



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (szs)
FOLDER: K080275 - 1345 pages
COMPANY: IASIS MEDICAL, INC. (IASIMEDI)
PRODUCT: NEGATIVE PRESSURE WOUND THERAPY POWERED SUCTION PUMP (OMP)
SUMMARY: Product: NPD 1000 NEGATIVE PRESSURE WOUND THERAPY SYSTEM
DATE REQUESTED: Feb 7, 2012
DATE PRINTED: Feb 7, 2012
Note: Printed



K050275

OCT 09 2008

510(k) Summary

Submitter:	Kalypto Medical 6393 Oakgreen Avenue Hastings, MN 55033
Contact Person:	John Buan, Vice President of Product Development Phone (612) 703-1204, Fax (763) 287-3836
Date Prepared:	August 14, 2008
Trade Name:	NPD 1000 Negative Pressure Wound Therapy System
Classification:	Powered Suction Pump Class II 21 CFR 878.4780
Product Code:	BFA JCK
Predicate Device(s):	The subject device is equivalent to the following device: <ul style="list-style-type: none"> • V.A.C. Therapy Systems-ActiV.A.C. Therapy Unit M: K063692 • Boehringer Laboratories Suction Pump System: K060277
Device Description:	The NPD 1000 Negative Pressure Wound Therapy System includes a small, portable, low powered, battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to remove exudates, which may promote wound healing.
Intended Use:	The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.
Functional and Safety Testing:	To verify that the device design met its functional and performance requirements, representative samples of the device underwent functional and mechanical testing, EMC testing in accordance with IEC 60601-1-2:2001 and electrical safety testing in accordance with UL 60601-1:2006.
Conclusion:	Kalypto Medical considers the NPD 1000 Negative Pressure Wound Therapy System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, and indications for use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 09 2008

Kalypto Medical
c/o Mr. John Baun
6393 Oakgreen Avenue
Hastings, MN 55033

Re: K080275

Trade/Device Name: NPD 1000 Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: August 14, 2008
Received: August 15, 2008

Dear Mr. Baun:

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.

Page 2 - Mr. John Baun

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080275

Device Name: NPD 1000 Negative Pressure Wound Therapy System

Indications for Use:

The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Dyer for me
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K 080275



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR -7 2009

Kalypto Medical
% Mr. John Baun
6393 Oakgreen Avenue
Hastings, Minnesota 55033

Re: K080275

Trade/Device Name: NPD 1000 Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: August 14, 2008
Received: August 15, 2008

Dear Mr. Baun:

This letter corrects our substantially equivalent letter of October 9, 2008.

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 (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

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Page 2 - Mr. John Baun

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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/dsma/dsmamain.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080275

Device Name: NPD 1000 Negative Pressure Wound Therapy System

Indications for Use:

The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil AP [Signature] for [Name]
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080275

Page 3 - Mr. John Baun

cc: HFZ-401 DMC
 HFZ-404 510(k) Staff
 HFZ- 410 Division
 D.O.

K080275 - Kalypto Medical NPD 1000 Negative Pressure Wound Therapy System

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date
410	Dang	3/30/09						
410	Krone	3/30/09						
410	Law	3/30/09						

K080275/A2



FDA CDRH DMC
AUG 21 2008
Received

August 20, 2008

Office of Device Evaluation
Document Mail Center (HFZ401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: K080275: **AMENDMENT** to "Additional Information for the NPD 1000 Negative Pressure Wound Therapy System" submitted August 15, 2008

Enclosed are one original and two copies of an AMENDMENT to the additional information to K080575: 510(k) PreMarket Notification for the NPD 1000 Negative Pressure Wound Therapy System received by FDA on August 15, 2008. The response to FDA question Q7 in the August 15 submission referenced the FCN files 98 and 34 for biocompatibility information regarding the Superabsorbent Polymer Matrix produced by Technical Absorbents. KALYPTO has recently obtained the reports for Toxicity and Mutagenicity Testing and are submitting them in this AMENDMENT for reviewer convenience, as an Amendment Attachment Q7 of the August 15 submission.

This submission contains technical, commercial and confidential trade secret information, and Kalypto Medical respectfully requests the maximum protection provided by law, in accordance with 21 CFR § 807.95.

If you have any questions, please contact John Buan at (763) 551-8959, by Fax at (763) 287-3836, or by email at jbuan@kalyptomedical.com.

Sincerely,

Pamela Vaughan
Alquest, Inc.
Consultant to Kalypto Medical

K29

CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.
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Date of Submission August 20, 2008	User Fee Payment ID Number MD6034663-956733	FDA Submission Document Number (if known) K080275
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SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 35-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify)
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Kalypto Medical		Establishment Registration Number (if known)	
Division Name (if applicable)		Phone Number (including area code) (612) 703-1204	
Street Address 6393 Oakgreen Avenue		FAX Number (including area code) (763) 287-3836	
City Hastings	State / Province MN	ZIP/Postal Code 55033	Country USA
Contact Name John Buan			
Contact Title Vice President of Product Development		Contact E-mail Address jbuan@iasismedical.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

FORM FDA 3514 (6/05)

SECTION D1 REASON FOR APPLICATION – PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

SECTION D2 REASON FOR APPLICATION – IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol – Feasibility <input type="checkbox"/> Protocol – Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		

SECTION D3 REASON FOR SUBMISSION – 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

FORM FDA 3514 (6/05)

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	JCX	2		
3		4		
5		6		

Information on devices to which substantial equivalence is claimed (if known)			
510(k) Number	Trade or Proprietary or Model Name	Manufacturer	
1	K063692	1	V.A.C. Therapy Systems-Acti-V.A.C. Therapy Unit M
2	K060277	2	Boehringer Laboratories Suction Pump System
3		3	
4		4	
5		5	
6		6	

SECTION F PRODUCT INFORMATION – APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Pump, Portable, Aspiration, (Manual or Powered)

Trade or Proprietary or Model Name for This Device	Model Number
NPD 1000 Negative Pressure Wound Therapy System	1 NPD 1000, NPD 1000i, NPD 1000c
	2
	3
	4
	5

FDA document numbers of all prior related submissions (regardless of outcome)					
1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION – APPLICATION TO ALL APPLICATIONS

Product Code BTA	C.F.R. Section (if applicable) 21 CFR 878.4780	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)
 The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.

FORM FDA 3514 (6/05)

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

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 2133810	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Minnetronix, Inc.		Establishment Registration Number 2133810	
Division Name (if applicable)		Phone Number (including area code) (651) 917-4060	
Street Address 1635 Energy Park Drive		FAX Number (including area code) ()	
City St. Paul		State / Province MN	ZIP/Postal Code 55108
		Country USA	
Contact Name	Contact Title	Contact E-mail Address	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name TapeMark Co.		Establishment Registration Number 2182681	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address 1685 Marthaler Lane		FAX Number (including area code) ()	
City West St. Paul		State / Province MN	ZIP/Postal Code 55118
		Country USA	
Contact Name	Contact Title	Contact E-mail Address	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 1450662	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Steris Inc, Isomedix Services		Establishment Registration Number 1450662	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address 1880 Industrial Drive		FAX Number (including area code) ()	
City Libertyville		State / Province IL	ZIP/Postal Code 60048
		Country USA	
Contact Name	Contact Title	Contact E-mail Address	

FORM FDA 3514 (6/05)

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601	IEC	Medical Electrical Equipment- Part 1-2: General requirements for safety	2 nd Edition	2001
2	60601	UL	Medical Electrical Equipment- Part 1: General requirements for safety	1 st Edition	2006
3	ISO 10993-5	ISO	Biological evaluation of medical devices- Part 5, Test for in vitro cytotoxicity	2 nd Edition	1999
4	BS, EN, ISO 10993-5	BS, EN, ISO	Biological evaluation of medical devices- Part 5, Test for in vitro cytotoxicity	2 nd Edition	1999
5	ISO 10993- 10	ISO	Biological evaluation of medical devices- Part 10, Test for Irritation and Sensitization	1 st Edition	1995
6	OECD 404	OECD	Acute Dermal Irritation	-----	May 1981
7	OECD 471	OECD	Genotoxicity, Mutagenicity	-----	May 1981

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

FORM FDA 3514 (6/05)

SECTION I UTILIZATION OF STANDARDS- continued

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
8	OECD 406		OECD Guideline No. 406, Buehler Method, Skin Sensitization	----	May 1981
9	OECD 401	OECD	OECD Guideline No. 410, Acute Toxicity	----	May 1981
10	UK GLP Standards	OECD	OECD Principles on Good Laboratory Practice	----	1997
11	Standards No.	Standards Organization	Standards Title	Version	Date
12	Standards No.	Standards Organization OECD	Standards Title	Version	Date

(b)(4)

Biocompatibility Information

Acute Eye Irritation Study

(b)(4)

ACUTE EYE IRRITATION STUDY

(b)(4)

Study Reference Number A/E/31018
July 1991

Report prepared by (b)(4)

SPONSOR

(b)(4)

Testing Facility

(b)(4)

ACUTE EYE IRRITATION STUDY

(b)(4)

(b)(4) REPORT REFERENCE A/E/31018

At the time of this study the Quality Assurance Unit of (b)(4) (b)(4) was inspecting one of each critical phase of every type of acute study each month as part of a comprehensive evaluation of such studies.

This report has been audited in compliance with the Principles of Good Laboratory Practice. As far as can be reasonably established, the methods described and the results incorporated in the report accurately reflect the raw data produced during this study.

In addition, facilities associated with this study were inspected according to Quality Assurance Unit Standard Operating Procedures.

(b)(4)

(Head of Quality Assurance)

Date: 20 April 1991

ACUTE EYE IRRITATION STUDY

(b)(4)

(b)(4) REPORT REFERENCE A/E/31018

I certify that this study report provides a true and complete record of the data generated and that the study was conducted in accordance with the principles of Good Laboratory Practice set forth in the following:-

1. The United Kingdom GLP Compliance Programme (D.o.H. London 1989).
2. The Principles of Good Laboratory Practice set forth in the OECD Guidelines for the Testing of Chemicals, ISBN 92-64-12367-9, Paris 1982.
3. The United States of America Code of Federal Regulations (EPA-TSCA) Toxic Substances Control Act, CFR 40, Part 792 (Volume 48 No. 230 November 29th 1983).

All raw data relating to this study will be stored in (b)(4) (b)(4) archives for a period of 2 years after which time they will be stored at a location designated by the sponsor.

Signed: (b)(4) Study Director

Date: 3.10.91

C O N T E N T S

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THE DRINKING WATER 14-15

1.0 SUMMARY

A 100mg aliquot of (b)(4) was instilled into the right eye of each of 3 rabbits and the resulting reaction to treatment assessed one, 24, 48 and 72 hours after dosing.

Reaction was restricted to some conjunctival hyperaemia in 2 rabbits, one hour after dosing and in one rabbit 24 hours after dosing. There were no corneal or iridial responses in any animal.

It is considered that (b)(4) is practically non-irritant, when administered ocularly.

2.0 INTRODUCTION

The purpose of this study was to investigate the degree of ocular irritation produced when the test article was introduced into the eye of the albino rabbit.

The procedures used meet the requirements of the test number 405, described in the Organisation for Economic Co-operation and Development (O.E.C.D.) Guidelines for the Testing of Chemicals, adopted on February 24th 1987.

The rabbit is indicated in the guidelines to be a suitable mammalian species and the route of administration is a potential route of exposure during manufacture, handling or use.

The experimental work described in this report took place during the period from 18th June 1991 to 28th June 1991.

3.0 TEST ARTICLE

The test article was (b)(4) supplied in a plastic bag labelled :-

(b)(4)

The test article arrived at (b)(4) and was coded with the (b)(4) Reference Number A/E/31018 for this study. When not in use the material was stored in the dark at room temperature.

4.0 METHODS

4.1 Animals, husbandry and diet

Healthy female New Zealand White rabbits were obtained from Ranch Rabbits, Crawley Down, Sussex. On arrival animals were identified with metal ear tags. Animals were allowed an acclimatisation period of at least 5 days.

The animals were individually housed in grid bottomed metal cages. An antibiotic-free rabbit diet (SQC standard rabbit pellets produced by Special Diets Services, Witham, Essex) and mains drinking water via an automatic watering system were freely available. Certificates of analysis for both diet and drinking water are presented as Appendices 3 and 4 of this report.

The rabbit room was air-conditioned with temperature maintained within the range of 18-21°C and relative humidity within the range of 58-69% during the acclimatisation and study periods. Fluorescent lighting was controlled to give an artificial cycle of 12 hours light/12 hours dark per day.

4.2 Preparation of test article

The test article (b)(4)

4.3 Dosing

Animals whose eyes were free from any irritation or other defects were selected. They were restrained in wooden stocks whilst being dosed.

One rabbit was dosed initially, to assess the severity of irritant response. As the response to treatment was not severe, a further 2 animals were dosed.

Test article (100mg) was instilled into the right eye of each animal by gently pulling away the lower lid from the eyeball to form a cup into which the material was placed. The lids were then held shut for a few seconds and moved gently about to distribute the test article around the surfaces of the eye and lids.

4.4 Observations

One, 24, 48 and 72 hours following instillation of the test article the animals were examined under a standard light source designed to comply with the requirements of BS 950 Part 1 (Artificial Daylight for the Assessment of Colour). The eye was assessed for damage or irritation to the cornea, iris and conjunctivae using the untreated eye as a control. Examination was confined to a macroscopic observation and aids such as a binocular loupe, slit lamp or fluorescein staining were not employed.

The reactions observed were given a numerical value based on the table below:-

Cornea

A.	Opacity : degree of density (area most dense taken for reading)	
	No ulceration or opacity	0
	Scattered or diffuse areas of opacity (other than slight dulling of normal lustre), details of iris clearly visible	1
	Easily discernible translucent area, details of iris slightly obscured	2
	Nacreous area, no details of iris visible, size of pupil barely discernible	3
	Opaque cornea, iris not discernible through the opacity	4
B.	Area of cornea involved *	
	One quarter (or less) but not zero	1
	Greater than one quarter, but less than half	2
	Greater than half but less than three quarters	3
	Greater than three quarters, up to whole area	4

* Not part of the Annex V grading procedure.

Iris

A.	Normal	0
	Markedly deepened rugae, congestion, swelling, moderate circumcorneal hyperaemia, or injection, any of these or combination of any thereof, iris still reacting to light (sluggish reaction is positive)	1
	No reaction to light, haemorrhage, gross destruction (any or all of these)	2

Conjunctivae

- A. Redness (refers to palpebral and bulbar conjunctivae)
 - Blood vessels normal 0
 - Some blood vessels definitely hyperaemic (injected) ... 1
 - Diffuse, crimson colour, individual vessels not easily discernible 2
 - Diffuse beefy red 3

- B. Chemosis : lids and/or nictitating membranes
 - No swelling 0
 - Any swelling above normal (includes nictitating membranes) 1
 - Obvious swelling with partial eversion of lids 2
 - Swelling with lids about half closed 3
 - Swelling with lids more than half closed 4

- C. Discharge *
 - No discharge 0
 - Any amount different from normal (does not include small amounts observed in inner canthus of normal animals) 1
 - Discharge with moistening of the lids and hairs just adjacent to lids 2
 - Discharge with moistening of the lids and hairs and considerable area around the eye 3

* Not part of the Annex V grading procedure.

5.0 RESULTS

One hour after dosing, conjunctival hyperaemia (grade 1) was noted in 2 rabbits, in one of which it persisted for 24 hours. There were no corneal or iridial responses at one hour or thereafter.

Forty-eight hours after dosing, the treated eyes of all 3 rabbits were normal.

6.0 CONCLUSION

(b)(4) is considered to be practically non-irritant, when administered ocularly.

APPENDIX 1 - IRRITATION - INDIVIDUAL VALUES1 Hour Observation

Rabbit Number	Conjunctivae			Cornea		Iris
	D	Ch	R	OP	A	IR
467	0	0	0	0	0	0
482	0	0	1	0	0	0
485	0	0	1	0	0	0

24 Hour Observation

Rabbit Number	Conjunctivae			Cornea		Iris
	D	Ch	R	OP	A	IR
467	0	0	0	0	0	0
482	0	0	1	0	0	0
485	0	0	0	0	0	0

48 Hour Observation

Rabbit Number	Conjunctivae			Cornea		Iris
	D	Ch	R	OP	A	IR
467	0	0	0	0	0	0
482	0	0	0	0	0	0
485	0	0	0	0	0	0

72 Hour Observation

Rabbit Number	Conjunctivae			Cornea		Iris
	D	Ch	R	OP	A	IR
467	0	0	0	0	0	0
482	0	0	0	0	0	0
485	0	0	0	0	0	0

KEY

D = Discharge
OP = Opacity

Ch = Chemosis
A = Area

R = Redness
IR = Iris

APPENDIX 2 - INDIVIDUAL BODYWEIGHTS (Kg)

Rabbit Number	467	482	485
Bodyweight	2.8	3.0	3.5

SPECIAL QUALITY CONTROL OF
 SMALL ANIMAL DIETS

Special Diets Services

CERTIFICATE OF ANALYSIS

PRODUCT: STANRAB SQC

BATCH NO: 5801

PREMIX BATCH NO: P925

DATE OF MANUFACTURE: 18-FEB-91

Nutrient	Found Analysis		Contaminant	Found Analysis		Limit of Detectic
Moisture	7.4	%	Fluoride	13	mg/kg	1.0 mg/k
Crude Fat	3.4	%	Nitrate as NaNO3	876	mg/kg	1.0 mg/k
Crude Protein	18.2	%	Nitrite as NaNO2	2.0	mg/kg	1.0 mg/k
Crude Fibre	11.4	%	Lead	Non Detected	mg/kg	0.25 mg/k
Ash	6.7	%	Arsenic	Non Detected	mg/kg	0.2 mg/k
Calcium	0.85	%	Cadmium	Non Detected	mg/kg	0.05 mg/k
Phosphorus	0.81	%	Mercury	Non Detected	mg/kg	0.01 mg/k
Sodium	0.35	%	Selenium	0.08	mg/kg	0.05 mg/k
Chloride	0.54	%				
Potassium	1.20	%				
Magnesium	0.25	%	Total Aflatoxins	Non Detected	mcg/kg	1 mcg/kg each of B1, B2, G1.
Iron	174	mg/kg				
Copper	11	mg/kg	Total P.C.B	Non Detected	mcg/kg	10.0 mcg/
Manganese	70	mg/kg	Total D.D.T	Non Detected	mcg/kg	1.0 mcg/
Zinc	65	mg/kg	Dieldrin	Non Detected	mcg/kg	1.0 mcg/
			Lindane	1	mcg/kg	1.0 mcg/
			Heptachlor	Non Detected	mcg/kg	1.0 mcg/
			Malathion	Non Detected	mcg/kg	20.0 mcg/
Vitamin A	5.8	iu/g	Total Viable Organisms x 1000	6.25	per grm	1000/g
Vitamin E	63	mg/kg				
Vitamin C		mg/kg	Mesophilic Spores x 100	38.75	per grm	100/g
			Salmonellae Species	Non Detected	per grm	Absent in 20 grm
			Presumptive E.coli	Non Detected	per grm	Absent in 20 grm
			E.coli Type 1	Non Detected	per grm	Absent in 20 grm
			Fungal Units	25	per grm	Absent in 20 grm
			Antibiotic Activity	Non Detected		

Signed (b)(4)
 Dated 18/3/91

APPENDIX 3 - Continued

SPECIAL QUALITY CONTROL OF
SMALL ANIMAL DIETS

S D S

Special Diets Services

CERTIFICATE OF ANALYSIS

PRODUCT: STANRAB SQC

BATCH NO: 5957

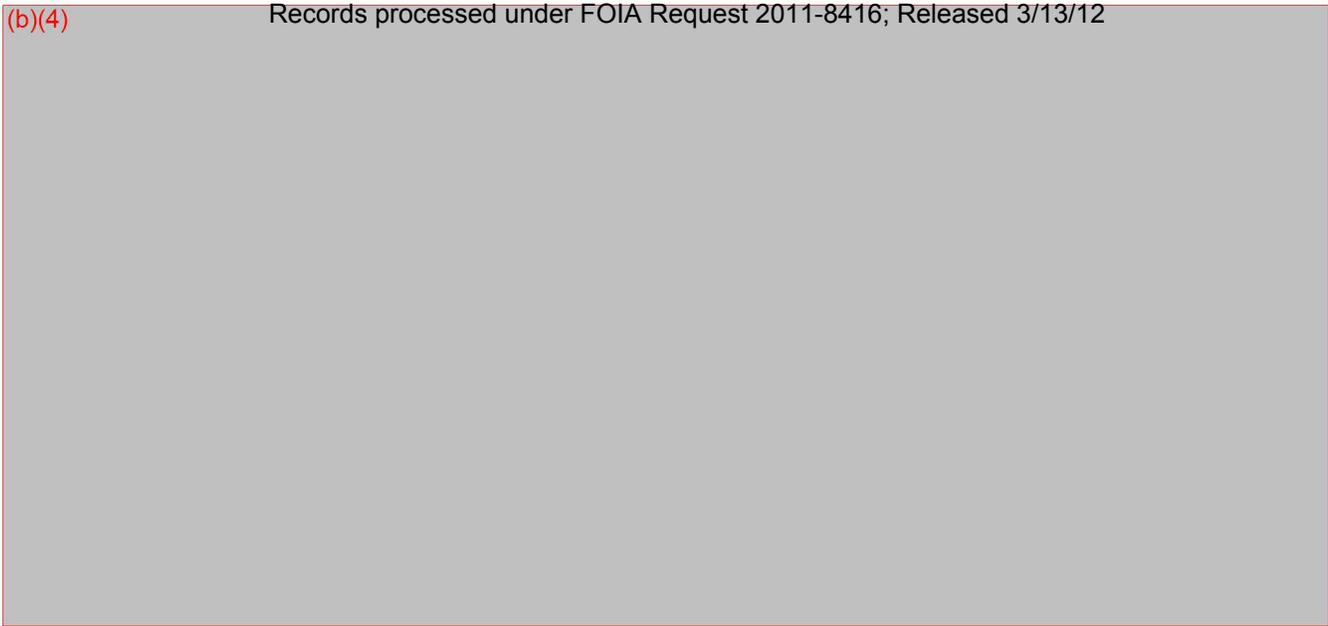
PREMIX BATCH NO: P932

DATE OF MANUFACTURE: 08-APR-91

Nutrient	Found Analysis		Contaminant	Found Analysis		Limit of Detection
Moisture	6.3	%	Fluoride	18	mg/kg	1.0 mg/kg
Crude Fat	3.4	%	Nitrate as NaNO3	1175	mg/kg	1.0 mg/kg
Crude Protein	19.6	%	Nitrite as NaNO2	3.2	mg/kg	1.0 mg/kg
Crude Fibre	12.5	%	Lead	0.35	mg/kg	0.25 mg/kg
Ash	6.7	%	Arsenic	Non Detected	mg/kg	0.2 mg/kg
Calcium	0.80	%	Cadmium	0.06	mg/kg	0.05 mg/kg
Phosphorus	0.68	%	Mercury	Non Detected	mg/kg	0.01 mg/kg
Sodium	0.28	%	Selenium	0.10	mg/kg	0.05 mg/kg
Chloride	0.54	%				
Potassium	1.09	%				
Magnesium	0.22	%	Total Aflatoxins	Non Detected	mcg/kg	1 mcg/kg each of B1, B2, G1, G2
Iron	178	mg/kg				
Copper	13	mg/kg	Total P.C.B	Non Detected	mcg/kg	10.0 mcg/kg
Manganese	74	mg/kg	Total D.D.T	Non Detected	mcg/kg	1.0 mcg/kg
Zinc	73	mg/kg	Dieldrin	Non Detected	mcg/kg	1.0 mcg/kg
			Lindane	Non Detected	mcg/kg	1.0 mcg/kg
			Heptachlor	Non Detected	mcg/kg	1.0 mcg/kg
			Malathion	Non Detected	mcg/kg	20.0 mcg/kg
Vitamin A	4.0	iu/g	Total Viable Organisms x 1000	5.25	per grm	1000/g
Vitamin E	64	mg/kg				
Vitamin C		mg/kg	Mesophilic Spores x 100	46.30	per grm	100/g
			Salmonellae Species	Non Detected	per grm	Absent in 20 grm
			Presumptive E.coli	Non Detected	per grm	Absent in 20 grm
			E.coli Type 1	Non Detected	per grm	Absent in 20 grm
			Fungal Units	Non Detected	per grm	Absent in 20 grm
			Antibiotic Activity	Non Detected		

