U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(jsh)
FOLDER:	K063503 - 1018 pages
COMPANY:	MALLINCKRODT INC., LIEBEL-FLARSHEIM BUSINESS (MALLLIEBFLARBUSI)
PRODUCT:	INJECTOR, CONTRAST MEDIUM, AUTOMATIC (IZQ)
SUMMARY:	Product: OPTIVANTAGE DH INJECTOR SYSTEM WITH ENHANCED COMMUNICATION
DATE REQUESTED:	Sep 8, 2014
DATE PRINTED:	Sep 8, 2014
Note:	Printed

K063503

APR 27 2007

Special 510(k) Summary

1. Company Identification

Mallinckrodt Inc., Liebel-Flarsheim Business
2111 East Galbraith Road
Cincinnati, OH 45237

Establishment Registration: 1518293

2. Contact Person

Dale Moore
Quality Manager
Phone: (513) 948-5771
Fax: (513) 948-5708
Email: dale.moore@tycohealthcare.com

3. 510(k) Preparation Date

11/15/2006

4. Device Name

Trade Name: OptiVantage DH Injector System with Enhanced Communication
Common Name: Power Injector

5. Device Classification

Class II

6. Indications for Use

The OptiVantage DH Injector System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

7. Description of Device

The OptiVantage DH Injector System with Enhanced Communication delivers radiographic contrast media and/or saline at a controlled flow rate and volume into a patient's vascular system for the purpose of obtaining enhanced diagnostic images. The OptiVantage DH Injector System with Enhanced Communication consists of 4 main components, just like the predicate device:

1. **Power Head**- Contains two electromechanical syringe drive systems, the syringe holding mechanisms, the main microprocessor, control electronics, control keypad for programming and initiating injection protocols, a status display, and two purge/retract manual knobs. The OptiVantage uses a drive system that is similar to existing Mallinckrodt injectors in the marketplace. It uses a motor and gearbox coupled to a ball screw. The ball screw drives a ram that attaches to the syringe plunger in order to fill or expel the contents of the syringe.

2. **Power Supply**- The power supply converts the line voltage to the working voltage for the power head and console (approximately 24-vdc).

3. **Console** - Communicates with the Power Head to program and initiate injection protocols, displays the injection status, and displays a timer.

4. **Syringes** - The OptiVantage DH Injector System with Enhanced Communication accommodates the Mallinckrodt 125-ml pre-filled syringe styles as well as a 200 ml front loading empty syringe. These syringes are commonplace on the market and are currently used with the predicate device.

8. Substantial Equivalence

The predicate injector to the OptiVantage DH Injector System with Enhanced Communication is the OptiVantage DH Power Injection System, 510(k) number K042744.

The OptiVantage DH Injector System with Enhanced Communication maintains the same intended use as the predicate device. It is intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

The OptiVantage DH Injector System with Enhanced Communication consists of four main components in the same manner as the predicate device: a Power Head, a Console, a Power Supply, and Syringes. Both the OptiVantage DH Injector System with Enhanced Communication and the predicate device consist of the same fundamental technology. They are motor driven, electromechanical devices which are software controlled. The OptiBolus function on the OptiVantage DH Injector System with Enhanced Communication and the predicate device implements a multiphasic injection method for injecting contrast media and/or saline.

The OptiVantage DH Injector System with Enhanced Communication differs from the predicate device in that it contains a product enhancement that adds a layer of enforcement for safety features found on the currently marketed predicate device.

Below is a table that compares the predicate device to the proposed OptiVantage DH Injector System with Enhanced Communication.

Feature	**OptiVantage DH Injector System with Enhanced Communication** (New Device)	**OptiVantage DH Power Injection System** Predicate Device (K042744)
Intended Use	Intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment	Intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment
Multi-phasic Injections	6 phases per protocol	6 phases per protocol
OptiBolus	Yes	Yes
Protocol Storage	40 protocols	40 protocols
Syringe Sizes	All pre-filled volumes of Mallinckrodt 125-ml syringes & Liebel-Flarsheim 200 ml empty syringe	All pre-filled volumes of Mallinckrodt 125-ml syringes & Liebel-Flarsheim 200 ml empty syringe
Single or Dual Syringe Modality	Single syringe and Dual syringe capability	Single syringe and Dual syringe capability
Syringe Drive System	Electromechanical	Electromechanical
Syringe Heater	Yes (Built-in, Powerhead controlled)	Yes (Built-in, Powerhead controlled)
Syringe Fill Rate	2 to 15 ml/sec	2 to 15 ml/sec
Flow Rate	0.1 to 10 ml/sec	0.1 to 10 ml/sec
Max Pressure Limit	325 psi	325 psi
Pressure Limit Control	User-settable or automatic 25 psi increments	User-settable or automatic 25 psi increments
Flushing System	Manual or via injector	Manual or via injector

Feature	OptiVantage DH Injector System with Enhanced Communication (New Device)	OptiVantage DH Power Injection System Predicate Device (K042744)
Remote Start	Yes	Yes
Scan Delay	0 – 600 seconds	0 – 600 seconds
Phase Delays	0 – 600 seconds plus Pause	0 – 600 seconds plus Pause
Console Controls	Touch screen Color LCD	Touch screen Color LCD
Power head Controls	Touch screen Color LCD	Touch screen Color LCD
Post Injection Readout	Yes	Yes
OEM Interface	Relays & Optical Couplings/Serial (CAN)	Relays & Optical Couplings/Serial (CAN)
Safety Stop Mechanism	Electrical Stop when injection parameters are out of specifications	Electrical Stop when injection parameters are out of specifications
Remote Check for Air	Yes	Yes
Volume Remaining Display	Displayed on Power Head and Console	Displayed on Power Head and Console
Used Syringe Detection	Yes (with Enhanced Communication)	Yes
Materials	Plastic and metal	Plastic and metal
Target Population	Humans	Humans
Sterility (Syringe)	Injectors are not sterile products. Syringes and Disposables are provided sterile.	Injectors are not sterile products. Syringes and Disposables are provided sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2007

Mallinckrodt, Inc., Liebel-Flarsheim Business
c/o Mr. Dale Moore
Quality Manager
2111 East Galbraith Road
Cincinnati, OH 45237

Re: K063503
OptiVantage DH Injector System with Enhanced Communication
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: II (two)
Product Code: IZQ
Dated: March 30, 2007
Received: April 2, 2007

Dear Mr. Moore:

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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

tyco Healthcare Division | MALLINCKRODT

Attachment #14

Indications for Use

510(k) Number (if known): **K063503**

Device Name: **OptiVantage DH Injector System with Enhanced Communication**

Indications For Use:

The OptiVantage DH Injector System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Donna R. Vachuska

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063503

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2007

Mallinckrodt, Inc., Liebel-Flarsheim Business
c/o Mr. Dale Moore
Quality Manager
2111 East Galbraith Road
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OptiVantage DH Injector System with Enhanced Communication
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Product Code: IZQ
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Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

tyco Healthcare Division | MALLINCKRODT

Attachment #14

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Donna R. Vo

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063503

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

April 03, 2007

MALLINCKRODT INC., LIEBEL-FLARSHEIM
2111 EAST GALBRAITH RD.
CINCINNATI, OH 45237
ATTN: DALE MOORE

510(k) Number: K063503
Product: OPTIVANTAGE DH INJECTOR SYSTEM WITH ENHANCED COMMUNICATION

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2007

Mallinckrodt, Inc.
c/o Mr. Dale Moore
Quality Manager
Liebel-Flarsheim
2111 East Galbraith Road
Cincinnati, OH 45237

Re: K063503
Trade Name: OptiVantage DH Injector System with Enhanced Communication
Dated: February 16, 2007
Received: February 20, 2007

Dear Mr. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate based solely on the information you provided. To complete the review of your submission, we require the following:

1. You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. B4 [redacted] showing that the original system was tested to EN 60601-1-2 for immunity and EN 55011 for emissions. You also include a letter dated January 24, The OptiVantage with RFID was tested to EN 301 489-3 for immunity and emissions. Please justify the change in the test standard. Please compare the test frequencies, immunity specifications and emissions levels used in EN 301 489-3 to those used in IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

2. Your response to deficiency 1 of our letter dated December 21, 2006 indicates that the RFID feature is intended to be used with both pre-filled contrast syringes and pre-filled saline syringes. The submission indicates that CDER will be reviewing information regarding the addition of the RFID feature to the pre-filled contrast syringes; however, this information does not address a submission for the addition of the RFID feature to the pre-filled saline syringes. Please explain what regulatory submission will be provided to address the addition of the RFID feature to the pre-filled saline syringes.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. 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 additional information 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.

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

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

If you have any questions concerning the contents of the letter, please contact Kimberly Bowie Peters at (240) 276-4222. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ashley B. Boam

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Mallinckrodt, Inc.
c/o Mr. Dale Moore
Quality Manager
Liebel-Flarsheim
2111 East Galbraith Road
Cincinnati, OH 45237

Re: K063503
Trade Name: OptiVantage DH Injector System with Enhanced Communication
Dated: February 16, 2007
Received: February 20, 2007

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Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-450 Division
D.O.

Prepared by:KBPeters:myb:03/22/07

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ450	Peters	3/22/07						
450	Boam	3/22/07						

U.S. GPO 1986-169-089

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

January 22, 2007

MALLINCKRODT INC., LIEBEL-FLARSHEIM
2111 EAST GALBRAITH RD.
CINCINNATI, OH 45237
ATTN: DALE MOORE

510(k) Number: K063503
Device: OPTIVANTAGE DH INJECTOR SYSTEM WITH ENHANCED COMMUNICATION

Extended Until: 20-FEB-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 fo up to a maximum of 180 days from the date of the AI request.

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

Sincerely yours,

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

521

tyco Healthcare

Mallinckrodt

Mallinckrodt Inc.
Liebel-Flarsheim
2111 East Galbraith Road
Cincinnati, OH 45237-1640

Tele: 513 761-2700
Fax: 513 761-2388
www.mallinckrodt.com

K063503

January 17, 2007

Food and Drug Administration
Center for Devices and Radiological Health
Attn: Ms. Kimberly Bowie Peters
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: K063503 – Request for Extension of Time
Trade Name: OptiVantage DH Injector System with Enhanced Communication

Dear Ms. Peters;

Thank you for taking the time to speak with us on Thursday, January 4th, to provide clarification and to answer questions regarding our Special 510(k) Submission on the above referenced device. The meeting was very beneficial in helping us to prepare a satisfactory response.

In preparing this response and providing the requested documentation, we have determined that an extension of time is necessary. We respectfully request an additional 30 days to provide our full and complete response. We will submit the response to your office on or before Friday, February 16, 2007.

Should you have any questions or concerns regarding this request, you may contact me by mail, phone at (513) 948-5771 or fax at (513) 948-5708

Sincerely,

Dale Moore

Dale Moore
Site Quality Manager
Direct: 513-948-5771
Fax: 513-948-5708

522

CV

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2006

Mallinckrodt, Inc.
c/o Mr. Dale Moore
Quality Manager
Liebel-Flarsheim
2111 East Galbraith Road
Cincinnati, OH 45237

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Dated: November 17, 2006
Received: November 20, 2006

Dear Mr. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate based solely on the information you provided. To complete the review of your submission, we require the following:

1. The device description information does not include a clear description of the modifications made to the currently marketed OptiVantage system for the development of the OptiVantage DH Injector System with Enhanced Communications. Please provide this information which should address both hardware and software modifications. In addition, it is unclear if the RFID feature is only intended to be used with the pre-filled contrast syringes or the pre-filled saline syringes. Please address this issue.

2. Please address the following regarding the bench testing information:

   a. You have provided protocols and acceptance criteria for testing the OptiVantage DH Injector System with Enhanced Communication, including B4 [redacted]. These reports indicate that the test results and conclusions are provided in separate referenced test reports. Please provide the referenced test reports B4 [redacted] for

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review, as well as the results for test B4. Please be advised that the testing information provided for review should testing procedures and protocols, sample size, acceptance criteria, justification for the chosen sample size and acceptance criteria, test results, and an analysis of the results. FDA acknowledges that you have submitted the enhanced communication change in a special 510(k) submission; however, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

b. For B4, please provide a scientifically valid justification for the acceptance criteria. In addition, the conclusion section for B4 indicates that B4. Please describe these test design recommendations, explain if the test protocol was modified to address these recommendations, if the test was repeated, etc.

3. You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

4. The risk analysis methods and summary information (Section 7) is inadequate. Please identify the risk analysis methods used to assess the impact of the modifications. The submission only indicates that the risk analysis was performed in accordance with work instructions B4. In addition, please provide a revised summary of the verification and validation activities that includes a description of the methods or tests used, acceptance criteria applied, and an indication of whether the acceptance criteria were met. The summary provided only includes bullets, such as "RFID system-level validation" and "verification testing of enable sequences," indicating that verification testing was performed.

5. Please address the following regarding the operator's manual for the OptiVantage DH Injection System with Enhanced Communication. Please provide a revised copy of the operator's manual for review.

   a. In the OptiVantage DH Injection System with Enhanced Communication operator's manual (pages 28 – 185), you have included information on RFID. To aid the user in avoiding electromagnetic interference problems, please include the transceiver power and field strength at a specified distance in the operator's manual.

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b. The operator's manual (Appendix A, page 46) indicates that "a subset of the syringe data provides parameters used for constraining the injection protocol and validating the system configuration." Please explain what syringe data parameters provided via the RFID are used for constraining the injection protocol and validating the system configuration.

6. Please provide the following software information and documentation for the OptiVantage DH Injection System with Enhanced Communication. The "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" may be a helpful reference.

a. On page 23 of the submission you have included the level of concern determination questions and answered "no" to all. However, in the risk analysis, you state that misreading injection parameters could lead to toxicity. Please address whether a failure to read the correct parameters or interpret the RFID correctly could lead to a serious injury or a minor injury. Please be advised that FDA believes the appropriate level of concern for the software should be at least moderate or major. Please address this issue.

b. Please provide a hazard analysis for the device software. This information should include identification of the hazardous event, the method of control, corrective measures taken, including aspects of the device design, that eliminate, reduce, or warn of a hazardous event, and testing demonstrating the implementation of the safety features.

c. Please provide a discussion of your software development lifecycle, including the activities that take place during each phase of the lifecycle, the quality control and assurance activities and methods, the development environment, the documentation generated, verification and validation activities, configuration management, version control, audits, and maintenance.

d. Please provide the current software and system requirements for the device. This information should include a discussion of system hardware requirements, internal software tests and checks, internal and external performance and functional requirements, and safety requirements. Block diagrams showing the system architecture/software design would also be helpful. Also, please discuss how you adequately qualified off-the-shelf software and hardware for incorporation into the device, if applicable, and provide appropriate documentation as discussed in the Guidance on Off-the-Shelf Software Use in Medical Devices.

e. Please provide the system level testing procedures and protocols, the pass/fail criteria, test results, and an analysis of the results. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a

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CDER application. Also, please provide a test report summarizing how all phases of testing (module, integration, and system) demonstrate that requirements were met. Note that testing should address all options and accessories, communications, and adequate regression testing. You should also explain how testing has adequately stressed the system, including communications, data throughput, device configurations, fault conditions, alarm conditions, boundary value conditions, error and range checking on parameters and calculations, interpretations and analyses made by the device, path analysis, etc. The testing you provide should be traceable to the software and system requirements of the device (i.e., trace matrix relating requirements to verification and validation tests). This report should also include a discussion and explanation of how you achieved the desired level of test coverage required for the device and how remaining software anomalies and bugs (listed in the report) do not present a risk to patient safety or effectiveness, directly or indirectly. Please specify the current version level of the software in the documentation you provide.

7. Please provide a completed indications for use form (see enclosure) for the OptiVantage DH Injector System with Enhanced Communication. The prescription information on the form should also be completed.

8. You have provided test protocol [redacted] Minutes from the May 9, 2006 meeting indicate that you would be submitting a Changes Being Effected-30 (CBE-30) supplement to the NDA for the OptiRay syringes. Please be advised that CDRH does not review drug quality testing, and this 510(k) submission will not resolve any issues of drug quality. Therefore, this testing information should also be included in your CDER submission. Please acknowledge this advisory.

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

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. 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 additional information 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.

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

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

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If you have any questions concerning the contents of the letter, please contact Kimberly Bowie Peters at (240) 276-4222. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name:

Indications For Use:

Prescription Use _____ 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)

DEC 21 2006

Mallinckrodt, Inc.
c/o Mr. Dale Moore
Quality Manager
Liebel-Flarsheim
2111 East Galbraith Road
Cincinnati, OH 45237

Re: K063503
Trade Name: OptiVantage DH Injector System with Enhanced Communication
Dated: November 17, 2006
Received: November 20, 2006

Dear Mr. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate based solely on the information you provided. To complete the review of your submission, we require the following:

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Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-450 Division
D.O.

Prepared by:12/20/06

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
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450	Boam	12/20/06						

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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
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9200 Corporate Blvd.
Rockville, Maryland 20850

November 20, 2006

MALLINCKRODT INC., LIEBEL-FLARSHEIM
2111 EAST GALBRAITH RD.
CINCINNATI, OH 45237
ATTN: DALE MOORE

510(k) Number: K063503
Received: 20-NOV-2006
Product: OPTIVANTAGE DH INJECTOR SYSTEM WITH ENHANCED COMMUNICATION

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

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resources and may help reviewers navigate through longer documents more easily. Under CDRHs e-Copy Program, you may replace one paper copy of an 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

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4 ENABLING SEQUENCE

This chapter discusses the proper techniques for loading syringes, filling syringes, purging air from both the syringe and tubing, and priming the tubing.

4.1 ENABLING SEQUENCE

Refer to Figure 4-1-1.

The [Enable] key is only active when:

- a new syringe(s) is loaded
- the syringe is filled (200 ml only)
- the powerhead is tilted up and air is purged from both syringes (plunger must move forward to expel a minimum of 1 (one) ml of contrast/saline)
- the powerhead is rotated at least 30° below horizontal
- there is sufficient volume in the syringes to perform the programmed injection.

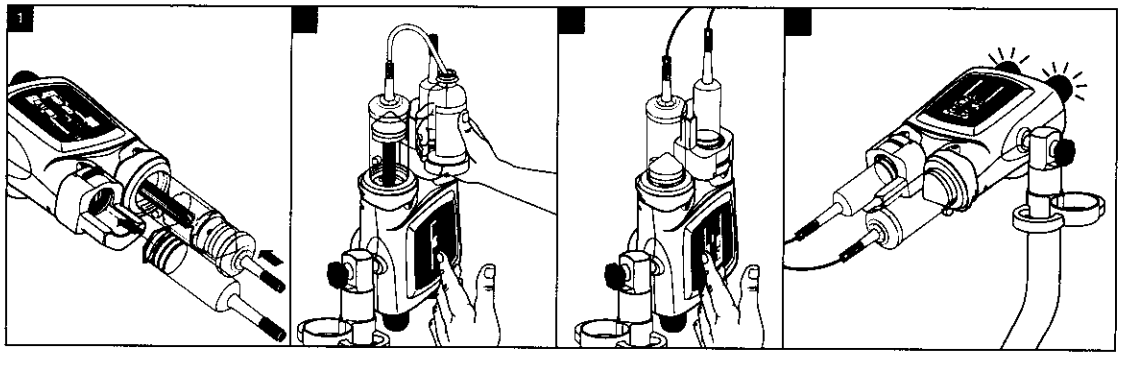

Figure 4-1-1 Enabling Sequence

4.1.1 DANGERS, WARNINGS, AND CAUTIONS

[redacted]

The danger of air embolism is always present when injecting into the circulatory system. The enabling sequence for the OptiVantage Injection System is designed to help prevent air injections. In order to enable the OptiVantage, the syringe load sequence and air purge sequence described in this chapter must be performed in order to ensure a safe injection. ***The enable sequence in itself does not guarantee that all air has been completely removed from the system. The operator is responsible for ensuring that all air has been completely evacuated from the syringe and tubing prior to delivery of the injection.***

[redacted]

Danger! Contamination Hazard!
Do not reuse syringe or other I.V. access components.

[redacted]

Danger! Air Embolism Hazard!
When filling an empty syringe, make sure a tight connection exists between the fill tube and syringe to ensure that air is not being drawn into the syringe. Entrapped air can cause patient injury or death if not properly removed prior to delivery of injection.

[redacted]

Warning! Infection Hazard!
Contamination of sterile-packed empty syringes is possible if proper precautions are not taken. Due to the risk of serious patient infection, do not touch the Linden-Luer adapter or the section of a fill tube that will be inserted into the contrast. Do not touch the interior of the syringe or expose the interior of the syringe to conditions which can cause contamination (coughing, sneezing, etc.). Immediately place syringe into injector sleeve to prevent contaminating the interior of the syringe.

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[redacted]

Install syringes containing the amount of contrast required by the procedure to be performed on the patient. Installing syringes containing more contrast than needed could result in the injection of excess contrast.

[redacted]

Fill syringes only with the minimum amount of contrast required by the procedure to be performed on the patient. Filling syringes with more contrast than needed could result in the injection of excess contrast.

4.1.2 NOTES

Preheating the contrast media will help in the removal of air bubbles.

tyco / Healthcare MALLINCKRODT

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4.2 TYPES OF INJECTIONS

The OptiVantage has the ability to deliver an injection with or without a saline flush. Both the A-side and the B-side can accommodate either a 125 ml prefilled syringe, 125 ml partial prefilled syringe, or an operator filled 200 ml syringe.

4.2.1 LOAD 125 ML SYRINGE (CONTRAST SIDE ONLY)

Refer to Figure 4-2-1.

1. If the ram is not home, move to the fully retracted position Ⓐ. Slide the 125 ml cradle Ⓑ onto the desired front plate mount of the powerhead (A-side is shown in Figure 4-2-1). Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Inspect syringe and its contents for irregularities prior to loading. Open the 125 ml syringe clamp Ⓒ. Install the 125 ml syringe into the cradle Ⓓ.
3. Securely close syringe latch. Ⓔ.
4. Proceed to Section 4.1.4 *Attach Tubing to Syringe(s).*

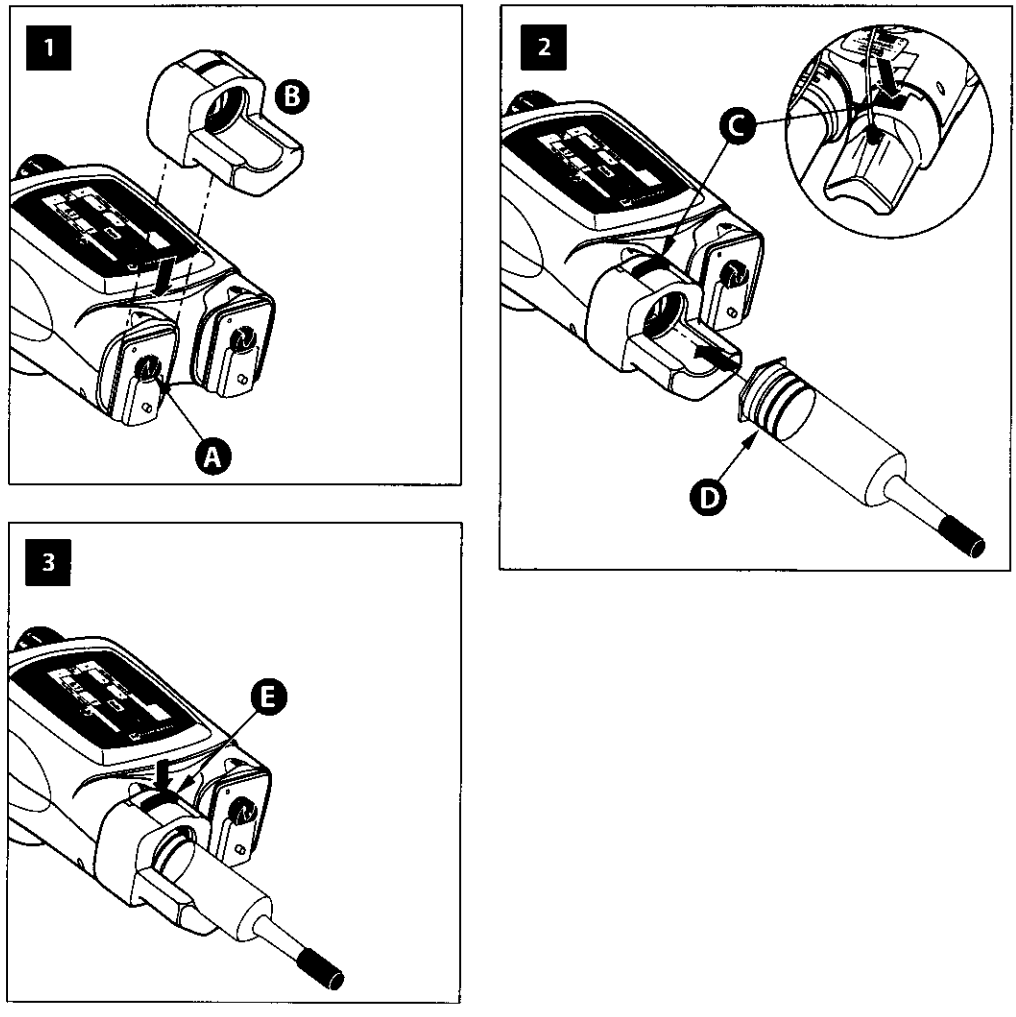

Figure 4-2-1 Load 125 ml Syringe (A-Side Only)

4.2.2 LOAD 200 ML SYRINGE (CONTRAST SIDE ONLY)

Refer to Figure 4-2-2.

1. Move the desired ram to the fully retracted position Ⓐ (A-side is shown in Figure 4-2-2). Rotate the pressure sleeve lever to the unlock position. Slide the 200 ml pressure sleeve onto the front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Extend the ram fully Ⓒ.
3. Using aseptic technique, remove the 200 ml syringe from its sterile packaging by grasping the umbrella cap Ⓓ. Inspect the syringe for irregularities prior to loading. Make sure the pressure sleeve lever is rotated to the unlock position. Insert the 200 ml syringe into the pressure sleeve by matching the load arrow on the syringe to the load arrow on the pressure sleeve Ⓔ.
4. Lock the syringe into place by either turning the pressure sleeve lever to the lock position or by rotating the umbrella cap clockwise until the load arrow aligns as shown Ⓕ. If the lever cannot be moved to the lock position, make sure the load arrow is aligned as shown Ⓔ, then gently push down on the umbrella cap. The lever should now lock easily. Leave the ram/plunger in the "fully expelled" or extended position in preparation to fill with contrast.
5. Proceed to section 4.3 Fill Syringe (200 mL Only).

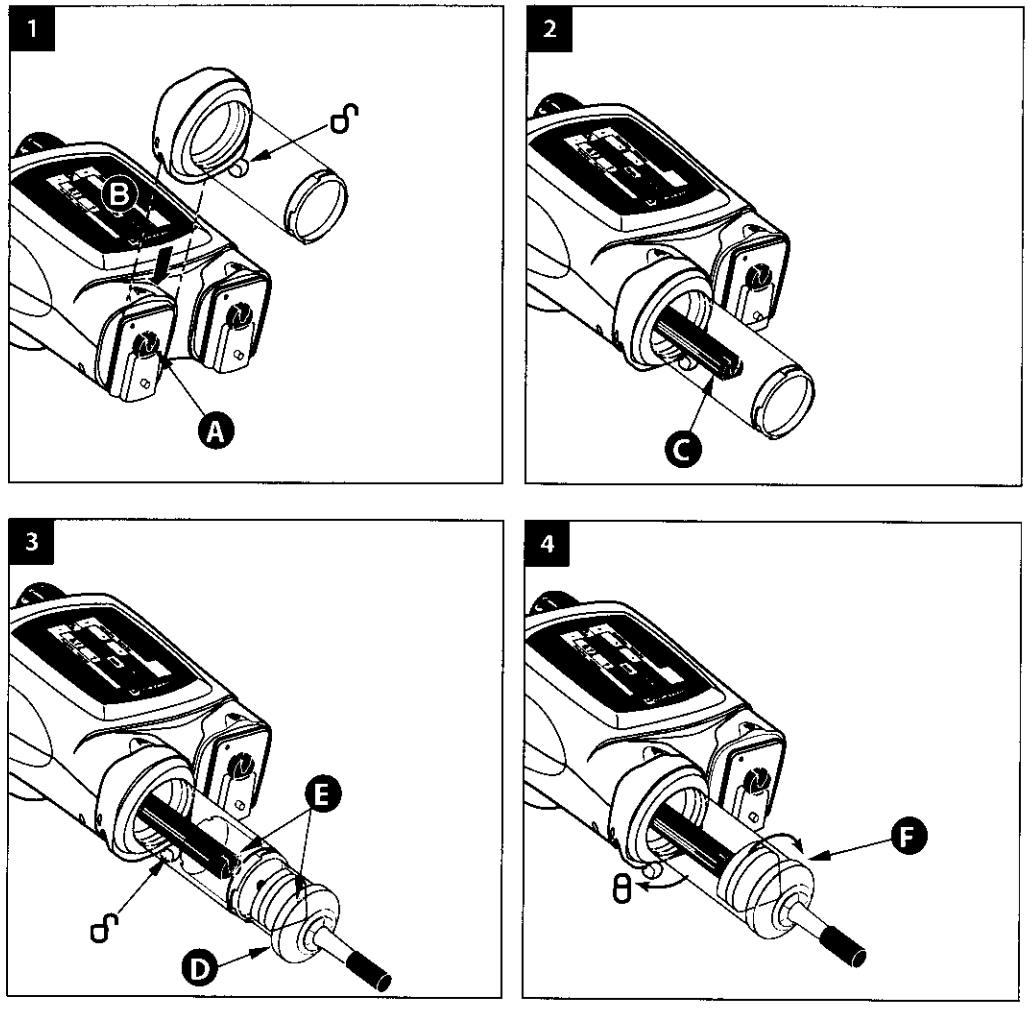

Figure 4-2-2 Load 200 mL Syringe (A-side Only)

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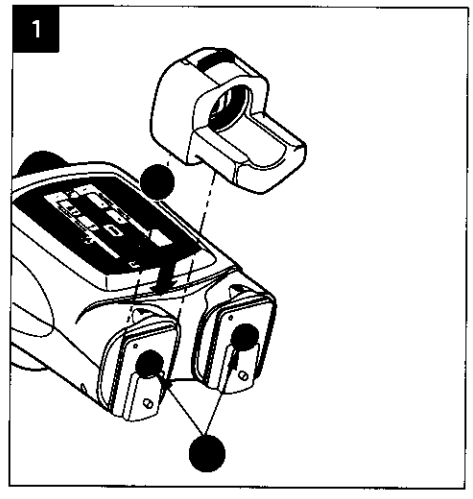
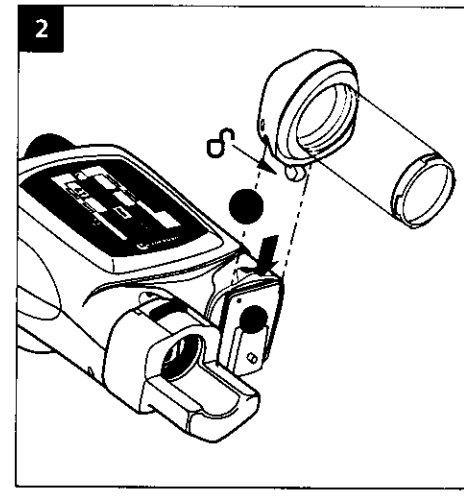
4.2.3 LOAD 125 ML/200 ML SYRINGE

Refer to Figure 4-2-3.

1. Move the A-side and B-side ram to the fully retracted position. Ⓐ. Slide the 125 ml cradle onto the A-side front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Rotate the pressure sleeve lever to the unlock position. Slide the 200 ml pressure sleeve onto the front plate mount of the powerhead Ⓒ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
3. Inspect 125 ml syringe and its contents for irregularities prior to loading. Open the tabs Ⓓ and install the 125 ml syringe into the cradle
4. Close the latch to secure the 125 ml syringe Ⓔ.
5. Extend the B-side ram fully Ⓕ.
6. Using aseptic technique, remove the 200 ml syringe from its sterile packaging by grasping the umbrella cap Ⓖ. Inspect the syringe for irregularities prior to loading. Insert the 200 ml syringe into the 200 ml pressure sleeve by matching the load arrow Ⓗ on the syringe to the load arrow on the pressure sleeve.
7. Lock the syringe into place by either turning the pressure sleeve lever to the "lock" position Ⓘ or by rotating the umbrella cap clockwise until the load arrow aligns as shown Ⓙ. If the lever cannot be moved to the lock position, make sure the load arrow is aligned as shown Ⓗ, then gently push down on the umbrella cap. The lever should now lock easily. Leave the ram/plunger in the "fully expelled" or extended position in preparation to fill with contrast.
8. Proceed to section 4.3 Fill Syringe (200 ml Only.





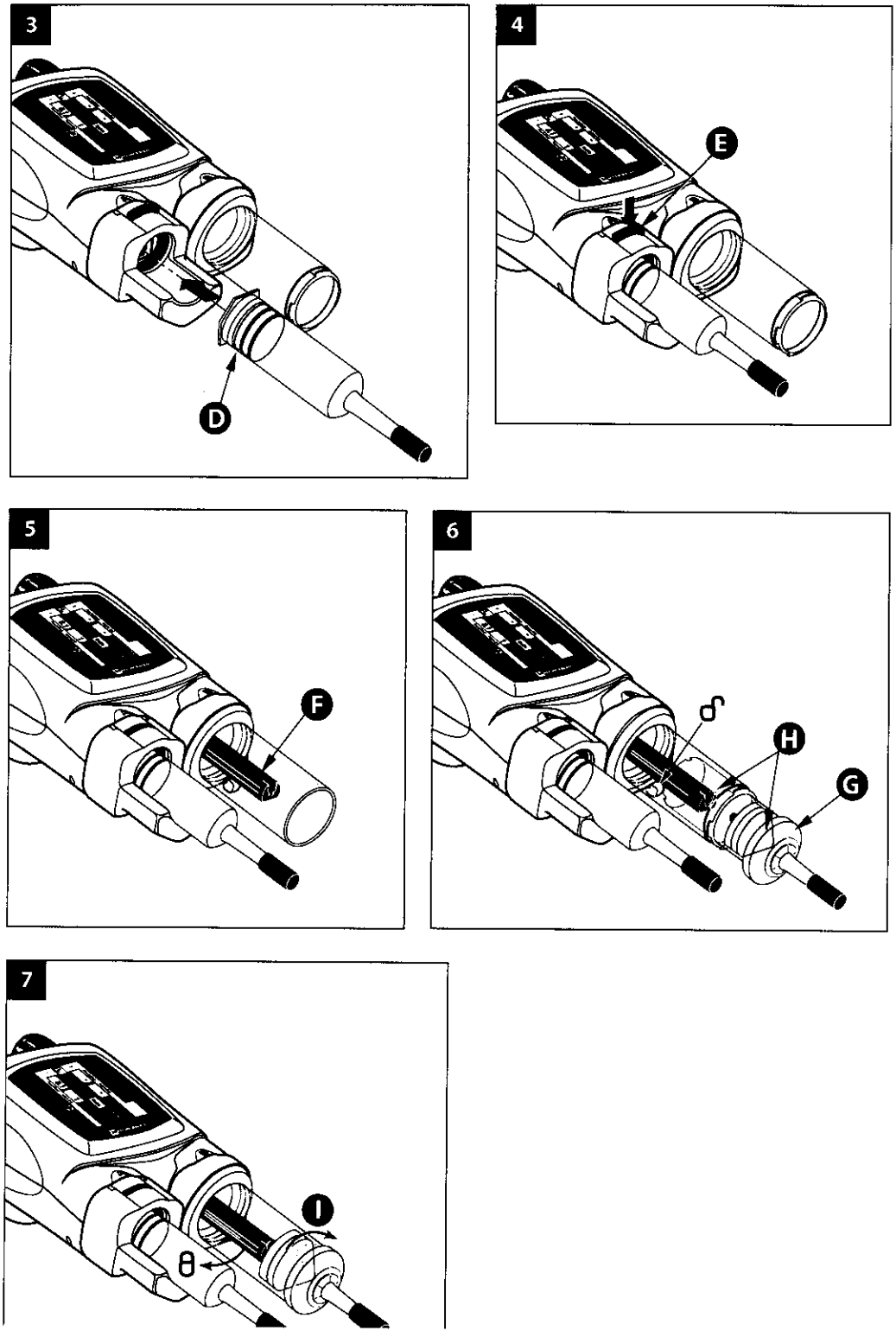


Figure 4-2-3 Load 125 ml/200 ml Syringe

4.2.4 LOAD 200 ML/200 ML SYRINGE

Refer to Figure 4-2-4.

1. Move the A-side and B-side ram to the fully retracted position Ⓐ. Rotate the pressure sleeve lever to the unlock position. Slide one of the 200 ml pressure sleeves onto the front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram. Slide the other 200 ml pressure sleeves onto the front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Extend both rams fully Ⓒ.
3. Using aseptic technique, remove the 200 ml syringes from their sterile packaging by grasping their umbrella caps Ⓓ. Inspect the syringes for irregularities prior to loading. Insert a 200 ml syringe into each pressure sleeve by matching the load arrow on the syringe to the load arrow on the pressure sleeve Ⓔ.
4. Lock the syringes into place by either turning the pressure sleeve levers to the "lock" position or by rotating the umbrella caps clockwise until the load arrows align as shown. If the lever cannot be moved to the lock position, make sure the load arrows are aligned as shown, then gently push down on the umbrella cap. The lever should now lock easily. Leave the ram/plungers in the "fully expelled" or extended position in preparation to fill with contrast.
5. Proceed to section 4.3 Fill Syringe (200 ml Only).

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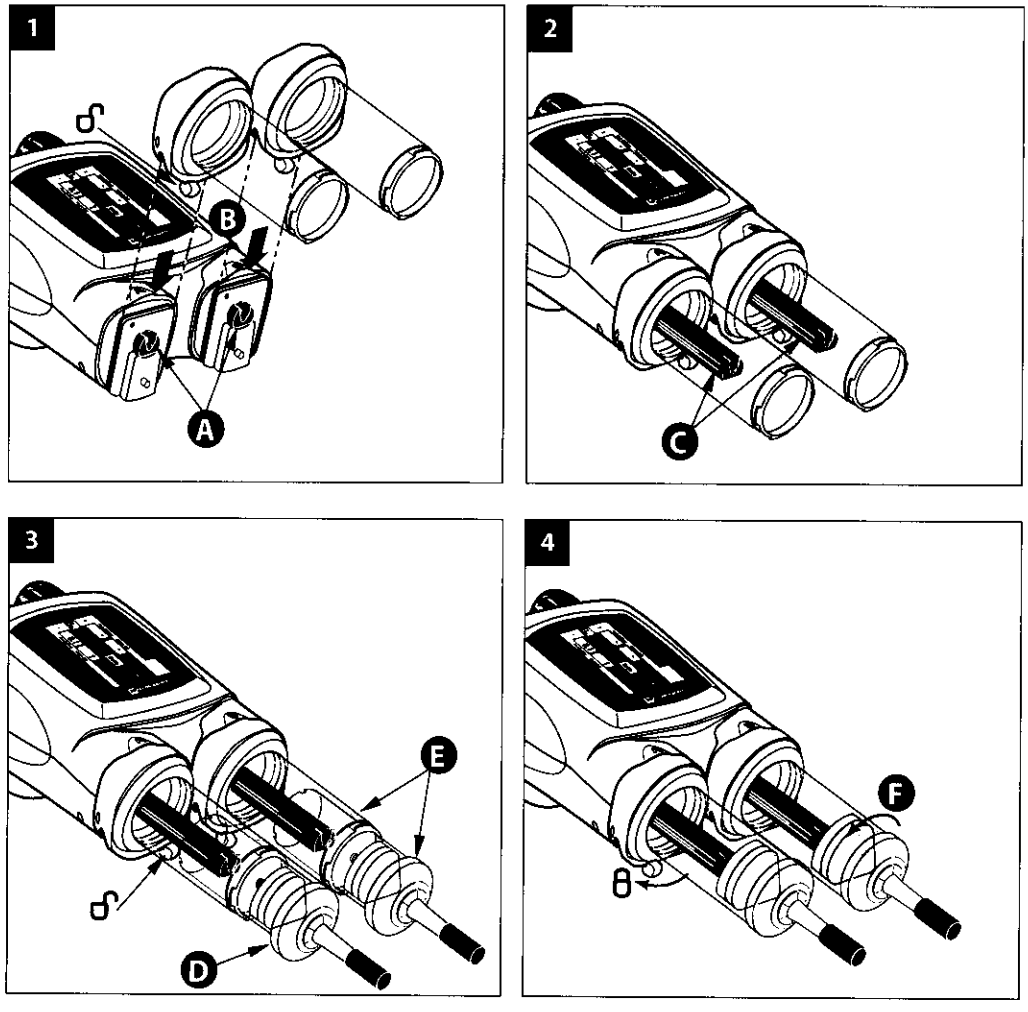

Figure 4-2-4 Load 200 ml/200 ml Syringe

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4.3 FILL SYRINGE (200 ML ONLY)

4.3.1 AUTO-FILL TECHNIQUE

Refer to Figure 4-3-1 and 4-3-2.

NOTE: This feature is only available if turned ON in the Setup screen.

The Auto-Fill feature has been designed to automatically fill the syringe while minimizing the introduction of air. To use the Auto-Fill feature:

1. Place the ram(s) in the "home" position (i.e. fully expelled), then load a 200 ml syringe into the pressure sleeve(s). If the powerhead is not in the vertical position, the following message will appear: *Rotate the Powerhead to the vertical position to activate Auto-Fill sequence.*
2. Rotate the powerhead to the vertical position. The screen shown in Figure 4-3-1 is displayed. NOTE: If the powerhead is utilizing a 200 ml syringe on both the A-side and the B-side, the Auto-Fill sequence will first fill the last installed syringe, then allow for filling the remaining empty syringe.
3. Set the desired Fill Volume (ml) by pressing the [Fill Volume] key Ⓐ for either the A-side or the B-side (B-side is shown in Figure 4-3-1), then change the value via the slide bar key Ⓑ.
4. Remove the protective cap from the syringe tip and store in a safe place for reuse in step 9.
5. Using aseptic technique, slide the end of the shorter section of the fill tube over the syringe tip. DO NOT TOUCH THE TIP. Place the end of the longer section of the fill tube into the container of contrast media. To keep aeration to a minimum, verify that this end of the tube is in the media and is NOT drawing air.
6. Press and release the respective [Start Auto-Fill] key Ⓒ. The injector will automatically retract the ram 25 ml at 4 ml/s, purge 25 ml at 10 ml/s, then retract to the Fill Volume at 15 ml/s. NOTE: Pressing the [Stop] key on the screen will disable the Auto-Fill feature.
7. Carefully remove the fill tube from the syringe tip by twisting while pulling off. NOTE: In order to prevent the contrast medium from spilling onto the syringe and pressure sleeve, make sure the curved portion of the fill tube is either completely empty or contains enough contrast medium so that the level in the longer end is slightly lower than the tip of the syringe. This will cause the fluid in the tube to return to the container.

8. Observe contrast medium to ensure all air bubbles are removed. If air bubbles are still clinging to the sides of the syringe, follow the steps outlined in the section 4.5 Purge Air/Prime Tubing.
9. To prevent contamination, replace the protective cap on the syringe tip. The powerhead should remain in the vertical position (to prevent leakage) until ready for injection.

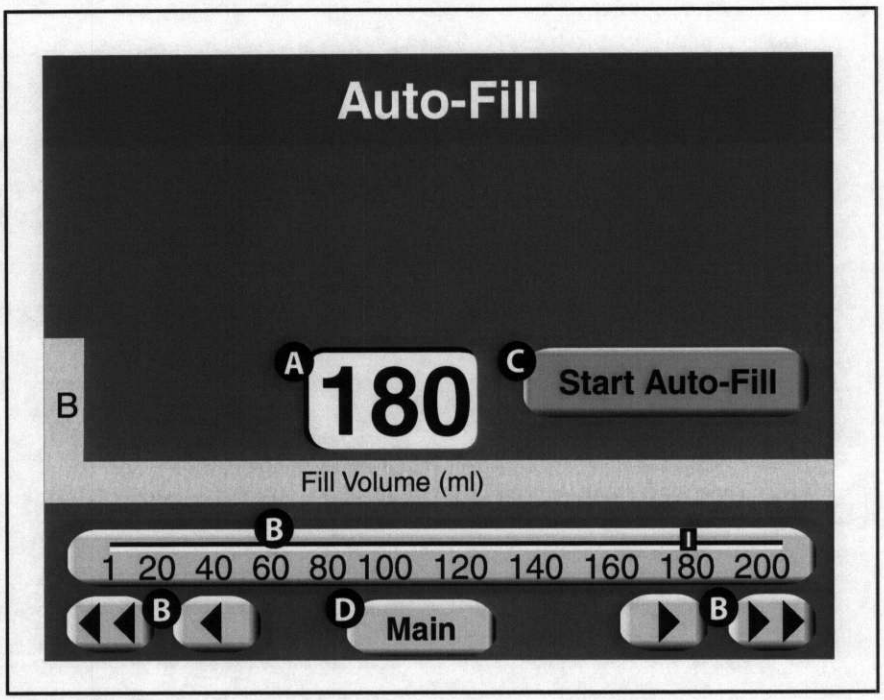

Figure 4-3-1 Auto-Fill Screen

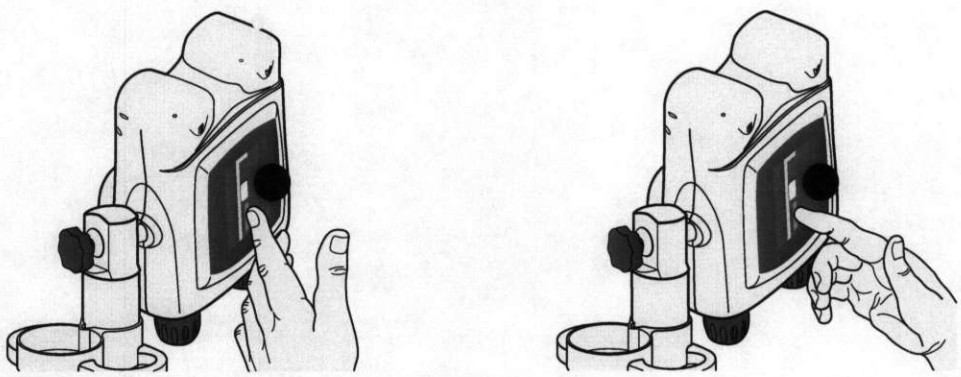

Figure 4-3-2 Fill Syringe Right-handed/Left-handed

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4.3.2 MANUAL FILL TECHNIQUE

Upon loading a 200 ml syringe, the screen shown in Figure 4-3-1 is displayed (if Auto-Fill feature is turned ON in the Setup screen) to allow for automatic filling of the syringe. The Auto-Fill feature has been designed to automatically fill the syringe while minimizing the introduction of air. However, to manually fill the syringe:

1. Disable the Auto-Fill feature by pressing the [Main] key (Ⓓ in Figure 4-3-1) to display the Main screen.
2. Rotate the powerhead to the vertical position.
3. Remove the protective cap from the syringe tip and store in a safe place for reuse in step 9.
4. Slide the end of the shorter section of the fill tube over the syringe tip. DO NOT TOUCH THE TIP. Place the end of the longer section of the fill tube into the container of contrast media. To keep aeration to a minimum, verify that this end of the tube is in the media and is NOT drawing air.
5. Press the respective syringe key to display the fill/expel arrows. Retract the plunger to draw the desired volume of contrast medium into the syringe. NOTE: A retract flow of 10 ml/s or less is optimum to minimize the introduction of air.
6. Move the plunger in the "expel" direction, to expel all air from the syringe.
7. Carefully remove the fill tube from the syringe tip by twisting while pulling off. NOTE: In order to prevent the contrast medium from spilling down around the syringe and pressure sleeve, make sure the curved portion of the fill tube is either completely empty or contains enough contrast medium so that the level in the longer end is slightly lower than the tip of the syringe. This will cause the fluid in the tube to return to the container.
8. Observe contrast medium to ensure all air bubbles are removed. If air bubbles are still clinging to the sides of the syringe, follow the steps outlined in the section 4.5 Purge Air/Prime Tubing.
9. To prevent contamination, replace the protective cap on the syringe tip. The powerhead should remain in the vertical position (to prevent leakage) until ready for injection.

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4.4 ATTACH TUBING TO SYRINGE(S)

To attach the catheter or tubing to the 125 ml prefill syringe or the 200 ml disposable syringe, using aseptic technique, insert the hub Ⓐ into the slot of the luer nut Ⓑ and rotate the nut clockwise to tighten the hub onto the syringe tip. Refer to Figure 4-4-1.

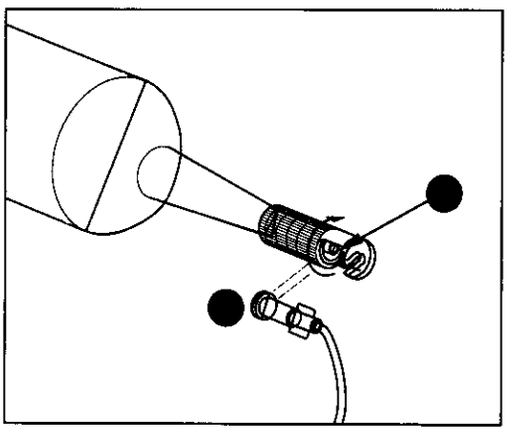

Figure 4-4-1 Attach Tubing to Syringe

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4.5 PURGE AIR FROM SYRINGE

[redacted]

DANGER! AIR EMBOLISM HAZARD!
Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

4.5.1 PURGE AIR 125 ML PREFILL SYRINGE

NOTE: The instructions that accompany the prefill syringe should be followed.

1. The air pocket trapped in the syringe MUST be removed to prevent injection of an air embolism into the patient. Rotate the powerhead vertically to point the tip of the syringe upward to allow the air pocket to rise to the tip.
2. Advance the plunger to remove air from the syringe and tubing. The plunger must move forward to expel a minimum of 1 ml of contrast to indicate that an attempt was made to purge the air.
3. Verify that both the syringe and tubing have been properly cleared of all air.

4.5.2 PURGE AIR 200 ML DISPOSABLE SYRINGE

1. Air bubbles trapped in contrast media and saline MUST be removed to prevent injection of an air embolism into the patient. Rotate the powerhead vertically to point the tip of the syringe upward to allow the air bubbles to rise to the tip to form an air pocket.
2. Dislodge any air bubbles attached to the side of the syringe by gently tapping with the heel of the hand.
3. Using the expel arrows or the manual knob, advance the plunger to push the air pocket out the syringe tip and through the tubing. The plunger must move forward to expel a minimum of 1 ml of contrast to indicate that an attempt was made to purge the air.

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4.6 PRIME TUBING

[redacted]

DANGER! AIR EMBOLISM HAZARD!
Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

4.6.1 PRIME TUBING WITH SALINE

Priming the tubing with saline is necessary for the delivery of *Drip Mode injections, Patency Check injections and Timing Bolus injections.* Advance the saline plunger to push saline past the Y-intersection of the Y-tubing and out through the remaining tubing.

4.6.2 PRIME TUBING WITH CONTRAST

Prime the tubing with contrast if Drip Mode injections, Patency Check injections and Timing Bolus injections are not to be performed. Advance the contrast plunger to push contrast past the Y-intersection of the Y-tubing and out through the remaining tubing.

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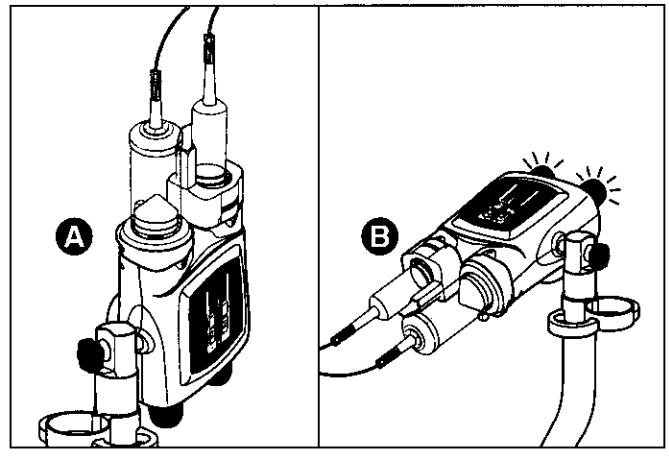
4.7 POWERHEAD IN VERTICAL POSITION

With all air removed and the tubing primed, the powerhead should remain in the vertical position Ⓐ (to prevent leakage) until ready to inject. The [Enable] key will activate once the powerhead is rotated 30° below horizontal Ⓑ.



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5 DELIVERING AN INJECTION

This chapter instructs the operator on the steps taken to safely deliver an injection.

5.1 DANGERS/WARNINGS/CAUTION

[redacted]

DANGER! AIR EMBOLISM HAZARD!
Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

[redacted]

REMOVE SYRINGE AFTER COMPLETION OF INJECTION!
Disposable syringes are designed for single use only. Used syringes should be promptly removed from the injector after a procedure is completed to avoid accidental reuse of an empty syringe. Failure to remove the syringe after completion of a procedure may lead to an inadvertent injection of air. Injecting air can cause patient injury or death.

[redacted]

Follow all manufacturers guidelines and do not operate any part of the OptiVantage Injection System within 6 inches (15 cm) of a pacemaker and/or defibrillator.

[redacted]

This device has been approved for use with only the consumables listed in Chapter 1. Use of other consumables could result in patient injury, operator injury and/or equipment damage.

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5.2 RECALL/ENTER PROTOCOL PARAMETERS

Recall required protocol from memory or enter required parameters. For more information about recalling a protocol from memory or entering parameters, refer to Chapter 3.

[redacted]

REVIEW PARAMETERS

Prior to delivering an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that contrast fluid is installed on the correct side of the powerhead.

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5.3 CONNECT TO PATIENT

[redacted]

Extravasation can be minimized through the following precautions:

- When choosing an I.V. site, use the largest vein possible.
- Use lowest flow rate practical to achieve enhancement.
- Use largest gauge teflon type catheter possible.
- Insure good backflow from catheter.
- Continue to monitor from remote location.
- Instruct patient to notify operator of any abnormal pain, pressure or swelling.

Follow proper venipuncture technique to connect the patient to the OptiVantage system.

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5.4 ENABLE INJECTOR

Refer to Figure 5-4-1.

1. ***The operator is responsible for ensuring that all air has been completely evacuated from the syringe and tubing prior to delivering the injection.*** Prior to enabling an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that the contrast fluid is installed on the correct side of the powerhead.
2. Follow the Enabling Sequence stated in Chapter 4 to properly load and fill syringes, purge air and prime the tubing.
3. Rotate the Powerhead at least 30° below horizontal. This safety precaution reduces the possibility of an air emboli. Any small remaining air bubbles will tend to float away from the tip and will not be injected into the patient.
4. Press the [Enable] key located on either the powerhead or console screen. A [Start] key Ⓐ will appear in the upper right-hand corner of both the console screen and the powerhead screen. The [Enable] key will change to a [Disable] key Ⓑ. The indicator lights on the powerhead will illuminate to signify the unit is now enabled for delivery of an injection.

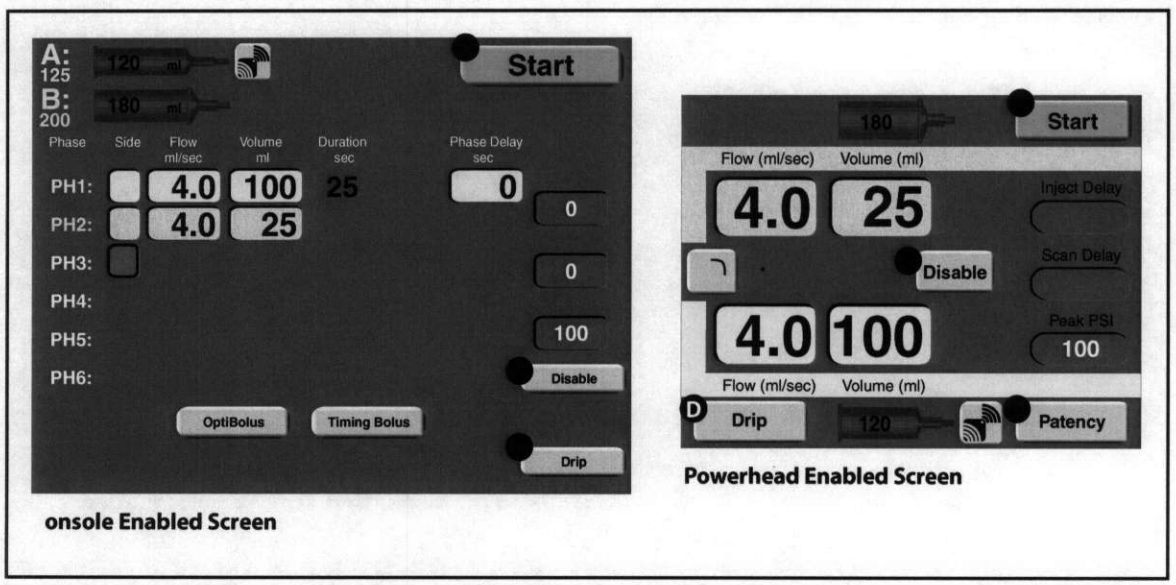

Figure 5-4-1 Enabled Screen

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5.5 CHECK PATENCY OF I.V. SITE

[redacted]

Extravasation can be minimized through the following precautions:

- When choosing an I.V. site, use the largest vein possible.
- Use lowest flow rate practical to achieve enhancement.
- Use largest gauge teflon type catheter possible.
- Insure good backflow from catheter.
- Continue to monitor from remote location.
- Instruct patient to notify operator of any abnormal pain, pressure or swelling.

NOTE: The injector does not have the capability to prevent or detect an extravasation. Patency Check is only available when turned On in the Setup screen.

Two different techniques exist to check the patency of the I.V. site. Once a protocol is enabled, the [Patency] key is available on the powerhead display to inject a small volume of saline at the same flow rate as the enabled protocol. Also, the manual knob is available to manually check patency. Instructions for both techniques follow:

5.5.1 CHECK PATENCY USING THE [PATENCY] KEY

Refer to Figure 5-5-1 and 5-5-2.

1. Press the [Patency] key Ⓒ (on Figure 5-4-1) located on the powerhead's enabled screen. The screen as shown in Figure 5-5-1 appears.
2. Adjust Patency Check flow Ⓔ and Patency Check volume Ⓕ as desired using the slide bar Ⓖ. Patency Check Volume can only be set to an amount that will not compromise the enabled protocol.
3. Press the [Start Patency] key Ⓗ to start the injection and the screen as shown in Figure 5-5-3 will display. Monitor the site and instruct patient to notify operator of any abnormal pain, pressure or swelling.
4. Total Time Ⓙ increments and syringe volume Ⓚ decrements while injecting. The [Stop] key Ⓛ is available to immediately stop the Patency Check injection at any time.
5. Once the Patency Check injection is delivered, the Enabled screen is displayed and the injector is ready to deliver the protocol or deliver another Patency Check.

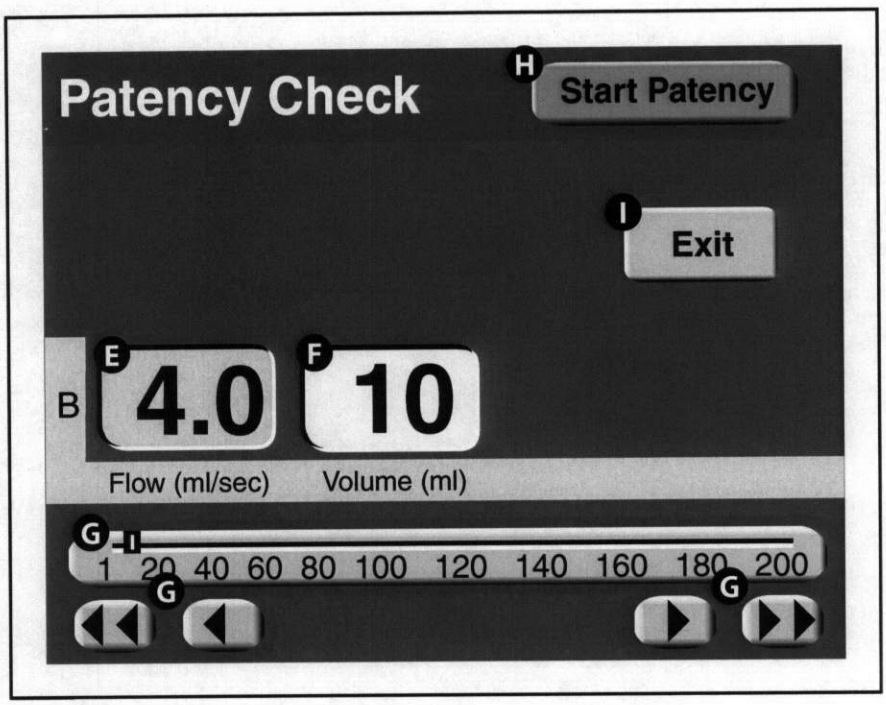

Figure 5-5-1 Patency Check Screen (Powerhead Only)

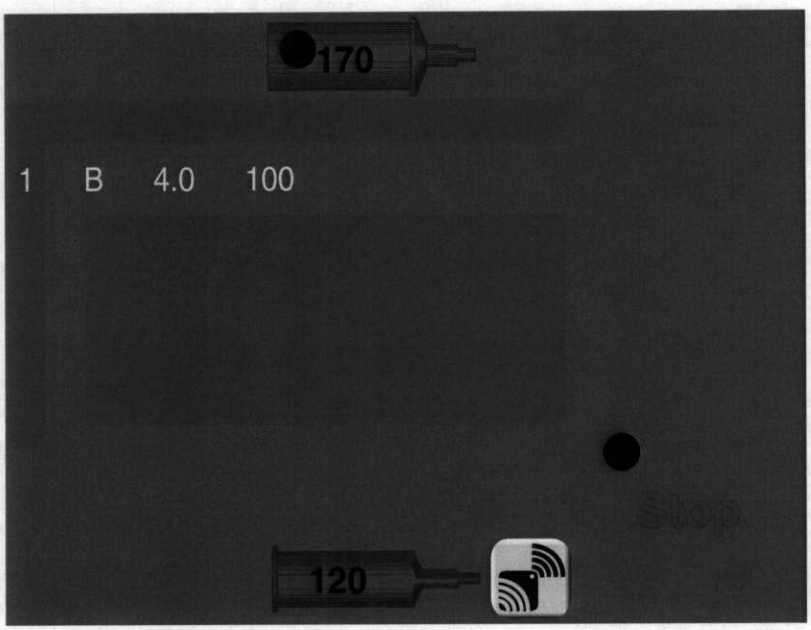

Figure 5-5-2 Patency Check Injecting Screen (Powerhead Only)

5.5.2 CHECK PATENCY USING THE MANUAL KNOB

[redacted]

DANGER! BLOOD CLOT HAZARD! Do not allow blood to remain in I.V. access line.

[redacted]

Care should be taken when retracting the plunger using the manual knob so that the integrity of the vein is maintained.

NOTE: This technique can NOT be performed if the syringe is connected to tubing with a check valve. Using the manual knob of the saline side, retract the plunger in order to check the patency of the I.V. site. Do not allow blood to remain in the I.V. access line.

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5.6 DELIVERING A DRIP MODE INJECTION

Refer to Figure 5-6-1 and 5-6-2.

[redacted]

REVIEW PARAMETERS

The enabled protocol can be delivered via the Drip Mode injecting screen by pressing the [Start Protocol] key Ⓧ. If this feature will be utilized, prior to pressing the [Drip] key on the enabled main screen, review all protocol parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that contrast fluid is installed on the correct side of the powerhead.

1. Press the [Drip] key Ⓓ on Figure 5-4-1) located on the powerhead's enabled screen. The screen as shown in Figure 5-6-1 appears.
2. Adjust Drip flow Ⓜ, Drip volume Ⓝ and Drip interval Ⓞ as desired using the slide bar Ⓟ. Drip volume can only be set to an amount that will not compromise the enabled protocol. Drip (injectable) Volume Ⓠ displays the amount of saline available for the Drip Mode injection. Drip Time Ⓡ displays the amount of time the Drip Mode injection will require.
3. Press the [Start Drip] key Ⓢ to start the injection and the screen as shown in Figure 5-6-2 will display. The [Exit] key Ⓣ is available to exit the Drip Mode and return to the Enabled protocol screen.
4. While injecting, Drip Time Ⓤ and syringe volume Ⓥ decrement. The [Stop] key Ⓦ is available to stop the injection at any time. Pressing the [Start Protocol] key Ⓧ immediately starts delivery of the main protocol.
5. Once the Drip injection is delivered, the following message is displayed:

   WARNING!
   The Drip Mode Injection is complete.
   Start the Enabled Protocol.
   Press Close to return to the Start screen.

   Press the [Close] key and the Enabled protocol screen (Start screen) is displayed. The injector is now ready to deliver the main protocol. Adjustments to the protocol parameters can be made prior to starting delivery of the main protocol.

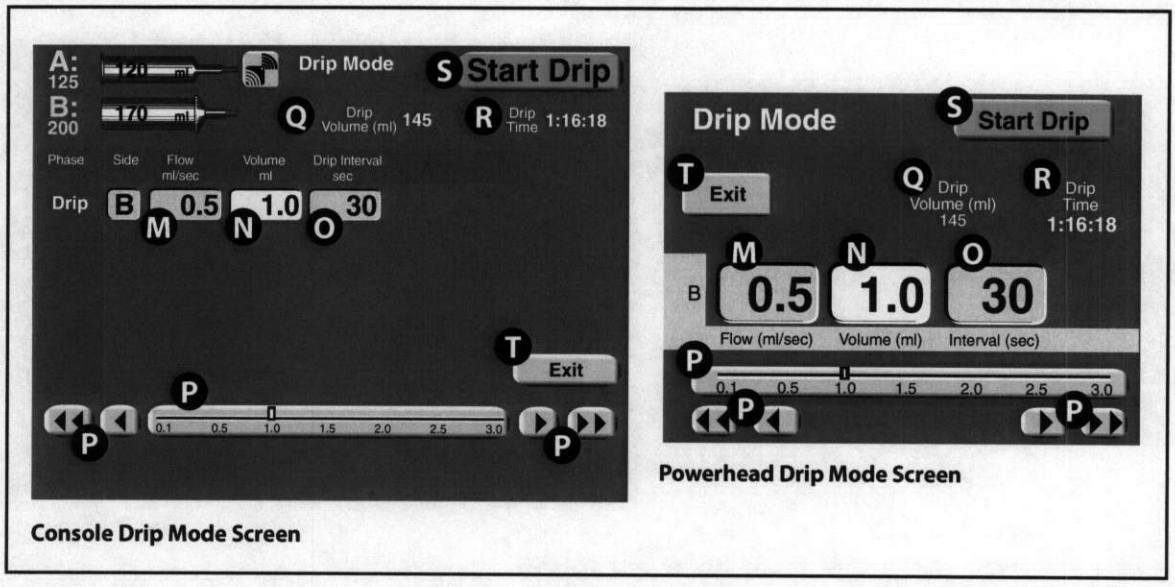


Figure 5-6-1 Drip Mode Screen

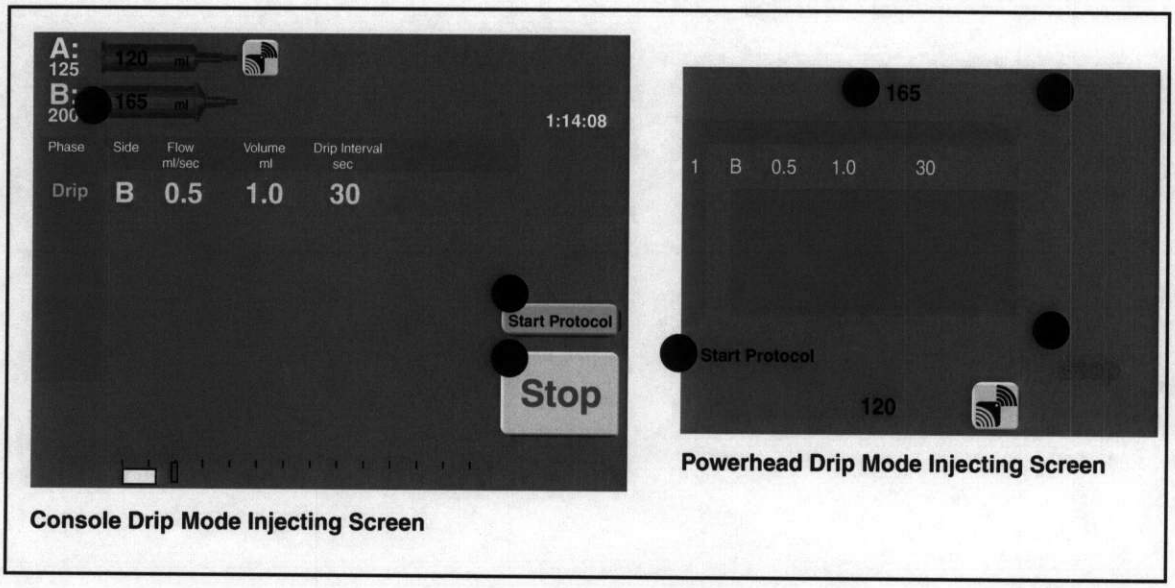


Figure 5-6-2 Drip Mode Injecting Screen

5.7 DELIVERING THE MAIN PROTOCOL

5.7.1 DANGERS, WARNINGS AND CAUTION

[redacted]

OPERATOR DUE DILIGENCE REQUIRED!
Delivering an injection to a patient requires due diligence on the part of the operator. Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

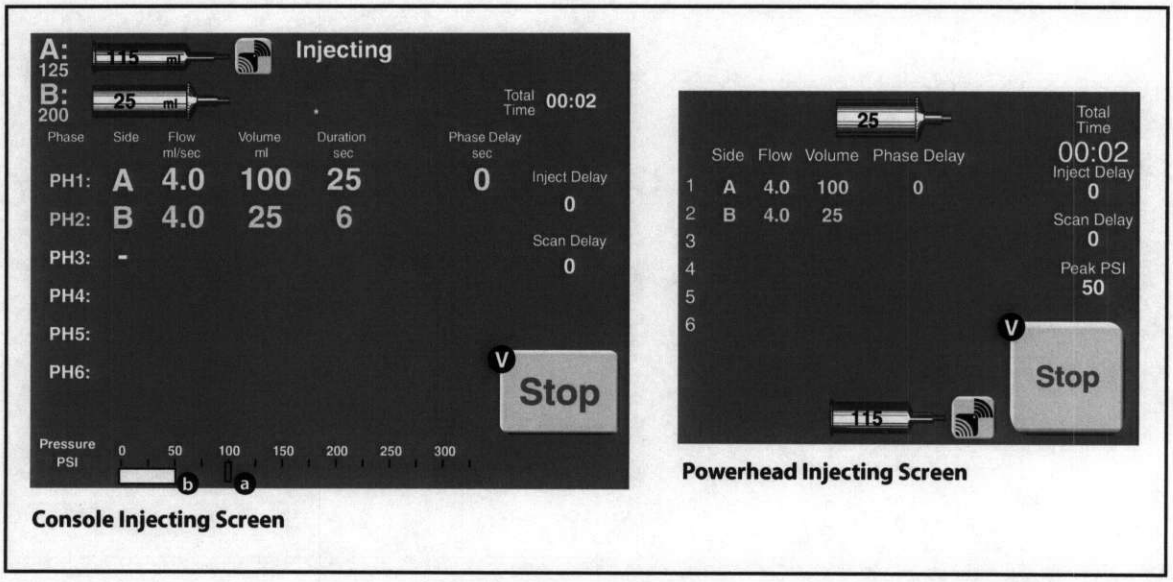
[redacted]

REVIEW PARAMETERS
Prior to delivering an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that the contrast fluid is installed on the correct side of the powerhead.

5.7.2 STARTING DELIVERY OF THE MAIN PROTOCOL

Refer to Figure 5-7-1.

The protocol can be delivered by pressing the [Start] key Ⓐ (on Figure 5-4-1) either on the powerhead or the console or by pressing the remote handswitch. Once the injection is initiated, the Injecting screen, shown in Figure 5-7-1, is displayed, Total Time increments and syringe volume decrements. Note that the Peak PSI (pressure limit) parameter is indicated by the red line ⓐ. The current injecting pressure is indicated by the white bar ⓑ.



Console Injecting Screen

Powerhead Injecting Screen

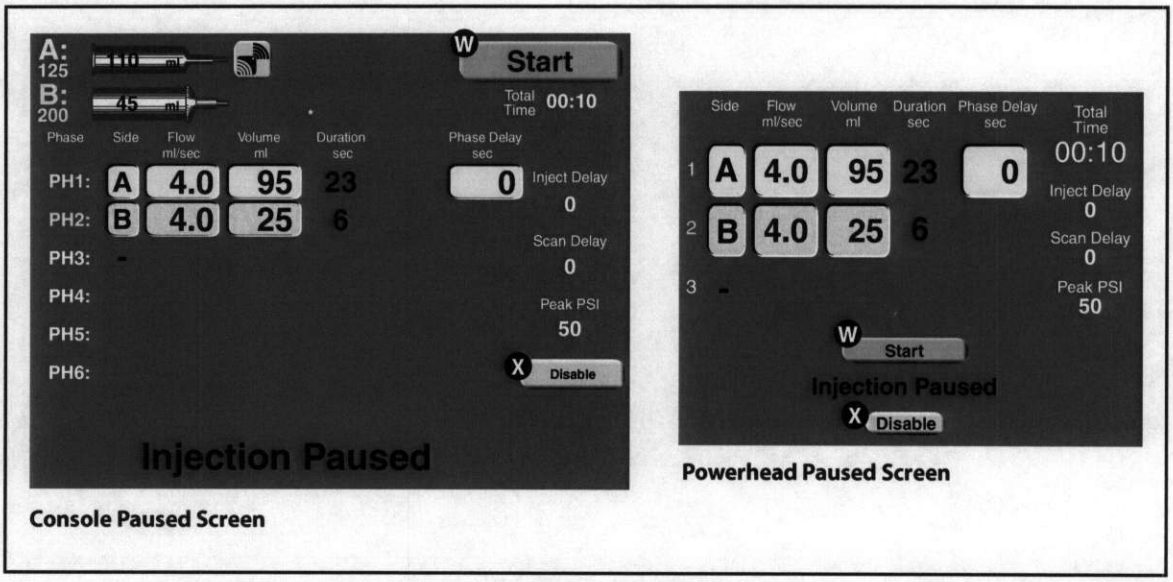
Figure 5-7-1 Injecting Screen

5.7.3 PAUSING AN INJECTION

Refer to Figure 5-7-1 and Figure 5-7-2.

An injection may be immediately paused by pressing the [Stop] key Ⓥ (on Figure 5-7-1) on the console display or the powerhead display and also by depressing once on the handswitch. When the injector is paused, the screen shown in Figure 5-7-2 is displayed and the status lights on the console and powerhead will flash their respective color every 1/2 second.

While the injection is paused, the values for the flow rate, volume and phase delay can be changed on either the console screen or the powerhead screen. However, phases cannot be added or deleted when the injector is paused.



Console Paused Screen

Powerhead Paused Screen

Figure 5-7-2 Injection Paused Screens

5.7.4 RESTARTING A PAUSED INJECTION

Refer to Figure 5-7-2.

The injection can be restarted by pressing the [Start] key Ⓦ on the console or the powerhead paused screens. The achieved values displayed on the Results screen after completion of the restarted injection represent the total volume delivered from the start of the injection and the average flow rate achieved since the restart.

5.7.5 TERMINATING AN INJECTION

Refer to Figure 5-7-1 and Figure 5-7-2.

Press the [Stop] key Ⓥ (on Figure 5-7-1) then the [Disable] key Ⓧ (on Figure 5-7-2) on the powerhead screen or console screen to terminate an injection.

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5.8 DISPLAYING RESULTS SCREEN

Refer to Figure 5-8-1.

Average flow rate, delivered volume and achieved pressure are displayed on both the console and the powerhead Results screen at the completion of the injection. Press the [Main] key Ⓐ to display the Main screen.

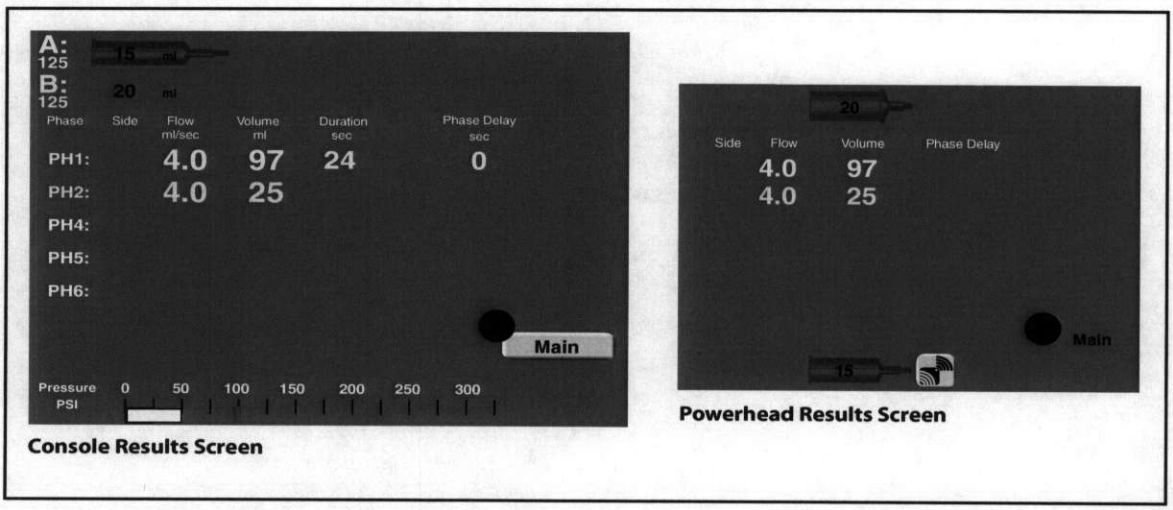

Figure 5-8-1 Results Screens

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5.9 REMOVING 125 ML SYRINGES

After the completion of the injection, disconnect the tubing from Prefilled syringe(s) prior to retracting the ram(s). NOTE: Retraction of rams while 125 ml syringes are connected to tubing that contains check valves will create a vacuum in the syringe.

1. Using aseptic technique, disconnect patient from tubing.
2. Disconnect tubing from 125 ml syringe(s) and remove 200 ml syringe(s) from the injector. Discard according to hospital policy.
3. Retract 125 ml ram(s) and remove 125 ml syringe(s) and discard according to hospital policy.

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6 SYSTEM GENERATED MESSAGES

This chapter contains instructions on responding to system generated messages. Messages are displayed on the powerhead and console screens in response to incorrect operator input or action and equipment status. These messages fall into two categories:

Operator Messages — Those messages that appear in response to incorrect operator input or to inform the operator of the status of the injector.

Alarm Messages — Those messages that appear when the OptiVantage's self-diagnostics detect a problem in the control circuitry.

6.1 OPERATOR MESSAGES

6.1.1 POWER UP MESSAGES

Hardware Initialization completed.

Message: Hardware Initialization completed. Searching for Power Control.

Occurs when: Upon power ON, the console displays this message to indicate the status of the injector.

Operator action: None.

6.1.2 INSERTING SYRINGE MESSAGES

Expired Syringe

Message: The syringe on Side A (B) has expired. Please remove the syringe and install a new one.

Occurs when: This message appears when a syringe with an expiration date that has expired is installed.

Operator action: Remove the syringe and dispose of properly. Install new, unexpired, syringe.

Fluid in Syringe does not Match Injector Setup

Message: The fluid type in the syringe in Side A (B) does not match the injector setup.

Occurs when: This message appears when a contrast syringe with a syringe data tag is installed in a side set up for saline.

Operator action: Install correct type of syringe or change injector settings under the Setup Screen. NOTE: Changing injector settings will delete all existing protocol memories.

Insert Syringe SIDE A

Message 1: The syringe latch on side A is open. Please insert a CONTRAST filled syringe in side A of the injector and close the latch.

Occurs when: Message 1 occurs when the A-side is set up for contrast use and the 200 ml load latch or the 125 ml load latches (dependent upon which syringe adapter/faceplate is installed on the A-side) are in the load position.

Message 2: The syringe latch on side A is open. Please insert a SALINE filled syringe in side A of the injector and close the latch.

Occurs when: Message 2 occurs when the A-side is set up for saline use and the 200 ml load latch or the 125 ml load latches (dependent upon which syringe adapter/faceplate is installed on the A-side) are in the load position.

Operator action: This message is to advise the operator to load the correct syringe type into Side A.

Insert Syringe SIDE B

Message 1: The syringe latch on side B is open. Please insert a SALINE filled syringe in side B of the injector and close the latch.

Occurs when: Message 1 occurs when the B-side is set up for saline use and the 200 ml load latch or the 125 ml load latches (dependent upon which syringe adapter/faceplate is installed on the B-side) are in the load position.

Message 2: The syringe latch on side B is open. Please insert a CONTRAST filled syringe in side B of the injector and close the latch.

Occurs when: Message 2 occurs when the B-side is set up for contrast use and the 200 ml load latch or the 125 ml load latches (dependent upon which syringe adapter/faceplate is installed on the B-side) are in the load position.

Operator action: This message is to advise the operator to load the correct syringe type into Side B.

Installed Used Syringe

Message: The syringe on Side A (B) has been used. Please remove the used syringe and install a new one.

Occurs when: This message appears when the syringe data tag is identified by the injector as being "used" and the operator is trying to install the syringe or enable the injector after the "used" syringe is installed. NOTE: A syringe with a syringe data tag is written with the status of "used" when 1) the injection protocol for the injector side containing the syringe starts to execute. This also includes Test Bolus and Drip protocols. 2) When 25-mL or more of fluid is manually expelled releative to the initial pre-fill volume of the syringe. 3) When the syringe is manually retacted by 10-mL or more relative to thelast forward movement position of the injector ram.

Operator action: Remove the syringe and dispose of properly.

Unable to Mark the Syringe as Used

Message: Unable to mark the syringe on Side A (B) as used. Please use and dispose of the syringe when operation is complete.

Occurs when: This message appears when the syringe data tag cannot be marked as used by the injector. NOTE: A syringe with a syringe data tag is written with the status of "used" when 1) the injection protocol for the injector side containing the syringe starts to execute. This also includes Test Bolus and Drip protocols. 2) When 25-mL or more of fluid is manually expelled releative to the initial pre-fill volume of the syringe. 3) When the syringe is manually retacted by 10-mL or more relative to thelast forward movement position of the injector ram.

Operator action: Remove the syringe and dispose of properly.

6.1.3 PROGRAMMING MESSAGES

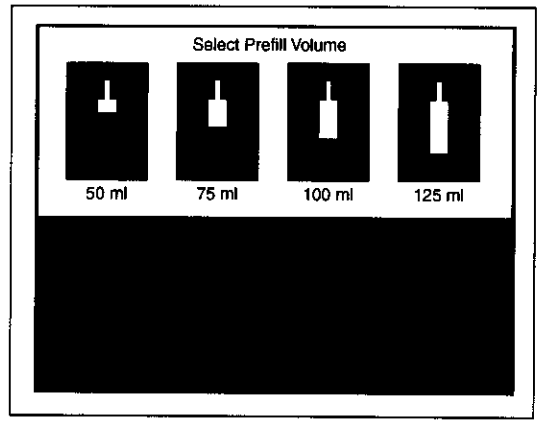
Auto-Fill in Progress

Message: Auto-Fill in progress. Please wait...

Occurs when: This message appears on the console screen when the powerhead is using the Auto-Fill feature to fill the syringe.

Operator action: None.

Automatic Prefill Syringe Size Sensor



Message: Select Prefill Volume 50 ml 75 ml 100 ml 125 ml

Occurs when: The injector's syringe size sensor has been unplugged or has failed.

Operator action: Plug in heater blanket/size sensor on underside of powerhead. Or, to use the injector without the sensor, press the corresponding graphic that matches the installed syringe size.

Changing Fluid Configuration

Message: The syringe fluid configuration has changed. This will prevent access to the stored protocols. Do you want to continue with these settings?

Occurs when: This message occurs when the operator updates the settings in the Setup screen changing the fluid configuration (i.e. A-side:contrast, B-side: saline changed to A-side:saline, B-side:contrast).

Operator action: This message is for informational purposes only in order to advise the operator that changing the fluid configurations will prevent access to stored protocols. Press the [Yes] key to continue with these settings. Press the [No] key to leave the fluid configuration unchanged.

OptiBolus Key is not Installed

Message: OptiBolus Key is not installed. Insert OptiBolus Key and press Close to continue.

Occurs when: This message appears when the operator attempts to recall an OptiBolus protocol when the OptiBolus Key has been removed from the injector.

Operator action: To recall an OptiBolus protocol, the OptiBolus key must be installed at the rear of the power control. Install the OptiBolus Key, press the [Close] key on the screen and continue.

Patency Check in Progress

Message: Patency Check in progress. Please wait...

Occurs when: This message appears on the console screen when the powerhead is delivering a Patency Check injection.

Operator action: None.

Programmed to Deliver Contrast from both Side A and Side B

Message: Attention, the current protocol is programmed to deliver contrast on Side A and Side B. Press Close to continue.

Occurs when: The injector is set up for Contrast (A-side)/Contrast (B-side) delivery.

Operator action: This message is for informational purposes only in order to advise the operator to use caution when delivering more than 125 ml of contrast into a patient. Delivering more than 125 ml of contrast into one patient is not advised.

Protocol Modification in Progress at Console

Message: Protocol modification in progress at console. Please wait...

Occurs when: This message appears on the Powerhead display to inform the operator that Protocol modification is taking place at the Console display.

Operator action: The Powerhead display will refresh upon pressing the [Main] key on the Console.

Protocol Name Already Exists

Message: Protocol name already exists. Please change or cancel.

Occurs when: The operator enters an existing protocol name on the keyboard when trying to store a new protocol.

Operator action: Enter a new protocol name or press the [Cancel] key.

Protocol Name Not Valid

Message: Protocol name not valid. Please change or cancel.

Occurs when: The operator enters a protocol name that is blank or begins with a space.

Operator action: Enter a new, valid protocol name or press the [Cancel] key.

Setup to Deliver Contrast from A-side and B-side

Message: Settings on the Setup Screen will allow contrast to be injected from both sides of the injector. Contrast injections in excess of a single full syringe are possible. Do you want to continue with these settings? Yes/No

Occurs when: This message occurs when the operator updates the settings in the Setup screen for Syringe Fluid A: Contrast (A-side)/Syringe Fluid B: Contrast (B-side) delivery.

Operator action: This message is for informational purposes only in order to advise the operator to use caution when injecting more than one syringe of contrast into a patient. Injecting more than one syringe of contrast into one patient is not advised. Press the [Yes] key to continue with Contrast (A-side)/Contrast (B-side) delivery. Press the [No] key to change the setting for either Syringe Fluid A or Syringe Fluid B.

Unreadable Data on Powerhead or Console Display

Message: NO MESSAGE ASSOCIATED WITH THIS CONDITION.

Occurs when: Any single user display contains unreadable data.

Operator action: The injector can be used, with caution, if any single user display contains unreadable data. Cycle power to reset injector. If this condition persists, contact your Service Department for corrective action. If this issue persists, contact your Service Department for corrective action.

Volume Key Flashing a Magenta Color

Message: NO MESSAGE ASSOCIATED WITH THIS CONDITION.

Occurs when 1: The volume key(s) on the main screen will flash a magenta color to indicate that its value(s) is greater than the volume contained in its respective syringe.

Operator action: Lower the value of the applicable volume key(s) or fill the syringe(s) with an adequate amount of fluid.

Occurs when 2: The volume key on the Drip Mode screen or Patency Check screen will flash a magenta color to indicate that delivering this amount will compromise the volume available for the main protocol. Note that if the Volume key is flashing a Magenta Color, the [Start Drip] key or the [Start Patency] key will not appear.

Operator action: Lower the value of the volume key or fill the syringe with more fluid.

Primary Pressure Sensing has Failed!

Message: Primary Pressure Sensing has Failed! Call Service! Continue with Caution!

Occurs when: Message appears after completion of injection when the Primary Pressure Limiting software has malfunctioned. The Secondary Pressure Limiting software is still operational.

Operator action: Contact your Service Department ***immediately*** for corrective action regarding this message! Press the close key **and continue with caution!**

6.1.4 FACEPLATE (SYRINGE ADAPTER) MESSAGES

Syringe Adapter/Faceplate Disconnected

Message: The faceplate on Side A (B) has become disconnected or has failed. The heater on Side A (B) has been turned off. Check connection or call Service.

Occurs when: The 125 mL RFID faceplate (syringe adapter) is uplugged or the injector diagnostics detects an error in the syringe adapter/faceplate electronics.

Operator action: Press the [Continue} key to continue without use of RFID detction or the heater. Contact your Service Department for corrective action.

6.1.5 AUTO-FILL MESSAGES

Rotate the Powerhead to Activate Auto-Fill

Message: Rotate the Powerhead to the vertical position to activate Auto-Fill sequence.

Occurs when: This message occurs when a 200 ml syringe is installed [with the ram in the "home' (fully expelled) position] but the powerhead is not oriented in the vertical position. The Auto-Fill screen is automatically displayed when 1) the ram is in the "home" position 2) a 200 ml syringe is installed and then 3) the powerhead is rotated to the vertical position.

Operator action: This message is for informational purposes only in order to advise the operator to rotate the powerhead to the vertical position in order to access the Auto-Fill feature.

6.1.6 HEATER BLANKET CONNECTIVITY

Heater Blanket

Powerhead Message: Heater Blanket on this side of the injector has become disconnected or has failed. Check connection or call service. To continue without heater blanket, close window.

Console Message: The heater blanket on the A-side of the injector has become disconnected or has failed. Check connection or call service. To continue without heater blanket, close window.

Console Message: The heater blanket on the B-side of the injector has become disconnected or has failed. Check connection or call service. To continue without heater blanket, close window.

Occurs when: One of the 200 ml heater blanket connectors is unplugged or malfunctioning.

Operator action: Plug the heater blanket in or to use the injector without the heater blanket, press the [Close] key on the screen and continue. Contact your Service Department for corrective action regarding this message.

6.1.7 SCANNER CONNECTIVITY

Scanner Interface Connection not Available

Message: The Scanner Interface connection is not available. To continue without the interface, close window.

Occurs when: When the OEM Interface on the Setup screen in set to On, but the OEM interface is not communicating with the injector properly, this message occurs.

Operator action: To continue without the OEM interface, press the [Close] key. Contact your Service Department for corrective action regarding this message.

6.1.8 ENABLE PROCESS MESSAGES

Enable sequence not completed

Console Message: The Enable sequence has not been completed at the Powerhead.

Powerhead Messages:

for 125 ml syringe/faceplate
The Enable sequence is not complete.
Install a new syringe.
Tilt Powerhead up.
Purge syringe.
Tilt powerhead down.

for 200 ml syringe/faceplate
The Enable sequence is not complete.
Install a new syringe.
Tilt Powerhead up.
Fill syringe.
Purge syringe.
Tilt powerhead down.

Occurs when: As an additional precaution against the injection of an air embolism, the injector's software checks for a "Purge sequence" (125 ml syringe) and a "Fill/Purge sequence" (200 ml syringe) before allowing the injector to be enabled. If the Purge Sequence or Fill/Purge Sequence has not occurred and the [Enable] key is pressed, the console message will appear and the appropriate powerhead message [missed step(s)] will appear. If correct steps have been taken on either the A-side or the B-side, the message "This side ready." will appear.

Operator action: Follow the step indicated on the powerhead to allow the injector to be enabled. ***Note that it is the operator's responsibility to ensure the syringe and tubing does not contain air.***

Hand switch is closed.

Message: The hand switch is closed. Please check hand switch and press Close to continue.

Occurs when: As a safety precaution to prevent unintentional injections, the injector cannot be enabled if its hand switch is closed. If the hand switch is closed and the injector's enable key is pressed, this message appears.

Operator action: Check the appropriate switch to ensure that it is open. Once checked, press the [Close] key and continue the enable process. If you are unable to open the switch (as indicated by the return of this message), unplug the hand switch and continue. Contact your Service Department for corrective action regarding the hand switch.

Insufficient volume

Message: Insufficient volume to run this injection.

Occurs when: The [Enable] key is pressed when a volume key is flashing a magenta color. The volume key(s) on the main screen flash a magenta color to indicate that its value(s) is greater than the volume contained in its respective syringe.

Operator action: Lower the value of the applicable volume key(s) or fill the syringe with more fluid. ***Note that it is the operator's responsibility to ensure the syringe and tubing does not contain air.***

6.1.9 INJECTION STOPPED MESSAGES

Drip Expired

Message: WARNING! The Drip Mode injection is complete. Start the Enabled Protocol. Press Close to return to the Start screen.

Occurs when: This message appears when the Drip Mode injection is complete.

Operator action: Press the [Close] key to return to the Start screen to allow for delivery of the main protocol.

Injector Stalled

Message: Injector Disabled! Injector stalled. Check fluid path for obstructions. Press Close to continue.

Occurs when: This message appears if the injector has started an injection but cannot move the ram.

Operator action: Press the [Close] key and check the fluid path for any obstructions and remove them. Restart the Enable process.

Pressure Limiting

Message: Injection is pressure limiting! Do you want to continue or stop?

Occurs when: This message appears when the injector is injecting under maximum pressure limit conditions and cannot achieve the set flow rate.

Operator action: Press the [Continue] key to perform the injection under maximum pressure limit conditions. Press the [Stop] key to review the Flow Rate parameter to ensure it is not set too high for the procedure and also review the Pressure Limit parameter to ensure it is not set too low. Check the delivery system for closed stopcocks or kinked tubing. Under normal circumstances, the injection pressure should not reach the pressure limit. Reaching the pressure limit defeats the purpose of a flow rate injector.

Syringe Latch Open

Message: The injection has stopped. A syringe latch is open. Press Close to continue.

Occurs when: While the injector is enabled or injecting, the injector software checks to ensure the 125 ml syringe clamps and/or the 200 ml syringe levers are in the loaded (closed) position. If either are opened, the injector will immediately disable and display this message.

Operator action: Close the syringe clamps and/or levers. Press the [Close] key and re-enable the injector.

6.1.10 RESULTS SCREEN MESSAGES

Pressure Limited

Message: This injection was pressure limited.

Occurs when: This message appears on the Results screen if the injector injects under maximum pressure limit conditions but cannot achieve the set flow rate.

Operator action: This message is to advise the operator that the injection was delivered but under pressure limited conditions. Under normal circumstances, the injection pressure should not reach the pressure limit. Reaching the pressure limit defeats the purpose of a flow rate injector. Review the Flow Rate parameter to ensure it was not set too high for the procedure and also review the Pressure Limit parameter to ensure it was not set too low. Check the delivery system for closed stopcocks or kinked tubing.

6.2 ALARM MESSAGES

Refer to Figure 6-2-1.

The microprocessor control circuits in the OptiVantage continuously monitor all important functions from the moment that the unit is turned on. These checks, transparent to the operator, occur many times each second, monitoring the safe performance of the injector. If a fault is detected, the unit will lock into a fault mode and display an Alarm code.

Cycle power to reset the injector. If the alarm persists, contact your Service Department for corrective action regarding this alarm.

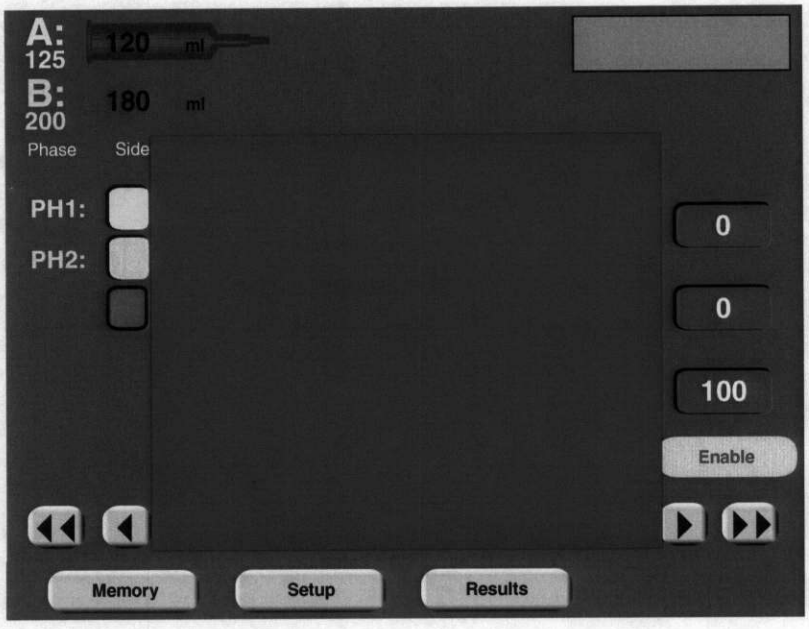


Figure 6-2-1 Alarm Message

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7 CARE OF UNIT

NOTE: Preventive maintenance schedule and service procedures are in the Service Manual.

7.1 DAILY INSPECTION

7.1.1 200 ML PRESSURE SLEEVE

The 200 ml pressure sleeve has a limited life-span and must be replaced periodically. Its expected life-span may range from thirty (30) days or less to over two (2) years depending on pressures encountered, the number of injection cycles and the cleaning and sterilization techniques utilized. Check the 200 ml pressure sleeve(s) daily for signs of stress, crazing lines, or cracks and replace immediately when any of these symptoms are found.

