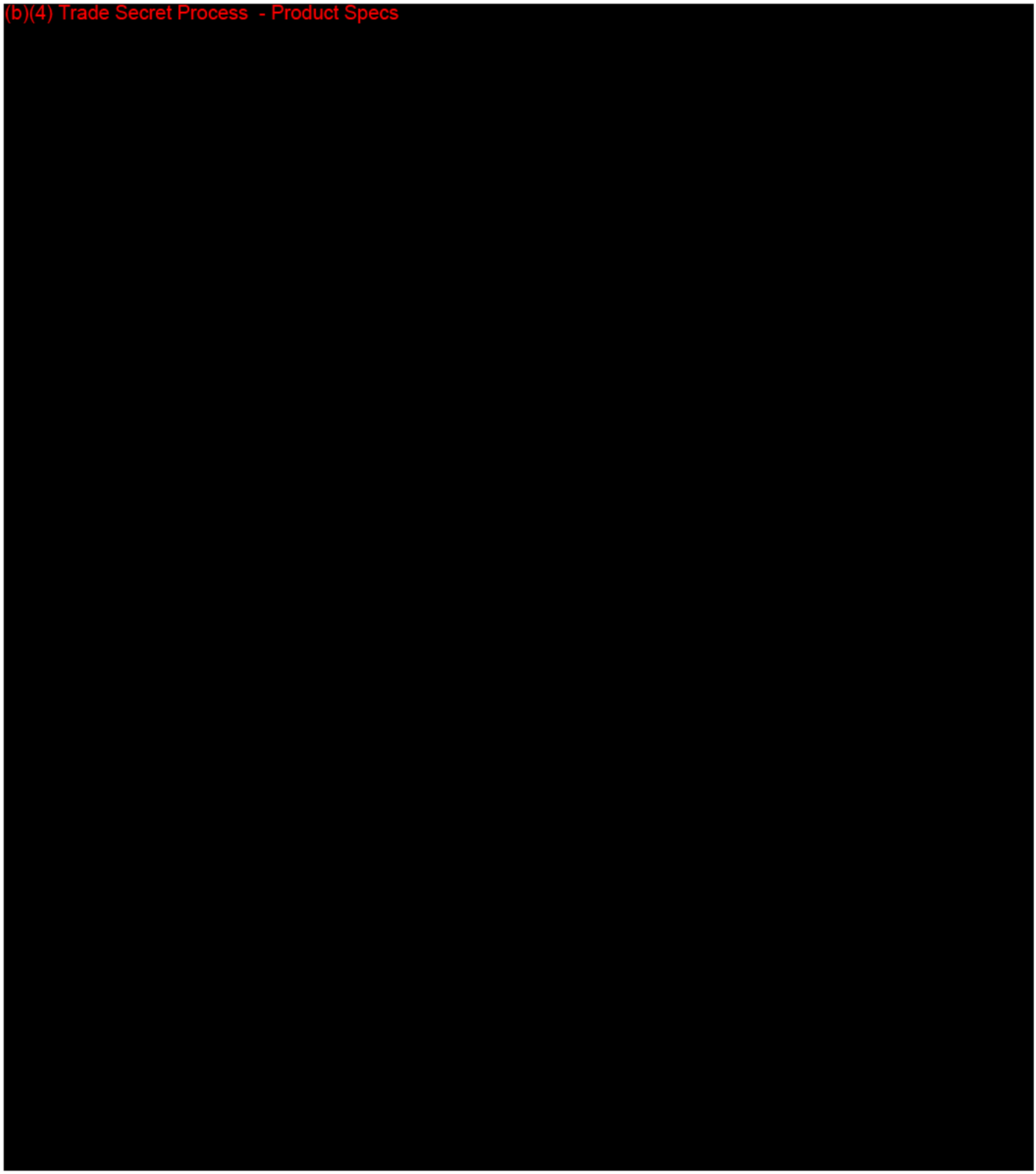
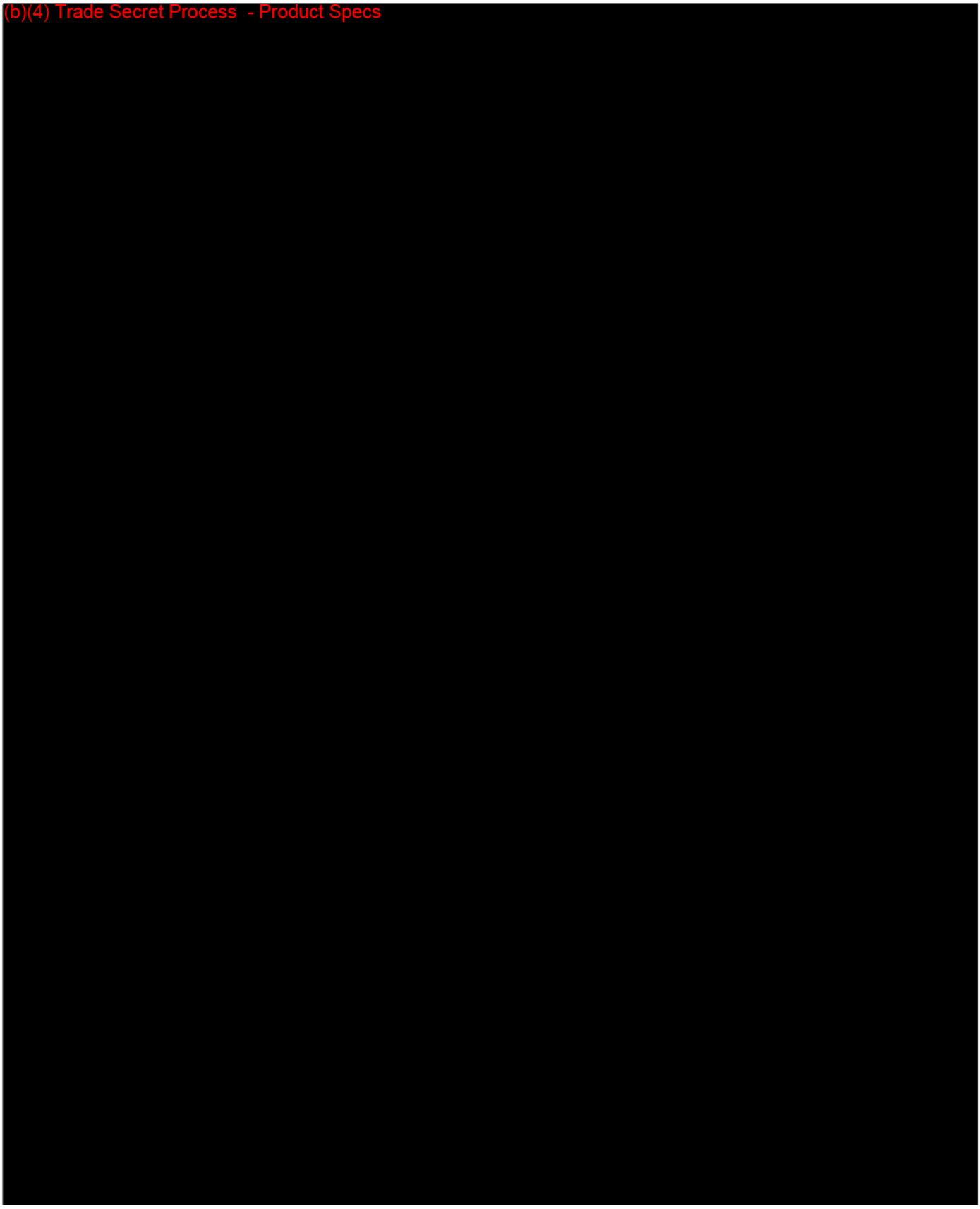


(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs

[redacted]

Reviewed by: Elaine S. Mayhall

Elaine Schalk Mayhall, Ph.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

February 12, 2007

From: Reviewer(s) - Name(s) Elaine Schalk Mayhall

Subject: 510(k) Number K063876

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

See memo dated 2/12/07 Phone Hold

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☐ YES	☑ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

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

☐ The required certification and summary for class III devices

☑ The indication for use form needs revision ?

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

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

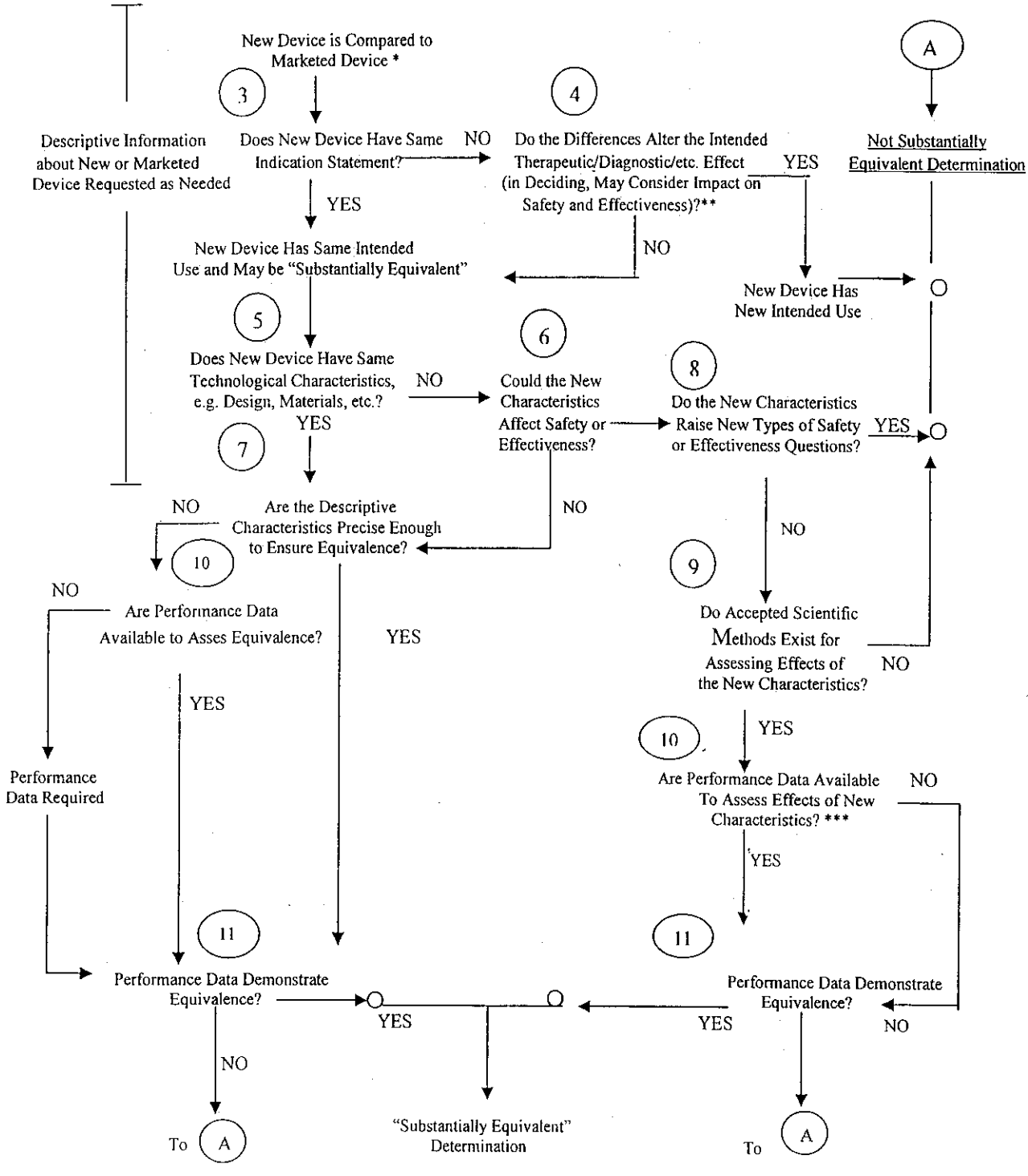
Review: Shuk H Mayhall / MCB 2/12/07
(Branch Chief) (Branch Code) (Date)

Final Review:
(Division Director) (Date)

Revised:4/2/03

631

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



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

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No
Reviewer:_____
Concurrence by Review Branch:_____

Date:_____

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

REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer: _____

Division/Branch: _____

Device Name: _____

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

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

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

1. Intended Use:

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

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

From: Mayhall, Elaine
Sent: Tuesday, February 13, 2007 8:35 AM
To: (b)(4) Trade Secret P P d t
Attachments: K063876 O Medivators MDS Letter.doc

Dear (b)(4) Trade Secret

(b)(4) Trade Secret Process - Product Specs

[redacted]

Sincerely,

Elaine Schalk Mayhall, Ph.D.
Chemist/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Blvd.
HFZ-480
Rockville, MD 20850
(240) 276-3747
(240)276-3789 fax

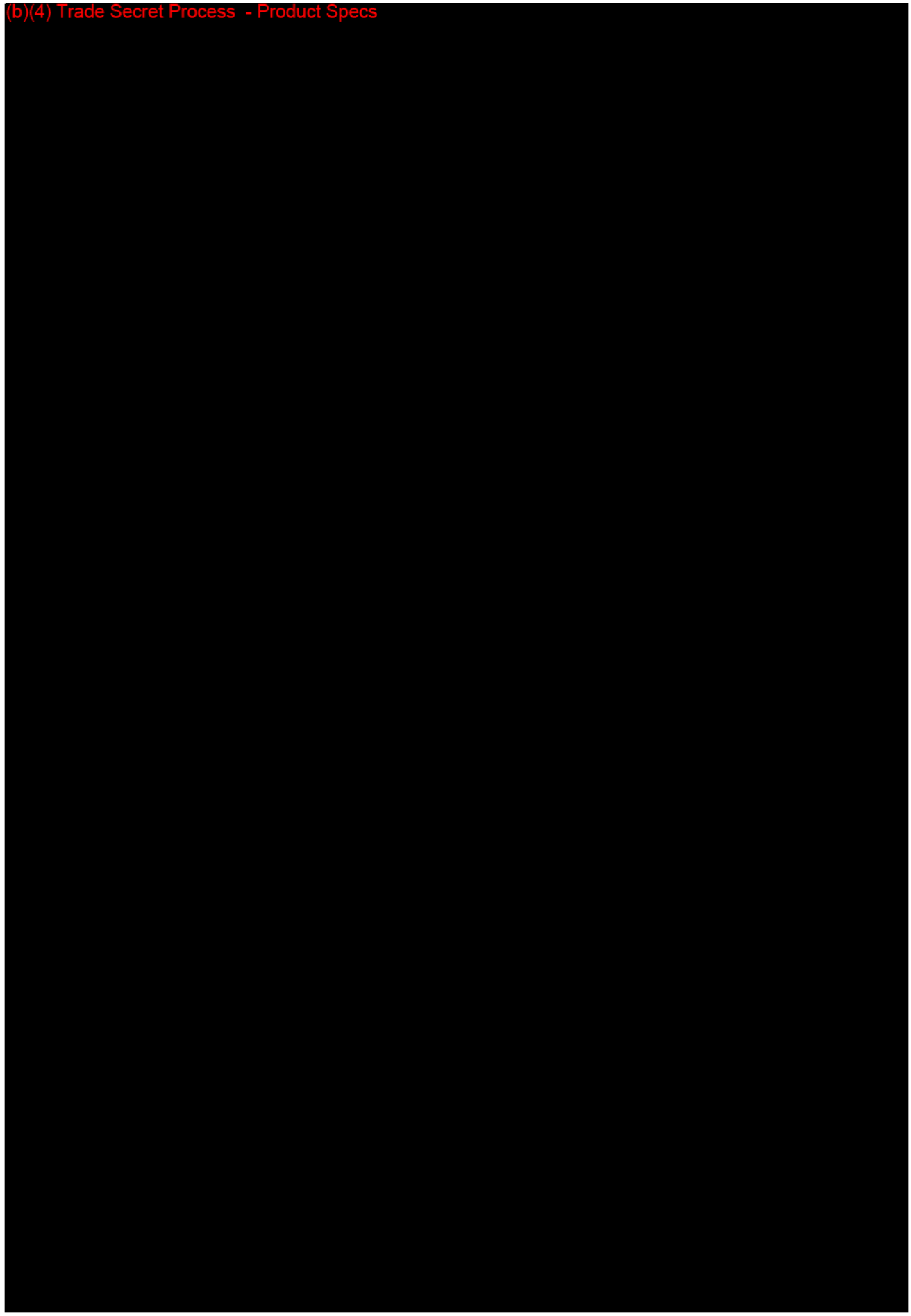
February 13, 2007

Dear (b)(4) Trade Secret:

(b)(4) Trade Secret Process - Product Specs

[redacted]

641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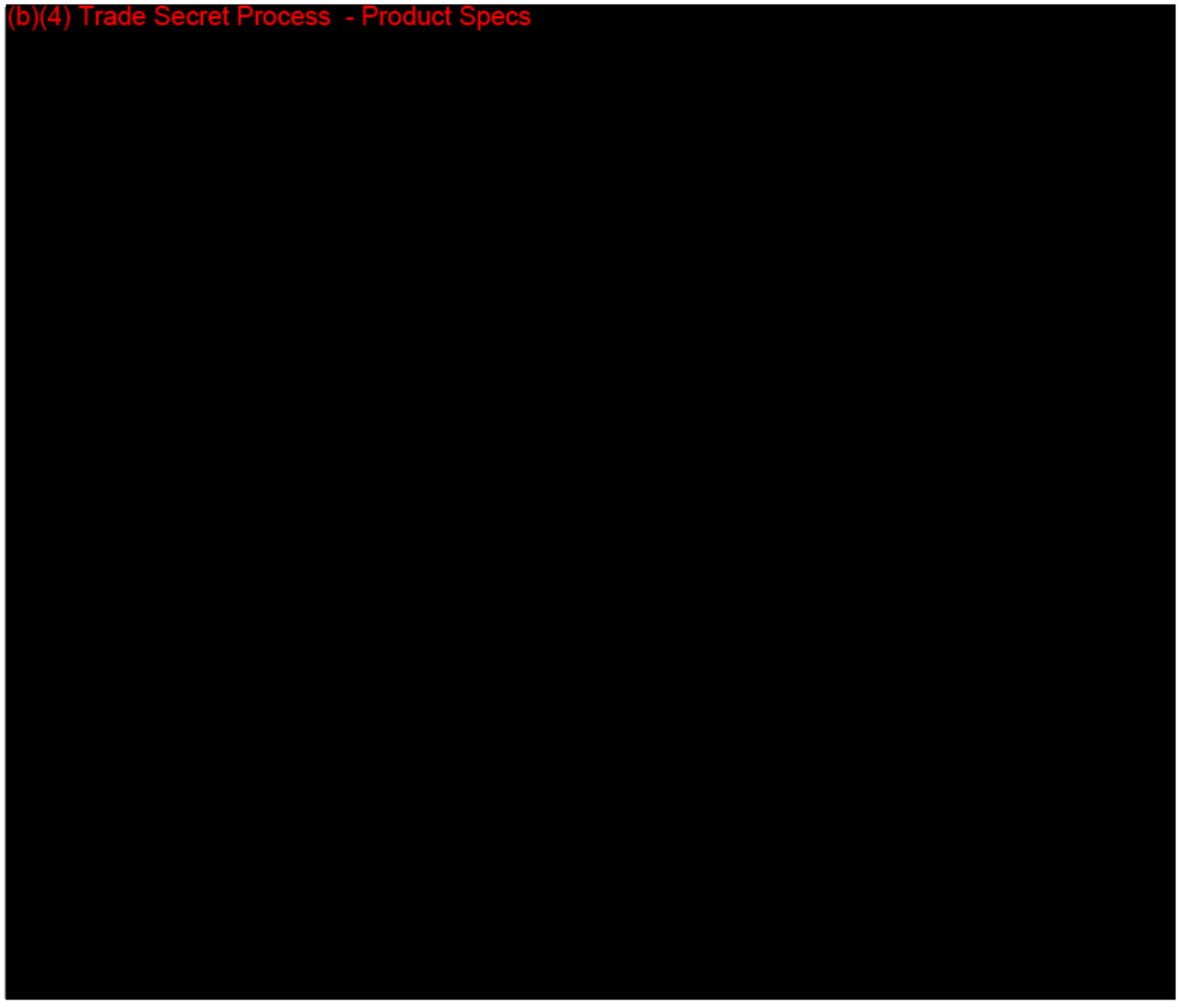

Sincerely,

Elaine Schalk Mayhall, Ph.D.
Chemist/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

MEMORANDUM

DATE: February 12, 2007

FROM: Elaine Schalk Mayhall, Chemist, Infection Control Devices Branch, DAGID, HFZ-480

SUBJECT: K063876 Original
Modular Disinfection System (MDS) for Endoscope Reprocessor
Medivators Reprocessing Systems
Minntech Corporation Business Group

CONTACT: (b)(4) Trade Secret Process - Product Specs

TO: The Record

Document date: 12/26/06

BACKGROUND

The firm also has submitted a Pre-IDE regarding testing to support a cleaning claim for the MDS. However, the current submission does not include a cleaning claim. The new indication will be submitted under a new 510(k).

INTENDED USE/INDICATIONS FOR USE

The Medivators Modular Disinfection System (MDS) for Endoscope Reprocessing tests, cleans, disinfects, and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses.

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DEVICE DESCRIPTION

The MDS is an electro-mechanical system intended to test, clean, disinfect, and rinse flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. It is capable of asynchronously reprocessing two scopes at time.

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Specifications: (b)(4) Trade Secret Process - Product Specs

MDS dimensions:

(b)(4) Trade Secret Process - Product Specs

Materials of Construction: The (b)(4) Trade Secret Process

(b)(4) Trade Secret Process - Product

Disinfectant: (b)(4) Trade Secret Process - Product Specs

Detergent: (b)(4) Trade Secret Process - Product Specs

- (b)(4) Trade Secret Process -

Alcohol: (b)(4) Trade Secret Process

(b)(4) Trade Secret Process - Product Specs

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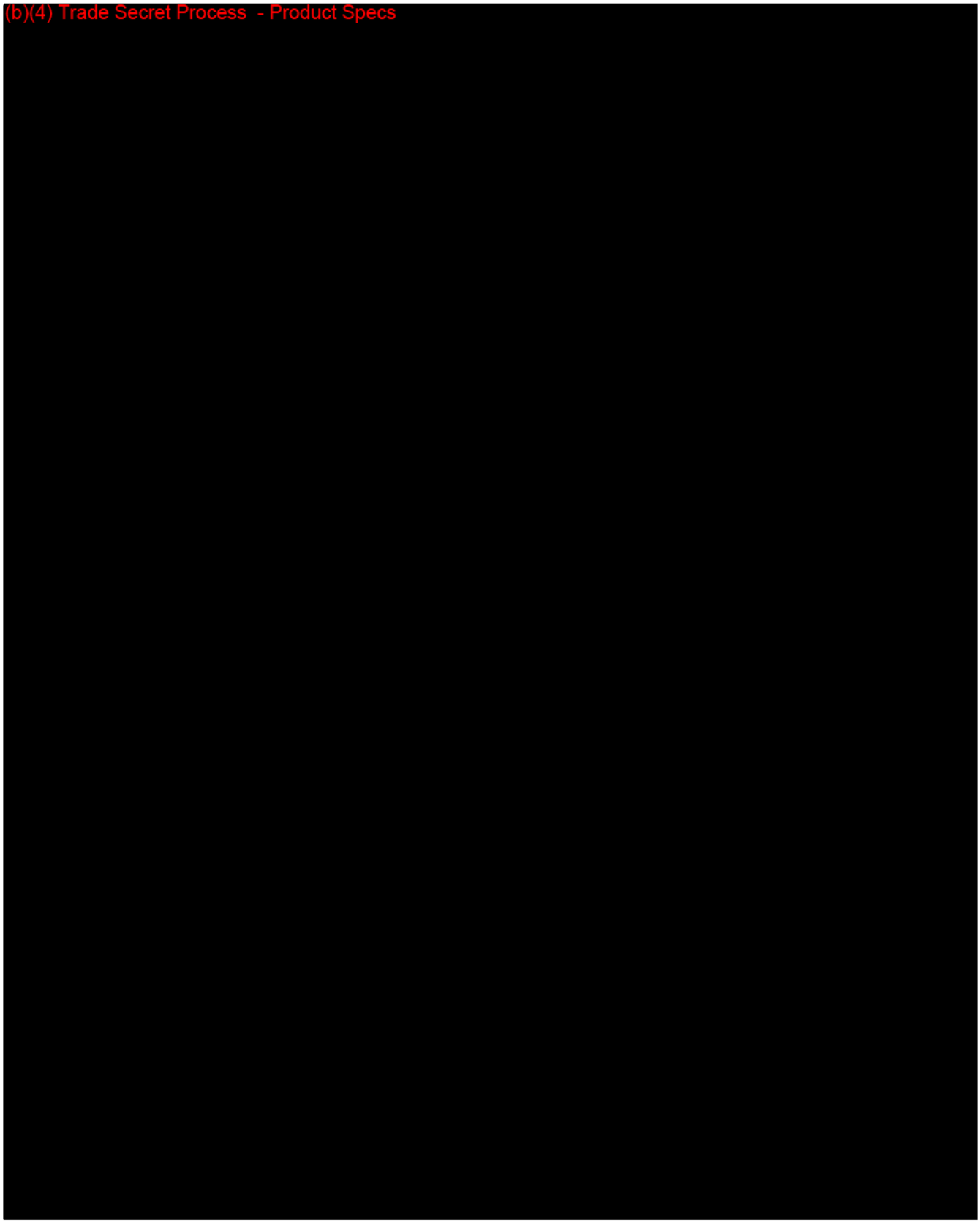

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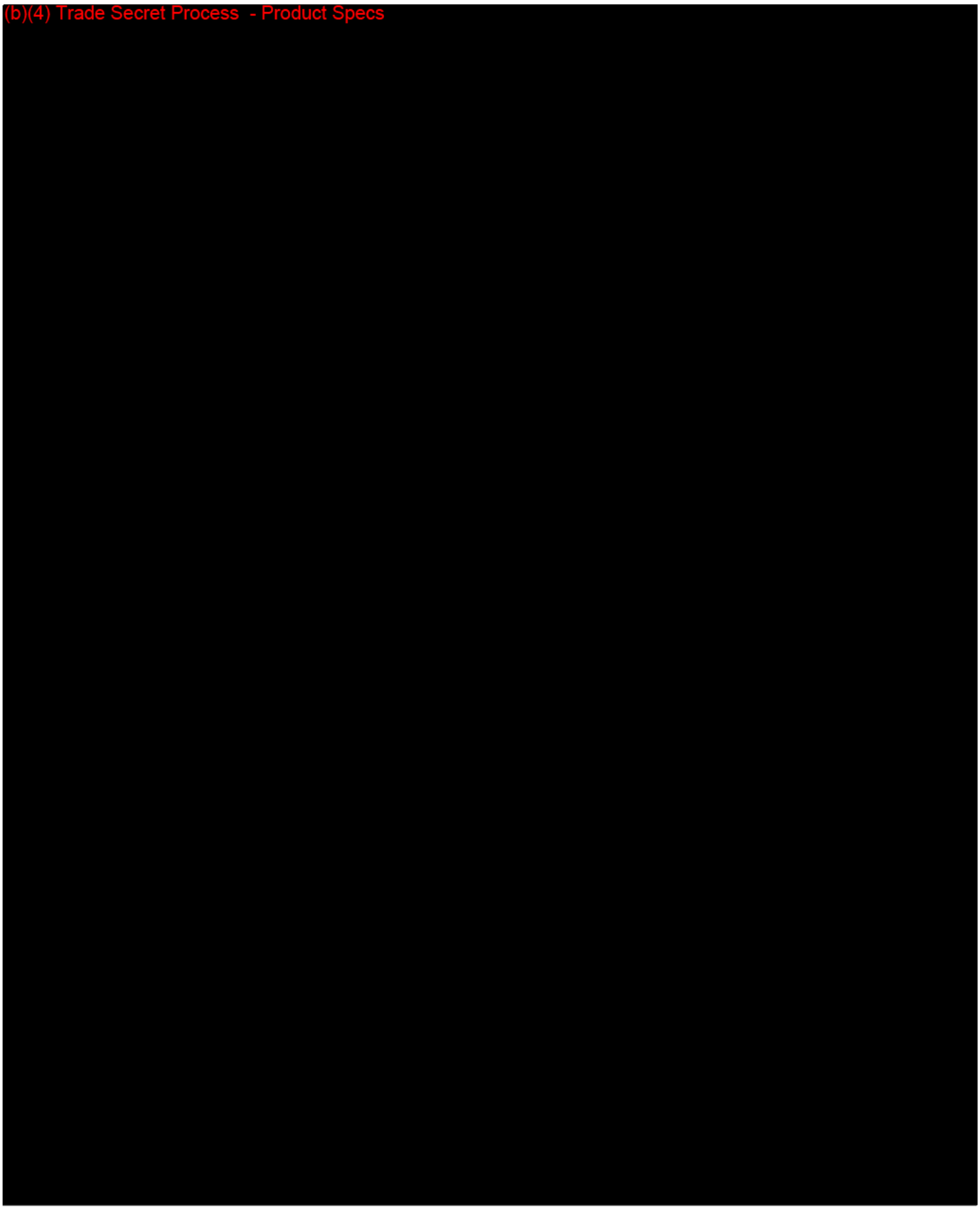

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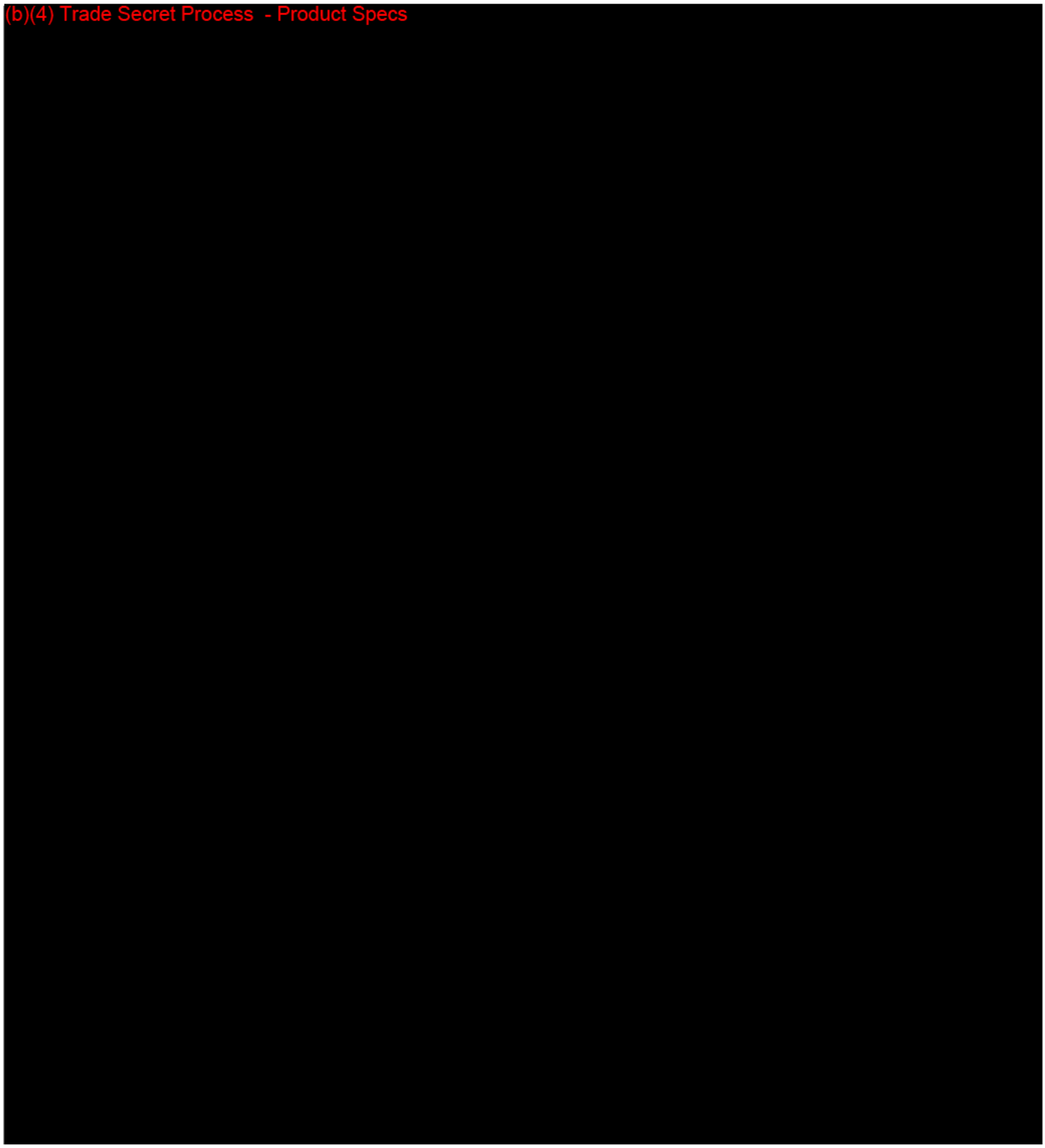

PERFORMANCE TESTING

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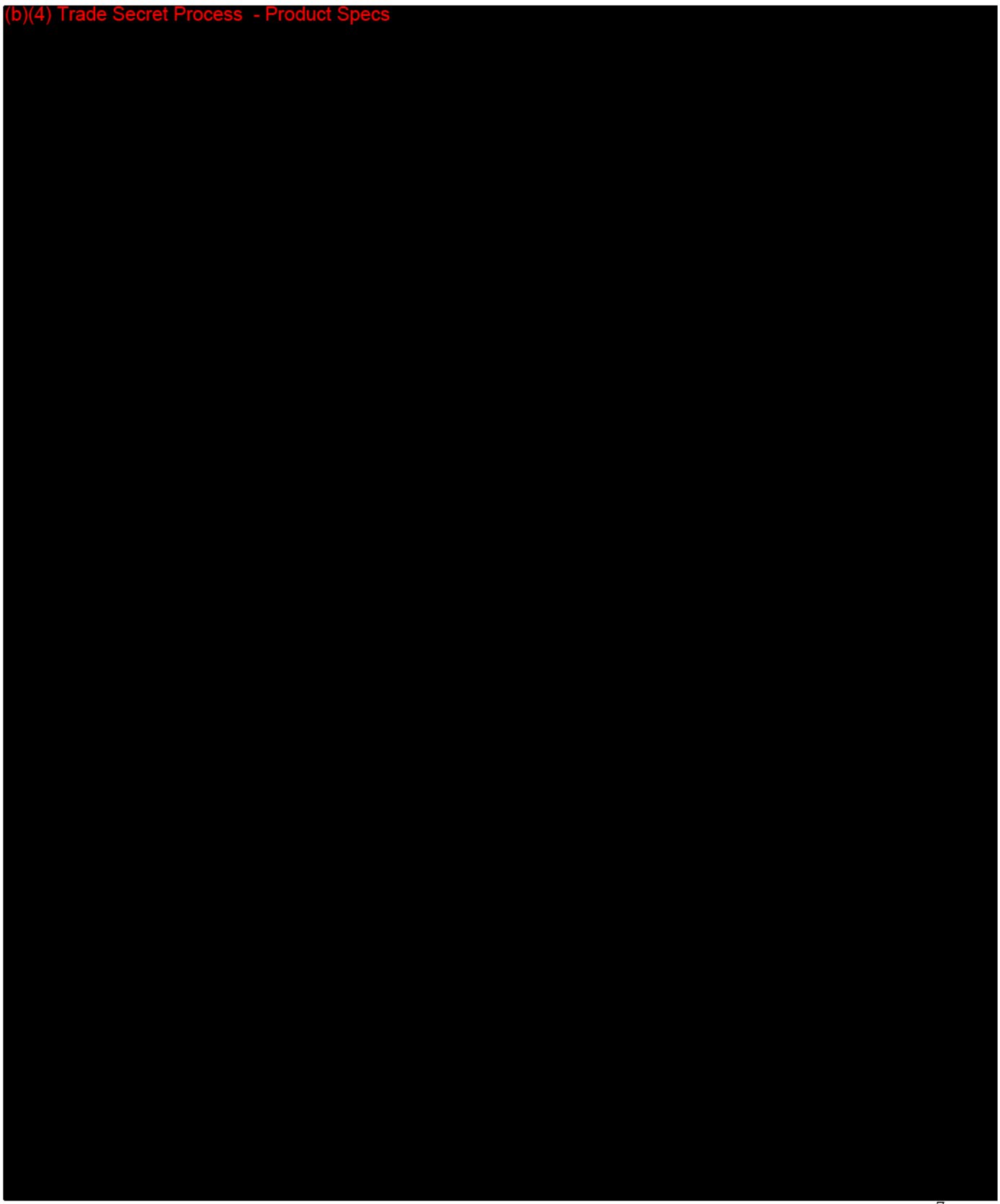

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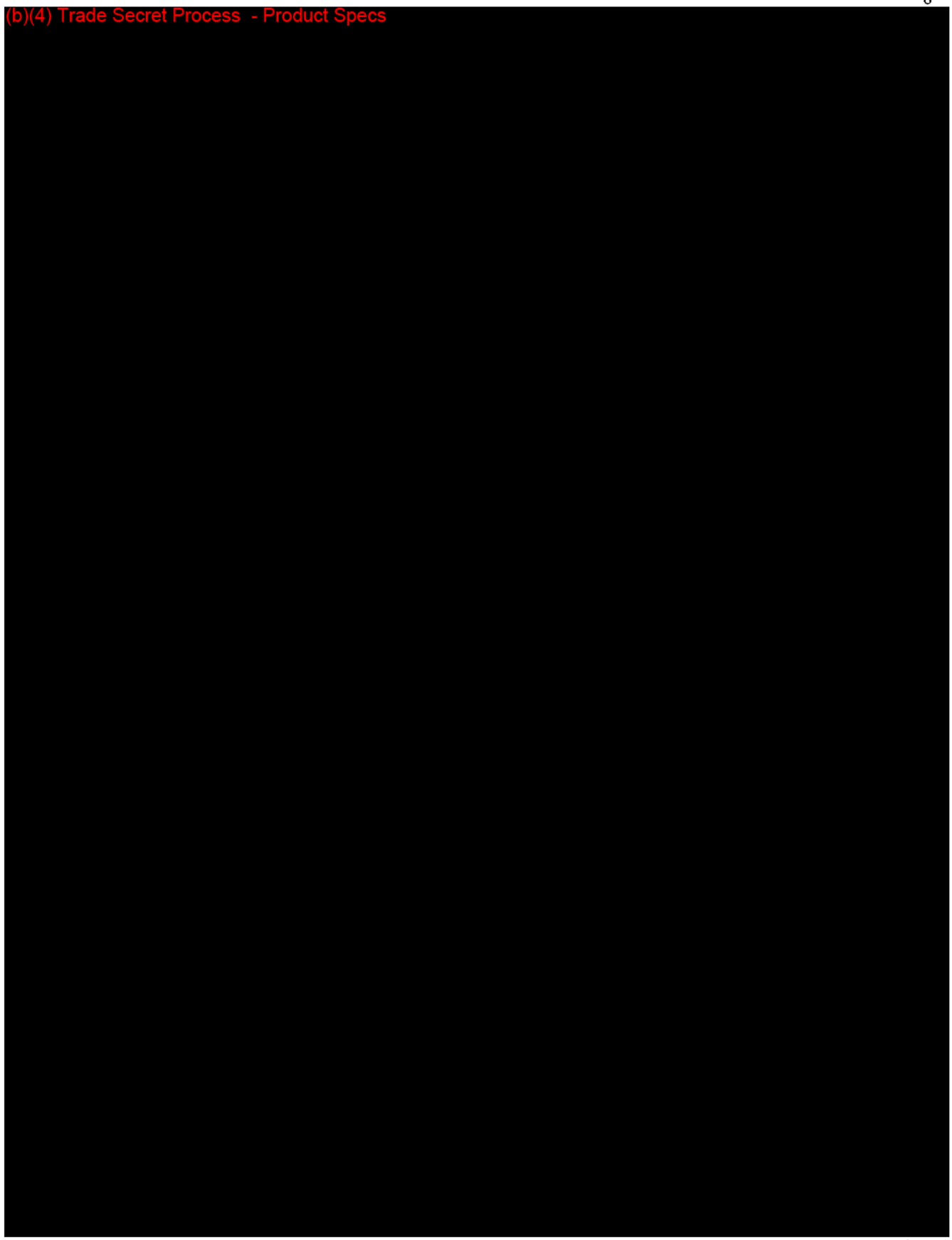

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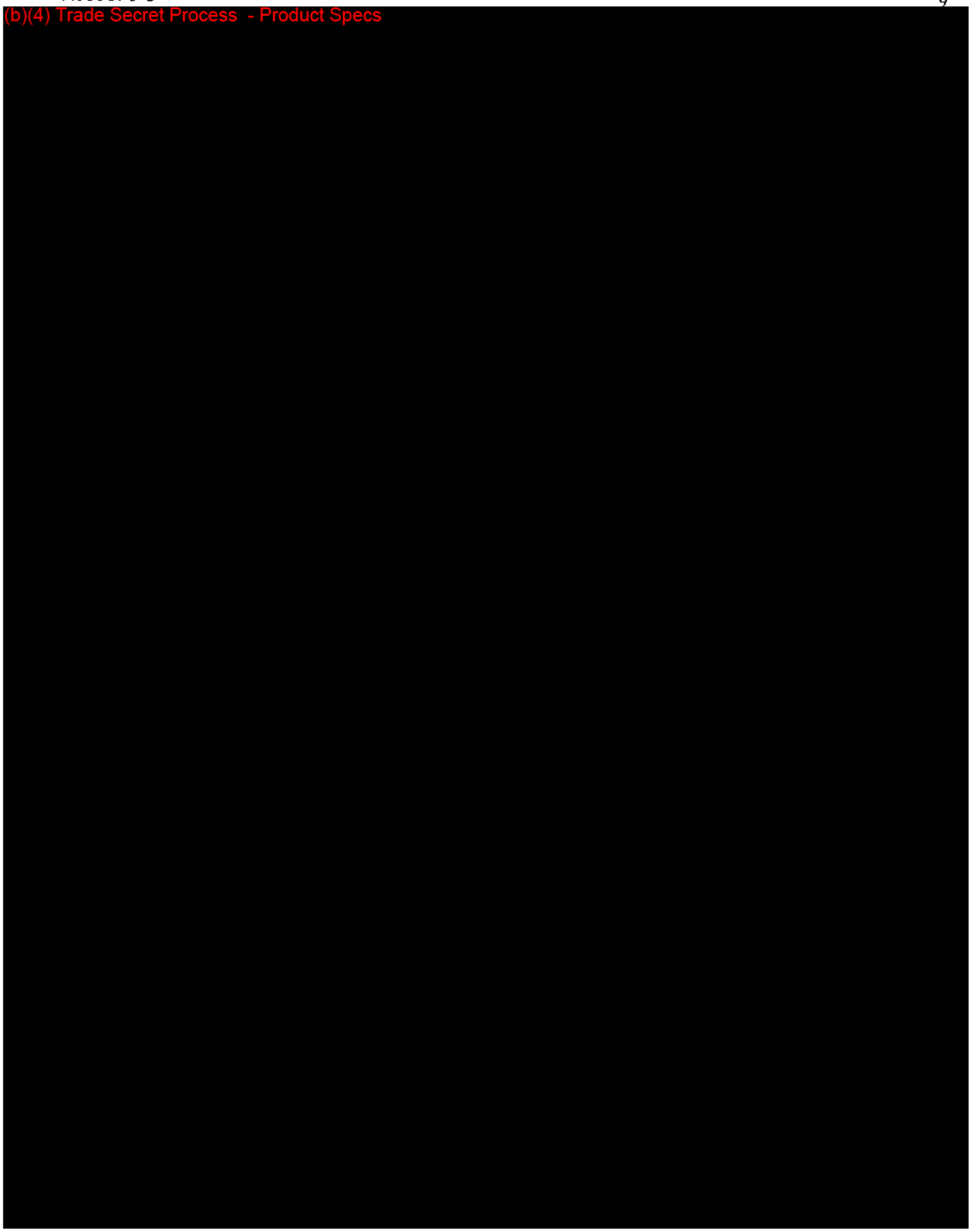

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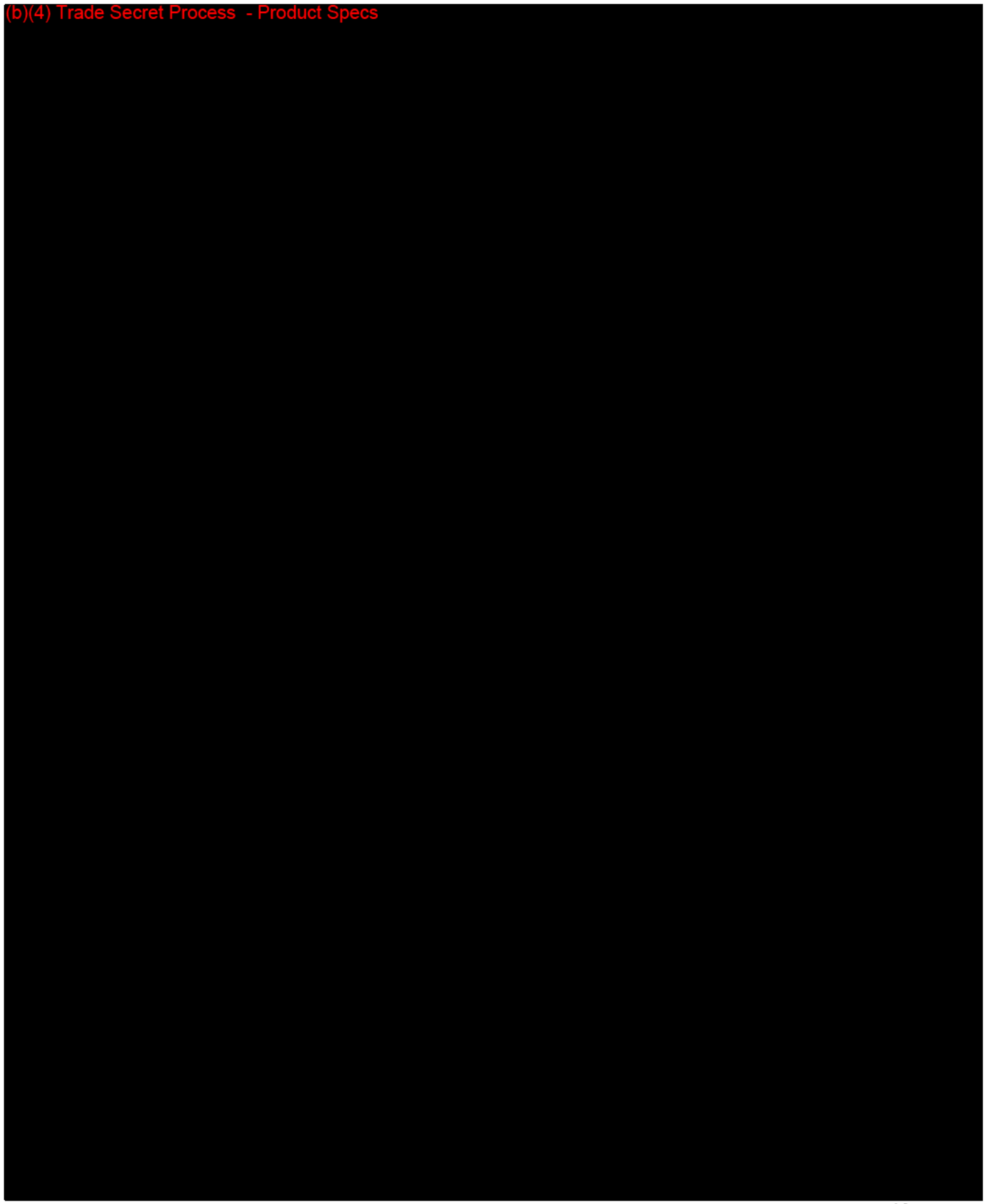

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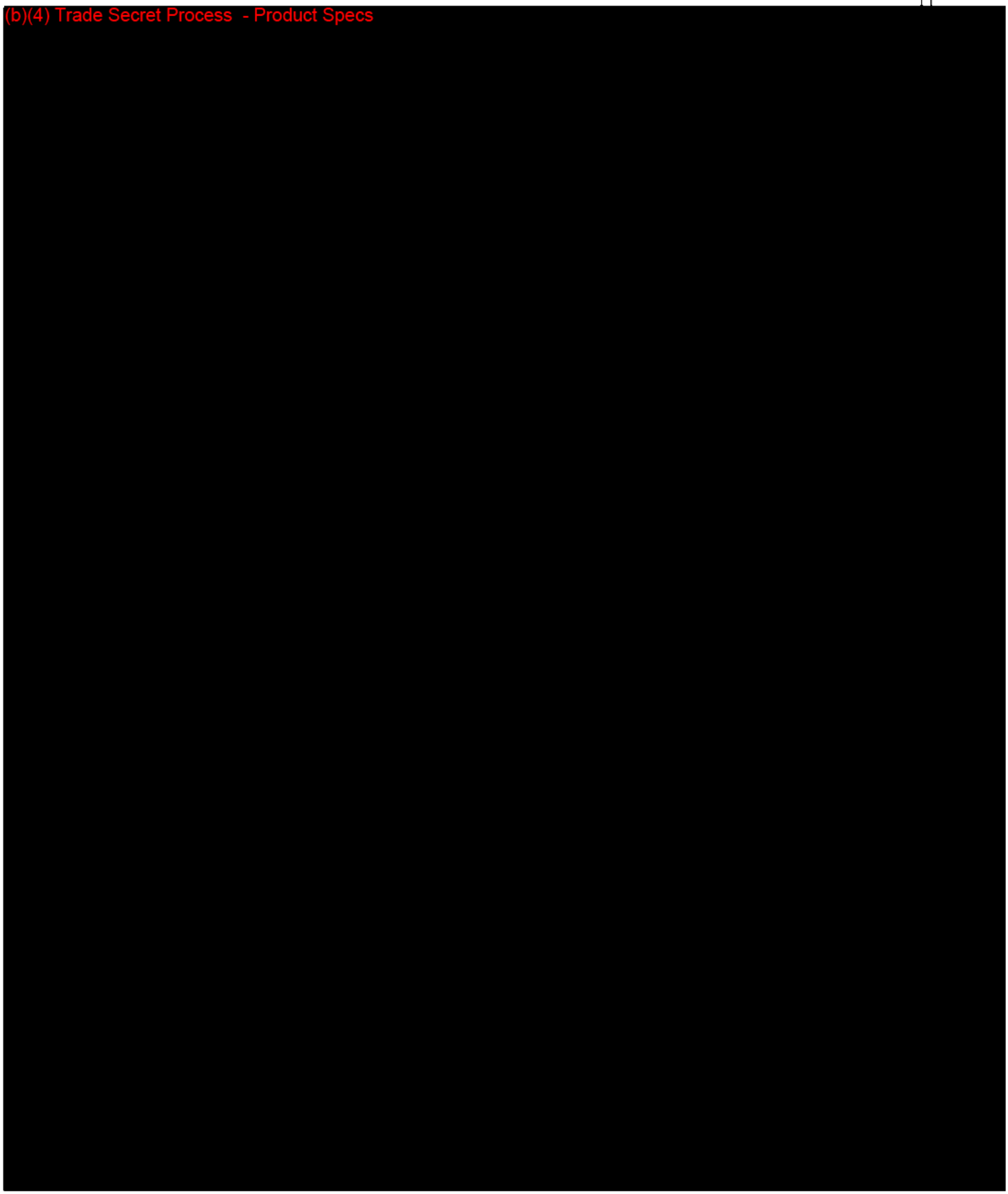

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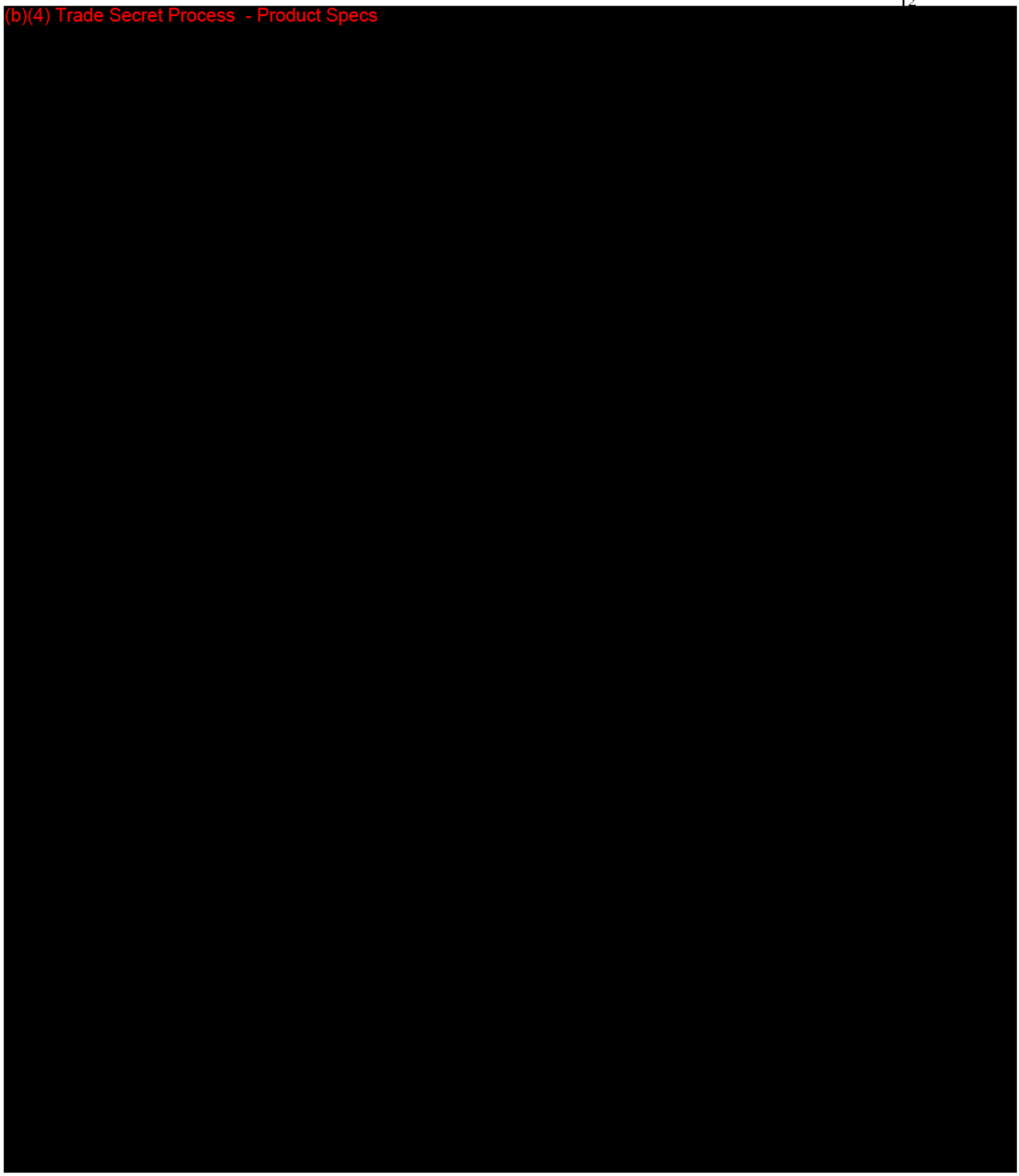

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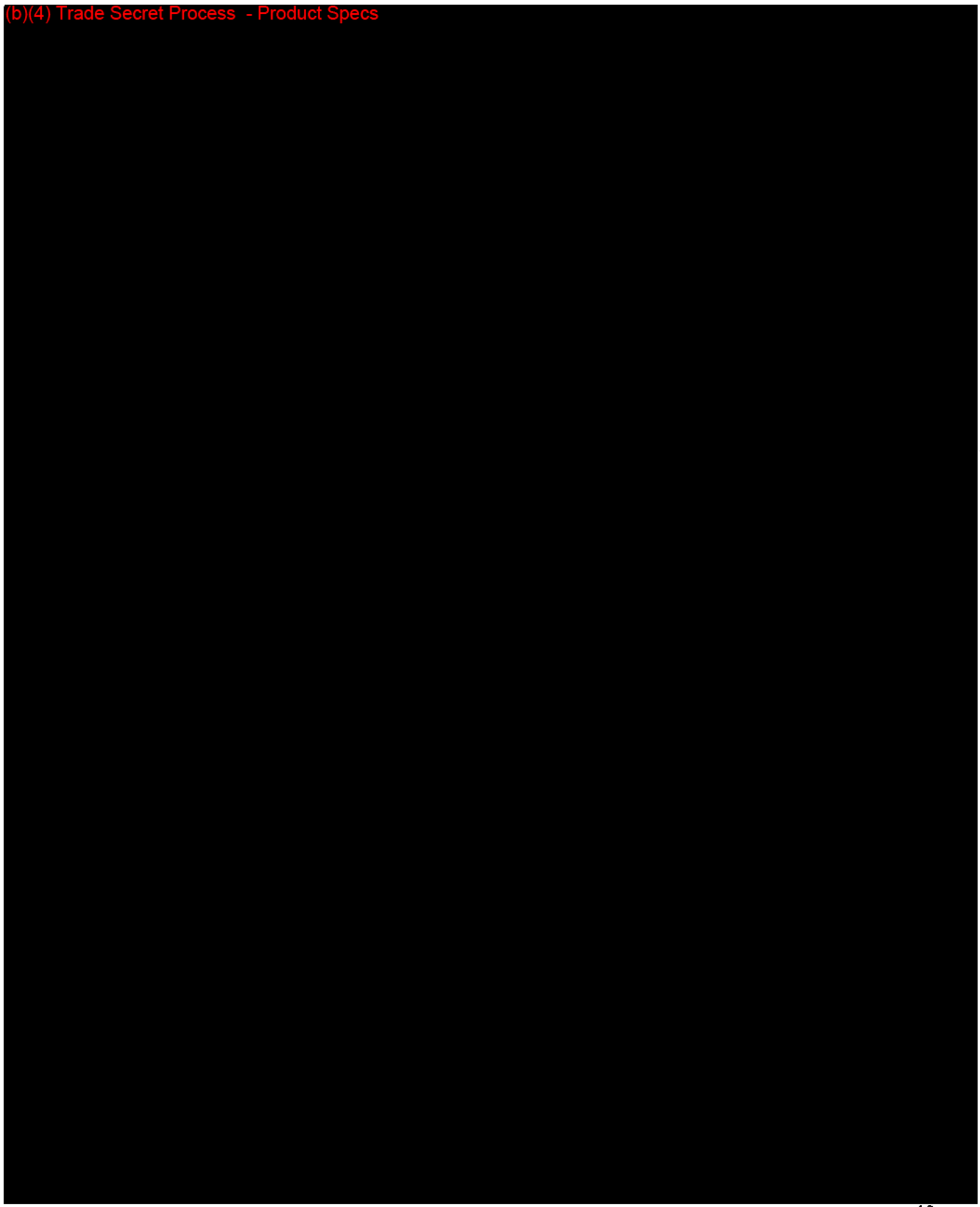

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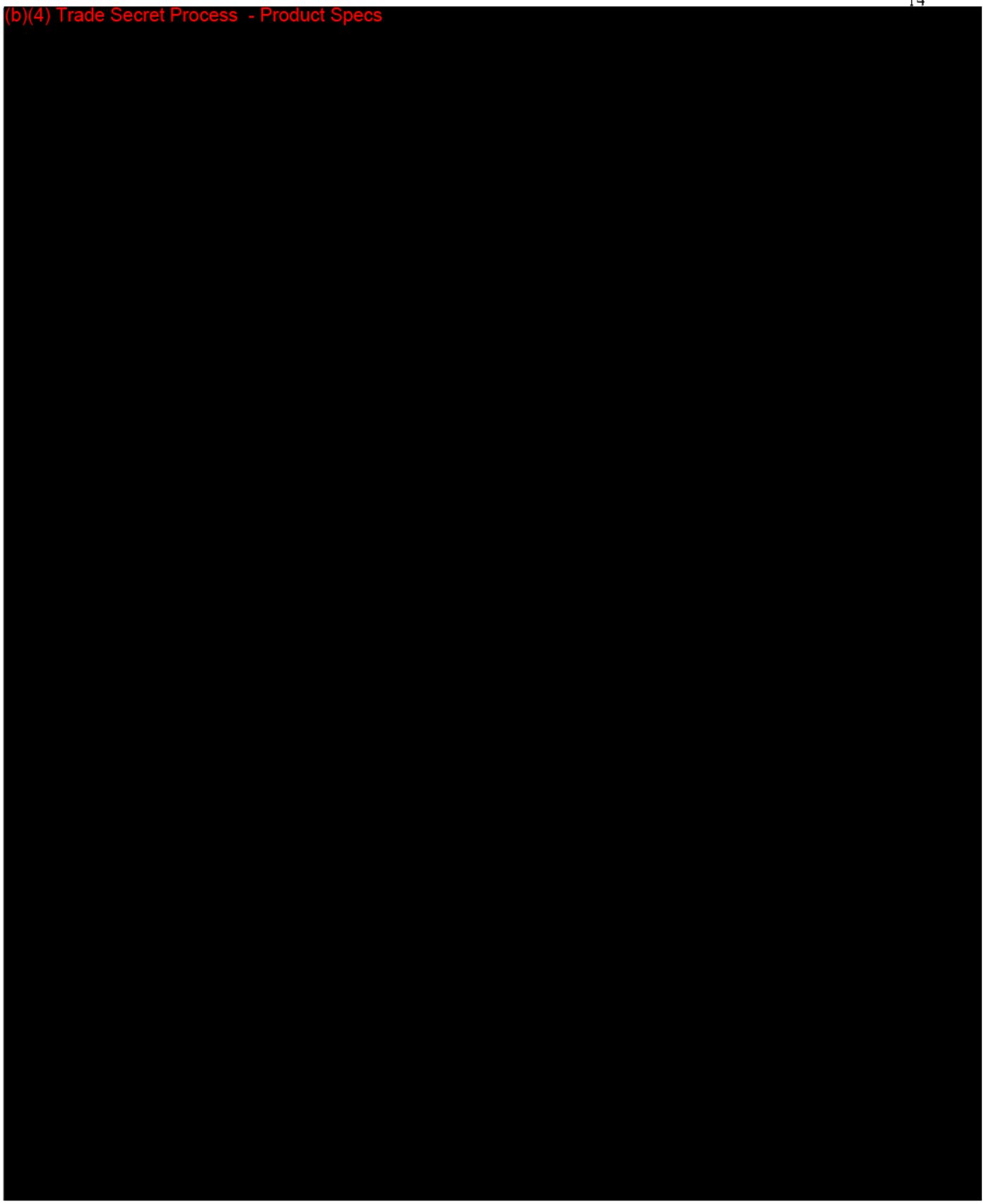

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[redacted]

Reviewed by: Elaine S. Mayhall
Elaine Schalk Mayhall, Ph.D.

SOFTWARE REVIEW

K063876

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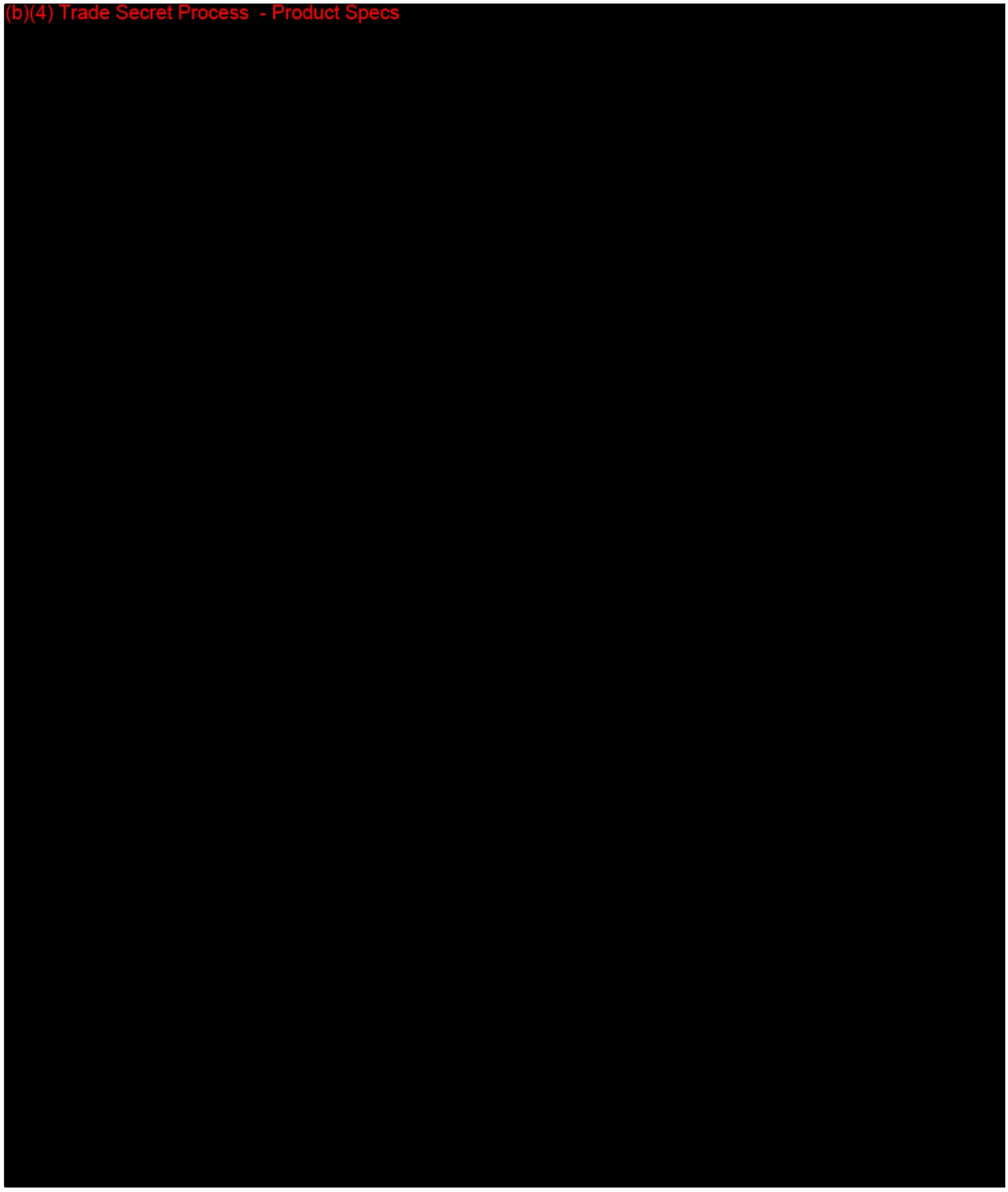

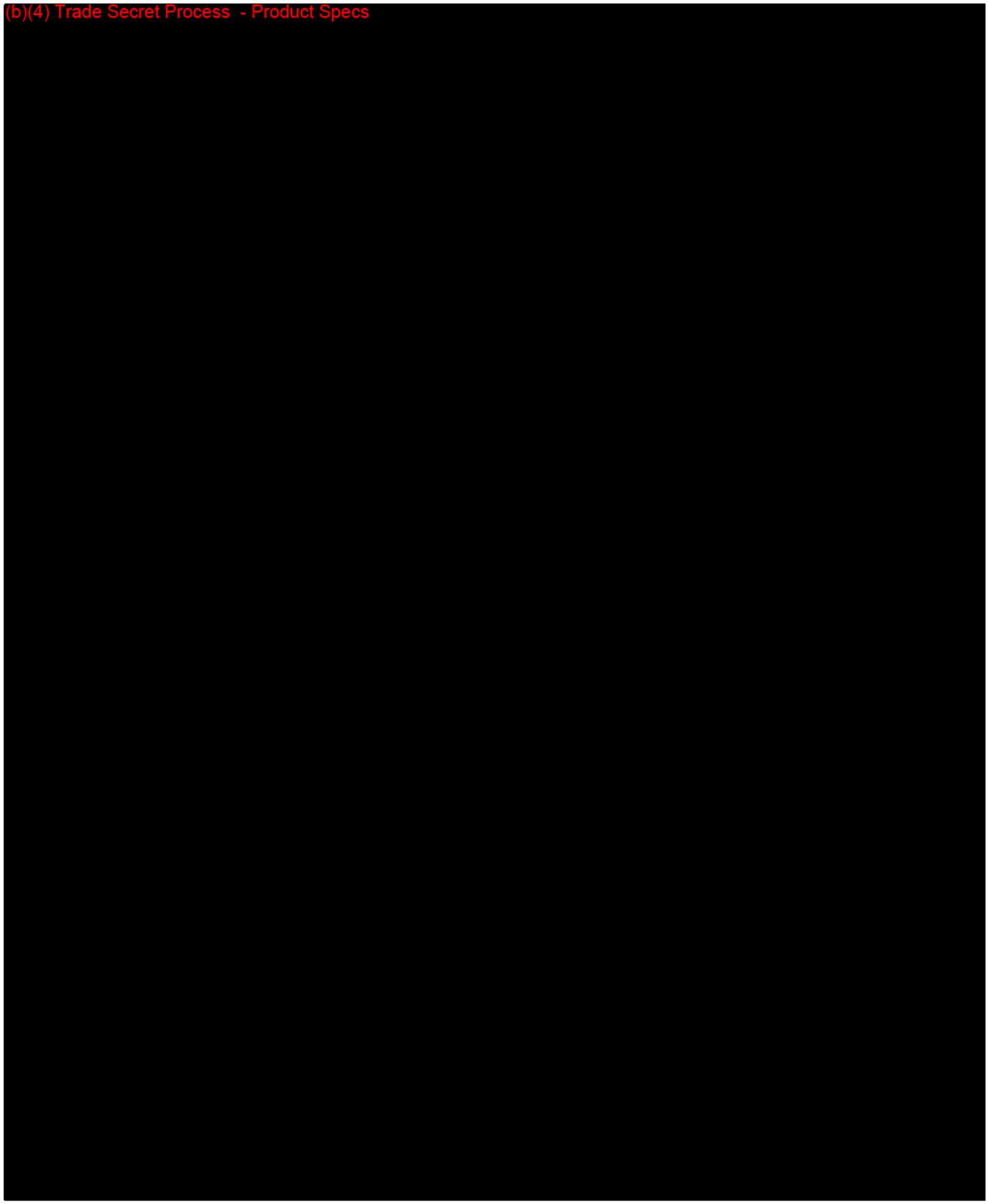
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INTEROFFICE MEMORANDUM

DATE: January 8, 2007

FROM: Elaine Schalk Mayhall, Ph.D., Chemist/Reviewer, Infection Control Devices Branch, DAGID, HFZ-480

THROUGH: Dr. Sheila Murphey, Chief, Infection Control Devices Branch, DAGID, HFZ-480 SM

AND: Anthony Watson, Chief, General Hospital Devices Branch, DAGID, HFZ-480_____

TO: Richard Chapman, Engineer, General Engineer, DAGID/GHDB, HFZ-480

SUBJECT: K063876
Modular Disinfection System (MDS) for Endoscope Reprocessing
Medivators Reprocessing Systems
Minntech Corporation Business Group

Medivators/Minntech has submitted a 510(k) for the above device. Please review the software information for a moderate level of concern.

Please provide your review by February 6, 2007.

Elaine S. Mayhall

Elaine Schalk Mayhall, Ph.D.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Avenue
Rockville, MD 20850

Date: January 30, 2007

From: Mechanical Engineer, General Hospital Devices Branch,
DAGID, ODE, CDRH, HFZ-480

Through: Anthony Watson, Chief, General Hospital Devices Branch, DAGID, ODE,
HFZ-480 1/30/07

To: Dr. Elaine Mayhall, Chemist/Reviewer, Infection Control Devices Branch
DAGID, ODE, CDRH HFZ-480

Subject: CON070184: Engineering Review: K063876 – Modular Disinfection System for Endoscope Reprocessing

Sponsor: Medivators Reprocessing Systems

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Alan Stevens
LT, USPHS

Indications for Use

510(k) Number (if Known): K063876

Device Name: Medivators Reprocessing Systems Modular Disinfection System for Endoscope Reprocessing

Indications for Use:

Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing tests, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. The MDS is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes. It is indicated for use with FDA cleared, liquid high level disinfectants.

The MDS does not replace manual cleaning of endoscopes, they must be precleaned and cleaned according to the endoscope manufacturer's instructions and professional guidelines prior to reprocessing them in the MDS.

Prescription Use ____ AND/OR Over-the Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Medivators Reprocessing Systems Modular Disinfection System
for Endoscope Reprocessing

510(k) Summary of Safety and Effectiveness

Manufacturer:	Medivators Reprocessing Systems, a Division of Minntech Corporation
Address:	14605 28th Avenue North Mpls., MN 55447 USA
Official Contact:	Lynn Lueders Director, Regulatory Affairs

Medivators has supplied the following information to the U.S. Food and Drug Administration to support substantial equivalence of the Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing to other endoscope reprocessors currently marketed in the U.S.

1. Device Description

The Modular Disinfection System (MDS) is an electro-mechanical system intended to test and high level disinfect heat sensitive semi-critical endoscopes. It is not intended for reprocessing rigid endoscopes. The machine can use any FDA cleared, reusable liquid germicide which is on the market that is labeled for high level endoscope disinfection. The testing provided to the FDA used both Medivators Rapicide® High Level Disinfectant and Cidex® OPA High Level Disinfectant.

The MDS does not replace manual cleaning of endoscopes, they must be precleaned and cleaned according to the endoscope manufacturer's instructions and professional guidelines prior to reprocessing them in the MDS.