Signed (b)(4)
Dated 16/5/91

(b)(4)



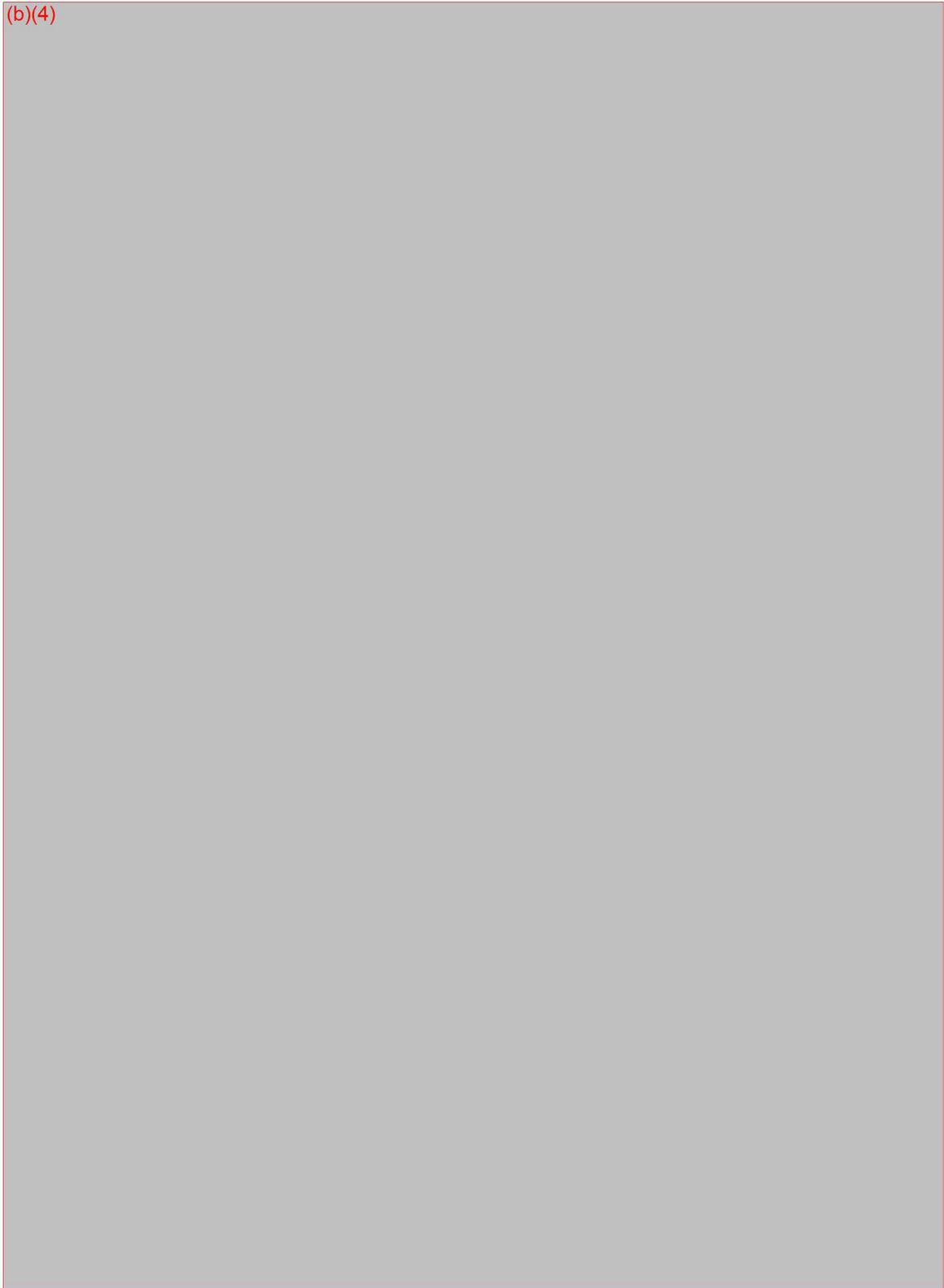
ANALYTICAL REPORT

(b)(4)



APPENDIX 4 - Continued

(b)(4)



(b)(4)

Biocompatibility Information

Acute Oral Toxicity Study

(b)(4)

ACUTE ORAL TOXICITY STUDY
IN THE RAT

Study Ref. No. A/O/31017

June 1991

Report prepared by (b)(4)

Sponsor

(b)(4)

Testing Facility

(b)(4)

ACUTE ORAL TOXICITY STUDY IN THE RAT

(b)(4)

(b)(4) REPORT REF: A/O/31017

At the time of this study the Quality Assurance Unit of (b)(4) (b)(4) was inspecting one of each critical phase of every type of acute study each month as part of a comprehensive evaluation of such studies.

This report has been audited in compliance with the principles of Good Laboratory Practice. As far as can be reasonably established, the methods described and the results incorporated in the report accurately reflect the raw data produced during this study.

In addition, facilities associated with this study were inspected according to Quality Assurance Unit Standard Operating Procedures.

(b)(4)

(Head of Quality Assurance)

Date: 3.17.09
.....

~~ACUTE ORAL TOXICITY STUDY IN MICE~~

(b)(4)

(b)(4)

REPORT REF: A/O/31017

I certify that this study report provides a true and complete record of the data generated and that the study was conducted in accordance with the principles of Good Laboratory Practice as set forth in the following:-

1. The United Kingdom GLP Compliance Programme (D.o.H. 1989).
2. The Principles of Good Laboratory Practice as set forth in the OECD Guidelines for the Testing of Chemicals, ISBN 92-64-12367-9, Paris 1982.
3. The United States of America Code of Federal Regulations (EPA-TSCA) Toxic Substances Control Act CFR 40 Part 792 (Volume 48 No. 230 November 29th 1983).

All raw data, tissues and a copy of the final report submitted to the sponsor will be stored in the archives of the testing facility for a period of 2 years after which time they will be stored at a location designated by the sponsor.

Signed: (b)(4) Study Director

Date: 3.10.91

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1.1

(b)(4) was administered orally, by gavage, to a group of 5 male and 5 female rats, at a dose level of 2000mg/kg bodyweight, following an overnight fast. The animals were observed for 14 days after which they were killed and necropsied.

1.2

No deaths occurred during the study.

1.3

All animals remained unremarkable throughout the study.

1.4

There were no adverse effects on bodyweight gain in animals of either sex.

1.5

There were no treatment related macroscopic post mortem findings.

1.6

It was concluded that (b)(4), administered orally at 2000mg/kg, had a median lethal dose in excess of 2000mg/kg and it is considered to be non-toxic acutely.

The purpose of this study was to assess the acute toxicity of the test article in the rat.

The procedures used in this study are based on test number 401 described in the Organisation for Economic Co-operation and Development (O.E.C.D) Guidelines for the Testing of Chemicals, adopted 24th February 1987.

The test article was administered orally since this is a potential route of human exposure. The rat was chosen since it is indicated in the guidelines to be an appropriate mammalian species.

The experimental work described in this report took place during the period 22nd May 1991 to 5th June 1991.

3.0 TEST ARTICLE

The test article was (b)(4) in a plastic bag labelled :-

(b)(4)

The material arrived at the testing facility on 9th May 1991 and was coded with the (b)(4) Reference Number A/O/31017 for this study. When not in use the material was stored in the dark at room temperature.

This study was performed as described in (b)(4) protocol number DP/2206/91/AC (A/O/31017) prepared on 12th April 1991.

4.1 Animals

Rats of the Crl:CD(SD)BR strain (VAF plus), weighing approximately 100g and aged 4-6 weeks, were supplied by Charles River (UK) Limited, Margate, Kent and were delivered on 17th May 1991. Animals were acclimatised for 5 days.

4.2 Environment

The animal room was air conditioned with temperature maintained within the range 19-22°C and recorded relative humidity within the range 39-66%.

The animal room was illuminated by fluorescent light to give an artificial cycle of 12 hours light/12 hours dark per day.

4.3 Caging

Animals were housed in groups of 5, by sex, in grid bottomed cages suspended over carboard lined excreta trays. Cardboard tray liners were changed as often as necessary to maintain hygiene.

4.4 Diet and water

Apart from an overnight fast before dosing, a pelleted diet (SQC Rat and Mouse Maintenance Diet No.1 Expanded, produced by Special Diets Services, Witham, Essex) was freely available. Mains drinking water in polypropylene bottles was also freely available. Certificates of analysis for both diet and drinking water are presented in appendices 3 and 4.

4.5 Preparation of the test article

The test article was (b)(4) and suspended in polyethylene glycol (PEG 400).

4.6 Experimental design

A limit test was conducted at a dose level of 2000mg/kg bodyweight and a dose volume of 10ml/kg, using a group of 5 males and 5 females.

Group number	Animal number/sex		Dose level (mg/kg) PKPS/TR 2294
	M	F	
1	11-15	16-20	2000

4.7 Dosing

Animals were fasted overnight before dosing. The following day the required number of animals was selected and tail marked for identification. The test article was administered as a single oral dose, by gavage. Animal 11M was dosed using a rubber catheter attached to a syringe. Due to its viscosity, the formulated test article proved difficult to administer using this method and a metal cannula was used to dose the remaining animals. Access to food was permitted immediately after dosing.

4.8 Clinical observations

All animals were examined shortly after dosing, approximately 30 minutes, one, 2 and 4 hours after dosing and daily for 14 consecutive days.

4.9 Bodyweight

On the day of dosing all animals were weighed in order to calculate the amount of test article to be administered. They were weighed again on day 8 and on day 15.

4.10 Necropsy

Animals were weighed and then killed by carbon dioxide asphyxiation after the 14 day observation period. All animals were necropsied to include the opening of the thoracic and visceral cavities; opening and examination of the stomach and representative sections of the gastro-intestinal tract and examination of the major organs.

5.0 RESULTS

5.1 Mortality and clinical signs

There were no deaths during the study.

All animals remained unremarkable throughout the study.

5.2 Bodyweight (Appendix 1)

Bodyweight gains for both male and females were considered to be normal for rats of this strain and age.

5.3 Necropsy (Appendix 2)

The incidence of thymic and submandibular lymph node enlargement is considered, along with the other necropsy findings, to be consistent with the background macroscopic pathology of this strain of rat.

6.0 CONCLUSION

(b)(4) , when administered orally at a dose level of 2000mg/kg, had a median lethal dose in excess of 2000mg/kg and it is considered to be non-toxic acutely.

Dose level mg/kg	Animal Number/sex	Bodyweight (g) on Day			Change in bodyweight Day 1 - 15
		1	8	15	
2000	11M	112	184	234	122
	12M	104	177	239	135
	13M	113	192	262	149
	14M	114	200	266	152
	15M	113	185	249	136
	MEAN	111	188	250	139
	S.D.	4.1	8.7	13.9	12.1
2000	16F	123	172	186	63
	17F	115	164	175	60
	18F	122	188	223	101
	19F	121	180	204	83
	20F	124	186	211	87
	MEAN	121	178	200	79
	S.D.	3.5	10.0	19.3	17.2

Dose level mg/kg	Animal number/sex	Tissue/organ	Observation
2000	11M		No abnormalities noted
	12M	Submandibular lymph nodes Thymus	Enlarged, up to 10x5x3mm Enlarged. Reddened area 5x2mm on left lobe
	13M		No abnormalities noted
	14M	Submandibular lymph nodes Thymus Urinary bladder	Enlarged, up to 13x10x3mm Enlarged Distended with fluid
	15M	Submandibular lymph nodes Thymus Urinary bladder	Enlarged, up to 10x7x2mm Enlarged Contained white waxy plug
	16F		No abnormalities noted
	17F		No abnormalities noted
	18F	Submandibular lymph nodes Thymus	Enlarged, up to 12x5x3mm Enlarged. Contained moderately reddened foci
	19F	Uterus	Moderately distended with fluid
	20F	Submandibular lymph nodes	Enlarged, up to 11x6x2mm

SPECIAL QUALITY CONTROL OF
SMALL ANIMAL DIETS

SDS

Special Diets Services

CERTIFICATE OF ANALYSIS

PRODUCT: R/M (E) SQ

BATCH NO: 5785

PREMIX BATCH NO: F913

DATE OF MANUFACTURE: 10-FEB-91

Nutrient	Found Analysis		Contaminant	Found Analysis		Limit of Detection
Moisture	11.2	%	Fluoride	13	mg/kg	1.0 mg/kg
Crude Fat	3.3	%	Nitrate as NaNO3	5	mg/kg	1.0 mg/kg
Crude Protein	15.9	%	Nitrite as NaNO2	2.1	mg/kg	1.0 mg/kg
Crude Fibre	3.0	%	Lead	0.75	mg/kg	0.25 mg/kg
Ash	4.9	%	Arsenic	Non Detected	mg/kg	0.2 mg/kg
Calcium	0.85	%	Cadmium	0.10	mg/kg	0.05 mg/kg
Phosphorus	0.59	%	Mercury	Non Detected	mg/kg	0.01 mg/kg
Sodium	0.27	%	Selenium	0.07	mg/kg	0.05 mg/kg
Chloride	0.37	%				
Potassium	9.74	%				
Magnesium	0.16	%	Total Aflatoxins	Non Detected	mcg/kg	1 mcg/kg each of B1, B2, G1, G2
Iron	145	mg/kg				
Copper	9	mg/kg	Total P.C.B	Non Detected	mcg/kg	10.0 mcg/kg
Manganese	56	mg/kg	Total D.O.T	Non Detected	mcg/kg	1.0 mcg/kg
Zinc	40	mg/kg	Dieldrin	Non Detected	mcg/kg	1.0 mcg/kg
			Lindane	Non Detected	mcg/kg	1.0 mcg/kg
			Heptachlor	Non Detected	mcg/kg	1.0 mcg/kg
			Malathion	Non Detected	mcg/kg	20.0 mcg/kg
Vitamin A	2.7	iu/g	Total Viable Organisms x 1000	Non Detected	per gm	1000/g
Vitamin E	66	mg/kg				
Vitamin C		mg/kg	Mesophilic Spores x 100	Non Detected	per gm	100/g
			Salmonellae Species	Non Detected	per gm	Absent in 20 gm
			Presumptive E.coli	Non Detected	per gm	Absent in 20 gm
			E.coli Type 1	Non Detected	per gm	Absent in 20 gm
			Fungal Units	Non Detected	per gm	Absent in 20 gm
			Antibiotic Activity	Non Detected		

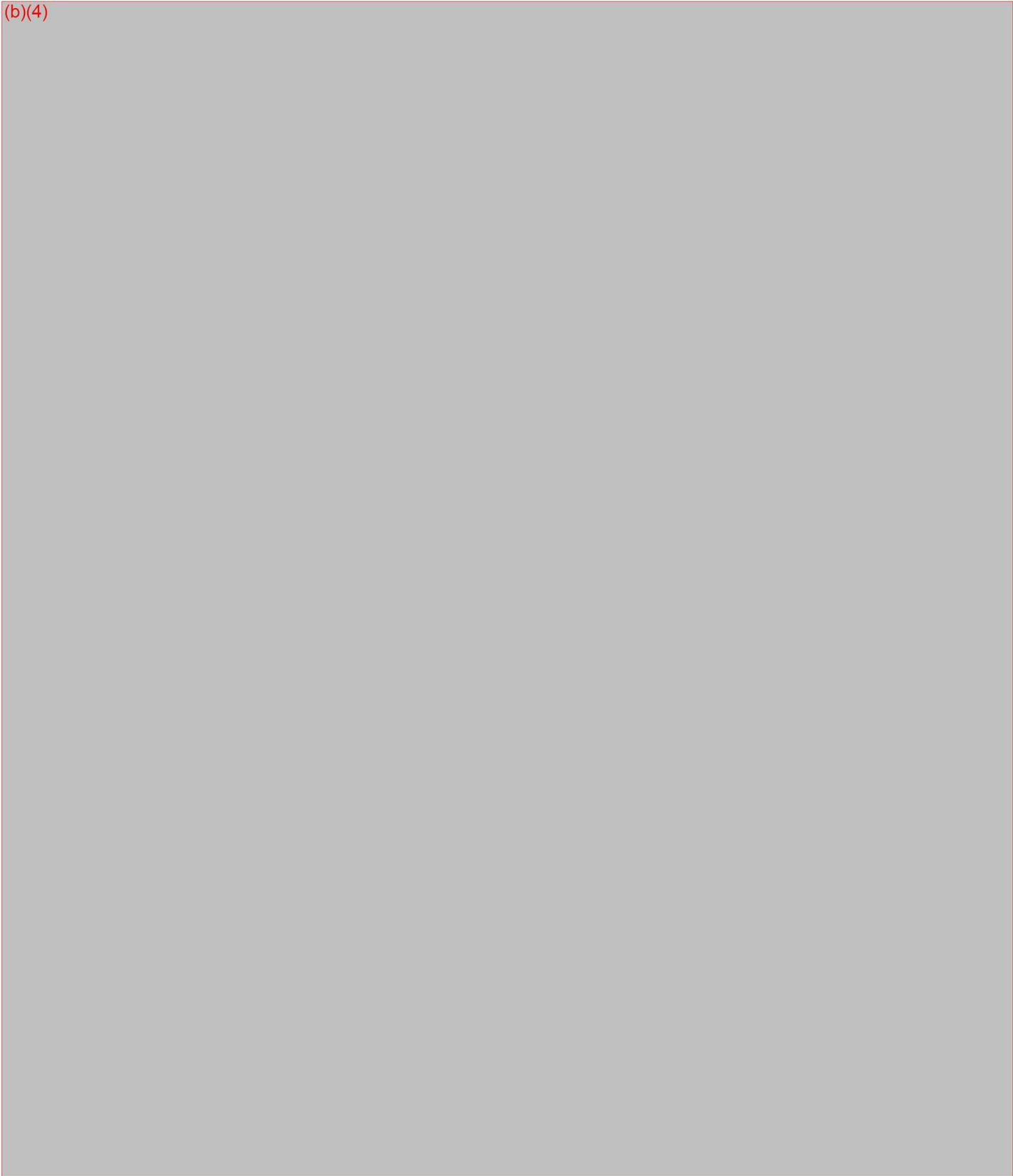
(b)(4)

Signed
Dated 4/3/91

(b)(4)



(b)(4)



(b)(4)

Biocompatibility Information

Testing for Mutagenic Activity

CONFIDENTIAL

(b)(4)

Report No. 9980

(b)(4)

BATCH NO. 00013365

TESTING FOR MUTAGENIC ACTIVITY WITH *Salmonella typhimurium*

TA 1535, TA 1537, TA 1538, TA 98 AND TA 100

(b)(4)

Author:

(b)(4)

Sponsor:

(b)(4)

Performing Laboratory:

(b)(4)

Total Number of Pages: 51

072

(b)(4)

2

AUTHENTICATION

'I, the undersigned, hereby declare that this work was performed under my direction and in accordance with the principles of Good Laboratory Practice. The study was conducted according to the procedures herein described and this report represents a true and accurate record of the results obtained.'

(b)(4)

Study Director

Date:

ISSUED

- 9 JUN 1994

(b)(4)

Report No. 9980

- 073

(b)(4)

QUALITY ASSURANCE STATEMENT

The execution of this type of short-term study is not individually inspected. The processes involved are inspected at intervals according to a predetermined schedule.

This report has been audited by (b)(4) Quality Assurance Personnel according to the appropriate Standard Operating Procedure and is considered to describe the methods and procedures used in the study. The reported results accurately reflect the original data of the study.