⚠ WARNING! ⚠

CHECK PRESSURE SLEEVE DAILY!
Syringe pressure sleeves must withstand high pressures generated during injection delivery. Defective sleeves may shatter or explode under these conditions. Always inspect pressure sleeve closely before using injector. While viewing all areas; look for stress cracks (around the front or at the shoulder area), discard any pressure sleeve exhibiting signs of stress, crazing lines or cracks. The use of such parts may cause injury and/or an aborted injection.

7.1.2 125 ML SYRINGE ADAPTER

Check the 125 ml syringe adapter(s) daily for signs of cracks or separation of mating parts and replace immediately when any of these are found.

[redacted]

If cracks or mating part separations cause the electronics inside to be exposed, do not plug the syringe adapter into the powerhead. Contact your Service Department for syringe adapter replacement.

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7.2 CLEANING

7.2.1 200 ML PRESSURE SLEEVE AND BASE

On a daily basis, move the ram to the fully retracted position and wipe out the inside of the pressure sleeve with a damp (with water), lint-free towel.

NOTE: Do not autoclave the pressure sleeve. *Autoclaving will shorten the life of the pressure sleeve.*

The entire base and pressure sleeve may be placed or soaked in warm water with a mild soap to remove any hardened contrast. This procedure is also helpful if the locking lever is hard to rotate. *Do not use alcohol-based detergents. The water should not contain the following substances, even in trace amounts:*

- esters
- ethers
- ketones
- chlorides
- n-Alkyl
- alcohols (other than ethyl alcohol)
- cleaners and disinfectants (such as SaniZide and TB-Cide Quat)
- products containing: dimethyl benzyl, ammonium chlorides, and dimethyl ethylbenzyl

7.2.2 125 ML SYRINGE ADAPTER

On a daily basis, move the ram(s) to the fully retracted position and wipe out the inside of the 125 mL syringe adapter(s) with warm water containing a mild soap. If the syringe latch becomes difficult to actuate due to contrast buildup, it is safe to unplug and remove the syringe adapter from the powerhead and run it under water while actuating the latch. **NOTE:** *Care must be taken, however, to keep the cable connector dry.*

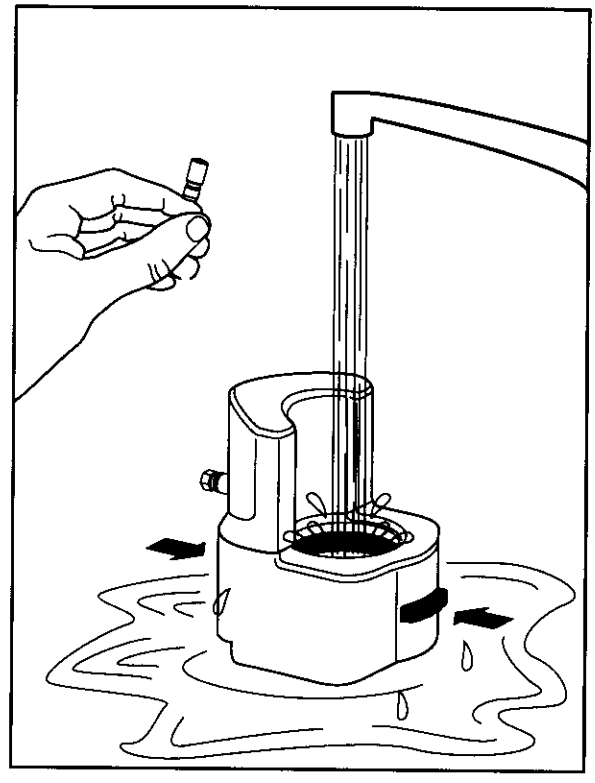

Figure 7-2-1.

7.2.3 CONSOLE AND POWERHEAD

The console and powerhead may be dusted by using a lint-free cloth. To clean the touch screen, use a *nonabrasive* cloth towel and any commercially available *non-ammonia* window cleaner to regularly clean the surface. *The cleaning solution should be applied to the towel rather than the surface of the touch screen.* The touch screen has air vents and is not designed with water tight bezels so fluid ingress may occur from behind the panel if not cleaned carefully.

7.2.4 POWER SUPPLY

Clean the exterior of the power supply by spraying a cloth with an all-purpose household cleaner, then gently wipe clean.

Index

Symbols

A

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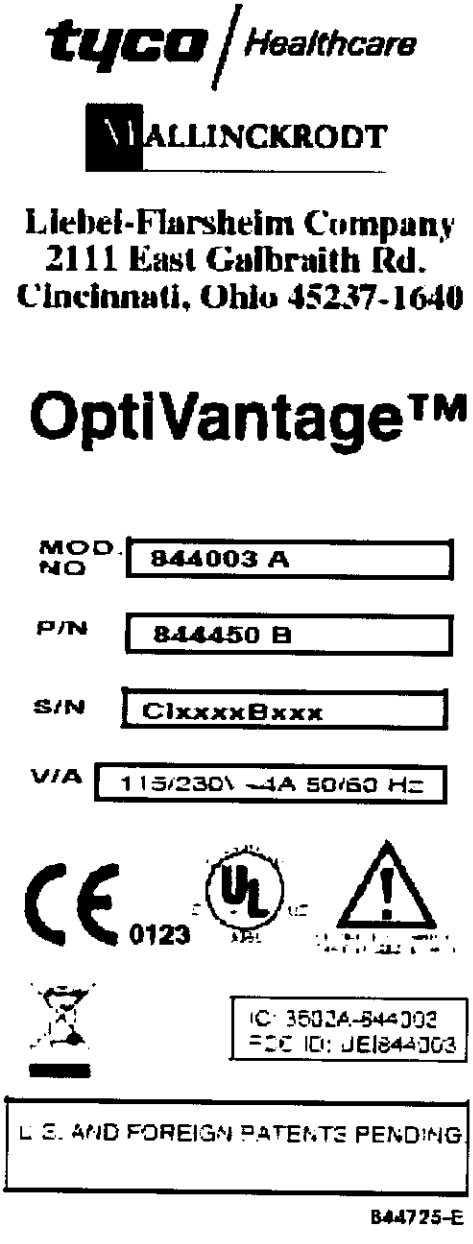
Appendix B Rating Plate



Appendix C Product Labeling

(Syringe Labels and Package Insert)

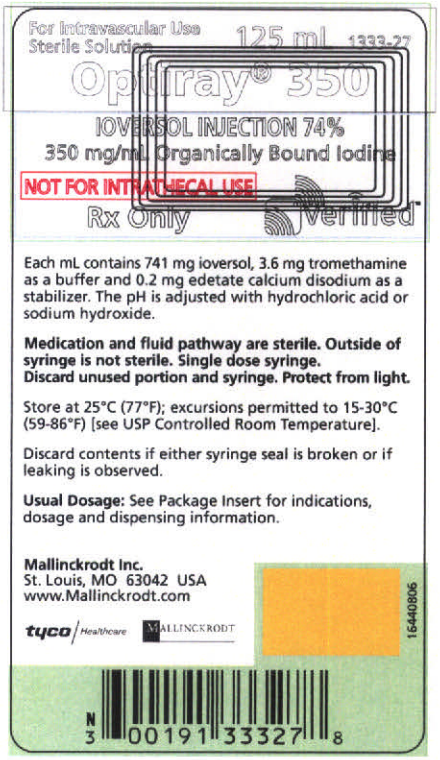
MALLINCKRODT (Raleigh) Label No.: 16440806

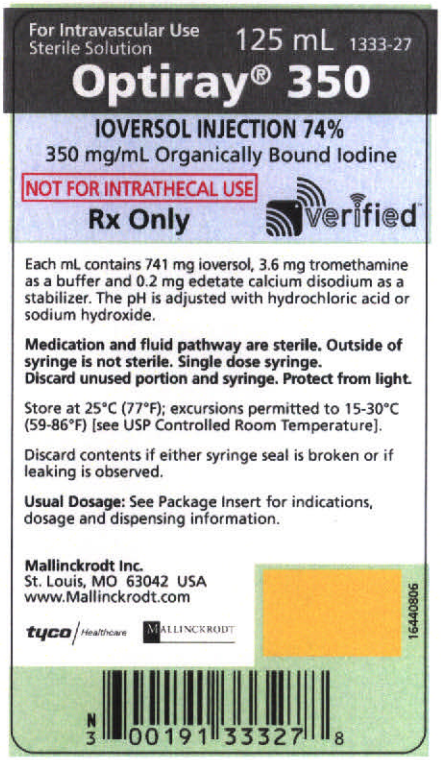
Size: 2.25" x 4.00" Date: 8/9/2006

Prepared By: BGW

Colors:
A) Red 186 CV
B) Grey 425 CV
C) Black 426 CV
D) White
E) Purple 2725 CV - 20%
F) No Varnish / In-house Print Area

RFID Tag Placement Only





WEB DIRECTION

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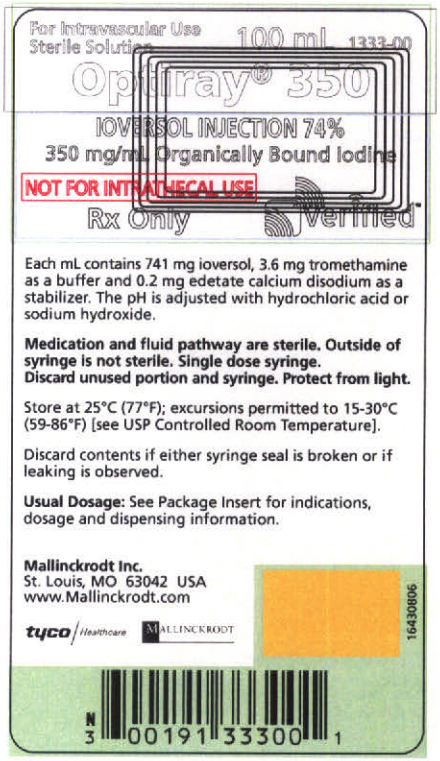
MALLINCKRODT (Raleigh) Label No.: **16430806**

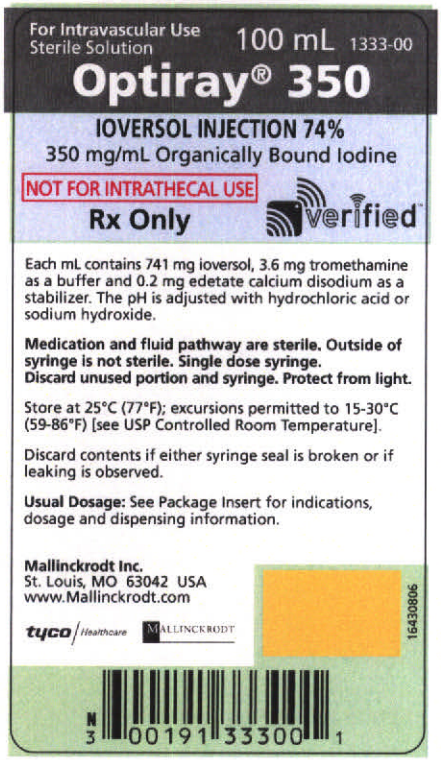
Size: **2.25" x 4.00"** Date: **8/9/2006**

Prepared By: **BGW**

Colors:
A) **Red 186 CV**
B) **Grey 425 CV**
C) **Black 426 CV**
D) **White**
E) **Purple 2725 CV - 20%**
F) **No Varnish / In-house Print Area**

RFID Tag Placement Only





WEB DIRECTION

776

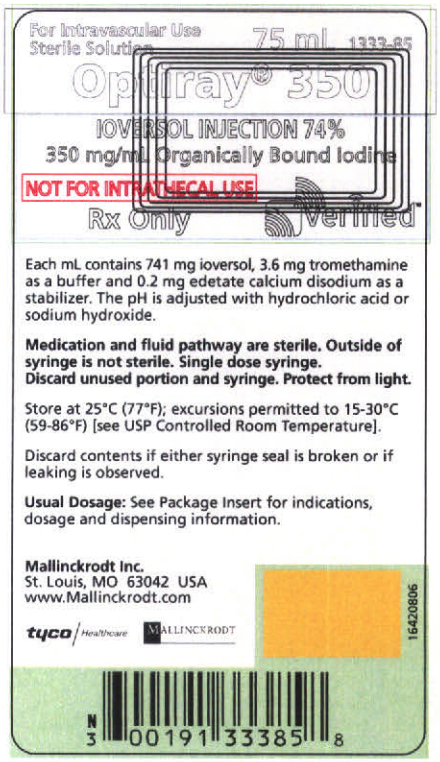
MALLINCKRODT (Raleigh) Label No.: **16420806**

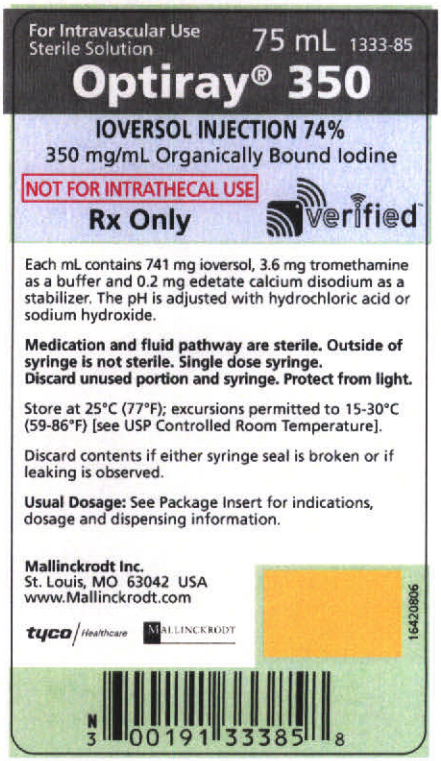
Size: **2.25" x 4.00"** Date: **8/9/2006**

Prepared By: **BGW**

Colors:
A) **Red 186 CV**
B) **Grey 425 CV**
C) **Black 426 CV**
D) **White**
E) **Purple 2725 CV - 20%**
F) **No Varnish / In-house Print Area**

RFID Tag Placement Only





WEB DIRECTION

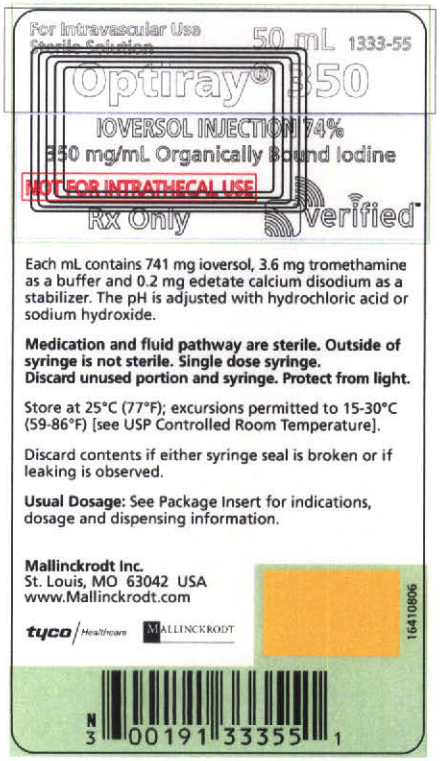
MALLINCKRODT (Raleigh) Label No.: **16410806**

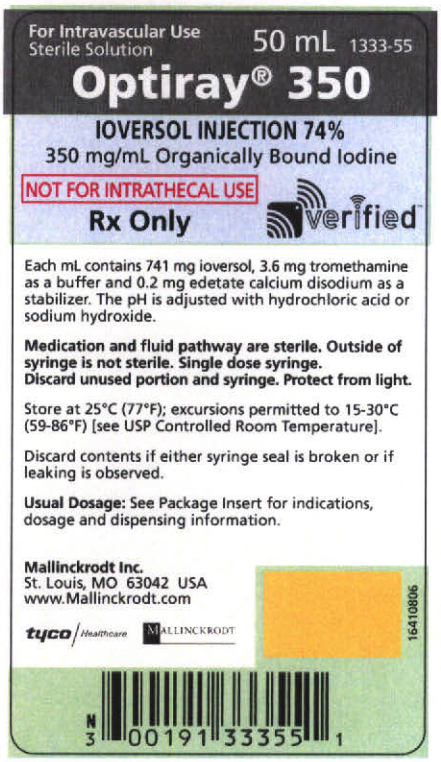
Size: **2.25" x 4.00"** Date: **8/9/2006**

Prepared By: **BGW**

Colors:
A) **Red 186 CV**
B) **Grey 425 CV**
C) **Black 426 CV**
D) **White**
E) **Purple 2725 CV - 20%**
F) **No Varnish / In-house Print Area**

RFID Tag Placement Only





WEB DIRECTION

778

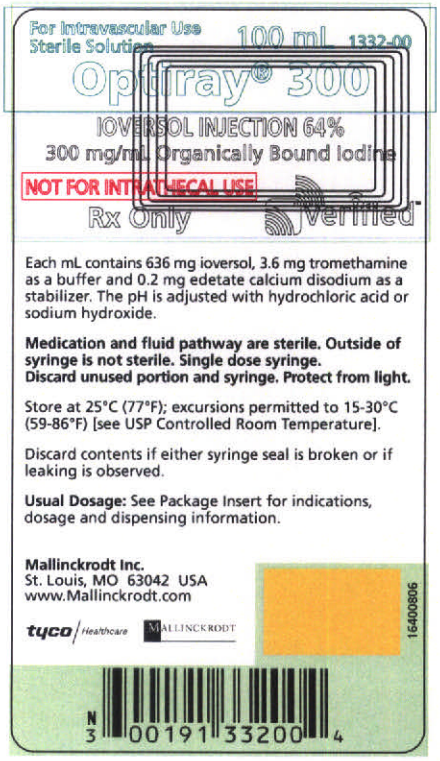
MALLINCKRODT (Raleigh) Label No.: **16400806**

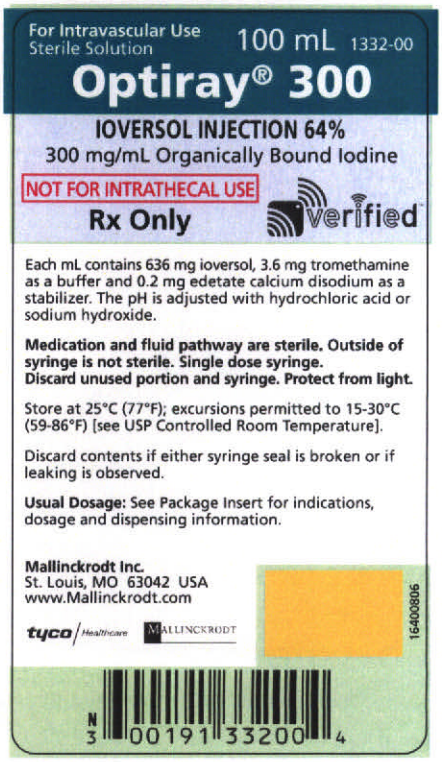
Size: **2.25" x 4.00"** Date: **8/9/2006**

Prepared By: **BGW**

Colors:
A) **Red 186 CV**
B) **Green 3405 CV**
C) **Black 426 CV**
D) **White**
E) **Purple 2725 CV - 20%**
F) **No Varnish / In-house Print Area**

RFID Tag Placement Only





WEB DIRECTION

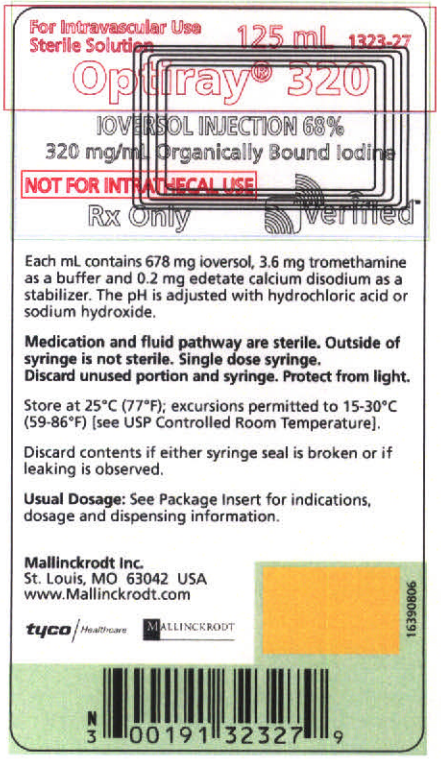
MALLINCKRODT (Raleigh) Label No.: **16390806**

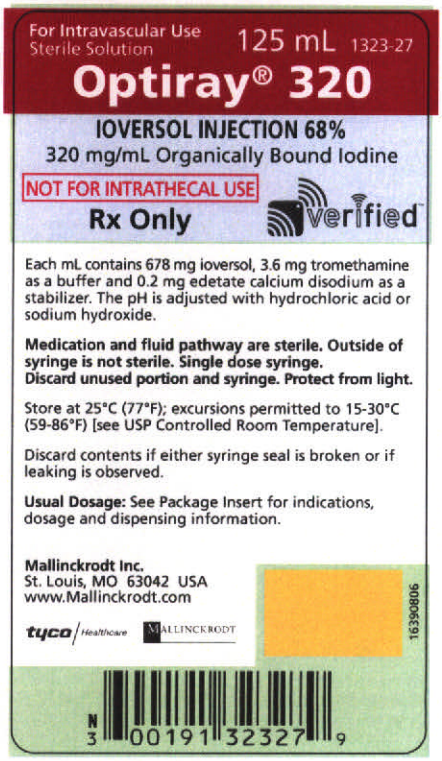
Size: **2.25" x 4.00"** Date: **8/9/2006**

Prepared By: **BGW**

Colors:
A) **Red 186 CV**
B) **Dark Red 201 CV**
C) **Black 426 CV**
D) **White**
E) **Purple 2725 CV - 20%**
F) **No Varnish / In-house Print Area**

RFID Tag Placement Only





WEB DIRECTION

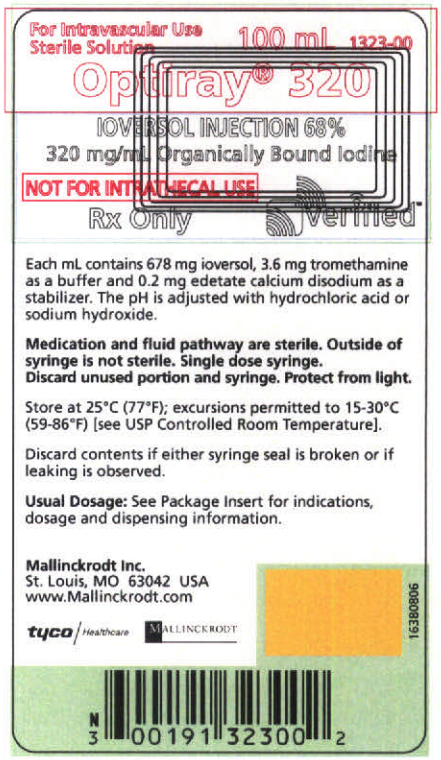
MALLINCKRODT (Raleigh) Label No.: **16380806**

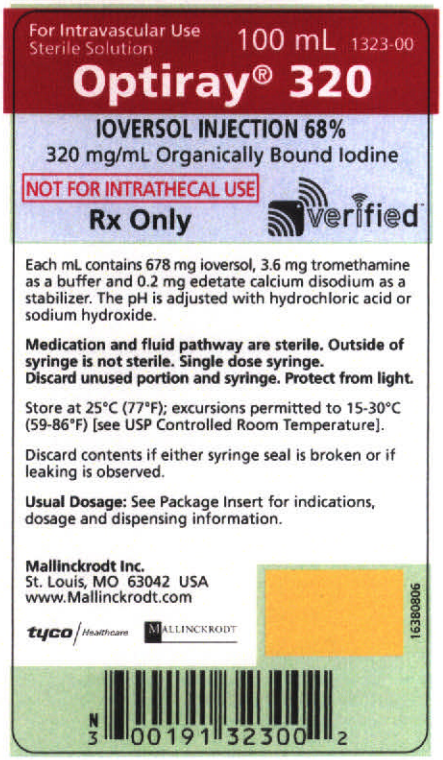
Size: **2.25" x 4.00"** Date: **8/9/2006**

Prepared By: **BGW**

Colors:
A) **Red 186 CV**
B) **Dark Red 201 CV**
C) **Black 426 CV**
D) **White**
E) **Purple 2725 CV - 20%**
F) **No Varnish / In-house Print Area**

RFID Tag Placement Only





WEB DIRECTION

781

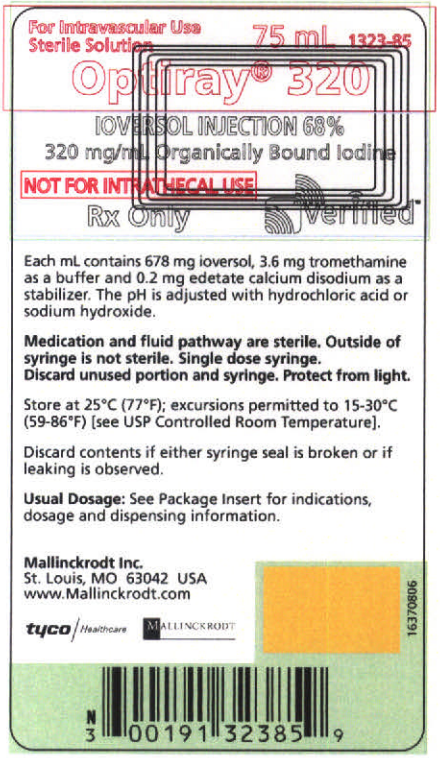
MALLINCKRODT (Raleigh) Label No.: **16370806**

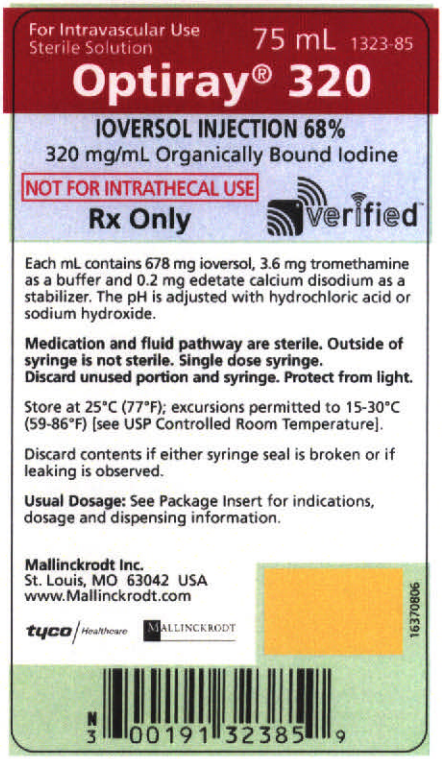
Size: **2.25" x 4.00"** Date: **8/9/2006**

Prepared By: **BGW**

Colors:
A) **Red 186 CV**
B) **Dark Red 201 CV**
C) **Black 426 CV**
D) **White**
E) **Purple 2725 CV - 20%**
F) **No Varnish / In-house Print Area**

RFID Tag Placement Only





WEB DIRECTION

782

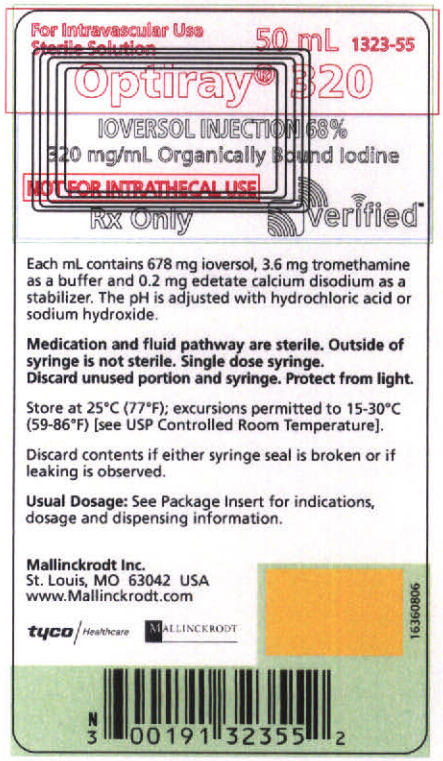
MALLINCKRODT (Raleigh) Label No.: **16360806**

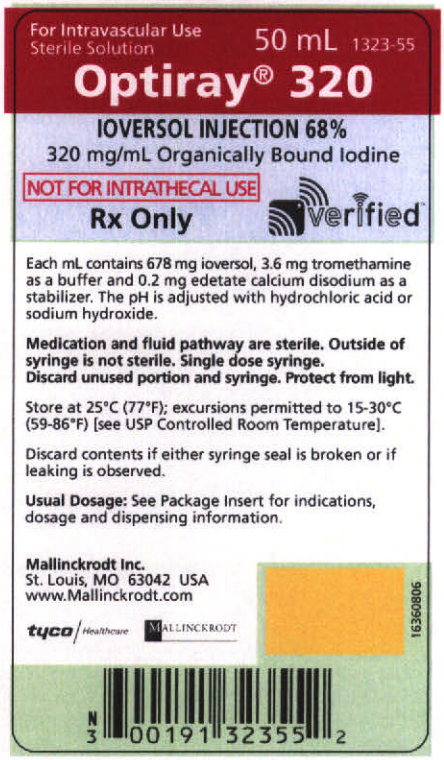
Size: **2.25" x 4.00"** Date: **8/8/2006**

Prepared By: **BGW**

Colors:
A) **Red 186 CV**
B) **Dark Red 201 CV**
C) **Black 426 CV**
D) **White**
E) **Purple 2725 CV - 20%**
F) **No Varnish / In-house Print Area**

RFID Tag Placement Only





WEB DIRECTION

783

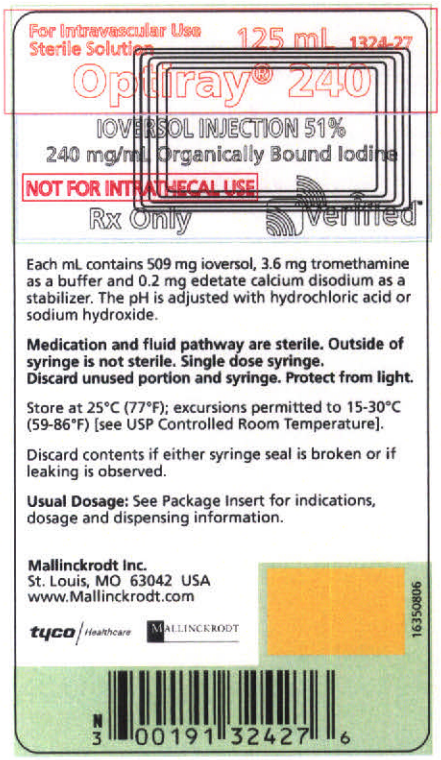
MALLINCKRODT (Raleigh) Label No.: **16350806**

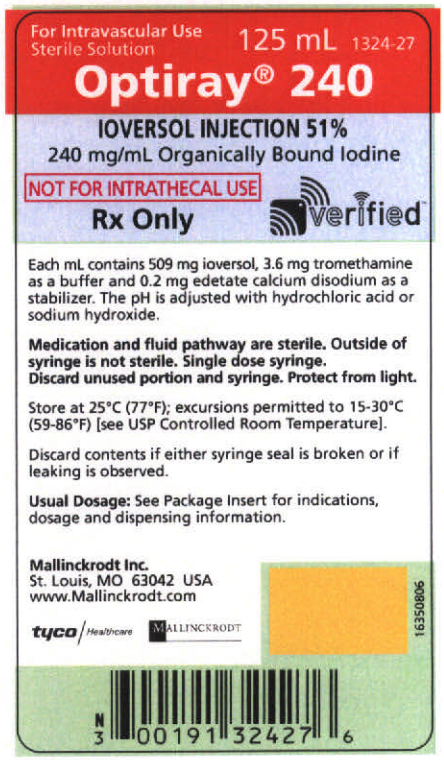
Size: **2.25" x 4.00"** Date: **8/9/2006**

Prepared By: **BGW**

Colors:
A) **Red 186 CV**
B) **Warm Red CV**
C) **Black 426 CV**
D) **White**
E) **Purple 2725 CV - 20%**
F) **No Varnish / In-house Print Area**

RFID Tag Placement Only





WEB DIRECTION

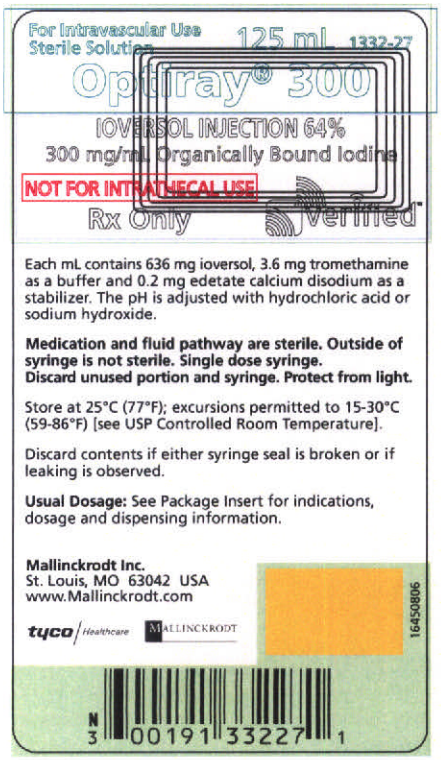
MALLINCKRODT (Raleigh) Label No.: **16450806**

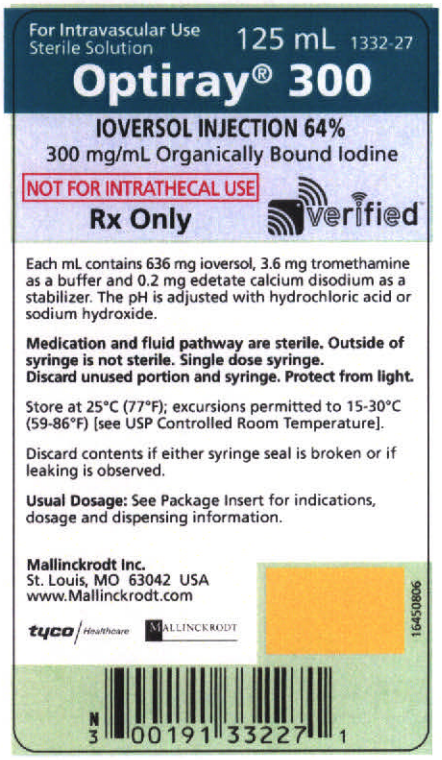
Size: **2.25" x 4.00"** Date: **8/9/2006**

Prepared By: **BGW**

Colors:
A) **Red 186 CV**
B) **Green 3405 CV**
C) **Black 426 CV**
D) **White**
E) **Purple 2725 CV - 20%**
F) **No Varnish / In-house Print Area**

RFID Tag Placement Only





WEB DIRECTION

785

August 2006

Optiray® 350
[IOVERSOL INJECTION 74%]
Optiray® 320
[IOVERSOL INJECTION 68%]
Optiray® 300
[IOVERSOL INJECTION 64%]
Optiray® 240
[IOVERSOL INJECTION 51%]
Optiray® 160
[IOVERSOL INJECTION 34%]

tyco Healthcare/Mallinckrodt

NOT FOR INTRATHECAL USE

Verified

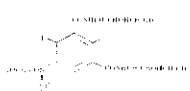
RFID Enabled Syringes

This Optiray syringe has been labeled with a Radio Frequency Identification (RFID) tag. This tag allows for the exchange of product information such as lot number, expiration and concentration. Exchange of patient information does not occur with the use of this RFID tag. Use of the RFID tag does not impact Optiray product quality.

RFID tag functionality will be verified by the OptiVantage DH Injector enabled with RFID capabilities. Instructions for use will be provided on the injector interface screens and operator's manual.

DESCRIPTION

OPTIRAY (ioversol injection, formulations are sterile, nonpyrogenic, aqueous solutions intended for intravascular administration as diagnostic radiopaque media. Ioversol is designated chemically as N,N'-Bis-(2,3-dihydroxypropyl)-5-[N-(2-hydroxyethyl)-glycolamido]-2,4,6-triiodoisophthalamide and has the following structural formula:



The molecular weight of ioversol is 807.11 and the organically bound iodine content is 47.2%. Ioversol is nonionic and does not dissociate in solution.

Each milliliter of OPTIRAY 350 (ioversol injection 74%) contains 741 mg of ioversol with 3.6 mg of tromethamine as a buffer and 0.2 mg of edetate calcium disodium as a stabilizer. OPTIRAY 350 provides 35% (350 mg/mL) organically bound iodine.

Each milliliter of OPTIRAY 320 (ioversol injection 68%) contains 678 mg of ioversol with 3.6 mg of tromethamine as a buffer and 0.2 mg of edetate calcium disodium as a stabilizer. OPTIRAY 320 provides 32% (320 mg/mL) organically bound iodine.

Each milliliter of OPTIRAY 300 (ioversol injection 64%) contains 636 mg of ioversol with 3.6 mg of tromethamine as a buffer and 0.2 mg of edetate calcium disodium as a stabilizer. OPTIRAY 300 provides 30% (300 mg/mL) organically bound iodine.

Each milliliter of OPTIRAY 240 (ioversol injection 51%) contains 509 mg of ioversol with 3.6 mg of tromethamine as a buffer and 0.2 mg of edetate calcium disodium as a stabilizer. OPTIRAY 240 provides 24% (240 mg/mL) organically bound iodine.

Each milliliter of OPTIRAY 160 (ioversol injection 34%) contains 339 mg of ioversol with 3.6 mg of tromethamine as a buffer and 0.2 mg of edetate calcium disodium as a stabilizer. OPTIRAY 160 provides 16% (160 mg/mL) organically bound iodine.

The pH of the OPTIRAY formulations has been adjusted to 6.0 to 7.4 with hydrochloric acid or sodium hydroxide. All solutions are sterilized by autoclaving and contain no preservatives. Unused portions should be discarded. OPTIRAY solutions are sensitive to light and therefore should be protected from exposure.

Some physical and chemical properties of these formulations are listed below.

	OPTIRAY 160	OPTIRAY 240	OPTIRAY 300	OPTIRAY 320	OPTIRAY 350
Ioversol content (mg/mL)	339	509	636	678	741
Iodine content (mg I/mL)	160	240	300	320	350
Osmolality (mOsm/kg water)	355	502	651	702	792
Viscosity (cps)					
at 25°C	2.7	4.6	8.2	9.9	14.9
at 37°C	1.9	3.0	5.5	5.8	9.0
Specific Gravity					
at 37°C	1.186	1.261	1.357	1.371	1.405

The OPTIRAY formulations are clear, colorless to pale yellow solutions containing no undissolved solids. Crystallization does not occur at room temperature. The products are supplied in containers from which the air has been displaced by nitrogen. OPTIRAY solutions have osmolalities 1.2 to 2.8 times that of plasma (285 mOsm/kg water) as shown in the above table and are hypertonic under conditions of use.

CLINICAL PHARMACOLOGY

The pharmacokinetics of ioversol intravascularly administered in normal subjects conform to an open two compartment model with first order elimination (a rapid alpha phase for drug distribution and a slower beta phase for drug elimination). Based on the blood clearance curves for 12 healthy volunteers (6 receiving 50 mL and 6 receiving 150 mL of OPTIRAY 320), the biological half-life was 1.8 hours for both dose levels and there was no evidence of any dose related difference in the rate of elimination.

Ioversol is excreted mainly through the kidneys following intravascular administration. In patients with impaired renal function, the elimination half-life is prolonged. In the absence of renal dysfunction, the mean half-life for urinary excretion following a 50 mL dose was 118 minutes (105 to 156) and following a 150 mL dose was 136 minutes (74 to 141). Greater than 95% of the administered dose was excreted with in the first 24 hours, with the peak urine concentration occurring in the first 2 hours after administration. Fecal elimination was negligible.

Ioversol does not bind to serum or plasma proteins to any extent and no significant metabolism, deiodination or biotransformation occurs.

OPTIRAY probably crosses the placental barrier in humans by simple diffusion. It is not known to what extent ioversol is excreted in human milk.

Intravascular injection of ioversol opacifies those vessels in the path of the flow of the contrast medium, permitting radiographic visualization of the internal structures until significant hemodilution occurs.

Ioversol may be visualized in the renal parenchyma within 30 to 60 seconds following rapid intravenous injection. Opacification of the calyces and pelves in patients with normal renal function becomes apparent within 1 to 3 minutes, with optimum contrast occurring within 5 to 15 minutes.

Animal studies indicate that ioversol does not cross the blood-brain barrier or cause endothelial damage to any significant extent.

OPTIRAY enhances computed tomographic imaging through augmentation of radiographic efficiency. The degree of density enhancement is directly related to the iodine content in an administered dose; peak iodine blood levels occur immediately following rapid intravenous injection. Blood levels fall rapidly within 5 to 10 minutes and the vascular compartment half-life is approximately 20 minutes. This can be accounted for by the dilution in the vascular and extravascular fluid compartments which causes an initial sharp fall in plasma concentration. Equilibration with the extracellular compartments is reached in about 10 minutes, thereafter, the fall becomes exponential.

The pharmacokinetics of ioversol in both normal and abnormal tissue have been shown to be variable. Contrast enhancement appears to be greatest immediately after bolus administration (15 seconds to 120 seconds). Thus, greatest enhancement may be detected by a series of consecutive two-to-three second scans performed within 30 to 90 seconds after injection (i.e., dynamic computed tomographic imaging). Utilization of a continuous scanning technique (i.e., dynamic CT scanning) may improve enhancement and diagnostic assessment of tumor and other lesions such as abscess, occasionally revealing unsuspected or more extensive disease. For example, a cyst may be distinguished from a vascularized solid lesion when precontrast and enhanced scans are compared; the nonperfused mass shows unchanged x-ray absorption (CT number). A vascularized lesion is characterized by an increase in CT number in the few minutes after a bolus of intravascular contrast agent. It may be malignant, benign or normal tissue, but would probably not be a cyst, hematoma, or other nonvascular lesion.

Because unenhanced scanning may provide adequate diagnostic information in the individual patient, the decision to employ contrast enhancement, which may be associated with risk and increased radiation exposure, should be based upon a careful evaluation of clinical, other radiological and unenhanced CT findings.

CT SCANNING OF THE HEAD

In contrast enhanced computed tomographic head imaging, OPTIRAY does not accumulate in normal brain tissue due to the presence of the normal blood-brain barrier. The increase in x-ray absorption in the normal brain is due to the presence of contrast agent within the blood pool. A break in the blood-brain barrier such as occurs in malignant tumors of the brain allows for the accumulation of contrast medium within the interstitial tissue of the tumor. Adjacent normal brain tissue does not contain the contrast medium.

Maximum contrast enhancement in tissue frequently occurs after peak blood iodine levels are reached. A delay in maximum contrast enhancement can occur. Diagnostic contrast enhanced images of the brain have been obtained up to 1 hour after intravenous bolus administration. This delay suggests that radiographic contrast enhancement is at least in part dependent on the accumulation of iodine containing medium within the lesion and outside the blood pool, although the mechanism by which this occurs is not clear. The radiographic enhancement of nontumoral lesions, such as arteriovenous malformations and aneurysms, is probably dependent on the iodine content of the circulating blood pool.

In patients where the blood-brain barrier is known or suspected to be disrupted, the use of any radiographic contrast medium must be assessed on an individual risk to benefit basis. However compared to ionic media, nonionic media are less toxic to the central nervous system.

CT SCANNING OF THE BODY

In contrast enhanced computed tomographic body imaging (nonneural tissue), OPTIRAY diffuses rapidly from the vascular into the extravascular space. Increase in x-ray absorption is related to blood flow concentration of the contrast medium, and extraction of the contrast medium by interstitial tissue of tumors since no barrier exists. Contrast enhancement is thus due to the relative differences in extravascular diffusion between normal and abnormal tissue, quite different from that in the brain.

INDICATIONS AND USAGE

OPTIRAY 350 is indicated in adults for peripheral and coronary arteriography and left ventriculography. OPTIRAY 350 is also indicated for contrast enhanced computed tomographic imaging of the head and body, intravenous excretory urography, intravenous digital subtraction angiography and venography. OPTIRAY 350 is indicated in children for angiocardiography.

OPTIRAY 320 is indicated in adults for angiography throughout the cardiovascular system. Its uses include cerebral, coronary, peripheral, visceral and renal arteriography, venography, aortography, and left ventriculography. OPTIRAY 320 is also indicated for contrast enhanced computed tomographic imaging of the head and body, and intravenous excretory urography.

OPTIRAY 320 is indicated in children for angiocardiography, contrast enhanced computed tomographic imaging of the head and body, and intravenous excretory urography.

OPTIRAY 300 is indicated for cerebral arteriography and peripheral arteriography. OPTIRAY 300 is also indicated for contrast enhanced computed tomographic imaging of the head and body, venography, and intravenous excretory urography.

OPTIRAY 240 is indicated for cerebral angiography and venography. OPTIRAY 240 is also indicated for contrast enhanced computed tomographic imaging of the head and body and intravenous excretory urography.

OPTIRAY 160 is indicated for intra-arterial digital subtraction angiography (IA-DSA).

CONTRAINDICATIONS

None.

WARNINGS

SEVERE ADVERSE EVENTS – INADVERTENT INTRATHECAL ADMINISTRATION: Serious adverse reactions have been reported due to the inadvertent intrathecal administration of iodinated contrast media that are not indicated for intrathecal use. These serious adverse reactions include: death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. Special attention must be given to ensure that this drug product is not administered intrathecally.

Non ionic iodinated contrast media inhibit blood coagulation, in vitro, less than ionic contrast media. Clotting has been reported when blood remains in contact with syringes containing nonionic contrast media.

Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported during angiographic procedures with both ionic and nonionic contrast media. Therefore, meticulous intravascular administration technique is necessary, particularly during angiographic procedures, to minimize thromboembolic events. Numerous factors, including length of procedure, catheter and syringe material, underlying disease state, and concomitant medications may contribute to the development of thromboembolic events. For these reasons, meticulous angiographic technique are recommended including close attention to guidewire and catheter manipulation, use of manifold systems and/or three-way stopcocks, frequent catheter flushing with heparinized saline solutions and minimizing the length of the procedure. The use of plastic syringes in place of glass syringes has been reported to decrease but not eliminate the likelihood of in vitro clotting.

Serious or fatal reactions have been associated with the administration of iodine-containing radiopaque media. It is of utmost importance to be completely prepared to treat any contrast medium reaction.

As with any contrast medium, serious neurologic sequelae, including permanent paralysis, can occur following cerebral arteriography, selective spinal arteriography, and arteriography of vessels supplying the spinal cord. A cause-effect relationship to the contrast medium has not been established since the patients' pre-existing condition and procedural technique are causative factors in themselves. The arterial injection of a contrast medium should never be made following the administration of vasopressors since they strongly potentiate neurologic effects.

Caution must be exercised in patients with severely impaired renal function, combined renal and hepatic disease, severe thyrotoxicosis, myelomatosis, or anuria, particularly when large doses are administered.

Intravascularly administered iodine-containing radiopaque media are potentially hazardous in patients with multiple myeloma or other paraproteinemia, particularly in those with therapeutically resistant anuria. Myeloma occurs most commonly in persons over age 40. Although neither the contrast agent nor dehydration has been proved separately to be the cause of anuria in myelomatous patients, it has been speculated that the combination of both may be causative. The risk in myelomatous patients is not a contraindication to the procedure; however special precautions, including maintenance of normal hydration and close monitoring, are required. Partial dehydration in the preparation of these patients prior to injection is not recommended since this may predispose the patient to precipitation of the myeloma protein.

Administration of radiopaque materials to patients known or suspected of having pheochromocytoma should be performed with extreme caution. If, in the opinion of the physician, the possible benefits of such procedures outweigh the considered risks, the procedures may be performed. However the amount of radiopaque medium injected should be kept to an absolute minimum. The blood pressure should be assessed throughout the procedure, and measures for treatment of a hypertensive crisis should be available.

Contrast media may promote sickling in individuals who are homozygous for sickle cell disease when administered intravascularly.

Reports of thyroid storm following the intravascular use of iodinated radiopaque agents in patients with hyperthyroidism or with an autonomously functioning thyroid nodule suggest that this additional risk be evaluated in such patients before use of any contrast medium.

PRECAUTIONS

General

Diagnostic procedures which involve the use of iodinated intravascular contrast agents should be carried out under the direction of personnel skilled and experienced in the particular procedure to be performed. A fully equipped emergency cart, or equivalent supplies and equipment, and personnel competent in recognizing and treating adverse reactions of all types should always be available. Since severe delayed reactions have been known to occur, emergency facilities and competent personnel should be available for at least 30 to 60 minutes after administration.

Preparatory dehydration is dangerous and may contribute to acute renal failure in patients with advanced vascular disease, diabetic patients, and in susceptible nondiabetic patients (often elderly with pre-existing renal disease). **Patients should be well hydrated prior to and following the administration of OPTIRAY.**

The possibility of a reaction, including serious, life-threatening, fatal, anaphylactoid or cardiovascular reactions, should always be considered (See Adverse Reactions). Increased risk is associated with a history of previous reaction to a contrast medium, a known sensitivity to iodine and known allergies (i.e., bronchial asthma, hay fever and food allergies) or hypersensitivities.

The occurrence of severe idiosyncratic reactions has prompted the use of several pretesting methods. However, pretesting cannot be relied upon to predict severe reactions and may itself be hazardous to the patient. It is suggested that a thorough medical history with emphasis on allergy and hypersensitivity, prior to the injection of any contrast medium, may be more accurate than pretesting in predicting potential adverse reactions. A positive history of allergies or hypersensitivity does not arbitrarily contraindicate the use of a contrast agent when a diagnostic procedure is thought essential, but caution should be exercised. Premedication with antihistamines or corticosteroids to avoid or minimize possible allergic reactions in such patients should be considered. Reports indicate that such pretreatment does not prevent serious life-threatening reactions, but may reduce both their incidence and severity.

General anesthesia may be indicated in the performance of some procedures in selected patients; however, a higher incidence of adverse reactions has been reported in these patients, and may be attributable to the inability of the patient to identify untoward symptoms or to the hypotensive effect of anesthesia which can prolong the circulation time and increase the duration of exposure to the contrast agent.

In angiographic procedures, the possibility of dislodging plaques or damaging or perforating the vessel wall should be considered during catheter manipulations and contrast medium injection. Test injections to ensure proper catheter placement are suggested.

Angiography should be avoided whenever possible in patients with homocystinuria because of the risk of inducing thrombosis and embolism.

Patients with congestive heart failure should be observed for several hours following the procedure to detect delayed hemodynamic disturbances which may be associated with a transitory increase in the circulating osmotic load.

Selective coronary arteriography should be performed only in selected patients and those in whom the expected benefits outweigh the procedural risk. The inherent risks of angiocardiography in patients with chronic pulmonary emphysema must be weighed against the necessity for performing this procedure.

Extreme caution during injection of a contrast medium is necessary to avoid extravasation. This is especially important in patients with severe arterial or venous disease.

Information for Patients

Patients receiving iodinated intravascular contrast agents should be instructed to:

1. Inform your physician if you are pregnant.
2. Inform your physician if you are diabetic or if you have multiple myeloma, pheochromocytoma, homozygous sickle cell disease or known thyroid disorder. (See WARNINGS).
3. Inform your physician if you are allergic to any drugs or food, or if you had any reactions to previous injections of dyes used for x-ray procedures. (See PRECAUTIONS, General).
4. Inform your physician about any other medications you are currently taking including non-prescription drugs.

Drug Interactions

Renal toxicity has been reported in a few patients with liver dysfunction who were given oral cholecystographic agents followed by intravascular contrast agents. Administration of any intravascular contrast agent should therefore be postponed in patients who have recently received a cholecystographic contrast agent.

Other drugs should not be mixed with ioversol injection.

Drug / Laboratory Test Interactions

The results of PBI and radioactive iodine uptake studies, which depend on iodine estimation, will not accurately reflect thyroid function for up to 16 days following administration of iodinated contrast media. However, thyroid function tests not depending on iodine estimations, e.g. T3 resin uptake and total or free thyroxine (T4) assays are not affected.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential. However, animal studies suggest that this drug is not mutagenic and does not affect fertility.

Pregnancy Category B

No teratogenic effects attributable to ioversol have been observed in teratology studies performed in animals. There are, however, no adequate and well controlled studies in pregnant women. It is not known whether ioversol crosses the placental barrier or reaches fetal tissues. However, many injectable contrast agents cross the placental barrier in humans and appear to enter fetal tissue passively. Because animal teratology studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. X-ray procedures involve a certain risk related to the exposure of the fetus.

Nursing Mothers

It is not known whether ioversol is excreted in human milk. However, many injectable contrast agents are excreted unchanged in human milk. Although it has not been established that serious adverse reactions occur in nursing infants, caution should be exercised when intravascular contrast media are administered to nursing women because of potential adverse reactions, and consideration should be given to temporarily discontinuing nursing.

Pediatric Use

Safety and effectiveness in children have been established for the use of OPTIRAY 350 and OPTIRAY 320 in angiocardiography, and for OPTIRAY 320 in contrast enhanced computed tomographic imaging of the head and body, and intravenous excretory urography.

Safety and effectiveness in newborns have not been established.

ADVERSE REACTIONS

Adverse reactions following the use of OPTIRAY formulations are usually mild to moderate, of short duration and resolve spontaneously (without treatment). However, serious, life-threatening and fatal reactions, mostly of cardiovascular origin, have been associated with the administration of iodine-containing contrast media.

Injections of contrast media are often associated with sensations of warmth and pain. In controlled double-blind clinical studies, significantly less warmth and pain were associated with the injection of OPTIRAY than with iothalamate meglumine, diatrizoate meglumine, and diatrizoate meglumine and diatrizoate sodium.

When OPTIRAY was used for coronary arteriography and ventriculography in double-blind clinical trials, electrocardiographic and hemodynamic changes occurred with less frequency and severity with ioversol injection than with diatrizoate meglumine and diatrizoate sodium.

Following coronary artery and left ventricular injection, electrocardiographic parameters were affected less with OPTIRAY ioversol injection than with diatrizoate meglumine and diatrizoate sodium injection. These parameters included the following: bradycardia, tachycardia, T-wave amplitude, ST depression and ST elevation.

OPTIRAY has also been shown to cause fewer changes in cardiac function and systemic blood pressure than conventional ionic media. These include cardiac output, left ventricular systolic and end-diastolic pressure, right ventricular systolic and pulmonary artery systolic pressures and decreases in systolic and diastolic blood pressures.

The following table of incidence of reactions is based upon clinical trials with OPTIRAY formulations in 2,098 patients. This listing includes all adverse reactions which were considered to the administration of ioversol regardless of their direct attributability to the drug or the procedure. Adverse reactions are listed by organ system and in decreasing order of occurrence. Significantly more severe reactions are listed before others in a system regardless of frequency.

Adverse Reactions

System	>1%	<1%
Cardiovascular	none	angina pectoris hypotension blood pressure fluctuation arterial spasm bradycardia conduction defect false aneurysm hypertension transient arrhythmia vascular trauma
Digestive	nausea(1.2)	vomiting dry mouth

Adverse Reactions, continued

System	>1%	<1%
Nervous	headache(1.1)	cerebral infarct blurred vision vertigo lightheadedness visual hallucination vasovagal reaction disorientation paresthesia dysphasia muscle spasm syncope
Respiratory	none	laryngeal edema pulmonary edema sneezing congestion coughing shortness of breath hypoxia
Skin	none	periorbital edema urticaria pruritus facial edema flush erythema
Miscellaneous	none	extravasation hematoma shaking chills bad taste general pain renal colic fever polyuria urinary retention

Regardless of the contrast medium employed, the overall incidence of serious adverse reaction is higher with coronary arteriography than with other procedures. Cardiac decompensation, serious arrhythmias, myocardial ischemia or myocardial infarction may occur during coronary arteriography and left ventriculography.

Pediatrics

In controlled clinical trials involving 159 patients for pediatric angiocardiography, contrast enhanced computed tomographic imaging of the head and body, and intravenous excretory urography, adverse reactions reported were as follows: fever (1.3%), nausea (0.6%), muscle spasm (0.6%), pressure changes (0.6%).

General Adverse Reactions to Contrast Media

The following adverse reactions are possible with any parenterally administered iodinated contrast medium. Severe life-threatening reactions and fatalities, mostly of cardiovascular origin, have occurred. Most deaths occur during injection or 5 to 10 minutes later, the main feature being cardiac arrest with cardiovascular disease as the main aggravating factor. Isolated reports of hypotensive collapse and shock are found in the literature, based upon clinical literature reported deaths from the administration of conventional iodinated contrast agents range from 6.6 per 1 million (0.00066 percent) to 1 in 10,000 patients (0.01 percent).

The reported incidence of adverse reactions to contrast media in patients with a history of allergy is twice that of the general population. Patients with a history of previous reactions to a contrast medium are three times more susceptible than other patients, however, sensitivity to contrast media does not appear to increase with repeated examinations.

Adverse reactions to injectable contrast media fall into two categories: idiosyncratic reactions and idiosyncratic reactions.

Chemotoxic reactions result from the physiochemical properties of the contrast medium, the dose and the speed of injection. All hemodynamic disturbances and injuries to organs or vessels perfused by the contrast medium are included in this category.

Idiosyncratic reactions include all other reactions. They occur more frequently in patients 20 to 40 years old. Idiosyncratic reactions may or may not be dependent on the dose injected, the speed of injection, the mode of injection and the radiographic procedure. Idiosyncratic reactions are subdivided into minor, intermediate and severe. The minor reactions are self-limited and of short duration; the severe reactions are life-threatening and treatment is urgent and mandatory.

In addition to the adverse reactions reported for ioversol, the following additional adverse reactions have been reported with the use of other contrast agents and are possible with any water soluble, iodinated contrast agent.

Nervous: convulsions, aphasia paralysis, visual field losses which are usually transient but may be permanent coma and death.

Cardiovascular: angioneurotic edema, peripheral edema, vasodilation thrombosis and rarely thrombophlebitis, disseminated intravascular coagulation and shock.

Skin: maculopapular rash, erythema, conjunctival symptoms, ecchymosis and tissue necrosis.

Respiratory: choking, dyspnea, wheezing which may be an initial manifestation of more severe and infrequent reactions including asthmatic attack, laryngospasm and bronchospasm, apnea and cyanosis. Rarely these allergic-type reactions can progress into anaphylaxis with loss of consciousness, coma, severe cardiovascular disturbances and death.

Miscellaneous: hyperthermia, temporary anuria or other nephropathy.

Other reactions may also occur with the use of any contrast agent as consequence of the procedural hazard, these include hemorrhage or pseudoaneurysms at the puncture site, brachial plexus palsy following axillary artery injections, chest pain, myocardial infarction, and transient changes in hepatorenal chemistry tests. Arterial thrombosis, displacement of arterial plaques, venous thrombosis, dissection of the coronary vessels and transient sinus arrest are rare complications.

(Adverse reactions for specific procedures receive comment in the Indications, Usage and Procedural Information section).

OVERDOSAGE

The adverse effects of overdosage are life-threatening and affect mainly the pulmonary and cardiovascular system. Treatment of an overdosage is directed toward the support of all vital functions and prompt institution of symptomatic therapy.

Ioversol does not bind to plasma or serum protein and is, therefore dialyzable.

The intravenous LD_{50} values (g/kg) for ioversol in animals were 17 (mice), and 15 (rats).

DOSAGE AND ADMINISTRATION

General

As with all radiopaque contrast agents, only the lowest dose necessary to obtain adequate visualization should be used. A lower dose may reduce the possibility of an adverse reaction. Most procedures do not require use of either the maximum volume or the highest concentration of OPTIRAY. The combination of volume and concentration of OPTIRAY to be used should be carefully individualized according for factors such as age, body weight, size of the vessel and the rate of blood flow within the vessel. Other factors such as anticipated pathology, degree and extent of opacification required, structure(s) or area to be examined, disease processes affecting the patient and equipment and technique to be employed should be considered.

It is desirable that intravascularly administered iodinated contrast agents be at or close to body temperature when injected.

If during administration a reaction occurs, the injection should be stopped until the reaction has subsided.

Patients should be well hydrated prior to and following OPTIRAY (ioversol injection) administration.

As with all contrast media, other drugs should not be mixed with ioversol solutions because of the potential for chemical incompatibility.

Sterile technique must be used in all vascular injections involving contrast media.

If nondisposable equipment is used, scrupulous care should be taken to prevent residual contamination with traces of cleansing agents.

Withdrawal of contrast agents from their containers should be accomplished under strict aseptic conditions using only sterile syringes and transfer devices. Contrast agents which have been transferred into other delivery systems should be used immediately.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration and should not be used if particulates are observed or marked discoloration has occurred.

The OPTIRAY formulations are supplied in single dose containers. Discard unused portion.

INDIVIDUAL INDICATIONS, USAGE AND PROCEDURAL INFORMATION

GENERAL ANGIOGRAPHY

Visualization of the cardiovascular system may be accomplished by any accepted radiological technique. Since intra-arterial digital subtraction angiography (IA-DSA) requires adjustments in the method of administration, this procedure is described separately.

Cerebral Arteriography

Additional Precautions and Adverse Reactions: Extreme caution is advised in patients with advanced arteriosclerosis, severe hypertension, cardiac decompensation, senility, recent cerebral thrombosis or embolism, and migraine. Cardiovascular reactions that may occur with some frequency are bradycardia and either an increase or decrease in systemic blood pressure. Neurological reactions that may occur are: seizures, drowsiness, transient paresis, and mild disturbances in vision.

Central nervous system reactions with OPTIRAY in controlled clinical studies in cerebral arteriography that were considered drug-related and occurred with frequencies greater than 1% were: headache, bradycardia, blood pressure fluctuation, disorientation, nausea and vertigo.

Dosage and Administration: OPTIRAY 240, OPTIRAY 300 or OPTIRAY 320 is recommended for this procedure. The usual individual injection for visualization of the carotid or vertebral arteries is 2 to 12 mL repeated as necessary. Aortic arch injection for a simultaneous four vessel study requires 20 to 50 mL. Total procedural doses should not usually exceed 200 mL.

Peripheral Arteriography

Additional Precautions: Pulsation should be present in the artery to be injected. In thromboangiitis obliterans or ascending infection associated with severe ischemia, angiography should be performed with extreme caution, if at all.

Dosage and Administration: OPTIRAY 300, OPTIRAY 320 or OPTIRAY 350 is recommended for this procedure. The usual individual injection volumes for visualization of various peripheral arteries are as follows:

aorta-iliac runoff	— 60 mL (range 20 to 99 mL)
common iliac, femoral	— 40 mL (range 10 to 50 mL)
subclavian, brachial	— 20 mL (range 15 to 30 mL)

These doses may be repeated as necessary. Total procedural doses should not usually exceed 250 mL.

Visceral and Renal Arteriography and Aortography

Additional Precautions and Adverse Effects: In aortography depending on the technique employed, the risks of this procedure also include the following: injury to the aorta and neighboring organs, pleural puncture, renal damage including infarction and acute tubular necrosis with oliguria and anuria, retroperitoneal hemorrhage from the translumbar approach and spinal cord injury and pathology associated with the syndrome of transverse myelitis.

Under conditions of slowed aortic circulation there is an increased likelihood for aortography to cause muscle spasm. Occasional serious neurologic complications, including paraplegia, have also been reported in patients with aortoiliac obstruction, femoral artery obstruction, abdominal compression, hypotension, hypertension, spinal anesthesia and injection of vasopressors to increase contrast. In these patients the concentration, volume, and number of repeat injections of the medium should be maintained at a minimum with appropriate intervals between injections. The position of the patient and catheter tip should be carefully monitored.

Entry of a large aortic dose into the renal artery may cause, even in the absence of symptoms, albuminuria, hematuria, and an elevated creatinine and urea nitrogen. Rapid and complete return of function usually follows.

Dosage and Administration: OPTIRAY 320 is recommended for visceral arteriography, renal arteriography, and aortography procedures. The usual individual injection volumes for visualization for the aorta and various visceral arteries are as follows:

aorta	— 45 mL (range 10 to 80 mL)
celiac	— 45 mL (range 12 to 60 mL)
superior mesenteric	— 45 mL (range 15 to 60 mL)
renal or inferior mesenteric	— 9 mL (range 6 to 15 mL)

These doses may be repeated as necessary. Total procedural doses should not usually exceed 250 mL.

Coronary Arteriography and Left Ventriculography

Additional Precautions: Mandatory prerequisites to the procedure are specialized personnel, ECG monitoring apparatus and adequate facilities for immediate resuscitation and cardioversion. Electrocardiograms and vital signs should be routinely monitored throughout the procedure.

Adverse Reactions: There were no cardiovascular system reactions with OPTIRAY in controlled clinical studies in coronary arteriography with left ventriculography that were considered drug-related and occurred with a frequency greater than 1%.

Dosage and Administration: OPTIRAY 320 or OPTIRAY 350 is recommended for this procedure. The usual individual injection volumes for visualization of the coronary arteries and left ventricle are:

left coronary	— 8 mL (range 2 to 10 mL)
right coronary	— 6 mL (range 1 to 10 mL)
left ventricle	— 40 mL (range 30 to 50 mL)

These doses may be repeated as necessary. Total procedural dose for the combined procedures should not usually exceed 250 mL. When large individual volumes are administered, as in ventriculography and aortography, it has been suggested that several minutes be permitted to elapse between each injection to allow for subsidence of possible hemodynamic disturbances.

Pediatric Angiocardiography

Additional Precautions: Mandatory prerequisites to the procedure are specialized personnel, ECG monitoring apparatus and adequate facilities for immediate resuscitation and cardioversion. Electrocardiograms and vital signs should be routinely monitored throughout the procedure. Pediatric patients at higher risk of experiencing adverse events during contrast medium administration may include those having asthma, a sensitivity to medication and/or allergens, congestive heart failure, a serum creatinine greater than 1.5 mg/dL, or those less than 12 months of age.

Dosage and Administration: OPTIRAY 350 or OPTIRAY 320 is recommended for this procedure. The usual single ventricular injection of OPTIRAY 350 or OPTIRAY 320 is 1.25 mL/kg of body weight with a range of 1 mL/kg to 1.5 mL/kg. When multiple injections are given, the total administered dose should not exceed 5 mL/kg up to a total volume of 250 mL.

Intra-arterial Digital Subtraction Angiography (IA-DSA)

All of the arteriographic procedures described above can be performed using digital subtraction techniques.

Dosage and Administration: OPTIRAY 160 is recommended for this procedure. As a general rule, the volume and concentration used for IA-DSA is about 50% or less, of that used for conventional procedures. The actual dosage and flow rate will vary depending on the selectivity of the injector site and the area being examined.

The following suggested volumes per injection are intended only as a guide. Injections may be repeated as necessary. It is advisable to inject at rates approximately equal to the flow of the vessel being injected.

Carotid Arteries	6 to 10 mL
Vertebral Arteries	4 to 8 mL
Aorta	25 to 50 mL
Subclavian or Brachial Arteries	2 to 10 mL
Major Branches of the Abdominal Aorta	2 to 20 mL

Dosage should not usually exceed 250 mL.

Venography

Additional Precautions: Special care is required when venography is performed in patients with suspected thrombosis, phlebitis, severe ischemic disease, local infection or a totally obstructed venous system. In order to minimize extravasation during injection, fluoroscopy is recommended.

Dosage and Administration: OPTIRAY 240, OPTIRAY 300, OPTIRAY 320 or OPTIRAY 350 is recommended for this procedure. The usual dose is 50 to 100 mL per extremity with smaller or larger volumes indicated in some cases. Dosage should not usually exceed 250 mL.

Following the procedure, the venous system should be flushed with Sodium Chloride Injection U.S.P. or 5% Dextrose in Water (D5W). Massage and elevation are also helpful for clearing the contrast medium from the extremity.

COMPUTED TOMOGRAPHY

OPTIRAY 350, OPTIRAY 320, OPTIRAY 300 or OPTIRAY 240 is recommended for head imaging.

OPTIRAY 350, OPTIRAY 320, OPTIRAY 300 or OPTIRAY 240 is recommended for body imaging.

Head Imaging

Tumors: OPTIRAY may be useful to investigate the presence and extent of certain malignancies such as: gliomas including malignant gliomas, glioblastomas, astrocytomas, oligodendrogliomas and ganglionmas, ependymomas, medulloblastomas, meningiomas, neuromas, pinealomas, pituitary adenomas, craniopharyngeomas, germinomas, and metastatic lesions. The usefulness of contrast enhancement for the investigation of the retrobulbar space and in cases of low grade or infiltrative glioma has not been demonstrated. In calcified lesions, there is less likelihood of enhancement. Following therapy, tumors may show decreased or no enhancement. The opacification of the inferior vermis following contrast media administration has resulted in false-positive diagnosis in a number of otherwise normal studies.

Nonneoplastic Conditions: OPTIRAY may be beneficial in the image enhancement of nonneoplastic lesions. Cerebral infarctions of recent onset may be better visualized with contrast enhancement, while some infarctions are obscured if contrast medium is used. The use of iodinated contrast media results in enhancement in about 50% of cerebral infarctions studied from one to four weeks from the onset of symptoms.

Sites of active infection may also be enhanced following contrast medium administration.

Arteriovenous malformations and aneurysms will show contrast enhancement. For these vascular lesions the enhancement is probably dependent on the iodine content of the circulating blood pool. Hematomas and intraparenchymal bleeders seldom demonstrate contrast enhancement. However, in cases of intraparenchymal clot, for which there is no obvious clinical explanation, contrast media administration may be helpful in ruling out the possibility of associated arteriovenous malformation.

Dosage and Administration: Adults: For adults, the usual dosage is 50 to 150 mL of OPTIRAY 350, OPTIRAY 320 or OPTIRAY 300 or 100 to 250 mL of OPTIRAY 240. Scanning may be performed immediately after completion of the intravenous administration. Dosage should not usually exceed 150 mL of OPTIRAY 350, OPTIRAY 320 or OPTIRAY 300 or 250 mL of OPTIRAY 240.

Children: The dosage recommended for use in children is 1 mL/kg to 3 mL/kg of OPTIRAY 320.

Body Imaging

OPTIRAY may be useful for enhancement of computed tomographic images for detection and evaluation of lesions in the liver, pancreas, kidneys, aorta, mediastinum, pelvis, abdominal cavity, and retroperitoneal space.

Enhancement of computed tomography with OPTIRAY may be of benefit in establishing diagnoses of certain lesions in these sites with greater assurance than is possible with CT alone. In other cases, the contrast agent may allow visualization of lesions not seen with CT alone (i.e., tumor extension) or may help to define suspicious lesions seen with unenhanced CT (i.e., pancreatic cyst).

Dosage and Administration: Adults: OPTIRAY 350, OPTIRAY 320, OPTIRAY 300 or OPTIRAY 240 may be administered by bolus injection, by rapid infusion, or by a combination of both. The usual doses are summarized below:

	bolus injection	infusion
OPTIRAY 350	25 to 75 mL	50 to 150 mL
OPTIRAY 320	25 to 75 mL	50 to 150 mL
OPTIRAY 300	25 to 75 mL	50 to 150 mL
OPTIRAY 240	35 to 100 mL	70 to 200 mL

Dosage should not usually exceed 150 mL of OPTIRAY 350, OPTIRAY 320 or OPTIRAY 300 or 250 mL of OPTIRAY 240.

Children: The dosage recommended for use in children is 1 mL/kg to 3 mL/kg of OPTIRAY 320, with a usual dose of 2 mL/kg.

INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY

Intravenous digital subtraction angiography (IV DSA) is a radiographic modality which allows dynamic imaging of the arterial system following intravenous injection of iodinated x-ray contrast media through the use of image intensification, enhancement of the iodine signal and digital processing of the image data. Temporal subtraction of the images obtained prior to and during the first arterial pass of the injected contrast medium yields images which are devoid of bone and soft tissue.

IV DSA is most frequently used to examine the heart, including coronary by-pass grafts, the pulmonary arteries, arteries of the brachiocephalic circulation, the aortic arch, the abdominal aorta and its major branches, the iliac arteries and the arteries of the extremities.

Patient Preparation

No special patient preparation is required for IV DSA. However it is advisable to insure that patients are well hydrated prior to examination.

Precautions

In addition to the general precautions previously described, the risks associated with IV DSA include those usually attendant with catheter procedures and include intramural injections, vessel dissection and tissue extravasation. The potential risk is reduced when small test injections of contrast medium are made under fluoroscopic observation to insure that the catheter tip is properly positioned and, in the case of peripheral placement that the vein is of adequate size.

Patient motion, including respiration and swallowing, can result in misregistration leading to image degradation and non-diagnostic studies.

Usual Dosage

OPTIRAY 350 may be injected centrally, in either the superior or inferior vena cava or right atrium; or peripherally into an appropriate arm vein. For central injections, catheters may be introduced at the antecubital fossa into either the basilic or cephalic vein or at the leg into the femoral vein and advanced to the distal segment of the corresponding vena cava. For peripheral injections, the catheter is introduced at the antecubital fossa into an appropriate size arm vein. In order to reduce the potential for extravasation during peripheral injection, a catheter of approximately 20 cm in length should be employed.

Depending on the area to be imaged, the usual dose range per injection is 30 to 60 mL. Injections may be repeated as necessary. The total procedural dose should not exceed 250 mL.

Injection rates will vary depending on the site of catheter placement and vessel size. Central catheter injections are usually made at a rate of between 10 and 30 mL/second. Peripheral injections are usually made at a rate of between 12 and 20 mL/second. Since the injected medium can sometimes remain in the arm vein for an extended period, it is advisable to flush the vein immediately following injection with an appropriate volume (20 to 25 mL) of Sodium Chloride Injection U.S.P. or 5% Dextrose in Water (D5W).

INTRAVENOUS UROGRAPHY

Dosage and Administration: OPTIRAY 350, OPTIRAY 320, OPTIRAY 300 or OPTIRAY 240 is recommended for routine and high dose excretory urography. Preparatory dehydration is dangerous and may contribute to acute renal failure (see PRECAUTIONS, General).

Adults: The usual dose for routine excretory urography in adults is 50 to 75 mL of OPTIRAY 350, OPTIRAY 320 or OPTIRAY 300 or 75 to 100 mL of OPTIRAY 240. Higher dosages may be indicated to achieve optimum results where poor visualization is anticipated (e.g., elderly patients or patients with impaired renal function). In these patients, high dose urography may be preferred, using OPTIRAY 350 at a dose of 1.4 mL/kg (maximum 140 mL) OPTIRAY 320 at a dose of 1.5 to 2 mL/kg (maximum 150 mL), OPTIRAY 300 at a dose of 1.8 mL/kg (maximum 150 mL) or OPTIRAY 240 at a dose of 2 mL/kg (maximum 200 mL).

Children: OPTIRAY 320 at doses of 0.5 mL/kg to 3 mL/kg of body weight has produced diagnostic opacification of the excretory tract. The usual dose for children is 1 mL/kg to 1.5 mL/kg. Dosage for infants and children should be administered in proportion to age and body weight. The total administered dose should not exceed 3 mL/kg.

HOW SUPPLIED

	NDC Number
OPTIRAY 350	
20x50 mL fill/125 mL power injector syringes	0019-1333-55
20x75 mL fill/125 mL power injector syringes	0019-1333-85
20x100 mL fill/125 mL power injector syringes	0019-1333-00
20x125 mL power injector syringes	0019-1333-27
OPTIRAY 320	
20x50 mL fill/125 mL power injector syringes	0019-1323-55
20x75 mL fill/125 mL power injector syringes	0019-1323-85
20x100 mL fill/125 mL power injector syringes	0019-1323-00
20x125 mL power injector syringes	0019-1323-27
OPTIRAY 300	
20x100 mL fill/125 mL power injector syringes	0019-1332-00
20x125 mL power injector syringes	0019-1332-27
OPTIRAY 240	
20x125 mL power injector syringes	0019-1324-27

For other approved concentrations and presentations of Optiray, please see Mallinckrodt website at http://imaging.mallinckrodt.com.

Storage: Store at 25°C (77°F), excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature]. These products are sensitive to light and must be protected from strong daylight or direct exposure to the sun. If product is frozen or if crystallization occurs, examine the container for physical damage. If no damage has occurred, the container should be brought to room temperature. Shake vigorously to assure complete dissolution of any crystals. The speed of dissolution may be increased by heating with circulating warm air. Submersion of syringes in water is not recommended. OPTIRAY may be stored at 37°C for up to one month in a contrast media warmer utilizing circulating warm air, for periods longer than one month, store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature]. Before use, examine the product to assure that all solids are redissolved. Do not reautoclave plastic container because of possible damage to syringe.

As with all contrast media, glass and plastic containers should be inspected prior to use to ensure that breakage or other damage has not occurred during shipping and handling. All containers should be inspected for closure integrity. Damaged containers should not be used.

tyco Healthcare

MALLINCKRODT

Mallinckrodt Inc.
St. Louis, MO 63042 USA

MKR 13RF0806
Revised 08/06

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Printed in U.S.A.

Appendix D B4 [redacted] Data Specifications

B4 Technical Specs

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Appendix E

Risk Analysis Software Verification Summary & Protocols

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Appendix F

Risk Analysis Hardware Verification Summary & Protocols

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Appendix I Special 510(k) Summary

Special 510(k) Summary

1. Company Identification

Mallinckrodt Inc., Liebel-Flarsheim Business
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Establishment Registration: 1518293

2. Contact Person

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Quality Manager
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3. 510(k) Preparation Date

11/15/2006

4. Device Name

Trade Name: OptiVantage DH Injector System with Enhanced Communication
Common Name: Power Injector

5. Device Classification

Class II

6. Indications for Use

The OptiVantage DH Injector System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

7. Description of Device

The OptiVantage DH Injector System with Enhanced Communication delivers radiographic contrast media and/or saline at a controlled flow rate and volume into a patient's vascular system for the purpose of obtaining enhanced diagnostic images. The OptiVantage DH Injector System with Enhanced Communication consists of 4 main components, just like the predicate device:

1. **Power Head**- Contains two electromechanical syringe drive systems, the syringe holding mechanisms, the main microprocessor, control electronics, control keypad for programming and initiating injection protocols, a status display, and two purge/retract manual knobs. The OptiVantage uses a drive system that is similar to existing Mallinckrodt injectors in the marketplace. It uses a motor and gearbox coupled to a ball screw. The ball screw drives a ram that attaches to the syringe plunger in order to fill or expel the contents of the syringe.

2. **Power Supply**- The power supply converts the line voltage to the working voltage for the power head and console (approximately 24-vdc).

3. **Console** - Communicates with the Power Head to program and initiate injection protocols, displays the injection status, and displays a timer.

4. **Syringes** - The OptiVantage DH Injector System with Enhanced Communication accommodates the Mallinckrodt 125-ml pre-filled syringe styles as well as a 200 ml front loading empty syringe. These syringes are commonplace on the market and are currently used with the predicate device.

8. Substantial Equivalence

The predicate injector to the OptiVantage DH Injector System with Enhanced Communication is the OptiVantage DH Power Injection System, 510(k) number K042744.

The OptiVantage DH Injector System with Enhanced Communication maintains the same intended use as the predicate device. It is intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

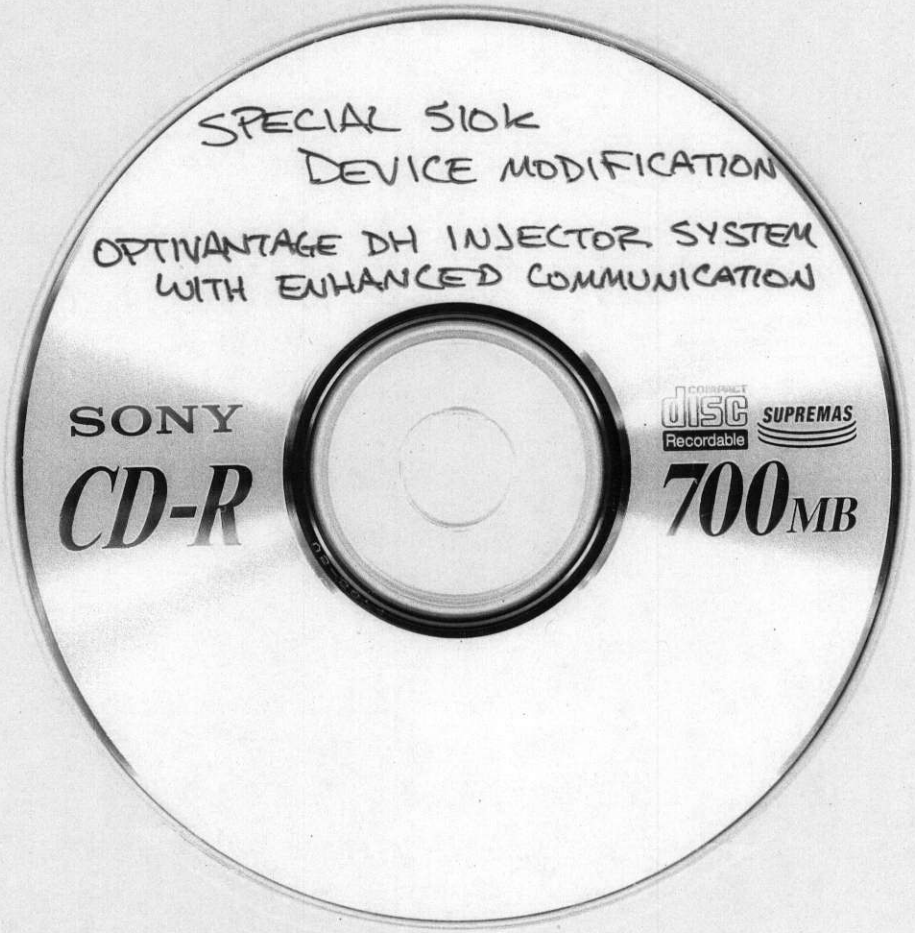
The OptiVantage DH Injector System with Enhanced Communication consists of four main components in the same manner as the predicate device: a Power Head, a Console, a Power Supply, and Syringes. Both the OptiVantage DH Injector System with Enhanced Communication and the predicate device consist of the same fundamental technology. They are motor driven, electromechanical devices which are software controlled. The OptiBolus function on the OptiVantage DH Injector System with Enhanced Communication and the predicate device implements a multiphasic injection method for injecting contrast media and/or saline.

The OptiVantage DH Injector System with Enhanced Communication differs from the predicate device in that it contains a product enhancement that adds a layer of enforcement for safety features found on the currently marketed predicate device.

Below is a table that compares the predicate device to the proposed OptiVantage DH Injector System with Enhanced Communication.

Feature	**OptiVantage DH Injector System with Enhanced Communication** (New Device)	**OptiVantage DH Power Injection System** Predicate Device (K042744)
Intended Use	Intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment	Intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment
Multi-phasic Injections	6 phases per protocol	6 phases per protocol
OptiBolus	Yes	Yes
Protocol Storage	40 protocols	40 protocols
Syringe Sizes	All pre-filled volumes of Mallinckrodt 125-ml syringes & Liebel-Flarsheim 200 ml empty syringe	All pre-filled volumes of Mallinckrodt 125-ml syringes & Liebel-Flarsheim 200 ml empty syringe
Single or Dual Syringe Modality	Single syringe and Dual syringe capability	Single syringe and Dual syringe capability
Syringe Drive System	Electromechanical	Electromechanical
Syringe Heater	Yes (Built-in, Powerhead controlled)	Yes (Built-in, Powerhead controlled)
Syringe Fill Rate	2 to 15 ml/sec	2 to 15 ml/sec
Flow Rate	0.1 to 10 ml/sec	0.1 to 10 ml/sec
Max Pressure Limit	325 psi	325 psi
Pressure Limit Control	User-settable or automatic 25 psi increments	User-settable or automatic 25 psi increments
Flushing System	Manual or via injector	Manual or via injector

Feature	**OptiVantage DH Injector System with Enhanced Communication** (New Device)	**OptiVantage DH Power Injection System** Predicate Device (K042744)
Remote Start	Yes	Yes
Scan Delay	0 – 600 seconds	0 – 600 seconds
Phase Delays	0 – 600 seconds plus Pause	0 – 600 seconds plus Pause
Console Controls	Touch screen Color LCD	Touch screen Color LCD
Power head Controls	Touch screen Color LCD	Touch screen Color LCD
Post Injection Readout	Yes	Yes
OEM Interface	Relays & Optical Couplings/Serial (CAN)	Relays & Optical Couplings/Serial (CAN)
Safety Stop Mechanism	Electrical Stop when injection parameters are out of specifications	Electrical Stop when injection parameters are out of specifications
Remote Check for Air	Yes	Yes
Volume Remaining Display	Displayed on Power Head and Console	Displayed on Power Head and Console
Used Syringe Detection	Yes (with Enhanced Communication)	Yes
Materials	Plastic and metal	Plastic and metal
Target Population	Humans	Humans
Sterility (Syringe)	Injectors are not sterile products. Syringes and Disposables are provided sterile.	Injectors are not sterile products. Syringes and Disposables are provided sterile.



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tyco Healthcare

Mallinckrodt

K063503

Mallinckrodt Inc.
Liebel-Flarsheim
2111 East Galbraith Road
Cincinnati, OH 45237-1640

Tele: 513 761-2700
Fax: 513 761-2388
www.mallinckrodt.com

November 17, 2006

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

Subject: Premarket Notification Special 510(k) Submission
OptiVantage DH Injector System with Enhanced Communication

Dear Staff,

The enclosed Special 510(k) Premarket Notification is submitted by Liebel-Flarsheim Business of Cincinnati, Ohio, a division of Mallinckrodt, Inc. of St. Louis, MO. Guidance for the submission was obtained from the FDA web site information "How To Prepare a Special Premarket Notification 510(k)".

The manufacturing site for the product will be:
Mallinckrodt Inc., Liebel-Flarsheim Business
2111 E. Galbraith Rd.
Cincinnati, Ohio 45237-1640
Est. Registration: 1518293

The information contained in this document is confidential and proprietary. Knowledge of the product and product line has been restricted to Mallinckrodt employees and/ or agents only. No public disclosures of the information have been made. We request that no part of this 510(k) be publicly released with the exception of the 510(k) Summary provided.

If you have any questions, please contact me at (513) 948-5771.

Sincerely,

Dale Moore

Dale Moore
Quality Manager

Enclosures: Two copies of the 510(k) Premarket Notification submission (One is electronic provided on CD);
FDA meeting minutes NDA 19-710 & Mallinckrodt meeting minutes of May 9, 2006.
Copy of Payment Identification Number MD6027600-95673.

K30

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Form Approved: OMB No. 0910-0511 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: B4 Testing [redacted]3
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

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

TYCO HEALTHCARE LLP
2111 East Galbraith Road
Cincinnati OH 45237
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
B4 [redacted]

2 CONTACT NAME
Dale Moore
2.1 E-MAIL ADDRESS
dale.moore@tycohealthcare.com
2.2 TELEPHONE NUMBER (Include Area code)
513-948-5771
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
513-948-5777

CV
II

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)
B4 [redacted]
19-Sep-2006

Close Window

Print Cover sheet

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9. Declaration of Conformity

1. Per the risk analysis, all verification and validation activities were performed and the results demonstrate that the predetermined acceptance criteria were met.
2. Liebel-Flarsheim is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 *(See section 6, Summary of Design Control Activities)*. Records are available upon request.

I certify that, in my capacity as Director of R&D of Mallinckrodt Inc., Liebel-Flarsheim Business, I believe to the best of my knowledge, that all data and information submitted in the Declaration of Conformity are truthful and accurate and that no material fact has been knowingly or willfully omitted.

Robert J. Ziemba Director of R&D

11/17/06

Date

11. Truthful and Accurate Statement

I certify that, in my capacity as Manager, Plant QA of Mallinckrodt Inc., Liebel-Flarsheim Business, I believe to the best of my knowledge, that all data and information submitted in the Premarket Notification are truthful and accurate and that no material fact has been knowingly or willfully omitted.

Dale Moore

Dale Moore Quality Manager

11/17/06

Date

tyco
Healthcare

Mallinckrodt

Mallinckrodt Inc.
Liebel-Flarsheim
2111 East Galbraith Road
Cincinnati, OH 45237-1640

Tele: 513 761-2700
Fax: 513 761-2388
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November 17, 2006

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If you have any questions, please contact me at (513) 948-5771.

Sincerely,

Dale Moore

Dale Moore
Quality Manager

Enclosures: Two copies of the 510(k) Premarket Notification submission (One is electronic provided on CD);
FDA meeting minutes NDA 19-710 & Mallinckrodt meeting minutes of May 9, 2006.
Copy of Payment Identification Number MD6027600-95673.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-710

Mallinckrodt, Inc.
Attention: Edward R. Porter
Manager, Regulatory Affairs
P.O. Box 5840
St. Louis, MO 63134-0840

Dear Mr. Porter:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Optiray (ioversol injection).

We also refer to the meeting between representatives of your firm and the FDA on May 9, 2006. The purpose of the meeting was to review the proposed submission strategy regarding the use of Radio Frequency Identification (RFID) tags placed on Optiray pre-filled syringes.

The official minutes of that meeting are enclosed. You are responsible for notifying us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions call me at (301) 796-1345.

Sincerely,

{See appended electronic signature page}

Valerie Jimenez, MS
Regulatory Project Manager
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure

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MEMORANDUM OF MEETING MINUTES

MEETING DATE: May 9, 2006

TIME: 11:00 a.m. to 12:00 noon

LOCATION: White Oak, Building 22

APPLICATION: NDA 19-710

DRUG NAME: Optiray (ioversol injection)

TYPE OF MEETING: Type C

MEETING CHAIR: Eric Duffy, Ph.D.
Director, Division of Post-Marketing Evaluation

MEETING RECORDER: Valerie Jimenez, MS
Regulatory Project Manager

FDA ATTENDEES:

Name	Title	Office/Division
1. Eric Duffy, Ph.D.	Director	Office of New Drug Quality Assessment
2. Hasmukh Patel, Ph.D.	Branch Chief	Office of New Drug Quality Assessment
3. Liang Zhou, Ph.D.	Pharmaceutical Assessment Lead	Office of New Drug Quality Assessment
4. Ann Ferriter	Scientific Reviewer	Center for Device and Radiological Health
5. Nancy Pressly	Policy Analyst	Center for Device and Radiological Health
6. Valerie Jimenez, MS	Regulatory Project Manager	Office of New Drug Quality Assessment
7. Michael Folkendt	Regulatory Project Manager	Office of New Drug Quality Assessment
8. James Moore	Regulatory Project Manager	Division of Medical Imaging and Radiopharmaceutical Products

EXTERNAL CONSTITUENT ATTENDEES:

Name	Title	Company
1. Edward Porter	Manager, Regulatory Affairs, Contrast Imaging	Mallinckrodt
2. Stacie Winter	Regulatory Affairs Associate II	Mallinckrodt
3. Vernon D. Ortenzi	Manager, Research and Development	Mallinckrodt
4. Scott Dickerhoff	Manager, Regulatory Affairs, Imaging Devices	Mallinckrodt

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BACKGROUND:
On March 24, 2006, Mallinckrodt submitted a meeting request to provide development plans and supportive data collected regarding RFID tags placed under the labels of Optiray syringes, the master validation plan, and drug and device submission strategies for Optiray and the OptiVantage Dual Head injector (K042744), respectively. Prior to the meeting it was determined that additional information was necessary to complete the review of the background information. The firm responded to the Agency's request on Monday, May 8, 2006.

DISCUSSION:
The meeting scheduled for May 9, 2006, began with Mallinckrodt's presentation on Optiray/OptiVantage and RFID. The presentation covered the RFID project scope, master validation plan overview, supportive documentation, and the regulatory submission strategy. Additionally, the firm proposed submission of the CBE-30 and 510K Special submission in August 2006. A demonstration of the product followed.

QUESTIONS:
The questions listed below relate to a RFID tagged Optiray syringe and the subsequent placement of the tagged syringe into the OptiVantage Dual Head contrast media injector (K042744) capable of reading and writing to the RFID tag as part of the contrast media dose administration. From a component perspective Mallinckrodt is aware that adequate information must be provided for three components of the system described in the background information; the Optiray syringe, the RFID tag, and the OptiVantage Injector.

Mallinckrodt proposes to submit two applications containing supportive information:

1. Changes Being Effected-30 (CBE-30) supplement to Optiray NDA 19-710 containing information supporting that there is no impact to Optiray, as well as documentation supporting RFID tag specifications, control, validation, and function. The CBE-30 would also provide data describing the master validation plan for Optiray, RFID tag, and OptiVantage.

2. Special 510K supplement to the OptiVantage device application to support the hardware and software necessary for reading and writing the tag information, as well as integration of the tag information into the existing software that controls contrast administration.

Does the Agency find the submission type and content acceptable?

FDA response:
Your submission should be submitted to the Agency as a Prior Approval supplement and a Special 510K.

When additional product information/data is added to the tag defined in the original supplement, i.e., post approval of the CBE-30, Mallinckrodt intends to provide the supportive information to the Agency via the NDA annual report. Correspondingly, when the OptiVantage Injector is upgraded to read or write additional informational/data, the device filing will be updated with a letter to file or 510K, as appropriate.

Does the Agency find the submission maintenance plan acceptable?

FDA response:
Additional product information/data should be submitted to the Agency as a Prior Approval supplement and a Special 510K.

ADDITIONAL INFORMATION: *None.*

ATTACHMENT:

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B4, B5 Tech Specs

B4, B5 Tech Specs

B4, B5 Tech Specs

B4, B5 Tech Specs

B4, B5 Tech Specs

B4, B5 Tech Specs

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B4, B5 Tech Specs

B4, B5 Tech Specs

B4, B5 Tech Specs

Form Approved: OMB No. 0910-0511 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: B4
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1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

TYCO HEALTHCARE LLP
2111 East Galbraith Road
Cincinnati OH 45237
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
B4

2. CONTACT NAME
Dale Moore
2.1 E-MAIL ADDRESS
dale.moore@tycohealthcare.com
2.2 TELEPHONE NUMBER (Include Area code)
513-948-5771
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
513-948-5777

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/cdrh/mdufma

Select an application type:
[X] Premarket notification(510(k)): except for third party
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[ ] 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
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
B4

19-Sep-2006

Form FDA 3601 (06/2005)

Close Window

Print Cover sheet

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Special 510(k) Device Modification OptiVantage DH Injector System with Enhanced Communication

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Table of Contents

1. CDRH Submission Cover Sheet

CDRH SUBMISSION COVER SHEET

Date of Submission: 11/17/06	FDA Document Number:

Section A — **Type of Submission**

PMA	**PMA Supplement**	***PDP***	**510(k)**	***Meeting***
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☐ Original submission ☐ Traditional ☒ **Special** ☐ Abbreviated ☐ Additional information: ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):

IDE	Humanitarian Device Exemption	***Class II Exemption***	Evaluation of Automatic Class III Designation	Other Submission: Describe submission:
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐Report	☐Original submission ☐Additional information	☐Original submission ☐Additional information	

Section B — **Applicant or Sponsor**

Company / Institution name: Mallinckrodt Inc., Liebel-Flarsheim Business		Establishment registration number: 1518293 Owner/Operator number: 1925021
Division name (if applicable):		Phone number (include area code) (513) 948-5771
Street address: 2111 East Galbraith Road		FAX number (include area code) (513) 948-5708
City: Cincinnati	State / Province: OH 45237	Country: USA
Contact name: Dale Moore		
Contact title: Quality Manager		Contact e-mail address: dale.moore@TycoHealthcare.com

5914

Submission correspondent (if different from above)

Section C

Company / Institution name:	Establishment registration number:	
Division name (if applicable)	Phone number (include area code) ( )	
Street address:	FAX number (include area code) ( )	
City:	State / Province:	Country:
Contact name:		
Contact title:	Contact e-mail address:	

Reason for Submission – PMA, PDP, or IDE

Section D1

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Process change
- ☐ Manufacturing
- ☐ Sterilization
- ☐ Packaging
- ☐ Other (specify below)
- ☐ Response to FDA correspondence:
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Other reason (specify):

- ☐ Change in design, component, or specification:
- ☐ Software
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other (specify below)
- ☐ Labeling change:
- ☐ Indications
- ☐ Instructions
- ☐ Performance Characteristics
- ☐ Shelf life
- ☐ Trade name
- ☐ Other (specify below)

- ☐ Location change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager
- ☐ Distributor
- ☐ Report submission:
- ☐ Annual or periodic
- ☐ Post-approval study
- ☐ Adverse reaction
- ☐ Device defect
- ☐ Amendment
- ☐ Change in ownership
- ☐ Change in correspondent

Reason for Submission --- IDE

Section D2

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse event
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Other reason (specify):

- ☐ Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor
- ☐ Report submission:
- ☐ Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

- ☐ Response to FDA letter concerning:
- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension of time to respond to FDA
- ☐ Request meeting

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Reason for Submission --- 510(k)

Section D3

☐ New device
☐ Additional or expanded indications
☐ Change in technology
☐ Change in design
☐ Change in materials
☐ Change in manufacturing process

☒ **Other reason (specify): To bring an updated CT Injector to market.**

Section E **Additional Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:

1 DXT	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:

☒ **510(k) Summary attached**
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or propriety or model name	Manufacturer
1 K042744	1 OptiVantage DH Power Injection System	1 Mallinckrodt Inc., Liebel-Flarsheim Business
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

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

Common or usual name or classification name:

Trade or propriety or model name	Model Number
1. OptiVantage DH Injector System with Enhanced Communication	1
2	2
3	3

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

1	2	3	4		6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Section G **Product Classification --- Applicable to All Applications**

Product code: DXT	C.F.R. Section: 21 C.F.R. § 870.1650	Device class: ☐ Class I ☒ **Class II** ☐ Class III ☐ Unclassified
Classification panel: Cardiovascular		

OptiVantage DH Injector System with Enhanced Communication is indicated for use as a prescription device only.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form	FDA Document Number:

Section H **Manufacturing / Packaging / Sterilization Sites Relating to a Submission**

☒ **Original** ☐ Add ☐ Delete	FDA establishment registration number: 1518293	☒ **Manufacturer** ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler	
Company / Institution name: Mallinckrodt Inc., Liebel-Flarsheim Business		Establishment registration number: 1518293		
Division name (if applicable)		Phone number (include area code) (513) 948-5771		
Street address: 2111 East Galbraith Road		FAX number (include area code) (513) 948-5708		
City: Cincinnati	State / Province: OH 45237	Country: USA		
Contact name: Dale Moore				
Contact title: Quality Manager		Contact e-mail address: dale.moore@TycoHealthcare.com		

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler	
Company / Institution name:		Establishment registration number:		
Division name (if applicable)		Phone number (include area code) ( )		
Street address:		FAX number (include area code) ( )		
City:	State / Province:	Country:		
Contact name:				
Contact title:		Contact e-mail address:		

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler	
Company / Institution name:		Establishment registration number:		
Division name (if applicable)		Phone number (include area code) ( )		
Street address:		FAX number (include area code) ( )		
City:	State / Province:	Country:		
Contact name:				
Contact title:		Contact e-mail address:		

2. Statement of Indications

The intended use of the OptiVantage DH Injector System with Enhanced Communication is substantially equivalent to the predicate OptiVantage DH Power Injection System (K042744), which is in commercial distribution.