During its software based reprocessing cycle, the machine tests the endoscopes for leaks and blockages. Before and during the machine cycles, connectivity with the machine through the connector blocks is evaluated. If the scopes pass these tests, they are flushed with water and detergent, disinfected and rinsed. The disinfection cycle takes approximately 30 minutes. The MDS is capable of asynchronously reprocessing two scopes at a time.

The machine has many built in safety features which stop the cycle and alarm when certain conditions exist which could indicate that disinfection might be compromised. These alarms and causes are defined in the directions for use for the product.

The machine also prints records by endoscope serial number indicating the results of testing, disinfection, number of disinfections, etc. which are required for permanent records.

2. Intended Use

Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing tests, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. The MDS is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes. It is indicated for use with FDA cleared, liquid high level disinfectants.

The MDS does not replace manual cleaning of endoscopes, they must be precleaned and cleaned according to the endoscope manufacturer's instructions and professional guidelines prior to reprocessing them in the MDS.

3. Comparison to Another Device in Commercial Distribution Within the United States

The MDS is equivalent in function and indications to the Medivators DSD-91E™ Endoscope Disinfector. This machine was found to be substantially equivalent in 1994 (K914145). Both machines have the same indications for use, the same methods of providing disinfection, can use the same reuseable disinfectants at the same temperatures and times. Both machines can reprocess two scopes asynchronously, one in each bay.

4. Summary of Testing

Medivators has provided testing to show that the MDS is safe and effective for its intended use following the requirements listed in the FDA's Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (dated August 1993).
This testing included:

Efficacy Testing

The MDS was tested using standard methods defined by the FDA guidance document. This testing included simulated use and in use testing.

The simulated use testing showed a $>10^6$ log reduction in the organism *Mycobacterium terrae* after the endoscopes were reprocessed in the MDS.

In use testing showed no viable organisms remained on the endoscopes following the disinfection cycle.

Additional in-use testing was performed to show that the MDS provided disinfected endoscopes when exposed to the entire endoscope cycle of disinfecting and rinsing.

Material Compatibility

The effect of disinfectants (Rapicide and Cidex OPA) on the materials used in the MDS was evaluated and showed that the materials had no significant deterioration over their use life. Studies were also presented to show that the filters used in the water filtration system were compatible with common disinfectants.

Biocompatibility

The amount of disinfectant residue left on endoscopes and in the MDS after the disinfection and rinsing cycles was evaluated and compared to determined safe levels. The results of the testing showed that any remaining residues would not have an effect on patients or users of the machine.

Performance Data

Data was provided to the FDA to show that the machine performs as required. This evaluation included testing to show that the leak check, blockage check, connectivity checks, disinfection cycle, rinse cycles, and drying cycles performed correctly. Any error messages were tested to ensure they function properly to notify users of any possible failure modes. Testing was performed to show that all critical parameters of the machine function correctly.

Testing was presented that showed that disinfectants which require heating remained at their required temperature for the length of time required in the labeling for the disinfectant.

Testing was completed that showed that the MDS self disinfection cycle works properly by disinfecting all areas of the machine, including the water filtration system.

Studies were performed to show that the water filtration system will function appropriately over time and that the machine will alarm if water filters are plugged to a point which will lower the water pressure below required input. This study also showed that the filters remained bacterial retentive even when plugged to a point that causes the machine to alarm.

5. Summary of Substantial Equivalence

Minntech Corporation has provided the above information in the form of a 510(k) to support the claim that the MDS is safe and effective when used in accordance with the device labeling.

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-40
9200 Corporate Blvd.
Rockville, Maryland 20850

May 10, 2007

MEDIVATORS REPROCESSING SYSTEMS
A MINNTECH CORPORATION BUSINESS GRO
14605 28TH AVE., NORTH
MINNEAPOLIS, MN 55447
ATTN: LYNN LUEDERS

510(k) Number: K063876
Product: MODULAR DISINFECTION SYSTEM (MDS) FOR ENDOSCOPE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 in 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 questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

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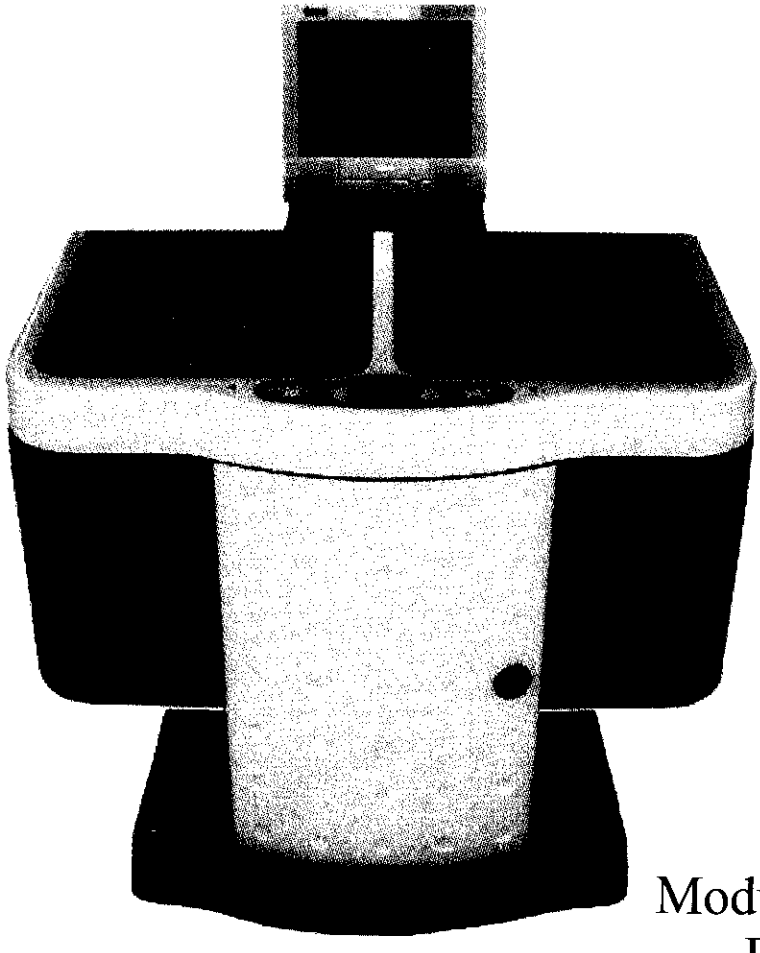
Medivators MDS

Endoscope Reprocessor

User Manual



Modular Disinfection System
For Multi-Use Chemistry

US Version

MEDIVATORS®
REPROCESSING SYSTEMS

50096-654 Rev. A

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Minntech reserves the right to make changes in the specifications shown herein without notice or obligation. Contact your Medivators representative or Medivators customer service for more information.

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Chapter 1

INTRODUCTION

This chapter describes the Medivators Modular Disinfection System (MDS) endoscope reprocessor.

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USING THIS MANUAL

This manual describes the features of the Medivators Modular Disinfection System (MDS) endoscope reprocessor, including the hardware, software, setup, operation, safety, maintenance, and troubleshooting procedures. It is important to follow the instructions provided to keep the MDS in proper operating order and to ensure that endoscopes receive adequate disinfection.

This is not a service manual and does not provide detailed instructions for service beyond general maintenance. See Service Manual for servicing instructions. Contact your service representative for additional service information.

MDS FEATURES

The Modular Disinfection System was designed for ease of use and maintenance in the disinfection of endoscopes. Features include:

- Individual channel connectivity, blockage monitoring, alarming, cleaning, and rinsing
- Asynchronous operation of two large independent basins with locking lids.
- A dedicated personal computer (PC) for system operation of reprocessing cycle, cycle recording, powerful quality assurance reporting, easy backups, networking availability, and remote diagnostics
- Easy-to-fill detergent and alcohol reservoirs
- Hook-up blocks dedicated to a family of endoscopes ensure correct connectivity and flow rates to meet manufacturers' specifications
- Diagnostics for operator assistance and troubleshooting
- Ability to use heated disinfectant chemistry (if heated reservoir system is purchased)

MACHINE SPECIFICATIONS

General Specifications

The basic machine specifications required for installation and operation of the MDS are summarized in *Table 1*.

Table 1 Machine Specifications

Equipment Type	Laboratory Equipment
Electrical rating	120 VAC, 60 Hz, 1 PH (US)
Power rating	2300 Watts
Maximum air pressure	145 psi (10 Bar)
Maximum water pressure	87 psi (6 Bar)
Humidity range for operation	20–80%, non-condensing
Temperature range for operation	80.6°F - 50°F (27°C - 10°C)
Environment	Indoor use only
Installation/Over voltage category	II
Pollution degree	2
Connection to power supply	Cord connection
Dimensions	1137 mm L X 919 mm W X 1499 mm H 44.8" L X 36" W X 59" H
Weight	~ 400 lb.~ 180 kg

Dimensions and Clearances

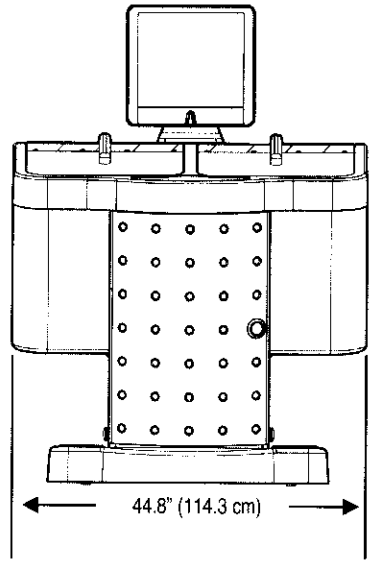


Figure 1 Front Dimensions

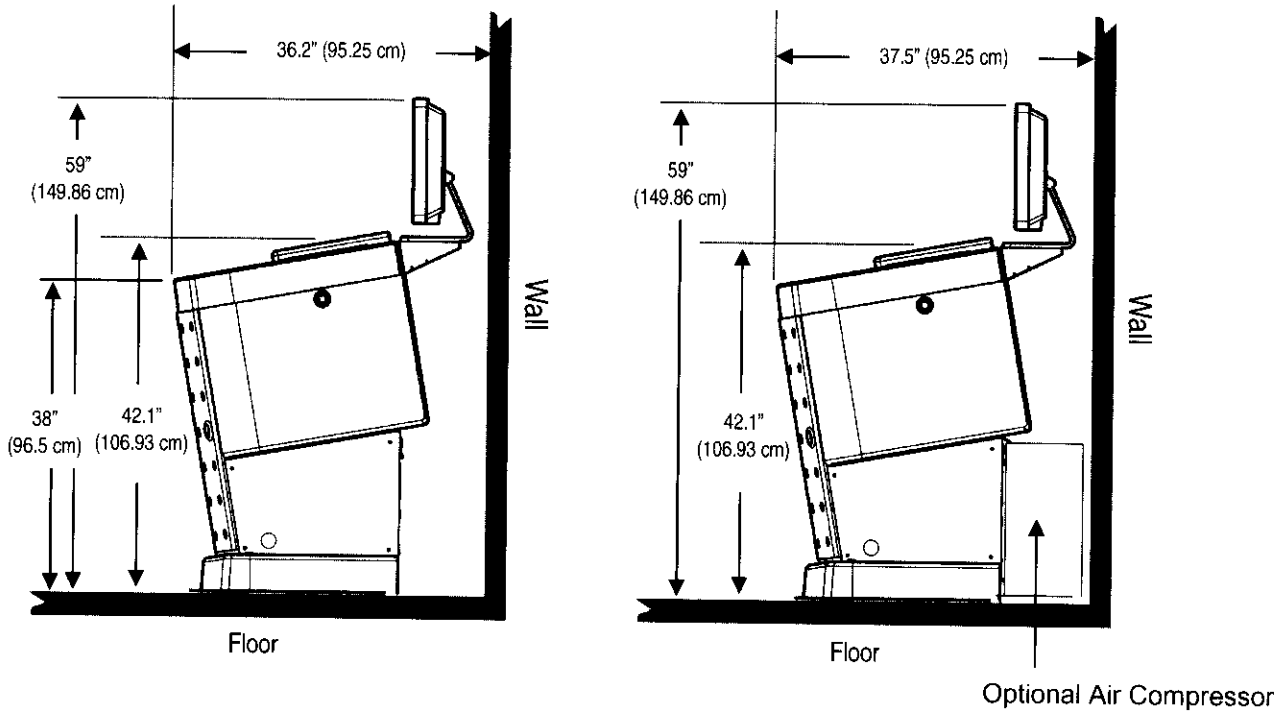


Figure 2 Side Dimensions and Clearance

SAFETY

Intended Use

The MDS is intended for the high level disinfection of flexible endoscopes. Only use high level disinfectants that are labeled to provide high level disinfection when used according to the manufacturer's specified conditions and contact times.

The MDS has been validated by Medivators for use with Cidex® OPA and Rapicide High-Level Disinfectants. The use of any other disinfectant requires validation by the user.

Caution ***Prior to placing used endoscopes into the MDS system, they must be precleaned and manually cleaned according to the SGNA guidelines and your facility procedures.***

Regulatory Compliance

The MDS complies with EN 61010-1-2 Electromagnetic Compatibility (EMC) Standards, and also meets the IEC 61010-1 electrical safety requirements for laboratory equipment.

Notes, Cautions, and Warnings

Throughout the manual are notes, service notes, cautions, and warnings. These provide important information and you should pay special attention to them. Examples are shown below.

Note: A note refers to important information to which you should pay special attention.

Service: A service note refers to operations or repairs that only a trained service technician may perform.

Caution ***A caution describes actions or conditions that may cause damage to or destruction of the equipment.***

WARNING A warning describes actions and conditions that may cause severe personal injury or death to the operator or patient.

Operator Safety

- Equipment must be operated solely by qualified personnel, and used for its intended use only.

WARNING: To avoid biological contamination and chemical burns, always wear appropriate personal protective clothing, gloves, and safety glasses when handling endoscopes or disinfectant solutions.

- Cleansing and disinfectant solutions must be used according to the regulations governing their use, safety, and shelf life.
- Do not attempt to open the reprocessor lid during operation.
- Do not place heavy objects on the glass covers.
- For glutaraldehyde disinfectant handling guidelines refer to the American National Standard *Safe use and handling of glutaraldehyde-based products in health care facilities* (AAMI/ANSI ST 58:2005).
- In the event of a disinfectant or other chemical leak, use personal protective clothing, gloves & safety glasses & follow the disinfectant manufacturer's guidelines for spill clean-up procedures.
- Place guidelines for disinfectant clean-up in an easily visible area near the machine to ensure users will have access to the information when needed.

Installation and Maintenance

Proper maintenance ensures effective disinfection and prolongs the life of the reprocessor.

- The MDS must be grounded in accordance with applicable regulations.
- The system default is factory-set for a specific disinfectant immersion time. This time may only be changed in the system parameters by a qualified individual. Verify the program is appropriate for the disinfectant used.
- All pressure regulators are factory-preset. Do not adjust the settings. Contact your Technical Support representative for assistance.
- Do not allow the cleaning solution to contact metal components.
- Do not use alcohol or alcohol-based products to clean the reprocessor cabinet.
- The hook-ups are not autoclavable and must be reprocessed by low temperature disinfection only.
- Do not remove covers, doors, or panels fastened with screws while the machine is in use.
- Replacement parts must be ordered from the manufacturer to maintain the warranty.
- Do not block ventilation openings.
- Regularly check all cables, tubing, and drains for damage or leaks.
- Do not carry out any maintenance that is not described in this manual.
- Do not disable temperature sensors in heated reservoirs (optional equipment). If service is required, contact your authorized Medivator distributor.
- Ensure that the power supply connection is accessible in the event that emergency disconnection is necessary.

GUIDELINES FOR RELIABLE DISINFECTION

Water Quality

Potable water is the minimum standard, Medivators recommends the use of a high quality water pre filtration system that filters incoming water to a minimum of 0.2 µm. A typical water pre-filtration system, such as the one offered by Medivators, filters incoming water through a 1 µm, .45 µm, .2 µm series of filters.

- The high performance 0.2 µm (absolute rated) water filter included with the reprocessor is highly effective at removing microorganisms and particles larger than 0.2 microns. Appropriate pre-filtration and regular disinfection are required to maintain the performance of this filter.

- The routine maintenance schedule recommends replacing the 0.2 µm water filter every six months or sooner, depending on the pre-filtration system and the quality of the incoming water. If the filter clogs to the point of non effectiveness, the machine will alarm and will not continue until the filter is replaced.

Detergent Solution

Medivators recommends the use of a detergent solution that is low-foaming and formulated to use with medical instruments. The detergent should have a neutral pH and also bacteriostatic properties to inhibit bacterial growth in the detergent reservoir and detergent lines.

Monitoring Disinfectant Potency

The efficacy of a disinfection procedure is directly related to the disinfectant solution used, and the amount of time the endoscope is exposed to that solution.

- Disinfectants must be monitored for potency every reprocessing cycle. Consult the disinfectant manufacturer recommendations for monitoring guidelines and procedure.

- Use the manufacturer's test strips to test the potency of the solution. If the potency of the solution is below its minimum recommended concentration (MRC), discard and replace it with fresh solution.

- Never use disinfectant beyond the manufacturer's recommended reuse life, even if the potency levels is acceptable.

- Never use disinfectant with unacceptable potency levels, even if the reuse date is unexpired.

Disinfectant Solution

Select a low-foaming, high-level disinfectant specifically manufactured for high-level medical instrument disinfection. The product must be capable of destroying *M. tuberculosis.*

Consult the product label and verify that the MDS contact time and temperature is correctly configured for the disinfectant solution. The MDS system can **only** be reconfigured by a service technician.

Endoscope Precleaning and Testing

Disinfection Requirements

The MDS may be used with all makes and sizes of flexible, immersible endoscopes that can be internally and externally disinfected. Proper endoscope disinfection is required because endoscopes have multiple internal valves and channels that have the potential to harbor microorganisms that could cross-contaminate patients. Reprocessing quality depends largely on a thorough flushing of all endoscope channels, valves and fittings where contamination can occur.

Different disinfection programs are available for the various endoscope channel configurations and sizes. Endoscope channels must be able to withstand the conditions shown in *Table 2.*

Table 2 Endoscope Disinfection Requirements

Endoscope Requirement	Maximum Disinfection Conditions
Biopsy and suction endoscope channels	≤ 1 bar (≤ 100 kPa) (14.5 psi)
Jet, water, and air	≤ 1.5 bar (≤ 150 kPa) (21 psi)
Elevator wire channel	≤ 2 bars (≤ 200 kPa) (29 psi)
Temperature stability	≤ 60°C (140°F)
Leak test pressure	≤ 300 mbar (≤ 30 kPa) (4.35 psi)
Stability to cleansing and disinfection agents	Varies based on agents used

Preclean and manually clean used endoscopes to SGNA guidelines and your internal facility procedures prior to disinfection. Leak test all endoscopes prior to disinfection. Follow the endoscope manufacturer's instructions and established professional guidelines while cleaning and disinfecting endoscopes. Note that endoscopes with an elevator wire channel requires additional manual cleaning and disinfection steps.

PROFESSIONAL GUIDELINES

The following organizations have published recommended guidelines for cleaning and disinfecting endoscopes.

Society of Gastroenterology
Nurses and Associates, Inc.
401 North Michigan Ave.
Chicago, IL 60611-4267
USA
Tel: 800-245-7462
Fax: 312-527-6658
www.sgna.org

Assoc. for Professionals in Infection
Control and Epidemiology, Inc.
1275 K Street NW, Suite 1000
Washington, DC 20005-4006
USA
Tel: 202-789-1890
Fax: 202-789-1899
www.apic.org

American Society for
Gastrointestinal Endoscopy
1520 Kensington Rd., Suite 202
Oak Brook, IL 60523-2141
USA
Tel: 630-573-0600
Fax: 630-573-0691
www.asge.org

American Society for
Testing and Materials
100 Barr Harbor Dr.
West Conshohocken, PA 19428-2959
USA
Tel: 610-832-9585
Fax: 610-832-9555
www.astm.org

Association of periOperative
Registered Nurses, Inc.
2170 S. Parker Rd., Suite 300
Denver, CO 80231-5711
USA
Tel: 800-755-2676
Fax: 303-750-3462
www.aorn.org

Canadian Society of Gastroenterology
Nurses & Associates
27 Nicholson Dr.
Lakeside, NS B3T 1B3
CANADA
Fax: 902-473-4406
www.csgna.com

British Society of
Gastroenterology
3 St. Andrews Place
Regents Park
London NW1 4LB
ENGLAND
Tel: (+44) (0)20 7387 3534
www.bsg.org.uk

Société Française d'Hygiène Hospitalière S.F.H.H.
Hôpital de la Croix-Rousse
Unité d'Hygiène Hospitalière-Épidémiologie
93 Grande Rue de la Croix-Rousse
69317 Lyon Cdx04
FRANCE
Tél: 04 72 07 19 83
Fax: 04 72 07 19 85
www.sfhh.net

MACHINE CONNECTIONS

Electrical

The MDS must be connected to a single electrical outlet capable of supplying 16 amps at 120 ± 5 volts AC. The outlet must be properly grounded.

Water

Potable water is the minimum standard. For optimum performance, water must be delivered at a minimum flow rate of 5 L/min (1.32 gpm) at a dynamic pressure of 30 psi (2 bar) during the basin fill. A back syphonage prevention device must be purchased separately and installed between the water line & the machine to prevent contamination of the water supply in the event of a sudden drop in water pressure.

Drain

For optimum performance the MDS should be connected to a vented sanitary drain system capable of draining at a minimum rate of 12 L/min (3.17 gpm).

Room Ventilation

The MDS must be installed in a room with a ventilation system capable of delivering a minimum of 10 air exchanges per hour.

An optional ventilator fan may be factory installed for customer convenience. The fan can be connected to a duct system capable of handling an air flow of 60 m^3/hour (35 CFM). Connection of this fan does not change the requirement for adequate room ventilation.

Air

The MDS must be connected to an air supply for proper operation. The air supply must be capable of delivering medical grade air at a minimum of 40 L/min (10.57 gpm) at 6 bar (87 psi).

An optional air compressor system is available for the Medivators MDS machine. The air compressor is factory installed and delivers proper air flows and pressures for correct system operation.

STORAGE

If the MDS will be out of service for an extended period of time, the following steps must be followed:

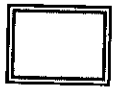
- Remove the side covers, purge all liquids from the system, and then replace the covers.
- Place a covering over the unit to protect it from dust and moisture.
- The storage temperature must not go below 0°C (32°F), or exceed 60°C (140°F).
- The maximum relative humidity must not exceed 80% during storage.

TRANSPORT

The MDS may be safely moved on its casters on a smooth, level floor. However, if you encounter any thresholds or floor level changes, the base cover must be removed to avoid damage. For all other moves, place the MDS on a pallet with a kraft liner.

SYMBOLS AND ICONS

Symbol	Symbol Meaning	Symbol	Symbol Meaning
	LIO software shortcut		Cancel
Management	Management software shortcut		Next
Server	Server software shortcut		Release All
	Expert Operation		Start
	Cancel		Stop
	Menu		Active report, filter applied.
	Open/Close		Edit
	OK/Enter		Expand
	Scroll Down		Export data
	Scroll Up		Filter data
	Start		Generate report
	Stop		Minimize report details
	Import data		New



The icons in the grayed area are only used by Service Personnel.

WARNING SUMMARY

WARNING Portable and mobile communication devices can affect electrically-operated medical equipment

WARNING Connecting a chemical container with the incorrect fluid may cause the endoscope to be improperly disinfected. Do not use the endoscope on a patient if this occurs.

WARNING Wear protective clothing, gloves and eyewear. The disinfectant and detergent manufacturers may recommend additional protection.

WARNING Do not insert hands into the disinfectant reservoir while it is connected to the system. This may result in injury due to contact with chemical or heater elements (optional equipment.)

WARNING Verify that the air pressure readings are within the acceptable ranges before every reprocessing cycle. Do not make air pressure adjustments during a disinfection process.

If the main air pressure regulator is not set correctly, the endoscope may not be properly disinfected.

If the leak test regulator cannot be set correctly, the endoscope may be damaged during the reprocessing cycle.

WARNING All endoscope hookups must be periodically inspected for wear. Discard and replace damaged hookups otherwise it could result in an endoscope that is not disinfected and therefore should not be used on a patient.

WARNING Verify all connections to the endoscope are secure and tubing is not linked. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.

WARNING Verify the connection tubing does not interfere with the spray head and confirm that the spray function is working during the cycle. Failure to do this could result in an endoscope that is not disinfected and therefore should not be used on a patient.

WARNING Before removing the endoscope, verify all connections to the endoscope are secure. If an adapter is loose or disconnected, the disinfection was not complete and must be repeated. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.

WARNING Report all system errors to your supervisor.

WARNING Wear clean gloves to prevent soiling of the disinfected endoscope.

If a run error was generated, a channel is blocked, or the endoscope is leaking, the endoscope must not be released for patient use. If there is any doubt as to whether an endoscope is correctly disinfected, it must be disinfected again before use. Contact your supervisor for further instructions.

Verify all endoscope connections are secure. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.

WARNING Avoid possible chemical burns. Always wear personal protective equipment (gloves, goggles) when handling disinfectant and/or detergent.

WARNING Use only cleaning and disinfectant fluids approved by Medivators.

Check the expiration date of the disinfectant in the machine each day.

Never use disinfectant beyond the manufacturer's expiration date, even if the MRC level is acceptable.

Never use disinfectant that tests below the acceptable MRC level, even if it has not yet reached the expiration date.

If using heated reservoirs, always heat chemical to manufacturer's stated temperature.

Never use heated reservoirs with a disinfectant intended for use at room temperature.

When replacing disinfectant, always wear protective clothing, gloves and eyewear. The disinfectant manufacturer may recommend additional protection.

If leaking liquid is present and you suspect it is disinfectant, read and follow the manufacturer's instructions before attempting a cleanup.

WARNING Ensure that the machine is installed and maintained in a position that allows access to the power cord for emergency disconnection if necessary.

Never use the equipment in a manner inconsistent with the manufacturer's guidelines. Using the equipment in a manner inconsistent with the manufacturer's guidelines may impair the protections that are designed into the device and may cause injury to the user.

NOTES

Chapter 2

OPERATOR CONTROLS

This chapter describes the MDS operator controls, and how to set up and program the reprocessor.

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MAIN COMPONENTS AND THEIR FUNCTIONS

Exterior Components

The MDS machine consists of two independent reprocessing modules. Each has a basin, automatic cover, endoscope hookups, and the necessary pumps and valves to disinfect, rinse, and dry most models of flexible, immersible endoscopes.

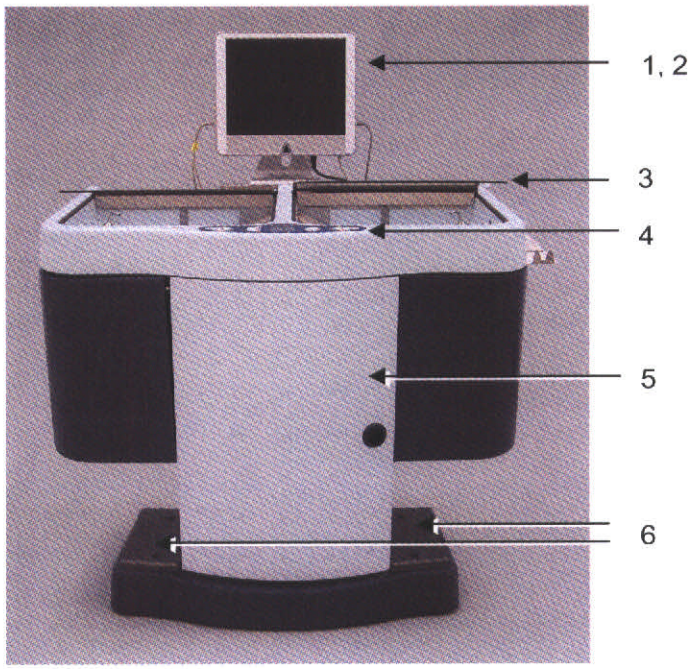

Figure 1 MDS Front View

1. **PC:** Runs the programs on the MDS that disinfect the machine and endoscopes.
2. **PC Monitor:** Displays messages, menu selections, and the operation status.
3. **Basin Lid:** Cover for the left or right basin of the MDS. Open the lid to add or remove endoscopes.
4. **Control Panel:** Use to select settings, operate the reprocessor, and view system messages, errors and warnings, and cycle information.
5. **Access Door:** Opens to allow access to the reservoirs, filters, transfer valves, and pressure gauges.
6. **Foot Switch:** Pressing the right foot switch opens the right basin lid, and pressing the left foot switch opens the left basin lid.

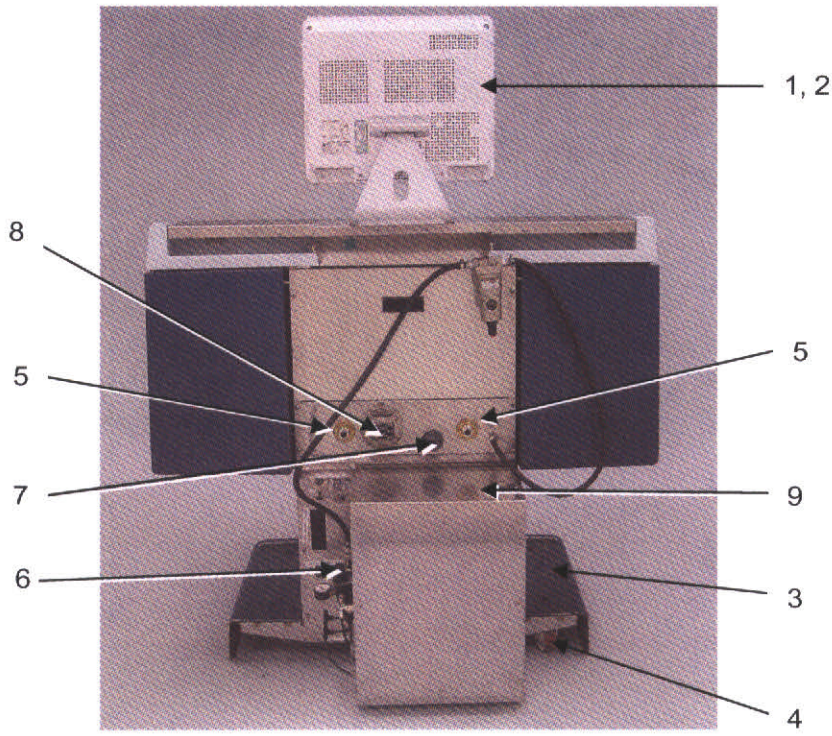

Figure 2 MDS Back View

1. **PC:** Runs the programs on the MDS that disinfect the machine and endoscopes.
2. **PC Monitor:** Displays messages, menu selections, and the operation status.
3. **Base Shroud:** Covers and protects the bottom of the MDS.
4. **Castors:** Wheels which make the MDS easier to move.
5. **Water Supply Inputs:** Inlet for filtered water, one for each module.
6. **System Power:** Electrical power supply connection.
7. **Discharge:** Fluids output to the drain.
8. **Vapor Venting:** Exhausts fumes from the modules, preventing operator exposure.
9. **On-Board Air Compressor (Optional accessory):** provides pressurized air to the system in the event that a pressurized air line from the facility is not available.
10. **Compressed Air Hook-up (not shown):** Connects with facility pressured air line, if on-board air compressor accessory is not purchased.

Interior Components

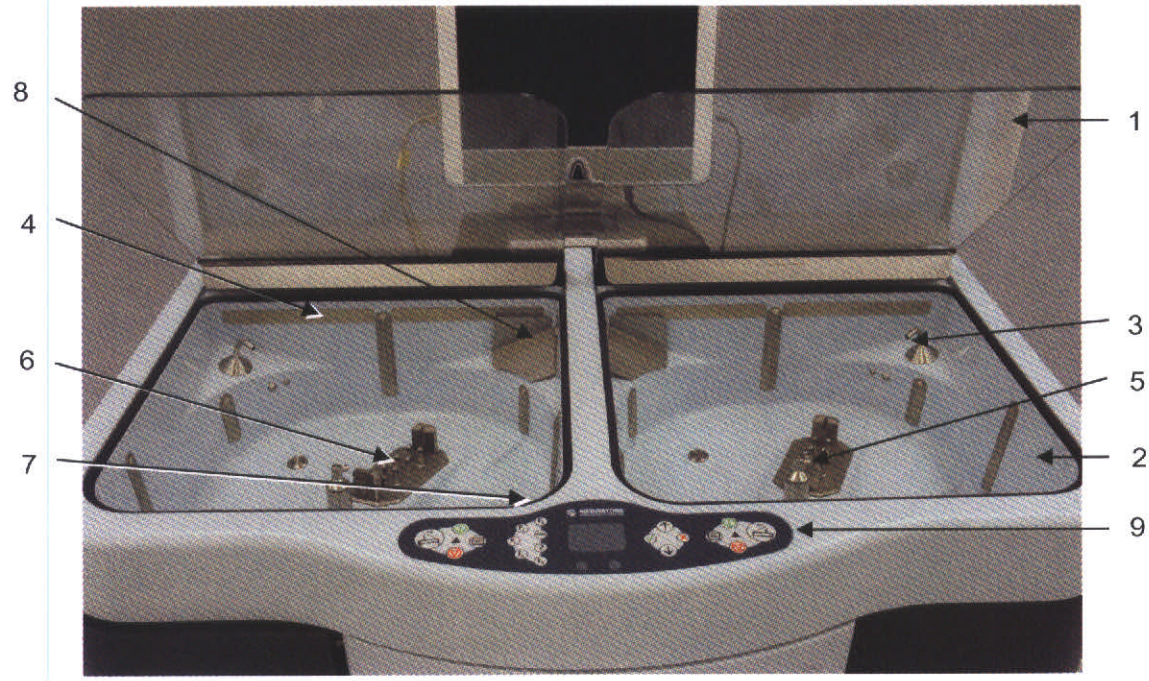

Figure 3 MDS Top View

1. **Basin Lid:** Cover for the left or right basin of the MDS. Open the cover to load or remove endoscopes.

2. **Basin:** Container where endoscopes are reprocessed.

3. **Fluid Inlet:** Port where liquids are dispensed into the basin.

4. **Vapor Ports:** Located beneath the overflow drain covers, and draws fumes away from the basin preventing operator exposure

5. **Spray Head:** Disperses a fine jet of fluid into the basin.

6. **Connection Manifold:** Attaches endoscope hookup block to the system.

7. **Drain:** Outlet port through which waste fluids are dispensed.

8. **Overflow:** Outlet used to drain off excess fluids.

9. **Control Panel:** Use to select settings, operate the reprocessor, and view system messages, errors and warnings and cycle information.

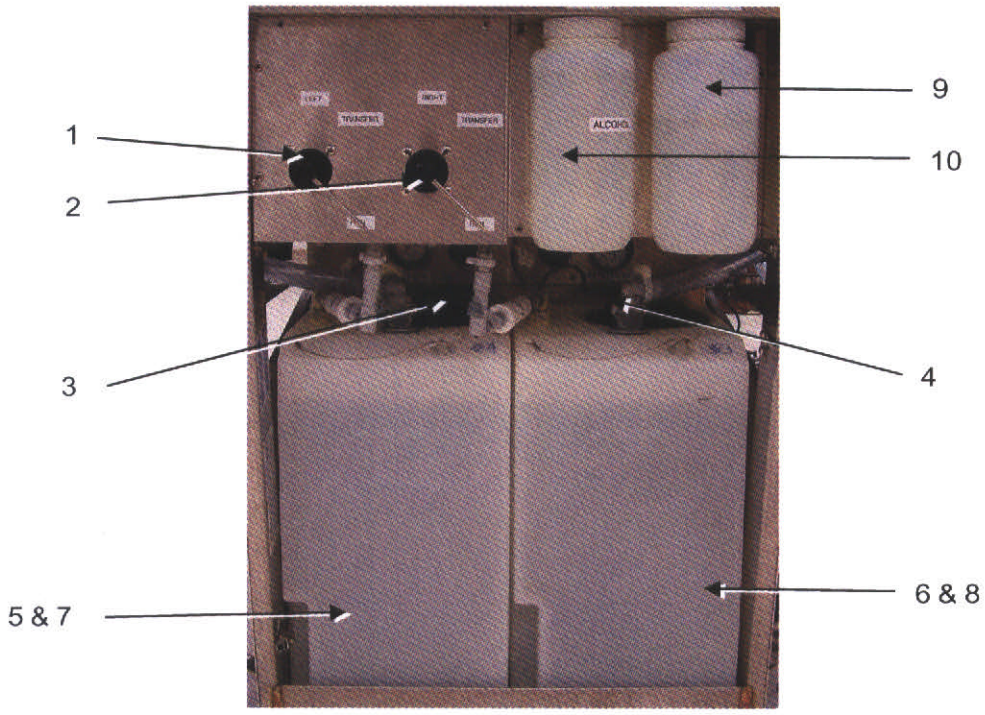

Figure 4 Chemical Reservoirs

1. **Left Transfer Valve:** Used to transfer fluid to the left reservoir.

2. **Right Transfer Valve:** Used to transfer fluid to the right reservoir.

3. **Main (High) Pressure Gauge (left):** Measures air pressure in the MDS system 3 bar (45 psi).

4. **Leak Test (Low) Pressure Gauge (right):** Measures air pressure in the endoscope and MDS system. Must be set to 0.25 bar (3.75 psi)

5. **Disinfectant Reservoir:** Holds disinfectant solution used in the disinfection process for left basin

6. **Disinfectant Reservoir:** Holds disinfectant solution used in the disinfection process for the right basin.

7. **Heated Disinfectant Reservoir (Optional):** Holds disinfectant solution at elevated temperature to be used in the disinfection process for left basin.

8. **Heated Disinfectant Reservoir (Optional):** Holds disinfectant solution at elevated temperature to be used in the disinfection process for right basin.

9. **Detergent Reservoir:** Holds detergent used in the disinfection process.

10. **Alcohol Reservoir:** Holds alcohol that may be used in the disinfection process.

PC and Connections

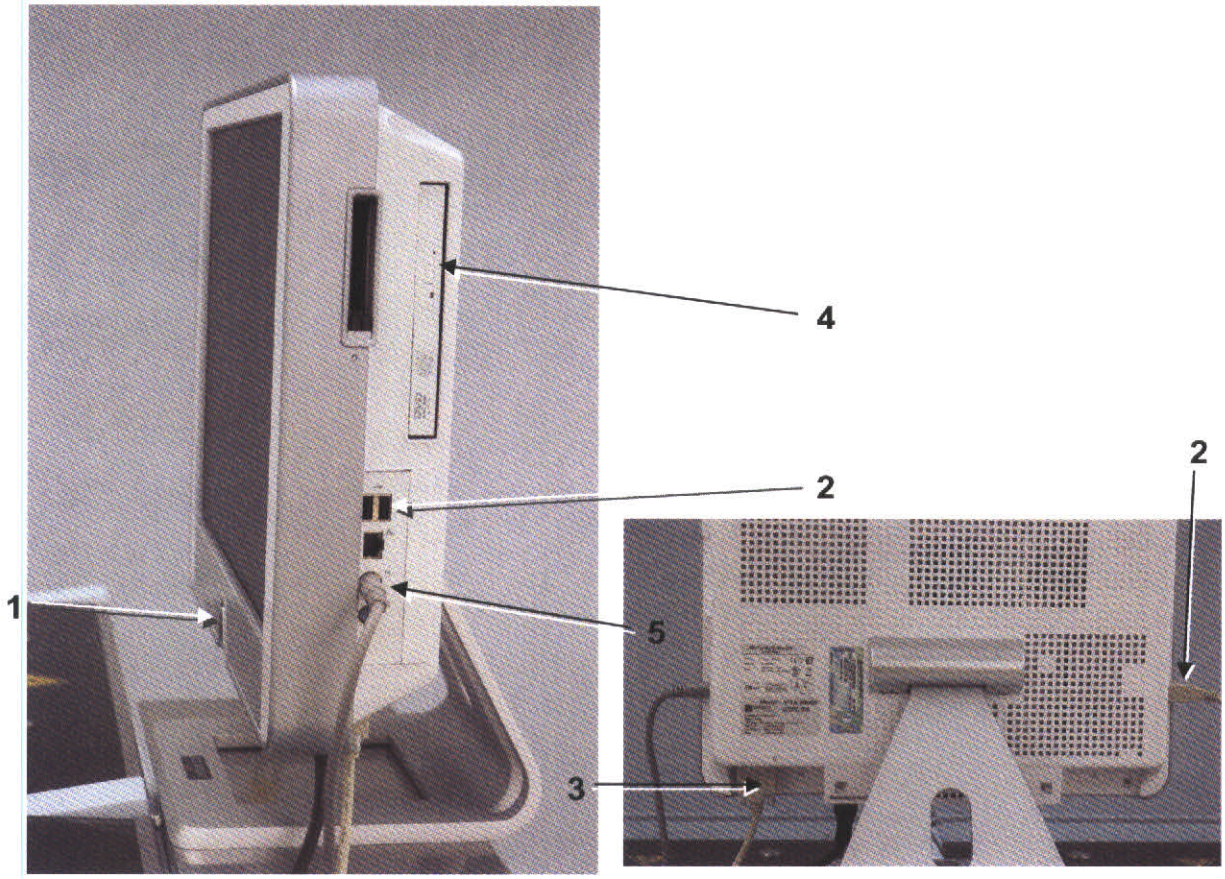

Figure 5 PC and Connections

1. **On/Off Switch:** Turns the computer on or off.
2. **USB Ports:** Connector between the PC and external peripherals.
3. **Serial Port:** Connector between the PC and external peripherals.
4. **CD Drive:** Reads and writes compact disks
5. **Mouse Connection:** Connection for the front panel mouse pad.
6. **Power Connection:** Bottom of monitor in back (not shown)

Control Panel

The control panel allows the operator to select settings, operate the reprocessor, and view system messages, errors and warnings, and cycle information. It consists of five main groups:

1. Left and right basin control buttons
2. Function buttons
3. Touchpad and mouse buttons
4. Selection buttons
5. Left and right basin LED lights

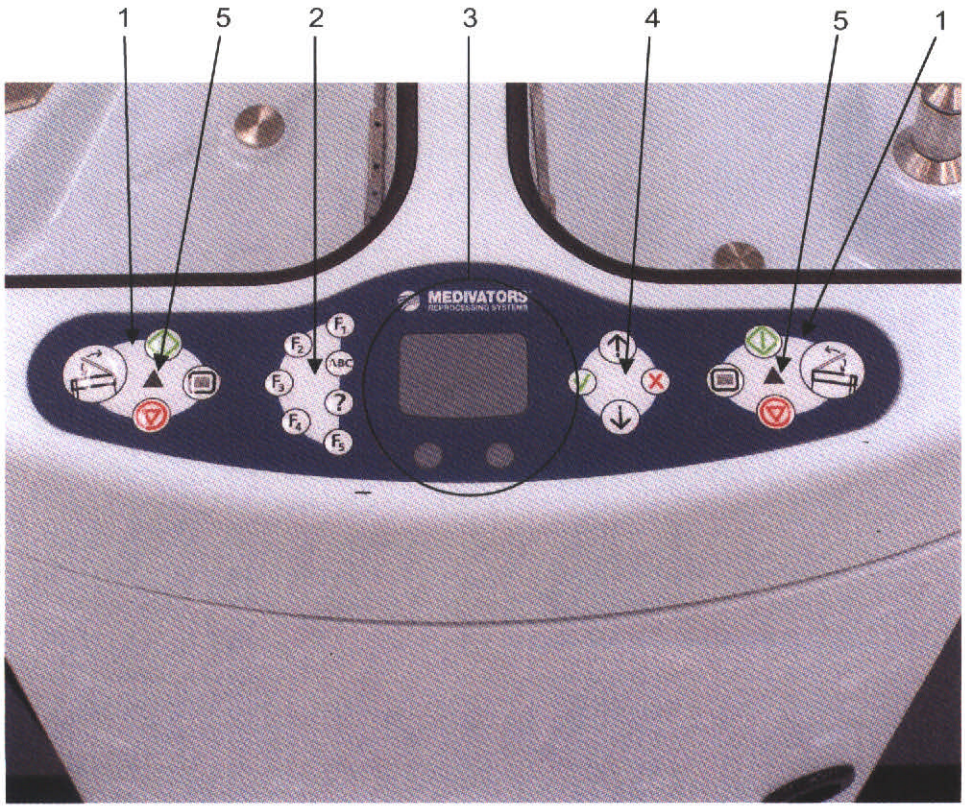

Figure 6 Control Panel

Basin Control Buttons

Each module is controlled by its own keypad grouping. The group shown in *Figure 7* is for the right module.

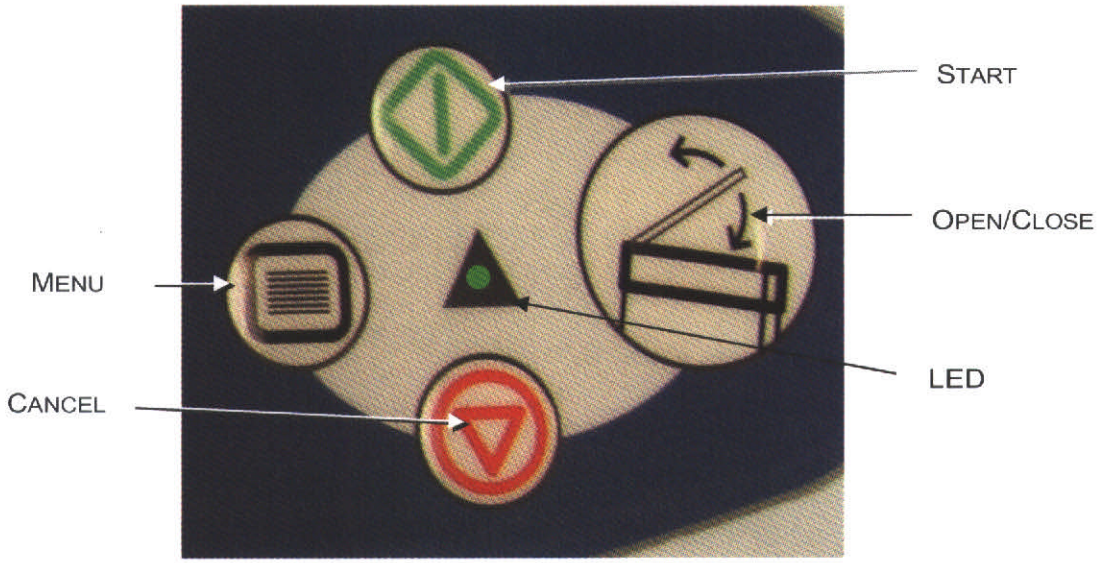

Figure 7 Basin Control Buttons

- Press the **Open/Close** button to open or close the lid on the basin. Note that during disinfection, the lids will not open.
- Press the **Start** button to start a disinfection program. The button is also used to restart a program after an error.
- Press the **Cancel** button whenever you have a reason to stop a disinfection program. If disinfectant is in contact with the endoscope when the button is pressed, the program will run until conditions are safe.
- Press the **Menu** button to log in, select programs, and enter data.
- The green LED will display when system is operating normally, LED flashes green upon cycle completion. If LED is red, system error has occurred. Verify the error condition. The endoscope may not be disinfected. Do not use.

TOUCHPAD AND MOUSE BUTTONS

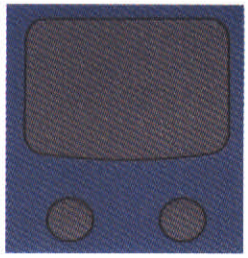

Figure 8 Touchpad and Buttons

The touchpad works as a mouse to enter information. Moving your finger on the pad causes the cursor to move on the monitor. Tapping the touchpad or pressing the left button has the same result as clicking the left button on a mouse. The two buttons correspond to the left and right buttons on a mouse.

FUNCTION BUTTONS

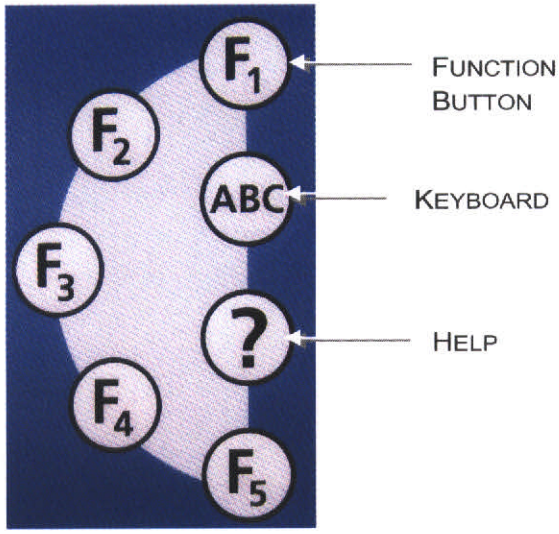

Figure 9 Function Buttons

Table 1. Function Buttons

Function Key	Press Button (No. of times)	Result
F1	1	I/O Inputs / Outputs, left basin
F1	2	I/O Inputs / Outputs, right basin
F1	3	I/O Inputs / Outputs, both basins
F1	4	Re-opens program window
F2	—	—
F3	1	Opens system parameters. Press again to close.
F4	1	History report for the current day. Press again to close.
F5	—	—
ABC	1	Get keyboard to appear on the monitor
ABC	2	Close keyboard screen
Help (?)	—	—

SELECTION BUTTONS

- Pressing the **OK** ✓ button is the same as clicking on the ✓ OK button in the software.
- The **Cancel** ⊗ button corresponds to the ✗ Cancel button in the software.
- Pressing the **Scroll Up** ⓣ button allows you to scroll up through a list on the monitor.
- Pressing the **Scroll Down** ⓓ button allows you to scroll down through a list on the monitor.

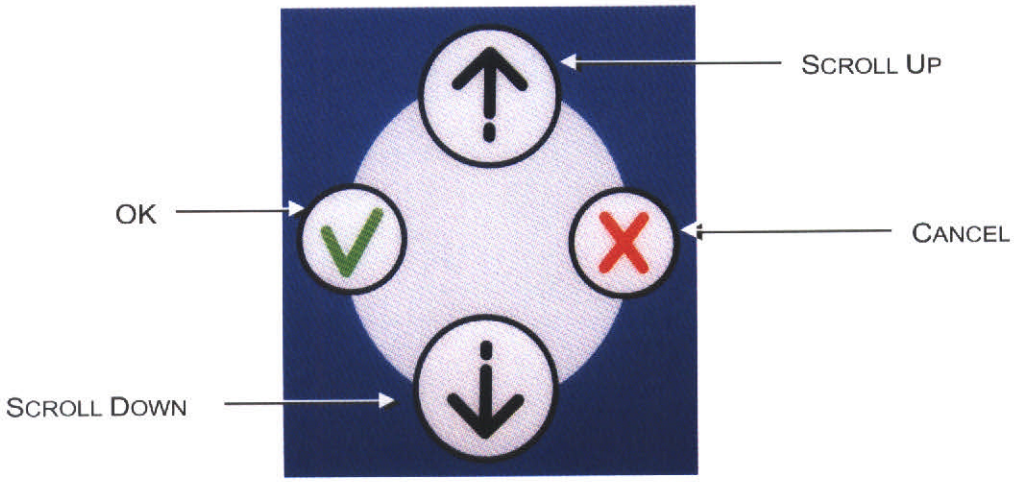

Figure 10 Selection Keys

Connector Blocks

The endoscope channels are connected to the MDS channel manifold via a connector block. Each endoscope model requires a unique connector block to ensure that proper disinfection can be achieved. Refer to the hookup application guide to identify the correct connector block to use for the endoscope to be reprocessed.

Note: Before a new type of endoscope is reprocessed or if you have any questions about a connection block, contact your field service representative.

Accessories

Endoscope valves and accessories must not be disinfected in Medivators MDS system. Valves and accessories must be disinfected per endoscope manufacturer's instructions.

Data Entry (Optional)

Bar Code Reader

An optional bar code scanner can be used to automatically enter data rather than manually entering it with the control panel. The system administrator may define a list for any of the following items:

- Operator login name
- Endoscope code
- Doctor/specialist ID
- Assistant ID
- Patient number

Figure 11 Bar Code Reader for Operator Login and Endoscope ID

I-DENT

An optional identification chip can be used to automatically enter codes rather than manually entering it with the control panel. The endoscope and operator both have I-Dent devices, as shown in *Figure 14*.

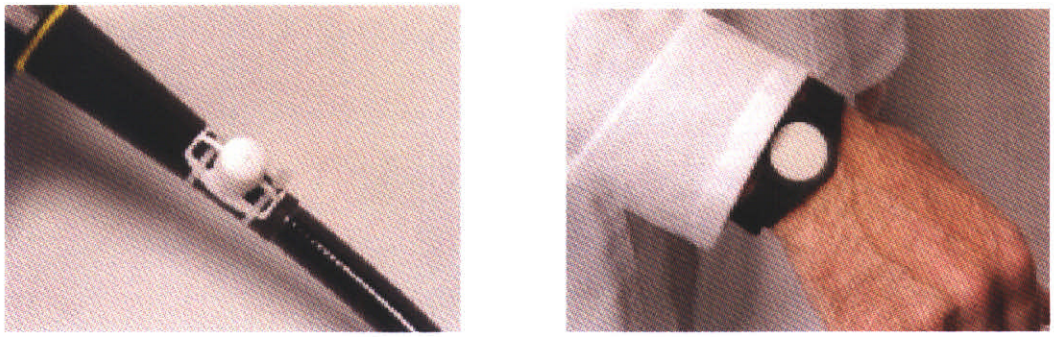

Figure 12 I-Dent Chip on Endoscope and Operator

To correctly read the data, the I-Dent chip on the endoscope and operator wrist band must be held in a specific position, as shown in *Figure 13* and *Figure 14*.

Figure 13 Reading the Operator I-Dent Chip

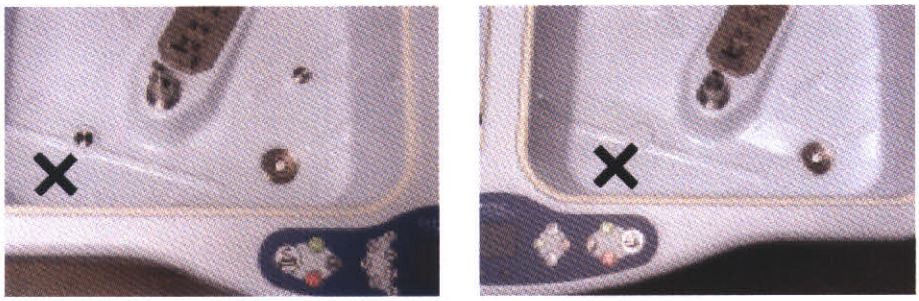

Figure 14 Reading Positions for the Endoscope

HEATED DISINFECTANT RESERVOIRS (OPTIONAL)

Optional heated disinfectant reservoirs allow the machine to heat disinfectant to elevated temperatures per manufacturer's guidelines. The heated disinfectant can then be delivered to the reprocessing basin during an endoscope reprocessing cycle. The operator will have the option of setting the heater to a schedule which will automatically turn it on and off at preset times, or can turn it on and off manually.

SOFTWARE SYSTEM

Available Programs

Five separate programs control the MDS:

1. **LIO (Logic Input/Output)** is the main software program that MDS operators use to perform and run an endoscope cycle. This part of the software controls the MDS system and is what runs and displays on the PC monitor. This program is used most often by daily operators of the MDS system.

2. **Management** is the MDS database for user and run information. It allows an administrator access to input data, process reports, and manage multiple MDS machines. This program runs on one computer only.

3. **Server** controls communication between LIO, Management, and MDS machines that may be on a network. This program runs in the background of the MDS system server.

4. **Print Service** automatically prints a certificate to the cycle log printer which is dedicated to each MDS machine. The certificate contains system information and reprocessing cycle details pertaining to a specific reprocessing cycle.

5. **Backup Utility** generates a backup copy of the MDS database. This provides a safeguard against the accidental deletion or corruption of the database files.

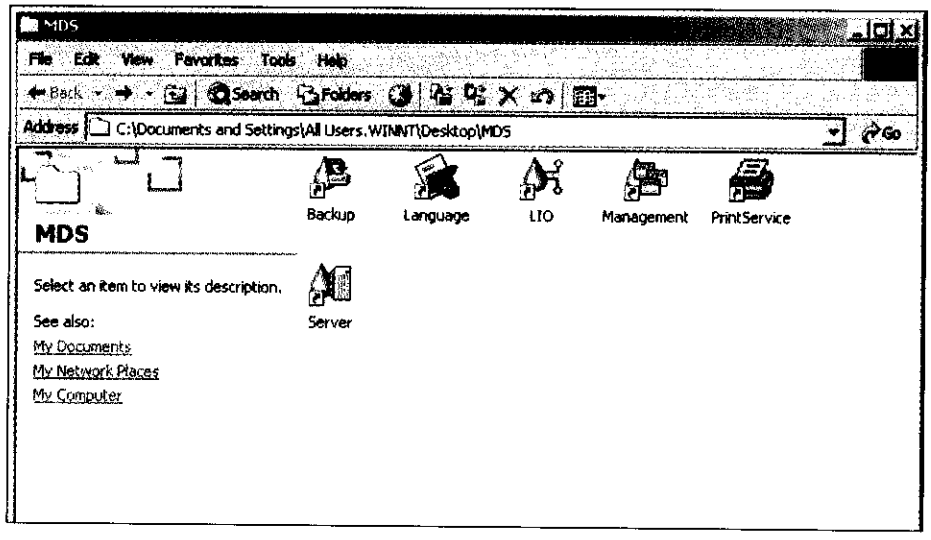

Figure 15 MDS Programs

Re-Starting LIO

Before using the LIO software, you should have a working knowledge of PC computers and the Windows operating system. Make sure you know how to use the control panel, including the touchpad and its buttons. If you are uncertain how to proceed, contact your supervisor or the system administrator for assistance. LIO and the server are initiated during normal PC power up.

1. Verify that the PC is on, Windows is running.

2. Find the MDS folder on the Windows desktop and double click on it.

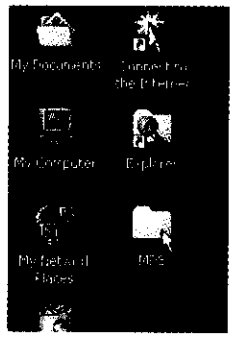

Figure 16 MDS Folder on the Desktop

3. In the MDS window that opens, locate the Server icon and double click on it to launch the database server.

4. Double click on the LIO icon to start the MDS operational program.

5. Double click the Print Server icon to start the cycle log print service.

6. The Backup utility is used to save and restore the database.

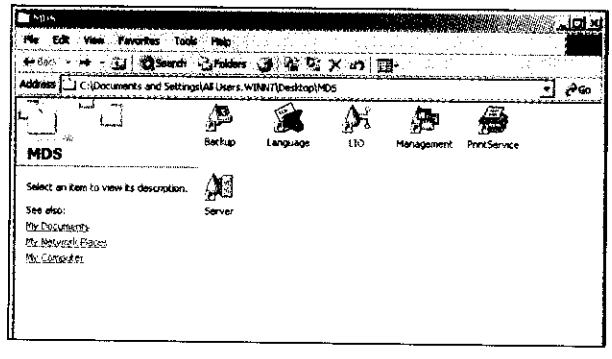

Figure 17 LIO in the MDS Window

The MDS Desktop

The monitor displays all necessary information for operating and maintaining the MDS. Use the buttons on the control panel, to access different screens, programs and functions.

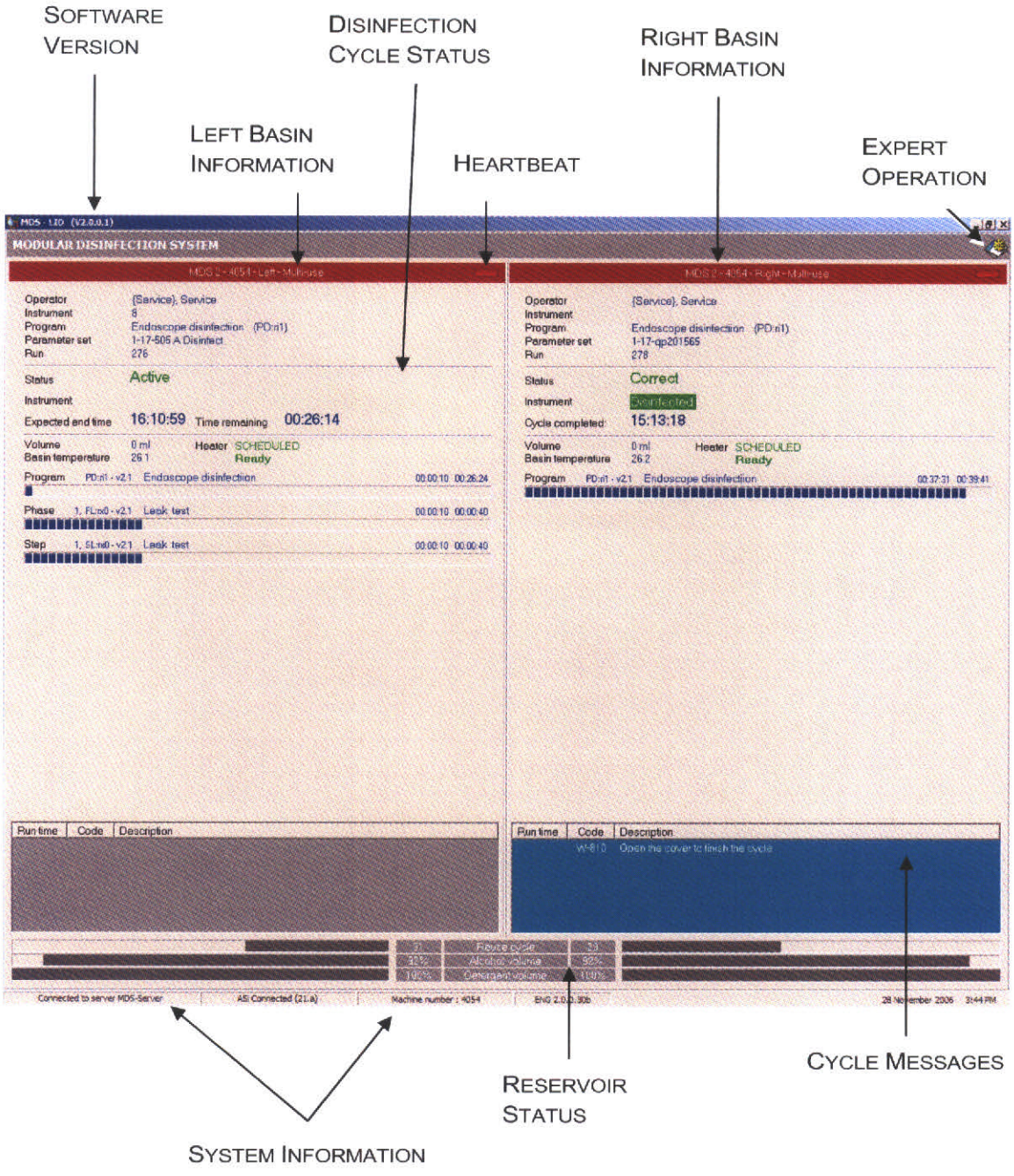

Figure 18 Typical Program Screen

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The Expert Operation icon appears in the upper right of the menu bar. Double clicking the icon will display a login dialog box. After logging in a side bar is displayed on the left with the following icons.

Figure 19 Side Bar with icons

MENU BAR

Each program has a separate release version shown in the upper left corner of the screen. If a system error occurs, a red message bar appears here until the error is resolved.

The Expert Operation icon appears in the upper right of the menu bar. The Side Bar Display shows a special application that allows supplemental operations outside the normal use of the MDS. Double-clicking the icon launches the program. You must enter a login name and password to access this application.

Module and Program Status

The status of each module is indicated in the main section of the screen. Program operations for the left module are on the left side of the screen; operations for the right module are on the right side of the screen.

Running program operations for each module are indicated in the section. The information provided includes:

- Operator name
- Endoscope ID
- Program name
- Parameter set
- Number of cycles
- Program status
- Expected run time
- Run time remaining
- Volume
- Temperature
- Program progress bar
- Phase progress bar
- Step progress bar
- Cycle messages

Heartbeat

The red heartbeat indicator blinks on and off to show that the current program is active. Each module has a heartbeat indicator.

PROGRAM MESSAGES

Program messages and operator instructions are shown in the lower section of the screen. The messages are presented with text and color. If an error occurs, an audible alarm also sounds.

The text shows the program time elapsed at which the message occurred, the message code, and a description of the message or instructions for the operator to follow. For troubleshooting purposes, the message codes and additional message details are listed in *Chapter 5 Troubleshooting*. The meaning of each screen color is shown in *Table 2*:

Table 2 Screen Color and Program Status

Screen Color	Program Status
Orange	Standby, no program active
Gray	Program active
Red	Error
Blue	Program complete

RESERVOIR STATUS

The percentage of alcohol and detergent removing in the reservoirs is provided at the bottom of the screen.

Note: The program does not stop at 0% volume. An error message appears and you must replace the fluids.

The fluid levels in the detergent and alcohol reservoirs are monitored with float switches. A cycle cannot be initiated if sufficient fluid is not available. The tank change utilities must be run once out of fluid is detected even though the reservoirs have been refilled.

For heated reservoirs (optional), the screen will also indicate when the heater is on and when it is ready.

SYSTEM INFORMATION

The bar at the bottom of the screen provides system communication information, machine identification, and the software version for your selected language.

MDS software has two possible system connections:

1. MDS PC to the MDS (AS-i)

2. MDS PC to a server application (may be networked)

The left field on the bar indicates if the MDS is connected to a server. The next field to the right indicates if the PC is correctly connected to the MDS AS-i. If the PC is disconnected the field appears red.

Login Name and Password

Many processes on the MDS require you to supply a login name and password. This confirms that you have the proper authorization to run each program. Data gathered from each process, including the operator's name, is stored in the database and printed on reports.

To enter your login name, move the cursor to the window. Press the down arrow on the right side and scroll down until your login name is highlighted. Click on the name to select it.

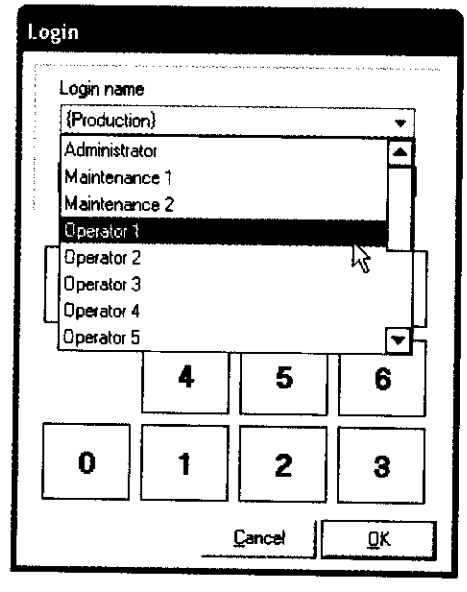


Figure 20 Login Name Selection

To enter your password, press the ABC button to display the keyboard. Click on the appropriate buttons in the window. If you enter an incorrect password, click the **CLR** button and enter the password again. Press the **OK** ✓ button to continue.

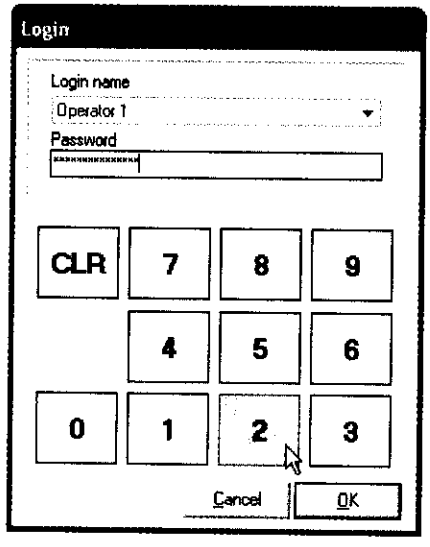


Figure 21 Password Entry

Printing

PRINT SERVICE UTILITY

1. Check for the printer icon in the system tray. The Print Server utility supports the printing of the Cycle Logs on the certificate printer.

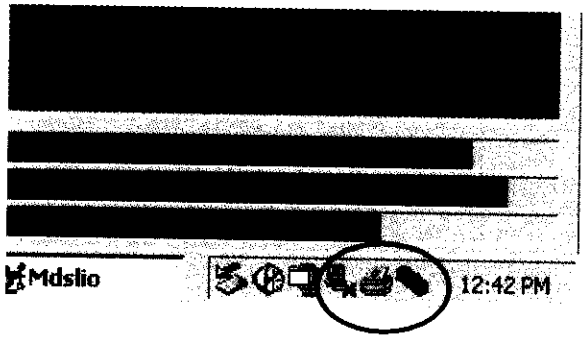


Figure 22 System Tray

2. If the icon is not present, display the Windows desktop by minimizing all open programs.

3. Open the MDS folder by double-clicking the **MDS** icon.

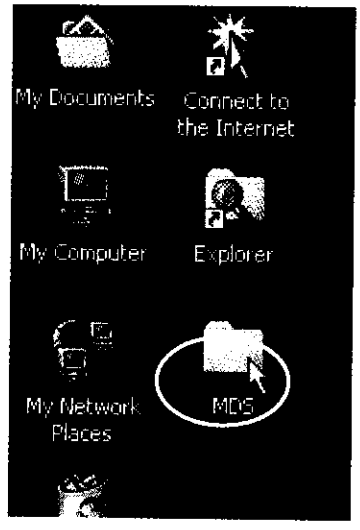


Figure 23 Desktop Detail

4. Double-click on the **PrintService** icon.

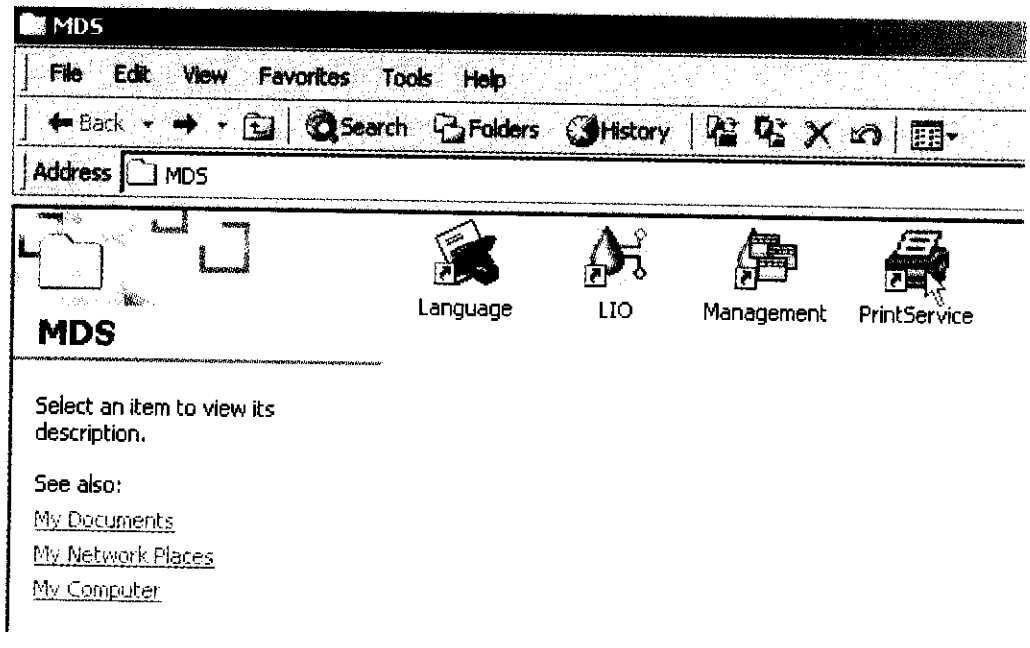


Figure 24 MDS Folder

5. The **PrintService** icon should now appear in the System Tray.

SET THE DEFAULT PRINTER

1. Click on `Start > Settings > Printers.`

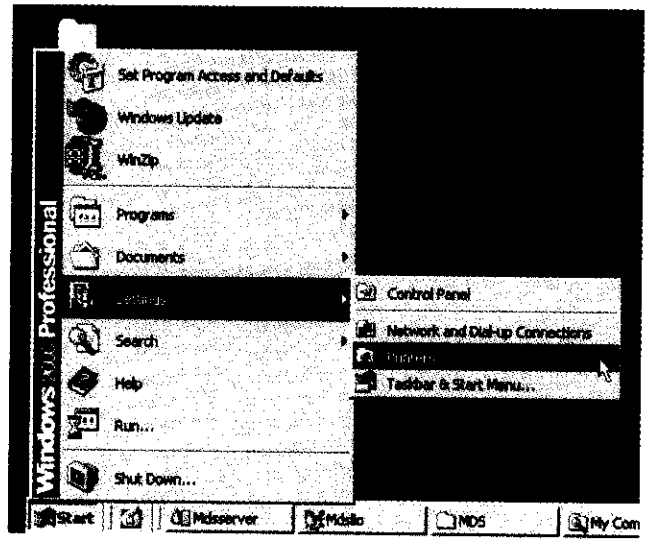


Figure 25 Printer Selection

2. Double-click the icon for your cycle log printer.

3. In the dialog box for the printer, double-click on **Set As Default Printer**. A checkmark appears above the printer icon and in the submenu the next time it is accessed.