(b)(4)

(b)(4)

Signed: (b)(4)
U (Quality Assurance)

Date: 2nd June 1994

(b)(4)

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076

(b)(4)

PERSONNEL INVOLVED IN PROJECT (b)(4)

Study Director/Project Leader:

(b)(4)

Technical Assistance:

Quality Assurance:

(b)(4)

7

SUMMARY

(b)(4) was tested for mutagenic activity in *Salmonella typhimurium* strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 at concentrations ranging from 2.08 to 625 μg per plate.

The tests were conducted on agar plates in the presence and absence of an Aroclor 1254 induced rat liver preparation and co-factors (S9 mix) required for mixed-function oxidase activity.

Concurrent positive controls demonstrated the sensitivity of the assay and the metabolising activity of the S9 mix.

The results obtained in all experiments were very similar.

No mutagenic activity was noted, in any of the 5 bacterial strains used, in any condition.

There was no precipitation of the test material and no toxicity to the bacteria was observed.

It was concluded that (b)(4) was not mutagenic to *Salmonella typhimurium* when tested to the limit of its solubility in sterile ultra-pure water.

078

(b)(4)

8

INTRODUCTION

The purpose of this study was to establish the potential of (b)(4) to induce gene mutation in the bacterium *Salmonella typhimurium*, causing the histidine-dependent strains to revert to the wild-type phenotype. The particular damage induced to DNA by a mutagen may cause reversions to occur which are observable in certain strains of *Salmonella typhimurium*, but not in others. It is necessary, therefore, to use a variety of bacterial strains in order to test for a broad range of chemical mutagens. At the present time, available data suggest that the use of the 5 strains used in this project permits the detection of a wide spectrum of mutagens.

It is well recognised, however, that many chemicals which may be reactive in a mammalian cell, following metabolic activation, are quite inactive in bacterial cells. Extracts of mammalian cells are combined, therefore, with the bacterial indicator cells in a tissue mediated assay to increase the relevance of the test in assessing the mutagenicity of chemicals to man.

The methods used in this study conform to OECD Guideline No. 471.

This report describes the methods used and the results obtained in tests carried out at the

(b)(4)

Key dates in the conduct of the study:

Study Initiation:	24 May 1993
Experimental Start Date:	1 September 1993
Experimental Completion Date:	12 October 1993

079

(b)(4)

9

Study Completion Date:

Please see Authentication page for date of Study Director's signature (Final reports only).

All data generated and recorded during this study, including a copy of the final report, will be stored in the Scientific Archives of (b)(4) for 5 years after issue of the final report. At the end of the 5 year period the Sponsor will be consulted regarding the disposal or continued storage of raw data.

080

(b)(4)

10

EXPERIMENTAL PROCEDURE

The procedures used are based on the method of Ames *et al* (1975). Aseptic techniques were used throughout.

MATERIALSTest Substance

(b)(4) Batch No. 00013365, (b)(4), was received from (b)(4) on 28 July 1993 and was stored in the dark at ambient temperature.

Positive Controls

Positive control substances used were 2-aminoanthracene (2-AAN) (Lot No. 33F-0816) from the Sigma Chemical Company Limited, Poole, Dorset, England; sodium azide (NaN_3) (Lot No. 6529052) from BDH Limited, Poole, Dorset, England; 9-aminoacridine (9-AA) (Lot No. N333JE) and 2-nitrofluorene (2-NF) (Lot No. A3A) from IIT Research Institute, Chicago, Illinois 60616, USA.

The positive control substances, except sodium azide, were dissolved in dimethylsulphoxide ('AnalaR' grade from BDH Limited, Poole, Dorset, England). Sodium azide was dissolved in sterile, ultra-pure water.

Vehicle Control

Sterile ultra-pure water was included as the vehicle control.

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(b)(4)

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Test Solution

(b)(4) was dissolved and diluted in sterile ultra-pure water. (b)(4) formed very viscous solutions and the highest concentration of test solution used ($6250 \mu\text{g}\cdot\text{ml}^{-1}$) was dosed using wide-bore tips.

Inducer

The polychlorinated biphenyl mixture, Aroclor 1254, was obtained from Monsanto (UK) Limited, Newport, Wales.

Agar Plates

The Vogel-Bonner Medium E agar plates with 2% glucose used in the Ames test were prepared in-house using BBL purified agar obtained from Becton Dickinson Limited, Oxford, England.

Animals

Male Fischer 344 rats were obtained from Charles River (UK) Limited, Margate, Kent.

Bacteria

Five strains of *Salmonella typhimurium* were used:

S. typhimurium TA 1535

S. typhimurium TA 1537

S. typhimurium TA 1538

S. typhimurium TA 98

S. typhimurium TA 100

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(b)(4)

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They were obtained in 1976 from Professor B N Ames, Department of Biochemistry, University of California, Berkeley, CA, USA, and stored in liquid nitrogen since that time until used.

All these strains contain mutations in the histidine operon, thereby imposing a requirement for histidine in the growth medium. Three mutations in the histidine operon are involved:

his G 46 in TA 1535 and TA 100

his C 3076 in TA 1537

his D 3052 in TA 1538 and TA 98

his G 46 is a mis-sense mutation which is reverted to prototrophy by a variety of mutagens that cause base-pair substitutions.

his C 3076 contains a frameshift mutation which appears to have added a $\begin{matrix} -G- \\ -C- \end{matrix}$ base-pair resulting in $\begin{matrix} -GGGG- \\ -CCCC- \end{matrix}$. This mutation is reverted by 9-aminoacridine, ICR-191 and epoxides of polycyclic hydrocarbons.

his D 3052 also contains a frameshift mutation with the sequence $\begin{matrix} -CGCGCG- \\ -GCGCGC- \end{matrix}$ which is reverted with the deletion of 2 base-pairs, $\begin{matrix} -CG- \\ -GC- \end{matrix}$. It is readily reverted by aromatic amines and derivatives.

All 5 strains contain the deep rough (*rfa*) mutation, which deletes the polysaccharide side chain of the lipopolysaccharide coat of the bacterial cell surface. This deletion increases cell permeability to more hydrophobic substances and, furthermore, greatly decreases the pathogenicity of these organisms.

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(b)(4)

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The second deletion, through *uvrB*, renders the organisms incapable of DNA excision repair and thus more susceptible to mutagenicity. These 2 deletions include the nitrate reductase (*chl*) and biotin (*bio*) genes also.

Differences between TA 1535 and TA 1538, on the one hand, and the corresponding TA 100 and TA 98 strains, on the other hand, are due to a plasmid the latter pair contains. A plasmid, R-Utrecht (pKM101), was originally shown to increase the sensitivity of the *his G 46* mutation in *S. typhimurium* to methyl methanesulphonate and trimethyl phosphate. The particular R-factor in TA 100 and TA 98 (pKM101) carries resistance to ampicillin. It is not yet clear why the presence of this particular R-factor should increase the sensitivity of strains TA 1535 and TA 1538 to the mutagenicity of certain chemicals. The involvement of an error-prone repair mechanism has been postulated.

METHODS

Preparation of the Metabolic Activation System

Animals

Male Fischer 344 rats (average weight 252 g) were injected once intraperitoneally with Aroclor 1254 (diluted in corn oil to a concentration of 200 mg.ml⁻¹) at a dosage of 500 mg.kg⁻¹. They were allowed drinking water continuously, but food was withheld for 16 h before they were killed in an atmosphere of carbon dioxide 5 days after injection.

Preparation of 9,000 g Supernatant Fluid (S9 Mix) from Livers

Freshly killed animals were totally immersed in cold 2% Tego (an ampholytic detergent), then excess fluid was wiped off. The abdomen was opened and the

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(b)(4)

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liver removed, taking special care not to cut the gastro-intestinal tract. Livers from several animals were collected in a tared beaker containing ice-cold 0.15 M KCl.

The beaker was weighed and the livers transferred to the homogenisation vessel. A volume of ice-cold 0.15 M KCl equivalent to 3 times the weight of the liver was added to the vessel and the livers chopped using long-handled scissors and homogenised by 8 strokes of a glass tube vessel while the Teflon pestle (radial clearance 0.14-0.15 mm) rotated at about 1,200 r.p.m. The homogenate was transferred to sterile polypropylene centrifuge tubes and spun at a relative centrifugal force of 9,000 g for 10 min at 0° to +2°C. The supernatant fluid was decanted leaving behind a thick pellet of (mainly) whole cells, nuclei and mitochondria.

Post-mitochondrial supernatant fluid was prepared in sufficient quantity for the experiment and stored, as 2 ml and 5 ml samples in sterile plastic tubes, immersed in liquid nitrogen (-196°C).

Enzyme Properties of the 9,000 g Supernatant Fluid

Details of the batch of S9 mix used in the mutation experiments are shown in Appendix 21 together with responses from positive control pre-mutagens in the Ames test using *S. typhimurium* strain TA 1538.

Preparation of S9 Mix

Ice-cold 0.05 M phosphate buffer, pH 7.4, was added to the following pre-weighed reagents to give final concentrations in S9 mix of:

NADP di-Na salt

4 mM (= 3.150 mg.ml⁻¹)

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(b)(4)

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Glucose-6-phosphate di-Na salt	25 mM (= 7.605 mg.ml ⁻¹)
MgCl ₂ .6H ₂ O	8 mM (= 1.626 mg.ml ⁻¹)
KCl	33 mM (= 2.460 mg.ml ⁻¹)

This solution was immediately filter-sterilised by passage through a 0.45 µm Millipore filter and mixed with the liver 9,000 g supernatant fluid in the following proportion:

co-factor solution	9 parts
liver preparation	1 part

This combination of co-factors and liver preparation was called the S9 mix.

Preparation of Bacteria

Samples of each strain were grown by culturing for 16 h at 37°C in nutrient broth (25 g Oxoid Nutrient Broth No. 2.litre⁻¹). These cultures were kept for up to 2 days at +4°C to allow relevant checks to be performed but fresh cultures were used for the experiments.

Preparation of the Assay Plates

Diluted agar (0.6% Difco Bacto-agar, 0.6% NaCl) was autoclaved and, just before use, 5 ml of sterile 1.0 mM L-histidine.HCl, 1.0 mM biotin solution was added to each 100 ml of soft agar and thoroughly mixed. This molten agar, maintained in a water bath at 45°C, was dispensed in 2 ml volumes into small sterile tubes to which were added in order:

- 0.5 ml S9 mix or 0.05 M phosphate buffer, pH 7.4
- 0.1 ml bacteria (ca 2 x 10⁹ cells.ml⁻¹)

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(b)(4)

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0.1 ml solvent or test solution

The tube contents, which were continually cooling, were mixed and then poured in minimal medium plates prepared in-house. These plates contained 25 ml of 1.5% BBL purified agar in Vogel-Bonner Medium E (Vogel *et al* (1956)) with 2% glucose. When the soft agar had set, the plates were inverted and incubated at 37°C for 2 days whereupon colonies were counted using a Biotran III automated counter (New Brunswick Incorporated, NJ, USA) at maximum sensitivity ie colonies of 0.1 mm or more in diameter counted. The plates were also examined for precipitates and, microscopically, for microcolony growth.

Toxicity Test

A toxicity test using strain TA 100 only was performed in the presence and absence of S9 mix to establish suitable dose levels for the mutation tests. One plate of each of the following concentrations of (b)(4) was used:

2.08 µg, 6.25 µg, 20.83 µg, 62.5 µg, 208.3 µg and 625 µg.plate⁻¹

Mutation Tests

Two independent mutation tests were conducted using 5 bacterial strains (TA 1535, TA 1537, TA 1538, TA 98 and TA 100). The dose levels used in both of these experiments and selected on the basis of the results of the toxicity test, were 2.08 µg, 6.25 µg, 20.83 µg, 62.5 µg, 208.3 µg and 625 µg per plate.

Triplicate plates were prepared for each bacterial strain and dose level in both the presence and absence of S9 mix.

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(b)(4)

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Quality Control

At the times that the experiments were conducted, each strain was tested for its resistance to ampicillin (indicating the presence of pKM101) and sensitivity to ultraviolet (u.v.) light and crystal violet (indicating persistence of the *uvrB* and *rfa* mutations). In addition, the following control groups were established, triplicate plates being poured for each mean datum point.

1. Sterile ultra-pure water, 0.1 ml per plate, used as the test compound vehicle, in both the presence and the absence of S9 mix.

2. With S9 Mix

2-Aminoanthracene (2-AAN), 2 μg per plate with TA 1535 and TA 1537 and 0.5 μg per plate with TA 1538, TA 98 and TA 100, used to demonstrate activity of the S9 mix and the mutability of the bacteria.

3. Without S9 Mix

Sodium azide (NaN_3), 1 μg per plate, with TA 1535 and TA 100;
2-nitrofluorene (2-NF), 1 μg per plate, with TA 1538 and TA 98;
9-aminoacridine (9-AA), 80 μg per plate, with TA 1537. These substances served as an aid to strain identification and to demonstrate the mutability of the bacteria.

Evaluation of Results

A test was considered acceptable if for each strain:

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- i) the bacteria demonstrated their typical responses to crystal violet, ampicillin and u.v. light.
- ii) at least 2 of the vehicle control plates were within the following ranges: TA 1535, 4-30; TA 1537, 1-20; TA 98, 10-60; TA 100, 60-200 and TA 1538, 5-35.
- iii) on at least 2 of the positive control plates there were $\times 2$ the mean vehicle control mutant numbers per plate, or in the case of TA 100, $\times 1.5$ the mean vehicle control mutant numbers per plate.

If the mean colony count on the vehicle control plates was less than 10 then a value of 10 was assumed for assessment purposes. In such cases a minimum count of 20 was required on at least 2 of the positive control plates.

- iv) no toxicity or contamination was observed in at least 4 dose levels.
- v) in cases where a mutagenic response was observed, that no more than one dose level was discarded before the dose which gave the highest significant mean colony number.

Where these criteria were met, a significant mutagenic response was recorded if there was:

- i) for *S. typhimurium* strains TA 1535, TA 1537, TA 1538 and TA 98, at least a doubling of the mean concurrent vehicle control values at some concentration of the test substances and, for *S. typhimurium* strain TA 100, a 1.5-fold increase over the control value. If the mean colony count on the vehicle control plates was less than 10 then a value of 10 was assumed for

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assessment purposes. In such cases a minimum count of 20 was required before a significant mutagenic response was identified.

- ii) a dose related response, although at high dose levels this relationship could be inverted because of, for example, (1) toxicity to the bacteria generally, (2) specific toxicity to the mutants and (3) inhibition of foreign compound metabolising enzymes where mutagens require metabolic activation by the liver.
- iii) a reproducible effect in independent tests.

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RESULTS AND DISCUSSION

Toxicity Test

The results of the toxicity test on (b)(4) are shown in Table 1.

There was no toxicity to the bacteria and no precipitation of the test material occurred.

Mutation Tests

The average numbers of *his*⁺ revertant colonies per dose level obtained in the main tests are shown in Tables 2-7, whilst the individual plate counts are displayed in Appendices 1-20.

Quality Control

All strains of *S. typhimurium* were sensitive to crystal violet, whereas only the plasmid-containing strains, TA 98 and TA 100, were resistant to ampicillin. The strains were also tested for sensitivity to u.v. light emitted over a period of 10 s from a CAMAG u.v. lamp set at 254 nm. Increased sensitivity to u.v. light was demonstrated. These results are consistent with the known properties of these bacteria.

Vehicle Control Groups

The vehicle control values were within the normal ranges experienced in this laboratory and reported in the literature with these strains of *S. typhimurium*.

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(b)(4)

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Positive Control Groups

The results obtained in the positive control groups were within the normal ranges expected for each bacterial strain and activation condition.

Test Rejection

All tests were acceptable according to the study criteria except TA100 in the first experiment where the strain was contaminated.

A successful repeat experiment was performed.

(b)(4)

The results obtained in all experiments were very similar.

There was no mutagenic activity in any of the 5 bacterial strains in any condition.

There was no precipitation of the test material and no toxicity to the bacteria occurred.

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(b)(4)

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CONCLUSION

It was concluded that (b)(4) was not mutagenic to *Salmonella typhimurium* when tested to the limit of its solubility in sterile ultra-pure water.

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(b)(4)

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REFERENCES

Ames B N, McCann J and Yamasaki E (1975). Methods for detecting carcinogens and mutagens with the *Salmonella*/mammalian microsome mutagenicity test. *Mutation Res*, 31, 347-364.

Vogel H J and Bonner D M (1956). Acetylornithinase of *E. coli*: partial purification and some properties. *J Biol Chem*, 218, 97-106.

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(b)(4)

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TABLE 1

Preliminary Study with *S. typhimurium* Strain TA 100 Showing Number of *his*⁺ Revertant Colonies Counted per Plate

Substance	Dose Level (μg per plate)	TA 100	
		with S9	without S9
Sterile ultra-pure water	100 μl	102	78
(b)(4)	2.08	113	85
	6.25	118	93
	20.83	127	104
	62.5	126	94
	208.3	101	102
	625	122	90

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(b)(4)

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TABLE 2

Test 1

Mean Numbers of *his*⁺ Revertant Colonies Obtained when 5 Strains of *S. typhimurium* were Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix) from the Livers of Male Rats Treated with Aroclor 1254 (FLI 073)

Substance	Dose Level (μg per plate)	TA 1535	TA 1537	TA 1538	TA 98	TA 100†
		Mean \pm SD				
Sterile ultra-pure water	100 μt	17 \pm 5	15 \pm 1	31 \pm 2	42 \pm 5	-
2-Aminoanthracene	0.5	-	-	419 \pm 56	404 \pm 49	-
	2	149 \pm 13	135 \pm 8	-	-	-
(b)(4)	2.08	17 \pm 2	18 \pm 2	32 \pm 4	45 \pm 4	-
	6.25	22 \pm 3	18 \pm 1	35 \pm 3	45 \pm 5	-
	20.83	16 \pm 4	15 \pm 2	33 \pm 3	42 \pm 5	-
	62.5	18 \pm 1	16 \pm 2	37 \pm 3	38 \pm 8	-
	208.3	17 \pm 2	16 \pm 3	39 \pm 5	39 \pm 10	-
	625	15 \pm 3	17 \pm 1	31 \pm 8	41 \pm 7	-

SD = Standard deviation

† = Strain contaminated

Note = The means values were calculated from triplicate plate counts except TA 1535 at 62.5 μg per plate where duplicate plates were used.

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(b)(4)

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TABLE 3

Test 1
 Mean Numbers of his⁺ Revertant Colonies Obtained when 5 Strains of *S. typhimurium*
 were Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μg per plate)	TA 1535	TA 1537	TA 1538	TA 98	TA 100 †
		Mean \pm SD				
Sterile ultra- pure water	100 μl	19 \pm 9	17 \pm 2	30 \pm 4	37 \pm 8	-
Sodium Azide	1	171 \pm 16	-	-	-	-
9-Aminoacridine	80	-	1095 \pm 50	-	-	-
2-Nitrofluorene	1	-	-	244 \pm 19	243 \pm 25	-
(b)(4)	2.08	16 \pm 5	17 \pm 1	31 \pm 3	38 \pm 6	-
	6.25	20 \pm 6	16 \pm 1	30 \pm 2	29 \pm 7	-
	20.83	22 \pm 4	16 \pm 2	28 \pm 6	35 \pm 3	-
	62.5	16 \pm 2	17 \pm 1	37 \pm 4	41 \pm 5	-
	208.3	23 \pm 7	15 \pm 2	32 \pm 4	37 \pm 5	-
	625	19 \pm 4	17 \pm 2	31 \pm 6	38 \pm 4	-

SD = Standard deviation
 † = Strain contaminated
 Note = The mean values were calculated from triplicate plate counts

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(b)(4)

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TABLE 4

Test 2

Mean Numbers of *his*⁺ Revertant Colonies Obtained when 5 Strains of *S. typhimurium* were Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix) from the Livers of Male Rats Treated with Aroclor 1254 (FLI 073)

Substance	Dose Level (μ g per plate)	TA 1535	TA 1537	TA 1538	TA 98	TA 100
		Mean \pm SD				
Sterile ultra-pure water	100 μ l	17 \pm 2	16 \pm 2	24 \pm 3	35 \pm 2	113 \pm 8
2-Aminoanthracene	0.5	-	-	222 \pm 12	213 \pm 7	450 \pm 12
	2	119 \pm 19	122 \pm 4	-	-	-
(b)(4)	2.08	15 \pm 1	16 \pm 2	24 \pm 3	34 \pm 1	117 \pm 1
	6.25	17 \pm 3	17 \pm 2	21 \pm 2	35 \pm 1	117 \pm 4
	20.83	16 \pm 4	16 \pm 2	23 \pm 2	36 \pm 3	117 \pm 1
	62.5	19 \pm 3	16 \pm 2	24 \pm 2	34 \pm 2	110 \pm 2
	208.3	17 \pm 2	15 \pm 1	24 \pm 3	35 \pm 4	108 \pm 2
	625	15 \pm 1	16 \pm 3	21 \pm 2	33 \pm 3	110 \pm 5

SD = Standard deviation
 Note = The mean values were calculated from triplicate plate counts

098

(b)(4)

28

TABLE 5

Test 2
 Mean Numbers of *his*⁺ Revertant Colonies Obtained when 5 Strains of *S. typhimurium*
 were Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μ g per plate)	TA 1535	TA 1537	TA 1538	TA 98	TA 100
		Mean \pm SD				
Sterile ultra- pure water	100 μ l	17 \pm 2	17 \pm 3	29 \pm 1	37 \pm 2	111 \pm 13
Sodium Azide	1	163 \pm 6	-	-	-	613 \pm 30
9-Aminoacridine	80	-	1026 \pm 10	-	-	-
2-Nitrofluorene	1	-	-	234 \pm 8	218 \pm 3	-
(b)(4)	2.08	19 \pm 2	19 \pm 2	28 \pm 2	38 \pm 1	119 \pm 12
	6.25	17 \pm 1	16 \pm 2	29 \pm 1	38 \pm 2	106 \pm 3
	20.83	16 \pm 2	15 \pm 2	28 \pm 2	36 \pm 2	115 \pm 6
	62.5	16 \pm 3	16 \pm 1	26 \pm 1	36 \pm 3	105 \pm 1
	208.3	20 \pm 1	17 \pm 3	23 \pm 2	39 \pm 1	110 \pm 2
	625	19 \pm 1	16 \pm 2	25 \pm 4	36 \pm 1	102 \pm 9