Indications for Use: The OptiVantage DH Injector System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

3. Description of Device

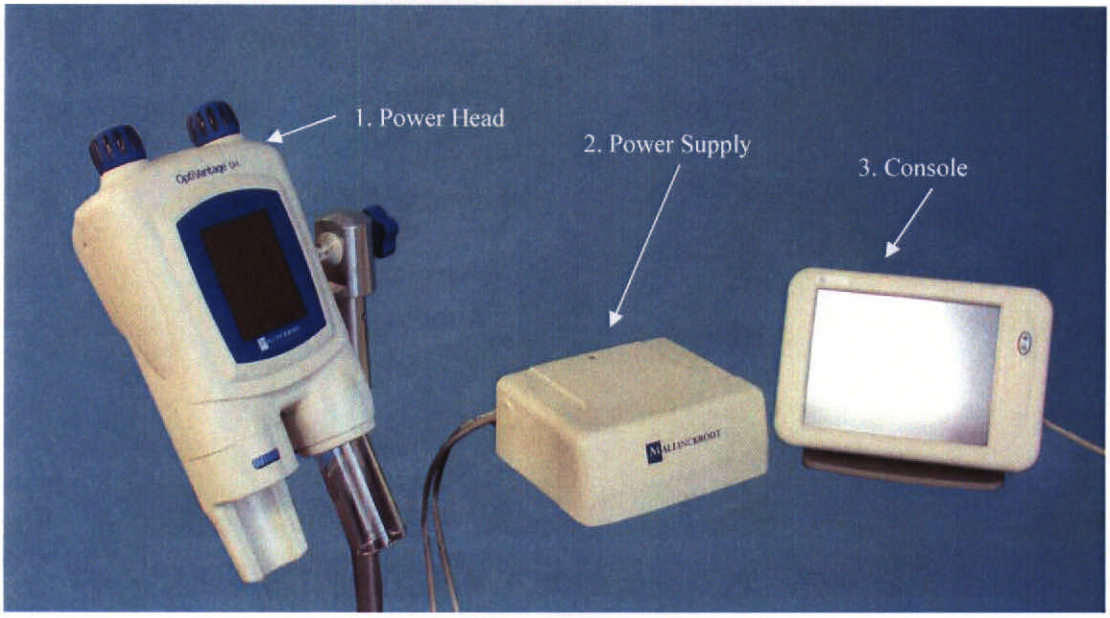
The OptiVantage DH Injector System with Enhanced Communication delivers radiographic contrast media and/or saline at a controlled flow rate and volume into a patient's vascular system for the purpose of obtaining enhanced diagnostic images. The OptiVantage DH Injector System with Enhanced Communication consists of 4 main components, just like the predicate device:

1. **Power Head-** Contains two electromechanical syringe drive systems, the syringe holding mechanisms, the main microprocessor, control electronics, control keypad for programming and initiating injection protocols, a status display, and two purge/retract manual knobs. The OptiVantage uses a drive system that is similar to existing Mallinckrodt injectors in the marketplace. It uses a motor and gearbox coupled to a ball screw. The ball screw drives a ram that attaches to the syringe plunger in order to fill or expel the contents of the syringe.

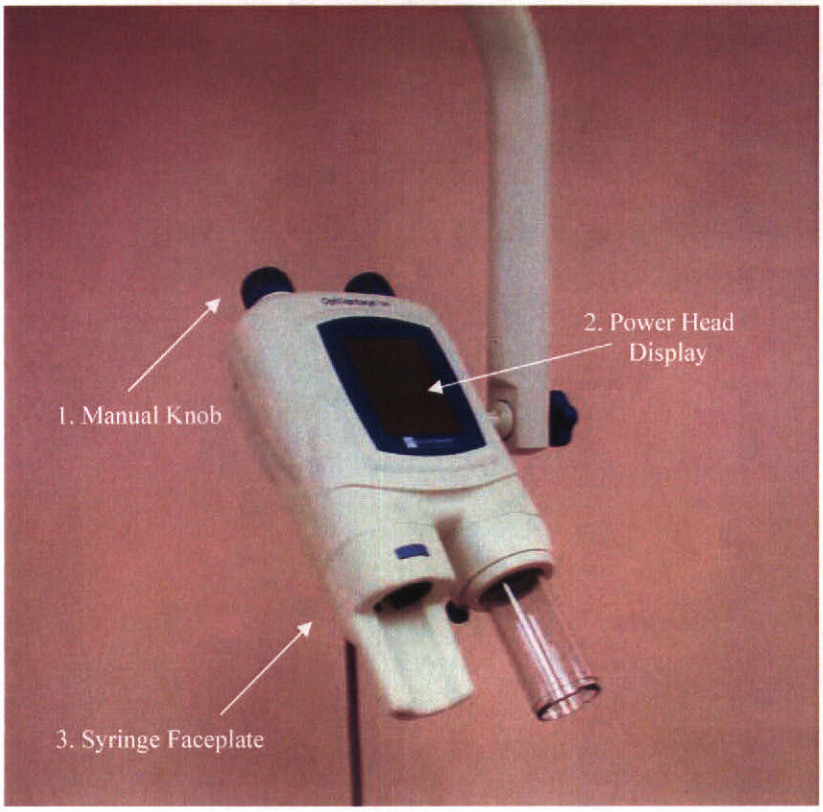
2. **Power Supply-** The power supply converts the line voltage to the working voltage for the power head and console (approximately 24-vdc).

3. **Console** - Communicates with the Power Head to program and initiate injection protocols, displays the injection status, and displays a timer.

4. **Syringes** – The OptiVantage DH Injector System with Enhanced Communication accommodates the Mallinckrodt 125-ml pre-filled syringe styles as well as a 200 ml front loading empty syringe. These syringes (not shown) are commonplace on the market and are currently used with the predicate device. Specifications and information regarding the syringe and labels, RFID tags, and data used by the RFID system are included in Appendix C, D and G.



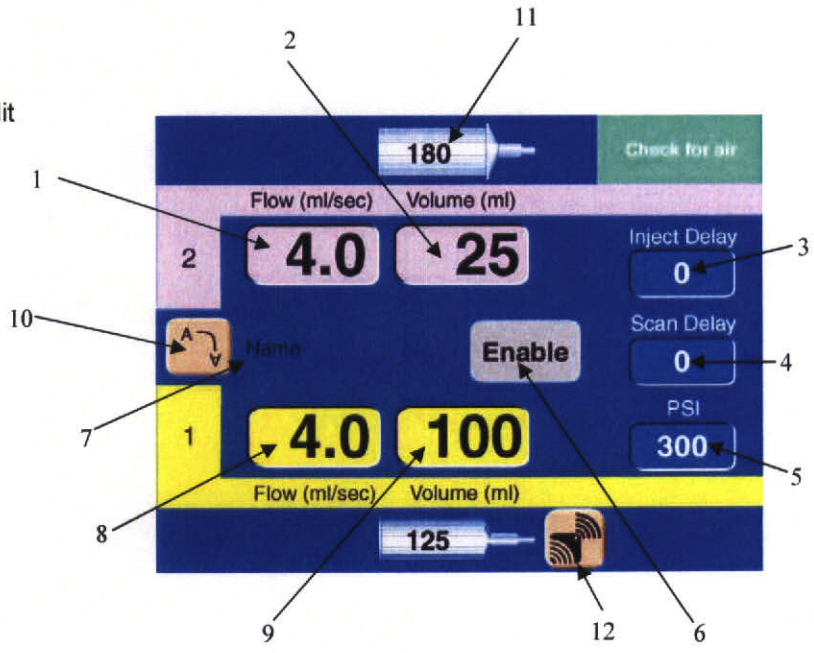
Power Head Features



1. Manual Knobs – Used to move rams forward or backward for drawing or expelling contrast
2. Power Head Display – Allows user to program injections and displays results
3. Syringe Faceplates – Faceplates hold either a prefilled 125 ml syringe or an empty 200 ml syringe. Either faceplate may be used on either side of the injector. May also house an RFID reader system for use with RFID-enabled syringes.

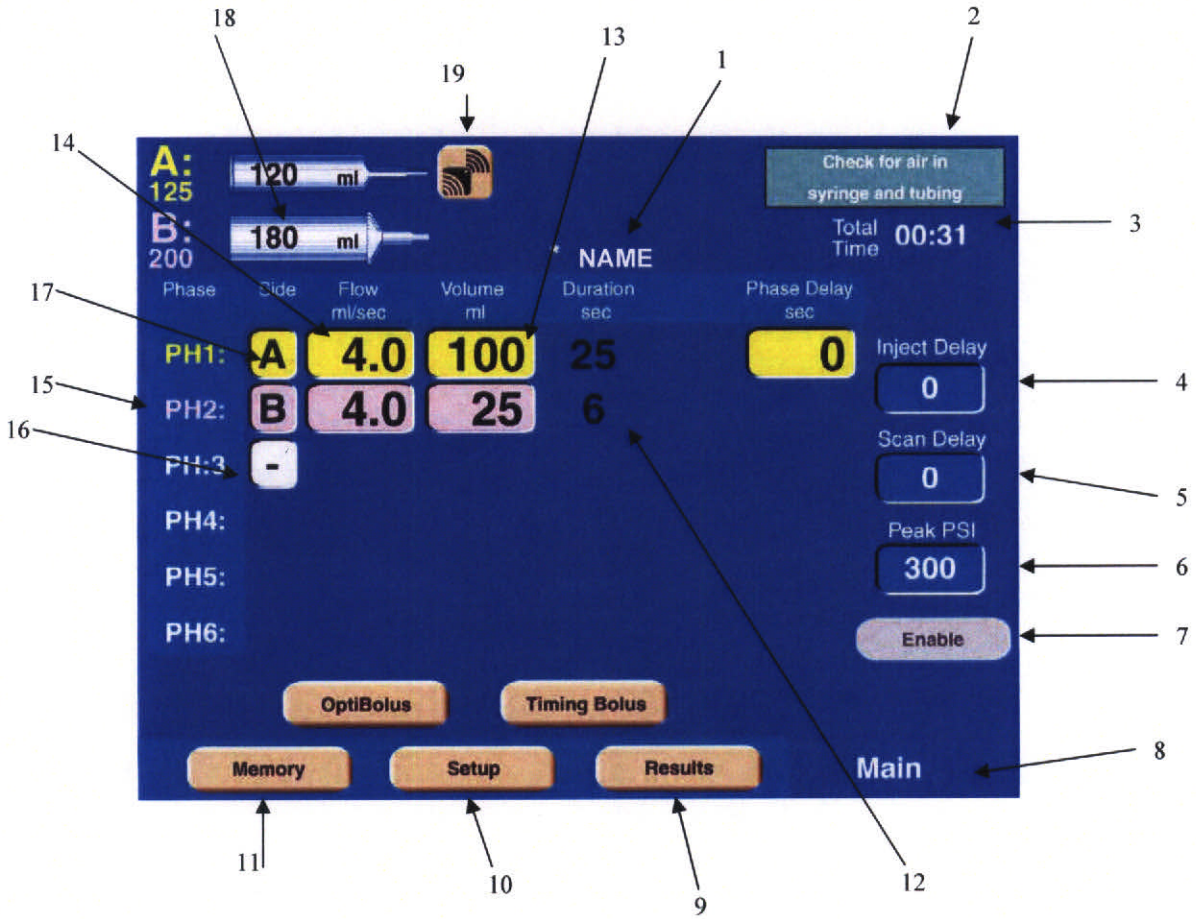
Power Head Display

1. Side A Flow Rate Indicator and Edit Button
2. Side A Volume Indicator and Edit Button
3. Inject Delay Button Indicator and Edit Button
4. Scan Delay Indicator and Edit Button
5. Pressure Limit Indicator and Edit Button
6. Enable Button
7. Protocol Name
8. Side B Flow Rate Indicator and Edit Button
9. Side B Volume Indicator and Edit Button
10. Flip Screen Button
11. Syringe Volume Remaining
12. RFID Data Button



Console Keys and Indicators

1. Protocol Name
2. Air Check warning and Start Button Location
3. Total Time Counter
4. Inject Delay Display and Edit Button
5. Scan Delay Display and Edit Button
6. Pressure Limit Indicator and Edit Button
7. Enable and Disable Button
8. Main Screen Button
9. Results Button
10. Setup Button
11. Memory Button
12. Duration Indicator for each Phase and Edit Button
13. Volume Indicator for each Phase and Edit Button
14. Flow Rate Indicator for each Phase and Edit Button
15. Protocol Phase Indicator
16. Add New Phase to Protocol Button
17. Ram Side Indicator and Edit Button
18. Remaining Volume Indicator for each Side
19. RFID Data Button



4. Comparison to Predicate and Cleared Devices

The predicate injector to the OptiVantage DH Injector System with Enhanced Communication is the OptiVantage DH Power Injection System, 510(k) number K042744.

The OptiVantage DH Injector System with Enhanced Communication maintains the same intended use as the predicate device. It is intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

The OptiVantage DH Injector System with Enhanced Communication consists of four main components in the same manner as the predicate device: a Power Head, a Console, a Power Supply, and Syringes. Both the OptiVantage DH Injector System with Enhanced Communication and the predicate device consist of the same fundamental technology. They are motor driven, electromechanical devices which are software controlled. The OptiBolus function on the OptiVantage DH Injector System with Enhanced Communication and the predicate device implements a multiphasic injection method for injecting contrast media and/or saline.

The OptiVantage DH Injector System with Enhanced Communication differs from the predicate device in that it contains RFID functionality which is a product enhancement that adds a layer of enforcement for safety features found on the currently marketed predicate device.

Below is a table that compares the predicate device to the proposed OptiVantage DH Injector System with Enhanced Communication.

Feature	**OptiVantage DH Injector System with Enhanced Communication** (New Device)	**OptiVantage DH Power Injection System** Predicate Device (K042744)
Intended Use	Intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment	Intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment
Multi-phasic Injections	6 phases per protocol	6 phases per protocol
OptiBolus	Yes	Yes
Protocol Storage	40 protocols	40 protocols
Syringe Sizes	All pre-filled volumes of Mallinckrodt 125-ml syringes & Liebel-Flarsheim 200 ml empty syringe	All pre-filled volumes of Mallinckrodt 125-ml syringes & Liebel-Flarsheim 200 ml empty syringe
Single or Dual Syringe Modality	Single syringe and Dual syringe capability	Single syringe and Dual syringe capability
Syringe Drive System	Electromechanical	Electromechanical
Syringe Heater	Yes (Built-in, Powerhead controlled)	Yes (Built-in, Powerhead controlled)
Syringe Fill Rate	2 to 15 ml/sec	2 to 15 ml/sec
Flow Rate	0.1 to 10 ml/sec	0.1 to 10 ml/sec
Max Pressure Limit	325 psi	325 psi
Pressure Limit Control	User-settable or automatic 25 psi increments	User-settable or automatic 25 psi increments
Flushing System	Manual or via injector	Manual or via injector
Remote Start	Yes	Yes
Scan Delay	0 – 600 seconds	0 – 600 seconds
Phase Delays	0 – 600 seconds plus Pause	0 – 600 seconds plus Pause
Console Controls	Touch screen Color LCD	Touch screen Color LCD
Power head Controls	Touch screen Color LCD	Touch screen Color LCD
Post Injection Readout	Yes	Yes
OEM Interface	Relays & Optical Couplings/Serial (CAN)	Relays & Optical Couplings/Serial (CAN)

Feature	**OptiVantage DH Injector System with Enhanced Communication** (New Device)	**OptiVantage DH Power Injection System** Predicate Device (K042744)
Safety Stop Mechanism	Electrical Stop when injection parameters are out of specifications	Electrical Stop when injection parameters are out of specifications
Remote Check for Air	Yes	Yes
Volume Remaining Display	Displayed on Power Head and Console	Displayed on Power Head and Console
Used Syringe Detection	Yes (with Enhanced Communication)	Yes
Materials	Plastic and metal	Plastic and metal
Target Population	Humans	Humans
Sterility (Syringe)	Injectors are not sterile products. Syringes and Disposables are provided sterile.	Injectors are not sterile products. Syringes and Disposables are provided sterile.

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5. Operators Manual and Proposed Labeling

The proposed labeling for the OptiVantage DH Injector System with Enhanced Communication is defined in Appendix A, Operators Manual and Appendix B, Rating Plate.

Syringe labeling and RFID tag information is included in Appendix C and D.

6. Summary of Design Control Activities

The OptiVantage DH Injector System with Enhanced Communication development process follows the Liebel-Flarsheim standard operating procedures that were developed per 21 CFR 820.30.

Liebel-Flarsheim Design Control Process Comparison to 21 CFR 820.30

	L-F Related Procedures	QSR (21CFR 820.30) Section
General	QSEP1	820.30[a]
Design & Development Planning	QSEP4	820.30[b]
Design Input	QSEP17	820.30[c]
Design Output	QSEWI6	820.30[d]
Design Review	QSEP5	820.30[e]
Design Verification	QSEP18	820.30[f]
Design Validation	QSEP16	820.30[g]
Design Changes	QSEP2	820.30[i]
Design Transfer	QSEP19	820.30[h]
Design History File/ Technical File	QSEP7	820.30[j]

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7. Risk Analysis Methods and Summary

The risk management process is composed of two major elements, risk analysis and risk control. Risk analysis involves hazard identification and risk estimation as outlined in Work Instructions QSEWI22, Risk Analysis and QSEWI12, Failure Modes and Effects Analysis.

Risk Control involves designing, implementing, and verifying design controls to mitigate safety hazards and failures identified in the risk analysis and FMEA. The design controls identified in the Risk Analysis and FMEA then become design requirements or design inputs. After design implementation, the design requirements are verified.

The following is a summary table from the Risk Analysis of the risks that were categorized as requiring risk mitigation. These risks are typical for power injectors and the proposed OptiVantage DH Injector System with Enhanced Communication does not introduce additional risks to the patient. The verification and validation activities listed in the table below are specific to the activities related to the mitigation of the identified risks and are not intended to be inclusive of all verification and validation activities of the system. The table identifies the control methods that are used to mitigate the risk to an acceptable level and the corresponding verification/validation activity used to confirm the control method. The test methods and acceptance criteria utilized in the software verification testing are detailed in the Risk Analysis Software Verification Summary & Protocols (Appendix E). This document describes each test case as well as the specific acceptance criteria. The electrical safety testing and EMC/EMI testing were performed according to the specified international standards (UL60601-1 and EN60601-4) and met the acceptance criteria defined in the standards. These and other hardware verification activities are detailed in the Risk Analysis Hardware Verification Summary & Protocols section (Appendix F).

Risk (Prior to risk mitigation)	**Control Method**	**Verification / Validation Activity**
Air Embolism – Caregiver fails to remove empty syringe from previous injection, retracts injector ram and later mistakes the empty syringe for a full syringe for the next injection	The Operator's Manual includes a statement concerning user qualifications and training, and a danger statement concerning checking for air before injecting. The injector can determine if syringe has not been removed between procedures and contains a "Used Syringe" warning. The injector has the capability to remove the syringe at any ram position. The injector has the capability to mark an RFID-enabled syringe used and prevent its injection. If the RFID tag cannot be read or written, the injector will display a warning stating the RFID tag may be damaged or is not present. If the corrupted data or a data error is detected while reading or writing an RFID tag, the injector will display a warning stating the RFID tag may be damaged or is not present. If the user chooses to use a pre-filled syringe with an undetectable or erroneous RFID tag, the system will prompt the user to select the pre-filled syringe volume.	• Design review of OptiVantage Manual • Verification testing of "Used Syringe" process and warnings. • Verification of capability to remove syringe at any ram position. • Verification of RFID read capability • Verification of RFID messages and warnings • RFID system-level validation • Verification of pre-filled selection option when RFID tag is not present or is damaged.
Air Embolism – Caregiver fails to purge air from syringe tubing.	The Operator's manual includes a danger statement concerning checking for air before injecting. The injector contains a "Check for Air" message. The injector requires the user to follow a process to enable and start the injector that reduces the chances of inadvertently injecting air.	• Design review of OptiVantage Manual • Verification testing of "Check for Air" message and enable process

Risk (Prior to risk mitigation)	**Control Method**	**Verification / Validation Activity**
Extravasation or Blood Vessel Damage – Patient Weak Veins, Improperly Placed Catheter, or User Selecting Too High a Flow Rate Extravasation is the injection of contrast into tissue instead of into the vein. It is the responsibility of the user to properly place the catheter in the vein and determine the proper flow rate for the patient.	The Operator's manual includes a statement and warning regarding catheter placement and flow rates to avoid extravasation. The injector shall have multiple intuitive ways of quickly stopping an injection. The injector has a means to inject a small amount of saline to check patency prior to the contrast injection	• Design Review of OptiVantage Manual • Verification testing of stop features and saline injection
Extravasation of Blood Vessel Damage Due to Injector Malfunction – Delivering Higher Flow Rate Than What the User Programmed – The injector malfunctions and delivers a higher flow rate than what the user programmed. The injector malfunction could be caused from electromagnetic interference, electronic component hardware failure, or software defect.	The injector contains a back up flow rate monitor in addition to primary flow rate monitoring. The product shall meet electromagnetic compatibility and safety requirements per EN60601-1. The injector software does not allow to user to program a simultaneous injection.	• Verification testing of flow rate monitoring • EMC/EMI and FCC testing
Extravasation or Blood Vessel Damage Due to Injector Self Run – If the injector is connected to a patient and the injector starts without being initiated by the operator, the injection could run at a rate higher than intended.	The product shall meet electromagnetic compatibility and electrical safety requirements per EN60601-1. Injector requires enabling sequence prior to ram movement. Operator's manual instructs that injector is programmed prior to connecting to the patient.	• EMC/EMI and FCC testing • Verification testing of enable sequences • Design Review of OptiVantage Manual
Blood Vessel Damage – Due to Operator retracting ram while connected to the patient.	The injector limits ram movement in the retract direction when the power head is pointed down.	• Verification testing of retract limiting
Blood Clotting Due to Blood Draw Back Into Tubing – Blood clotting could occur if blood is drawn back into the tubing by the operator to verify correct needle or catheter placement and left in this condition for a period of time before injecting.	The injector is equipped with a "drip mode" which assists in preventing clogging by keeping a flow present. The Operator's manual includes a statement to warn against drawing blood back into the tubing and left for a period of time to allow the blood to clot prior to injecting.	• Verification testing of drip mode • Design review of OptiVantage Manual

Risk (Prior to risk mitigation)	Control Method	Verification / Validation Activity
Pacemaker/Defibrillator Interference Due to Electromagnetic interference or Magnetic Components – Pacemakers and defibrillators can be susceptible to certain levels of electromagnetic interference. The OptiVantage DH Injector will have a permanent magnet motor.	The Operator's manual includes a warning to follow the manufacturer's guidelines for electromagnetic safety or to keep the unit at least 6 inches (15 cm) away from pacemakers or defibrillators. The product shall meet electromagnetic compatibility and electrical safety requirements per EN60601-1. The design of the injector will limit gauss levels to 5 gauss or less beyond the covers.	• Design Review of OptiVantage DH Manual • EMC/EMI and FCC Testing • Test of Gauss level
Misdiagnosis – Contrast deliver not as programmed due to injector error in flow rate or volume or mixing of contrast and saline.	The injector contains back up flow rate monitoring The injector displays achieved results such that the clinician can verify proper contrast delivery The injector will not allow both rams to move simultaneously	• Verification testing of flow rate monitoring • Verification testing of achieved values • Verification testing of ram movement
Toxicity – Clinician loads too much contrast or injector delivers more volume than is programmed. This is primarily an issue for pediatric cases or for patients with renal or hepatic compromise.	The Operator's manual contains warnings and instructions related to volumes that are selected. The injector contains predefined protocols. The injector uses a servo chip to accurately deliver the volume and also contains back up volume checking When using RFID-enabled syringes, the injector compares the injector setup to the installed syringe type.	• Design Review of OptiVantage Manual • Verification testing of preprogrammed protocols • Verification testing of volume delivered • Verification of RFID read capability
Bodily Injury Due to Ceiling Mount Failure – Falling mass due to suspension failure.	A secondary retaining system is designed into the suspension system.	• Design review of retention system • Verification testing of retention system
Bodily Injury Due to Roll-Around Stand Tipping – Stand or power head hits patient or user after tipping.	Stand designed to pass UL tip test	• UL Testing and Certification
Electric Shock – User, patient or service person exposed to AC line current.	The product shall meet electrical safety requirements for EN60601-1.	• UL Testing and Certification

Risk (Prior to risk mitigation)	**Control Method**	**Verification / Validation Activity**
Electrical Fire – Electrical part fails and results in a fire.	The product shall meet electrical safety requirements per EN60601-1. Per the UL Standards, the electrical components are enclosed in a fire rated plastic material. Each Injector is run through wear-in testing to detect infant electrical failures.	• UL Testing and Certification • Review of Manufacturing and Quality procedures.
Injury Due to Syringe Exploding Under Pressure – If a small needle or catheter is used along with a high flow rate, or if the injector were to inject into a closed valve or blocked line, syringe pressure could build and cause the syringe to explode.	The injector incorporates pressure limiting so the injection pressure will not exceed the pressure that could cause a syringe to burst. The injector also contains back up pressure monitoring.	• Verification testing of pressure limit
Increased Body Temperature Due to Overheated Contrast- Heater Malfunctions	Injector contains a temperature sensing device to monitor heater performance. The injector physically limits the fault condition temperature to safe limits.	• Verification testing of heater

Risk (Prior to risk mitigation)	**Control Method**	**Verification / Validation Activity**
Cross Infection Due to Reuse of Syringe or IV Tubing – Cross Infection directly from the injector would not be possible. Reuse of syringe or IV tubing can cross infect patients.	Although the injector cannot cause cross infection the Operator's Manual contains a warning to the user not to reuse single use syringes and tubing. The injector also contains a "Used Syringe" warning when it detects that a syringe has not been changed between procedures. The injector has the capability to remove the syringe at any ram position. The injector has the capability to mark an RFID-enabled syringe used and prevent its injection. If the RFID tag cannot be read or written, the injector will display a warning stating the RFID tag may be damaged or is not present. If the corrupted data or a data error is detected while reading or writing an RFID tag, the injector will display a warning stating the RFID tag may be damaged or is not present. If the user chooses to use a pre-filled syringe with an undetectable or erroneous RFID tag, the system will prompt the user to select the pre-filled syringe volume.	• Design review of OptiVantage Manual • Verification testing of "Used Syringe" warning • Verification of capability to remove syringe at any ram position. • Verification of RFID read capability • Verification of RFID messages and warnings • RFID System-level validation • Verification of pre-filled selection option when RFID tag is not present or is damaged.

8. Software

a. *Overview of Software Design*

The OptiVantage DH Injector System with Enhanced Communication software consists of three subsystems; the Power Head software, Console software and Faceplate software. The Power Head software injects fluids at specified volume and flow rate as programmed by the user. The Console software displays injector status and allows the user to program and start an injection from a remote location. The Faceplate software controls operation of the RFID reader hardware.

The primary functions of the software for OptiVantage DH Injector System with Enhanced Communication and the predicate device are the same. These primary functions are shown below:

- Uses a microprocessor and software technology to monitor and control the syringe plunger for injecting fluid as programmed by the caregiver.
- The software in both the Power Head and the Console contain power-on self-tests that check for injector component failure before allowing injector operation
- Checks injector integrity during injector operation. If an injector malfunction is detected the software transitions to a "safe state" where a failure code is displayed and further injector operation is prohibited.
- Monitor syringe pressure and stop or reduce the flow rate if programmed pressure limit is reached.
- Allow the caregiver to program the volume, flow rate and pressure limit for the injection and to store these parameters as protocols to recall for future procedures.
- Allow the user to control the syringe plunger to fill or retract the syringe and purge or expel fluid.

In addition to the above listed functions, the new device provides the following additional functionality

- RFID technology allows the injector to "mark" an RFID-enabled syringe as used when an injection is initiated and disallow further use of that syringe.
- RFID technology allows the injector to determine whether an RFID-enabled syringe is expired and prevent further use of that syringe.
- RFID technology allows the injector to obtain drug product attributes from an RFID-enabled syringe (Product Name, Concentration, Fill Volume, Lot Number, Expiration)
    - No patient-specific data is ever entered into or stored on the RFID-enabled syringe or injector system.

The OptiVantage DH Injector System with Enhanced Communication software was developed according to procedure QSEP12, Software Development and is summarized as follows:

Software Development Plan
Requirements Tracing
Risk Management
Reviews
Software Requirements
Software Design
Verification Tests
Product Validation

b. *Determination of Software Level of Concern*

Level of Concern Determination	Yes	No
Does the device software control a life supporting or life-sustaining device?		X
Does the device software control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and so forth?		X
Does the device software control treatment delivery, such that an error or malfunction with the delivery could result in death or serious injury?		X
Does the device software provide diagnostic information on which treatment or therapy is based, such that if misapplied it could result in serious injury or death?		X
Does the device software provide vital signs monitoring and alarms for potentially life threatening situations in which intervention is necessary?		X

9. Declaration of Conformity

1. Per the risk analysis, all verification and validation activities were performed and the results demonstrate that the predetermined acceptance criteria were met.
2. Liebel-Flarsheim is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 *(See section 6, Summary of Design Control Activities)*. Records are available upon request.

I certify that, in my capacity as Director of R&D of Mallinckrodt Inc., Liebel-Flarsheim Business, I believe to the best of my knowledge, that all data and information submitted in the Declaration of Conformity are truthful and accurate and that no material fact has been knowingly or willfully omitted.

Robert J. Ziemba Director of R&D

11/17/06
Date

10. Special 510(k) Summary

Appendix H contains the Special 510(k) Summary.

11. Truthful and Accurate Statement

I certify that, in my capacity as Manager, Plant QA of Mallinckrodt Inc., Liebel-Flarsheim Business, I believe to the best of my knowledge, that all data and information submitted in the Premarket Notification are truthful and accurate and that no material fact has been knowingly or willfully omitted.

Dale Moore

Dale Moore Quality Manager

11/17/06

Date

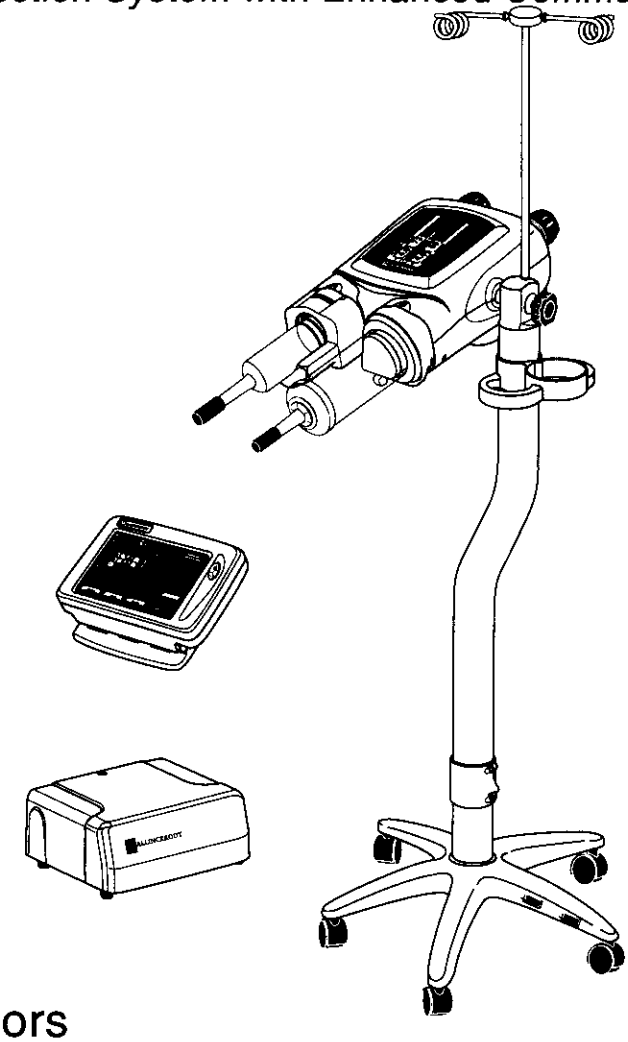
Appendix A OptiVantage DH Injector System with Enhanced Communication

Operators Manual

MALLINCKRODT

OptiVantage™

Injection System with Enhanced Communication



Operators Manual

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tyco / Healthcare MALLINCKRODT

FOREWORD

Congratulations on the purchase of your OptiVantage™ Injection System with Enhanced Communication. The OptiVantage system represents our effort to provide a quality product to support better health care throughout the world.

Regardless of how well equipment is designed, misuse or abuse will deny its owner the expected quality of service. Misuse or abuse may occur unintentionally because the proper method of operating the equipment is unknown. Read this manual carefully before operating the OptiVantage system. Retain this manual for future reference.

LIEBEL-FLARSHEIM TECHNICAL SUPPORT

Phone No. 1-800-877-0791

RECORDING MODEL NUMBER, PART NUMBERS, AND SERIAL NUMBERS

The model number (Mod. No.), part numbers (P/N), and serial numbers (S/N) must be supplied when requesting replacement parts or optional accessories. For convenience, record the requested information below:

Power Supply

Mod.No. ☐☐☐☐☐☐-☐

P/N ☐☐☐☐☐☐-☐

S/N **CI** ☐☐☐☐ **B** ☐☐☐

Powerhead

P/N ☐☐☐☐☐☐-☐

S/N **CI** ☐☐☐☐ **B** ☐☐☐

Console S/N

P/N ☐☐☐☐☐☐-☐

S/N **CI** ☐☐☐☐ **B** ☐☐☐

Date of Installation ☐☐/☐☐/☐☐

Installing Company _____

Address _____

Phone No. _____

TRADEMARK AND PATENT INFORMATION

OptiVantage™, Patency Check™, Timing Bolus ™ and Verified ™ are trademarks of Mallinckrodt, Inc. OptiBolus® and OptiRay® are Registered trademarks of Mallinckrodt, Inc.

The OptiVantage is protected under the following U.S. Patents:

5,279,569	5,300,031	5,451,211	5,456,669
5,658,261	5,662,612	5,681,286	5,758,659
5,928,197	6,315,758	6,635,030	6,659,979

Other U.S. and Foreign Patents Pending.

MEANINGS OF SYMBOLS

SYMBOLS LOCATED IN THE MANUAL

Please regard any message that follows a Danger, Warning, or Caution symbol.

[redacted]

DANGER!—Hazards which could result in severe personal injury or death.

[redacted]

WARNING!—Hazards which could result in personal injury.

[redacted]

CAUTION!—Hazards which could result in equipment or property damage.

SYMBOLS LOCATED ON THE POWER CONTROL

J1		Powerhead Cable Connector
J2		Startswitch Cable Connector
J3		Ethernet Port
J5	RS232/ RS422	RS232/RS422 Port
J6		Universal Interface Connector
J10A		Console Cable Connector
J10B	OptiBolus™ 	OptiBolus™ Console Cable Connector
P4	**CAN**	Controller Area Network Port
		Equipment sensitive to Electrostatic Discharge. DO NOT TOUCH exposed connectors.
		ATTENTION! Consult User's/Service Manual.
		CAUTION! Risk of electrical shock. Do not remove cover. Refer servicing to qualified personnel.
		Fuse Rating (Voltage, Amperage, Type)
	Mod. No.	Model Number
	S/N	Serial Number
	P/N	Part Number
	V/A	Volts Amps

SYMBOLS LOCATED ON THE CONSOLE

		Push ON / Push OFF
J1		Power Supply Cable Connector
J2		Handswitch Cable Connector
		RFID (Radio Frequency Identification) active
		RFID (Radio Frequency Identification) inactive

SYMBOLS LOCATED ON THE POWERHEAD

		Manual Knob Light Status Flashing Blue: Injector Powering Up Solid Yellow/Purple: Enabled or injecting contrast (yellow) or saline (purple) Flashing Purple: Drip Mode injecting saline Flashing Yellow and Purple: Injector Paused Flashing Red: Alarm condition Flashing Blue quickly: Injector rotated vertically or 30 degrees below horizontal.
		A-side of Powerhead
		B-side of Powerhead
		Install pressure sleeve/Load syringe
		Lock pressure sleeve onto the powerhead/ Lock syringe into the pressure sleeve
		Heater Blanket Cable Connector
		Powerhead classified IEC 601-1, Type CF

CLASSIFICATION IN ACCORDANCE WITH EN 60601-1

TYPE OF PROTECTION AGAINST ELECTRIC SHOCK

Class I equipment

DEGREE OF PROTECTION AGAINST ELECTRIC SHOCK

Type CF applied part.

DEGREE OF PROTECTION AGAINST INGRESS OF WATER

Ordinary Equipment

ELECTROMAGNETIC COMPATIBILITY

The OptiVantage meets the radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices

UL/CSA CLASSIFICATION

CLASSIFIED UL C US 33SL

OptiVantage (Medical Equipment)
UL60601-1, IEC60601-1
CAN/CSA C22.2 No. 601.1

OptiVantage™ DH Injection System

CLASSIFIED BY UNDERWRITERS LABORATORIES INC.
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1
33SL

OptiVantage™ DH Injection System
CLASSIFIED WITH RESPECT TO ELECTRIC SHOCK, FIRE MECHANICAL AND OTHER SPECIFIED HAZARDS ONLY IN ACCORDANCE WITH CAN/CSA C22.2 NO. 60601.1,

33SL

CE MARK INFORMATION

CE 0123

uthorized EC Representativ
TYCO HEALTHCARE UK

Conforms to the European Medical Device Directive (MDD)

FCC/IC INFORMATION

All Radio type devices embedded in the OptiVantage Injector have met all qualifications for use under FCC Part 15 and Industry Canada RSS-210.

Model#: 844003 (OptiVantage Injector with Enhanced Communication)

IC: 3502A-844003

FCC ID: UEI844003

This device complies with Industry Canada RSS-210 and with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: The term "IC:" before the radio certification number only signifies that Industry Canada technical specifications were met.

Note: Changes or modifications to the OptiVantage Injector not expressly approved by Tyco Healthcare/Mallinckrodt could void the user's authority to operate the equipment.

This manual originally written in English.

Table Of Contents

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1 SYSTEM OVERVIEW

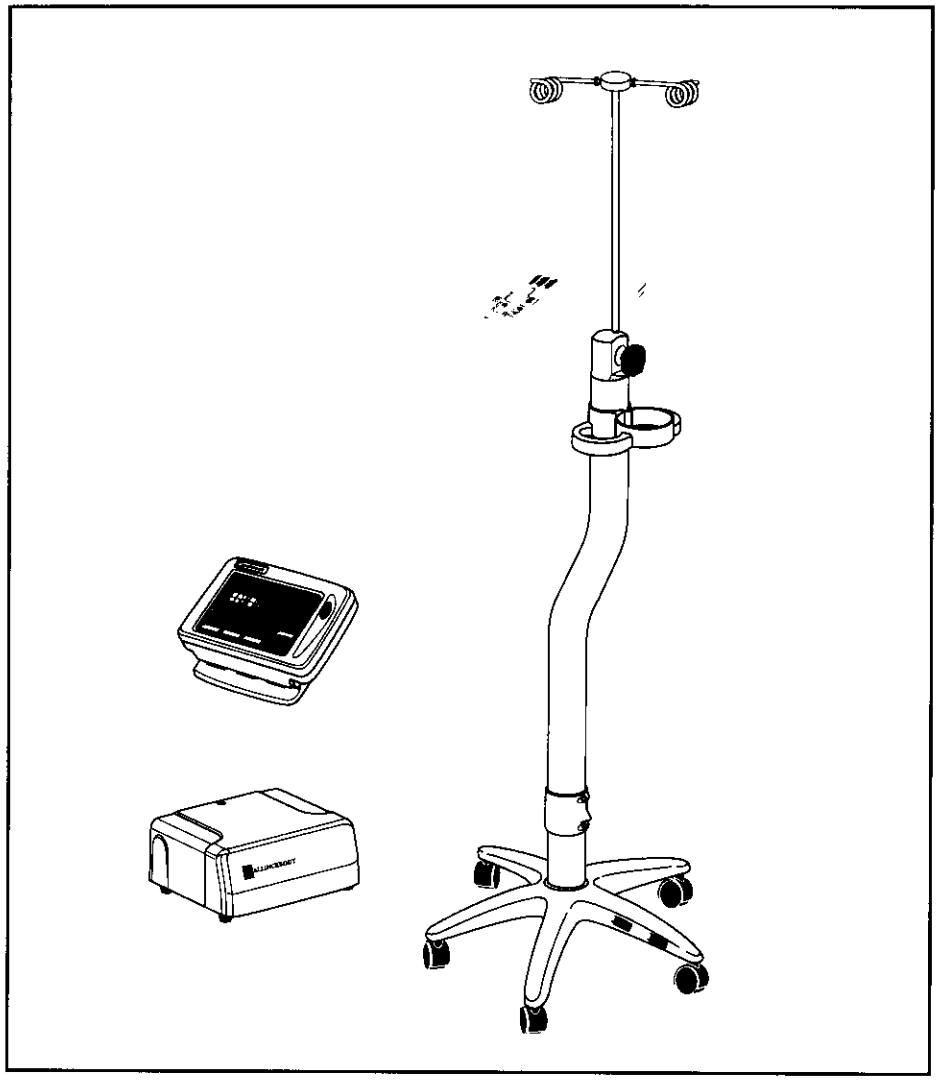

Figure 1-1-1 OptiVantage Injection System

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1.1 INDICATIONS FOR USE

The OptiVantage Injection System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

1.2 USER QUALIFICATION

The OptiVantage Injection System should be operated ONLY by qualified personnel who:

- are completely familiar with the unit,
- have read and understood this Operator's Manual,
- have been trained concerning the process of how to stop an injection in the case of an emergency (described in Chapter 5 of this manual), and
- are otherwise properly trained in the use of equipment and procedures of this type.

Failure to follow these guidelines could result in serious injury to the patient or the operator.

[redacted]

Federal law restricts this device to sale by or on the order of a physician.

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1.3 SYSTEM FEATURES

1.3.1 VERSATILITY

The injector is microprocessor-controlled and can perform injections within the following variable parameters:

- Flow Rate
- Volume
- Pressure Limit
- Inject Delay
- Scan Delay
- Phase Delays

1.3.2 RFID CAPABILITIY

The RFID (Radio Frequency Identification) feature provides the capability to transfer product information from an Ultraject syringe fitted with an RFID data tag to the OptiVantage injector system. The injector system stores the syringe data for inclusion in the injection reports. A subset of the syringe data provides parameters used for constraining the injection protocol and validating the system configuration. A key feature of the RFID data tag is that the injector system can mark a syringe as being 'used' and therefore preventing the syringe from being used for multiple injections.

1.3.3 TOUCH-SCREEN DISPLAYS

The console and powerhead both contain touch screen displays for operator interaction. Refer to Chapter 3-1-1 for detailed descriptions.

When using the touch screen displays, keep the following information in mind

[redacted]

Do not press on the touch screens with sharp or pointed items such as fingernails, pens or pencils. Using items of this type may cause damage to your screen, resulting in a nonworking unit. Do not allow objects, such as pens and pencils, to lay on the touch screen.

1.3.4 PROTOCOL MEMORY WITH PASSWORD PROTECTION

A convenient, user-friendly feature of the OptiVantage is its ability to store the parameters of as many as 40 protocols in its memory. Password protection is also available.

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1.4 FEATURES

1.4.1 SAFETY

The OptiVantage Injector System has been designed to enhance the safety of both patient and operator. Specific safety features include:

Self-testing Design

When the OptiVantage is switched ON, it automatically performs a series of power-up tests to monitor the status of all systems. If a problem is detected, an appropriate message will appear in the system display. Also, during the enable process and during an injection, all necessary functions are constantly checked. If a fault is detected, the system will automatically shut down and an appropriate message will be displayed.

Patency Check™ Feature

Prior to the delivery of the main injection, a Patency Check—an injection of a small volume of saline—can be performed to determine the integrity of the I.V. site.

Timing Bolus™ Feature

Prior to the delivery of the main injection, a Timing Bolus injection—an injection of a small volume of contrast, followed by a small volume of saline—can be delivered to the patient to determine the optimal scan delay needed to capture the contrast agent in the area of interest.

Drip Mode Feature

Prior to the delivery of the main injection, a Drip Mode injection—a low flow rate injection of a small volume of saline—can be delivered to keep the fluid pathway open.

OptiBolus® Feature (Optional)

The OptiBolus feature is used to deliver an exponentially decaying flow rate injection that optimizes the contrast usage and provides an extended period of uniform enhancement of the area of interest. The End Flow Rate is automatically calculated by the OptiVantage and displayed only on the console Main screen.

Pointing Powerhead Downward prior to Starting an Injection

After completion of the Enable sequence, the [Enable] key is only active after tilting the powerhead to the downward position. Pointing the powerhead in the downward position allows any trapped air in the syringe to move to the plunger end of the syringe, away from the syringe tip, possibly preventing it from being inadvertently injected into the patient.

Start/Stop Key on Powerhead

Because the powerhead is near the patient during an injection, both the [Start] key and the [Stop] key are integrated into the powerhead for starting or quickly stopping an injection.

Remote Control Operation

Use of the remote handswitch allows the operator to perform injections from outside the area of direct radiation.

Electrically Isolated Syringe

All syringes are isolated from any electrical contact with the injector.

Syringe Clarity

Semitransparent syringes are used on the OptiVantage. Small air bubbles can be seen with careful observation.

Positive Positioning of the Powerhead

A preset friction device in the powerhead holds the syringe in the desired position during injection.

Physical Stability

The wide stance of the base of the pedestal assembly reduces the possibility of tipping. Two of the casters may be locked to prevent unwanted rolling and turning.

1.4.2 OPERATOR CONVENIENCE FEATURES

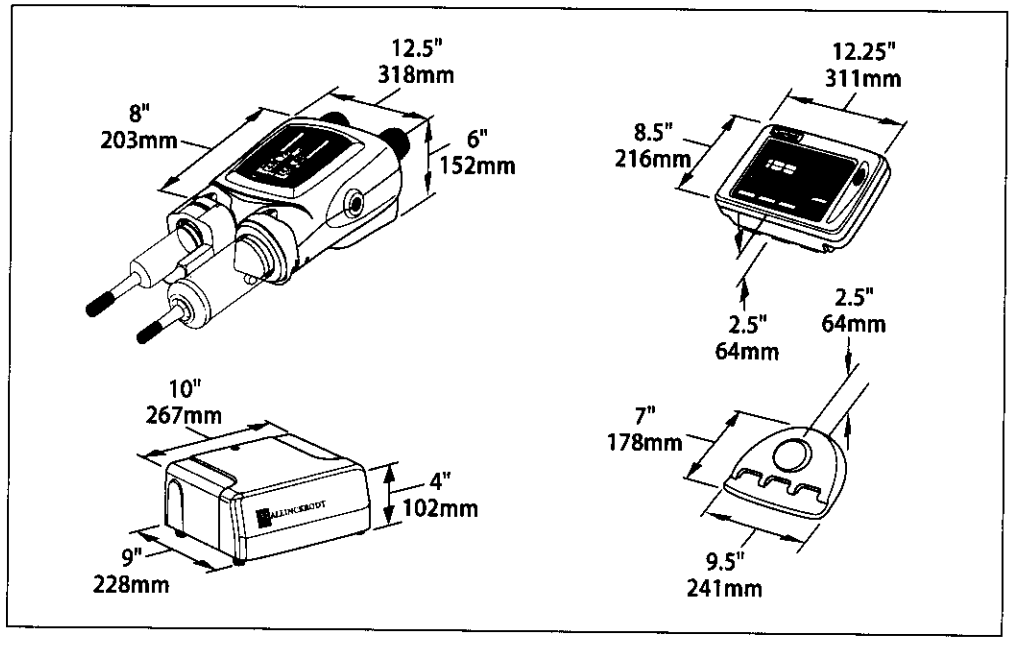
Auto-Fill Feature

This feature is designed to automatically fill the syringe while minimizing the introduction of air into the syringe. Upon loading a 200 ml syringe, the powerhead can automatically fill to 25 ml at 4 ml/s, expel to 0 ml at 10 ml/s, then fill to the operator programmed Auto-Fill Volume at 15 ml/s.

1.5 SPECIFICATIONS

1.5.1 DIMENSIONS

Console	12.25 W x 2.5 H x 8.5 D inches (311 W x 64 H x 216 D mm)
Console Base	9.5 W x 2.5 H x 7 D inches (241 W x 64 H x 178 D mm)
Powerhead	12.5 W x 6 H x 8 D inches (318 W x 152 H x 203 D mm)
Power Supply	10 W x 9 D x 4 H inches (267 W x 228 D x 102 H mm)



1.5.2 WEIGHT

Console w/Base	5.8 lbs (2.6 kg)
Powerhead	14.5 lbs (6.57 kg)
Power Supply	6 lbs (2.7 kg)

1.5.3 POWER REQUIREMENTS

Standby	less than 1 A
Standard	115 VAC, 4 A, 50/60 Hz 230 VAC, 2 A, 50/60 Hz

1.5.4 VOLTAGE REQUIREMENTS

Unit automatically adapts for input voltages from 100 to 240 VAC.

1.5.5 ELECTRICAL LEAKAGE

Chassis	less than 300 microamps

1.5.6 ENVIRONMENTAL

Transport and Storage Temperature: ..... -40° to +158° F (-40° to +70° C)
10% to 100% relative humidity

Operating Temperature: ..... 32° to +104° F (0° to +40°C)
30% to 75% relative humidity

Btu Output: ..... 510 Btu

Biohazard Disposal: Dispose of bioharzards in accordance with the requirements of your hospital, facility or local regulations.

Electromagnetic Compatibility (EMC): The OptiVantage meets EN60601-1-2 for level B conducted and radiated emissions and EMI immunity. **NOTE:** If any anomalies in the injector performance are noticed, identify devices within the immediate area that are capable of producing electromagnetic interference and call a qualified service representative.

⚠ DANGER! ⚠

Possible explosion hazard if used in the presence of flammable anesthetics. The unit is not designed for use in explosive environment.

⚠ WARNING! ⚠

The injector may only be operated in an area that is located beyond the 20 gauss limit. Operating the unit within magnetic fields that are higher than this limit may cause the unit to malfunction, resulting in operator or patient injury.

⚠ CAUTION! ⚠

Only the powerhead is considered spill proof. The console and power control are not spill-proof. Fluid spilled in these components can cause the unit to malfunction, resulting in patient or operator injury. If fluid is spilled on the console or power control, remove the unit from operation and contact your authorized service personnel.

1.5.7 RFID TRANSCEIVER

- Transceiver: P/N 844760, OptiVantage RFID Faceplate, 125 mL
- Operation Frequency: 13.56 MHz
- Antenna Gain: 1.13 dBi

1.5.8 SYRINGE SIZES

125 ml, 100 ml, 75 ml, 50 ml pre-filled

200 ml empty

1.5.9 SYRINGE HEATER

98° ± 6° F (37° ± 3° C) nominal. Maintains the temperature of pre-heated contrast.

1.5.10 FLOW RATE

Flow Rate Parameters	0.1 – 10 ml/second adjustable in increments of 0.1 ml/second
Flow Rate Running Tolerance:	0.2 ml/second or +/-20% whichever is smaller.

1.5.11 PEAK PRESSURE LIMIT

pounds per square inch (psi)	50 – 325 adjustable in 5 psi increments
kPa	345 – 2240 adjustable in 34 kPa increments

1.5.12 PHASE DELAY

Phase Delay Parameters	0—600 seconds adjustable in increments of 1 second.

1.5.13 INJECT DELAY

Inject Delay Parameters	0—600 seconds adjustable in increments of 1 second.

1.5.14 SCAN DELAY

Scan Delay Parameters	0—600 seconds adjustable in increments of 1 second

The Scan Delay timer shall count down in one second increments. Three beeps (250 ms) occur when the timer reaches 10 seconds. Two beeps (440 ms) occur when the timer reaches 5 seconds. One beep (1000 ms) occurs when the timer reaches 0 seconds. A start signal is sent to the CT Scanner when the timer reaches 0 seconds.

1.5.15 TOTAL TIME

Total Time Display Parameters.....0—99:59 (minutes:seconds)

1.5.16 PROGRAMMABLE DRIP MODE PARAMETERS (SALINE SIDE)

- Flow Rate: 0.1 to 1.0 ml/s
- Volume: 0.1 to 3.0 ml
- Interval: 0 to 60 seconds

1.5.17 PROGRAMMABLE PATENCY CHECK PARAMETERS (SALINE SIDE)

- Flow Rate: 0.1 to 10 ml/s (defaults to maximum flow rate of protocol)
- Volume: 1 to 200 ml
- Default Volume: 1 to 200 ml

1.5.18 STORED PROTOCOLS

40 protocols can be stored and recalled.

NOTE: *Liebel-Flarsheim reserves the right to change product designs and specifications in the continuing effort to improve their products.*

1.6 CONSUMABLES

NOTE: The use of consumables not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include evidence that the safety certification of the consumables has been performed in accordance to the appropriate EN 60601-1 and/or EN 60601-1-1 harmonized national standard.

1.6.1 SYRINGES

Dual Head Procedures

- **P/N 844020** Multipack 200 ml OptiVantage Front Load Syringe w/Handi-Fil and 60" Coiled Y-Tube *w/No check valve*
- **P/N 844015** Multipack 200 ml OptiVantage Front Load Syringe w/Handi-Fil and 60" Coiled Y-Tube *w/Single check valve*
- **P/N 844021** Multipack 200 ml OptiVantage Front Load Syringe w/Handi-Fil and 60" Coiled Y-Tube *w/Dual check valves*
- **P/N 844022** DualPack (2) 200 ml OptiVantage Front Load Syringes w/(2) Handi-Fils and 60" Coiled Y-Tube *w/No check valve*
- **P/N 844016** DualPack (2) 200 ml OptiVantage Front Load Syringes w/(2) Handi-Fils and 60" Coiled Y-Tube *w/Single check valve*
- **P/N 844023** DualPack (2) 200 ml OptiVantage Front Load Syringes w/(2) Handi-Fils and 60" Coiled Y-Tube *w/Dual check valves*

UltraJect Prefilled Contrast Syringes

NOTE: Consult Sales Representative for part number information.

50 ml	Optiray® 350 (Ioversol Injection USP 74%) 350 mgI/ml
75 ml	Optiray 350 (Ioversol Injection USP 74%) 350 mgI/ml
100 ml	Optiray 350 (Ioversol Injection USP 74%) 350 mgI/ml
125 ml	Optiray 350 (Ioversol Injection USP 74%) 350 mgI/ml
50 ml	Optiray 320 (Ioversol Injection USP 68%) 320 mgI/ml
75 ml	Optiray 320 (Ioversol Injection USP 68%) 320 mgI/ml
100 ml	Optiray 320 (Ioversol Injection USP 68%) 320 mgI/ml
125 ml	Optiray 320 (Ioversol Injection USP 68%) 320 mgI/ml
100 ml	Optiray 300 (Ioversol Injection USP 64%) 300 mgI/ml
125 ml	Optiray 240 (Ioversol Injection USP 51%) 240 mgI/ml

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UltraJect Prefilled Saline Syringes

NOTE: May not be available in your area, consult Sales Representative for availability and part number information.

50 ml	UltraJect Prefilled Saline Syringe
75 ml	UltraJect Prefilled Saline Syringe
100 ml	UltraJect Prefilled Saline Syringe
125 ml	UltraJect Prefilled Saline Syringe

Single Head Procedures

- **P/N 800099** Multipack 200 ml Front Load Syringe w/Handi-Fil and 60" Coiled Tube
- **P/N 800096** Multipack 200 ml Front Load Syringe w/Handi-Fil

1.6.2 LOW PRESSURE TUBING

- **P/N 601195** 60" Coiled Tube
- **P/N 844010** 60" Coiled Y-Tubing *w/No check valve*, 5" Y-Legs
- **P/N 844011** 60" Coiled Y-Tubing *w/Single check valve*, 5" Y-Legs
- **P/N 844012** 60" Coiled Y-Tubing *w/Dual check valves*, 5" Y-Legs

1.6.3 CATHETERS, CONNECTORS AND TUBING

It is recommended that catheters, connectors and tubing used with the OptiVantage Injection System be rated for a minimum of 325 psi. If such products are rated at a pressure below 325 psi, it is the responsibility of the user to use manual mode to select a pressure limit that is appropriate for the product. The selection of manual mode is covered in section 3.1.6. Setting of the peak pressure limit is discussed in Sections 3.1.3 and 3.2.6 of this manual.

Use only safety-approved catheters suitable for connection to the LLN-K-A Luer male-threaded locking coupler (DIN 13 090).

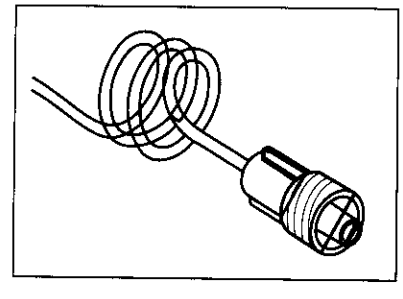

Figure 1-6-1

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1.7 ACCESSORIES

A list of the accessories for use with the OptiVantage Injector is available through your Mallinckrodt sales representative.

NOTE: The use of accessories not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the patient vicinity
- evidence that the safety certification of the accessory has been performed in accordance to the appropriate EN 60601-1 and/or EN 60601-1-1 harmonized national standard.

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2 POWER ON / POWER OFF

2.1 TURNING THE SYSTEM POWER ON

Refer to Figure 2-1-1.

1. At the rear of the power supply, place the switch to the ON position Ⓐ. The blue LED located on the top of the power supply will illuminate to indicate power is ON .
2. At the console, push the System ON/OFF button Ⓑ or press on the powerhead touchscreen. The ON/OFF button on the console will illuminate to indicate power to the console and powerhead is ON. The injector will perform a power-up check sequence, then display screens on the powerhead and the console to correctly position the rams for proper loading of the syringe(s).

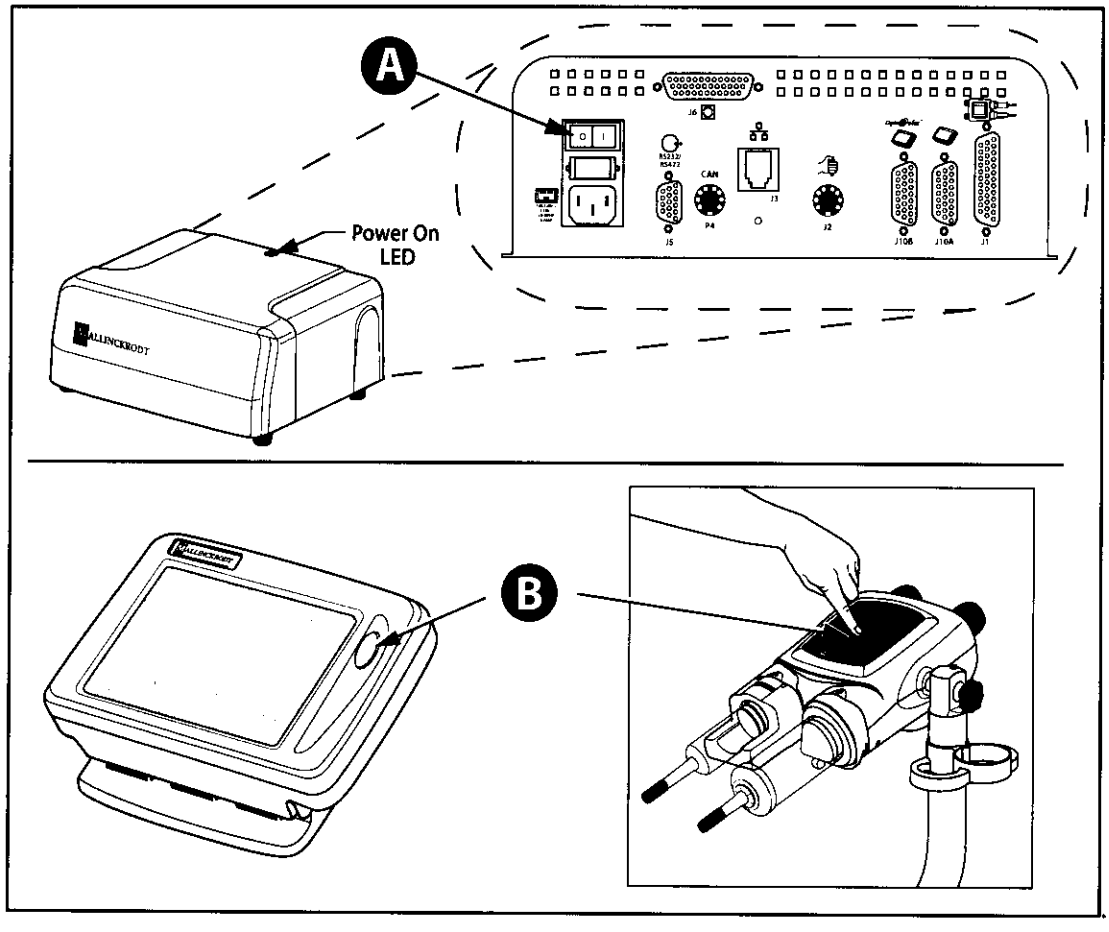

Figure 2-1-1 Switching the System Power ON

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2.2 HOMING THE RAMS

Each time power is cycled, the injector automatically performs a ram homing sequence to properly position the rams for loading of the syringes.

[redacted]

Disconnect the tubing from all 125 ml syringes prior to performing the homing sequence. Retracting the ram during the homing sequence, while connected to tubing *not containing* a check valve, may cause inadvertent retraction of blood from the patient. Retracting the 125 ml ram during the homing sequence, while connected to tubing *containing* a check valve, will cause a vacuum in the syringe.

Remove all 200 ml syringes prior to performing the homing sequence. Expelling the ram during the homing sequence, when a 200 ml syringe is loaded, may cause inadvertent injection of contrast or saline into the patient.

Follow the instructions on the powerhead display to perform the homing sequence.

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2.3 TURNING THE SYSTEM POWER OFF

Refer to Figure 2-3-1.

At the console, push the ON/OFF button to switch the system OFF Ⓑ. The power supply can be left ON. This allows for quicker and easier restarts from the console .

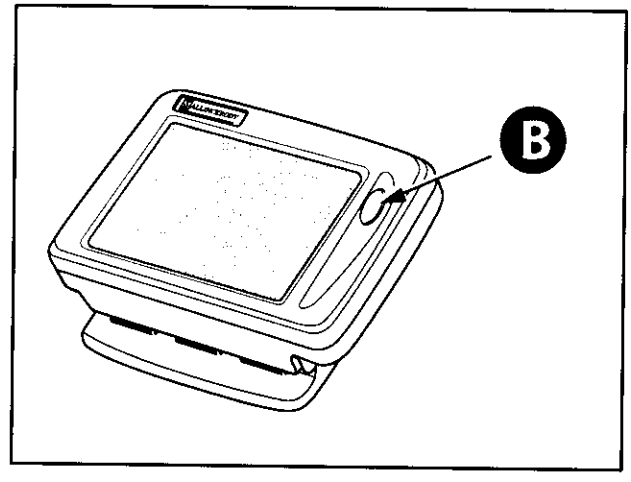

Figure 2-3-1 Switching the System Power OFF

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3 CONSOLE AND POWERHEAD

Operating the OptiVantage requires knowledge of the operator interfaces located on both the console and the powerhead. The console and powerhead both contain touch screen displays in order to interact with the operator.

Through use of the *console's touch screen display*, the operator can:

- enter protocol parameters
- save protocols
- delete protocols
- recall protocols
- enable/start/stop a Drip injection
- enable/start/stop an injection
- review achieved parameters of delivered protocols

Through use of the *powerhead's touch screen display*, the operator can:

- enter protocol parameters
- recall protocols
- fill/expel syringes
- enable/start/stop a Patency Check injection
- enable/start/stop a Drip injection
- enable/start/stop an injection

3.1 CONSOLE

3.1.1 CONSOLE POWER BUTTON

Refer to Figure 3-1-1.

Power Button/Power ON Indicator Ⓐ — The LED located on the power button glows to indicate that power is ON. With the power supply switch in the ON position, the injector system can be powered ON and OFF through use of the console power button.

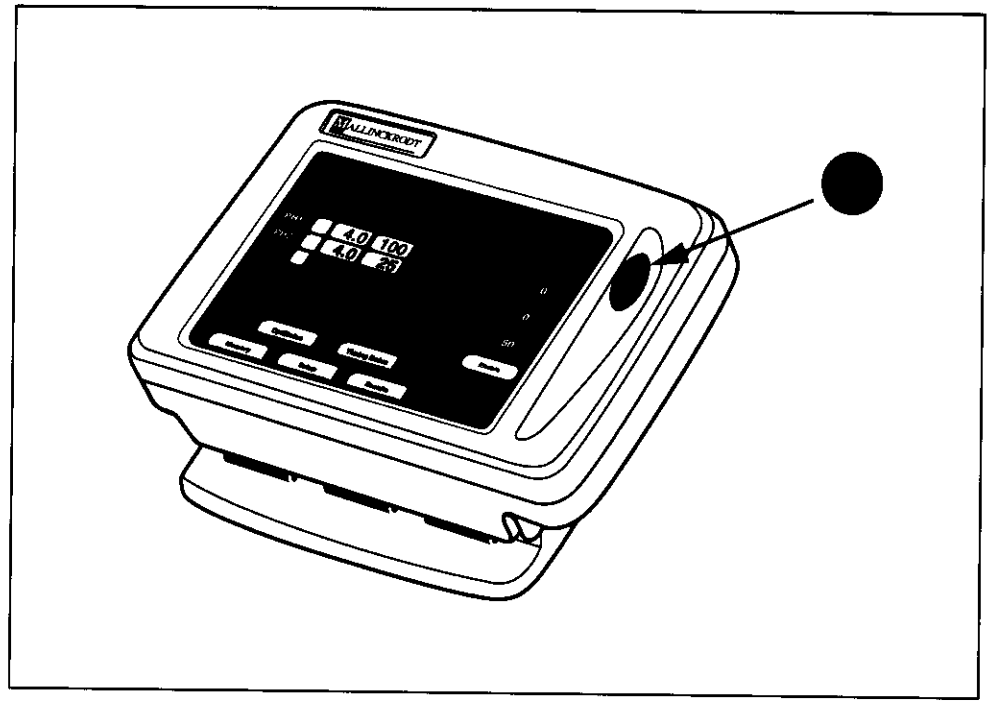

Figure 3-1-1 Console Power Button

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3.1.2 CONSOLE DISPLAY MODES OF OPERATION

Refer to Figure 3-1-2.

Located along the lower portion of the console display are the following 4 keys: [Memory], [Setup], [Results] and [Main]. These keys allow access to their respective modes of operation.

Main Screen — Upon power-up, this screen is automatically displayed as shown in Figure 3-1-2. All protocol information needed by the injector is contained within the Main screen. To access the Main screen when displaying the Results screen, Setup screen or Memory screen, press the active [Main] key located on the lower right-hand side of the screen.

Enabled Main Screen — The Enabled Main screen allows for the delivery of the main protocol or a Drip Mode Injection.

Memory Screen — All stored protocol information is located within the Memory screen. Accessing this screen allows the operator to recall, store, rename and delete protocols. To access the Memory screen, press the [Memory] key Ⓑ located on the lower portion of the screen.

Setup Screen — Accessing this screen allows the operator to change the language, change the unit of measure for pressure, set the time, set parameter defaults, display the Alarm History, and access the service mode. To access the Setup screen, press the [Setup] key Ⓒ located on the lower portion of the screen.

Results Screen — All information pertaining to the results of a delivered injection is located within the Results screen. To access the Results screen, press the [Results] key Ⓓ located on the lower portion of the screen.

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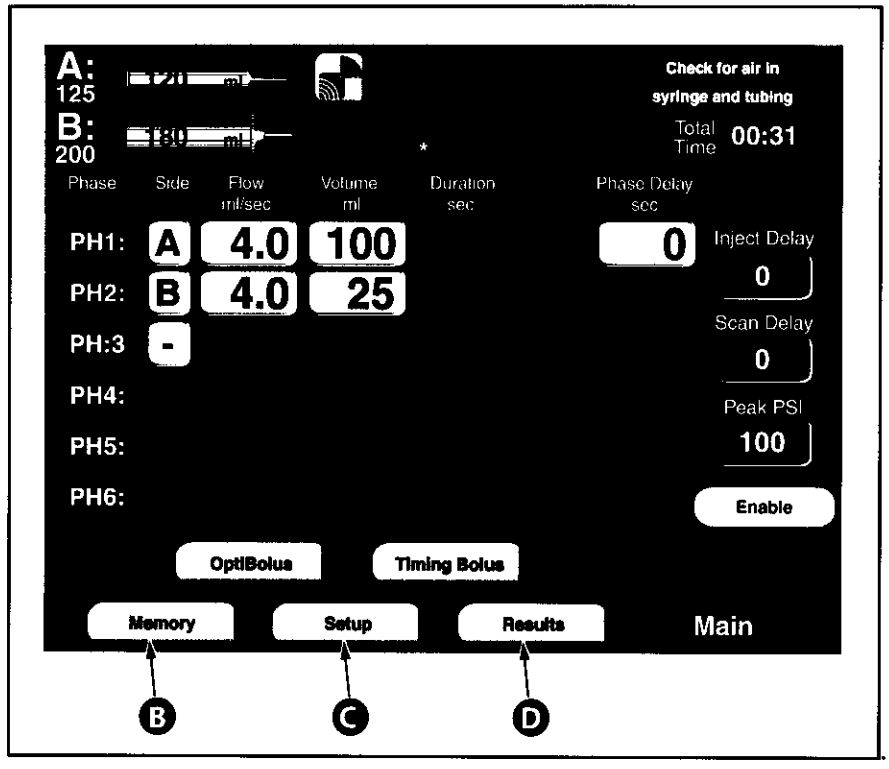

Figure 3-1-2 Console Main Screen with Location of Mode Keys

3.1.3 CONSOLE MAIN SCREEN

Refer to Figure 3-1-3 and Figure 3-1-4.

Protocol Name (E) — The name of the protocol currently displayed on the Main Screen is located in this area of the screen. An asterisk located at the end of the name indicates that the displayed parameters have been modified and no longer match the originally stored parameters.

A: Syringe Size (F) — This information indicates the size of the syringe currently installed in the A-side of the powerhead. Note that contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple.

RFID Active (Fi) — This key allows the operator to view attributes of any installed Ultraject syringe fitted with a syringe data tag. The RFID icon will de-highlight if an installed syringe does not contain a syringe data tag. Once the [RFID Active] key (Fi) is pressed, the screen shown in Figure 3-1-5 is displayed.

B: Syringe Size (G) — This information indicates the size of the syringe currently installed in the B-side of the powerhead. Note that contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple.

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Phase (H) — Within a protocol, up to six phases can be input. "PH" is the abbreviation of Phase.

Side (I) — These keys toggle among the following symbols: [A], [B], [-]. Pressing an [A] key will toggle the key to a [B] key, thus indicating injecting from the B-side. Pressing a [B] key will toggle the key to a white [-], indicating no injecting for and past that phase. Pressing a white [-] key will toggle the key to a [A] key, thus indicating injecting from the A-side.

Flow (J) — The values entered in this column indicate rate of delivery of the contrast medium and saline during each respective phase. Flow is expressed in milliliters/second.

Volume (K) — The values entered in this column indicate the volume of contrast medium and saline to be delivered during each respective phase. Volume is expressed in milliliters.

Duration (L) — The value in this column indicates the duration of a protocol phase (i.e., time to complete injection in seconds) based on the entered volume and flow rate values. Duration is displayed in the nearest whole second.

Phase Delay (M) — Phase Delay is a count down timer that delays the start of the next phase. The next phase will start when the phase delay counter reaches 0 (zero). Phase Delay is expressed in seconds. Phase Delay can also be set to pause the injection. Access the Pause feature by scrolling past either the 0 (zero) lower limit or the 600 (six-hundred) upper limit.

Total Time (N) — The Total Time field is an accumulation of all the calculated Duration and Delay fields for all phases. The total time field starts counting up from 0 (zero) after the injector receives a start signal. Total time continues to count after the injection is completed as long as the Results screen is displayed or up to 21 minutes. Total time is expressed in minutes:seconds.

Inject Delay (O) — Inject Delay is a count down timer that begins counting when the Start command is activated. The injection is started when the inject delay counter reaches 0 (zero). If Inject Delay is greater than 0 (zero), Scan Delay is automatically set to 0 (zero). Inject Delay is expressed in seconds.

Scan Delay (P) — Scan Delay is a count down timer that begins counting when the Start command is activated and stops when the counter reaches 0 (zero). The scan start signal will initiate once the timer reaches 0 (zero). If Scan Delay is greater than 0 (zero), Inject Delay is automatically set to 0 (zero). Scan Delay is expressed in seconds.

Peak PSI/Peak kPA (Q) — The value set in this key indicates the maximum allowable pressure that can occur during an injection. Pressure is expressed in either PSI or kPa. Refer to section *3.1.6 Setup Screen Parameters and Symbols* for more information about changing the unit of measure.

Enable Ⓡ — **This key is only active when proper enabling sequence is followed and after the powerhead is tilted downward.** Pressing the active [Enable] key "enables" the injector (displays the [Start] key) for delivery of a protocol.

OptiBolus (optional) Ⓢ — *This key is only active if a port-key is present at the OptiBolus port located on the rear of the power supply.* Pressing this key allows the operator to program an OptiBolus injection. The OptiBolus Mode delivers an exponentially decaying flow rate injection that optimizes the contrast usage and provides an extended period of uniform enhancement of the area of interest. Once the [Optibolus] key Ⓢ is pressed, the screen shown in Figure 3-1-6 is displayed. Note the addition of the Optibolus symbol Ⓥ to the left of the first phase along with the addition of End Flow Rate Ⓦ. End Flow Rate Ⓦ is a function of the Optibolus mode and is automatically calculated by the OptiVantage for the entered parameters and is displayed only on the console Main screen.

Timing Bolus Ⓣ — *This key is only active if turned ON at the Setup Screen and when 4 or less phases are programmed in a protocol.* Pressing this key allows the operator to program a Timing Bolus injection. A Timing Bolus injection--an injection of a small volume of contrast, followed by a small volume of saline--can be delivered to the patient to determine the optimal scan delay needed to capture the contrast agent in the are of interest. Once the [Timing Bolus] key Ⓣ is pressed, the screen shown in Figure 3-1-7 is displayed. Note the addition of "Text" Ⓧ to the left of the first and second phase.

Change Parameter Values via the Slide Bar Ⓤ — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, or use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

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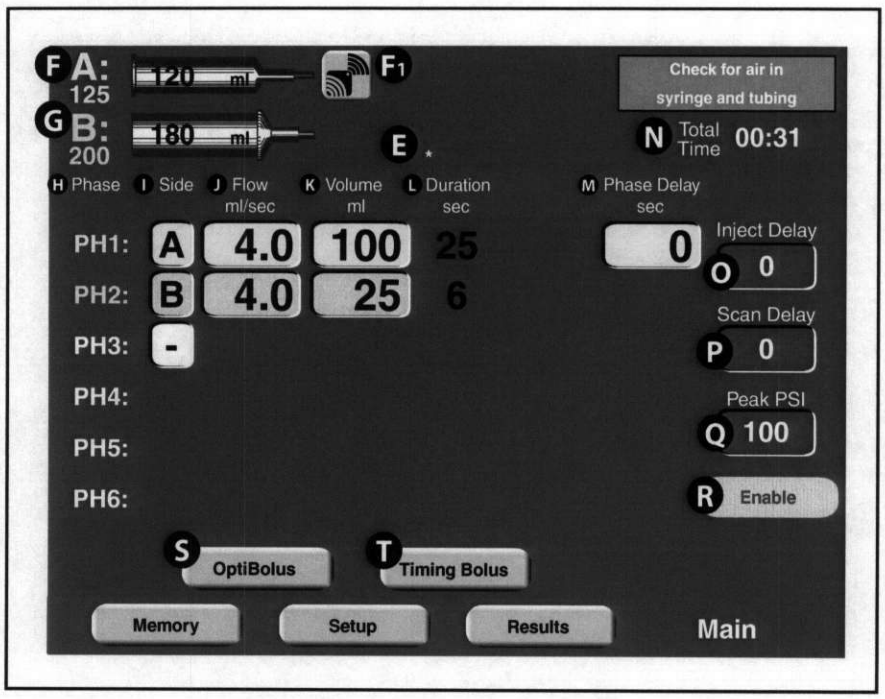

Figure 3-1-3 Console Main Screen

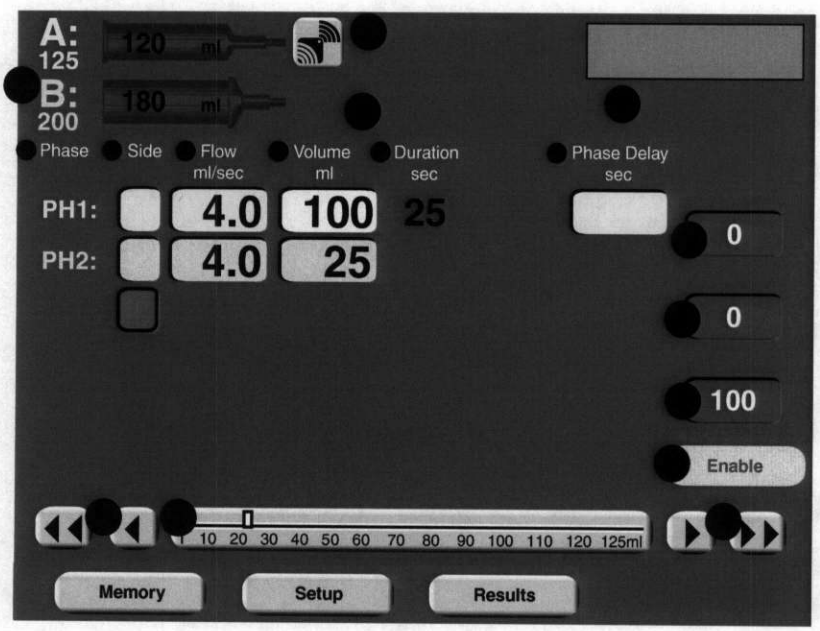

Figure 3-1-4 Console Main Screen with Active Slide B

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Figure 3-1-5 RFID Syringe Information

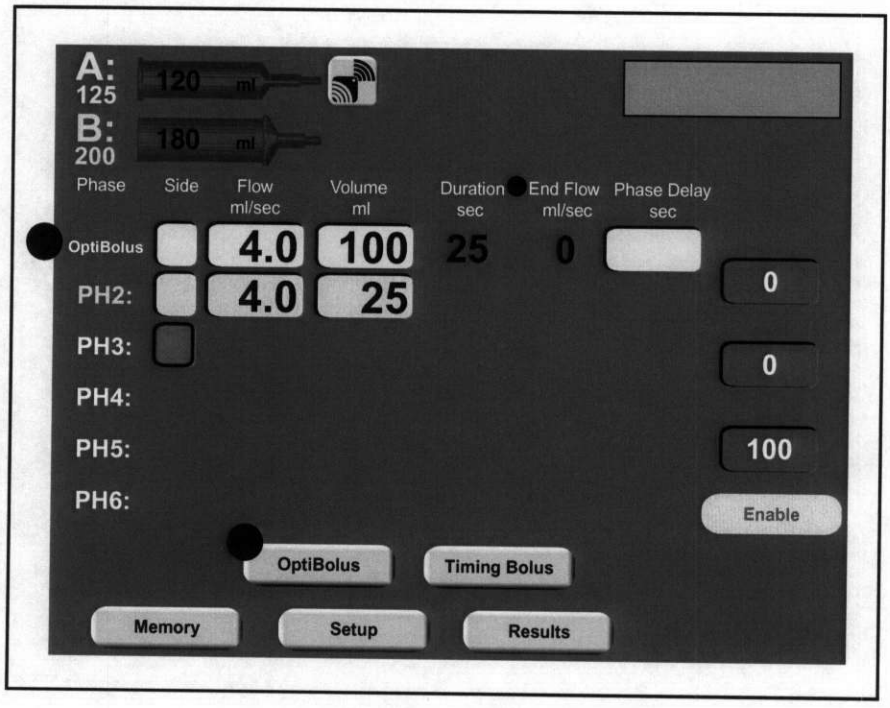

Figure 3-1-6 Console OptiBolus Injection Screen

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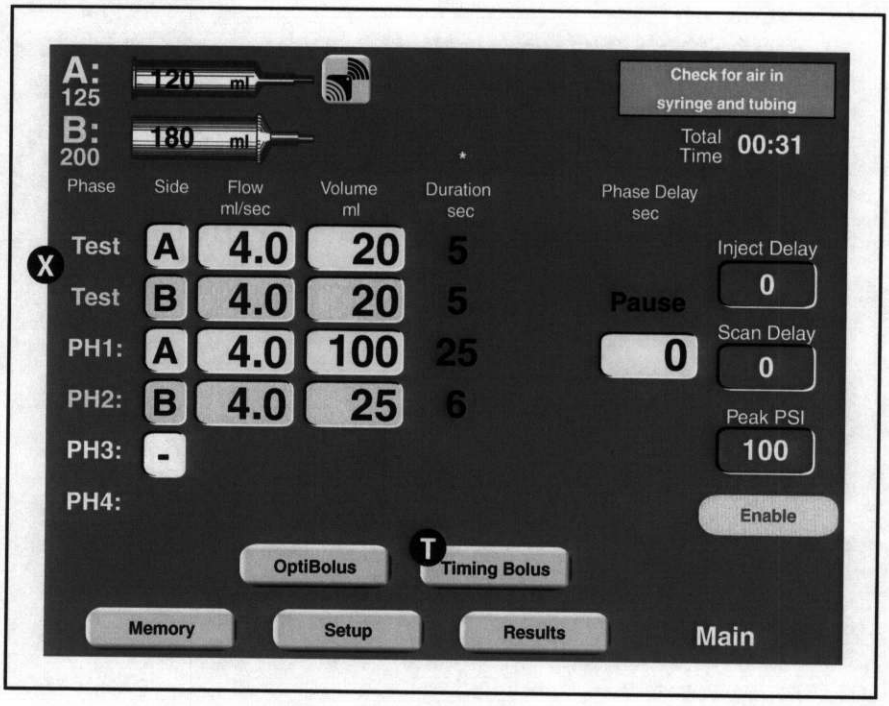

Figure 3-1-7 Console Timing Bolus Injection Screen

3.1.4 ENABLED CONSOLE MAIN SCREEN (START SCREEN)

Refer to Figure 3-1-8.

After pressing the active [Enable] key, the screen shown in Figure 3-1-8 is displayed. From this screen, the operator can change parameters, program an OptiBolus injection, program a Timing Bolus injection, enter the Drip Mode, or start the delivery of the protocol.

Start Ⓨ — This key starts the delivery of the programmed protocol. For more information about delivering injections, refer to Chapter 5.

Drip Ⓩ — *This key is active if turned ON at the Setup Screen and only displayed after the [Enable] key is pressed.* Pressing this key allows the operator to program a "drip" injection--a low flow rate injection of a small volume of saline delivered to keep the fluid pathway open. Refer to Figure 3-1-9.

Disable ⒶⒶ — This keys allows the injector to disable from the enabled mode.

Figure 3-1-8 Enabled Console Main Screen

Drip Mode Screen

Refer to Figure 3-1-9.

The Drip Mode allows the injector to deliver a "drip" injection to keep the fluid path open during patient set up and between injections of contrast. The Drip Mode is accessible from either the Console Enabled Main Screen or the Powerhead Enabled Main Screen.

To access the Drip Mode screen as shown in Figure 3-1-9, press the [Drip] key Ⓩ located on the enabled Main screen (shown in Figure 3-1-8).

Side Ⓐ — The Drip injection can only be delivered from the saline side. (In Figure 3-1-9, the B-side is set up as the saline side.)

Drip Mode Flow Ⓑ — This value indicates rate of delivery of the saline. Drip Mode flow is expressed in milliliters/second.

Drip Mode Volume Ⓒ — This value indicates the volume of saline to be delivered during each drip injection. Drip Mode volume is expressed in milliliters.

Interval Ⓓ — This value indicates the amount of time the injector pauses between each delivery of drip injections. Drip Mode interval is expressed in seconds.

Change Parameter Values via the Slide Bar Ⓔ — To change the value of a param-

eter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Drip Time **F** — Calculated automatically by the injector by using the programmed Flow, Volume and Interval values, this value indicates the amount of time the Drip Injection will require. Once the [Start Drip] key is pressed, the value counts down until it reaches zero. Once Drip Time reaches zero, an audible signal will indicate to the operator that the Drip Injection is complete.

Drip Volume **G** — Calculated automatically by the injector by subtracting the programmed Volume of the main protocol (saline side) from the syringe volume (saline side), this value indicates the amount of saline the Drip Injection can inject. Drip Volume is expressed in ml.

Start Drip **H** — This key starts the drip injection. For more information about delivering a drip injection, refer to Chapter 5.

Exit **I** — This key disables the drip injection and displays the Enabled Main screen.

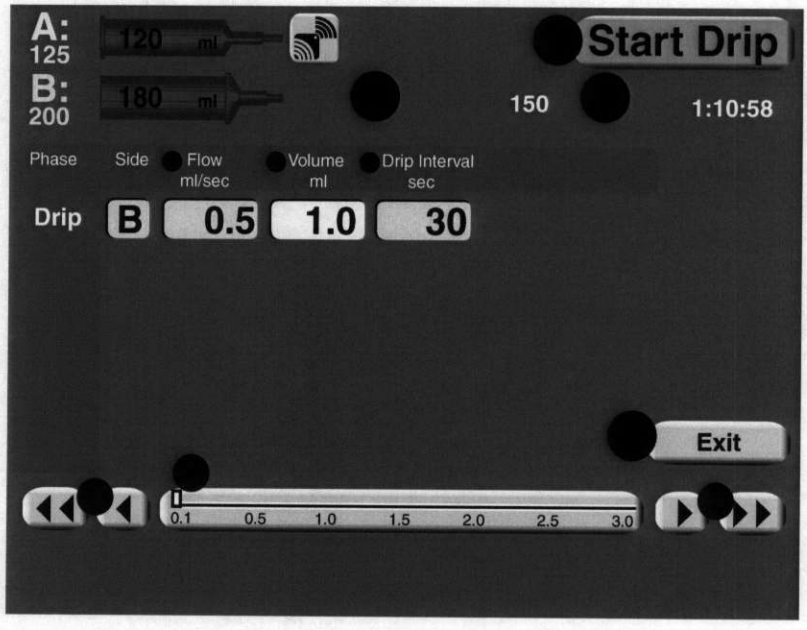

Figure 3-1-9 Drip Mode Screen

3.1.5 MEMORY SCREEN

Refer to Figure 3-1-10.

NOTE: If password protection is ON, moving, deleting, renaming or storing protocols is not permitted unless the correct password is entered.

Memory Location Ⓐ — The unit can store up to 40 six-phase protocols with 8 protocols listed per page. Each protocol can have a name consisting of up to 20 alpha-numeric characters. To display the protocol on the Main Screen, simply press the Protocol's corresponding key. OptiBolus protocols are indicated by the "OptiBolus" logo located on the key.

Protocol Parameters Ⓑ — Each protocol can contain up to six phases.

Current Values Ⓒ — The current values displayed on the Main screen are located in this area.

Memory Page Number Ⓓ — The memory screen contains five pages with eight protocols listed per page.

Move Ⓔ — This key allows the operator to move a protocol into a different slot or onto a different page.

Delete Ⓕ — This key activates the delete feature. Press the [Delete] key, then press the key of the protocol to be deleted.

Edit Ⓖ — This key allows the operator to edit the name of a protocol.

Store Ⓗ — This key stores the current values into a protocol memory slot.

Cancel (not shown) — This key is only displayed after pressing the [Move] key, the [Delete] key, the [Edit] key or the [Store] key and is used to cancel the feature.

Main Ⓘ — This key allows the operator to return to the Main screen.

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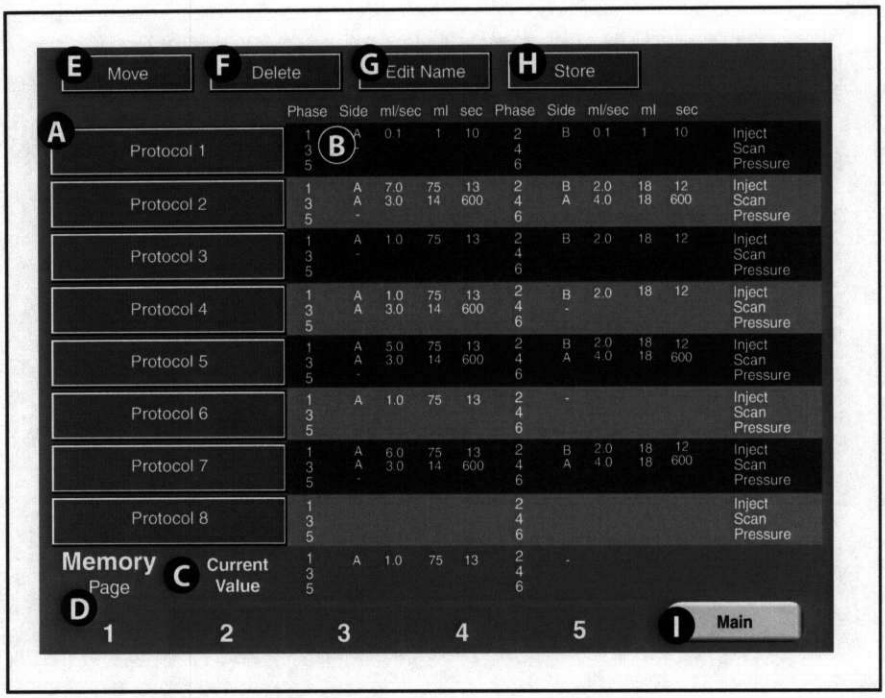

Figure 3-1-10 Memory Screen Keys and Definitions

Recall a Protocol

Refer to Figure 3-1-10.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) Ⓓ on which the Protocol is stored.
3. Press the key Ⓐ of the desired Protocol Name. The protocol will be immediately displayed on both the powerhead display and the console display.

Store a Protocol in Memory

Refer to Figure 3-1-10 and Figure 3-1-11. This feature is only accessible from the console.

1. Enter all required parameters on the Main screen.
2. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
3. Press the appropriate page (1, 2, 3, 4 or 5) Ⓓ on which to store the Protocol.
4. Press the [Store] key Ⓗ. The display will prompt the user with "Select memory location."
5. Press the desired memory location key Ⓐ. A keyboard will appear in order to name the protocol. Refer to Figure 3-1-11.
6. Enter the desired name using the keyboard. Press the keyboard [Enter] key Ⓙ when finished. The protocol will be stored at the memory location selected.

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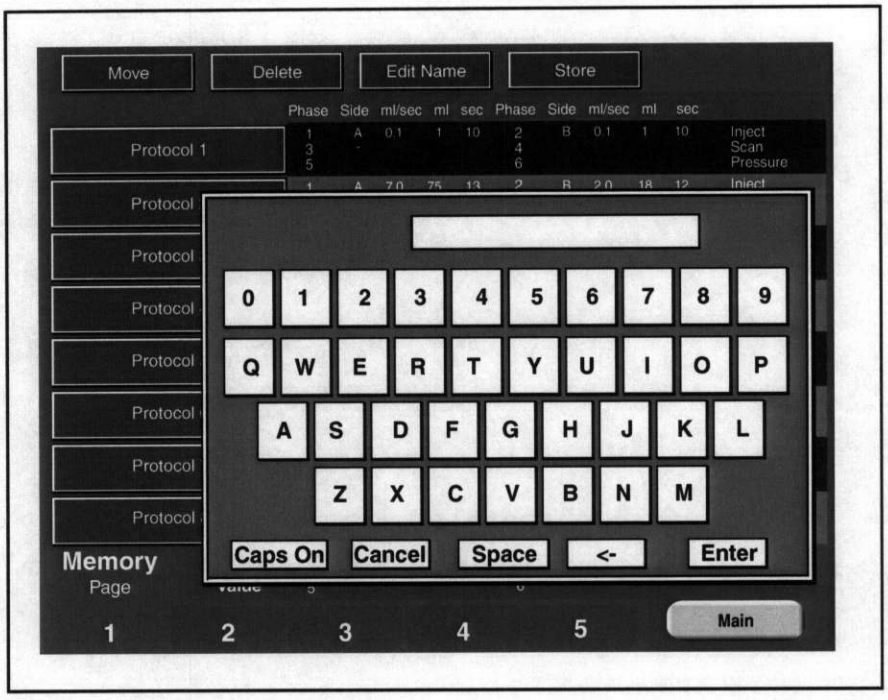

Figure 3-1-11 Memory Keyboard

Move a Protocol in Memory

Refer to Figure 3-1-10. This feature is only accessible from the console.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) Ⓓ on which the Protocol is stored.
3. Press the [Move] key Ⓔ. The display will prompt the user with "Select protocol to move."
4. Press the key of the protocol to be moved. The display will prompt the user with "Select position to insert moved protocol."
5. Press the desired memory location key Ⓐ onto which the Protocol is to be relocated. The protocols will be shifted upwards or downwards to accommodate the new location of the moved protocol.

Delete a Protocol from Memory

Refer to Figure 3-1-10. This feature is only accessible from the console.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4, or 5) Ⓓ on which the Protocol is stored.
3. Press the [Delete] key Ⓕ. The display will prompt the user with "Select protocol to delete."
4. Press the key of the protocol to be deleted. The display will prompt the user with "Are you sure?" Pressing the [Yes] key deletes the protocol from memory. Pressing the [No] key returns you to the Memory screen without deleting the protocol from memory.

Rename (Edit Name) a Protocol Name or Page

Refer to Figure 3-1-10 and Figure 3-1-11. This feature is only accessible from the console.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) Ⓓ on which the Protocol is stored.
3. Press the [Edit Name] key Ⓖ. The display will prompt the user with "Select protocol to rename."
4. Press the key of the protocol to be renamed and enter the new name using the displayed keyboard (shown in Figure 3-1-11). Press the keyboard [Enter] key Ⓙ when finished. The protocol will be stored under the new name at the same memory location.

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3.1.6 SETUP

Refer to Figures 3-1-12 and 3-1-13.

Access the Setup screens by pressing the [Setup] key Ⓑ (on Figure 3-1-2) located on the Main Screen of the Console. Note: The Setup Screen and its features are not accessible from the Powerhead screen. Also, if password protection is ON, access to the Setup screens is not permitted unless the correct password is entered.

The Setup Screen allows the operator to adjust injection parameters, set the time and date, select the language, enter the service mode, and view the alarm history of the injector. Use the [<, >] keys Ⓒ keys to toggle between the two set up screens.

Date and Time Ⓐ — Indicates the Date and Time as set in item Ⓓ.

Software Versions Ⓑ — Indicates the software installed in the console, powerhead, and the current Scanner Interface software.

[<, >] keys Ⓒ — These keys allow the user to toggle between the two Set Up screens as shown in Figure 3-1-12 and 3-1-13.

[Time] key Ⓓ — This key allows the user to set the time and date. Refer to Figure 3-1-15.

[Language] key Ⓔ — This key allows the user to change the language of the injector. Refer to Figure 3-1-16.

[Service] key Ⓕ — This key allows service personnel access to the service screens. Note: The service screens are only accessible through use of a service key. Refer to the Service Manual.

[Alarm] key Ⓖ — The injector's alarm history is accessible through use of this key.

[Main] key Ⓗ — This key allows the user to exit the Set Up screens and return to the Main Screen.

OEM Interface Ⓘ — Select On or Off. Selecting "On" allows the OEM Interface to exercise limited control over the injector. Selecting "Off" disables the OEM Interface.