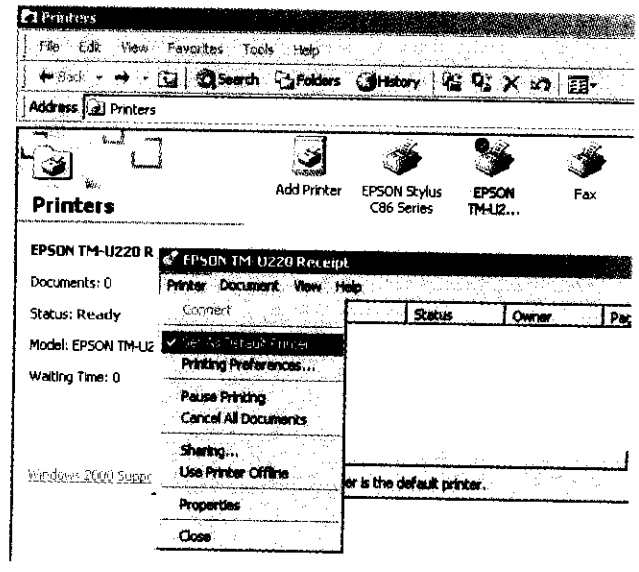


Figure 26 Set As Default Printer

Backups

Backup Utility

1. Shut down all MDS applications including the Server.
2. Open the MDS folder by double-clicking the MDS icon.
3. Double-click on the Backup icon.
4. The Backup script executes and the Backup status window should appear.
5. The Backup utility creates a backup copy of the two MDS database files, MDSLOG.GDB and MDSSETUP.GDB. The files are copied from C:\Program Filtes\MDS to C:\Program Files\MDS\Backup and are named Log.gdb and Data.gdb respectively.

MDS Reprocessor

Fluid Reservoir Status

The system monitors the use of disinfectant, alcohol, and detergent. The percentage of fluid remaining for alcohol and detergent appears in the footer of all screens.

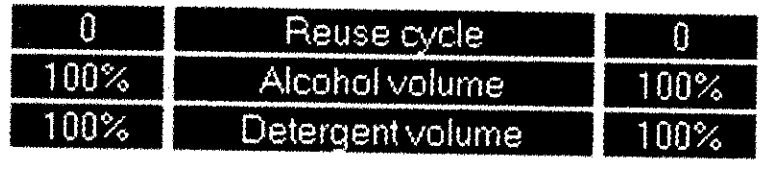


Figure 27 Reservoir Levels

The reuse count is the number of cycles run on this fill of the disinfectant reservoirs.

If the fluid reservoir status indicates that the detergent or alcohol volume is low, then you must follow the alcohol or disinfectant loading process to fill the appropriate fluid reservoir.

Detergent and Alcohol

The detergent and alcohol reservoirs serve both the left and right modules. Each reservoir is threaded into a captive header and is removed by unscrewing the body.

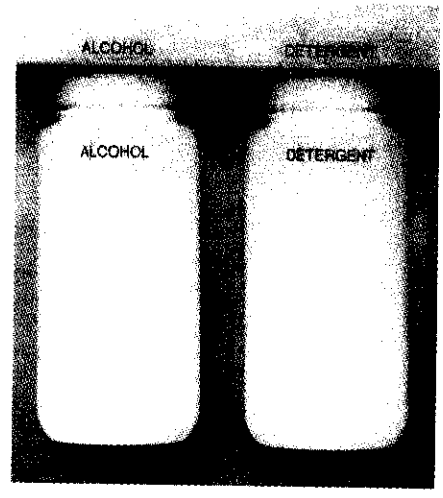


Figure 28 Alcohol and Detergent Reservoirs

NOTE: Upon refilling of the detergent or alcohol reservoirs, the Tank Change utility must be run. If a container empty condition has been detected, the Tank Change utility must be run to correct the error condition.

Because the two reservoirs are identical, you must pay attention to the labeling to ensure that the correct fluid is in each reservoir. To prevent errors, complete refilling one reservoir before removing the other.

WARNING To prevent the accidental switching of the Alcohol and Detergent reservoirs always remove, refill and replace each reservoir bottle separately. Return the reservoir (bottle) to its original position by matching up the reservoir label to the label above the reservoir header.

WARNING Refilling the container with the incorrect fluid may cause the endoscope to be improperly disinfected. Do not use the endoscope on a patient if this occurs.

Wear protective clothing, gloves and eyewear. The disinfectant and detergent manufacturers may recommend additional protection.

Disinfectant

Contact Time

Some disinfectant and cleaning agents may be harsh on endoscopes and the MDS if used improperly. The disinfectant contact and rinse time is variable and must be used as specified by the chemical manufacturer. Before operating the MDS, verify the disinfectant temperature (if used), concentration, and contact time is used in accordance with the specifications provided by the manufacturer.

WARNING Use only cleaning and disinfectant fluids approved by Minntech Corporation.

Fluids

WARNING *Refilling a reservoir with the incorrect fluid may cause the endoscope to be improperly disinfected. Do not use the endoscope on a patient if this occurs.*

Wear protective clothing, gloves and eyewear. The detergent and disinfectant manufacturers may recommend additional protection.

LOADING DETERGENT

Remove, refill and replace the detergent reservoir.

1. Press the **Menu** button on the control panel. Log in to the system.

2. When the **Program Selection** screen opens, select `Replace Fluids` and click the **OK** ✓ button.

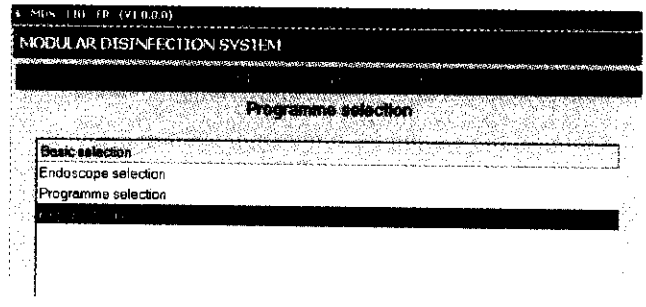


Figure 29 Program Selection Screen

3. When the **Select Fluid Type** screen opens, select `Detergent` and click the **OK** ✓ button.

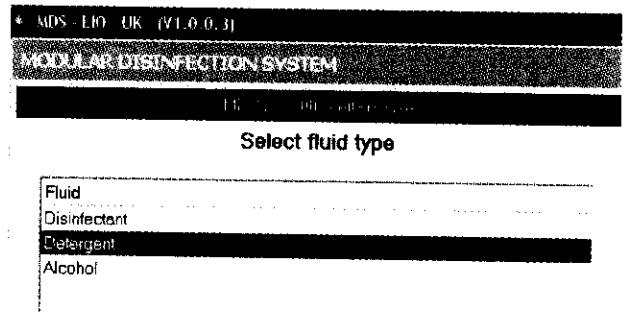


Figure 30 Select Fluid Type Screen

4. Enter the code found on the manufacturer's container and press the **OK** ✓ button.

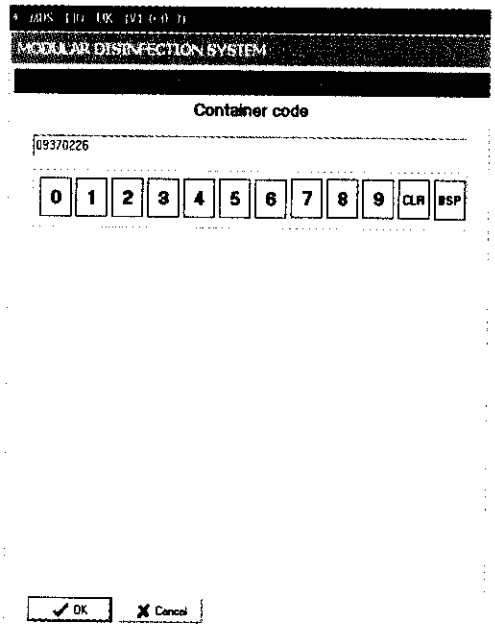


Figure 31 Container Code

5. Remove, refill and replace the reservoir.

LOADING ALCOHOL (OPTIONAL)

Alcohol is an optional feature and may not be configured in the system

1. Press the **Menu** button on the control panel.

2. Log in to the system.

3. When the **Program Selection** screen opens, select `Replace Fluids` and click the **OK** button.

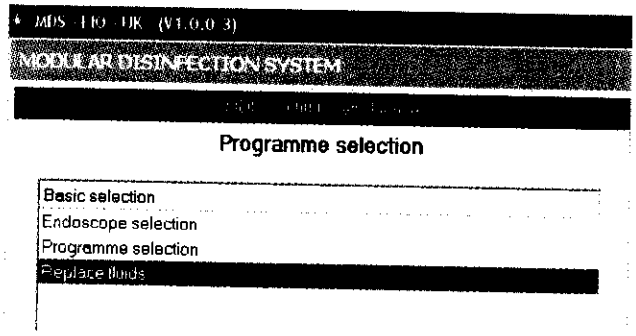


Figure 32 Program Selection Screen

4. When the **Select Fluid Type** screen opens, select `Alcohol` and click the **OK** ✓ button.

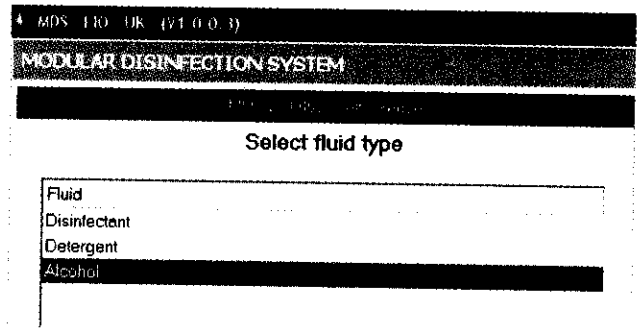


Figure 33 Select Fluid Type Screen

5. Enter the code found on the manufacturer's container and press **OK** ✓ button.

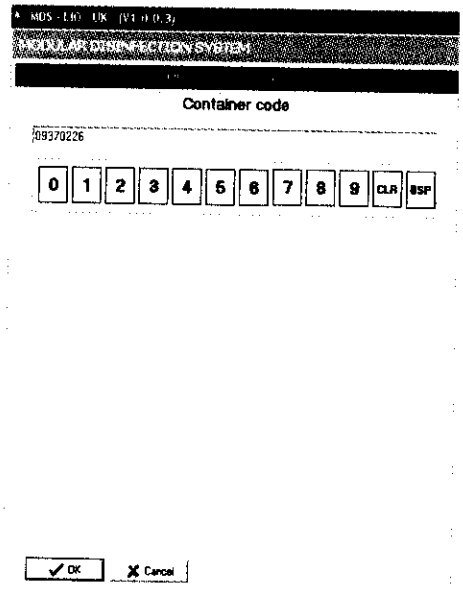


Figure 34 Container Code

6. Remove, refill and replace the reservoir.

LOADING DISINFECTANT

DISINFECTANT CHANGE UTILITIES

The disinfectant change utilities are summarized in *Table 3*.

Table 3 Disinfectant Change Utilities

Utility	Function
Dump disinfectant from reservoir	Pumps the disinfectant from the reservoir to the drain
Fill disinfectant from basin	Module cover is opened and disinfectant is poured from container(s) into the basin
Fill disinfectant reservoir from bottle	Three-way valves pump disinfectant from the supply container(s) to the reservoir

WARNING When filling or draining disinfectant, Wear protective clothing, gloves and eyewear when filling or draining disinfectant. The disinfectant manufacturer may recommend additional protection.

If leaking liquid is present and you suspect it is disinfectant, read and follow the manufacturer's instructions before attempting a cleanup.

Service: If leaking fluids are present, contact a qualified service technician.

Dumping Disinfectant

1. Open the cover by pressing the **Open/Close** button.

2. If present, remove any endoscopes.

3. For each reservoir to be emptied (left and right), install a Machine Disinfection block on the corresponding basin connector block receptacle and close the cover.

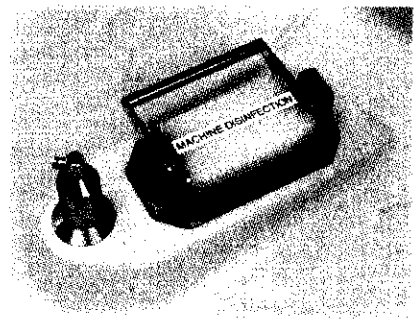


Figure35 Machine Disinfection Block

4. Press the **Menu** button on the control panel.

5. Log in to the system.

6. When the **Program Selection** screen opens, select `Replace Fluids` and click the **OK** button.

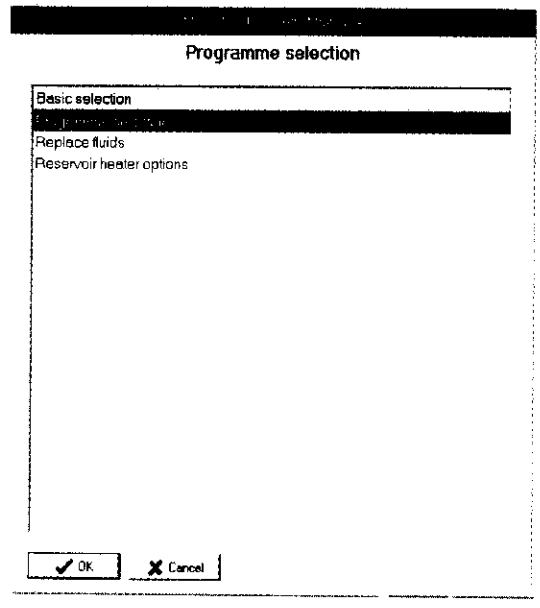


Figure 36 Program Selection Screen

7. When the Select Fluid Type screen opens, select `Disinfectant` and click the **OK** ✓ button.

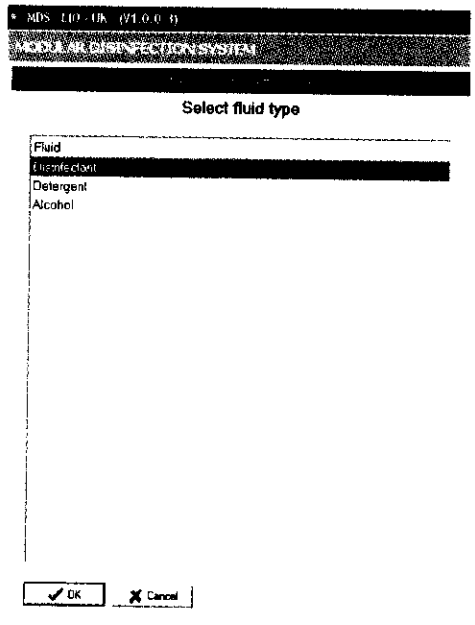


Figure 37 Select Fluid Type screen

8. From the **Disinfectant Transfer** screen, select `Dump disinfectant from reservoir` and click the **OK** ✓ button.

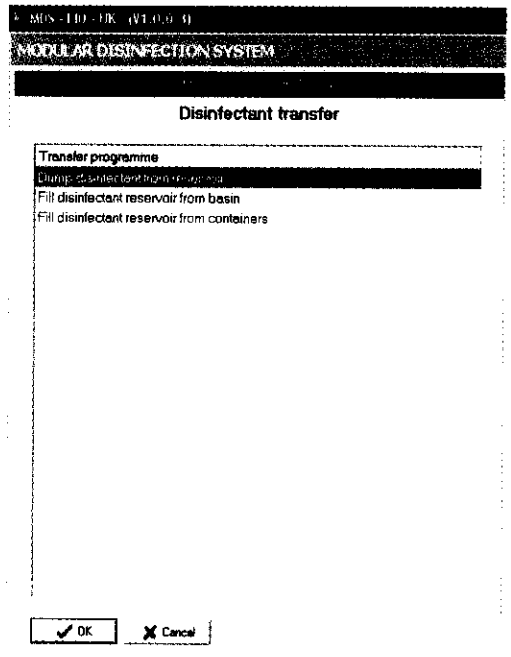


Figure 38 Dump Disinfectant from Reservoir

9. Press the **Start** ⏀ button when prompted by the utility.

10. Disinfectant is pumped from the reservoir to the basin where it flows to the facility drain.

11. After a short rinse cycle, the utility ends.

Loading Disinfectant from the Basin

With this utility, disinfectant is poured directly into the basin and then pumped to the reservoir.

1. Open the cover by pressing the **Open/Close** ⏁ button.

2. Remove any endoscope(s).

3. For each reservoir (left and right), install a machine disinfection block on the corresponding basin connector block receptacle and close the cover.

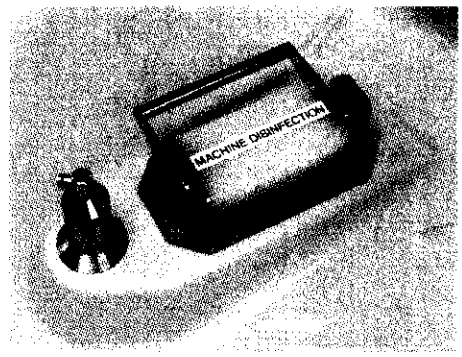


Figure 39 Machine Disinfection Block

4. Press the **Menu** button on the control panel.

5. Log in to the system.

6. When the **Program Selection** screen opens, select `Replace Fluids` and click the **OK** button.

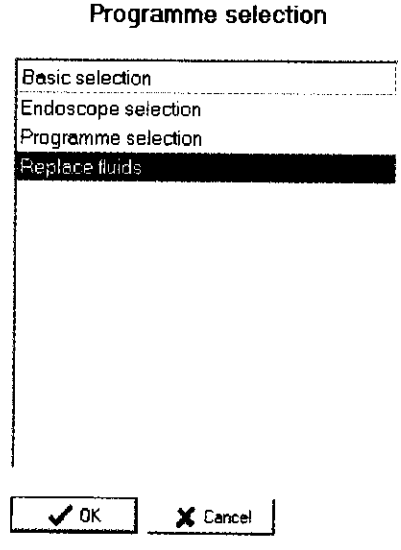


Figure 40 Program Selection Screen

7. When the **Select Fluid Type** screen opens, select `Disinfectant` and click the **OK** button.

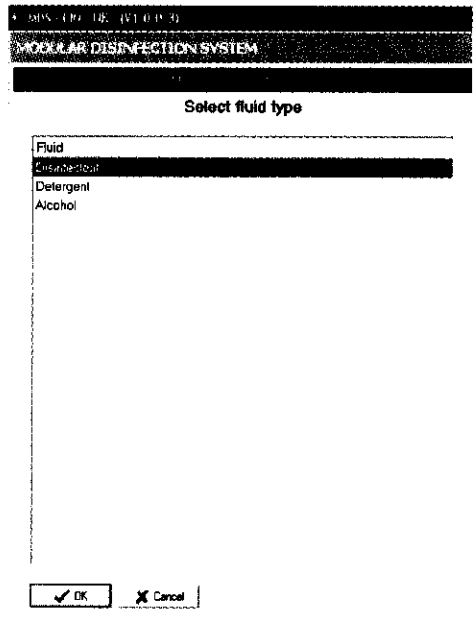


Figure 41 Select Fluid Type screen

8. From the **Disinfectant Transfer** screen, select `Fill disinfectant reservoir from basin` and click the **OK** ✓ button.

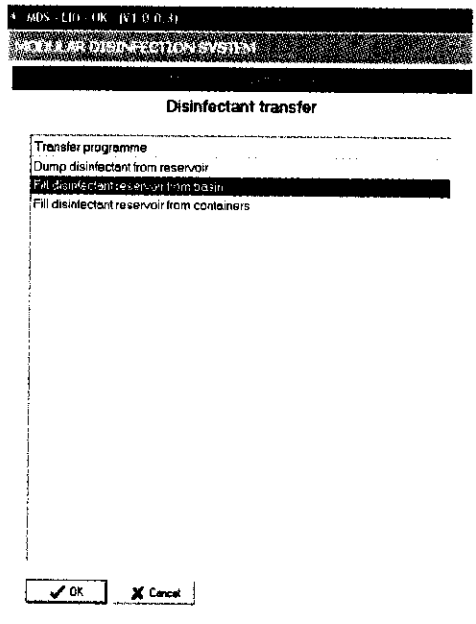


Figure 42 Fill Disinfectant Reservoir from Basin

9. Press the **Start** ◈ button when prompted by the utility.

10. After a short rinse of the basin, the cover opens.

11. Follow the disinfectant manufacturer's instructions to prepare the disinfectant for loading.

12. Pour 5.29 gallons (20 L) disinfectant into the basin.

13. After all the disinfectant has drained from the basin to the reservoir, press the **Start** ◈ button.

14. The cover closes, the basin rinses, and the utility ends.

15. The machine disinfection block can now be removed form the basin(s).

Note: Pressing Start any time before all the disinfectant has drained into the reservoir terminates the utility. Any disinfectant left in the reservoir is directed to the drain.

If the reservoir overfills, the utility terminates and any disinfectant in the basin is directed to the drain.

Loading Disinfectant from Disinfectant Container

With this utility, the original disinfectant container is connected to the MDS with an uptake tube. The utility pumps the disinfectant from the container to the reservoir.

The disinfectant supply lines are located under the manual three-way valve panel above the left-side disinfectant reservoir.

1. Open the cover by pressing the **Open/Close** ⊜ button.

2. Remove any endoscope(s).

3. For each reservoir (left and right), install a machine disinfection block on the corresponding basin connector block receptacle and close the cover.

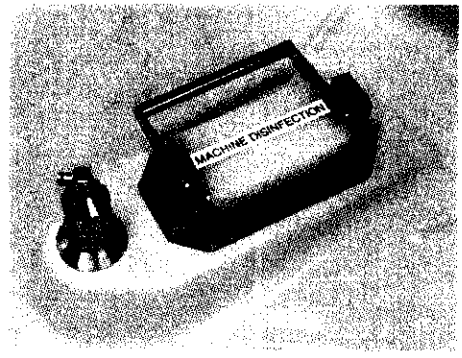


Figure 43 Machine Disinfection Block

4. Press the **Menu** button on the control panel.

5. Log in to the system.

6. When the **Program Selection** screen opens, select `Replace Fluids` and click the **OK** button.

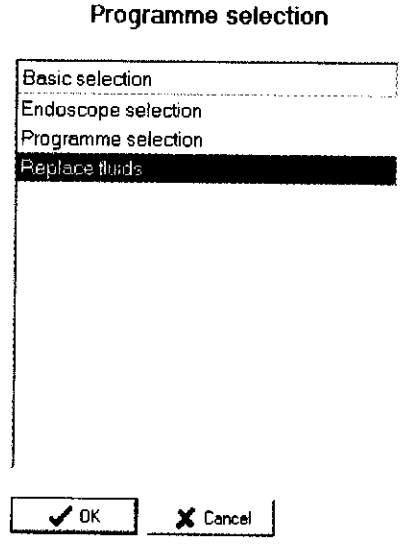


Figure 44 Program Selection Screen

7. When the **Select Fluid Type** screen opens, select `Disinfectant` and click the **OK** button.

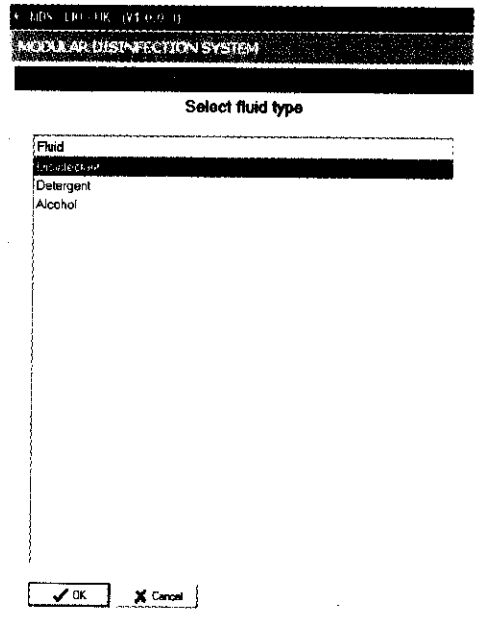


Figure 45 Select Fluid Type screen

8. From the **Disinfectant Transfer** screen, select `Fill disinfectant reservoir from containers` and click the **OK** ✓ button.

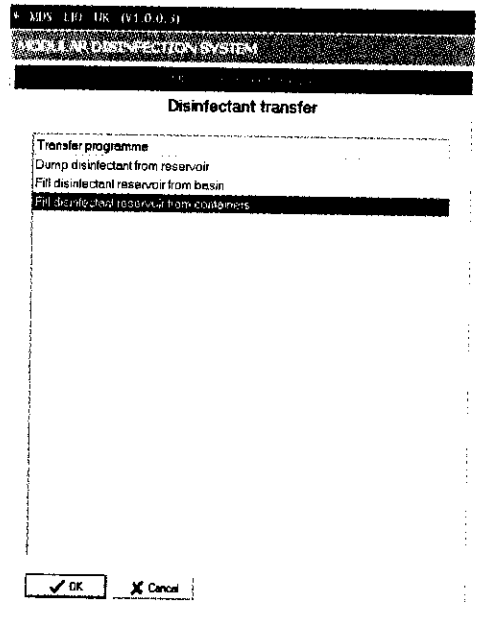


Figure 46 Fill Disinfection Reservoir from Containers

9. Attach the uptake tube to the disinfectant connection at the base of the three-way valve panel.

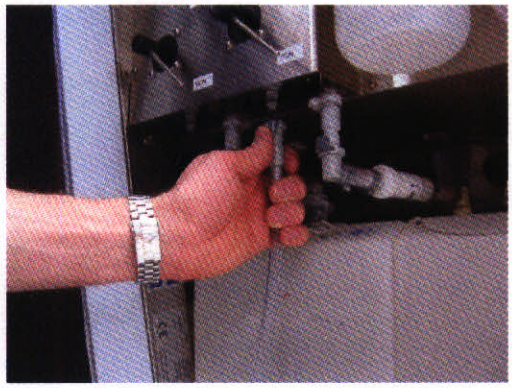


Figure 47 Uptake Tube Attached to Disinfectant Connection

10. Follow the disinfectant manufacturer's instructions to prepare the disinfectant for loading.

11. Turn the three-way valve to the transfer position.

Figure 48 Transfer Position

12. Place the uptake tube in the disinfectant container.

Figure 49 Uptake Tube in Disinfectant Container

13. Press the **Start** ⏀ button to start the utility and the transfer.

14. If necessary, press the **Start** ⏀ button to pause the transfer when the container is empty and install the uptake tube in the next disinfectant container.

15. Press the **Start** ⏀ button to continue the transfer.

16. After 5.29 gallons (20 L) of disinfectant has transferred and the basin is empty, the utility terminates.

17. Return the three-way valve to the Run position.

Figure 50 Valve Run Position

18. Disconnect and rinse the uptake tube.

19. The machine disinfection block can now be removed form the basin(s)

Reservoir Heater Options

1. Press the **Menu** button on the control panel.

2. Log in to the system.

3. Select and Click **OK** button.

4. When the **Program Selection** screen opens, select Reservoir Heater options and click **OK** button.

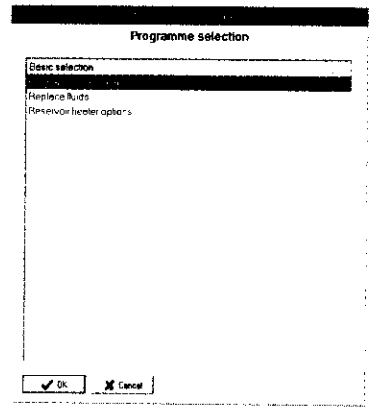


Figure 51 Screen shot of Program Selection

5. When the **Select Reservoir Heater State** screen opens, select the option from the menu that corresponds to the operation that you intend to do.

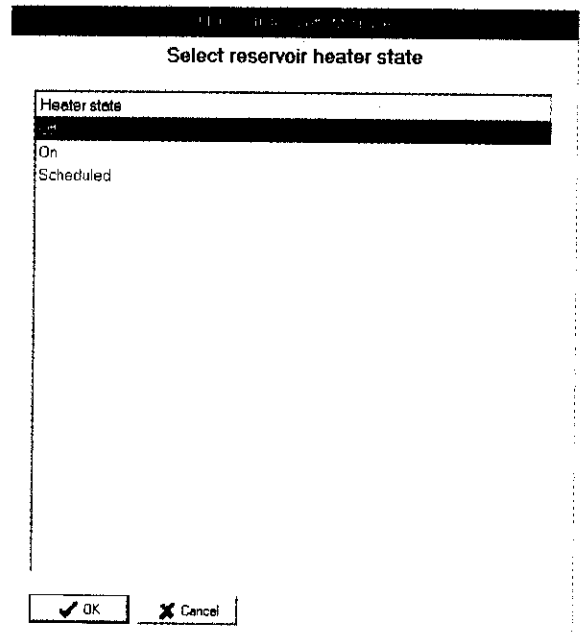


Figure 52 Screen shot of Select Reservoir Heater State

To Turn Off Reservoir Heater

1. From the **Select Reservoir Heater State** screen, select Off to turn the heater off manually.

Note: Turning the heater off manually will override any scheduled settings. The reservoir heater will remain off until the system is reset with scheduled settings or the On selection is made.

To Turn On Reservoir Heater

1. From the **Select Reservoir Heater State** screen, select On to turn the heater on manually.

Note: Turning the heater on manually will override any scheduled settings. The reservoir heater will remain on until the system is reset with scheduled settings or the Off selection is made.

Note: It will take some time to reach the correct temperature for the heated disinfectant. No cycles may be started until the correct temperature is reached.

Selecting a Reservoir Heater Schedule

1. From the **Select Reservoir Heater State** screen, select Scheduled to set the heater to run on a defined schedule.

Note: The reservoir heater schedule is defined in the system parameters. To change the days and times that the heater is scheduled to turn on and off, see section Setting Heater Schedule on page 2-43.

2. The heater status can be viewed on the Status Operational screen. The following area examples of the Status Operational screen for several heater status conditions.

HEATER STATUS NOTED HERE

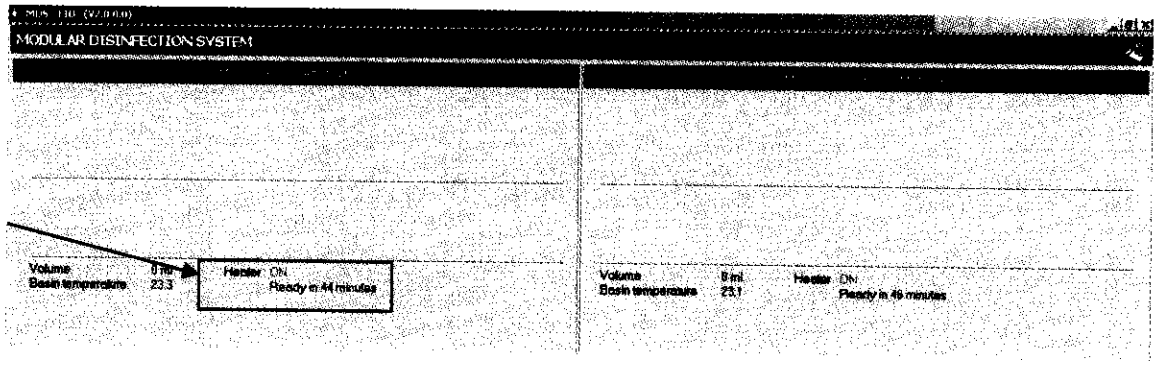


Figure 53 Heater is On, but not ready. Estimated ready time is given.

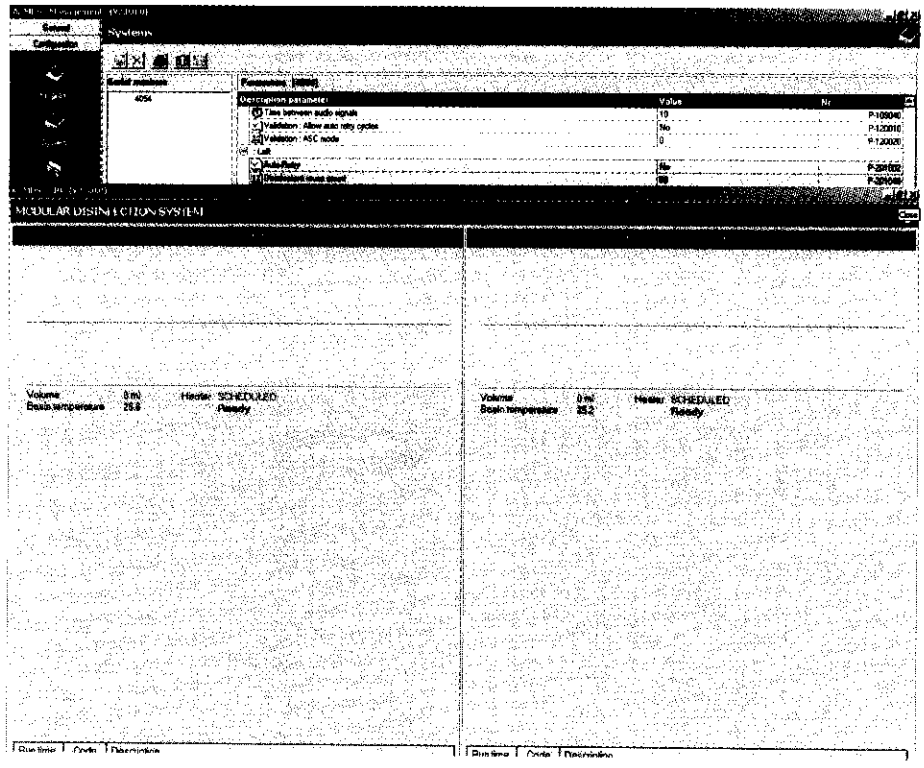


Figure 54 Heater is On, and ready

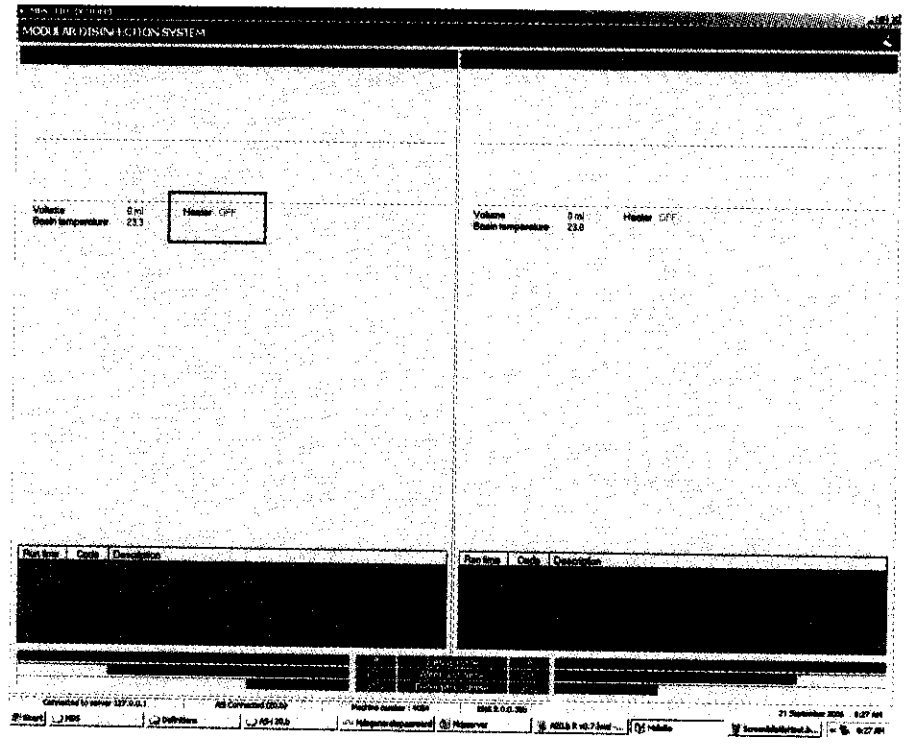


Figure 55 Heater is Off.

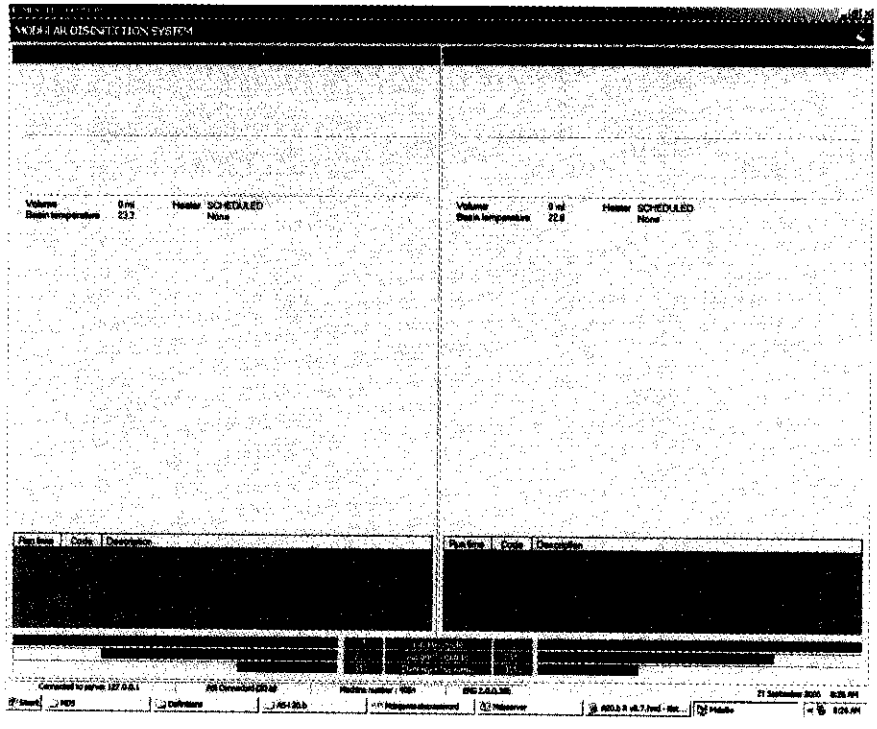


Figure 56 Heater is scheduled

Setting Heater Schedule

1. Load Management application and login using user name and password.

NOTE: Must have Administration Privileges.

2. Select **Configuration** button in lower left corner of screen.

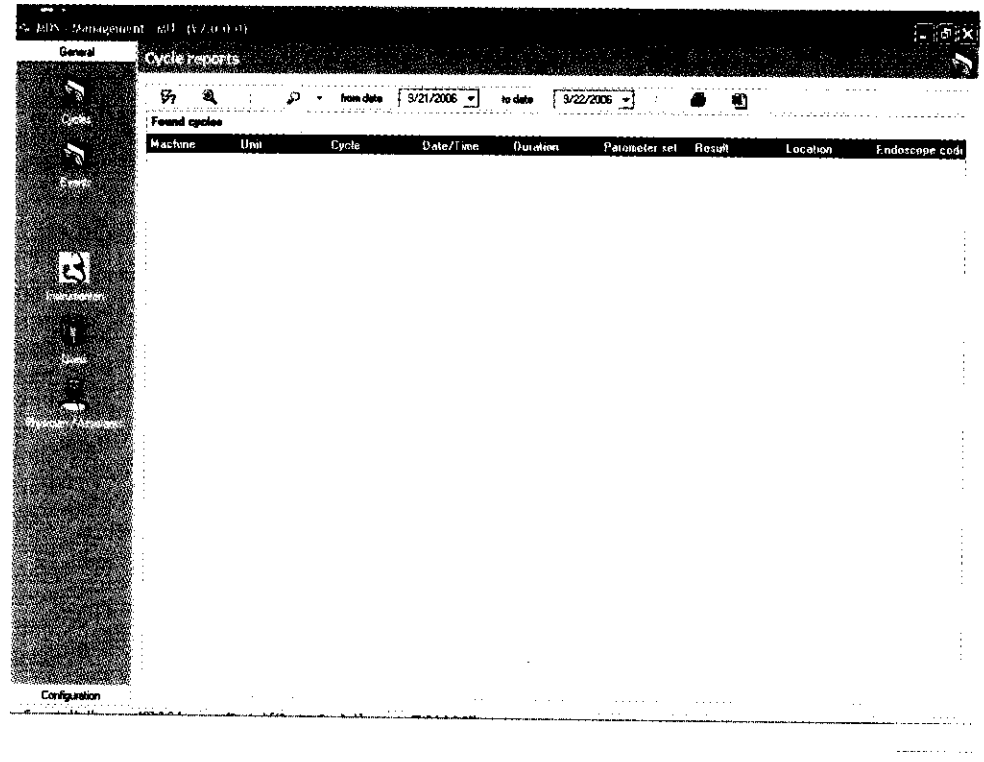


Figure 57 Screen Shot of Management

3. Select systems from side bar.

4. Click on Machine Serial # to bring up system parameter settings. Scroll down to left side settings and select **Yes** for any day that the machine should run on schedule.

5. Set the **Heater Start** and **Stop** times. Repeat for right side, save all changes using the **SAVE** icon and exit **OUT** Management.

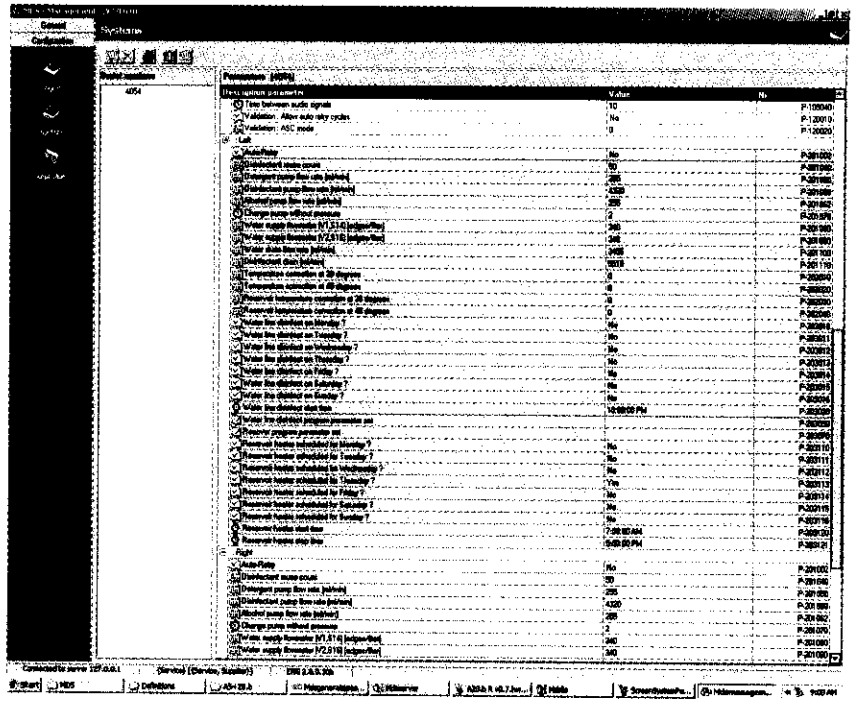


Figure 58 Screen Shot of Parameter Settings

Water Line and Water Filter Disinfection

Chemical disinfection of the machine must be performed on a regular basis. This prevents bacterial growth in the water lines, pipes, and tubing of the MDS. To ensure an effective machine disinfection cycle, verify that the disinfectant in the reservoir exceeds the manufacturer's minimum recommended concentration (MRC) before initiating the cycle.

The Water Line Disinfection program or utility is used to disinfect both the water line and the water filter. Activating this utility fills the water line and water filter with disinfectant, and circulates it through the channels and the basin.

1. Ensure that the disinfectant reservoirs are filled and the water supply is turned on.

2. Open the cover by pressing the **Open/Close** button.

3. Remove any endoscope(s).

4. Install a Water Line Disinfection block on the each of the basin connection manifold.

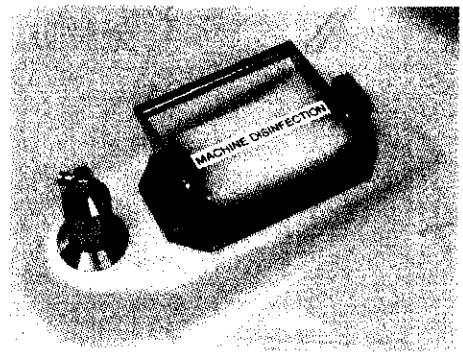


Figure 59 Machine Disinfection Block

5. Press the **Menu** button for the left module on the control panel. The left side of the MDS controls this utility.

6. Log in to the system.

7. When the **Program Selection** screen opens, click on Program Selection and click the **OK** ✓ button.

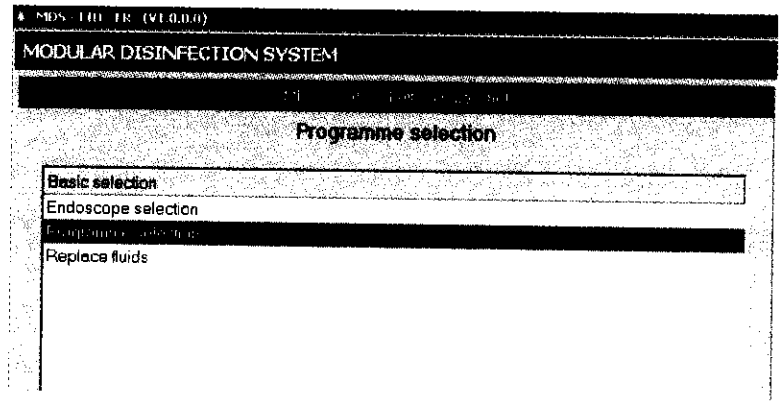


Figure 60 Program Selection

8. Select Water Line Disinfect from the **Select Program** screen and click the **OK** ✓ button.

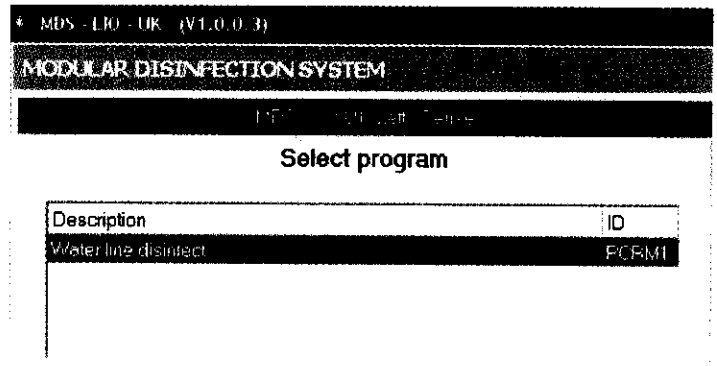


Figure 61 Water Line Disinfect

9. When the **Program Set Selection** screen opens, choose the sanitization sycle desired and then click on the **OK** ✓ button.

Each Sanitization Cycle has a different time duration as follows:

1-17-001 A	Sanitize	3.5 hours
1-17-002 A	Sanitize Short	10 minutes
1-17-003 A	Sanitize Extend	8 hours

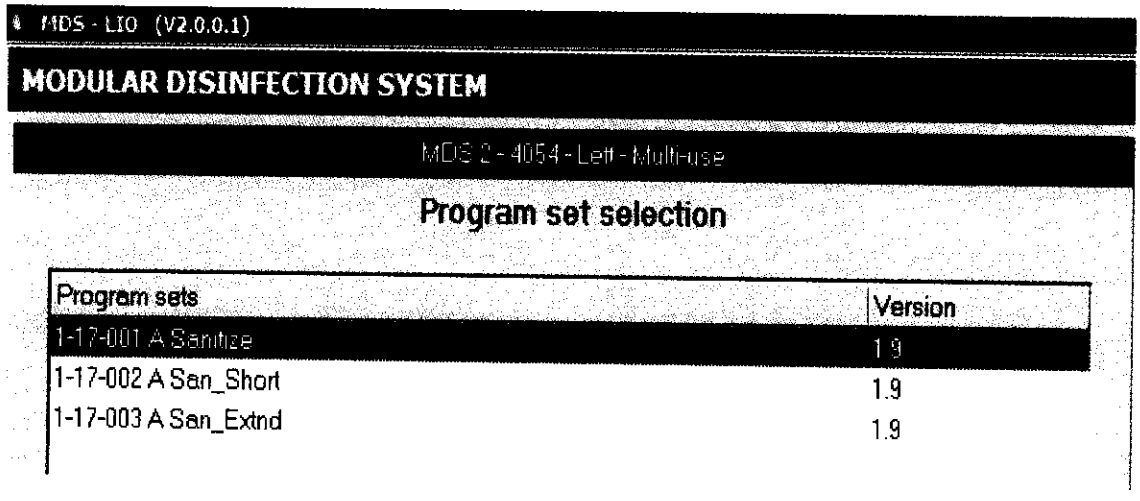


Figure 62 Program Set Seleciton

10. Select either `Normal Start` or `Delayed Start` and click on the **OK** ✓ button.

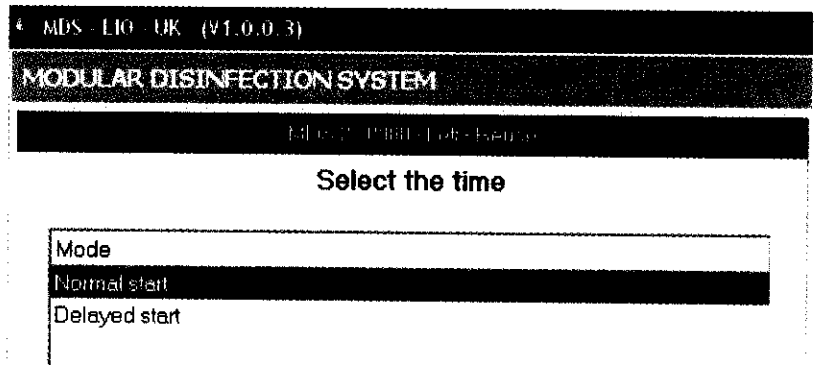


Figure 63 Normal Start

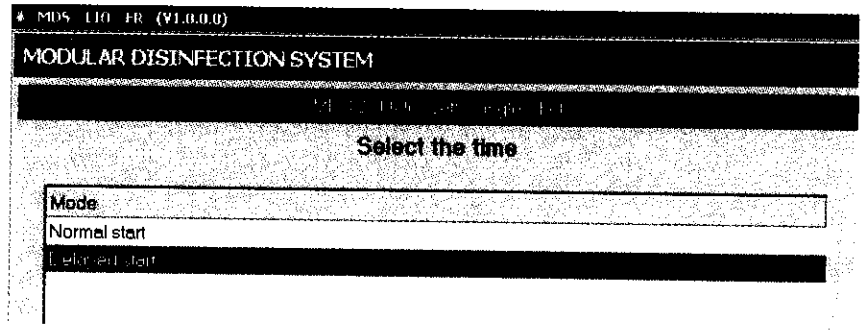


Figure 64 Delayed Start

11. If a delayed start is selected, a screen opens called Select the Time. It lists start times in 15 minute increments for the next 7 days. Note that the dates are listed in MM/DD/YYYY, where M = month, D = day, and Y = year. Scroll down to select the desired start time and click the **OK** ✓ button.

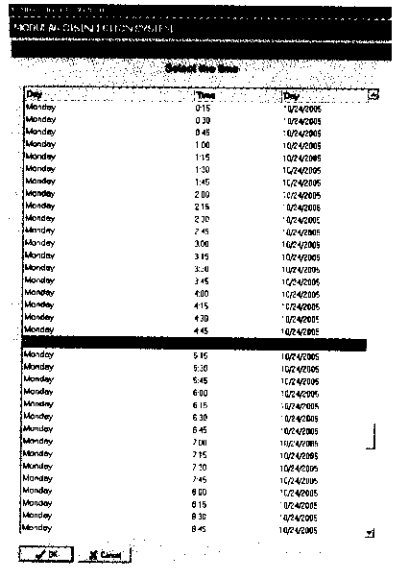


Figure 65 Select Delayed Start Time

12. An informational screen is displayed to verify that the water line disinfection blocks are installed. Select the **OK** ✓ button if the blocks are in place or select the **Cancel** ✕ button to install the water line disinfect blocks.

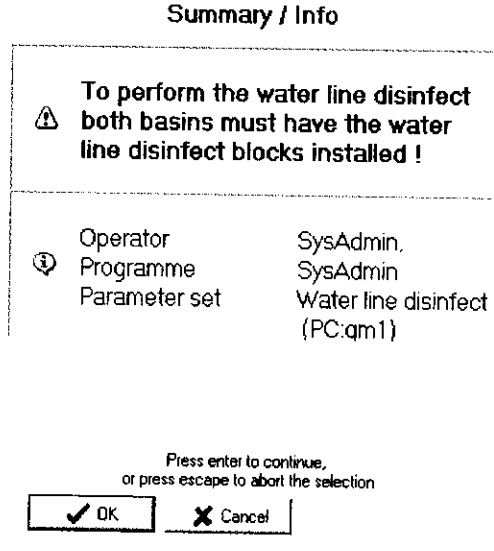


Figure 66 Summary/Information Screen

13. Press the **Start** button to initiate the water line disinfection. Disinfectant is flushed through the water line and water filled. The disinfectant remains in the water filter and water lines while the system is disinfected. The water lines and filter are flushed, the basin is rinsed and the utility terminates.

Taking a Water Sample

After running the Water Line Disinfection utility, you should take a water sample.

1. Place a container under the sample port or direct the flow from the sample port to a drain.

2. Activate the filtration system water valve by clicking on the **Expert Control** icon in the menu bar.

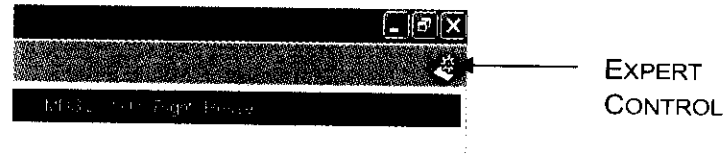


Figure 67 Expert Control Icon

3. Log in to the system.

4. Slowly turn the sample port three-way valve to the sample position (handle down).

5. Allow the water to run for fifteen (15) minutes.

6. Take a water sample.

Figure 68 Taking a Water Sample

7. Turn the valve back to the normal position (handle horizontal).

8. Test water sample to ensure disinfectant has been adequately flushed out.

Aseptic Collection of Water Samples from Sampling Port

Purpose: This procedure describes the method for acquiring water samples from the MDS incoming water line immediately after the 0.2 µm filter. Samples must be taken so that no microbial contamination is introduced during the sampling process.

Equipment:

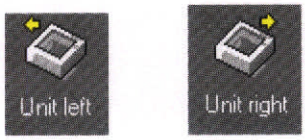
- New disposable gloves
- Sterile container that will hold at least 100 ml.
- Sanitizer solution, preferably 70% alcohol, in a spray or squirt bottle.

Method:

1. Spray the inside and outside of the valve/port with sanitizer. Wet the surfaces thoroughly and let stand at least 5 minutes. Do not touch the surfaces after sanitization.

2. The valve in the water filter must be turned on to take the water sample. Using the mouse pad, double click the Expert Control icon in the upper right corner of the operational screen and login. The user must have administration privileges.

3. Single click the unit (basin) icon in the side bar to display the Expert Control screen for the left or right basin. Note: the Expert Control screen is displayed on the opposite side of the operational screen.



4. Turn on Y90 the water filter supply valve by double clicking on Y90 on the expert screen outputs. The valve will stay on to take the water sample.

5. Open the valve in the sampling port and let the water run for at least 15 minutes. The flow rate should be fast enough to wet the inside surfaces of the port. Keep the water flowing until after the sample is collected.

6. Put on a pair of clean gloves and open a sterile sampling container.

7. Hold the container near the bottom and fill with water. Immediately cover the container. If you touch the inside of the container or lid, discard the sample and resample into a second container.

8. To turn off the water and remove the system from manual mode, double click the Release All icon.

Medivators MDS System

TAKING A WATER SAMPLE USING THE EXPERT SCREEN

A water sample may be taken from the basins using the Expert Screen. The Expert Screen not only allows direct manipulation of the valves and pumps but also provides access to a number of utilities supported by the ASi (PLC) controller. A utility is used to calibrate the flow meters by turning on the inlet water for a minute. The utility used is "LIO #3 Flow Test". The utility turns the inlet water supply on for one minute then turns it off.

1. Using the mouse pad, double click the Expert mode icon in the upper right hand corner of the operational screen and login. The user must have administration privileges.

2. Single click the unit (basin) icon in the side bar to display the Expert screen for the left or right basin. NOTE: the expert screen is displayed on the opposite side of the operational screen.

3. Open the cover and install a Machine Disinfection block.

4. The utility used is "LIO #3 Flow Test". Double click on the "LIO #3 Flow Test" to turn on the inlet water.

5. After approximately 45 seconds, take a water sample.

6. Wait for the water to turn off.

7. To remove the system from manual mode, double click the Release All icon.

8. Close the cover.

THIS PROCEDURE CONFIGURES A WATER LINE DISINFECT PARAMETER SET:

- To extend the time the disinfectant is flushed through the water filter.
- To increase the disinfectant contact time in the 0.2 µ water filter and the water lines.

There are two ways to create an extended water line disinfect parameter set. The first is to import the parameter set (**1-17-003 A San_Extnd.par** file) into the MDS database using the Management utility. The second is to create a new water line disinfect parameter set from the existing parameter set **1-17-001 A Sanitize**.

Import New Parameter Set

1. Obtain the password or day code from Service.
2. Copy the water line disinfect parameter set into the **Program Files\MDS\Import** folder.
3. Start the Management utility and login as **SysAdmin**. Use the Service day code for the password.
4. Select the **Configuration** tab

in the side bar.
5. Select the **Programmes** icon

and select the base water line disinfect parameter set **PC:gm1**.
6. Click on the import icon and open **1-17-003 A San_Extnd**.
7. Close the Management utility.

Create Parameter Set 1-17-003 A San_Extnd

This procedure creates a new parameter set with the water filter and water line disinfectant rinse times are extended and the disinfectant contact time to 8 hours.

1. Obtain the password or day code from Service.
2. Start the Management utility and login as **SysAdmin**. Use the Service day code for the password.
3. Select the Configuration tab

in the side bar.
4. Select the Programmes icon

and select the base water line disinfect parameter set **PC:gm1**.
5. Increase the maximum value for the **Basin disinfect dwell time [sec]** parameter in **Phase 3,8 Disinfect the basins** phase from 18000 (5 hours) to 36000 (10 hours).
6. Select another filed to update the grid and save the base water line disinfect **PC:gm1** using the **Save** icon .

7. Select the water line disinfect parameter set **1-17-001 A Sanitize**.

8. Using the **Save as** icon , create a new parameter set **1-17-003 A San_Extnd**.

9. Increase the **Water line disinfect dwell time [sec]** in **Phase 3,7 Disinfect the water lines and the water filter** phase from 300 (5 minutes) to 420 (7 minutes).

10. Increase the Basin disinfect dwell time [sec] in **Phase 3,8 Disinfect the basins** from 12600 (3.5 hours) to 28800 (8 hours).

11. Select another field to update the grid and save the changes to **1-17-003 A San_Extnd** water line disinfect parameter set using the **Save** icon .

12. Close the Management utility.

Machine Disinfection

Chemical disinfection of the machine must be performed on a regular basis. This prevents bacterial growth in the water lines, pipes, and tubing of the MDS. To ensure an effective machine disinfection cycle, verify that the disinfectant in the reservoir exceeds the manufacturer's minimum recommended concentration (MRC) before initiating the cycle.

AUTOMATIC START

The day and start time for automatic machine disinfection is set by the system administrator. After the last endoscope disinfection of the day, the disinfection blocks are placed in the MDS to prepare for automatic machine disinfection. The machine will report an error the following morning if the machine disinfection has not been carried out properly.

1. Open the basin lids by pressing the **Open/Close** ⊜ buttons on the control panel.

2. Fit the machine disinfection blocks in both basins.

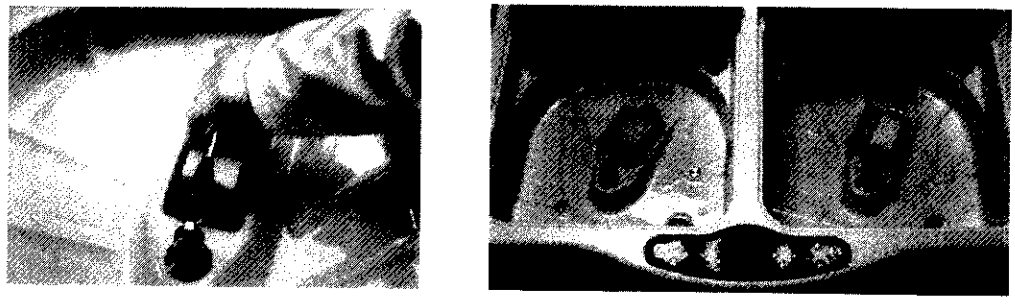


Figure 69 Machine Disinfection Blocks

1. Close the covers by pressing the **Open/Close** buttons.

2. Press the **Menu** button on the control panel. Outline list "Operator selection" appears.

3. Log in to the system.

4. When the Program Selection screen opens, click on `Program Selection` and click the **OK** button.

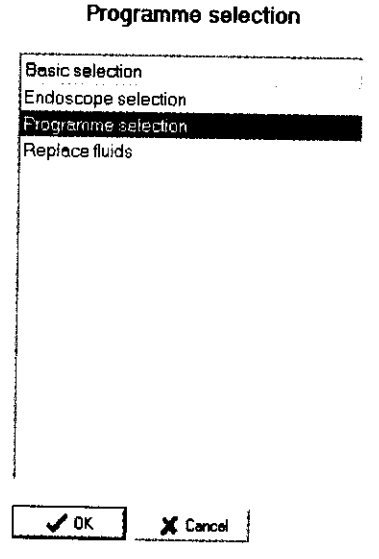


Figure 70 Program Selection

5. Select the desired program: Water Line Disinfect (*option 1*). Click the **OK** button.

6. When the outline list "Parameter set selection" appears, select a parameter set. Click the **OK** button.

7. The unit screen appears with the message: `Wait for Start.` Verify the data at the top of the screen with your selection then start the program by pressing the **Start** ◈ button:

Note: To cancel the process at any time, press the **Cancel** ⊗ button. Then click on the **Open/Close** ⏻ button and enter your login name and password. Begin the process again at step 4.

Chapter 3

OPERATION

This chapter explains how to prepare and disinfect an endoscope in the MDS.

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DISINFECTION PROCESS SUMMARY

The complete reprocessing cycle in an MDS system is comprised of a number of specific steps designed to ensure proper endoscope disinfection. These steps include: startup, detergent wash, disinfectant, rinse, alcohol (optional), and air phases. All steps must be properly followed and should not be modified beyond manufacturer recommendations.

Startup Phase

During the start-up phase, the software reads and monitors all system sensors. If an error is detected, a message is displayed and the process is halted. The system operator then needs to resolve the error before the cycle can be continued.

Next the leak test is activated. The endoscope is pressurized and the pressure is monitored for a period of time. If the pressure drops below a set reading, an error message is displayed and the process is halted.

Refer to *Chapter 5: Troubleshooting* for appropriate instructions to resolve errors.

Detergent Wash Phase

During the wash phase, detergent and water enter the basin. This basin fluid is then flushed through the endoscope channels. At the completion of the wash phase, the basin is drained and the endoscope channels are flushed with fresh water. A rinse soak period without detergent then follows.

Disinfectant Phase

During the disinfectant phase, the endoscope channels are flushed with disinfectant. The basin is filled with disinfectant solutions and the endoscope is soaked for the disinfectant contact time as recommended by the disinfectant manufacturer. After the soak, the disinfectant is drained from the basin and returned to the reservoir.

Rinse Phase

During the rinse phase, the basin is partially filled with water and then drained to eliminate foam residue from inside the endoscope and from the basin. The basin is then filled with fresh water while the endoscope channels are being flushed. Once the basin fills up, water flushes through the endoscope channels. The basin is then drained while the channels are purged with fresh water.

Alcohol Purge Phase (Optional)

During the alcohol phase, alcohol is injected through the endoscope channels. The alcohol is used to help purge any residual fluids from the endoscope.

Air Purge Phase

The air phase is simply a programmed time during which air is purged through the endoscope channels. The air is used to aid in drying of the endoscope.

STARTUP

1. Verify that the MDS PC and main power source are on.
2. Open the shutoff valve to the incoming water line. For optimum performance the water supply must be capable of delivering a minimum of 1.32 6/min (5 L/min) of flow at a dynamic pressure of less than 30 psi (2 bar) during the basin fill.
3. Turn the external air source on (if applicable). External air supply must be capable of delivering medical grade air at a minimum rate of 40 L/min (10.58 G/min) at 6 bar (87 psi).

DAILY SERVICE

System Air Pressures

The main air pressure and leak test air pressure are maintained by regulators. The air pressure adjustment controls and corresponding gauges are located behind the front access door, just above the disinfectant reservoirs.

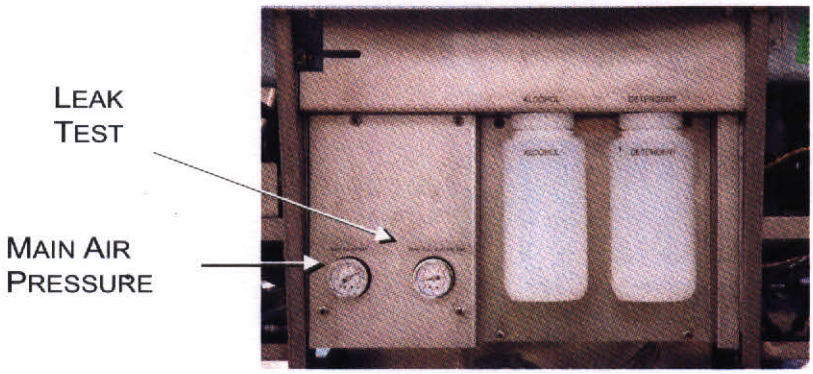


Figure 1 Air Pressure Controls

Proper operation of the MDS reprocessor requires that the air pressure be set and maintained at the values shown in the table below.

Table 1 Acceptable Pressure Ranges

Pressure Control	Acceptable Pressure Range
Main Air Pressure	42 – 45 psi (2.8–3.0 bar)
Leak Test Air Pressure	3.6 – 3.75 psi (0.24–0.25 bar)
Channel Connectivity	25.5 – 30 psi (1.7 – 2.0 bar)

If the pressure control readings do not fall within the acceptable ranges, contact technical service. Do not attempt to adjust the settings yourself as damage may occur to the MDS.

WARNING *Verify the air pressure readings are within the acceptable ranges before every reprocessing cycle. Do not make air pressure adjustments during a disinfection process.*

If the main air pressure regulator is not set correctly, the endoscope may not be properly disinfected.

If the leak test regulator cannot be set correctly, the endoscope may be damaged during the reprocessing cycle.

O-Rings

Check the connection manifolds to verify that all the O-rings are present and undamaged. The manifolds are located in each basin and are the studs onto which the connector block slides down and seals.

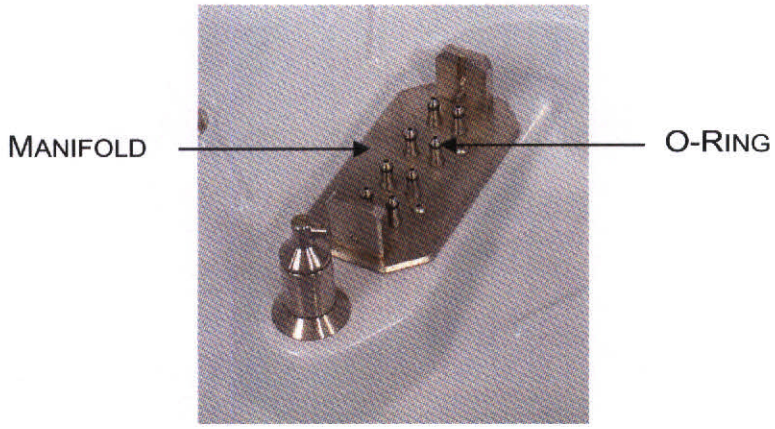


Figure 2 Connection Manifold

Drain Screens

Replace the screens in the rinse basin if they are excessively soiled.

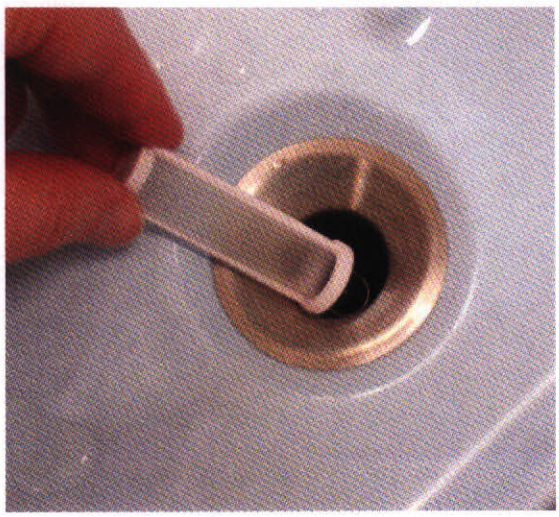


Figure 3 Drain Screens

PREPARE THE ENDOSCOPE

Caution ***Prior to placing used endoscopes into the system, they must be precleaned and manually cleaned according to the SGNA guidelines and your facility procedures.***

Place the Endoscope in the Basin

1. Endoscopes fit best in the machine if they are installed in a particular fashion. The final position of the endoscope in the rinse basin depends primarily on the type of endoscope. To a lesser extent, the brand of endoscope may also affect the final position in the basin. Do not forcibly bend the endoscope to get it to fit. When positioned properly, the endoscope will fit appropriately in the basin.

2. Hold the control housing in your left hand and the insertion tube and light guide in your right hand.

3. Place the control housing in the basin with the button upwards.

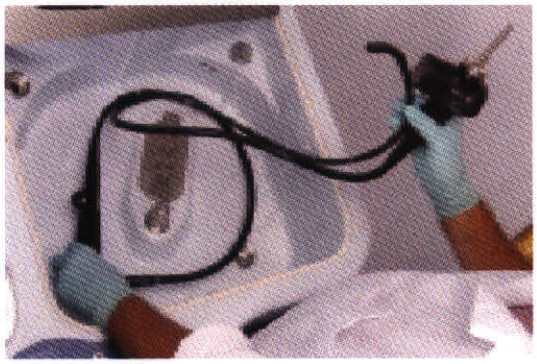


Figure 4 Place Control Housing in Basin

4. Set the insertion tube in a circle in the basin.

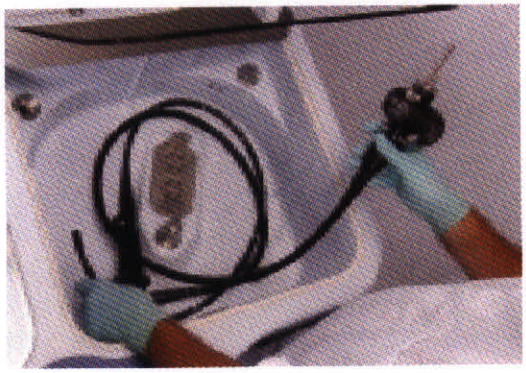


Figure 5 Set the Image Guide in Basin

5. Fit the light guide.

6. Select the proper connection block and channel separation from the endoscope hookup guide.

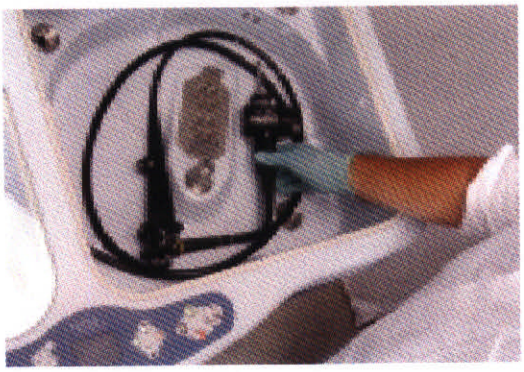


Figure 6 Fit the Light Guide Mantel

I-Dent System

If an I-Dent System is used, place the RFID tag in the slot for the I-Dent reader.

Install the Channel Separator

Note: Only large endoscopes such as: gastroscopes, colonoscopes and duodenoscopes should use a channel separator.

Select the correct channel separator for the endoscope to be disinfected. Position the adapter in so that the stem with the o-ring fits properly in the water/air valve.

Because the valve design may vary depending on the brand and type of endoscope, fixing the adapters varies also.

Table 2 Fitting the Adapter

Brand	How to Fit the Adapter
Fujinon	Firmly push in the rubber caps.
Olympus	Press downward on the channel separator housing to slide it under the flanged edge of the valve.
Pentax	Screw the channel separator into the water/air valve. Close off the exhaust valve with a screw cap. Firmly press in the white cap on the two valve vents.
XION	Press downward on the channel separator to slide it under the flanged edge of the valve.