SD = Standard deviation
 Note = The mean values were calculated from triplicate plate counts

099

(b)(4)

29

TABLE 6

Test 3

Mean Numbers of *his*⁺ Revertant Colonies Obtained when 1 Strain of *S. typhimurium* was Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix) from the Livers of Male Rats Treated with Aroclor 1254 (Fl: 073)

Substance	Dose Level (μ g per plate)	TA 100
		Mean \pm SD
Sterile ultra-pure water	100 μ l	114 \pm 4
2-Aminoanthracene	0.5	413 \pm 33
(b)(4)	2.08	113 \pm 2
	6.25	108 \pm 4
	20.83	113 \pm 1
	62.5	108 \pm 4
	208.3	109 \pm 8
	625	110 \pm 2

SD = Standard deviation

Note = The mean values were calculated from triplicate plate counts

100

(b)(4)

30

TABLE 7

Test 3
 Mean Numbers of *his*⁺ Revertant Colonies Obtained when 1 Strain of *S. typhimurium*
 was Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μ g per plate)	TA 100
		Mean \pm SD
Sterile ultra- pure water	100 μ l	99 \pm 2
Sodium Azide	1	632 \pm 18
(b)(4)	2.08	102 \pm 4
	6.25	99 \pm 2
	20.83	98 \pm 5
	62.5	105 \pm 3
	208.3	109 \pm 3
	625	110 \pm 2

SD = Standard deviation

Note = The mean values were calculated from triplicate plate counts

101

(b)(4)

31

APPENDIX 1

Test 1

Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1535 was Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix) from the Livers of Male Rats Treated with Aroclor 1254 (FLI 073)

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	12	17	22	17 \pm 5
2-Aminoanthracene	2	161	149	136	149 \pm 13
(b)(4)	2.08	17	19	16	17 \pm 2
	6.25	23	24	19	22 \pm 3
	20.83	14	20	13	16 \pm 4
	62.5	c	18	19	18 \pm 1
	208.3	15	17	19	17 \pm 2
	625	17	12	15	15 \pm 3

SD = Standard deviation

c = Contamination

102

(b)(4)

APPENDIX 2

Test 1
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1537
 was Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix)
 from the Livers of Male Rats Treated with Aroclor 1254 (FLI 073)

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	14	16	16	15 \pm 1
2-Aminoanthracene	2	138	141	126	135 \pm 8
(b)(4)	2.08	19	16	18	18 \pm 2
	6.25	17	18	18	18 \pm 1
	20.83	16	13	15	15 \pm 2
	62.5	14	16	18	16 \pm 2
	208.3	13	15	19	16 \pm 3
	625	18	17	16	17 \pm 1

SD = Standard deviation

(b)(4)

33

APPENDIX 3

Test 1

Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1538 was Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix) from the Livers of Male Rats Treated with Aroclor 1254 (FLI 073)

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	31	30	33	31 \pm 2
2-Aminoanthracene	0.5	477	366	413	419 \pm 56
(b)(4)	2.08	36	31	29	32 \pm 4
	6.25	37	32	37	35 \pm 3
	20.83	33	30	35	33 \pm 3
	62.5	35	35	41	37 \pm 3
	208.3	39	34	44	39 \pm 5
	625	23	33	38	31 \pm 8

SD = Standard deviation

(b)(4)

34

APPENDIX 4

Test 1
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 98
 was Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix)
 from the Livers of Male Rats Treated with Aroclor 1254 (FL1 073)

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	46	36	43	42 \pm 5
2-Aminoanthracene	0.5	458	363	390	404 \pm 49
(b)(4)	2.08	49	42	43	45 \pm 4
	6.25	50	41	44	45 \pm 5
	20.83	47	42	38	42 \pm 5
	62.5	45	30	40	38 \pm 8
	208.3	29	49	39	39 \pm 10
	625	47	43	34	41 \pm 7

SD = Standard deviation

105

(b)(4)

35

APPENDIX 5

Test 1

Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1535 was Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	28	11	18	19 \pm 9
Sodium Azide	1	189	159	166	171 \pm 16
(b)(4)	2.08	10	18	19	16 \pm 5
	6.25	25	14	22	20 \pm 6
	20.83	19	27	21	22 \pm 4
	62.5	18	14	15	16 \pm 2
	208.3	21	30	17	23 \pm 7
	625	16	17	24	19 \pm 4

SD = Standard deviation

106

(b)(4)

36

APPENDIX 6

Test 1
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1537
 was Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	16	19	17	17 \pm 2
9-Aminoacridine	80	1038	1132	1116	1095 \pm 50
(b)(4)	2.08	17	18	17	17 \pm 1
	6.25	16	17	15	16 \pm 1
	20.83	16	14	18	16 \pm 2
	62.5	16	18	18	17 \pm 1
	208.3	15	13	16	15 \pm 2
	625	16	16	19	17 \pm 2

SD = Standard deviation

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(b)(4)

37

APPENDIX 7

Test 1
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1538
 was Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	35	29	27	30 \pm 4
2-Nitrofluorene	1	255	255	222	244 \pm 19
(b)(4)	2.08	29	30	35	31 \pm 3
	6.25	30	32	28	30 \pm 2
	20.83	32	30	21	28 \pm 6
	62.5	40	39	33	37 \pm 4
	208.3	28	33	35	32 \pm 4
	625	37	31	25	31 \pm 6

SD = Standard deviation

(b)(4)

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APPENDIX B

Test 1
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 98
 was Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	40	43	28	37 \pm 8
2-Nitrofluorene	1	261	214	254	243 \pm 25
(b)(4)	2.08	44	37	32	38 \pm 6
	6.25	32	33	21	29 \pm 7
	20.83	34	38	33	35 \pm 3
	62.5	45	36	41	41 \pm 5
	208.3	41	39	31	37 \pm 5
	625	35	36	43	38 \pm 4

SD = Standard deviation

109

(b)(4)

39

APPENDIX 9

Test 2

Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1535 was Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix) from the Livers of Male Rats Treated with Aroclor 1254 (FL 073)

Substance	Dose Level (μg per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μl	15	19	16	17 \pm 2
2-Aminoanthracene	2	99	122	136	119 \pm 19
(b)(4)	2.08	15	14	16	15 \pm 1
	6.25	19	19	14	17 \pm 3
	20.83	13	15	21	16 \pm 4
	62.5	19	16	21	19 \pm 3
	208.3	15	16	19	17 \pm 2
	625	16	14	16	15 \pm 1

SD = Standard deviation

110

(b)(4)

40

APPENDIX 10

Test 2
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1537
 was Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix)
 from the Livers of Male Rats Treated with Aroclor 1254 (FLI 073)

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	15	19	15	16 \pm 2
2-Aminanthracene	2	121	126	118	122 \pm 4
(b)(4)	2.08	16	14	17	16 \pm 2
	6.25	15	19	16	17 \pm 2
	20.83	17	17	14	16 \pm 2
	62.5	17	14	17	16 \pm 2
	208.3	16	15	14	15 \pm 1
	625	13	19	15	16 \pm 3

SD = Standard deviation

111

(b)(4)

41

APPENDIX 11

Test 2

Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1538 was Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (59 Mix) from the Livers of Male Rats Treated with Aroclor 1254 (FL1 073)

Substance	Dose Level (μg per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μl	25	27	21	24 \pm 3
2-Aminoanthracene	0.5	208	226	231	222 \pm 12
(b)(4)	2.08	21	26	25	24 \pm 3
	6.25	20	21	23	21 \pm 2
	20.83	25	23	21	23 \pm 2
	62.5	24	26	23	24 \pm 2
	208.3	21	26	24	24 \pm 3
	625	23	20	21	21 \pm 2

SD = Standard deviation

(b)(4)

42

APPENDIX 12

Test 2
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 98
 was Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix)
 from the Livers of Male Rats Treated with Aroclor 1254 (FLI 073)

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	33	35	36	35 \pm 2
2-Aminoanthracene	0.5	221	208	210	213 \pm 7
(b)(4)	2.08	33	35	33	34 \pm 1
	6.25	36	35	34	35 \pm 1
	20.83	33	35	39	36 \pm 3
	62.5	34	33	36	34 \pm 2
	208.3	36	39	31	35 \pm 4
	625	30	33	35	33 \pm 3

SD = Standard deviation

113

(b)(4)

43

APPENDIX 13

Test 2
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 100
 was Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix)
 from the Livers of Male Rats Treated with Aroclor 1254 (FLI 073)

Substance	Dose Level (μg per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μl	118	116	104	113 \pm 8
2-Aminoanthracene	0.5	451	462	438	450 \pm 12
(b)(4)	2.08	116	116	118	117 \pm 1
	6.25	121	116	114	117 \pm 4
	20.83	118	116	116	117 \pm 1
	62.5	108	111	110	110 \pm 2
	208.3	108	110	106	108 \pm 2
	625	104	112	113	110 \pm 5

SD = Standard deviation

114

(b)(4)

44

APPENDIX 14

Test 2
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1535
 was Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	15	16	19	17 \pm 2
Sodium Azide	1	163	158	169	163 \pm 6
(b)(4)	2.08	18	21	19	19 \pm 2
	6.25	18	16	17	17 \pm 1
	20.83	14	17	18	16 \pm 2
	62.5	16	13	18	16 \pm 3
	208.3	19	21	19	20 \pm 1
	625	19	18	20	19 \pm 1

SD = Standard deviation

115

(b)(4)

45

APPENDIX 15

Test 2
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1537
 was Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μg per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μl	19	19	14	17 \pm 3
9-Aminoacridine	80	1019	1022	1038	1026 \pm 10
(b)(4)	2.08	17	19	20	19 \pm 2
	6.25	14	17	18	16 \pm 2
	20.83	14	17	14	15 \pm 2
	62.5	15	16	17	16 \pm 1
	208.3	14	19	17	17 \pm 3
	625	18	14	16	16 \pm 2

SD = Standard deviation

116

(b)(4)

APPENDIX 16

Test 2
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 1538
 was Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	29	30	28	29 \pm 1
2-Nitrofluorene	1	238	225	239	234 \pm 8
(b)(4)	2.08	26	29	30	28 \pm 2
	6.25	28	29	30	29 \pm 1
	20.83	30	26	28	28 \pm 2
	62.5	26	26	25	26 \pm 1
	208.3	21	24	23	23 \pm 2
	625	22	29	24	25 \pm 4

SD = standard deviation

(b)(4)

47

APPENDIX 17

Test 2
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 98
 was Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	35	36	39	37 \pm 2
2-Nitrofluorene	1	221	218	216	218 \pm 3
(b)(4)	2.08	38	38	39	38 \pm 1
	6.25	36	39	40	38 \pm 2
	20.83	38	34	36	36 \pm 2
	62.5	39	34	35	36 \pm 3
	208.3	38	40	39	39 \pm 1
	625	36	35	37	36 \pm 1

SD = Standard deviation

(b)(4)

48

APPENDIX 18

Test 2
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 100
 was Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	103	105	126	111 \pm 13
Sodium Azide	1	648	593	598	613 \pm 30
(b)(4)	2.08	123	129	105	119 \pm 12
	6.25	104	106	109	106 \pm 3
	20.83	121	115	108	115 \pm 6
	62.5	106	105	104	105 \pm 1
	208.3	108	110	111	110 \pm 2
	625	108	106	91	102 \pm 9

SD = Standard deviation

119

(b)(4)

49

APPENDIX 19

Test 3

Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 100 was Treated with (b)(4) in the Presence of a Post-mitochondrial Fraction (S9 Mix) from the Livers of Male Rats Treated with Aroclor 1254 (FL 073)

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	112	118	111	114 \pm 4
2-Aminoanthracene	0.5	451	392	396	413 \pm 33
(b)(4)	2.08	112	112	116	113 \pm 2
	6.25	104	108	112	108 \pm 4
	20.83	114	112	114	113 \pm 1
	62.5	106	112	105	108 \pm 4
	208.3	104	106	118	109 \pm 8
	625	110	108	111	110 \pm 2

SD = Standard deviation

120

(b)(4)

50

APPENDIX 20

Test 3
 Number of *his*⁺ Revertant Colonies per Plate Obtained when *S. typhimurium* Strain TA 100
 was Treated with (b)(4) in the Absence of S9 Mix

Substance	Dose Level (μ g per plate)	Colonies Counted			Mean \pm SD
		Plate 1	Plate 2	Plate 3	
Sterile ultra-pure water	100 μ l	101	98	99	99 \pm 2
Sodium Azide	1	646	638	612	632 \pm 18
(b)(4)	2.08	98	106	102	102 \pm 4
	6.25	99	98	101	99 \pm 2
	20.83	102	93	99	98 \pm 5
	62.5	104	103	108	105 \pm 3
	208.3	112	108	106	109 \pm 3
	625	112	108	109	110 \pm 2

SD = Standard deviation

121



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 09 2008

Kalypto Medical
c/o Mr. John Baun
6393 Oakgreen Avenue
Hastings, MN 55033

Re: K080275

Trade/Device Name: NPD 1000 Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: August 14, 2008
Received: August 15, 2008

Dear Mr. Baun:

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.

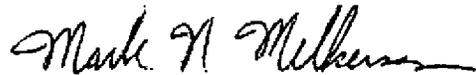
001

Page 2 - Mr. John Baun

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

002

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

July 16, 2008

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

IASIS MEDICAL, INC.
6393 OAKGREEN AVENUE
HASTINGS, MN 55033
ATTN: JOHN BUAN

510(k) Number: K080275
Device: MODEL NPD 1000
NEGATIVE
PRESSURE WOUND
THERAPY SYSTEM

Extended Until: 18-AUG-2008

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(1)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

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

Sincerely yours,

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

K080275



July 15, 2008

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

FDA CDRH DMC

JUL 16 2008

Received

Attn: David Krause, Ph.D.
Chief, Plastic and Reconstructive Surgery Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Re: Kalypto Medical, 510(k) K080275
Request for extension to respond to FDA request for additional information

Dear Dr. Krause,

On June 19, 2008 we received your letter requesting additional information to support our premarket notification submission for the NPD 1000 Negative Pressure Wound Therapy System.

This letter is written to inform you that Kalypto Medical intends to respond to the request for additional information as soon as possible. However, we require an extension past the 30 days specified response time, so that we can have adequate time to obtain biocompatibility data on the super absorbent non-woven polymer matrix, and to compile the information related to cleaning and disinfection of the reusable pump component of the device. Therefore, we request an extension to permit us to respond to the FDA letter on or before August 18, 2008.

If any questions arise in the future, or if you should need to contact us for any reason regarding this 510(k) submission, please contact me at 612-703-1204 or by Fax at 763-287-3836; or at my email address at jbuan@kalyptomedical.com.

Best Regards,

John Buan
Vice President of Product Development

cc: Suzanne Malli, CDRH

K-1

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

June 20, 2008

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

IASIS MEDICAL, INC.
6393 OAKGREEN AVENUE
HASTINGS, MN 55033
ATTN: JOHN BUAN

510(k) Number: K080275
Product: MODEL NPD 1000
NEGATIVE
PRESSURE WOUND
THERAPY SYSTEM

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

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

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

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

Sincerely yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

May 12, 2008

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

IASIS MEDICAL, INC.
6393 OAKGREEN AVENUE
HASTINGS, MN 55033
ATTN: JOHN BUAN

510(k) Number: K080275
Device: MODEL NPD 1000
NEGATIVE
PRESSURE WOUND
THERAPY SYSTEM

Extended Until: 16-JUN-2008

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(1)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

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

Sincerely yours,

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



May 9, 2008

FDA/CDRH/DMC

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

MAY 12 2008

Received

Attn: David Krause, Ph.D.
Chief, Plastic and Reconstructive Surgery Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Re: IASIS Medical, Inc. 510(k) K080275
Request for extension to respond to FDA deficiency letters

Dear Dr. Krause,

On April 17, 2008 we received your letter regarding the predicates referenced in the above listed 510(k), for the NPD 1000 Negative Pressure Wound Therapy System. On April 29, 2008 we received another letter requesting additional information regarding traceability analysis, software validation, Therapy Duration and Pressure Loss prevention tests, patient labeling and usability testing results, shelf life, and product claims.

This letter is written to inform you that IASIS Medical, Inc. (renamed Kalypto Medical, Inc.) intends to respond to the request for additional information as soon as possible. However, we require an extension past the 30 days specified response time, so that we can have adequate time to conduct the requested side by side comparison testing with the predicate devices. Therefore, we request an extension to permit us to respond to the FDA letters on or before June 16, 2008.

If any questions arise in the future, or if you should need to contact us for any reason regarding this 510(k) submission, please contact me at 612-703-1204 or by Fax at 763-287-3836; or at my email address at jbuan@kalyptomedical.com.

Best Regards,


John Buan
Vice President of Product Development

cc: Suzanne Malli, CDRH

709



May 9, 2008

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

Attn: David Krause, Ph.D.
Chief, Plastic and Reconstructive Surgery Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

FDA CDRH DMC

MAY 12 2008

Received

Re: IASIS Medical, Inc. 510(k) K080275
Request for extension to respond to FDA deficiency letters

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Best Regards,

A handwritten signature in black ink that reads "John S. Buan".

John Buan
Vice President of Product Development

cc: Suzanne Malli, CDRH



May 9, 2008

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

Attn: David Krause, Ph.D.
Chief, Plastic and Reconstructive Surgery Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Re: IASIS Medical, Inc. 510(k) K080275
Request for extension to respond to FDA deficiency letters

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If any questions arise in the future, or if you should need to contact us for any reason regarding this 510(k) submission, please contact me at 612-703-1204 or by Fax at 763-287-3836; or at my email address at jbuan@kalyptomedical.com.

Best Regards,

A handwritten signature in black ink that reads "John S. Buan". The signature is written in a cursive style with a large initial "J".

John Buan
Vice President of Product Development

cc: Suzanne Malli, CDRH



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

IASIS Medical, Inc.
% Mr. John Buan
VP of Product Development
6393 Oakgreen Avenue
Hastings, Minnesota 55033

APR 17 2008

Re: K080275
Trade Name: NPD 1000 Negative Pressure Wound Therapy System
Dated: January 31, 2008
Received: February 1, 2008

Dear Mr. Buan:

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

You have identified (K0636⁹72) as a predicate device. This device is powered suction pump capable of providing negative pressure wound therapy to a wound bed. This is done by packing the wound with various foam dressings and removing the wound exudate away into a suction canister. The above referenced predicate device is not an adequate predicate device for your device which is a modified occlusive wound dressing that collects exudate at the wound. The other referenced predicate device, Boehringer Laboratories Suction Pump System (K060277) is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials. This is also not an appropriate predicate device for your device as the intended use is different. FDA is not aware of a predicate device with similar technological characteristics and intended use. If you are aware of a predicate device(s) with technological characteristics and intended uses that you feel are substantially equivalent to your proposed device, please identify such a predicate device(s).

Please be advised that in the case that an appropriate predicate device(s) can be identified, additional deficiencies (including clinical data) may arise as a result of a more thorough review of the materials included as part of your 510(k) submission.

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.

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Page 2 – Mr. John Buan

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. For guidance on 510(k) actions, please see our guidance document entitled, “Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements” at www.fda.gov/cdrh/ode/guidance/1655.html.

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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Page 3 – Mr. John Buan

If you have any questions concerning the contents of the letter, please contact Suzanne Malli at (240) 276-3621. 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,

A handwritten signature in black ink that reads "David Krause". The signature is written in a cursive style with a large initial "D" and a long horizontal stroke at the end.

David Krause, Ph.D.
Chief, Plastic and Reconstructive
Surgery Branch
Division of General, Restorative,
and Neurological Devices

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Page 4 – Mr. John Buan

cc: HFZ-401 DMC
 HFZ-404 510(k) Staff
 HFZ-410 (DGRND/PRSB)
 D.O.
 f/t:SWM:tlm:4-16-08

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date
HFZ-410	<i>[Signature]</i>	4/16/08						
+10	<i>Rouse</i>	4/16/08						

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

February 04, 2008

IASIS MEDICAL, INC.
 6393 OAKGREEN AVENUE
 HASTINGS, MN 55033
 ATTN: JOHN BUAN

510(k) Number: K080275
 Received: 01-FEB-2008
 Product: MODEL NPD 1000
 NEGATIVE PRESSURE
 WOUND THERAPY SYSTEM

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.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (<http://prsinfo.clinicaltrials.gov>). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

form may be found at the following link to the Federal Register Notice (<http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm>).

Please note the following documents as they relate to 510(k) review:

- 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process.
- 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).

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

K080275

Traditional 510(k)

for the

IASIS Medical, Inc.

NPD 1000 Negative Pressure Wound Therapy System

January 31, 2008

Contact:

John Buan, Vice President of Product Development
6393 Oakgreen Avenue
Hastings, MN 55033
Telephone (612) 703-1204
Fax 763-287-3836
jbuana@iasismedical.com

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II

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Section 1 – Medical Device User Fee Cover Sheet

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: MD6034663-956733 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) IASIS MEDICAL 6393 Oakgreen Ave. S Hastings MN 55033 US		2. CONTACT NAME John Buan 2.1 E-MAIL ADDRESS jbuan@iasismedical.com 2.2 TELEPHONE NUMBER (include Area code) 612-7031204 2.3 FACSIMILE (FAX) NUMBER (Include Area code) null-null	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 261193935			
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: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> 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.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> 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).)			
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION \$3,404.00			
			23-Jan-2008

Form FDA 3601 (01/2007)

IASIS Medical, Inc.