Timing Bolus Ⓙ — Select either On or Off. If On is selected, a [Timing Bolus] key will be made available on the Main screen to deliver a "Timing Bolus" injection to determine optimum image quality in order to determine the ideal scan delay.

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Patency Check (K) — Select either On or Off. If On is selected, a [Patency] key will be made available (after the injector is enabled) on the Powerhead to inject a small volume of saline at the maximum flow rate as the enabled protocol in order to check patency of the I.V. site.

Patency Check Volume (L) — The [Patency Check Volume] key allows the operator to set a default value for the Patency Check injection.

Drip Mode (M) — Select either On or Off. If On is selected, a [Drip Mode] key will be made available (after the injector is enabled) to deliver a "drip" injection (series of small volumes of saline) to keep the fluid path open.

Drip Flow Rate (N) — The [Drip Flow Rate] key allows the operator to set a default Flow Rate value for the Drip Injection.

Drip Volume (O) — The [Drip Volume] key allows the operator to set a default Volume value for the Drip Injection.

Drip Interval (P) — The [Drip Interval] key allows the operator to set a default value for the delay between Drip Injections.

Pause on Pressure Limit (Q) — Select either On or Off. Selecting "On" will cause the injector to automatically pause in the instance of a pressure limited injection. Selecting "Off" will allow the injector to continue injecting at a lower flow rate but will also display a message giving the operator the ability to either pause or continue.

Pressure Limit (R) — Select either Manual or Auto. Selecting "Manual" allows the operator to input a value for Peak Pressure Limit on the Main screen. Selecting "Auto" allows the injector to calculate a default value based on the highest flow rate of the displayed protocol. However, this value can be updated by the operator on the Main screen.

Pressure Units (S) — Select either PSI or kPA.

Auto-Fill (T) — Select either On or Off. If On is selected, the Auto-Fill feature is available to the operator to automatically fill a 200 ml syringe while minimizing the introduction of air.

Syringe Fluid A (U) — Select either Contrast or Saline to be used in the A-side syringe.

Syringe Fluid B (V) — Select either Contrast or Saline to be used in the B-side syringe.

Injection Duration Display (W) — Select either On or Off. Selecting Off removes the Injection Duration value (time to complete injection in seconds) from the Main Screen.

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Phase Delay Display Ⓧ — Select either On or Off. Selecting Off removes the [Phase Delay] key and its value from the Main Screen.

Console Brightness (display) Ⓨ — Select between Low or High.

Console Volume (display) Ⓩ — Select among Off, Low, Med or High.

Powerhead Brightness (display) ⓐ — Select between Low or High.

Powerhead Volume (display) ⓑ — Select among Off, Low, Med or High.

Auto Syringe Size Sense ⓒ — Select either On or Off. Selecting "On" allows the injector to determine the size of the installed pre-filled syringe.

Partial Prefills ⓓ — Select either On or Off. Select On if Partial Prefill syringes are to be used.

Password ⓔ — Once Password is set to ON, a keyboard, as shown in Figure 3-1-14, is displayed to enter and re-enter the password. When Password is set to ON, access to the Setup screens and Memory features is only available after entering the password.

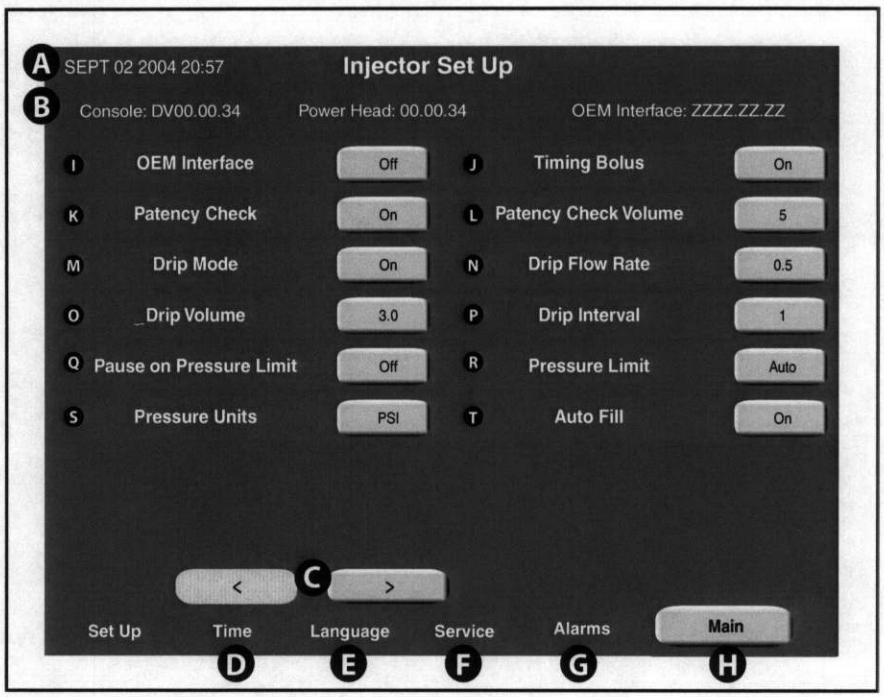

Figure 3-1-12 Injector Set Up Screen 1

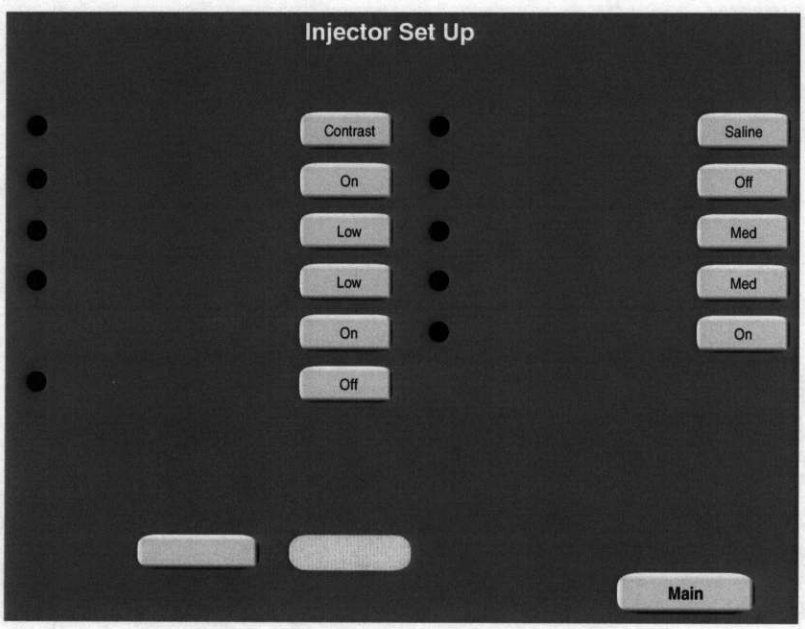

Figure 3-1-13 Injector Set Up Screen 2

Figure 3-1-14 Enter Password

Time/Date

Refer to Figure 3-1-15.

Access the ability to set the Time and Date by pressing the [Time] key (Ⓓ in Figure 3-1-11) .

Press the [Change Date] key ⓘ and/or the [Change Time] ⓙ key to update the date and time. Use the [▲▼] keys ⓚ to select the desired date and time.

After changing the Date and/or Time to the desired value, press the [Set Date] key ⓛ and/or the [Set Time] key ⓜ for the change to take effect.

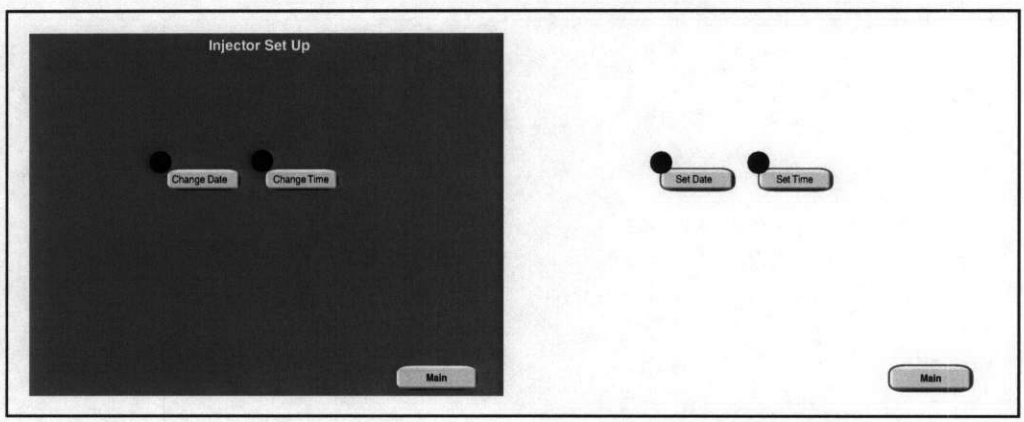

Figure 3-1-15 Setting the Time/Date

Language

Refer to Figure 3-1-16.

Select the Language from among the selections located under the [Language] key (Ⓕ in Figure 3-1-12).

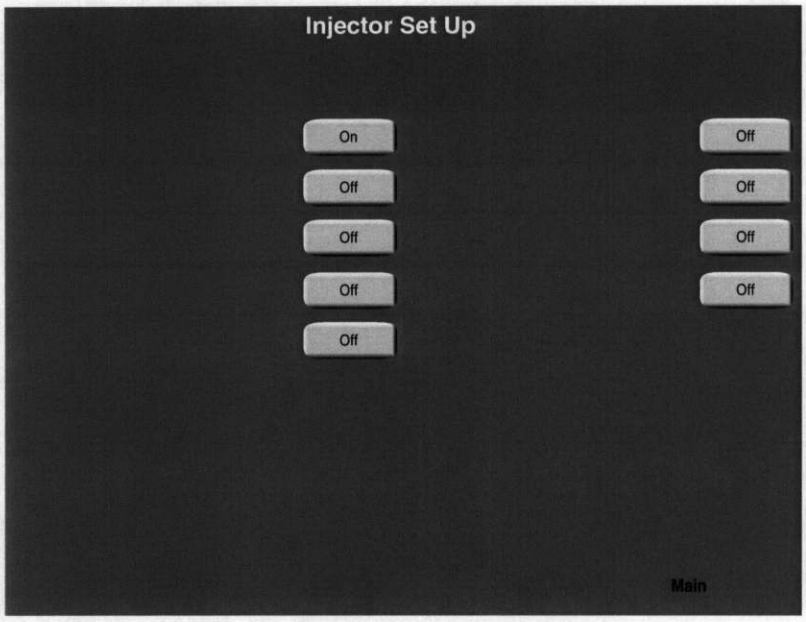

Figure 3-1-16 Selecting the Language

Alarms

Refer to Figure 3-1-17

Display the Alarm History screen by pressing the [Alarm] key (G in Figure 3-1-12). Pressing the [<, >] keys (n in Figure 3-1-17), displays the most recent Alarms (up to 24) (on the console screen only) along with the protocol's settings at the time of the alarm.

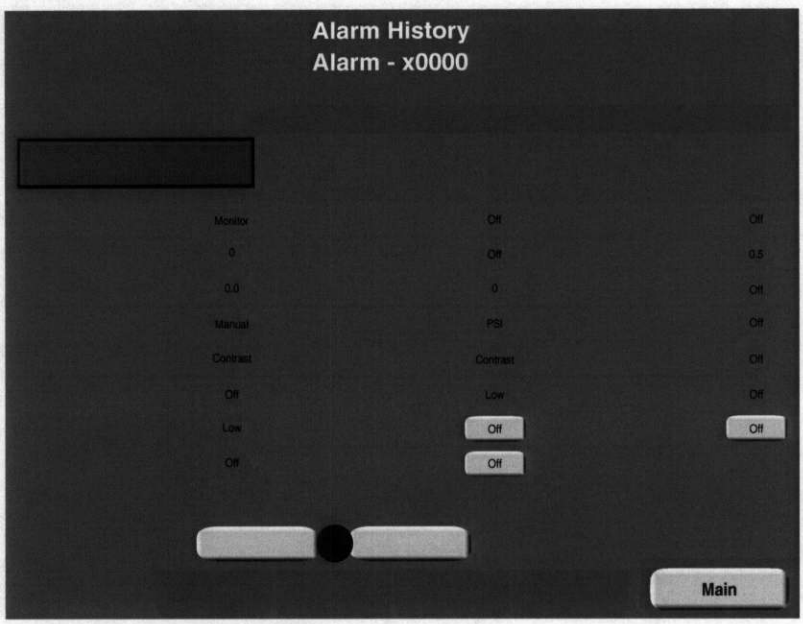

Figure 3-1-17 Alarm Screen

3.1.7 RESULTS SCREEN PARAMETERS AND SYMBOLS

Refer to Figure 3-1-18 and 3-1-19

The Results Screen is automatically displayed after the delivery of an injection and only shows the achieved results of that injection. The Results screen is displayed for either 21 minutes or until the [Main] key is pressed. Refer to Figure 3-1-18.

Pressing the [Results] key (Ⓓ in Figure 3-1-2) , however, displays the results of the last 24 injections (on the console screen only) along with the protocol's settings. Refer to Figure 3-1-18.

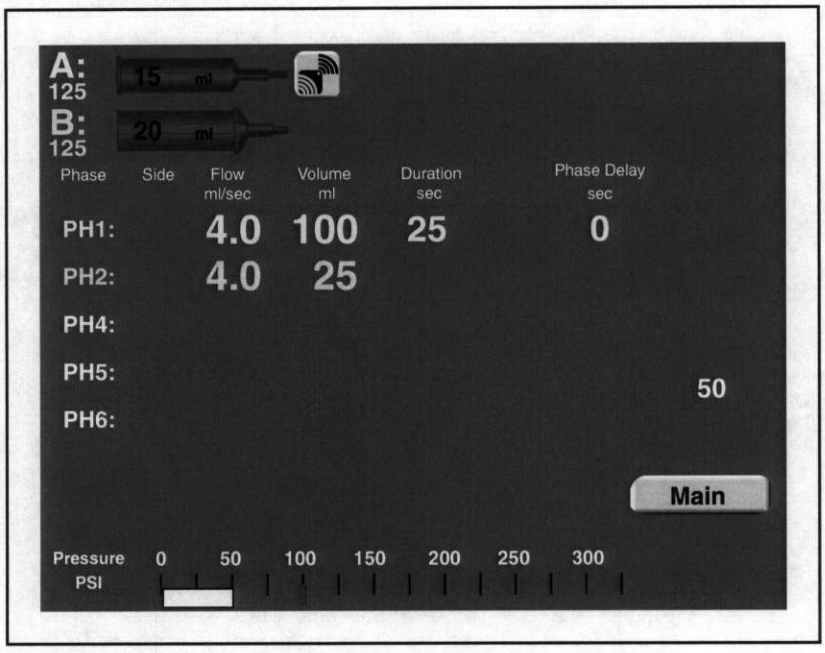

Figure 3-1-18 Results Screen displayed after delivery of an Injection

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Figure 3-1-19 Results Screen displayed after pressing the [Results] Key

3.2 POWERHEAD

3.2.1 POWERHEAD POWER ON DISPLAY

Refer to Figure 3-2-1.

Power ON Display — With the power supply switch in the ON position, the powerhead display acts as a power ON switch. Simply press and hold down for 2 (two) seconds to turn the injector system ON.

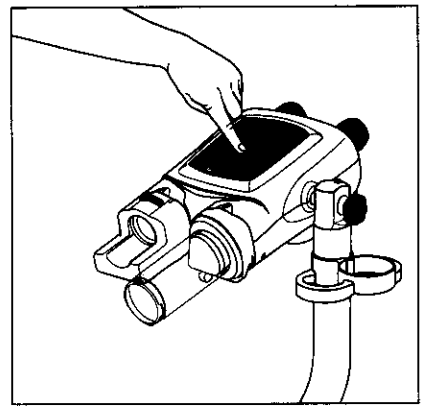

Figure 3-2-1 Powerhead Power ON Display

3.2.2 MANUAL KNOBS

Refer to Figure 3-2-2.

By turning either of the two knobs, the operator can move its respective ram/plunger. This is useful in the instance of purging air from the syringe and when drawing back blood to ensure proper venous placement of the catheter.

Turn the A-side manual knob Ⓐ clockwise to advance the A-side ram/plunger. Turn the B-side manual knob Ⓑ clockwise to advance the B-side ram/plunger. Turn the knobs counterclockwise to retract the ram/plunger. Refer to the following table for the manual knob light status.

Flashing Blue	Injector powering up.
Solid Yellow/Solid Purple	Enabled or injecting contrast (Yellow) or saline (Purple)
Flashing Purple	Injecting saline (Drip Mode)
Flashing Purple or Yellow	Injector paused
Flashing Red	Alarm Condition
Flashing Blue quickly	Injector rotated vertically or 30 degrees below horizontal.

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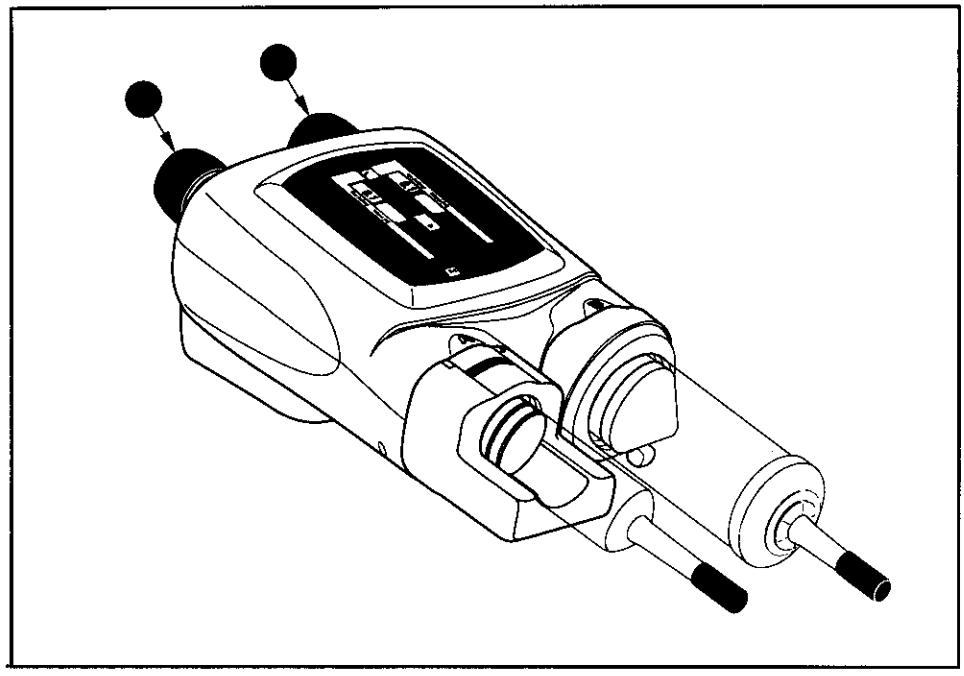

Figure 3-2-2 Powerhead A-side and B-side Indicators

3.2.3 POWERHEAD SYRINGE LOAD LATCHES

Refer to Figure 3-2-3.

125 ml Syringe Load Latch Ⓐ — The latch is pushed up from the bottom to allow loading ⚷ of a 125 ml syringe. Push the latch down to lock ⚷ the syringe in the syringe adapter.

200 ml Syringe Load Latch Ⓑ — The latch rotates counterclockwise to allow loading ⚷ of a 200 ml syringe. Rotate the latch clockwise to lock ⚷ the syringe in the pressure sleeve.

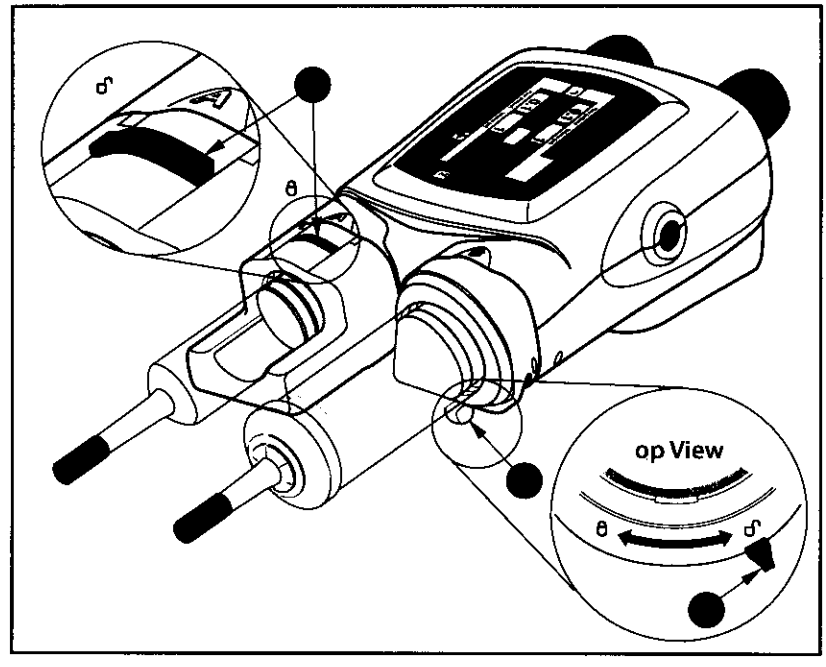

Figure 3-2-3 125 ml Syringe Load Clamp and 200 ml Syringe Load Lever

3.2.4 ENHANCED COMMUNICATION / HEATER BLANKET CONNECTION

Refer to Figure 3-2-4.

125 ml Syringe Adapter

The 125 ml syringe adapter Ⓐ contains a built in heater to maintain the temperature of preheated contrast and sensors to read the size of the installed syringe. Connection of the heater blanket/syringe size sensor is as shown in Figure 3-2-4.

200 ml Heater Blanket

The 200 ml heater blanket Ⓑ maintains the temperature of preheated contrast. Connection of the heater blanket is as shown in Figure 3-2-4.

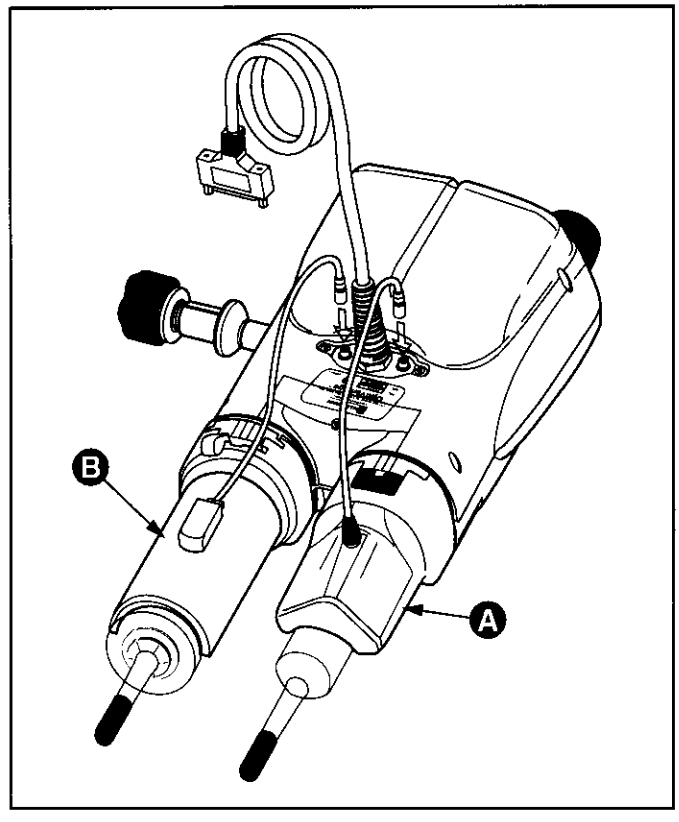

Figure 3-2-4 Heater Blanket Connections

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3.2.5 POWERHEAD DISPLAY MODES OF OPERATION

Refer to Figures 3-2-5 and Figure 3-2-6.

Main Screen — The Powerhead Main screen Ⓐ is shown in Figure 3-2-5. Only the first phase of the A-side and the B-side is displayed on the Powerhead Main screen. The complete protocol is displayed on the expanded Protocol Parameter Entry screen Ⓒ.

Fill/Expel Arrows — Two [Syringe] keys Ⓑ, located in the upper and lower portion of the Main screen, change to the fill/expel arrows as shown in Figure 3-2-5. Press on the [Syringe] key to activate the fill/expel arrows.

Pressing on the active fill/expel arrows will retract/expel the ram at a rate that is proportional to the position touched in a range from 0.5 ml/sec to 15 ml/sec. Pressing the fill arrows for longer than 2 seconds will latch plunger movement. Once plunger movement has latched on, press anywhere on the powerhead display to cease plunger movement. Refer to Figure 3-2-6. Note: The fill/expel arrows do not appear if the injector is enabled.

Protocol Parameter Entry Screen Ⓒ — To access the Protocol Parameter Entry screen, press any parameter key Ⓓ located on the Powerhead Main Screen. The Protocol Parameter Entry screen allows modification of the parameters as well as access to the Memory screen. To access the Powerhead Main screen when displaying the Protocol Parameter Entry screen, press the [Main] key Ⓕ located on the lower portion of the screen.

Enabled Main Screen — The Enabled Main screen allows for the delivery of the main protocol, a Patency Check, or a Drip Mode Injection.

Memory Screen — All stored protocol information is located on the Memory screen. Displaying the Powerhead Memory screen allows the operator to only recall protocols. Storing, renaming and deleting protocols is only available on the console Memory screen. To access the Powerhead Memory screen, press the [Memory Ⓔ key located on the lower portion of the Protocol Parameter Entry screen as shown in Figure 3-2-5. When the Memory screen is displayed, press the [Main] key Ⓕ to display the Main screen.

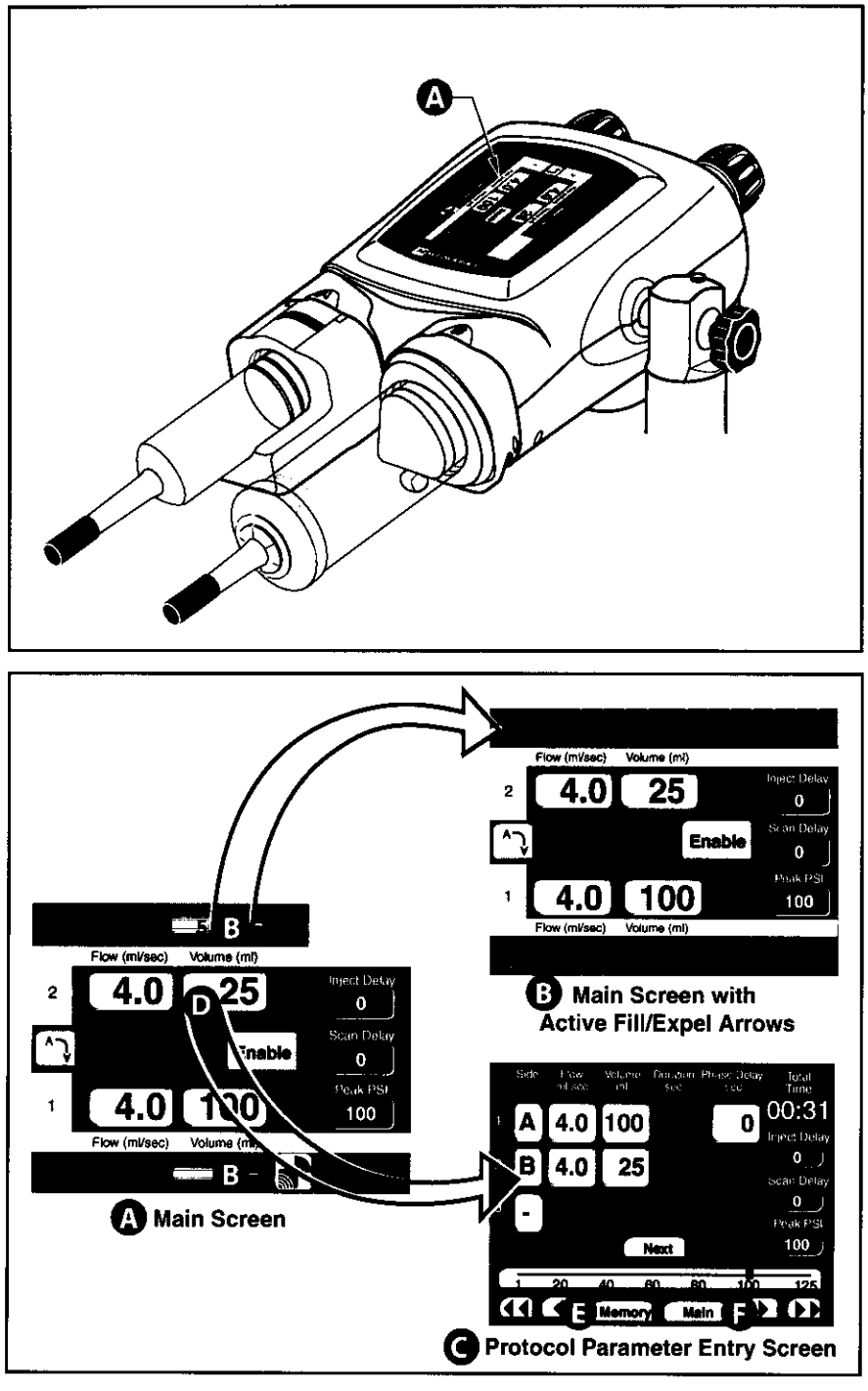

Figure 3-2-5 Powerhead Interfaces

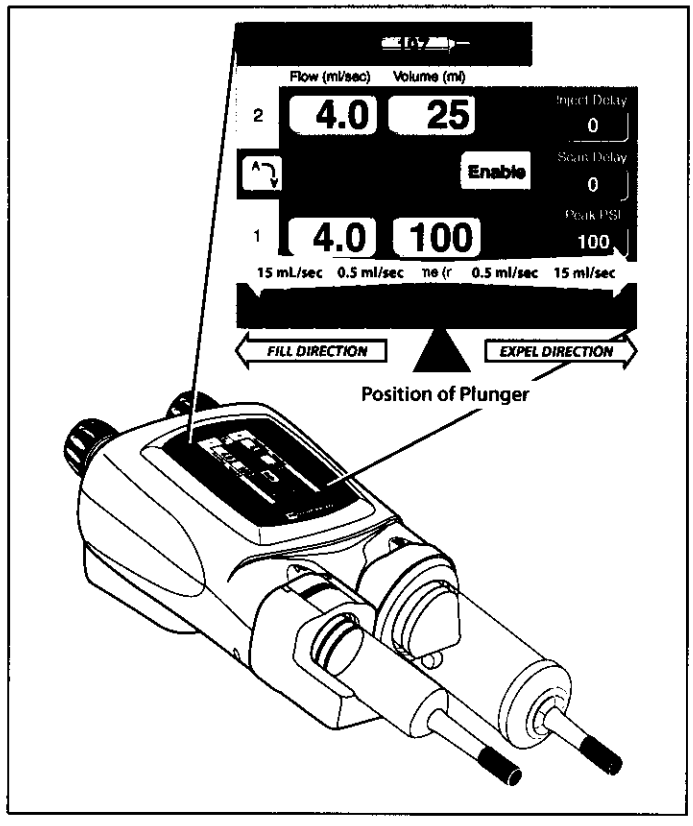

Figure 3-2-6 Fill/Expel Arrow Range of Speed

3.2.6 POWERHEAD MAIN SCREEN

Refer to Figure 3-2-7 and Figure 3-2-8.

A-Side Syringe (mL)/A-side Fill/Expel arrows Ⓐ — The syringe symbol indicates the relative position of the plunger in the syringe thus indicating how much fluid may be in the A-side syringe. Pressing the syringe symbol activates the A-side Fill/Expel arrows in order to move the ram/plunger.

RFID Active Ⓐ$_1$ — This key allows the operator to view attributes of any installed Ultraject syringe fitted with a syringe data tag. The RFID icon will de-highlight if an installed syringe does not contain a syringe data tag. Once the [RFID Active] key Ⓕ$_1$ is pressed, the screen shown in Figure 3-2-8 is displayed.

B-Side Syringe (mL)/B-side Fill/Expel arrows Ⓑ — The syringe symbol indicates the relative position of the plunger in the syringe thus indicating how much fluid may be in the B-side syringe. Pressing the syringe symbol activates the B-side Fill/Expel arrows in order to move the ram/plunger.

Fill/Expel arrows — Upon pressing either the A-side Ⓐ or B-side Ⓑ [Syringe] keys as shown in Figure 3-2-5, the fill/expel arrows are activated. Pressing on the fill/expel arrows will retract/expel the ram at a rate that is proportional to the position touched in a range from 0.1 ml/sec to 15 ml/sec. Pressing the retract fill arrows for longer than 2 seconds will latch ram retraction movement. Once ram retraction movement has latched on, the arrows will turn green and have a white background. Press anywhere on the powerhead display to cease latched movement. See Figure 3-2-6.

1 (1st Phase) Ⓒ — The 1 indicates the first phase of the protocol. Contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple. To access the remaining protocol information, press any parameter key to display the Protocol Parameter Entry screen as shown in Figure 3-2-5.

2 (2nd Phase) Ⓓ — The 2 indicates the second phase of the protocol. If only a one phase protocol is programmed, the 2 will revert to a B to indicate the B-side. Contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple. To access the remaining protocol information, press any parameter key to display the Protocol Parameter Entry screen as shown in Figure 3-2-5.

Display Orientation Ⓔ — To view the powerhead display from either the A-side or the B-side, the [Display Orientation] key allows the screen to flip as shown in Figure 3-2-9.

Flow Ⓕ — The values shown in this column indicate rate of delivery during each respective phase. When delivering a protocol, the values reflect the flow rate of the current phase being injected. Flow is expressed in milliliters/second.

Volume Ⓖ — The values entered in this column indicate the volume to be delivered during each phase. When delivering a protocol, the values reflect the volume of the current phase being injected. Volume is expressed in milliliters.

Protocol Name Ⓗ — The name of the protocol currently displayed on the Main Screen.

Enable Ⓘ — **Only active after proper enabling sequence is followed and when the powerhead is tilted downward**, pressing this key "enables" or readies the injector for delivery of a protocol.

Inject Delay Ⓙ — Inject Delay is a count down timer that begins counting when the Start command is activated. The injection is started when the inject delay counter reaches 0 (zero). If Inject Delay is greater than 0 (zero), Scan Delay is automatically set to 0 (zero). Inject Delay is expressed in seconds.

Scan Delay Ⓚ — Scan Delay is a count down timer that begins counting when the Start command is activated and stops when the counter reaches 0 (zero). The scan start signal will initiate once the timer reaches 0 (zero). If Scan Delay is greater than 0 (zero), Inject Delay is automatically set to 0 (zero). Scan Delay is expressed in seconds.

Peak PSI Ⓛ — The value set in this key indicates the maximum allowable pressure that can occur during an injection. Pressure is expressed in either PSI or kPa. Refer to section *3.1.6 Setup Screen Parameters and Symbols for* more information about changing the unit of measure.

Check for Air message Ⓜ — This message acts as a reminder to the operator to confirm no air exists in the syringe and tubing prior to enabling an injection.

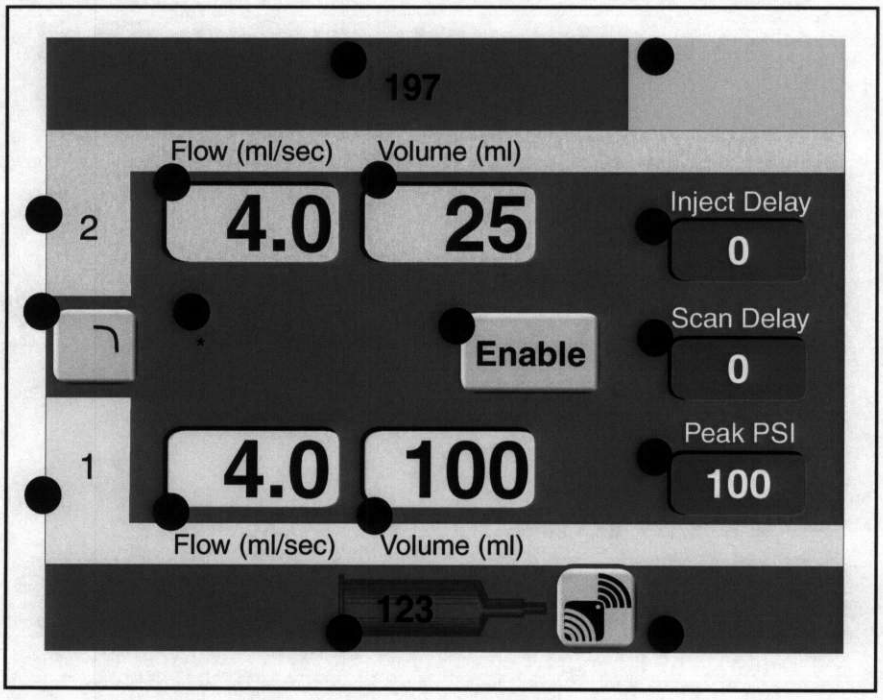

Figure 3-2-7 Powerhead Display Main Screen

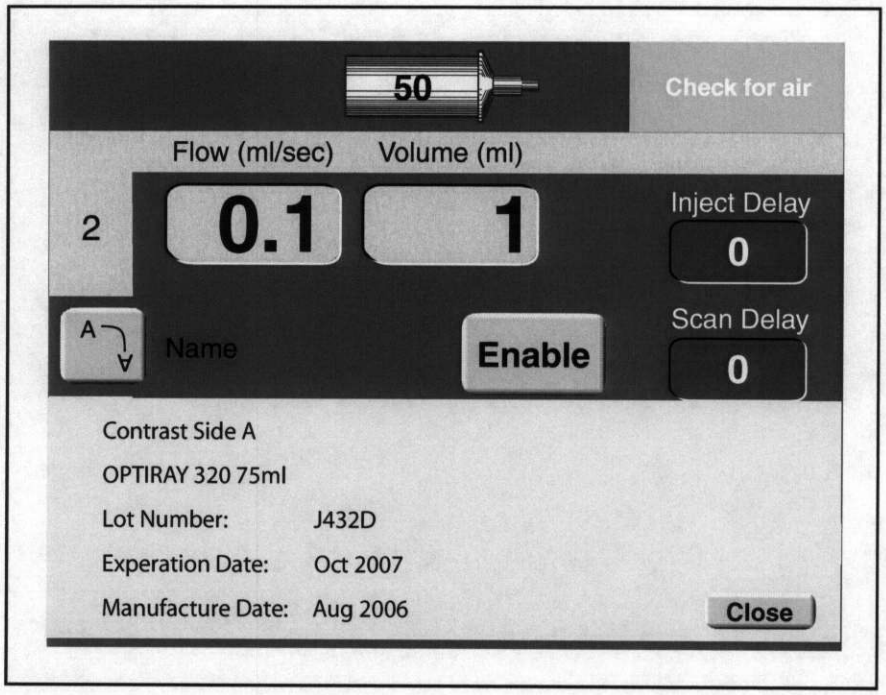

Figure 3-2-8 RFID Syringe Information

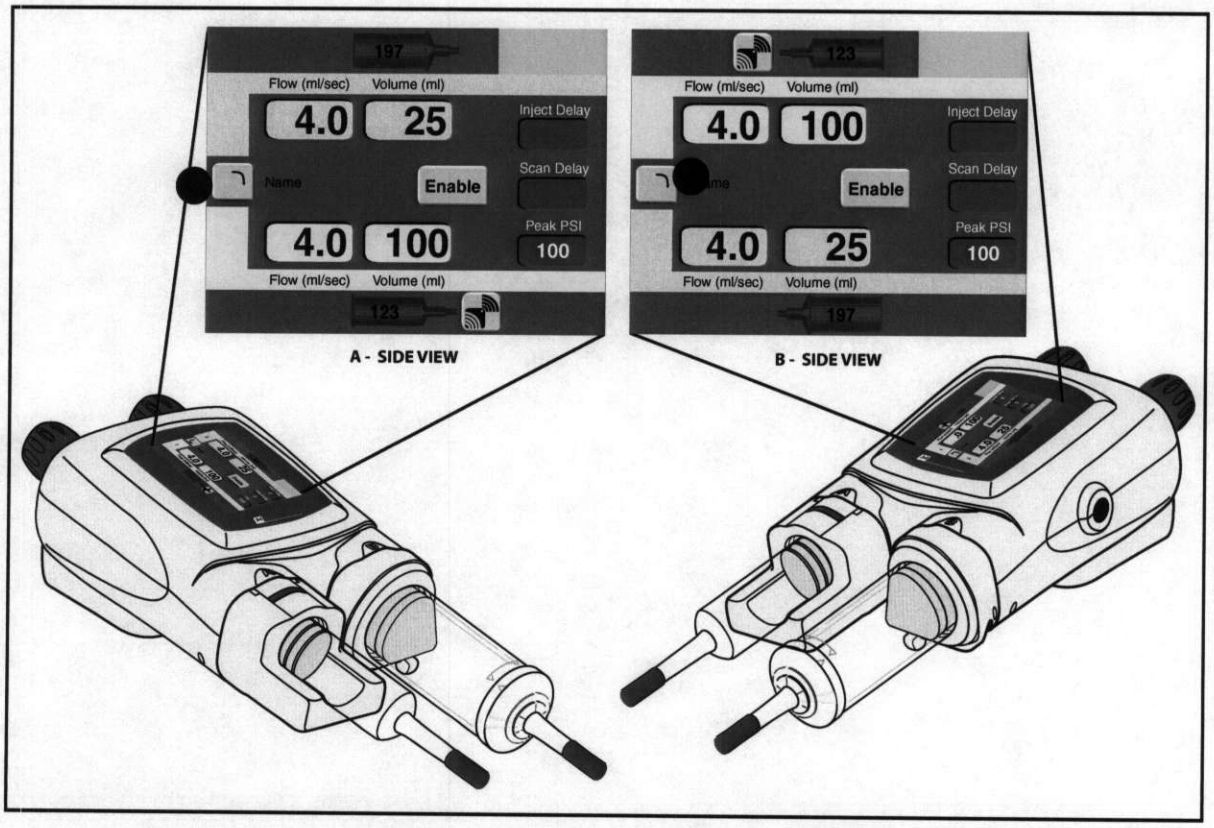

Figure 3-2-9 A-side Display or B-side Display using the [Display Orientation] Key.

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3.2.7 POWERHEAD PROTOCOL PARAMETER ENTRY SCREEN

Refer to Figure 3-2-10.

All protocol information needed by the injector is contained within the expanded Protocol Parameter Entry screen. The Protocol Parameter Entry screen allows the parameters to be modified via the slide bar. To access this screen, press any parameter key located on the Main Screen as shown in Figure 3-2-5.

Phase Ⓐ — Within a protocol, up to six phases can be input. Press the [Next] key Ⓚ to view the next 3 phases.

Side Ⓑ — These keys toggle among the following symbols: [A], [B], [-]. Pressing an [A] key will toggle the key to a [B] key, thus indicating injecting from the B-side. Pressing a [B] key will toggle the key to a white [-], indicating no injecting for and past that phase. Pressing a white [-] key will toggle the key to a [A] key, thus indicating injecting from the A-side.

Flow Ⓒ — The values entered in this column indicate rate of delivery during each respective phase. Flow is expressed in milliliters/second.

Volume Ⓓ — The values entered in this column indicate the volume to be delivered during each respective phase. Volume is expressed in milliliters.

Duration Ⓔ — The value in this column indicates the duration of an injection (i.e., time to complete injection in seconds) based on the previously entered volume and flow rate values. Duration is displayed in the nearest whole second.

Phase Delay Ⓕ — Phase Delay is a count down timer that delays the start of the next phase. The next phase will start when the phase delay counter reaches 0 (zero). Phase Delay is expressed in seconds. Phase Delay can also be set to pause the injection. Access the Pause feature by scrolling past either the 0 (zero) lower limit or the 600 (six-hundred) upper limit.

Total Time Ⓖ — The Total Time field is an accumulation of all the calculated Duration and input Phase Delay fields for all phases. After the [Start] key is pressed, the total time field starts counting from 0 and continues to count after the injection is completed as long as the Results screen is displayed or up to 21 minutes. Total time is expressed in minutes:seconds.

Inject Delay Ⓗ — Inject Delay is a count down timer that begins counting when the [Start] key is pressed. When Inject Delay reaches 0 (zero), the injection is started. If Inject Delay is set with a value greater than 0 (zero), Scan Delay is automatically set to 0 (zero). Inject Delay is expressed in seconds.

Scan Delay Ⓘ — Scan Delay is a count down timer that begins counting when the [Start] key is pressed. The scan start signal will initiate once the timer reaches 0 (zero). If Scan Delay is set with a value greater than 0 (zero), Inject Delay is automatically set to 0 (zero). Scan Delay is expressed in seconds.

Peak PSI (J) — The value set in this key indicates the maximum allowable pressure that can occur during an injection. Pressure is expressed in either PSI or kPa. Refer to section *3.1.5 Setup Screen Parameters and Symbols* for more information about changing the unit of measure.

Next (K) — *This key is only active when more than 3 phases exist on the Protocol Parameter Entry screen.* Pressing this key displays the next 3 phases of the protocol. The key will then toggle to a [Previous] key to allow access to the first 3 phases of the protocol.

Change Parameter Values via the Slide Bar (L) — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will appear at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Memory (M) — All stored protocol information is located within the Memory screen. Accessing this screen allows the operator to recall protocols. To access the Memory screen, press the [Memory] key located on the lower portion of the screen. For more information, refer to the section *Powerhead Memory Screen* in this chapter.

Main (N) — Pressing this key displays the Powerhead Main Screen.

OptiBolus (optional) (O) — *This key is only active if a port-key is present at the OptiBolus port located on the rear of the power supply.* Pressing this key allows the operator to program an OptiBolus injection. The OptiBolus Mode delivers an exponentially decaying flow rate injection that optimizes the contrast usage and provides an extended period of uniform enhancement of the area of interest. Once the [Optibolus] key (O) is pressed, the screen shown in Figure 3-2-11 is displayed. Note the addition of "O" (OptiBolus) (Q) to the left of the first phase. End Flow Rate is a function of the Optibolus mode and is automatically calculated by the OptiVantage for the entered parameters and is displayed only on the console Main screen.

Timing Bolus (P) — *This key is only active if turned ON at the Setup Screen and when 4 or less phases are programmed in a protocol.* Pressing this key allows the operator to program a Timing Bolus injection. A Timing Bolus injection--an injection of a small volume of contrast, followed by a small volume of saline--can be delivered to the patient to determine the optimal scan delay needed to capture the contrast agent in the are of interest. Once the [Timing Bolus] key (P) is pressed, the screen shown in Figure 3-2-12 is displayed. Note the addition of "T" (Timing Bolus) (R) to the left of the first and second phase.

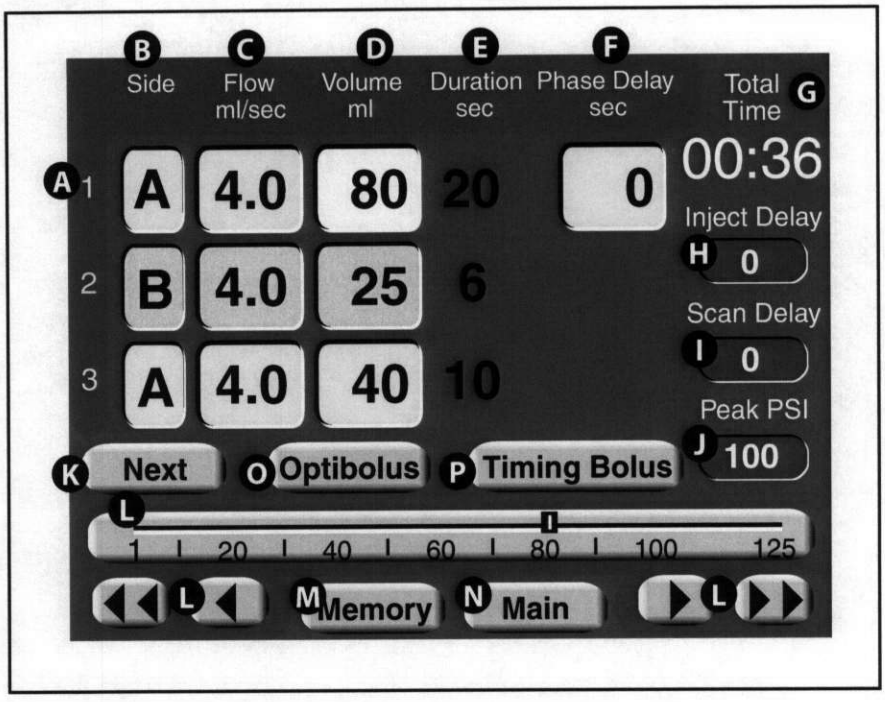

Figure 3-2-10 Powerhead Protocol Parameter Entry Screen

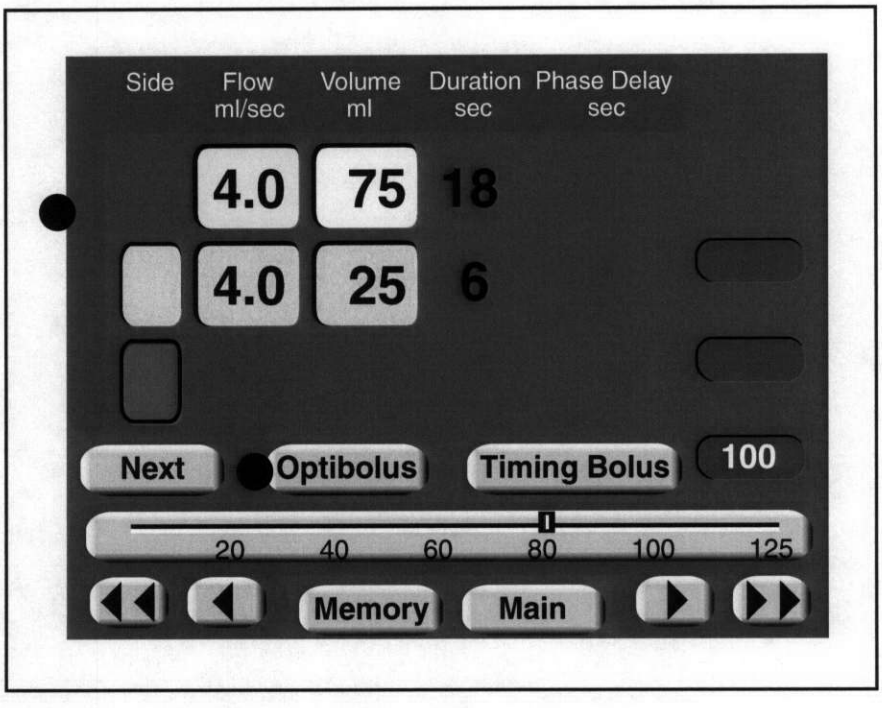

Figure 3-2-11 Powerhead OptiBolus Injection

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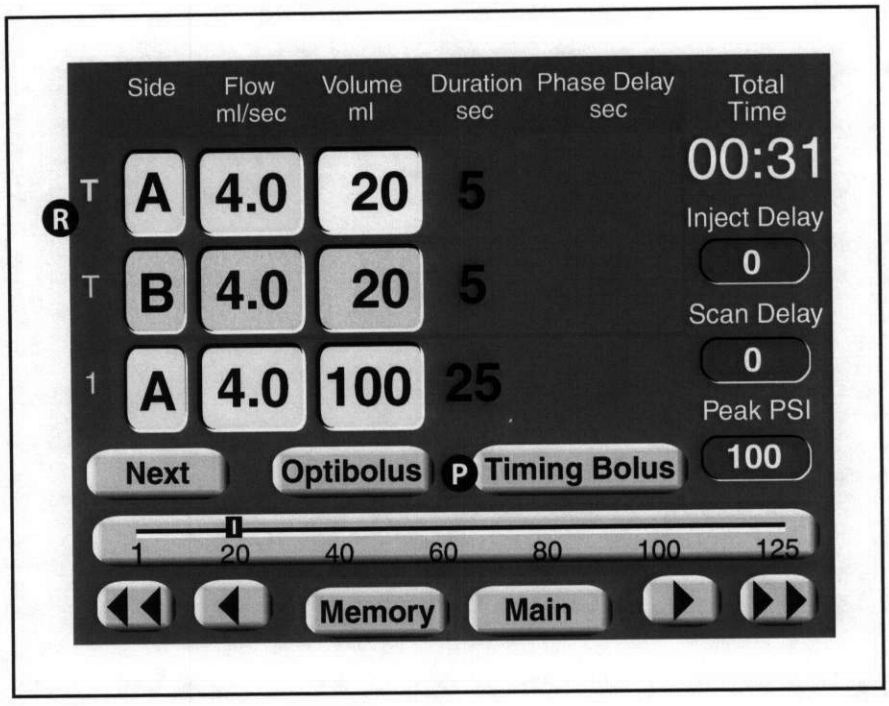

Figure 3-2-12 Powerhead Timing Bolus Injection Screen

3.2.8 ENABLED POWERHEAD MAIN SCREEN

Refer to Figure 3-2-13.

Once the [Enable] key is pressed, the Powerhead Main screen displays an Enabled screen as shown in Figure 3-2-1.

Start Ⓐ — Pressing the [Start] key begins the delivery of the protocol. This key is functionally interchangeable with both the [Stop] key and the [Start] key on the console and the optional Handswitch.

Disable Ⓑ —The [Disable] key disables the enabled injector.

Protocol Parameters Ⓒ — The protocol parameter entry keys are active and can be changed as needed without disabling the injector.

Patency Ⓓ — *This key is only active if turned ON at the Setup Screen.* The [Patency] key is available to deliver a Patency Check--an injection of a small volume of saline--to determine the integrity of the I.V. site. Refer to Figure 3-2-1.

Drip Ⓔ — *This key is only active if turned ON at the Setup Screen.* The [Drip] key is available to deliver a Drip Mode Injection--a low flow rate injection of a small volume of saline--to keep the fluid pathway open. Refer to Figure 3-2-15.

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A-Side Syringe (mL) and B-Side Syringe (mL) (F) — These symbols indicate the relative position of the plunger in the syringe thus indicating how much fluid may be in the syringes. Once the injector is enabled, the fill/expel arrows will not appear when the A-side Syringe symbol or the B-side Syringe symbol is pressed.

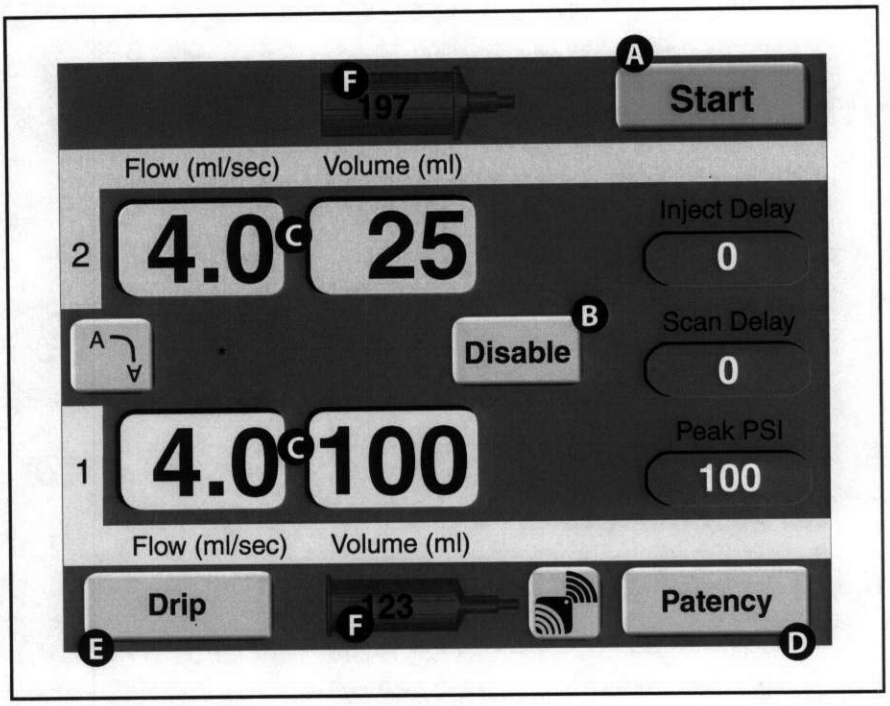

Figure 3-2-13 Powerhead Enabled Main Screen Keys and Definitions

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Patency Check Screen

Refer to Figure 3-2-14.

Prior to the delivery of the main injection, a Patency Check--an injection of a small volume of saline--can be performed to determine the integrity of the I.V. site. The Patency Check feature is only accessible from the Powerhead Enabled Main Screen.

To access the Patency Check screen as shown in Figure 3-2-14, press the [Patency] key Ⓓ located on the Powerhead Enabled Main screen as shown in Figure 3-2-13.

B (side) Ⓐ — Patency check can only be delivered from the saline side. (In Figure 3-2-14, the B-side is set up as the saline side.)

Patency Check Flow Ⓑ — This value indicates rate of delivery of the saline. Patency check flow rate, expressed in milliliters/second, will automatically be set to the greatest value occurring in the enabled protocol. The value can be modified by the operator.

Patency Check Volume Ⓒ — This value indicates the volume of saline to be delivered. Patency check volume, expressed in milliliters, is initially set to the default value as defined in the Set Up screen. The value can be modified by the operator. If the value is set for an amount that compromises the enabled protocol, the [Patency Check Volume] key background will flash a magenta color and the [Start Patency] key will be removed from the screen.

Change Parameter Values via the Slide Bar Ⓓ — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Start Patency Ⓔ — This key starts the patency check injection. For more information about delivering a patency check injection, refer to Chapter 5.

Exit Ⓕ — This key disables the patency check screen and displays the Enabled Main screen.

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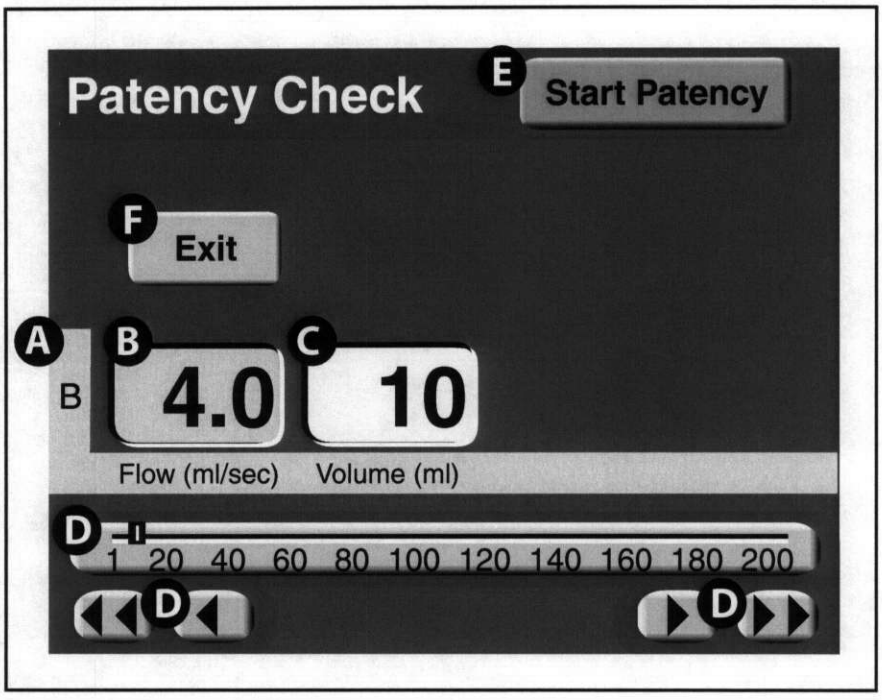

Figure 3-2-14 Powerhead Patency Check Screen

Powerhead Drip Mode Screen

Refer to Figure 3-2-15.

The Drip Mode allows the injector to deliver a "drip" injection to keep the fluid path open during patient set up and between injections of contrast. The Drip Mode is accessible from either the Console Enabled Main Screen or the Powerhead Enabled Main Screen.

To access the Drip Mode screen as shown in Figure 3-2-15, press the [Drip] key Ⓔ located on the Enabled Main screen as shown in Figure 3-2-13.

Side Ⓐ — The Drip injection can only be delivered from the saline side. (In Figure 3-2-15, the B-side is set up as the saline side.)

Drip Mode Flow Ⓑ — This value indicates rate of delivery of the saline. Drip Mode flow is expressed in milliliters/second. The value can be modified by the operator.

Drip Mode Volume Ⓒ — This value indicates the volume of saline to be delivered during each drip injection. Drip Mode volume is expressed in milliliters. The value can be modified by the operator. If the value is set for an amount that compromises the enabled protocol, the [Drip Mode Volume] key background will flash a magenta color and the [Start Drip] key will be removed from the screen.

Interval Ⓓ — This value indicates the amount of time the injector pauses between each delivery of drip injections. Drip Mode interval is expressed in seconds.

Change Parameter Values via the Slide Bar Ⓔ — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Drip Time Ⓕ — Calculated automatically by the injector by using the programmed Flow, Volume and Interval values and the Drip Volume, this value indicates the amount of time the Drip Injection will require. Once the [Start Drip] key is pressed, the value counts down until it reaches zero. Once Drip Time reaches zero, an audible signal will indicate to the operator that the Drip Injection is complete.

Drip Volume Ⓖ — Calculated automatically by the injector by subtracting the programmed Volume of the main protocol (saline side) from the syringe volume (saline side), this value indicates the amount of saline the Drip Injection can inject. Drip Volume is expressed in ml.

Start Drip ❽ — This key starts the drip injection. For more information about delivering a drip injection, refer to Chapter 5.

Exit ❾ — This key disables the drip injection and displays the Enabled Main screen.

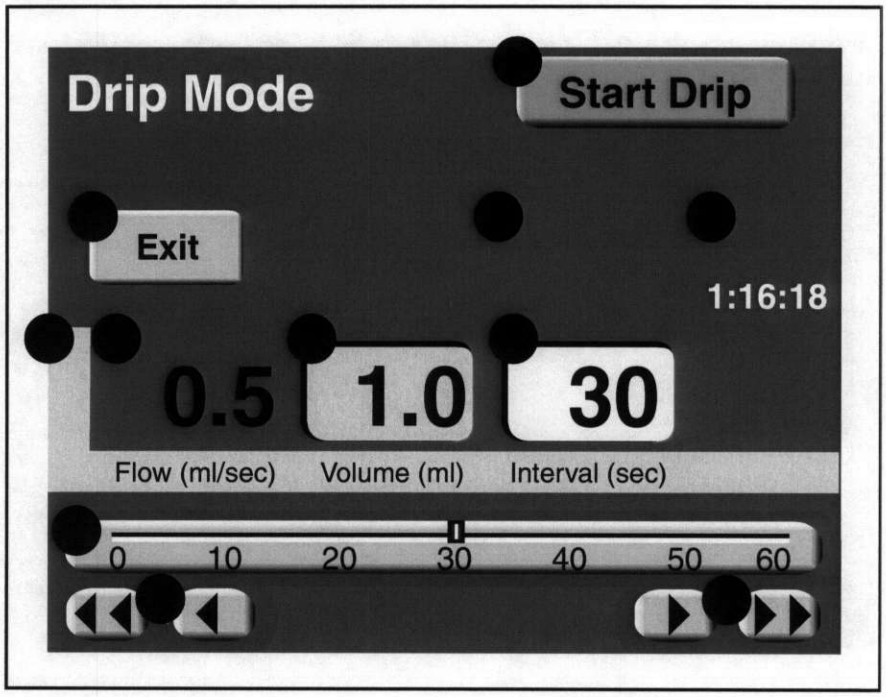

Figure 3-2-15 Powerhead Drip Mode Screen

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3.2.9 POWERHEAD MEMORY SCREEN

Refer to Figure 3-2-16.

Memory Location Ⓐ — Eight protocols are listed per page. Each protocol can have a name consisting of up to 20 alpha-numeric characters. OptiBolus protocols are indicated by the "OptiBolus" logo located on the key.

Protocol Parameters Ⓑ — Each protocol can contain up to six phases. Once a protocol key is highlighted, the protocol parameters are displayed in this area.

Memory Page Number Ⓒ — The memory screen contains five pages with eight protocols listed per page.

Main Ⓓ Pressing this key displays the Powerhead Main screen.

Recalling a Protocol

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the powerhead Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) on which the Protocol is stored.
3. Press the Protocol's corresponding key to highlight Ⓔ, then press the [Select] key Ⓕ. The protocol will be immediately displayed on both the powerhead display and the console display.

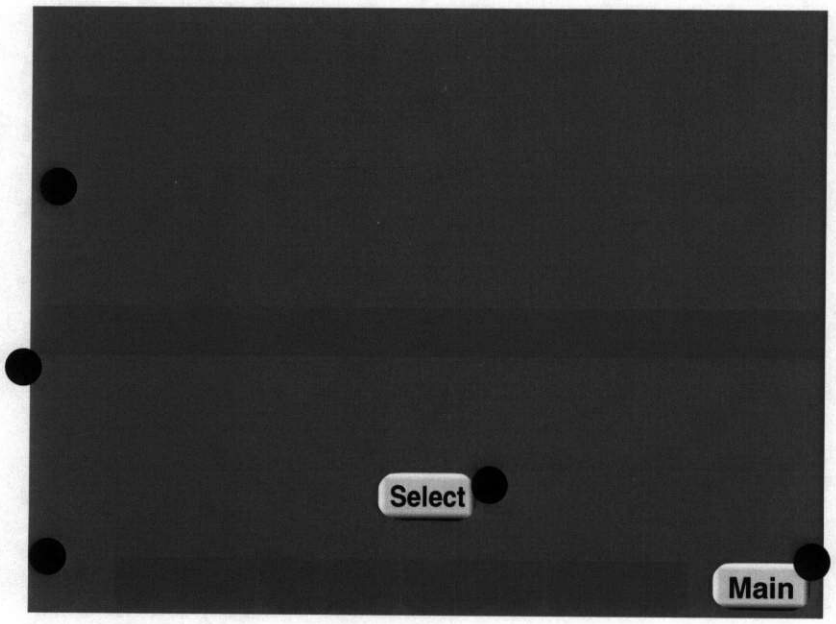

Figure 3-2-16 Powerhead Memory Screen Keys and Definitions

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3.2.10 POWERHEAD RESULTS SCREEN

Refer to Figure 3-2-17.

The Results Screen as shown in Figure 3-2-17 is automatically displayed after the delivery of an injection and only shows the achieved results of that injection. The Results screen is displayed for either 21 minutes or until the [Main] key is pressed.

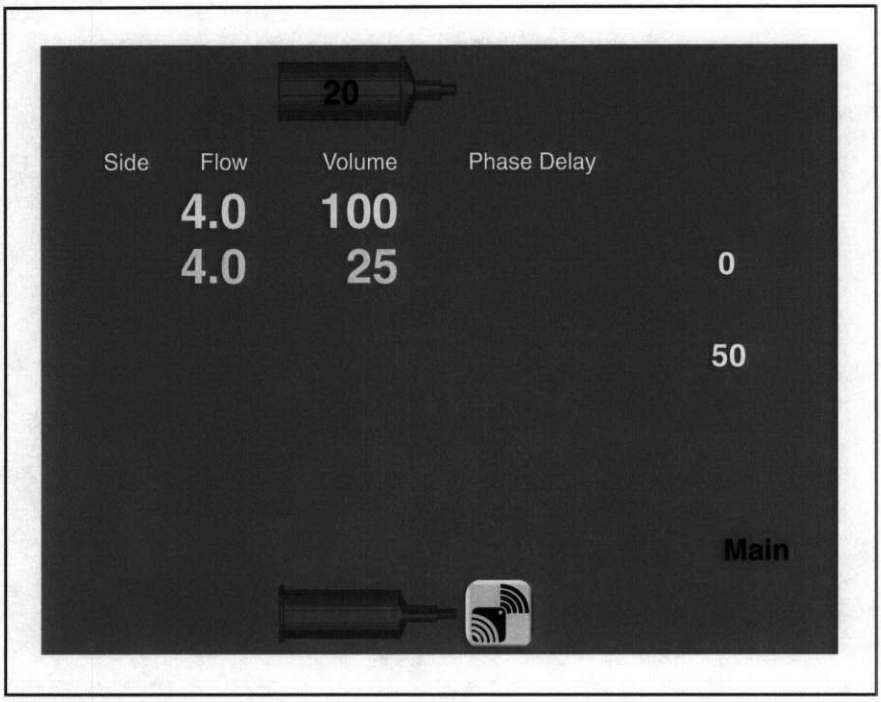

Figure 3-2-17 Results Screen displayed after delivery of an Injection

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

April 26, 2007

From: Reviewer(s) - Name(s) Kimberly Bowie Peters

Subject: 510(k) Number K063503/S2

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. See attached review
- ☐ 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 (Section 11, p.26)

☑ A 510(k) summary OR ☐ A 510(k) statement Appendix #1

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

☑ The indication for use form (S1, Attachment 14)

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):

74 IZQ Class II § 870.1650 Injector, Contrast Medium, Automatic

Review: Ashley B. Boam ICOB 4/26/07
(Branch Chief) (Branch Code) (Date)

Final Review: Donna R. Lechner 4/27/07
(Division Director) (Date)

Revised: 4/2/03

4

See attached review form

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.

6

See attached review form

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?	NA	
4. If, not, has POS been notified?	NA	
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)?	NA	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	NA	
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.	NA	

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K063503/S2

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
   OptiVantage DH Injection System (K042744) (Section 4, page 12)

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
   The indications for use statement is provided in Section 2 (page 8) of the submission and is as follows:

   "The OptiVantage DH Injector System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e., "CT") equipment."

   The currently marketed OptiVantage DH Injection System (K042744) features the same indications for use statement. (Section 4, page 12)

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
   The change under review in this submission is for the addition of the RFID function to the OptiVantage DH Injection System only. A description of the modifications being made for the development of the OptiVantage DH with Enhanced Communication is included in the meeting minutes information and in S1.

   The addition of the RFID tags to the prefilled syringes (Optiray) will be addressed in a Changes Being Effected-30 (CBE-30) supplement to NDA 19-710 submitted to CDER, and the submission is to include information supporting that there is no impact to the Optiray, as well as documentation supporting RFID tag specifications, control, validation, and function. The CBE-30 should also "provide data describing the master validation plan for Optiray, RFID tag, and OptiVantage." As noted in the 12/11/06 email from Guirag Poochikian of CDER (copy in S0), the firm has not submitted the CMC portion for the Optiray prefilled syringe. The CDER/ONDQA post-approval review division told the firm to submit to CDRH first so the device aspects are in order and then the CMC studies could be appropriately designed. S2 of the submission indicates that the addition of the RFID feature to the prefilled syringes was addressed in a prior approval supplement, Sodium Chloride Injection, USP 0.9% NDA 21-569, supplement 2, submitted 3/13/07.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and specifications.
   Comparison information is included in Section 4

5. A **Design Control Activities Summary** which includes:
   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
      Section 7 (pages 16-21) - The submission indicates that the risk management process is performed in accordance with Work Instructions QSEWI22, Risk Analysis and QSEWI12, Failure Modes and Effects Analysis. A description of the work instructions is provided in S1.

b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

The summary of the verification and validation activities is provided in S1. Complete testing information was requested due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

c) A declaration of conformity with design controls. The declaration of conformity should include:
   i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
   ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

(Section 9, page 24)

6. A **Truthful and Accurate Statement** *(Section 11, page 26)*, a **510(k) Summary** *(Appendix I)* **or Statement** and the **Indications for Use Enclosure** *(S1, Attachment 14)* **(and Class III Summary for Class III devices).**

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K063503/S2

Reviewer: Kimberly Bowie Peters

Consulting Reviewer: Ann Ferriter, DGRND/OSDB (Consulting review on injector RFID capabilities)

Division/Branch: DCD/ICDB

Device Name: OptiVantage DH Injector System with Enhanced Communication

Product To Which Compared (510(K) Number If Known): K042744

History of Submission:

This submission includes a special 510(k) submission for the OptiVantage DH Injector System with Enhanced Communication. On May 9, 2006, there was a meeting between Mallinckrodt and CDER to discuss a proposed submission strategy regarding the used of Radio Frequency Identification (RFID) tags placed on Optiray (ioversol injection) pre-filled syringes (NDA 19-710). Ms. Ann Ferriter of DGRND/OSDB was the CDRH representative for this meeting, since Ms. Ferriter has expertise in the review of RFID devices. The meeting minutes (prepared and provided to the firm by CDER) are included in the submission (S0, after the cover letter). During the meeting, the firm was informed that the change to incorporate RFID to the injector system would qualify as a special 510(k), and the submission should address the hardware and software necessary for reading and writing the tag information, as well as integration of the tag information into the existing software that controls the contrast administration. The changes to the Optiray should be submitted as a Changes Being Effected-30 (CBE-30) supplement to NDA 19-710, and the submission should include information demonstrating that there is no impact to the Optiray, as well as documentation supporting RFID tag specifications, control, validation, and function. The CBE-30 should also "provide data describing the master validation plan for Optiray, RFID tag, and OptiVantage." As noted in the 12/11/06 email from Guirag Poochikian of CDER (copy in S0), the firm has not submitted the CMC portion for the Optiray prefilled syringe. The CDER/ONDQA post-approval review division advised the firm to submit to CDRH first so that the device aspects are addressed and then the CMC studies could be appropriately designed.

Indications for Use:

The OptiVantage DH Injector System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e., "CT") equipment.

The currently marketed OptiVantage DH Injection System (K042744) features the same indications for use statement.

Device Description

The device description information is provided in Section 3 of the submission as well as in the background information provided for the 5/9/06 meeting between FDA/CDER and Mallinckrodt.

The OptiVantage DH Injector System with Enhanced Communication delivers radiographic contrast media and/or saline at a controlled flow rate and volume into a patient's vascular system for the purpose of obtaining enhanced diagnostic images. Like the predicate device (K042744), the OptiVantage DH Injector System with Enhanced Communication consists of 4 main components:

- Power Head – The power head contains 2 electromechanical syringe drive systems, the syringe holding mechanisms, the main processor, control electronics, control keypad for programming and initiating injection protocols, a status display, and 2 purge/retract manual knobs. The OptiVantage uses a drive system uses a motor and gearbox coupled to a ball screw. The ball screw drives a ram that attaches to the syringe plunger in order to fill or expel the contents of the syringe.
- Power Supply – The power supply converts the line voltage to the working voltage for the power head and console.
- Console – The console communicates with the power head to program and initiate injection protocols, displays the injection status, and displays a timer.
- Syringes – The OptiVantage DH Injector System with Enhanced Communication accommodates the Mallinckrodt 125ml pre-filled syringe styles as well as a 200ml front loading empty syringe. These are the same syringes currently used with the predicate device.

The submission (page 2 of 5/8/06 background information provided for 5/9/06 meeting) indicates that the RFID electrical hardware has been designed by Tyco Healthcare using an IC from B4 [redacted]. The hardware is designed to use the ISO 15693 Wireless Protocol (operating at a frequency of 13.56MHz), and radiates a maximum of 150mW from one of two antennas. The system has the capability to read an RFID tag using the ISO 15693 protocol. B4 [redacted] supplies the RFID tags, which are integrated into a label supplied by B4 [redacted]. The submission (page 4 of 5/8/06 background information provided for 5/9/06 meeting) indicates that integration of the RFID functionality will require a faceplate upgrade and a new software release.

The wireless connector only exists between the injector faceplate and the syringe RFID tag. The system features allow the transfer of drug product name, concentration, fill volume, drug lot number, manufactured date, expiration and used/unused status from the syringe to the injector. The injector will write back to the syringe that use has occurred. No patient information will be exchanged.

The submission (page 9) indicates that specifications and information regarding the syringe and labels, RFID tags, and data used by the RFID system are included in Appendices C, D, and G. Appendix C includes the syringe labels and package inserts. Appendix D includes the RFID Syringe, tag, and data specifications.

The submission (page 2 of 5/8/06 background information provided for 5/9/06 meeting) indicates that the RFID system has been designed to meet FCC 15.225 requirement: "Section 15.225 Operation within the band 13.553-13.567MHz." The submission indicates that testing with an accredited EMC test facility has shown that the RFID system meets these requirements.

With regard to verification of the coexistence, data integrity, security and performance requirements, the submission (page 3 of 5/8/06 background information provided for 5/9/06 meeting) indicates that ISO 15693 protocol (RFID data protocol) specifies both data integrity checks and collision detection mechanisms for data transfer. Collision of data can occur when 2 or more RFID tags are within the read field. Data transmission errors can occur if an RFID tag is damaged or if it is outside the read range. The submission indicates that tests have been performed to ensure: 1) RFID tags entering the manufacturing facility are functional and have correct data encoded; 2) RFID tags on syringes leaving the manufacturing facility are functional and have correct data encoded; 3) the RFID reader on the injector system can reliably read functional tags on an inserted syringe.

In addition, a calculated cyclic redundancy check (CRC) or checksum value is written to the tag each time data is stored on the tag to ensure data integrity. The injector will verify the checksum values to ensure the data has not been changed or damaged since leaving the syringe manufacturing facility. The read-only data fields on the tag (i.e., expiration date) are locked, preventing any change after being written by the factory. All wireless data transfers between the faceplate and the injector also have a checksum to ensure data integrity. In the event that a tag cannot

be read or the data is corrupt, the injector panel displays messages to notify the user.

If a wireless connection cannot be established, the injector reverts to its current mode of operation.

Bench Testing Information:
Appendix D (pages 208-212) includes an engineering report for the label function verification test. The purpose of this test was to determine the failure rate of the B4 [redacted] tags incorporated into the labels manufactured by B4 [redacted]. The sample size for the test was 22605 labels (representing the various Optiray syringe volume and concentration) due to label availability, 22547 labels were read, and 58 tags/labels (0.256%) were determined to be "bad."

Appendix F includes hardware verification testing information. The submission indicates that testing was performed to demonstrate:

- Sufficient antenna read range – This testing was performed on "product equivalent units and was performed to determine how reliably the Optivantage DH could read data from the Optiray syringe's RFID tag. The submission references test report D4284. Report D4284 only includes the test procedure and this report indicates that the results/conclusions are provided in D4297. Complete test reports were requested and are provided in S1.
- Minimal heater temperature (under normal and fault conditions) – The submission indicates that testing was performed to ensure that both the surface temperature and contrast media temperature remained at safe levels if fault conditions occurred. The submission references test report D4294. Report D4294 only includes the test procedure and this report indicates that results/conclusions are provided in D4307. The submission also indicates that "test design recommendations and discussions are presented in D4307 rev B." Complete test reports were requested and are provided in S1.
- Capability to remove the Optiray syringe at any ram position – The submission indicates that a verification test was performed and verified that this requirement was met using production equivalent. The submission references test report D4188. D4188 only includes the test procedure. Complete test reports were requested and are provided in S1.
- Regulatory compliance for an intentional RF transmitter – The submission indicates that all applicable standards for a radio transmitter at 13.56MHz were met, including FCC Section 15.225, FCC Part 15.107, FCC Part 15.109, RSS-210, ICES-003, EN 300 330, and EN 301 489-3. The submission references test report D4291. Report D4291 only identifies the above standards as the test procedure and indicates that "test results shall be documented in D4303." Complete test reports were requested and are provided in S1.

Appendix G includes a 16 hour RF impact study. During this test, the Optiray 350 125ml pre-filled syringes were exposed to controlled RF energy for an extended time at 2 temperature levels. After RF exposure, the syringes will be analyzed to determine if there is any quality impact on the drug product. This information will be reviewed by CDER during the review of the CBE-30 submission.

Appendix H includes RFID System Technology Validation testing information. This test was performed to demonstrate that production equivalent Optiray prefilled syringes with RFID would function correctly in the OptiVantage DH Injector System with Enhanced Communication. The submission indicates that testing was conducted in accordance with test protocol D4406 rev B. The submission (page 368) indicates that the result met all requirements of the protocol. Test report D4406 (page 372) indicates that "test results shall be documented in D4407." Complete test reports were requested and are provided in S1.

Refer to the consulting review from Ann Ferriter for additional details regarding the bench testing.

Software Documentation:
Software information is included in Section 8 (pages 22-23) and Appendix E of the original submission. Complete software documentation was requested and is provided in S1 (see request for additional information section of this review).

The submission (page 22) indicates that The OptiVantage DH Injector System with Enhanced Communication software consists of 3 subsystems:

- Power Head software – Injects fluids at specified volume and flow rate as programmed by the user
- Console software - Displays injector status and allows the user to program and start an injection from a remote location
- Faceplate software – Controls the operation of the RFID reader hardware

In addition to the software features provided with the predicate device, the modified system provides the following additional functions:

- RFID technology allows the injector to "mark" an RFID-enabled syringe as used when an injection is initiated and disallow further use of that syringe.
- RFID technology allows the injector to determine whether an RFID-enabled syringe is expired and prevent further use of that syringe.
- RFID technology allows the injector to obtain drug product attributes from an RFID-enabled syringe (product name, concentration, fill volume, lot number, expiration)

Appendix E includes the "Risk Analysis Software Verification Summary and Protocols." Appendix E only includes a copy of the verification and validation test protocol (D4349).

The submission (page 243) indicates that verification testing was performed on the following development versions of software which implement RFID functionality on the OptiVantage DH Injection System:

- OptiVantage DH Powerhead Software Version: D03.00.10
- OptiVantage DH Console Software Version: D03.00.10
- OptiVantage DH 125ml RFID Faceplate Software Version: D00.08

Request for Additional Information:

Due to the lack of complete bench testing information and software documentation in the original submission (S0), the following information was requested in the 12/21/06 hold letter. The firm's response to the 12/21/06 letter is included in the 2/16/07 submission (S1). Concerns regarding the responses are identified in bold or in the comments section below. If there is no bold notation, the response is adequate.

1. *The device description information does not include a clear description of the modifications made to the currently marketed OptiVantage system for the development of the OptiVantage DH Injector System with Enhanced Communications. Please provide this information which should address both hardware and software modifications. In addition, it is unclear if the RFID feature is only intended to be used with the pre-filled contrast syringes or the pre-filled saline syringes. Please address this issue.*

Response: The response indicates that the only hardware changes from the predicate device are the incorporation of RFID electronics (IC and antenna) in the faceplate to enable communication with the RFID tagged pre-filled syringes. The response indicates that the software modifications enable operation of the RFID hardware and associated safety features. This combination allows the transfer of prefilled contrast and/or prefilled saline syringe attributes (i.e. product name, fill volume, expiry, lot number, manufacture date) to the injector and allows the injector to mark a syringe as "used". The RFID technology does not change how protocols are currently entered or controlled. It does allow the injector to ensure that an unused, unexpired prefilled syringe of the correct volume has been loaded. Should the RFID functionality fail, the injector will notify the user and will continue to operate the same as the predicate device. It should be noted that the response to this deficiency indicates that the RFID feature is intended to be used with both pre-filled contrast syringes and pre-filled saline syringes. The submission indicates that CDER will be reviewing the addition of the RFID feature to the pre-filled contrast syringes. Supplement 2 indicates that the addition of the RFID feature to the pre-filled saline syringes is addressed in a CDER prior approval supplement, Sodium Chloride Injection, USP 0.9% NDA 21-569, Supplement 2, submitted 3/13/07.

2. *Please address the following regarding the bench testing information:*

   a. *You have provided protocols and acceptance criteria for testing the OptiVantage DH Injector System with Enhanced Communication, including D4284 – Sufficient antenna range, D4294 – Minimal heater temperatures, D4188 – Capability to remove syringe, D4291 Regulatory compliance for intentional RF transmitter, and D4406 RFID validation. These reports indicate that the test results and conclusions are provided in separate referenced test reports. Please provide the referenced test reports D4297, D4307, D4304, and D4407 for review, as well as the results for test D4188. Please be advised that the testing information provided for review should testing procedures and protocols, sample size, acceptance criteria, justification for the chosen sample size and acceptance criteria, test results, and an analysis of the results. FDA acknowledges that you have submitted the enhanced communication change in a special 510(k) submission; however, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.*

Response: The response indicates that the requested reports are provided in Attachments 1-5:

- D4284/D4297 RFID Reader Performance Testing – Attachment 1

- D4294/D4307 Heater Performance Testing – Attachment 2
- D4188/D4423 Syringe Removal Test – Attachment 3
- D4291/D4304 EMC/FCC Compliance Testing – Attachment 4
- D4406/D4407 RFID System Technology Validation – Attachment 5

Comment: The bench testing information was reviewed by Ann Ferriter. Ms. Ferriter's memo indicates that the tests for sufficient antenna range, minimal heater temperature, capability to remove syringe, and RFID validation are adequate. Ms. Ferriter's memo did raise concerns regarding the EMC/FCC compliance testing. Ms. Ferriter's concerns were included in the 3/22/07 letter to the firm (see second request for additional information section of this review).

b. *For D4294 – Minimal heater temperatures test, please provide a scientifically valid justification for the acceptance criteria. In addition, the conclusion section for D4294 indicates that "test design recommendations and discussions are presented in D4307 rev B." Please describe these test design recommendations, explain if the test protocol was modified to address these recommendations, if the test was repeated, etc.*

Response: The response indicates that the temperature values in the acceptance criteria were selected based on IEC safety requirements for surface temperature and applied part temperature (IEC 60601 clauses 42.1 and 42.3). The response indicates that the acceptance criteria in D4294 required demonstration that IEC standards were met (compliance certificate is included in Attachment 6). With regard to the statement in the conclusion of D4294, the response indicates that since the product met the acceptance criteria, no changes to the product design were made.

3. *You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.*

Response: The response indicates that the information regarding compliance testing is provided in Attachment 4, D4304.
Comment: Refer to the 3/18/07 consulting review from Ms. Ferriter for a summary of, and concerns regarding, the testing conducted. Ms. Ferriter's review notes that in the manual (Section 1.5.2) the sponsor claims that the device meets radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices; however, the OptiVantage with RFID was tested to EN 301 489-3 for immunity and emission. This issue was raised to the firm in the 3/22/07 letter (see second request for additional information section of this review).

4. *The risk analysis methods and summary information (Section 7) is inadequate. Please identify the risk analysis methods used to assess the impact of the modifications. The submission only indicates that the risk analysis was performed in accordance with work instructions QSEW122 and QSEW112. In addition, please provide a revised summary of the verification and validation activities that includes a description of the methods or tests used, acceptance criteria applied, and an indication of whether the acceptance criteria were met. The summary provided only includes bullets, such as "RFID system-level validation" and "verification testing of enable sequences," indicating that verification testing was performed.*

Response: The response indicates that the risk analysis methods are modeled after ISO 1497:2000(E) Medical Devices, Application of Risk Management to Medical Devices. The response indicates that to identify and evaluate the risks associated with the modifications for RFID, we used the risk analysis and FMEA for the predicate device as a template, and these documents were updated to reflect the addition of the RFID technology. Attachment 7 includes a summary table which traces from identified hazards through risk mitigation requirements to subsystem requirements and corresponding V&V activities.

5. *Please address the following regarding the operator's manual for the OptiVantage DH Injection System with Enhanced Communication. Please provide a revised copy of the operator's manual for review.*

a. *In the OptiVantage DH Injection System with Enhanced Communication operator's manual (pages 28 – 185), you have included information on RFID. To aid the user in avoiding electromagnetic interference problems, please include the transceiver power and field strength at a specified distance in the operator's manual.*

Response: The response indicates that the manual has been revised to include the maximum field strength at a specified distance; however, the transceiver power was not included in the manual. The response indicates that the original manual included both pieces of information, but during the FCC licensing process, the licensing body (American TCB) requested that the transceiver power be removed before they would certify the product and grant the FCC license. The response indicates that testing for FCC certification does not include transceiver power, but does include certification of maximum field strength at a specified distance. The revised manual is included in Attachment 8 and page 1-5-2 includes the maximum field strength at a specified distance.

Comment: Refer to the 3/18/07 consulting review from Ms. Ferriter for a discussion as to why the above response is acceptable.

b. *The operator's manual (Appendix A, page 46) indicates that "a subset of the syringe data provides parameters used for constraining the injection protocol and validating the system configuration." Please explain what syringe data parameters provided via the RFID are used for constraining the injection protocol and validating the system configuration.*

Response: The response indicates that the statement in the operator's manual is ambiguous. The response indicates that the data provided by the RFID is not used to "constrain" the injection protocol or validate the system configuration. The response indicates that this section has been updated to provide more clarity about the function of the RFID (Attachment 8, Section 1.3.2, page 1-3-1. The revised manual indicates that the syringe data is used to verify the correct syringe type has been loaded based on system configuration, the injector compares the RFID data on the syringe to the programmed protocol to ensure it has sufficient volume, and the injector can mark a syringe as being "used."

6. *Please provide the following software information and documentation for the OptiVantage DH Injection System with Enhanced Communication. The Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices maybe a helpful reference.*

a. *On page 23 of the submission you have included the level of concern determination questions and answered no to all. However, in the risk analysis, you state that misreading injection parameters could lead to toxicity. Please address whether a failure to read the correct parameters or interpret the RFID correctly could lead to a serious injury or a minor injury. Please be advised that FDA believes the appropriate level of concern for the software should be at least moderate or major. Please address this issue.*

Response: The response indicates that misreading parameters could lead to toxicity and that the firm agrees that the appropriate level of concern for the RFID software is moderate. The response indicates that the tables in Attachment 9 address the determination of the level of concern as defined in the software guidance.

b. *Please provide a hazard analysis for the device software. This information should include identification of the hazardous event, the method of control, corrective measures taken, including aspects of the device design, that eliminate, reduce, or warn of a hazardous event, and testing demonstrating the implementation of the safety features.*

Response: The response references the information included in Attachment 7 and the response to deficiency 4.

c. *Please provide a discussion of your software development lifecycle, including the activities that take place during each phase of the lifecycle, the quality control and assurance activities and methods, the development environment, the documentation generated, verification and validation activities, configuration management, version control, audits, and maintenance.*

Response: Attachment 10 includes a summary of the software development lifecycle.

d. *Please provide the current software and system requirements for the device. This information should include a discussion of system hardware requirements, internal software tests and checks, internal and external performance and functional requirements, and safety requirements. Block diagrams showing the system architecture/software design would also be helpful. Also, please discuss how you adequately qualified off-the-shelf software and hardware for incorporation into the device, if applicable, and provide appropriate documentation as discussed in the Guidance on Off-the-Shelf Software Use in Medical Devices.*

Response: The response indicates that the software and systems requirements for the device as they relate to the RFID functionality are provided in Attachment 11. Block diagrams are also included in Attachment 11. The response indicates that no off-the-shelf software or hardware was incorporated into the device to implement RFID.

e. *Please provide the system level testing procedures and protocols, the pass/fail criteria, test results, and an analysis of the results. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application. Also, please provide a test report summarizing how all phases of testing (module, integration, and system) demonstrate that requirements were met. Note that testing should address all options and accessories, communications, and adequate regression testing. You should also explain how testing has adequately stressed the system, including communications, data throughput, device*

configurations, fault conditions, alarm conditions, boundary value conditions, error and range checking on parameters and calculations, interpretations and analyses made by the device, path analysis, etc. The testing you provide should be traceable to the software and system requirements of the device (i.e., trace matrix relating requirements to verification and validation tests). This report should also include a discussion and explanation of how you achieved the desired level of test coverage required for the device and how remaining software anomalies and bugs (listed in the report) do not present a risk to patient safety or effectiveness, directly or indirectly. Please specify the current version level of the software in the documentation you provide.

Response: The response indicates that the RFID verification results and report are provided in Attachment 12. The response indicates that in order to stress the system, the individual test cases were developed to cover minimum, maximum, and out of bounds conditions. The response indicates that the test cases include all injector configurations, valid and invalid RFID tag data, forced communication errors, simulated user errors, and heater fault conditions. The software version levels are: OptiVantage DH Powerhead Software Version - D03.00.10, Optivantage DH Console Software Version – D03.00.10, and Optivantage DH 125ml RFID Faceplate Software Version – D00.08.

Section 6.0 (page 5) of the RFID verification report indicates that 26 anomalies were reported during the testing. Of these 26 anomalies, 4 were determined to be high priority (510AN006, 510AN007, 510AN026, and 510AN013). A software change was required to fix these anomalies. Software version D03.00.11 was created and downloaded into the 2 verification injectors. A list of tests was developed for regression testing (Appendix E). The report indicates that many of the regression tests were copied from the 510(k) software verification protocol and the remaining tests were created to specifically test for the anomalies. All of the regression tests passed and the 4 anomalies have been resolved. The report indicates that the remaining anomalies are not related to safety and effectiveness and will not be addressed at this time. It should be noted that 10 of the 26 anomalies involve an issue with the wording of the individual test case and the procedure for performing the test, and are not software issues.

A summary of the anomalies, which includes a list of anomalies, a description of the regression testing performed, and a discussion of the risk associated with each anomaly, is included in Attachment 13.

7. *Please provide a completed indications for use form (see enclosure) for the OptiVantage DH Injector System with Enhanced Communication. The prescription information on the form should also be completed.*

Response: A completed indications for use form is provided in Attachment 14.

8. *You have provided test protocol D4313 – RF Exposure of OptiRay 350 in the submission. Minutes from the May 9, 2006 meeting indicate that you would be submitting a Changes Being Effected-30 (CBE-30) supplement to the NDA for the OptiRay syringes. Please be advised that CDRH does not review drug quality testing, and this 510(k) submission will not resolve any issues of drug quality. Therefore, this testing information should also be included in your CDER submission.*

Response: The response acknowledges that this testing information should be included in the corresponding PAS submission.

Second Request for Additional Information:

Due to the concerns regarding the responses to deficiencies 1 and 3 of the 12/21/06 hold letter (above), the following information was requested in the 3/22/07 hold letter to the firm. The firm's response is included in the 3/30/07 submission (S2).

1. *You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. You also include a letter dated January 24, 2007 from DLS Electronic Systems, Inc. showing that the original system was tested to EN 60601-1-2 for immunity and EN 55011 for emissions. The OptiVantage with RFID was tested to EN 301 489-3 for immunity and emissions. Please justify the change in test standard. Please compare the test frequencies, immunity specifications and emissions levels used in EN 301 489-3 to those used in IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application*

Response: The response indicates that the OptiVantage DH prior to the development of the Enhanced Communications feature met the following standards: EN 61000-3-2, -3; EN 60601-1-2; and EN 55011. The response indicates that the OptiVantage DH with Enhanced Communication (RFID) was presented to DLS Electronic Systems in 7/06 to be analyzed for compliance to:

EN 61000-3-2, -3; EN/IEC 60601-1-2; and EN 55011. The response indicates that the addition of the radio transmitter device to the system required compliance to additional standards: ICES-003; RSS-210; FCC Part 15.107; FCC Part 15.225; EN 300 330-1; and EN 301 489-3 Emissions/immunity. B4 [redacted] certified that the OptiVantage DH Injector System with Enhanced Communications (RFID) meets both sets of the identified EMC standards (Attachment 1). Attachment 2 includes a table which compares test frequencies, specifications, and emission levels of EN 60601-1-2:2001 with EN 301 489-3 V1.4.1. Attachment 3 includes the test reports for each of the standards.

Comment: The 4/25/07 consulting review from Ann Ferriter includes a detailed description of the firm's response. Ms. Ferriter's review concludes that although the IEC 60601-1-2 testing was not repeated for the OptiVantage with Enhanced Communication (RFID), the testing provided is adequate. The table comparing IEC 60601-1-2 to EN 301 489-3 demonstrates that the standards are similar for each of the tests. Ms. Ferriter's review indicates that although in the future the sponsor would be asked to test to IEC 60601-1-2, EN 301 489 is written specifically for RFID EMC and provides similar assurance that the device will be electromagnetically compatibile.

2. *Your response to deficiency 1 of our letter dated December 21, 2006 indicates that the RFID feature is intended to be used with both pre-filled contrast syringes and pre-filled saline syringes. The submission indicates that CDER will be reviewing the addition of the RFID feature to the pre-filled contrast syringes; however, this information does not address a submission for the changes to the pre-filled saline syringes. Please explain what regulatory submission will be provided to address the changes to the pre-filled saline syringes.*

Response: The response indicates that Mallinckrodt provided a Prior Approval Supplement for the addition of the RFID feature to prefilled saline syringes (Sodium Chloride Injection, USP 0.9% NDA 21-569, supplement S-002, submitted 3/13/07).

		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: SE

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.

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

1. Explain why not a device: OptiVantage DH Injector System with Enhanced Communication is a device.

2. Explain why not subject to 510(k): The device is subject to a 510(k) submission.

3. How does the new indication differ from the predicate device's indication: The indications for use statement is identical to that of the predicate.

4. Explain why there is or is not a new effect or safety or effectiveness issue: NA

5. Describe the new technological characteristics: The OptiVantage DH Injector System with Enhanced Communication differs from the predicate device in that it features an RFID capability. A RFID capability is not a new technological characteristic for medical devices.

6. Explain how new characteristics could or could not affect safety or effectiveness: NA

7. Explain how descriptive characteristics are not precise enough: Descriptive characteristics are not precise enough. Testing demonstrating the function, performance, immunity, and accuracy of the RFID capability is necessary.

8. Explain new types of safety or effectiveness questions raised or why the questions are not new: NA

9. Explain why existing scientific methods can not be used: NA

10. Explain what performance data is needed: Testing demonstrating the function, performance, immunity, and accuracy of the RFID capability is necessary.

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: The submission includes testing information demonstrating the function, performance, immunity, and accuracy of the RFID capability is within specification and acceptable. Please refer to the above information and the consulting reviews from Ms. Ferriter for a detailed discussion of the testing information.