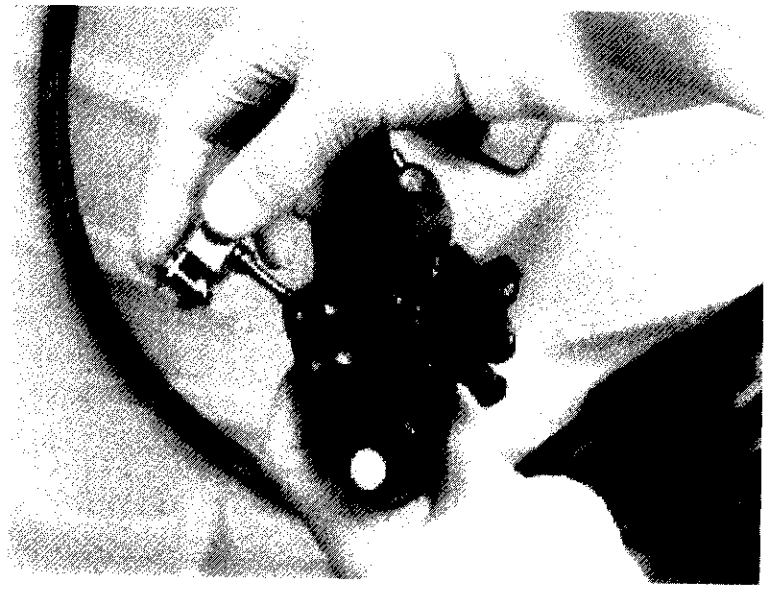


Figure 7 Fitting the Separator (Olympus)

Install the Connector Block

1. Hold the connector block handle as shown below in *Figure 8.*

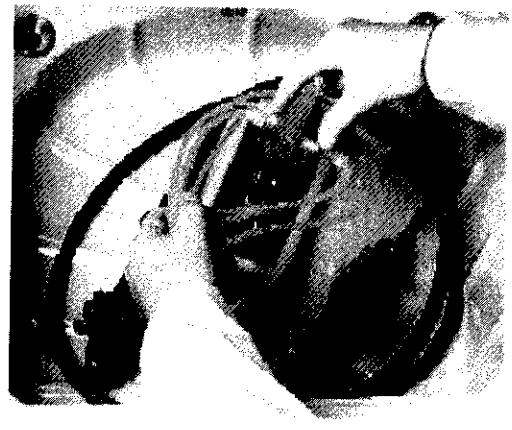


Figure 8 Fitting the Connector Block

2. Using your thumb and index finger, make certain the handle sits squarely on the block.

3. Hold the side with the sheath leak test connection to the left.

4. Hold the hoses with your other hand, making certain that none of the hoses run under the block.

5. Press the block lightly over the manifold as shown in *Figure 9*.

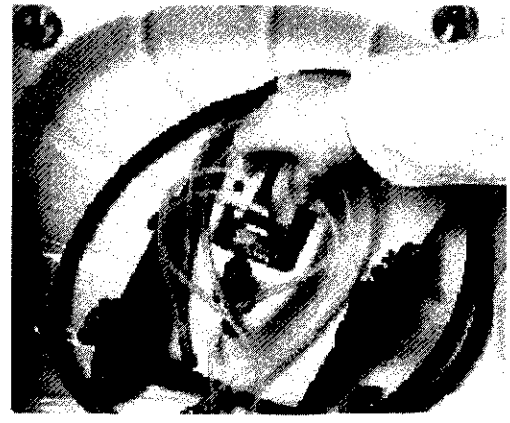


Figure 9 Press Block Over the Manifold

6. Close the handle as shown in *Figure 10*.

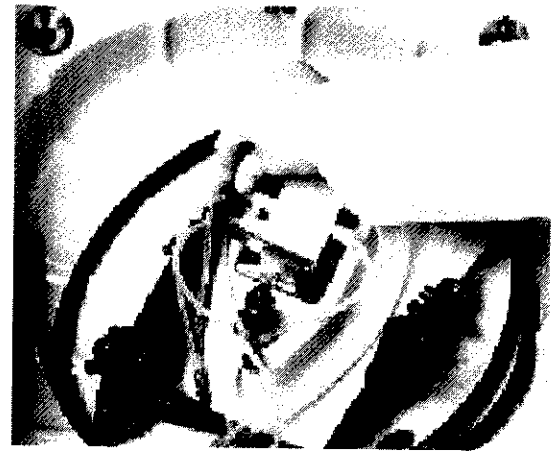


Figure 10 Close the Handle

WARNING

Inspect the seating of the connector block to the manifold. Failure to achieve a proper connection could result in an endoscope that is not disinfected and therefore should not be used on a patient.

Connect the Channels

1. Connect the endoscope channels. The names of the connections of the different channels may be found in the endoscope user manual. See *Figure 11* for details on how to hookup the endoscope to the connectors.

WARNING *All endoscope hookups must be periodically inspected for damage, and replaced if damaged, otherwise it could result in an endoscope that is not disinfected and therefore should not be used on a patient.*

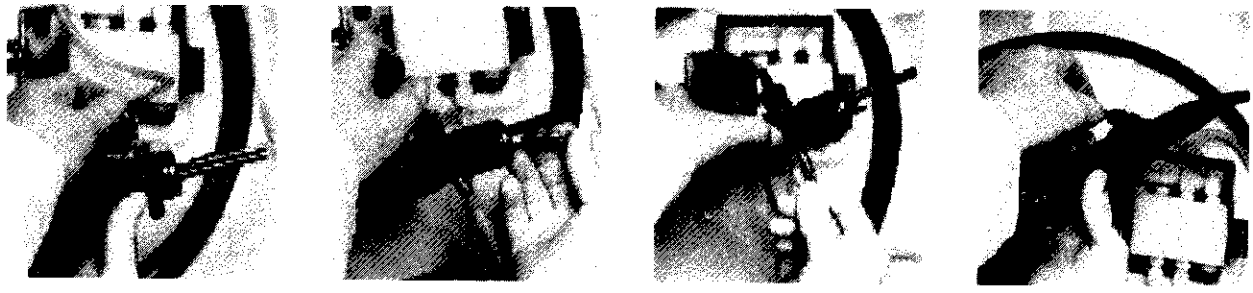


Figure 11 Connecting the Channels

2. Attach the leak test connection on the endoscope to the connector block with the leak test connector. Secure the tubing under the endoscope so that it does not float during disinfection.

3. Make sure the hoses do not have any sharp bends or kinks.

4. Set the connection hoses down in such a way that they will be submersed in the disinfectant.

Verify the Connections

WARNING *Verify all connection to the endoscope are secure. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.*

- Before closing the cover, inspect the hookup to ensure that all connections are made properly and the tubing does not interfere with the sprayer.
- The endoscope must be low enough in the basin to be completely submerged.
- All channels must be connected correctly.
- The channel separator must be installed.
- The leak test tubing must be secured under the endoscope so that it does not float or interfere with the sprayer.
- The feed lines must not be kinked.

- Move any lines lying against the head of the sprayer so that it can turn freely.

WARNING *Verify the connection tubing does not interfere with the spray head and confirm that the spray function is working during the cycle. Failure to do this could result in an endoscope that is not disinfected and therefore should not be used on a patient.*

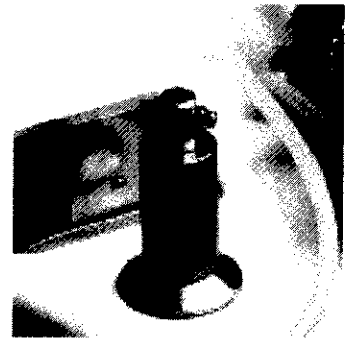


Figure 12 Sprayer Must Turn Freely

RUN THE DISINFECTION PROGRAM

Normal Start

Data entry must be carried out carefully. Each selection or input must be checked and confirmed by the operator. Entering erroneous information may lead to machine faults or inadequate disinfection of an endoscope channel.

1. Close the basin lid by pressing the **Open/Close** button or the foot switch.

2. Press the **Menu** button.

3. When the Operator Selection window opens, select your login name by using the **Scroll Down** button, or use the touchpad, bar code reader, or I-Dent chip. Then click the **OK** button.

4. The Authorization window opens. Enter your password with the touchpad, bar code reader, or I-Dent chip and then click the **OK** button.

5. When the **Program Selection** window opens, highlight `Endoscope Selection` and click the **OK** ✓ button.

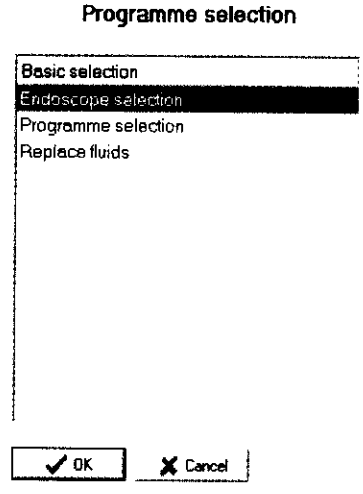


Figure 13 Program Selection

6. From the **Endoscope Selection** window, choose the instrument code or endoscope that you wish to disinfect by using the touchpad, bar code reader, or I-Dent chip. Click the **OK** ✓ button.

Note: The endoscope code or ID is required for the disinfection program to run. If pre-programmed endoscope codes have been entered by your system administrator, the specific disinfection program for that endoscope is selected automatically.

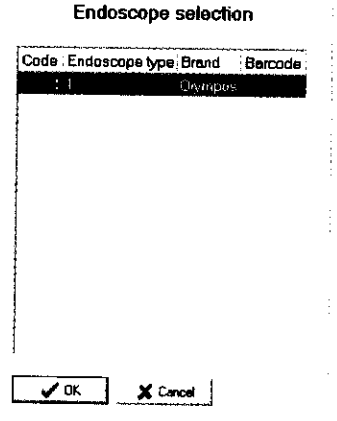


Figure 14 Endoscope Selection

7. Select the correct parameter set from the **Endoscope Type Parameter Set Selection** window by scrolling up or down with the **Scroll Down** ⓓ button or **Scroll Up** ⓤ button. Then click the **OK** ✓ button.

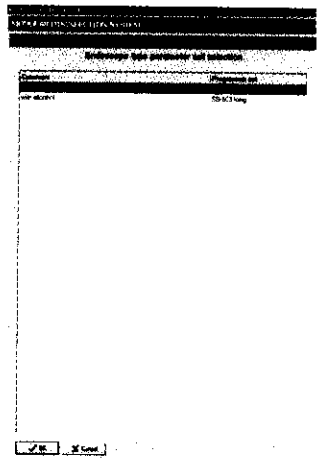


Figure 15 Parameter Set

WARNING *Ensure the correct parameter set is selected for the type of endoscope to be processed. An endoscope is not disinfected and should not be used on a patient if the incorrect parameter set is used during a cycle.*

Verify detergent rates and concentrates are properly set prior to initiating an endoscope cycle.

8. The **Patient Code** window opens. Enter the patient ID with the touchpad or bar code reader and click the **OK** ✓ button.

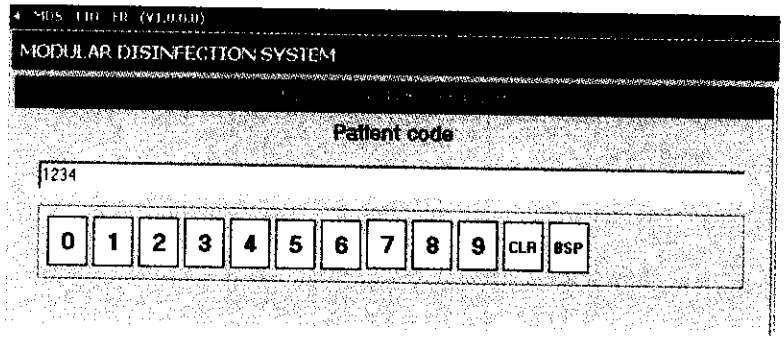


Figure 16 Patient Code

9. When the **Physician Selection** window opens, select the desired name by scrolling with the **Scroll Down** ↓ button, or use the touchpad, bar code reader, or I-Dent chip. Then click the **OK** ✓ button.

10. If the **Physician Assistant Selection** window opens, select the desired name by scrolling with the **Scroll Down** ↓ button, or use the touchpad, bar code reader, or I-Dent chip. Then click the **OK** ✓ button.

Note: The patient code, physician code, and assistant code on your MDS system are configurable. If your system administrator has determined that these items do not have to be tracked, the screens will not be shown.

11. The **Start Program** window opens. Verify that the Start data on the screen is all correct, and then click the **OK** ✓ button. The process LED indicator light is green.

12. A system check is carried out. If a yellow error report appears at the bottom of the screen, attempt to remove it by consulting *Chapter 5: Troubleshooting.*

13. The **Program Screen** opens and allows you to follow the progress of the disinfection process.

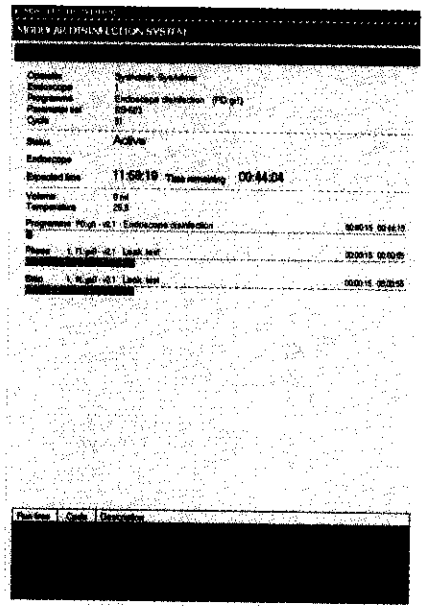


Figure 17 Process Window

Delayed Start

When selecting an delayed start, the endoscope is placed in the basin but the disinfection cycle will not begin until a pre-determined time. This is an administrative function and is available only during the time period as set up and allowed by the system administrator.

1. Prepare and connect the endoscope as described in steps 1-12 for the normal start above.

2. The **Select the Time** window opens. Select `Delayed Start` and press the **OK** ✓ button. If the **Select the Time** window does *not* open, the delayed start is not available.

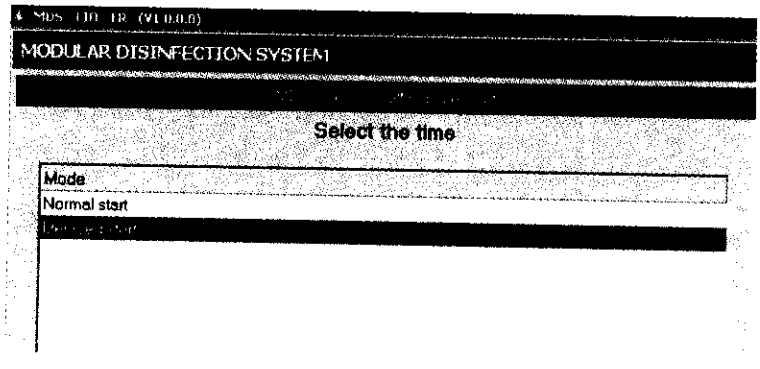


Figure 18 Delayed Start

3. When the **Select the Time** window opens, scroll down to select the desired start time and date. Click the **OK** ✓ button.

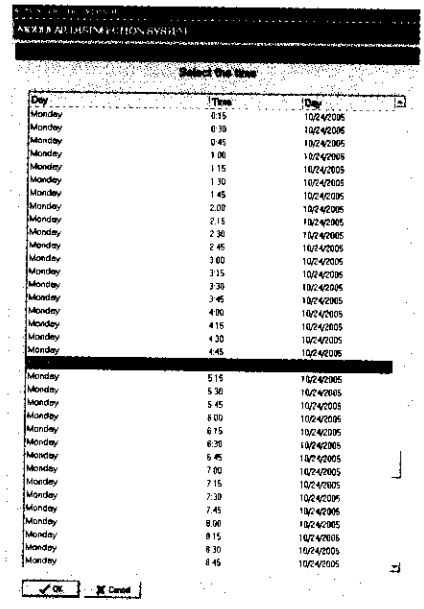


Figure 19 Select the Time

4. The **Delay Start** program window opens. Verify that the data on the screen is all correct, and then click the **Start** ◈ button.

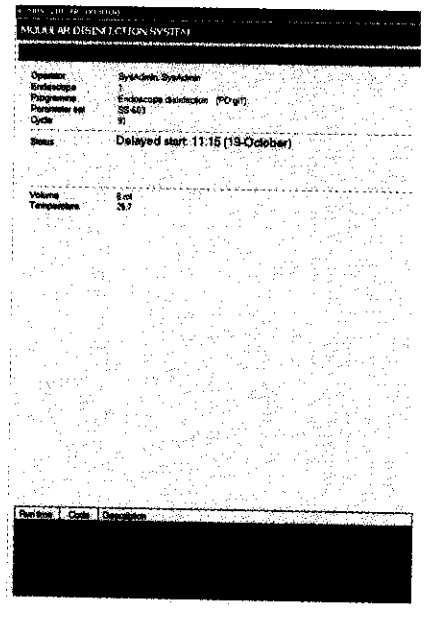


Figure 20 Delayed Start Progress

5. When the designated start time is reached, a system check is carried out. If a yellow error report appears at the bottom of the screen, attempt to remove it by consulting *Chapter 4: Maintenance.*

6. The reprocessing cycle's initialed at the selected start time.

PROCESS INTERRUPTIONS

Introduction

At startup and during the disinfection program cycle, the MDS monitors process parameters for the endoscope, machine, and software to ensure accurate disinfection of the endoscope. Reports, program errors, and system errors appear on the screen to communicate the cycle progress to you.

Operator messages and program errors appear at the bottom of the screen in the Reports field. A code number and short description of the report or error is shown. The elapsed time at which the message or error is generated is also provided.

System errors appear at the top of the screen in white letters on a red background.

Detailed error reports and troubleshooting steps are provided in *Chapter 5.*

WARNING *If system power is lost during a reprocessing cycle, the system will not complete the reprocessing cycle once the power is restored. The endoscope is not disinfected and should not be used on a patient. You must start the reprocessing cycle over so that the endoscope is properly disinfected.*

Program Errors

Program Restart

In a few instances, an error disappears after restarting the program. You may attempt to restart the program if the following conditions are true:

- The basin lid is closed.
- The volume indicators on the screen show 0 mL.
- No error reports appear in the field program.
- No system errors appear at the top of the monitor.
- The LED is green.

If a program stop lasts longer than 60 minutes, the program can not be restarted, the LED turns red, and the program status is ASC (Reject). See *Table 4* for additional information.

To restart the program:

1. Press the **Start** ◈ button.
2. If the program restarts and progresses without any further errors, the disinfection cycle is valid.
3. If the program does not restart, or one or more errors appear, press the **Cancel** ▽ button. Follow the instructions below for the steps to take next.

Program Cancel

If the **Cancel** ▽ button is pressed, the program runs until a safe state is reached.

The alarm sounds and text appears in the Report section of the screen.

Every time the **Cancel** ▽ button is pressed, the current program step is stopped and the next step in the cancel sequence is called. By pressing the **Cancel** ▽ button multiple times, the program can be forced to the end of the cycle. However, caution must be taken because the endoscope channels remain filled with fluid.

One of two status messages appears on the monitor. Follow the instructions below for the status message on your monitor.

Status: Error Recovery

1. Press the **Cancel** button.
2. Press the **Open/Close** button.
3. Select your login name and press the **OK** button.
4. Enter your login name and password.
5. The basin lid opens.
6. Remove the endoscope or correct the cause of the error.
7. Re-start the disinfection program.

Status: Shutdown

The endoscope can not be removed from the machine. Continue the disinfection program.

After the incorrect program is completed, run the disinfection program again. Except for the operator login name, all entered data are automatically copied from the previous run if these steps are followed:

1. Press the **Open/Close** button.
2. Select your login name and press the **OK** button.
3. Enter your login name and password.
4. The basin cover opens.
5. Within 30 seconds, press the **Menu** button.
6. Select your login name and press the **OK** button.
7. Enter your login name and password.
8. Select "**Repeat last run**" and press the **OK** button.

System Errors

If a system error occurs during standby mode, a warning message appears as the fault occurs but disappears as the situation is corrected.

If the error occurs during a disinfection cycle, the program ends and fluids are drained from the basin. A recovery program runs until a safe state is reached and the endoscope can be removed. The recovery program can not be stopped by the operator.

WARNING Report all system errors to your supervisor.

COMPLETE THE DISINFECTION PROCESS

When the disinfection process is complete, the process LED indicator light blinks green, the message "Completed" displays on the LCD screen, and the alarm sounds.

Table 3 Post-Disinfection Program Status

Status	Description
ACTIVE	The program is progressing correctly.
CORRECT	The endoscope was disinfected without any faults or program interruptions.
CORRECT!!!	The endoscope was disinfected with errors reported.
STOP (fault)	The program is stopped due to an error.
STOP (ASC)	The safety control program stopped the program.
STOP (OPERATOR)	The operator stopped the program without a fault report
STOP (LIO)	The program stopped automatically after an error report or the maximum error time (50 minutes) was reached.
SHUTDOWN (fault)	After an error, the endoscope is rinsed so that it can be safely removed.
SHUTDOWN (OPERATOR)	The operator stopped the program. Run down program.
SHUTDOWN (ASC)	The safety control program stopped the disinfection. Completion program.
ASC (REJECT)	The safety control program rejected the disinfection. Open the lid to close the program.
LIO (REJECT)	Disinfection was rejected due to an automatic program stop.

Table 4 Post-Disinfection Instrument Status

Status	Description
DISINFECTED	The endoscope was run through a complete disinfection program.
NOT APPLICABLE	The program is not an endoscope disinfection program. **Warning: The endoscope can be used only if the connectors are correctly connected after the program.**
NOT SUITABLE FOR USE	The endoscope is insufficiently disinfected.

WARNING

Wear clean gloves to prevent soiling of the disinfected endoscope.
If a run error was generated, a channel is blocked, or the endoscope is leaking, the endoscope must not be released for patient use. If there is any doubt as to whether an endoscope is correctly disinfected, it must be disinfected again before use. Contact your supervisor for further instructions.

Verify all connection to the endoscope are secure. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.

1. Open the basin lid by pressing the **Open/Close** button or by using the foot switch. The run status report disappears and the Operator selection window opens.

2. Enter your login name and password.

3. Check that the basin lid is wet to verify that the sprayer worked correctly.

4. Verify that the endoscope has been properly rinsed and dried. Disinfectant residue left on the endoscope as a result of a loose hose can lead to serious complications in a patient.

5. Check that all adapters are still connected to the channel connections. If an adapter is loose or disconnected, the disinfection was not complete and must be repeated.

WARNING *Before removing the endoscope, verify all connections to the endoscope are secure. If an adapter is loose or disconnected, the disinfection was not complete and must be repeated. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.*

6. Disconnect the channel adapters
7. Remove the separation adapter(s).
8. Take the connector block out of the rinse basin and hang up the block.
9. Take the endoscope out of the rinse basin.
10. If appropriate, fit the valves.
11. The endoscope is now ready for a new examination. If it will not be used right away, the endoscope must be stored in an airing cupboard or on a suspension rack.
12. If automatic cycle log printing is enabled, the log is printed.

REPORTS

Run Data Recorded

For each disinfection program run, the following data is recorded and stored on the PC hard drive:

- Machine ID
- Run number
- Date and time
- Endoscope Code

- Operator ID
- Patient ID
- Process step times
- Errors
- Additional information as set up by the system administrator

Printing Reports

CURRENT REPORT

A cycle log prints automatically whenever the MDS module cover opens at the end of a disinfection cycle. To redisplay the current cycle log, double-click the printer icon in the system tray.

EARLIER REPORTS

All completed cycle logs may be viewed and reprinted at any time from the Management program.

1. Display the Windows desktop by minimizing all running programs.
2. Double click on the MDS icon to open the folder.

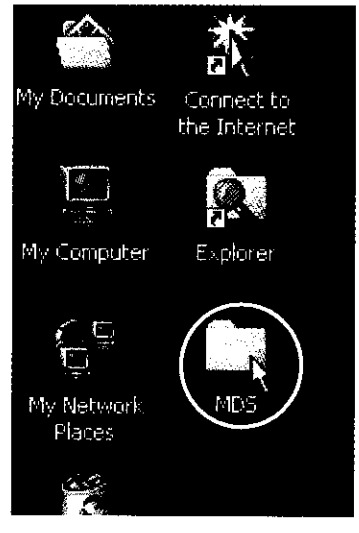


Figure 21 MDS Desktop Folder

3. Double-click on the **Management** icon.

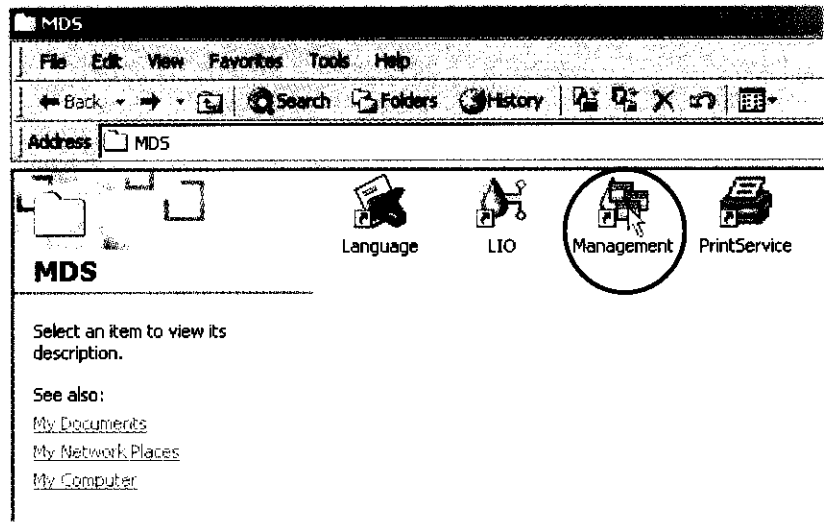


Figure 22 Management Icon

4. Log in to the Management system.

5. On the **Management** screen sidebar, click on the `General` tab.

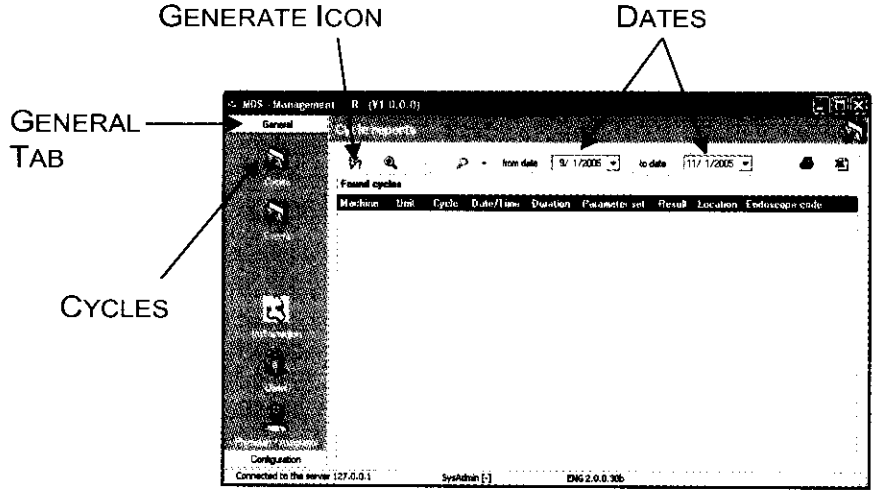


Figure 23 Management Screen

6. On the sidebar, click on the **Cycles** icon.

7. On the blank **Cycle Reports** screen, set the `From Date` and `To Date` parameters, and then click on the **Generate** icon in the toolbar.

8. The **Cycle Reports** screen opens. Double-click on the desired cycle. Click on the icon to display the **Cycle Log Screen**. Click on to display the detailed **Cycle Report**.

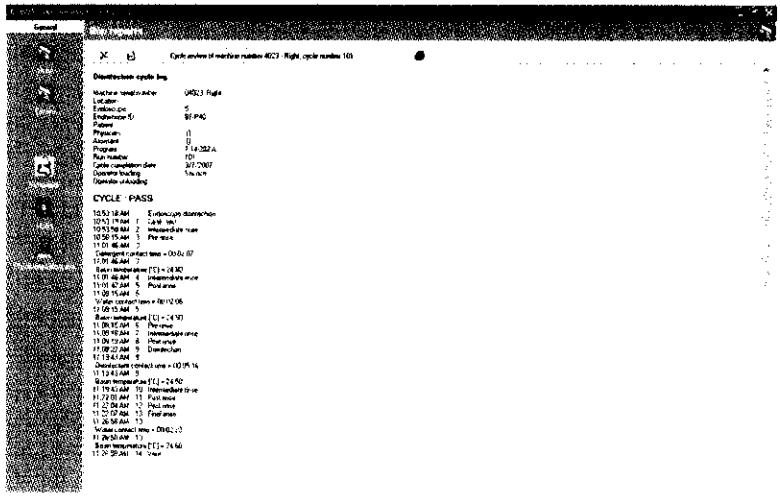
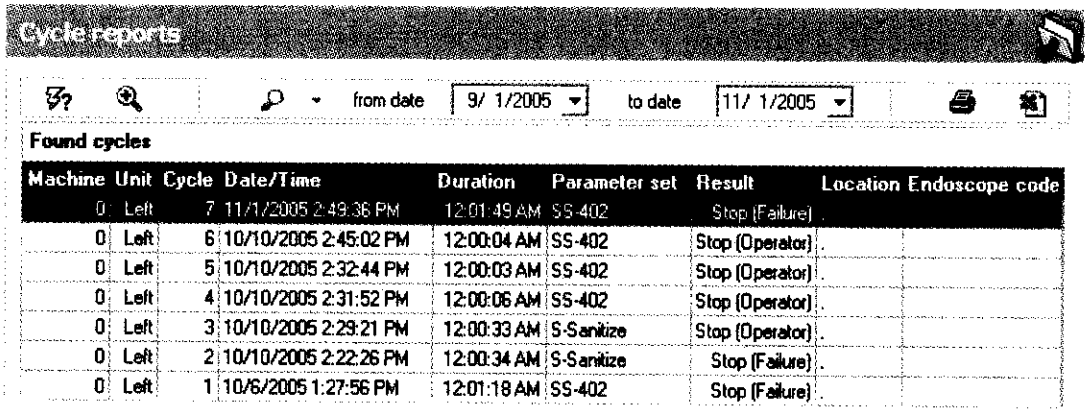


Figure 24 Cycle Log Screen



Machine	Unit	Cycle	Date/Time	Duration	Parameter set	Result	Location	Endoscope code
0	Left	7	11/1/2005 2:49:36 PM	12:01:49 AM	SS-402	Stop (Failure)		
0	Left	6	10/10/2005 2:45:02 PM	12:00:04 AM	SS-402	Stop (Operator)		
0	Left	5	10/10/2005 2:32:44 PM	12:00:03 AM	SS-402	Stop (Operator)		
0	Left	4	10/10/2005 2:31:52 PM	12:00:06 AM	SS-402	Stop (Operator)		
0	Left	3	10/10/2005 2:29:21 PM	12:00:33 AM	S-Sanitize	Stop (Operator)		
0	Left	2	10/10/2005 2:22:26 PM	12:00:34 AM	S-Sanitize	Stop (Failure)		
0	Left	1	10/6/2005 1:27:56 PM	12:01:18 AM	SS-402	Stop (Failure)		

Figure 25 Cycle Reports Screen

9. The **Cycle Details** screen appears. Click on the plus sign to the left of each line to expand the report. Click on the printer icon to print a copy of the report.

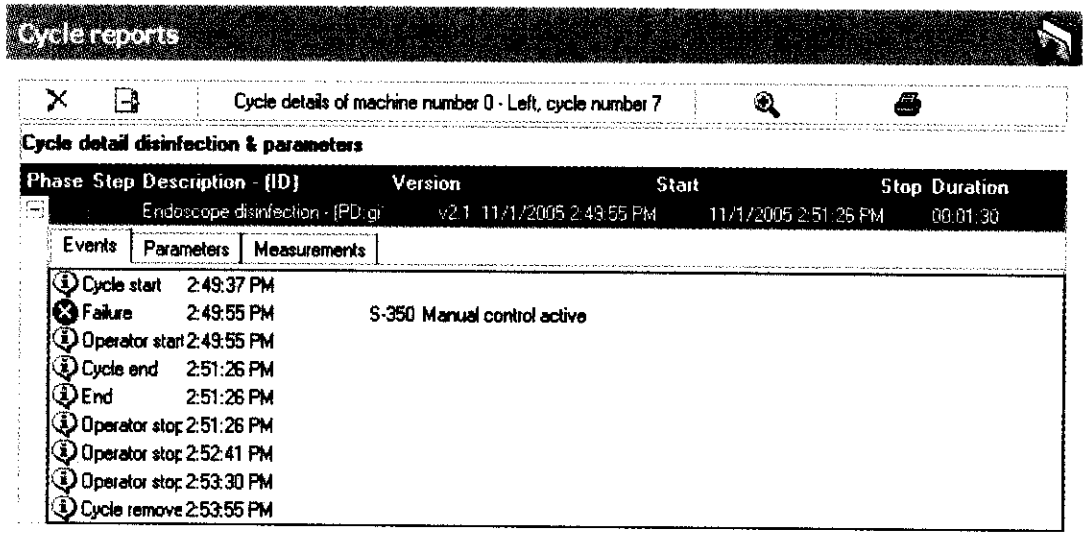


Figure 26 Cycle Details Screen

SHUTDOWN

Use the following process to shutdown the reprocessor at the end of the day.

1. Clean the system by wiping down all surfaces with a non-scouring cleansing agent. Use a lime dissolving, non-scouring agent for the rinse basin and inside the lids. Use soap and water to clean the rubber covers.

WARNING *Avoid possible chemical burns. Always wear personal protective equipment (gloves, goggles) when handling disinfectant and/or detergent.*

2. Check the detergent and alcohol reservoirs for appropriate levels. Refill them if necessary.

3. Clean the detergent cap, bracket and reservoir. Flush the reservoir thoroughly with hot water. Refill the detergent reservoir, if necessary.

4. Close the incoming water line shutoff valve.

5. Turn the external air source to Off (if applicable).

PROCEDURE SUMMARY

1. Open the cover.
2. Connect the endoscope.
3. Close the cover.
4. Enter your login name and password, the endoscope ID, the patient number, the physician ID, and the assistant ID.
5. Start the program.
6. After disinfection, open the basin lid.
7. Enter your login name and password.
8. Check the sprayer and the connections.
9. Disconnect the connector block.
10. Remove the endoscope from the basin.
11. Print a report.

DOWNTIME

Brief Downtime

- If the MDS will be down for a brief period time—less than seven days—it should remain powered on.
- To prevent moisture in the leak test system, fit disinfection blocks in the MDS when it is not is use.

Prolonged Downtime

- If the MDS will be down for more than seven days, it should be powered off.
- The tubing, blocks, filters and heaters in the machine contain a lot of water where bacterial growth may occur. After a long downtime, replace the bacterial filter and disinfect the MDS before running any endoscope disinfection procedures.
- To shut down the MDS, close all running programs first before pressing the main PC power switch. Failure to do this may result in software errors.

NOTES

Chapter 4

MAINTENANCE

This chapter contains basic service procedures required for maintaining the MDS. Strict adherence to these requirements guarantees optimum continuous quality in endoscope reprocessing. Failure to perform required maintenance may result in injury or death to the operator or patient.

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NOTES

DAILY MAINTENANCE

Details and instructions for the daily service requirements are included in *Chapter 3: Operation.*

The following daily maintenance procedures must be completed at the start of each day:

- Confirm that the main air pressure regulator is set between 2.8–3.0 bar (40.6 – 45.0 psi).
- Confirm that the leak test air pressure regulator is set at 0.24–0.25 bar (3.48 – 3.75 psi).
- Verify a sufficient flow of water into the basin or replace the system filters.
- Check that all O-rings on the connection columns are present and undamaged.
- Replace the screens in the rinse basin if they are soiled.

At the end of each day, clean the MDS:

- For the top and outside covers, use a non-scouring cleansing agent.
- On the rinse basin and inside covers, use a non-scouring, lime-dissolving cleansing agent.
- Use soap and water to clean the cover gaskets and prevent them from sticking.

WEEKLY MAINTENANCE

Inspection

Inspect the following on a weekly basis. Adjustments or changes should be made by a qualified service technician.

- **Connector Blocks:** Check for cracks in the silicone hoses, especially at the connections to the connector block. If cracks have formed, the hose should be shortened or replaced.
- **Glass Covers:** The basin lids should open and close easily.
- **Door:** The front door should open and close easily.

- **MDS Tubing, Connections, Fittings, Hydraulics and Dosing System:** Check for wear and leakage and replace as needed.

Lubrication

1. Using a cloth, dry the O-rings on the connection columns.
2. Take a small amount of O-ring grease between your thumb and index finger and spread it diagonally on the connector plate along the first two columns.
3. Repeat these two steps for the other three pairs of columns.
4. Spread the grease lengthwise along the O-rings with your thumb and index finger.

Discharge Screen

Using a screen hook, remove and clean the screen as it becomes soiled.

DISINFECTANT FILTER REPLACEMENT

A disinfectant filter is connected above each of the disinfectant reservoirs. The filter assembly consists of a 65 µm fiber filter, tubing, and fittings that connect to the disinfectant lines. Replace the filter assembly every time the disinfectant is replaced. Use only Minntech-approved filters reorder part # 78399-377.

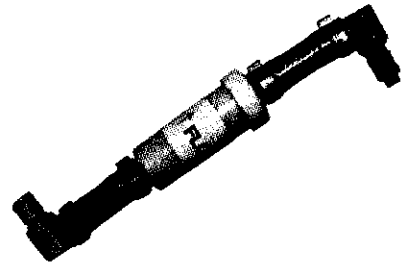

Figure 1 Disinfectant Filter Assembly

1. Remove the disinfectant filter by depressing the thumb latches at each end and uncoupling the mating components.

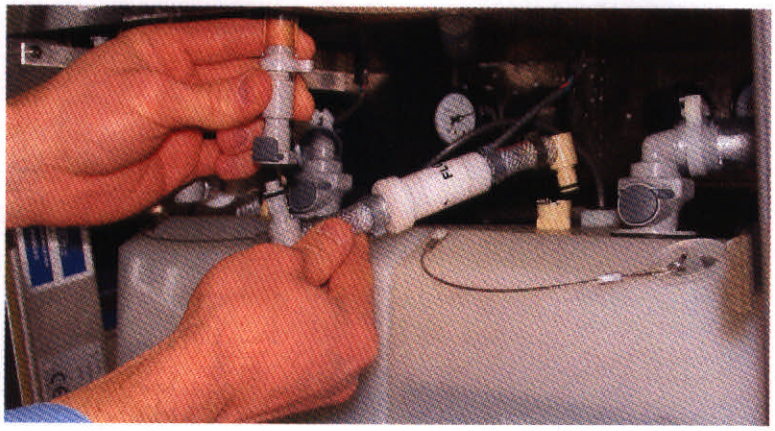

Figure 2 Uncoupling the Filter Assembly

2. Insert the disinfectant filter connector into the matching quick-connect coupling on the reservoir. Insert the other end into the matching coupling on the vertical tube. The couplings differ on each end of the filter to ensure proper orientation. Both connections will click when properly fit. The filter is installed correctly if the flow direction arrow on the filter label points away from the reservoir.

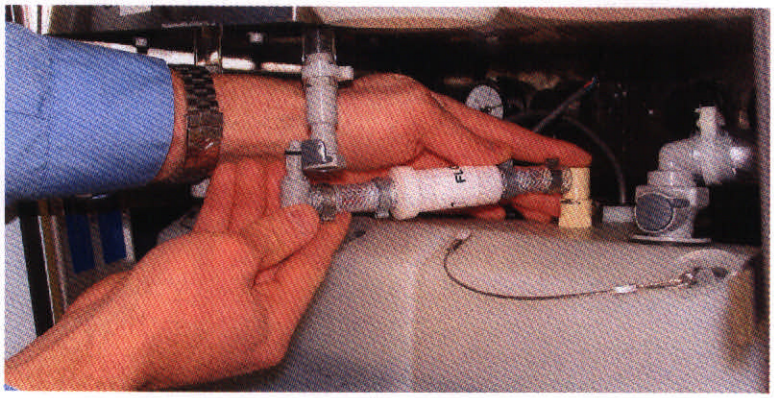

Figure 3 Installing New Filter Assembly

WATER FILTER REPLACEMENT

WARNING: Only replace one water filter at a time. When replacing the water filter, make sure that the filter being removed is the same as the filter replacing it.

The water filtration system removes particulates down to 0.45 µm and biological contaminants as small as 0.2 µm from the supply water. During the water line disinfection procedure, the system disinfects the 0.2 µm filter and the incoming water line for the MDS.

Note: A water line and water filtration disinfection process must be performed whenever a water filter is replaced. *Refer to Chapter 2 Waterline and Water Filter Disinfection.*

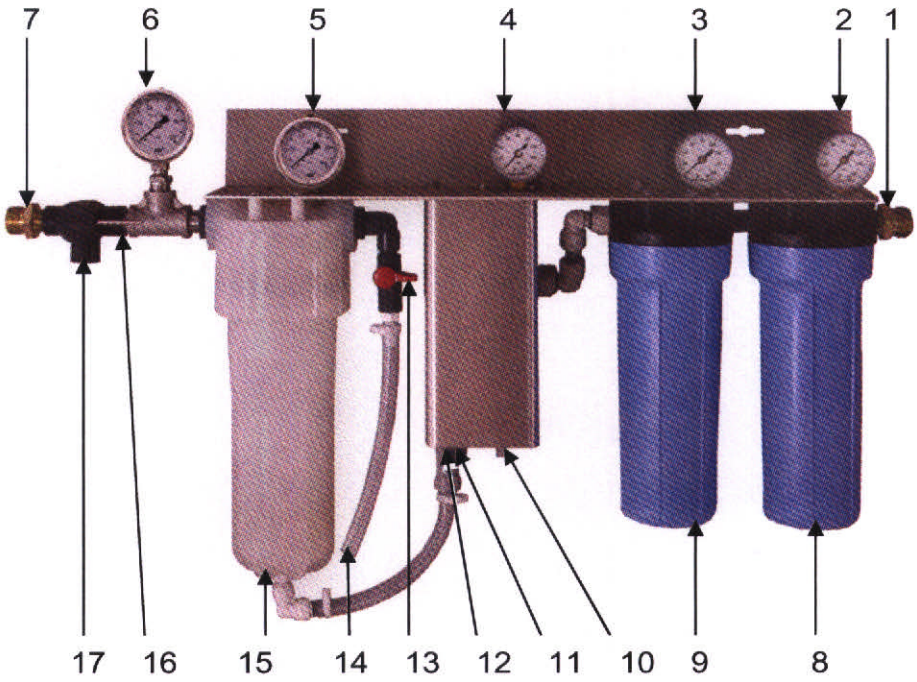

Figure 4 Water Filtration System

1. Water inlet
2. Inlet pressure gauge
3. 1 µm filter outlet pressure gauge
4. 0.45 µm filter outlet pressure gauge
5. 0.2 µm filter inlet pressure gauge
6. 0.2 µm filter outlet pressure gauge
7. Water outlet
8. 1 µm filter
9. 0.45 µm filter
10. Disinfectant inlet
11. 0.2 µm filter inlet/housing drain
12. Communication cable connector
13. Bleed valve
14. Bleed valve outlet
15. 0.2 µm filter
16. Sample port valve
17. Sample port

The following conditions must be before changing a filter:

- No endoscope reprocessing cycles are running.
- No water line disinfection procedure is running.
- The inlet water supply is turned off.

You will need the following materials:

- A filter bowl wrench.
- The necessary filter cartridges (*see Table 1*).

Table 1 Filter Cartridges

Key	Filtration Porosity	Filter Type	Part Number
1	0.2µm	Hollow fiber	MF01-0013
2	0.45 µm	Pleated	MF01-0015
3	1 µm	Microfiber	MF01-0014

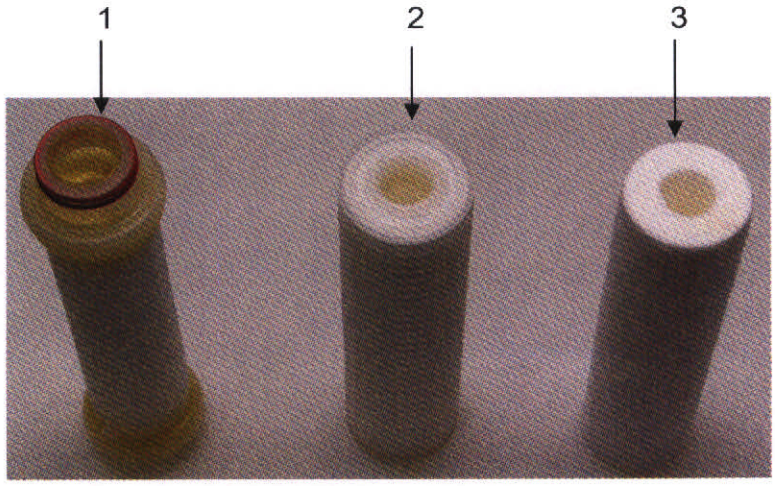

Figure 5 Filter Cartridges

1. Open the **Expert Control** screen by clicking on the icon at the top of the screen. Enter *your login name* and *password* when prompted.

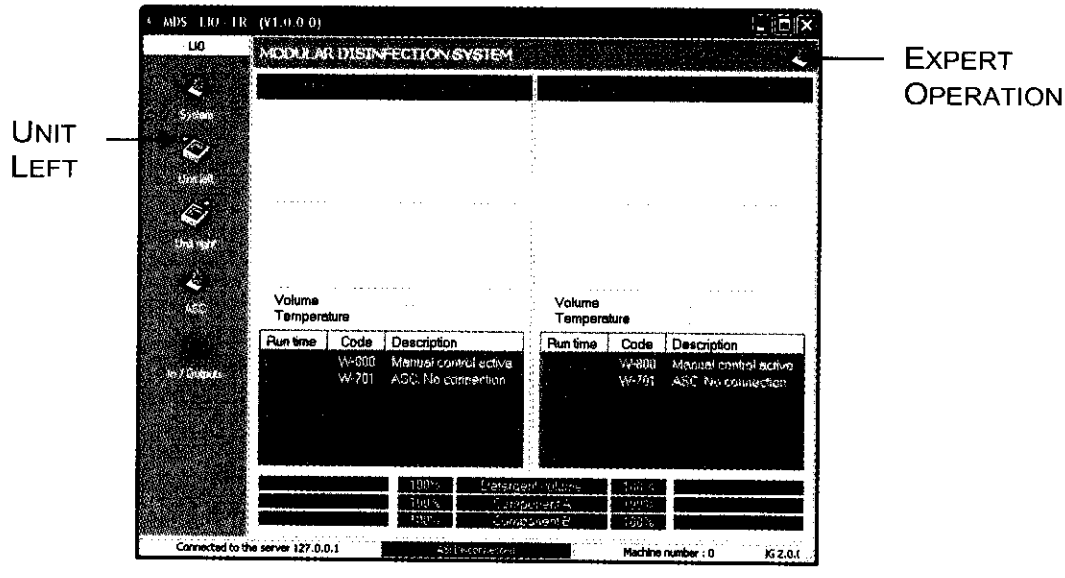

Figure 6 Expert Control and Unit Left

2. Click on the *Unit Left* icon on the left menu bar.

3. In the I/O screen that opens, double click on the Water Supply valve Y02.

4. Scroll down in the Outputs column until `Y90-Filter Water` appears.

5. Double click on your selection to gain manual control.

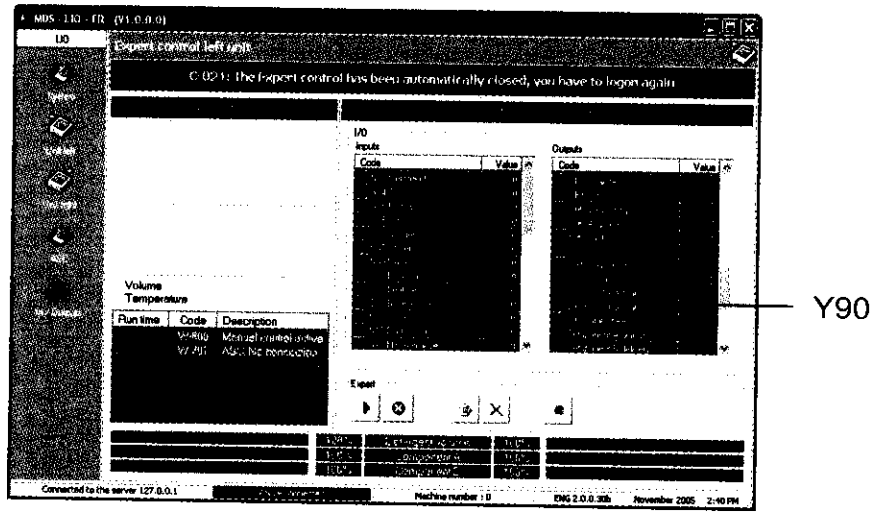

Figure 7 Y90 Filter Water

6. Relieve the pressure in the filtration system by opening the Y90 filter water valve.

7. Check the inlet pressure gauge to ensure that the pressure is at zero. Click on the Release All Icon to reset the valves.

8. Using a filter bowl wrench, remove the 1 µm filter housing and discard the used filter cartridge.

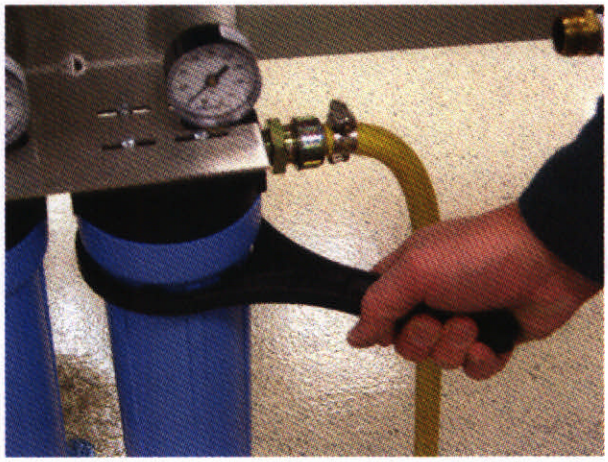

Figure 8 Loosen Filter Housing

Figure 9 Remove Housing and Filter

9. Open the bleed valve and drain the filter housing.

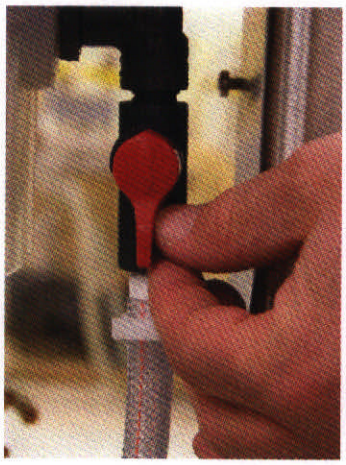

Figure 10 Open Bleed Valve

10. Return the bleed valve to the closed position.

11. Using a filter bowl wrench, remove the 0.2 µm filter housing.

12. Rotate the used filter cartridge counterclockwise, pull downward, and discard.

13. Insert a new filter cartridge into the housing header and rotate clockwise until the tabs lock into place *figure 11*.

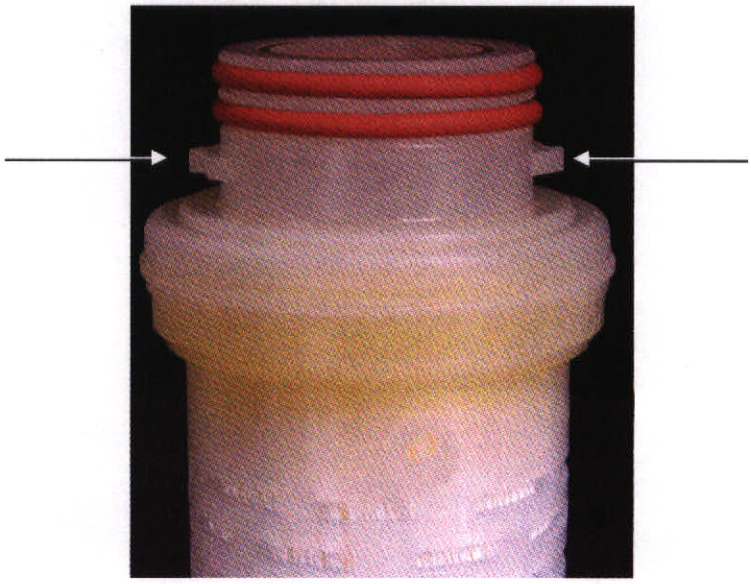

Figure 11 Filter Mounting Tabs

14. Place a new filter in the housing, ensuring that the O-ring is in place.

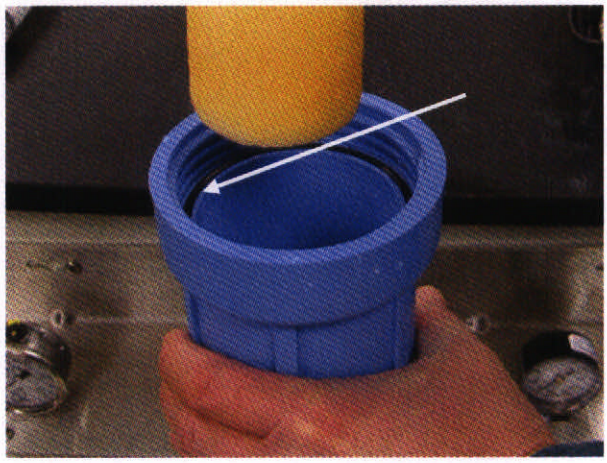

Figure 12 Check O-Ring

15. Thread the housing onto the header and tighten by hand.

16. Repeat the procedure to replace the 0.45 µm filter.

17. Check the 0.2 µm inlet and outlet pressure gauges to verify that both read zero.

18. Place a container under the filter housing.

19. Disconnect the water filter feed line and place the end in a container.

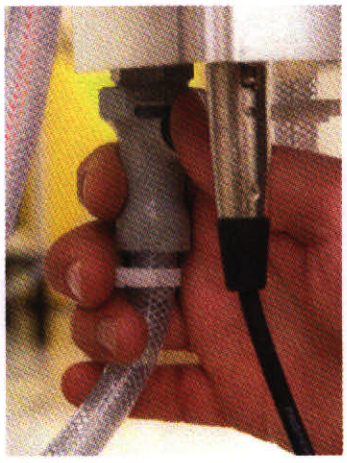

Figure 13 Release Water Filter Feed

20. Thread the housing into place on the header and tighten by hand.

21. Slowly open the main water supply valve and check for any leaks.

22. Bleed any air from the 0.2 µm filter housing and then close the valve.

23. Activate the filtration water valve Y90 from the **Expert Control** screen.

24. Place a container under the bleed valve outlet tube and slowly open the bleed valve. Let the water run until it is a steady stream.

25. Close the bleed valve.

26. Activate the MDS water Y12 and drain Y01valves, and the filtration water valve Y90 from the Expert Control screen.

27. Allow the water to run for at least ten minutes to completely wet the filter.

28. Perform a water line and water filtration disinfection procedure. *Refer to Section 2-31 of Chapter 2.*

AIR COMPRESSOR SUBASSEMBLY INTAKE FILTER REPLACEMENT (OPTIONAL)

1. Acquire an Intake Filter service kit (reorder part # 3-9-452).
2. Remove the eleven screws and lift the cover off the compressor sub-assembly.

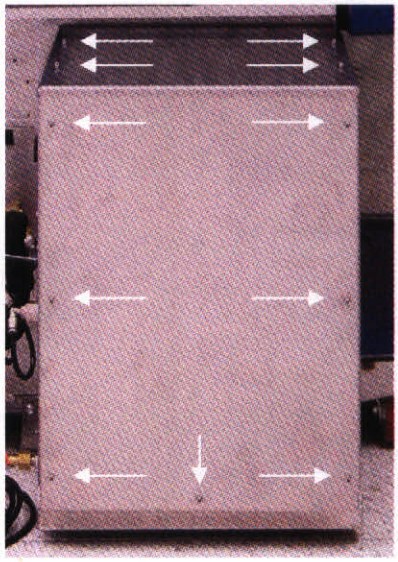

Figure 14 Access Cover Screw Locations

3. Pull downward on the safety valve pull-ring to bleed off pressure.

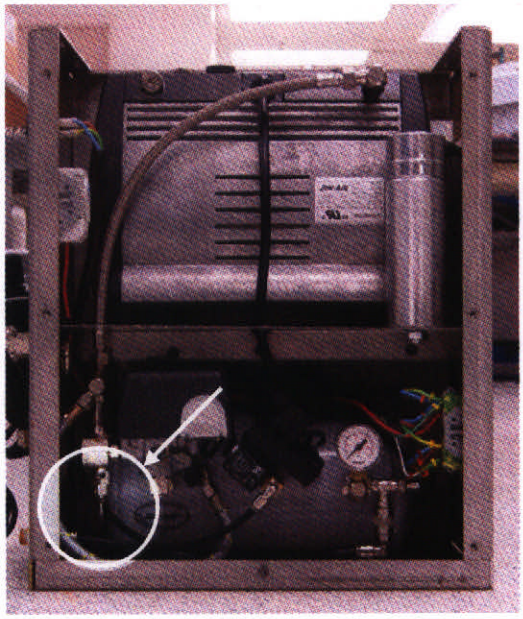

Figure 15 Safety Valve Pull Ring

4. Locate the two filters on the compressor.

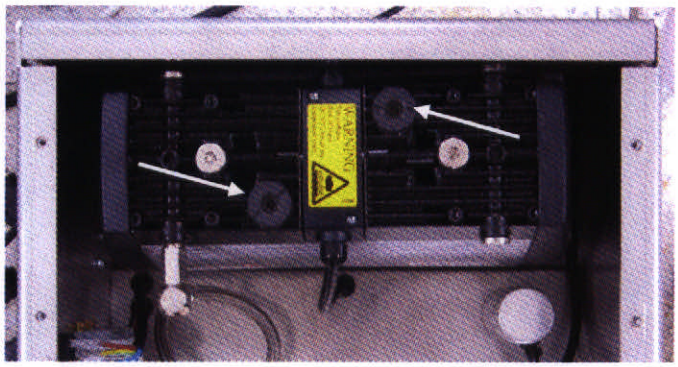

Figure 16 Filter Locations

5. Loosen each filter with a medium size coin. Remove and discard the filters.

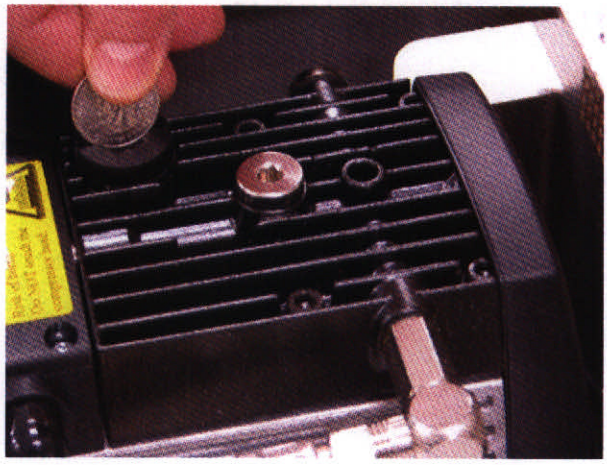

Figure 17 Loosen Filter

Figure 18 Remove Filter

6. Insert the new filters, tighten with a coin, and reattach the cover.

INLINE AIR FILTER REPLACEMENT

1. Acquire two new inline filter assemblies (reorder part # 3-9-421).

2. Remove the shrouds and locate the filters.

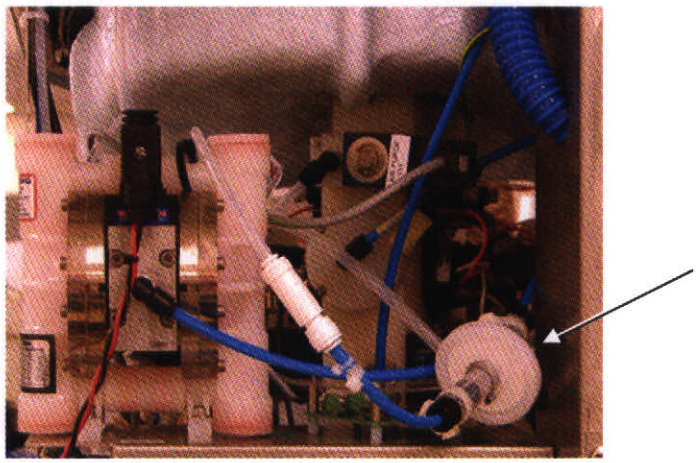

Figure 19 Right Side Filter Location

3. Move the filter away from the machine to allow access to the fittings.

Figure 20 Tubing Removal

4. Press on the push-in fitting to release the outlet tubing.

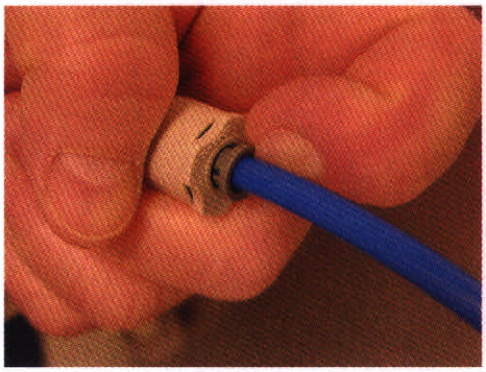

Figure 21 Push-In Fitting

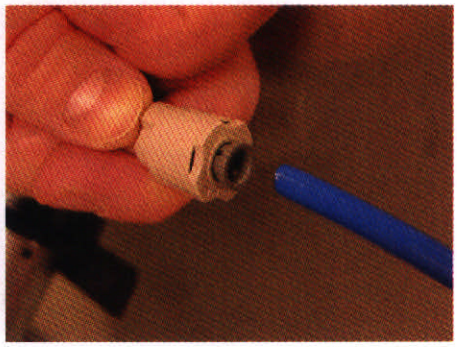

Figure 22 Tubing Release

5. Release the inlet tubing in the same way as the outlet tubing. Remove and discard the filter assembly.

6. Replace the filter by attaching the inlet and outlet tubing. Ensure that the side of the filter marked "IN" is toward the center of the machine.

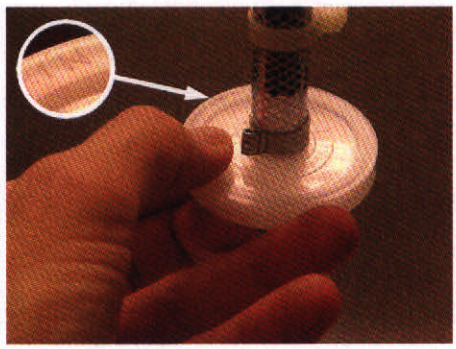

Figure 23 Filter Orientation

7. Replace the shrouds.

FUSE INFORMATION

If your fuses needed to be replaced, seek qualified repair personnel. The fuses are located on the main control panel inside the machine, as shown in *Table 2*.

Table 2 Fuses

Key	Reorder P/N	Fuse Rating
F1	4-6-250	4.00A, 250V Fast Acting 5X20mm Fuse
F3	4-6-248	10.0A, 250V Fast Acting 5X20mm Fuse
F4	4-6-243	2.5A, 250V Time Lag 5X20mm Fuse
F5	4-6-254	12.5A, 250V Time Lag 5X20mm Fuse
F6	4-6-254	12.5A, 250V time Lag 5X20mm Fuse
F10	4-6-250	4.00A, 250V Fast Acting 5X20mm Fuse

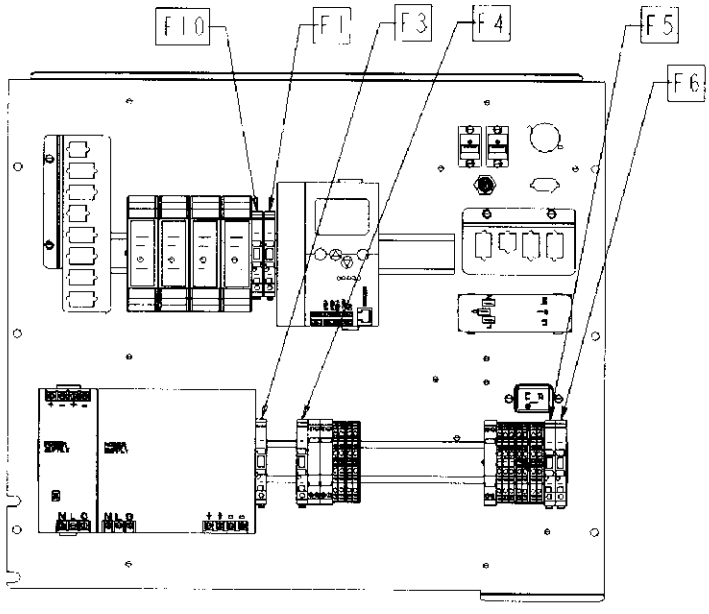

Figure 24 Fuse Location

Chapter 5

TROUBLESHOOTING

This chapter lists error messages you may encounter while using the MDS. If the suggested action does not solve a problem or if the error recurs, contact your Technical Service representative.

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NOTES

INTRODUCTION

Error Reports

The MDS system can report and display different types of errors which signal and identify specific areas requiring attention. Error types include:

- **System Errors:** A communication problem identified by the prefix C with errors ranging from C-001 through C-099. This is a catastrophic error cause by the Windows base PC or MDS system.
- **Bar Code Errors:** A bar code problem identified by the prefix M with errors ranging from M910 through M-940.
- **Endoscope Errors:** An endoscope problem identified by the prefix S with errors ranging from S102 through S-177.
- **Reprocessing Cycle Errors:** A problem identified during the endoscope disinfection cycle identified by the prefix S with errors ranging from S-201 through S-297, and S-511 through S-832
- **Control Errors (AS-I):** Lists any deviations in the disinfection program as monitored by the AS-I drive controller, and identified by the pre-fix S with errors ranging from S-300 through S-399.
- **Warning Errors:** An alert or warning identified so that the operator is aware of a machine condition that requires attention. Warnings are identified by the prefix W and range from W-701 through W-821.

Onscreen Program Progress

The disinfection program consists of phases and steps. For each disinfection cycle, the phase names, status, and run codes appear on the monitor. Information for the left module appears on the left side of the screen; information for the right module is on the right side.

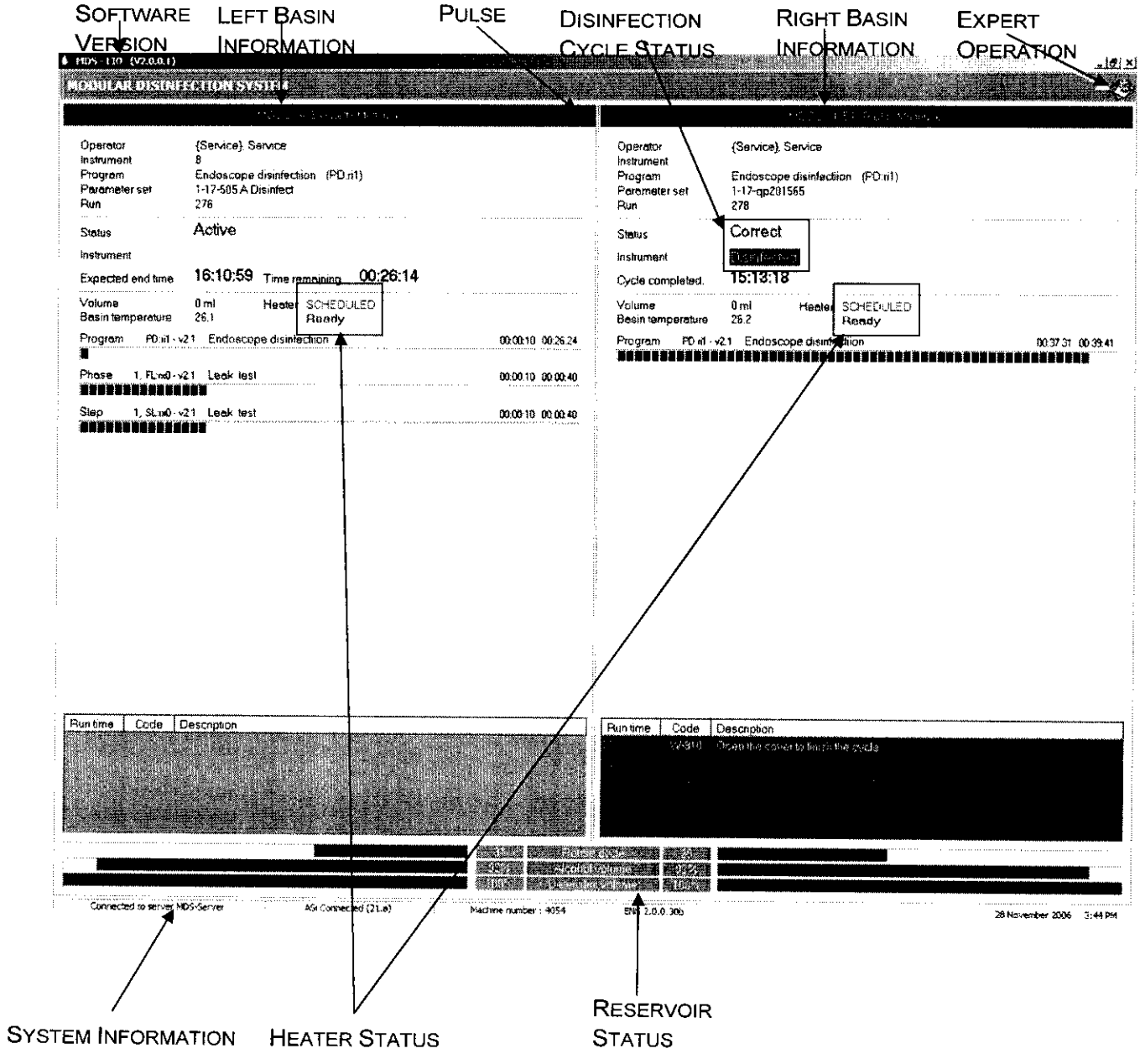

Figure 1 Disinfection Program in Process (Optional Heater Reservoir Equipment installed)

Program Information

This field displays operator and endoscope information as well as the normal progress of the disinfection program. The pre-programmed run time, on the left, is fixed. Real time, on the right, is measured from the start of the cycle. This counter normally decreases as a normal cycle progresses, but may increase or become fixed if an error occurs. The progression of the steps, below the timers, is illustrated with blue time bars. The real time is measured from the start of each step or phase.

Expert Information

This field is visible and active to operators and system administrators with valid passwords. It provides extra information for maintenance and troubleshooting.

Reports and Program Errors

Operator messages and errors appear in the Reports field and communicate cycle progress. An audible alarm also sounds to communicate certain information.

A code number and short description of the report or error is shown, along with the elapsed time at which it is generated. The most recent message is at the top of the field. The meaning of each screen color is shown in the table below:

Table 1 Screen Color and Program Status

Screen Color	Program Status
Orange	Standby, no program active
Gray	Program active
Red	Error
Blue	Program complete

System Errors

Current system errors appear at the top of the screen in white letters on a red background. The message disappears once the error is corrected.

If a system error occurs during standby mode, a warning message appears as the fault occurs but disappears as the situation is corrected.

If the error occurs during a disinfection cycle, the program ends and fluids are pumped out of the basin. A recovery program runs until a safe state is reached and the endoscope can be removed. The recovery program can not be stopped by the operator.

System Information

The bar at the bottom of the screen provides system communication information, machine identification, and the software version.

MDS software has two possible system connections:

1. MDS PC to the MDS (ASi)

2. MDS PC to an external server (optional)

The left field on the bar indicates if the MDS is connected to a server. The next field to the right indicates if the PC is correctly connected to the MDS. The bar is red if an error exists.

ERROR OVERVIEW

Screen reports and errors are summarized by category and number in the following tables. More specific information including potential causes, and actions for each error are included following that. For complex problems, it is advisable to notify the maintenance department and/or your supervisor.

System Errors

Code	Description
C-001	AS-i error: %d: %S
C-011	Server disconnected. Run data will be buffered.
C-012	No hardware definition received. Hardware not initialized.
C-015	Server disconnected. Selection aborted.
C-019	The clock has been synchronized with the server computer
C-021	The expert control has been automatically closed, you have to log on again.
C-030	The previous run has ended incorrectly. Program aborted to a safe situation.
C-032	A failure occurred during the execution of a run. Program aborted to a safe state.
C-033	Program aborted to a safe situation, but incorrect parameter set.
C-040	The hardware definition contains an unknown signal: %d.
C-041	The hardware definition contains an unknown data source for the signal: %d.
C-042	Selected hardware definition not correct for "%s" type.
C-052	Automatic start of program is not possible in the current state.
C-053	Automatic program start up is not possible because another program is already active.
C-054	Automatic start of program is not possible, heater temperature outside limits.
C-060	Delayed start of program is not possible in the current state.
C-080	The tag-reader is not available.
C-099	Internal LIO failure :

Bar Code Errors

Code	Description
M-910	The scanned barcode is unknown.
M-920	The scanned tag is an unknown operator code.
M-922	The scanned tag is an unknown instrument code.
M-930	OK barcode read but no active selection
M-940	The code "%s" is not the correct %s code.

Endoscope Errors

Code	Description
S-102	Start not possible: leak test sensor high.
S-103	Endoscope leaking or incorrectly connected.
S-104	Leak test pressure dropped after check.
S-105	Leak test vented but remains on pressure.
S-106	The block is not pressurizing or is not connected.
S-112	Start not possible: air sensor high.
S-113	No flow: air channel.
S-114	Blocked air channel.
S-115	No pressure: air channel.
S-116	No connectivity air channel
S-117	Air channel not connected
S-122	Start not possible: biopsy sensor high.
S-123	No flow: biopsy channel.
S-124	Blocked biopsy channel.
S-125	No pressure: biopsy channel.
S-126	No connectivity biopsy channel
S-127	Biopsy channel not connected
S-132	Start not possible: jet sensor high.
S-133	No flow: jet channel.
S-134	Blocked jet channel.
S-135	No pressure: jet channel.
S-136	No connectivity jet channel.
S-137	Jet channel not connected.
S-142	Start not possible: suction sensor high.
S-143	No flow: suction channel.
S-144	Blocked suction channel.
S-145	No pressure: suction channel.
S-146	No connectivity suction channel.
S-147	Suction channel not connected.
S-152	Start not possible: water sensor high.
S-153	No flow: water channel.
S-154	Blocked water channel.

S-155	No pressure: water channel.
S-156	No connectivity water channel.
S-157	Water channel not connected.
S-162	Start not possible: extra sensor high.
S-163	No flow: extra channel.
S-164	Blocked extra channel.
S-165	No pressure: extra channel.
S-166	No connectivity extra channel.
S-167	Extra channel not connected.
S-172	Start not possible: elevator wire channel sensor high.
S-173	No flow: elevator wire channel.
S-174	Blocked elevator wire channel.
S-175	No pressure: elevator wire channel.
S-176	No connecting elevator wire channel.
S-177	Elevator wire channel not connected.