CONFIDENTIAL

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PreMarket Notification for the NPD 1000 Negative Pressure Wound Therapy System

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

Section 2 – CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.		
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET					
Date of Submission January 31, 2008		User Fee Payment ID Number MD6034663-956733		FDA Submission Document Number (if known)	
SECTION A TYPE OF SUBMISSION					
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement		PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 35-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other		PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	
				510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	
				Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify)	
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement		Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment		Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	
				Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	
				Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):	
Have you used or cited Standards in your submission? <input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)					
SECTION B SUBMITTER, APPLICANT OR SPONSOR					
Company / Institution Name IASIS Medical, Inc.			Establishment Registration Number (if known)		
Division Name (if applicable)			Phone Number (including area code) (612) 703-1204		
Street Address 6393 Oakgreen Avenue			FAX Number (including area code) (763) 287-3836		
City Hastings		State / Province MN	ZIP/Postal Code 55033	Country USA	
Contact Name John Buan					
Contact Title Vice President of Product Development			Contact E-mail Address jbuan@iasismedical.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)					
Company / Institution Name					
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name					
Contact Title			Contact E-mail Address		

FORM FDA 3514 (6/05)

IASIS Medical, Inc.

CONFIDENTIAL

Page 6 of 55

PreMarket Notification for the NPD 1000 Negative Pressure Wound Therapy System

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

SECTION D2 REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		

SECTION D3 REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

FORM FDA 3514 (6/05)

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	JCX	2	JCX	3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

Information on devices to which substantial equivalence is claimed (if known)					
510(k) Number	Trade or Proprietary or Model Name	Manufacturer			
1	K060277	1	Boehringer Laboratories Suction Pump System	1	Boehringer Laboratories
2	K083692	2	V.A.C. Therapy Systems-Acti-V.A.C. Therapy Unit M.	2	KCI USA, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Pump, Portable, Aspiration, (Manual or Powered)

Trade or Proprietary or Model Name for This Device	Model Number
1	NPD 1000 Negative Pressure Wound Therapy System
	1
	NPD 1000, NPD 1000i, NPD 1000c
	2
3	
	3
4	
	4
5	
	5

FDA document numbers of all prior related submissions (regardless of outcome)					
1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code BTA	C.F.R. Section (if applicable) 21 CFR 878.4780	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)
 The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

FORM FDA 3514 (6/05)

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

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 2133810	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer	<input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Minnetronix, Inc.		Establishment Registration Number 2133810	
Division Name (if applicable)		Phone Number (including area code) (651) 917-4060	
Street Address 1635 Energy Park Drive		FAX Number (including area code) ()	
City St. Paul	State / Province MN	ZIP/Postal Code 55108	Country USA
Contact Name	Contact Title	Contact E-mail Address	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 2182681	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer	<input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name TapeMark Co.		Establishment Registration Number 2182681	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address 1685 Marthaler Lane		FAX Number (including area code) ()	
City West St. Paul	State / Province MN	ZIP/Postal Code 55118	Country USA
Contact Name	Contact Title	Contact E-mail Address	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 1450662	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Sterilizer	<input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Steris Inc, Isomedix Services		Establishment Registration Number 1450662	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address 1880 Industrial Drive		FAX Number (including area code) ()	
City Libertyville	State / Province IL	ZIP/Postal Code 60048	Country USA
Contact Name	Contact Title	Contact E-mail Address	

FORM FDA 3514 (6/05)

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601	IEC	Medical Electrical Equipment- Part 1-2: General requirements for safety	2 nd Edition	2001
2	60601	UL	Medical Electrical Equipment- Part 1: General requirements for safety	1 st Edition	2006
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

FORM FDA 3514 (6/05)

Section 3 – 510(k) Cover Letter

IASIS Medical, Inc.

January 31, 2008

Office of Device Evaluation
 Document Mail Center (HFZ401)
 Center for Devices and Radiological Health
 Food and Drug Administration
 9200 Corporate Boulevard
 Rockville, Maryland 20850

FDA CDRH DMC

FEB - 1 2008

Received

RE: Traditional 510(k) Notification for the NPD 1000 Negative Pressure Wound Therapy System

In accordance with 21 CFR 807, Subpart E, enclosed are three copies of a traditional 510(k) PreMarket Notification for the NPD 1000 Negative Pressure Wound Therapy System. IASIS Medical, Inc. is seeking clearance to release a new device, NPD 1000 Negative Pressure Wound Therapy System, into commercial distribution in the United States. This submission demonstrates that the NPD 1000 Negative Pressure Wound Therapy System is substantially equivalent to devices in commercial distribution in the United States.

This PreMarket notification has been formatted in accordance with the FDA's August 12, 2005 guidance document titled *Guidance for Industry and Staff: Format for Traditional and Abbreviated 510(k)s*.

Principal Factors About the Design and Use of the Product Name		
Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	x	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		x
Does the device contain components derived from a tissue or other biologic source?		x
Is the device provided sterile?	x	x
Is the device intended for single use?	x	x
Is the device a reprocessed single use device?		x
Does the device contain a drug?		x
Does the device contain a biologic?		x
Does the device use software?	x	
Does the submission include clinical information?		x
Is the device implanted?		x

This submission contains technical, commercial and confidential trade secret information, and IASIS Medical respectfully requests the maximum protection provided by law, in accordance with 21 CFR § 807.95.

Sincerely,



John Buan, Vice President of Product Development

Section 4 – Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: NPD 1000 Negative Pressure Wound Therapy System

Indications for Use:

The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 – 510(k) Summary

Submitter:	IASIS Medical, Inc. 6393 Oakgreen Avenue Hastings, MN 55033
Contact Person:	John Buan, Vice President of Product Development Phone (612) 703-1204, Fax (763) 287-3836
Date Prepared:	January 31, 2008
Trade Name:	NPD 1000 Negative Pressure Wound Therapy System
Classification:	Powered Suction Pump Class II 21 CFR 878.4780
Product Code:	BTA
Predicate Device(s):	The subject device is equivalent to the following devices: <ul style="list-style-type: none"> o V.A.C. Therapy Systems-ActiV.A.C. Therapy Unit M: K063692 o Boehringer Laboratories Suction Pump System: K060277
Device Description:	The NPD 1000 Negative Pressure Wound Therapy System includes a small, portable battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing.
Intended Use:	The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.
Functional and Safety Testing:	To verify that device design met its functional and performance requirements, representative samples of the device underwent functional and mechanical testing, EMC testing in accordance with IEC 60601-1-2:2001 and electrical safety testing in accordance with UL 60601-1:2006.
Conclusion:	IASIS Medical, Inc. considers the NPD 1000 Negative Pressure Wound Therapy System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, and indications for use.

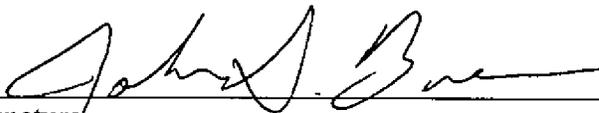
Section 6 – Truthful and Accurate Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR 807.87(k))

I certify that, in my capacity as Vice President of Product Development at IASIS Medical, Inc., 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 omitted.



Signature

John Buan

1/31/08

Date

Section 7 - Class III Product Summary and Certification

This is not a class III device, and is not substantially equivalent to a class III device; therefore the Literature Search and Certification requirement of the Safe Medical Devices Amendments (SMDA) of 1990 is not applicable.

Section 8 – Financial Certification / Disclosure Statement

Clinical studies were not required in support of the premarket notification application, thus financial certifications and/or disclosures are not required.

Section 9 – Declarations of Conformity and Summary Reports

Not applicable, as this application is being submitted as a Traditional 510(k), not an Abbreviated 510(k).

Indications for Use

The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Substantial Equivalence

IASIS Medical, Inc. believes that the NPD 1000 Negative Pressure Wound Therapy System is substantially equivalent to the devices listed below:

- V.A.C. Therapy Systems-ActiV.A.C. Therapy Unit M: K063692
- Boehringer Laboratories Suction Pump System: K060277

Similarities

The basic design (pump/ control unit/ tubing/ collection device), the pump/ control unit operating principle, the therapy delivery modes, the pump pressure, the sterilization method, the use of safety alarms and indicators, the power source, the bandage components and the indication for use of the subject device are equivalent to those of the predicate device(s).

Differences

The differences in dimensions, weight, battery type, collection device type, exudate collection volume, specific safety alarms, and bandage construction do not raise any new questions of safety and effectiveness over the predicate devices. The information demonstrates that the subject device is substantially equivalent to the predicate devices.

A comparison of the subject device to the predicate device(s) is provided in the table below. The information provided demonstrates the subject device is substantially equivalent to the predicate devices.

Section 10 – Executive Summary

Device Description

The NPD 1000 Negative Pressure Wound Therapy System is a small, compact portable system comprised of a battery operated electromechanical pump with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing. This is achieved by bringing the wound edges together, reducing edema, promoting granulation tissue formation and perfusion, and by removing wound fluids and infectious material.

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting. The dressing has 3 windows near the pressure port to monitor when the dressing is nearing its exudate capacity.

The NPD1000 dressing is comprised of the following:

- semi-occlusive outer layer that maintains the negative pressure,
- pressure port with an in-line hydrophobic, anti-bacterial 0.2 μm filter and fitting to which the NPD pump system is attached via PVC tubing,
- hydrogel gasket to seal the wound area,
- super absorbent non-woven polymer matrix to absorb exudates, and
- non-stick Silverlon[®] wound contact layer.

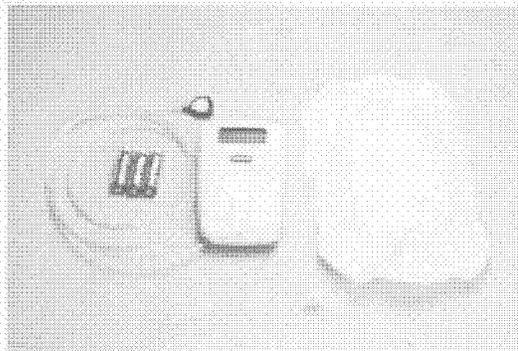


Figure 1: The NPD 1000 Negative Pressure Wound Therapy System

Table 1: Comparison to Predicate Devices

	IASIS Medical, Inc. NPD 1000 Negative Pressure Wound Therapy System	V.A.C.® Therapy Systems-ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)	Boehringer Laboratories Suction Pump System
510(k) Number	N/A	K063692	K060277
Decision Date		06/07/2007	03/03/2006
Manufacturer	IASIS Medical, Inc.	KCI USA, Inc	Boehringer Laboratories
Classification	Class II	Class II	Class II
Product Code	BTA	JCX	JCX
Regulation	878.4780	878.4780	878.4780
Indications for Use	The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.	The V.A.C.® Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	The Boehringer Laboratories Suction Pump System is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.
Device Design	The device consists of a suction pump/control unit, tubing and bandage assembly.	The device consists of a suction pump/control unit, collection canister, and canister tubing. The dressing is not included with the therapy unit.	The device consists of a suction pump/control unit, collection canister, tube attachment device, wound cover and wound dressing.
Dimensions	32" W x 5.1" H x 1.3" D	7.6" W x 6" H x 2.5" D	Unknown (larger than V.A.C. and IASIS)
Pump Pressure	40-125 mm.Hg	25-200 mm Hg	30-75 mm Hg
Therapy Delivery	Intermittent and continuous	Intermittent and continuous	Intermittent and continuous
Weight	8.02	2.4 lbs	5 lbs

Table 1: Comparison to Predicate Devices

	IASIS Medical, Inc. NPD 1000 Negative Pressure Wound Therapy System	V.A.C.® Therapy Systems- Activ.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)	Boehringer Laboratories Suction Pump System
Power, Battery Life	Alkaline or rechargeable NiMH battery, 3 weeks or more battery life	Lithium ion rechargeable battery, 14 hour average battery life	12.0V DC rechargeable battery, up to 16 hour battery life
Storage Temperature	-20°C to 60°C	-20°C to 40°C	-18°C to 46°C
Storage Humidity	0-95% non-condensing	0-95% non-condensing	0-95% non-condensing
Operating Temp.	5°C to 40°C	5°C to 40°C	10°C to 38°C
Operating Humidity	0-95% non-condensing	0-95% non-condensing	0-95% non-condensing
Storage Alt. Range	-1000 to 18,000 feet	0 to 14,000 feet	Unknown
Operating Alt. Range	-1000 to 10,000 feet	0 to 8000 feet	
Safety	Alarms for system fault, pressure leak, and low battery. Indicator icons for pressure leak and low battery	Alarms for low pressure, tubing blockage, full or missing canister, inactive therapy, low battery, leak in dressing seal, system error	Alarms for high leak rate, tubing blockage, full canister, discharged battery or no hours left on pump. Indicator lights for all alarm conditions and low level leak with adequate suction and normal operation
IEC Classification	Type B, Class II	Type B, Class II	Type B, Class II
Collection Device	50-cc absorbent wound dressing	300 cc collection canister	500 cc collection canister
Bandage	One multilayer assembly: wound contact layer, superabsorber pad, filter, fitting, cover assembly, release liner, tubing, and quick connect fitting	Separate components: polyurethane foam dressing, drape, and pad/tubing/connector	Separate components: Bio-dome™ wound dressing, wound cover, and Opti-Flo™ tube attachment device
Sterility	Only bandage provided sterile	Only bandage provided sterile	All components, except the pump, provided sterile
Sterilization Method	Radiation	Radiation	Radiation

Performance Testing

Verification and validation testing was performed according to the Verification Test Procedures document DP-0001-84-0. This document details the individual tests and the acceptance criteria. No Animal Testing was performed to verify the design of this device. The testing included is listed in the table below. ~~All testing passed the acceptance criteria except the Pressure Loss Prevention test. This is non-critical open issue (does not affect patient safety) possibly leading to false leak detect errors and reduced battery life.~~ The position of a check valve in the pump plumbing will be moved and the Pressure Loss Prevention test will be repeated to address this issue. The Therapy Duration test is still in progress and will be completed in mid March 2008. The packaging integrity and shelf life validation testing is in progress and will be completed beginning April 2008.

Table 2: Verification and Validation Summary

Test	Acceptance Criteria (System Requirement Number Reference)	Summary of Results
Functional Tests		
Power on Self Tests	SYSREQ 54681, 54688, 57195, 54795	Pass
Therapy Mode Selection	SYSREQ 54686, 54751, 54691, 54675, 54728	Pass
Continuous Mode	SYSREQ 54639	Pass
Intermittent Mode	SYSREQ 54744, 54640, 64795	Pass
Therapy Duration: 4 pressure sensors and 4 therapy devices (2 continuous, 2 intermittent)	SYSREQ 54643, 54644, 54746	In Progress ¹
Vacuum Pressure	SYSREQ 54794, 54795, 54746, 54643, 54743, 54644, 54730, 54674	Pass
Pressure Loss Prevention	SYSREQ 54725	Fail ²
Parameter Retention and Autostart	SYSREQ 84690, 57537	Pass
Device Calibration: document review and inspection only	SYSREQ 54764	Pass
Multiple Bandages: 2 pressure sensors, 2 bandage kits	SYSREQ 54637, 54801	Pass
Device and Bandage Disposal: document review and inspection only	SYSREQ 54716, 54715, 54717, 54646	Pass
Software Upgrade	SYSREQ 55853, 57195	Pass
Reverse Polarity	SYSREQ 57243	Pass
Low Battery	SYSREQ 54799, 54750, 54684, 54729, 55903, 57609, 54728	Pass
Leak Detected	SYSREQ 54799, 54683, 54760, 54729, 54800, 55903, 55904, 57671, 57672, 54728	Pass
System Fault	SYSREQ 54685, 54799, 54795, 54729, 55903, 57673, 57675, 54794, 54728	Pass

Table 2: Verification and Validation Summary

User Interface Tests		
Audible Annunciation	SYSREQ 54550, 54802	Pass
Programming Controls	SYSREQ 54727	Pass
UI Display	SYSREQ 54676, 54678, 54677, 54726, 55903, 54537	Pass
Pump On/Off Control	SYSREQ 54687, 54665, 54798, 54671, 54728	Pass
Hardware Interface Tests		
External Interface Connections	SYSREQ 54539	Pass
Control Unit to Pump Unit Connection	Verify pump runs as expected and verify actual results are as expected	Pass
Stress and Robustness Tests		
Simulated User Evaluation	No expected outputs or pass/fail criteria	Pass
Continuous Pump Life: 6 pumps	SYSREQ 54672	Pass
Intermittent Pump Life: 6 pumps	SYSREQ 54745	Pass
Quick Connect Tubing Cycle Life	SYSREQ 54803	Pass
Environmental Tests		
Operating Conditions: document review and inspection only	SYSREQ 54693, 54694, 54695, 54696, 54660, 54658, 54659, 54781, 54657	Pass
Storage Conditions: document review and inspection only	SYSREQ 54755, 54756, 54757, 54758, 54754, 54753	Pass
Unpackaged Drop and Vibration: document review and inspection only (3 devices)	SYSREQ 54697, 54766, 54777	Pass
Packaged Shock and Vibe: document review and inspection only	SYSREQ 54752	Pass
Fluid Ingress: document review and inspection only	SYSREQ 54673	Pass
EMC: document review and inspection only	SYSREQ 54734, 54735	Pass
Shelf Life (Bandage Only): document review and inspection only	SYSREQ 54719	Pass
Cleaning	SYSREQ 54648, 547862	Pass
Quality, Regulatory and Safety Tests		
Product Safety: document review and inspection only	SYSREQ 54541, 54780	Pass
Device Classification: document review and inspection only	SYSREQ 54541	Pass
Quality Approval: document review and inspection only	SYSREQ 54778, 54779	Test Removed ³
Biocompatibility: document review and inspection only	SYSREQ 54788, 54785, 54543	Pass

Table 2: Verification and Validation Summary

Physical And Mechanical Tests		
Physical	SYSREQ 54773, 54776, 54774, 54767, 54775, 54548, 54711, 54710, 54655, 54692, 54797, 54723, 54549	Pass
Mechanical	SYSREQ 54765, 54782, 54748, 54747, 57244, 54803	Pass
Unit and Integration Tests		
Unit and Integration	SYSREQ 54689, 54681, 54795	Pass
IASIS Medical Testing		
Instruction for Use, Tubing Set, Bandage	SYSREQ 54789, 54783, 54654, 54641, 54797, 54647, 54712, 54713, 54653, 54709, 54703, 54704, 54705, 54706, 54707, 54700, 54699, 54663, 54701, 54708, 54702, 54892	Pass ⁴

¹ The Therapy Duration testing is in progress and will be completed in mid March 2008.

² The Pressure Loss Prevention test does not meet the acceptance criteria that the device's loss of vacuum pressure is no more than 10 mmHg/hour (averaged over 5 hours) when the pump is in the off state.

³ The test was removed because issues were not created in the Capricorn Issue Tracking project. An Open Issues Report was created and attached to the end of the Verification Report.

⁴ The packaging integrity and shelf life testing is in progress and will be completed beginning April 2008.

Section 11 – Device Description

Intended Use

The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Models and Accessories

The NPD 1000 Negative Pressure Wound Therapy System consists of the following components.

Table 3: Component Model Numbers

Component	Subassembly	Model	Part No.
Electromechanical Pump	System controller	NPD 1000 Control Unit	50001
	Intermittent pump housing	NPD 1000i Pump Module	50002
	Continuous pump housing	NPD 1000c Pump Module	50003
Wound Dressing	N/A	N/A	N/A

Device Description

The NPD 1000 Negative Pressure Wound Therapy System is comprised of a small, compact portable battery operated electromechanical pump and a wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing. This is achieved by bringing the wound edges together, ~~reducing edema, promoting granulation tissue formation and perfusion,~~ and by removing wound fluids and infectious material. The pump components are manufactured by Minnetronix (FDA registration Number 2133810), a contract manufacturer located in St. Paul, MN. The wound dressing is manufactured by ~~TapeMark Co.~~ (FDA Registration Number 2182681), a contract manufacturer located in West St. Paul, MN.

NPD 1000 Pump

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting in the dressing.

The NPD 1000 pump is shipped in 2 pieces, a system controller and 1 of 2 pump housings, either continuous or intermittent. Both pump housings can provide continuous therapy, but only the intermittent housing can provide intermittent therapy. The user fits the 2 subassemblies together by matching the male and female connector housings. The system controller automatically recognizes whether a continuous or intermittent pump has been attached. Neither the system controller nor the pump housing is provided sterile. The system controller and the intermittent

pump housing are reusable and do not need to be sterilized between subsequent patients. The continuous pump housing is single use.

The NPD 1000 pump contains a microprocessor controlled pump and pressure sensor working in feed back fashion to control the pressure under the dressing at the physician programmed setting. It has a user interface of 3 buttons to control the power (on/off), treatment mode (intermittent or continuous), and pressure setting (40, 50, 65, 80, 95, 110, and 125 mmHg). The pump is powered by 3 AA batteries, either alkaline or NiMH rechargeable. There is 6 feet of tubing, with a pressure fitting between the pump and the dressing, which can be trimmed to the desired length. A proprietary quick connect fitting is placed in the tubing for easily disconnecting the dressing from the pump. For therapy status notification, the pump has a leak detection indicator icon, a low battery indicator icon and therapy proceeding indicator icon. An alarm buzzer will sound for a leak detection, low battery or system fault.

The Product Specifications for the pump are listed in the table below.