RECOMMENDATION:

I believe that this device is equivalent to: 74 IZQ

Classification should be based on:

870.1650 Automatic Contrast Medium Injector **Class:** II

Kimberly Bowie Peters, April 26, 2007
Division of Cardiovascular Devices

4/26/07

Peters, Kimberly B.

m: Ferriter, Ann M
nt: Wednesday, April 25, 2007 8:54 AM
To: Peters, Kimberly B.
Cc: Duffy, Eric P
Subject: k063503 s2

Attachments: K063503 S2 OptiVantage DH injector RFID consult amf.doc

Kim,
I am recommending SE. The electrical testing was sufficient.

K063503 S2
ptiVantage DH inje.

Please let Eric Duffy know when the device is cleared. He is working on the NDA for CDER.
Thanks,
Ann Ferriter

Office of Surveillance and Biometrics
Center for Devices and Radiological Health
FDA

240-276-3367

Memorandum

To: Kimberly Bowie Peters, Biomedical Engineer
ODE/DCD/ICDB

From: Ann Ferriter, Mechanical Engineer

Date: 25-April-07

Regarding: K063503 S2 Optivantage DH Injector System with Enhanced communication
RFID consult

Recommendation: SE

Ann Ferriter
Reviewer, ODE/DGRND/OSDB

SE-- The sponsor has provided adequate testing to integrate RFID into the DH Injector testing. The 510(k) supplement was submitted to address the deficiencies raised in the S001 supplement special 510(k). The special 510(k) was submitted to clear the use of RFID on the contrast media with an injector cleared in K042744. There is no other change to the device identified in the submission. This engineering consult review covers the responses to deficiency #1 from the March 22, 2007 letter. The original history, intended use, device description, testing, and labeling sections of the consult review are included for reference.

1. You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. You also include a letter dated January 24, 2007 from B4 [redacted] showing that the original system was tested to EN 60601-1-2 for immunity and EN 55011 for emissions. The OptiVantage with RFID was tested to EN 301 489-3 for immunity and emissions. Please justify the change in test standard. Please compare the test frequencies, immunity specifications and emissions levels used in EN 301 489-3 to those used in IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

Mallinckrodt Response and AMF review: The sponsor has provided a comparison table of EN 60601-1-2 and EN 301-489 and the test reports for EMC testing of the original device and with the RFID added. Although the IEC 60601-1-2 testing was not repeated with the RFID subsystem, the testing provided is adequate. The EMC testing for the original submission and for the OptiVantage with RFID is shown in the table below.

Optivantage Contrast Injector Original EMC testing August 2004

Report #	Date Tested	Standard
10909	8/2/2004	EN 61000-3-2 Harmonic
10909	8/2/2004	EN 61000-3-3 Flicker
10908	8/3/2004	En 60601 -1-2 Immunity
10904	8/6/2004	EN 55011 Emissions

Optivantage Contrast Injector with RFID- July 2006

Report #	Date Tested	Standard
12459	7/19/2006	ICES-003 Receiver
12458	7/19/2006	RSS-210 Transmitter
12457	7/19/2006	FCC Part 15.107
12456	7/19/2006	FCC Part 15.225
12455	7/19/2006	EN 300 330-1
12454	7/19/2006	EN 301 489-3 Emissions
12453	7/19/2006	EN 301 489-3 Immunity
w/o RFID	8/2/2004	EN 61000-3-2, -3
w/o RFID	8/3-5/2004	EN/IEC 60601-1-2
w/o RFID	8/6/2004	EN 55011

Note that the sponsor claims that the EMC testing on the original device applies to the Optivantage with RFID. I disagree. Adding an emitting electrical subsystem could effect the EMC characteristics of the device.

The sponsor provided the test procedures or reports for EN 301-489-3 Emissions and Immunity (Tabs 9 and 10). The sponsor also provided a table comparing IEC 60601-1-2 to EN 301 489-3 (see below). The table shows that for the three

critical EMC tests : electrostatic discharge, radiated immunity (susceptibility), and radiated emissions the acceptance criteria and test parameters are similar.

- The device meets CISPR 22 Class A with RFID. Other than the 13.56 MHz RFID the device is not electrically noisy.
- For radiated immunity IEC 60601-1-2 goes to 2.5GHz while EN 301-489-3 only goes to 2 GHz. Whether the RFID is immune to very high RF signals is not a critical safety concern. IEC 60601-1-2 just increased the frequency range from 2 GHz to 2.5 GHz a few years ago. There are more devices operating in the higher range (RFID and cell phones) but this RFID operates at 13.56 MHz and the system (without RFID) will operate even when exposed to the higher frequency RF.
- For ESD the contact test was conducted at 4 kV instead of 6 kV. A strong static shock to the RFID unit may cause it to fail. If the RFID unit fails, the operator will have to enter the data as it is entered now.

Even in the six tests that I feel are less important, the standards are the similar. Only the power frequency magnetic field testing was not repeated. Although I would ask future sponsor's to test to IEC 60601-1-2, EN 301 489 is written specifically for RFID EMC and provides similar assurance that the device will be electromagnetically compatible.

Test	EN 60601-1-2	EN 301 489-3
Radiated Emissions- How much electrical noise is generated by the device	CISPR 11 Class A	CISPR 22 Class A
ESD- How well the device withstands a shock (static electricity discharge)	±2, 4 and 8 kV air ±2, 4 and 6 kV contact	± 8 kV air, ± 4 kV contact
Radiated Immunity (susceptibility) – How well the device operates in an electrically noisy environment	3 V/m 80 MHz to 2.5 GHz, 80% AM at 1 kHz	3 V/m 80 MHz to 2 GHz, 80% AM at 1 kHz
Electrical Fast Transients - How well the device operates the changes in the input power	±2 kV AC, ± 2 kV DC, ±1kV I/O > 3 m	±1 kV AC, ± .5 kV DC, ±.5 kV Signal, Control, Telecom
Surge - How well the device operates with a sudden increase in input power	AC power ±.5, 1kV DM ±.5, 1, 2 kV CM	AC power ±.5kV DM, ±1kV CM DC ±.5kV Telecom ±.5kV to ground
Conducted RF – How well the device operates if there is RF noise on the input power	3 V rms 80% AM at 1 kHz	3 V rms 80% AM at 1 kHz
Power Frequency Magnetic Field – Measures the magnetic field emitted by the device	3 A/m	Not repeated
Voltage dips and interrupts – how well the device operates with changes in the power input	30% dip at .5 s 60% dip at 100 ms 100% dip at 10 ms 100% interrupt at 5 s	30% dip at 100 ms 60% dip at .5 ms >95% interrupt at 5 s
Conducted Emissions – How much electrical noise is generated back into the power grid	CISPR 11 Class A	CISPR 22 Class A

For reference

Intended Use

The OptiVantage DH Injector system with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

From the software section and May 8, 2006 letter page 2:

The system monitors and controls the syringe plunger for injecting fluid as programmed by the caregiver. The functions include a power on self test for injector failure, detection of malfunction during operation, monitoring syringe pressure and allowing fill or retract of syringe. The new RFID features include: marking a syringe as used, identifying expired syringes and automatic identification of drug product attributes (product name, concentration, fill volume, lot number and expiration). The operator's manual also references the ability for the system to detect saline vs. contrast syringes and warn the user if the fluid in the syringe does not match the injector set up. The sponsor claims that the RFID will enhance the safety features of the OptiVantage Injector.

I agree with Lead Reviewer Kim Peters that devices which operate without sufficient user input are high risk devices so I checked for closed loop or automatic use. This device does not have a sensor or any diagnostic capability; therefore it cannot be truly closed loop. Section 5 of the operator's manual describes the injection procedure. The operator is instructed to review the parameters (RFID enters syringe data) before pressing the "start protocol key". This seems sufficient.

The intended use is the same as the predicate device (K042744) intended use. No new intended use issues are raised by the addition of RFID.

Device Description
The only identified difference between this system and K042744 is the addition of RFID for "enhanced communication" or adding a layer of enforcement for safety features.

RFID specifications and comparison to cleared RFID tag

File	K042555	K063503
Name	Surgichip	OptiVantage DH injector with Enhanced Communication
Common Name	adhesive marker	
Classification	21 CFR 878.4660 Class I, FZZ	
Tag		
Tag vendor	B4 [redacted]	B4 [redacted]
Capability	read/write	Read/write – some fields are locked (read only)
Activation	passive	passive
Frequency	13.56 MHz	13.56 MHz
Defect Rate		3-5% from mfg, 100% verified for function
Reader		
Reader vendor	B4 [redacted]	B4 [redacted]
Protocol	B4 [redacted]	B4 [redacted]
Transmitting power	0.5 W	150 mW
Radiated emissions		121.2 dBµV at 3 m (new information in S1)
Antenna Gain		1.13 dBi
Reading distance	18 cm (max)	2-3 inches

Although not formally recognized by FDA, ISO 15693 Identification cards — Contactless integrated circuit(s) cards — Vicinity cards is sufficient to define the electrical characteristics, modulation and protocol for this RFID application. ISO 15693 is composed of three parts: Part 1: Physical characteristics, Part 2:Air interface and initialization Identification cards and Part 3: Anticollision and transmission protocol. A few details from the standard are included below:

The frequency fc of the RF operating field is 13.56 MHz ±7 kHz.
The minimum operating field is Hmin and has a value of 150 mA/m rms.
The maximum operating field is Hmax and has a value of 5 A/m rms.
Communications between the VCD and the VICC takes place using the modulation principle of ASK. Two modulation indexes are used, 10% and 100%. The VICC shall decode both. The VCD determines which index is used.

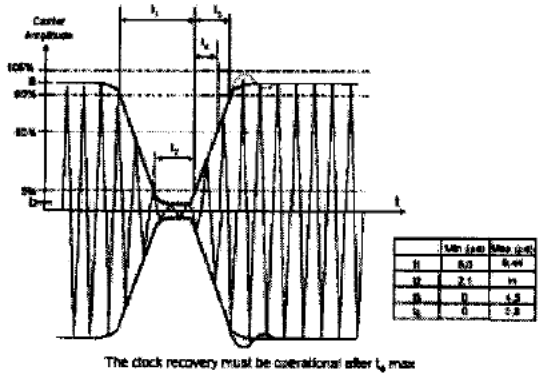

Figure 1 — Modulation of the carrier for 100% ASK

Up to 256 blocks can be addressed. The specified block size can be of up to 256 bits. This leads to a maximum memory capacity of up to 8 kBytes (64 kBits).

Some comments on possible interference:

121 dBμV at 3 meters (or 150 mW output power) is low. The frequency and field strength information can be used to avoid electromagnetic interference problems.
In 2006 OSEL (Paul Ruggera/Seth Seidman 2006) conducted interference testing with pacemakers and defibrillators and RFID. They found that the passive RFID systems operating at 134 kHz and 13.56 MHz did interfere with the operation of the pacemakers and defibrillators (at distances from 2.3 to 60 cm). They did not include a measurement of output power but typical RFID readers operate around 2 to 4 W. In the OSEL testing, the magnetic field strengths for the RFID readers at 13.56 MHz were 2 to 7 A/m at 2.3 cm.
The labeling for the OptiVantage includes a warning to prohibit pacemakers from within 6". The low power and 6" distance are adequate safety measures.

⌘ The fundamental scientific technology has not changed. The sponsor has provided a comparison with their legally marketed device showing only RFID differences. The above comparison with a cleared RFID device show similarities. Risk Analysis and testing are required.

Testing

Some of the hardware testing used the system transfer functions (an equation expressing the relationship between system inputs and system outputs) and the Cpk or process capability index (adjusted for non centered distribution). The sponsor used Cpk to show that the outputs are within the specification limits. The larger the index the less likely it is that any result will be outside the specification.

Hardware Verification testing :

Title	Description	Acceptance criteria	Result	Issues?
D4284- Sufficient antenna read range	The distance between the syringe and antennas, the distance from the RFID tag to antenna center, resonant voltage of the RFID antennas and the rotational position of the RFID label was varied and measured for 12 cases. The resulting values were input into the system transfer function.	Cpk >1.33	Cpk = 4.51	Test results, conclusions, design recommendations and discussions presented in D4297 S1. No Issues
D4294- Minimal heater temperatures	Determine powerhead output voltage, maximum steady state surface temperature, maximum steady state contrast temperature 10 samples tested	Contrast media <40°C PCB cover surface <85°C	Contrast media 27 to 30.81°C PCB cover surface 45 to 60°C	Test results presented in D4307 S1 No issues
D4188- Capability to remove syringe	The syringe is removed at various ram locations for each syringe size and each faceplate assembly 16 samples tested	80% confidence <2 failures in 42 samples	All syringes removed, some with more difficultly	D4423 provided in S1 No issues
D4291Regulatory compliance for intentional RF transmitter - FCC part 15	EMC testing to FCC part 15 (specified sections), RSS 210, ICES-003, EN 300 330 and EN 301 489	Complies with standard	?	General test compliance reported in D4304 S1. Radiated emissions are not specified for RF reader. Page 34 of manual states that emissions meet IEC 60601-1-2. RF reader not tested to 60601-1-2. Immunity test specifications not provided for RF system. See new deficiency
D4313 RF exposure	Exposing OptiRay 350 to RF and checking drug quality (two temperatures 25 °C and 40 °C, two RF exposure levels 13.56 MHz-7.57 and 7.62 dBm)	No significant difference in stability tests p>0.05	Color P=0.6 Assay P=0.2 MP2197 P=0.6 MP 2206 P=0.4 MP 429 P=0.8 pH P=0.9 Impurities P=1	Results reported in D4314; not provided. Results applicable to NDA not 510(k).
D4406 RFID validation	Read the syringe with the injector, empty syringe, read to get "used" warning 5 syringes, 3 injectors, see that user is prompted Qty 30 -125 mL syringes tested Qty 30 – 50 mL syringes tested	Read correctly, Used warning, Correct operation	All syringes correctly read, all match information provided, all removable. Damaged tags detected. Prompt text is different from protocol.	The test results are reported in D4407 S1 No issues

Labeling

S1 includes a revised The OptiVantage Injection with Enhanced Communication Operator's Manual. There are section numbers but no page numbers. The order and format has changed but the following comments are still acceptable:

S1 section 1.5.2 meets radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices.

S1 section 1.3.1 RFID capability – stores syringe data, constraining injection protocol, validating system configuration, prevents reuse

S1 section 1.5.7 RFID transceiver- frequency 13.56 MHz, antenna gain 1.13 dBi- radiated emissions 121.2 dBμV at 3m

S1 section 1.5.1 warning to keep device more than 6 inches from pacemakers or defibrillator

The device labels and package insert contain the logo indicating use of RFID.

The Optiray drug package insert states "The Optiray syringe has been labeled with a Radio Frequency identification (RFID) tag. This tag allows for the exchange of information such as lot number, expiration and concentration. Exchange of patient information does not occur with the use of this RFID tag. Use of the RFID tag does not impact Optiray product quality." The RFID frequency and power are not specified.

References

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
http://www.fda.gov/cdrh/ode/guidance/337.html#7

ISO 15693 Identification cards — Contactless integrated circuit(s) cards — Vicinity cards

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Kimberly Bowie Peters March 21, 2007

Subject: 510(k) Number K063503/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). See attached review
- ☐ 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 NA

☑ 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: Ashley B. Boam ICOB 3/22/07
(Branch Chief) (Branch Code) (Date)

Final Review:
(Division Director) (Date)

Revised:4/2/03

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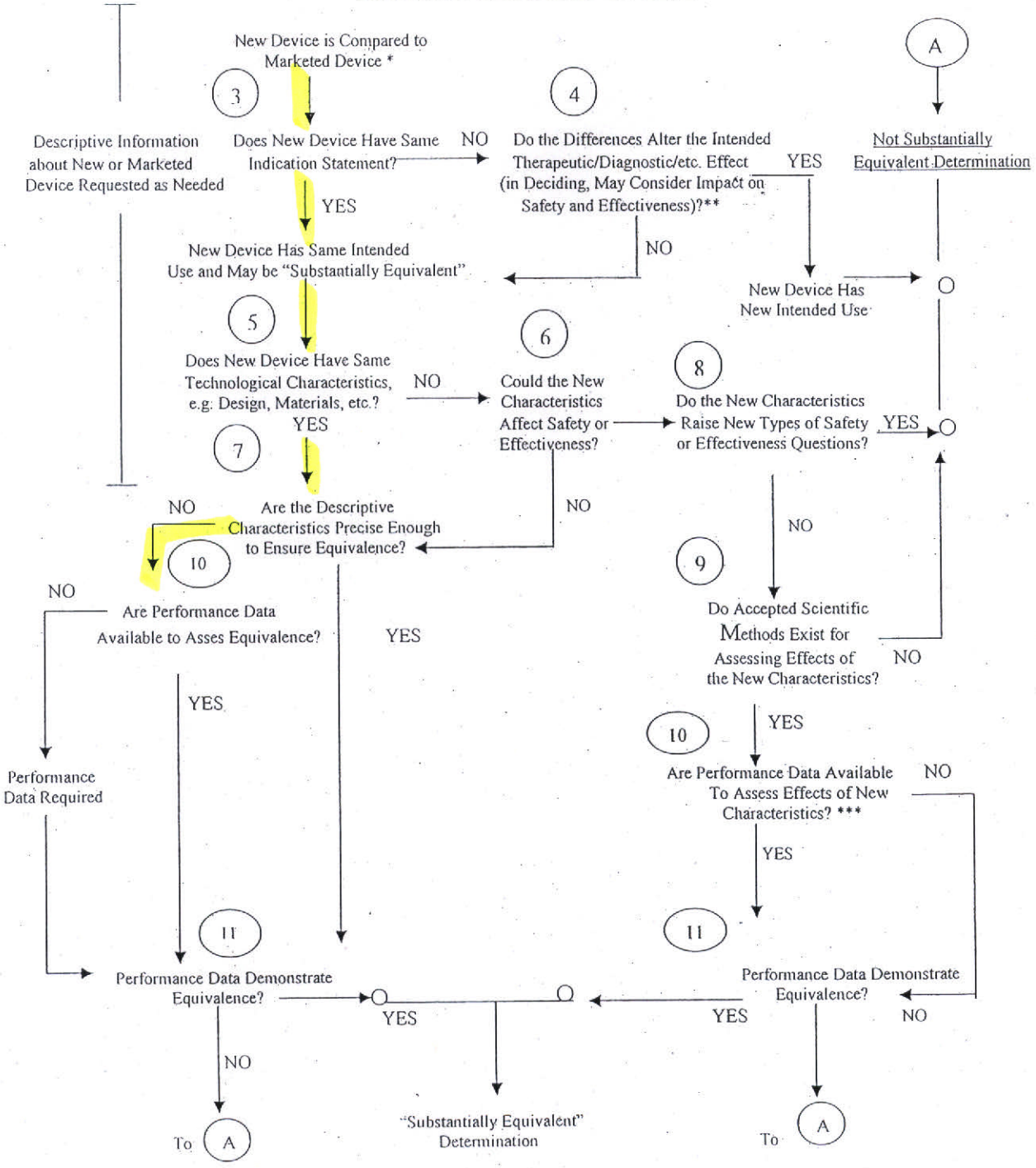
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 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.

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See attached review

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.

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See attached review

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?	NA	
4. If, not, has POS been notified?	NA	
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)?	NA	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	NA	
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.	NA	

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K063503/S1

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
   OptiVantage DH Injection System (K042744) (Section 4, page 12)

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
   The indications for use statement is provided in Section 2 (page 8) of the submission and is as follows:

   "The OptiVantage DH Injector System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e., "CT") equipment."

   The currently marketed OptiVantage DH Injection System (K042744) features the same indications for use statement. (Section 4, page 12)

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
   The change under review in this submission is for the addition of the RFID function to the OptiVantage DH Injection System only. A description of the modifications being made for the development of the OptiVantage DH with Enhanced Communication is included in the meeting minutes information and in S1.

   The addition of the RFID tags to the prefilled syringes (Optiray) will be addressed in a Changes Being Effected-30 (CBE-30) supplement to NDA 19-710 submitted to CDER, and the submission is to include information supporting that there is no impact to the Optiray, as well as documentation supporting RFID tag specifications, control, validation, and function. The CBE-30 should also "provide data describing the master validation plan for Optiray, RFID tag, and OptiVantage." As noted in the 12/11/06 email from Guirag Poochikian of CDER (copy attached), the firm has not submitted the CMC portion for the Optiray prefilled syringe. The CDER/ONDQA post-approval review division told the firm to submit to CDRH first so the device aspects are in order and then the CMC studies could be appropriately designed. ***The submission does not address the addition of the RFID feature to the prefilled saline syringes.***

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and specifications.
   Comparison information is included in Section 4

5. A **Design Control Activities Summary** which includes:
   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
      Section 7 (pages 16-21) - The submission indicates that the risk management process is performed in accordance with Work Instructions QSEWI22, Risk Analysis and QSEWI12, Failure Modes and Effects Analysis. A description of the work instructions is provided in S1.
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

The summary of the verification and validation activities is provided in S1. Complete testing information was requested due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

c) A declaration of conformity with design controls. The declaration of conformity should include:
   i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
   ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
   (Section 9, page 24)

6. A **Truthful and Accurate Statement** *(Section 11, page 26)*, a **510(k) Summary** *(Appendix H)* **or Statement** and the **Indications for Use Enclosure** *(S1, Attachment 14)* **(and Class III Summary for Class III devices).**

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K063503/S1

Reviewer: Kimberly Bowie Peters

Consulting Reviewer: Ann Ferriter, DGRND/OSDB (Consulting review on injector RFID capabilities)

Division/Branch: DCD/ICDB

Device Name: OptiVantage DH Injector System with Enhanced Communication

Product To Which Compared (510(K) Number If Known): K042744

History of Submission:
This submission includes a special 510(k) submission for the OptiVantage DH Injector System with Enhanced Communication. On May 9, 2006, there was a meeting between Mallinckrodt and CDER to discuss a proposed submission strategy regarding the user of Radio Frequency Identification (RFID) tags placed on Optiray (ioversol injection) pre-filled syringes (NDA 19-710). Ms. Ann Ferriter of DGRND/OSDB was the CDRH representative for this meeting, since Ms. Ferriter has expertise in the review of RFID devices. The meeting minutes (prepared and provided to the firm by CDER) are included in the submission (after the cover letter). During the meeting, the firm was informed that the change to incorporate RFID to the injector system would qualify as a special 510(k), and the submission should address the hardware and software necessary for reading and writing the tag information, as well as integration of the tag information into the existing software that controls the contrast administration. The changes to the Optiray should be submitted as a Changes Being Effected-30 (CBE-30) supplement to NDA 19-710, and the submission should include information demonstrating that there is no impact to the Optiray, as well as documentation supporting RFID tag specifications, control, validation, and function. The CBE-30 should also "provide data describing the master validation plan for Optiray, RFID tag, and OptiVantage." As noted in the 12/11/06 email from Guirag Poochikian of CDER (copy in S0), the firm has not submitted the CMC portion for the Optiray prefilled syringe. The CDER/ONDQA post-approval review division advised the firm to submit to CDRH first so that the device aspects are addressed and then the CMC studies could be appropriately designed.

Indications for Use:
The OptiVantage DH Injector System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e., "CT") equipment.

The currently marketed OptiVantage DH Injection System (K042744) features the same indications for use statement.

Device Description
The device description information is provided in Section 3 of the submission as well as in the background information provided for the 5/9/06 meeting between FDA/CDER and Mallinckrodt.

The OptiVantage DH Injector System with Enhanced Communication delivers radiographic contrast media and/or saline at a controlled flow rate and volume into a patient's vascular system for the purpose of obtaining enhanced diagnostic images. Like the predicate device (K042744), the OptiVantage DH Injector System with Enhanced Communication consists of 4 main components:

- Power Head – The power head contains 2 electromechanical syringe drive systems, the syringe holding mechanisms, the main processor, control electronics, control keypad for programming and initiating injection protocols, a status display, and 2 purge/retract manual knobs. The OptiVantage uses a drive system uses a motor and gearbox coupled to a ball screw. The ball screw drives a ram that attaches to the syringe plunger in order to fill or expel the contents of the syringe.
- Power Supply – The power supply converts the line voltage to the working voltage for the power head and console.
- Console – The console communicates with the power head to program and initiate injection protocols, displays the injection status, and displays a timer.
- Syringes – The OptiVantage DH Injector System with Enhanced Communication accommodates the Mallinckrodt 125ml pre-filled syringe styles as well as a 200ml front loading empty syringe. These are the same syringes currently used with the predicate device.

The submission (page 2 of 5/8/06 background information provided for 5/9/06 meeting) indicates that the RFID electrical hardware has been designed by B4 [redacted] using an IC from B4 [redacted]. The hardware is designed to use the ISO 15693 Wireless Protocol (operating at a frequency of 13.56MHz), and radiates a maximum of 150mW from one of two antennas. The system has the capability to read an RFID tag using the B4 [redacted] protocol. B4 [redacted] supplies the RFID tags, which are integrated into a label supplied b B4 [redacted] submission (page 4 of 5/8/06 background information provided for 5/9/06 meeting) indicates that integration of the RFID functionality will require a faceplate upgrade and a new software release.

The wireless connector only exists between the injector faceplate and the syringe RFID tag. The system features allow the transfer of drug product name, concentration, fill volume, drug lot number, manufactured date, expiration and used/unused status from the syringe to the injector. The injector will write back to the syringe that use has occurred. No patient information will be exchanged.

The submission (page 9) indicates that specifications and information regarding the syringe and labels, RFID tags, and data used by the RFID system are included in Appendices C, D, and G. Appendix C includes the syringe labels and package inserts. Appendix D includes the RFID Syringe, tag, and data specifications.

The submission (page 2 of 5/8/06 background information provided for 5/9/06 meeting) indicates that the RFID system has been designed to meet FCC 15.225 requirement: "Section 15.225 Operation within the band 13.553-13.567MHz." The submission indicates that testing with an accredited EMC test facility has shown that the RFID system meets these requirements.

With regard to verification of the coexistence, data integrity, security and performance requirements, the submission (page 3 of 5/8/06 background information provided for 5/9/06 meeting) indicates that ISO 15693 protocol (RFID data protocol) specifies both data integrity checks and collision detection mechanisms for data transfer. Collision of data can occur when 2 or more RFID tags are within the read field. Data transmission errors can occur if an RFID tag is damaged or if it is outside the read range. The submission indicates that "tests have been or will be performed to

ensure: 1) RFID tags entering the manufacturing facility are functional and have correct data encoded; 2) RFID tags on syringes leaving the manufacturing facility are functional and have correct data encoded; 3) the RFID reader on the injector system can reliably read functional tags on an inserted syringe."

In addition, a calculated cyclic redundancy check (CRC) or checksum value is written to the tag each time data is stored on the tag to ensure data integrity. The injector will verify the checksum values to ensure the data has not been changed or damaged since leaving the syringe manufacturing facility. The read-only data fields on the tag (i.e., expiration date) are locked, preventing any change after being written by the factory. All wireless data transfers between the faceplate and the injector also have a checksum to ensure data integrity. In the event that a tag cannot be read or the data is corrupt, the injector panel displays messages to notify the user.

If a wireless connection cannot be established, the injector reverts to its current mode of operation.

Bench Testing Information:

Appendix D (pages 208-212) includes an engineering report for the label function verification test. The purpose of this test was to determine the failure rate of the B4 [redacted] tags incorporated into the labels manufactured by B4 [redacted]. The sample size for the test was 22605 labels (representing the various Optiray syringe volume and concentration) due to label availability, 22547 labels were read, and 58 tags/labels (0.256%) were determined to be "bad."

Appendix F includes hardware verification testing information. The submission indicates that testing was performed to demonstrate:

- Sufficient antenna read range – This testing was performed on "product equivalent units and was performed to determine how reliably the Optivantage DH could read data from the Optiray syringe's RFID tag. The submission references test report D4284. Report D4284 only includes the test procedure and this report indicates that the results/conclusions are provided in D4297. Complete test reports were requested and are provided in S1.
- Minimal heater temperature (under normal and fault conditions) – The submission indicates that testing was performed to ensure that both the surface temperature and contrast media temperature remained at safe levels if fault conditions occurred. The submission references test report D4294. Report D4294 only includes the test procedure and this report indicates that results/conclusions are provided in D4307. The submission also indicates that "test design recommendations and discussions are presented in D4307 rev B." Complete test reports were requested and are provided in S1.
- Capability to remove the Optiray syringe at any ram position – The submission indicates that a verification test was performed and verified that this requirement was met using production equivalent. The submission references test report D4188. D4188 only includes the test procedure. Complete test reports were requested and are provided in S1.
- Regulatory compliance for an intentional RF transmitter – The submission indicates that all applicable standards for a radio transmitter at 13.56MHz were met, including FCC Section 15.225, FCC Part 15.107, FCC Part 15.109, RSS-210, ICES-003, EN 300 330, and EN 301 489-3. The submission references test report D4291. Report D4291 only identifies the above standards as the test procedure and indicates that "test results shall be documented in D4303." Complete test reports were requested and are provided in S1.

Appendix G includes a 16 hour RF impact study. During this test, the Optiray 350 125ml pre-filled syringes were exposed to controlled RF energy for an extended time at 2 temperature levels. After RF exposure, the syringes will be analyzed to determine if there is any quality impact on the drug product. This information will be reviewed by CDER during the review of the CBE-30 submission.

Appendix H includes RFID System Technology Validation testing information. This test was performed to demonstrate that production equivalent Optiray prefilled syringes with RFID would function correctly in the OptiVantage DH Injector System with Enhanced Communication. The submission indicates that testing was conducted in accordance with test protocol D4406 rev B. The submission (page 368) indicates that the result met all requirements of the protocol. Test report D4406 (page 372) indicates that "test results shall be documented in D4407." Complete test reports were requested and are provided in S1.

Software Documentation:

Software information is included in Section 8 (pages 22-23) and Appendix E of the original submission. Complete software documentation was requested and is provided in S1 (see request for additional information section of this review).

The submission (page 22) indicates that The OptiVantage DH Injector System with Enhanced Communication software consists of 3 subsystems:

- Power Head software – Injects fluids at specified volume and flow rate as programmed by the user
- Console software - Displays injector status and allows the user to program and start an injection from a remote location
- Faceplate software – Controls the operation of the RFID reader hardware

In addition to the software features provided with the predicate device, the modified system provides the following additional functions:

- RFID technology allows the injector to "mark" an RFID-enabled syringe as used when an injection is initiated and disallow further use of that syringe.
- RFID technology allows the injector to determine whether an RFID-enabled syringe is expired and prevent further use of that syringe.
- RFID technology allows the injector to obtain drug product attributes from an RFID-enabled syringe (product name, concentration, fill volume, lot number, expiration)

Appendix E includes the "Risk Analysis Software Verification Summary and Protocols." Appendix E only includes a copy of the verification and validation test protocol (D4349).

The submission (page 243) indicates that verification testing was performed on the following development versions of software which implement RFID functionality on the OptiVantage DH Injection System:

- OptiVantage DH Powerhead Software Version: D03.00.10
- OptiVantage DH Console Software Version: D03.00.10
- OptiVantage DH 125ml RFID Faceplate Software Version: D00.08

Request for Additional Information:

Due to the lack of complete bench testing information and software documentation, the following information was requested in the 12/21/06 hold letter. The firm's response to the 12/21/06 letter is included in the 2/16/07 submission (S1). Concerns regarding the responses are identified in bold or in the comments section below. If there is no bold notation, the response is adequate.

1. *The device description information does not include a clear description of the modifications made to the currently marketed OptiVantage system for the development of the OptiVantage DH Injector System with Enhanced Communications. Please provide this information which should address both hardware and software modifications. In addition, it is unclear if the RFID feature is only intended to be used with the pre-filled contrast syringes or the pre-filled saline syringes. Please address this issue.*

Response: The response indicates that the only hardware changes from the predicate device are the incorporation of RFID electronics (IC and antenna) in the faceplate to enable communication with the RFID tagged pre-filled syringes. The response indicates that the software modifications enable operation of the RFID hardware and associated safety features. This combination allows the transfer of prefilled contrast and/or prefilled saline syringe attributes (i.e. product name, fill volume, expiry, lot number, manufacture date) to the injector and allows the injector to mark a syringe as "used". The RFID technology does not change how protocols are currently entered or controlled. It does allow the injector to ensure that an unused, unexpired prefilled syringe of the correct volume has been loaded. Should the RFID functionality fail, the injector will notify the user and will continue to operate the same as the predicate device. **It should be noted that the response to this deficiency indicates that the RFID feature is intended to be used with both pre-filled contrast syringes and pre-filled saline syringes. The submission indicates that CDER will be reviewing the addition of the RFID feature to the pre-filled contrast syringes; however, there is no mention of a submission for the changes to the pre-filled saline syringes.**

2. *Please address the following regarding the bench testing information:*

   a. *You have provided protocols and acceptance criteria for testing the OptiVantage DH Injector System with Enhanced Communication, including D4284 – Sufficient antenna range, D4294 –*

Minimal heater temperatures, D4188 – Capability to remove syringe, D4291 Regulatory compliance for intentional RF transmitter, and D4406 RFID validation. These reports indicate that the test results and conclusions are provided in separate referenced test reports. Please provide the referenced test reports D4297, D4307, D4304, and D4407 for review, as well as the results for test D4188. Please be advised that the testing information provided for review should testing procedures and protocols, sample size, acceptance criteria, justification for the chosen sample size and acceptance criteria, test results, and an analysis of the results. FDA acknowledges that you have submitted the enhanced communication change in a special 510(k) submission; however, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

Response: The response indicates that the requested reports are provided in Attachments 1-5:

- D4284/D4297 RFID Reader Performance Testing – Attachment 1
- D4294/D4307 Heater Performance Testing – Attachment 2
- D4188/D4423 Syringe Removal Test – Attachment 3
- D4291/D4304 EMC/FCC Compliance Testing – Attachment 4
- D4406/D4407 RFID System Technology Validation – Attachment 5

Comment: The bench testing information was reviewed by Ann Ferriter. **Ms Ferriter's consulting review (3/18/07) indicates that the tests for regulatory compliance for intentional RF transmitter are not adequate and the review references the response to, and her comments regarding, deficiency 3.** Ms. Ferriter's memo indicates that the tests for sufficient antenna range, minimal heater temperature, capability to remove syringe, and RFID validation are adequate.

b. *For D4294 – Minimal heater temperatures test, please provide a scientifically valid justification for the acceptance criteria. In addition, the conclusion section for D4294 indicates that "test design recommendations and discussions are presented in D4307 rev B." Please describe these test design recommendations, explain if the test protocol was modified to address these recommendations, if the test was repeated, etc.*

Response: The response indicates that the temperature values in the acceptance criteria were selected based on IEC safety requirements for surface temperature and applied part temperature (IEC 60601 clauses 42.1 and 42.3). The response indicates that the acceptance criteria in D4294 required demonstration that IEC standards were met (compliance certificate is included in Attachment 6). With regard to the statement in the conclusion of D4294, the response indicates that since the product met the acceptance criteria, no changes to the product design were made.

3. *You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.*

Response: The response indicates that the information regarding compliance testing is provided in Attachment 4, D4304.
Comment: Refer to the consulting review from Ms. Ferriter for a summary of, and concerns regarding, the testing conducted. Ms. Ferriter's review notes that in the manual (Section 1.5.2) the sponsor claims that the device meets radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices; however, the OptiVantage with RFID was tested to EN 301 489-3 for immunity and emission.

4. *The risk analysis methods and summary information (Section 7) is inadequate. Please identify the risk analysis methods used to assess the impact of the modifications. The submission only indicates that the risk analysis was performed in accordance with work instructions QSEW122 and QSEW112. In addition, please provide a revised summary of the verification and validation activities that includes a description of the methods or tests used, acceptance criteria applied, and an indication of whether the acceptance criteria were met. The summary provided only includes bullets, such as "RFID system-level validation" and "verification testing of enable sequences," indicating that verification testing was performed.*

Response: The response indicates that the risk analysis methods are modeled after ISO 1497:2000(E) Medical Devices, Application of Risk Management to Medical Devices. The response indicates that to identify and evaluate the risks associated with the modifications for RFID, we used the risk analysis and FMEA for the predicate device as a template, and these

documents were updated to reflect the addition of the RFID technology. Attachment 7 includes a summary table which traces from identified hazards through risk mitigation requirements to subsystem requirements and corresponding V&V activities.

5. *Please address the following regarding the operator's manual for the OptiVantage DH Injection System with Enhanced Communication. Please provide a revised copy of the operator's manual for review.*

   a. *In the OptiVantage DH Injection System with Enhanced Communication operator's manual (pages 28 – 185), you have included information on RFID. To aid the user in avoiding electromagnetic interference problems, please include the transceiver power and field strength at a specified distance in the operator's manual.*

Response: The response indicates that the manual has been revised to include the maximum field strength at a specified distance; however, the transceiver power was not included in the manual. The response indicates that the original manual included both pieces of information, but during the FCC licensing process, the licensing body (American TCB) requested that the transceiver power be removed before they would certify the product and grant the FCC license. The response indicates that testing for FCC certification does not include transceiver power, but does include certification of maximum field strength at a specified distance. The revised manual is included in Attachment 8 and page 1-5-2 includes the maximum field strength at a specified distance.
Comment: Refer to the consulting review from Ms. Ferriter for a discussion as to why the above response is acceptable.

   b. *The operator's manual (Appendix A, page 46) indicates that "a subset of the syringe data provides parameters used for constraining the injection protocol and validating the system configuration." Please explain what syringe data parameters provided via the RFID are used for constraining the injection protocol and validating the system configuration.*

Response: The response indicates that the statement in the operator's manual is ambiguous. The response indicates that the data provided by the RFID is not used to "constrain" the injection protocol or validate the system configuration. The response indicates that this section has been updated to provide more clarity about the function of the RFID (Attachment 8, Section 1.3.2, page 1-3-1. The revised manual indicates that the syringe data is used to verify the correct syringe type has been loaded based on system configuration, the injector compares the RFID data on the syringe to the programmed protocol to ensure it has sufficient volume, and the injector can mark a syringe as being "used."

6. *Please provide the following software information and documentation for the OptiVantage DH Injection System with Enhanced Communication. The Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices maybe a helpful reference.*

   a. *On page 23 of the submission you have included the level of concern determination questions and answered no to all. However, in the risk analysis, you state that misreading injection parameters could lead to toxicity. Please address whether a failure to read the correct parameters or interpret the RFID correctly could lead to a serious injury or a minor injury. Please be advised that FDA believes the appropriate level of concern for the software should be at least moderate or major. Please address this issue.*

Response: The response indicates that misreading parameters could lead to toxicity and that the firm agrees that the appropriate level of concern for the RFID software is moderate. The response indicates that the tables in Attachment 9 address the determination of the level of concern as defined in the software guidance.

   b. *Please provide a hazard analysis for the device software. This information should include identification of the hazardous event, the method of control, corrective measures taken, including aspects of the device design, that eliminate, reduce, or warn of a hazardous event, and testing demonstrating the implementation of the safety features.*

Response: The response references the information included in Attachment 7 and the response to deficiency 4.

   c. *Please provide a discussion of your software development lifecycle, including the activities that take place during each phase of the lifecycle, the quality control and assurance activities and methods, the development environment, the documentation generated, verification and validation activities, configuration management, version control, audits, and maintenance.*

Response: Attachment 10 includes a summary of the software development lifecycle.

d. *Please provide the current software and system requirements for the device. This information should include a discussion of system hardware requirements, internal software tests and checks, internal and external performance and functional requirements, and safety requirements. Block diagrams showing the system architecture/software design would also be helpful. Also, please discuss how you adequately qualified off-the-shelf software and hardware for incorporation into the device, if applicable, and provide appropriate documentation as discussed in the Guidance on Off-the-Shelf Software Use in Medical Devices.*

Response: The response indicates that the software and systems requirements for the device as they relate to the RFID functionality are provided in Attachment 11. Block diagrams are also included in Attachment 11. The response indicates that no off-the-shelf software or hardware was incorporated into the device to implement RFID.

e. *Please provide the system level testing procedures and protocols, the pass/fail criteria, test results, and an analysis of the results. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application. Also, please provide a test report summarizing how all phases of testing (module, integration, and system) demonstrate that requirements were met. Note that testing should address all options and accessories, communications, and adequate regression testing. You should also explain how testing has adequately stressed the system, including communications, data throughput, device configurations, fault conditions, alarm conditions, boundary value conditions, error and range checking on parameters and calculations, interpretations and analyses made by the device, path analysis, etc. The testing you provide should be traceable to the software and system requirements of the device (i.e., trace matrix relating requirements to verification and validation tests). This report should also include a discussion and explanation of how you achieved the desired level of test coverage required for the device and how remaining software anomalies and bugs (listed in the report) do not present a risk to patient safety or effectiveness, directly or indirectly. Please specify the current version level of the software in the documentation you provide.*

Response: The response indicates that the RFID verification results and report are provided in Attachment 12. The response indicates that in order to stress the system, the individual test cases were developed to cover minimum, maximum, and out of bounds conditions. The response indicates that the test cases include all injector configurations, valid and invalid RFID tag data, forced communication errors, simulated user errors, and heater fault conditions. The software version levels are: OptiVantage DH Powerhead Software Version - D03.00.10, Optivantage DH Console Software Version – D03.00.10, and Optivantage DH 125ml RFID Faceplate Software Version – D00.08.

Section 6.0 (page 5) of the RFID verification report indicates that 26 anomalies were reported during the testing. Of these 26 anomalies, 4 were determined to be high priority (510AN006, 510AN007, 510AN026, and 510AN013). A software change was required to fix these anomalies. Software version D03.00.11 was created and downloaded into the 2 verification injectors. A list of tests was developed for regression testing (Appendix E). The report indicates that many of the regression tests were copied from the 510(k) software verification protocol and the remaining tests were created to specifically test for the anomalies. All of the regression tests passed and the 4 anomalies have been resolved. The report indicates that the remaining anomalies are not related to safety and effectiveness and will not be addressed at this time. It should be noted that 10 of the 26 anomalies involve an issue with the wording of the individual test case and the procedure for performing the test, and are not software issues.

A summary of the anomalies, which includes a list of anomalies, a description of the regression testing performed, and a discussion of the risk associated with each anomaly, is included in Attachment 13.

7. *Please provide a completed indications for use form (see enclosure) for the OptiVantage DH Injector System with Enhanced Communication. The prescription information on the form should also be completed.*

Response: A completed indications for use form is provided in Attachment 14.

8. *You have provided test protocol D4313 – RF Exposure of OptiRay 350 in the submission. Minutes from*

the May 9, 2006 meeting indicate that you would be submitting a Changes Being Effected-30 (CBE-30) supplement to the NDA for the OptiRay syringes. Please be advised that CDRH does not review drug quality testing, and this 510(k) submission will not resolve any issues of drug quality. Therefore, this testing information should also be included in your CDER submission.

Response: The response acknowledges that this testing information should be included in the corresponding PAS submission.

Second Request for Additional Information:

Due to the concerns regarding the responses to deficiencies 1 and 3 above, it is recommended that the following information be requested in a hold letter to the firm:

1. You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. You also include a letter dated January 24, 2007 from [redacted] showing that the original system was tested to EN 60601-1-2 for immunity and EN 55011 for emissions. The OptiVantage with RFID was tested to EN 301 489-3 for immunity and emissions. Please justify the change in test standard. Please compare the test frequencies, immunity specifications and emissions levels used in EN 301 489-3 to those used in IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

2. Your response to deficiency 1 of our letter dated December 21, 2006 indicates that the RFID feature is intended to be used with both pre-filled contrast syringes and pre-filled saline syringes. The submission indicates that CDER will be reviewing the addition of the RFID feature to the pre-filled contrast syringes; however, this information does not address a submission for the changes to the pre-filled saline syringes. Please explain what regulatory submission will be provided to address the changes to the pre-filled saline syringes.

		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.

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

1. Explain why not a device: OptiVantage DH Injector System with Enhanced Communication is a device.
2. Explain why not subject to 510(k): The device is subject to a 510(k) submission.
3. How does the new indication differ from the predicate device's indication: The indications for use statement is identical to that of the predicate.
4. Explain why there is or is not a new effect or safety or effectiveness issue: NA
5. Describe the new technological characteristics: The OptiVantage DH Injector System with Enhanced Communication differs from the predicate device in that it features an RFID capability. RFID capability is not a new technological characteristic for medical devices.
6. Explain how new characteristics could or could not affect safety or effectiveness: NA
7. Explain how descriptive characteristics are not precise enough: Descriptive characteristics are not precise enough. Testing demonstrating the function, performance, immunity, and accuracy of the RFID capability is necessary.
8. Explain new types of safety or effectiveness questions raised or why the questions are not new: NA
9. Explain why existing scientific methods can not be used: NA
10. Explain what performance data is needed: Testing demonstrating the function, performance, immunity, and accuracy of the RFID capability is necessary.
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

Kimberly Boone Poe
(Reviewer's Signature)

3/20/07
(Date)

ASB 3/22/07

Peters, Kimberly B.

›m: Ferriter, Ann M
.nt: Monday, March 19, 2007 7:05 AM
To: Peters, Kimberly B.
Subject: K063503

Attachments: K063503 S1 OptiVantage DH injector RFID consult amf.doc

Kim,
It looks like Mallinckrodt has not done the right EMC testing.

K063503 S1
›ptiVantage DH inje.

Thank you for the extension-

Ann Ferriter
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
FDA
240-276-3367

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Memorandum

To: Kimberly Bowie Peters, Biomedical Engineer
ODE/DCD/ICDB
From: Ann Ferriter, Mechanical Engineer

Date: 18-March-2007

Regarding: K063503 S1 Optivantage DH Injector System with Enhanced communication
RFID consult

Recommendation: A1 – needs EMC testing see original deficiency #3

Ann Ferriter
Reviewer, ODE/DGRND/OSDB

The 510(k) supplement was submitted to address the deficiencies raised in the original special 510(k). The original submission was submitted to clear the use of RFID on the contrast media with an injector cleared in K042744. There is no other change to the device identified in the submission. This engineering consult review covers the responses to deficiencies 2a, 3, 5a, 6a, and 8. The original history, intended use, device description, testing, and labeling sections of the consult review have been up dated to reflect the S1 submission.

2. Please address the following regarding the bench testing information:
a. You have provided protocols and acceptance criteria for testing the OptiVantage DH Injector System with Enhanced Communication, including D4284 – Sufficient antenna range, D4294 – Minimal heater temperatures, D4188 – Capability to remove syringe, D4291 Regulatory compliance for intentional RF transmitter, and D4406 RFID validation. These reports indicate that the test results and conclusions are provided in separate referenced test reports. Please provide the referenced test reports D4297, D4307, D4304, and D4407 for review, as well as the results for test D4188. Please be advised that the testing information provided for review should include testing procedures and protocols, sample size, acceptance criteria, justification for the chosen sample size and acceptance criteria, test results, and an analysis of the results. FDA acknowledges that you have submitted the enhanced communication change in a special 510(k) submission; however, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

Mallinckrodt Response: Provided D4297, D4307, D4304, D4407 and the results for test D4188. The submission includes testing procedures and protocols, sample size, acceptance criteria, justification for the chosen sample size and acceptance criteria, test results, and an analysis of the results.
AMF comment: The sponsor has provided the testing procedures and protocols, sample size, acceptance criteria, justification for the chosen sample size and acceptance criteria, test results, and an analysis of the results. The tests for Regulatory compliance for intentional RF transmitter are not adequate. See response to deficiency #3.

The tests for Sufficient antenna range, Minimal heater temperatures, Capability to remove syringe, and RFID validation are adequate.

- Sufficient antenna read range --The distance between the syringe and antennas, the distance from the RFID tag to antenna center, resonant voltage of the RFID antennas and the rotational position of the RFID label was varied and measured for 12 cases. The resulting values were input into the system transfer function. The Process Capability Index (Cpk) indicates a reliable and repeatable antenna read range with a variety of system inputs. The read range is within specifications.
- Minimal heater temperatures The maximum steady state temperature of the PCB cover surface and of the contrast media were below the specified acceptance criteria.
- Capability to remove syringe--The 125 mL and 50 mL syringes were removed at various ram locations .
- RFID validation -- All syringes correctly read, all match information provided, all removable. Damaged tags detected. Prompt text is different from protocol.

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3. You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

Mallinckrodt Response: The EMC testing for the original submission and for the OptiVantage with RFID is shown in the table below.

Optivantage Contrast Injector Original EMC testing August 2004

Report #	Date Tested	Standard
10909	8/2/2004	EN 61000-3-2 Harmonic
10909	8/2/2004	EN 61000-3-3 Flicker
10908	8/3/2004	En 60601 -1-2 Immunity
10904	8/6/2004	EN 55011 Emissions

Optivantage Contrast Injector with RFID- July 2006

Report #	Date Tested	Standard
12459	7/19/2006	ICES-003 Receiver
12458	7/19/2006	RSS-210 Transmitter
12457	7/19/2006	FCC Part 15.107
12456	7/19/2006	FCC Part 15.225
12455	7/19/2006	EN 300 330-1
12454	7/19/2006	EN 301 489-3 Emissions
12453	7/19/2006	EN 301 489-3 Immunity

In the manual section 1.5.2, the sponsor claims that the device meets radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices. The RFID transmitter has not been tested to these standards. The sponsor has not provided the test procedures or reports for EN 301-489-3 Emissions or Immunity.

AMF comment: In the manual section 1.5.2, the sponsor claims that the device meets radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices. The RFID transmitter has not been tested to these standards. The sponsor has not provided the test procedures or reports for EN 301-489-3 Emissions or Immunity. It is not clear whether the frequency test range, the immunity specifications or the emissions levels are the same as those in IEC 60601-1-2.

New Deficiency: You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. You also include a letter dated January 24, 2007 from DLS Electronic Systems, Inc. showing that the original system was tested to EN 60601-1-2 for immunity and EN 55011 for emissions. The OptiVantage with RFID was tested to EN 301 489-3 for immunity and emissions. Please justify the change in test standard. Please compare the test frequencies, immunity specifications and emissions levels used in EN 301 489-3 to those used in IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

5. Please address the following regarding the operator's manual for the OptiVantage DH Injection System with Enhanced Communication. Please provide a revised copy of the operator's manual for review.

a. In the OptiVantage DH Injection System with Enhanced Communication operator's manual (pages 28 – 185), you have included information on RFID. To aid the user in avoiding electromagnetic interference problems, please include the transceiver power and field strength at a specified distance in the operator's manual.

Mallinckrodt Response: Provided a revised operator's manual with the field strength at 3 m. FCC regulations discourage both power and strength.

AMF comment: 121 dBμV at 3 meters (or 150 mW output power) is low. The frequency and field strength information can be used to avoid electromagnetic interference problems.

In 2006 OSEL (Paul Ruggera/Seth Seidman 2006) conducted interference testing with pacemakers and defibrillators and RFID. They found that the passive RFID systems operating at 134 kHz and 13.56 MHz did interfere with the operation of the pacemakers and defibrillators (at distances from 2.3 to 60 cm). They did not include a measurement of output power but typical RFID readers operate around 2 to 4 W. In the OSEL testing, the magnetic field strengths for the RFID readers at 13.56 MHz were 2 to 7 A/m at 2.3 cm.

The labeling for the OptiVantage includes a warning to prohibit pacemakers from within 6". The low power and 6" distance are adequate safety measures. Adequate response.

6. Please provide the following software information and documentation for the OptiVantage DH Injection System with Enhanced Communication. The "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" may be a helpful reference.

a. On page 23 of the submission you have included the level of concern determination questions and answered "no" to all. However, in the risk analysis, you state that misreading injection parameters could lead to toxicity. Please address whether a failure to read the correct parameters or interpret the RFID correctly could lead to a serious injury or a minor injury. Please be advised that FDA believes the appropriate level of concern for the software should be at least moderate or major. Please address this issue.

Mallinckrodt Response: Level of concern – moderate, RFID is a safety enhancement feature

AMF comment: Adequate- with the moderate level of concern the sponsor should provide appropriate software documentation.

8. You have provided test protocol D4313 -- RF Exposure of OptiRay 350 in the submission. Minutes from the May 9, 2006 meeting indicate that you would be submitting a Changes Being Effected-30 (CBE-30) supplement to the NDA for the OptiRay syringes. Please be advised that CDRH does not review drug quality testing, and this 510(k) submission will not resolve any issues of drug quality. Therefore, this testing information should also be included in your CDER submission. Please acknowledge this advisory.

Mallinckrodt Response: Acknowledged. Mallinckrodt will submit to CDER.

AMF comment: Adequate.

History:

December 2006, FDA completed review of K063503 Optivantage special 510(k). We asked for additional information in 8 areas: device description, bench testing, EMC testing, risk analysis, labeling, software, indications for use and aCDER submission required advisory.

On May 9, 2006, Mallinckrodt and FDA met at CDER to discuss adding RFID to the Optiray/OptiVantage injector system. We recommended that Mallinckrodt submit a CBE-30 (changes being effected) supplement to CDER for the Optiray NDA 19-710 and a Special 510(k) to CDRH to build on K042733, the OptiVantage Dual Head contrast media injector. I asked Mallinckrodt the following RFID questions for which they have provided answers and/or support in the submission:

- Define all functions which will be implemented wirelessly.
- Define the information to be transmitted.
- Provide the RF wireless communication specifications (transmission frequency, transmission power, protocol).
- Validate operation in the presence of other in-band transmitters and provide restrictions on the number or characteristics of other in-band transmitters. Provide specifications for dropped transmissions and transmission rate.
- Verify transmitted data integrity. Please provide transmission accuracy testing.
- Ensure wireless connectivity and provide testing of alarms or alternate modes if wireless communication path is lost or corrupted
- Describe the security features of your device.
- Provide verification and validation test data of the security features to prevent unauthorized access to data or networks.
- Verify environmental design specifications (temperature and humidity limitations)

Intended Use

The OptiVantage DH Injector system with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

From the software section and May 8, 2006 letter page 2:

The system monitors and controls the syringe plunger for injecting fluid as programmed by the caregiver. The functions include a power on self test for injector failure, detection of malfunction during operation, monitoring syringe pressure and allowing fill or retract of syringe. The new RFID features include: marking a syringe as used, identifying expired syringes and automatic identification of drug product attributes (product name, concentration, fill volume, lot number and expiration). The operator's manual also references the ability for the system to detect saline vs. contrast syringes and warn the user if the fluid in the syringe does not match the injector set up. The sponsor claims that the RFID will enhance the safety features of the OptiVantage Injector.

I agree with Lead Reviewer Kim Peters that devices which operate without sufficient user input are high risk devices so I checked for closed loop or automatic use. This device does not have a sensor or any diagnostic capability; therefore it cannot

be truly closed loop. Section 5 of the operator's manual describes the injection procedure. The operator is instructed to review the parameters (RFID enters syringe data) before pressing the "start protocol key". This seems sufficient.

⌘ The intended use is the same as the predicate device (K042744) intended use. No new intended use issues are raised by the addition of RFID.

Device Description
The only identified difference between this system and K042744 is the addition of RFID for "enhanced communication" or adding a layer of enforcement for safety features.

RFID specifications and comparison to cleared RFID tag

File	K042555	K063503
Name	Surgichip	OptiVantage DH injector with Enhanced Communication
Common Name	adhesive marker	
Classification	21 CFR 878.4660 Class I, FZZ	
Tag		
Tag vendor	B4 [redacted]	B4 [redacted]
Capability	read/write	Read/write – some fields are locked (read only)
Activation	passive	passive
Frequency	13.56 MHz	13.56 MHz
Defect Rate		3-5% from mfg, 100% verified for function
Reader		
Reader vendor	B4 [redacted]	B4 [redacted]
Protocol	iscan standard multi tag protocol	ISO 15693 Wireless Protocol
Transmitting power	0.5 W	150 mW
Radiated emissions		121.2 dBµV at 3 m (new information in S1)
Antenna Gain		1.13 dBi
Reading distance	18 cm (max)	2-3 inches

Although not formally recognized by FDA, ISO 15693 Identification cards — Contactless integrated circuit(s) cards — Vicinity cards is sufficient to define the electrical characteristics, modulation and protocol for this RFID application. ISO 15693 is composed of three parts: Part 1: Physical characteristics, Part 2:Air interface and initialization Identification cards and Part 3: Anticollision and transmission protocol. A few details from the standard are included below:

The frequency fc of the RF operating field is 13.56 MHz ±7 kHz.
The minimum operating field is Hmin and has a value of 150 mA/m rms.
The maximum operating field is Hmax and has a value of 5 A/m rms.
Communications between the VCD and the VICC takes place using the modulation principle of ASK. Two modulation indexes are used, 10% and 100%. The VICC shall decode both. The VCD determines which index is used.

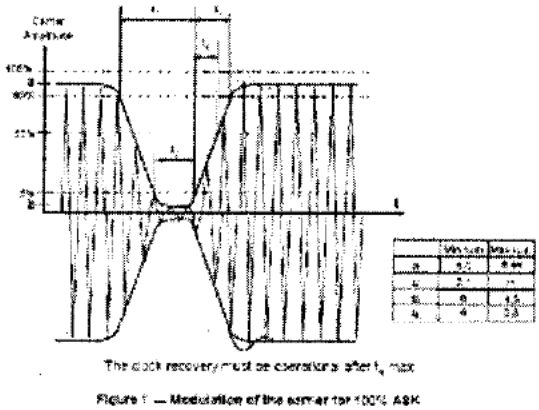

Figure 1 — Modulation of the carrier for 100% ASK

Up to 256 blocks can be addressed. The specified block size can be of up to 256 bits. This leads to a maximum memory capacity of up to 8 kBytes (64 kBits).

⌘ The fundamental scientific technology has not changed. The sponsor has provided a comparison with their legally marketed device showing only RFID differences. The above comparison with a cleared RFID device show similarities. Risk Analysis and testing are required.

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Testing

Some of the hardware testing used the system transfer functions (an equation expressing the relationship between system inputs and system outputs) and the Cpk or process capability index (adjusted for non centered distribution). The sponsor used Cpk to show that the outputs are within the specification limits. The larger the index the less likely it is that any result will be outside the specification.

Hardware Verification testing :

Title	Description	Acceptance criteria	Result	Issues?
D4284- Sufficient antenna read range	The distance between the syringe and antennas, the distance from the RFID tag to antenna center, resonant voltage of the RFID antennas and the rotational position of the RFID label was varied and measured for 12 cases. The resulting values were input into the system transfer function.	Cpk >1.33	Cpk = 4.51	Test results, conclusions, design recommendations and discussions presented in D4297 S1. No Issues
D4294- Minimal heater temperatures	Determine powerhead output voltage, maximum steady state surface temperature, maximum steady state contrast temperature 10 samples tested	Contrast media <40°C PCB cover surface <85°C	Contrast media 27 to 30.81°C PCB cover surface 45 to 60°C	Test results presented in D4307 S1 No issues
D4188- Capability to remove syringe	The syringe is removed at various ram locations for each syringe size and each faceplate assembly 16 samples tested	80% confidence <2 failures in 42 samples	All syringes removed, some with more difficultly	D4423 provided in S1 No issues
D4291Regulatory compliance for intentional RF transmitter - FCC part 15	EMC testing to FCC part 15 (specified sections), RSS 210, ICES-003, EN 300 330 and EN 301 489	Complies with standard	?	General test compliance reported in D4304 S1. Radiated emissions are not specified for RF reader. Page 34 of manual states that emissions meet IEC 60601-1-2. RF reader not tested to 60601-1-2. Immunity test specifications not provided for RF system. See new deficiency
D4313 RF exposure	Exposing OptiRay 350 to RF and checking drug quality (two temperatures 25 °C and 40 °C, two RF exposure levels 13.56 MHz-7.57 and 7.62 dBm)	No significant difference in stability tests p>0.05	Color P=0.6 Assay P=0.2 MP2197 P=0.6 MP 2206 P=0.4 MP 429 P=0.8 pH P=0.9 Impurities P=1	Results reported in D4314; not provided. Results applicable to NDA not 510(k).
D4406 RFID validation	Read the syringe with the injector, empty syringe, read to get "used" warning 5 syringes, 3 injectors, see that user is prompted Qty 30 -125 mL syringes tested Qty 30 – 50 mL syringes tested	Read correctly, Used warning, Correct operation	All syringes correctly read, all match information provided, all removable. Damaged tags detected. Prompt text is different from protocol.	The test results are reported in D4407 S1 No issues

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Labeling

S1 includes a revised The OptiVantage Injection with Enhanced Communication Operator's Manual. There are section numbers but no page numbers. The order and format has changed but the following comments are still acceptable:

S1 section 1.5.2 meets radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices.

S1 section 1.3.1 RFID capability – stores syringe data, constraining injection protocol, validating system configuration, prevents reuse

S1 section 1.5.7 RFID transceiver- frequency 13.56 MHz, antenna gain 1.13 dBi- radiated emissions 121.2 dBμV at 3m

S1 section 1.5.1 warning to keep device more than 6 inches from pacemakers or defibrillator

The device labels and package insert contain the logo indicating use of RFID.

The Optiray drug package insert states "The Optiray syringe has been labeled with a Radio Frequency identification (RFID) tag. This tag allows for the exchange of information such as lot number, expiration and concentration. Exchange of patient information does not occur with the use of this RFID tag. Use of the RFID tag does not impact Optiray product quality." The RFID frequency and power are not specified.

References

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
http://www.fda.gov/cdrh/ode/guidance/337.html#7

ISO 15693 Identification cards — Contactless integrated circuit(s) cards — Vicinity cards

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: December 19, 2006 Reviewer(s) - Name(s) Kimberly Bowie Peters

Subject: 510(k) Number K063503

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

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept). see attached review
- ☐ 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 NA

☐ The indication for use form Requested

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 day

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

Review: Ashley B. Boam (Branch Chief) ICRB (Branch Code) 12/19/06 (Date)

Final Review: (Division Director) (Date)

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Revised:4/2/03

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?	NA	
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)?	NA	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	NA	
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.	NA	

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K063503

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. **	NA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	NA	
510(k) Kit Certification ***	NA	

* - 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.

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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: K. Peters

Concurrence by Review Branch: [illegible]

Date: 12/19/06

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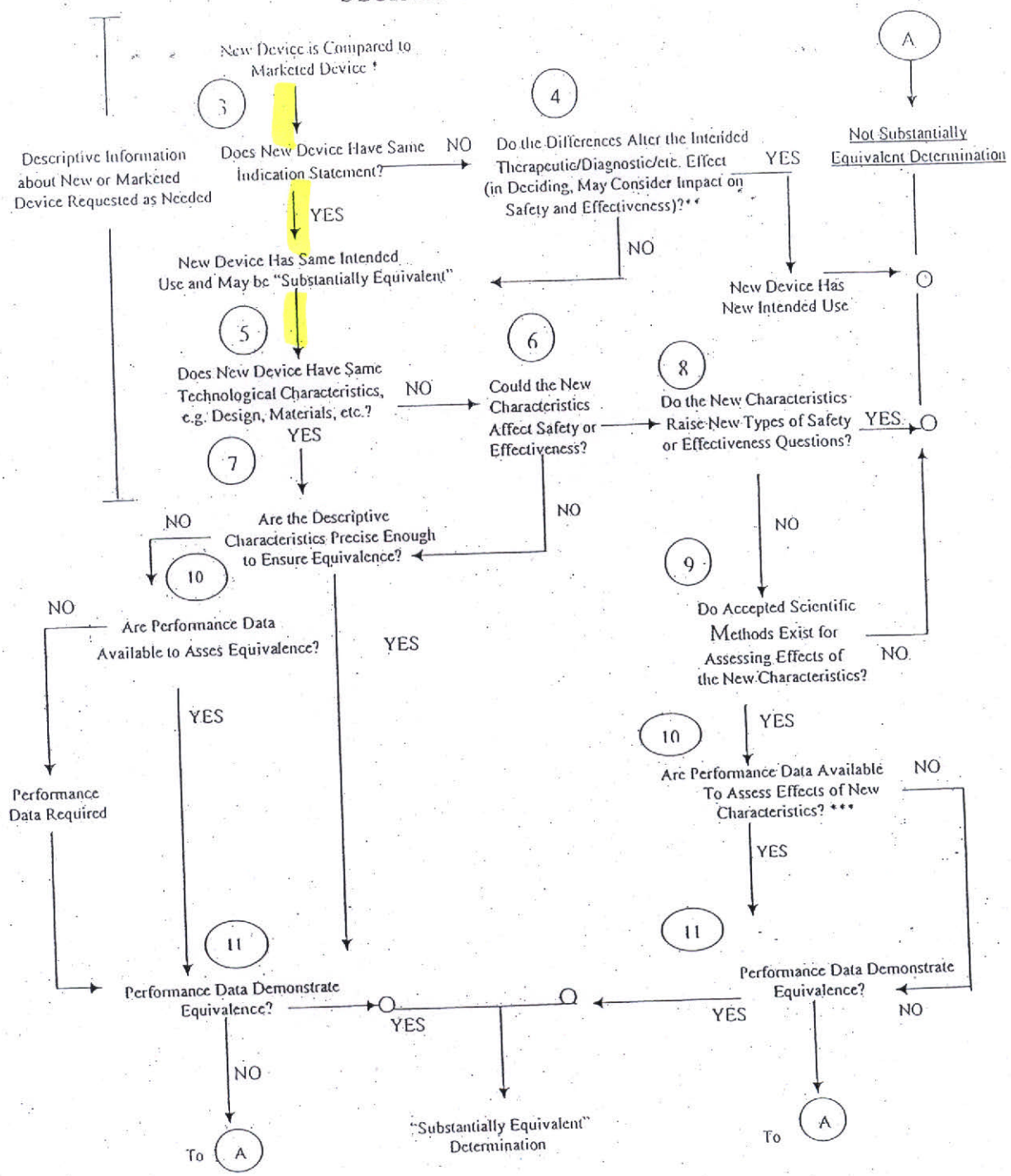
The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, 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

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



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

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be from the 510(k), other 510(k)s, the Center's classification files, or the literature.

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See attached review

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.

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See attached review

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

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SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K063503

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
   OptiVantage DH Injection System (K042744) (Section 4, page 12)

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
   The indications for use statement is provided in Section 2 (page 8) of the submission and is as follows:

   "The OptiVantage DH Injector System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e., "CT") equipment."

   The currently marketed OptiVantage DH Injection System (K042744) features the same indications for use statement. (Section 4, page 12)

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
   The change under review in this submission is for the addition of the RFID function to the OptiVantage DH Injection System only. ***Other than the meeting minute information, the submission does not include a detailed description of the modifications being made for the development of the OptiVantage DH with Enhanced Communication.***

   The addition of the RFID tags to the prefilled syringes (Optiray) will be addressed in a Changes Being Effected-30 (CBE-30) supplement to NDA 19-710 submitted to CDER, and the submission is to include information supporting that there is no impact to the Optiray, as well as documentation supporting RFID tag specifications, control, validation, and function. The CBE-30 should also "provide data describing the master validation plan for Optiray, RFID tag, and OptiVantage." As noted in the 12/11/06 email from Guirag Poochikian of CDER (copy attached), the firm has not submitted the CMC portion for the Optiray prefilled syringe. The CDER/ONDQA post-approval review division told the firm to submit to CDRH first so the device aspects are in order and then the CMC studies could be appropriately designed.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and specifications.
   Comparison information is included in Section 4

5. A **Design Control Activities Summary** which includes:
   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
      Section 7 (pages 16-21) - The submission indicates that the risk management process is performed in accordance with Work Instructions QSEWI22, Risk Analysis and QSEWI12, Failure Modes and Effects Analysis. ***A description of the work instructions should be provided for review.***
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

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The summary of the verification and validation activities does not identify the test method, or acceptance criteria, nor does it indicate whether the acceptance criteria were met. In addition, complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

c) A declaration of conformity with design controls. The declaration of conformity should include:
   i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
   ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
   (Section 9, page 24)

6. A **Truthful and Accurate Statement** *(Section 11, page 26)*, a **510(k) Summary** *(Appendix H)* **or Statement** and the **Indications for Use Enclosure** ***(Not Provided)*** **(and Class III Summary for Class III devices).**

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K063503

Reviewer: Kimberly Bowie Peters

Consulting Reviewer: Ann Ferriter, DGRND/OSDB (Consulting review on injector RFID capabilities)

Division/Branch: DCD/ICDB

Device Name: OptiVantage DH Injector System with Enhanced Communication

Product To Which Compared (510(K) Number If Known): K042744

History of Submission:
This submission includes a special 510(k) submission for the OptiVantage DH Injector System with Enhanced Communication. On May 9, 2006, there was a meeting between Mallinckrodt and CDER to discuss a proposed submission strategy regarding the user of Radio Frequency Identification (RFID) tags placed on Optiray (ioversol injection) pre-filled syringes (NDA 19-710). Ms. Ann Ferriter of DGRND/OSDB was the CDRH representative for this meeting, since Ms. Ferriter has expertise in the review of RFID devices. The meeting minutes (prepared and provided to the firm by CDER) are included in the submission (after the cover letter). During the meeting, the firm was informed that the change to incorporate RFID to the injector system would qualify as a special 510(k), and the submission should address the hardware and software necessary for reading and writing the tag information, as well as integration of the tag information into the existing software that controls the contrast administration. The changes to the Optiray should be submitted as a Changes Being Effected-30 (CBE-30) supplement to NDA 19-710, and the submission should include information demonstrating that there is no impact to the Optiray, as well as documentation supporting RFID tag specifications, control, validation, and function. The CBE-30 should also "provide data describing the master validation plan for Optiray, RFID tag, and OptiVantage." As noted in the 12/11/06 email from Guirag Poochikian of CDER (copy attached), the firm has not submitted the CMC portion for the Optiray prefilled syringe. The CDER/ONDQA post-approval review division advised the firm to submit to CDRH first so that the device aspects are addressed and then the CMC studies could be appropriately designed.

Indications for Use:
The OptiVantage DH Injector System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e., "CT") equipment.

The currently marketed OptiVantage DH Injection System (K042744) features the same indications for use statement.

Device Description
The device description information is provided in Section 3 of the submission as well as in the background information provided for the 5/9/06 meeting between FDA/CDER and Mallinckrodt.

The OptiVantage DH Injector System with Enhanced Communication delivers radiographic contrast media and/or saline at a controlled flow rate and volume into a patient's vascular system for the purpose of obtaining enhanced diagnostic images. Like the predicate device (K042744), the OptiVantage DH Injector System with Enhanced Communication consists of 4 main components:

- Power Head – The power head contains 2 electromechanical syringe drive systems, the syringe holding mechanisms, the main processor, control electronics, control keypad for programming and initiating injection protocols, a status display, and 2 purge/retract manual knobs. The OptiVantage uses a drive system uses a motor and gearbox coupled to a ball screw. The ball screw drives a ram that attaches to the syringe plunger in order to fill or expel the contents of the syringe.
- Power Supply – The power supply converts the line voltage to the working voltage for the power head and console.
- Console – The console communicates with the power head to program and initiate injection protocols, displays the injection status, and displays a timer.
- Syringes – The OptiVantage DH Injector System with Enhanced Communication accommodates the Mallinckrodt 125ml pre-filled syringe styles as well as a 200ml front loading empty syringe. These are the same syringes currently used with the predicate device.

The submission (page 2 of 5/8/06 background information provided for 5/9/06 meeting) indicates that the RFID electrical hardware has been designed by [redacted] using an IC from [redacted]. The hardware is designed to use the ISO 15693 Wireless Protocol (operating at a frequency of 13.56MHz), and radiates a maximum of 150mW from one of two antennas. The system has the capability to read an RFID tag using the ISO 15693 protocol. [redacted] supplies the RFID tags, which are integrated into a label supplied by [redacted]. The submission (page 4 of 5/8/06 background information provided for 5/9/06 meeting) indicates that integration of the RFID functionality will require a faceplate upgrade and a new software release.

The wireless connector only exists between the injector faceplate and the syringe RFID tag. The system features allow the transfer of drug product name, concentration, fill volume, drug lot number, manufactured date, expiration and used/unused status from the syringe to the injector. The injector will write back to the syringe that use has occurred. No patient information will be exchanged.

The submission (page 9) indicates that specifications and information regarding the syringe and labels, RFID tags, and data used by the RFID system are included in Appendices C, D, and G. Appendix C includes the syringe labels and package inserts. Appendix D includes the RFID Syringe, tag, and data specifications.

The submission (page 2 of 5/8/06 background information provided for 5/9/06 meeting) indicates that the RFID system has been designed to meet FCC 15.225 requirement: "Section 15.225 Operation within the band 13.553-13.567MHz." The submission indicates that testing with an accredited EMC test facility has shown that the RFID system meets these requirements.

With regard to verification of the coexistence, data integrity, security and performance requirements, the submission (page 3 of 5/8/06 background information provided for 5/9/06 meeting) indicates that ISO 15693 protocol (RFID data protocol) specifies both data integrity checks and collision detection mechanisms for data transfer. Collision of data can occur when 2 or more RFID tags are within the read field. Data transmission errors can occur if an RFID tag is damaged or if it is outside the read range. The submission indicates that "tests have been or will be performed to

ensure: 1) RFID tags entering the manufacturing facility are functional and have correct data encoded; 2) RFID tags on syringes leaving the manufacturing facility are functional and have correct data encoded; 3) the RFID reader on the injector system can reliably read functional tags on an inserted syringe."

In addition, a calculated cyclic redundancy check (CRC) or checksum value is written to the tag each time data is stored on the tag to ensure data integrity. The injector will verify the checksum values to ensure the data has not been changed or damaged since leaving the syringe manufacturing facility. The read-only data fields on the tag (i.e., expiration date) are locked, preventing any change after being written by the factory. All wireless data transfers between the faceplate and the injector also have a checksum to ensure data integrity. In the event that a tag cannot be read or the data is corrupt, the injector panel displays messages to notify the user.

If a wireless connection cannot be established, the injector reverts to its current mode of operation.

Bench Testing Information:

Appendix D (pages 208-212) includes an engineering report for the label function verification test. The purpose of this test was to determine the failure rate of the B4 [redacted] tags incorporated into the labels manufactured by B4 [redacted]. The sample size for the test was [redacted] (representing the various Optiray syringe volume and concentration) due to label availability, B4 [redacted] labels were read, and B4 [redacted] tags/labels [redacted] were determined to be "bad."

Appendix F includes hardware verification testing information. The submission indicates that testing was performed to demonstrate:

- Sufficient antenna read range – This testing was performed on "product equivalent units and was performed to determine how reliably the Optivantage DH could read data from the Optiray syringe's RFID tag. The submission references test report D4284. Report D4284 only includes the test procedure and this report indicates that the results/conclusions are provided in D4297. **Test report D4297 should be provided for review.**
- Minimal heater temperature (under normal and fault conditions) – The submission indicates that testing was performed to ensure that both the surface temperature and contrast media temperature remained at safe levels if fault conditions occurred. The submission references test report D4294. Report D4294 only includes the test procedure and this report indicates that results/conclusions are provided in D4307. The submission also indicates that "test design recommendations and discussions are presented in D4307 rev B." **Test report D4307 should be provided for review, and as well as clarification as to why the conclusions include "test design recommendations."**
- Capability to remove the Optiray syringe at any ram position – The submission indicates that a verification test was performed and verified that this requirement was met using production equivalent. The submission references test report D4188. D4188 only includes the test procedure. **Results of this test should be provided for review.**
- Regulatory compliance for an intentional RF transmitter – The submission indicates that all applicable standards for a radio transmitter at 13.56MHz were met, including FCC Section 15.225, FCC Part 15.107, FCC Part 15.109, RSS-210, ICES-003, EN 300 330, and EN 301 489-3. The submission references test report D4291. Report D4291 only identifies the above standards as the test procedure and indicates that "test results shall be documented in D4303." **This statement implies that the testing has not been completed. Test results should be provided for review.**

Appendix G includes a 16 hour RF impact study. During this test, the Optiray 350 125ml pre-filled syringes were exposed to controlled RF energy for an extended time at 2 temperature levels. After RF exposure, the syringes will be analyzed to determine if there is any quality impact on the drug product. **This information will be reviewed by CDER during the review of the CBE-30 submission.**

Appendix H includes RFID System Technology Validation testing information. This test was performed to demonstrate that production equivalent Optiray prefilled syringes with RFID would function correctly in the OptiVantage DH Injector System with Enhanced Communication. The submission indicates that testing was conducted in accordance with test protocol D4406 rev B. The submission (page 368) indicates that the result met all requirements of the protocol. Test report D4406 (page 372) indicates that "test results shall be documented in D4407." **This statement implies that testing has not been completed. Test results should be provided for**

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review.

Software Documentation:
Software information is included in Section 8 (pages 22-23) and Appendix E. **The software documentation is inadequate. The software documentation did not include a hazard analysis, requirements document, software development life cycle information, complete verification and validation including results, and an trace matrix relating the requirements with the V&V tests.**

The submission (page 22) indicates that The OptiVantage DH Injector System with Enhanced Communication software consists of 3 subsystems:

- Power Head software – Injects fluids at specified volume and flow rate as programmed by the user
- Console software - Displays injector status and allows the user to program and start an injection from a remote location
- Faceplate software – Controls the operation of the RFID reader hardware

In addition to the software features provided with the predicate device, the modified system provides the following additional functions:

- RFID technology allows the injector to "mark" an RFID-enabled syringe as used when an injection is initiated and disallow further use of that syringe.
- RFID technology allows the injector to determine whether an RFID-enabled syringe is expired and prevent further use of that syringe.
- RFID technology allows the injector to obtain drug product attributes from an RFID-enabled syringe (product name, concentration, fill volume, lot number, expiration)

Appendix E includes the "Risk Analysis Software Verification Summary and Protocols." Appendix E only includes a copy of the verification and validation test protocol (D4349).

The submission (page 243) indicates that verification testing was performed on the following development versions of software which implement RFID functionality on the OptiVantage DH Injection System:

- OptiVantage DH Powerhead Software Version: D03.00.10
- OptiVantage DH Console Software Version: D03.00.10
- OptiVantage DH 125ml RFID Faceplate Software Version: D00.08

Request for Additional Information:
Due to the lack of complete bench testing information and software documentation, it is recommended that the following information be requested in a hold letter to the firm:

1. The device description information does not include a clear description of the modifications made to the currently marketed OptiVantage system for the development of the OptiVantage DH Injector System with Enhanced Communications. Please provide this information which should address both hardware and software modifications. In addition, it is unclear if the RFID feature is only intended to be used with the pre-filled contrast syringes or the pre-filled saline syringes. Please address this issue.

2. Please address the following regarding the bench testing information:

   a. You have provided protocols and acceptance criteria for testing the OptiVantage DH Injector System with Enhanced Communication, including D4284 – Sufficient antenna range, D4294 – Minimal heater temperatures, D4188 – Capability to remove syringe, D4291 Regulatory compliance for intentional RF transmitter, and D4406 RFID validation. These reports indicate that the test results and conclusions are provided in separate referenced test reports. Please provide the referenced test reports D4297, D4307, D4304, and D4407 for review, as well as the results for test D4188. Please be advised that the testing information provided for review should testing procedures and protocols, sample size, acceptance criteria, justification for the chosen sample size and acceptance criteria, test results, and an analysis of the results. FDA acknowledges that you have submitted the enhanced communication change in a special 510(k) submission; however,

FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

b. For D4294 – Minimal heater temperatures test, please provide a scientifically valid justification for the acceptance criteria. In addition, the conclusion section for D4294 indicates that "test design recommendations and discussions are presented in D4307 rev B." Please describe these test design recommendations, explain if the test protocol was modified to address these recommendations, if the test was repeated, etc.

3. You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

4. The risk analysis methods and summary information (Section 7) is inadequate. Please identify the risk analysis methods used to assess the impact of the modifications. The submission only indicates that the risk analysis was performed in accordance with work instructions QSEW122 and QSEW112. In addition, please provide a revised summary of the verification and validation activities that includes a description of the methods or tests used, acceptance criteria applied, and an indication of whether the acceptance criteria were met. The summary provided only includes bullets, such as "RFID system-level validation" and "verification testing of enable sequences," indicating that verification testing was performed.

5. Please address the following regarding the operator's manual for the OptiVantage DH Injection System with Enhanced Communication. Please provide a revised copy of the operator's manual for review.

a. In the OptiVantage DH Injection System with Enhanced Communication operator's manual (pages 28 – 185), you have included information on RFID. To aid the user in avoiding electromagnetic interference problems, please include the transceiver power and field strength at a specified distance in the operator's manual.

b. The operator's manual (Appendix A, page 46) indicates that "a subset of the syringe data provides parameters used for constraining the injection protocol and validating the system configuration." Please explain what syringe data parameters provided via the RFID are used for constraining the injection protocol and validating the system configuration.

6. Please provide the following software information and documentation for the OptiVantage DH Injection System with Enhanced Communication. The Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices maybe a helpful reference.

a. On page 23 of the submission you have included the level of concern determination questions and answered no to all. However, in the risk analysis, you state that misreading injection parameters could lead to toxicity. Please address whether a failure to read the correct parameters or interpret the RFID correctly could lead to a serious injury or a minor injury. Please be advised that FDA believes the appropriate level of concern for the software should be at least moderate or major. Please address this issue.

b. Please provide a hazard analysis for the device software. This information should include identification of the hazardous event, the method of control, corrective measures taken, including aspects of the device design, that eliminate, reduce, or warn of a hazardous event, and testing demonstrating the implementation of the safety features.

c. Please provide a discussion of your software development lifecycle, including the activities that take place during each phase of the lifecycle, the quality control and assurance activities and methods, the development environment, the documentation generated, verification and validation activities, configuration management, version control, audits, and maintenance.

d. Please provide the current software and system requirements for the device. This information should include a discussion of system hardware requirements, internal software tests and checks, internal and external performance and functional requirements, and safety requirements. Block diagrams showing the system architecture/software design would also be helpful. Also, please discuss how you adequately qualified off-the-shelf software and hardware for incorporation into the device, if applicable, and provide appropriate documentation as discussed in the Guidance on Off-the-Shelf Software Use in Medical Devices.

e. Please provide the system level testing procedures and protocols, the pass/fail criteria, test results, and an analysis of the results. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application. Also, please provide a test report summarizing how all phases of testing (module, integration, and system) demonstrate that requirements were met. Note that testing should address all options and accessories, communications, and adequate regression testing. You should also explain how testing has adequately stressed the system, including communications, data throughput, device configurations, fault conditions, alarm conditions, boundary value conditions, error and range checking on parameters and calculations, interpretations and analyses made by the device, path analysis, etc. The testing you provide should be traceable to the software and system requirements of the device (i.e., trace matrix relating requirements to verification and validation tests). This report should also include a discussion and explanation of how you achieved the desired level of test coverage required for the device and how remaining software anomalies and bugs (listed in the report) do not present a risk to patient safety or effectiveness, directly or indirectly. Please specify the current version level of the software in the documentation you provide.

7. You have provided test protocol D4313 – RF Exposure of OptiRay 350 in the submission. Minutes from the May 9, 2006 meeting indicate that you would be submitting a Changes Being Effected-30 (CBE-30) supplement to the NDA for the OptiRay syringes. Please be advised that CDRH does not review drug quality testing, and this 510(k) submission will not resolve any issues of drug quality. Therefore, this testing information should also be included in your CDER submission.

8. Please provide a completed indications for use form (see enclosure) for the OptiVantage DH Injector System with Enhanced Communication. The prescription information on the form should also be completed.

		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**

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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.

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

1. Explain why not a device: OptiVantage DH Injector System with Enhanced Communication is a device.
2. Explain why not subject to 510(k): The device is subject to a 510(k) submission.
3. How does the new indication differ from the predicate device's indication: The indications for use statement is identical to that of the predicate.
4. Explain why there is or is not a new effect or safety or effectiveness issue: NA
5. Describe the new technological characteristics: The OptiVantage DH Injector System with Enhanced Communication differs from the predicate device in that it features an RFID capability. RFID capability is not a new technological characteristic for medical devices.
6. Explain how new characteristics could or could not affect safety or effectiveness: NA
7. Explain how descriptive characteristics are not precise enough: Descriptive characteristics are not precise enough. Testing demonstrating the function, performance, immunity, and accuracy of the RFID capability is necessary.
8. Explain new types of safety or effectiveness questions raised or why the questions are not new: NA
9. Explain why existing scientific methods can not be used: NA
10. Explain what performance data is needed: Testing demonstrating the function, performance, immunity, and accuracy of the RFID capability is necessary.
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

Kimberly Boone Ph

(Reviewer's Signature)

12/19/06

(Date)

12/19/06

Memorandum

To: Kimberly Bowie Peters, Biomedical Engineer
ODE/DCD/ICDB

From: Ann Ferriter, Mechanical Engineer

Date: 17-December-2006

Regarding: K063503 Optivantage DH Injector System with Enhanced communication
RFID consult

Recommendation: AI – needs testing, software documentation, labeling change and CDER advisory

Ann Ferriter
Reviewer, ODE/DGRND/OSDB

The special 510(k) was submitted to clear the use of RFID on the contrast media with an injector cleared in K042744. There is no other change to the device identified in the submission. This review covers the intended use, RFID and software information supplied in:

- Meeting Minutes front of submission
- Indication for Use pg 8
- Device Description pg 9
- Risk Analysis pg 16
- Appendix A OptiVantage DH Injector System with Enhanced Communications Operators Manual pg 27
- Appendix B Rating Plate 186
- Appendix C Product Labeling Package Insert pg 199
- Appendix D RFID Syringe, Tag and Data Specifications
- Appendix E Risk Analysis Software Verification Summary and Protocol
- Appendix F Risk Analysis Hardware Verification Summary and Protocols
- Appendix G 16 hr RF Impact Study
- Appendix H RFID System Technology Validation Summary & Protocol
- Appendix I Special 510(k) Summary

History:
On May 9, 2006, Mallinckrodt and FDA met at CDER to discuss adding RFID to the Optiray/OptiVantage injector system. We recommended that Mallinckrodt submit a CBE-30 (changes being effected) supplement to CDER for the Optiray NDA 19-710 and a Special 510(k) to CDRH to build on K042733, the OptiVantage Dual Head contrast media injector. I asked Mallinckrodt the following RFID questions for which they have provided answers and/or support in the submission:

- Define all functions which will be implemented wirelessly.
- Define the information to be transmitted.
- Provide the RF wireless communication specifications (transmission frequency, transmission power, protocol).
- Validate operation in the presence of other in-band transmitters and provide restrictions on the number or characteristics of other in-band transmitters. Provide specifications for dropped transmissions and transmission rate.
- Verify transmitted data integrity. Please provide transmission accuracy testing.
- Ensure wireless connectivity and provide testing of alarms or alternate modes if wireless communication path is lost or corrupted
- Describe the security features of your device.
- Provide verification and validation test data of the security features to prevent unauthorized access to data or networks.
- Verify environmental design specifications (temperature and humidity limitations)

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Intended Use
The OptiVantage DH Injector system with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

From the software section and May 8, 2006 letter page 2:
The system monitors and controls the syringe plunger for injecting fluid as programmed by the caregiver. The functions include a power on self test for injector failure, detection of malfunction during operation, monitoring syringe pressure and allowing fill or retract of syringe. The new RFID features include: marking a syringe as used, identifying expired syringes and automatic identification of drug product attributes (product name, concentration, fill volume, lot number and expiration). The operator's manual also references the ability for the system to detect saline vs. contrast syringes and warn the user if the fluid in the syringe does not match the injector set up. The sponsor claims that the RFID will enhance the safety features of the OptiVantage Injector.

I agree with Lead Reviewer Kim Peters that devices which operate without sufficient user input are high risk devices so I checked for closed loop or automatic use. This device does not have a sensor or any diagnostic capability; therefore it cannot be truly closed loop. Section 5 of the operator's manual describes the injection procedure. The operator is instructed to review the parameters (RFID enters syringe data) before pressing the "start protocol key". This seems sufficient.

☒ The intended use is the same as the predicate device (K042744) intended use. No new intended use issues are raised by the addition of RFID.

Device Description
The only identified difference between this system and K042744 is the addition of RFID for "enhanced communication" or adding a layer of enforcement for safety features.

RFID specifications and comparison to cleared RFID tag

File	K042555	K063503
Name	Surgichip	OptiVantage DH injector with Enhanced Communication
Common Name	adhesive marker	
Classification	21 CFR 878.4660 Class I, FZZ	
Tag		
Tag vendor	B4 [redacted] B4 1 [redacted]	B4 [redacted] B4 [redacted] B4 [redacted] (read only)
Capability	passive	passive
Activation	13.56 MHz	13.56 MHz
Frequency		
Defect Rate		3-5% from mfg, 100% verified for function
Reader		
Reader vendor	B4 [redacted]	B4 [redacted]
Protocol	iscan standard multi tag protocol	ISO 15693 Wireless Protocol
Transmitting power	0.5 W	150 mW
Antenna Gain		1.13 dBi
Reading distance	18 cm (max)	2-3 inches

Although not formally recognized by FDA, ISO 15693 Identification cards — Contactless integrated circuit(s) cards — Vicinity cards is sufficient to define the electrical characteristics, modulation and protocol for this RFID application. ISO 15693 is composed of three parts: Part 1: Physical characteristics, Part 2:Air interface and initialization Identification cards and Part 3: Anticollision and transmission protocol. A few details from the standard are included below:

The frequency fc of the RF operating field is 13,56 MHz ±7 kHz.
The minimum operating field is Hmin and has a value of 150 mA/m rms.
The maximum operating field is Hmax and has a value of 5 A/m rms.
Communications between the VCD and the VICC takes place using the modulation principle of ASK. Two modulation indexes are used, 10% and 100%. The VICC shall decode both. The VCD determines which index is used.

SSS

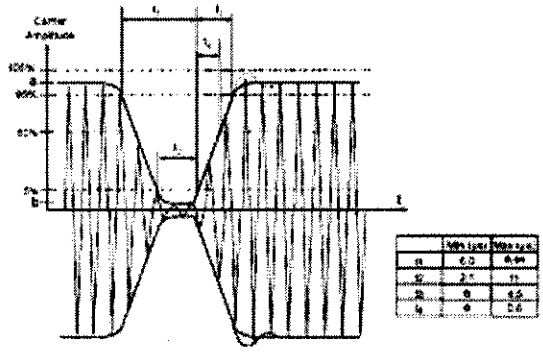


Figure 1 — Modulation of the carrier for 100% ASK

Up to 256 blocks can be addressed. The specified block size can be of up to 256 bits. This leads to a maximum memory capacity of up to 8 kBytes (64 kBits).

⌘ The fundamental scientific technology has not changed. The sponsor has provided a comparison with their legally marketed device showing only RFID differences. The above comparison with a cleared RFID device show similarities. Risk Analysis and testing are required.

Risk Analysis

The sponsor states that there is no additional risk to the patient due to the use of RFID and then provides a risk analysis that includes RFID as a control method. I have used their information to discuss possible risks due to RFID and have modified the risk analysis.

Risk	Mitigation Method
RFID can interfere with implanted medical devices. Following preliminary testing that showed that RFID readers could disrupt pacemakers, the ANSI AAMI PC69 group has proposed lowering the radiated immunity test frequency to cover those used for RFID.	Operator's manual includes warning to keep unit at least 6" (15 cm) from pacemakers or defibrillators. <5 guass field, 150 mW output power
RFID can interfere with other medical devices	IEC 60601-1-2 radiated emissions – not provided, see deficiency
RFID failure- "used syringe" warning will not appear	Warning displayed saying RFID cannot be read or is not present. System prompts for user input
RFID failure – injection parameters incorrect or not provided- could lead to toxicity	Warning displayed saying RFID cannot be read or is not present. Incorrect parameters – operator is instructed to check parameters before start

⌘ Labeling for potential interference, limiting the power output, performing the indicated testing and using the existing technique if the RFID fails could acceptably mitigate risks. The testing should be provided to support this risk analysis.

Testing

Hardware Verification testing :

Title	Description	Acceptance criteria	Result	Issues
D4284- Sufficient antenna read range	The distance between the syringe and antennas, the distance from the RFID tag to antenna center, resonant voltage of the RFID antennas and the rotational position of the RFID label was varied and measured for 12 cases. The resulting values were input into the system transfer function.	Cpk >1.33	Cpk = 4.51	Could an operator be holding the syringe during RFID read? Test specifies all body parts >2 inches from antennas. Test results, conclusions, design recommendations and discussions presented in D4297. Where is D4297?
D4294- Minimal heater	Determine powerhead output voltage, maximum steady state	Contrast media <40°C	??	Test results presented in D4307

temperatures	surface temperature, maximum steady state contrast temperature	PCB cover surface <85°C		Where is D4307?
D4188-Capability to remove syringe	The syringe is removed at various ram locations for each syringe size and each faceplate assembly	80% confidence <2 failures in 42 samples	?	no test results or test report.
D4291Regulatory compliance for intentional RF transmitter - FCC part 15	EMC testing to FCC part 15 (specified sections), RSS 210, ICES-003, EN 300 330 and EN 301 489	Complies with standard	?	Test results reported in D4304. Where is D4304? Check to see that radiated emissions are low. Page 34 of manual states that emissions meet IEC 60601-1-2. Is this with the RF transmission exemption?
D4313 RF exposure	Exposing OptiRay 350 to RF and checking drug quality (two temperatures 25 °C and 40 °C, two RF exposure levels 13.56 MHz-7.57 and 7.62 dBm)	No significant difference in stability tests p>0.05	Color P=0.6 Assay P=0.2 MP2197 P=0.6 MP 2206 P=0.4 MP 429 P=0.8 pH P=0.9 Impurities P=1	Results reported in D4314; not provided. Results applicable to NDA not 510(k).
D4406 RFID validation	Read the syringe with the injector, empty syringe, read to get "used" warning 5 syringes, 3 injectors, see that user is prompted	Read correctly, Used warning, Correct operation	?	The test results are reported in D4407. Where is D4407.

Software

The software documentation was reviewed. The documentation is not complete and does not follow the software guidance.

On page 23 the sponsor has listed the level of concern determination questions and answered no to all. However, for the following question the answer may be yes.

c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?

In the risk analysis the sponsor stated that misreading the injection parameters could lead to toxicity. The sponsor should address whether a failure of the system would lead to a serious injury or a minor injury.

Level of Concern	The severity of injury that a device could permit of inflict as a result of latent failures, design flaws or using the software.	? page 23
Software Description	Comprehensive overview of device features controlled by software and the intended operational environment	√
Device Hazard Analysis	Hazardous events, level of concern, cause(s) of hazard, method of control, corrective measures taken, testing	Not provided
Software Requirements Specification	Functional, performance, interface, design and developmental requirements	Not provided
Architecture Design Chart	Chart partitioning the software into functional blocks	Not provided
Design Specification	Description of what the program should do and how it should do it (includes programming language)	Not provided
Traceability Analysis	Traceability matrix links requirements, design specifications, hazards and validation	Not provided
Development	Summary of the software life cycle plans	Not provided
Validation, Verification and Testing	Systematic application of analyses, evaluations, assurances and testing of the software	Protocol only
Revision Level History	Revision History Log	Software revision history not provided
Unresolved Anomalies	For moderate and major concern software, all unresolved	Not addressed

	anomalies	
Release Version Number	Current version number	Not provided

✂ Test reports and results have not been provided. It is unclear whether the device met the acceptance criteria. See deficiencies.

Labeling
The OptiVantage Injection with Enhanced Communication Operator's Manual (pages 28-185) includes information on RFID.
Page 34 meets radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices. Does this include the transmission band?
Page 48 RFID capability – stores syringe data, constraining injection protocol, validating system configuration, prevents reuse
Page 53 RFID transceiver- frequency 13.56 MHz, antenna gain 1.13 dBi- power or radiated emissions not specified
Pages 115-116 no mention of RFID in dangers, warnings and cautions
Pages 140 warning to keep device more than 6 inches from pacemakers or defibrillator

The device labels and package insert contain the logo indicating use of RFID.
The Optiray drug package insert states "The Optiray syringe has been labeled with a Radio Frequency identification (RFID) tag. This tag allows for the exchange of information such as lot number, expiration and concentration. Exchange of patient information does not occur with the use of this RFID tag. Use of the RFID tag does not impact Optiray product quality." The RFID frequency and power are not specified.

✂ Labeling is not sufficient – see deficiencies.

Deficiencies:
You have provided protocols for testing the OptiVantage DH injector including D4284- Sufficient antenna read range, D4294- Minimal heater temperatures, D4188- Capability to remove syringe, D4291Regulatory compliance for intentional RF transmitter, and D4406 RFID validation. You have also provided acceptance criteria but you have not provided test reports and results. Please provide the referenced test reports D4297, D4307, D4304 and D4407.

You state in the operator's manual and in the submission that the device has been tested to IEC 60601-1-2. Please provide the protocols and test reports.

In the OptiVantage Injection with Enhanced Communication Operator's Manual (pages 28-185) you have included information on RFID. To aid the user in avoiding electromagnetic interference problems, please include the transceiver power and field strength at a specified distance in the Operator's Manual.

On page 23 you have included the level of concern determination questions and answered no to all. However, in the risk analysis you stated that misreading the injection parameters could lead to toxicity. Please address whether a failure to read the correct parameters or interpret the RFID correctly would lead to a serious injury or a minor injury. Please refer to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/cdrh/ode/guidance/337.html#7 and include the appropriate documentation.

You have provided D4313 RF exposure of OptiRay 350. Minutes from the May 2006 meeting indicate that you would be submitting a CBE 30 for NDA 19-710 to CDER. Please be advised that CDRH does not review drug quality testing. This 510(k) submission will not resolve issues of drug quality.