Reprocessing Cycle Errors

Code	Description
S-201	Fluid leak in the system
S-203	Wrong connector block
S-211	Cover open
S-222	Start not allowed: Detergent sensor high
S-223	No flow detergent
S-224	Start not allowed: Detergent level low
S-242	Start not allowed: Alcohol sensor high
S-243	No flow alcohol
S-244	Start not allowed: Alcohol level low
S-271	Start not allowed: Insufficient disinfectant
S-272	Start not allowed: Basin not empty
S-273	Basin suddenly empty
S-274	Basin not emptying
S-275	Basin level dropped
S-276	Basin minimum level not reached
S-281	Volume measurement no pulses
S-282	Water inlet flow too high

S-283	Water inlet flow too low
S-285	No water supply
S-286	Volume measurement V1 > V2
S-287	Volume measurement V1 < V2
S-288	Unrequested inlet water detected
S-289	External water supply valve failed
S-292	Basin temperature sensor defective
S-293	Water temperature too high
S-294	Water temperature too low
S-297	Basin temperature too high
S-511	Measure contact time too short
S-611	Start not allowed. Disinfectant reuse count exceeded
S-631	Start not allowed: Disinfectant reservoir is empty
S-632	Start: Disinfectant reservoir is not empty
S-633	Start: The disinfectant reservoir is full
S-634	Start not allowed: Disinfectant reservoir does not detect minimum level
S-635	Start not allowed: Disinfectant reservoir overflowed.
S-636	Start not allowed: Disinfectant reservoir sensor defective
S-641	Disinfectant reservoir full
S-642	Disinfectant reservoir detects minimum level
S-643	Disinfectant reservoir not empty
S-651	Disinfectant reservoir does not detect low level
S-652	Disinfectant reservoir does not detect minimum level
S-671	"Machine control" locked by the other side
S-672	Wrong system side
S-831	Air cylinder does not charge
S-832	Air cylinder not discharged

Control Errors (AS-i)

Code	Description
S-300	ASC message: F.../S.../T...
S-301	ASC in "OK" state
S-302	ASC : wrong configuration.
S-304	ASC no connection.
S-350	Manual control active
S-360	Stopped by the operator

Warnings Errors

Code	Description
W-701	ASC: No connection.
W-702	ASC: Wrong configuration.
W-703	ASC: Incorrect status and cover inactive.
W-704	ASC: Incorrect status.
W-705	ASC: in "OK" state
W-711	Cover is open.
W-712	Cover will not open.
W-713	Cover will not close.
W-715	Basin not empty.
W-716	Fluid leak in system.
W-721	Water temperature sensor defective.
W-727	Reservoir temperature too high.
W-728	Scheduled stop time incorrect, reset to midnight.
W-743	Sensor S03: Detergent high.
W-744	Sensor S17 Minimum level high
W-749	Sensor S24: Alcohol high
W-751	Sensor S11 Leak test #1 high
W-757	Sensor S33 high
W-764	Channel sensor S04 high (Air)
W-765	Channel sensor S05 high (Biopsy)
W-766	Channel sensor S06 high (Jet)
W-767	Channel sensor S07 high (Suction)

W-768 Channel sensor S08 high (Water)
W-769 Channel sensor S09 high (Extra)
W-770 Channel sensor S10 high (Elevator)
W-800 Manual control active
W-801 Purge active, start blocked
W-802 Alcohol sensor venting, start blocked
W-803 Discharging air vessel, start blocked
W-805 Left side controls the water line disinfect
W-810 Open the cover to finish the cycle
W-820 Disinfectant in the basin (The cover is locked)
W-821 Disinfectant in the supply lines, (The cover is locked)

SYSTEM ERRORS

Asi error: %d: %s	C-001

Cause: There is a temporary interruption in the connection between the ASi and the MDS machine.

Action: Check the message at the lower left of the screen. If it says "ASi connected" then the connection has been restored. Press the **Open/Close** button or the **Start** button to continue. If the message says "ASi disconnected" then attempt the action listed below.

Cause: There is a power failure in the machine or the plug is loose.

Action: Check the plug. If it is not loose, report the failure to the maintenance department.

Server disconnected. Run data will be buffered	C-011

Cause: The connection to the database has been interrupted.

- The LIO program cannot retrieve the overview lists and the selection screen is empty.
- The connection to the server is interrupted in stand-by mode.
- It is not possible to start a program.

Action: Report the error to the system manager. As long as "Disconnected from server" appears at the bottom of the screen, the program can not be restarted.

No hardware definition received. Hardware not initialized	**C-012**

Cause: This error occurs if there is a problem with the ASi control software. This definition is the layout of the ASi control and is determined by the configuration of machine. Possible issues are in the following list:

- Installation of the ASi layout is not found.
- The LIO program was incorrectly installed.
- Software problem.
- Communication problem with the ASi interface.

Action: Report the error to the MDS system manager.

Server disconnected. Selection aborted.	**C-015**

Causes: The connection to the database has been interrupted.

- The LIO program cannot retrieve the overview lists and the selection screen is empty.
- The connection to the server is interrupted in stand-by mode.
- It is not possible to start a program.

Action: Report the error to the system manager. As long as "Disconnected from server" appears at the bottom of the screen, the program can not be restarted.

The clock has been synchronized with the server computer (%s)	**C-019**

Cause: If the MDS clock and the server clock have a time difference of more than 30 seconds, a time variance occurs in the run report.

Action: Reset the clocks on the computer:

- Press the **Start** button.
- Press the **Help** button.
- Select change computer time.
- Open date/time.

The Expert control has been automatically closed, you have to log on again	**C-021**

Cause: The Expert screen has timed out.

Action: to continue using the Expert functions login again.

The previous run has ended incorrectly. Program aborted to a safe situation.	**C-030**

If a system error occurs, then it is not possible to create a correct run report. If the error is repaired, then the error message disappears and the restoration program automatically runs to rinse the endoscope with water so that it can be safely removed of the machine. This program can not be stopped and the endoscope is not disinfected.

Cause: A black screen means the program is not visible. Possible causes are as follows:

- The PC was switched off.

- There is a PC defect.
- There was a power failure.

Action: Try pressing the **On/Off** switch on the PC. If this does not solve the error, contact the maintenance department.

Cause: There is a communication problem so the program cannot be run correctly. Possible causes are as follows:

- There is a cable fault.
- A cable is loose.
- There is a program error.
- The MDS control unit is defective.
- There is a blown or defective fuse.

Action: Contact the maintenance department and the system manager.

Cause: There is a communication problem with the ASi interface and message *W-701* is also on the screen. Possible causes are as follows:

- There is a fault with the ASi interface.
- A network cable is disconnected.
- A cable is faulty.
- There is a communication problem with the server.
- There is a server error.

Action: Check the cable connection between the network and the machine. Restore the connection if possible and start the machine program again. If you are unable to repair the connection, report the error to the system manager

Cause: The LIO program was interrupted. Message *W-703* also appears on the screen and the cover knob is blocked.

Action: Start the restore program.

A failure occurred during the execution of a run. Program aborted to a safe situation.	**C-032**

If an ASi error occurs, then it is not possible to carry out a correct disinfection cycle. If the error is repaired, then this *C-032* message appears and the restoration program is automatically selected. The endoscope is rinsed with water so that it can be safely removed from the MDS but it will not be disinfected. The restoration program works automatically and can not be stopped.

The endoscope must be run through a complete disinfection program before use.

Cause: There is an internal communication problem with the PC. Possible causes are as follows:

- There is a cable fault.
- A cable is loose.
- There is a program error.
- The ASi interface in the MDS is defective.
- A fuse is blown or defective.

Action: Report the problem to the maintenance department.

Cause: A new program was started while another one was already active.

Action: Press the **Start** ⏀ button to start the restore program.

Program aborted to a safe situation, but incorrect parameter set	**C-033**

Cause: An incorrect parameter set was selected for the machine disinfection or the restore program.

Action: Select the correct parameter set for the restore program.

Cause: The LIO program was interrupted or shut down during a run. Message *W-703* also appears and the lid can not be opened.

Action: Start a restore program.

Hardware definition contains an invalid signal %d	**C-040**

Cause: An incorrect address is entering the controller from the ASi slaves or a slave has been incorrectly coded.

Action: Report the error to the maintenance department. Note the unknown signal number: nn.

The hardware definition contains an unknown data source for the signal: nn	**C-041**

Cause: An address was incorrectly set up in the AS-I software or a slave was incorrectly coded.

Action: Report the error to the MDS system manager. Note the signal number: nn.

Selected hardware definition not correct for "%s" type	**C-042**

Cause: The system settings parameters for the left/right unit type have not been selected.

Action: Report the error to the MDS system manager.

Automatic start of program is not possible in the current state	C-052

Cause: There is warning text in the report field.

Action: Ensure that all error messages are resolved. Select a machine disinfection auto start. If necessary, consult the MDS system manager.

Cause: An auto start for endoscope disinfection is already set up.

Action: Cancel the auto start for the endoscope disinfection.

Another program is active	C-053

Cause: Machine disinfection should start but there is an active cycle running.

Action: Let the current program run to completion. When the MDS is ready and the basin cover is still open, insert the machine disinfection block and close the cover. The machine disinfection will start automatically.

Automatic start of program is not possible, heater temperature outside limits	C-054

Cause: The disinfectant temperature in the reservoir is either too cold or too hot.

Action: Report the error to Maintenance.

Delayed start of program is not possible in the current state.	**C-060**

Cause: Warning messages (numbers *W700-W799*) are present on the screen during automatic start up of a disinfection program.

Action: Ensure that the messages are resolved. Select the automatic restart. Consult the maintenance department if necessary.

Cause: Auto start for another program is already set up.

Action: For the delayed start, the other program must first be shut down.

Tag-reader not available	**C-080**

Cause: The I-Dent system is defective.

Action: Report the error to the maintenance department and the MDS system manager to have the chip (=Tag) system disconnected. The program can be started after switching off I-Dent.

Internal LIO failure : %s	**C-099**

Cause: A wrong selection was executed when setting the machine system parameters.

Action: Report the error to the MDS system manager to correct the settings. Then restart the program.

BAR CODE ERRORS

The scanned bar code is unknown	M-910

If the system is set up to require the use of the bar code reader, manual selection with the cursor is not possible.

Cause: The bar code belongs to another item to be read.

Action: Check if the bar code type is the same as the selected input field on the screen. Scan the correct bar code again.

Cause: The bar code is not entered in the management system.

Action: Report the error to the MDS manager along with a request to add the bar code for the selected item.

The scanned tag is an unknown operator code	M-920

The system is set up to require use of the automatic identification (I-Dent) system for operator identification.

Cause: The read tag is entered incorrectly or is not reported in the management database.

Action: Report the situation to the MDS manager along with a request to add the correct tag code to the operator list.

The scanned tag is an unknown endoscope code	M-922

The system is set up to require use of the automatic identification (I-Dent) system for endoscope selection.

Cause: The read tag is entered incorrectly or is not reported in the management database.

Action: Report the situation to the MDS manager along with a request to add the correct tag code to the endoscope list.

OK barcode read but no active selection	**M-930**

Cause: The barcode was read but the **OK** ✓ button was not enabled.

Action: Click the **OK** ✓ button.

The code "%s" is not the correct %s code.	**M-940**

Cause: An incorrect code or lot number was entered while performing the Tank Change utility for either the detergent or alcohol.

Action: Rerun the Tank Change utility and enter a valid code.

ENDOSCOPE ERRORS

Start not possible: leak test sensor high.	**S-102**

This message appears if no disinfection program is active and the leak test sensor is on. When this message occurs, no disinfection program can be started.

Cause: If the endoscope is vented too quickly, then it remains pressurized, causing the leak test sensor to be on.

Action: Stop the program and disengage the terminal block to reduce the pressure. This causes the message *W-751* to disappear. If the error message remains, see the next cause and action below.

Cause: A faulty sensor faulty continues to incorrectly read on.

Action: Report the situation to the maintenance department for repairs.

Cause: The air valve leaks.

Action: Report the error to the maintenance department.

Endoscope leak or connected incorrectly	**S-103**

Cause: The endoscope or connection hose is leaking seriously. The leak test connection is not in order.

Action: Use a manual leak tester (with a pressure gauge) to see if the endoscope leaks. If so, have the endoscope repaired. If there is no leak, check the endoscope connection and restart the program. If the report recurs, consult the maintenance department.

Cause: The block is out of alignment to the connection plate in the rinse basin.

Action: Stop the program, disconnect, and place the block anew. Restart the program.

Leak test pressure dropped after check.	**S-104**

Cause: Very tiny leak in the endoscope.

Action: Using the pressure gauge, pump the endoscope to pressurize and check to see if it is leaking. If there is a leak, report it to the maintenance department. If the endoscope is not leaking, see other causes of the error below.

Cause: Very tiny leak in the leak test system of the MDS, the terminal connector, or the connection block.

Action: Consult the maintenance department to repair the leakage.

Cause: A power failure vents the endoscope and the error message follows.

Action: If the machine automatically started up after the error, no further action is required. Otherwise, contact the maintenance department.

Cause: If the endoscope stays pressurized, a sensor is faulty.

Action: Report the situation to the maintenance department.

Leak test vented but stays on pressure	**S-105**

Cause: There may be an air valve defect if air does not vent from the endoscope during the ventilation process.

Action: Try to start the process again by pressing the **Start** ⏀ button. If the message recurs, press the **Stop** ▽ button. Remove the connection block and check to see if air is escaping (there is a hissing noise). If so, report it to the maintenance department. If air is not escaping, see other possible causes of the error below.

Cause: The leak test sensor is defective or out of alignment. This causes the signal to be maintained after the block is removed.

Action: Report to the maintenance department for repairs.

Cause: The flow control air valve is contaminated or out of alignment.

Action: Try to start the process step again by pressing the **Start** ⏀ button. If the error recurs, ask the maintenance service to align the valve.

Block not pressurized or not connected	**S-106**

Cause: The endoscope is not properly connected.

Action: Stop the machine and check if the leak test connections and the terminal block are properly placed. Connect the leak test and block again. Start the program.

Cause: Machine fault.

Action: Consult the maintenance department.

Start not possible: suction sensor high	**S-112, S-122, S-132, S-142, S-152, S-162, S-172**

This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Suction
- Jet
- Water
- Elevator

These errors appear if a disinfection program is selected and the specific channel sensor is on. When this message occurs no disinfection program can be started.

Stop the program and open the lid. An endoscope warning (*W-764* through *W-770*) appears. This message must be cleared before a restart takes place.

Cause: The endoscope channel is blocked, causing the sensor to be on.

Action: Disconnect the connector from the channel in the endoscope. If the message disappears, report the blocked endoscope to the maintenance department. If the message remains, see other possible causes of the error below.

Cause: The connection block is blocked when the endoscope is not connected.

Action: Disconnect the connection block and replace it with another. If the message disappears, let the maintenance department unclog the block. If the message remains, see other possible causes of the error below.

Cause: The channel sensor is defective or out of alignment

Action: Report the faulty sensor to the maintenance department.

No flow: channel	**S-113, S-123, S-133, S-143, S-153, S-163, S-173**

This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Suction
- Jet
- Water
- Elevator

Action: First try the process step again by pressing the **Start** ⓘ button. If the report recurs, press the **Stop** ⓥ button.

Cause: Channel connector not connected.

Action: Press the **Stop** ⓥ button and connect the endoscope. Start the program again.

Cause: The connector terminal block handle is not connected, or the block is out of alignment.

Action: Press the **Stop** ⓥ button and open the cover. Place the terminal block and make sure that the handle is fastened in the lock pins on both sides. Start the program again.

Cause: An incorrect program choice was selected for the instrument.

Action: Check that the number of channel connections (excluding the leak test) agrees with the statement on the screen after "Parameter set." In the case of an anomaly or doubts, stop the program and report the error directly to the system manager.

Cause: Wrong block.

Action: Check that the number of hoses on the block (excluding the leak test) is the same as the number of channel connections on

the endoscope. In the case of a deviation, replace the block with the correct implementation and start the program again.

Cause: Too little pump pressure or the channel sensor is faulty.

Action: Consult the maintenance department. After restart, the channel sensor does not become high. Press the **F1** or **F2** buttons to see the signal units.

Cause: The sprayer is worn, which causes too much pressure (flow) loss along the bearing.

Action: A horizontal spray pattern of the leaking water can be seen with a restart. Report the error to the maintenance department.

Cause: The channel sensor is out of alignment.

Action: After restart the signal blinks too much and is unstable. Press the **F1** button to signal units. Report the situation to the maintenance department for carrying out calibration.

Blocked channel	**S-114, S-124, S-134, S-144, S-154, S-164, S-174**

This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Suction
- Jet
- Water
- Elevator

Try to start the process again by pressing the **Start** ◈ button. This can be done once. If the message recurs, the **Stop** ▽ button must be pressed.

Cause: Connection hose(s) is kinked or pinched.

Action: Check all hoses. If kinked or pinched, straighten out hose(s) and start the program again. If none of the hoses is kinked or pinched, see other possible causes of the error below.

Cause: Channel blocked.

Action: If the channel is blocked, have the endoscope checked or repaired. If there is no blockage, try the endoscope in a different MDS system. If the error is repeated, check the connection block. See other possible causes of the error below.

Cause: Connection block obstructed.

Action: Press a properly fitting hose of a small bellows pump (manual leak test) in the holes on the underside of the terminal block. Squeeze the bellows. Air should come out of the channel connection. If there is a blockage, consult the instrument service manual to unclog the connection block. If the block is not obstructed, then a machine fault is probably the cause. Consult the maintenance department.

No pressure: channel	**S-115, S-125, S-135, S-145, S-155, S-165, S175**

This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Suction
- Jet
- Water
- Elevator

Cause: There is insufficient air pressure to blow the moisture out of the channels.

Action: Press the **Start** ◈ button to try the process step again. If the message recurs, press the **Stop** ▽ button.

Cause: A hose is detached.

Action: Verify all hoses are still connected to the endoscope then start the program again.

Cause: Incorrect parameter set.

Action: When in doubt or if the wrong parameter is set, report the problem to the MDS system manager.

No connectivity: channel	**S-116, S-126, S-136, S-146, S-156, S-166, S-176**

This control checks interconnected endoscope channels and the message is given per channel, i.e.:

- Air
- Biopsy
- Extra
- Suction
- Jet
- Water
- Elevator

Cause: There is a connector loose from the endoscope.

Action: If you see a loose connection, press the **Stop** ⊽ button. Close the program, connect the loose connection, and restart the cycle.

Cause: It is not clear if all channels are connected.

Action: Try to start the process again by pressing the **Start** ◈ button. This may be tried once. If the message reoccurs, you must press the **Stop** ⊽ button and call Maintenance.

Channel not connected	**S-117, S-127, S-137, S-147, S-157, S-167, S-177**

This control checks small endoscope channels and the message is given per channel, i.e.:

- Air
- Biopsy
- Extra
- Suction
- Jet
- Water
- Elevator

Cause: There is a connector loose from the endoscope.

Action: If you see a loose connection, press the **Stop** ▽ button. Close the program, connect the loose connection, and restart the cycle.

Cause: It is not clear if all channels are connected.

Action: Try to start the process again by pressing the **Start** ◇ button. This may be tried once. If the message reoccurs, you must press the **Stop** ▽ button and call Maintenance.

REPROCESSING CYCLE ERRORS

Fluid leak in the system	**S-201**

If the message report is visible, then the program can not be stopped. After drying out, it can take 5–10 minutes before the sensor message disappears. If the sensor is released, only the program can be stopped.

Cause: There is liquid in the front of the machine as result of a leak.

Action: If possible, close the water supply tap and consult the maintenance department

Cause: If the reservoir is dry, a sensor is out of alignment.

Action: Remove the two reservoirs and dry the green sensor with a cloth. If the message remains, report the error to the maintenance department to have the sensor aligned, or to have the program shut down for technical service.

Wrong connection block	**S-203**

The machine disinfection automatically started and checked whether the hot water block is fitted.

Cause: No connection block is present:

Action: Place the machine disinfection connection block and then press the **Start** ⏀ button.

Cause: The endoscope connection block is present.

Action: Exchange this block for a machine disinfection connection block and press the **Start** ⏀ button.

Cause: The machine disinfection connection block is present.

Action: Try pressing the **Start** ⏀ button again. If the message recurs, then consult the maintenance department.

Cover open	**S-211**

Cause: The cover is closed: During the program, the cover sensor has failed and now indicates that the cover is open.

Action: The program can be stopped only via the expert operation. Report the error to the maintenance department to adjust the sensor, if necessary.

Cause: During the program the cover was opened.

Action: Close the cover and press the **Start** ⏀ button to continue the program.

Start not allowed: detergent sensor high	**S-222**

Cause: The detergent sensor is out of alignment or faulty.

Action: Report the fault to the maintenance department.

No flow detergent	**S-223**

Cause: The detergent reservoir is empty.

Action: Check if the detergent reservoir is empty. If so, fill the reservoir. If there is sufficient detergent in the reservoir, press the **Start** ⏀ button. If the error repeats, see the alternate cause below.

Cause: The detergent sensor or pump is defective.

Action: Report the fault to instrument service.

Start not allowed : Detergent level low. Start not allowed : Alcohol level low.	**S-224,** **S-244**

Cause: The reservoir is empty.

Action: Check if the level of fluid in the reservoir. If it is empty, fill or replace the reservoir. If there is sufficient fluid in the reservoir, press the **Start** ⏀ button. If the error repeats, see the alternate cause below.

Cause: The sensor in the reservoir is defective.

Action: Report the fault to Maintenance.

Start not allowed: Alcohol sensor high	S-242

Cause: The alcohol sensor is out of alignment or faulty.

Action: Report the fault to the maintenance department.

No flow alcohol	S-243

Cause: The alcohol reservoir is empty.

Action: Check if the alcohol reservoir is empty. If so, fill the reservoir. If there is sufficient alcohol in the reservoir, press the **Start** ⏀ button. If the error repeats, see the alternate cause below.

Cause: The alcohol sensor or pump is defective.

Action: Report the fault to instrument service.

Start not allowed : Insufficient disinfectant	S-271

This message appears if no disinfection program is active and the level sensor is on. When this report occurs, a disinfection program can not be started.

Cause: Water in the rinse basin is causing the level sensor to report liquid.

Action: Wait until the basin is empty. Make sure that the cover is closed so that the basin can automatically run empty.

Cause: The basin level sensor is faulty, causing it to remain high even though the basin is empty.

Action: Report the fault to instrument service for repairs.

Start not allowed : Basin not empty	**S-272**

This message appears if no disinfection program is active and the basin empty sensor is on. When this message occurs, a disinfection program can not be started.

Cause: Water in the rinse basin is causing the level sensor to report liquid.

Action: Wait until the basin is empty. Make sure that the cover is closed so that the basin can automatically run empty.

Cause: The volume report on the screen is not 0, so the system is not released.

Action: Close the cover and wait until the message moves to zero. This may take a few minutes. If there is no effect, see the following cause below.

Cause: The basin empty sensor is faulty, causing it to read high when the basin is empty

Action: Report the fault to instrument service for repairs.

Basin suddenly empty	**S-273**

Cause: The drain valve leaks due to contamination. The rinse basin empties during rinsing.

Action: Check if there is still any liquid in the basin. If the basin is empty, press the **Stop** ▽ button and report the fault to the maintenance department. If the basin is filled see the cause below.

Cause: The basin empty sensor is faulty.

Action: Press the **Stop** ▽ button and report the error to the maintenance department.

Basin not emptying	S-274

Try the process again by pressing the **Start** ⓘ button. If the message recurs, press the **Stop** ⓥ button.

Cause: The drain is blocked.

Action: Check if the rinse basin runs empty properly. If it does not, contact the maintenance department. If is does, see the causes listed below.

Cause: The drain valve is faulty if the volume level does not go down.

Action: If the level does not go down, report the error to the maintenance department. If the level goes down, see the causes listed below.

Cause: The drainage hose sags which causes the rinse basin to run empty too slowly.

Action: Check the drainage hose. If it is sagging, report the situation to the maintenance department. If the hose does not sag, see the cause listed below.

Cause: The basin empty sensor is faulty.

Action: Report the situation to instrument service.

Basin level dropped	S-275

Cause: Liquid ran out of the basin due to contamination on the valve seal.

Action: Report the fault to the maintenance department. If the tank is full, press the **Start** ⓘ button to try running the program. If the tank is empty, change the tank and restart the program.

Cause: The drainage valve opened due to an error control.

Action: Report the fault to the maintenance department.

Cause: The rinse basin level sensor is defective or contaminated.

Action: Report the fault to the maintenance department.

Basin minimum level not reached	**S-276**

Water must be present in the rinse basin to check for the correct connection block.

Cause: The drainage valve leaks.

Action: Press the **Start** ⓞ button and to see if water drains from the basin. If it doesn't, contact the maintenance department. If water drains, see the cause below.

Cause: The basin empty sensor is defective so the control of the block is incorrectly carried out.

Action: Report the fault to the maintenance department.

Volume measurement no pulses	**S-281**

Cause: There is water in the rinse basin but the volume is not measured.

Action: Press the **Stop** ▽ button. Consult the maintenance department.

Water inlet flow too high	**S-282**

Press the **Start** ⓞ button to attempt to run the process step again. If the message recurs, press the **Stop** ▽ button.

Cause: - The rinse basin fills too quickly because the water supply pressure is too high.

Action: Press the **Stop** ▽ button and report the situation to the maintenance department.

Water inlet flow too low	**S-283**

Press the **Start** ◇ button to attempt to run the process step again. If the message recurs, press the **Stop** ▽ button.

Cause: The basin fills too slowly because the water supply pressure is too low or the filter is contaminated.

Action: Press the **Start** ◇ button to continue the program and pay close attention to the water as it enters the basin. If the flow is weak, report it to the maintenance department. If the flow is normal, see the possible cause below.

Cause: The volume meter is contaminated or defective.

Action: Press the **Stop** ▽ button and report the situation to the maintenance department.

No water supply	**S-285**

Cause: The water tap is closed.

Action: Check the water tap. If it is open, see the possible cause below. If the tap is closed, open it and press the **Start** ◇ button.

Cause: The water supply valve is defective.

Action: Report the situation to the maintenance department.

Volume measurement V1 > V2	**S-286**

Cause: The volume measurement and volume control indicate deviating values

Action: Stop the program and report the error to the maintenance service.

Volume measurement V1 < V2	**S-287**

Cause: The volume measurement and volume control indicate deviating values

Action: Stop the program and report the error to the maintenance service.

Unrequested inlet water detected	**S-288**

Cause: The water supply valve is leaking and may dilute the disinfectant.

Action: Report the error to the maintenance department.

External water supply valve failed	**S-289**

Cause: The water supply valve on the filter unit is leaking, so machine disinfection can not be performed.

Action: Report the error to the maintenance department.

Basin temperature sensor defective	**S-292**

This error occurs independently of the software and is an extreme situation. Pressing the **Stop** ▽ button has no effect. Interrupting the program is only recommended after a technician has judged the situation. The program can be stopped via the expert operation. After resolving the fault, the program can be continued.

Cause: The temperature sensor is defective if the temperature message on the screen is higher than 100°C.

Action: Report the error to the maintenance department.

Cause: If the heater is switched on, the heater temperature sensor rises and the rinse basin temperature measurement does not.

Action: Report the fault to the maintenance department.

Water temperature too high	**S-293**

Press the **Start** ◇ button to start the process step again. If the message recurs, press the **Stop** ▽ button.

Cause: The drainage block is too warm after a disinfection program.

Action: Wait five minutes, or pour cold water in the rinse basin to see if the temperature indicated on the screen drops.

Cause: The setting or mixing valve is out of order, causing the supplied water to be too hot.

Action: Press the **Stop** ▽ button and check or adjust the setting of the mixing valve. Wait for a while until the water in the machine has cooled down. Then start the program again.

Water temperature too low	**S-294**

Press the **Start** ⓥ button to start the process step again. If the message recurs, press the **Stop** ⓥ button.

Cause: The adjustment or mixing valve is out of order, causing the water supply to be too cold.

Action: Contact the maintenance department. Press the **Stop** ⓥ button and check or adjust the mixing valve. Start the program and check if the temperature indicated on the screen is correct for the program.

Cause: The warm water supply is stagnated.

Action: Press the **Stop** ⓥ button and consult the maintenance department.

Basin temperature too high	**S-297**

This error occurs independently of the software and is an extreme situation. Pressing the **Stop** ⓥ button has no effect. Interrupting the program is only recommended after a technician has judged the situation. The program can be stopped via the expert operation. After resolving the fault, the program can be continued.

Cause: The water temperature in the rinse basin is too high:

- Instrument disinfection: >50°C.
- Machine disinfection: >90°C.

Action: Stop the program and report the fault to the maintenance service.

Measured contact time is too short	S-511

The prescribed contact time is a sum of the time for different steps (SV + SS + SC + RS = option).

Cause: There was a change in the drain and fill time for the basin.

Action: Report the error to Maintenance so they can recalibrate.

Cause: The program parameters have been changed.

Action: Report the fault to the system administration.

Start not allowed: Disinfectant reuse count exceeded	S-611

Cause: The disinfectant has been reused the maximum allowed number of times.

Action: Dump disinfectant and replace with new disinfectant.

Start not allowed: Disinfectant reservoir is empty	S-631

Cause: The disinfectant reservoir is empty.

Action: Refill reservoir with new disinfectant.

Cause: The reservoir empty sensor is defective.

Action: Report the error to maintenance.

Start: Disinfectant reservoir is not empty	**S-632**

Cause: The disinfectant reservoir fill utility has been started but the disinfectant reservoir is not empty.

Action: Empty reservoir and then rerun the reservoir fill utility.

Cause: The reservoir minimum level sensor is defective.

Action: Report the error to maintenance.

Start: The disinfectant reservoir is full	**S-633**

Cause: The disinfectant reservoir fill utility has been started but the disinfectant reservoir is full.

Action: Empty reservoir and then rerun the reservoir fill utility.

Start not allowed: Disinfectant reservoir does not detect minimum level	**S-634**

Cause: The disinfectant reservoir is low.

Action: Fill reservoir with new disinfectant.

Cause: The reservoir minimum level sensor is defective.

Action: Report the error to maintenance.

Start not allowed: Disinfectant reservoir overflowed	**S-635**

Cause: The disinfectant reservoir has overflowed.

Action: Dump some of the disinfectant in the reservoir.

Cause: The reservoir overflow sensor is defective.

Action: Report the error to maintenance.

Start not allowed: Disinfectant reservoir sensor defective	**S-636**

Cause: One of the reservoir sensors is defective.

Action: Report the error to maintenance.

Disinfectant reservoir full	**S-641**

Cause: The disinfectant being drained to the reservoir has reached the overflow sensor. Water may have been drained into the disinfectant reservoir.

Action: Dump the disinfectant in the reservoir and refill with new disinfectant.

Cause: The reservoir overflow sensor is defective.

Action: Report the error to maintenance.

Disinfectant reservoir detects minimum level	**S-642**

Cause: The disinfectant pump is defective.

Action: Report the error to maintenance.

Cause: The reservoir minimum level sensor is defective.

Action: Report the error to maintenance.

Cause: The disinfectant uptake filter is blocked.

Action: Report the error to maintenance.

Disinfectant Reservoir Not Empty	**S-643**

Cause: The disinfectant reservoir is not emptying within acceptable time period.

Action: Low-level disinfectant sensor faulty or sticking.

Cause: Disinfectant filter restricted – requires replacement.

Action: Disinfectant pump delivery system requires flow recalibration.

Disinfectant Reservoir Does Not Detect Low Level	**S-651**

Cause: No disinfectant in reservoir.

Action: Fill reservoir with disinfectant.

Cause: Low-level sensor faulty or sticking.

Action: Report the error to the maintenance.

Disinfectant Reservoir does not detect minimum level	**S-652**

Cause: The disinfectant reservoir is low.

Action: Check for leakage then fill reservoir with new disinfectant.

Cause: The reservoir minimum level sensor is defective.

Action: Report the error to the maintenance.

"Machine Control" Locked by the other side	S-671

Cause: The machine disinfection program is active. It is not possible to use this side of the machine.

Action: Wait until the program has run completely.

Wrong system side	S-672

Cause: The machine disinfection program is started from the right side rather than the left side.

Action: Cancel the selection from the right side and restart it on the left side.

Air cylinder does not charge	S-831

Cause: The cylinder is used to check connectivity from the endoscope to the MDS. The cylinder is not filled so the check can not be performed.

Action: This is the last step of the disinfection cycle. When all channels are still connected, the endoscope is properly disinfected. Visually check the connection and report the error to maintenance.

Air cylinder not discharged (reservoir pressurized)	S-832

Cause: The cylinder is used to check connectivity from the endoscope to the MDS. The cylinder can not be vented after the check is performed.

Action: Report the error to maintenance.

CONTROL ERRORS (AS-I)

ASC	S-300

The report codes are as follows:

- F = error number
- S = step number where the error occurred in the program
- T = error text describing the undesired situation

After an error S-300, the phase is stopped and the program automatically goes to the post-rinse phase (a safe run down process).

The possible errors are listed in Table 1 below.

Figure 2 S-300 Control Error Details

Error Number	Description	Additional Details
F011	No step release	PC software error. The program runs through an incorrect step or closes the step before it is complete.
F012	Unknown step	PC software error. An active program step is not programmed into the ASC.
F013	Wrong step	The Stop ▽ button is pressed after a run failure. The program skipped over steps to finish the run. End the program via the Open/Close ⏻ button and operator selection.
F014	Setting flow #01	The volume measurement is out of alignment due to contamination, a defective meter, or incorrect calibration.
F015	Setting flow #02	
F021	Minimal time	LIO program step time duration deviates from ASC

Error Number	Description	Additional Details
F022	Maximum time	program control time; or an error report lasted too long before Start ◈ or Stop ▽ button was pressed.
F031	Cover open detection	During a disinfection program, the cover sensor is off or the air valve is operated manually. A mechanical defect of either of the components can create an unsafe situation.
F032	Cover open drive	
F033	Heater driven	The heater is on due to a software or electrical error. The endoscope may become too hot.
F034	Safety relay	The heater safety relay is malfunctioning; heating disabled (Heated Reservoir system only)
F041	Air channel or extra-1 channel	To control flow, the relevant channel sensor must read high or low for a minimal period of time. A "high" error occurs if a pump or valve is broken, or if the sensor is defective or blinks. A "low" error may be caused by a partially-blocked channel or terminal block.
F042	Biopsy channel or biopsy-1 channel	
F043	Jet channel or suction-1 channel	
F044	Suction channel or suction-2 channel	
F045	Water channel or biopsy-2 channel	
F046	Extra channel	
F047	Elevator wire channel: or extra-2 channel	
F051	Basin empty	The basin empty sensor does not detect the rinse basin draining. If there is water in the basin, the sensor is defective or the drainage hose is blocked. If when adding disinfectant, the basin empty sensor does not go on, the sensor is out of alignment, is

Error Number	Description	Additional Details
		defective, or the endoscope housing is blocking the flow of disinfectant.
F052	Minimal level	The basin full sensor is not activated when the basin fills. The sensor is contaminated or the water supply is too slow. During rinsing the basin full level sensor reads incorrectly due to a valve leak.
F062	Detergent	The relevant sensor is activated when it is not applicable in the step. When adding disinfectant or detergent, a message appears if the minimal dosage time is not achieved or the maximum dosage time was exceeded.
F063	Disinfect_Over	Disinfectant reservoir overflow sensor indicated fluid is present (Reuseable system only)
F064	Disinfect_Low	Disinfectant reservoir low sensor indicates fluid is present when it is not supposed to be (Reusable system only)
F065	Disinfect_Full	Disinfectant reservoir fill-level sensor indicates incorrectly low or high (Reuseable system only)
F071	Pump disinfectant	The pump runs at the incorrect time due to a software or electronics error.
F072	Pump detergent	
F073	Pump channels	
F074	Pump alcohol	Alcohol pump high during step
F081	Drainage valve	The valve is open at the wrong step due to a software or electronics error.
F082	Water supply	
F083	STX	Sterilox disinfectant valve is powered when it should not be
F084	SRW	Sterilox rinse water valve is powered when it should not be

Error Number	Description	Additional Details
F091	Volume change	The volume meter counts pulses at the wrong step, possibly due to a leaking supply valve.
F092	Volume minimal	When filling the rinse basin, the measured volume is less than the minimum or more than the maximum setting.
F093	Volume maximum	
F094	V1 > V2	During filling the V2 meter verifies the amount measured by V1. The deviation between the two meters is greater than 10%.
F095	V1 < V2	
F101	Temperature upper limit	The water is warmer than the upper limit (40°C) or colder than the lower limit (30°C). Water temperature adjustment is done externally.
F102	Temperature bottom limit	

Cause: The ASi Safety Control (ASC) program detects an error. A sensor or valve may have had an incorrect status for a short period of time so the program was rejected as unsafe. If the fault occurred at the end of a step, the message is in the run report of the next step.

Action: A correct description is important for a good analysis.

- Note the codes and the text.
- Report the fault and description to the maintenance department.
- Wait until the program has stopped.
- Press the **Open/Close** button.
- Start a restore program.
- Restart the endoscope disinfection.

Cause: A PC error disrupts the program. The ASC signals the unsafe situation and sends an error message.

Action: Note the code and description. Evaluate if the PC is working. Report the fault and description to the maintenance department.

ASC in "OK" state	**S-301**

ASC : Wrong configuration	**S-302**

The PC communicates with the ASi operation interface in the MDS. This interface transmits a signal every 20 msec to check the status of the signal in and out of the PC. If this communication stops or is interrupted the error appears.

Cause: The ASi safety control program found a fault in one of the electronic components or the controller is not running.

Action: Report the fault to the maintenance department.

ASC : no connection	**S-304**

Cause: A communication error occurred between the PC and the electronics drive controller.

1. No serial connection with the PC
2. The power or plug is disconnected
3. The drive controller is defective.

Action: Make certain all cables are connected to the PC and the 230V plug. Report the fault to the maintenance department.

Manual control active	**S-350**

Cause: The manual control in the Expert screen is active and has not been released.

Action: Click the "release all" button on the Expert screen.

Stopped by operator	S-360

Cause: During an active program, the **Stop** ▽ button was pressed.

Action: The message is automatically stored in the run report.

WARNING ERRORS

ASC: No connection	W-701

Cause: A communication error occurred between the PC and the electronics drive controller.

1. No serial connection with the PC
2. The power or plug is disconnected
3. The drive controller is defective.

Action: Make certain all cables are connected to the PC and the 230V plug. Report the fault to the maintenance department.

ASC: wrong configuration	W-702

Cause: The ASi Safety control program found a fault in one of the electronic components, or the controller is not in the run.

Action: Report the fault with number to the maintenance department.

ASC: Incorrect status and cover inactive	**W-703**

Cause: The ASi Safety control program rejected the previous run and blocked the cover. The LED is red. The cover remains closed under the following conditions:

- An error occurred during a restore program.
- There was a power outage.
- There is a software error.
- The LIO-program shut down.
- There is an electronics error.

Action: The maintenance department can access the expert service to shut down the process in order to make a repair.

- Run the disinfection program to a safe situation by starting a restore program.
- Press the **Start** button.
- Press the **Menu** button.
- Select your operator ID
- Select the program Restore after interrupted program.
- Press the **Start** button.
- If this program is ready, then the cover can be opened to safely remove the endoscope. After opening the cover, the message disappears and the red LED goes off. The status message "ASC (rejection)" is applicable to the program. The instrument status "not appropriate for use" is applicable to the endoscope.

ASC: Incorrect status	**W-704**

Cause: The ASC-i safety control program rejected the run and the LED is red.

Action: Open the cover so the message disappears and the red LED goes out. This takes 4 seconds. The control program is now on stand-by.

ASC: on "OK" state	W-705

Cause: ASC status is OK.

Action: None.

Cover open	W-711

This message appears if no disinfection program is active and the cover sensor is on. No disinfection program can be started.

Cause: The cover is open.

Action: Press the **Open/Close** button and then the **Start** button.

Cause: There is a cover sensor defect, causing the message to appear even though the cover is closed.

Action: Report the situation to the maintenance department for repairs.

Cover will not open	W-712

Action: Try to open the cover by pressing the **Start** button.

Cause: The air pressure is too low to open the cover.

Action: Open the front cover and check the pressure gauges. Report any unusual readings to instrument service.

Cause: The cover is blocked.

Action: See if the blocking can be noticed visually, also on the rear side, and try if possible to remove this. If this does not work: report problem to the maintenance department.

Cause: A problem control valve is causing the cover cylinder to malfunction.

Action: Report the situation to the maintenance department.

Cause: The **Open/Close** button was pressed down too long.

Action: Press the button again but for a shorter time.

Cover will not close	**W-713**

Action: Press the **Start** button to close the cover or close the cover carefully by hand and test to see if it moves.

Cause: The cover is blocked.

Action: See if the blockage can be seen and attempt to remove it if possible. If no blockage can be seen, report the problem to the maintenance department.

Cause: The cover sensor is defective or out of alignment.

Action: Consult the maintenance department.

Cause: The **Open/Close** button was pressed down too long.

Action: Press the button again but for a shorter time.

Cause: There is a defective air valve or the compressed air pressure is too low to open the cover.

Action: Report the situation to the maintenance department.

Basin not empty	W-715

Cause: The program was aborted and there is still fluid in the basin.

Action: Open the cover to shut down the program and automatically drain the basin.

Cause: There is liquid in the basin because the drain is blocked or the valve is defective.

Action: Check if the drain is used and report the problem to the maintenance department.

Cause: There is no liquid in the rinse basin. There is a basin sensor defect.

Action: Report the problem to the maintenance department.

Fluid leak in system	W-716

Cause: Liquid was spilled while changing a reservoir.

Action: Remove the liquid and dry the sensor (the green plug) carefully. Resetting the sensor can take a few minutes.

Cause: While in stand-by, liquid is detected at the bottom of the machine. Possible causes are leaking or a sensor set at the wrong level

Action: Report the situation to the maintenance department.

Water temperature sensor defective	W-721

Cause: There is a temperature sensor defect if the reading is >100°C.

Action: Report the problem to the maintenance department.

Cause: If the heater is switched on, the heater temperature sensor rises and the rinse basin temperature measurement does not.

Action: Report the problem to the maintenance department.

Reservoir temperature too high	**W-727**

Cause: Reservoir temperature sensor defective.

Action: Report the error to maintenance.

Cause: Reservoir heater defective.

Action: Report the error to maintenance.

Scheduled stop time incorrect, reset to midnight	**W-728**

Cause: The reservoir heater was scheduled to turn off before the scheduled start time..

Action: Reset the scheduled stop time in the system parameters. If no action is taken the stop time is automatically reset to midnight.

Sensor S03 Detergent high	**W-743**

Cause: A sensor is out of alignment or the detergent dosage system is clogged.

Action: Report the warning to the maintenance department.

Sensor S17 Minimum level high	W-744

Cause: There is water in the rinse basin or a sensor defect.

Action: Close the cover to allow the basin to run empty. Report the warning to the maintenance department.

Sensor S24 : Alcohol high	W-749

Cause: A sensor is out of alignment or the alcohol dosage system is clogged.

Action: Report the warning to the maintenance department.

Sensor S11 Leak test #1 high	W-751

Cause: Disinfection cycle fails or the user pushed the cancel button to end the cycle

Action: Open the basin lid and disconnect the channel block from the channel manifold. The pressure should now be released and the warning message should disappear. Reinstall the channel block, close the basin lid, and a new cycle can now be initiated

Sensor S33 high	W-757

This message appears if not disinfection program is active. The warning must be cleared before a program is restarted.

Cause: The air cylinder sensor is out of alignment or faulty.

Action: Report the error to Maintenance.

Sensor high	**W-764, W-765, W-766, W-767, W-768, W-769, W-770**

This message appears when the machine is in stand-by and one of the channel sensors is high. This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Water
- Suction
- Jet
- Elevator wire

Cause: The connection block is obstructed and the endoscope is not connected.

Action: Disengage the block. If the message disappears, report the obstructed block to the maintenance department. If the message remains see the next possible cause.

Cause: There is a channel sensor defect.

Action: Report the defective sensor to the maintenance department.

Manual control active	**W-800**

Cause: One or more functions are manually set. This means a disinfection program can not be started.

Action: Contact the maintenance department with a request to cancel the setting.

Purge active, start blocked	**W-801**

Cause: This message appears when the machine is in stand-by and the machine leak test system is blown through. This is an automatic routine that occurs every hour and lasts one minute.

Action: Wait until the message disappears and start the program.

Alcohol sensor venting, start blocked	**W-802**

Cause: Alcohol lines are pressurized while unit is idle.

Action: Wait until venting process completes, then start cycle.

Discharging air cylinder, start blocked	**W-803**

Cause: Air cylinder is pressurized while unit is idle.

Action: Wait until venting process completes, then start cycle.

Left side controls the water line disinfect	**W-805**

Cause: Right side cannot control the water line disinfect cycle.

Action: Use left side control panel to control water line disinfect cycle.

Open the cover to finish the cycle	**W-810**

Cause: The program is finished. This report indicates how the program needs to be shut down.

Action: Press the **Open/Close** button and follow the instructions on the screen. After selecting the correct operator ID, the cover opens automatically and the program shuts down.

Disinfectant in the basin (the cover is locked)	**W-820**

Cause: The water line disinfect cycle failed while disinfectant was in the basin.

Action: Restart the water line disinfect cycle.

Disinfectant in the supply line (the cover is locked)	**W-821**

Cause: The water line disinfect cycle failed while disinfectant was in the water supply lines.

Action: Restart the water line disinfect cycle.

Chapter 6

SYSTEM ADMINISTRATION

Chapter Six is meant for *Administrative Use Only*. It shows the System Administrator how to setup and manage all process-specific data, along with the daily operations of the MDS machines, server and programs. The System Administrator must have a strong background in PC computers and Windows Operating Software. If you are uncertain of how to proceed, contact your Hospital Data Center or call Technical Support for assistance.

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NOTES

MDS SYSTEM SOFTWARE

The MDS system software consists of three main programs:

1. **LIO (Logic Input/Output)** is the program operators use to communicate with the MDS. The software also controls the MDS machine and the disinfection processes. This program runs on every computer with an MDS machine connected.

2. **Management** is the MDS database for user and cycle run information. The system administrator has access to input data, process reports, and manage multiple MDS machines. This program runs on only one computer, usually a server of the MDS system.

3. **Server** controls communication between LIO, Management, and the MDS machines that may be on a network. This program runs in the background of the MDS system server and is available only to users with administrator access.

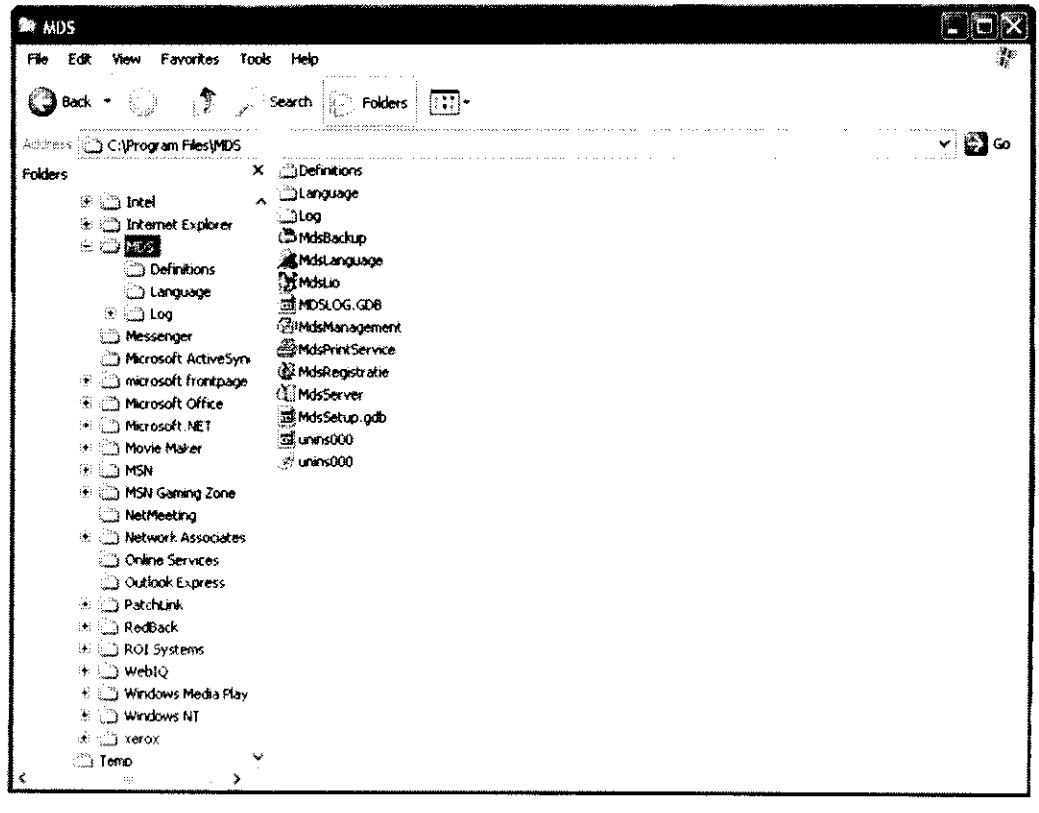


Figure 1 MDS Directory Structure

SERVER SOFTWARE

General Information

The server application is installed on the MDS system or on a server in an MDS network. It controls communication between the LIO applications on the MDS machines and the database on the server computer.

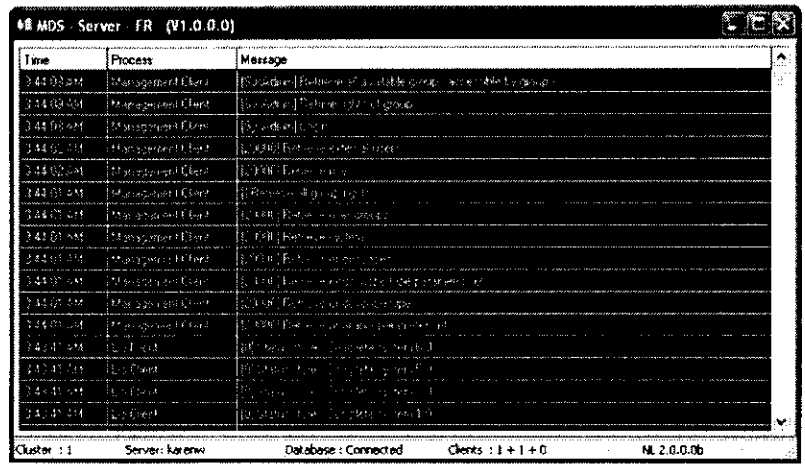


Figure 2 Server Window

The server Log Report shows each communication between the server PC and the linked machines. The machine number is in brackets. The application provides information if a communication problem arises.

Finding the Server

The server program is installed on the server computers. It may be on the PC controlling the MDS machine, or on a separate PC in a network of machines. The program controls communication between LIO applications on one or more MDS machines and the database on the server computer.

If the server program can not be found, a dialog box appears and you are asked for the IP address of the server computer.

1. In the serial number window, enter the MDS machine number which is found on the name plate inside the MDS cover.

2. In the server address window, enter the IP address of the PC that runs the Server program. To find the IP address, go to `Start > Run`. Enter `IPCONFIG` in the window and press the **OK** ✓ button. Contact the data center for further assistance.

3. Enter the IP address in the window and press the **OK** ✓ button.

Hospital Administrator Login

The MDS database can only be accessed using a Hospital Administrator account. A Hospital Administrator account is created during MDS system installation. A Hospital Administrator can add and update:

- Users
- Physicians/Assistants
- Instruments
- Modify and create parameter sets
- Modify non-critical system parameters
- Launch the Server program if it is not already running.

To login as a Hospital Administrator:

1. Launch the Server Program if it is not already running.

2. Launch the Management program by going to `Start > All Programs > MDS > Management`, or by double clicking on the Management shortcut in the MDS folder on the computer desktop.

3. When the authorization window appears, click on the down arrow to select your Login name.

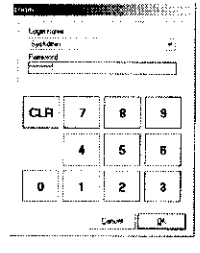


Figure 3 Authorization Window

4. Enter your numeric password. Press the **CLR** button if you make an entry error and want to re-enter the password. Press the **Cancel** button to close the Management Program without creating your password. Press the **OK** button to complete your password entry and continue on to the Management program.

Note: To prevent unauthorized access to the Management program, close the program when you have finished your work.

Under special circumstances, a temporary password can be issued to login as a System Administrator. Contact technical service to describe the problem. If you receive a password, it will be valid only for the date it was granted and only for specific applications.

MANAGEMENT PROGRAM

Structure

The Management program is subdivided into general and configuration applications. These are available as links on the management screen.

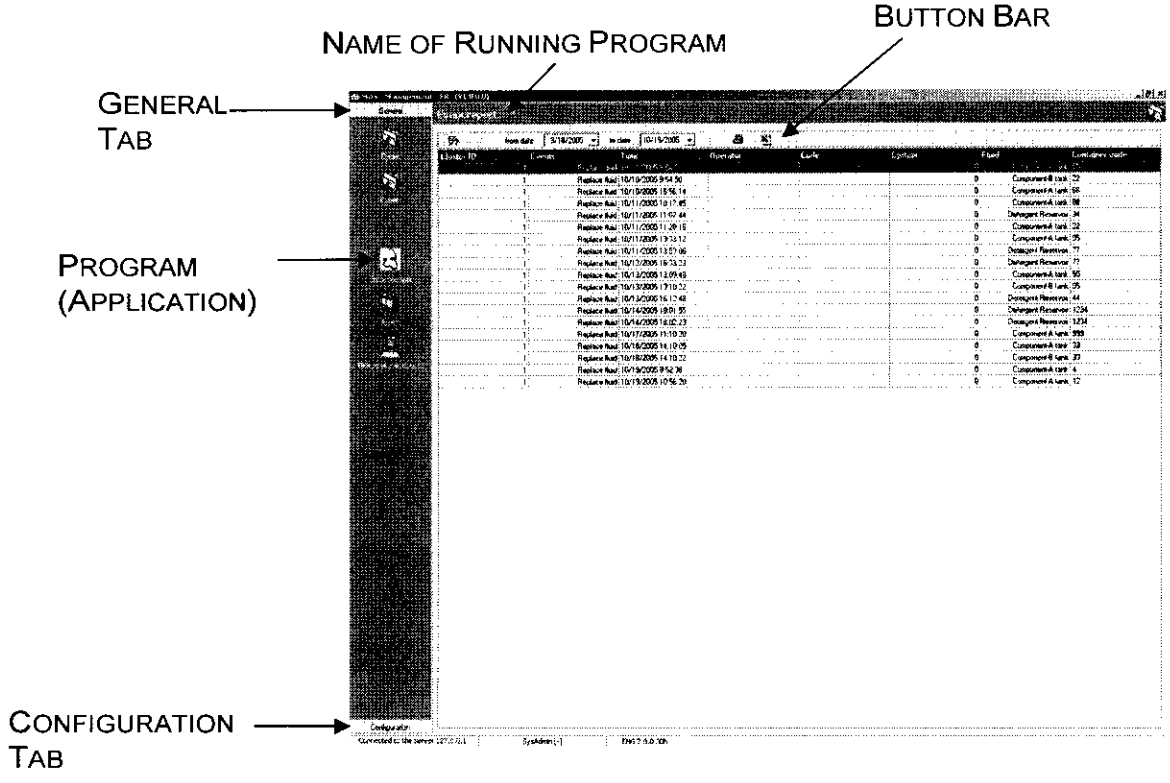


Figure 4 Management Screen

General Applications

There are five general applications:

1. **Cycles** collects information from the disinfection programs. Specific data can be called up from the database with the sort and search options.

2. **Events** gathers data from non-program activities, such as fluid changes.

3. **Instruments** maintains data relating to instruments and endoscopes.

4. **Users** stores data on MDS operators and other authorized personnel who may work with the MDS or any peripheral hardware or software.

5. **Physician/Assistants** is a database used to identify physicians and other medical personnel who use endoscopes for patient examinations.

Configuration Applications

There are two configuration applications:

1. **Programs** provides an overview of the programs and the relevant settings.

2. **Systems** is where all machine settings are entered. These settings are mostly for maintenance and calibration.

Setup

The Management software is delivered with many base settings already established. However, before the MDS can be released for use, the hospital administrator or service technician must enter customer-specific data for the following:

- Instruments (if different from those already in the base settings)
- Users
- Physicians/Assistants

Network availability of the MDS management program is the responsibility of the hospital data center. The hospital administrator is the one who enters user login names, access options, and access rights. You also set the passwords which are distributed to

other users. It is your responsibility to keep the passwords confidential to protect the data and to meet all legal obligations. Forms are provided so that you can collect all the necessary information if the data is not available at a single location.

Note: File the forms in a safe location so that you maintain a record of the passwords that you assign. There is no other method available to retrieve passwords.

The following sections provide detailed instructions to assist you in entering data specific for your facility.

Navigation

The name of a button usually appears if you mouse over it. Information on the function of buttons unique to the program is described below. Buttons with a commonly understood function, such as **Save** are not covered.

Select: Press the arrow at the top right of a list to selection from a drop-down list.

Sort: Sort the information in any column by pressing the arrow at the top right of the column. By pressing the arrow again, the sequence is reversed. For example, sort alphabetically A to Z, or Z to A.

Export: Send a copy of the data to a CD or other external media.

Import: Retrieve stored data from another location.

Printing

To print specific lists from various applications, press the **Print** button. Properties and settings are specific for your printer. See your printer user manual for additional information.

Data Management

Caution ***Importing or modifying data may result in its loss. Backup your data regularly and verify that only one management application is active when data is modified.***

BACKUPS

All data should be backed up on a regular basis. Follow the procedures established by your facility for scheduling and storing backups.

MDS data is stored on the PC hard drive. Backups may be saved to a CD, diskette, memory stick, or an external server: Depending on the application, backups are created by the following steps:

1. Click the **Save** or **Save As** button
2. Copy the file(s) to the desired location via Windows Explorer.

IMPORTING DATA

Only MDS-specific files such as program parameter sets, endoscope codes, and user information can be imported. Two file formats are available:

- XLS = Microsoft Excel files
- TXT = Comma Separated Values (CSV) text files

1. Click on the **Import Data** button .
2. When the Import Data Wizard screen appears, select the file format of the original application. For example, to reset the edited list, the original destination file should be given as source file:
    - For Excel: Data file-1-MDS.xls
    - For Word: Data file–1-MDS.txt
3. If the system parameters have changed, all LIO applications must be restarted.

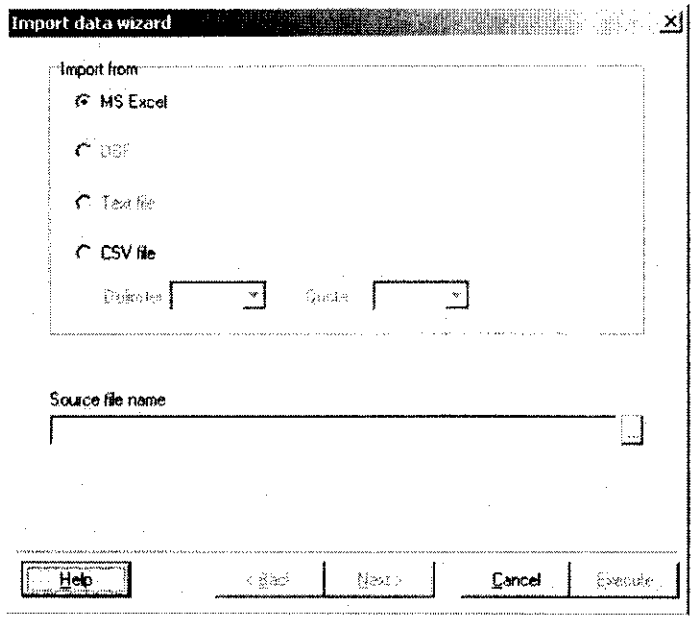


Figure 5 Import Data Wizard

EXPORTING DATA

Data can be exported only if the **Export Data** button is present in the button bar.

1. Click the **Export Data** button so the Export Dialog screen appears.

2. Using the menu, select the formats appropriate for the application (program) to which the file will be transferred. The file name is entered in the input line under Destination File. For example, to process a data file which may be re-imported later, the file name can be used as the destination file name:

   - For Excel: Data file-1-MDS.xls
   - For Word: Data file–1-MDS.txt

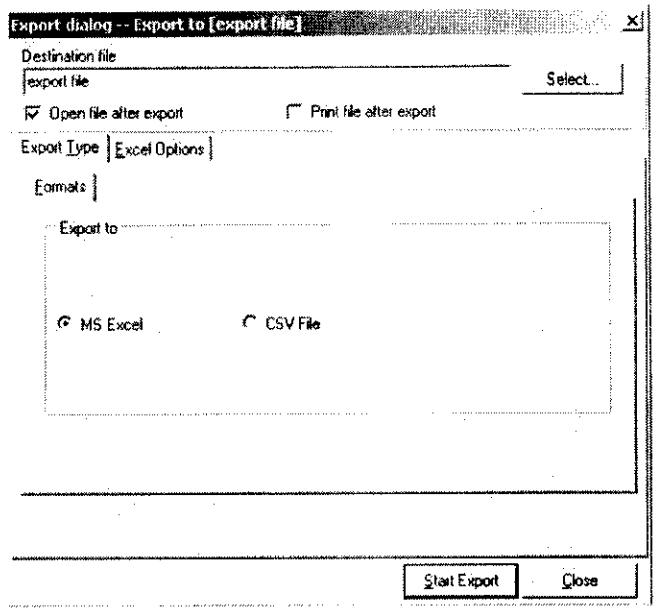


Figure 6 Export Dialog Window

STANDARD CODING

Developing a System

When assigning ID codes to operators, physicians, and instruments, it is best to develop a system for assigning numbers. For example, you may wish to start each ID with a letter that signifies the type of code:

A = Assistant

E = Endoscope code

O = Operator

P = Patient (if applicable)

R = Reservoir (if applicable)

S = Specialist (physician)

It is also advisable create a system that leaves several open numbered positions for each category, so that new IDs can be added in the future.

Endoscopes should have watertight, adhesive labels printed with their ID code. Affix the labels so that the ID can be read while the endoscope is lying in the MDS rinse basin.

Bar Codes (Optional)

With the optional bar code reader, IDs can be quickly and easily entered into the system. After establishing a coding system, create bar code labels for the endoscopes and operators. For ease of use, a human-readable code or name should be printed along with each bar code.

Endoscope bar codes should be attached to the instrument with watertight, adhesive labels. Operators may wear their bar code on a badge or wrist band.

You may also create bar codes for physicians and assistants. Print the codes on a piece of paper for easy reading by the operator and the bar code reader.

I-Dent System (Optional)

The I-Dent system is another optional method to quickly and easily enter endoscope and operator IDs. To prepare the system, assign the appropriate ID codes, print labels, and assemble the tags. Be careful to document the information so that the correct tag and label are placed on the correct endoscope or operator wrist band. The tag holder on the endoscopes must be placed so it can be read by the sensor while the instrument is in the MDS rinse basin. If you don't know a particular tag code, it can be read at the MDS machine. Proceed as follows:

1. Launch the LIO software.
2. Double click on the Expert Operation icon in the top right of the screen.
3. Enter your login name and password.
4. Click on the Tag icon to cause the Read screen to appear.
5. Hold the tag in front of the reader.
6. After the tag number appears on the monitor, add it to your documentation.

ENDOSCOPE REGISTRATION

Categorizing Endoscopes

WARNING *Incorrectly categorizing an endoscope may result in incomplete disinfection. If you have questions about an endoscope, contact the endoscope manufacturer or technical service for advice.*

The MDS has different programs for different types of endoscopes. The objective is to monitor only those channels that are connected, preventing the generation of incorrect failure messages. Each endoscope requires a specific connector block and a specific parameter set. Reference the Endoscope Hook-up guide to identify the endoscope that you are using and the appropriate connector block and parameter set to use. Failure to sue the correct connector block and parameter set can result in an endoscope that is not disinfected properly and therefore should not be used on a patient. If you are uncertain about the correct channel setup of an endoscope, call technical support for assistance.

Entering Data

WARNING *Endoscope codes are unique, and can be assigned once only. If a single endoscope must be registered under two different programs, then it must be done under different codes.*

DATA FIELDS

Endoscopes can be registered as single units or defined sets. The following data is entered:

- **Code** is a short ID number used for quick recognition. It is applied to the control head.
- **Endoscope Type** provides a reference to a defined parameter set.

- **Connection Block** is the part number for the connection block.
- **Brand** is the name of the endoscope manufacturer.
- **Bar Code** (optional) is the human-readable information in the endoscope bar code.
- **Type Number** is the model of endoscope.
- **Serial Number** is the manufacturer-assigned identification number on the endoscope.
- **Internal ID** is the hospital identification number for the endoscope. The internal ID is printed on the cycle log.
- **Tag** (optional) is the human-readable information encoded in the identification chip.
- **Memo** is a field where extra information can be entered as text.

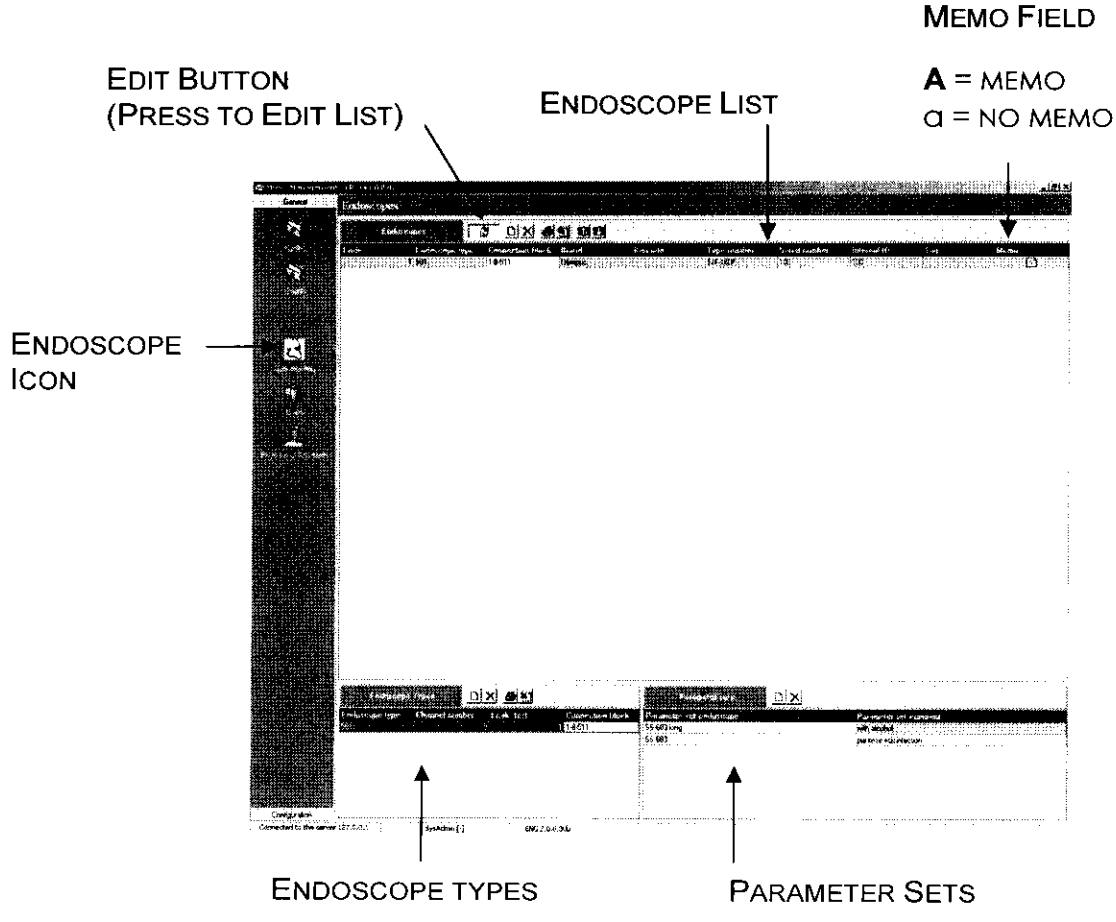


Figure 7 Endoscope Fields

ADDING ENDOSCOPE TYPES

Before entering data for specific endoscopes, the endoscope types must be entered:

1. Click on the Edit icon to enable editing.
2. Click on the **New** button at the top of the Endoscopes Type window at the lower left of the screen. An empty input line appears.
3. Place the cursor in the Endoscope Type field and enter the appropriate data.
4. Move the cursor to the next field and continue entering data in all applicable fields.
5. Click on the Edit icon to disable editing.

Note: There is no Save button. Data is saved only if you click or move the cursor to another field in the list.

ADDING PARAMETER SETS

Different types of endoscopes can be linked to a parameter set in the disinfection program. A standard disinfection program is then provided. These are the most common types of endoscopes:

- Bronchoscope
- Colonoscope
- Cystoscope
- Duodenoscope
- Gastroscope

Reference the Hookup Application Guide for the applicable hookup part number and parameter set.

Additional parameter sets may be required upon acquiring new or additional endoscopes.

To add a new parameter copy the parameter set to the program Files/MDS/Import folder. Open the Management program using the shortcut in the MDS folder on the desktop. Select the configuration tab and select programs. Click on the Import Icon . Select the parameter set from the Open Dialog Box.

ADDING A NEW ENDOSCOPE

Information for a new endoscope is entered as follows:

1. Click on Edit Icon to enable editing.

2. Click on the **New** button at the top of the Endoscope field. An empty input line appears.

3. Place the cursor in the Code field and enter the data.

4. Move the cursor to the next field. Click on the arrow on the right side to select the appropriate endoscope type.

5. Continue entering data in all applicable fields.

6. If you wish to add a memo, click on the arrow key to open a small notepad. Type in your memo and click the **OK** button to save.

7. Click on the Edit Icon to disable editing.

ENDOSCOPE SETS

It is possible to disinfect a registered set of endoscopes. The entire set has one endoscope code. A description of the set can be entered in the Memo field.

There are two possible disinfection procedures for endoscope sets:

1. **Individual:** The set is selected as a normal endoscope and runs with the special instrument program. The set must be selected first and any additional selection is not possible.

2. **Combined:** The set is added to an endoscope already placed in the basin and is disinfected along with the endoscope. In this case, the set must be selected last.

Registration is set up as follows:

1. Define the set on the Endoscope Types section of the window.
2. Enter the following data:
   a. Code = "10" followed by the serial number.
   b. Endoscope Type = "Set-individual"
   c. Connection Block = (blank)
   d. Brand = Manufacturer's name
   e. Bar code = "10" followed by the serial number
   f. Type number = Type number
   g. Serial number = Serial number on the endoscope
   h. Internal ID = Internal ID for the endoscope
   i. TAG code does not need to be entered.
   j. Memo = a description of the set

ENDOSCOPE REPLACEMENT

If an endoscope is replaced by a new one, data traceability may be lost. There are two solutions:

1. **Consecutively number the endoscope codes.** Although the old endoscope is no longer used, the code and data remain stored in the system.
2. **Create a Memo report.** The information for the replaced endoscope is noted in the memo field along with the replacement date.

New endoscope data are entered via the endoscope registration.

EDITING DATA

To change any information already entered, do the following:

1. Click on the Edit Icon .
2. Click on the field to be modified and enter the new information.
3. Select another field to save the data.
4. Click on the Edit Icon to disable editing.

DELETING DATA

To completely remove an endoscope and all the information entered for it, follow these steps:

1. Click on the Edit Icon to enable editing.
2. Click on the line to be deleted in the overview list.
3. Click on the **Delete** button.
4. A window opens asking for confirmation. Click **OK** to delete the information. Click Cancel to go back without deleting any data.
5. Click on the Edit Icon to disable editing.

USER (OPERATOR) REGISTRATION

Users/Operators

Users are the people who have access to the system data and operate the MDS machine. For security and data protection, operator access is limited to specific programs and functions.

For each operator the following data can be entered:

- Name
- Login
- Group
- Bar Code
- Tag
- Personal Code or Employee Number
- Password

Note: Passwords consist of numbers only.

User Groups

User groups are set up to establish access rights for different types of operators. A user may actually operate the MDS to disinfect endoscopes, or may use the data stored. The following groups are standard:

- Hospital operator = Daily operator
- Hospital maintenance = Hospital technicians and maintenance
- Hospital Administrator = System manager able to add to and update MDS system database
- Supplier R&D = Supplier system management

- Supplier maintenance = Field technician
- Supplier production = Manufacturer production personnel

The software is supplied with a number of base settings for these groups. They can be changed by the system administrator and new groups may be added.