Table 4: Pump Specifications

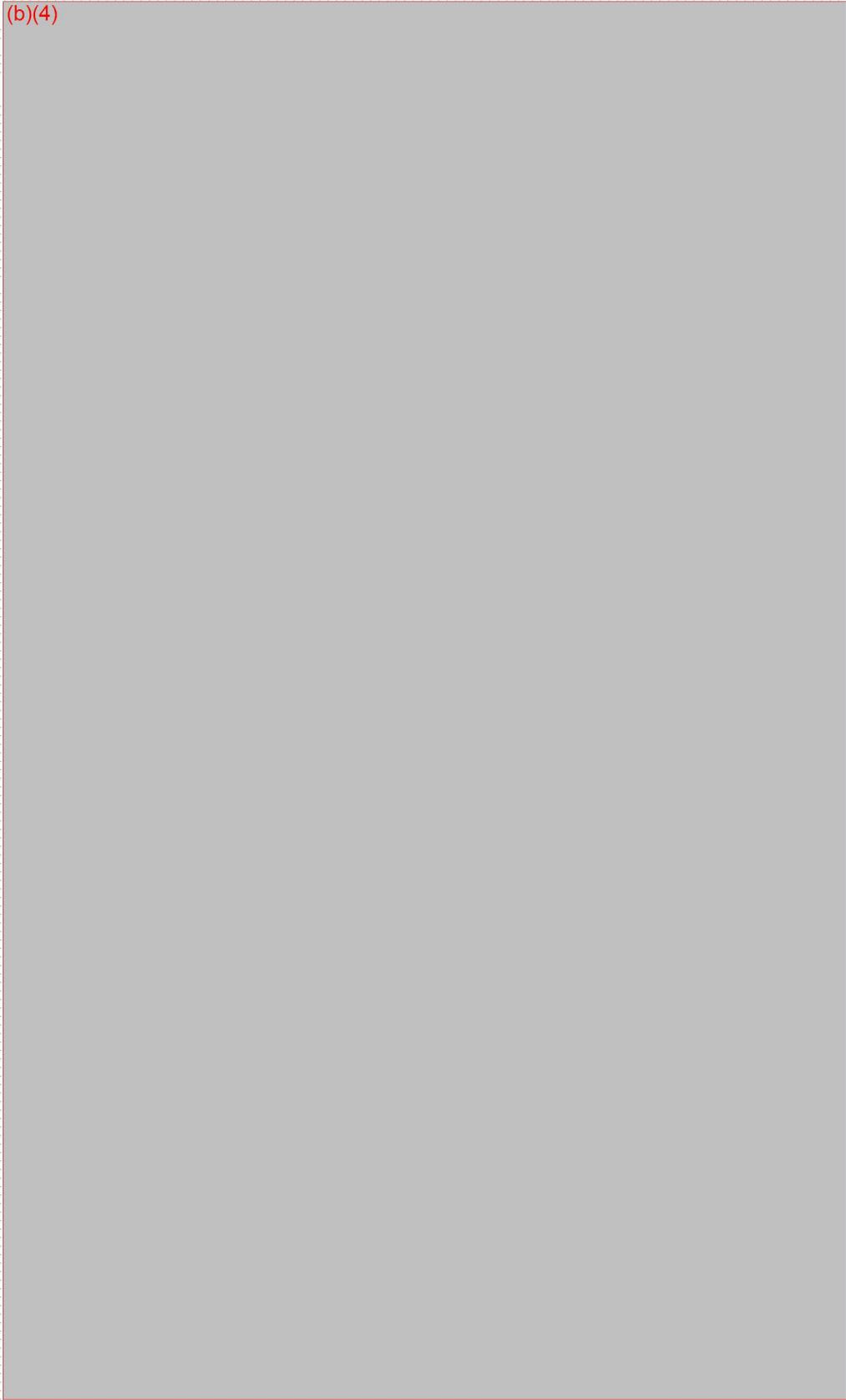
Parameter	Specification
Dimensions	3.2"W x 5.1" H x 1.3" D
Weight	8 ounces
Pressure Options	-40 to -125 mmHg
Therapy Delivery Modes	Continuous and Intermittent
Battery Type	Alkaline or Rechargeable NiMH
Battery Life	3 weeks or more
Storage Conditions	Temperature: -20°C to +60°C; Humidity: 0-95% non-condensing
Operating Conditions	Temperature: +5°C to +40°C; Humidity: 0-95% non-condensing
Altitude Range	Operating: -1000 ft. to +10,000 ft.; Storage: -1000 ft. to +18,000 ft.
IEC Classification	Medical Equipment; Equipment not suitable for use in the presence of flammable anesthetic mixture; Type B, Applied Part; Class II; IPXO

The materials for the pump are listed in the table below.

Table 5: Pump Component Materials

Pump Component	Materials
System Controller	GE Cycloy resin C6600
Controller Keypad	Silicone rubber
Continuous or Intermittent Pump Housing	GE Cycloy resin C6600
Tubing	PVC (Tygon R-3603) 55A
Quick Connect Fitting	Black ABS

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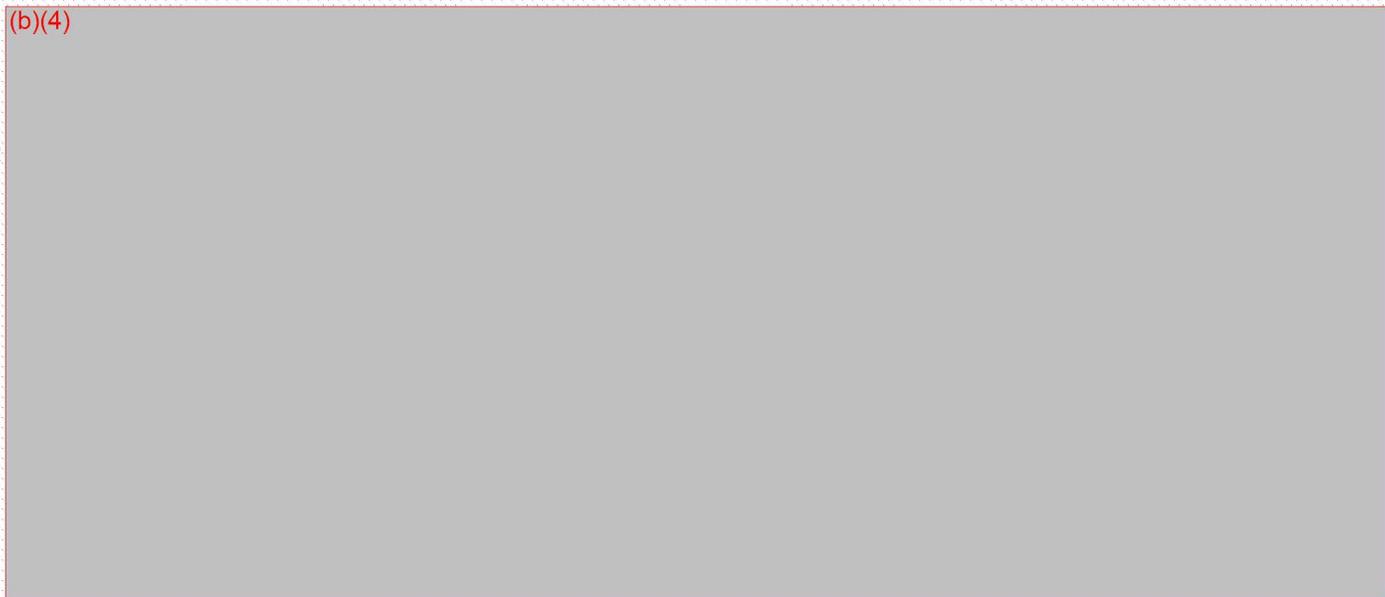


Table 6: Bandage Component Materials

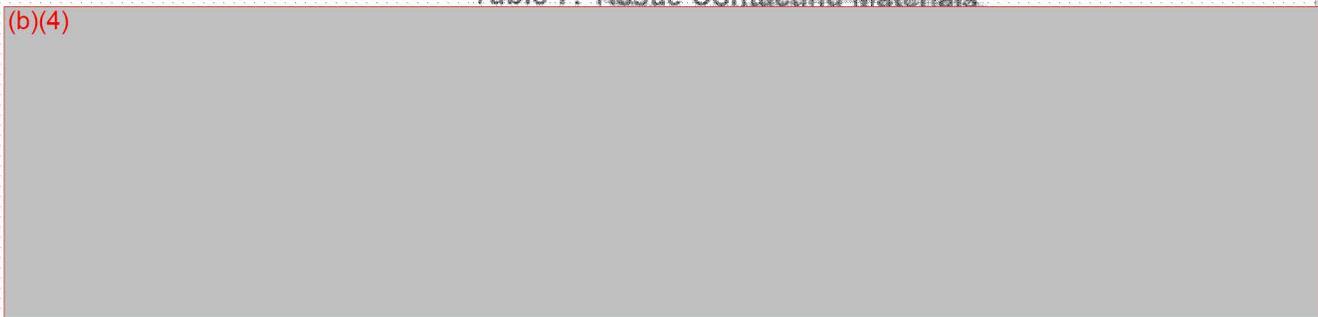
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The tissue contacting materials are listed in the following table.

Table 7: Tissue Contacting Materials

(b)(4)



Section 12 – Substantial Equivalence Discussion

The IASIS Medical, Inc. NPD 1000 Negative Pressure Wound Therapy System is substantially equivalent to the following devices:

- V.A.C. Therapy Systems- ActiV.A.C. Therapy Unit M: K063692
- Boehringer Laboratories Suction Pump System: K060277

Similarities

The basic design (pump/ control unit/ tubing/ collection device), the pump/ control unit operating principle, the therapy delivery modes, the pump pressure, the sterilization method, the use of safety alarms and indicators, the power source, the bandage components and the indication for use of the subject device are equivalent to those of the predicate device(s).

Differences

The differences in dimensions, weight, battery type, collection device type, exudate collection volume, specific safety alarms, and specific bandage construction do not raise any new questions of safety and effectiveness over the predicate devices. The information demonstrates that the subject device is substantially equivalent to the predicate devices.

The table on the following pages provides a summary of the pertinent comparison information. In summary, the information provided demonstrates the subject device is substantially equivalent to the predicate devices.

Table 8: Comparison to Predicate Device

	IASIS Medical, Inc. NPD 1000 Negative Pressure Wound Therapy System	V.A.C.® Therapy Systems- ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)	Boehringer Laboratories Suction Pump System
510(k) Number	N/A	K063692	K060277
Decision Date		06/07/2007	03/03/2006
Manufacturer	IASIS Medical, Inc.	KCI USA, Inc	Boehringer Laboratories
Classification	Class II	Class II	Class II
Product Code	BTA	JCX	JCX
Regulation	878.4780	878.4780	878.4780
Indications for Use	The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.	The V.A.C.® Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	The Boehringer Laboratories Suction Pump System is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.
Device Design	The device consists of a suction pump/control unit, tubing and bandage assembly.	The device consists of a suction pump/control unit, collection canister, and canister tubing. The dressing is not included with the therapy unit.	The device consists of a suction pump/control unit, collection canister, tube attachment device, wound cover and wound dressing.
Dimensions	3.2" W x 5.1" H x 1.3" D	7.6" W x 6" H x 2.5" D	Unknown (larger than V.A.C. and IASIS)
Pump Pressure	40-125 mm Hg	25-200 mm Hg	30-75 mm Hg
Therapy Delivery	Intermittent and continuous	Intermittent and continuous	Intermittent and continuous

Page 32 of 55

IASIS Medical, Inc. PreMarket Notification for the NPD 1000 Negative Pressure Wound Therapy System

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Table 8: Comparison to Predicate Device

	IASIS Medical, Inc. NPD 1000 Negative Pressure Wound Therapy System	V.A.C.® Therapy Systems-ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)	Boehringer Laboratories Suction Pump System
Weight	8 oz	2.4 lbs	5 lbs
Power; Battery Life	Alkaline or rechargeable NiMH battery; 3 weeks or more battery life	Lithium ion rechargeable battery; 14 hour average battery life	12.0V DC rechargeable battery; up to 16 hour battery life
Storage Temperature	-20°C to 60°C	-20°C to 40°C	-18°C to 46°C
Storage Humidity	0-95% non-condensing	0-95% non-condensing	0-95% non-condensing
Operating Temp.	5°C to 40°C	5°C to 40°C	10°C to 38°C
Operating Humidity	0-95% non-condensing	0-95% non-condensing	0-95% non-condensing
Storage Alt. Range	-1000 to 18,000 feet	0 to 14,000 feet	Unknown
Operating Alt. Range	-1000 to 10,000 feet	0 to 8000 feet	
Safety	Alarms for system fault, pressure leak, and low battery. Indicator icons for pressure leak and low battery.	Alarms for low pressure, tubing blockage, full or missing canister, inactive therapy, low battery, leak in dressing seal, system error.	Alarms for high leak rate, tubing blockage, full canister, discharged battery or no hours left on pump. Indicator lights for all alarm conditions and low level leak with adequate suction and normal operation.
IEC Classification	Type B, Class II	Type B, Class II	Type B, Class II
Collection Device	50 cc absorbent wound dressing	300 cc collection canister	500 cc collection canister
Bandage	One multilayer assembly: wound contact layer, superabsorber pad, filter, fitting, cover assembly, release liner, tubing, and quick connect fitting	Separate components: polyurethane foam dressing, drape, and pad/tubing/connector	Separate components: Bio-dome™ wound dressing, wound cover, and Opti-Flo™ tube attachment device
Sterility	Only bandage provided sterile	Only bandage provided sterile	All components, except the pump, provided sterile
Sterilization Method	Radiation	Radiation	Radiation

Section 13 – Proposed Labeling

Device labels and Instructions for Use have been developed in accordance with the requirements stated 21 CFR §801 – Labeling and 21 CFR §1, Subpart B – General Labeling Requirements.

Copies of the proposed labels and the Instructions for Use are provided in **Appendix 2**.

Section 14 – Sterilization and Shelf-Life

Packaging

The NPD 1000 Wound Dressing is the only component of the NPD 1000 Negative Wound Therapy System that is provided sterile. The wound dressing is packaged in a polyester/foil laminate pouch suitable for radiation sterilization. The laminate layers of the pouch include PET, LDPE, aluminum foil and a Surlyn® sealant layer. The wound dressing packaging process is performed by TapeMark Co, the contract manufacturer located in West St. Paul, MN, in accordance with their standard operating procedures in a Class 100,000 controlled environment.

The pump components are packaged by Minnetronix. The packaging consists of a light weight corrugated board carton with a polyurethane foam insert. The controller, pump housing with tubing, and batteries are placed into the insert and another polyurethane foam pad is placed on top of the components. This carton and the sterile packaged bandage are shipped either together or separately in a heavyweight cardboard shipping box.

Sterilization

Method of Sterilization

The packaged NPD 1000 Wound Dressing will be sterilized using electron beam radiation by a contract sterilizer, Steris Isomedix Services located in Libertyville, Illinois. The sterilization dose will be 25 kGy minimum. Steris will perform both the routine sterilization of the product and quarterly dose auditing on 20 random samples from a single batch. The dose auditing includes bioburden testing on 10 samples and irradiation at the verification dose followed by sterility testing on the remaining 10 samples. Nelson Laboratories, Inc. located in Salt Lake City, Utah will perform the bioburden and sterility testing.

Description of Validation Method

Steris will perform the irradiation sterilization validation in accordance with ANSI/AAMI/ISO 11137:2006, VDmax 25 guideline for multiple production batches to achieve a Sterility Assurance Level (SAL) of 10^{-6} . The validation will include bioburden testing to select a verification dose (SAL 10^{-1}), sub-lethal dose irradiation followed by sterility testing, routine sterilization dose mapping, and establishing routine sterilization specifications. For bioburden 10 random samples from each of a minimum of 3 separate production batches will be tested. For sub-lethal dose verification 13 random samples from a single batch will be tested, 10 for sterility and 3 for bacteriostasis/fungistasis.

The sterilization validation protocol is provided in **Appendix 3**.

Shelf-Life

The packaging validation of the NPD 1000 Wound Dressing will be performed by DDL located in Eden Prairie, MN to ~~support the recommended shelf life of 12 months.~~ The validation will consist of accelerated aging to one (1) year, seal integrity testing (bubble leak test) and seal strength testing in accordance with the following standards.

Table 9: Packaging and Shelf Life Validation

Parameter	Standard
Accelerated Aging to 1 Year	ASTM F 1980-02
Seal Integrity (Bubble Leak)	ASTM F 2096-04
Seal Strength	ASTM F 88-07

Thirty (30) sterile packaged wound dressings and sixty (60) sterile empty sealed pouches will undergo accelerated aging to one (1) year per ASTM 1980-02. After aging, thirty (30) empty pouches will be tested for seal integrity (bubble leak) and another thirty (30) empty pouches will be tested for seal strength. All thirty wound dressings will be functionally tested after aging.

Functional testing will consist of verifying the following.

- Achieving and maintaining vacuum integrity over the full range of therapeutic pressures: 40-125 mmHg
- Achieving set pressure in less than 3 minutes
- Verifying the therapeutic fluid capacity of 50 cc of fluid \pm 10% is not impacted by aging

A draft packaging and shelf life validation protocol is provided in **Appendix 3**.

Section 15 – Biocompatibility

The following table identifies the materials that are tissue contacting in the NPD 1000 Wound Therapy System.

Table 10: Tissue Contacting Materials

Component	Contact Material	Contact	Duration
Bandage Assembly	Silverlon®	Wound	24 hour to 30 days
	(b)(4)	Skin	24 hour to 30 days
	Hydrogel	Skin	24 hour to 30 days

The table below provides a summary of the testing performed per ISO 10993 to demonstrate the biocompatibility of the materials used in this device. Copies of testing were obtained from the material manufacturers. Testing was not performed on final sterilized devices because all of the materials used are well established materials used in medical devices. There are no new materials used in the construction of the NPD 1000 Wound Dressing.

Table 11: Summary of Biocompatibility Testing

Material	Test Description	Test Result
(b)(4)	Cytotoxicity, Sensitization, Irritation	Pass
Hydrogel	Cytotoxicity, Sensitization, Irritation	Pass

Based on the test results, these materials used in this device are demonstrated to be biocompatible. Copies of the test reports are provided in **Appendix 4**.

A copy of biocompatibility testing per ISO 10993 was not obtained on the Silverlon® material. The material and its intended use as a wound contact material in the NPD 1000 Wound Dressing are identical to that cleared in 510(k) K981299.

Section 16 – Software

Introduction

The software (referred to as Capricorn in the contract manufacturer, Minnetronix, documents) is contained in the control unit which manages the display, buttons, pump, valves and power supply for the device. The system is based on an Atmel ATmega169P microprocessor, and runs the Minnetronix Operating System (OS). The Negative Pressure Wound Therapy (NPWT) application is dependent on the Minnetronix OS. The System Software Design document DP-0001-84-3 which contains the software description, software design specifications and software architecture design is provided in **Appendix 5**.

The controller implements the following functionality:

- Perform Power On Self Test (POST).
- Manage the User Interface.
 - Display operational information and notification indicators on the LCD screen.
 - Sound notification audio.
 - Respond to button inputs.
- Store configuration parameters in non-volatile memory.
- Control pumps and valves to perform therapy.
- Monitor for system leaks.
- Monitor battery capacity.

Level of Concern

The level of concern for device software is Moderate.

This level of concern was determined based upon the answers to the questions posed in the FDA guidance document titled *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* as shown in the table below.

Table 12: Basis for Level of Concern Conclusion

Decision Questions	Yes	No	Discussion
Major Level of Concern Questions – a <i>Yes</i> response of any of the following questions the level of concern is likely to be Major.			
1. Does the Software Device qualify as Blood Establishment Computer Software?		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	

Table 12: Basis for Level of Concern Conclusion

Decision Questions	Yes	No	Discussion
<p>4. Prior to mitigation of hazards, could failure of the Software Device result in death or serious injury, either to a patient or to a user of the device?</p> <ul style="list-style-type: none"> ○ Does the Software Device control a life supporting or life sustaining function? ○ 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? ○ Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in death or serious injury? ○ Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary? 		<p>X</p> <p>X</p> <p>X</p> <p>X</p> <p>X</p>	
Moderate Level of Concern Questions – a <i>Yes</i> response of any of the following questions 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 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 latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would lead to a Minor Injury?	X		Failure of the software could result in reduction of, loss of or incorrect delivery of treatment which could lead to minor injury.

Software Description

The software description is located in the System Software Design document DP-0001-84-3 provided in **Appendix 5**. **Figure 4** is high-level view of the expected users and uses of the system. The user modes are listed top to bottom in order of highest to lowest priority. A higher priority user can perform all the operations allowed to a lower priority user.

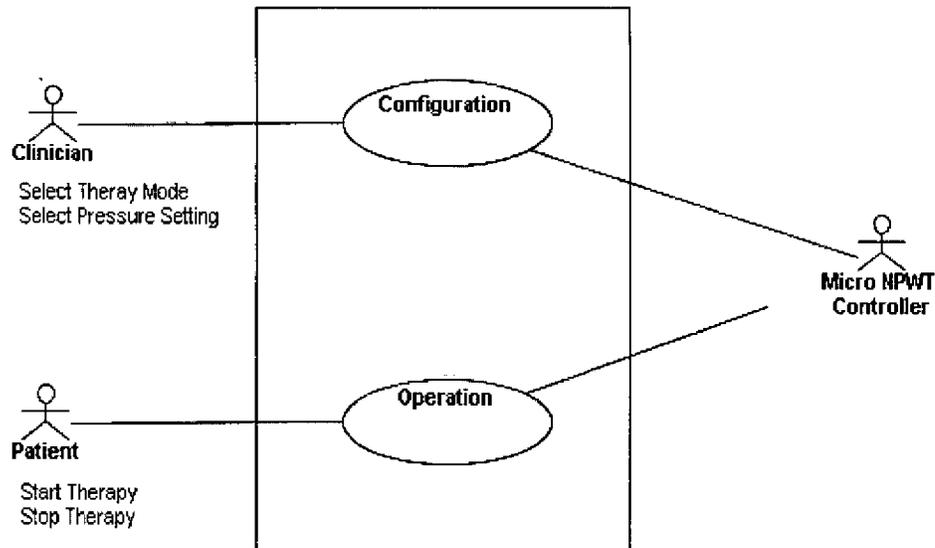


Figure 4: Case Diagram

Figure 5 is a high-level state machine for the system. These are the states that a user would notice when operating the device.

After a successful POST the controller will read configuration parameters from NvRAM, and determine the type of pump unit (continuous, intermittent, or none) that is attached. It will then transition to the Ready state.

In the Ready state, the controller will wait for input from the user. The user can either put the controller in configuration mode, or turn the therapy on. The controller will remain in either the Ready, Configure, or Therapy in Progress state until the unit is powered off.

If the controller fails the POST, or if at any time a system fault occurs, the system will transition to the Broken state, where it will remain until the unit is powered off.