References
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
http://www.fda.gov/cdrh/ode/guidance/337.html#7
ISO 15693 Identification cards — Contactless integrated circuit(s) cards — Vicinity cards

Peters, Kimberly B.

m: Poochikian, Guiragos K
nt: Monday, December 11, 2006 5:05 PM
To: Ferriter, Ann M
Cc: Peters, Kimberly B.
Subject: RE: Optivantage injector by Mallinckrodt

Ann,

Thanks for keeping us in the loop. The product is Optiray. Mallincrodt hasn't submitted the CMC portion yet - The ONDQA post-approval review division has told them to submit to CDRH first so they know whether the devise aspects are in order so CMC studies could be appropriately designed. We'll let you know when it arrives. Please continue to keep us apprised of your activities in this 510(k).

Thanks,
Guirag

Guirag Poochikian, Ph.D.
Associate Director for Regulatory Science
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave
Bldg 21, Rm 2618
Silver Spring, Maryland 20993-002
Phone: 301-796-1900
Fax: 301-796-9748
'iragos.Poochikian@fda.hhs.gov

From: Ferriter, Ann M [mailto:ann.ferriter@fda.hhs.gov]
Sent: Monday, December 11, 2006 9:12 AM
To: Poochikian, Guiragos K
Cc: Peters, Kimberly B.
Subject: Optivantage injector by Mallinckrodt

Guirag-
CDRH has a special 510(k) to add the RFID to the Optivantage Injector. This is in line with what we told the sponsor at the CDER meeting in May- special 510(k) for CDRH and a separate submission for CDER. I'm looking at the special 510(k) now. They have done a very thorough job. We could send an SE letter at the end of this week- it may be SE pending the CDER review. Is this still the right path? Do you have the CDER submission? Are there any new issues?
Thanks!
Ann Ferriter
Reviewer, Orthopedic Spine Devices Branch
Division of General, Restorative & Neurological Devices
Office of Device Evaluation
240-276-3716

559

Peters, Kimberly B.

m: Ferriter, Ann M
nt: Tuesday, December 12, 2006 9:25 AM
To: Peters, Kimberly B.
Subject: RE: k063503

yes - this is perfect-
I will review the software.
I will check to see that there is confirmation of the injector parameters- closed loop was my concern also.
Thanks for the ecopy.
Ann

From: Peters, Kimberly B.
Sent: Tuesday, December 12, 2006 9:21 AM
To: Ferriter, Ann M
Subject: RE: k063503

Ann,
My apologies - electronic copy is now on the P drive (P:\D C D\510(k)\ICDB\Mallinkrodt RFID\Electronic Copy).
With regard to the software, if you have time to take a look at it, I would appreciate you input on the software documentation (especially since the V&V testing will further support the performance of the RFID). If you don't have time, I can review it.
With regard to the product name, concentration and fill volumes being read from the RFID and being used to set the injector parameters (I am assuming flow rate, pressure, etc.), I would have some concerns if the system did not require confirmation of the injector parameters by the user and/or did not allow the parameters to be adjusted by the user before the infusion started. If the system does not require user confirmation/input, then the system is functioning as a closed-loop system and I think we would need to see rigorous testing demonstrating the accuracy, reliability, etc. of the system.

I hope this answers your questions. If you need anything else, please let me know (email is best way to reach me today - working from home).
Thanks again for all of your help,
Kim

From: Ferriter, Ann M
Sent: Tuesday, December 12, 2006 8:36 AM
To: Peters, Kimberly B.
Subject: k063503

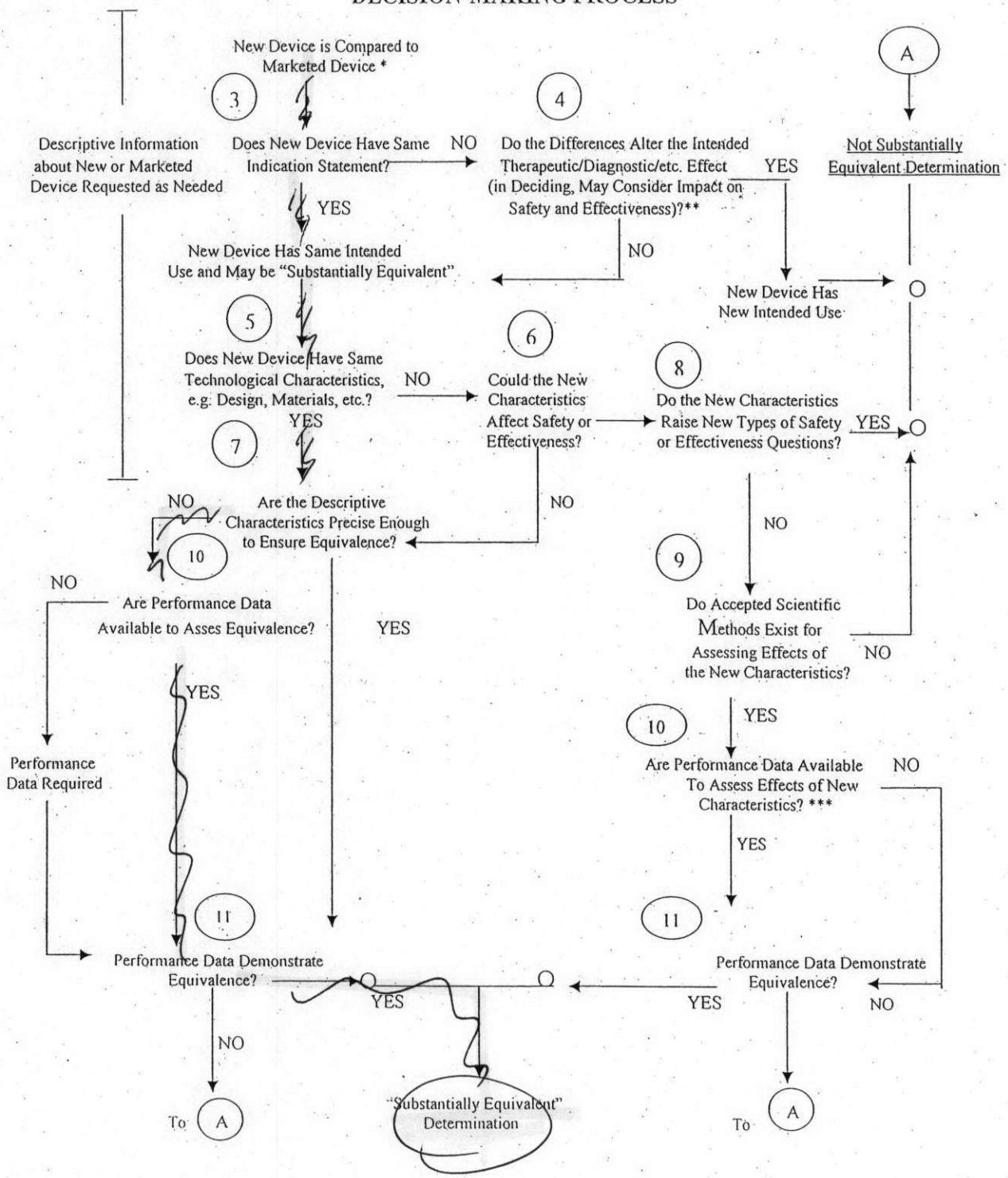
Kim,
I am almost done with my review but I have three questions-
did you want me to do the software review?
The product name, concentration and fill volume are read from the RFID and used to set the injector parameters. Do you have a problem with this intended use?
Where is the electronic version? I didn't see it on the P: drive

I have a few deficiencies- mostly they have not provided test results but only protocols. For a special 510(k) I refer sponsors to the new paradigm guidance which says tests must be completed and acceptance criteria met.
<< File: K063503 OptiVantage DH injector RFID consult amf.doc >> Here is the current draft- things in pink I'd like to copy from the e-version or the ISO std I need to look up.

Ann Ferriter
Reviewer, Orthopedic Spine Devices Branch
Division of General, Restorative & Neurological Devices
Office of Device Evaluation
240-276-3716

560

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.

5

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

February 20, 2007

MALLINCKRODT INC., LIEBEL-FLARSHEIM
2111 EAST GALBRAITH RD.
CINCINNATI, OH 45237
ATTN: DALE MOORE

510(k) Number: K063503
Product: OPTIVANTAGE DH INJECTOR SYSTEM WITH ENHANCED COMMUNICATION

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.

S1

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

K063503/S1

tyco Healthcare Division | MALLINCKRODT

February 16, 2007

Food and Drug Administration
Center for Devices and Radiological Health
Attn: Ms. Kimberly Bowie Peters
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: K063503
Trade Name: OptiVantage DH Injector System with Enhanced Communication

Dear Ms. Peters;

In response to your questions regarding the referenced 510(k) submission, we offer the following information:

1. **The device description does not include a clear description of the modifications made to the current marketed OptiVantage system for the development of the OptiVantage DH Injector System with Enhanced Communication. Please provide this information which should address both hardware and software modifications. In addition, it is unclear if the RFID feature is only intended to be used with pre-filled contrast syringes or the pre-filled saline syringes. Please address this issue.**

   Response: *The OptiVantage DH Injector System with Enhanced Communication maintains the same intended use as the predicate device. It differs from the predicate device in that it contains RFID functionality which is a product enhancement that adds a layer of enforcement for safety features found on the currently marketed predicate device. The only hardware changes from the predicate device are incorporation of RFID electronics (IC and antenna) in the faceplate to enable communication with the RFID tagged pre-filled syringes. The software modifications enable operation of the RFID hardware and associated safety features. This combination allows the transfer of prefilled contrast and/or prefilled saline syringe attributes (ie product name, fill volume, expiry, lot number, manufacture date) to the injector and allows the injector to mark a syringe as "used". The RFID technology does not change how protocols are currently entered or controlled. It does allow the injector to ensure that an unused, unexpired prefilled syringe of the correct volume has been loaded. Should the RFID functionality fail, the injector will notify the user, (see operator's manual for user messages) and will continue to operate the same as the predicate device. RFID does not eliminate the need for good clinical practice.*

2. **Please address the following regarding the bench testing information:**

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a. **You have provided protocols and acceptance criteria for testing the OptiVantage DH Injector System with Enhanced Communication, including D4284 – Sufficient Antenna Range, D4294 – Minimal Heater Temperature, D4188 – Capability to Remove Syringe, D4291 – Regulatory Compliance for Intentional RF Transmitter, and D4406 RFID Validation. These reports indicate that the test results and conclusions are provided in separate referenced test reports. Please provide the referenced test reports D4297, D4307, D4304, and D4407 for review. As well as the results for test D4188. Please be advised that the testing information provided for review should [include] testing procedures and protocols, sample size, acceptance criteria, test results, and an analysis of the results. FDA acknowledges that you have submitted the enhanced communication change in a special 510(k) submission; however, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.**

Response: *The requested test reports are provided as attachments. The table below links the test protocol, appropriate test report and attachment number. We have also included the summary certification pages for every test report referenced in D4304 as a part of attachment 4.*

Protocol	Description	Test Report	Attachment
D4284	RFID Reader Performance Testing	D4297	1
D4294	Heater Performance Testing	D4307	2
D4188	Syringe Removal Test	D4423	3
D4291	EMC / FCC Regulatory Compliance Testing	D4304	4
D4406	RFID System Technology Validation	D4407	5

b. **For D4294 – Minimal Heater Temperature Test, please provide a scientifically valid justification for the acceptance criteria. In addition, the conclusion section for D4294 indicates that "test design recommendations and discussions are presented in D4307 rev B." Please describe these test design recommendations, explain if the test protocol was modified to address these recommendations, if the test was repeated, etc.**

Response: *The temperature values in the acceptance criteria were selected based on medical device industry standard IEC safety requirements for surface temperature and applied part temperature, IEC 60601 clauses 42.1 and 42.3. The acceptance criteria in D4294 required demonstration that the IEC standards were met. Conformance to the IEC standard was tested by UL and the compliance certificate is enclosed as attachment 6. Additionally, a performance capability of Cpk>1.33 for heater performance was demonstrated through internal testing. Test report D4307 Rev B is included as attachment 2.*

The statement in the conclusion section of D4294 is intended to convey the possible need for product design changes based on test outcome, not changes to the test protocol. The product met the acceptance criteria, therefore, no changes to the product design were made.

3. **You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.**

   Response: *Information regarding this compliance testing is provided in attachment 4, D4304. Page 5-6 of the attachment is a letter from the independent testing firm stating that the injector complies with IEC 60601-1-2. Also included are the summary certification pages from the test reports referenced in D4304.*

4. **The risk analysis methods and summary information (Section7) is inadequate. Please identify the risk analysis methods used to assess the impact of the modification. The submission only indicates that the risk analysis was performed in accordance with work instructions QSEW 122 and QSEW112. In addition, please provide a revised summary of the verification and validation activities that includes a description of the methods or tests used, acceptance criteria applied, and an indication of whether the acceptance criteria were met. The summary provided only includes bullets, such as "RFID System-Level Validation" and "Verification Testing of Enable Sequences," indicating that verification testing was performed.**

   Response: *Our risk analysis methods are modeled after ISO 14971:2000(E) Medical Devices, Application of Risk Management to Medical Devices. To identify and evaluate the risks associated with the modifications for RFID, we used the risk analysis and Failure Modes and Effects Analysis (FMEA) for the predicate device as a template. We updated these documents to reflect the addition of RFID technology. This required understanding of how RFID technology can fail, and the resulting impact on the injector. New requirements for risk mitigations were identified and evaluated. Enclosed in attachment 7 is a summary table which traces from identified hazards through risk mitigation requirements to subsystem requirements and corresponding Verification and Validation activities. Acceptance criteria are defined in each test protocol and all criteria must be met. In the case of software testing, the acceptance criteria are defined for each individual test within the overall protocol and again, each criteria must be met in order to "pass".*

5. **Please address the following regarding the operator's manual for the OptiVantage DH Injector System with Enhanced Communication. Please provide a revised copy of the operator's manual for review.**

   a. **In the OptiVantage DH Injector System with Enhanced Communication operator's manual (pages 28 – 185), you have included information on RFID. To aid the user in avoiding electromagnetic interference problems, please include the transceiver power and field strength at a specified distance in the operator's manual.**

   Response: *An updated operator's manual is enclosed as attachment 8. The manual has been updated to include maximum field strength at a specified distance but we did not include transceiver power. Our original draft of the operator's manual included both pieces of information. During the FCC licensing process, the licensing body (American TCB) requested we remove transceiver power from the operator's manual before they would certify the product and grant our FCC license. The testing for FCC certification does not include transceiver power but does include certification of maximum field strength at a specified distance. See page 1-5-2 in the attached manual (attachment 8) and page 7 of attachment 4 for the FCC license certificate.*

   b. **The operator's manual (Appendix A, page 48) indicates that "a subset of the syringe data provides parameters used for constraining the injection protocol and validating the system configuration." Please explain what syringe data parameters provided via RFID are used for constraining the injection protocol and validating the system configuration.**

   Response: *We agree the statement in the operator's manual is ambiguous. Data provided by RFID is not used to "constrain" the injection protocol or validate the system configuration. This section of the manual has been updated to provide more clarity around the functionality of RFID. The RFID data is used to verify that the correct syringe type (contrast or saline) has been loaded in the correct faceplate based on system configuration settings. The injector also compares the RFID data to the protocol to ensure that it has sufficient volume and that the syringe is new and unexpired. The RFID system does not control or change the programmed protocol or system configuration; rather, the data is used to ensure the loaded syringes match what has been selected by the user. Please reference page 1-3-1, section 1.3.2 RFID Capability, in attachment 8.*

6. **Please provide the following software information and documentation for the OptiVantage DH Injector System with Enhanced Communication. The**

"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" may be a helpful reference.

a. **On page 23 of the submission you have included the level of concern determination questions and answered "no" to all. However, in the risk analysis, you state that misreading injection parameters could lead to toxicity. Please address whether a failure to read the correct parameters or interpret the RFID correctly could lead to a serious injury or a minor injury. Please be advised that the FDA believes the appropriate level of concern for the software should be at least moderate or major. Please address this issue.**

Response: *Misreading parameters could lead to toxicity. We agree with the FDA that the appropriate level of concern for the software is moderate for the RFID functionality of the injector. The tables in attachment 9 address the determination of level of concern as defined in the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005.*

RFID provides a control method in addition to all of the current safety features. We believe the safety features on our injector are an aid to good clinical practice. RFID is an enhancement to currently existing safety features on an already cleared and marketed device (Predicate Device K042744). If the RFID function were to fail, this injector operates exactly like the predicate device. The RFID enhancement does not create any new hazards but is an additional mitigation method to existing hazards identified in the Risk Analysis.

b. **Please provide a hazard analysis for the device software. This information should include identification of the hazardous event, the method of control, corrective measures taken, including aspects of the device design, that eliminate, reduce, or warn of a hazardous event, and testing demonstrating the implementation of the safety features.**

Response: *See attachment 7, from the response to question 4, for a summary trace which identifies hazards, risk mitigation requirements, sub-system requirements and associated verification and validation activities. The software requirements implemented as risk mitigations are identified in the table with the prefix SR.*

c. **Please provide a discussion of your software development lifecycle, including the activities that take place during each phase of the lifecycle, the quality control and assurance activities and methods, the development environment, the documentation generated, verification and validation activities, configuration management, version control, audits, and maintenance.**

Response: *Attachment 10 provides a summary of our software development lifecycle including quality control, development procedures, documentation and testing activities.*

d. **Please provide the current software and systems requirements for the device. This information should include a discussion of system hardware requirements, internal software tests and checks, internal and external performance and functional requirements, and safety requirements. Block diagrams showing the system architecture/software design would also be helpful. Also, please provide how you adequately qualified off-the-shelf software and hardware for incorporation into the device, if applicable, and provide appropriate documentation as discussed in the Guidance on Off-the Shelf Software Use in Medical Devices.**

Response: *The software and systems requirements for the device as they relate to the RFID functionality are provided in attachment 11. Block diagrams are included in this attachment. No off-the-shelf software or hardware was incorporated into the device to implement RFID.*

e. **Please provide the system level testing procedures and protocols, the pass/fail criteria, test results, and an analysis of the results. As noted above, FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application. Also, please provide a test report summarizing how all phases of testing (module, integration, and system) demonstrate that requirements were met. Note that testing should address all options and accessories, communications, and adequate regression testing. You should also explain how testing has adequately stressed the system, including communications, data throughput, device configurations, fault conditions, alarm conditions, boundary value conditions, error and range checking on parameters and calculations, interpretations and analyses made by the device, path analysis, etc. The testing you provide should be traceable to the software and system requirements of the device (i.e., trace matrix relating requirements to verification and validation tests). This report should also include a discussion and explanation of how you achieved the desired level of test coverage required for the device and how remaining software anomalies and bugs (listed in the report) do not present a risk to patient safety or effectiveness, directly or indirectly. Please specify the current version level of the software in the documentation you provide.**

Response: *In attachment 12, we have provided the RFID Software Verification Results & Report. The first six pages of this attachment*

provide a summary of the test methods, coverage and results. This document also includes detailed pass/fail criteria for each test, results and analysis. In order to stress the system, the individual test cases were developed to cover minimum, maximum, and out of bounds conditions. The test cases include, for example, all injector configurations, valid and invalid RFID tag data, forced communications errors, simulated user errors, and heater fault conditions. As shown in attachment 7, these test cases trace back to the software and system requirements for the device. A summary table of the anomalies has been provided as attachment 13 which includes a list of anomalies, a description of the regression testing performed and discussion of the risk associated with each anomaly.

7. **Please provide a completed indications for use form (see enclosure) for the OptiVantage DH Injector System with Enhanced Communication. The prescription information on the form should also be completed.**

   Response: *A completed indications for use form for the OptiVantage DH Injector System with Enhanced Communication is included as Attachment 14.*

8. **You have provided test protocol D4313 –RF Exposure of OptiRay 350 in the submission. Minutes from the May 9, 2006 meeting indicate that you would be submitting a Changes Being Effected – 30 (CBE-30) supplement to the NDA for the OptiRay syringes. Please be advised that CDRH does not review drug quality testing, and this 510(k) submission will not resolve any issues of drug quality. Therefore this testing information should also be included in your CDER submission. Please acknowledge this advisory.**

   Response: *It is acknowledged that this testing information should be included in the Special 510(k) submission and the corresponding PAS Submission as agreed upon during our meeting on May 9, 2006.*

Should you have any further questions regarding the contents of this response or to the actual submission, you may contact me by mail, phone at (513) 948-5771 or fax at (513) 948-5708.

Sincerely,

Dale Moore

Dale Moore
Quality Manager

attachments

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TCB

GRANT OF EQUIPMENT AUTHORIZATION

TCB

Certification
Issued Under the Authority of the
Federal Communications Commission
By:

American TCB, Inc.
6731 Whittier Avenue Suite C110
McLean, VA 22101

Date of Grant: 08/28/2006

Application Dated: 08/28/2006

Tyco Healthcare / Mallinckrodt
2111 E Galbraith Rd
Cincinnati, OH 45237

Attention: Chad Gibson , FCC Contact

NOT TRANSFERABLE

EQUIPMENT AUTHORIZATION is hereby issued to the named GRANTEE, and is VALID ONLY for the equipment identified hereon for use under the Commission's Rules and Regulations listed below.

FCC IDENTIFIER: UEI844003
Name of Grantee: Tyco Healthcare / Mallinckrodt
Equipment Class: Part 15 Low Power Transceiver, Rx Verified
Notes: Medical Radio Plaque Contrast Injector

Grant Notes	FCC Rule Parts	Frequency Range (MHZ)	Output Watts	Frequency Tolerance	Emission Designator
20	15C	13.56 - 13.56		0.01 %	

20: All electrical and mechanical devices employed for spurious radiation suppression, including any modifications made during certification testing, must be incorporated in each unit marketed.

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IEC IECEE CB SCHEME

Ref. Certif. No.

US/8942B/UL

IEC SYSTEM FOR CONFORMITY TESTING AND CERTIFICATION OF ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ESSAIS DE CONFORMITE ET DE CERTIFICATION DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Product
Produit

Injector

Name and address of the applicant
Nom et adresse du demandeur

Liebel-Flarsheim Co
2111 E Galbraith Rd
Cincinnati, OH 45237, USA

Name and address of the manufacturer
Nom et adresse du fabricant

Liebel-Flarsheim Co.
2111 E Galbraith Rd
Cincinnati, OH 45237, USA

Name and address of the factory
Nom et adresse de l'usine

Liebel-Flarsheim Co
2111 E Galbraith Rd
Cincinnati, OH 45237, USA

Rating and principal characteristics
Valeurs nominales et caractéristiques principales

115/230 Vac, 4 A, 50/60 Hz

Trademark (if any)
Marque de fabrique (si elle existe)

LF Liebel-Flarsheim

Model / Type Ref.
Ref. de type

OptiVantage

Additional information (if necessary)
Information complémentaire (si nécessaire)

This report comprises 8 enclosures. The CB Test Certificate was amended on May 5, 2005 and December 7, 2006 to add alternate construction and critical components.

A sample of the product was tested and found to be in conformity with
Un échantillon de ce produit a été essayé et a été considéré conforme à la

PUBLICATION	EDITION
IEC 60601-1 (1988) Second Edition, with Amendment No. 1 (1991) and No. 2 (1995) with the exception of: Clause 36, Electromagnetic Compatibility, Clause 48, Biocompatibility, and Clause 52.1, Programmable Electronic Systems. Inclusive of CENELEC Common Modifications. See Test Report for National Differences.	

as shown in the Test Report Ref. No.
which forms part of this Certificate
comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat

E186466-A11-CB-2

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

Underwriters Laboratories Inc.®

Underwriters Laboratories Inc. / Certification Programs Office
333 Pfingsten Road, Northbrook, IL 60062-2096
United States of America
TEL INT* 1-847-272-8800, Ext. 43008 FAX INT* 1-847-313-3008
email: jolanta.m.wroblewska@us.ul.com

Date:
Issued: 2004 December 2
Amended: 2005 May 5 (Am. 1)
Amended: 2006 December 7 (Am. 2)

Signature:

Jolanta M. Wroblewska

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Issued 03-2

Identified Hazard in Risk Analysis	Risk Analysis Requirements (Hazard Mitigation Method)	Sub-System Requirements	Verification & Validation Activity	Status (Pass/Fail)	Test Report
	RA4 The injector shall ensure the user follows a proper fill/purge sequence on the 200ml disposable syringe.	SR1249	SWVER2115	PASS	D4350
			SWVER2482	PASS	
		SR1591	SWVER2487	PASS	D4350
	RA5 The injector shall ensure the user follows a proper purge sequence on the 125ml pre-filled syringe.	SR183	SWVER2511	PASS	D4350
			SWVER2512	PASS	
			SWVER2513	PASS	
			SWVER2514	PASS	
	RA6 The injector shall require the user to expel a minimum of 1ml before allowing the injection to enable.	SR1249	SWVER2115	PASS	D4350
			SWVER2482	PASS	
	RA8 The injector shall contain a "Used Syringe" warning message.	SR1591	SWVER2487	PASS	D4350
	RA8 The injector shall contain a "Used Syringe" warning message.	SR183	SWVER2511	PASS	D4350
			SWVER2512	PASS	
			SWVER2513	PASS	
			SWVER2514	PASS	
			SWVER3067	PASS	
			SWVER3068	PASS	
			SWVER3069	PASS	
			SWVER3074	PASS	
			SWVER3073	PASS	
			SWVER3070	PASS	
			SWVER3072	PASS	
			SWVER3071	PASS	
		SR1000	SWVER2507	PASS	D4350
		SR1001	SWVER2508	PASS	D4350
		SR1249	SWVER2115	PASS	D4350
			SWVER2482	PASS	
		SR1591	SWVER2487	PASS	D4350
	RA96 The injector shall employ a means to automatically detect the size of the pre-filled syringe.	SR34	SWVER2029	PASS	D4350
			SWVER3067	PASS	
			SWVER3068	PASS	
			SWVER3069	PASS	
			SWVER3070	PASS	
		SR35	SWVER2030	PASS	D4350
			SWVER2031	PASS	
			SWVER2032	PASS	
			SWVER2033	PASS	
			SWVER3067	PASS	
			SWVER3068	PASS	
			SWVER3069	PASS	
			SWVER3074	PASS	
			SWVER3073	PASS	
			SWVER3072	PASS	
			SWVER3071	PASS	
			SWVER3070	PASS	
Air Embolism – Empty Syringe Caregiver completes a previous injection (usually with a 125ml pre-filled syringe), retracts the injector ram, fails to remove the empty syringe, and later mistakes the empty syringe for a full syringe for the next injection.	RA171 The injector shall display a warning and prevent the programmed injection of an RFID syringe that has been previously marked as 'used'.	SR2154	SWVER3007	PASS	D4350
		SR2155	SWVER3008	PASS	D4350
		SR2156			
		SR2158			
		SR2155	SWVER3009	PASS	D4350
		SR2157			
		SR2158			
		SR2155	SWVER3010	PASS	D4350
		SR2156			
		SR2157			
		SR2158			
		SR2210	SWVER3020	PASS	D4350
			SWVER3055	PASS	
		SR2216	SWVER3022	PASS	D4350
		SR2217	SWVER3024	PASS	
			SWVER3025	PASS	
			SWVER3026	PASS	
			SWVER3027	PASS	
			SWVER3028	PASS	
			SWVER3056	PASS	
			SWVER3057	PASS	
		SR2218	SWVER3029	PASS	D4350
			SWVER3030	PASS	
			SWVER3031	PASS	
			SWVER3032	PASS	
			SWVER3033	PASS	
			SWVER3034	PASS	
			SWVER3035	PASS	
			SWVER3036	PASS	
		SR2219	SWVER3037	PASS	D4350
		SR2476	SWVER3082	PASS	D4350
	RA175 If an RFID tag cannot be read or written, the system shall display a warning indicating the syringe RFID tag may be damaged or is not present.	SR2169	SWVER3014	PASS	D4350
			SWVER3015	PASS	
			SWVER3016	PASS	
		SR2313	SWVER3041	PASS	D4350
		SR2312			
		SR2310	SWVER3042	PASS	D4350
		SR2170	SWVER3014	PASS	D4350
			SWVER3015	PASS	
			SWVER3016	PASS	
		SR2171	SWVER3015	PASS	D4350
	RA177 The system shall prevent the injector from being enabled and started until a new syringe is inserted if the user chooses to not use a syringe with an undetectable or erroneous RFID tag.	SR2326	SWVER2998	PASS	D4350
			SWVER2999	PASS	
		SR2178	SWVER3014	PASS	D4350
			SWVER3015	PASS	
			SWVER3016	PASS	
			SWVER3017	PASS	
			SWVER3018	PASS	
		SR2414	SWVER3017	PASS	D4350
			SWVER3018	PASS	

Air Embolism – Empty Syringe Cont'd Caregiver completes a previous injection (usually with a 125ml pre-filled syringe), retracts the injector ram, fails to remove the empty syringe, and later mistakes the empty syringe for a full syringe for the next injection.	RA178 The system shall require the selection of the pre-filled syringe volume if the user chooses to continue using a syringe with an undetectable or erroneous RFID tag.	SR2174 SR2175 SR2411 SR2169	SWVER3014 SWVER3015	PASS PASS	D4350
		SR2178	SWVER3014 SWVER3015 SWVER3016 SWVER3017 SWVER3018	PASS PASS PASS PASS PASS	D4350
	RA184 The RFID enabled Faceplate shall allow the user to remove the syringe at any ram position.	MHRS20 MHRS21 MHRS24	HWVER28:D4456	PASS	D4423
		MHRS32	HWVER25:D4123 HWVER34:D4598	PASS PASS	D4634 D4619
		MHRS49	HWVER28:D4456	PASS	D4423
Air Embolism – Syringe/Tubing not Purged Operator fails to purge air out of syringe and/or tubing.	RA11 The injector shall ensure the user follows a proper fill/purge sequence on the 200ml disposable syringe.	SR1249	SWVER2115 SWVER2482	PASS PASS	D4350
		SR1591	SWVER2487	PASS	D4350
	RA12 The injector shall ensure the user follows a proper purge sequence on the 125ml pre-filled syringe. RA13 The injector shall require the user to expel a minimum of 1ml before allowing the injection to enable. RA16 The injector shall require the syringe be pointed downward to enable and start an injection.	SR183	SWVER2511 SWVER2512 SWVER2513 SWVER2514 SWVER3067 SWVER3068 SWVER3069 SWVER3074 SWVER3073 SWVER3070 SWVER3072 SWVER3071	PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS	D4350
		SR1249	SWVER2115 SWVER2482	PASS PASS	D4350
		SR1591	SWVER2487	PASS	D4350
	RA170 The injector shall require the syringe be pointed downward to enable and start an injection	SR1591	SWVER2487	PASS	D4350
		SR183	SWVER2511 SWVER2512 SWVER2513 SWVER2514 SWVER3067 SWVER3068 SWVER3069 SWVER3074 SWVER3073 SWVER3070 SWVER3072 SWVER3071	PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS	D4350
Air Embolism – Small Air Bubbles Small air bubbles sometimes stick to the walls of the syringe. Theses bubbles are most often created in a 200ml syringe when the user fills the syringe too rapidly. These bubbles can occur in pre-filled syringes if the syringes are shaken	RA16 The injector shall require the syringe be pointed downward to enable and start an injection.	SR180	SWVER2881	PASS	D4350
	RA12 The injector shall ensure the user follows a proper purge sequence on the 125ml pre-filled syringe. RA13 The injector shall require the user to expel a minimum of 1ml before allowing the injection to enable. RA16 The injector shall require the syringe be pointed downward to enable and start an injection.	SR183	SWVER2511 SWVER2512 SWVER2513 SWVER2514 SWVER3067 SWVER3068 SWVER3069 SWVER3074 SWVER3073 SWVER3070 SWVER3072 SWVER3071	PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS	D4350
		SR1249	SWVER2115 SWVER2482	PASS PASS	D4350
		SR1591	SWVER2487	PASS	D4350
Extravasation - Patient Weak Veins, Improperly Placed Catheter, or User Selecting Too High a Flow Rate Some patients, especially older patients, tend to have weaker veins that are more susceptible to extravasation. It is the responsibility of the user to select the proper needle size, properly place the catheter into the patient's vein, and determine the proper flow rate for the patient. The causes of extravasation described in this paragraph are due to user error, and there are limited technological means to mitigate this hazard. If the user sees an extravasation occurring they will need to quickly stop the injector before injury to the patient occurs.	RA18 The injector shall incorporate a quick, easy, and intuitive way to for the user to stop an injection.	SR154	SWVER2433	PASS	D4350
		SR742	SWVER2355 SWVER2354	PASS PASS	D4350
		SR1729	SWVER2355	PASS	D4350
Worsening Extravasation Due to Injector Malfunction – Injector Not Stopping When User Attempts To Stop an Injection Injector malfunctions and fails to stop when caregiver sees an extravasation occurring and attempts to abort injection. The injector failing to stop could be caused from several failure modes such as, electronic circuit or component failure, electromagnetic interference, or software defect.	RA23 All the requirements of section "General Safety Requirements" shall apply. (Multiple means provided to stop an injection.)	SR1729	SWVER2355	PASS	D4350

Extravasation Due to Un-commanded Start of the Injector If the injector is connected to a patient and the injector has not yet been programmed for the patient being injected, un-commanded start of the injector at a flow rate not suitable for the patient could cause extravasation.	RA25 The injector shall require an enabling sequence before a start command can initiate an injection.	SR180	SWVER2881	PASS	D4350
Extravasation Due to Over Flow Rate if both rams inject at the same time Excessive flow rate due to an injector failure can cause damage to the vessel wall and lead to extravasation. **Blood Vessel Damage Due to Injector Failing to Stop** If the injector fails to stop when the caregiver attempts to abort an injection due to some other potentially hazardous situation, an ongoing injection may contribute-to or worsen blood vessel damage.	RA27 All the requirements of section "General Safety Requirements" shall apply. (Backup flow rate monitor. Multiple means provided to stop an injection and minimize an extravasation.)All the requirements of section "General Safety Requirements" shall apply. (Backup flow rate monitor. Multiple means provided to stop an injection and minimize an extravasation.) RA39 All the requirements of section "General Safety Requirements" shall apply. (Multiple means provided to stop injection.)	SR155	SWVER2438 SWVER2437 SWVER2435 SWVER2434 SWVER2566	PASS PASS PASS PASS PASS	D4350
		SR154	SWVER2433	PASS	D4350
		SR1729	SWVER2355	PASS	D4350
Blood Vessel Damage Due to Un-commanded Start of the Injector If the injector is connected to a patient and the injector has not yet been programmed for the patient being injected, an un-commanded start of the injector at a flow rate not suitable for the patient could cause damage to the patient's vein.	RA38 The injector shall require an enabling sequence before a start command can initiate an injection.	SR180	SWVER2881	PASS	D4350
Toxicity due to User Error: Excessive contrast injected from both syringes. User intentionally or accidentally installs contrast syringes on both sides of the injector.	RA54 If the user attempts to program an injection with greater than 200ml of volume when two 200ml contrast syringes are installed, a message shall appear and ask the user to confirm their intentions. RA55 If the user attempts to program an injection with greater than 125ml of volume when two 125ml contrast syringes are installed, a message shall appear and ask the user to confirm their intentions.	SR1286	SWVER2502	PASS	D4350
	RA113 When the user opens a faceplate to remove a syringe, the injector shall prompt the user to install a syringe containing the proper fluid as defined on the Setup Screen.	SR1091	SWVER2046	PASS	D4350
		SR1092	SWVER2047	PASS	D4350
		SR1094	SWVER2049	PASS	D4350
		SR1095	SWVER2050	PASS	D4350
	RA173 The system shall display a warning and prevent a programmed injection if an RFID syringe containing contrast is latched in an RFID faceplate designated for saline according to the injector setup.	SR2215	SWVER3020 SWVER3055 SWVER3019	PASS PASS PASS	D4350
		SR2182 SR2185 SR2186 SR2187 SR2188	SWVER3039	PASS	D4350
		SR2214 SR2215 SR2213 SR2183	SWVER3040	PASS	D4350
	RA174 The system shall display a warning and prevent a programmed injection if an RFID syringe containing saline is latched in an RFID faceplate designated for contrast according to the injector setup.	SR2215	SWVER3020 SWVER3055 SWVER3019	PASS PASS PASS	D4350
		SR2182 SR2185 SR2186 SR2187 SR2188	SWVER3039	PASS	D4350
		SR2214	SWVER3040	PASS	D4350
Toxicity due to Incorrect/Unreadable Values Displayed on Console or Powerhead Displays	RA56 The injector design shall include two or more user displays.	SR1855	SWVER2651	PASS	D4350
		SR1854	SWVER2650	PASS	D4350
		SR155	SWVER2438 SWVER2437 SWVER2435 SWVER2434 SWVER2566	PASS PASS PASS PASS PASS	D4350
		SR205 SR1201 SR1202	SWVER2566	PASS	D4350
		SR39	SWVER2030 SWVER2031 SWVER2032 SWVER2033	PASS PASS PASS PASS	D4350
	RA59 The injector shall contain an Enabling Sequence with visual indicators that must be followed before an injection can be started.	SR183	SWVER2511 SWVER2512 SWVER2513 SWVER2514 SWVER3067 SWVER3068 SWVER3069 SWVER3074 SWVER3073 SWVER3070 SWVER3072 SWVER3071	PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS	D4350
	RA60 All the requirements of section "General Safety Requirements" shall apply.	SR180	SWVER2881	PASS	D4350
Increased Body Temperature due to Failure of the Syringe Heater	RA88 The injector design shall require two methods to turn the heater(s) on.	SR41	SWVER2909	PASS	D4350
	RA89 The injector design shall incorporate a temperature sensing device to limit power to the heater.	SR1342 SR1343 SR1344	SWVER2915	PASS	D4350
		SR2241	SWVER3081 SWVER3082	PASS PASS	D4350
		SR2242	SWVER3075	PASS	D4350

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Increased Body Temperature due to Failure of the Syringe Heater Cont'd	RA90 Heater operation shall be verified when power is applied to the injector.	SR18	SWVER2915 SWVER1983 SWVER1984 SWVER1985 SWVER1987	PASS PASS PASS PASS PASS	D4350
		SR916	SWVER1989 SWVER1991	PASS PASS	D4350
		SR1338 SR1339 SR1340 SR1341	SWVER2915	PASS	D4350
		SR1451	SWVER1985 SWVER1987	PASS PASS	D4350
		SR1452	SWVER1987	PASS	D4350
		SR2388	SWVER2994	PASS	D4350
		SR2245	SWVER3075 SWVER3076 SWVER3079	PASS PASS PASS	D4350
Misdiagnosis due to Poor Image caused by non-obvious Injector Malfunction Power injectors typically display the results of an injection. These results are typically reviewed by the technologists and/or radiologists to determine if the contrast was delivered as prescribed. If the contrast is not delivered as prescribed a poor diagnostic image may result. So it is important the user know if the injection ran as expected. If an injector malfunction of any type goes undetected, the displayed results can provide valuable information to the user. **Misdiagnosis due to Low Flow Rate out of Tolerance** An injection that does not deliver contrast at the programmed flow rate may disrupt scanner timing and may have a negative impact on image quality.	RA107 The injector shall display an Achieved Values Screen containing the results of the injection. RA108 The injector shall display an Achieved Values Screen containing the results of the injection.	SR157	SWVER2444	PASS	D4350
Syringe Failure due to user selecting wrong pre-filled syringe size If the user selects a 125ml pre-filled syringe on the Console display, but installs a smaller pre-fill; programming a volume in excess of the size installed will cause the ram to dead-head into the end of the syringe. This could cause the syringe to break	RA121 Injectors equipped with faceplate part number 844810 or 844760 shall employ a means to automatically detect the size of the pre-filled syringe in order to minimize user error.	SR2148 SR2149 SR2150 SR2151	SWVER3064 SWVER3065 SWVER3066	PASS PASS PASS	D4350
		SR2152 SR2153 SR2237	SWVER3061	PASS	D4350
		SR35	SWVER2030 SWVER2031 SWVER2032 SWVER2033 SWVER3067 SWVER3068 SWVER3069 SWVER3074 SWVER3073 SWVER3072 SWVER3071 SWVER3070	PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS	D4350
		SR976	SWVER3074 SWVER3073 SWVER3072 SWVER3071 SWVER2030 SWVER2031 SWVER2032 SWVER2033	PASS PASS PASS PASS PASS PASS PASS PASS	D4350
	RA122 All the requirements of section "General Safety Requirements" shall apply. (Backup pressure monitor.)	SR2148 SR2149 SR2150 SR2151	SWVER3064 SWVER3065 SWVER3066	PASS PASS PASS	D4350
		SR2152 SR2153	SWVER3061	PASS	D4350
Cross Infection Due to Reuse of Syringe or IV Tubing Cross infection directly from the injector is not possible. Cross infection from reuse of the syringe or IV tubing can cross-infect patients.	RA123 The injector software contains a Used Syringe Warning to reduce the likelihood the user will re-use a syringe.	SR2155 SR2156 SR2158	SWVER3008	PASS	D4350
		SR2155 SR2157 SR2158	SWVER3009	PASS	D4350
		SR2155 SR2156 SR2157 SR2158	SWVER3010	PASS	D4350
		SR2210	SWVER3020 SWVER3055	PASS PASS	D4350
		SR1249	SWVER2115 SWVER2482	PASS PASS	D4350
		SR1000	SWVER2507	PASS	D4350
		SR1001	SWVER2508	PASS	D4350
		SR1591	SWVER2487	PASS	D4350
		SR183	SWVER2511 SWVER2512 SWVER2513 SWVER2514 SWVER3067 SWVER3068 SWVER3069 SWVER3074 SWVER3073 SWVER3070 SWVER3072 SWVER3071	PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS	D4350

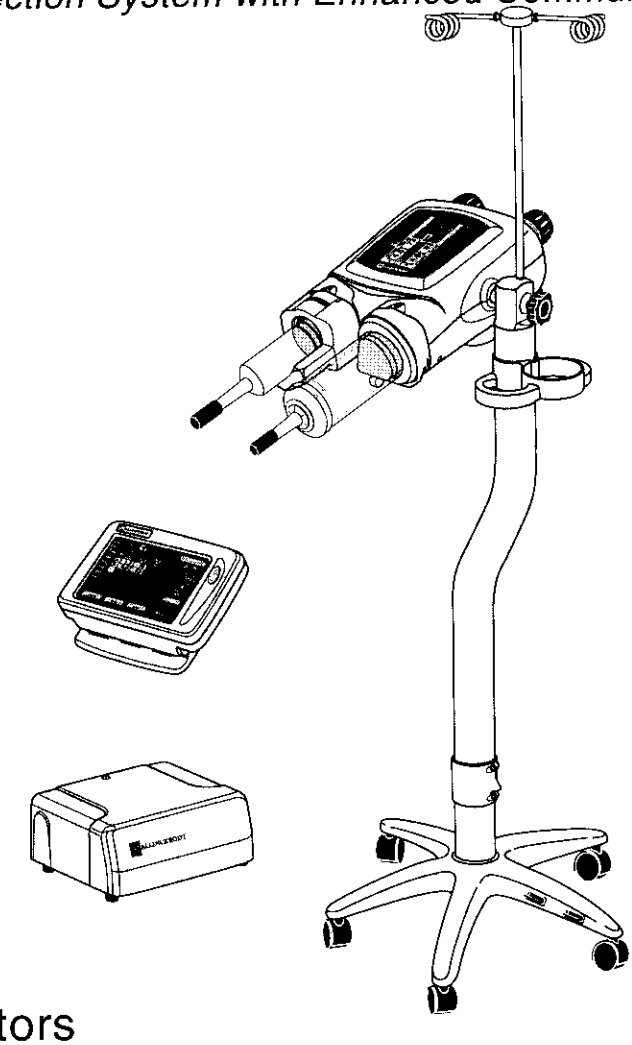
Cross Infection Due to Reuse of Syringe or IV Tubing Cont'd Cross infection directly from the injector is not possible. Cross infection from reuse of the syringe or IV tubing can cross-infect patients.	RA175 If a data error or corrupted data is detected while reading or writing an RFID tag, the system shall display a warning indicating the syringe RFID tag may be damaged or is not present.	SR2171	SWVER3015	PASS	D4350
		SR2170	SWVER3014 SWVER3015 SWVER3016	PASS PASS PASS	D4350
		SR2233 SR2431	SWVER3004 SWVER3054	PASS PASS	D4350
Unpredictable Injector Operation due to Incompatible Software Versions	RA124 The injector shall compare software versions installed in the injector's subsystems and generate an Alarm if these versions are not compatible.	SR22	SWVER1994 SWVER1995	PASS PASS	D4350
Power-On Self-Test	RA129 To minimize unsafe injector operation due to electrical component failure, a power-on self-test shall be performed whenever the injector is power on. RA130 If any of the power-on self-tests fail the injector shall indicate an Alarm condition and not allow injector ram movement to occur except by the Manual Knob(s).	SR22	SWVER1994 SWVER1995	PASS PASS	D4350
		SR18	SWVER2915 SWVER1983 SWVER1984 SWVER1985 SWVER1987	PASS PASS PASS PASS PASS	D4350
		SR1451	SWVER1985 SWVER1987	PASS PASS	D4350
		SR1452	SWVER1987	PASS	D4350
Multiple User Inputs to Stop an Injection	RA137 The injector shall provide at least two user methods for stopping ram movement.	SR1855	SWVER2651	PASS	D4350
		SR1854	SWVER2650	PASS	D4350
		SR154	SWVER2433	PASS	D4350
		SR742	SWVER2355 SWVER2354	PASS PASS	D4350
		SR1729	SWVER2355	PASS	D4350
		SR2132	SWVER2391	PASS	D4350
		SR1075	SWVER2464	PASS	D4350
		SR1078	SWVER2466	PASS	D4350
		SR1079 SR1076	SWVER2478	PASS	D4350
Unintentional Ram Movement	RA143 The injector shall incorporate two independent methods for monitoring and detecting unintentional ram movement.	SR1249	SWVER2115 SWVER2482	PASS PASS	D4350
	RA144 To reduce the possibility of injector self-run, the injector shall control ram movement so that forward or reverse ram movement requires two inputs to be activated by the operator. One acceptable input is the Enabling Sequence	SR183	SWVER2511 SWVER2512 SWVER2513 SWVER2514 SWVER3067 SWVER3068 SWVER3069 SWVER3074 SWVER3073 SWVER3070 SWVER3072 SWVER3071	PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS PASS	D4350
Pacemaker Interference Due To Electromagnetic Interference Pacemakers and defibrillators can be susceptible to certain levels of electromagnetic interference.	RA172 The OptiVantage injector shall meet all US and international requirements for a radio transmitter device at 13.56MHz in a clinical environment	EHRS19 EHRS20 EHRS21 EHRS22 EHRS23 EHRS24 EHRS25	HWVER8:D4291	PASS	D4304
Electromagnetic Compatibility	RA183 To control failure modes associated with intentional radiated RF energy, the system shall be designed to meet the requirements of FCC part 15.225, FCC part 15.107, FCC part 15.109, EN 300 330, and EN 301 489-3 emissions using EN 55022 / 55011 for intentional radiators at 13.560MHz in a clinical environment.	EHRS19 EHRS20 EHRS21 EHRS22 EHRS23 EHRS24 EHRS25	HWVER8:D4291	PASS	D4304
Infection Due to Poor Handling by User of Syringe or IV Tubing	RA179 If an RFID tag cannot be read or written, the system shall display a warning indicating the syringe RFID tag may be damaged or is not present.	SR2170 SR2189	SWVER3014 SWVER3015 SWVER3016	PASS PASS PASS	D4350
		SR2312 SR2313	SWVER3041	PASS	D4350
		SR2171	SWVER3015 SWVER3016	PASS PASS	D4350
		SR2310 SR2311	SWVER3042	PASS	D4350
	RA180 If a data error or corrupted data is detected while reading or writing an RFID tag, the system shall display a warning indicating the syringe RFID tag may be damaged or is not present.	SR2233 SR2431	SWVER3004 SWVER3054	PASS PASS	D4350
		SR2170	SWVER3014 SWVER3015 SWVER3016	PASS PASS PASS	D4350
		SR2171	SWVER3015 SWVER3016	PASS PASS	D4350
	RA181 The system shall prevent the injector from being enabled and started until a new syringe is inserted if the user chooses to not use a syringe with an undetectable or erroneous RFID tag	SR2326	SWVER2998 SWVER2999	PASS PASS	D4350
		SR2178	SWVER3014 SWVER3015 SWVER3016 SWVER3017 SWVER3018	PASS PASS PASS PASS PASS	D4350
		SR2414	SWVER3017 SWVER3018	PASS PASS	D4350
	RA182 The system shall require the selection of the pre-filled syringe volume if the user chooses to continue using a syringe with an undetectable or erroneous RFID tag	SR2169	SWVER3014 SWVER3015 SWVER3016	PASS PASS PASS	D4350
		SR2178	SWVER3014 SWVER3015 SWVER3016 SWVER3017 SWVER3018	PASS PASS PASS PASS PASS	D4350
		SR2174 SR2175	SWVER3014 SWVER3015 SWVER3016	PASS PASS PASS	D4350
		SR2411	SWVER3014 SWVER3015	PASS PASS	D4350

MALLINCKRODT

Erbe Elektromedizin

OptiVantage™

Injection System with Enhanced Communication



Operators Manual

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FOREWORD

Congratulations on the purchase of your OptiVantage™ Injection System with Enhanced Communication. The OptiVantage system represents our effort to provide a quality product to support better health care throughout the world.

Regardless of how well equipment is designed, misuse or abuse will deny its owner the expected quality of service. Misuse or abuse may occur unintentionally because the proper method of operating the equipment is unknown. Read this manual carefully before operating the OptiVantage system. Retain this manual for future reference.

LIEBEL-FLARSHEIM TECHNICAL SUPPORT

Phone No. 1-800-877-0791

RECORDING MODEL NUMBER, PART NUMBERS, AND SERIAL NUMBERS

The model number (Mod. No.), part numbers (P/N), and serial numbers (S/N) must be supplied when requesting replacement parts or optional accessories. For convenience, record the requested information below:

Power Supply

Mod.No. ☐☐☐☐☐☐-☐

P/N ☐☐☐☐☐☐-☐

S/N **CI** ☐☐☐☐ **B** ☐☐☐

Powerhead

P/N ☐☐☐☐☐☐-☐

S/N **CI** ☐☐☐☐ **B** ☐☐☐

Console S/N

P/N ☐☐☐☐☐☐-☐

S/N **CI** ☐☐☐☐ **B** ☐☐☐

Date of Installation ☐☐/☐☐/☐☐

Installing Company _____

Address _____

Phone No. _____

TRADEMARK AND PATENT INFORMATION

OptiVantage™, Patency Check™, Timing Bolus ™ and Verified ™ are trademarks of Mallinckrodt, Inc. OptiBolus® and OptiRay® are Registered trademarks of Mallinckrodt, Inc.

The OptiVantage is protected under the following U.S. Patents:

5,279,569	5,300,031	5,451,211	5,456,669
5,658,261	5,662,612	5,681,286	5,758,659
5,928,197	6,315,758	6,635,030	6,659,979

Other U.S. and Foreign Patents Pending.

MEANINGS OF SYMBOLS

SYMBOLS LOCATED IN THE MANUAL

Please regard any message that follows a Danger, Warning, or Caution symbol.

⚠ DANGER! ⚠

DANGER!—Hazards which could result in severe personal injury or death.

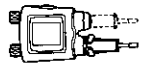
⚠ WARNING! ⚠

WARNING!—Hazards which could result in personal injury.

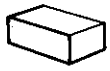
⚠ CAUTION! ⚠

CAUTION!—Hazards which could result in equipment or property damage.

SYMBOLS LOCATED ON THE POWER CONTROL

Connection	Symbol	Definition
J1		Powerhead Cable Connector
J2		Startswitch Cable Connector
J3		Ethernet Port
J5		RS232/RS422 Port
J6		Universal Interface Connector
J10A		Console Cable Connector
J10B		OptiBolus™ Console Cable Connector
P4	**CAN**	Controller Area Network Port
		Equipment sensitive to Electrostatic Discharge. DO NOT TOUCH exposed connectors.
		ATTENTION! Consult User's/Service Manual.
		CAUTION! Risk of electrical shock. Do not remove cover. Refer servicing to qualified personnel.
		Fuse Rating (Voltage, Amperage, Type)
	Mod. No.	Model Number
	S/N	Serial Number
	P/N	Part Number
	V/A	Volts Amps

SYMBOLS LOCATED ON THE CONSOLE

Connection	Symbol	Definition
		Push ON / Push OFF
J1		Power Supply Cable Connector
J2		Handswitch Cable Connector
		RFID (Radio Frequency Identification) active
		RFID (Radio Frequency Identification) inactive

SYMBOLS LOCATED ON THE POWERHEAD

Connection	Symbol	Definition
		Manual Knob Light Status Flashing Blue: Injector Powering Up Solid Yellow/Purple: Enabled or injecting contrast (yellow) or saline (purple) Flashing Purple: Drip Mode injecting saline Flashing Yellow and Purple: Injector Paused Flashing Red: Alarm condition Flashing Blue quickly: Injector rotated vertically or 30 degrees below horizontal.
		A-side of Powerhead
		B-side of Powerhead
		Install pressure sleeve/Load syringe
		Lock pressure sleeve onto the powerhead/ Lock syringe into the pressure sleeve
		Powerhead classified IEC 601-1, Type CF

CLASSIFICATION IN ACCORDANCE WITH EN 60601-1

TYPE OF PROTECTION AGAINST ELECTRIC SHOCK

Class I equipment

DEGREE OF PROTECTION AGAINST ELECTRIC SHOCK

Type CF applied part.

DEGREE OF PROTECTION AGAINST INGRESS OF WATER

Ordinary Equipment

ELECTROMAGNETIC COMPATIBILITY

The OptiVantage meets the radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices

UL/CSA CLASSIFICATION

CLASSIFIED UL C US 33SL

OptiVantage (Medical Equipment)
UL60601-1, IEC60601-1
CAN/CSA C22.2 No. 601.1

OptiVantage™ DH Injection System

CLASSIFIED BY UNDERWRITERS LABORATORIES INC.
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL
HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1
33SL

OptiVantage™ DH Injection System
CLASSIFIED WITH RESPECT TO ELECTRIC SHOCK, FIRE MECHANICAL AND
OTHER SPECIFIED HAZARDS ONLY IN ACCORDANCE WITH CAN/CSA C22.2
NO. 60601.1,

33SL

CE MARK INFORMATION

CE 0123

Authorized EC Repres
TYCO HEALTHCARE UK

Conforms to the European Medical Device Directive (MDD)

FCC/IC INFORMATION

All Radio type devices embedded in the OptiVantage Injector have met all qualifications for use under FCC Part 15 and Industry Canada RSS-210.

Model#: 844003 (OptiVantage Injector with Enhanced Communication)

IC: 3502A-844003

FCC ID: UEI844003

This device complies with Industry Canada RSS-210 and with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: The term "IC:" before the radio certification number only signifies that Industry Canada technical specifications were met.

Note: Changes or modifications to the OptiVantage Injector not expressly approved by Tyco Healthcare/Mallinckrodt could void the user's authority to operate the equipment.

This manual originally written in English.

Table Of Contents

tyco / Healthcare MALLINCKRODT

1 SYSTEM OVERVIEW

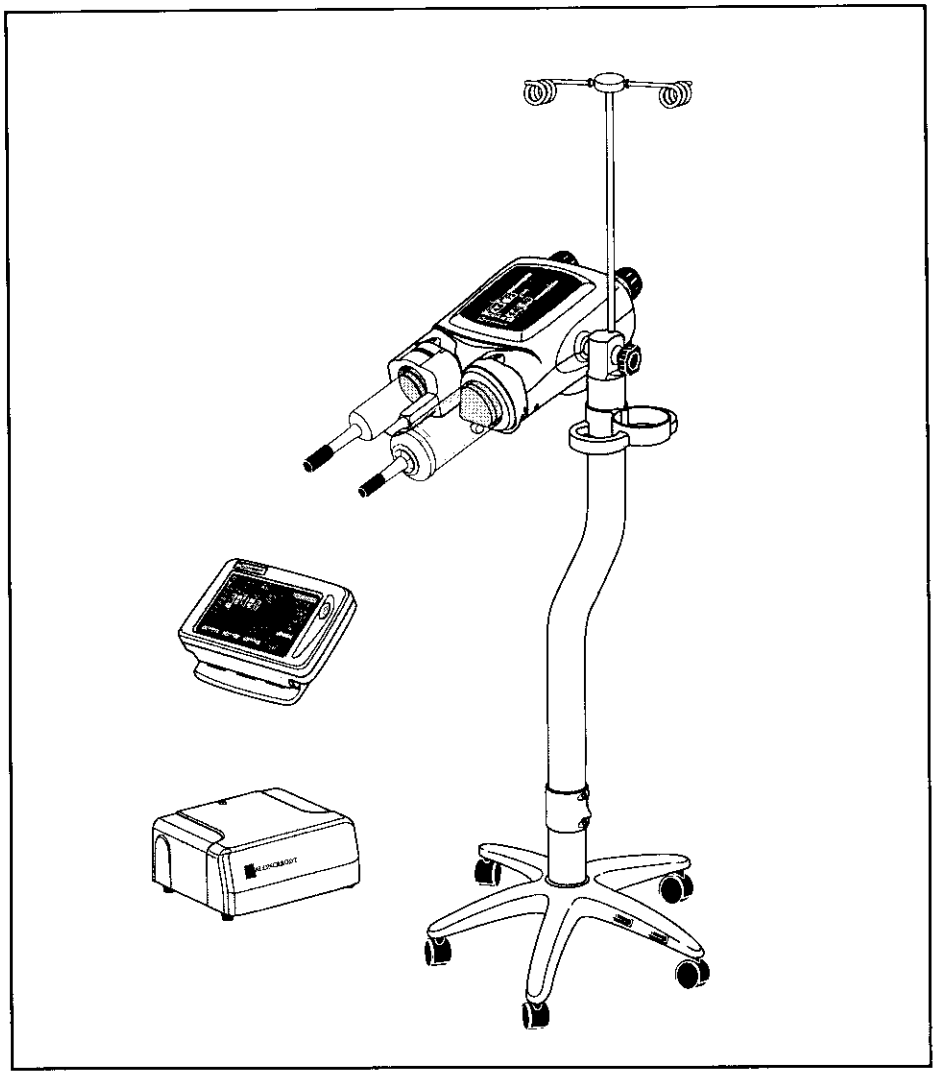


Figure 1-1-1 OptiVantage Injection System

1.1 INDICATIONS FOR USE

The OptiVantage Injection System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

1.2 USER QUALIFICATION

The OptiVantage Injection System should be operated ONLY by qualified personnel who:

- are completely familiar with the unit,
- have read and understood this Operator's Manual,
- have been trained concerning the process of how to stop an injection in the case of an emergency (described in Chapter 5 of this manual), and
- are otherwise properly trained in the use of equipment and procedures of this type.

Failure to follow these guidelines could result in serious injury to the patient or the operator.

⚠ CAUTION! ⚠

Federal law restricts this device to sale by or on the order of a physician.

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1.3 SYSTEM FEATURES

1.3.1 VERSATILITY

The injector is microprocessor-controlled and can perform injections within the following variable parameters:

- Flow Rate
- Volume
- Pressure Limit
- Inject Delay
- Scan Delay
- Phase Delays

1.3.2 RFID CAPABILITY

The RFID (Radio Frequency Identification) feature provides the capability to transfer product information from an Ultraject syringe fitted with an RFID data tag to the OptiVantage injector system. The injector system stores the syringe data for inclusion in the injection reports. The syringe data is used to verify the correct syringe type has been loaded based on system configuration. The injector system also compares the RFID data on the syringe to the programmed protocol to ensure it has sufficient volume. A key feature of the RFID data tag is that the injector system can mark a syringe as being 'used' and therefore preventing the syringe from being used for multiple injections.

1.3.3 TOUCH-SCREEN DISPLAYS

The console and powerhead both contain touch screen displays for operator interaction. Refer to Chapter 3-1-1 for detailed descriptions.

When using the touch screen displays, keep the following information in mind

⚠ CAUTION! ⚠

Do not press on the touch screens with sharp or pointed items such as fingernails, pens or pencils. Using items of this type may cause damage to your screen, resulting in a nonworking unit. Do not allow objects, such as pens and pencils, to lay on the touch screen.

1.3.4 PROTOCOL MEMORY WITH PASSWORD PROTECTION

A convenient, user-friendly feature of the OptiVantage is its ability to store the parameters of as many as 40 protocols in its memory. Password protection is also available.

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1.4 FEATURES

1.4.1 SAFETY

The OptiVantage Injector System has been designed to enhance the safety of both patient and operator. Specific safety features include:

Self-testing Design

When the OptiVantage is switched ON, it automatically performs a series of power-up tests to monitor the status of all systems. If a problem is detected, an appropriate message will appear in the system display. Also, during the enable process and during an injection, all necessary functions are constantly checked. If a fault is detected, the system will automatically shut down and an appropriate message will be displayed.

Patency Check™ Feature

Prior to the delivery of the main injection, a Patency Check—an injection of a small volume of saline—can be performed to determine the integrity of the I.V. site.

Timing Bolus™ Feature

Prior to the delivery of the main injection, a Timing Bolus injection—an injection of a small volume of contrast, followed by a small volume of saline—can be delivered to the patient to determine the optimal scan delay needed to capture the contrast agent in the area of interest.

Drip Mode Feature

Prior to the delivery of the main injection, a Drip Mode injection—a low flow rate injection of a small volume of saline—can be delivered to keep the fluid pathway open.

OptiBolus® Feature (Optional)

The OptiBolus feature is used to deliver an exponentially decaying flow rate injection that optimizes the contrast usage and provides an extended period of uniform enhancement of the area of interest. The End Flow Rate is automatically calculated by the OptiVantage and displayed only on the console Main screen.

Pointing Powerhead Downward prior to Starting an Injection

After completion of the Enable sequence, the [Enable] key is only active after tilting the powerhead to the downward position. Pointing the powerhead in the downward position allows any trapped air in the syringe to move to the plunger end of the syringe, away from the syringe tip, possibly preventing it from being inadvertently injected into the patient.

Start/Stop Key on Powerhead

Because the powerhead is near the patient during an injection, both the [Start] key and the [Stop] key are integrated into the powerhead for starting or quickly stopping an injection.

Remote Control Operation

Use of the remote handswitch allows the operator to perform injections from outside the area of direct radiation.

Electrically Isolated Syringe

All syringes are isolated from any electrical contact with the injector.

Syringe Clarity

Semitransparent syringes are used on the OptiVantage. Small air bubbles can be seen with careful observation.

Positive Positioning of the Powerhead

A preset friction device in the powerhead holds the syringe in the desired position during injection.

Physical Stability

The wide stance of the base of the pedestal assembly reduces the possibility of tipping. Two of the casters may be locked to prevent unwanted rolling and turning.

1.4.2 OPERATOR CONVENIENCE FEATURES

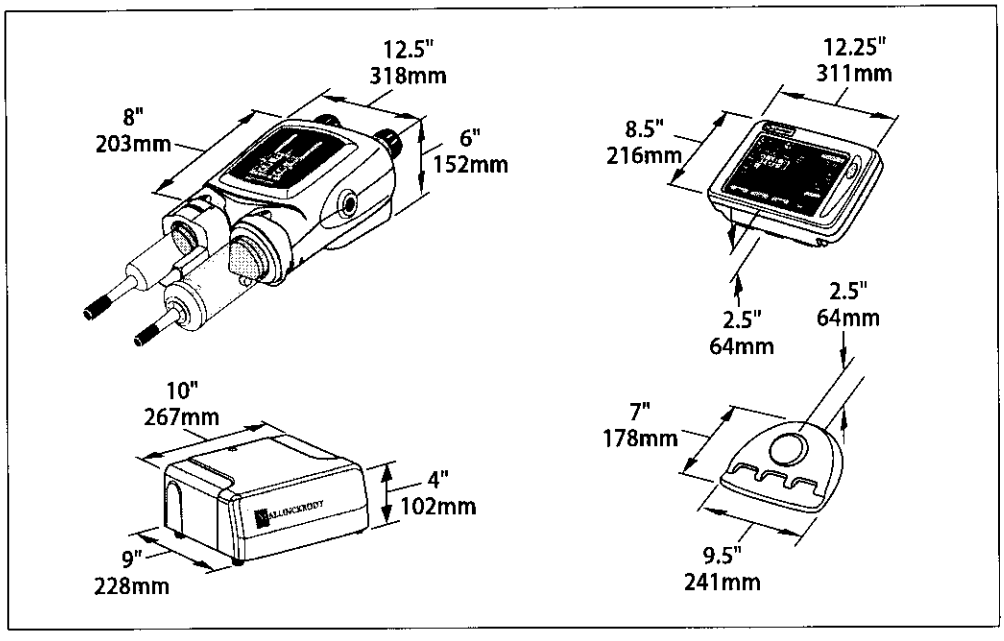
Auto-Fill Feature

This feature is designed to automatically fill the syringe while minimizing the introduction of air into the syringe. Upon loading a 200 ml syringe, the powerhead can automatically fill to 25 ml at 4 ml/s, expel to 0 ml at 10 ml/s, then fill to the operator programmed Auto-Fill Volume at 15 ml/s.

1.5 SPECIFICATIONS

1.5.1 DIMENSIONS

Console	12.25 W x 2.5 H x 8.5 D inches (311 W x 64 H x 216 D mm)
Console Base	9.5 W x 2.5 H x 7 D inches (241 W x 64 H x 178 D mm)
Powerhead	12.5 W x 6 H x 8 D inches (318 W x 152 H x 203 D mm)
Power Supply	10 W x 9 D x 4 H inches (267 W x 228 D x 102 H mm)



1.5.2 WEIGHT

Console w/Base	5.8 lbs (2.6 kg)
Powerhead	14.5 lbs (6.57 kg)
Power Supply	6 lbs (2.7 kg)

1.5.3 POWER REQUIREMENTS

Standby	less than 1 A
Standard	115 VAC, 4 A, 50/60 Hz 230 VAC, 2 A, 50/60 Hz

1.5.4 VOLTAGE REQUIREMENTS

Unit automatically adapts for input voltages from 100 to 240 VAC.

1.5.5 ELECTRICAL LEAKAGE

Chassis	less than 300 microamps

1.5.6 ENVIRONMENTAL

Transport and Storage Temperature: ..... -40° to +158° F (-40° to +70° C)
10% to 100% relative humidity

Operating Temperature: ..... 32° to +104° F (0° to +40°C)
30% to 75% relative humidity

Btu Output: ..... 510 Btu

Biohazard Disposal: Dispose of bioharzards in accordance with the requirements of your hospital, facility or local regulations.

Electromagnetic Compatibility (EMC): The OptiVantage meets EN60601-1-2 for level B conducted and radiated emissions and EMI immunity. **NOTE:** If any anomalies in the injector performance are noticed, identify devices within the immediate area that are capable of producing electromagnetic interference and call a qualified service representative.

⚠ DANGER! ⚠

Possible explosion hazard if used in the presence of flammable anesthetics. The unit is not designed for use in explosive environment.

⚠ WARNING! ⚠

The injector may only be operated in an area that is located beyond the 20 gauss limit. Operating the unit within magnetic fields that are higher than this limit may cause the unit to malfunction, resulting in operator or patient injury.

⚠ CAUTION! ⚠

Only the powerhead is considered spill proof. The console and power control are not spill-proof. Fluid spilled in these components can cause the unit to malfunction, resulting in patient or operator injury. If fluid is spilled on the console or power control, remove the unit from operation and contact your authorized service personnel.

1.5.7 RFID TRANSCEIVER

- Transceiver: P/N 844760, OptiVantage RFID Faceplate, 125 mL
- Operation Frequency: 13.56 MHz
- Antenna Gain: 1.13 dBi
- Maximum field strength: 121.2 dBµV at 3 meters (normalized from test results 31.88 dBµA @ 10m).

1.5.8 SYRINGE SIZES

125 ml, 100 ml, 75 ml, 50 ml pre-filled

200 ml empty

1.5.9 SYRINGE HEATER

98° ± 6° F (37° ± 3° C) nominal. Maintains the temperature of pre-heated contrast.

1.5.10 FLOW RATE

Flow Rate Parameters	0.1 – 10 ml/second adjustable in increments of 0.1 ml/second
Flow Rate Running Tolerance:	0.2 ml/second or +/-20% whichever is smaller.

1.5.11 PEAK PRESSURE LIMIT

pounds per square inch (psi)	50 – 325 adjustable in 5 psi increments
kPa	345 – 2240 adjustable in 34 kPa increments

1.5.12 PHASE DELAY

Phase Delay Parameters	0—600 seconds adjustable in increments of 1 second.

1.5.13 INJECT DELAY

Inject Delay Parameters	0—600 seconds adjustable in increments of 1 second.

1.5.14 SCAN DELAY

Scan Delay Parameters	0—600 seconds adjustable in increments of 1 second

The Scan Delay timer shall count down in one second increments. Three beeps (250 ms) occur when the timer reaches 10 seconds. Two beeps (440 ms) occur when the timer reaches 5 seconds. One beep (1000 ms) occurs when the timer reaches 0 seconds. A start signal is sent to the CT Scanner when the timer reaches 0 seconds.

1.5.15 TOTAL TIME

Total Time Display Parameters.....0—99:59 (minutes:seconds)

1.5.16 PROGRAMMABLE DRIP MODE PARAMETERS (SALINE SIDE)

- Flow Rate: 0.1 to 1.0 ml/s
- Volume: 0.1 to 3.0 ml
- Interval: 0 to 60 seconds

1.5.17 PROGRAMMABLE PATENCY CHECK PARAMETERS (SALINE SIDE)

- Flow Rate: 0.1 to 10 ml/s (defaults to maximum flow rate of protocol)
- Volume: 1 to 200 ml
- Default Volume: 1 to 200 ml

1.5.18 STORED PROTOCOLS

40 protocols can be stored and recalled.

NOTE: *Liebel-Flarsheim reserves the right to change product designs and specifications in the continuing effort to improve their products.*

1.6 CONSUMABLES

NOTE: The use of consumables not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include evidence that the safety certification of the consumables has been performed in accordance to the appropriate EN 60601-1 and/or EN 60601-1-1 harmonized national standard.

1.6.1 SYRINGES

Dual Head Procedures

- **P/N 844020** Multipack 200 ml OptiVantage Front Load Syringe w/Handi-Fil and 60" Coiled Y-Tube *w/No check valve*
- **P/N 844015** Multipack 200 ml OptiVantage Front Load Syringe w/Handi-Fil and 60" Coiled Y-Tube *w/Single check valve*
- **P/N 844021** Multipack 200 ml OptiVantage Front Load Syringe w/Handi-Fil and 60" Coiled Y-Tube *w/Dual check valves*
- **P/N 844022** DualPack (2) 200 ml OptiVantage Front Load Syringes w/(2) Handi-Fils and 60" Coiled Y-Tube *w/No check valve*
- **P/N 844016** DualPack (2) 200 ml OptiVantage Front Load Syringes w/(2) Handi-Fils and 60" Coiled Y-Tube *w/Single check valve*
- **P/N 844023** DualPack (2) 200 ml OptiVantage Front Load Syringes w/(2) Handi-Fils and 60" Coiled Y-Tube *w/Dual check valves*

UltraJect Prefilled Contrast Syringes

NOTE: Consult Sales Representative for part number information.

50 ml	Optiray® 350 (Ioversol Injection USP 74%) 350 mgI/ml
75 ml	Optiray 350 (Ioversol Injection USP 74%) 350 mgI/ml
100 ml	Optiray 350 (Ioversol Injection USP 74%) 350 mgI/ml
125 ml	Optiray 350 (Ioversol Injection USP 74%) 350 mgI/ml
50 ml	Optiray 320 (Ioversol Injection USP 68%) 320 mgI/ml
75 ml	Optiray 320 (Ioversol Injection USP 68%) 320 mgI/ml
100 ml	Optiray 320 (Ioversol Injection USP 68%) 320 mgI/ml
125 ml	Optiray 320 (Ioversol Injection USP 68%) 320 mgI/ml
100 ml	Optiray 300 (Ioversol Injection USP 64%) 300 mgI/ml
125 ml	Optiray 240 (Ioversol Injection USP 51%) 240 mgI/ml

UltraJect Prefilled Saline Syringes

NOTE: May not be available in your area, consult Sales Representative for availability and part number information.

50 ml	UltraJect Prefilled Saline Syringe
75 ml	UltraJect Prefilled Saline Syringe
100 ml	UltraJect Prefilled Saline Syringe
125 ml	UltraJect Prefilled Saline Syringe

Single Head Procedures

- **P/N 800099** Multipack 200 ml Front Load Syringe w/Handi-Fil and 60" Coiled Tube
- **P/N 800096** Multipack 200 ml Front Load Syringe w/Handi-Fil

1.6.2 LOW PRESSURE TUBING

- **P/N 601195** 60" Coiled Tube
- **P/N 844010** 60" Coiled Y-Tubing *w/No check valve*, 5" Y-Legs
- **P/N 844011** 60" Coiled Y-Tubing *w/Single check valve*, 5" Y-Legs
- **P/N 844012** 60" Coiled Y-Tubing *w/Dual check valves*, 5" Y-Legs

1.6.3 CATHETERS, CONNECTORS AND TUBING

It is recommended that catheters, connectors and tubing used with the OptiVantage Injection System be rated for a minimum of 325 psi. If such products are rated at a pressure below 325 psi, it is the responsibility of the user to use manual mode to select a pressure limit that is appropriate for the product. The selection of manual mode is covered in section 3.1.6. Setting of the peak pressure limit is discussed in Sections 3.1.3 and 3.2.6 of this manual.

Use only safety-approved catheters suitable for connection to the LLN-K-A Luer male-threaded locking coupler (DIN 13 090).

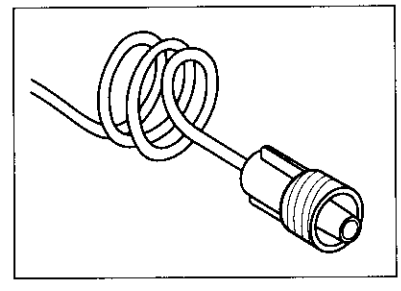


Figure 1-6-1
Luer Male-threaded Locking Coupler of the LF Spiral Extension Tubing

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1.7 ACCESSORIES

A list of the accessories for use with the OptiVantage Injector is available through your Mallinckrodt sales representative.

NOTE: The use of accessories not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the patient vicinity
- evidence that the safety certification of the accessory has been performed in accordance to the appropriate EN 60601-1 and/or EN 60601-1-1 harmonized national standard.

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2 POWER ON / POWER OFF

2.1 TURNING THE SYSTEM POWER ON

Refer to Figure 2-1-1.

1. At the rear of the power supply, place the switch to the ON position Ⓐ. The blue LED located on the top of the power supply will illuminate to indicate power is ON .
2. At the console, push the System ON/OFF button Ⓑ or press on the powerhead touchscreen. The ON/OFF button on the console will illuminate to indicate power to the console and powerhead is ON. The injector will perform a power-up check sequence, then display screens on the powerhead and the console to correctly position the rams for proper loading of the syringe(s).

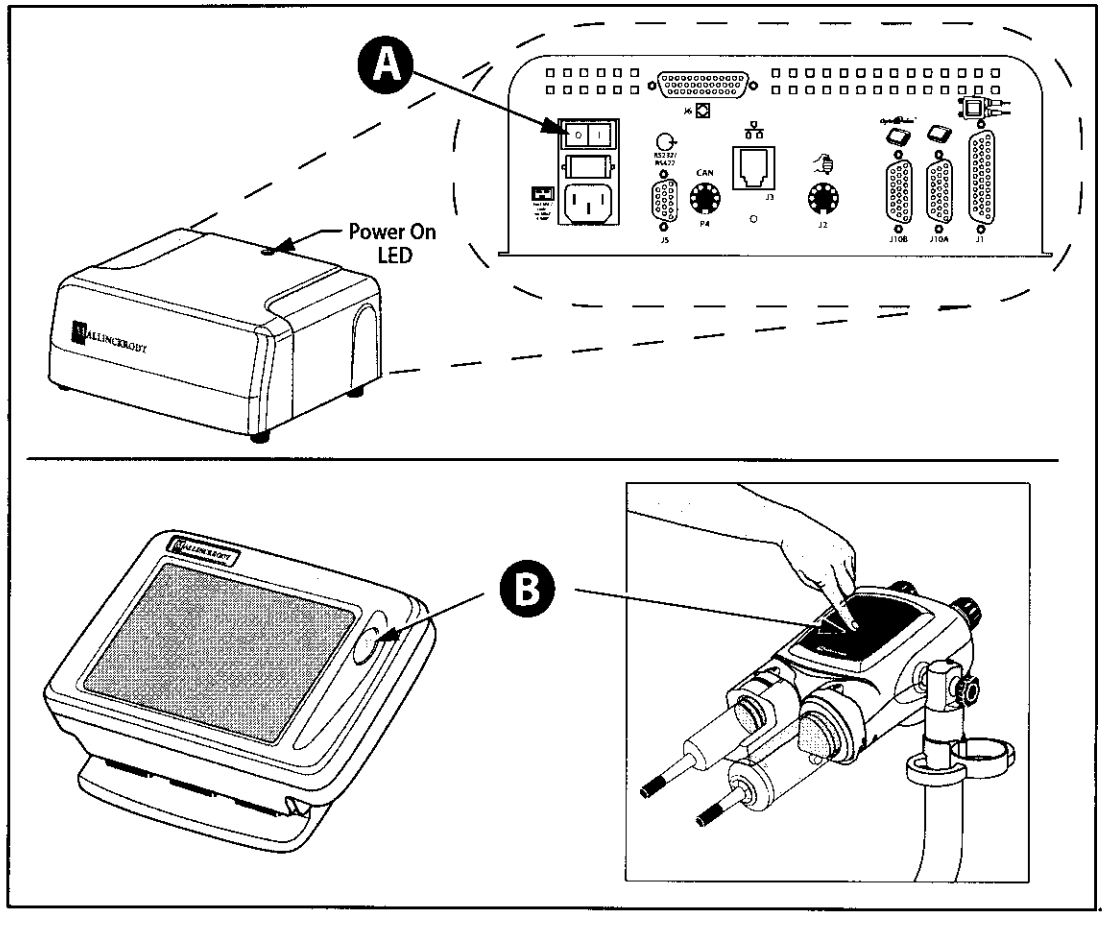

Figure 2-1-1 Switching the System Power ON

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2.2 HOMING THE RAMS

Each time power is cycled, the injector automatically performs a ram homing sequence to properly position the rams for loading of the syringes.

⚠ CAUTION! ⚠

Disconnect the tubing from all 125 ml syringes prior to performing the homing sequence. Retracting the ram during the homing sequence, while connected to tubing *not containing* a check valve, may cause inadvertent retraction of blood from the patient. Retracting the 125 ml ram during the homing sequence, while connected to tubing *containing* a check valve, will cause a vacuum in the syringe.

Remove all 200 ml syringes prior to performing the homing sequence. Expelling the ram during the homing sequence, when a 200 ml syringe is loaded, may cause inadvertent injection of contrast or saline into the patient.

Follow the instructions on the powerhead display to perform the homing sequence.

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2.3 TURNING THE SYSTEM POWER OFF

Refer to Figure 2-3-1.

At the console, push the ON/OFF button to switch the system OFF Ⓑ. The power supply can be left ON. This allows for quicker and easier restarts from the console .

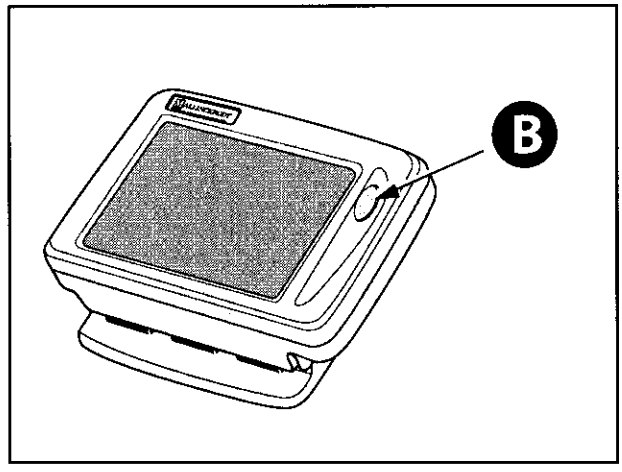

Figure 2-3-1 Switching the System Power OFF

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3 CONSOLE AND POWERHEAD

Operating the OptiVantage requires knowledge of the operator interfaces located on both the console and the powerhead. The console and powerhead both contain touch screen displays in order to interact with the operator.

Through use of the *console's touch screen display*, the operator can:

- enter protocol parameters
- save protocols
- delete protocols
- recall protocols
- enable/start/stop a Drip injection
- enable/start/stop an injection
- review achieved parameters of delivered protocols

Through use of the *powerhead's touch screen display*, the operator can:

- enter protocol parameters
- recall protocols
- fill/expel syringes
- enable/start/stop a Patency Check injection
- enable/start/stop a Drip injection
- enable/start/stop an injection

3.1 CONSOLE

3.1.1 CONSOLE POWER BUTTON

Refer to Figure 3-1-1.

Power Button/Power ON Indicator Ⓐ — The LED located on the power button glows to indicate that power is ON. With the power supply switch in the ON position, the injector system can be powered ON and OFF through use of the console power button.

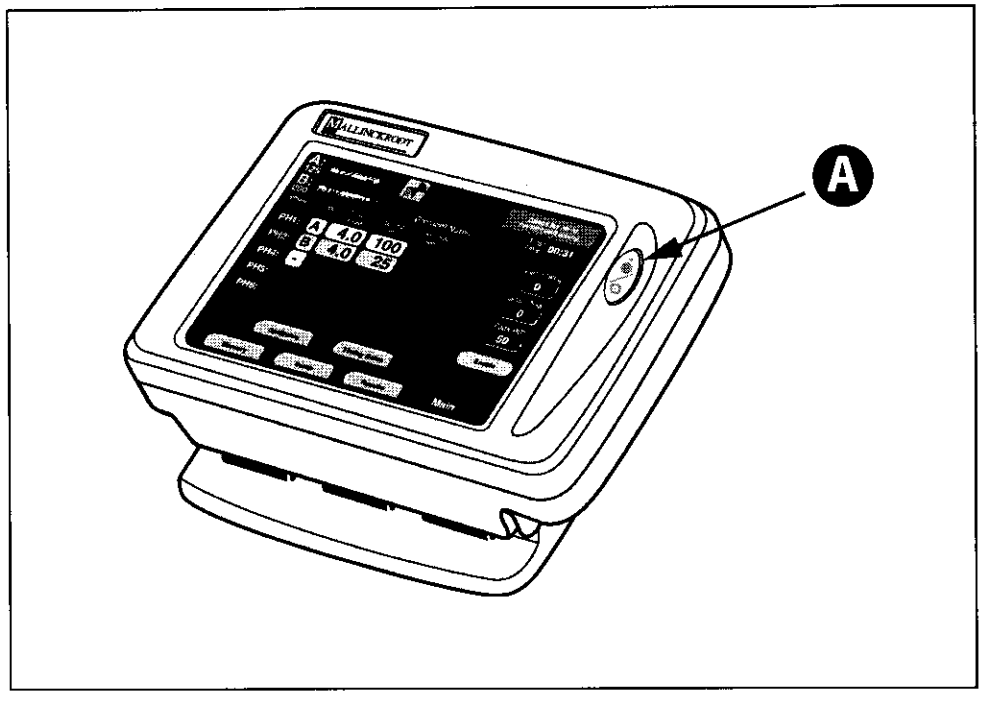

Figure 3-1-1 Console Power Button

3.1.2 CONSOLE DISPLAY MODES OF OPERATION

Refer to Figure 3-1-2.

Located along the lower portion of the console display are the following 4 keys: [Memory], [Setup], [Results] and [Main]. These keys allow access to their respective modes of operation.

Main Screen — Upon power-up, this screen is automatically displayed as shown in Figure 3-1-2. All protocol information needed by the injector is contained within the Main screen. To access the Main screen when displaying the Results screen, Setup screen or Memory screen, press the active [Main] key located on the lower right-hand side of the screen.

Enabled Main Screen — The Enabled Main screen allows for the delivery of the main protocol or a Drip Mode Injection.

Memory Screen — All stored protocol information is located within the Memory screen. Accessing this screen allows the operator to recall, store, rename and delete protocols. To access the Memory screen, press the [Memory] key Ⓑ located on the lower portion of the screen.

Setup Screen — Accessing this screen allows the operator to change the language, change the unit of measure for pressure, set the time, set parameter defaults, display the Alarm History, and access the service mode. To access the Setup screen, press the [Setup] key Ⓒ located on the lower portion of the screen.

Results Screen — All information pertaining to the results of a delivered injection is located within the Results screen. To access the Results screen, press the [Results] key Ⓓ located on the lower portion of the screen.

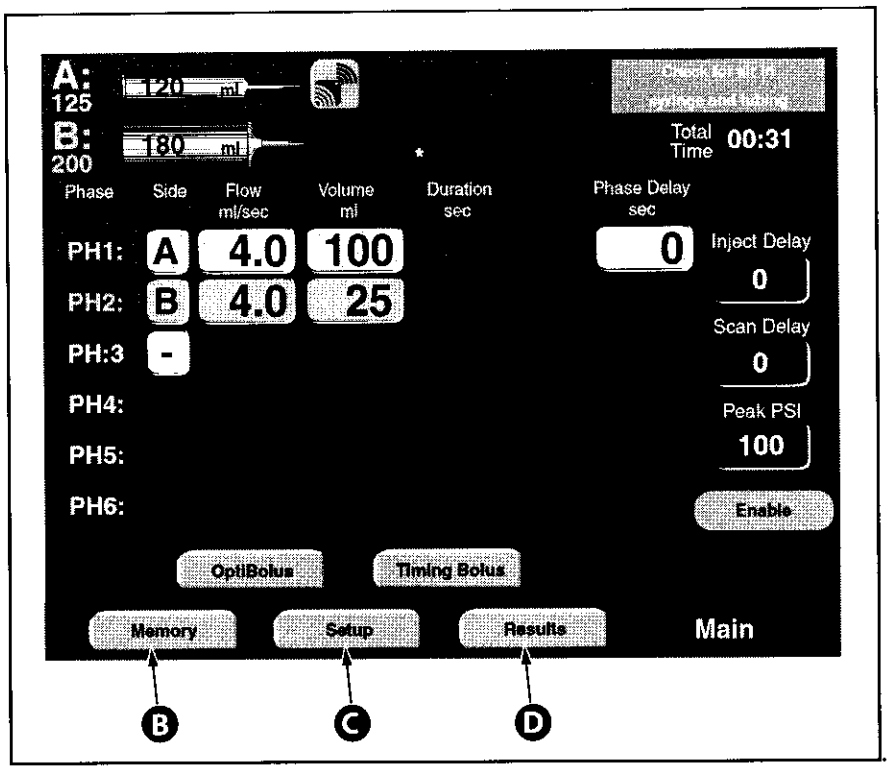

Figure 3-1-2 Console Main Screen with Location of Mode Keys

3.1.3 CONSOLE MAIN SCREEN

Refer to Figure 3-1-3 and Figure 3-1-4.

Protocol Name (E) — The name of the protocol currently displayed on the Main Screen is located in this area of the screen. An asterisk located at the end of the name indicates that the displayed parameters have been modified and no longer match the originally stored parameters.

A: Syringe Size (F) — This information indicates the size of the syringe currently installed in the A-side of the powerhead. Note that contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple.

RFID Active (F1) — This key allows the operator to view attributes of any installed Ultraject syringe fitted with a syringe data tag. The RFID icon will de-highlight if an installed syringe does not contain a syringe data tag. Once the [RFID Active] key (F1) is pressed, the screen shown in Figure 3-1-5 is displayed.

B: Syringe Size (G) — This information indicates the size of the syringe currently installed in the B-side of the powerhead. Note that contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple.

Phase (H) — Within a protocol, up to six phases can be input. "PH" is the abbreviation of Phase.

Side (I) — These keys toggle among the following symbols: [A], [B], [-]. Pressing an [A] key will toggle the key to a [B] key, thus indicating injecting from the B-side. Pressing a [B] key will toggle the key to a white [-], indicating no injecting for and past that phase. Pressing a white [-] key will toggle the key to a [A] key, thus indicating injecting from the A-side.

Flow (J) — The values entered in this column indicate rate of delivery of the contrast medium and saline during each respective phase. Flow is expressed in milliliters/second.

Volume (K) — The values entered in this column indicate the volume of contrast medium and saline to be delivered during each respective phase. Volume is expressed in milliliters.

Duration (L) — The value in this column indicates the duration of a protocol phase (i.e., time to complete injection in seconds) based on the entered volume and flow rate values. Duration is displayed in the nearest whole second.

Phase Delay (M) — Phase Delay is a count down timer that delays the start of the next phase. The next phase will start when the phase delay counter reaches 0 (zero). Phase Delay is expressed in seconds. Phase Delay can also be set to pause the injection. Access the Pause feature by scrolling past either the 0 (zero) lower limit or the 600 (six-hundred) upper limit.

Total Time (N) — The Total Time field is an accumulation of all the calculated Duration and Delay fields for all phases. The total time field starts counting up from 0 (zero) after the injector receives a start signal. Total time continues to count after the injection is completed as long as the Results screen is displayed or up to 21 minutes. Total time is expressed in minutes:seconds.

Inject Delay (O) — Inject Delay is a count down timer that begins counting when the Start command is activated. The injection is started when the inject delay counter reaches 0 (zero). If Inject Delay is greater than 0 (zero), Scan Delay is automatically set to 0 (zero). Inject Delay is expressed in seconds.

Scan Delay (P) — Scan Delay is a count down timer that begins counting when the Start command is activated and stops when the counter reaches 0 (zero). The scan start signal will initiate once the timer reaches 0 (zero). If Scan Delay is greater than 0 (zero), Inject Delay is automatically set to 0 (zero). Scan Delay is expressed in seconds.

Peak PSI/Peak kPA (Q) — The value set in this key indicates the maximum allowable pressure that can occur during an injection. Pressure is expressed in either PSI or kPa. Refer to section *3.1.6 Setup Screen Parameters and Symbols* for more information about changing the unit of measure.

Enable (R) — **This key is only active when proper enabling sequence is followed and after the powerhead is tilted downward**. Pressing the active [Enable] key "enables" the injector (displays the [Start] key) for delivery of a protocol.

OptiBolus (optional) (S) — *This key is only active if a port-key is present at the OptiBolus port located on the rear of the power supply.* Pressing this key allows the operator to program an OptiBolus injection. The OptiBolus Mode delivers an exponentially decaying flow rate injection that optimizes the contrast usage and provides an extended period of uniform enhancement of the area of interest. Once the [Optibolus] key (S) is pressed, the screen shown in Figure 3-1-6 is displayed. Note the addition of the Optibolus symbol (V) to the left of the first phase along with the addition of End Flow Rate (W). End Flow Rate (W) is a function of the Optibolus mode and is automatically calculated by the OptiVantage for the entered parameters and is displayed only on the console Main screen.

Timing Bolus (T) — *This key is only active if turned ON at the Setup Screen and when 4 or less phases are programmed in a protocol.* Pressing this key allows the operator to program a Timing Bolus injection. A Timing Bolus injection--an injection of a small volume of contrast, followed by a small volume of saline--can be delivered to the patient to determine the optimal scan delay needed to capture the contrast agent in the are of interest. Once the [Timing Bolus] key (T) is pressed, the screen shown in Figure 3-1-7 is displayed. Note the addition of "Text" (X) to the left of the first and second phase.

Change Parameter Values via the Slide Bar (U) — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, or use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

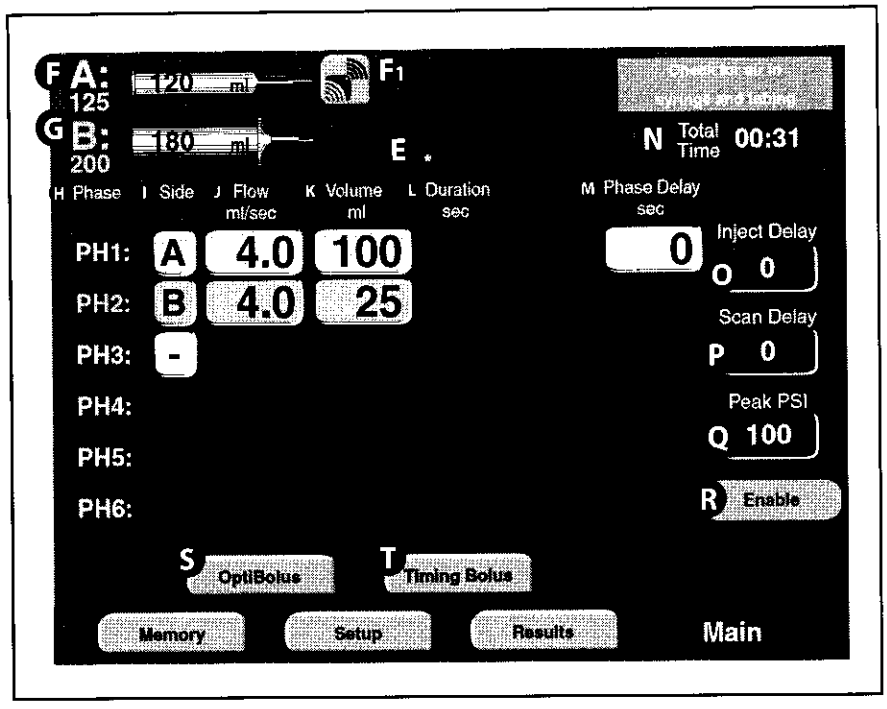

Figure 3-1-3 Console Main Screen

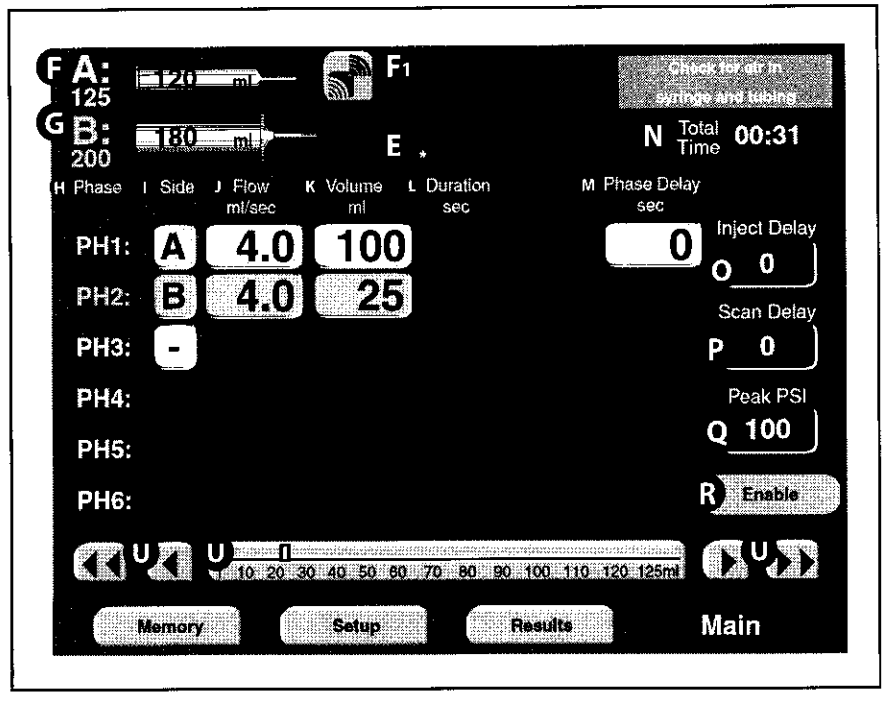

Figure 3-1-4 Console Main Screen with Active Slide B

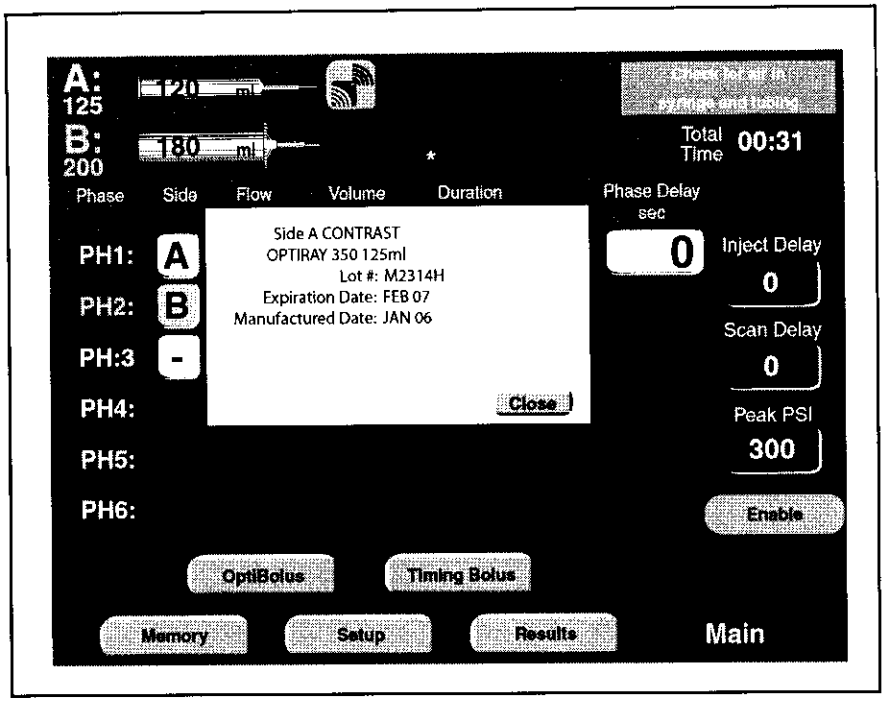

Figure 3-1-5 RFID Syringe Information

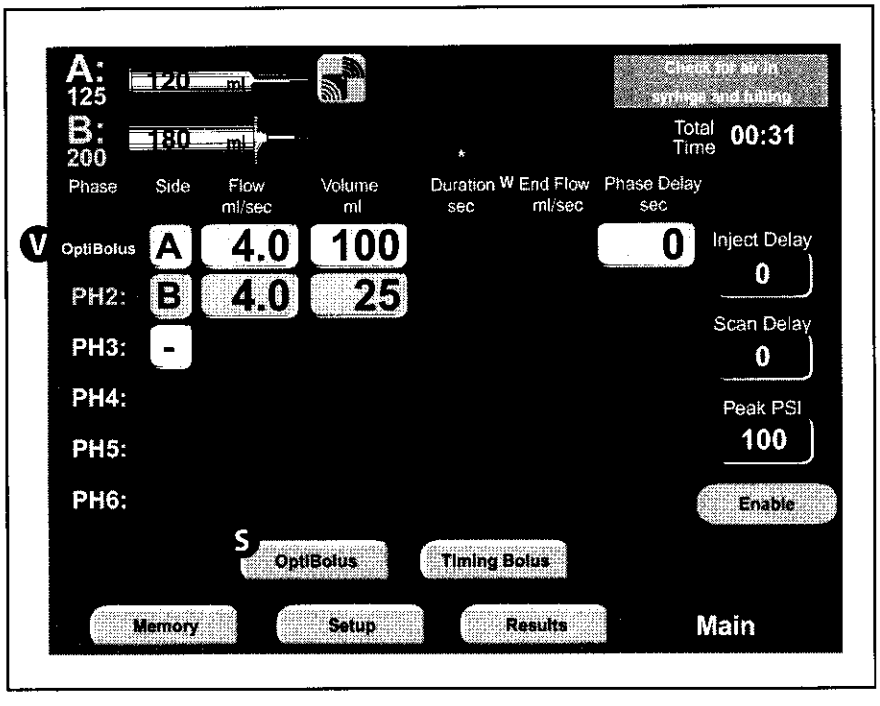

Figure 3-1-6 Console OptiBolus Injection Screen

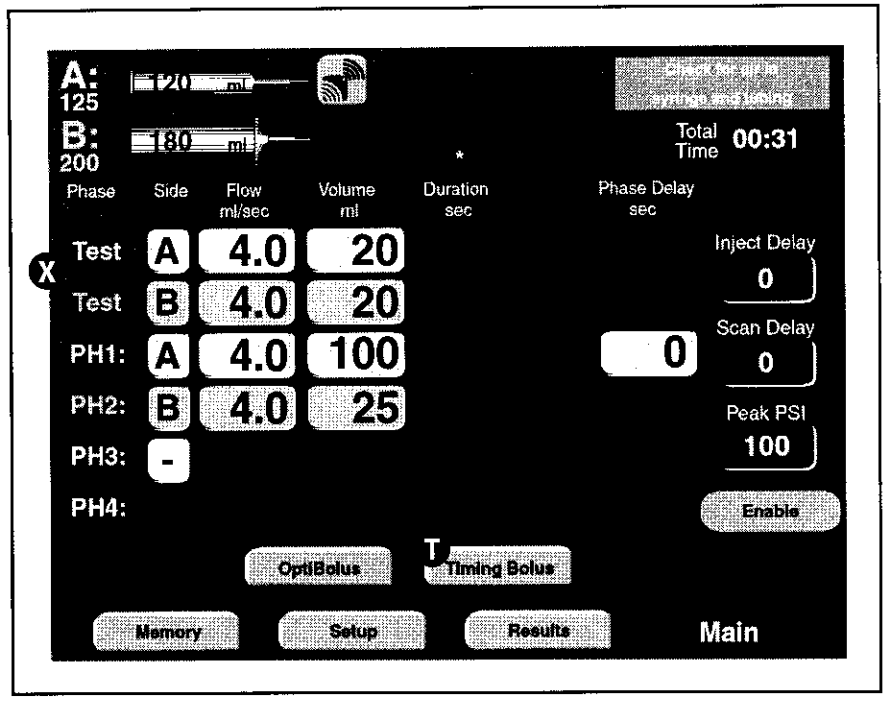

Figure 3-1-7 Console Timing Bolus Injection Screen

3.1.4 ENABLED CONSOLE MAIN SCREEN (START SCREEN)

Refer to Figure 3-1-8.