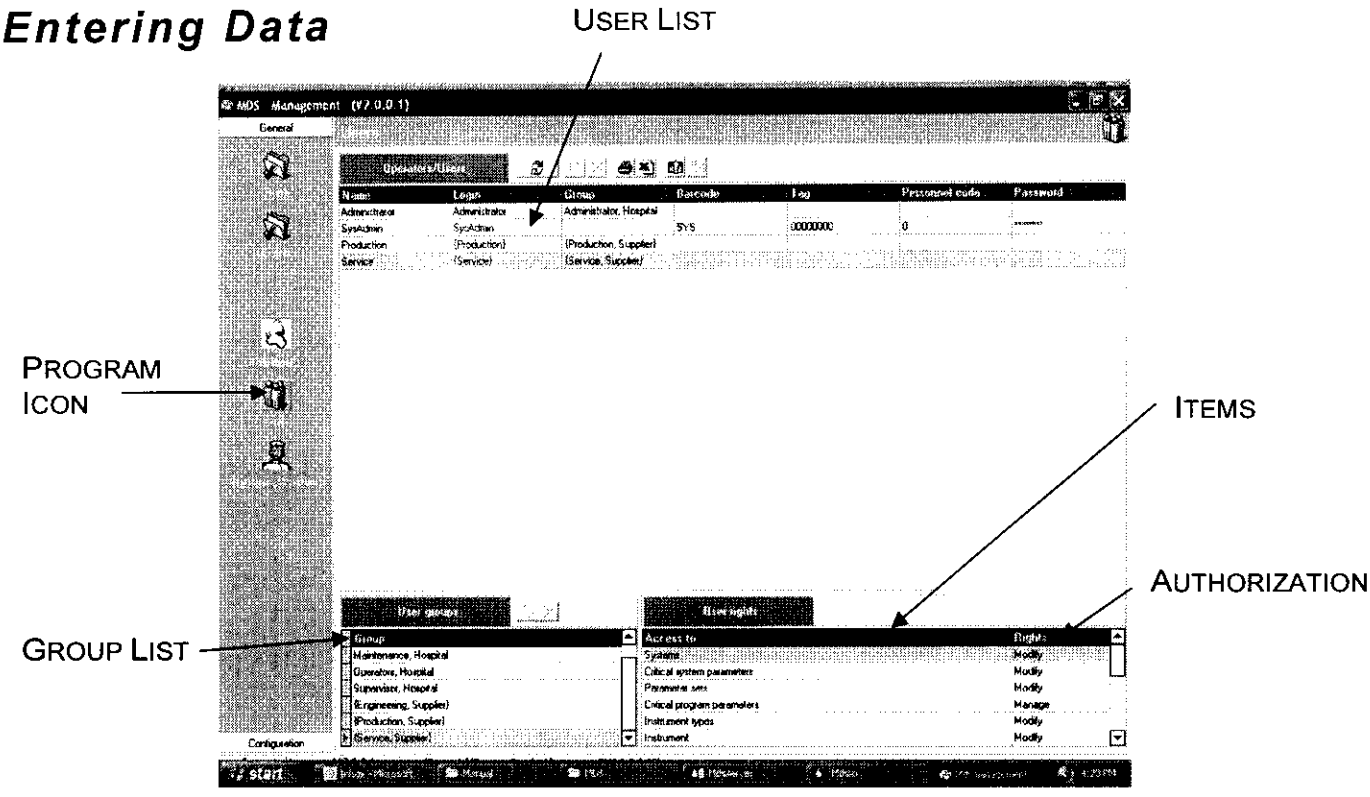


Figure 8 Users Screen

ADDING A NEW USER

To add a new user, follow these steps:

1. Click on the Edit icon to enable editing.
2. Click on the **Add** button to add an empty record at the top of the list.
3. Position the cursor in the first field and enter the appropriate information.
4. **Name:** Complete user name.

5. **Login:** Login in name
6. **Group:** Select the appropriate group for this user.
7. **Tag:** Chip number for I-Dent system.
8. **Personal Code:** Employee number, bar code number, or other ID.
9. **Password:** Personal access code.
10. Click on another line to save the data.
11. When completed, click on the Edit Icon to disable editing.

CHANGING USER DATA

To modify user data, follow these steps:

1. Click on the Edit icon to enable editing.
2. Select the field to be changed and enter the new information.
3. Click on another line to save the data.
4. Click on the Edit icon to disable editing.

DELETING USER DATA

To delete a user profile, follow these steps:

1. Click on the Edit Icon to enable editing.
2. Select the line to be deleted in the overview list.
3. Click on the **Delete** button.
4. When a confirmation window opens, click **OK** to delete the user, or click **Cancel** to go back without deleting the information.
5. Click on the Edit Icon to disable editing.

PHYSICIAN/ASSISTANTS REGISTRATION

General Information

Under Doctors are listed the people who have a connection to the patient and endoscope, but who are not actively involved in the disinfection process. Because they do not operate the MDS, they have no user rights on the system.

For the doctor or assistant the following data can be entered:

- Internal ID such as employee number
- Name
- Bar Code
- Type (Physician or Assistant)

Note: If an MDS operator assists in a patient examination, then the operator's name must be registered as an operator *and* as an assistant.

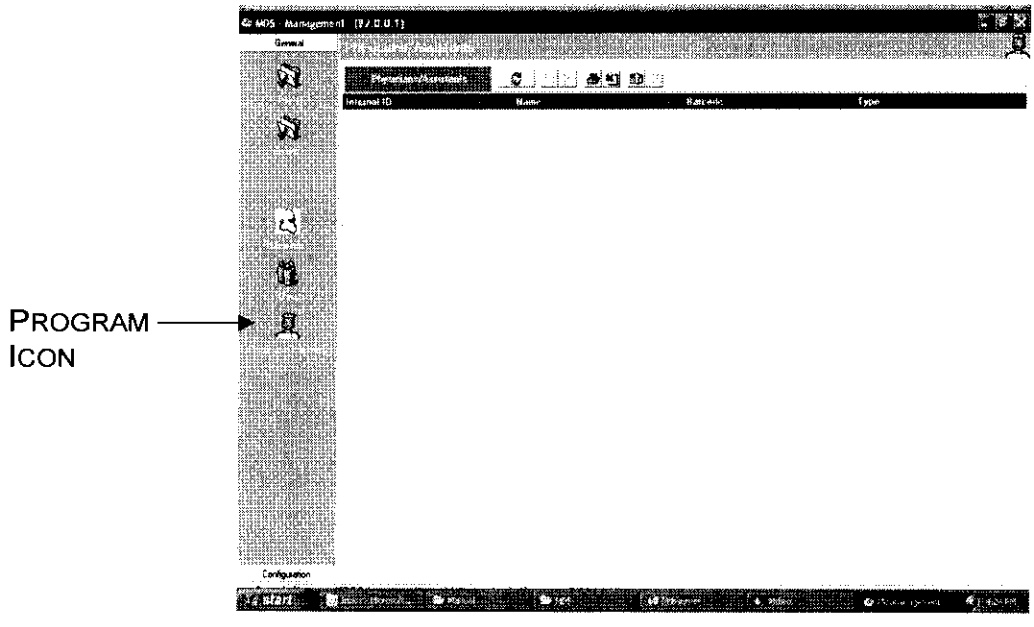


Figure 9 Physician and Assistant Window

Adding Physician Information

Doctor and Assistant information is entered by doing the following:

1. Click on the **Physician/Assistants** icon on the left side of the screen.
2. Click on the **Edit** icon at the top of the window if editing is turned off.
3. Click on the **New** button at the top of the window. A new, empty input line appears.
4. Place the cursor in the Internal ID field and enter the appropriate information.
5. Continue to enter data in the fields.
6. In the Type field, click on the arrow mark and select **Specialist** (physician) or **Assistant** (other medical personnel present at the patient examination).

Changing Physician Information

To change existing information, do the following:

1. Click on the field to be modified and enter the new information.
2. Press **Enter** to save the data.

Deleting Physician Information

To completely delete a physician ID, follow these steps:

1. Select the line to be deleted and press the **Delete** button.
2. When a confirmation window opens, press **OK** to delete the information or **Cancel** to go back without deleting.

REPORTS

Introduction

By clicking on the **Cycles** icon on the left side of the Management General window, program data can be called up. The information is based on the cycles run and data entered.

If the database is large, searching specific items may be time consuming. Non-applicable criteria can be excluded. A selection can be made from:

- Date or time period
- Machine number
- Operator
- Patient
- Program level

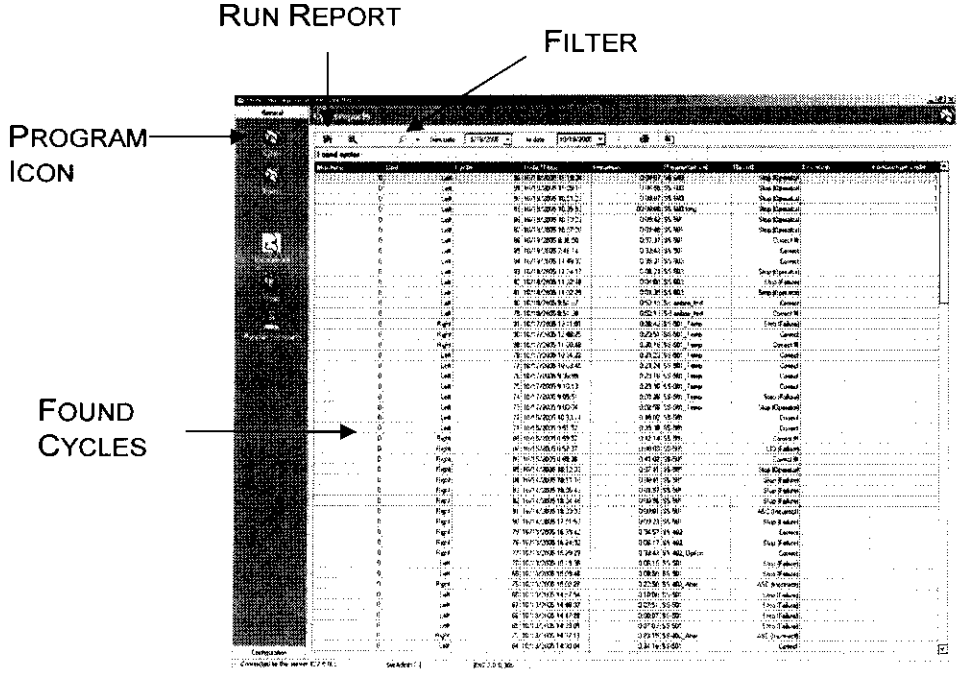


Figure 10 Report Screen

Selecting Report Criteria

TIME PERIOD SELECTION

1. Narrow down your search criteria by gathering data from a specific time period.
2. With buttons "`from date`" and "`to date`" select the dates for your report.
3. Click on the arrow key to the right of each date window.
4. Select the desired start and end dates from the calendars that pop up.
5. Press the **Run** button to run the report.

NARROW CRITERIA

1. The overview report is easier to read if it is shorter and more concise. To narrow or filter your search criteria, press the arrow key beside the **Filter** button, and chose the desired selection in the menu.

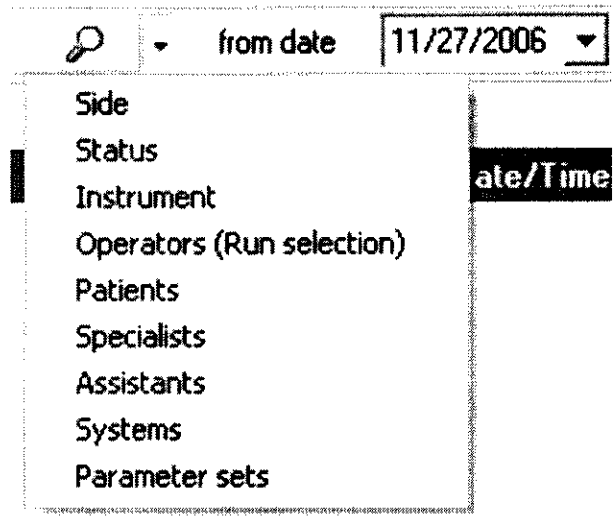


Figure 11 Narrow Criteria

2. In the window that opens, chose the selections which you want displayed.

3. For the status selection, for example, you can choose the following items.

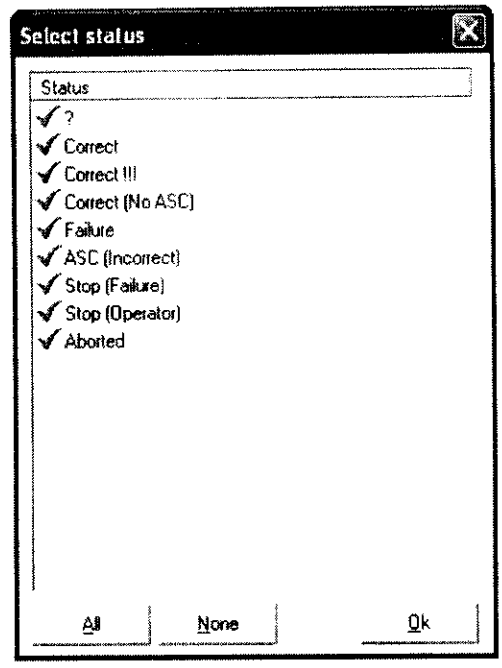


Figure 12 Status Selection

4. Double click on an item to select it or to cancel the selection.

5. Press **OK** and **Run** to run the report.

6. If a selection is active, then the icon changes to to indicate that a selection has been implemented.

7. A selection can be made from:

   - Assistants
   - Endoscope code
   - Operators
   - Parameters
   - Left or right side of the MDS
   - Patients
   - Physicians
   - Run status
   - Systems

Run Report

By pressing the **Run Report** button, the report overview is set up and the report is shown on the screen.

1. Click on the upper blue bar to sort the list in the appropriate column. Click again to reverse the selection.
2. The data of each run goes horizontally by line.
3. Double click on a line if more information is desired. The screen run details are displayed.

Run Details

In the Run Details field, a number of columns are included with specific run data.

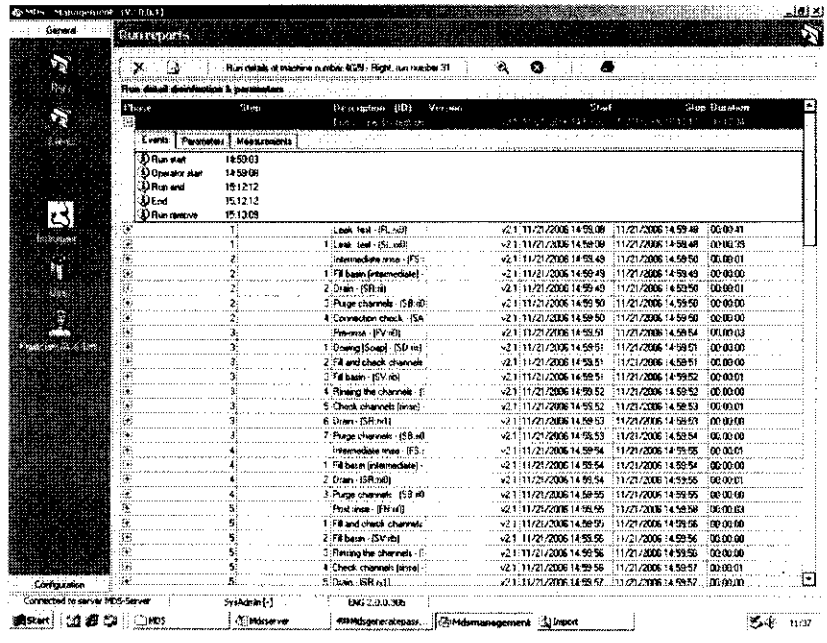


Figure 13 Run Details

- The button displays the details for all steps. While the button minimizes all details.
- Press the plus sign to the left of each step to see more information, or press the minus sign to close the step overview.
- Errors are indicated with the symbol.

EVENTS

The Events overview is accessed from the icon on the left side of the Management General screen.

1. The selected time period is set from the buttons "`from date`" and "`to date.`"

2. Pressing the **Selection** button retrieves the overview.

3. To simplify the selection, click on any column to sort the data.

PROGRAM ICON

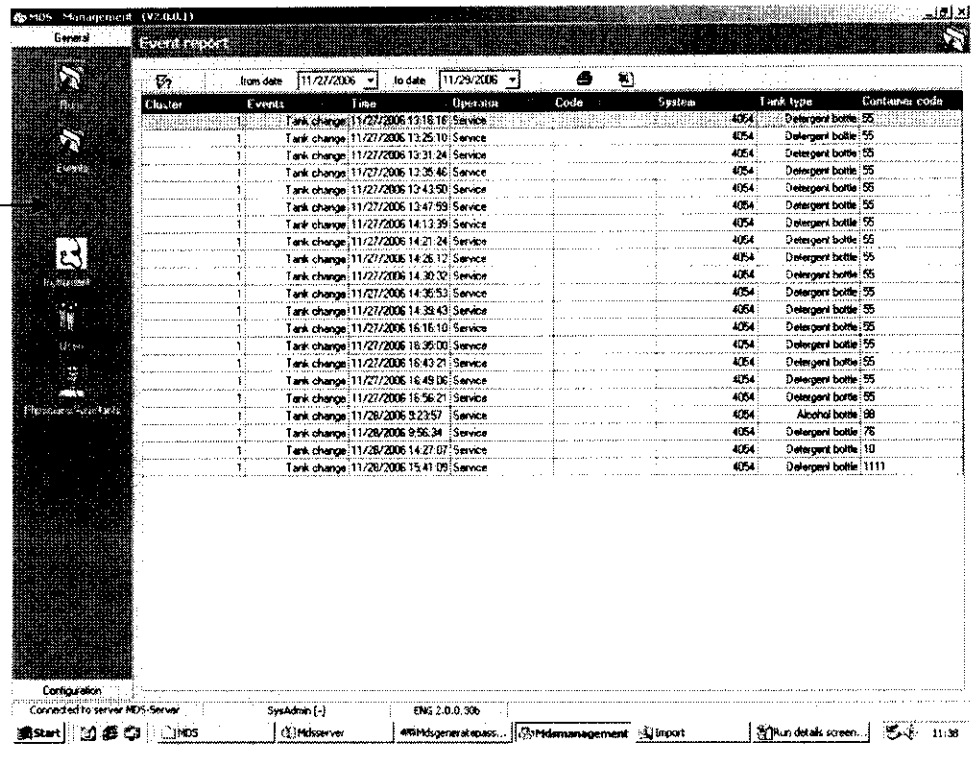


Figure 14 Events Overview

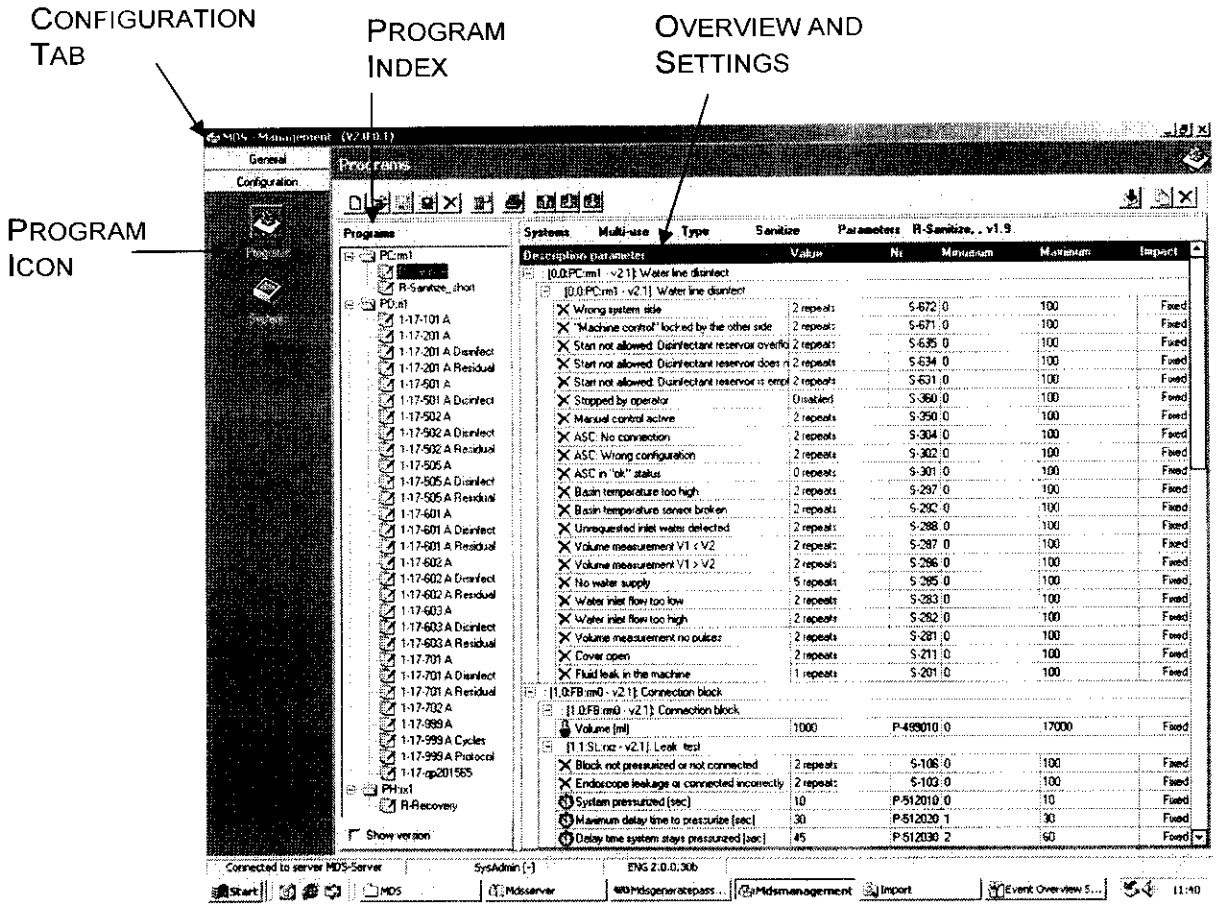


Figure 15 Programs Screen

The program window shows a list of program folders. The folders are labeled with the following codes:

PD Instrument disinfection programs

PH Recovery program after an interrupted disinfection

PC Water line disinfect parameter sets

To select a specific program, follow these steps:

1. Click the plus sign in front of a folder to view the programs inside.
2. Select the program you want by clicking on the name.
3. Click on the **Open File** button.
4. The parameter overview and settings for the program appears in the next window to the right.

SYSTEMS

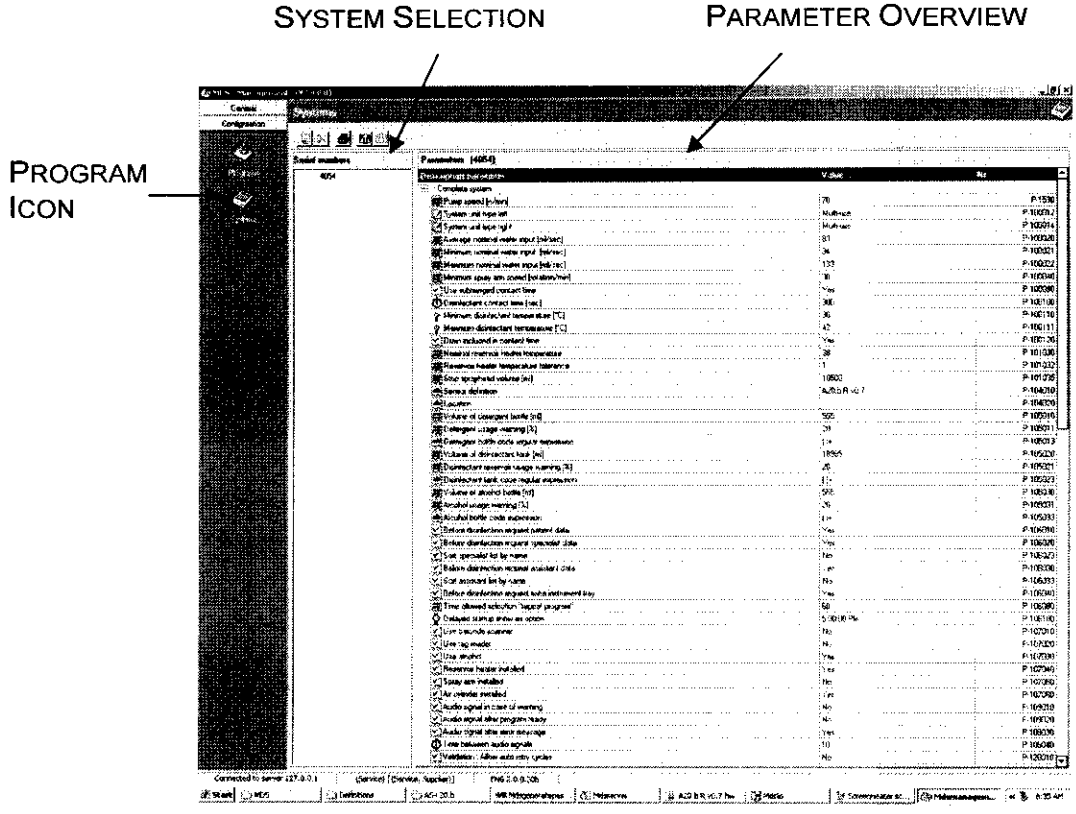


Figure 16 System Window

System settings may be adjusted as desired with the Server application. Some settings may require calibration before use.

The system overview gives one or more machine numbers, which via the server application are connected to the central management database.

MDS machines are selected by their serial number. This can be found on the name plate inside the front door. To select a machine and its parameters, follow these steps:

1. Select the machine by clicking on the serial number in the System Overview window.

2. Click on the **Open** button on the icon bar.

3. The parameter overview appears in the Parameter Overview window.

4. A description of each parameter function appears in the tables below.

Table 1 System Parameters

Parameter	Function
For patient disinfection data call-ups	If set to "Yes," the requirement to enter patient data is activated and appears on the screen.
Specialist/assistant	If set to "Yes," the requirement to enter physician or assistant data is activated and appears on the screen.
Sort list by name	If set to "Yes," overviews for physicians and assistants are sorted alphabetically by name in the selection screen. If set to "No," the overview is sorted by number.
Time allowed for selection (seconds) (Repeat Program)	If a run did not proceed correctly, then the program can be restarted. If this occurs within the time input, then all input data is automatically re-entered, except the operator login and password.
Audio signal	If set to "Yes," an audible signal sounds for a warning, error, and when the program is done.
Reservoir Heater Installed	If set to "YES", the reservoir heaters are enabled.
Drain included in contact time (rinse)	If "YES", then contact time is measured as the basin drains during the rinse phases.
Drain included in contact time (disinfect)	If "YES", then contact time is measured as the basin drains during the disinfection phases.
Delayed startup show as option	Set the time when the delayed startup option will be displayed when setting up a disinfectant cycle to run.

Table 2 Left/Right Parameters

Parameter	Function
Machine program	Choose the machine disinfection program from the parameter sets
Restore program	The program to implement after a system failure. Choose from the restore parameter sets: E (single),or R (recirculation).
Machine program (Monday through Sunday)	Select the day to automatically execute the machine cleaning program.
Machine program (time period)	Start time for the automatic start. Either basin may have a delayed start of up to two hours.
Reservoir heater schedule (Monday through Sunday)	Select the day to automatically start the reservoir heaters.
Reservoir Heater Start Time	Start time for the scheduled reservoir heater.
Reservoir Heater Stop Time	Stop time for the scheduled reservoir heater.
Water line disinfect program parameter set	Parameter set to be used when water line disinfect program has been scheduled.

LIO EXPERT OPERATION

Introduction

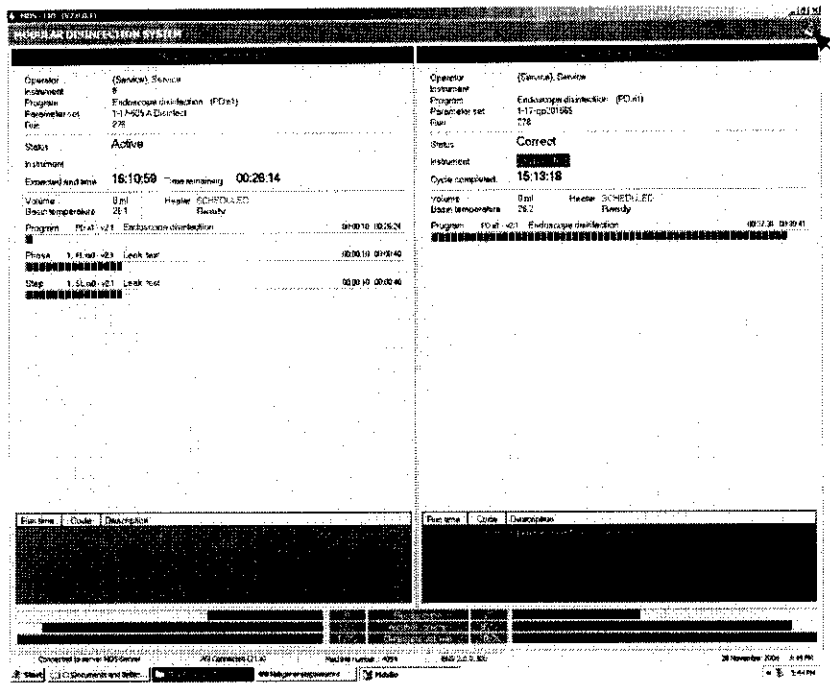


Figure 17 MDS LIO Window

Expert Operation is a special application of the LIO program. It is used to carry out operations that fall outside the normal use of the MDS.

Expert Operation is launched by double clicking on the icon in the upper right of the window. A login window appears and shows the names of the operators who have access rights to the program.

306

System

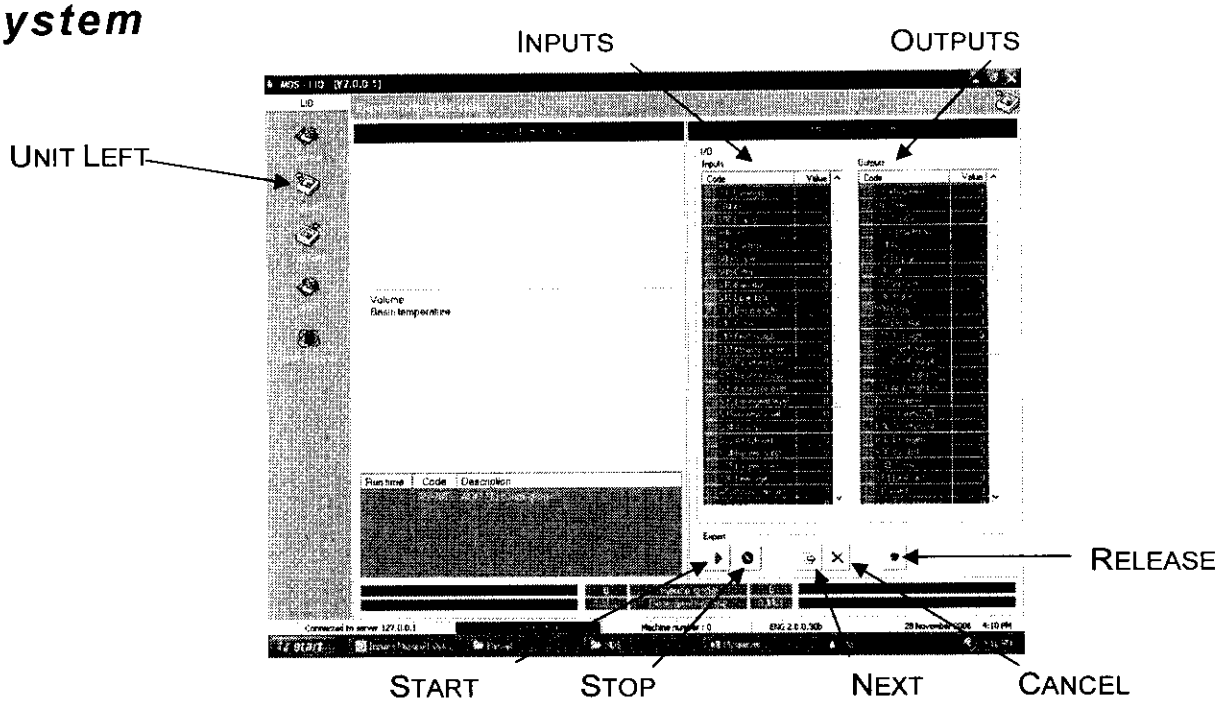


Figure 18 Unit Left Expert Operation

- Selecting either the **Unit Left** or **Unit Right** icons allows that half of the system to be monitored and manually operated:
- If a sensor sends a signal to an input, the indicator turns green.
- Double clicking on an output allows it to be manually driven. The indicator turns red when the output is activated and report *W-800* appears in the status field.
- Pressing the **Start** or **Stop** button affects an already active program. Clicking the **Stop** button sends the program to the final step in the process.
- Pressing the **Next** Step button sends the program to the following step in the process. This is useful when simulating an error report or testing a component after a repair.
- **Release All *(Reset)*** must be pressed to undo all manual operations. You may also need to double click on the output.

WARNING *The Reset button must be pressed before another program can be started.*

ASi Master (ASC)

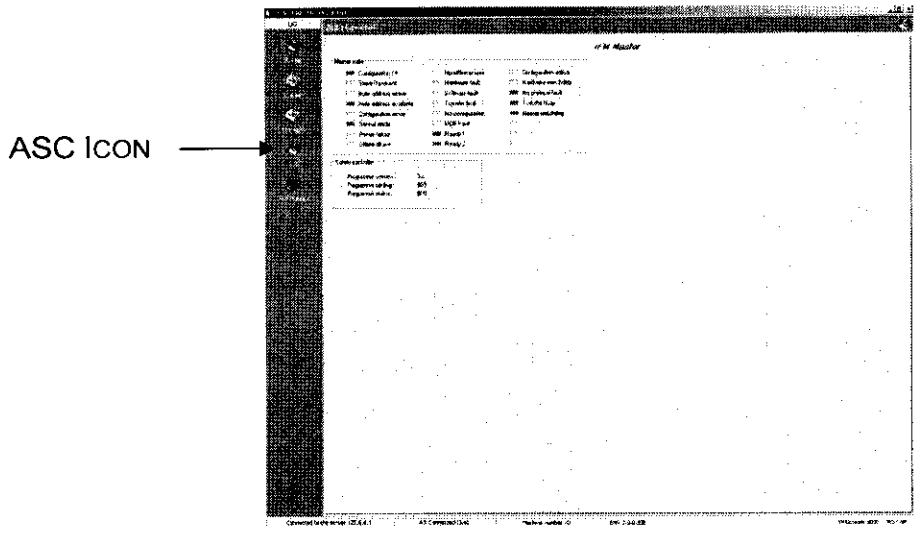


Figure 19 ASC Window

Clicking the ASC icon opens the status overview for the ASi master and safety controller.

In the overview, master states are marked gray, green, or red. A state that is gray is inactive, a green state is running OK, and deviations are red.

In the safety controller field, the version number of the safety controller software is reported.

Inputs/Outputs

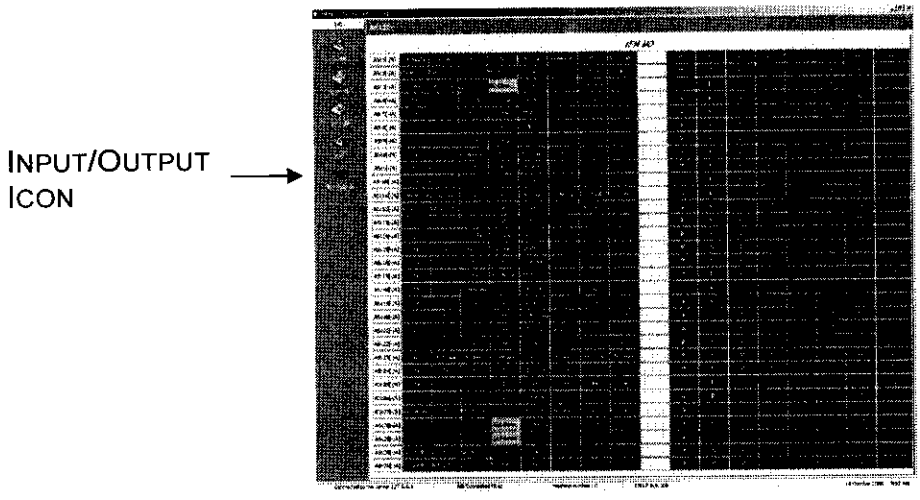


Figure 20 Input/Output Window

You can see input and output status onscreen by clicking the In/Outputs icon. The data comes from the IFM-ASi controller in the MDS machine. The controller communicates between the MDS machine and the PC.

Tag

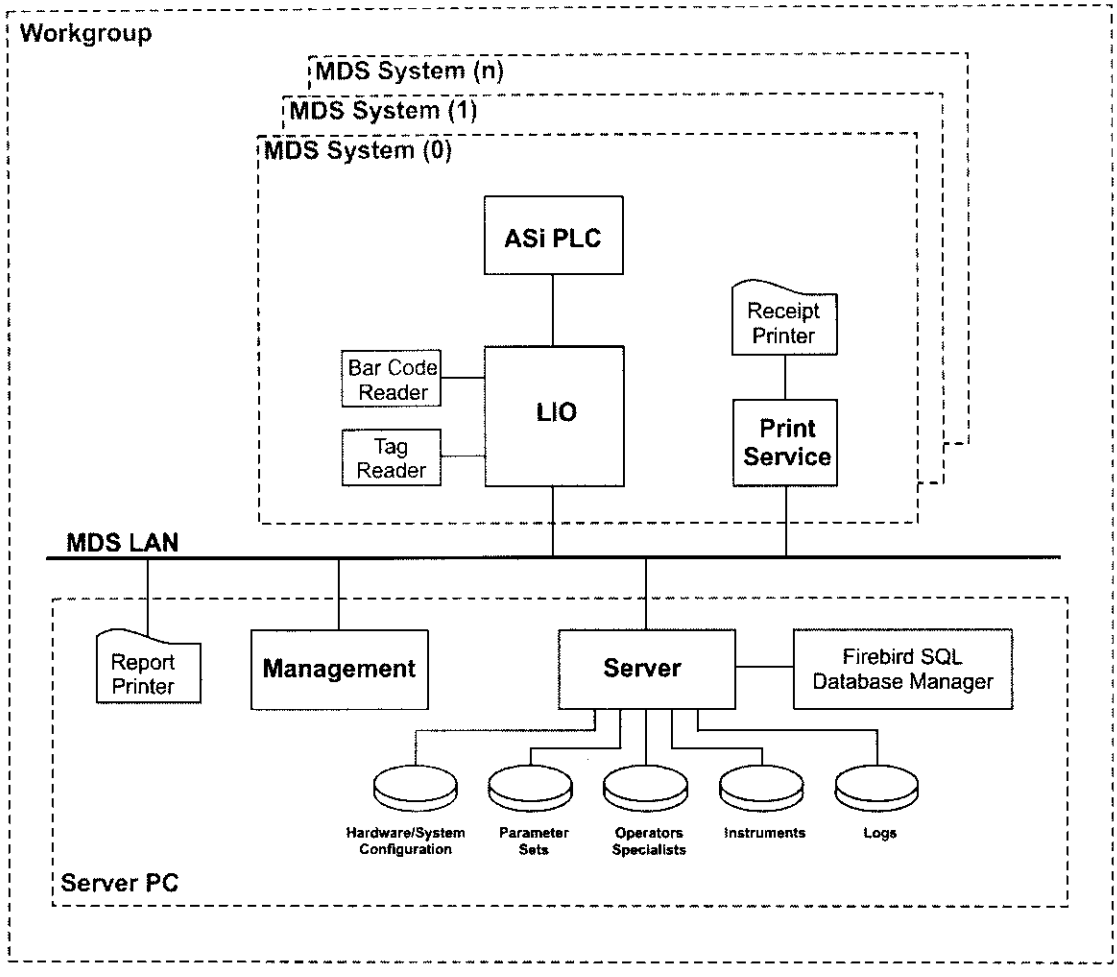
The Tag window allows you to find the number of a tag chip or to check the operation of a tag reader.

1. Click on the **Tag** button.
2. Move the chip across the reader.
3. Read the number on the monitor.

NETWORKING

The MDS endoscope reprocessor shall be capable of being networked with other MDS units on a local area network. One PC, either part of an MDS unit or a separate stand-alone PC, may be used as the Server. The other MDS units are considered Clients of the Server. The Server PC would run the Server and Management applications and contain the MDS database where all parameters and cycle results are stored. The Clients would run the LIO and Print Service applications. In the way each MDS unit (Client) could independently initiate and execute the Disinfection, Recovery or Water Line Disinfect programs with the cycle results being printed to its dedicated receipt printer, while all access to management and administrative functions (parameters, users, cycle logs, etc.) would only be possible through the one Server PC.

To create a network of MDS units, each MDS unit (Client) and the Server PC must be connected to a hub and assigned a unique IP address. In addition, a unique Workgroup must be created and each Client and the Server PC must be configured to belong to this Workgroup. Once the Workgroup has been established, the appropriate applications of the MDS PC software can be loaded on each unit, starting with the Server PC. During the install, when asked for the "Server name or server IP-address" each unit should enter the computer name of the Server PC. Finally, each Client should allow the MDS folder, where the MDS executable applications reside, to be "shared". All these changes can be done through the Control Panel of each unit.



A detailed step-by-step description of the network setup process is described below:

Network Setup

This set of Instructions describes how to set up a network of MDS reprocessors as clients connected to a single server PC. It is assumed the PCs are running Windows XP and the MDS PC software has not been installed on any of the machines.

SERVER (DATABASE PC)

1. Connect PC to HUB
2. Go to Control Panel → System → Computer Name
3. Click on "Change…", and change name if necessary. (MDS-Server)
4. Select "Workgroup" and enter "MDS". Click "OK".
5. Go to your Control Panel → Network Connections.
6. Click with your right mouse button on "Local Area Connections" and select "Properties".

7. Select "Internet Protocol (TCP/IP)" and click on "Properties".
8. Select "Use the following IP address" and enter an IP address, for example 254.169.0.1 (MDS-Server). If Subnet Mask is blank, enter something like 255.255.255.0, then click "OK".
9. Install the Server, Management, Database Server and Setup Database applications from the MDS PC software setup file. Enter the computer name when asked for the "Server name or server IP-address".

CLIENT (MDS SYSTEM)

10. Connect PC to HUB
11. Go to Control Panel → System → Computer Name
12. Click on "Change...", and change name if necessary.
13. Select "Workgroup" and enter "MDS". Click "OK".
14. Go to your Control Panel → Network Connections.
15. Click with your right mouse button on "Local Area Connections" and select "Properties".
16. Select "Internet Protocol (TCP/IP)" and click on "Properties".
17. Select "Use the following IP address" and enter an IP address, for example 254.169.0.10 (MDS 4010). If Subnet Mask is blank, enter something like 255.255.255.0, then click "OK".
18. Install the LIO and Print Service applications from the MDS PC software setup file. Enter the name of the Server PC (MDS-Server) when asked for the "Server name or server ip-address".
19. Go to the MDS folder in Program Files, click on your right mouse button and select "Sharing and Security...".
20. Select "Share this folder" and click "OK".

BOTH PCS (SERVER AND CLIENT)

21. Restart Windows on both PC's.
22. Open "My Network Places" from your desktop and click on "Entire Network --> Microsoft Windows Network". You should see a MDS folder with two PC's inside (the shared MDS-Server and MDS-4010 folder).

SERVER (DATABASE PC)

23. Start the server application on the Server PC.

CLIENT (MDS SYSTEM)

24. Start LIO on the MDS PC.

If the MDS PC software has previously been installed on the MDS reprocessor units, these instructions should be followed instead of those described above.

Both PCs (Client and Server)

1. Take a HUB
2. Connect each PC with a network cable to the HUB
3. Make sure both computers have a unique computer name (for example MDS-Server and MDS-4010)
4. Go to your Control Panel → System → Computer Name
5. Click on "Change...", and change name if necessary.
6. Select "Workgroup" and enter "MDS".
7. Go to your Control Panel → Network Connections.
8. Click with your right mouse button on "Local Area Connections" and select "Properties".
9. Select "Internet Protocol (TCP/IP)" and click on "Properties".
10. Select "Use the following IP address" and enter an IP address, for example 254.169.0.10 (MDS 4010). If Subnet Mask is blank, enter something like 255.255.255.0, then click "OK".
11. Do the same for the second PC (or server), for example 254.169.0.1 (MDS-Server). If Subnet Mask is blank, enter something like 255.255.255.0, then click "OK".

Client (MDS System)

12. Go to "Start" on your taskbar and select "Run..." and then enter "regedit"
13. In the Registry Editor open <HKEY_LOCAL_MACHINE> → <SOFTWARE> → <MDS>
14. Select "LIO" folder and double click on "ServerAddress". Change the "value data" to the name of the server (for example MDS-Server)

15. Select "Management" folder and double click on "ServerAddress". Change the "value data" to the name of the server (for example MDS-Server)
16. Go to the MDS folder in Program Files, click on your right mouse button and select "Sharing and Security...".
17. Select "Share this folder" and click "OK".

Both PCs (Client and Server)

18. Restart Windows on both PC's.
19. Open "My Network Places" from your desktop and click on "Entire Network --> Microsoft Windows Network".
20. You should see a MDS folder with two PC's inside (the shared MDS-server and MDS-4010 folder).

Server (Database PC)

21. Start the server application on the Server PC.

Client (MDS System)

22. Start LIO on the MDS PC.

NOTES

Appendix A

REGISTRATION FORMS

Sample registration forms are provided for system administration functions.

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INSTRUMENT REGISTRATION FORM A-3
OPERATOR REGISTRATION FORM A-5
PHYSICIAN REGISTRATION FORM A-7

NOTES

MODULAR DISINFECTION SYSTEM

INSTRUMENT REGISTRATION FORM

Endoscope code .....

Instrument type .....

Brand .....

Bar code .....

Type code .....

Serial number .....

Internal ID .....

Tag code .....

Date .....

Endoscope code .....

Instrument type .....

Brand .....

Bar code .....

Type code .....

Serial number .....

Internal ID .....

Tag code .....

Date .....

Endoscope code .....

Instrument type .....

Brand .....

Bar code .....

Type code .....

Serial number .....

Internal ID .....

Tag code .....

Date .....

NOTES

MODULAR DISINFECTION SYSTEM

OPERATOR REGISTRATION FORM

Name .....

Login Name .....

Group .....

Bar code .....

Tag code .....

Staff code .....

Password .....

Date .....

Name .....

Login Name .....

Group .....

Bar code .....

Tag code .....

Staff code .....

Password .....

Date .....

Name .....

Login Name .....

Group .....

Bar code .....

Tag code .....

Staff code .....

Password .....

Date .....

NOTES

MODULAR DISINFECTION SYSTEM

PHYSICIAN REGISTRATION FORM

Name .....

Staff code .....

Bar code .....

Specialist or Assistant .....

Date .....

Name .....

Staff code .....

Bar code .....

Specialist or Assistant .....

Date .....

Name .....

Staff code .....

Bar code .....

Specialist or Assistant .....

Date .....

Name .....

Staff code .....

Bar code .....

Specialist or Assistant .....

Date .....

Name .....

Staff code .....

Bar code .....

Specialist or Assistant .....

Date .....

NOTES

Appendix B

WARRANTIES

CONTENTS

I. LIMITED WARRANTY B-2
II. LIMITATION OF REMEDY B-2
III. WARRANTY DISCLAIMER B-3

NEW EQUIPMENT LIMITED WARRANTY

Limited Warranty

Medivators Reprocessing Systems, a division of Minntech Corporation (the "Company"), warrants that the endoscope reprocessor and associated equipment it manufactures (collectively, the "Products") will conform to the Company's written specifications and will be free from defects in material and workmanship under normal use and service for a period (the "Warranty Period") of fifteen (15) months from date of shipment from the Company or one (1) year from the date of installation, whichever occurs first.

Notwithstanding anything herein to the contrary, the Warranty Period for consumables and accessories supplied by the Company, including, but not limited to, endoscope hook-ups, filters, printers, printer supplies, test strips, and accessory bags, is ninety (90) days from the date of installation.

The warranty does not cover, and the Company will have no warranty obligation whatsoever with respect to, any damage to a Product caused by or associated with: (i) external causes, including without limitation, accident, vandalism, acts-of-God, power failure or electric power surges, (ii) abuse, misuse or neglect of the Product by the customer or use of unauthorized third party filters or other consumables and accessories, (iii) usage not in accordance with product instructions, (iv) the customer's failure to perform required preventive maintenance, or (iv) servicing or repair not authorized by the Company.

Limitation of Remedy

The warranty obligation of the Company hereunder is limited to the repair or replacement (at its option) of the defective Products or any parts it deems defective. This will be customer's exclusive remedy for a covered defect.

In order to recover under the warranty, the customer must notify the Company in the state (if in the U.S.A.) or the country of installation of the defect (describing the problem in reasonable detail) prior to the expiration of the warranty period and within thirty (30) days of discovery of the defect. Upon receiving the Company's official "return goods authorization" (RGA), the customer must promptly return the defective part or Product to the Company (or the service center indicated on the RGA), freight and insurance prepaid. The Company will not be responsible for any damage during shipment.

Warranty Disclaimer

THE WARRANTY ABOVE IS THE COMPANY'S ENTIRE WARRANTY OBLIGATION TO THE PURCHASER OF PRODUCTS. IT IS IN LIEU OF ALL OTHER WARRANTIES OF THE COMPANY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND THE COMPANY DOES NOT REPRESENT OR WARRANT THAT ANY PRODUCT WILL MEET CUSTOMER'S REQUIREMENTS. THE COMPANY'S RESPONSIBILITY FOR DEFECTS IN A PRODUCT IS LIMITED SOLELY TO REPAIR AND REPLACEMENT AS SET FORTH IN THIS WARRANTY STATEMENT.

TO THE EXTENT PERMITTED BY LAW, THE COMPANY SHALL NOT, UNDER ANY CIRCUMSTANCES, BE LIABLE TO CUSTOMER FOR CONSEQUENTIAL, INCIDENTAL, INDIRECT OR SPECIAL DAMAGES OR LOSSES, INCLUDING WITHOUT LIMITATION, DAMAGES ARISING OUT OF OR IN CONNECTION WITH ANY MALFUNCTIONS, DELAYS, LOSS OF PROFIT, INTERRUPTION OF SERVICE, OR LOSS OF BUSINESS OR ANTICIPATORY PROFITS, EVEN IF THE COMPANY HAS BEEN APPRISED OF THE LIKELIHOOD OF SUCH DAMAGES OCCURRING.

This Warranty gives the customer of Products specific legal rights, and customers may also have other rights which vary from jurisdiction to jurisdiction.

In no event shall the Company's liability exceed the original purchase price of the covered Product.

No representative or agent of the Company has any authority to bind the Company to any other representation or warranty with respect to the Products, and the customer accepts the Products subject to all of the terms above.

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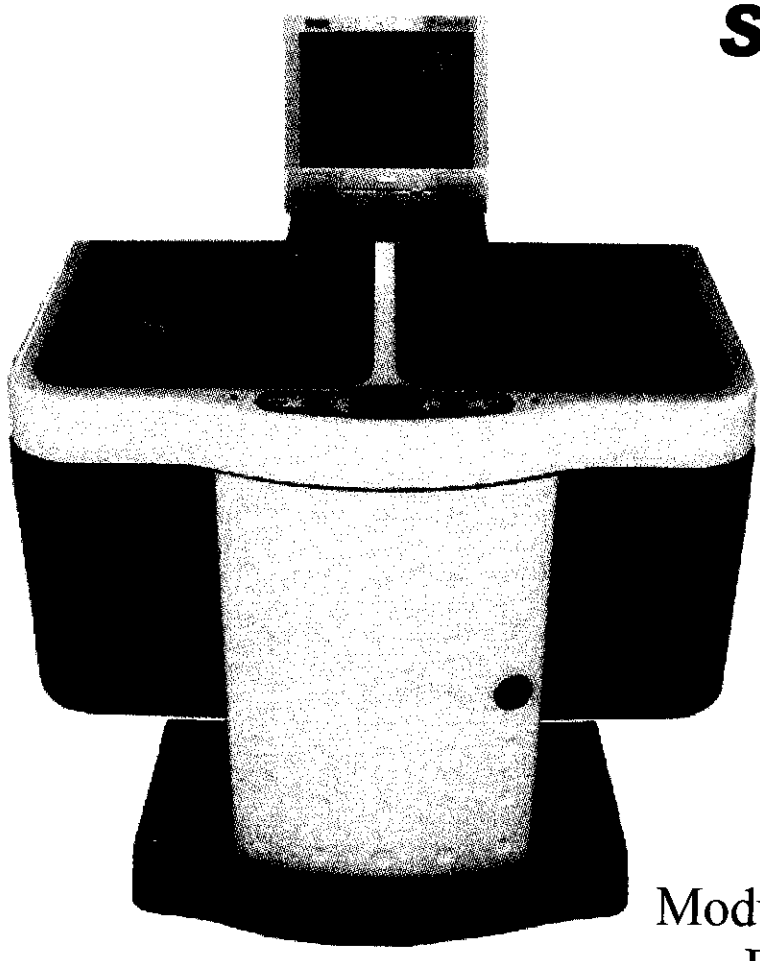
Medivators MDS

Endoscope Reprocessor

Service Manual



Modular Disinfection System
For Multi-Use Chemistry

US version

MEDIVATORS®
REPROCESSING SYSTEMS

50096-653 Rev A

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Chapter 1

OVERVIEW MDS

THE FOLLOWING FIGURES ARE AVAILABLE:

Figure 1 – Hydraulic schematic
Figure 2 – Basin layout
Figure 3 – Channel position connecting plate channels block
Figure 4 – Channels block sensors / valves / slaves
Figure 5 – Machine outputs and sensors
Figure 6 – Machine maintenance points.

THE FOLLOWING TABLES ARE AVAILABLE:

Table 1 – Outputs
Table 2 – Inputs
Table 3 – Overview Diagram Codes – Filters
Table 4 – Overview Diagram Codes – Regulators
Table 5 – Overview Diagram Codes – other components
Table 6 – Overview Maintenance Consumables
Table 7 – Maintenance Sets
Table 8 – Tools
Table 9 – Miscellaneous
Table 10 – Overview Spare Parts
Table 11 – Guidance and Manufacturer's Declaration – Electromagnetic Immunity
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Table 13 – Guidance and Manufacturer's Declaration – Electromagnetic Immunity
Table 14 – Recommended Separation Distance Between Portable and Mobil RF Communications Equipment and the MDS
Table 15 – Test Conditions: Cables
Table 16 – Test Conditions: Accessories

SENSOR TYPE ABBREVIATIONS

SET	=	Adjustment necessary
RU	=	MDS – Re-use
PS	=	Pressure switch
CB	=	Conductivity board
OS	=	Optical switch
S	=	Switch (pulse)
RS	=	Reed switch
PC	=	Pulse counter
CS	=	Capacity sensor

OUTPUT / INPUT CODES

Table 1 Outputs

Code	Description	
Y01	Drain	
Y02	Water supply	
Y03	Spray head	
Y04	Channel valve:	air
Y05		biopsy
Y06		jet
Y07		suction
Y08		water
Y09		extra
Y10		elevator
Y11	Air purge	
Y12	Disinfectant return	
Y13	Disinfectant supply	
Y15	Air cylinder fill	
Y16	Air cylinder discharge	
P0A	Channel pump	
P0C	Alcohol pump	
P0D	Disinfectant pump	
P0Z	Detergent pump	
Y0D	Air valve cover	
Y0E	Leak test	
Y0F	Leak test vent	
Y0G	Elevator pump	
Y0H	Air purge	
K90	Ventilator	
K01	Heater	

Table 2 Inputs

Code	Description		Type	Set
U01a	Temperature basin		PT-100	X
U01b	Temperature disinfectant reservoir		PT-100	X
S02	Disinfectant quantity		P.S.	X
S03	Detergent pressure switch		P.S.	X
S04	Channels	air	P.S.	X
S05		biopsy	P.S.	X
S06		jet	P.S.	X
S07		suction	P.S.	X
S08		water	P.S.	X
S09		extra	P.S.	X
S10		elevator	P.S.	X
S11	Leak test=		P.S.	X
S12	Basin empty		P.S.	X
S13	Cover		P.S.	X
S14	Basin volume		P.C.	X
S15	Foot switch		S	-
S16	Basin volume		P.C.	X
S17	Minimum level		O.S.	-
S19	Disinfectant reservoir low		R.S.	-
S20	Disinfectant reservoir minimum		R.S.	-
S21	Disinfectant reservoir overflow		R.S.	-
S22	Detergent reservoir empty		R.S.	-
S23	Alcohol reservoir empty		R.S.	-
S24	Alcohol pressure		P.S.	X
S90	Leakage sensor		C.S.	X

Table 3 Overview Diagram Codes - Filters

Code	Description		#
F1	Internal bacteria retentive water filter	0.2 µ	1
F2		0.45 µ	1
F3		1.0 µ	1
F4	Rinsing tank sieve		2
F5	Air flow		2
F6			
F7	Disinfectant		2
F11	Compressor – first		1
F12	Compressor – middle		1
F13	Compressor – final		1
F14	Compressor – air		1

Table 4 Overview Diagram Codes - Regulators

Code	Description	Type	Set
R1	Water supply	Liquid regulator	X
R2	Liquid channels	Liquid regulator	X
R3	Air leakage test	Air regulator	X
R4	Air general	Air regulator	X
R6	Air compressor	Air regulator	X
R7	Leakage test flow	Flow regulator	X
R8	Cover cylinder	Flow regulator	X
R9	Rinsing tank ventilation	Air regulator	X
R10	Water source valve	Liquid regulator	X

Table 5 Overview Diagram Codes – Other Components

Code	Description		#
CV1	Flow return stroke		4
CV3	Filter return stroke		2
PR1	Purge restrictor		2
PH	Metering pump head valve		4
V1	Over pressure valve channel block		2
MV1	Supply tap	(manual valve)	1
MV2	Conversion tap		1
MV3	Vent valve		1
MD1	Speed coupling filter	(manual disconnect)	1
MD2	Speed coupling disinfectant	(manual disconnect)	1
SH	Spray head		2
PR	Pillar o-ring		16
CS	Cover seal		2
LM	Elevator diaphragm		2

Table 6 Overview Maintenance Consumables

Part Number	Description
MF01-0013	F1 – Bacteria filter 0.2 µ
MF01-0015	F2 – Pre filter 1 0.45µ
MF01-0014	F3 – Pre filter 2 1.0µ
3-9-420	F4 – Drain filter
3-9-421	F5 – Air purge filter 0.2µ
2-4-640	F7 – Disinfectant filter
3-9-520	F11 – Regulator filter 0.01µ
3-9-510	F12 – Air pre filter 5µ
3-9-522	F13 – Machine air filter
3-9-500	F14 – Compressor air inlet filter
3-4-261	CV4 – Non return valve compressor
3-6-224	PR1 – Purge restriction 0.74mm orifice
	PH – Metering pump hose coupling
3-2-280	SL – Hose water supply
3-8-110	O1 – O-ring pillar
3-4-411	LM – Elevator diaphragm (VITON)
6-8-300	CS – Cover seal
2-3-222	SH – Spray head assembly
37590-205	- RVS hose clamp in aid of filters 3/8" O.D.

Table 7 Maintenance Sets

Part Number	Description
3-9-452	PO – Intake filter service kit

Table 8 Tools

Description
Torque screwdriver
Screwdriver: Cross PH 1x 35
Screwdriver: Cross PH 1x 80
Screwdriver: Cross PH 2x 35
Screwdriver: Cross PH 2x 100
Screwdriver: Cross PH 2x 300
Screwdriver: Flat 4.0 x 35
Screwdriver: Flat 4.0 x 75
Screwdriver: Flat 5.5 x 100
Screwdriver: Flat 7.0 x 150
Screwdriver: Right-angled flat: 5.5 x 125
Screwdriver: Right-angled cross : 6 x 100
Hollow-head screw wrench set 1.5-2-2, 5-3-4-5-6-8-10
Open-ended ring spanner set 19-17-14-13-12-11-10-9-8-7-55-5
Box spanner: 5.5 x 7
Box spanner: 14 x 15
Drill set: Ø6.8, Ø5.1- Ø5.0- Ø4.9- Ø4.2- Ø2.0- Ø2.7- Ø2.5- Ø2.4- Ø2.3
Water pump pliers
Small point pliers
Small side-cutting pliers
Grip pliers
Fuse pullers
Tie wrap installation tool
Hose-cutter
Hammer
Scissors
Ballpoint pen
Tweezers
"Steel" brush
Automatic center point

Description *(continued)*
Hand pump 0-300 mmHg
Multimeter + temperature recorder
Kocher clamp 2x
Tap holder with tap set: M3/M4/M5/M6
Small knife and large knife
Soldering iron and solder

Table 9 Miscellaneous

Part Number	Description	
--	Loctite 5331	
--	Loctite 577	
--	Silicone kit / transparent	
--	Silicone spray	
--	O-ring filter housing	
--	Hose clips	- Ø 30
		- Ø 100
--	Drainage	- coupling PVC
		- bends PVC
		- valve pieces PVC
--	Curve	- ¾ - ½ EXT-INT
		- ½-1/4 EXT-INT
		- ¼ - 1/8 EXT-INT
--	Silicone kit	-transparent
		-black
--	Paint	-grey
		-green
--	Filler	-glass
		-polyester
--	Tape	-painters
		-linen
		-teflon
		-aluminium
3-1-640	Silicone grease	
--	Citric acid	
--	Teflon tape	
--	PVC glue	
3-1-611	2 K glue (Permabond)	

Table 10 Overview – Spare Parts

Part Number	Description
1-4-112	Assy. Disinfectant block double
1-4-114	Assy. Disinfectant single
1-4-124	Assy. Connecting block – single
1-4-404	Barcode Scanner USB
2-2-305	Main pump 80gr (Wilden pump)
2-2-810	Assy. Foot switch
2-3-222	Assy. Sprayer-2
2-3-310	Assy. Dosing pump
2-3-530	Assy. Air cylinder
2-4-510	Assy. Regulator [Air valves and tubing assy]
2-4-533	Assy. Over-pressure valve
2-4-611	Assy. Heater MDS
2-4-830	Control panel and touch pad
2-5-431	Assy. PT-100 Cable-B
2-5-432	Assy. PT-100 Cable-H
2-5-481	Assy. Led Red/Grn MDS
2-5-600	Assy. Transformer
3-2-310	Screw-in coupling 1/8" 4/6"
3-2-330	Full Screw-in coupling ¼" male connector
3-4-210	Sirai component set D144 solenoid valve NC
3-4-211	Sirai component set D344 solenoid valve NO
3-4-220	Valve Sirai L-180
3-4-260	Component set drainage valve
3-4-410	Pressure switch 25-220mBar
3-4-411	Diaphragm Viton
3-4-412	Pressure switch 80-2000mBar
3-4-414	Pressure switch 12.5-200mBar
3-4-415	Pressure switch 6-75mBar
3-4-416	Pressure switch 12.5-200mBar
3-4-417	Tank empty sensor 2-8mBar
3-4-420	Spring for 304 - 417
3-5-140	ASF Thomas pump 24V DC
3-5-232	Extraction ventilator EBM G2S085-AA-03-01
3-6-223	Pressure Regulator

3-6-321	Gauge 0-1 Bar
3-6-323	Gauge 0-4 Bar
3-6-410	Bimba Cylinder EM 25-80-U
3-8-110	O-ring 008 Viton
4-1-114	ASi In/Out plug (small)
4-1-115	ASi slave out
4-1-116	ASi slave ASi in/out
4-1-118	Connector M12 right-angle AS-i
4-1-119	ASi cable distributor
4-1-450	Controller Cable AS-I serial cable
4-3-213	Solid State Relay 845160
4-3-222	Relay EMG10REL/KSR-G24/1-10
4-3-310	Reed switch Fek-110-Aox
4-3-510	ASi interface PT-100
4-3-511	ASi slave PT-100 Temperature Module
4-3-600	Capacitive sensor
4-3-640	Optical sensor
4-3-650	Flow meter 0.2-10l/min
4-4-130	ASi supply +24V
4-4-140	ASi-interface supply
4-4-142	ASi power supply
4-5-301	Asi PLC controller with 24V/5A
4-5-304	ASi slave 41/40
4-6-242	Fuse 250V-1 6A
4-6-245	Fuse 250V-5A
4-6-248	Fuse 250V-10A
4-6-249	Heater fuse
4-6-320	Heater element Heater band
3-2-252	Hose – silicone: 3.2 x 6.4
3-2-254.1	Hose – silicone: 4.8 x 1.6
3-2-250	Hose – silicone: 1.6 x 5.8
3-2-220.1	Hose – PVS: 4 x 1
3-2-240	Hose – PU: 4 x 1
3-2-210.1	Hose – PVDF: 6 x 1
3-2-222	Hose – drainage drain
4-6-248	Fuse 10A – 250V
3-0-432	Screw – Socket Lead M3x30

3-0-461	Screw – M6x10
3-2-330	MDS coupling for block ¼"
3-2-332	MDS coupling for pump ¼"
3-2-311.1	Coupling for block 1/8"
3-2-500	Coupling for plug 1/8"
3-9-420	Rinsing tank filters
3-9-310	Leakage test pump + pillar
6-8-225	O-ring drainage block 23x28

ELECTROMAGNETIC COMPATIBILITY

This section covers the electromagnetic compatibility (EMC) aspects of the MDS Endoscope Reprocessor.

WARNING *Portable and mobile communication devices can affect electrically-operated medical equipment.*

Medical equipment requires special precautions regarding EMC. The MDS must be installed and put into service according to the EMC information in this section.

Table 11 Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The MDS is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be ≥30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Main power quality should be that of a typical commercial or hospital environment. If you require continued operation during power interruptions, the MDS should be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC voltage prior to application of the test level.

Table 12 Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The MDS is intended for use in the electromagnetic environment specified below. The customer or the user of the MDS should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment—Guidance**
RF emissions CISPR 11	Group 1	The MDS uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The MDS is suitable for use in commercial buildings, but not in domestic establishments or facilities directly connected to the public low-voltage power network that supplies domestic buildings.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 13 Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The MDS is intended for use in the electromagnetic environment specified below. The customer or operator should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz–80 MHz 3 V/m 80 MHz–2.5 GHz	3V 3V/m	Portable and mobile RF communications equipment used near the MDS and its cables should be outside the recommended distance calculated from the equation applicable to the transmitter frequency. Recommended separation distance: d = 1.17 P d = 1.17 P 80 MHz–800 MHz d = 2.33 P 800 MHz–2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the MDS is used exceeds the applicable RF compliance level above, the MDS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MDS.

[b]Over the frequency range 150 kHz–80 MHz, field strengths should be < 3 V/m.

Table 14 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the MDS

The MDS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The MDS customer or operator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MDS as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation distance according to transmitter frequency (m)		
	150 kHz–80 MHz $d = 1.17\sqrt{P}$	80 MHz–800 MHz $d = 1.17\sqrt{P}$	800 MHz–2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.370	0.370	0.737
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EMC testing was conducted with the cables and accessories shown in Table 15 and Table 16.