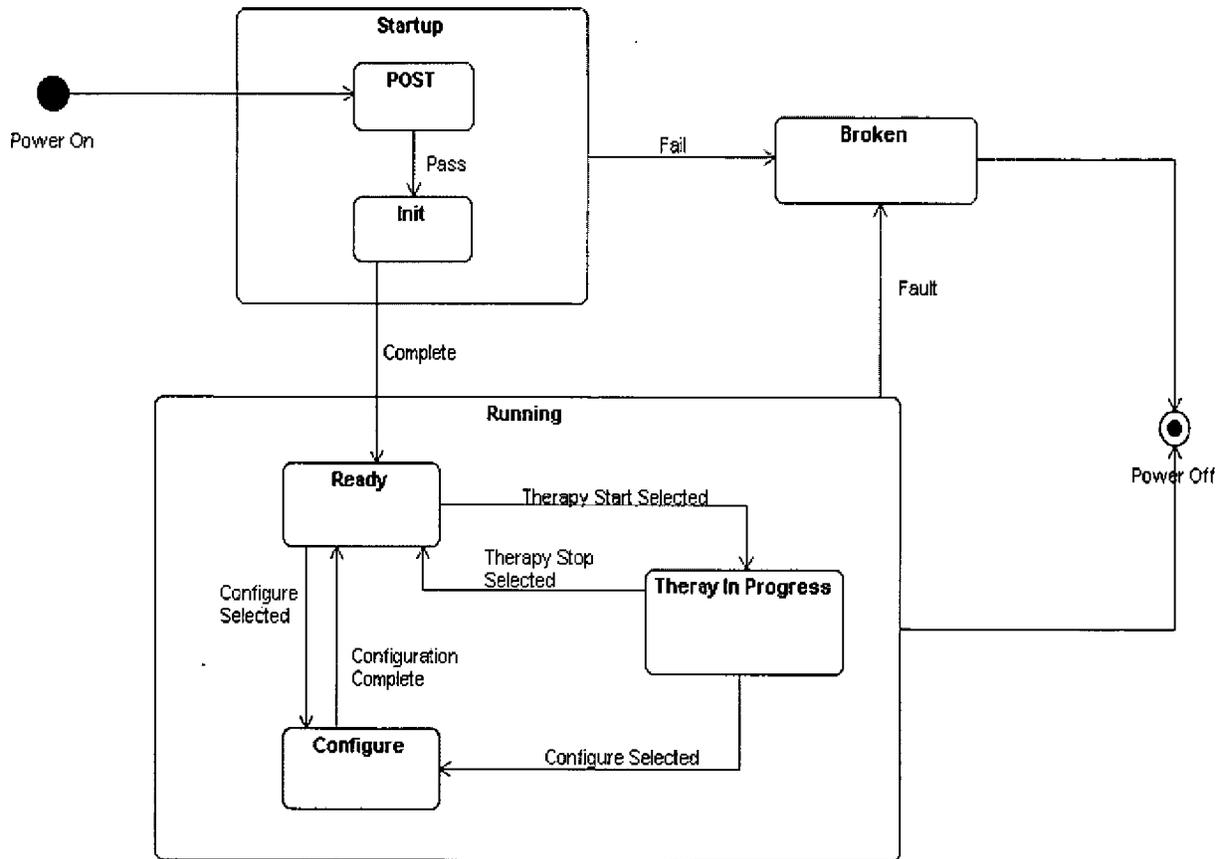


Figure 5: System State Diagram

Figure 6 is the deployment/implementation diagram which illustrates how the software is distributed in the system. The three dimensional box represents the Atmel ATmega169P microprocessor. The smaller boxes are the principal software components that execute within the processor. The dashed line that connects the NPWT Application and the Minnetronix OS indicate a dependency. The NPWT application depends on the Minnetronix OS which is described in detail in the System Software Design document.

The software is contained in the control unit which manages the display, buttons, pump, valves and power supply (AA batteries) for the device.

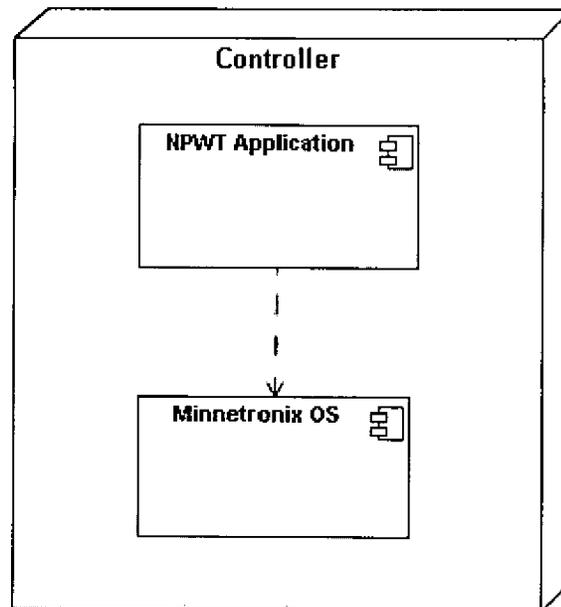


Figure 6: Implementation Diagram

Device Hazard Analysis

A Failure Modes Effects and Criticality Analysis was performed per ISO 14971:2007. The results of the analysis, DP-0001-84-1, are provided in **Appendix 6**. This analysis is intended to address only faults related to the functional performance of electronic and software subsystems which comprise the NPWT device. All identified failure modes have an acceptable level of risk based on pre-mitigation RPN acceptability or based on mitigation implementation. The highest pre-mitigation level of severity given in this FMECA is for Loss of Therapy which is considered a moderate level of concern.

In addition, a Hazard Analysis was performed per ISO 14971:2007. The results of the analysis, DP-0001-83-7, are also provided in **Appendix 6**. This analysis summarizes potential system hazards for the NPWT system. All identified failure modes have an acceptable level of risk based on pre-mitigation RPN acceptability or based on mitigation implementation. The highest pre-mitigation level of severity given in this Hazard Analysis is for Disruption of Therapy which is considered a moderate level of concern. The hazard descriptions include:

- energy hazards,
- biological hazards;
- environmental hazards,
- hazards resulting from incorrect output of energy and substances,
- hazards relating to use of the medical device,
- inappropriate, inadequate or over complicated user interface,
- and hazards arising from functional failure, maintenance and aging.

All hazard mitigations identified in the Hazard Analysis and FMECA trace to System Requirements. The control numbers of the hazards in the Hazard Analysis document relating to software are 017, 022, 023, 026, 027, 054, 055, 059 and 062.

Software Requirements Specification

The System Requirements Specification (SRS) DP-0001-84-2, provided in **Appendix 7**, describes the functional and performance requirements of the NPWT device.

The document includes:

- functional and performance requirements for the system unit, pump, and bandage,
- user interface requirements for ease of use, bandage-full detection, user controls, and user feedback,
- other interface requirements for international language support, external equipment interface, bandage interconnect system, pump module/tubing interface, adjustable system tubing, and multiple bandage interface,
- regulatory and safety requirements for product safety, biocompatibility, sterility or cleanability, and safety
- power requirements for device power, battery replacement tool, battery procurement, and battery type,
- physical requirements for size, weight, acoustic noise limits, and labeling and packaging,
- mechanical requirements for tubing quick connect and mated connectors,
- environmental requirements for operating conditions, storage and transport conditions, package integrity/shipping, and disposal.

The requirements related to software are listed in the table below.

Section/ SRS Number	Requirement Title	Section/ SRS Number	Requirement Title	Section/ SRS Number	Requirement Title
3.1.1.1/ 54746	Set point pressure tolerance	3.2.3.3/ 54674	Vacuum pressure selection	3.2.4.5.2.4/ 54799	Beep mute capability
3.1.1.3/ 54643	Minimum system vacuum	3.2.3.4/ 54675	Therapy mode selection	3.2.4.5.2.4.1/ 54800	Mute time
3.1.1.4/ 54743	Default system vacuum pressure	3.2.3.5/ 54727	Patient lock out	3.2.4.5.3/ 54685	Pump inoperable
3.1.1.5/ 54644	Maximum system vacuum	3.2.4.5.1.2/ 54684	Low battery indication	3.2.4.5.4/ 57675	Pump inactivity check
3.1.1.6/ 54637	Bandage accommodation	3.2.4.5.1.3/ 54683	Leak detection indication	3.2.4.5.5/ 54794	Loss of pump control
3.1.1.7/ 54639	Continuous mode requirement	3.2.4.5.1.3.1/ 55904	Leak detection threshold (minor)	3.2.4.5.6/ 54686	Improper therapy mode
3.1.1.8/ 54640	Intermittent mode requirement	3.2.4.5.1.3.2/ 57671	Leak detection threshold (major)	3.2.4.5.7/ 54751	Attempted improper therapy mode
3.1.1.8.1/ 54744	Intermittent mode cycle time	3.2.4.5.1.3.3/ 57672	Inactivate leak detected	3.2.4.5.8/ 54687	Missing pump mode

Table 13: Software Requirements					
Section/ SRS Number	Requirement Title	Section/ SRS Number	Requirement Title	Section/ SRS Number	Requirement Title
3.1.1.13/ 54690	Non-volatile RAM requirements	3.2.4.5.2/ 54729	Audible notifications	3.2.4.5.9/ 54688	POST failure
3.1.1.14/ 57537	Therapy restart	3.2.4.5.2.2/ 54750	Low battery beep	3.2.4.5.10/ 54689	NVRAM error checks
3.2.3.1.1/ 55903	Backlight operation	3.2.4.5.2.3/ 54760	Leak detected beep	3.2.4.5.11/ 57195	Software version number
				3.4.6.1/ 54681	Power on self test check

Architecture Design Chart

The software architecture description is found in the System Software Design document DP-0001-84-3 provided in **Appendix 5**. The software operates under the Minnetronix Operating System (OS). The purpose of this design is to decompose the Capricorn application into a number of modules. The following class diagram, **Figure 7**, shows the basic interconnections and operations between all modules that occur during “normal runtime”. Interconnections used in error handling and initialization are not shown. The underlying OS classes are not included here but are described in the System Software Design document.

Classes that show a function name of the form “gModuleTask” are implemented as an OS task. Classes that show an attribute called “Timer” are actually OS tasks with periodic timers. The timer will cause the task to wake up periodically. The numeric value of the attribute is the timer period in milliseconds.

To simplify the diagram, not all functions are shown for each class. Examples of functions not shown are the main OS tasks, the OS timers, and the watchdog mechanism. The intent is to show the functions in the interface of each class that are of interest to clients of the class. Private functions are shown only where they would aid in understanding of the class.

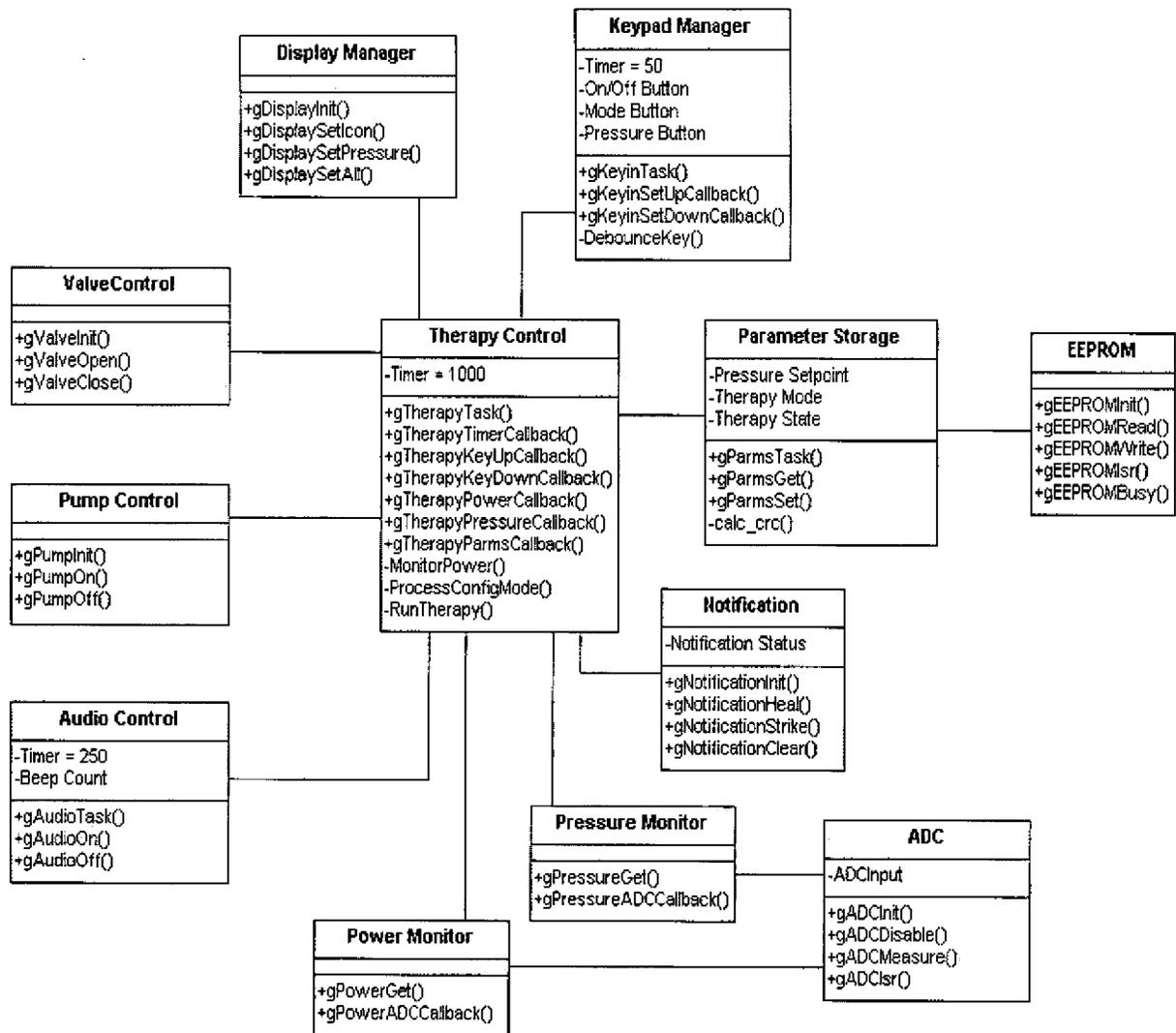


Figure 7: Class Diagram

Software Design Specification

The software design specifications are provided in the System Software Design document DP-0001-84-3, provided in **Appendix 5**.

Traceability Analysis

The FMECA document DP-0001-84-1 and the Hazard Analysis document DP-0001-83-7 trace the control or mitigation of each hazard to the applicable System Requirements. The Verification Test Procedures document DP-0001-84-0 traces each test to the applicable System Requirements. These documents are provided in **Appendices 6 and 8** respectively. **Table 2** also provides a listing of the verification and validation tests and the related system requirements.

Software Development Environment Description

The software was developed by the contract manufacturer Minnetronix according to their standard operating procedure, Minnetronix System Development, DQ-0000-24-0. The development environment for the NPWT software is described in the System Software Design document DP-0001-84-3 provided in **Appendix 5**. This includes the development tools, tool qualification, file location and build procedure.

The software development life cycle includes planning and control, system design and verification, and implementation activities. The system development plan identifies project goals, all required deliverables for the project, team structure and responsibilities, critical assumptions and risks, and the project schedule. Project planning information is tracked and updated throughout the project by the project leader. All design documentation is maintained at Minnetronix.

Any deviations from approved project plans or Minnetronix SOPs are justified and approved by the project leader and quality assurance representative and documented in the design history file. Design changes that occur prior to system release are handled as part of the initial development. Any issues which impact the design are tracked via a project Issues List. Design changes that occur after system release are implemented by reentering the development cycle and performing a subset of the initial development tasks. This process is described in the Minnetronix Design Change SOP DQ-0000-72-6.

Configuration management and documentation control will be performed in accordance with Minnetronix Configuration Management Plan SOP DQ-0000-08-0, Minnetronix Engineering Change SOP DQ-000-13-0, and Minnetronix Document Control SOP DQ-9001-05-0. The Configuration Management Plan SOP specifies procedures for controlling hardware and software units during the development process. There are three 'stages' of configuration management for the project: Development, Requirements Verification and Customer Release.

Verification and Validation Documentation

The major objectives of the verification and validation (V&V) process are to determine that the system performs its intended functions correctly, to ensure that it performs no unintended functions, and to provide information about its quality and reliability. V&V evaluates how well the system meets its technical requirements and its safety, and reliability objectives. It also helps to ensure that requirements are not in conflict with each other or with any relevant standards. V&V tasks analyze, review, demonstrate, or test all system development outputs.

The System Verification and Validation Plan (DP-0001-85-0), the Verification Test Procedures (DP-0001-84-0), and the NPD 1000 Negative Pressure Dressing Verification and Validation Test Procedures (QFM-04-3b), provided in **Appendix 8**, detail the tests, methods and acceptance criteria to confirm that the hardware, software and wound dressing designs are implemented correctly and completely and that they are traceable to the device's System Requirements Specification (DP-0001-84-2) provided in **Appendix 7**. **Table 2** shows the tests performed traced to their specific system requirement specifications. The default unit under test (UUT) sample size is one (1) unless specified otherwise in each individual test. All timing and performance requirements had a tolerance of $\pm 10\%$ unless specified in the individual test.

The system V&V testing was performed by Minnetronix. The testing results are summarized in the table below. Details of the Minnetronix test results are provided in the Verification Report,

DR-0000-09-0, which is provided in **Appendix 9**. There are two open items as a result of the Minnetronix verification testing which are noted below. One long duration test is in progress and there is one test with a non-critical open issue. The Therapy Duration test will be completed in mid March 2008. The Pressure Loss Prevention test did not meet the acceptance criteria. During verification testing it was found that both the continuous and intermittent pumps have greatly different leak rates from pump to pump. Most intermittent pumps and half the continuous pumps meet the acceptance criteria. The others do not which may lead to false leak detect errors and reduced battery life, neither of which affect patient safety. The position of a check valve in the pump plumbing will be moved and retesting of the Pressure Loss Prevention will be performed to address this issue.

Table 14: Minnetronix Verification and Validation Summary

Test	Software Version	Software Version	Results
Functional Tests			
Power on Self Tests	05	06	Pass on both
Therapy Mode Selection	05		Pass
Continuous Mode	05		Pass
Intermittent Mode	05		Pass
Therapy Duration: 4 pressure sensors and 4 therapy devices (2 continuous, 2 intermittent))	-	06	In Progress ¹
Vacuum Pressure	05		Pass
Pressure Loss Prevention	05		Fail ²
Parameter Retention and Autostart	05		Pass
Device Calibration: document review and inspection only	05		Pass
Multiple Bandages: 2 pressure sensors, 2 bandage kits	05		Pass
Device and Bandage Disposal: document review and inspection only	05		Pass
Software Upgrade	05		Pass
Reverse Polarity	05		Pass
Low Battery	05	06	Pass on both
Leak Detected	05		Pass
System Fault	05	06	Pass on 06
User Interface Tests			
Audible Annunciation	05		Pass
Programming Controls	05		Pass
UI Display	05		Pass
Pump On/Off Control	05		Pass
Hardware Interface Tests			
External Interface Connections	05		Pass

Table 14: Minnetronix Verification and Validation Summary

Control Unit to Pump Unit Connection	05		Pass
Stress and Robustness Tests			
Simulated User Evaluation	05	06	Pass on both
Continuous Pump Life: 6 pumps	N/A		Pass
Intermittent Pump Life: 6 pumps	N/A		Pass
Quick Connect Tubing Cycle Life	05		Pass
Environmental Tests			
Operating Conditions: document review and inspection only	05		Pass
Storage Conditions: document review and inspection only	05		Pass
Unpackaged Drop and Vibration: document review and inspection only (3 devices)	05		Pass
Packaged Shock and Vibe: document review and inspection only	05		Pass
Fluid Ingress: document review and inspection only	N/A		Pass
EMC: document review and inspection only	EMC		Pass
Shelf Life (Bandage Only): document review and inspection only	-		Pass
Cleaning	N/A		Pass
Quality, Regulatory and Safety Tests			
Product Safety: document review and inspection only	05		Pass
Device Classification: document review and inspection only	05		Pass
Quality Approval: document review and inspection only	-	-	Test Removed ³
Biocompatibility: document review and inspection only	N/A		Pass
Physical And Mechanical Tests			
Physical	N/A		Pass
Mechanical	N/A		Pass
Unit and Integration Tests			
Unit and Integration	N/A		Pass

¹ The Therapy Duration testing is in progress and will be completed in mid March 2008.

(b)(4)

³ The test was removed because issues were not created in the Capricorn Issue Tracking project. An Open Issues Report was created and attached to the end of the Verification Report.

The final usability verification of the dressing, tubing and instructions for use was performed by IASIS Medical. The testing results are summarized in the table below. Details of the IASIS test results are provided in the NPD 1000 Negative Pressure Dressing Verification and Validation Test Report, QFM-04-3c, which is provided in **Appendix 9**. There is one open issue. The bandage shelf life testing is in progress and will be completed beginning April 2008.

Table 15: IASIS Usability Testing Summary

System Requirement	Test	Results
SYSREQ54709	The NPD 1000 dressing shall have a fluid capacity of at least 25 cc of wound exudates.	Pass
SYSREQ54699	The NPD 1000 Negative Pressure Dressing shall be wearable by the user for 3 days or until bandage is full.	Pass
SYSREQ54663	The NPD 1000 dressing has a design feature to allow the user to detect if the dressing has reached its fluid capacity during treatment.	Pass
SYSREQ54701	The Micro NPWT bandage shall adhere to the healthy skin at the perimeter of the wound such that it remains in place for at least three days.	Pass
SYSREQ54700	This procedure will verify that the NPD 1000 dressing has an IPX rating of IPX0.	Pass
SYSREQ54789	The NPD 1000 IFU shall contain a warning of the presence of Ag in the Negative Pressure Dressing and the possibility exists for an allergic reaction.	Pass
SYSREQ54792	the IFU for the NPD 1000 system shall include user instructions detailing necessary device maintenance and cleaning.	Pass
SYSREQ54797	The IFU for the NPD 1000 system shall include user instructions that the device is intended for single patient treatment.	Pass
SYSREQ54783	The NPD 1000 system shall include user instructions of proper device operation in proximity to strong magnetic fields.	Pass
SYSREQ54647	The IFU for the NPD 1000 system shall include user instructions that the control unit is reusable between patients.	Pass
SYSTST55547	The NPD 1000 bandage shall have a minimum shelf life of 1 year.	In Progress
SYSREQ54712	The Micro NPWT bandage shall be connectable to a tubing set in less than 30 seconds. Note: tubing set to be used with the Micro NPWT system is 3/32 inch I.D. tubing.	Pass
SYSREQ54713	The Micro NPWT pump module shall be connectable to a tubing set in less than 30 seconds.	Pass

Revision Level History

A summary of the revisions made to the software is provided in the table below.