After pressing the active [Enable] key, the screen shown in Figure 3-1-8 is displayed. From this screen, the operator can change parameters, program an OptiBolus injection, program a Timing Bolus injection, enter the Drip Mode, or start the delivery of the protocol.

Start Ⓨ — This key starts the delivery of the programmed protocol. For more information about delivering injections, refer to Chapter 5.

Drip Ⓩ — *This key is active if turned ON at the Setup Screen and only displayed after the [Enable] key is pressed.* Pressing this key allows the operator to program a "drip" injection--a low flow rate injection of a small volume of saline delivered to keep the fluid pathway open. Refer to Figure 3-1-9.

Disable ⒶⒶ — This keys allows the injector to disable from the enabled mode.

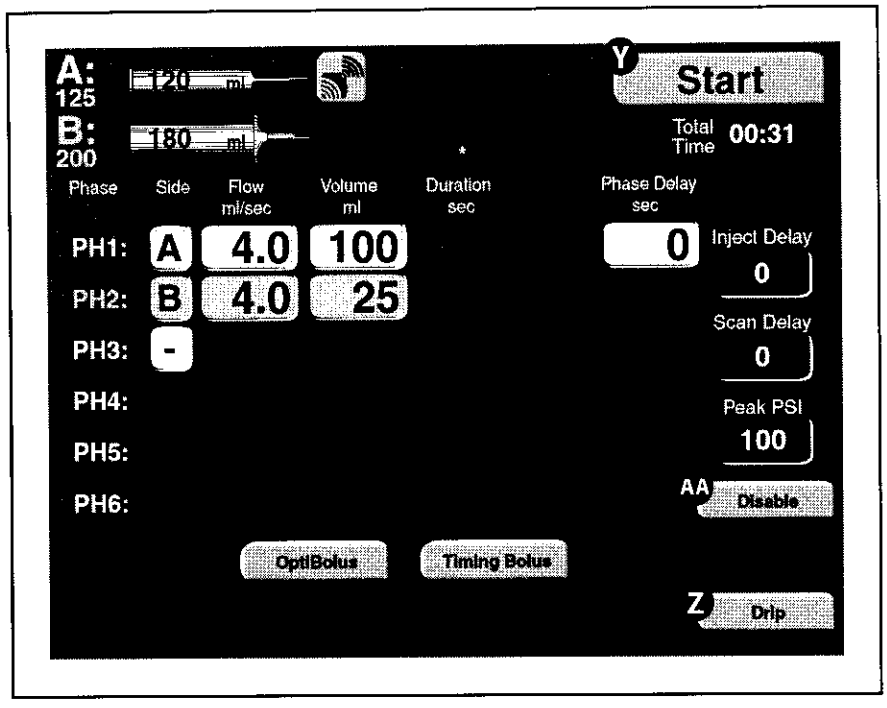

Figure 3-1-8 Enabled Console Main Screen

Drip Mode Screen

Refer to Figure 3-1-9.

The Drip Mode allows the injector to deliver a "drip" injection to keep the fluid path open during patient set up and between injections of contrast. The Drip Mode is accessible from either the Console Enabled Main Screen or the Powerhead Enabled Main Screen.

To access the Drip Mode screen as shown in Figure 3-1-9, press the [Drip] key Ⓩ located on the enabled Main screen (shown in Figure 3-1-8).

Side Ⓐ — The Drip injection can only be delivered from the saline side. (In Figure 3-1-9, the B-side is set up as the saline side.)

Drip Mode Flow Ⓑ — This value indicates rate of delivery of the saline. Drip Mode flow is expressed in milliliters/second.

Drip Mode Volume Ⓒ — This value indicates the volume of saline to be delivered during each drip injection. Drip Mode volume is expressed in milliliters.

Interval Ⓓ — This value indicates the amount of time the injector pauses between each delivery of drip injections. Drip Mode interval is expressed in seconds.

Change Parameter Values via the Slide Bar Ⓔ — To change the value of a param-

eter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Drip Time **F** — Calculated automatically by the injector by using the programmed Flow, Volume and Interval values, this value indicates the amount of time the Drip Injection will require. Once the [Start Drip] key is pressed, the value counts down until it reaches zero. Once Drip Time reaches zero, an audible signal will indicate to the operator that the Drip Injection is complete.

Drip Volume **G** — Calculated automatically by the injector by subtracting the programmed Volume of the main protocol (saline side) from the syringe volume (saline side), this value indicates the amount of saline the Drip Injection can inject. Drip Volume is expressed in ml.

Start Drip **H** — This key starts the drip injection. For more information about delivering a drip injection, refer to Chapter 5.

Exit **I** — This key disables the drip injection and displays the Enabled Main screen.

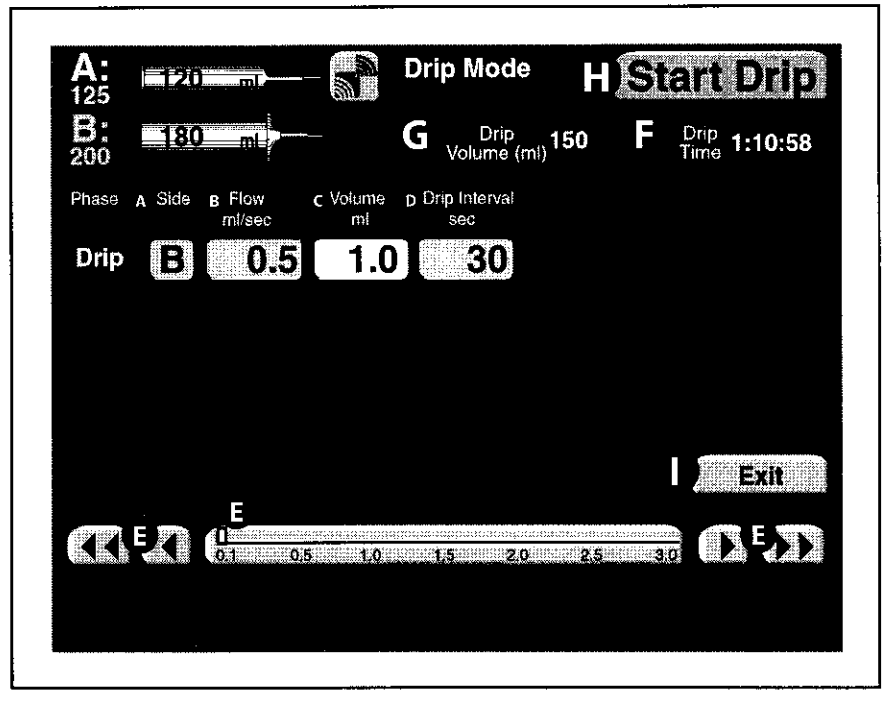

Figure 3-1-9 Drip Mode Screen

3.1.5 MEMORY SCREEN

Refer to Figure 3-1-10.

NOTE: If password protection is ON, moving, deleting, renaming or storing protocols is not permitted unless the correct password is entered.

Memory Location Ⓐ — The unit can store up to 40 six-phase protocols with 8 protocols listed per page. Each protocol can have a name consisting of up to 20 alpha-numeric characters. To display the protocol on the Main Screen, simply press the Protocol's corresponding key. OptiBolus protocols are indicated by the "OptiBolus" logo located on the key.

Protocol Parameters Ⓑ — Each protocol can contain up to six phases.

Current Values Ⓒ — The current values displayed on the Main screen are located in this area.

Memory Page Number Ⓓ — The memory screen contains five pages with eight protocols listed per page.

Move Ⓔ — This key allows the operator to move a protocol into a different slot or onto a different page.

Delete Ⓕ — This key activates the delete feature. Press the [Delete] key, then press the key of the protocol to be deleted.

Edit Ⓖ — This key allows the operator to edit the name of a protocol.

Store Ⓗ — This key stores the current values into a protocol memory slot.

Cancel (not shown) — This key is only displayed after pressing the [Move] key, the [Delete] key, the [Edit] key or the [Store] key and is used to cancel the feature.

Main Ⓘ — This key allows the operator to return to the Main screen.

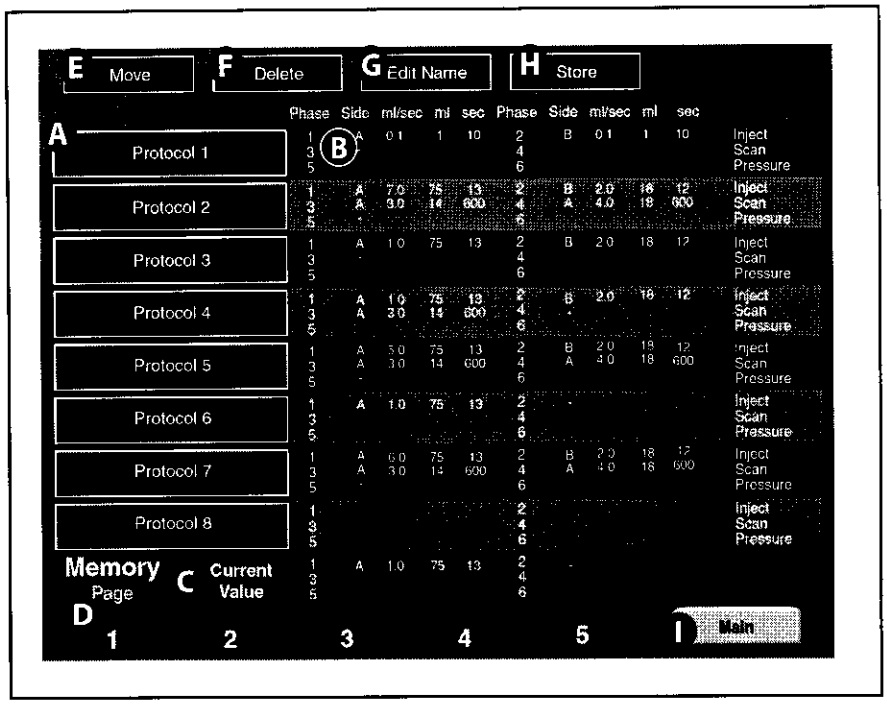

Figure 3-1-10 Memory Screen Keys and Definitions

Recall a Protocol

Refer to Figure 3-1-10.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) Ⓓ on which the Protocol is stored.
3. Press the key Ⓐ of the desired Protocol Name. The protocol will be immediately displayed on both the powerhead display and the console display.

Store a Protocol in Memory

Refer to Figure 3-1-10 and Figure 3-1-11. This feature is only accessible from the console.

1. Enter all required parameters on the Main screen.
2. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
3. Press the appropriate page (1, 2, 3, 4 or 5) Ⓓ on which to store the Protocol.
4. Press the [Store] key Ⓗ. The display will prompt the user with "Select memory location."
5. Press the desired memory location key Ⓐ. A keyboard will appear in order to name the protocol. Refer to Figure 3-1-11.
6. Enter the desired name using the keyboard. Press the keyboard [Enter] key Ⓙ when finished. The protocol will be stored at the memory location selected.

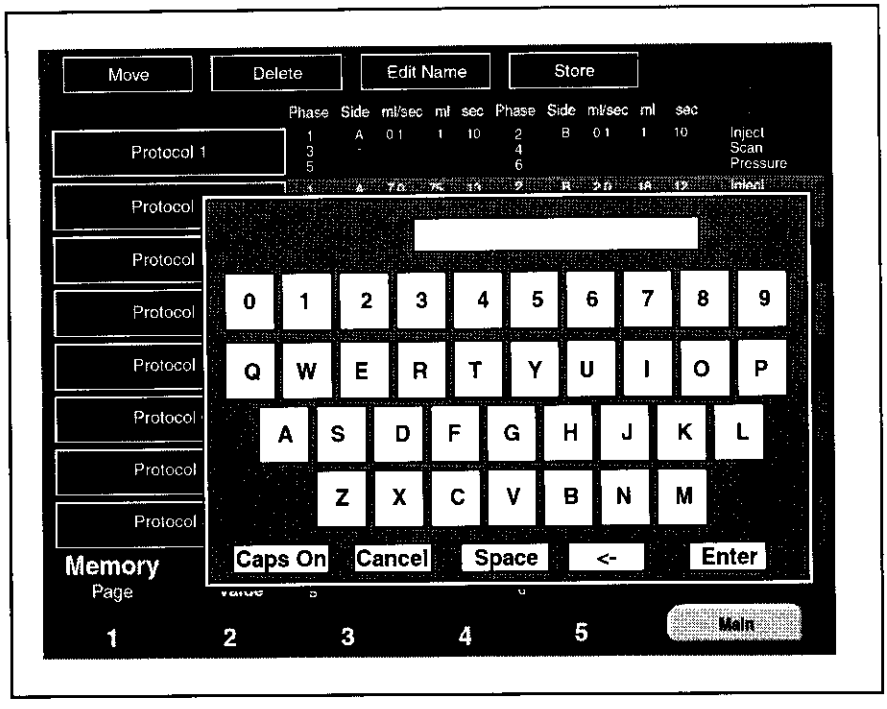

Figure 3-1-11 Memory Keyboard

Move a Protocol in Memory

Refer to Figure 3-1-10. This feature is only accessible from the console.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) Ⓓ on which the Protocol is stored.
3. Press the [Move] key Ⓔ. The display will prompt the user with "Select protocol to move."
4. Press the key of the protocol to be moved. The display will prompt the user with "Select position to insert moved protocol."
5. Press the desired memory location key Ⓐ onto which the Protocol is to be relocated. The protocols will be shifted upwards or downwards to accommodate the new location of the moved protocol.

Delete a Protocol from Memory

Refer to Figure 3-1-10. This feature is only accessible from the console.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4, or 5) Ⓓ on which the Protocol is stored.
3. Press the [Delete] key Ⓕ. The display will prompt the user with "Select protocol to delete."
4. Press the key of the protocol to be deleted. The display will prompt the user with "Are you sure?" Pressing the [Yes] key deletes the protocol from memory. Pressing the [No] key returns you to the Memory screen without deleting the protocol from memory.

Rename (Edit Name) a Protocol Name or Page

Refer to Figure 3-1-10 and Figure 3-1-11. This feature is only accessible from the console.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) Ⓓ on which the Protocol is stored.
3. Press the [Edit Name] key Ⓖ. The display will prompt the user with "Select protocol to rename."
4. Press the key of the protocol to be renamed and enter the new name using the displayed keyboard (shown in Figure 3-1-11). Press the keyboard [Enter] key Ⓙ when finished. The protocol will be stored under the new name at the same memory location.

3.1.6 SETUP

Refer to Figures 3-1-12 and 3-1-13.

Access the Setup screens by pressing the [Setup] key Ⓑ (on Figure 3-1-2) located on the Main Screen of the Console. Note: The Setup Screen and its features are not accessible from the Powerhead screen. Also, if password protection is ON, access to the Setup screens is not permitted unless the correct password is entered.

The Setup Screen allows the operator to adjust injection parameters, set the time and date, select the language, enter the service mode, and view the alarm history of the injector. Use the [<, >] keys Ⓒ keys to toggle between the two set up screens.

Date and Time Ⓐ — Indicates the Date and Time as set in item Ⓓ.

Software Versions Ⓑ — Indicates the software installed in the console, powerhead, and the current Scanner Interface software.

[<, >] keys Ⓒ — These keys allow the user to toggle between the two Set Up screens as shown in Figure 3-1-12 and 3-1-13.

[Time] key Ⓓ — This key allows the user to set the time and date. Refer to Figure 3-1-15.

[Language] key Ⓔ — This key allows the user to change the language of the injector. Refer to Figure 3-1-16.

[Service] key Ⓕ — This key allows service personnel access to the service screens. Note: The service screens are only accessible through use of a service key. Refer to the Service Manual.

[Alarm] key Ⓖ — The injector's alarm history is accessible through use of this key.

[Main] key Ⓗ — This key allows the user to exit the Set Up screens and return to the Main Screen.

OEM Interface Ⓘ — Select On or Off. Selecting "On" allows the OEM Interface to exercise limited control over the injector. Selecting "Off" disables the OEM Interface.

Timing Bolus Ⓙ — Select either On or Off. If On is selected, a [Timing Bolus] key will be made available on the Main screen to deliver a "Timing Bolus" injection to determine optimum image quality in order to determine the ideal scan delay.

Patency Check (K) — Select either On or Off. If On is selected, a [Patency] key will be made available (after the injector is enabled) on the Powerhead to inject a small volume of saline at the maximum flow rate as the enabled protocol in order to check patency of the I.V. site.

Patency Check Volume (L) — The [Patency Check Volume] key allows the operator to set a default value for the Patency Check injection.

Drip Mode (M) — Select either On or Off. If On is selected, a [Drip Mode] key will be made available (after the injector is enabled) to deliver a "drip" injection (series of small volumes of saline) to keep the fluid path open.

Drip Flow Rate (N) — The [Drip Flow Rate] key allows the operator to set a default Flow Rate value for the Drip Injection.

Drip Volume (O) — The [Drip Volume] key allows the operator to set a default Volume value for the Drip Injection.

Drip Interval (P) — The [Drip Interval] key allows the operator to set a default value for the delay between Drip Injections.

Pause on Pressure Limit (Q) — Select either On or Off. Selecting "On" will cause the injector to automatically pause in the instance of a pressure limited injection. Selecting "Off" will allow the injector to continue injecting at a lower flow rate but will also display a message giving the operator the ability to either pause or continue.

Pressure Limit (R) — Select either Manual or Auto. Selecting "Manual" allows the operator to input a value for Peak Pressure Limit on the Main screen. Selecting "Auto" allows the injector to calculate a default value based on the highest flow rate of the displayed protocol. However, this value can be updated by the operator on the Main screen.

Pressure Units (S) — Select either PSI or kPA.

Auto-Fill (T) — Select either On or Off. If On is selected, the Auto-Fill feature is available to the operator to automatically fill a 200 ml syringe while minimizing the introduction of air.

Syringe Fluid A (U) — Select either Contrast or Saline to be used in the A-side syringe.

Syringe Fluid B (V) — Select either Contrast or Saline to be used in the B-side syringe.

Injection Duration Display (W) — Select either On or Off. Selecting Off removes the Injection Duration value (time to complete injection in seconds) from the Main Screen.

Phase Delay Display Ⓧ — Select either On or Off. Selecting Off removes the [Phase Delay] key and its value from the Main Screen.

Console Brightness (display) Ⓨ — Select between Low or High.

Console Volume (display) Ⓩ — Select among Off, Low, Med or High.

Powerhead Brightness (display) ⓐ — Select between Low or High.

Powerhead Volume (display) ⓑ — Select among Off, Low, Med or High.

Auto Syringe Size Sense ⓒ — Select either On or Off. Selecting "On" allows the injector to determine the size of the installed pre-filled syringe.

Partial Prefills ⓓ — Select either On or Off. Select On if Partial Prefill syringes are to be used.

Password ⓔ — Once Password is set to ON, a keyboard, as shown in Figure 3-1-14, is displayed to enter and re-enter the password. When Password is set to ON, access to the Setup screens and Memory features is only available after entering the password.

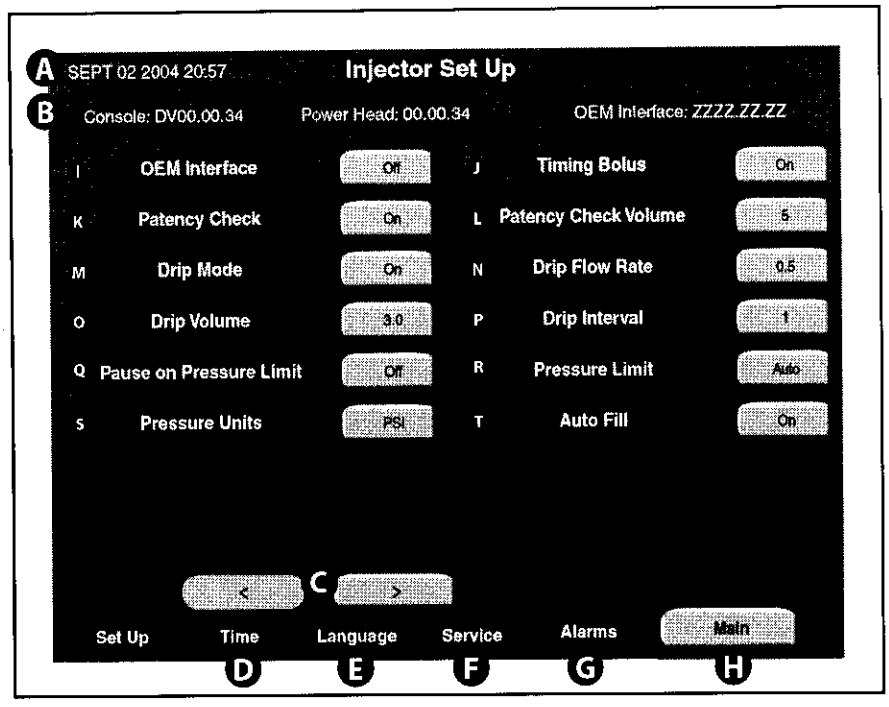

Figure 3-1-12 Injector Set Up Screen 1

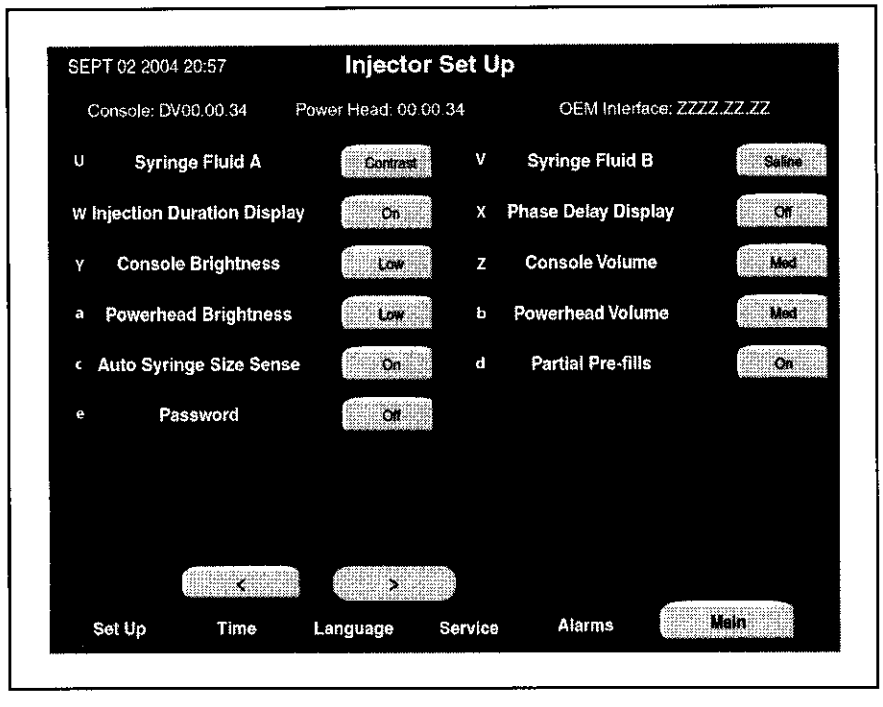

Figure 3-1-13 Injector Set Up Screen 2

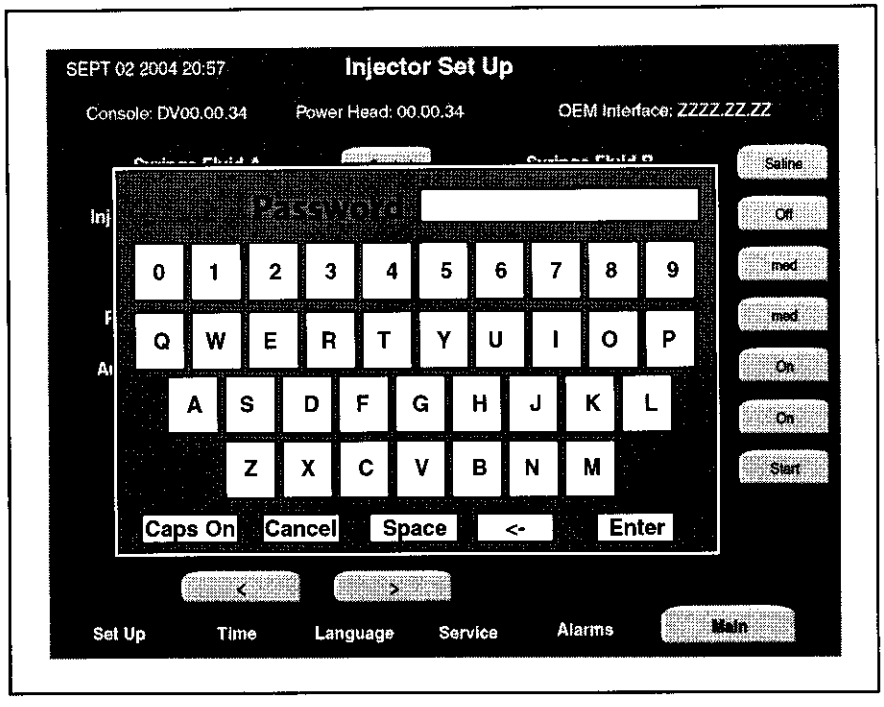

Figure 3-1-14 Enter Password

Time/Date

Refer to Figure 3-1-15.

Access the ability to set the Time and Date by pressing the [Time] key (ⓓ in Figure 3-1-11) .

Press the [Change Date] key ⓘ and/or the [Change Time] ⓙ key to update the date and time. Use the [▲▼] keys ⓚ to select the desired date and time.

After changing the Date and/or Time to the desired value, press the [Set Date] key ⓛ and/or the [Set Time] key ⓜ for the change to take effect.

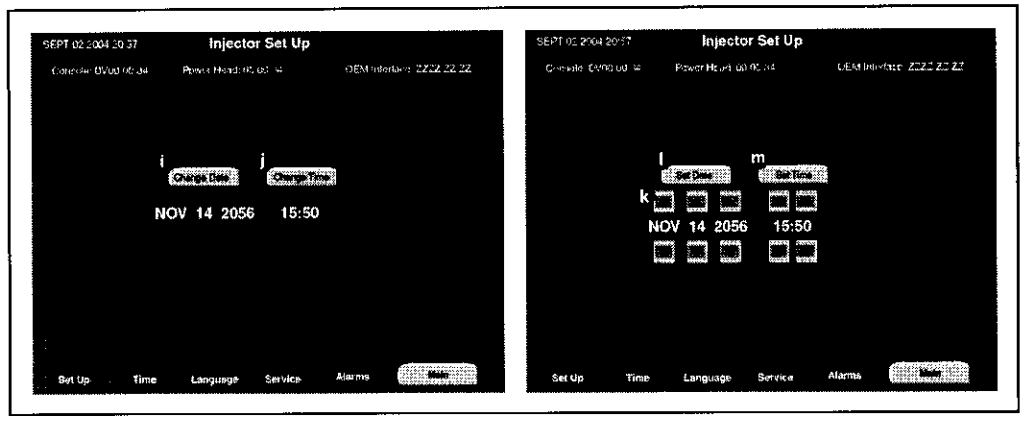

Figure 3-1-15 Setting the Time/Date

Language

Refer to Figure 3-1-16.

Select the Language from among the selections located under the [Language] key (F in Figure 3-1-12).

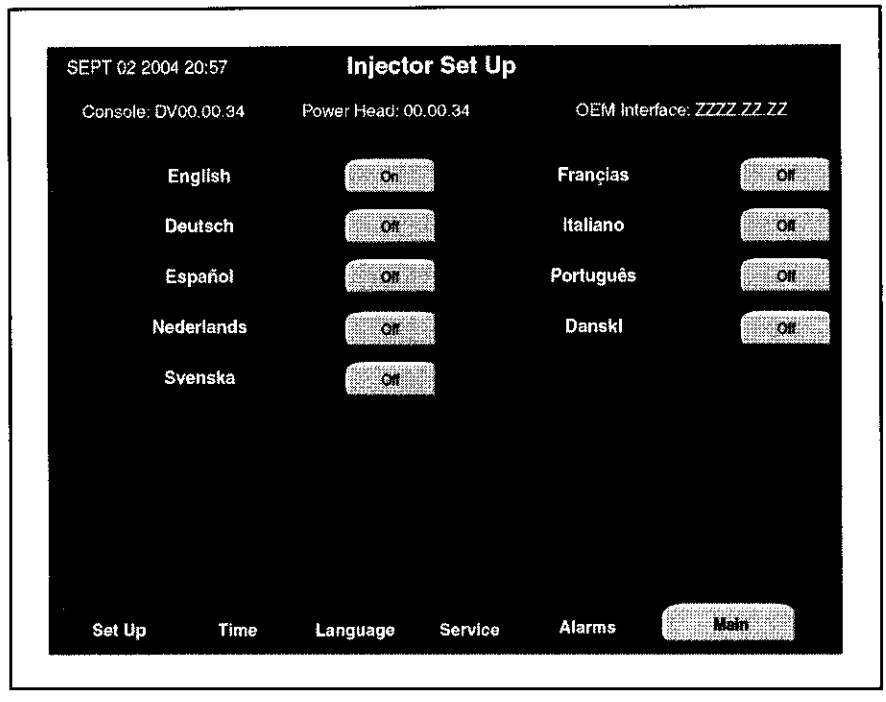

Figure 3-1-16 Selecting the Language

Alarms

Refer to Figure 3-1-17

Display the Alarm History screen by pressing the [Alarm] key (G in Figure 3-1-12). Pressing the [<, >] keys (n in Figure 3-1-17), displays the most recent Alarms (up to 24) (on the console screen only) along with the protocol's settings at the time of the alarm.

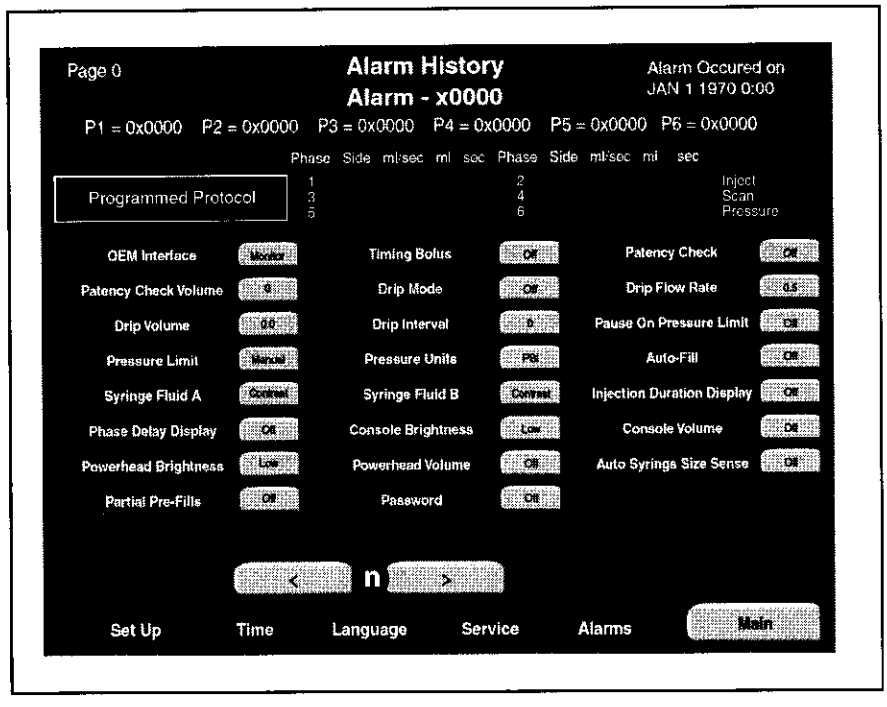

Figure 3-1-17 Alarm Screen

3.1.7 RESULTS SCREEN PARAMETERS AND SYMBOLS

Refer to Figure 3-1-18 and 3-1-19

The Results Screen is automatically displayed after the delivery of an injection and only shows the achieved results of that injection. The Results screen is displayed for either 21 minutes or until the [Main] key is pressed. Refer to Figure 3-1-18.

Pressing the [Results] key (Ⓓ in Figure 3-1-2) , however, displays the results of the last 24 injections (on the console screen only) along with the protocol's settings. Refer to Figure 3-1-18.

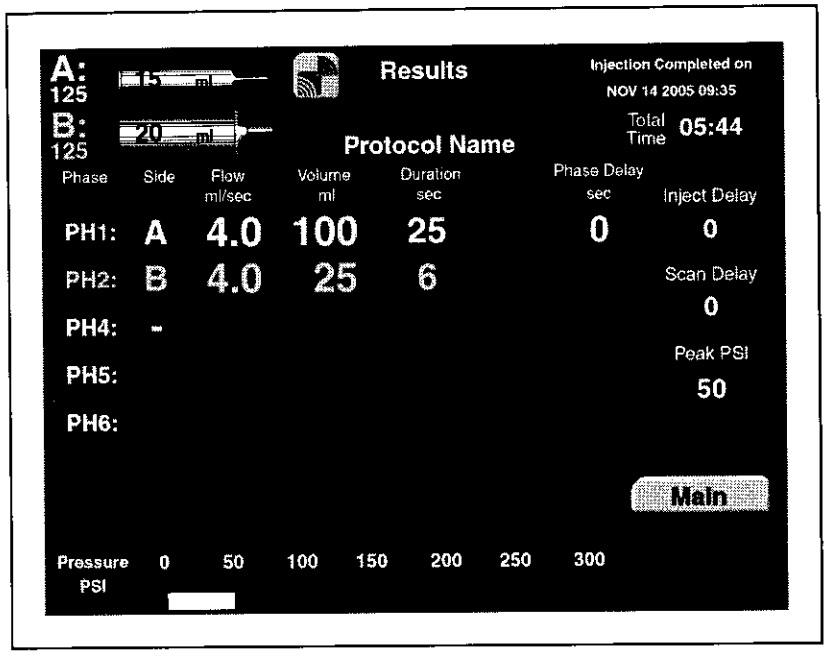

Figure 3-1-18 Results Screen displayed after delivery of an Injection

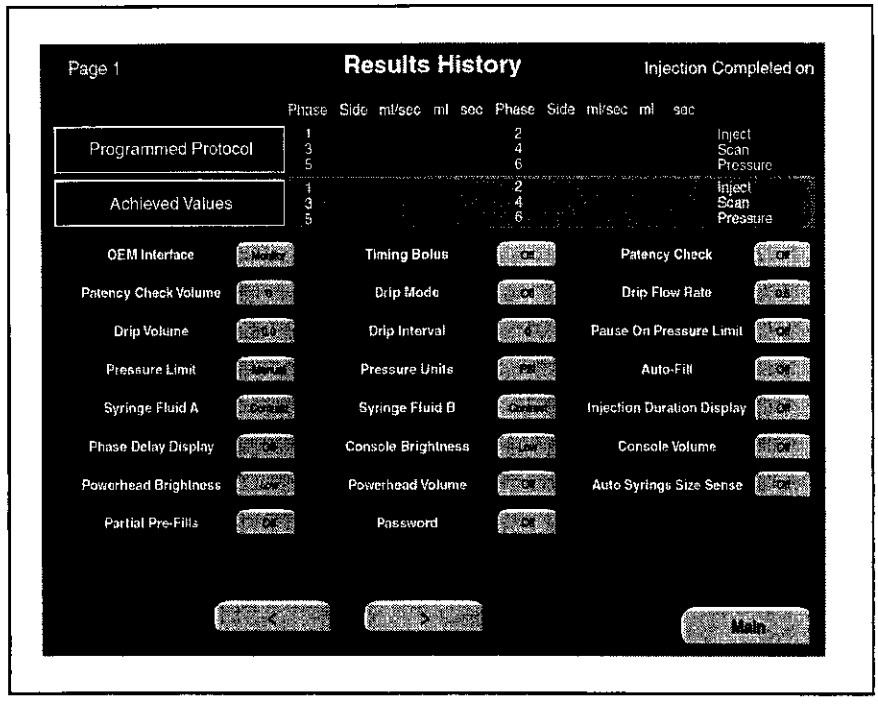

Figure 3-1-19 Results Screen displayed after pressing the [Results] Key

3.2 POWERHEAD

3.2.1 POWERHEAD POWER ON DISPLAY

Refer to Figure 3-2-1.

Power ON Display — With the power supply switch in the ON position, the powerhead display acts as a power ON switch. Simply press and hold down for 2 (two) seconds to turn the injector system ON.

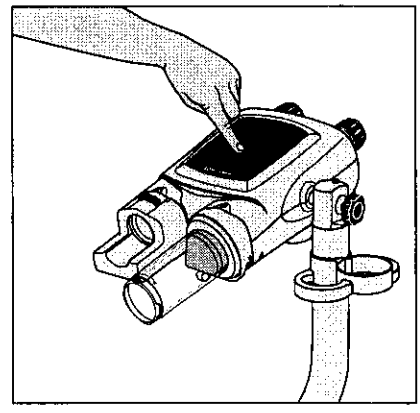

Figure 3-2-1 Powerhead Power ON Display

3.2.2 MANUAL KNOBS

Refer to Figure 3-2-2.

By turning either of the two knobs, the operator can move its respective ram/plunger. This is useful in the instance of purging air from the syringe and when drawing back blood to ensure proper venous placement of the catheter.

Turn the A-side manual knob Ⓐ clockwise to advance the A-side ram/plunger. Turn the B-side manual knob Ⓑ clockwise to advance the B-side ram/plunger. Turn the knobs counterclockwise to retract the ram/plunger. Refer to the following table for the manual knob light status.

Manual Knobs Light Status	Definition
Flashing Blue	Injector powering up.
Solid Yellow/Solid Purple	Enabled or injecting contrast (Yellow) or saline (Purple)
Flashing Purple	Injecting saline (Drip Mode)
Flashing Purple or Yellow	Injector paused
Flashing Red	Alarm Condition
Flashing Blue quickly	Injector rotated vertically or 30 degrees below horizontal.

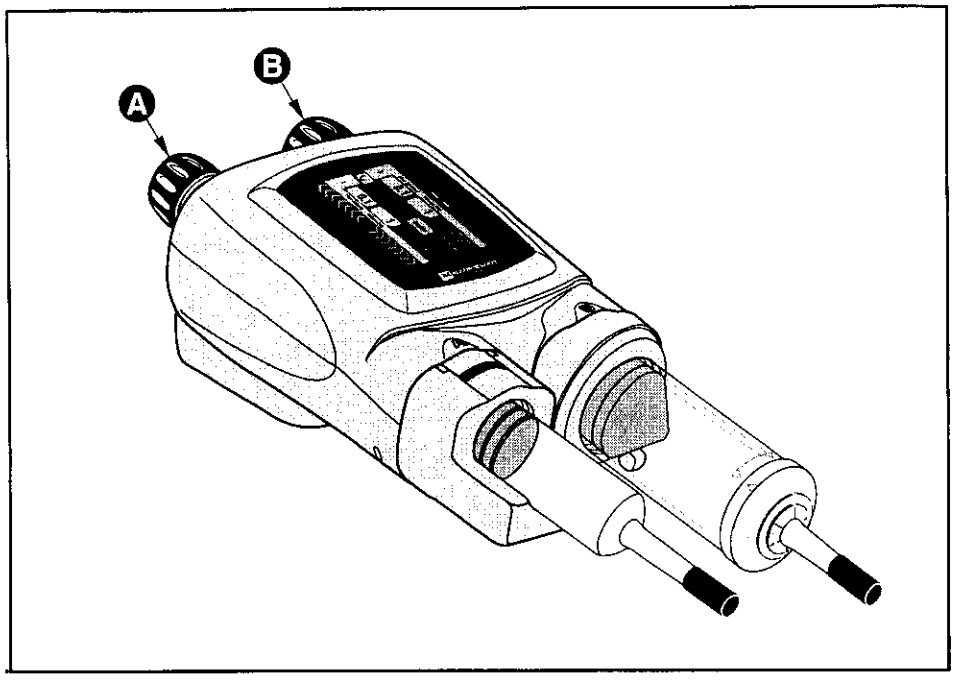

Figure 3-2-2 Powerhead A-side and B-side Indicators

3.2.3 POWERHEAD SYRINGE LOAD LATCHES

Refer to Figure 3-2-3.

125 ml Syringe Load Latch Ⓐ — The latch is pushed up from the bottom to allow loading ♂ of a 125 ml syringe. Push the latch down to lock θ the syringe in the faceplate adapter.

200 ml Syringe Load Latch Ⓑ — The latch rotates counterclockwise to allow loading ♂ of a 200 ml syringe. Rotate the latch clockwise to lock θ the syringe in the pressure sleeve.

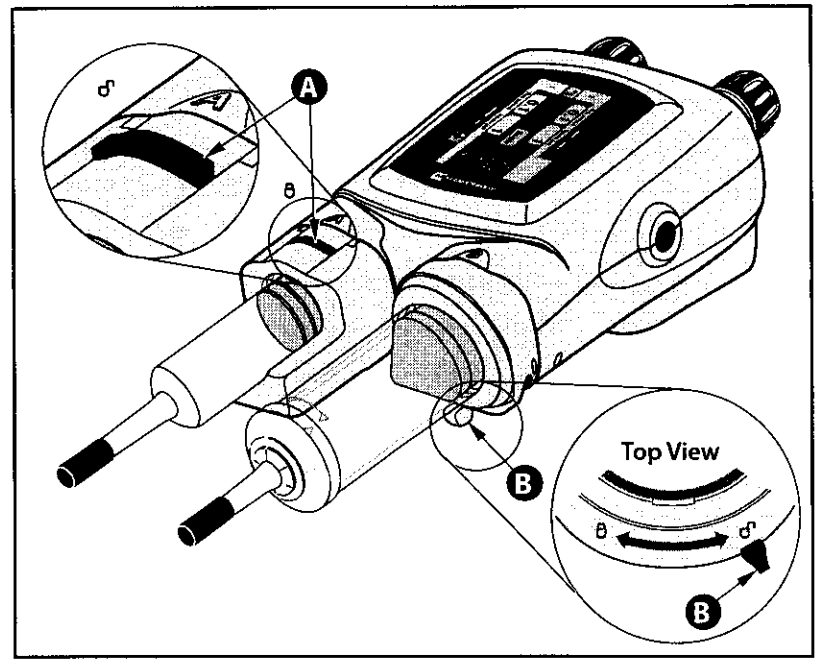

Figure 3-2-3 125 ml Syringe Load Clamp and 200 ml Syringe Load Lever

3.2.4 ENHANCED COMMUNICATION / HEATER BLANKET CONNECTION

Refer to Figure 3-2-4.

125 ml Faceplate Adapter

The 125 ml faceplate adapter Ⓐ contains a built in heater to maintain the temperature of preheated contrast and sensors to read the size of the installed syringe. Connection of the heater blanket/syringe size sensor is as shown in Figure 3-2-4.

200 ml Heater Blanket

The 200 ml heater blanket Ⓑ maintains the temperature of preheated contrast. Connection of the heater blanket is as shown in Figure 3-2-4.

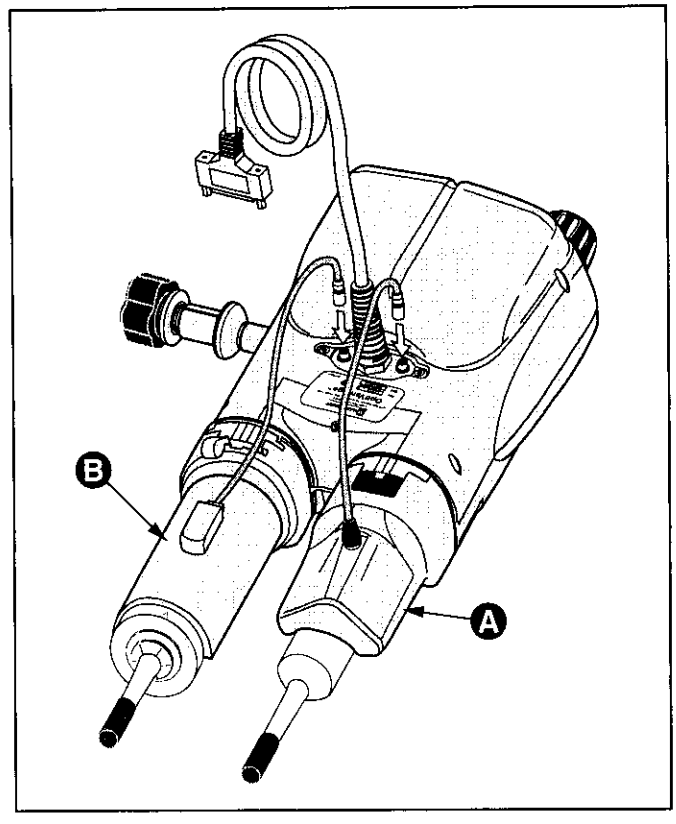

Figure 3-2-4 Heater Blanket Connections

3.2.5 POWERHEAD DISPLAY MODES OF OPERATION

Refer to Figures 3-2-5 and Figure 3-2-6.

Main Screen — The Powerhead Main screen Ⓐ is shown in Figure 3-2-5. Only the first phase of the A-side and the B-side is displayed on the Powerhead Main screen. The complete protocol is displayed on the expanded Protocol Parameter Entry screen Ⓒ.

Fill/Expel Arrows — Two [Syringe] keys Ⓑ, located in the upper and lower portion of the Main screen, change to the fill/expel arrows as shown in Figure 3-2-5. Press on the [Syringe] key to activate the fill/expel arrows.

Pressing on the active fill/expel arrows will retract/expel the ram at a rate that is proportional to the position touched in a range from 0.5 ml/sec to 15 ml/sec. Pressing the fill arrows for longer than 2 seconds will latch plunger movement. Once plunger movement has latched on, press anywhere on the powerhead display to cease plunger movement. Refer to Figure 3-2-6. Note: The fill/expel arrows do not appear if the injector is enabled.

Protocol Parameter Entry Screen Ⓒ — To access the Protocol Parameter Entry screen, press any parameter key Ⓓ located on the Powerhead Main Screen. The Protocol Parameter Entry screen allows modification of the parameters as well as access to the Memory screen. To access the Powerhead Main screen when displaying the Protocol Parameter Entry screen, press the [Main] key Ⓕ located on the lower portion of the screen.

Enabled Main Screen — The Enabled Main screen allows for the delivery of the main protocol, a Patency Check, or a Drip Mode Injection.

Memory Screen — All stored protocol information is located on the Memory screen. Displaying the Powerhead Memory screen allows the operator to only recall protocols. Storing, renaming and deleting protocols is only available on the console Memory screen. To access the Powerhead Memory screen, press the [Memory Ⓔ key located on the lower portion of the Protocol Parameter Entry screen as shown in Figure 3-2-5. When the Memory screen is displayed, press the [Main] key Ⓕ to display the Main screen.

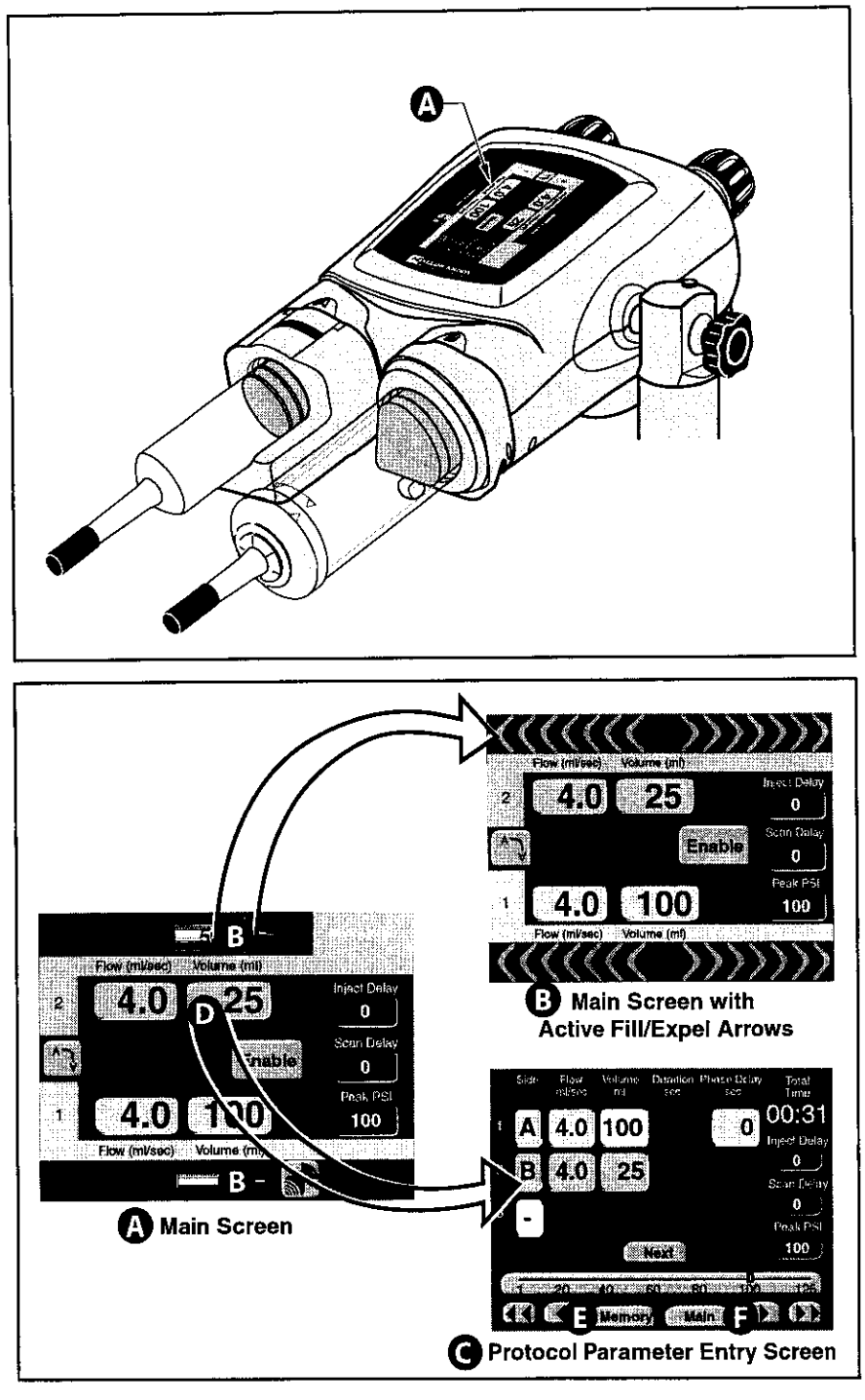

Figure 3-2-5 Powerhead Interfaces

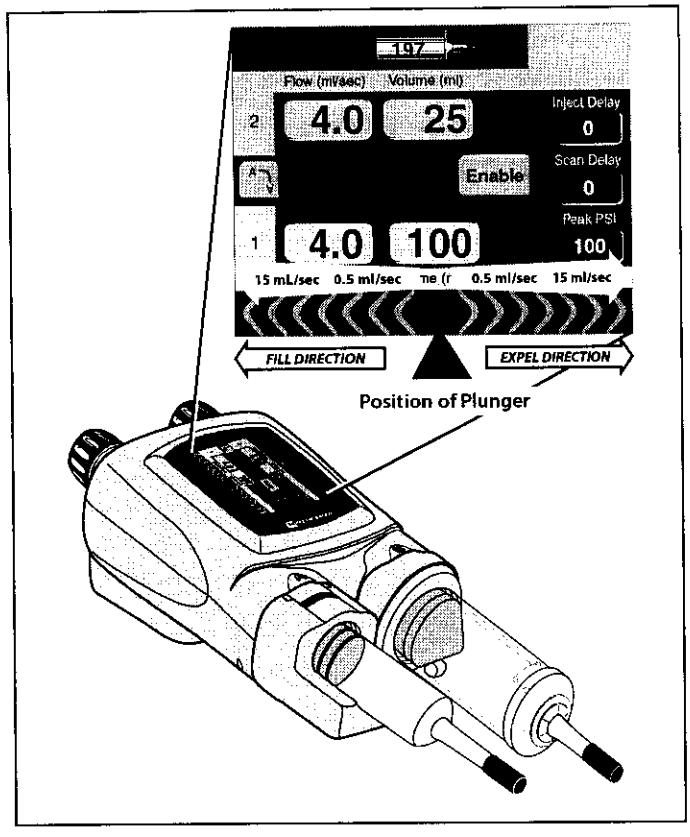

Figure 3-2-6 Fill/Expel Arrow Range of Speed

3.2.6 POWERHEAD MAIN SCREEN

Refer to Figure 3-2-7 and Figure 3-2-8.

A-Side Syringe (mL)/A-side Fill/Expel arrows Ⓐ — The syringe symbol indicates the relative position of the plunger in the syringe thus indicating how much fluid may be in the A-side syringe. Pressing the syringe symbol activates the A-side Fill/Expel arrows in order to move the ram/plunger.

RFID Active Ⓐ1 — This key allows the operator to view attributes of any installed Ultraject syringe fitted with a syringe data tag. The RFID icon will de-highlight if an installed syringe does not contain a syringe data tag. Once the [RFID Active] key Ⓕ is pressed, the screen shown in Figure 3-2-8 is displayed.

B-Side Syringe (mL)/B-side Fill/Expel arrows Ⓑ — The syringe symbol indicates the relative position of the plunger in the syringe thus indicating how much fluid may be in the B-side syringe. Pressing the syringe symbol activates the B-side Fill/Expel arrows in order to move the ram/plunger.

Fill/Expel arrows — Upon pressing either the A-side Ⓐ or B-side Ⓑ [Syringe] keys as shown in Figure 3-2-5, the fill/expel arrows are activated. Pressing on the fill/expel arrows will retract/expel the ram at a rate that is proportional to the position touched in a range from 0.1 ml/sec to 15 ml/sec. Pressing the retract fill arrows for longer than 2 seconds will latch ram retraction movement. Once ram retraction movement has latched on, the arrows will turn green and have a white background. Press anywhere on the powerhead display to cease latched movement. See Figure 3-2-6.

1 (1st Phase) Ⓒ — The 1 indicates the first phase of the protocol. Contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple. To access the remaining protocol information, press any parameter key to display the Protocol Parameter Entry screen as shown in Figure 3-2-5.

2 (2nd Phase) Ⓓ — The 2 indicates the second phase of the protocol. If only a one phase protocol is programmed, the 2 will revert to a B to indicate the B-side. Contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple. To access the remaining protocol information, press any parameter key to display the Protocol Parameter Entry screen as shown in Figure 3-2-5.

Display Orientation Ⓔ — To view the powerhead display from either the A-side or the B-side, the [Display Orientation] key allows the screen to flip as shown in Figure 3-2-9.

Flow Ⓕ — The values shown in this column indicate rate of delivery during each respective phase. When delivering a protocol, the values reflect the flow rate of the current phase being injected. Flow is expressed in milliliters/second.

Volume Ⓖ — The values entered in this column indicate the volume to be delivered during each phase. When delivering a protocol, the values reflect the volume of the current phase being injected. Volume is expressed in milliliters.

Protocol Name Ⓗ — The name of the protocol currently displayed on the Main Screen.

Enable Ⓘ — **Only active after proper enabling sequence is followed and when the powerhead is tilted downward**, pressing this key "enables" or readies the injector for delivery of a protocol.

Inject Delay Ⓙ — Inject Delay is a count down timer that begins counting when the Start command is activated. The injection is started when the inject delay counter reaches 0 (zero). If Inject Delay is greater than 0 (zero), Scan Delay is automatically set to 0 (zero). Inject Delay is expressed in seconds.

Scan Delay (K) — Scan Delay is a count down timer that begins counting when the Start command is activated and stops when the counter reaches 0 (zero). The scan start signal will initiate once the timer reaches 0 (zero). If Scan Delay is greater than 0 (zero), Inject Delay is automatically set to 0 (zero). Scan Delay is expressed in seconds.

Peak PSI (L) — The value set in this key indicates the maximum allowable pressure that can occur during an injection. Pressure is expressed in either PSI or kPa. Refer to section *3.1.6 Setup Screen Parameters and Symbols for* more information about changing the unit of measure.

Check for Air message (M) — This message acts as a reminder to the operator to confirm no air exists in the syringe and tubing prior to enabling an injection.

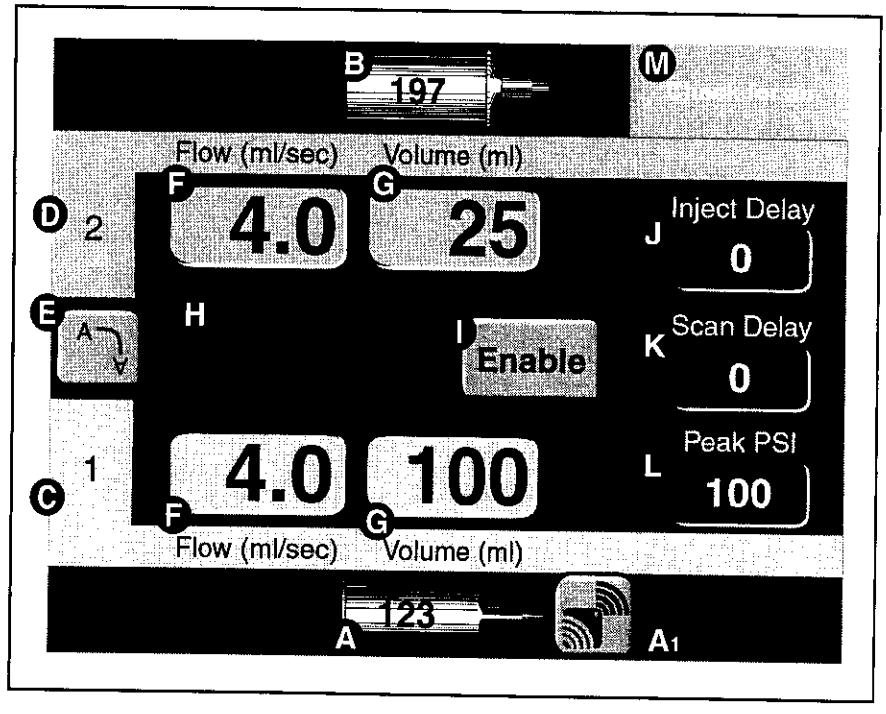

Figure 3-2-7 Powerhead Display Main Screen

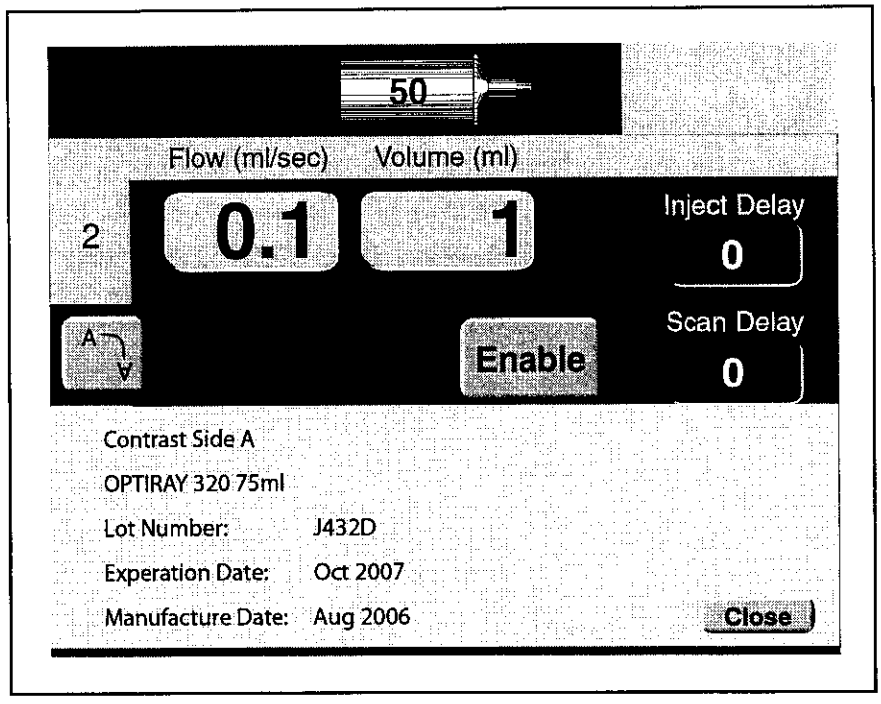

Figure 3-2-8 RFID Syringe Information

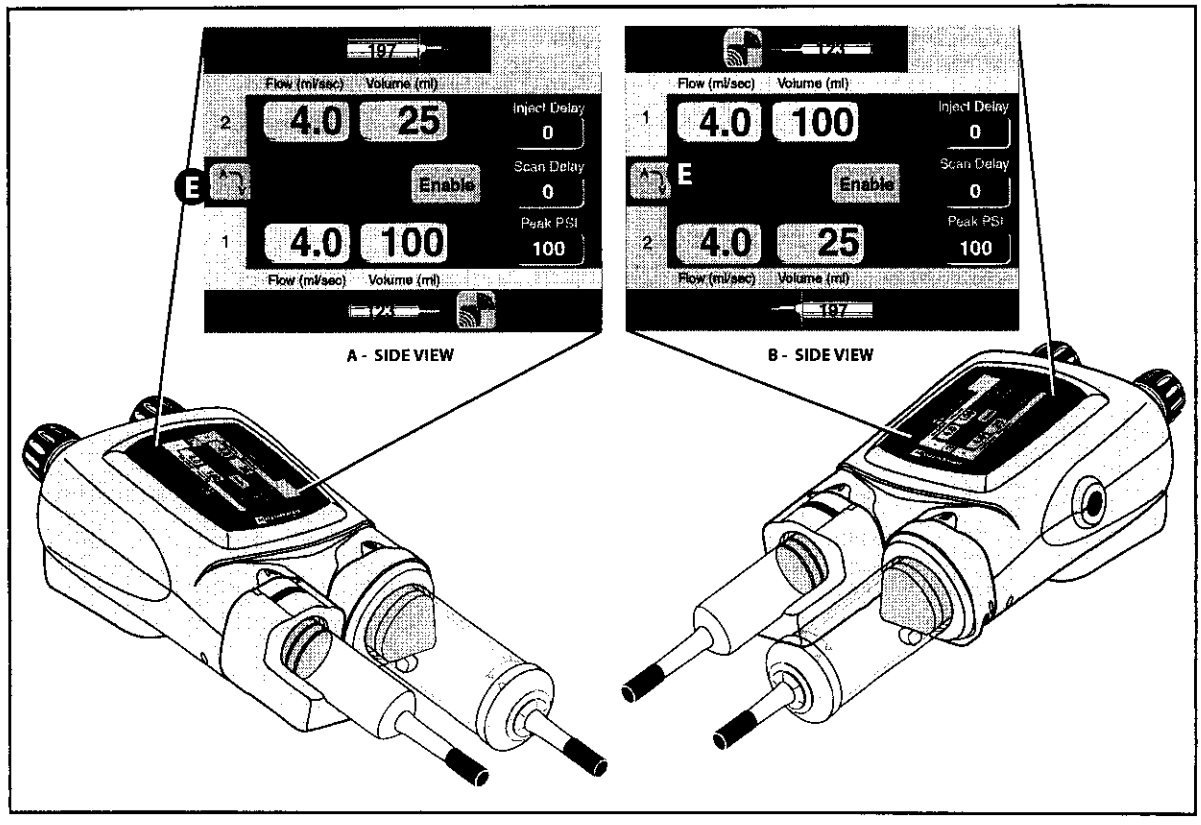

Figure 3-2-9 A-side Display or B-side Display using the [Display Orientation] Key.

3.2.7 POWERHEAD PROTOCOL PARAMETER ENTRY SCREEN

Refer to Figure 3-2-10.

All protocol information needed by the injector is contained within the expanded Protocol Parameter Entry screen. The Protocol Parameter Entry screen allows the parameters to be modified via the slide bar. To access this screen, press any parameter key located on the Main Screen as shown in Figure 3-2-5.

Phase Ⓐ — Within a protocol, up to six phases can be input. Press the [Next] key Ⓚ to view the next 3 phases.

Side Ⓑ — These keys toggle among the following symbols: [A], [B], [-]. Pressing an [A] key will toggle the key to a [B] key, thus indicating injecting from the B-side. Pressing a [B] key will toggle the key to a white [-], indicating no injecting for and past that phase. Pressing a white [-] key will toggle the key to a [A] key, thus indicating injecting from the A-side.

Flow Ⓒ — The values entered in this column indicate rate of delivery during each respective phase. Flow is expressed in milliliters/second.

Volume Ⓓ — The values entered in this column indicate the volume to be delivered during each respective phase. Volume is expressed in milliliters.

Duration Ⓔ — The value in this column indicates the duration of an injection (i.e., time to complete injection in seconds) based on the previously entered volume and flow rate values. Duration is displayed in the nearest whole second.

Phase Delay Ⓕ — Phase Delay is a count down timer that delays the start of the next phase. The next phase will start when the phase delay counter reaches 0 (zero). Phase Delay is expressed in seconds. Phase Delay can also be set to pause the injection. Access the Pause feature by scrolling past either the 0 (zero) lower limit or the 600 (six-hundred) upper limit.

Total Time Ⓖ — The Total Time field is an accumulation of all the calculated Duration and input Phase Delay fields for all phases. After the [Start] key is pressed, the total time field starts counting from 0 and continues to count after the injection is completed as long as the Results screen is displayed or up to 21 minutes. Total time is expressed in minutes:seconds.

Inject Delay Ⓗ — Inject Delay is a count down timer that begins counting when the [Start] key is pressed. When Inject Delay reaches 0 (zero), the injection is started. If Inject Delay is set with a value greater than 0 (zero), Scan Delay is automatically set to 0 (zero). Inject Delay is expressed in seconds.

Scan Delay Ⓘ — Scan Delay is a count down timer that begins counting when the [Start] key is pressed. The scan start signal will initiate once the timer reaches 0 (zero). If Scan Delay is set with a value greater than 0 (zero), Inject Delay is automatically set to 0 (zero). Scan Delay is expressed in seconds.

Peak PSI (J) — The value set in this key indicates the maximum allowable pressure that can occur during an injection. Pressure is expressed in either PSI or kPa. Refer to section *3.1.5 Setup Screen Parameters and Symbols* for more information about changing the unit of measure.

Next (K) — *This key is only active when more than 3 phases exist on the Protocol Parameter Entry screen.* Pressing this key displays the next 3 phases of the protocol. The key will then toggle to a [Previous] key to allow access to the first 3 phases of the protocol.

Change Parameter Values via the Slide Bar (L) — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will appear at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Memory (M) — All stored protocol information is located within the Memory screen. Accessing this screen allows the operator to recall protocols. To access the Memory screen, press the [Memory] key located on the lower portion of the screen. For more information, refer to the section *Powerhead Memory Screen* in this chapter.

Main (N) — Pressing this key displays the Powerhead Main Screen.

OptiBolus (optional) (O) — *This key is only active if a port-key is present at the OptiBolus port located on the rear of the power supply.* Pressing this key allows the operator to program an OptiBolus injection. The OptiBolus Mode delivers an exponentially decaying flow rate injection that optimizes the contrast usage and provides an extended period of uniform enhancement of the area of interest. Once the [Optibolus] key (O) is pressed, the screen shown in Figure 3-2-11 is displayed. Note the addition of "O" (OptiBolus) (Q) to the left of the first phase. End Flow Rate is a function of the Optibolus mode and is automatically calculated by the OptiVantage for the entered parameters and is displayed only on the console Main screen.

Timing Bolus (P) — *This key is only active if turned ON at the Setup Screen and when 4 or less phases are programmed in a protocol.* Pressing this key allows the operator to program a Timing Bolus injection. A Timing Bolus injection--an injection of a small volume of contrast, followed by a small volume of saline--can be delivered to the patient to determine the optimal scan delay needed to capture the contrast agent in the are of interest. Once the [Timing Bolus] key (P) is pressed, the screen shown in Figure 3-2-12 is displayed. Note the addition of "T" (Timing Bolus) (R) to the left of the first and second phase.

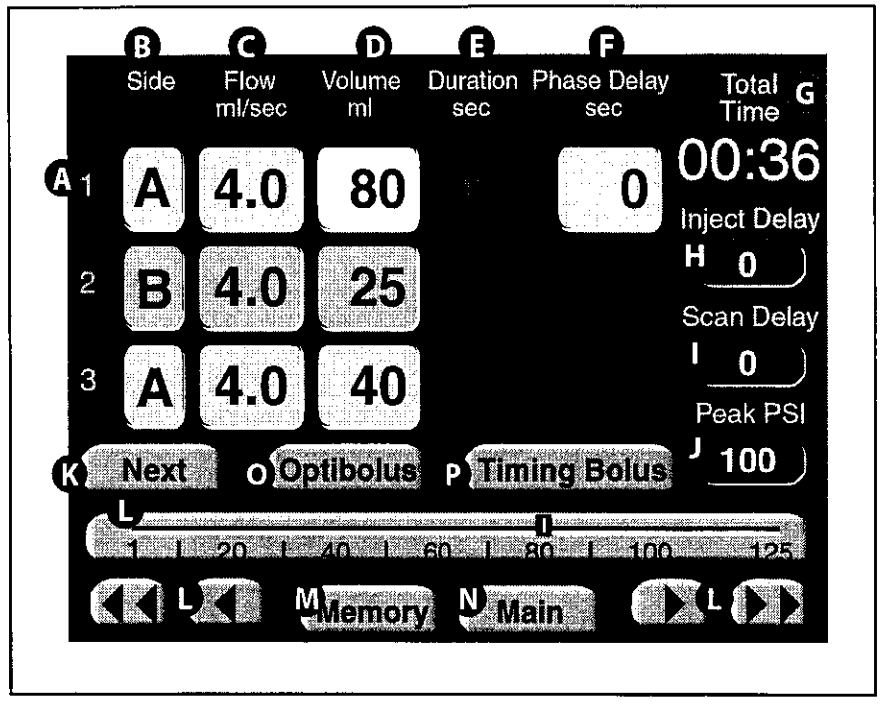

Figure 3-2-10 Powerhead Protocol Parameter Entry Screen

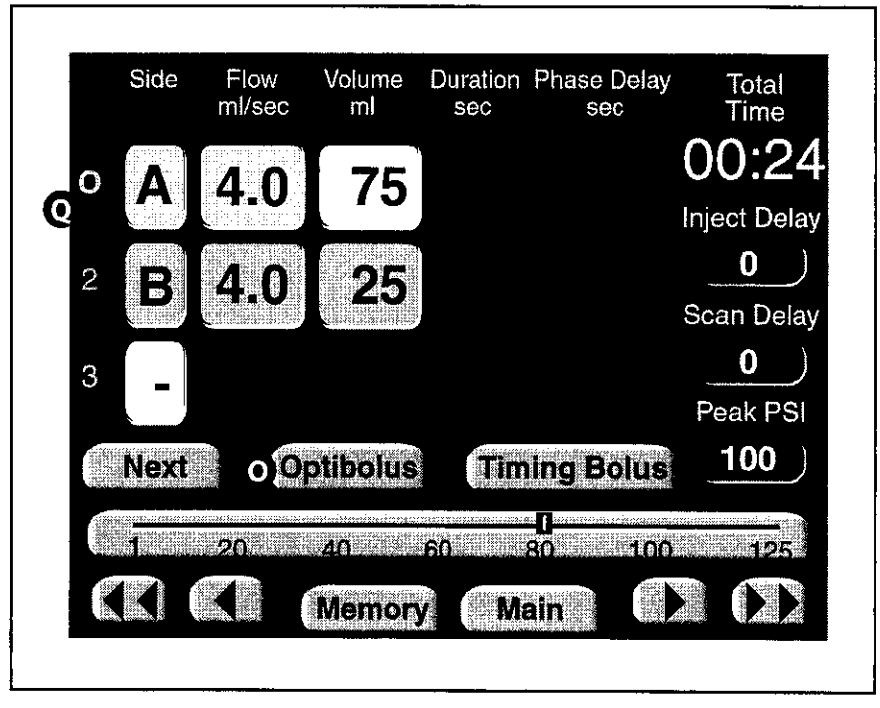

Figure 3-2-11 Powerhead OptiBolus Injection

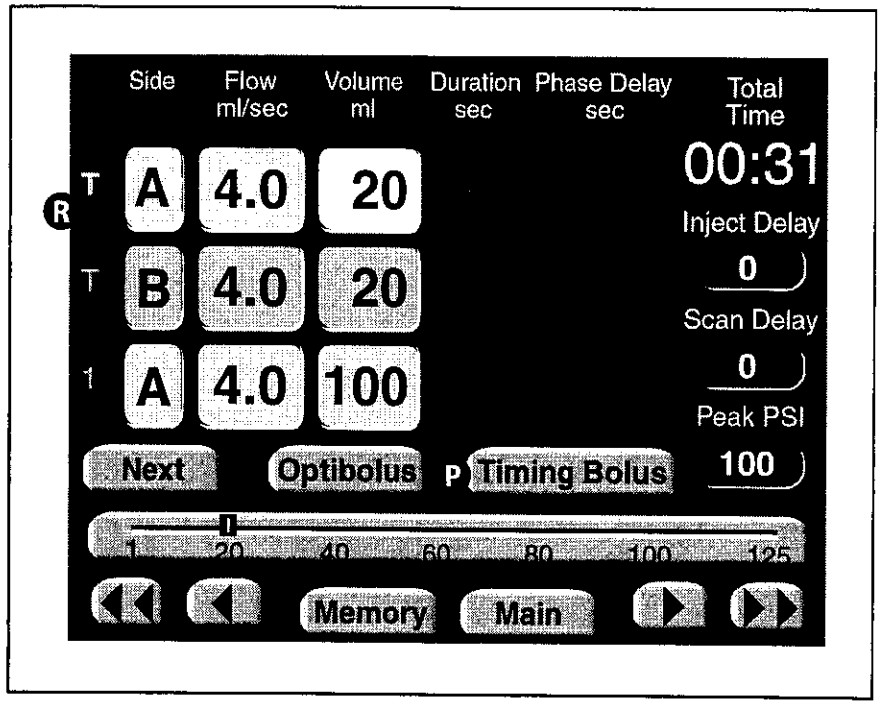

Figure 3-2-12 Powerhead Timing Bolus Injection Screen

3.2.8 ENABLED POWERHEAD MAIN SCREEN

Refer to Figure 3-2-13.

Once the [Enable] key is pressed, the Powerhead Main screen displays an Enabled screen as shown in Figure 3-2-1.

Start Ⓐ — Pressing the [Start] key begins the delivery of the protocol. This key is functionally interchangeable with both the [Stop] key and the [Start] key on the console and the optional Handswitch.

Disable Ⓑ —The [Disable] key disables the enabled injector.

Protocol Parameters Ⓒ — The protocol parameter entry keys are active and can be changed as needed without disabling the injector.

Patency Ⓓ — *This key is only active if turned ON at the Setup Screen.* The [Patency] key is available to deliver a Patency Check--an injection of a small volume of saline--to determine the integrity of the I.V. site. Refer to Figure 3-2-1.

Drip Ⓔ — *This key is only active if turned ON at the Setup Screen.* The [Drip] key is available to deliver a Drip Mode Injection--a low flow rate injection of a small volume of saline--to keep the fluid pathway open. Refer to Figure 3-2-15.

A-Side Syringe (mL) and B-Side Syringe (mL) (F) — These symbols indicate the relative position of the plunger in the syringe thus indicating how much fluid may be in the syringes. Once the injector is enabled, the fill/expel arrows will not appear when the A-side Syringe symbol or the B-side Syringe symbol is pressed.

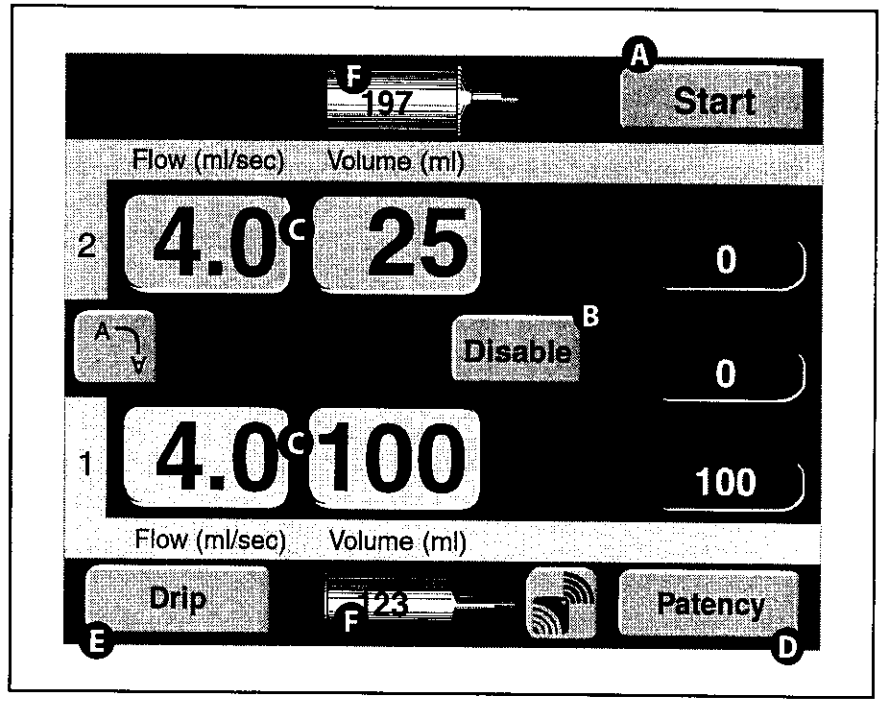

Figure 3-2-13 Powerhead Enabled Main Screen Keys and Definitions

Patency Check Screen

Refer to Figure 3-2-14.

Prior to the delivery of the main injection, a Patency Check--an injection of a small volume of saline--can be performed to determine the integrity of the I.V. site. The Patency Check feature is only accessible from the Powerhead Enabled Main Screen.

To access the Patency Check screen as shown in Figure 3-2-14, press the [Patency] key Ⓓ located on the Powerhead Enabled Main screen as shown in Figure 3-2-13.

B (side) Ⓐ — Patency check can only be delivered from the saline side. (In Figure 3-2-14, the B-side is set up as the saline side.)

Patency Check Flow Ⓑ — This value indicates rate of delivery of the saline. Patency check flow rate, expressed in milliliters/second, will automatically be set to the greatest value occurring in the enabled protocol. The value can be modified by the operator.

Patency Check Volume Ⓒ — This value indicates the volume of saline to be delivered. Patency check volume, expressed in milliliters, is initially set to the default value as defined in the Set Up screen. The value can be modified by the operator. If the value is set for an amount that compromises the enabled protocol, the [Patency Check Volume] key background will flash a magenta color and the [Start Patency] key will be removed from the screen.

Change Parameter Values via the Slide Bar Ⓓ — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Start Patency Ⓔ — This key starts the patency check injection. For more information about delivering a patency check injection, refer to Chapter 5.

Exit Ⓕ — This key disables the patency check screen and displays the Enabled Main screen.

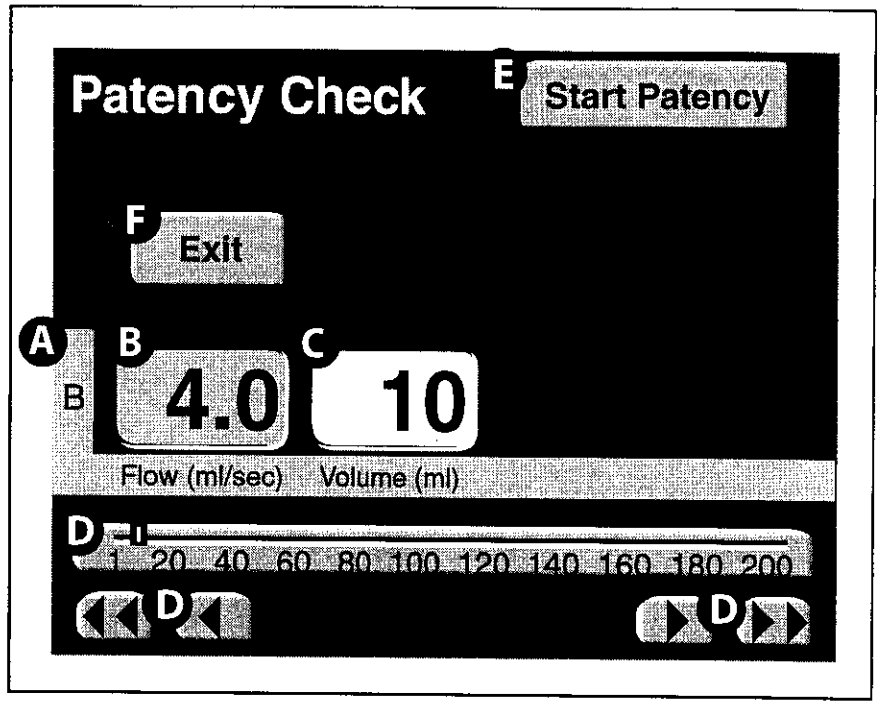

Figure 3-2-14 Powerhead Patency Check Screen

Powerhead Drip Mode Screen

Refer to Figure 3-2-15.

The Drip Mode allows the injector to deliver a "drip" injection to keep the fluid path open during patient set up and between injections of contrast. The Drip Mode is accessible from either the Console Enabled Main Screen or the Powerhead Enabled Main Screen.

To access the Drip Mode screen as shown in Figure 3-2-15, press the [Drip] key Ⓔ located on the Enabled Main screen as shown in Figure 3-2-13.

Side Ⓐ — The Drip injection can only be delivered from the saline side. (In Figure 3-2-15, the B-side is set up as the saline side.)

Drip Mode Flow Ⓑ — This value indicates rate of delivery of the saline. Drip Mode flow is expressed in milliliters/second. The value can be modified by the operator.

Drip Mode Volume Ⓒ — This value indicates the volume of saline to be delivered during each drip injection. Drip Mode volume is expressed in milliliters. The value can be modified by the operator. If the value is set for an amount that compromises the enabled protocol, the [Drip Mode Volume] key background will flash a magenta color and the [Start Drip] key will be removed from the screen.

Interval Ⓓ — This value indicates the amount of time the injector pauses between each delivery of drip injections. Drip Mode interval is expressed in seconds.

Change Parameter Values via the Slide Bar Ⓔ — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Drip Time Ⓕ — Calculated automatically by the injector by using the programmed Flow, Volume and Interval values and the Drip Volume, this value indicates the amount of time the Drip Injection will require. Once the [Start Drip] key is pressed, the value counts down until it reaches zero. Once Drip Time reaches zero, an audible signal will indicate to the operator that the Drip Injection is complete.

Drip Volume Ⓖ — Calculated automatically by the injector by subtracting the programmed Volume of the main protocol (saline side) from the syringe volume (saline side), this value indicates the amount of saline the Drip Injection can inject. Drip Volume is expressed in ml.

Start Drip Ⓗ — This key starts the drip injection. For more information about delivering a drip injection, refer to Chapter 5.

Exit Ⓘ — This key disables the drip injection and displays the Enabled Main screen.

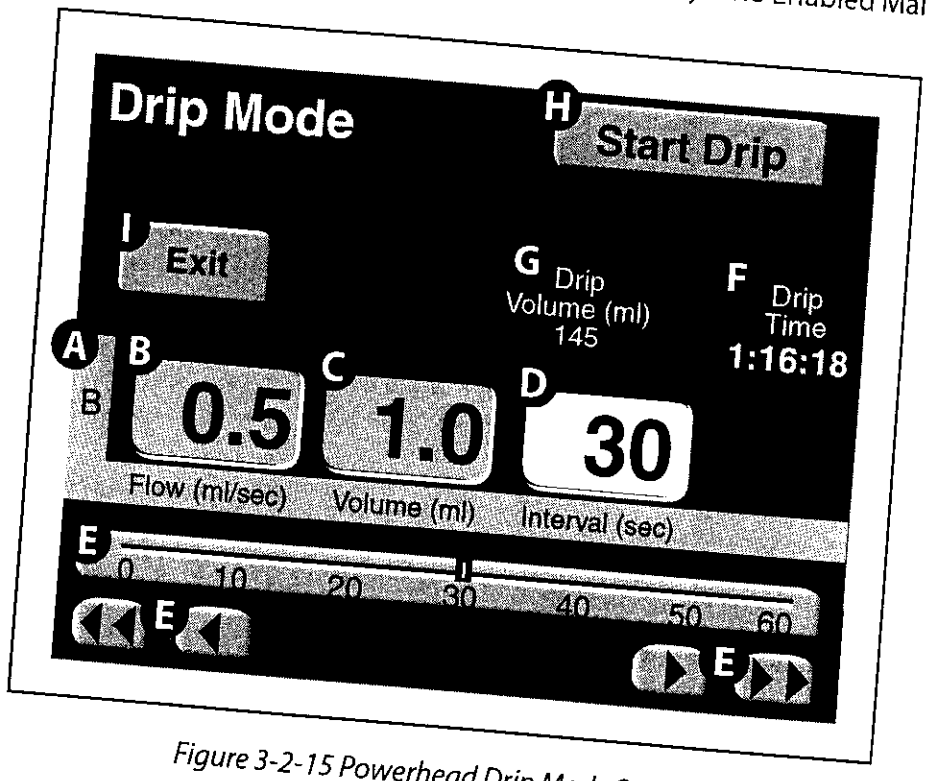

Figure 3-2-15 Powerhead Drip Mode Screen

3.2.9 POWERHEAD MEMORY SCREEN

Refer to Figure 3-2-16.

Memory Location Ⓐ — Eight protocols are listed per page. Each protocol can have a name consisting of up to 20 alpha-numeric characters. OptiBolus protocols are indicated by the "OptiBolus" logo located on the key.

Protocol Parameters Ⓑ — Each protocol can contain up to six phases. Once a protocol key is highlighted, the protocol parameters are displayed in this area.

Memory Page Number Ⓒ — The memory screen contains five pages with eight protocols listed per page.

Main Ⓓ Pressing this key displays the Powerhead Main screen.

Recalling a Protocol

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the powerhead Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) on which the Protocol is stored.
3. Press the Protocol's corresponding key to highlight Ⓔ, then press the [Select] key Ⓕ. The protocol will be immediately displayed on both the powerhead display and the console display.

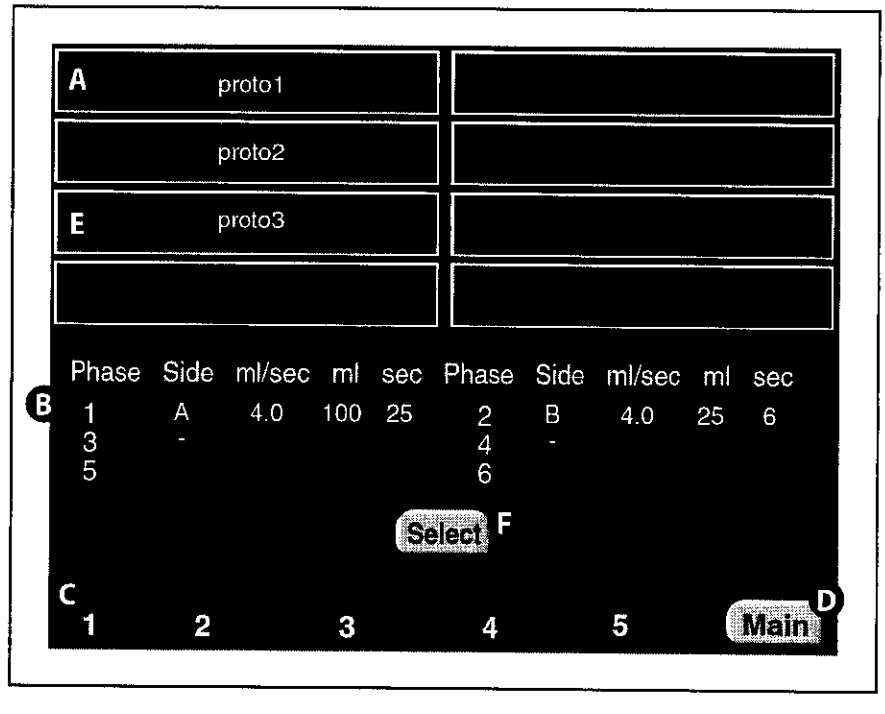

Figure 3-2-16 Powerhead Memory Screen Keys and Definitions

3.2.10 POWERHEAD RESULTS SCREEN

Refer to Figure 3-2-17.

The Results Screen as shown in Figure 3-2-17 is automatically displayed after the delivery of an injection and only shows the achieved results of that injection. The Results screen is displayed for either 21 minutes or until the [Main] key is pressed.

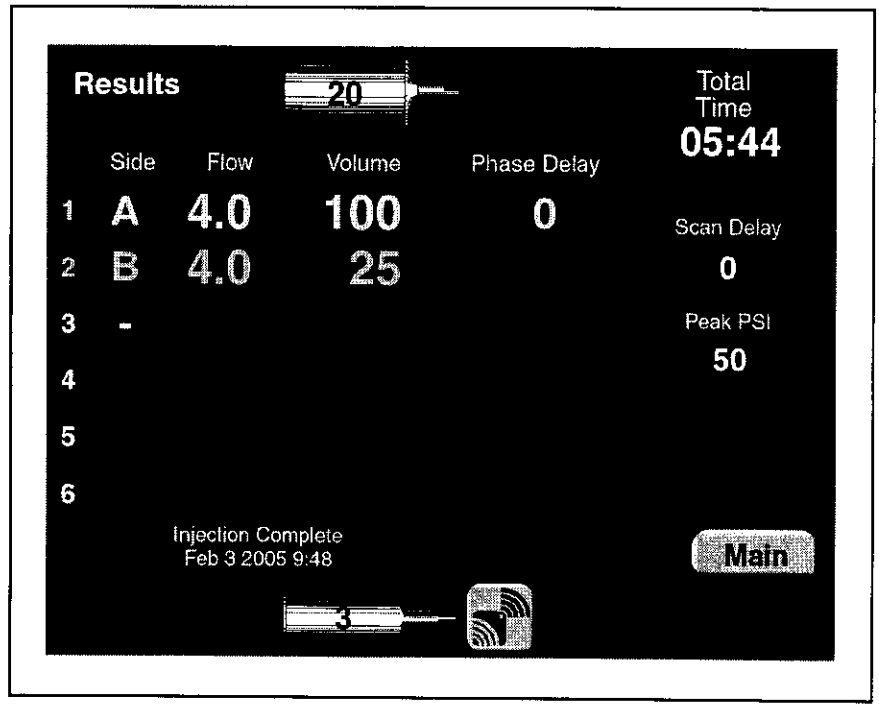

Figure 3-2-17 Results Screen displayed after delivery of an Injection

4 ENABLING SEQUENCE

This chapter discusses the proper techniques for loading syringes, filling syringes, purging air from both the syringe and tubing, and priming the tubing.

4.1 ENABLING SEQUENCE

Refer to Figure 4-1-1.

The [Enable] key is only active when:

- a new syringe(s) is loaded
- the syringe is filled (200 ml only)
- the powerhead is tilted up and air is purged from both syringes (plunger must move forward to expel a minimum of 1 (one) ml of contrast/saline)
- the powerhead is rotated at least 30° below horizontal
- there is sufficient volume in the syringes to perform the programmed injection.

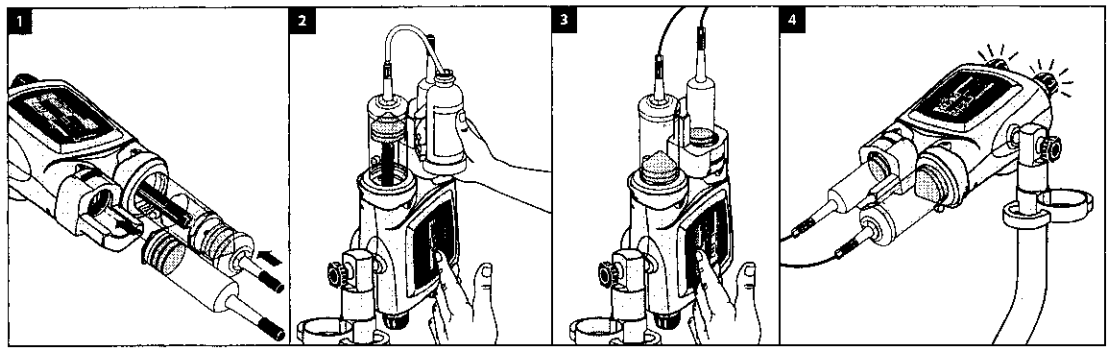

Figure 4-1-1 Enabling Sequence

4.1.1 DANGERS, WARNINGS, AND CAUTIONS

⚠ DANGER! ⚠

Danger! Air Embolism Hazard!
The danger of air embolism is always present when injecting into the circulatory system. Air entrapped in the delivery system can cause patient injury or death. The enabling sequence for the OptiVantage Injection System is designed to help prevent air injections. In order to enable the OptiVantage, the syringe load sequence and air purge sequence described in this chapter must be performed in order to ensure a safe injection. ***The enable sequence in itself does not guarantee that all air has been completely removed from the system. The operator is responsible for ensuring that all air has been completely evacuated from the syringe and tubing prior to delivery of the injection.***

⚠ DANGER! ⚠

Danger! Contamination Hazard!
Do not reuse syringe or other I.V. access components.