Table 15 Test Conditions: Cables

Port Type (Name)	Cable Type	Cable Length
4 x AC main supply	Unshielded	1 m
USB printer	Shielded	3 m
Filtration system	Microphone XLR	3 m

Table 16 Test Conditions: Accessories

Accessory	Manufacturer	Part Number
Printer	Epson	M-188B
Printer power supply	Epson	DA-36E24
Air compressor	Jun-Air	OF 302-4S
Command processor	Clevo Promedian	L295P
Water filtration system	Minntech Corp.	2-3-524

Figures MDS

Contents:

Figure 1 Hydraulic schematic

Figure 2 Basin Diagram

Figure 3 Channel positions connecting plate channel block

Figure 4 Channel block sensors / valves / slaves

Figure 5 Machine outputs + sensors

Figure 6 Machine maintenance points

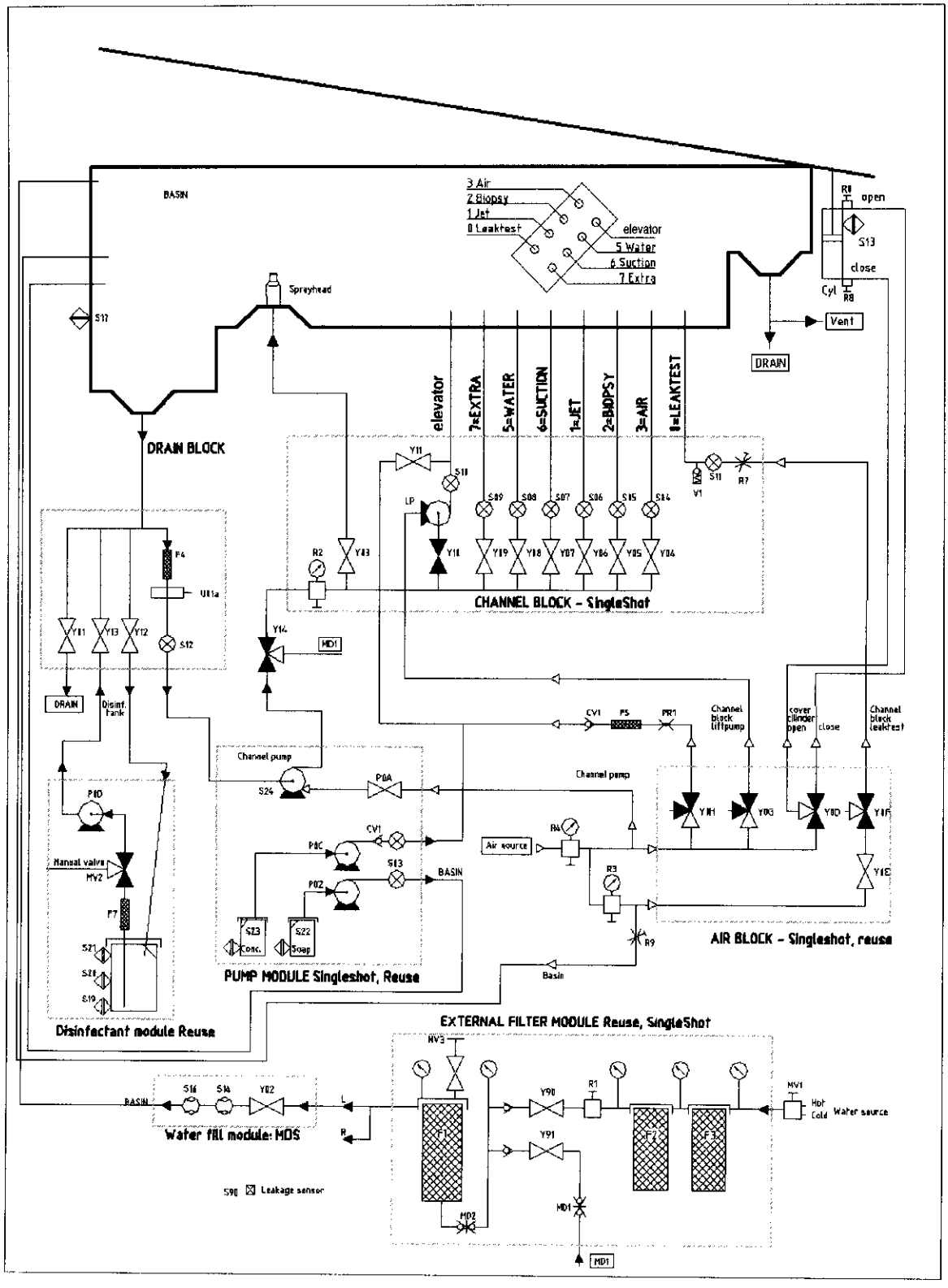


Figure 1. Hydraulic Schematic diagram

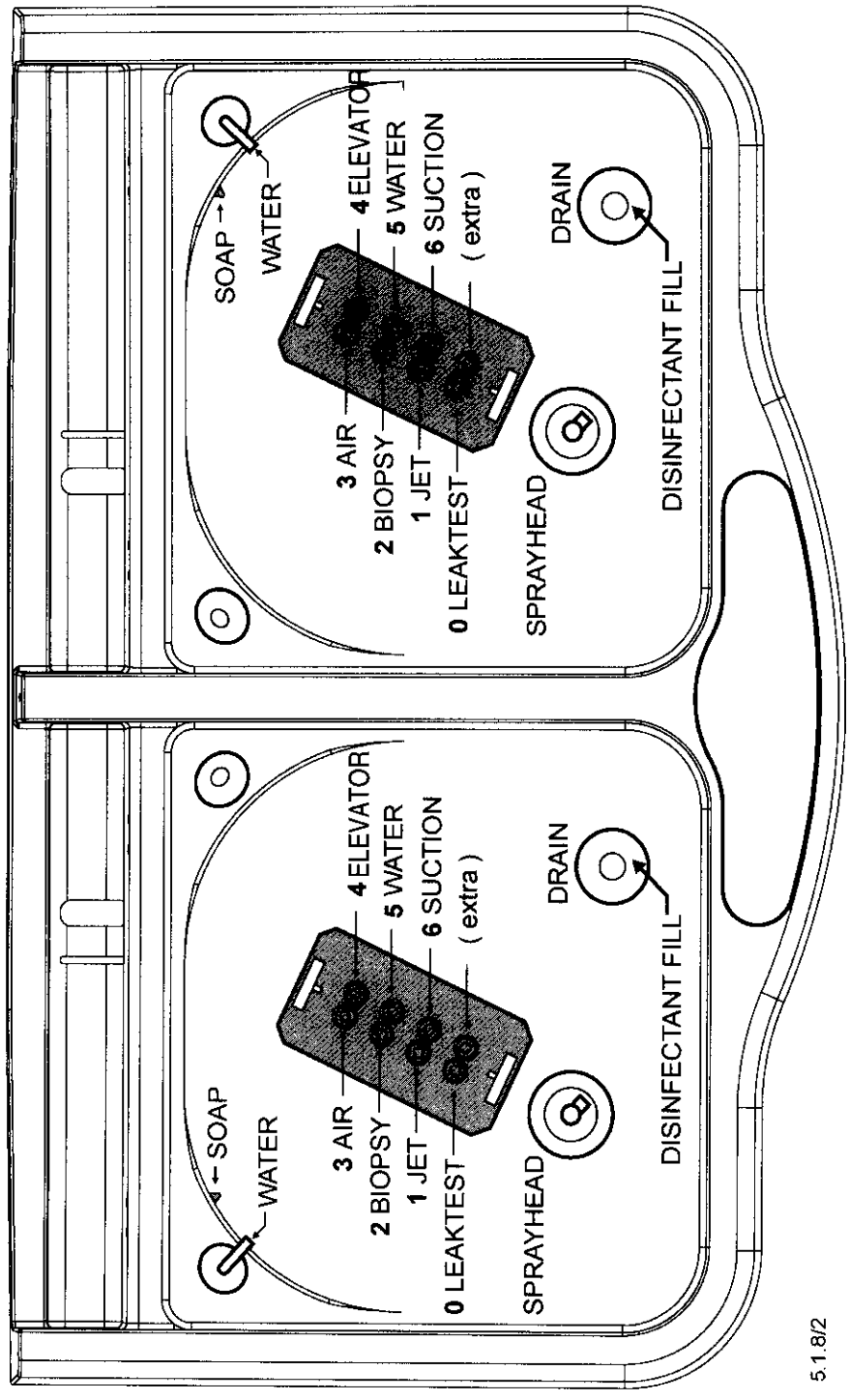


Figure 2. Basin layout

350

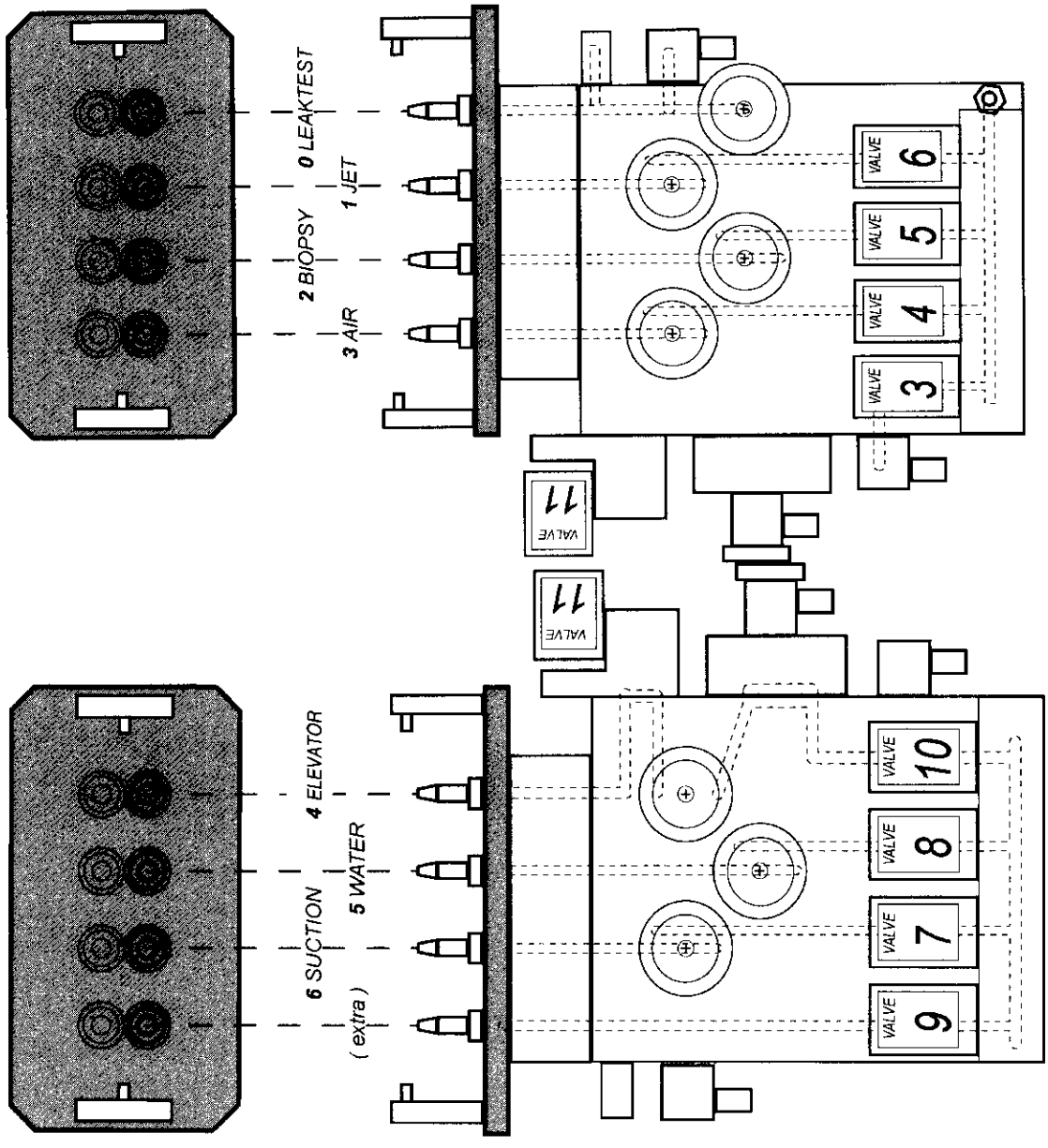


Figure 3. Channel positions connecting plate / channel block

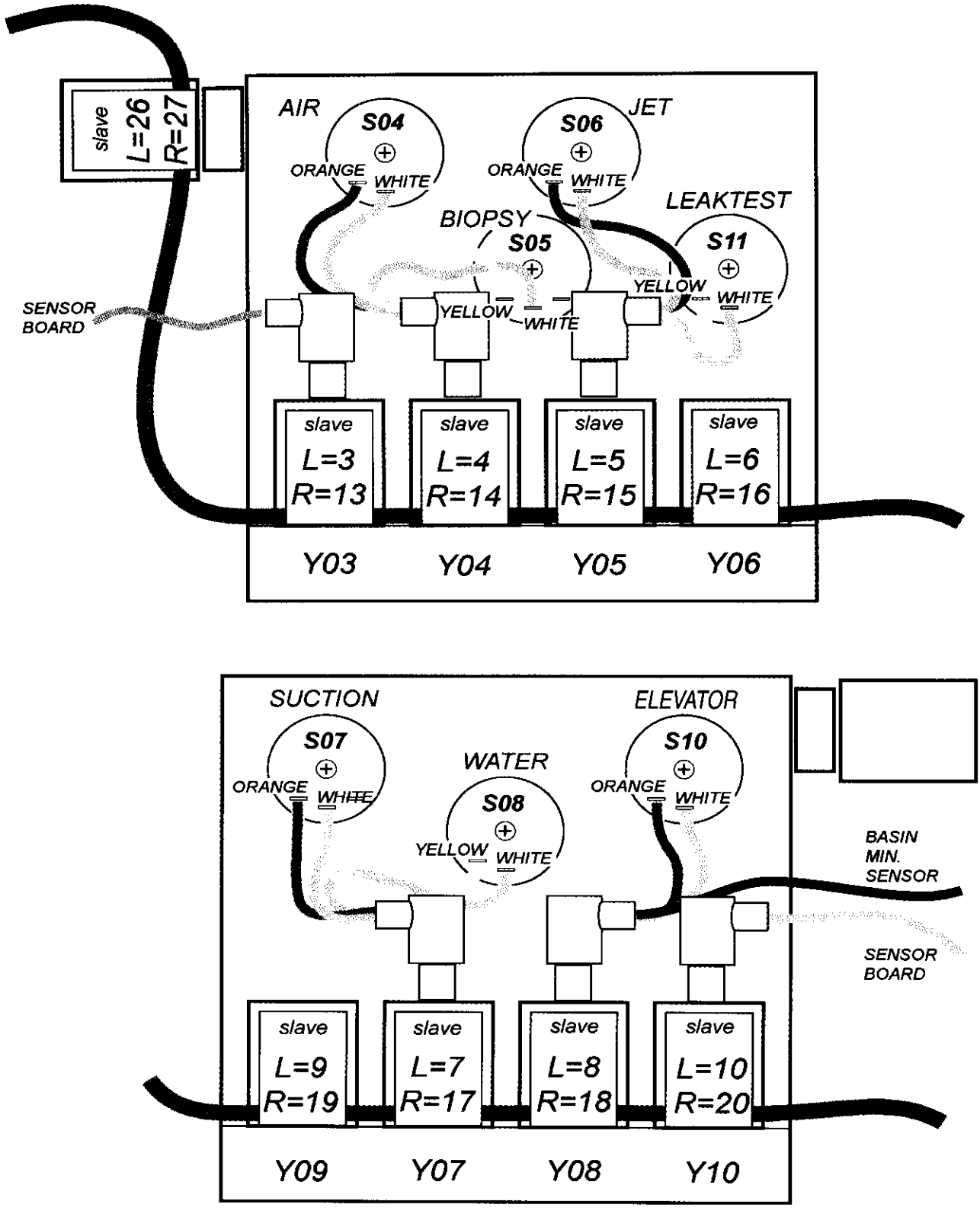


Figure 4. Channel block sensors / valves / slaves

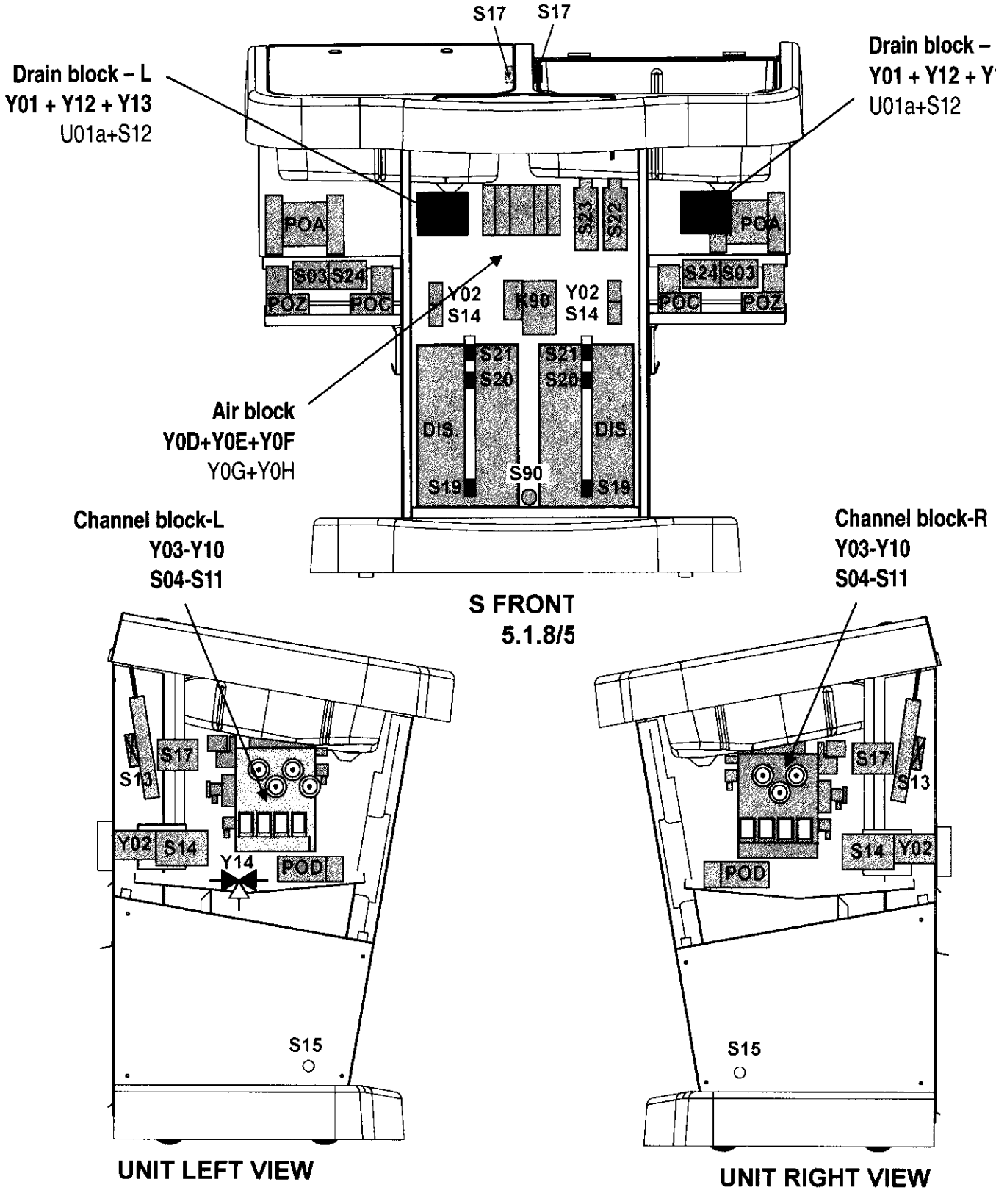
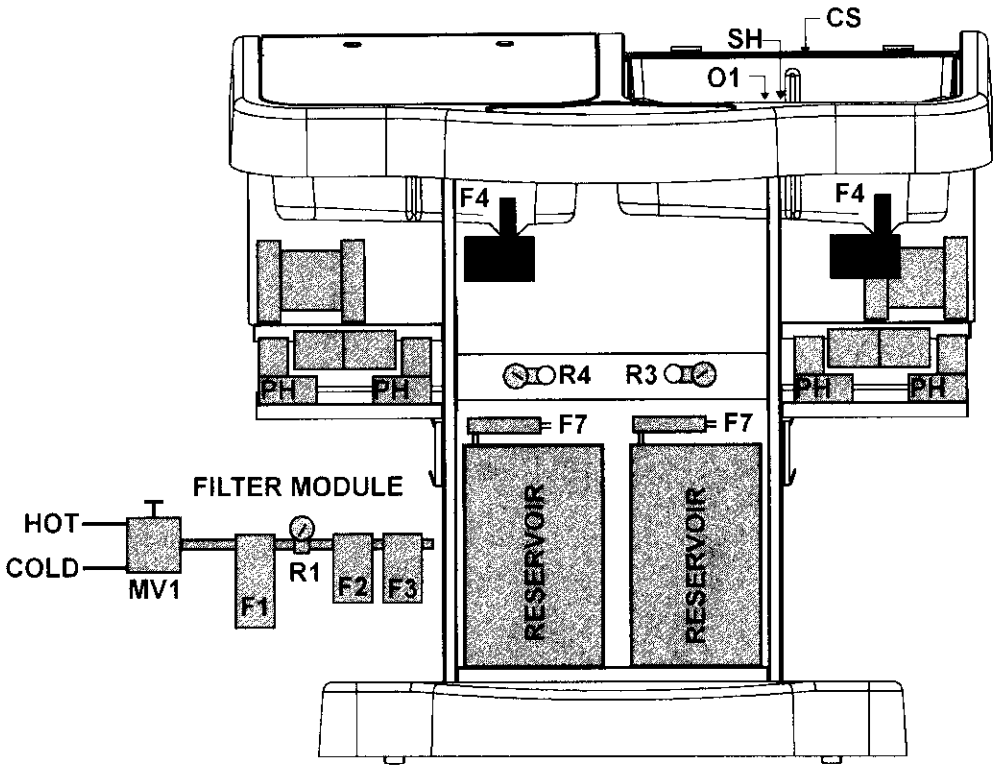
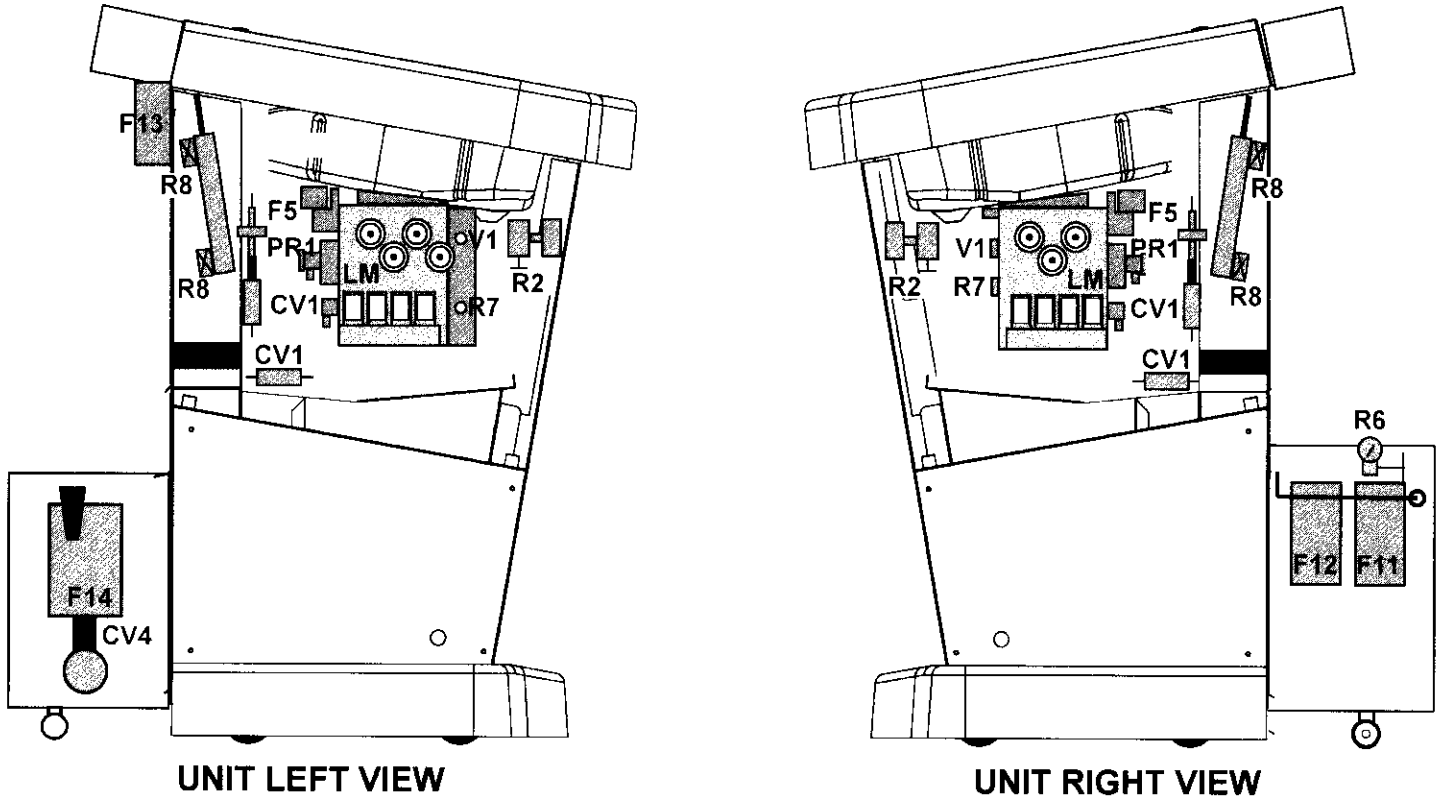


Figure 5. Machine outputs + sensors



MDS FRONT VIEW
5.1.8/6



UNIT LEFT VIEW

UNIT RIGHT VIEW

Figure 6. Machine maintenance points

FORMS

CONTENTS

1. service report
2. installation report
3. maintenance report
4. system check

SERVICE REPORT

SERVICE REPORT – 50096-653

CUSTOMER:

Hospital _____ State: _____

Street Address: _____ Date: _____

Contact Person: _____ Department: _____

Inventory code: _____

MACHINE DATA **Visit Data**

Machine location: _____ Date: _____

Machine Type: _____ Time in: _____

Machine S/N: _____ Time out: _____

Software Version: _____ Technician: _____

ACTIVITIES:

Report: _____

Analysis: _____

Action Taken: _____

PARTS USED

Part No.	Description	Number	Lot No.

SYSTEM DATA

	Side 1	Side 2	Results:
Test Run			
Machine Disinfection			

☐ Data Copy _____ (File Name)

Signature Hospital Contact Signature Service Technician

☐ Warranty ☐ Contract ☐ Invoice

Minntech Contact Information: (763) 553-3300, 14605 28th Avenue North, Mpls, MN 55447

INSTALLATION REPORT

INSTALLATION REPORT

Data

MACHINE TYPE:		**S/N:**	
LOCATION:		**Date:**	

Installation

Electrical 120V:		Compressed Air:		Modem:		Network:	
Filters:		Vent:		Water:		Drain:	
System Setup:				Alignment:			
I-Dent System:				Barcode:			

Block Connections:

Activities

Disinfectant Codes:		Barcodes:	
Operator Codes:		I-Dent Code:	

Note:

Logbook:		Operating Instructions:		Product Info:	

Name Minntech		Name Client:	
Signature		Signature:	

MAINTENANCE REPORT

Maintenance Report

Machine Type:		**Serial Number:**	
Location:		**Date:**	

Sensor	L	R
U01a – Temp. Tank		
U01b – Temp. Heater		
S03 – Detergent		
S04 – Channel 3 = Air		
S05 – Channel 2 = Biopsy		
S06 – Channel 1 = Jet		
S07 – Channel 6 = Suction		
S09 – Channel 7 - Extra		
S08 – Channel 5 = Water		
S10 – Channel 4 = Elevator		
S11 – Leakage test – 1		
S12 – Tank P.S.		
S13 – Cover		
S14 – Flow – 1		
S16 – Flow – 2		
S24 – Alcohol		
S90 – Leakage		
Y01 – Drain		

Replaced Items	L	R
CS – Cover Seal		
LB – Lift Diaphragm		
CV1 – Flow Check Valve		
PH – Tube pump Head		
PR – O-ring set of 8 pieces		
SH – Sprayhead		

Regulators	L	R
R1 – Water source		
R2 – Channels (2x)		
R3 – Leakage test		
R4 – General		
R6 – Compressor		
R7 – Leakage test flow		
R8 – Cover Flow		
Pumps	L	R
POZ - Detergent		
POD – Disinfectant		
POC – Alcohol		
Replaced Filters	L	R
F1 – Bacterial		
F2 – RRE -1		
F3 – PRE – 2		
F4 – Basin		
F5 – Air Flow		
F7 – Disinfectant		
F11 – Compressor – 1		
F12 – Compressor – 2		
F13 – Compressor – 3		
F14 – Compressed - Air		

Name Technician:	Name Customer:
Signature:	Signature:

SYSTEM CHECK

System Check MDS

Machine Type:		Serial Number:
Location:		Date:
LIO Version:	Man. Version:	Server Version:

R	Check	Type	L	R
X	1. Supply	Y01 + S12 + S17 / Y90 + Y02 + S14 + S16		
X	2. Channels	POA – Y04 + S04 + - Y05 + S05 – Y06 + S06 / Y07 + S07 – Y08 + S08 – Y09 + S09 – Y10 + S10 – Y03		
X	3. Air	YOH – YOD + S13 – YOE + S11 – YOF / Y01 + S18 – YOJ – YOG		
X	4. Air Tank	Y15 + S33 – Y16		
X	5. Metering	POD + S02 – S22 + POZ + S03 / S23 + POC +S24		
X	7. DES. SS	POF + S28 + S27 + S25 + POE / POG + S03 + S29 + S26 = POH		
X	8. OTHERS	S90 – U01a – U01b – K01		
X	9. LED	RED + GREEN		

Appearance:	
Doors Panels:	
Wiring:	
Drains:	
Others:	

Conclusion / Deviation

Disinfection:	L	R	Cleaning:	L	R

Name Technician:	Name Customer:
Signature:	Signature:

LOGBOOK

The logbook should always be located in the department where the machine is placed.

The following pages describe the contents of the logbook.

The service technician should also be aware of the use of it and release the written sheets , procedure and use of the forms.

WARNING: The described adjustment data is indicative and consequently does not provide current values. Refer to the machine logbook.

Logbook Contents

MACHINE INFORMATION AND CONTACTS

Machine Number:	Type:
Location:	Place:
Hospital Administrator:	Tel:
Service Technician:	Tel:

LOGBOOK USE

Introduction

The Logbook contains documentation of the:
- software set-ups
- process parameters
- failure reports
- service/maintenance
- calibrations

Maintenance Log

Failures-, remarks- and maintenance activities are described on this by the service technician.

Installation

Gives an overview of the installation data of the machines.

Specifications

There are standard settings and adjustments
Applies to supplier and user.

There are change tables for:
- software updates
- calibration
- program times

Failures / maintenance reports

The relevant data is noted in the maintenance , as well as the number of the (failure) report.

This procedure provides a check list to be executed following system maintenance and prior to releasing the system for endoscope reprocessing.

SYSTEM RELEASE PROCEDURE

A test program, without endoscope, should be run after repair/maintenance activities.

Machine check list:

- fit all covers on the machine
- place the machine back in its operation mode
- place reservoirs in the machine

Regulated Pressure:

Check the regulators to ensure the pressure readings match the values recorded in the log book.

Release

Release follows when the program runs without fault. Any fault should be rectified and the release procedure must be repeated until a normal run has been carried out.

Reporting (by client or technician)

After each periodic maintenance a report of the test run, is printed.

The report from the test log is archived in the log book with a entry made in the maintenance log.

CHANGE PROCEDURE

Optional parameter set phases can be enabled by the service technician. User access codes provide protection to the critical cycle parameters.

Warning: Critical cycle parameters are validated and tested. Critical parameters can not be changed.

MASTER Log

Run no.:	Description:
Date:	
Name:	

Run no.:	Description:
Date:	
Name:	

Run no.:	Description:
Date:	
Name:	

Run no.:	Description:
Date:	
Name:	

Run no.:	Description:
Date:	
Name:	

Run no.:	Description:
Date:	
Name:	

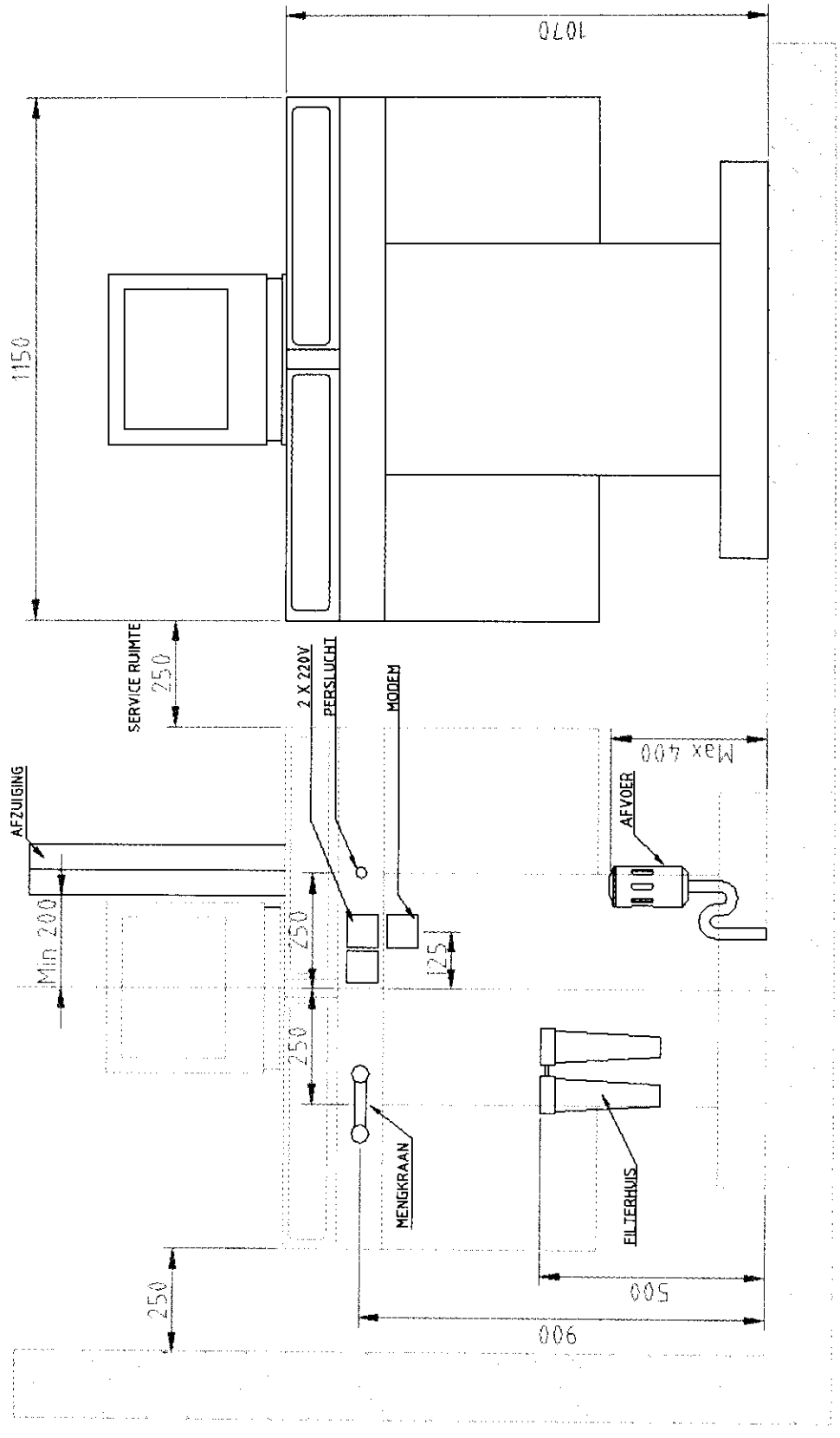
Use :

Each operation carried out on the machine is documented, as a short description, in the maintenance log, including:

- when each periodic maintenance has been carried out.
- interim calibrations are carried out by service technicians.
- interim filter exchanges.

With this, the status of the machine is determined. The maintenance log is also used when there has been a problem and the data is no longer available.

DIMENSIONS / CONNECTIONS



CONNECTION CONDITIONS (PER MACHINE)

Electric connection

Current		:120V - 60 Hz
Tolerance	:	3 KW
Fuse	:	16 Amp. (slow)
Contact		:Wall socket, 2-pin with rim earth, 2 pieces
Placing in room		:(according to NEN-3134)
Direct	:	class S0 and S1
Not permitted	:	class S2 and S3

Water connection

Pressure	:	20-87 psi
Supply	:	Single line for hot and cold
Coupling	:	Mixing valve
Setting	:	± 30°C
Connection	:	¾ " G outer thread
Quality	:	Drinking water
Consumption	:	Max. 10 ltr./min. at 1 Bar

Air connection

Pressure	:	5-10 Bar
Connection	:	Ø 6 mm (internal)
Quality	:	Medicinal
Consumption	:	Max. 100 ltr./min. at 1 Bar 10 ltr./min. at 10 Bar 5 ltr./min. at 5 Bar

Water drainage

Connection	:	Ø 40 mm
Height	:	Max. 25 cm
Type	:	Free-fall with odorous extraction

Moisture extraction

Low pressure	:	± 100 Pascal (minimal)
Take-off	:	50 m^3/hour
Connection	:	Ø 100 mm
Circuit	:	Adjustable by means of time clock

Warning: The adjustment data provided is indicative and consequently does not represent the current values. For this, one should refer to the machine log book.

CONNECTION BLOCK

The machine cannot function without a connection block. The channel block provides the following endoscope connections:

0. Leakage test.
1. Jet.
2. Biopsy.
3. Air
4. Elevator channel.
5. Water.
6. Suction.
7. Extra.

Connection blocks are provided for each endoscope architecture and model. Reference the MDS Master Hookup List (PN 20601-242) to identify the proper hookup for a specific endoscope model.

FORMS:

Machine Type:	Serial Number:
Location:	Date:

CALIBRATION:

AIR REGUL.: - Leakage		[bar]	(0.25)		WATER REGULATOR DYNAMIC		[bar]	(2.0)	
- general		[bar]	(2.8-3.0)		CONNECTIVITY		[bar]	(31.7)	
LEFT TANK			Valve		**RIGHT TANK**			Valve/statu	
SENSOR cover open		[cm]	(1.5)		SENSOR cover open		[cm]	(1.5)	
SENSOR basin empty		[ml]	(60)		SENSOR tank empty		[cm]	(1.5)	
Temp. correction 30° C		[°C]	Max. ± x		Temp. correction 30° C		[°C]	Max. ± x	
SENSOR : - Leakage Test		[mmHg]	(60-50)		SENSOR : - Leakage Test		[mmHg]	(60-50)	
	- jet	[mmHg]	(120-100)			- jet	[mmHg]	(120-100)	
	- biopsy	[mmHg]	(50-40)			- biopsy	[mmHg]	(50-40)	
	- air	[mmHg]	(120-100)			- air	[mmHg]	(120-100)	
	- water	[mmHg]	(120-100)			- water	[mmHg]	(120-100)	
	- suction	[mmHg]	(50-40)			- suction	[mmHg]	(50-40)	
	- elevator (elevator)	[mmHg]	(280-220)			- elevator (elevator)	[mmHg]	(280-220)	
	- alcohol	[mmHg]	(80-70)			- alcohol	[mmHg]	(80-70)	
	- detergent	[mmHg]	(50-40)			- detergent	[mmHg]	(50-40)	
PUMP alcohol		[ml/min]	Min 200		PUMP alcohol		[ml/min]	Min 200	
PUMP detergetn		[ml/min]	Min 200		PUMP detergent		[ml/min]	Min 200	
FLOWMETER 1		[fl/tr]	(261-391)		FLOWMETER 1		[fl/tr]	(261-391)	
FLOWMETER 2		[fl/tr]	(261-391)		FLOWMETER 2		[fl/tr]	(261-391)	
LEAKAGE TEST -		[mmHg]	Min 180		LEAKAGE TEST -		[mmHg]	Min 180	
	- flow	[sec]	(2)			- flow	[sec]	(2)	
DISINFECTANT SUPPLY		[ml/min]	Min 3000		DISINFECTANT SUPPLY		[ml/min]	Min 3000	
DISINFECTANT RETURN		[ml/min]	Min 3000		DISINFECTANT RETURN		[ml/min]	Min 3000	
BASIN DRAIN		[ml/min]	Min 3000		BASIN DRAIN		[ml/min]	Min 3000	

Software Version: Changes After Installation

DATA

MDS Type:		Serial Number:		Year of Manufacture:	
Location:				Date:	
Details:					

SOFTWARE

Date:	LIO: Version No.	MANAGEMENT Version No.	SERVER Version No.	Initial:
Installation:				
Update:				

Use :

At installation the data is entered in the topmost frame.
The service technician should keep the version changes of the MDS programs up-to-date.

PC Sets: Changes after Installation

Change	Value	Date	Name	Remarks

Use :

The service technician must record any changes to the windows configuration.

Parameter Sets: Changes after Installation

Parameter set	Version	Name	Remarks

Use:

The service technician must record any changes to the parameter sets.
User access protects the critical parameters from being modified. Only optional phases can be enabled.

DELIVERY CALIBRATION

Execution		Unit Left				Unit Right			
Name	Date	Water: FL/Ltr.		Detergent	Disinf.	Water: FL./Ltr.		Detergent	Disinf.
		S14	S16	ml/min	ml/min	S14	S16	ml/min	ml/min

Use:

At each periodic maintenance the calibration values are recorded.
Also the interim calibrations that are carried out by the service technician are entered here.
The values are documented when there has been a pc problem and the adjustments are no longer known.

FILTER REPLACEMENT

Filter:		Filter:		Filter	
Frequency:		Frequency:		Frequency:	
Name	Date	Name	Date	Name	Date

Use :

At installation record which filters have been placed in the water supply of the machine.
The exchange frequency per filter must be entered.
With each periodic maintenance record which filters have been replaced.

INSTALLATION

PREPARATION

Filling in forms

Installation report

Maintenance report

Service report (if it concerns a re-installation)

Tools

Standard tool-box for maintenance

Empty tank: 5 liters

Printer

PROCEDURE

Introduction

The installation is divided into 11 steps.

When a step has been completed then it is signed off on the installation report.

See *Chapter 1 page 1-14* Connection Section of Users Manual (50096-654) for additional information.

PROCEDURE POSITION :

1 filling in report
2 monitor - pc
3 drainage
4 water supply
5 air supply
6 extraction
7 turning on machine
8 ventilate filter
9 placing liquid tanks
10 system settings
11 introduce scope codes

Filling in report

At installation the form: Installation report is filled in.

Depending on completion or when it concerns a replacement (after a repair) some steps are not applicable.

When a step has been completed, it is signed off on the installation report:
"OK" if the item is correct.

"NA" : when it is not applicable.

Monitor

The PC-monitor is mounted on the machine by means of two holes on the protruding bolt. First place the nut. Then the two nuts are screwed tight. Finally the power cable and cables are connected.

Drainage

Connect the PVC hose fitting to the drain outlet.

The drain hose must not be clamped on the drain.

The hose should hang freely in the drain. (This is to prevent backflow from the drain).

Water supply

Install the water filter system and connect to hospital provided mixing valve.

Connect the system water line to the two water inlets and then connect to the outlet of the water filter assembly.

Refer to *Chapter 4 Maintenance page 4-6* , The Water Filter Replacement Section in the Medivators MDS Endoscope Reprocessing Multi-Use Chemistry User Manual.

Compressed air supply

Install the air compressor to the back of the system. Connect the air line from the compressor to the air filter. If the hospital air is provided connect directly to the air filter.

Ventilation System

The elastic vent hose slides over the round tube-piece and is sealed with a clamp.

Turning on machine

Plug the system into the wall socket and press the main switch of the PC.

The application software initiates automatically. Verify the communication with AS-I controller in the system.

Bleed the Water Filters

Install the water line disinfectant blocks in each basin.

Valve 13 are turned "on" via the "manual control".

Open the tap a little so that the air can be filtered out slowly by the water.

Loading Disinfectant

See *Chapter 2: page 2-34*, Operator Controls the Loading Disinfection section in the Medivators MDS Endoscope Reprocessor Multi-Use Chemistry User Manual.

System settings

These settings are adjusted once at installation. The parameters to be adjusted are below.

NOMINAL DRAINAGE:

- go to the expert screen
- close the drain
- fill the basin with 5 liters of water
- open the drain and measure the time that the basin takes to drain
- fill in the value = 5000 ml / x sec. on the screen

NOMINAL WATER SUPPLY :

- let water run in the basin using the expert screen and valve 2
- measure the time to fill the basin with 5000 ml, see screen S14 and S16.
- fill in the value = 5000 ml / x sec. on the screen

ENTER THE FOLLOWING DATA IN CONSULTATION WITH THE HOSPITAL ADMINISTRATOR:

- Optional: patient code
- Optional: specialist code
- Optinal: assistant code
- Barcode use optional
- Tag-reader use optional
- Audio signal warning
- Audio signal end program
- Audio signal failure
- Machine disinfection: day of the week

SAVING

- Save all imported data on the server by regularly clicking the export icon in the tool bar

DEVELOPMENT

Development Procedure:

1. check endoscope database
2. check connection blocks
3. alignment
4. concentrations
5. test run
6. print lists
7. administration

Check Endoscope Database

- check with the system administrator of the client whether all correct scope codes and types, are imported and coupled to the right parameter set 2K, 3K, 4K etc.
- check also whether all user codes have been imported correctly
- with barcode application the bar codes must be made so that they can be verified (optional).
- check whether all read in i-dent system chips have been given the correct code (optional)

When all this data is correct then this it is signed off per item on the installation form.

Check connection blocks

Note on the Installation form the number of each type of connection blocks delivered.

Adjustment

The installation circumstances with the client can be different from the adjustment circumstances.

- therefore the machine should be adjusted again
- note in the activities square: "Installation" of calibration form
- the procedure is described in the Calibration Section

Concentrations

Check / correct the detergent concentration in all parameter sets.

Note the concentration on the installation form.

Test run

Put the machine through a test run:

- import as parameter set: 1-17-999 test
- import your own initials as operator
- using endoscope simulator (PN 1-9-001) start up unit left and right one minute after each other
- write the run numbers on the installation form

Save and Export Database

Export and save following database entries:

- instruments (endoscope database)
- users (operators / users database)
- doctor (physicians / assistants)

Provide a printout of the databases for administration signature.

Note: The signature is important to enable subsequent discussions concerning the correct import and coupling of scope data to the parameter sets.

Administration

- export and save the system settings, record the date and machine number
- check whether the form: Installation MDS is filled in completely
- have the form signed by an authorised employee of the hospital (system administration)
- add a print of the form and the system settings in the logbook
- put the following forms in the logbook:
    - installation checklist: installation + date
    - filter replacement: date
    - calibration: date + value
    - software: version
- check whether the three files are present
- submit another example to the office staff employee

Note: The logbook, operating instructions and product info are left with the machine. The administration is now the responsibility of the service technician

Chapter 2

PREVENTIVE MAINTENANCE

PREPARATION

Filling in forms

- Service report
- Maintenance report
- System check
- Note form

Tools

- standard maintenance tool box
- windows external keyboard

Documentation and software:

- Medivators MDS Endoscope Reprocessing Multi-Use Chemistry Service Manual (PN 50096-653)
- MDS software

Precaution

Wear gloves when removing tanks and cleaning machine parts.

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PROCEDURE

Executer: technical service

Explanation

The maintenance is divided into a standard- and major maintenance. For major maintenance see *Chapter 4*, Major Maintenance for Preventative maintenance..

The overview list indicates the minimum that must be carried out at a service. This also corresponds with what must be filled in on the form.

The procedures contain a complete description of each individual activity.

Machine Layout

In *Chapter 1* Figure 1 through 6 provide locations of components referred to in the following procedure..

Standard maintenance service

All activities mentioned in this procedure.

Overview activities:

1 Filling in report

2 Complaints / noting remarks

3 Removing covers

4 General inspection

5 Activities:
- dismantling components
- cleaning
- carrying out activities/repairs
- components

6 System check

7 Check / Calibration

8 Dismantlement

Filling in report:

The activities carried out are kept up-to-date on the maintenance log and service report by noting the items. When a specific action, component or check is not present then " - " is filled in behind the item.

After performing the "inspection" the most important items that deviate are mentioned.

The used spare parts, with part number, are mentioned on the service report.

Activities which are necessary in order to make the machine optimal again but that deviate from the general activities are mentioned on the service report.

For the alignment the maintenance form is filled in. All existing alignments are entered here. With a correct alignment the measured setting value of the sensor is stated.

Complaints / noting remarks:

The client can have remarks about the functioning of:

the machine

the supplier

- Complaints about the supplier should be mentioned on the note form, and submitted to the service manager.
- General remarks, advices and complaints about the machine which are not directly rectifiable by repair, are mentioned on the note form under Fault and submitted to the service manager.
- Complaints which can be rectified should be carried out as much as possible during the P.O.
- For large repairs there is a separate form: Service report filled in and dealt with in accordance with PROCEDURE fault settlement in Chapter 6, Section 1. Implementation takes place in consultation with the client.

When an extra form is filled in then it is indicated on the maintenance report under: "Activities".

Removing Covers:

For an attainability for the maintenance the following plate parts are removed:

- left and right side covers
- left and right receiving plate
- inside screening covers
- upper and lower back panel

General inspection:

The inspection points below should be checked one by one. When a point is not correct, note the correction to be made on the form under Inspection, so that it can be fixed later.

The working of the system is also determined by the status of the wiring, the connections and the mechanical components.

The inspection involves carrying out all the attention points below. Established deviations are noted as much as possible in the maintenance report.

All problems concerning the MDS are taken care during the maintenance procedures.

Points of attention:

- Wiring in electronics unit.
- Wiring in the system and the slaves
- External connections for leakages.
- Contamination
  - rinsing tank and kit flange
  - inside the system, e.g. as a result of leakage
  - covers
  - filter unit
- Dismantability of the side tanks.
- Appearance status (damages and/or contamination).
- Position of the leak tanks.
- Cover status
  - position/start
  - working
  - contamination
- Status front door
  - closure/hinges
  - insulating edge
- Pump
  - couplings
  - mounting nuts
- Extraction, rinsing tank
  - remove extraction hose and check whether ventilator still works
- Status connection blocks
  - handle
  - hinge points
  - pillar bores
- Status adhesive seams rinsing tank
  - seams rinsing tank inserts

- Discharge
  - connector plate
  - leakage traces
  - underside block 3 on rinsing tank
  - drainage block on rinsing tank
  - couplings general
  - main pump
  - mixing valve
  - hot and cold working button
  - status flow blocks
  - condition liquid couplings
  - status / leakage pressure sensors
  - contamination by leakage

MAINTENANCE ACTIVITIES

This section describes activities to be carried out during preventative maintenance service.

Cleaning:

Note: Cleaning the system is the only visible proof that maintenance has been implemented. For the user the alignments are just as important as justifying the need for the preventive maintenance.

- Covers:
  Non-abrasive cleaning agent. Remove lime with a sponge.
  Remove light contamination with cleaner.
- Receiving plates:
  Rinse off with warm water. Dissolve with hot water
  Disinfectant: (thickened)
- Rinsing basin:
  Remove scale with a non-abrasive agent.
  Remove lime scale on the RVS parts with citric acid.
- Housing external sides:
  With non-abrasive agent.
  Remove stains and dust from side- and foot-cap
- Filters: Replace in basin.
- Leakage receiving tank:
  Fill with some warm water. Let de-contamination take effect.
  Remove damp and dirt.

Replace cover seal:

- Close the drain off with adhesive tape or a paper wad
- Remove the rubber and scrape the edge clean
- Remove adhesive remnants with dry-cleaning naphta.
- Apply drops of transparent silicone adhesive (small Ø 3mm) to the edge, around 10cm.
- Spread the adhesive around the edge with an old piece of seal.
- Apply rubber, do not stretch but lightly press.
- Close covers
- Check sealing by sticking a double-folded piece of paper between the cover and around the seal
- Remove the adhesive remnants from the basin

Connection blocks:

- The screw of the connection blocks can come loose
- Check each screw, tightening them with a hexagon (2.5 mm), 0.65 N/cm by using a torque key

Adhesive seals rinsing tank inserts:

Thefastners of drain, sprayer, water inlet and supply can be loose because the adhesive shrinks. Tighten nuts and/or renew the adhesive by removing the complete unit and mounting again.

Install new silicone kit as follows:

- clean unit and basain glue surface with dry-cleaning naphta.
- apply adhesive bead on the glue surface of the unit.
- replace unit and tighten nut.
- remove excess adhesive immediately.

F1, F2, F3 / F9, F10 = Replace water filters:

- Close water supply
- For the applicable filters use the maintenance articles overview, *Chapter 1.4*

  See *Chapter 4,* the Water Filter Replacement Section of the Medivators MDS Endoscope Reprocessor Multi-Use Chemistry User Manual (PN 50096-654).
- Work as follows:

  - Get the pressure of the filter housing

- Turn the filter case loose. Pay attention to water in the filter
- Let the case drop slightly
- Pull filter down
- Remove filter and case together
- Grease O-ring of the case
- Re-place new filter
- Place case and tighten until ready

- Filling with water
  - Place water line disinfection on the connector plate
  - Open via the manual control valve 2: Supply :
  - Turn the water tap open halfway.

Note: Filling must occur slowly in order to fill the filter membranes

- Open the blood valve and bleed remaining air from the 0.2 µ filter

When the water flows, the regulator is adjusted to the required value according to MDS adjustment.

Other filters :

-F4 : BASIN FILTER

--Drain the filter in the basin with the strainer hook.

--Push the new filter over the metal case.

-F5 : AIR FILTER

--Push the ring round the hose on the filter connector and pull on the hose.

--Replace complete filter with connector.

-F7 : DISINFECTANT FILTER

--Press the grey button of the quick-connect coupling, both sides.

--Replace the complete filter unit with a new one.

Air compressor (option):

See *Chapter 4*, Air Compressor Subassembly Intake Filter Replacement section of the Medivators MDS Endoscope Reprocessor Multi-Use Chemistry User Manual (PN 50096-654.

-F11 : REGULATOR FILTER

--Remove the tank cap.

--Unscrew the filter holder.

--Replace the white filter.

--Place the components back.

-F12 : AIR PRE-FILTER

--Remove the tank cap.

--Unscrew the filter holder.

--Replace the green filter.

--Place the components back.

-F13 : SYSTEM AIR FILTER

--Dismantle the holder re 3 mm socket.

--Remove the metal filter,

--Place a new filter in the holder with hole at the top.

--Re-mount the holder.

-F14 : AIR INTAKE FILTER

--Remove the metal cap from the compressor unit.

--Unscrew the filter with a penny coin and remove.

--Place a new filter and screw it tight.

-CV 4 : NON-RETURN VALVE

--Remove the valve placed between the compressor and the tank.

--Place a new valve.

Flow components :

Flow components are the restrictions and the non-return valves. When these are jammed, serious damage to the machine can occur. See overview other components.

-CV1 : FLOW CHECK VALVE

--Set the ring round the hose pressed on the check valve and pull the hose.

--Ensure with replacement in the direction of the current, pipe on check valve.

-CV2 : METERING CHECK VALVE

--Place a rag above the two slaves.

--Turn the two holder parts round one quarter turn.

--Remove the check valve and the two o-rings and replace them.

--Ensure with replacement is in the direction of the current, open direction basin.

PH : Metering pump hose:

- Dismantle the two leakage collection plates by unscrewing the two cross screws 2 turns.
- Replace the complete hose coupling of the detergent and alcohol metering pumps.
- Turn the knurled ring of the connecting coupling from the hose and pull the supply hose loose.
- The head is fixed with two click connections. Cut these and pull the complete head of the motor housing.
- Place the new head until it clicks in.
- Connect the two hoses with the tubes.

Cover seals:

Lubricate the lower points of the covers are spotted with silicone oil.

Elevator pump diaphragm:

- Dismantle the housing of the elevator pump
- Remove old diaphragm
- Check block for damages and/or contamination
- Replace the diaphragm with PN 3-4-411. Ensure the material is Viton, black.
- Replace with new diaphragm
- Mount the housing of the elevator pump

Pillar o-rings (Channel manifold):

- With two fingers press the o-ring on the pillar in one direction and remove the loosened ring with a small screwdriver.
- Remove all 16 o-rings.
- Press the new o-rings over the pillar.
- Grease thumb and forefinger lightly with silicone oil.
- Grease the o-rings by moving along the pillars in a diagonal and lengthwise direction.

Spray head:

- Unscrew the two sprayers and replace them with the exchanged sprayers.
- Place a red reject sticker on the sprayer after the maintenance.

System check

In order to guarantee that all in- and outputs still function correctly a system check should be carried out according to the procedure in *Chapter 8.* Fill in the form: **System Check.**

Check / Calibration

Check whether all regulator adjustments are in accordance with the data in the log book. Adjust the machine in accordance with the calibration procedure in *Chapter 7.*

Fill in the values on form: **Maintenance Report.**

Tests

Calibrate the machine in accordance with the work description in Calibration section.

PROCEDURE TESTS

GENERAL

During the test run there must be regular checks for leakages. The particular points of attention are the:

- canning-in in the flow-blocks
- the basin
- system unit

DISINFECTION PROGRAM

- Place two test connection blocks and start unit L and R around the same time, program 1-17-999 test
- Note the run number in the Maintenance log

MACHINE DISINFECTION

The system must be disinfected after re-assembly. See *Chapter 2*, the Water Line and Water Filter Disinfection section of the Medivators MDS Endoscope Reprocessor Mult-Use Chemistry User Manual (50096-654).

COMPLETION

- All plates are re-installed
- The machine is placed in its original position.

Administration

1. Let the machine run a normal program on system 1 and 2, preferably program with elevator.
   - Connect two endoscopes to the machine
   - Select scope number
   - Enter your own name in as operator
   - Start program left system
   - Repeat for right system
   - Fill in run number on the form
2. Initial the form when the test run has progressed normally.
3. Completion
   - Add the print-out of filled-in form to the log book
   - Fill in the maintenance log of the log book

NOTES

Chapter 3

MAJOR MAINTENANCE

PREPARATION

FILLING IN FORMS

fault report

calibration report

system check

TOOLS

Standard tools vehicle for the maintenance activities at the client.

MATERIAL

Type definition

On the basis of the order or machine number, define which process diagram the machine to be revised has. This defines the sub modules to be replaced.

Replace / exchange components	#
Screw countersunk M5	8
O-ring 008-pillar	16
O-ring drain	2
Block channels	2
Block drain	2
Heater	2
Alcohol / Detergent / Disinfectant metering unit	2
Channel pump	2
Disinfectant pump	2
Water supply unit	2
Regulator R2 channels	2
Extraction ventilator (new)	1
Preventive maintenance set (new)	1

Precaution

Make an appointment around 4 weeks beforehand so that the machine is available for 2 days:

one day for the maintenance activities

one day for the end check, adjustment and validation

Two technical employees are planned for the implementation unless contractually agreed that the client assists.

Check beforehand the type and operation form of the machine to be revised (see process diagram). Correspond the sub-assemblies to be taken for this.

PREPARATION ON-SITE:

Rinse through the blocks and the pumps with the expert control: fill unit L and R tank

- valve 1 = off
- valve 2 = on
- until tank is filled with water = 2 litre
- pump = on
- 2 minutes circulation
- reset manual control

Save the disinfectant used, described in *Chapter 2*, the Disinfectant Change Utilitiesof the Medivators MDS Endoscope Reprocessor Multi-Use Chemistry User Manual (PN 50096-654).

Rinse pipe and pumps of the metering unit (type dependent)

- remove tanks
- place tank with water
- set "on" via manual control:
  -detergent + concentration pump unit left
- after 30 seconds: reset
- set "on" via manual control:
  -detergent + concentration pump right
- after 30 seconds: reset
- wear gloves for pulling the hoses loose from the metering unit

Disconnect the machine

- water
- air
- drain
- 120V
- monitor

Procedure

To keep an overview of the activities carried out the assembled parts per system are replaced one by one.

It is possible to work on two systems at the same time.

The sequence is indicated in the procedure.

Plating

DISMANTLE / REMOVE:

fluid tanks (2x)

side covers (2x)

door

inner screen

hoses of the adaptors

Dismantling metering pump (if applicable)

DISMANTLING:

- connections to metering barbs in the basin L and R
- AS-i cable of the metering pump
- metering unit (2x crossheads)

ASSEMBLY:

- assemble metering pump with the 2 cross screws
- connect the AS-i cables. Attention wire colours!

  BLACK: - blue on : aux – and - brown on : aux +

  YELLOW: - blue on : as-i – and - brown on : as-i +
- place the metering hoses (via metering unit sides) on the barbs of the basin
- bind the hoses to the barbs with tie-wraps
- connect the hoses (via upper side of metering pump) to the tank adaptors

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Repair Channel Manifold

DISMANTLING:

- mark wiring on the sensors, leakage test, elevator, etc.
- mark hoses, elevator pump, elevator blows
- *remove:*

  --hoses (5x)

  --connectors (9x)

  --wiring sensors (7x)

  --silicone plugs in connection plate (4x)
- unscrew the 4 countersunk screws in the connection plate out the block (block supports)
- *remove:*

  --block by levering it lightly and pulling it down

  --moisture from screw holes

  --o-rings on the pillars

  --potential silicone remains in the screw-plates and on the underside of the connection plate

  --let the water run out of the blocks, rinsing by pressing with the hand = valve open.

ASSEMBLY:

- assembly new O-rings (008)
- grease the O-rings with: Silubrin grease
- push the channel block on the pillars and screw it tightly with 2 screws, diagonal
- prior to assembling the other 2 screws, first put a groove of silicone adhesive on the underside of the screw head
- remove the first 2 screws and also put silicone adhesive under the screw head here
- fill the first 4 screw holes in the connecting plate with silicone adhesive and then wipe smooth with a spatula
- *assemble:*

  --AS-i connectors

  --pressure switch contacts

  --water hose

  --air hose

Drain Manifold

DISMANTLE:

- *remove*:
  --hoses (3x)
  --connectors (2x)
- screw the socket screws loose in the block under the mounting
- undo the drainage hose

ASSEMBLY:

- slide the socket screws through the block and slide an O-ring over the screw thread screw block 1 tight on the ring
- *assemble*:
  --hoses
  --connectors
- check whether everything is fastened

Main pump

DISMANTLING:

- *remove:*
  --hoses (3x)
  --connector
- screw the 4 screws loose under the mounting bracket
- let the pump run empty by holding it on the hood

ASSEMBLY:

- screw the pump tight with 4 screws
- *assemble:*
  --hoses
  --connector

Ventilation Fan

DISMANTLING:

- disconnect plug next to the pneumatic unit
- make suction hoses loose
- unscrew the 4 socket screws on the rear side

ASSEMBLY:

- place the new ventilator
- tighten the 4 screws
- place the hoses and the plug back

Water Inlet Supply Valve

DISMANTLING:

- disengage water supply hoses
- loosen slave plug of the valve coil
- screw the nut on the underside loose

ASSEMBLY:

- place the replaced water supply
- place the plug back
- tighten the nut
- connect the hoses again

Water Line Disinfection

- After replacing the water inlet valve, a water line disinfect cycle **MUST** be run.

MAINTENANCE

After all modules and components of the major maintenance are replaced, the preventive maintenance procedure, Check/Calibration needs to be carried out, including the consumables.

COMPLETION

System check

This check is intended to verify whether all connectors and connections have been placed back correctly.

Carry out this check according to the system check: see System.

Alignment

The alignment of the machine is carried out in accordance with the definition in Calibration Section.

Tests

- test the working of the metering pumps via the manual control
- install the water line disinfection blocks
- turn the detergent or disinfectant pump "on" via the manual control
- one by one
- reset the manual control

Note: the detergent sensor and alcohol sensors go high.

Chemical Reservoir

- refill chemical reservoir if emptied
- run water line disinfection

Validation

The machine is validated according to the procedure described in *Chapter 5*.

Administration

Check whether the forms have been correctly signed, also by the client, in accordance with the instructions.

After signing the machine is officially released for use.

- attach a print-out of the forms to the log book
- fill in the maintenance log of the log book

Chapter 4
CALIBRATION

PREPARATION

Filling in forms

Maintenance report:

Logbook:

Maintenance log

LOGBOOK:

- Maintenance log: enter the nature of the maintenance, date, name
- Filter replacement: name, date
- Metering pump calibration: take over values of the calibration report, name, date

Each item to be adjusted is mentioned on the maintenance form.

- For each item that is adjusted L and R, note the adjusted value on the form. This should fall within the tolerance value of the adjustment data.
- Note the value of the measured items which are also entered into the system settings of the management program. Do this for Left and Right.
- Note the number of items that are replaced on the form.

MDS SERVICE REPORT:

- Fill in the data as described in *Chapter 6* of the workshop manual.
- On this note the replaced components which are not mentioned on the forms:
  --maintenance set number.
  --number of the replaced components.

Tools

- standard maintenance tool box.
- pressure meter 0-300 mmHg.
- scales to min. 2 Kg.
- graduated beaker of 2 liter.
- stopwatch.
- connector cable for sensor board.
- multimeter.
- temperature gauge.

Material

Precaution

Look for the following data of the apparatus to be adjusted:

- machine type
- serial number
- hydraulic schematic
- adjustment data

The sensor values can be found in the logbook of the machine.

OVERVIEWS

This regulation describes the primary settings of the MDS. These should be checked and/or restored during the periodic maintenance and, when applicable, after a repair.

Operation overview

The settings of the machine include the activities below:
The procedure is described in the next procedure.

1. PS = Pressure switch
   - S11, S18 : leakage test
   - S10 : elevator channel
   - S04, S09 : other channels
   - S02,S03,S24 : metering system
   - S12 : tank empty
2. R7 = Leakage test flow regulator
3. V1 = Leakage test overpressure regulator
4. AR = Compressed air regulators
   - R3 : leakage test
   - R4 : general
   - R5 : air tank
   - R6 : compressor
5. LR = Fluid regulator
6. RS = Reed switch
7. R8 = Cover flow regulator
8. PC = Flow meters:
9. POC, POD, POZ = Disinfectant / detergent / alcohol metering
10. PT 100 = Temperature calibration
11. CB = Guiding pins
    - S12 en S17 : tank sensors
12. CS = Leakage sensor
13. Drain sensor
14. R2 = Channel regulator
15. S33 = air tank sensor

Sensors Diagram

Most MDS sensors must be calibrated. *Chapter 1* gives an overview of all sensor codes of the hydraulic schematics, the type of sensor and the application with the MDS performance.

Figure 5 of the images gives the location of the sensors.

Regulator overview

The regulators should be adjusted. Figure 6 of *Chapter 1* gives an overview of all regulators from the hydraulic schematic and the application with the MDS performance.

Adjustment overview

A logbook is attached to each MDS. The contents of the logbook are described in *Chapter 3.*

Warning: Always use the calibration values as they are mentioned in the logbook of MDS.

Machine layout

In layout sketches are recorded with regard to the calibration:

Endoscope channel connections

The connections on the channel manifold in the basin all have a specific function. The correct operation is essential for the functioning of the machine.

Figure 2 shows the layout of the basin. The number indicates the pillar position:

0	=	leakage test of the endoscope
1 - 7	=	endoscope channels

Figures 3 and 4 corresponding, shows the corresponding access valves on the channel blocks.

Channel block sensors / slaves

On the channel blocks, the corresponding sensors, valves and slaves of the endoscope connections are confirmed. See chapter 1 and the corresponding figures 3 and 4.

PROCEDURE

When there are several user applications for one sensor type, then a separate description for this is made.

PS = S12, & S24 Pressure switches

The pressure switches are mounted on the channel block and the metering units. They are tested with the aid of a calibrated hand pump. During operation two switch points are important:
on switch point (higher value)
off switch point (lower value)

The status of the leakage test, - channels, - detergent- and disinfectant sensor can be made visible in the "Signal Overview".
This expert screen can be reached via menu:

F1 for left unit
F2 for right unit

ALIGNMENT (GENERAL)

Adjustment switch point

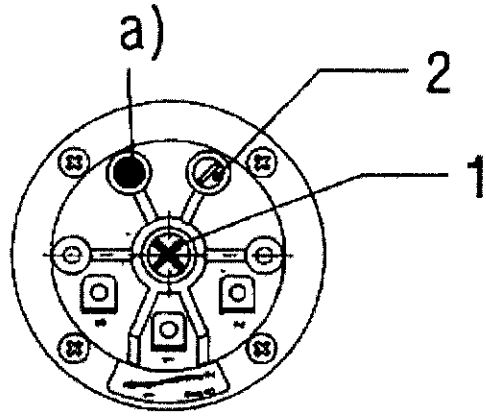
- the switch point is the value whereby when switching on the signal "1" is given. the switch is represented in the figure below.
- Connect middle and left contacts of the pressure switch.
- the relevant signal must stand at "0".If necessary unscrew the central screw.
- bring the switch to the desired pressure by using the bellow-pump.
- turn the central screw in (1) until the switch switches on:
- audible click sound
- on the screen is the signal overview: "1"

with this the highest switch-on point is set

ADJUSTMENT HYSTERESIS

Hysteresis is the pressure difference between switching on and switching off points.

- apply pressure to the sensor
- let the pressure fall slowly to check the lowest (switch down) switching off point
- too low (pressure difference too big) then adjusting screw 2 should be turned more clockwise
- if necessary turn the central screw a little until the higher value is reached
- too high (pressure difference too small) then the adjusting screw should be turned counter-clockwise



Machine adjustment

The connections in the basin are connected to pressure switches on the drain manifold, see Figures 1 to 9. The image also indicates which pillar must be used for the various settings.

S04 THRU S09 = CHANNEL SENSORS

The switches are mounted on the channel block, right under the corresponding channel pillar.
By sliding the pump with pressure gauge over a channel pillar, pressure on the system can be set.

- Slide the hose over the pillar
- Slowly pump up the bellow-pump

Also look at the screen signal: "channel sensor"
When the switch point is reached the signal is "green"
Check the switch value on the pressure gauge

- vent the pump and check the fall-off point

When the value is not correct, it should be corrected by turning the central screw (1), see figure.

S11 = LEAKAGE TEST

To avoid moisture coming into the leakage test system the pump should be pumped through a few times.
Proceed further in accordance with the procedure of the channel sensor.

S10 = ELEVATOR CHANNEL

Adjustment lower than 300 mmHg:
- set valve 10 "on" with the manual control L or R Unit
- slide the hose of the bellow-pump over the pillar of the elevator control
- adjust the sensor elevator channel according to specification

S03, S24 = Metering system

The Figure 5 shows the position of the disinfectant (d) and detergent (s) pumps and sensors.

S03 = Detergent sensor

IMPLEMENTATION

- place hose of the pressure meter on the metering nipple in the rinsing tank
- pump the bellows up slowly until the correct value is reached
- at the correct value the detergent sensor signal is: "green"

S24 = Alcohol sensor

- set valves Y10 (elevator) and Y11 "on" via the expert control
- slide the hose of the bellow-pump over the pillar of elevator channel 4.
- pump the bellow-pump up slowly, when the switch point is reached the signal S24 "green"
- check the switch value and re-adjust sensor
- repeat until the correct setting
- reset the expert control

R7 = Leakage test flow regulator

This regulator protects the endoscope against overpressure and is mounted in the channel block.

SETTING:

- screw in the flow regulator until ready + quarter turn back

TESTS:

- set the Y0F valve via the expert control: leakage test de-ventilate "on"

- slide the hose of the bellow-pump over the leakage test pillar
  - bellow-pump on pressure to 250mmHg
  - drop-off time to 50mmHg ± 4 sec : adjust by means of the central screw of the flow regulator.

V1 = Leakage test overpressure

This regulator protects the endoscope against overpressure and is mounted in the channel block.

Verify the over pressure valve is functioning correctly. Pressurize the leak test pillar to 225 mmHg (4.5 psi) with hand pump. The over pressure valve should open.

TESTS LEAKAGE DENSITY V1 :

Is applicable for both models.

- reset the valves and remove the block.
- slide the hose of the bellow-pump over the leakage test pillar
  - bellow-pump on pressure to 250mmHg
  - meter of the pump may not run back.

A.R. = Compressed air regulator

Pressure readings are statistic values: no program active.

SETTINGS:

By turning the knob on the regulator, the settings change. The position of reducer and meter is represented in Figure 6 of chapter 1.

CHECK:

When a meter is re-adjusted, then the system valves must first be opened, because after that the exact statistic value is read only when the valves are closed again.

R3 = ADJUST LEAKAGE TEST REGULATOR

- set the valve E "on" via the expert screen
- close off the leakage test pillar in the basin
- adjust the meter
- allow air to escape and check the new meter reading 0.25 BAR (3.6 psi)
- repeat until the correct value is reached

R4 = ADJUST SYSTEM PRESSURE

- set valve 11 and H "on" via the expert control
- close valve H: "off" and check the new meter reading 2.9 BAR (42 psi)
- adjust the regulator if this deviates
- repeat until correect value is reached

R5 = CONNECTIVITY REGULATOR

- adjust connectivity air vessel pressure to 1.7 BAR (25 psi)

R6 = ADJUST AIR COMPRESSOR REGULATOR

- close valve on the air tank
- turn the compressor on
- check whether the pressure of the tank increases. When tank is full:
- turn the reducer open
- turn off the regulator R6 until the pressure gauge 6 BAR (87 psi)

L.R. = Fluid Regulators

R1 = ADJUST WATER SUPPLY

- the water reducer is dynamically set
- place water line disinfect in each basin for the machine disinfection
- via the manual control valves 2 are: set to water supply "on":
- do this for the left and right units at the same time
- when the water flows, the reducer is set to the required value.1.1 BAR (16.5 psi)

R2 = ADJUSTMENT CHANNEL PUMP REGULATOR

- adjust left and right separately
- via the expert control, set the drain valve to "closed"
- fill the basin via valve 2 with 2 liters water
- place a water line disinfect in the basin, close cover
- valve 5 and 6, turn pump channels "on"
- turn regulator until the pressure gauge R2 indicates 1.7 BAR (24 psi)
- adjust other side
- reset the expert control

S13 = R.S. = Reed switch (cover working)

This is determined by the signaling position and open / closed movement.

COVER POSITION

The position of the cover sensor is signaled by a reed contact. The contact is activated by a magnet on the piston rod of the compressed air cylinder.

ADJUSTMENT:

Message: "cover is open" must disappear in the closed movement when the cover is ± 1.5 cm above the closed position.

- place a block of ± 1.5 cm under the cover
- undo the reed contact bracket
- move the reed contact to the R: "cover is open" disappears from the screen
- check this for the closed movement
- re-adjust contact if necessary
- tighten bracket again

R8 = Cover open / closing

The opening and closing of the covers is adjusted by means of two speed-control vents on the air cylinders. The covers should open and close easily.
When the covers close or open too slowly or not at all, then there are two possibilities:

1. Grease the lower points with silicone spray.
2. Adjust the control valve.

IMPLEMENTATION

Only carry out when the working of the cover demands it.

- adjust compressed air on system and pressure regulator according to the specification of the corresponding process diagram.
- close cover: adjust with lowest adjusting valve, first turn off completely and then unscrew 2 and a half turns.
- open cover: adjust with topmost shock-absorber, first turn off completely and then unscrew 1 turn.
- Tests:
  close cover: cover must be closed smoothly and not slammed, last piece cushioned.
  Open cover: cover must be opened smoothly and last piece cushioned.
- adjust pressure regulator to the value according to the specification. Covers must always be open and close well.

COVER LOCK

With a locked cover, the lock must prevent the cover from being opened from the back. Adjust front side of cover to max. 15 mm settings via movement of the adjusting plate on the back of the machine at the height of the cylinder.

Note: In a locked position the lock must not touch the adjusting plate. Adjust clearance + 0.5 mm.

S14, S16 =Flow Meter Calibration

The flow through both flow meters can be calibrated simultaneously. Flow meter 1 is S14, flow meter 2 is S16. Use the screen volume message and the calibration value as indicated at S14 and S16 in the management application:

Set the water delivery flow meter [edges / liter] to 340 for S14 and S15 both basins.

- check dynamic pressure to be 16.5 psi (± 0.5 psi)
- start the expert manual control
- select left / right unit
- place bucket on a scale and reset this to zero
- run LIO #3 flow test
- when the water flow stops measure (weigh) the volume
- the calibration value for flow meters 1 and 2 is corrected by the following calculation: (screen volume) *340 / (volume water) = new calibration value.
- fill in the new calibration value on form Maintenance / Calibration Report.

- A: POC, POZ = detergent / alcohol metering:

With the help of the access code select the manual control screen for left unit.

- place the reservoir filled with alcohol on the scales.
- reset the scales to 0.
- attach the reservoir to the correct position in the machine.
- meter alcohol for 1 minute via the expert manual control. Use lid # 5 Alcohol Calibration.
- weight reduction is the metering per minute.
- calculate the weight reduction for the pump and note this in the maintenance report as follows.

(WEIGHT BEFORE) – (WEIGHT AFTER) = METERING (ml/min)

Repeat this procedure for:

- detergent, use LIO #4 Detergent Calibration

Now select the manual control of right unit and repeat the procedure for:

- alcohol
- detergent

Note the volume outputs in the maintenance report.

PT-100 = Temperature sensor

Using the access code select the expert manual control for left unit

- close the drain
  - press the right mouse button
  - click on drain
  - select stop
- place a temperature gauge in the drain.
- pour water of ~ 30 degrees in the tank. Let it stand for a few minutes.
- note the temperature deviation on the screen with regard to the meter on the form
- let the tank run empty.
- pour 200 ml water of ~ 80 degrees in the rinsing tank. Let it stand for a few minutes.
- note the temperature deviation on the screen with regard to the meter on the form.

Repeat the procedure for right unit.

Import the values of the maintenance report in the database of the machine.

Do this separately for left and right unit.

- modify temperature correction value in "management" program under:
  - systems
  - left or right
  - temperature correction:
- save setting
- close off "LI0" and start "LI0" again
- check by repeating the metering

S12 = Basin Empty

The " basin-empty" and "basin-full" sensors are essential for the correct disinfectant concentration. The volumes are adjusted to a set value and proportions.

Basin-empty sensor left / right

- tighten screw 2 to maximum position (you feel resistance)
- loosen screw 2 with 1 rotation (360°)
- tighten central screw (1) to a maximum position.
- fill drain wit water till it enters the basin (in between 60 and 70 ml)
- loosen central screw till "basin empty" sensor (S12) activates (audible click)
- check through filling for a consistent switch moment (2 times)

S17 = Basin minimum level

- display the expert screen
- fill each basin until the minimum level sensor is covered
- verify S17 is ON (Green) in the expert screen

S90 = CS = Leakage sensor

On the back of the capacitive sensor there is a small adjusting screw. Use a Micro screwdriver. Sensor is high when the LED is lit.

ADJUSTMENT:

sensor high, by pressing finger on green sensor face.
sensor drops off with releasing sensor.

Y01 = Drainage discharge

- ensure that the machine is connected to the drain.
- fill the rinsing tank with 5 liters water, set to "stop" via valve 1 and "on" via valve 2 of the expert control.
- press the "release all" button and measure the time until the tank empty sensor drops.
- divide the time by 5 and verify the system parameter water drain [ml/min].

R2 = Channel regulator

- place system water line disinfection block
- set valve 1 to "stop" via the expert control.
- let 3500 ml water run into the tank via valve Y02 and Y90 (supply).
- pull the button of the regulator up and turn this completely open.
- close the elevator valve Y10.
- set the channel pump POA "on" and spray valve Y03.
- turn the regulator tight until the pressure gauge result lies between 15 and 18 PSI.
- set channel air Y04 "on" and elevator Y10 "off".
- set channel Y04 "off" and Y10 "on" channel block is filled with water.
- close the sprayer valve Y03.
- open the sprayer and close again after 10 sec.
- pump pressure against fixed volume.
- adjust regulator higher or lower to 24 ± 1 PS1.
- open and close sprayer valve to check.

Lock the button of the regulator and press on "Release All" button of the expert control.

ADMINISTRATION

End check

Check whether all data on the master card and maintenance report has been filled in and corresponds with the system settings in the management program.

System settings

All settings on the applicable MDS type must now be imported via the management program. The values should taken up from the maintenance report.

Warning: The program can no longer be changed. Access is only obtainable via a code!!!! Changing the program settings can cause system faults. All settings which are filled in on the check list should be signed for approval.

- Activate "Management" in the program via the maintenance access code.
- Select the: "Configuration" application then "Systems".
- Change the applicable data from the maintenance log:
  - systems
  - left or right
  - disinfectant flow rate (ml/min)
  - detergent flow rate (ml/min)
  - alcohol flow rate (ml/min)
  - water flow rate (ml/min)
  - water flow rate S14 (edges/min)
  - water flow rate S16 (edges/min)
  - save setting
  - close "LI0" and start "LI0" again
  - check by repeating the measurement

Completion

- let the maintenance report be signed by the client to release the machine.
- fill in the logbook as described in *Chapter 5.3*

Chapter 5
SYSTEM CHECK

PREPARATION

Filling in forms

System check
Maintenance log

On the system check form, each item to be adjusted is mentioned.
Note "OK" on the form for each item that is checked and found to be good.
Do this for left and right.

Tools

1/2/4-8-001: instruments connecting block

Material

Precaution

Couple the machine completely to:
- 120V
- supply water
- drain water
- compressed air

PROCEDURE

Mechanical procedure

Inspection actions to be carried out are listed below, make sure to note the results from all check points on the "System Check Form" *page 1-21.*

There is space provided on the form for additional remarks or criticism regarding the system.

EXTERIOR INSPECTION

- of the various housing connections to each other
- finishing of adhesive seams on glass plates and rinsing tanks
- dirt on or in the machine

INSPECTION OF DOORS AND PANELS

Working and releasability of :
- foot-caps and side-caps
- back panels
- door and cover

These must be moved gently or be removed with little effort.

WIRING INSPECTION

The convenient arrangement, safety and reach ability of components is determined by the positioning of the wiring
- bundled as much as possible
- concealed as much as possible
- no sharp edges

INSPECTION OF HOSES

- couplings not to tightly screwed (2 mm leeway)
- no sharp edges

OTHER INSPECTIONS

- check whether the nuts of inserts in the rinsing tank are firmly screwed in
- check whether all connectors on the air and fluid valves are screwed tight.

Procedure control

All in- and outputs should be checked one by one for good operation. The check can be carried out visually or audibly *figures 1 to 4 in Chapter 5.1* represent the positions of the in- and outputs stated in the check.
Carry out procedure 2 first for left unit and then for right unit.

The tests of the outputs contain the activities below:

FILLING IN FORM

Each step should be signed on the "System Check" form immediately after implementation.

CHECK OUTPUTS

The outputs can be guided via the expert control of the LIO program.
For this click on the icon in the upper right-hand. After login and selection the expert screen appears.
Note: De-activate the output after each test handling and before starting the next.

First do the guidings of left unit and then right unit. The reaction of the outputs are described in the checks below.

Proceed as follows:
- set the output to be inspected to "ON = red ", by double-clicking the track pad
- check whether the reaction is according to the description
- note:
  - "OK" when component reaction conforms to the description
  - "N.A." when the component is not applicable to the machine operation
  - "ERROR" when component reaction is wrong or does not take place
- set the output to "off" (double-click)
- set the next output to be inspected to "on"
- repeat this until all outputs have been inspected.

CHECK INPUTS

The inputs can be read via the keyboard-option:
F1 for left unit
F2 for right unit
First carry out the check of left unit and then the right unit
Proceed as follows:

- carry out the signal handling
- check whether the correct system signal changes from "0" to "1 = green"
- note reaction on inspection form
- repeat this until all inputs have been inspected

Note: an "ERROR" reaction in the "conclusion / deviations" field:
- check number, relevant component code and description

CONNECTION BLOCK

The check can better be carried out with a test block with closed leakage test connection or instruments block. Place this block in the rinsing tank of both units.

CHECKS

At each check a number of in- and outputs are tested in a small circuit. After the part test, these can be signed as "OK".

LIQUID VALVES: CHECK 1 + 2

These valves have a connector which is equipped with two LED's. When the valve is addressed these LED's light up. It can also be seen that the plunger is pulled into the solenoid. A click is then audible. The position of the connection to the blocks is essential for the functioning of the machine. Pay attention to this at the inspection. Figures 2 / 3 and 4 show the valve numbers and their positions.

SUPPLY CHECK 1

- set valves Y90 and Y02 "on", water flows into the rinsing tank. Volume sensor S14 and S16 indicate an increasing value.
- when sensor S12 is "high" then the drain opens.
- set valve Y01-drain to "stop" via the right mouse button.
- valve 2 closes itself and tank proceeds to fill.
- let tank run full to the min. Sensor S17 is "high".
- set valves Y90 and Y02 "off".
- go to channel check 2.

CHANNEL CHECK 2

- set valves Y04 and Y10 and pump POA "on", water flows via the block connection.
  - air and sensor S04 air is "high".
- set valve Y05 "on" and Y04 "off". Water flows via the block connection.
  - biopsy and sensor S05 biopsy is "high".
- set valve Y06 "on" and Y05 "off", water flows via the block connection.
  - jet and sensor S06 jet is "high".
- set valve Y07 "on" and Y06 "off", water flows via the block connection.
  - extract and sensor S07 extract is "high"
- set valve Y08 "on" and Y07 "off", water flows via the block connection.
  - water and sensor S08 water is "high"
- set valve Y09 "on" and Y08 "off", water flows via the block connection.
  - extra and sensor S09 extra is "high"
- set valve Y10 "off" and Y09 "off", water flows via the block connection.
  - elevator and sensor S10 elevator is "high"
- set valve Y10 "on" and Y03 "on", water flows via spray head.
- press the "Release all" button in the expert control. Rinsing tank runs empty and all outputs are "empty".
- go to air valves check 3 and 4.

LIQUID SENSORS

As an alternative for check 2, the working can be checked by putting the system under pressure with a bellow-pump. In the signal overview the relevant input must then be high = "green". Putting it under pressure is carried out by sliding the hose of the pump on the relevant "metering nipple" or "pillar" on the connecting plate. See figure 2, 3 and 4 in Chapter 5.1 for the position of the pillars and nipples. Proceed as follows:

LEAKAGE TEST: S11 + S18

- slide the hose on the pillar in the rinsing tank
- pump bellow: leakage test signal is "green"

CHANNELS: S04-S05-S06-S07-S08-S09

- place the hose on the pillar in the rinsing tank jet, biopsy, air, water, extract
  - pump bellow: channel sensor signal is "green"

ELEVATOR: S10

- set valve 10 "on" via the manual control
- slide the hose on the pillar: elevator control

- pump bellow (to 300 mm Hg): elevator sensor signal is "green"
- when this is not the case: unscrew the central knob until signal is "green"

DETERGENT: S03

- place hose on dosering nipple in the rinsing tank
- pump bellow: detergent sensor signal is "green"

AIR VALVES: CHECK 3 + 4

When an air valve is activated then it is visible through a mechanical indicator on the underside of the valve block. A soft 'tick' is also audible. Repeat this a few times

Inspection occurs through checking the system reaction
Make sure: set air reducer:

- GENERAL 2.5 bar
- leakage test : 0.5 bar
- air tank: 2.5 bar

Air block check 3:

- set valve blowers YOH + Y10 + Y11 "on" air blows out the elevator connection.
- set valve cover Y0D "on" cover opens and cover sensor S13 is "low".
- set valve Y0D "off" cover closes and sensor S13 is "low".
- set valve leakage test Y0E "on" after some time the leakage test sensor S11 is "high".
- set valve Y0E "off" .
- set valve ventilate Y0F "on" sensor S11 is "low".
- set valve leakage test: 2 Y0I "on" after some time leakage test sensor S18 is "high".
- set valve Y0I "off".
- set valve Y0J "on" sensor S18 is "low".
- remove the air hose of the elevator pump.
- set valve elevator pump Y0G "on" air flows from the hose.
- press "Release all" button.

Metering Pumps check 4:

- place disinfectant tank at red socket.
- set disinfectant pump POD "on". Pump turns "on" and after ± 30 sec. the tank empty sensor is "high", disinfectant sensor S02 is "high".
- set pump P0D "off".
- remove the detergent container and place full container back. Detergent empty sensor S22 is "high".
- set detergent pump P0Z "on" sensor detergent S03 is "high", liquid flows in the tank.

- set pump P0Z "off".
- remove the alcohol container and place back full. Alcohol sensor S23 is "high".
- set alcohol pump P0C and valves Y11 and Y10 "on: sensor alcohol S24 is "high", liquid flows in the tank via the elevator connection.

Disinfectant check 5:

- tank is empty: stock tank. Sensors S19 + S20 + S21 are "low".
- remove the sensor unit from the tank.
- move the 3 drivers one by one over the holder so that tank sensors S19 + S20 + S21 are "high".
- place the sensor unit back.
- set valves Y90 + Y02 + Y12 "on".
- set valve Y01 via mouse button to "stop". Water flows in the stock tank, sensor S19 is "high".
- after 30 sec. press "Release all" button.
- set disinfectant pump P0D and supply valve Y13 "on", liquid flows in the rinsing tray.
- when air is lightly pumped, press the "Release all" button.

Other sensor check 6:

- hold a wet cloth against the leakage sensor S90. Sensor S90 is "high".
- fill the tank with 1 liter water via valve Y90 and Y02 valve drain to "stop".
- set the heater "on" temperature sensor U01a and U01b run on.
- pressure after 1 min. on the "Release all" button.
- operate the foot-switch S15. Cover opens and sensor S13 is "high".

LED working:

- remove the communication cable from the AS-i master on the back of the PC
- the two LED's must be red
- place the cable back
- start up left program 00-instr
- LED left is "green"
- stop the program
- LED left is "red"
- repeat process for right unit

DEVIATIONS

When an output does not function or an input does not react then the relevant component must be repaired or replaced.

After the repair the relevant system check should be repeated.

COMPLETION

Approved:

- note this as conclusion
- initial the form and attach it to the machine logbook

Chapter 6

TROUBLESHOOTING

INTRODUCTION

Error Reports

The MDS system can report and display different types of errors which signal and identify specific areas requiring attention. Error types include:

- **System Errors:** A communication problem identified by the prefix C with errors ranging from C-001 through C-099. This is a catastrophic error cause by the Windows base PC or MDS system.
- **Bar Code Errors:** A bar code problem identified by the prefix M with errors ranging from M910 through M-940.
- **Endoscope Errors:** An endoscope problem identified by the prefix S with errors ranging from S102 through S-177.
- **Reprocessing Cycle Errors:** A problem identified during the endoscope disinfection cycle identified by the prefix S with errors ranging from S-201 through S-297, and S-511 through S-832
- **Control Errors (AS-I):** Lists any deviations in the disinfection program as monitored by the AS-I drive controller, and identified by the pre-fix S with errors ranging from S-300 through S-399.
- **Warning Errors:** An alert or warning identified so that the operator is aware of a machine condition that requires attention. Warnings are identified by the prefix W and range from W-701 through W-821.

Onscreen Program Progress

The disinfection program consists of phases and steps. For each disinfection cycle, the phase names, status, and run codes appear on the monitor. Information for the left module appears on the left side of the screen; information for the right module is on the right side.

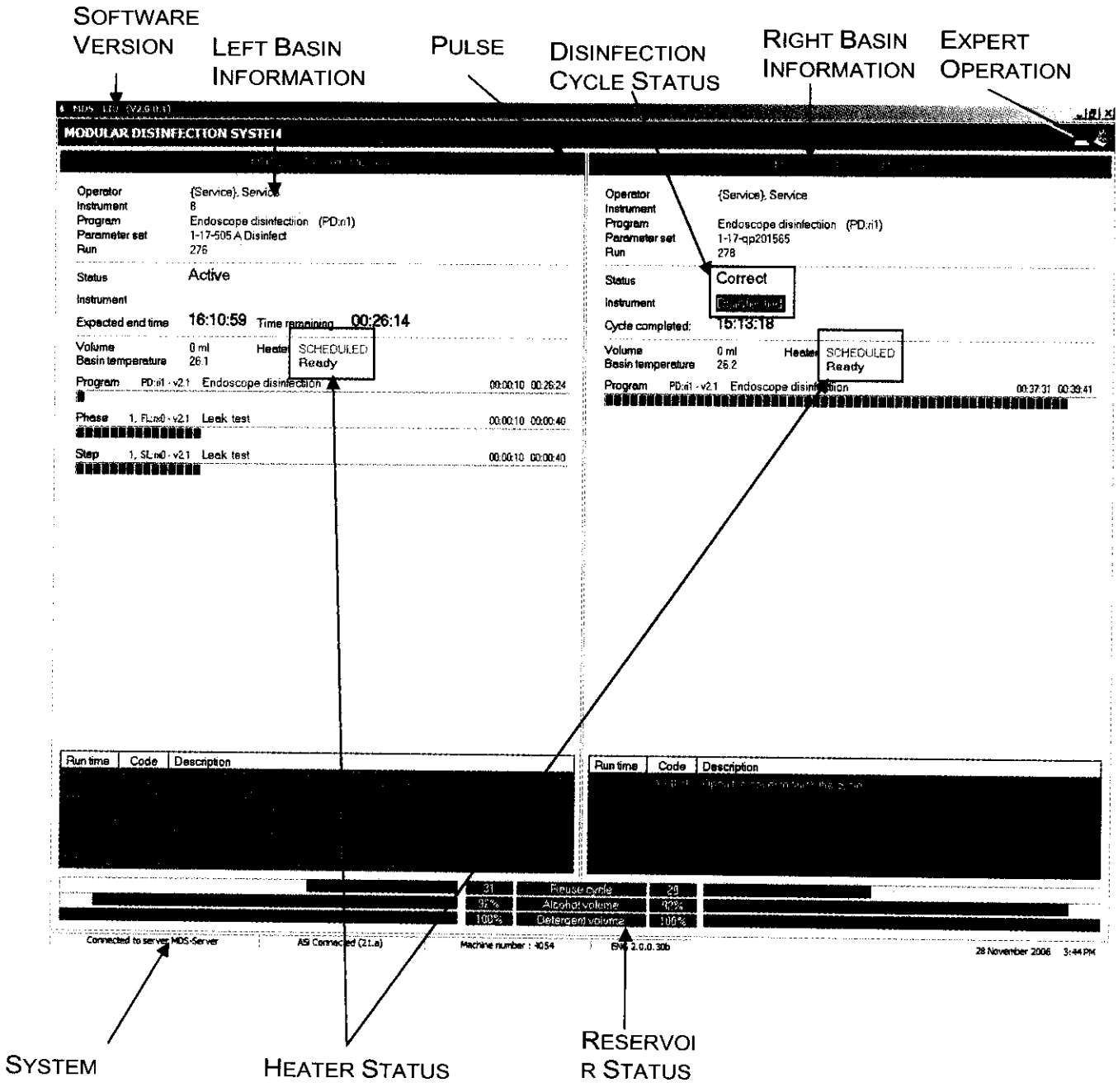


Figure 1 Disinfection Program in Process (Optional Heater Reservoir Equipment installed)

Program Information

This field displays operator and endoscope information as well as the normal progress of the disinfection program. The pre-programmed run time, on the left, is fixed. Real time, on the right, is measured from the start of the cycle. This counter normally decreases as a normal cycle progresses, but may increase or become fixed if an error occurs. The progression of the steps, below the timers, is illustrated with blue time bars. The real time is measured from the start of each step or phase.

Expert Information

This field is visible and active to operators and system administrators with valid passwords. It provides extra information for maintenance and troubleshooting.

Reports and Program Errors

Operator messages and errors appear in the Reports field and communicate cycle progress. An audible alarm also sounds to communicate certain information.

A code number and short description of the report or error is shown, along with the elapsed time at which it is generated. The most recent message is at the top of the field. The meaning of each screen color is shown in the table below:

Table 2 Screen Color and Program Status

Screen Color	Program Status
Orange	Standby, no program active
Gray	Program active
Red	Error
Blue	Program complete

System Errors

Current system errors appear at the top of the screen in white letters on a red background. The message disappears once the error is corrected.

If a system error occurs during standby mode, a warning message appears as the fault occurs but disappears as the situation is corrected.

If the error occurs during a disinfection cycle, the program ends and fluids are pumped out of the basin. A recovery program runs until a safe state is reached and the endoscope can be removed. The recovery program can not be stopped by the operator.

System Information

The bar at the bottom of the screen provides system communication information, machine identification, and the software version.

MDS software has two possible system connections:

1. MDS PC to the MDS (ASi)

2. MDS PC to an external server (optional)

The left field on the bar indicates if the MDS is connected to a server. The next field to the right indicates if the PC is correctly connected to the MDS. The bar is red if an error exists.

ERROR OVERVIEW

Screen reports and errors are summarized by category and number in the following tables. More specific information including potential causes, and actions for each error are included following that. For complex problems, it is advisable to notify the maintenance department and/or your supervisor.

System Errors

Code	Description
C-001	AS-i error: %d: %S
C-011	Server disconnected. Run data will be buffered.
C-012	No hardware definition received. Hardware not initialized.
C-015	Server disconnected. Selection aborted.
C-019	The clock has been synchronized with the server computer
C-021	The expert control has been automatically closed, you have to log on again.
C-030	The previous run has ended incorrectly. Program aborted to a safe situation.
C-032	A failure occurred during the execution of a run. Program aborted to a safe state.
C-033	Program aborted to a safe situation, but incorrect parameter set.
C-040	The hardware definition contains an unknown signal: %d.
C-041	The hardware definition contains an unknown data source for the signal: %d.
C-042	Selected hardware definition not correct for "%s" type.
C-052	Automatic start of program is not possible in the current state.
C-053	Automatic program start up is not possible because another program is already active.
C-054	Automatic start of program is not possible, heater temperature outside limits.
C-060	Delayed start of program is not possible in the current state.
C-080	The tag-reader is not available.
C-099	Internal LIO failure :

Bar Code Errors

Code	Description
M-910	The scanned barcode is unknown.
M-920	The scanned tag is an unknown operator code.
M-922	The scanned tag is an unknown instrument code.
M-930	OK barcode read but no active selection
M-940	The code "%s" is not the correct %s code.

Endoscope Errors

Code	Description
S-102	Start not possible: leak test sensor high.
S-103	Endoscope leaking or incorrectly connected.
S-104	Leak test pressure dropped after check.
S-105	Leak test vented but remains on pressure.
S-106	The block is not pressurizing or is not connected.
S-112	Start not possible: air sensor high.
S-113	No flow: air channel.
S-114	Blocked air channel.
S-115	No pressure: air channel.
S-116	No connectivity air channel
S-117	Air channel not connected
S-122	Start not possible: biopsy sensor high.
S-123	No flow: biopsy channel.
S-124	Blocked biopsy channel.
S-125	No pressure: biopsy channel.
S-126	No connectivity biopsy channel
S-127	Biopsy channel not connected
S-132	Start not possible: jet sensor high.
S-133	No flow: jet channel.
S-134	Blocked jet channel.
S-135	No pressure: jet channel.
S-136	No connectivity jet channel.
S-137	Jet channel not connected.
S-142	Start not possible: suction sensor high.
S-143	No flow: suction channel.
S-144	Blocked suction channel.
S-145	No pressure: suction channel.
S-146	No connectivity suction channel.
S-147	Suction channel not connected.
S-152	Start not possible: water sensor high.
S-153	No flow: water channel.
S-154	Blocked water channel.

S-155	No pressure: water channel.
S-156	No connectivity water channel.
S-157	Water channel not connected.
S-162	Start not possible: extra sensor high.
S-163	No flow: extra channel.
S-164	Blocked extra channel.
S-165	No pressure: extra channel.
S-166	No connectivity extra channel.
S-167	Extra channel not connected.
S-172	Start not possible: elevator wire channel sensor high.
S-173	No flow: elevator wire channel.
S-174	Blocked elevator wire channel.
S-175	No pressure: elevator wire channel.
S-176	No connecting elevator wire channel.
S-177	Elevator wire channel not connected.

Reprocessing Cycle Errors

Code	Description
S-201	Fluid leak in the system
S-203	Wrong connector block
S-211	Cover open
S-222	Start not allowed: Detergent sensor high
S-223	No flow detergent
S-224	Start not allowed: Detergent level low
S-242	Start not allowed: Alcohol sensor high
S-243	No flow alcohol
S-244	Start not allowed: Alcohol level low
S-271	Start not allowed: Insufficient disinfectant
S-272	Start not allowed: Basin not empty
S-273	Basin suddenly empty
S-274	Basin not emptying
S-275	Basin level dropped
S-276	Basin minimum level not reached
S-281	Volume measurement no pulses
S-282	Water inlet flow too high

S-283	Water inlet flow too low
S-285	No water supply
S-286	Volume measurement V1 > V2
S-287	Volume measurement V1 < V2
S-288	Unrequested inlet water detected
S-289	External water supply valve failed
S-292	Basin temperature sensor defective
S-293	Water temperature too high
S-294	Water temperature too low
S-297	Basin temperature too high
S-511	Measure contact time too short
S-611	Start not allowed. Disinfectant reuse count exceeded
S-631	Start not allowed: Disinfectant reservoir is empty
S-632	Start: Disinfectant reservoir is not empty
S-633	Start: The disinfectant reservoir is full
S-634	Start not allowed: Disinfectant reservoir does not detect minimum level
S-635	Start not allowed: Disinfectant reservoir overflowed.
S-636	Start not allowed: Disinfectant reservoir sensor defective
S-641	Disinfectant reservoir full
S-642	Disinfectant reservoir detects minimum level
S-643	Disinfectant reservoir not empty
S-651	Disinfectant reservoir does not detect low level
S-652	Disinfectant reservoir does not detect minimum level
S-671	"Machine control" locked by the other side
S-672	Wrong system side
S-831	Air cylinder does not charge
S-832	Air cylinder not discharged

Control Errors (AS-i)

Code	Description
S-300	ASC message: F.../S.../T...
S-301	ASC in "OK" state
S-302	ASC : wrong configuration.
S-304	ASC no connection.
S-350	Manual control active
S-360	Stopped by the operator

Warnings Errors

Code	Description
W-701	ASC: No connection.
W-702	ASC: Wrong configuration.
W-703	ASC: Incorrect status and cover inactive.
W-704	ASC: Incorrect status.
W-705	ASC: in "OK" state
W-711	Cover is open.
W-712	Cover will not open.
W-713	Cover will not close.
W-715	Basin not empty.
W-716	Fluid leak in system.
W-721	Water temperature sensor defective.
W-727	Reservoir temperature too high.
W-728	Scheduled stop time incorrect, reset to midnight.
W-743	Sensor S03: Detergent high.
W-744	Sensor S17 Minimum level high
W-749	Sensor S24: Alcohol high
W-751	Sensor S11 Leak test #1 high
W-757	Sensor S33 high
W-764	Channel sensor S04 high (Air)
W-765	Channel sensor S05 high (Biopsy)
W-766	Channel sensor S06 high (Jet)
W-767	Channel sensor S07 high (Suction)

W-768	Channel sensor S08 high (Water)
W-769	Channel sensor S09 high (Extra)
W-770	Channel sensor S10 high (Elevator)
W-800	Manual control active
W-801	Purge active, start blocked
W-802	Alcohol sensor venting, start blocked
W-803	Discharging air vessel, start blocked
W-805	Left side controls the water line disinfect
W-810	Open the cover to finish the cycle
W-820	Disinfectant in the basin (The cover is locked)
W-821	Disinfectant in the supply lines, (The cover is locked)

SYSTEM ERRORS

Asi error: %d: %s	C-001

Cause: There is a temporary interruption in the connection between the ASi and the MDS machine.

Action: Check the message at the lower left of the screen. If it says "ASi connected" then the connection has been restored. Press the **Open/Close** button or the **Start** button to continue. If the message says "ASi disconnected" then attempt the action listed below.

Cause: There is a power failure in the machine or the plug is loose.

Action: Check the plug. If it is not loose, report the failure to the maintenance department.

Server disconnected. Run data will be buffered	C-011

Cause: The connection to the database has been interrupted.

- The LIO program cannot retrieve the overview lists and the selection screen is empty.
- The connection to the server is interrupted in stand-by mode.
- It is not possible to start a program.

Action: Report the error to the system manager. As long as "Disconnected from server" appears at the bottom of the screen, the program can not be restarted.

No hardware definition received. Hardware not initialized	**C-012**

Cause: This error occurs if there is a problem with the ASi control software. This definition is the layout of the ASi control and is determined by the configuration of machine. Possible issues are in the following list:

- Installation of the ASi layout is not found.
- The LIO program was incorrectly installed.
- Software problem.
- Communication problem with the ASi interface.

Action: Report the error to the MDS system manager.

Server disconnected. Selection aborted.	**C-015**

Causes: The connection to the database has been interrupted.

- The LIO program cannot retrieve the overview lists and the selection screen is empty.
- The connection to the server is interrupted in stand-by mode.
- It is not possible to start a program.

Action: Report the error to the system manager. As long as "Disconnected from server" appears at the bottom of the screen, the program can not be restarted.

The clock has been synchronized with the server computer (%s)	**C-019**

Cause: If the MDS clock and the server clock have a time difference of more than 30 seconds, a time variance occurs in the run report.

Action: Reset the clocks on the computer:

- Press the **Start** button.
- Press the **Help** button.
- Select change computer time.

- Open date/time.

The Expert control has been automatically closed, you have to log on again	**C-021**

Cause: The Expert screen has timed out.

Action: to continue using the Expert functions login again.

The previous run has ended incorrectly. Program aborted to a safe situation.	**C-030**

If a system error occurs, then it is not possible to create a correct run report. If the error is repaired, then the error message disappears and the restoration program automatically runs to rinse the endoscope with water so that it can be safely removed of the machine. This program can not be stopped and the endoscope is not disinfected.

Cause: A black screen means the program is not visible. Possible causes are as follows:

- The PC was switched off.
- There is a PC defect.
- There was a power failure.

Action: Try pressing the **On/Off** switch on the PC. If this does not solve the error, contact the maintenance department.

Cause: There is a communication problem so the program cannot be run correctly. Possible causes are as follows:

- There is a cable fault.
- A cable is loose.
- There is a program error.
- The MDS control unit is defective.
- There is a blown or defective fuse.

Action: Contact the maintenance department and the system manager.

Cause: There is a communication problem with the ASi interface and message *W-701* is also on the screen. Possible causes are as follows:

- There is a fault with the ASi interface.
- A network cable is disconnected.
- A cable is faulty.

- There is a communication problem with the server.
- There is a server error.

Action: Check the cable connection between the network and the machine. Restore the connection if possible and start the machine program again. If you are unable to repair the connection, report the error to the system manager

Cause: The LIO program was interrupted. Message *W-703* also appears on the screen and the cover knob is blocked.

Action: Start the restore program.

A failure occurred during the execution of a run. Program aborted to a safe situation.	**C-032**

If an ASi error occurs, then it is not possible to carry out a correct disinfection cycle. If the error is repaired, then this *C-032* message appears and the restoration program is automatically selected. The endoscope is rinsed with water so that it can be safely removed from the MDS but it will not be disinfected. The restoration program works automatically and can not be stopped.

The endoscope must be run through a complete disinfection program before use.

Cause: There is an internal communication problem with the PC. Possible causes are as follows:

- There is a cable fault.
- A cable is loose.
- There is a program error.
- The ASi interface in the MDS is defective.
- A fuse is blown or defective.

Action: Report the problem to the maintenance department.

Cause: A new program was started while another one was already active.

Action: Press the **Start** ⏀ button to start the restore program.

Program aborted to a safe situation, but incorrect parameter set	**C-033**

Cause: An incorrect parameter set was selected for the machine disinfection or the restore program.

Action: Select the correct parameter set for the restore program.

Cause: The LIO program was interrupted or shut down during a run. Message *W-703* also appears and the lid can not be opened.

Action: Start a restore program.

Hardware definition contains an invalid signal %d	C-040

Cause: An incorrect address is entering the controller from the ASi slaves or a slave has been incorrectly coded.

Action: Report the error to the maintenance department. Note the unknown signal number: nn.

The hardware definition contains an unknown data source for the signal: nn	C-041

Cause: An address was incorrectly set up in the AS-I software or a slave was incorrectly coded.

Action: Report the error to the MDS system manager. Note the signal number: nn.

Selected hardware definition not correct for "%s" type	C-042

Cause: The system settings parameters for the left/right unit type have not been selected.

Action: Report the error to the MDS system manager.

Automatic start of program is not possible in the current state	C-052

Cause: There is warning text in the report field.

Action: Ensure that all error messages are resolved. Select a machine disinfection auto start. If necessary, consult the MDS system manager.

Cause: An auto start for endoscope disinfection is already set up.

Action: Cancel the auto start for the endoscope disinfection.

Another program is active	C-053

Cause: Machine disinfection should start but there is an active cycle running.

Action: Let the current program run to completion. When the MDS is ready and the basin cover is still open, insert the machine disinfection block and close the cover. The machine disinfection will start automatically.

Automatic start of program is not possible, heater temperature outside limits	**C-054**

Cause: The disinfectant temperature in the reservoir is either too cold or too hot.

Action: Report the error to Maintenance.

Delayed start of program is not possible in the current state.	**C-060**

Cause: Warning messages (numbers *W700-W799*) are present on the screen during automatic start up of a disinfection program.

Action: Ensure that the messages are resolved. Select the automatic restart. Consult the maintenance department if necessary.

Cause: Auto start for another program is already set up.

Action: For the delayed start, the other program must first be shut down.

Tag-reader not available	**C-080**

Cause: The I-Dent system is defective.

Action: Report the error to the maintenance department and the MDS system manager to have the chip (=Tag) system disconnected. The program can be started after switching off I-Dent.

Internal LIO failure : %s	**C-099**

Cause: A wrong selection was executed when setting the machine system parameters.

Action: Report the error to the MDS system manager to correct the settings. Then restart the program.

BAR CODE ERRORS

The scanned bar code is unknown	M-910

If the system is set up to require the use of the bar code reader, manual selection with the cursor is not possible.

Cause: The bar code belongs to another item to be read.

Action: Check if the bar code type is the same as the selected input field on the screen. Scan the correct bar code again.

Cause: The bar code is not entered in the management system.

Action: Report the error to the MDS manager along with a request to add the bar code for the selected item.

The scanned tag is an unknown operator code	M-920

The system is set up to require use of the automatic identification (I-Dent) system for operator identification.

Cause: The read tag is entered incorrectly or is not reported in the management database.

Action: Report the situation to the MDS manager along with a request to add the correct tag code to the operator list.

The scanned tag is an unknown endoscope code	M-922

The system is set up to require use of the automatic identification (I-Dent) system for endoscope selection.

Cause: The read tag is entered incorrectly or is not reported in the management database.

Action: Report the situation to the MDS manager along with a request to add the correct tag code to the endoscope list.

OK barcode read but no active selection	M-930

Cause: The barcode was read but the **OK** ✓ button was not enabled.

Action: Click the **OK** ✓ button.

The code "%s" is not the correct %s code.	M-940

Cause: An incorrect code or lot number was entered while performing the Tank Change utility for either the detergent or alcohol.

Action: Rerun the Tank Change utility and enter a valid code.

ENDOSCOPE ERRORS

Start not possible: leak test sensor high.	S-102

This message appears if no disinfection program is active and the leak test sensor is on. When this message occurs, no disinfection program can be started.

Cause: If the endoscope is vented too quickly, then it remains pressurized, causing the leak test sensor to be on.

Action: Stop the program and disengage the terminal block to reduce the pressure. This causes the message *W-751* to disappear. If the error message remains, see the next cause and action below.

Cause: A faulty sensor faulty continues to incorrectly read on.

Action: Report the situation to the maintenance department for repairs.

Cause: The air valve leaks.

Action: Report the error to the maintenance department.

Endoscope leak or connected incorrectly	S-103

Cause: The endoscope or connection hose is leaking seriously. The leak test connection is not in order.

Action: Use a manual leak tester (with a pressure gauge) to see if the endoscope leaks. If so, have the endoscope repaired. If there is no leak, check the endoscope connection and restart the program. If the report recurs, consult the maintenance department.

Cause: The block is out of alignment to the connection plate in the rinse basin.

Action: Stop the program, disconnect, and place the block anew. Restart the program.

Leak test pressure dropped after check.	S-104

Cause: Very tiny leak in the endoscope.

Action: Using the pressure gauge, pump the endoscope to pressurize and check to see if it is leaking. If there is a leak, report it to the maintenance department. If the endoscope is not leaking, see other causes of the error below.

Cause: Very tiny leak in the leak test system of the MDS, the terminal connector, or the connection block.

Action: Consult the maintenance department to repair the leakage.

Cause: A power failure vents the endoscope and the error message follows.

Action: If the machine automatically started up after the error, no further action is required. Otherwise, contact the maintenance department.

Cause: If the endoscope stays pressurized, a sensor is faulty.

Action: Report the situation to the maintenance department.

Leak test vented but stays on pressure	S-105

Cause: There may be an air valve defect if air does not vent from the endoscope during the ventilation process.

Action: Try to start the process again by pressing the **Start** ◈ button. If the message recurs, press the **Stop** ▽ button. Remove the connection block and check to see if air is escaping (there is a hissing noise). If so, report it to the maintenance department. If air is not escaping, see other possible causes of the error below.

Cause: The leak test sensor is defective or out of alignment. This causes the signal to be maintained after the block is removed.

Action: Report to the maintenance department for repairs.

Cause: The flow control air valve is contaminated or out of alignment.

Action: Try to start the process step again by pressing the **Start** ◈ button. If the error recurs, ask the maintenance service to align the valve.

Block not pressurized or not connected	S-106

Cause: The endoscope is not properly connected.

Action: Stop the machine and check if the leak test connections and the terminal block are properly placed. Connect the leak test and block again. Start the program.

Cause: Machine fault.

Action: Consult the maintenance department.

Start not possible: suction sensor high	S-112, S-122, S-132, S-142, S-152, S-162, S-172

This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Suction
- Jet
- Water
- Elevator

These errors appear if a disinfection program is selected and the specific channel sensor is on. When this message occurs no disinfection program can be started.

Stop the program and open the lid. An endoscope warning (*W-764* through *W-770*) appears. This message must be cleared before a restart takes place.

Cause: The endoscope channel is blocked, causing the sensor to be on.

Action: Disconnect the connector from the channel in the endoscope. If the message disappears, report the blocked endoscope to the maintenance department. If the message remains, see other possible causes of the error below.

Cause: The connection block is blocked when the endoscope is not connected.

Action: Disconnect the connection block and replace it with another. If the message disappears, let the maintenance department unclog the block. If the message remains, see other possible causes of the error below.

Cause: The channel sensor is defective or out of alignment

Action: Report the faulty sensor to the maintenance department.

No flow: channel	**S-113, S-123, S-133, S-143, S-153, S-163, S-173**

This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Suction
- Jet
- Water
- Elevator

Action: First try the process step again by pressing the **Start** ⏻ button. If the report recurs, press the **Stop** ⏻ button.

Cause: Channel connector not connected.

Action: Press the **Stop** ⏻ button and connect the endoscope. Start the program again.

Cause: The connector terminal block handle is not connected, or the block is out of alignment.

Action: Press the **Stop** ⏻ button and open the cover. Place the terminal block and make sure that the handle is fastened in the lock pins on both sides. Start the program again.

Cause: An incorrect program choice was selected for the instrument.

Action: Check that the number of channel connections (excluding the leak test) agrees with the statement on the screen after "Parameter set." In the case of an anomaly or doubts, stop the program and report the error directly to the system manager.

Cause: Wrong block.

Action: Check that the number of hoses on the block (excluding the leak test) is the same as the number of channel connections on the endoscope. In the case of a deviation, replace the block with the correct implementation and start the program again.

Cause: Too little pump pressure or the channel sensor is faulty.

Action: Consult the maintenance department. After restart, the channel sensor does not become high. Press the **F1** or **F2** buttons to see the signal units.

Cause: The sprayer is worn, which causes too much pressure (flow) loss along the bearing.

Action: A horizontal spray pattern of the leaking water can be seen with a restart. Report the error to the maintenance department.

Cause: The channel sensor is out of alignment.

Action: After restart the signal blinks too much and is unstable. Press the **F1** button to signal units. Report the situation to the maintenance department for carrying out calibration.

Blocked channel	**S-114, S-124, S-134, S-144, S-154, S-164, S-174**

This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Suction
- Jet
- Water
- Elevator

Try to start the process again by pressing the **Start** ⏀ button. This can be done once. If the message recurs, the **Stop** ▽ button must be pressed.

Cause: Connection hose(s) is kinked or pinched.

Action: Check all hoses. If kinked or pinched, straighten out hose(s) and start the program again. If none of the hoses is kinked or pinched, see other possible causes of the error below.

Cause: Channel blocked.

Action: If the channel is blocked, have the endoscope checked or repaired. If there is no blockage, try the endoscope in a different MDS system. If the error is repeated, check the connection block. See other possible causes of the error below.

Cause: Connection block obstructed.

Action: Press a properly fitting hose of a small bellows pump (manual leak test) in the holes on the underside of the terminal block. Squeeze the bellows. Air should come out of the channel connection. If there is a blockage, consult the instrument service manual to unclog the connection block. If the block is not obstructed, then a machine fault is probably the cause. Consult the maintenance department.

No pressure: channel	**S-115, S-125, S-135, S-145, S-155, S-165, S175**

This report occurs for the following channels:

- Air
- Suction
- Elevator
- Biopsy
- Jet
- Extra
- Water

Cause: There is insufficient air pressure to blow the moisture out of the channels.

Action: Press the **Start** ⓘ button to try the process step again. If the message recurs, press the **Stop** ▽ button.

Cause: A hose is detached.

Action: Verify all hoses are still connected to the endoscope then start the program again.

Cause: Incorrect parameter set.

Action: When in doubt or if the wrong parameter is set, report the problem to the MDS system manager.

No connectivity: channel	**S-116, S-126, S-136, S-146, S-156, S-166, S-176**

This control checks interconnected endoscope channels and the message is given per channel, i.e.:

- Air
- Suction
- Elevator
- Biopsy
- Jet
- Extra
- Water

Cause: There is a connector loose from the endoscope.

Action: If you see a loose connection, press the **Stop** ▽ button. Close the program, connect the loose connection, and restart the cycle.

Cause: It is not clear if all channels are connected.

Action: Try to start the process again by pressing the **Start** ⓘ button. This may be tried once. If the message reoccurs, you must press the **Stop** ▽ button and call Maintenance.

Channel not connected	**S-117, S-127, S-137, S-147, S-157, S-167, S-177**

This control checks small endoscope channels and the message is given per channel, i.e.:

- Air
- Suction
- Elevator

- Biopsy
- Extra
- Jet
- Water

Cause: There is a connector loose from the endoscope.

Action: If you see a loose connection, press the **Stop** ⊽ button. Close the program, connect the loose connection, and restart the cycle.

Cause: It is not clear if all channels are connected.

Action: Try to start the process again by pressing the **Start** ◈ button. This may be tried once. If the message reoccurs, you must press the **Stop** ⊽ button and call Maintenance.

REPROCESSING CYCLE ERRORS

Fluid leak in the system	**S-201**

If the message report is visible, then the program can not be stopped. After drying out, it can take 5–10 minutes before the sensor message disappears. If the sensor is released, only the program can be stopped.

Cause: There is liquid in the front of the machine as result of a leak.

Action: If possible, close the water supply tap and consult the maintenance department

Cause: If the reservoir is dry, a sensor is out of alignment.

Action: Remove the two reservoirs and dry the green sensor with a cloth. If the message remains, report the error to the maintenance department to have the sensor aligned, or to have the program shut down for technical service.

Wrong connection block	**S-203**

The machine disinfection automatically started and checked whether the hot water block is fitted.

Cause: No connection block is present:

Action: Place the machine disinfection connection block and then press the **Start** ◈ button.

Cause: The endoscope connection block is present.

Action: Exchange this block for a machine disinfection connection block and press the **Start** ⏀ button.

Cause: The machine disinfection connection block is present.

Action: Try pressing the **Start** ⏀ button again. If the message recurs, then consult the maintenance department.

Cover open	**S-211**

Cause: The cover is closed: During the program, the cover sensor has failed and now indicates that the cover is open.

Action: The program can be stopped only via the expert operation. Report the error to the maintenance department to adjust the sensor, if necessary.

Cause: During the program the cover was opened.

Action: Close the cover and press the **Start** ⏀ button to continue the program.

Start not allowed: detergent sensor high	**S-222**

Cause: The detergent sensor is out of alignment or faulty.

Action: Report the fault to the maintenance department.

No flow detergent	**S-223**

Cause: The detergent reservoir is empty.

Action: Check if the detergent reservoir is empty. If so, fill the reservoir. If there is sufficient detergent in the reservoir, press the **Start** ⏀ button. If the error repeats, see the alternate cause below.

Cause: The detergent sensor or pump is defective.

Action: Report the fault to instrument service.

Start not allowed : Detergent level low. Start not allowed : Alcohol level low.	**S-224, S-244**

Cause: The reservoir is empty.

Action: Check if the level of fluid in the reservoir. If it is empty, fill or replace the reservoir. If there is sufficient fluid in the reservoir,

press the **Start** ⏀ button. If the error repeats, see the alternate cause below.

Cause: The sensor in the reservoir is defective.

Action: Report the fault to Maintenance.

Start not allowed: Alcohol sensor high	**S-242**

Cause: The alcohol sensor is out of alignment or faulty.

Action: Report the fault to the maintenance department.

No flow alcohol	**S-243**

Cause: The alcohol reservoir is empty.

Action: Check if the alcohol reservoir is empty. If so, fill the reservoir. If there is sufficient alcohol in the reservoir, press the **Start** ⏀ button. If the error repeats, see the alternate cause below.

Cause: The alcohol sensor or pump is defective.

Action: Report the fault to instrument service.

Start not allowed : Insufficient disinfectant	**S-271**

This message appears if no disinfection program is active and the level sensor is on. When this report occurs, a disinfection program can not be started.

Cause: Water in the rinse basin is causing the level sensor to report liquid.

Action: Wait until the basin is empty. Make sure that the cover is closed so that the basin can automatically run empty.

Cause: The basin level sensor is faulty, causing it to remain high even though the basin is empty.

Action: Report the fault to instrument service for repairs.

Start not allowed : Basin not empty	**S-272**

This message appears if no disinfection program is active and the basin empty sensor is on. When this message occurs, a disinfection program can not be started.

Cause: Water in the rinse basin is causing the level sensor to report liquid.

Action: Wait until the basin is empty. Make sure that the cover is closed so that the basin can automatically run empty.

Cause: The volume report on the screen is not 0, so the system is not released.

Action: Close the cover and wait until the message moves to zero. This may take a few minutes. If there is no effect, see the following cause below.

Cause: The basin empty sensor is faulty, causing it to read high when the basin is empty

Action: Report the fault to instrument service for repairs.

Basin suddenly empty	**S-273**

Cause: The drain valve leaks due to contamination. The rinse basin empties during rinsing.

Action: Check if there is still any liquid in the basin. If the basin is empty, press the **Stop** ⓥ button and report the fault to the maintenance department. If the basin is filled see the cause below.

Cause: The basin empty sensor is faulty.

Action: Press the **Stop** ⓥ button and report the error to the maintenance department.

Basin not emptying	**S-274**

Try the process again by pressing the **Start** ⓢ button. If the message recurs, press the **Stop** ⓥ button.

Cause: The drain is blocked.

Action: Check if the rinse basin runs empty properly. If it does not, contact the maintenance department. If is does, see the causes listed below.

Cause: The drain valve is faulty if the volume level does not go down.

Action: If the level does not go down, report the error to the maintenance department. If the level goes down, see the causes listed below.

Cause: The drainage hose sags which causes the rinse basin to run empty too slowly.

Action: Check the drainage hose. If it is sagging, report the situation to the maintenance department. If the hose does not sag, see the cause listed below.

Cause: The basin empty sensor is faulty.

Action: Report the situation to instrument service.

Basin level dropped	S-275

Cause: Liquid ran out of the basin due to contamination on the valve seal.

Action: Report the fault to the maintenance department. If the tank is full, press the **Start** ⓘ button to try running the program. If the tank is empty, change the tank and restart the program.

Cause: The drainage valve opened due to an error control.

Action: Report the fault to the maintenance department.

Cause: The rinse basin level sensor is defective or contaminated.

Action: Report the fault to the maintenance department.

Basin minimum level not reached	S-276

Water must be present in the rinse basin to check for the correct connection block.

Cause: The drainage valve leaks.

Action: Press the **Start** ⓘ button and to see if water drains from the basin. If it doesn't, contact the maintenance department. If water drains, see the cause below.

Cause: The basin empty sensor is defective so the control of the block is incorrectly carried out.

Action: Report the fault to the maintenance department.

Volume measurement no pulses	S-281

Cause: There is water in the rinse basin but the volume is not measured.

Action: Press the **Stop** ⓥ button. Consult the maintenance department.

Water inlet flow too high	S-282

Press the **Start** ⓢ button to attempt to run the process step again. If the message recurs, press the **Stop** ⓢ button.

Cause: - The rinse basin fills too quickly because the water supply pressure is too high.

Action: Press the **Stop** ⓢ button and report the situation to the maintenance department.

Water inlet flow too low	**S-283**

Press the **Start** ⓢ button to attempt to run the process step again. If the message recurs, press the **Stop** ⓢ button.

Cause: The basin fills too slowly because the water supply pressure is too low or the filter is contaminated.

Action: Press the **Start** ⓢ button to continue the program and pay close attention to the water as it enters the basin. If the flow is weak, report it to the maintenance department. If the flow is normal, see the possible cause below.

Cause: The volume meter is contaminated or defective.

Action: Press the **Stop** ⓢ button and report the situation to the maintenance department.

No water supply	**S-285**

Cause: The water tap is closed.

Action: Check the water tap. If it is open, see the possible cause below. If the tap is closed, open it and press the **Start** ⓢ button.

Cause: The water supply valve is defective.

Action: Report the situation to the maintenance department.

Volume measurement V1 > V2	**S-286**

Cause: The volume measurement and volume control indicate deviating values

Action: Stop the program and report the error to the maintenance service.

Volume measurement V1 < V2	**S-287**

Cause: The volume measurement and volume control indicate deviating values

Action: Stop the program and report the error to the maintenance service.

Unrequested inlet water detected	**S-288**

Cause: The water supply valve is leaking and may dilute the disinfectant.

Action: Report the error to the maintenance department.

External water supply valve failed	**S-289**

Cause: The water supply valve on the filter unit is leaking, so machine disinfection can not be performed.

Action: Report the error to the maintenance department.

Basin temperature sensor defective	**S-292**

This error occurs independently of the software and is an extreme situation. Pressing the **Stop** ▽ button has no effect. Interrupting the program is only recommended after a technician has judged the situation. The program can be stopped via the expert operation. After resolving the fault, the program can be continued.

Cause: The temperature sensor is defective if the temperature message on the screen is higher than 100°C.

Action: Report the error to the maintenance department.

Cause: If the heater is switched on, the heater temperature sensor rises and the rinse basin temperature measurement does not.

Action: Report the fault to the maintenance department.

Water temperature too high	**S-293**

Press the **Start** ◇ button to start the process step again. If the message recurs, press the **Stop** ▽ button.

Cause: The drainage block is too warm after a disinfection program.

Action: Wait five minutes, or pour cold water in the rinse basin to see if the temperature indicated on the screen drops.

Cause: The setting or mixing valve is out of order, causing the supplied water to be too hot.

Action: Press the **Stop** ▽ button and check or adjust the setting of the mixing valve. Wait for a while until the water in the machine has cooled down. Then start the program again.

Water temperature too low	**S-294**

Press the **Start** ◇ button to start the process step again. If the message recurs, press the **Stop** ▽ button.

Cause: The adjustment or mixing valve is out of order, causing the water supply to be too cold.

Action: Contact the maintenance department. Press the **Stop** ▽ button and check or adjust the mixing valve. Start the program and check if the temperature indicated on the screen is correct for the program.

Cause: The warm water supply is stagnated.

Action: Press the **Stop** ▽ button and consult the maintenance department.

Basin temperature too high	**S-297**

This error occurs independently of the software and is an extreme situation. Pressing the **Stop** ▽ button has no effect. Interrupting the program is only recommended after a technician has judged the situation. The program can be stopped via the expert operation. After resolving the fault, the program can be continued.

Cause: The water temperature in the rinse basin is too high:

- Instrument disinfection: >50°C.
- Machine disinfection: >90°C.

Action: Stop the program and report the fault to the maintenance service.

Measured contact time is too short	**S-511**

The prescribed contact time is a sum of the time for different steps (SV + SS + SC + RS = option).

Cause: There was a change in the drain and fill time for the basin.

Action: Report the error to Maintenance so they can recalibrate.

Cause: The program parameters have been changed.

Action: Report the fault to the system administration.

Start not allowed: Disinfectant reuse count exceeded	S-611

Cause: The disinfectant has been reused the maximum allowed number of times.

Action: Dump disinfectant and replace with new disinfectant.

Start not allowed: Disinfectant reservoir is empty	S-631

Cause: The disinfectant reservoir is empty.

Action: Refill reservoir with new disinfectant.

Cause: The reservoir empty sensor is defective.

Action: Report the error to maintenance.

Start: Disinfectant reservoir is not empty	S-632

Cause: The disinfectant reservoir fill utility has been started but the disinfectant reservoir is not empty.

Action: Empty reservoir and then rerun the reservoir fill utility.

Cause: The reservoir minimum level sensor is defective.

Action: Report the error to maintenance.

Start: The disinfectant reservoir is full	S-633

Cause: The disinfectant reservoir fill utility has been started but the disinfectant reservoir is full.

Action: Empty reservoir and then rerun the reservoir fill utility.

Start not allowed: Disinfectant reservoir does not detect minimum level	S-634

Cause: The disinfectant reservoir is low.

Action: Fill reservoir with new disinfectant.

Cause: The reservoir minimum level sensor is defective.

Action: Report the error to maintenance.

Start not allowed: Disinfectant reservoir overflowed	S-635

Cause: The disinfectant reservoir has overflowed.

Action: Dump some of the disinfectant in the reservoir.

Cause: The reservoir overflow sensor is defective.

Action: Report the error to maintenance.

Start not allowed: Disinfectant reservoir sensor defective	S-636

Cause: One of the reservoir sensors is defective.

Action: Report the error to maintenance.

Disinfectant reservoir full	S-641

Cause: The disinfectant being drained to the reservoir has reached the overflow sensor. Water may have been drained into the disinfectant reservoir.

Action: Dump the disinfectant in the reservoir and refill with new disinfectant.

Cause: The reservoir overflow sensor is defective.

Action: Report the error to maintenance.

Disinfectant reservoir detects minimum level	S-642

Cause: The disinfectant pump is defective.

Action: Report the error to maintenance.

Cause: The reservoir minimum level sensor is defective.

Action: Report the error to maintenance.

Cause: The disinfectant uptake filter is blocked.

Action: Report the error to maintenance.

Disinfectant Reservoir Not Empty	S-643

Cause: The disinfectant reservoir is not emptying within acceptable time period.

Action: Low-level disinfectant sensor faulty or sticking.

Cause: Disinfectant filter restricted – requires replacement.

Action: Disinfectant pump delivery system requires flow recalibration.

Disinfectant Reservoir Does Not Detect Low Level	**S-651**

Cause: No disinfectant in reservoir.

Action: Fill reservoir with disinfectant.

Cause: Low-level sensor faulty or sticking.

Action: Report the error to the maintenance.

Disinfectant Reservoir does not detect minimum level	**S-652**

Cause: The disinfectant reservoir is low.

Action: Check for leakage then fill reservoir with new disinfectant.

Cause: The reservoir minimum level sensor is defective.

Action: Report the error to the maintenance.

"Machine Control" Locked by the other side	**S-671**

Cause: The machine disinfection program is active. It is not possible to use this side of the machine.

Action: Wait until the program has run completely.

Wrong system side	**S-672**

Cause: The machine disinfection program is started from the right side rather than the left side.

Action: Cancel the selection from the right side and restart it on the left side.

Air cylinder does not charge	**S-831**

Cause: The cylinder is used to check connectivity from the endoscope to the MDS. The cylinder is not filled so the check can not be performed.

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Action: This is the last step of the disinfection cycle. When all channels are still connected, the endoscope is properly disinfected. Visually check the connection and report the error to maintenance.

Air cylinder not discharged (reservoir pressurized)	**S-832**

Cause: The cylinder is used to check connectivity from the endoscope to the MDS. The cylinder can not be vented after the check is performed.

Action: Report the error to maintenance.

CONTROL ERRORS (AS-I)

ASC	**S-300**

The report codes are as follows:

- F = error number
- S = step number where the error occurred in the program
- T = error text describing the undesired situation

After an error S-300, the phase is stopped and the program automatically goes to the post-rinse phase (a safe run down process).

The possible errors are listed in *Table 2* below.

Table 2 S-300 Control Error Details

Error Number	Description	Additional Details
F011	No step release	PC software error. The program runs through an incorrect step or closes the step before it is complete.
F012	Unknown step	PC software error. An active program step is not programmed into the ASC.
F013	Wrong step	The Stop ▽ button is pressed after a run failure. The program skipped over steps to finish the run. End the program via the Open/Close ⏻ button and operator selection.
F014	Setting flow #01	The volume measurement is out of alignment due to contamination, a defective meter, or incorrect calibration.
F015	Setting flow #02	
F021	Minimal time	LIO program step time duration deviates from ASC program control time; or an error report lasted too long before Start ◇ or Stop ▽ button was pressed.
F022	Maximum time	
F031	Cover open detection	During a disinfection program, the cover sensor is off or the air valve is operated manually. A mechanical defect of either of the components can create an unsafe situation.
F032	Cover open drive	
F033	Heater driven	The heater is on due to a software or electrical error. The endoscope may become too hot.
F034	Safety relay	The heater safety relay is malfunctioning; heating disabled (Heated Reservoir system only)
F041	Air channel or extra-1 channel	To control flow, the relevant channel sensor must read high or low for a minimal period of time. A "high" error occurs if a pump or valve is broken, or if the sensor is defective or blinks. A "low" error may be caused by a partially-blocked channel or terminal block.
F042	Biopsy channel or biopsy-1 channel	
F043	Jet channel or suction-1 channel	

Error Number	Description	Additional Details
F044	Suction channel or suction-2 channel	
F045	Water channel or biopsy-2 channel	
F046	Extra channel	
F047	Elevator wire channel: or extra-2 channel	
F051	Basin empty	The basin empty sensor does not detect the rinse basin draining. If there is water in the basin, the sensor is defective or the drainage hose is blocked. If when adding disinfectant, the basin empty sensor does not go on, the sensor is out of alignment, is defective, or the endoscope housing is blocking the flow of disinfectant.
F052	Minimal level	The basin full sensor is not activated when the basin fills. The sensor is contaminated or the water supply is too slow. During rinsing the basin full level sensor reads incorrectly due to a valve leak.
F062	Detergent	The relevant sensor is activated when it is not applicable in the step. When adding disinfectant or detergent, a message appears if the minimal dosage time is not achieved or the maximum dosage time was exceeded.
F063	Disinfect_Over	Disinfectant reservoir overflow sensor indicated fluid is present (Reuseable system only)
F064	Disinfect_Low	Disinfectant reservoir low sensor indicates fluid is present when it is not supposed to be (Reusable system only)
F065	Disinfect_Full	Disinfectant reservoir fill-level sensor indicates

Error Number	Description	Additional Details
		incorrectly low or high (Reuseable system only)
F071	Pump disinfectant	The pump runs at the incorrect time due to a software or electronics error.
F072	Pump detergent	
F073	Pump channels	
F074	Pump alcohol	Alcohol pump high during step
F081	Drainage valve	The valve is open at the wrong step due to a software or electronics error.
F082	Water supply	
F083	STX	Sterilox disinfectant valve is powered when it should not be
F084	SRW	Sterilox rinse water valve is powered when it should not be
F091	Volume change	The volume meter counts pulses at the wrong step, possibly due to a leaking supply valve.
F092	Volume minimal	When filling the rinse basin, the measured volume is less than the minimum or more than the maximum setting.
F093	Volume maximum	
F094	V1 > V2	During filling the V2 meter verifies the amount measured by V1. The deviation between the two meters is greater than 10%.
F095	V1 < V2	
F101	Temperature upper limit	The water is warmer than the upper limit (40°C) or colder than the lower limit (30°C). Water temperature adjustment is done externally.
F102	Temperature bottom limit	

Cause: The ASi Safety Control (ASC) program detects an error. A sensor or valve may have had an incorrect status for a short period of time so the program was rejected as unsafe. If the fault occurred at the end of a step, the message is in the run report of the next step.

Action: A correct description is important for a good analysis.

- Note the codes and the text.
- Report the fault and description to the maintenance department.
- Wait until the program has stopped.
- Press the **Open/Close** button.
- Start a restore program.
- Restart the endoscope disinfection.

Cause: A PC error disrupts the program. The ASC signals the unsafe situation and sends an error message.

Action: Note the code and description. Evaluate if the PC is working. Report the fault and description to the maintenance department.

ASC in "OK" state	**S-301**

ASC : Wrong configuration	**S-302**

The PC communicates with the ASi operation interface in the MDS. This interface transmits a signal every 20 msec to check the status of the signal in and out of the PC. If this communication stops or is interrupted the error appears.

Cause: The ASi safety control program found a fault in one of the electronic components or the controller is not running.

Action: Report the fault to the maintenance department.

ASC : no connection	**S-304**

Cause: A communication error occurred between the PC and the electronics drive controller.

1. No serial connection with the PC
2. The power or plug is disconnected
3. The drive controller is defective.

Action: Make certain all cables are connected to the PC and the 230V plug. Report the fault to the maintenance department.

Manual control active	**S-350**

Cause: The manual control in the Expert screen is active and has not been released.

Action: Click the "release all" button on the Expert screen.

Stopped by operator	S-360

Cause: During an active program, the **Stop** ⊽ button was pressed.

Action: The message is automatically stored in the run report.

WARNING ERRORS

ASC: No connection	W-701

Cause: A communication error occurred between the PC and the electronics drive controller.

1. No serial connection with the PC
2. The power or plug is disconnected
3. The drive controller is defective.

Action: Make certain all cables are connected to the PC and the 230V plug. Report the fault to the maintenance department.

ASC: wrong configuration	W-702

Cause: The ASi Safety control program found a fault in one of the electronic components, or the controller is not in the run.

Action: Report the fault with number to the maintenance department.

ASC: Incorrect status and cover inactive	W-703

Cause: The ASi Safety control program rejected the previous run and blocked the cover. The LED is red. The cover remains closed under the following conditions:

- An error occurred during a restore program.
- There was a power outage.
- There is a software error.

- The LIO-program shut down.
- There is an electronics error.

Action: The maintenance department can access the expert service to shut down the process in order to make a repair.

- Run the disinfection program to a safe situation by starting a restore program.
- Press the **Start** button.
- Press the **Menu** button.
- Select your operator ID
- Select the program Restore after interrupted program.
- Press the **Start** button.
- If this program is ready, then the cover can be opened to safely remove the endoscope. After opening the cover, the message disappears and the red LED goes off. The status message "ASC (rejection)" is applicable to the program. The instrument status "not appropriate for use" is applicable to the endoscope.

ASC: Incorrect status	**W-704**

Cause: The ASC-i safety control program rejected the run and the LED is red.

Action: Open the cover so the message disappears and the red LED goes out. This takes 4 seconds. The control program is now on stand-by.

ASC: on "OK" state	**W-705**

Cause: ASC status is OK.

Action: None.

Cover open	**W-711**

This message appears if no disinfection program is active and the cover sensor is on. No disinfection program can be started.

Cause: The cover is open.

Action: Press the **Open/Close** button and then the **Start** button.

Cause: There is a cover sensor defect, causing the message to appear even though the cover is closed.

Action: Report the situation to the maintenance department for repairs.

Cover will not open	**W-712**

Action: Try to open the cover by pressing the **Start** button.

Cause: The air pressure is too low to open the cover.

Action: Open the front cover and check the pressure gauges. Report any unusual readings to instrument service.

Cause: The cover is blocked.

Action: See if the blocking can be noticed visually, also on the rear side, and try if possible to remove this. If this does not work: report problem to the maintenance department.

Cause: A problem control valve is causing the cover cylinder to malfunction.

Action: Report the situation to the maintenance department.

Cause: The **Open/Close** button was pressed down too long.

Action: Press the button again but for a shorter time.

Cover will not close	**W-713**

Action: Press the **Start** button to close the cover or close the cover carefully by hand and test to see if it moves.

Cause: The cover is blocked.

Action: See if the blockage can be seen and attempt to remove it if possible. If no blockage can be seen, report the problem to the maintenance department.

Cause: The cover sensor is defective or out of alignment.

Action: Consult the maintenance department.

Cause: The **Open/Close** button was pressed down too long.

Action: Press the button again but for a shorter time.

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Cause: There is a defective air valve or the compressed air pressure is too low to open the cover.

Action: Report the situation to the maintenance department.

Basin not empty	W-715

Cause: The program was aborted and there is still fluid in the basin.

Action: Open the cover to shut down the program and automatically drain the basin.

Cause: There is liquid in the basin because the drain is blocked or the valve is defective.

Action: Check if the drain is used and report the problem to the maintenance department.

Cause: There is no liquid in the rinse basin. There is a basin sensor defect.

Action: Report the problem to the maintenance department.

Fluid leak in system	W-716

Cause: Liquid was spilled while changing a reservoir.

Action: Remove the liquid and dry the sensor (the green plug) carefully. Resetting the sensor can take a few minutes.

Cause: While in stand-by, liquid is detected at the bottom of the machine. Possible causes are leaking or a sensor set at the wrong level

Action: Report the situation to the maintenance department.

Water temperature sensor defective	W-721

Cause: There is a temperature sensor defect if the reading is >100°C.

Action: Report the problem to the maintenance department.

Cause: If the heater is switched on, the heater temperature sensor rises and the rinse basin temperature measurement does not.

Action: Report the problem to the maintenance department.

Reservoir temperature too high	W-727

Cause: Reservoir temperature sensor defective.

Action: Report the error to maintenance.

Cause: Reservoir heater defective.

Action: Report the error to maintenance.

Scheduled stop time incorrect, reset to midnight	**W-728**

Cause: The reservoir heater was scheduled to turn off before the scheduled start time..

Action: Reset the scheduled stop time in the system parameters. If no action is taken the stop time is automatically reset to midnight.

Sensor S03 Detergent high	**W-743**

Cause: A sensor is out of alignment or the detergent dosage system is clogged.

Action: Report the warning to the maintenance department.

Sensor S17 Minimum level high	**W-744**

Cause: There is water in the rinse basin or a sensor defect.

Action: Close the cover to allow the basin to run empty. Report the warning to the maintenance department.

Sensor S24 : Alcohol high	**W-749**

Cause: A sensor is out of alignment or the alcohol dosage system is clogged.

Action: Report the warning to the maintenance department.

Sensor S11 Leak test #1 high	**W-751**

Cause: Disinfection cycle fails or the user pushed the cancel button to end the cycle

Action: Open the basin lid and disconnect the channel block from the channel manifold. The pressure should now be released and the

warning message should disappear. Reinstall the channel block, close the basin lid, and a new cycle can now be initiated

Sensor S33 high	W-757

This message appears if not disinfection program is active. The warning must be cleared before a program is restarted.

Cause: The air cylinder sensor is out of alignment or faulty.

Action: Report the error to Maintenance.

Sensor high	W-764, W-765, W-766, W-767, W-768, W-769, W-770

This message appears when the machine is in stand-by and one of the channel sensors is high. This report occurs for the following channels:

- Air
- Biopsy
- Extra
- Water
- Suction
- Jet
- Elevator wire

Cause: The connection block is obstructed and the endoscope is not connected.

Action: Disengage the block. If the message disappears, report the obstructed block to the maintenance department. If the message remains see the next possible cause.

Cause: There is a channel sensor defect.

Action: Report the defective sensor to the maintenance department.

Manual control active	W-800

Cause: One or more functions are manually set. This means a disinfection program can not be started.

Action: Contact the maintenance department with a request to cancel the setting.

Purge active, start blocked	W-801

Cause: This message appears when the machine is in stand-by and the machine leak test system is blown through. This is an automatic routine that occurs every hour and lasts one minute.

Action: Wait until the message disappears and start the program.

Alcohol sensor venting, start blocked	**W-802**

Cause: Alcohol lines are pressurized while unit is idle.

Action: Wait until venting process completes, then start cycle.

Discharging air cylinder, start blocked	**W-803**

Cause: Air cylinder is pressurized while unit is idle.

Action: Wait until venting process completes, then start cycle.

Left side controls the water line disinfect	**W-805**

Cause: Right side cannot control the water line disinfect cycle.

Action: Use left side control panel to control water line disinfect cycle.

Open the cover to finish the cycle	**W-810**

Cause: The program is finished. This report indicates how the program needs to be shut down.

Action: Press the **Open/Close** button and follow the instructions on the screen. After selecting the correct operator ID, the cover opens automatically and the program shuts down.

Disinfectant in the basin (the cover is locked)	**W-820**

Cause: The water line disinfect cycle failed while disinfectant was in the basin.

Action: Restart the water line disinfect cycle.

Disinfectant in the supply line (the cover is locked)	**W-821**

Cause: The water line disinfect cycle failed while disinfectant was in the water supply lines.

Action: Restart the water line disinfect cycle.

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(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Testing Validation Procedures

(b)(4) Trade Secret Process - Testing

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(b)(4) Trade Secret Process - Testing

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Test Reports

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TABLE 2. Diffusion Rate Results
Filter Identification: M4

TEST PRESSURE	DIFFUSION RATE PRE-STERILIZATION	DIFFUSION RATE POST-STERILIZATION	DIFFUSION RATE POST-CHALLENGE
@30 psig	50 mL/min.	<1 mL/min.	<1 mL/min.

TABLE 3. Diffusion Rate Results
Filter Identification: M5

TEST PRESSURE	DIFFUSION RATE PRE-STERILIZATION	DIFFUSION RATE POST-STERILIZATION	DIFFUSION RATE POST-CHALLENGE
@30 psig	56 mL/min.	<1 mL/min.	<1 mL/min.

TABLE 4. Diffusion Rate Results
Filter Identification: M7

TEST PRESSURE	DIFFUSION RATE PRE-STERILIZATION	DIFFUSION RATE POST-STERILIZATION	DIFFUSION RATE POST-CHALLENGE
@30 psig	10 mL/min.	<1 mL/min.	11 mL/min.

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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)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 08, 2007

MEDIVATORS REPROCESSING SYSTEMS
A MINNTECH CORPORATION BUSINESS GRO
14605 28TH AVE., NORTH
MINNEAPOLIS, MN 55447
ATTN: LYNN LUEDERS

510(k) Number: K063876
Product: MODULAR DISINFECTION SYSTEM (MDS) FOR ENDOSCOPE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 in 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 questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

(b)(4) Trade Secret Process - Product Specs

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USING THIS MANUAL

This manual describes the features of the Medivators Modular Disinfection System (MDS) endoscope reprocessor, including the hardware, software, setup, operation, safety, maintenance, and troubleshooting procedures. It is important to follow the instructions provided to keep the MDS in proper operating order and to ensure that endoscopes receive adequate disinfection.

This is not a service manual and does not provide detailed instructions for service beyond general maintenance. See Service Manual for servicing instructions. Contact your service representative for additional service information.

MDS FEATURES

The Modular Disinfection System was designed for ease of use and maintenance in the disinfection of endoscopes. Features include:

- Individual channel connectivity, blockage monitoring, alarming, washing, and rinsing.

  All endoscopes must be precleaned prior to disinfection. Follow the endoscope manufacturer's instructions and established professional guidelines to properly preclean the endoscope. Endoscopes with elevator wire channels require additional manual cleaning and disinfection steps. Leak test endoscopes prior to disinfection procedures.

- Asynchronous operation of two large independent basins with locking lids.

- A dedicated personal computer (PC) for system operation of reprocessing cycle, cycle recording, powerful quality assurance reporting, easy backups, networking availability, and remote diagnostics

- Easy-to-fill detergent and alcohol reservoirs

- Hook-up blocks dedicated to a family of endoscopes ensure correct connectivity and flow rates to meet manufacturers' specifications

- Diagnostics for operator assistance and troubleshooting

- Ability to use heated disinfectant chemistry (if heated reservoir system is purchased)

Installation and Maintenance

Proper maintenance ensures effective disinfection and prolongs the life of the reprocessor.

- The MDS must be grounded in accordance with applicable regulations.
- The system default is factory-set for a specific disinfectant immersion time. This time may only be changed in the system parameters by a qualified individual. Verify the program is appropriate for the disinfectant used.
- All pressure regulators are factory-preset. Do not adjust the settings. Contact your Technical Support representative for assistance.
- Do not allow the cleaning solution to contact metal components.
- Do not use alcohol or alcohol-based products to clean the reprocessor cabinet.
- Medivator endoscope hook-ups are not autoclavable. The hookups are automatically disinfected with each use due to their exposure to the entire disinfection cycle; no further disinfection or rinsing is required prior to their next use.
- Do not remove covers, doors, or panels fastened with screws while the machine is in use.
- Replacement parts must be ordered from the manufacturer to maintain the warranty.
- Do not block ventilation openings.
- Regularly check all cables, tubing, and drains for damage or leaks.
- Do not carry out any maintenance that is not described in this manual.
- Do not disable temperature sensors in heated reservoirs (optional equipment). If service is required, contact your authorized Medivator distributor.
- Ensure that the power supply connection is accessible in the event that emergency disconnection is necessary.

Indications for Use

510(k) Number (if Known): K063876

Device Name: Medivators Reprocessing Systems Modular Disinfection System for Endoscope Reprocessing

Indications for Use:

Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing tests, cleans, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. The MDS is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes.

Prescription Use __X__ AND/OR Over-the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Medivators Reprocessing Systems Modular Disinfection System
for Endoscope Reprocessing

510(k) Summary of Safety and Effectiveness

Manufacturer:	Medivators Reprocessing Systems, a Division of Minntech Corporation
Address:	14605 28th Avenue North Mpls., MN 55447 USA
Official Contact:	Lynn Lueders Director, Regulatory Affairs

Medivators has supplied the following information to the U.S. Food and Drug Administration to support substantial equivalence of the Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing to other endoscope reprocessors currently marketed in the U.S.

1. Device Description

The Modular Disinfection System (MDS) is an electro-mechanical system intended to test, clean, and high level disinfect heat sensitive semi-critical endoscopes. It is not intended for reprocessing rigid endoscopes. The machine can use any reusable germicide which is on the market that is labeled for high level endoscope disinfection. The testing provided to the FDA used both Medivators Rapicide® High Level Disinfectant and Cidex® OPA High Level Disinfectant.

During its software based reprocessing cycle, the machine tests the endoscopes for leaks and blockages. Before and during the machine cycles, connectivity with the machine through the connector blocks is evaluated. If the scopes pass these tests, they are flushed with water and detergent, disinfected and rinsed. The disinfection cycle takes approximately 30 minutes. The MDS is capable of asynchronously reprocessing two scopes at a time.

The machine has many built in safety features which stop the cycle and alarm when certain conditions exist which could indicate that disinfection might be compromised. These alarms and causes are defined in the directions for use for the product.

The machine also prints records by endoscope serial number indicating the results of testing, disinfection, number of disinfections, etc. which are required for permanent records.

2. Intended Use

The Modular Disinfection System (MDS) is an electro-mechanical system intended to test, clean, and high level disinfect heat sensitive semi-critical endoscopes.

3. Comparison to Another Device in Commercial Distribution Within the United States

The MDS is equivalent in function and indications to the Medivators DSD-91E™ Endoscope Disinfector. This machine was found to be substantially equivalent in 1994 (K914145). Both machines have the same indications for use, the same methods of providing disinfection, can use the same reuseable disinfectants at the same temperatures and times. Both machines can reprocess two scopes asynchronously, one in each bay.

4. Summary of Testing

Medivators has provided testing to show that the MDS is safe and effective for its intended use following the requirements listed in the FDA's Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (dated August 1993). This testing included:

Efficacy Testing

The MDS was tested using standard methods defined by the FDA guidance document. This testing included simulated use and in use testing.

The simulated use testing showed a $>10^6$ log reduction in the organism *Mycobacterium terrae* after the endoscopes were reprocessed in the MDS.

In use testing showed no viable organisms remained on the endoscopes following the disinfection cycle.

Additional in-use testing was performed to show that the MDS provided disinfected endoscopes when exposed to the entire endoscope cycle of cleaning, disinfecting and rinsing.

Material Compatibility

The effect of disinfectants (Rapicide and Cidex OPA) on the materials used in the MDS was evaluated and showed no that the materials had no significant deterioration over their its use life. Studies were also presented to show that the filters used in the water filtration system were compatible with common disinfectants.

Biocompatibility

The amount of disinfectant residue left on endoscopes and in the MDS after the disinfection and rinsing cycles was evaluated and compared to determined safe levels. The results of the testing showed that any remaining residues would not have an effect on patients or users of the machine.

Performance Data

Data was provided to the FDA to show that the machine performs as required. This evaluation included testing to show that the leak check, blockage check, connectivity checks, disinfection cycle, rinse cycles, and drying cycles performed correctly. Any error messages were tested to ensure they function properly to notify users of any possible failure modes. Testing was performed to show that all critical parameters of the machine function correctly.

Testing was presented that showed that disinfectants which require heating remained at their required temperature for the length of time required in the labeling for the disinfectant.

Testing was completed that showed that the MDS self disinfection cycle works properly by disinfecting all areas of the machine, including the water filtration system.

Studies were performed to show that the water filtration system will function appropriately over time and that the machine will alarm if water filters are plugged to a point which will lower the water pressure below required input. This study also showed that the filters remained bacterial retentive even when plugged to a point that causes the machine to alarm.

5. Summary of Substantial Equivalence

Minntech Corporation has provided the above information in the form of a 510(k) to support the claim that the MDS is safe and effective when used in accordance with the device labeling.