⚠ DANGER! ⚠

Danger! Air Embolism Hazard!
When filling an empty syringe, make sure a tight connection exists between the fill tube and syringe to ensure that air is not being drawn into the syringe. Entrapped air can cause patient injury or death if not properly removed prior to delivery of injection.

⚠ WARNING! ⚠

Warning! Infection Hazard!
Contamination of sterile-packed empty syringes is possible if proper precautions are not taken. Due to the risk of serious patient infection, do not touch the Linden-Luer adapter or the section of a fill tube that will be inserted into the contrast. Do not touch the interior of the syringe or expose the interior of the syringe to conditions which can cause contamination (coughing, sneezing, etc.). Immediately place syringe into injector sleeve to prevent contaminating the interior of the syringe.

⚠ WARNING! ⚠

This device has been approved for use with only the consumables listed in section 1.7 Consumables. Use of other consumables could result in patient injury, operator injury and/or equipment damage.

⚠ WARNING! ⚠

Review Parameters!
Prior to enabling an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure.

⚠ WARNING! ⚠

Install syringes containing the amount of contrast required by the procedure to be performed on the patient. Installing syringes containing more contrast than needed could result in the injection of excess contrast.

⚠ WARNING! ⚠

Fill syringes only with the minimum amount of contrast required by the procedure to be performed on the patient. Filling syringes with more contrast than needed could result in the injection of excess contrast.

⚠ WARNING! ⚠

Rotate Powerhead Down
Prior to injecting, rotate the powerhead down to allow any small remaining air bubbles to float away from the tip, reducing the possibility of injecting air into the patient.

4.1.2 NOTES

Preheating the contrast media will help in the removal of air bubbles.

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4.2 TYPES OF INJECTIONS

The OptiVantage has the ability to deliver an injection with or without a saline flush. Both the A-side and the B-side can accommodate either a 125 ml prefilled syringe, 125 ml partial prefilled syringe, or an operator filled 200 ml syringe.

4.2.1 LOAD 125 ML SYRINGE (CONTRAST SIDE ONLY)

Refer to Figure 4-2-1.

1. If the ram is not home, move to the fully retracted position Ⓐ. Slide the 125 ml cradle Ⓑ onto the desired front plate mount of the powerhead (A-side is shown in Figure 4-2-1). Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Inspect syringe and its contents for irregularities prior to loading. Open the 125 ml syringe clamp Ⓒ. Install the 125 ml syringe into the cradle Ⓓ.
3. Securely close syringe latch. Ⓔ.
4. Proceed to Section 4.1.4 *Attach Tubing to Syringe(s).*

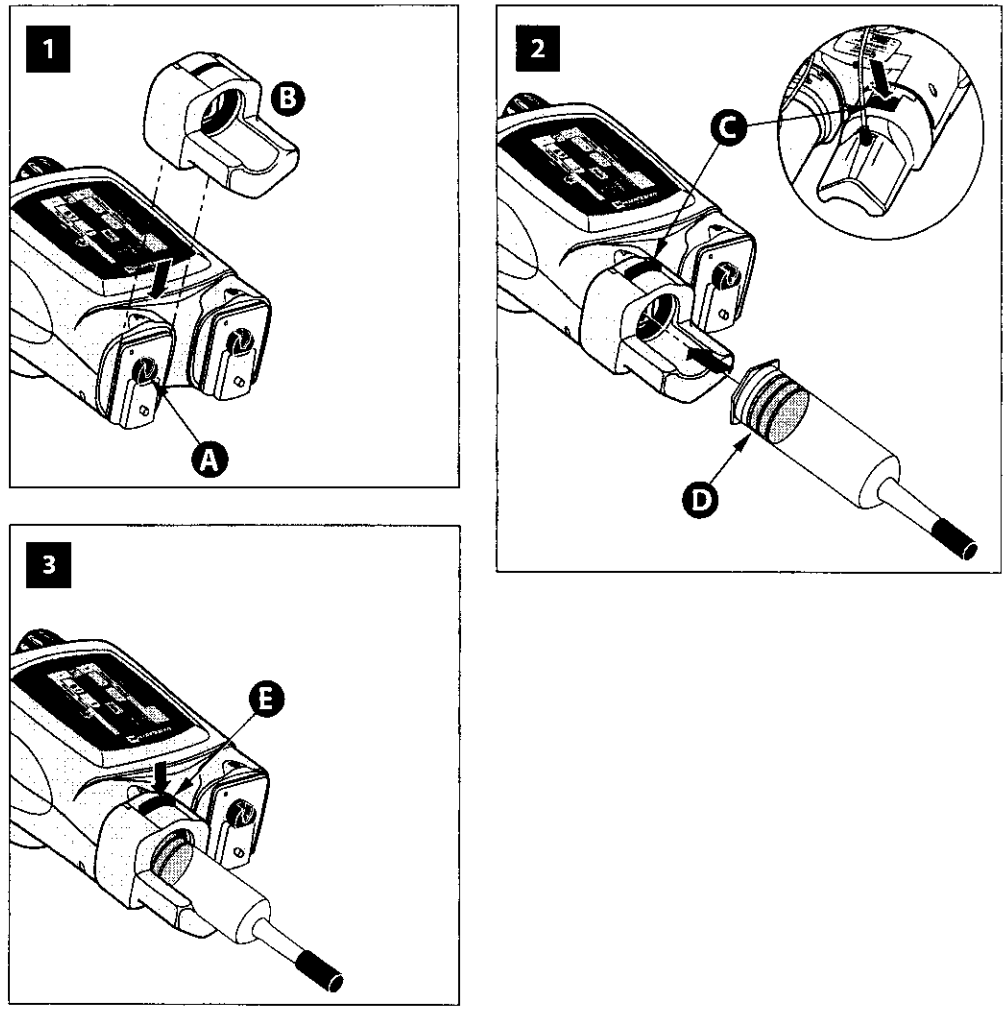


Figure 4-2-1 Load 125 ml Syringe (A-Side Only)

4.2.2 LOAD 200 ML SYRINGE (CONTRAST SIDE ONLY)

Refer to Figure 4-2-2.

1. Move the desired ram to the fully retracted position Ⓐ (A-side is shown in Figure 4-2-2). Rotate the pressure sleeve lever to the unlock position 🔓. Slide the 200 ml pressure sleeve onto the front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Extend the ram fully Ⓒ.
3. Using aseptic technique, remove the 200 ml syringe from its sterile packaging by grasping the umbrella cap Ⓓ. Inspect the syringe for irregularities prior to loading. Make sure the pressure sleeve lever is rotated to the unlock position 🔓. Insert the 200 ml syringe into the pressure sleeve by matching the load arrow on the syringe to the load arrow on the pressure sleeve Ⓔ.
4. Lock the syringe into place by either turning the pressure sleeve lever to the lock position 🔒 or by rotating the umbrella cap clockwise until the load arrow aligns as shown Ⓕ. If the lever cannot be moved to the lock position, make sure the load arrow is aligned as shown Ⓔ, then gently push down on the umbrella cap. The lever should now lock easily. Leave the ram/plunger in the "fully expelled" or extended position in preparation to fill with contrast.
5. Proceed to section 4.3 Fill Syringe (200 mL Only).

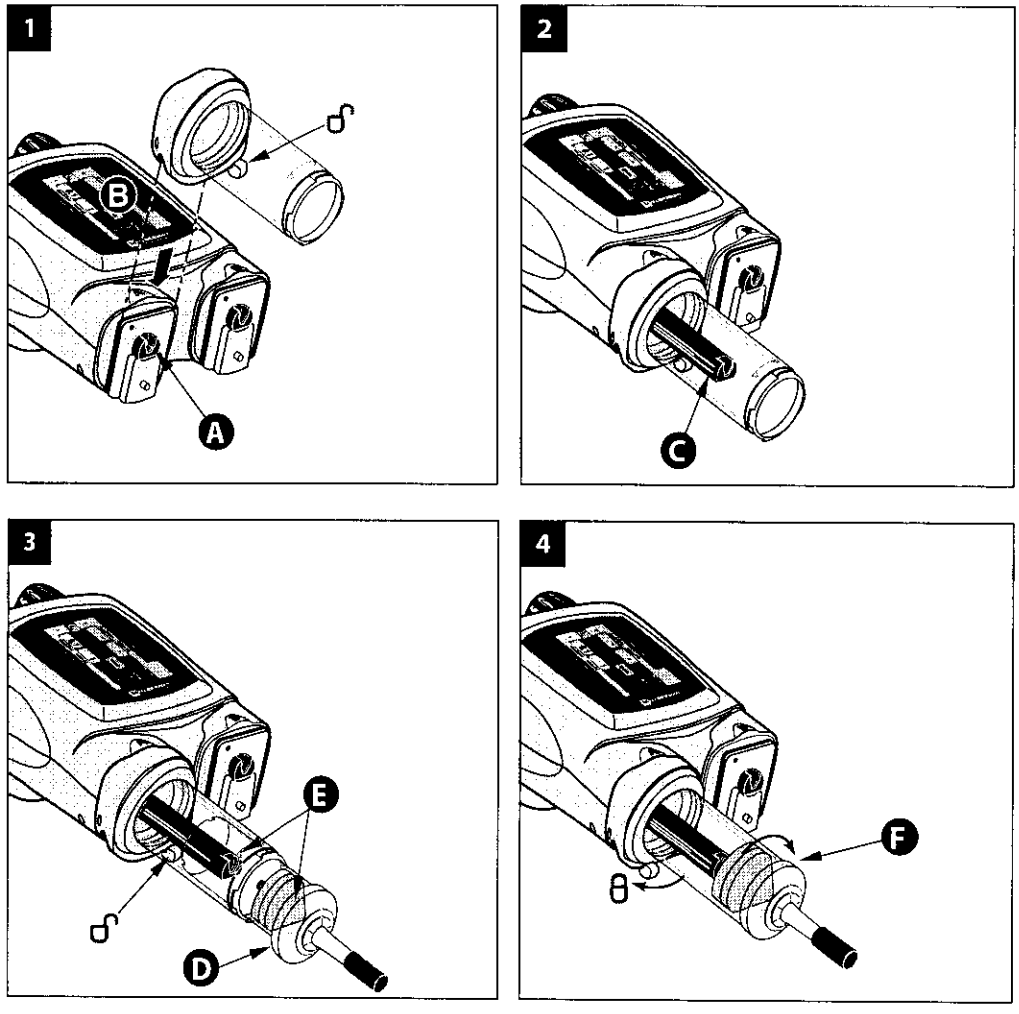
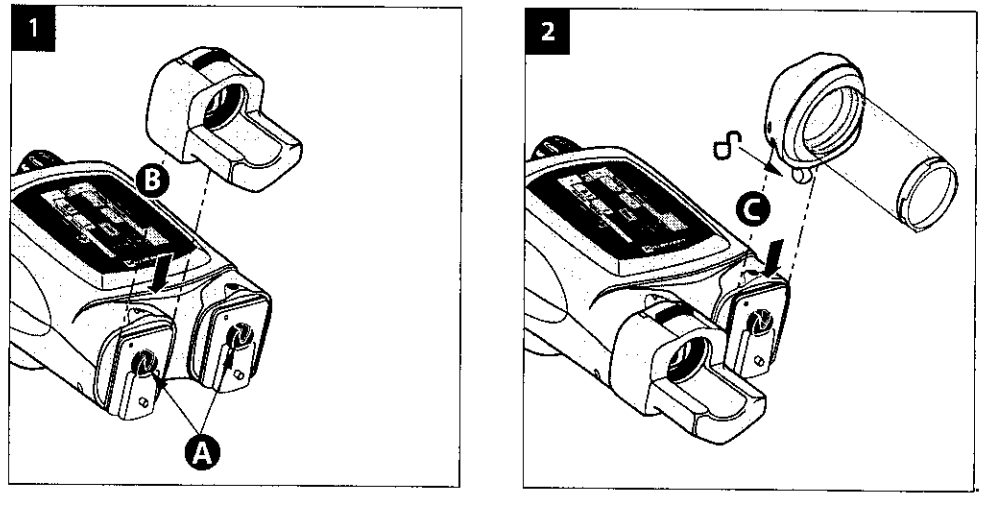


Figure 4-2-2 Load 200 mL Syringe (A-side Only)

4.2.3 LOAD 125 ML/200 ML SYRINGE

Refer to Figure 4-2-3.

1. Move the A-side and B-side ram to the fully retracted position. Ⓐ. Slide the 125 ml cradle onto the A-side front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Rotate the pressure sleeve lever to the unlock position. Slide the 200 ml pressure sleeve onto the front plate mount of the powerhead Ⓒ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
3. Inspect 125 ml syringe and its contents for irregularities prior to loading. Open the tabs Ⓓ and install the 125 ml syringe into the cradle
4. Close the latch to secure the 125 ml syringe Ⓔ.
5. Extend the B-side ram fully Ⓕ.
6. Using aseptic technique, remove the 200 ml syringe from its sterile packaging by grasping the umbrella cap Ⓖ. Inspect the syringe for irregularities prior to loading. Insert the 200 ml syringe into the 200 ml pressure sleeve by matching the load arrow Ⓗ on the syringe to the load arrow on the pressure sleeve.
7. Lock the syringe into place by either turning the pressure sleeve lever to the "lock" position or by rotating the umbrella cap clockwise until the load arrow aligns as shown Ⓘ. If the lever cannot be moved to the lock position, make sure the load arrow is aligned as shown Ⓗ, then gently push down on the umbrella cap. The lever should now lock easily. Leave the ram/plunger in the "fully expelled" or extended position in preparation to fill with contrast.
8. Proceed to section 4.3 Fill Syringe (200 ml Only.



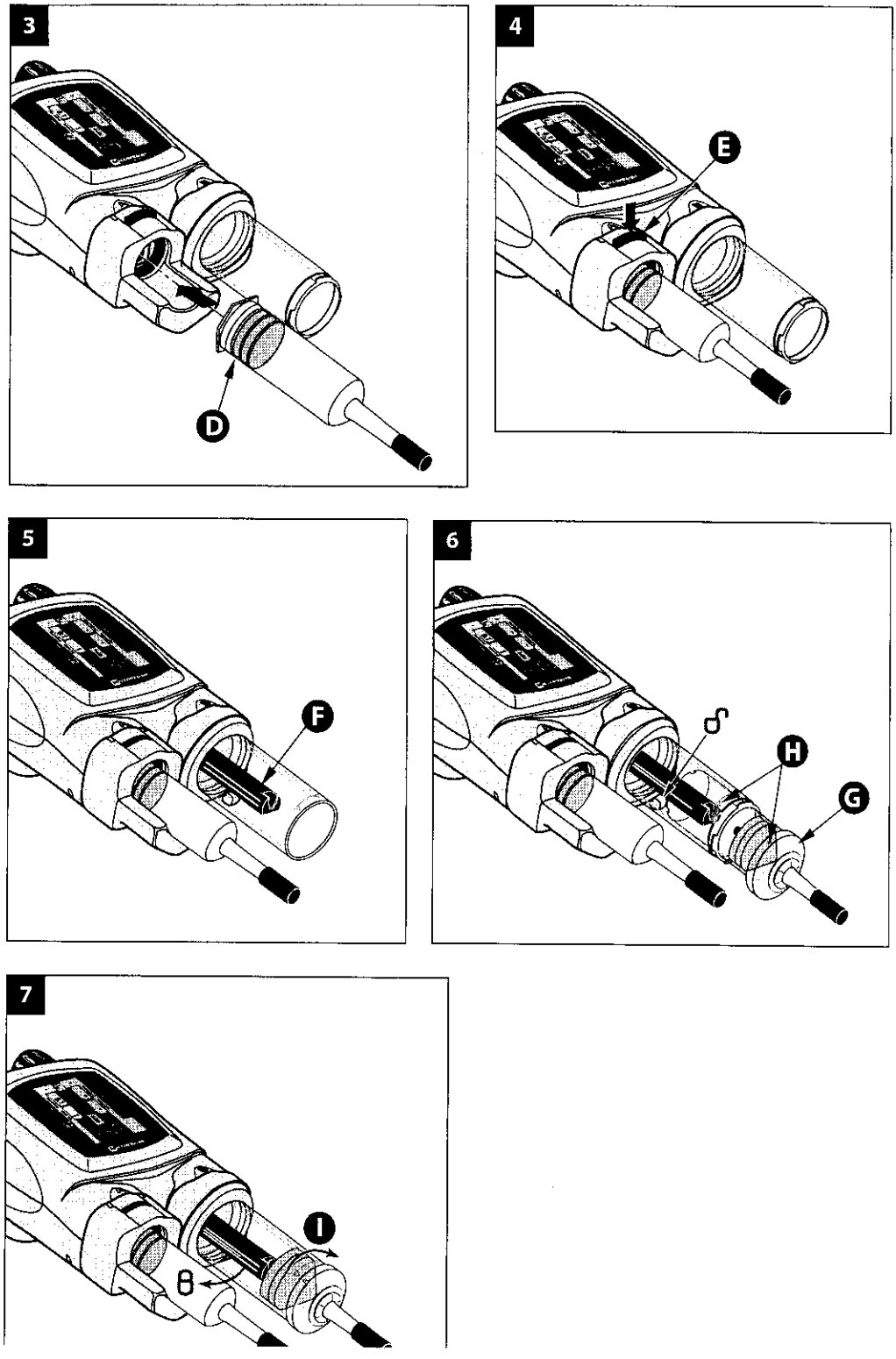


Figure 4-2-3 Load 125 ml/200 ml Syringe

4.2.4 LOAD 200 ML/200 ML SYRINGE

Refer to Figure 4-2-4.

1. Move the A-side and B-side ram to the fully retracted position Ⓐ. Rotate the pressure sleeve lever to the unlock position. Slide one of the 200 ml pressure sleeves onto the front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram. Slide the other 200 ml pressure sleeves onto the front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Extend both rams fully Ⓒ.
3. Using aseptic technique, remove the 200 ml syringes from their sterile packaging by grasping their umbrella caps Ⓓ. Inspect the syringes for irregularities prior to loading. Insert a 200 ml syringe into each pressure sleeve by matching the load arrow on the syringe to the load arrow on the pressure sleeve Ⓔ.
4. Lock the syringes into place by either turning the pressure sleeve levers to the "lock" position or by rotating the umbrella caps clockwise until the load arrows align as shown. If the lever cannot be moved to the lock position, make sure the load arrows are aligned as shown, then gently push down on the umbrella cap. The lever should now lock easily. Leave the ram/plungers in the "fully expelled" or extended position in preparation to fill with contrast.
5. Proceed to section 4.3 Fill Syringe (200 ml Only).

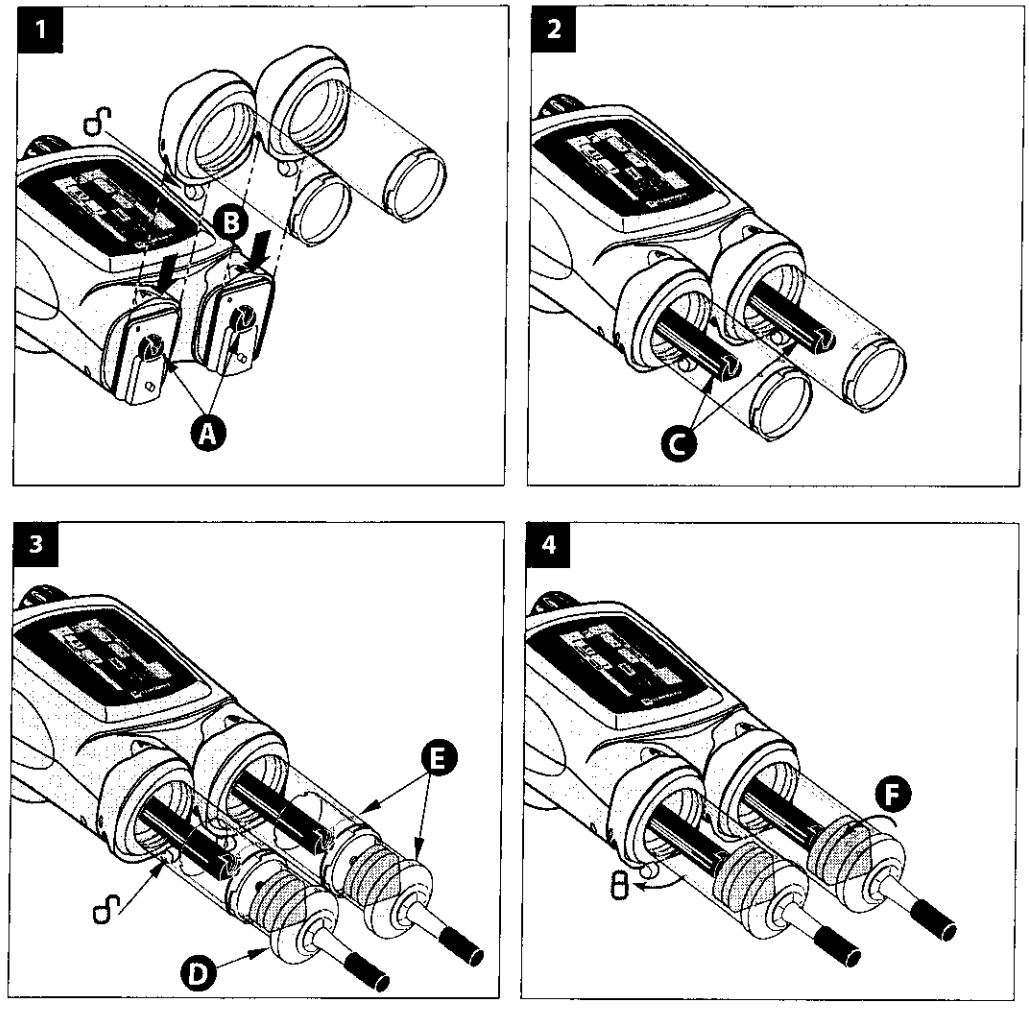


Figure 4-2-4 Load 200 ml/200 ml Syringe

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4.3 FILL SYRINGE (200 ML ONLY)

4.3.1 AUTO-FILL TECHNIQUE

Refer to Figure 4-3-1 and 4-3-2.

NOTE: This feature is only available if turned ON in the Setup screen.

The Auto-Fill feature has been designed to automatically fill the syringe while minimizing the introduction of air. To use the Auto-Fill feature:

1. Place the ram(s) in the "home" position (i.e. fully expelled), then load a 200 ml syringe into the pressure sleeve(s). If the powerhead is not in the vertical position, the following message will appear: *Rotate the Powerhead to the vertical position to activate Auto-Fill sequence.*
2. Rotate the powerhead to the vertical position. The screen shown in Figure 4-3-1 is displayed. NOTE: If the powerhead is utilizing a 200 ml syringe on both the A-side and the B-side, the Auto-Fill sequence will first fill the last installed syringe, then allow for filling the remaining empty syringe.
3. Set the desired Fill Volume (ml) by pressing the [Fill Volume] key Ⓐ for either the A-side or the B-side (B-side is shown in Figure 4-3-1), then change the value via the slide bar key Ⓑ.
4. Remove the protective cap from the syringe tip and store in a safe place for reuse in step 9.
5. Using aseptic technique, slide the end of the shorter section of the fill tube over the syringe tip. DO NOT TOUCH THE TIP. Place the end of the longer section of the fill tube into the container of contrast media. To keep aeration to a minimum, verify that this end of the tube is in the media and is NOT drawing air.
6. Press and release the respective [Start Auto-Fill] key Ⓒ. The injector will automatically retract the ram 25 ml at 4 ml/s, purge 25 ml at 10 ml/s, then retract to the Fill Volume at 15 ml/s. NOTE: Pressing the [Stop] key on the screen will disable the Auto-Fill feature.
7. Carefully remove the fill tube from the syringe tip by twisting while pulling off. NOTE: In order to prevent the contrast medium from spilling onto the syringe and pressure sleeve, make sure the curved portion of the fill tube is either completely empty or contains enough contrast medium so that the level in the longer end is slightly lower than the tip of the syringe. This will cause the fluid in the tube to return to the container.

8. Observe contrast medium to ensure all air bubbles are removed. If air bubbles are still clinging to the sides of the syringe, follow the steps outlined in the section 4.5 Purge Air/Prime Tubing.
9. To prevent contamination, replace the protective cap on the syringe tip. The powerhead should remain in the vertical position (to prevent leakage) until ready for injection.

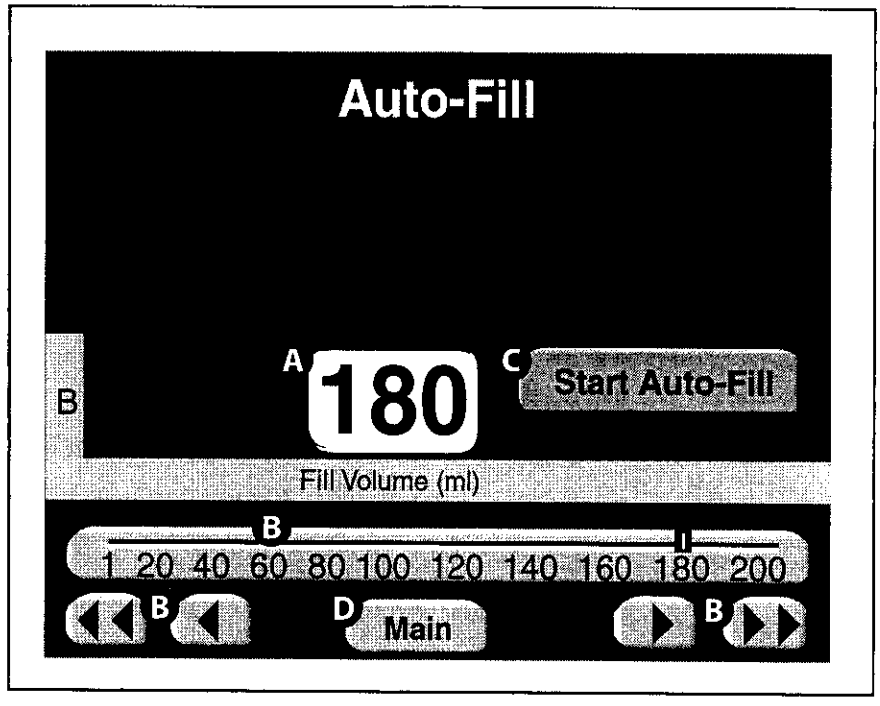

Figure 4-3-1 Auto-Fill Screen

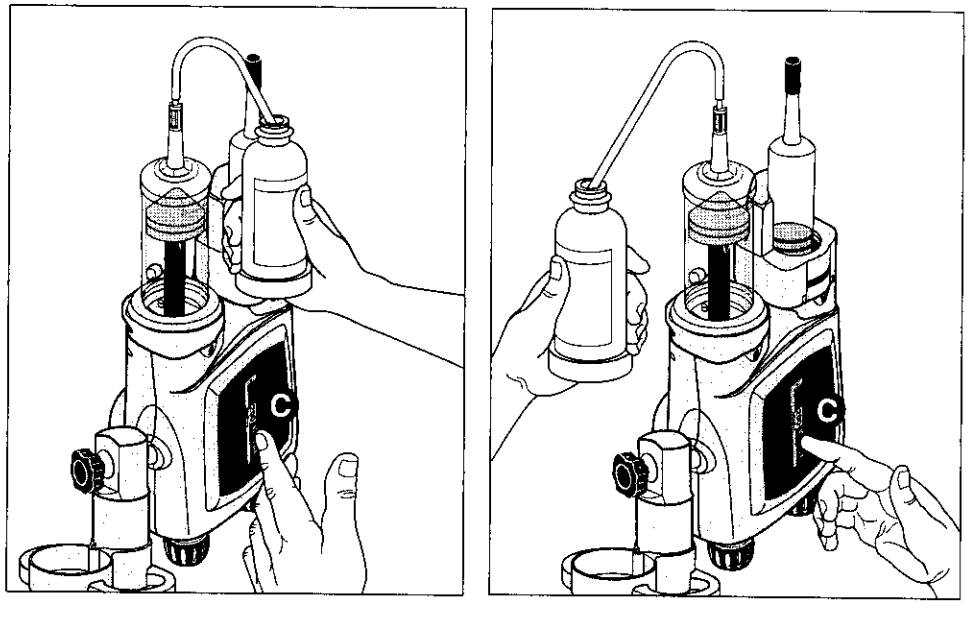

Figure 4-3-2 Fill Syringe Right-handed/Left-handed

4.3.2 MANUAL FILL TECHNIQUE

Upon loading a 200 ml syringe, the screen shown in Figure 4-3-1 is displayed (if Auto-Fill feature is turned ON in the Setup screen) to allow for automatic filling of the syringe. The Auto-Fill feature has been designed to automatically fill the syringe while minimizing the introduction of air. However, to manually fill the syringe:

1. Disable the Auto-Fill feature by pressing the [Main] key (Ⓓ in Figure 4-3-1) to display the Main screen.
2. Rotate the powerhead to the vertical position.
3. Remove the protective cap from the syringe tip and store in a safe place for reuse in step 9.
4. Slide the end of the shorter section of the fill tube over the syringe tip. DO NOT TOUCH THE TIP. Place the end of the longer section of the fill tube into the container of contrast media. To keep aeration to a minimum, verify that this end of the tube is in the media and is NOT drawing air.
5. Press the respective syringe key to display the fill/expel arrows. Retract the plunger to draw the desired volume of contrast medium into the syringe. NOTE: A retract flow of 10 ml/s or less is optimum to minimize the introduction of air.
6. Move the plunger in the "expel" direction, to expel all air from the syringe.
7. Carefully remove the fill tube from the syringe tip by twisting while pulling off. NOTE: In order to prevent the contrast medium from spilling down around the syringe and pressure sleeve, make sure the curved portion of the fill tube is either completely empty or contains enough contrast medium so that the level in the longer end is slightly lower than the tip of the syringe. This will cause the fluid in the tube to return to the container.
8. Observe contrast medium to ensure all air bubbles are removed. If air bubbles are still clinging to the sides of the syringe, follow the steps outlined in the section 4.5 Purge Air/Prime Tubing.
9. To prevent contamination, replace the protective cap on the syringe tip. The powerhead should remain in the vertical position (to prevent leakage) until ready for injection.

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4.4 ATTACH TUBING TO SYRINGE(S)

To attach the catheter or tubing to the 125 ml prefill syringe or the 200 ml disposable syringe, using aseptic technique, insert the hub Ⓐ into the slot of the luer nut Ⓑ and rotate the nut clockwise to tighten the hub onto the syringe tip. Refer to Figure 4-4-1.

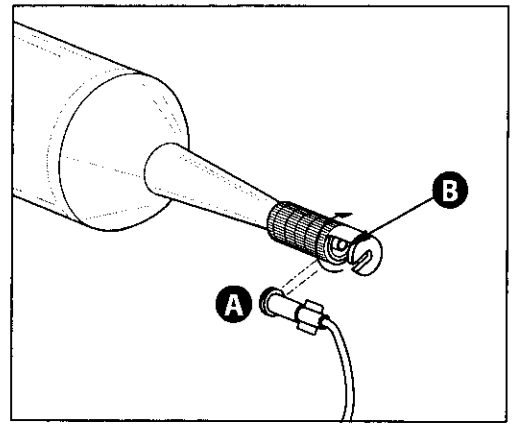

Figure 4-4-1 Attach Tubing to Syringe

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4.5 PURGE AIR FROM SYRINGE

⚠ DANGER! ⚠

DANGER! AIR EMBOLISM HAZARD!
Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

4.5.1 PURGE AIR 125 ML PREFILL SYRINGE

NOTE: The instructions that accompany the prefill syringe should be followed.

1. The air pocket trapped in the syringe MUST be removed to prevent injection of an air embolism into the patient. Rotate the powerhead vertically to point the tip of the syringe upward to allow the air pocket to rise to the tip.
2. Advance the plunger to remove air from the syringe and tubing. The plunger must move forward to expel a minimum of 1 ml of contrast to indicate that an attempt was made to purge the air.
3. Verify that both the syringe and tubing have been properly cleared of all air.

4.5.2 PURGE AIR 200 ML DISPOSABLE SYRINGE

1. Air bubbles trapped in contrast media and saline MUST be removed to prevent injection of an air embolism into the patient. Rotate the powerhead vertically to point the tip of the syringe upward to allow the air bubbles to rise to the tip to form an air pocket.
2. Dislodge any air bubbles attached to the side of the syringe by gently tapping with the heel of the hand.
3. Using the expel arrows or the manual knob, advance the plunger to push the air pocket out the syringe tip and through the tubing. The plunger must move forward to expel a minimum of 1 ml of contrast to indicate that an attempt was made to purge the air.

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4.6 PRIME TUBING

⚠ DANGER! ⚠

DANGER! AIR EMBOLISM HAZARD!
Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

4.6.1 PRIME TUBING WITH SALINE

Priming the tubing with saline is necessary for the delivery of *Drip Mode injections, Patency Check injections and Timing Bolus injections*. Advance the saline plunger to push saline past the Y-intersection of the Y-tubing and out through the remaining tubing.

4.6.2 PRIME TUBING WITH CONTRAST

Prime the tubing with contrast if Drip Mode injections, Patency Check injections and Timing Bolus injections are not to be performed. Advance the contrast plunger to push contrast past the Y-intersection of the Y-tubing and out through the remaining tubing.

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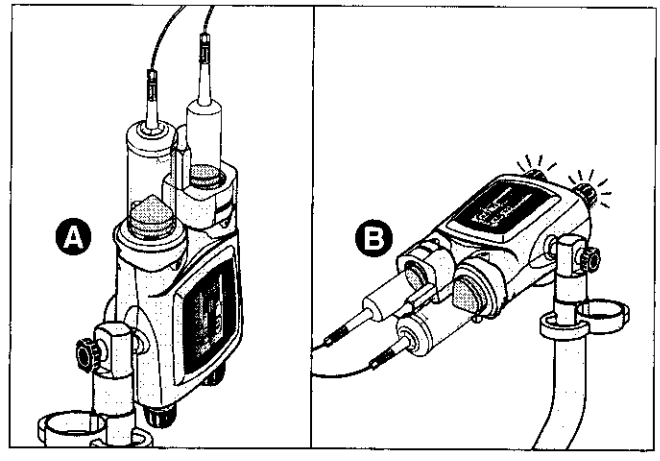
4.7 POWERHEAD IN VERTICAL POSITION

With all air removed and the tubing primed, the powerhead should remain in the vertical position Ⓐ (to prevent leakage) until ready to inject. The [Enable] key will activate once the powerhead is rotated 30° below horizontal Ⓑ.



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5 DELIVERING AN INJECTION

This chapter instructs the operator on the steps taken to safely deliver an injection.

5.1 DANGERS/WARNINGS/CAUTION

⚠ DANGER! ⚠

DANGER! AIR EMBOLISM HAZARD!
Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

⚠ DANGER! ⚠

REMOVE SYRINGE AFTER COMPLETION OF INJECTION!
Disposable syringes are designed for single use only. Used syringes should be promptly removed from the injector after a procedure is completed to avoid accidental reuse of an empty syringe. Failure to remove the syringe after completion of a procedure may lead to an inadvertent injection of air. Injecting air can cause patient injury or death.

⚠ DANGER! ⚠

Follow all manufacturers guidelines and do not operate any part of the OptiVantage Injection System within 6 inches (15 cm) of a pacemaker and/or defibrillator.

⚠ WARNING! ⚠

This device has been approved for use with only the consumables listed in Chapter 1. Use of other consumables could result in patient injury, operator injury and/or equipment damage.

⚠ WARNING! ⚠

Rotate Powerhead Down

Prior to injecting, rotate the powerhead down to allow any small remaining air bubbles to float away from the tip, reducing the possibility of injecting air into the patient.

5.2 RECALL/ENTER PROTOCOL PARAMETERS

Recall required protocol from memory or enter required parameters. For more information about recalling a protocol from memory or entering parameters, refer to Chapter 3.

⚠ CAUTION! ⚠

RE**VIEW PARAMETERS**
Prior to delivering an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that contrast fluid is installed on the correct side of the powerhead.

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5.3 CONNECT TO PATIENT

⚠ WARNING! ⚠

Extravasation can be minimized through the following precautions:

- When choosing an I.V. site, use the largest vein possible.
- Use lowest flow rate practical to achieve enhancement.
- Use largest gauge teflon type catheter possible.
- Insure good backflow from catheter.
- Continue to monitor from remote location.
- Instruct patient to notify operator of any abnormal pain, pressure or swelling.

Follow proper venipuncture technique to connect the patient to the OptiVantage system.

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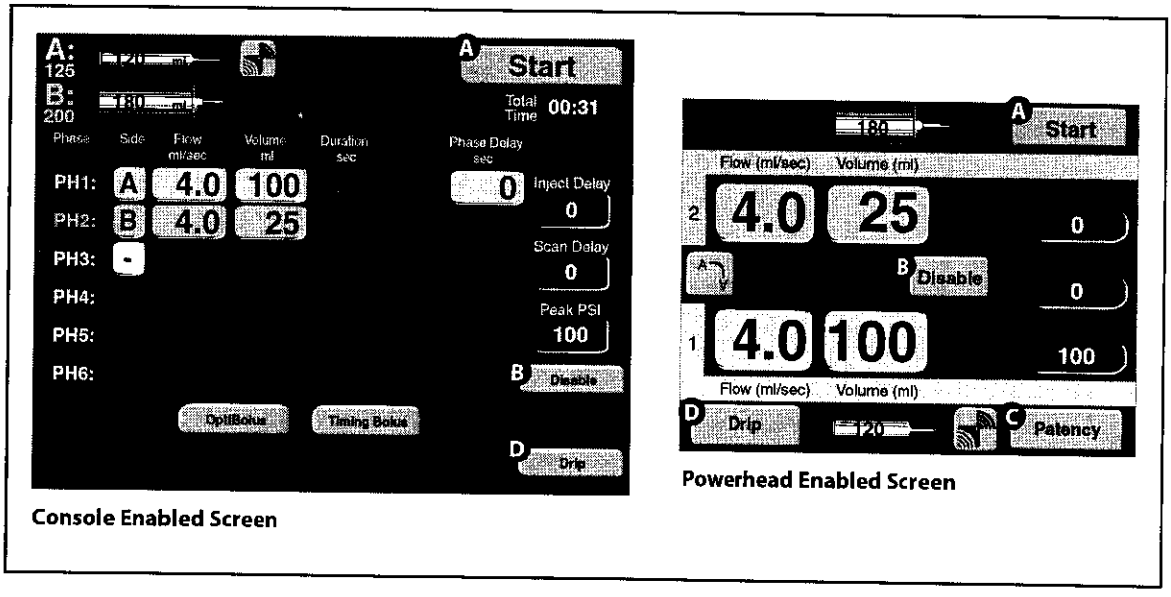
5.4 ENABLE INJECTOR

Refer to Figure 5-4-1.

1. ***The operator is responsible for ensuring that all air has been completely evacuated from the syringe and tubing prior to delivering the injection.*** Prior to enabling an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that the contrast fluid is installed on the correct side of the powerhead.
2. Follow the Enabling Sequence stated in Chapter 4 to properly load and fill syringes, purge air and prime the tubing.
3. Rotate the Powerhead at least 30° below horizontal. This safety precaution reduces the possibility of an air emboli. Any small remaining air bubbles will tend to float away from the tip and will not be injected into the patient.
4. Press the [Enable] key located on either the powerhead or console screen. A [Start] key Ⓐ will appear in the upper right-hand corner of both the console screen and the powerhead screen. The [Enable] key will change to a [Disable] key Ⓑ. The indicator lights on the powerhead will illuminate to signify the unit is now enabled for delivery of an injection.



Console Enabled Screen

Powerhead Enabled Screen

Figure 5-4-1 Enabled Screen

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5.5 CHECK PATENCY OF I.V. SITE

⚠ WARNING! ⚠

Extravasation can be minimized through the following precautions:

- When choosing an I.V. site, use the largest vein possible.
- Use lowest flow rate practical to achieve enhancement.
- Use largest gauge teflon type catheter possible.
- Insure good backflow from catheter.
- Continue to monitor from remote location.
- Instruct patient to notify operator of any abnormal pain, pressure or swelling.

NOTE: The injector does not have the capability to prevent or detect an extravasation. Patency Check is only available when turned On in the Setup screen.

Two different techniques exist to check the patency of the I.V. site. Once a protocol is enabled, the [Patency] key is available on the powerhead display to inject a small volume of saline at the same flow rate as the enabled protocol. Also, the manual knob is available to manually check patency. Instructions for both techniques follow:

5.5.1 CHECK PATENCY USING THE [PATENCY] KEY

Refer to Figure 5-5-1 and 5-5-2.

1. Press the [Patency] key Ⓒ (on Figure 5-4-1) located on the powerhead's enabled screen. The screen as shown in Figure 5-5-1 appears.
2. Adjust Patency Check flow Ⓔ and Patency Check volume Ⓕ as desired using the slide bar Ⓖ. Patency Check Volume can only be set to an amount that will not compromise the enabled protocol.
3. Press the [Start Patency] key Ⓗ to start the injection and the screen as shown in Figure 5-5-3 will display. Monitor the site and instruct patient to notify operator of any abnormal pain, pressure or swelling.
4. Total Time Ⓙ increments and syringe volume Ⓚ decrements while injecting. The [Stop] key Ⓛ is available to immediately stop the Patency Check injection at any time.
5. Once the Patency Check injection is delivered, the Enabled screen is displayed and the injector is ready to deliver the protocol or deliver another Patency Check.

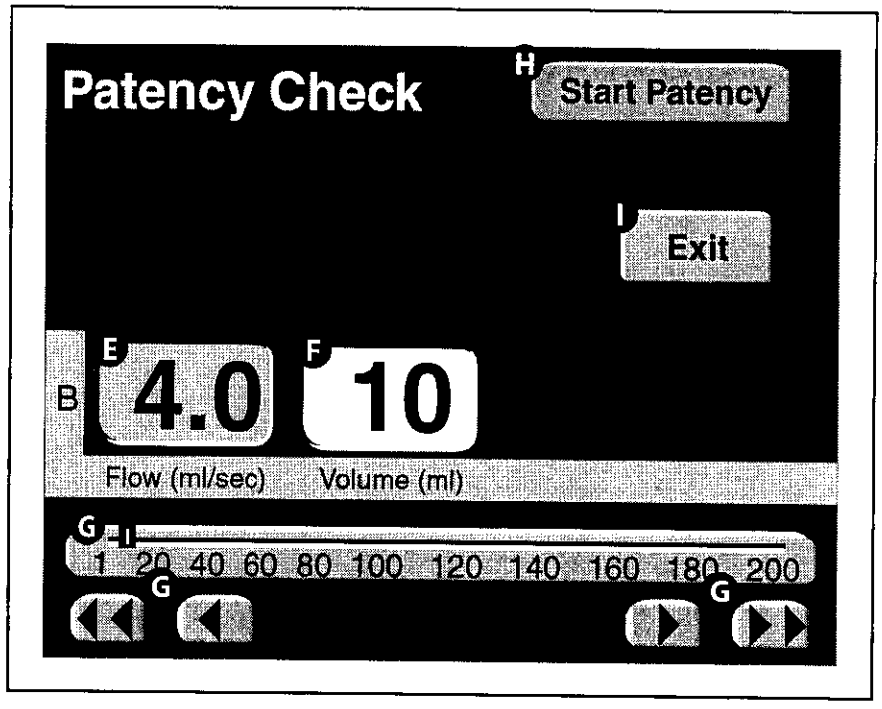

Figure 5-5-1 Patency Check Screen (Powerhead Only)

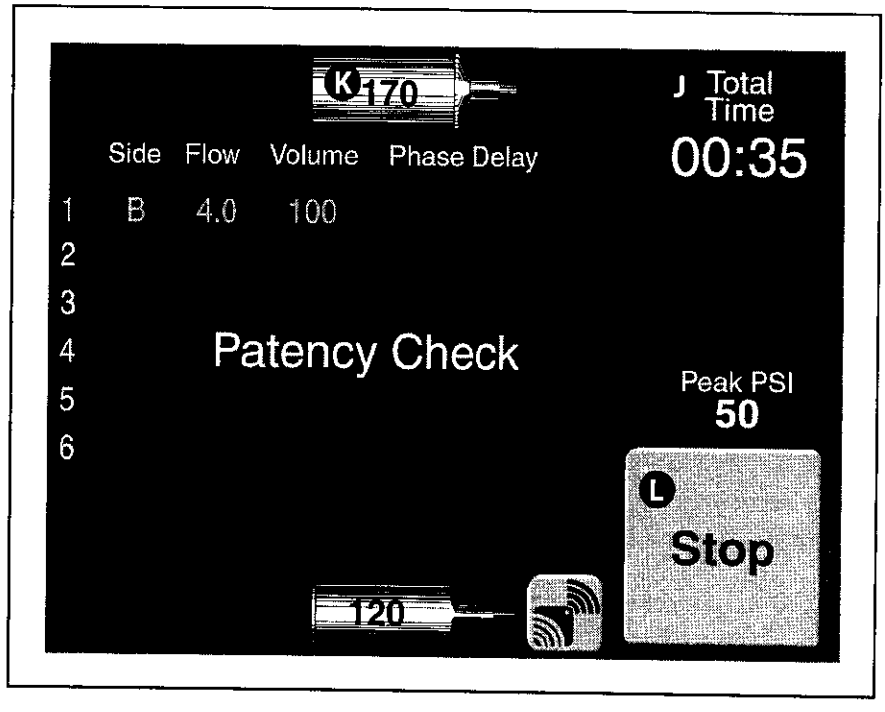

Figure 5-5-2 Patency Check Injecting Screen (Powerhead Only)

5.5.2 CHECK PATENCY USING THE MANUAL KNOB

⚠ DANGER! ⚠

DANGER! BLOOD CLOT HAZARD! Do not allow blood to remain in I.V. access line.

⚠ CAUTION! ⚠

Care should be taken when retracting the plunger using the manual knob so that the integrity of the vein is maintained.

NOTE: This technique can NOT be performed if the syringe is connected to tubing with a check valve. Using the manual knob of the saline side, retract the plunger in order to check the patency of the I.V. site. Do not allow blood to remain in the I.V. access line.

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5.6 DELIVERING A DRIP MODE INJECTION

Refer to Figure 5-6-1 and 5-6-2.

⚠ CAUTION! ⚠

REVIEW PARAMETERS

The enabled protocol can be delivered via the Drip Mode injecting screen by pressing the [Start Protocol] key ⓧ. If this feature will be utilized, prior to pressing the [Drip] key on the enabled main screen, review all protocol parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that contrast fluid is installed on the correct side of the powerhead.

1. Press the [Drip] key Ⓓ on Figure 5-4-1) located on the powerhead's enabled screen. The screen as shown in Figure 5-6-1 appears.
2. Adjust Drip flow Ⓜ, Drip volume Ⓝ and Drip interval Ⓞ as desired using the slide bar Ⓟ. Drip volume can only be set to an amount that will not compromise the enabled protocol. Drip (injectable) Volume Ⓠ displays the amount of saline available for the Drip Mode injection. Drip Time Ⓡ displays the amount of time the Drip Mode injection will require.
3. Press the [Start Drip] key Ⓢ to start the injection and the screen as shown in Figure 5-6-2 will display. The [Exit] key Ⓣ is available to exit the Drip Mode and return to the Enabled protocol screen.
4. While injecting, Drip Time Ⓤ and syringe volume Ⓥ decrement. The [Stop] key Ⓦ is available to stop the injection at any time. Pressing the [Start Protocol] key ⓧ immediately starts delivery of the main protocol.
5. Once the Drip injection is delivered, the following message is displayed:

   WARNING!
   The Drip Mode Injection is complete.
   Start the Enabled Protocol.
   Press Close to return to the Start screen.

   Press the [Close] key and the Enabled protocol screen (Start screen) is displayed. The injector is now ready to deliver the main protocol. Adjustments to the protocol parameters can be made prior to starting delivery of the main protocol.

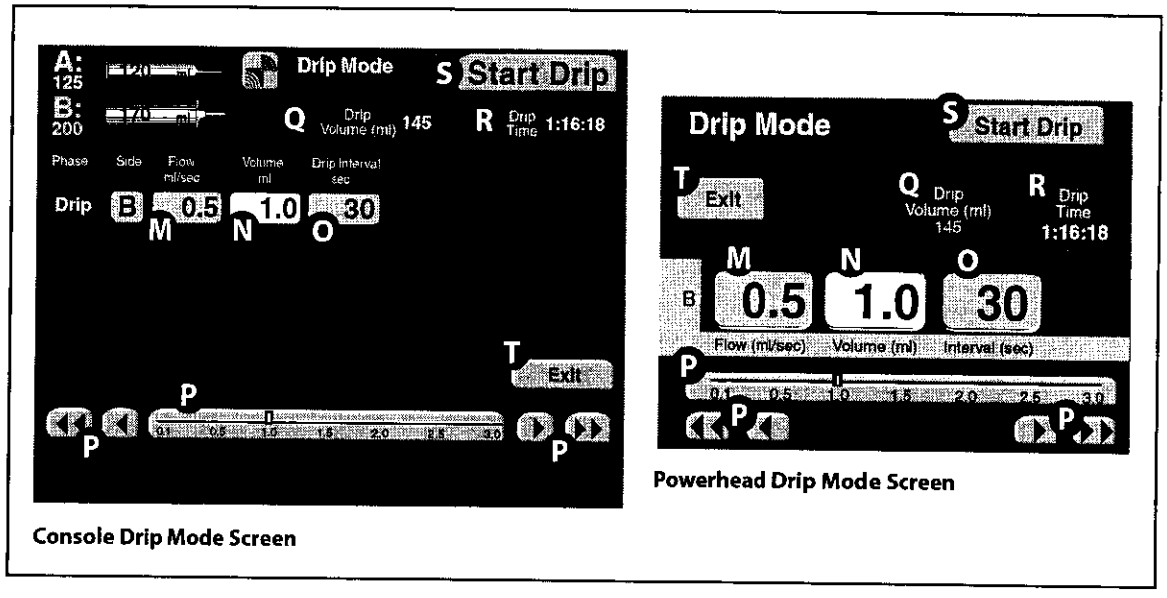


Figure 5-6-1 Drip Mode Screen

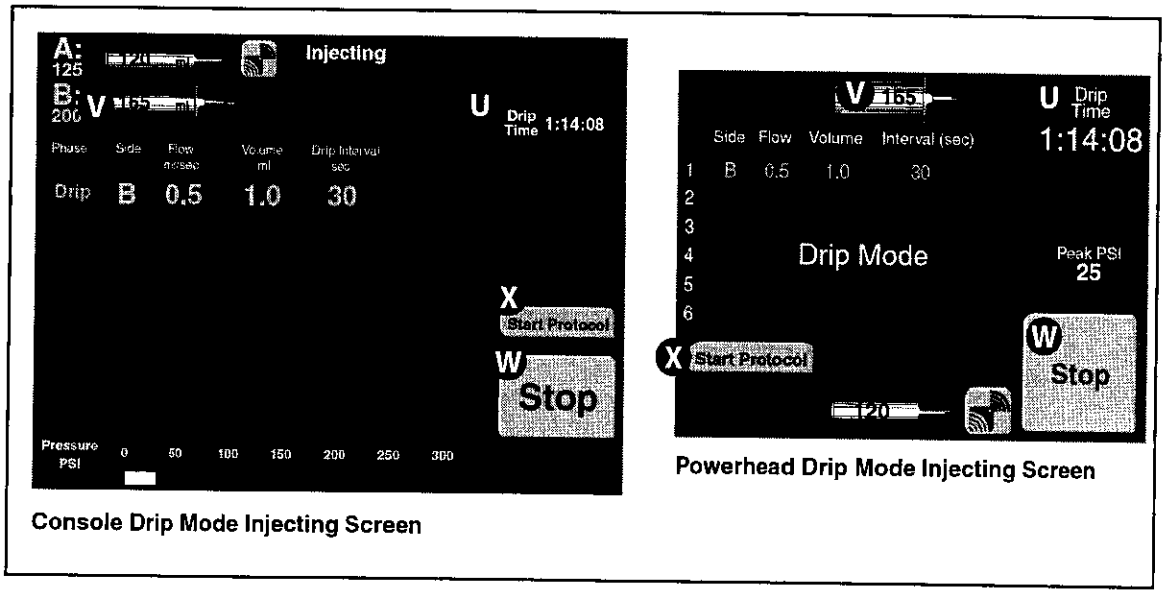


Figure 5-6-2 Drip Mode Injecting Screen

5.7 DELIVERING THE MAIN PROTOCOL

5.7.1 DANGERS, WARNINGS AND CAUTION

⚠ DANGER! ⚠

OPERATOR DUE DILIGENCE REQUIRED!

Delivering an injection to a patient requires due diligence on the part of the operator. Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

⚠ CAUTION! ⚠

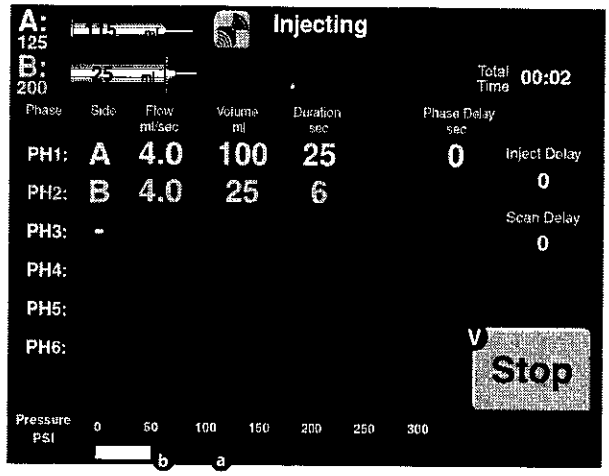
REVIEW PARAMETERS

Prior to delivering an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that the contrast fluid is installed on the correct side of the powerhead.

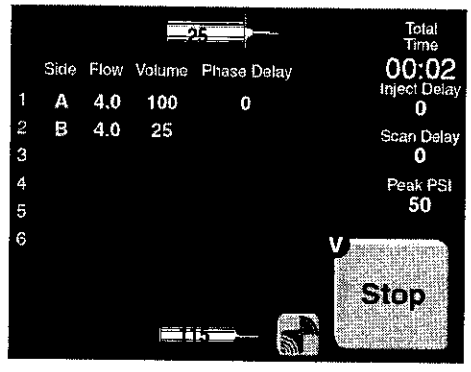
5.7.2 STARTING DELIVERY OF THE MAIN PROTOCOL

Refer to Figure 5-7-1.

The protocol can be delivered by pressing the [Start] key Ⓐ (on Figure 5-4-1) either on the powerhead or the console or by pressing the remote handswitch. Once the injection is initiated, the Injecting screen, shown in Figure 5-7-1, is displayed, Total Time increments and syringe volume decrements. Note that the Peak PSI (pressure limit) parameter is indicated by the red line Ⓐ. The current injecting pressure is indicated by the white bar Ⓑ.



Console Injecting Screen



Powerhead Injecting Screen

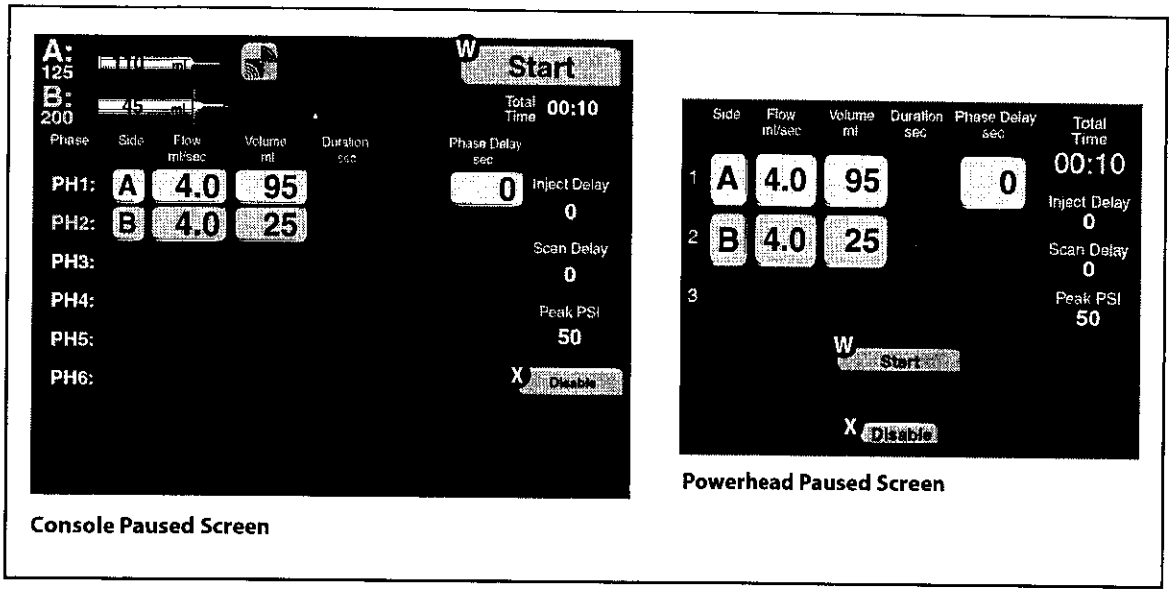
Figure 5-7-1 Injecting Screen

5.7.3 PAUSING AN INJECTION

Refer to Figure 5-7-1 and Figure 5-7-2.

An injection may be immediately paused by pressing the [Stop] key Ⓥ (on Figure 5-7-1) on the console display or the powerhead display and also by depressing once on the handswitch. When the injector is paused, the screen shown in Figure 5-7-2 is displayed and the status lights on the console and powerhead will flash their respective color every 1/2 second.

While the injection is paused, the values for the flow rate, volume and phase delay can be changed on either the console screen or the powerhead screen. However, phases cannot be added or deleted when the injector is paused.



Console Paused Screen

Powerhead Paused Screen

Figure 5-7-2 Injection Paused Screens

5.7.4 RESTARTING A PAUSED INJECTION

Refer to Figure 5-7-2.

The injection can be restarted by pressing the [Start] key Ⓦ on the console or the powerhead paused screens. The achieved values displayed on the Results screen after completion of the restarted injection represent the total volume delivered from the start of the injection and the average flow rate achieved since the restart.

5.7.5 TERMINATING AN INJECTION

Refer to Figure 5-7-1 and Figure 5-7-2.

Press the [Stop] key Ⓥ (on Figure 5-7-1) then the [Disable] key Ⓧ (on Figure 5-7-2) on the powerhead screen or console screen to terminate an injection.

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5.8 DISPLAYING RESULTS SCREEN

Refer to Figure 5-8-1.

Average flow rate, delivered volume and achieved pressure are displayed on both the console and the powerhead Results screen at the completion of the injection. Press the [Main] key Ⓐ to display the Main screen.

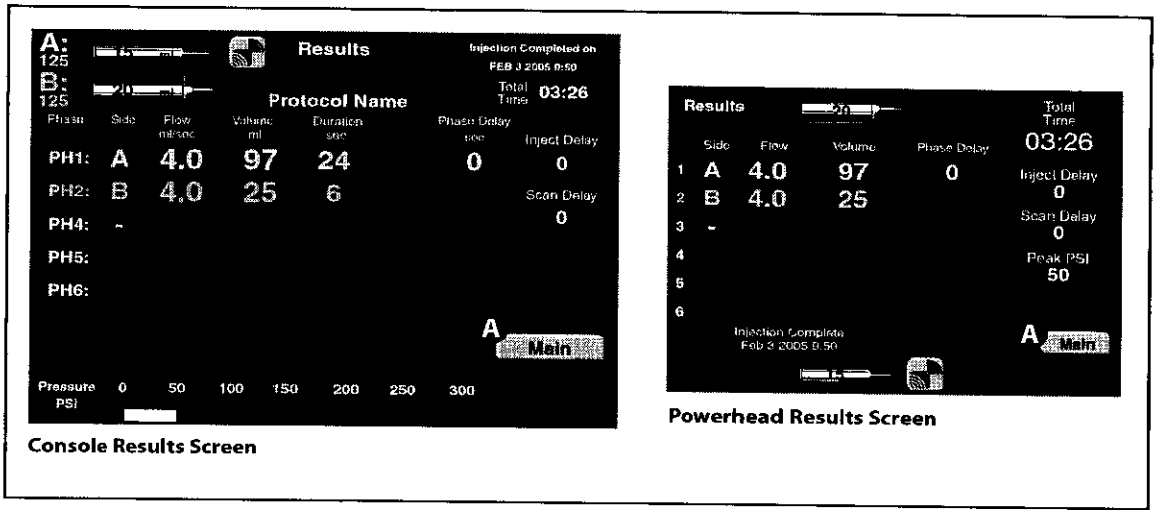

Figure 5-8-1 Results Screens

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5.9 REMOVING 125 ML SYRINGES

After the completion of the injection, disconnect the tubing from Prefilled syringe(s) prior to retracting the ram(s). NOTE: Retraction of rams while 125 ml syringes are connected to tubing that contains check valves will create a vacuum in the syringe.

1. Using aseptic technique, disconnect patient from tubing.
2. Open the syringe levers on both the 125 ml and/or 200 ml faceplate adapters.
3. Remove syringes from faceplate adapters.
4. Discard used syringes and tubing according to hospital policy.

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6 SYSTEM GENERATED MESSAGES

This chapter contains instructions on responding to system generated messages. Messages are displayed on the powerhead and console screens in response to incorrect operator input or action and equipment status. These messages fall into two categories:

Operator Messages — Those messages that appear in response to incorrect operator input or to inform the operator of the status of the injector.

Alarm Messages — Those messages that appear when the OptiVantage's self-diagnostics detect a problem in the control circuitry.

6.1 OPERATOR MESSAGES

6.1.1 POWER UP MESSAGES

Hardware Initialization completed.

Message: Hardware Initialization completed. Searching for Power Control.

Occurs when: Upon power ON, the console displays this message to indicate the status of the injector.

Operator action: None.

6.1.2 INSERTING SYRINGE MESSAGES

Expired Syringe

Message: The syringe on Side A (B) has expired. Please remove the syringe and install a new one.

Occurs when: This message appears when a syringe with an expiration date that has expired is installed.

Operator action: Remove the syringe and dispose of properly. Install new, unexpired, syringe.

Fluid in Syringe does not Match Injector Setup

Message: The fluid type in the syringe in Side A (B) does not match the injector setup.

Occurs when: This message appears when a contrast syringe with a syringe data tag is installed in a side set up for saline.

Operator action: Install correct type of syringe or change injector settings under the Setup Screen. NOTE: Changing injector settings will delete all existing protocol memories.

Insert Syringe SIDE A

Message 1: The syringe latch on side A is open. Please insert a CONTRAST filled syringe in side A of the injector and close the latch.

Occurs when: Message 1 occurs when the A-side is set up for contrast use and the 200 ml load latch or the 125 ml load latches (dependent upon which syringe adapter/faceplate is installed on the A-side) are in the load position.

Message 2: The syringe latch on side A is open. Please insert a SALINE filled syringe in side A of the injector and close the latch.

Occurs when: Message 2 occurs when the A-side is set up for saline use and the 200 ml load latch or the 125 ml load latches (dependent upon which syringe adapter/faceplate is installed on the A-side) are in the load position.

Operator action: This message is to advise the operator to load the correct syringe type into Side A.

Insert Syringe SIDE B

Message 1: The syringe latch on side B is open. Please insert a SALINE filled syringe in side B of the injector and close the latch.

Occurs when: Message 1 occurs when the B-side is set up for saline use and the 200 ml load latch or the 125 ml load latches (dependent upon which syringe adapter/faceplate is installed on the B-side) are in the load position.

Message 2: The syringe latch on side B is open. Please insert a CONTRAST filled syringe in side B of the injector and close the latch.

Occurs when: Message 2 occurs when the B-side is set up for contrast use and the 200 ml load latch or the 125 ml load latches (dependent upon which syringe adapter/faceplate is installed on the B-side) are in the load position.

Operator action: This message is to advise the operator to load the correct syringe type into Side B.

Installed Used Syringe

Message: The syringe on Side A (B) has been used. Please remove the used syringe and install a new one.

Occurs when: This message appears when the syringe data tag is identified by the injector as being "used" and the operator is trying to install the syringe or enable the injector after the "used" syringe is installed. NOTE: A syringe with a syringe data tag is written with the status of "used" when 1) the injection protocol for the injector side containing the syringe starts to execute. This also includes Test Bolus and Drip protocols. 2) When 25-mL or more of fluid is manually expelled releative to the initial pre-fill volume of the syringe. 3) When the syringe is manually retacted by 10-mL or more relative to thelast forward movement position of the injector ram.

Operator action: Remove the syringe and dispose of properly.

Unable to Mark the Syringe as Used

Message: Unable to mark the syringe on Side A (B) as used. Please use and dispose of the syringe when operation is complete.

Occurs when: This message appears when the syringe data tag cannot be marked as used by the injector. NOTE: A syringe with a syringe data tag is written with the status of "used" when 1) the injection protocol for the injector side containing the syringe starts to execute. This also includes Test Bolus and Drip protocols. 2) When 25-mL or more of fluid is manually expelled releative to the initial pre-fill volume of the syringe. 3) When the syringe is manually retacted by 10-mL or more relative to thelast forward movement position of the injector ram.

Operator action: Remove the syringe and dispose of properly.

6.1.3 PROGRAMMING MESSAGES

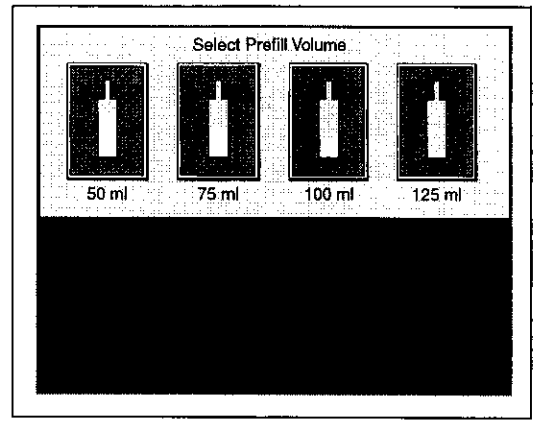
Auto-Fill in Progress

Message: Auto-Fill in progress. Please wait...

Occurs when: This message appears on the console screen when the powerhead is using the Auto-Fill feature to fill the syringe.

Operator action: None.

Automatic Prefill Syringe Size Sensor



Message: Select Prefill Volume 50 ml 75 ml 100 ml 125 ml

Occurs when: The injector's syringe size sensor has been unplugged or has failed.

Operator action: Plug in heater blanket/size sensor on underside of powerhead. Or, to use the injector without the sensor, press the corresponding graphic that matches the installed syringe size.

Changing Fluid Configuration

Message: The syringe fluid configuration has changed. This will prevent access to the stored protocols. Do you want to continue with these settings?

Occurs when: This message occurs when the operator updates the settings in the Setup screen changing the fluid configuration (i.e. A-side:contrast, B-side: saline changed to A-side:saline, B-side:contrast).

Operator action: This message is for informational purposes only in order to advise the operator that changing the fluid configurations will prevent access to stored protocols. Press the [Yes] key to continue with these settings. Press the [No] key to leave the fluid configuration unchanged.

OptiBolus Key is not Installed

Message: OptiBolus Key is not installed. Insert OptiBolus Key and press Close to continue.

Occurs when: This message appears when the operator attempts to recall an OptiBolus protocol when the OptiBolus Key has been removed from the injector.

Operator action: To recall an OptiBolus protocol, the OptiBolus key must be installed at the rear of the power control. Install the OptiBolus Key, press the [Close] key on the screen and continue.

Patency Check in Progress

Message: Patency Check in progress. Please wait...

Occurs when: This message appears on the console screen when the powerhead is delivering a Patency Check injection.

Operator action: None.

Programmed to Deliver Contrast from both Side A and Side B

Message: Attention, the current protocol is programmed to deliver contrast on Side A and Side B. Press Close to continue.

Occurs when: The injector is set up for Contrast (A-side)/Contrast (B-side) delivery.

Operator action: This message is for informational purposes only in order to advise the operator to use caution when delivering more than 125 ml of contrast into a patient. Delivering more than 125 ml of contrast into one patient is not advised.

Protocol Modification in Progress at Console

Message: Protocol modification in progress at console. Please wait...

Occurs when: This message appears on the Powerhead display to inform the operator that Protocol modification is taking place at the Console display.

Operator action: The Powerhead display will refresh upon pressing the [Main] key on the Console.

Protocol Name Already Exists

Message: Protocol name already exists. Please change or cancel.

Occurs when: The operator enters an existing protocol name on the keyboard when trying to store a new protocol.

Operator action: Enter a new protocol name or press the [Cancel] key.

Protocol Name Not Valid

Message: Protocol name not valid. Please change or cancel.

Occurs when: The operator enters a protocol name that is blank or begins with a space.

Operator action: Enter a new, valid protocol name or press the [Cancel] key.

Setup to Deliver Contrast from A-side and B-side

Message: Settings on the Setup Screen will allow contrast to be injected from both sides of the injector. Contrast injections in excess of a single full syringe are possible. Do you want to continue with these settings? Yes/No

Occurs when: This message occurs when the operator updates the settings in the Setup screen for Syringe Fluid A: Contrast (A-side)/Syringe Fluid B: Contrast (B-side) delivery.

Operator action: This message is for informational purposes only in order to advise the operator to use caution when injecting more than one syringe of contrast into a patient. Injecting more than one syringe of contrast into one patient is not advised. Press the [Yes] key to continue with Contrast (A-side)/Contrast (B-side) delivery. Press the [No] key to change the setting for either Syringe Fluid A or Syringe Fluid B.

Unreadable Data on Powerhead or Console Display

Message: NO MESSAGE ASSOCIATED WITH THIS CONDITION.

Occurs when: Any single user display contains unreadable data.

Operator action: The injector can be used, with caution, if any single user display contains unreadable data. Cycle power to reset injector. If this condition persists, contact your Service Department for corrective action. If this issue persists, contact your Service Department for corrective action.

Volume Key Flashing a Magenta Color

Message: NO MESSAGE ASSOCIATED WITH THIS CONDITION.

Occurs when 1: The volume key(s) on the main screen will flash a magenta color to indicate that its value(s) is greater than the volume contained in its respective syringe.

Operator action: Lower the value of the applicable volume key(s) or fill the syringe(s) with an adequate amount of fluid.

Occurs when 2: The volume key on the Drip Mode screen or Patency Check screen will flash a magenta color to indicate that delivering this amount will compromise the volume available for the main protocol. Note that if the Volume key is flashing a Magenta Color, the [Start Drip] key or the [Start Patency] key will not appear.

Operator action: Lower the value of the volume key or fill the syringe with more fluid.

Primary Pressure Sensing has Failed!

Message: Primary Pressure Sensing has Failed! Call Service! Continue with Caution!

Occurs when: Message appears after completion of injection when the Primary Pressure Limiting software has malfunctioned. The Secondary Pressure Limiting software is still operational.

Operator action: Contact your Service Department ***immediately*** for corrective action regarding this message! Press the close key **and continue with caution!**

6.1.4 FACEPLATE (SYRINGE ADAPTER) MESSAGES

Syringe Adapter/Faceplate Disconnected

Message: The faceplate on Side A (B) has become disconnected or has failed. The heater on Side A (B) has been turned off. Check connection or call Service.

Occurs when: The 125 mL RFID faceplate adapter is uplugged or the injector diagnostics detects an error in the faceplate adapter electronics.

Operator action: Press the [Continue} key to continue without use of RFID detction or the heater. Contact your Service Department for corrective action.

6.1.5 AUTO-FILL MESSAGES

Rotate the Powerhead to Activate Auto-Fill

Message: Rotate the Powerhead to the vertical position to activate Auto-Fill sequence.

Occurs when: This message occurs when a 200 ml syringe is installed [with the ram in the "home' (fully expelled) position] but the powerhead is not oriented in the vertical position. The Auto-Fill screen is automatically displayed when 1) the ram is in the "home" position 2) a 200 ml syringe is installed and then 3) the powerhead is rotated to the vertical position.

Operator action: This message is for informational purposes only in order to advise the operator to rotate the powerhead to the vertical position in order to access the Auto-Fill feature.

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6.1.6 HEATER BLANKET CONNECTIVITY

Heater Blanket

Powerhead Message: Heater Blanket on this side of the injector has become disconnected or has failed. Check connection or call service. To continue without heater blanket, close window.

Console Message: The heater blanket on the A-side of the injector has become disconnected or has failed. Check connection or call service. To continue without heater blanket, close window.

Console Message: The heater blanket on the B-side of the injector has become disconnected or has failed. Check connection or call service. To continue without heater blanket, close window.

Occurs when: One of the 200 ml heater blanket connectors is unplugged or malfunctioning.

Operator action: Plug the heater blanket in or to use the injector without the heater blanket, press the [Close] key on the screen and continue. Contact your Service Department for corrective action regarding this message.

6.1.7 SCANNER CONNECTIVITY

Scanner Interface Connection not Available

Message: The Scanner Interface connection is not available. To continue without the interface, close window.

Occurs when: When the OEM Interface on the Setup screen in set to On, but the OEM interface is not communicating with the injector properly, this message occurs.

Operator action: To continue without the OEM interface, press the [Close] key. Contact your Service Department for corrective action regarding this message.

6.1.8 ENABLE PROCESS MESSAGES

Enable sequence not completed

Console Message: The Enable sequence has not been completed at the Powerhead.

Powerhead Messages:

for 125 ml syringe/faceplate
The Enable sequence is not complete.
Install a new syringe.
Tilt Powerhead up.
Purge syringe.
Tilt powerhead down.

for 200 ml syringe/faceplate
The Enable sequence is not complete.
Install a new syringe.
Tilt Powerhead up.
Fill syringe.
Purge syringe.
Tilt powerhead down.

Occurs when: As an additional precaution against the injection of an air embolism, the injector's software checks for a "Purge sequence" (125 ml syringe) and a "Fill/Purge sequence" (200 ml syringe) before allowing the injector to be enabled. If the Purge Sequence or Fill/Purge Sequence has not occurred and the [Enable] key is pressed, the console message will appear and the appropriate powerhead message [missed step(s)] will appear. If correct steps have been taken on either the A-side or the B-side, the message "This side ready." will appear.

Operator action: Follow the step indicated on the powerhead to allow the injector to be enabled. ***Note that it is the operator's responsibility to ensure the syringe and tubing does not contain air.***

Hand switch is closed.

Message: The hand switch is closed. Please check hand switch and press Close to continue.

Occurs when: As a safety precaution to prevent unintentional injections, the injector cannot be enabled if its hand switch is closed. If the hand switch is closed and the injector's enable key is pressed, this message appears.

Operator action: Check the appropriate switch to ensure that it is open. Once checked, press the [Close] key and continue the enable process. If you are unable to open the switch (as indicated by the return of this message), unplug the hand switch and continue. Contact your Service Department for corrective action regarding the hand switch.

Insufficient volume

Message: Insufficient volume to run this injection.

Occurs when: The [Enable] key is pressed when a volume key is flashing a magenta color. The volume key(s) on the main screen flash a magenta color to indicate that its value(s) is greater than the volume contained in its respective syringe.

Operator action: Lower the value of the applicable volume key(s) or fill the syringe with more fluid. ***Note that it is the operator's responsibility to ensure the syringe and tubing does not contain air.***

6.1.9 INJECTION STOPPED MESSAGES

Drip Expired

Message: WARNING! The Drip Mode injection is complete. Start the Enabled Protocol. Press Close to return to the Start screen.

Occurs when: This message appears when the Drip Mode injection is complete.

Operator action: Press the [Close] key to return to the Start screen to allow for delivery of the main protocol.

Injector Stalled

Message: Injector Disabled! Injector stalled. Check fluid path for obstructions. Press Close to continue.

Occurs when: This message appears if the injector has started an injection but cannot move the ram.

Operator action: Press the [Close] key and check the fluid path for any obstructions and remove them. Restart the Enable process.

Pressure Limiting

Message: Injection is pressure limiting! Do you want to continue or stop?

Occurs when: This message appears when the injector is injecting under maximum pressure limit conditions and cannot achieve the set flow rate.

Operator action: Press the [Continue] key to perform the injection under maximum pressure limit conditions. Press the [Stop] key to review the Flow Rate parameter to ensure it is not set too high for the procedure and also review the Pressure Limit parameter to ensure it is not set too low. Check the delivery system for closed stopcocks or kinked tubing. Under normal circumstances, the injection pressure should not reach the pressure limit. Reaching the pressure limit defeats the purpose of a flow rate injector.

Syringe Latch Open

Message: The injection has stopped. A syringe latch is open. Press Close to continue.

Occurs when: While the injector is enabled or injecting, the injector software checks to ensure the 125 ml syringe levers and/or the 200 ml syringe levers are in the loaded (closed) position. If either are opened, the injector will immediately disable and display this message.

Operator action: Close the syringe clamps and/or levers. Press the [Close] key and re-enable the injector.

6.1.10 RESULTS SCREEN MESSAGES

Pressure Limited

Message: This injection was pressure limited.

Occurs when: This message appears on the Results screen if the injector injects under maximum pressure limit conditions but cannot achieve the set flow rate.

Operator action: This message is to advise the operator that the injection was delivered but under pressure limited conditions. Under normal circumstances, the injection pressure should not reach the pressure limit. Reaching the pressure limit defeats the purpose of a flow rate injector. Review the Flow Rate parameter to ensure it was not set too high for the procedure and also review the Pressure Limit parameter to ensure it was not set too low. Check the delivery system for closed stopcocks or kinked tubing.

6.2 ALARM MESSAGES

Refer to Figure 6-2-1.

The microprocessor control circuits in the OptiVantage continuously monitor all important functions from the moment that the unit is turned on. These checks, transparent to the operator, occur many times each second, monitoring the safe performance of the injector. If a fault is detected, the unit will lock into a fault mode and display an Alarm code.

Cycle power to reset the injector. If the alarm persists, contact your Service Department for corrective action regarding this alarm.

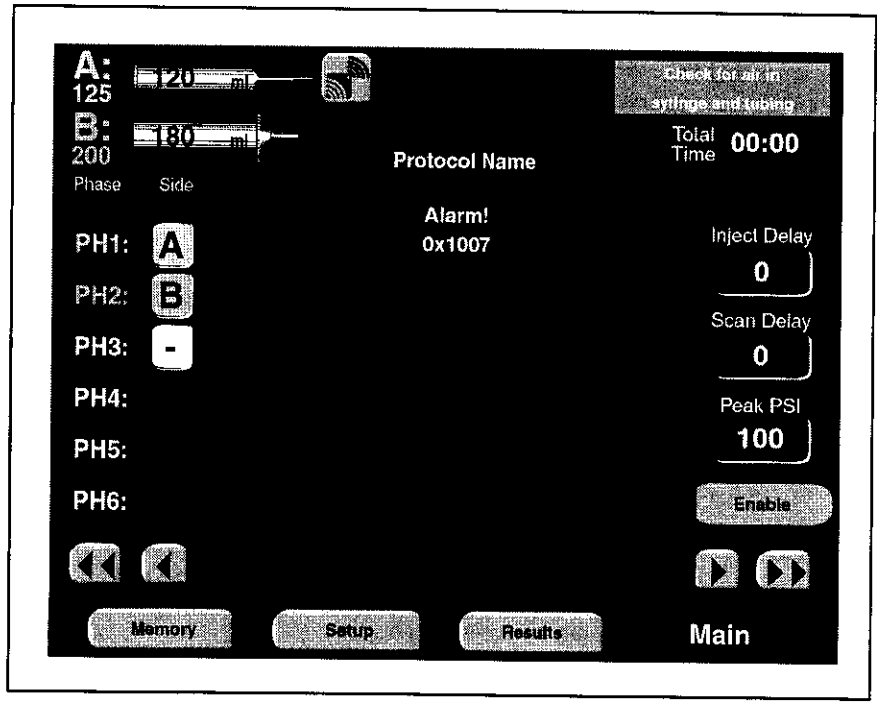

Figure 6-2-1 Alarm Message

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7 CARE OF UNIT

NOTE: Preventive maintenance schedule and service procedures are in the Service Manual.

7.1 DAILY INSPECTION

7.1.1 200 ML PRESSURE SLEEVE

The 200 ml pressure sleeve has a limited life-span and must be replaced periodically. Its expected life-span may range from thirty (30) days or less to over two (2) years depending on pressures encountered, the number of injection cycles and the cleaning and sterilization techniques utilized. Check the 200 ml pressure sleeve(s) daily for signs of stress, crazing lines, or cracks and replace immediately when any of these symptoms are found.

⚠ WARNING! ⚠

CHECK PRESSURE SLEEVE DAILY!
Syringe pressure sleeves must withstand high pressures generated during injection delivery. Defective sleeves may shatter or explode under these conditions. Always inspect pressure sleeve closely before using injector. While viewing all areas; look for stress cracks (around the front or at the shoulder area), discard any pressure sleeve exhibiting signs of stress, crazing lines or cracks. The use of such parts may cause injury and/or an aborted injection.

7.1.2 125 ML FACEPLATE ADAPTER

Check the 125 ml faceplate adapter(s) daily for signs of cracks or separation of mating parts and replace immediately when any of these are found.

⚠ CAUTION! ⚠

If cracks or mating part separations cause the electronics inside to be exposed, do not plug the faceplate adapter into the powerhead. Contact your Service Department for faceplate adapter replacement.

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7.2 CLEANING

7.2.1 200 ML PRESSURE SLEEVE AND BASE

On a daily basis, move the ram to the fully retracted position and wipe out the inside of the pressure sleeve with a damp (with water), lint-free towel.

NOTE: Do not autoclave the pressure sleeve. *Autoclaving will shorten the life of the pressure sleeve.*

The entire base and pressure sleeve may be placed or soaked in warm water with a mild soap to remove any hardened contrast. This procedure is also helpful if the locking lever is hard to rotate. *Do not use alcohol-based detergents. The water should not contain the following substances, even in trace amounts:*

- esters
- ethers
- ketones
- chlorides
- n-Alkyl
- alcohols (other than ethyl alcohol)
- cleaners and disinfectants (such as SaniZide and TB-Cide Quat)
- products containing: dimethyl benzyl, ammonium chlorides, and dimethyl ethylbenzyl

7.2.2 125 ML SYRINGE ADAPTER

On a daily basis, move the ram(s) to the fully retracted position and wipe out the inside of the 125 mL syringe adapter(s) with warm water containing a mild soap. If the syringe latch becomes difficult to actuate due to contrast buildup, it is safe to unplug and remove the syringe adapter from the powerhead and run it under water while actuating the latch. **NOTE:** *Care must be taken, however, to keep the cable connector dry.*

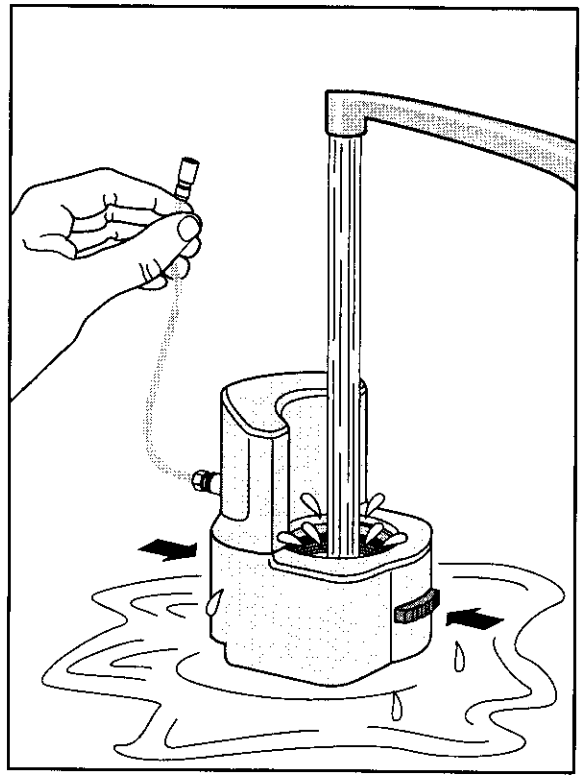

Figure 7-2-1.

7.2.3 CONSOLE AND POWERHEAD

The console and powerhead may be dusted by using a lint-free cloth. To clean the touch screen, use a *nonabrasive* cloth towel and any commercially available *non-ammonia* window cleaner to regularly clean the surface. *The cleaning solution should be applied to the towel rather than the surface of the touch screen.* The touch screen has air vents and is not designed with water tight bezels so fluid ingress may occur from behind the panel if not cleaned carefully.

7.2.4 POWER SUPPLY

Clean the exterior of the power supply by spraying a cloth with an all-purpose household cleaner, then gently wipe clean.

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Attachment 9

Table 1 Major Level of Concern	Yes	No
If the answer to any one question below is Yes, the Level of concern for the Software Device is likely to be Major.		
1. Does the Software Device qualify as Blood Establishment Computer Software? (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)		X
2. Is the Software Device intended to be used in combination with a drug or biologic?		X
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?		X
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:		X
a. Does the Software Device control a life supporting or life sustaining function?		X
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?		X
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?		X
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?		X
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?		X

Table 2 Moderate Level of Concern	Yes	No
If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.		
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?		X
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	X	
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	X	
If the answers to all of the questions in Tables 1 and 2 above are No, the Level of Concern is Minor.		

1 Software Development Life Cycle Model

The Software Development Life Cycle Model is described in the Software Development Procedure (QSEP12). In brief, this Model includes the following cycles: Project Planning, Risk Analysis, Requirements Analysis and Specifications, Design Documentation, Implementation, Review, Verification Test, Validation Test, Release and Maintenance.

1.1 Project Planning

A Software Development Plan (SDP) is jointly prepared by Software Engineering and Software Quality Assurance (SQA) and can be one or separate documents. It documents how a project will satisfy the requirements of this procedure. This plan identifies tools, techniques, standards, and methodologies that the development and SQA team will apply during development, software verification, and validation, including analysis, reviews, audits, and levels of testing. This plan also shows the tasks and documents planned and what resources are required.

1.1.1 Process Adherence

It is the responsibility of the Core Team Leader and the Software Core Team Member to ensure all procedures are followed and documented.

1.1.2 Project Document Control

Requirements tracing will be handled by Requisite Pro. Requirements will be traced forward and backward from Customer Requirements Specification, Product Requirements Specification, Software Requirements Specification, Software Design Specification, and Software Verification Test. Inputs from the Risk Analysis and FMEA will be traced through to the Software Verification Test.

All software procedures and documents will be stored, released, and controlled through Agile.

1.1.3 Anomaly Tracking

Anomaly Tracking will be performed according to Software Event Tracking Work Instruction (QSEWI3).

1.1.4 Software Configuration Management Plan

The OptiVantage DH CT Injector Project will use PVCS Version Manager V6.8.00 (or later) to provide comprehensive control of revisions and labeling of source code. PVCS includes the basic Check-in/Check-out feature to prevent simultaneous access to a source file.

1.1.5 Development Tools

The Metrowerks CodeWarrior IDE V6.2, including editor, compiler, and debugger will be used to develop the software for the Dual-head CT Injector Project.

1.1.6 COTS Revisions & Validations

No additional COTS was added to the OptiVantage DH injector for the implementation of the RFID feature.

1.2 Risk Analysis

Risk Management for product safety shall follow the Risk Management Plan developed based in ISO 14971:2000 (E).

A Risk Analysis will be performed prior to software implementation and revised as needed thereafter.

Results of the Risk Analysis will become inputs to the Software Requirements Specification and will be traced via Requisite Pro through to the Software Verification Protocol.

1.3 Requirements Analysis and Specifications

An initial Software Requirements Specification (SRS) document will be developed and approved by the Software Development Team and Quality Assurance prior to the start of software implementation. The Customer Requirements Specification, Product Requirements Specification, and Risk Analysis and FMEA are the inputs to the SRS. The SRS will be traced via Requisite Pro through to the Software Verification Protocol.

The SRS will be reviewed and approved by the Software Development Team, Marketing, and Software Quality Assurance before the start of the Design phase of the development.

Subsequent revisions to the SRS may take place. New software requirements shall be added to the SRS and approved by the Software Development Team, Marketing, and Software Quality Assurance before design of those requirements begins.

1.4 Design Documentation

An initial Software Design Specification (SDS) document will be developed and released prior to the start of software implementation. The Software Requirements Specification is the input to the Software Design Specification. The SDS will become an input to the Software Verification Protocol and will be traced via Requisite Pro.

The SDS will be reviewed and approved by the Software Development Team and Software Quality Assurance before the start of the implementation phase of the development.

Subsequent revisions to the SDS may take place. New Design Specifications shall be added to the SDS and approved by the Software Development Team and Software Quality Assurance before implementation of those specifications begins.

1.5 Software Implementation

1.5.1 Integrated Development Environment (IDE)

The Motorola IDE package Metrowerks Code Warrior will be used. Metrowerks Code Warrior consists of a code editor, project make utility, compiler, assembler, linker and debugger which will serve as the code implementation environment.

All compiler Warnings should be fixed as they occur.

A document containing the Software Build Instructions shall be created. The Instructions shall include all the steps needed to check out all the necessary files from PVCS to a Clean PC, build the software, download the software, and save the software to the Master/Master CD and the Production/Service CD per QSEWI39.

1.5.2 Programming

The Rhapsody UML Tool is used to generate "C++" included in the system. Additional "C++ and "C" coding is done to implement parts of the system not included in the Rhapsody UML model. Some assembly language will be used where required.

Code implemented by developers shall adhere to the Coding Standards specified in QSEWI28.

1.5.3 Testing and Software Quality Assurance

Unit testing is testing of individual software units or groups of related units such as functions/subroutines. Documented unit testing is required for risk controls where safety requirements can be traced to specific units. ANSI /IEEE Std 1008-1987, standard for software unit testing shall be used as a guide when performing unit testing.

Integration testing is testing in which software components, hardware components, or both are combined and tested to evaluate the interaction between them.

System testing is testing conducted on a complete, integrated system to evaluate the system's compliance with its specified requirements.

1.6 Reviews

Software reviews are an important part of the Software Development Cycle and Quality Assurance activities. Reviews occur throughout the Cycle. Although really part of Verification Test, reviews are listed in Software Development Procedure (QSEP12), Software Development Procedure as a separate phase to reinforce their importance and demonstrate the iterative process of software development. Guidance for all Software Reviews is provided in Work Instruction QSEWI29, Software Reviews.

1.7 Verification Test

The purpose of verification testing is to verify the proper operation of the software based on requirements. Verification testing shall be accomplished through unit, integration and system level testing. The scope of verification testing activities is commensurate with the requirement under test and the level of risk of the item.

Verification of software on the OptiVantage DH WKRP Project will adhere to the Software Development Procedure (QSEP12).

1.8 Validation Test

The purpose of validation testing is to assure the system meets its customer requirements and achieves its intended use. Validation shall be based on the level of risk of the new or changed module(s) and their impact to the rest of the system.

- Validation testing shall be conducted per QSEP16
- Validation testing shall be conducted using approved validation test protocols.
- Testing results and reports shall meet the requirements of work instruction QSEWI8, Engineering Test.

1.9 Release and Audit

Release of software into Document Control shall be accomplished via the release of a Software Reference document. This document contains a Bill Of Materials which contains a link to all documentation that is created and released during the software development process as well as the software its self. The Software Release Document provides a single point of reverence to identify all of the software analysis and design documentation and other materials that relate to a specific release of software. The Software Reference document shall contain pertinent information for the software in the set, including:

- Version number for the software release (i.e. all components together)
- Links to SRS, SDS, Risk Analysis, and Trace Matrix
- Links to All test documentation including Verification and Validation test protocols and results
- Links to All review meeting minutes and actions items.

The release of the Software Reference document and associated supporting documents must be reviewed and approved by Marketing, Engineering, Quality, and Manufacturing.

1.10 Software Maintenance

Software maintenance projects shall follow the same life cycle as a new development project. The Software Development Plan for software maintenance types of projects shall incorporate those elements from Software Development Life Cycle, required by the scope of the project. The SDP shall included a list of specific defect corrections, design modifications and feature enhancements along with their corresponding defect, anomaly, or issue number if applicable. For a Maintenance project the SDP will define the scope of the project. Release requirements are the same as those listed in section 1.9.

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Attachment #14
Indications for Use

510(k) Number (if known): **K063503**

Device Name: **OptiVantage DH Injector System with Enhanced Communication**

Indications For Use:

The OptiVantage DH Injector System with Enhanced Communication is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

520

K063503/S2

tyco Healthcare Division MALLINCKRODT

March 30, 2007

Food and Drug Administration
Center for Devices and Radiological Health
Attn: Ms. Kimberly Bowie Peters
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: K063503
Trade Name: OptiVantage DH Injector System with Enhanced Communication

Dear Ms. Peters:

In response to your questions dated March 22, 2007 regarding the referenced 510(k) submission, we offer the following information:

1. You state in the operator's manual and in the submission that the device has been tested in accordance with IEC 60601-1-2. You also include a letter dated January 24, 2007 from DLS Electronic Systems, Inc. showing that the original system was tested to EN 60601-1-2 for immunity and EN 55011 for emissions. The OptiVantage with RFID was tested to EN 301 489-3 for immunity and emissions. Please justify the change in the test standard. Please compare the test frequencies, immunity specifications and emissions levels used in EN 301 489-3 to those used in IEC 60601-1-2. Please provide the test protocols and reports demonstrating compliance with IEC 60601-1-2 for review. FDA believes that complete testing information is necessary due to the fact that the function and performance of injector system will impact testing provided to support a CDER application.

Response: *The OptiVantage DH, prior to the development of the Enhanced Communications feature, met the following standards:*

EN 61000-3-2,-3
EN 60601-1-2
EN 55011

The OptiVantage DH with Enhanced Communication (RFID) was presented to DLS Electronic Systems, Inc. in July 2006 to be analyzed for compliance to the following standards:

EN 61000-3-2,-3
EN / IEC 60601-1-2
EN 55011

1-24

The addition of a radio transmitter device to the system required compliance to <u>additional</u> standards. The following standards were met in addition to the standards listed above:

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ICES-003 (Canada)
RSS-210 (Canada)
FCC Part 15.107 (US)
FCC Part 15.225 (US)
EN 300 330-1
EN 301 489-3 Emissions / Immunity

B4 [redacted] *certified that the OptiVantage DH Injector System with Enhanced Communications (RFID) meets both sets of the above listed EMC requirements in full. Please refer to Attachment 1 for a letter from DLS stating that the injector complies with these standards.*

In Attachment 2, we have provided a summary table which compares test frequencies, specifications and emissions levels of EN 60601-1-2:2001 with EN 301 489-3 V1.4.1.

Attachment 3 includes test protocols and reports for each standard listed above. Page 1 of the attachment provides an index of the test reports. The test protocol and report for IEC 60601-1-2 can be found behind Tab 1 of Attachment 3.

2. Your response to deficiency 1 of our letter dated December 21, 2006 indicates that the RFID feature is intended to be used with both pre-filled contrast syringes and prefilled saline syringes. The submission indicates that CDER will be reviewing information regarding the addition of the RFID feature to the pre-filled contrast syringes; however, this information does not address a submission for the addition of the RFID feature to the pre-filled saline syringes. Please explain what regulatory submission will be provided to address the addition of the RFID feature to the prefilled saline syringes.

Response: *Mallinckrodt, Inc. provided a Prior Approval Supplement for the addition of RFID to prefilled saline syringes. Please reference CDER submission: Sodium Chloride Injection, USP 0.9% NDA 21-569, supplement number S-002, submitted 3/13/07.*

Should you have any further questions regarding the contents of this response or to the actual submission, you may contact me by mail, phone at (513) 948-5771 or fax at (513) 948-5708.

Sincerely,

Dale Moore

Dale Moore
Quality Manager

Attachments

tyco Healthcare Division MALLINCKRODT

March 30, 2007

Food and Drug Administration
Center for Devices and Radiological Health
Attn: Ms. Kimberly Bowie Peters
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: K063503
Trade Name: OptiVantage DH Injector System with Enhanced Communication

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ICES-003 (Canada)
RSS-210 (Canada)
FCC Part 15.107 (US)
FCC Part 15.225 (US)
EN 300 330-1
EN 301 489-3 Emissions / Immunity

B4 [redacted]*. certified that the OptiVantage DH Injector System with Enhanced Communications (RFID) meets both sets of the above listed EMC requirements in full. Please refer to Attachment 1 for a letter from DLS stating that the injector complies with these standards.*

In Attachment 2, we have provided a summary table which compares test frequencies, specifications and emissions levels of EN 60601-1-2:2001 with EN 301 489-3 V1.4.1.

Attachment 3 includes test protocols and reports for each standard listed above. Page 1 of the attachment provides an index of the test reports. The test protocol and report for IEC 60601-1-2 can be found behind Tab 1 of Attachment 3.

2. Your response to deficiency 1 of our letter dated December 21, 2006 indicates that the RFID feature is intended to be used with both pre-filled contrast syringes and prefilled saline syringes. The submission indicates that CDER will be reviewing information regarding the addition of the RFID feature to the pre-filled contrast syringes; however, this information does not address a submission for the addition of the RFID feature to the pre-filled saline syringes. Please explain what regulatory submission will be provided to address the addition of the RFlD feature to the prefilled saline syringes.

Response: *Mallinckrodt, Inc. provided a Prior Approval Supplement for the addition of RFID to prefilled saline syringes. Please reference CDER submission: Sodium Chloride Injection, USP 0.9% NDA 21-569, supplement number S-002, submitted 3/13/07.*

Should you have any further questions regarding the contents of this response or to the actual submission, you may contact me by mail, phone at (513) 948-5771 or fax at (513) 948-5708.

Sincerely,

Dale Moore
Quality Manager

Attachments

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