Table 16: Revision Level History

(b)(4)



Section 17 – Electromagnetic Compatibility and Electrical Safety

Introduction

Electromagnetic compatibility (EMC) testing was performed on the NPWT device by Intertek Testing Services located in Oakdale, MN. The EMC testing was performed in accordance with IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests (Second Edition, 2001). The electrical safety testing was performed by Medical Equipment Compliance Associates, LLC located in Oak Creek, WI in accordance with UL 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety (First Edition, 2006). The Standards Data Reports (Form FDA 3654) and the EMC and Electrical Safety testing reports are provided in **Appendix 10**.

EMC Testing

The NPWT device under test was operated under Continuous Normal Mode conditions in both Continuous Therapy and Intermittent Therapy modes. The following EMC testing was performed. Line Conducted Emissions, Harmonic Emissions, Voltage Fluctuations Emissions, Burst Immunity, Conducted RF Immunity, Surge Immunity and Voltage Dips/Short Interruptions Immunity testing is not applicable since the NPWT device is battery operated and has no connection to mains/system.

Table 17: EMC Testing

IEC 60601-1-2 Section	Test	Acceptance Criteria	Result
36.201.1	Emissions: protection of radio services (radiated emissions)	< 30.0 dB μ V/m for 30-124 MHz < 37.0 dB μ V/m for 340-440 MHz	Pass
36.202.2	Immunity: Electrostatic discharge (ESD)	No degradation of essential performance at 2kV, 4kV, 6kV for contact discharge and 2kV, 4kV, 6kV, 8kV for air discharge.	Pass
36.202.3	Immunity: Radiated RF electromagnetic fields	No degradation of essential performance at 3V/m over frequency range of 80-1000 MHz and 1.0-2.5GHz.	Pass
36.202.8.1	Immunity: Magnetic Fields-Power frequency magnetic fields	No degradation of essential performance at 3A/m at frequencies of 50 Hz and 60Hz.	Pass

Conclusion

The results of these tests show that the NPWT device meets the EMC requirements of IEC 60601-1-2.

Electrical Safety Testing

The NPWT device under test was operated under Continuous Normal Mode conditions in both Continuous Therapy and Intermittent Therapy modes. The following electrical safety tests were performed. The Abnormal Operation and Fault Conditions (section 52) was not performed because the device is powered by a limited power source (<15W).

Table 18: Electrical Safety Testing

UL 60601-1 Section	Test	Acceptance Criteria	Result
6.1	Marking Durability	Markings do not come loose or curl at edges and are clearly readable.	Pass
19.4g	Enclosure Leakage	< 100 μ A	Pass
19.4h	Patient Leakage	< 10 μ A	Pass
20.4	Dielectric Voltage Withstand	No indication of dielectric breakdown.	Pass
21a	Enclosure Mechanical Strength-Force	No cracking of the enclosure.	Pass
21b	Enclosure Mechanical Strength-Impact	No live parts that become accessible.	Pass
21.5	Drop Impact	No damage to the interior or exterior which causes exposure to live parts or increases risk of electric shock.	Pass
42	Temperature	< 41°	Pass
44.5	Humidity	No dielectric breakdown.	Pass
44.7	Cleaning	No dielectric breakdown.	Pass
49	Interruption of Power Supply	No safety hazard other than interruption of intended function.	Pass
52.4.1	Power Availability	< 15 W	Pass
55	Mold Stress Relief	No warping, cracking or breaking; no exposure of live parts.	Pass
56.7	Reversed Battery Connection	Battery shows no signs of emission of flames, toxic gases, molten metal or risk of explosion.	Pass
59.2	Ball Pressure	Depression < 2 mm	Pass

Conclusion

The results of these tests and the verification of all applicable requirements as listed in the report show that the NPWT device meets the electrical safety requirements of UL 60601-1.

Safety Testing Conclusion

The results obtained from the above-described testing show that the device meets its performance requirements for safety of medical electrical equipment.

Section 18 – Performance Testing - Bench

Introduction

Representative samples of the NPD 1000 Negative Pressure Wound Therapy System were tested in accordance with the System Verification and Validation Plan (DP-0001-85-0) and the Verification Test Procedures (DP-0001-84-0), provided in **Appendix 8**. These documents detail the tests, methods and acceptance criteria to confirm that the hardware and software designs were implemented correctly and to ensure that the performance requirements of the device were met. The default unit under test (UUT) sample size is one (1) unless specified otherwise in each individual test. All timing and performance requirements had a tolerance of $\pm 10\%$ unless specified in the individual test.

The system verification and validation testing performed by Minnetronix included functional tests, user interface tests, hardware interface tests, stress and robustness tests, environmental tests, quality, regulatory and safety tests, physical and mechanical tests, and unit integration tests. The verification test results are summarized in Section 16, **Table 14**. Details of the Minnetronix test results are provided in the Verification Report, DR-0000-09-0, which is provided in **Appendix 9**. There are two open items as a result of the Minnetronix verification testing. The Therapy Duration testing is in progress and will be completed in mid March 2008. The Pressure Loss Prevention test did not meet the acceptance criteria that the device's loss of vacuum pressure is no more than 10 mmHg/hour (averaged over 5 hours) when the pump is in the off state. During verification testing it was found that both the continuous and intermittent pumps have greatly different leak rates from pump to pump. Most intermittent pumps and half the continuous pumps meet the acceptance criteria. The others do not meet acceptance criteria which may lead to false leak detect errors and reduced battery life, both of which are non-critical and will not affect patient safety. The position of a check valve in the pump plumbing will be moved and the Pressure Loss Prevention test will be repeated to address this issue.

The final usability verification of the dressing, tubing and instructions for use was performed by IASIS Medical. A description of the tests and the results are summarized in **Table 15**. Details of the IASIS test results are provided in the NPD 1000 Negative Pressure Dressing Verification and Validation Test Report, QFM-04-3c, which is provided in **Appendix 9**. There is one open issue. The bandage package integrity and shelf life validation testing is in progress and will be completed beginning April 2008.

The results of these tests show that the NPD 1000 Negative Pressure Wound Therapy System meets the requirements of the verification and validation testing.

Section 19 – Performance Testing - Animal

No animal studies were performed in support of the development of this product; therefore this section is not applicable.

Section 20 – Performance Testing – Clinical

No clinical studies were performed in support of the development of this product; therefore this section is not applicable.

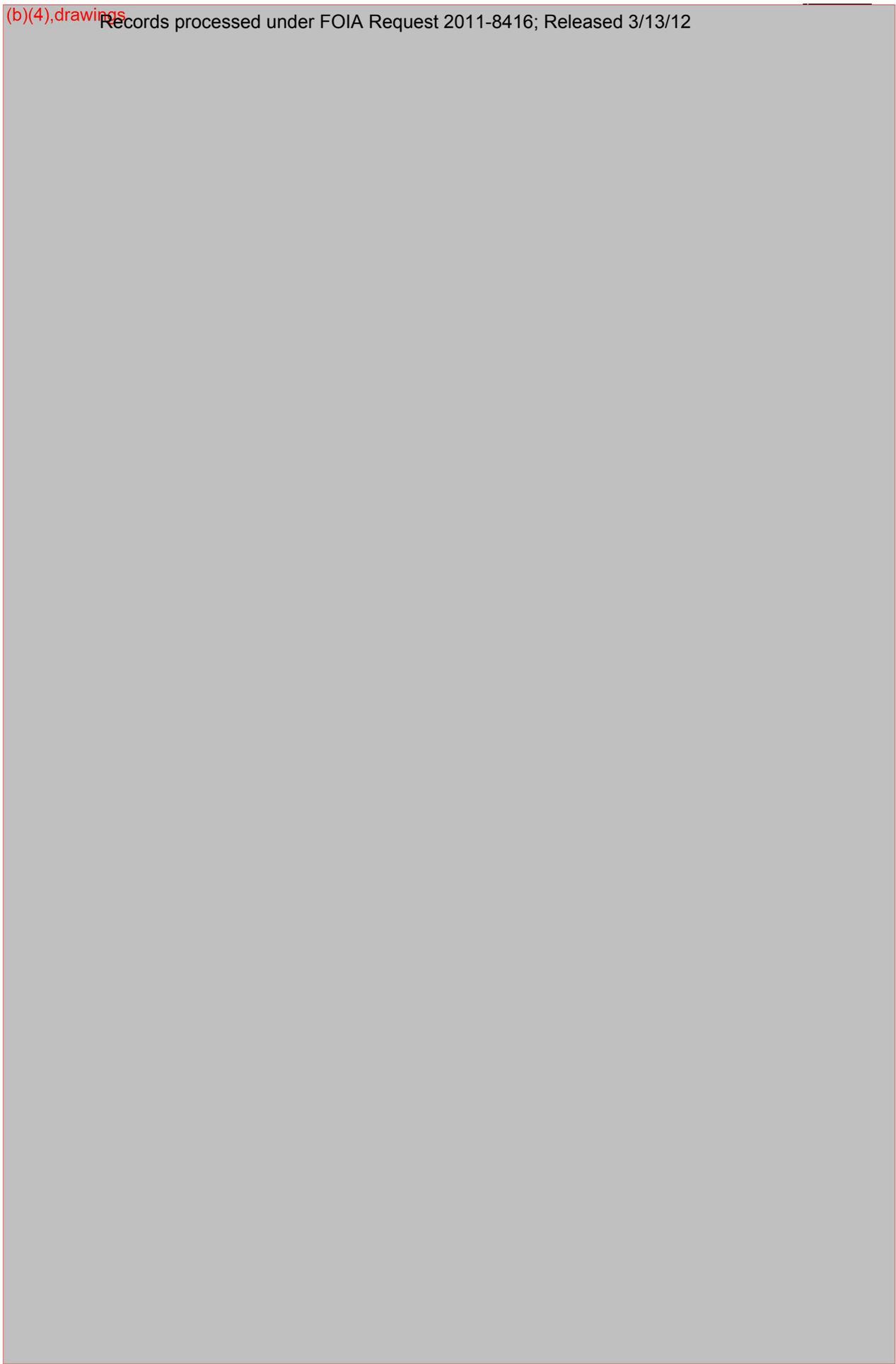
Appendix 1: Pump Unit and Bandage Drawings

Pump Unit Drawings

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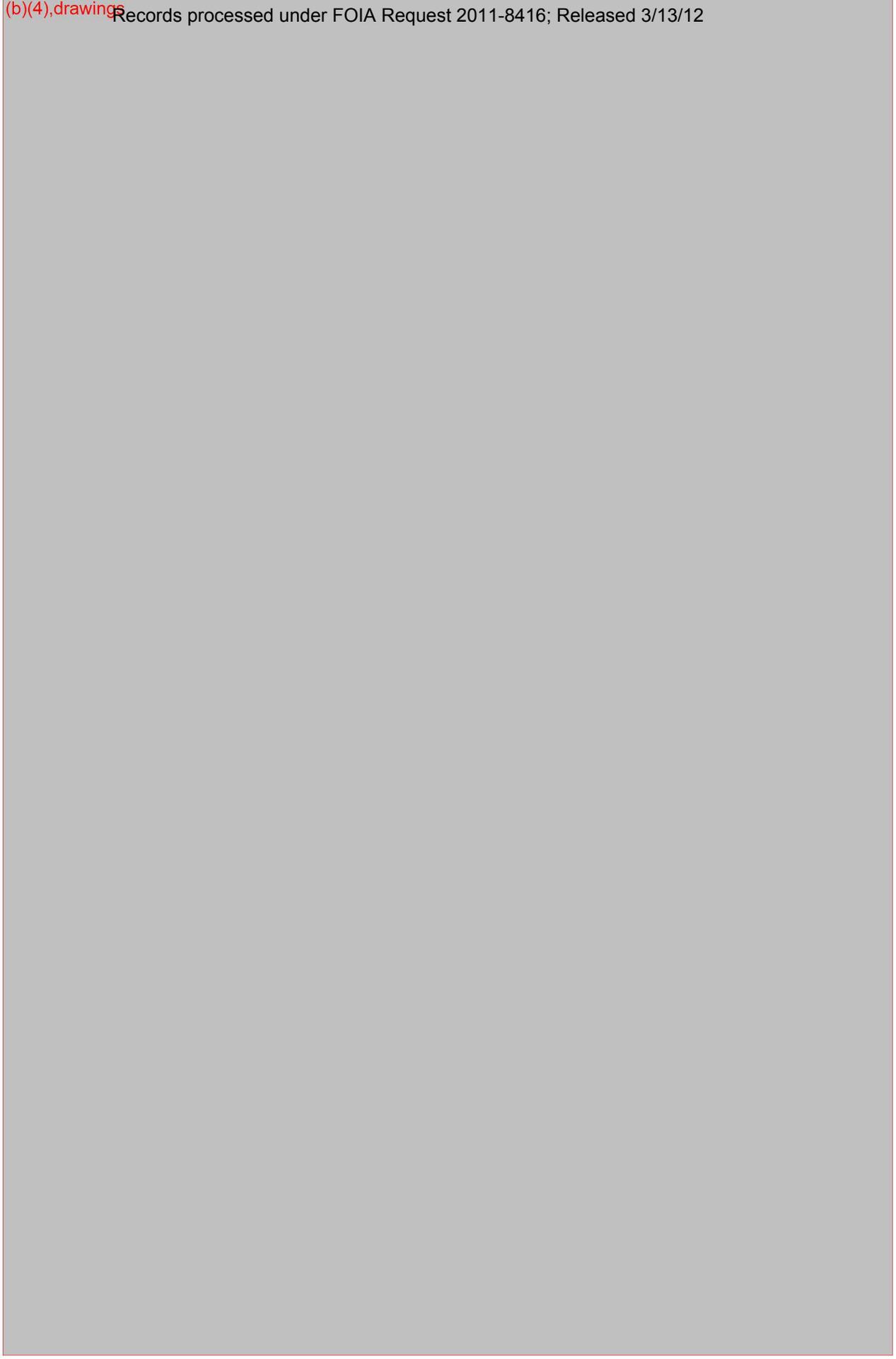
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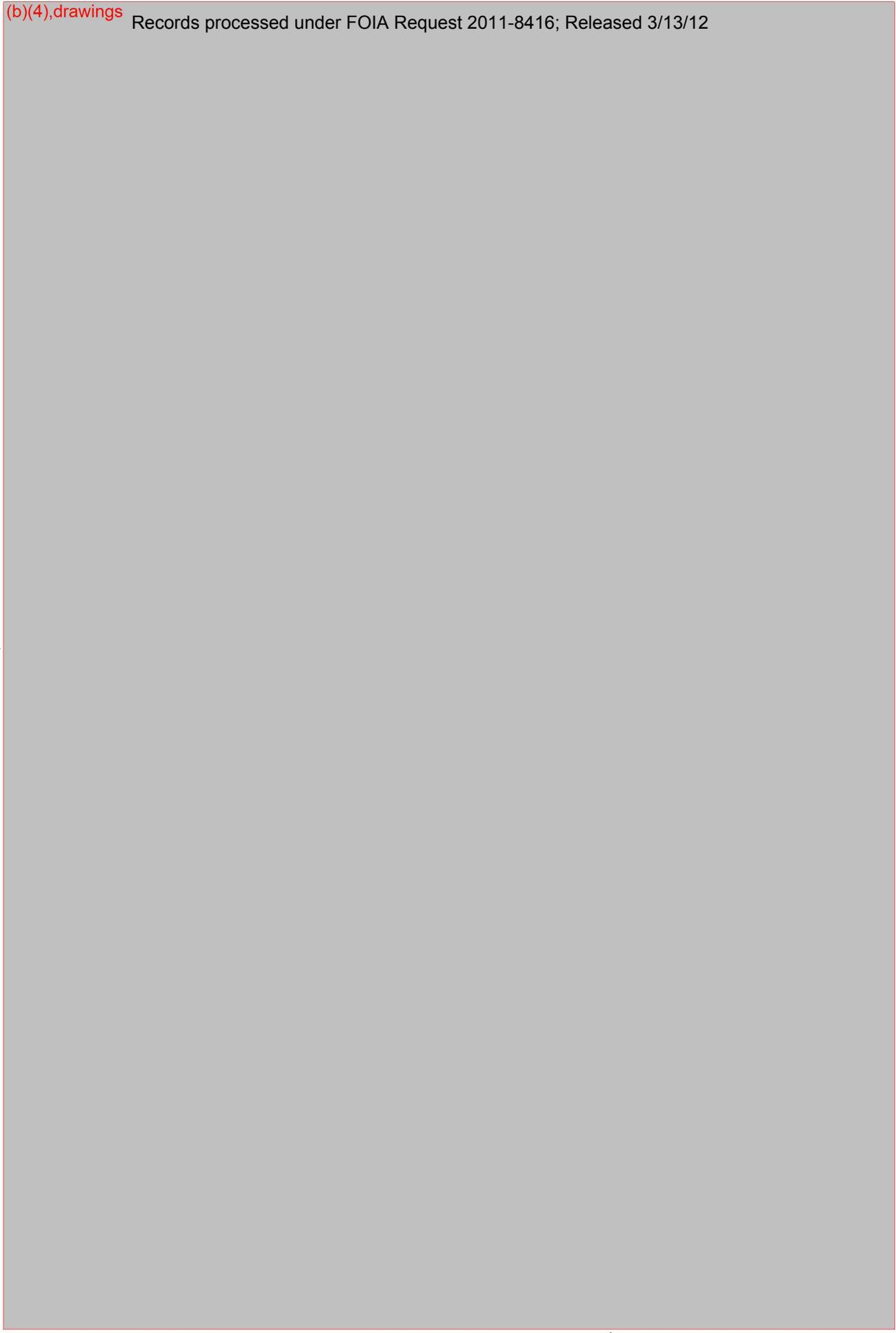
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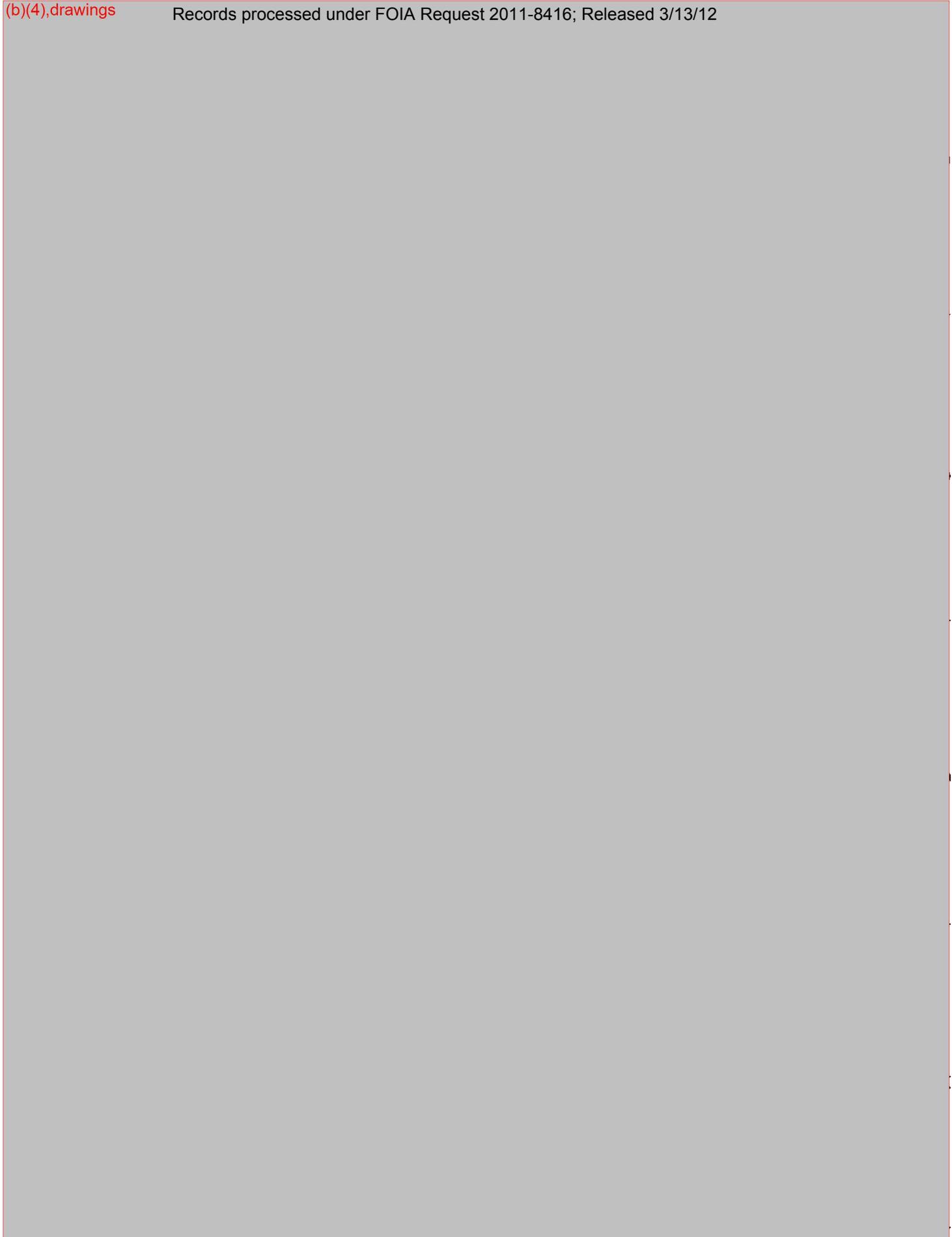
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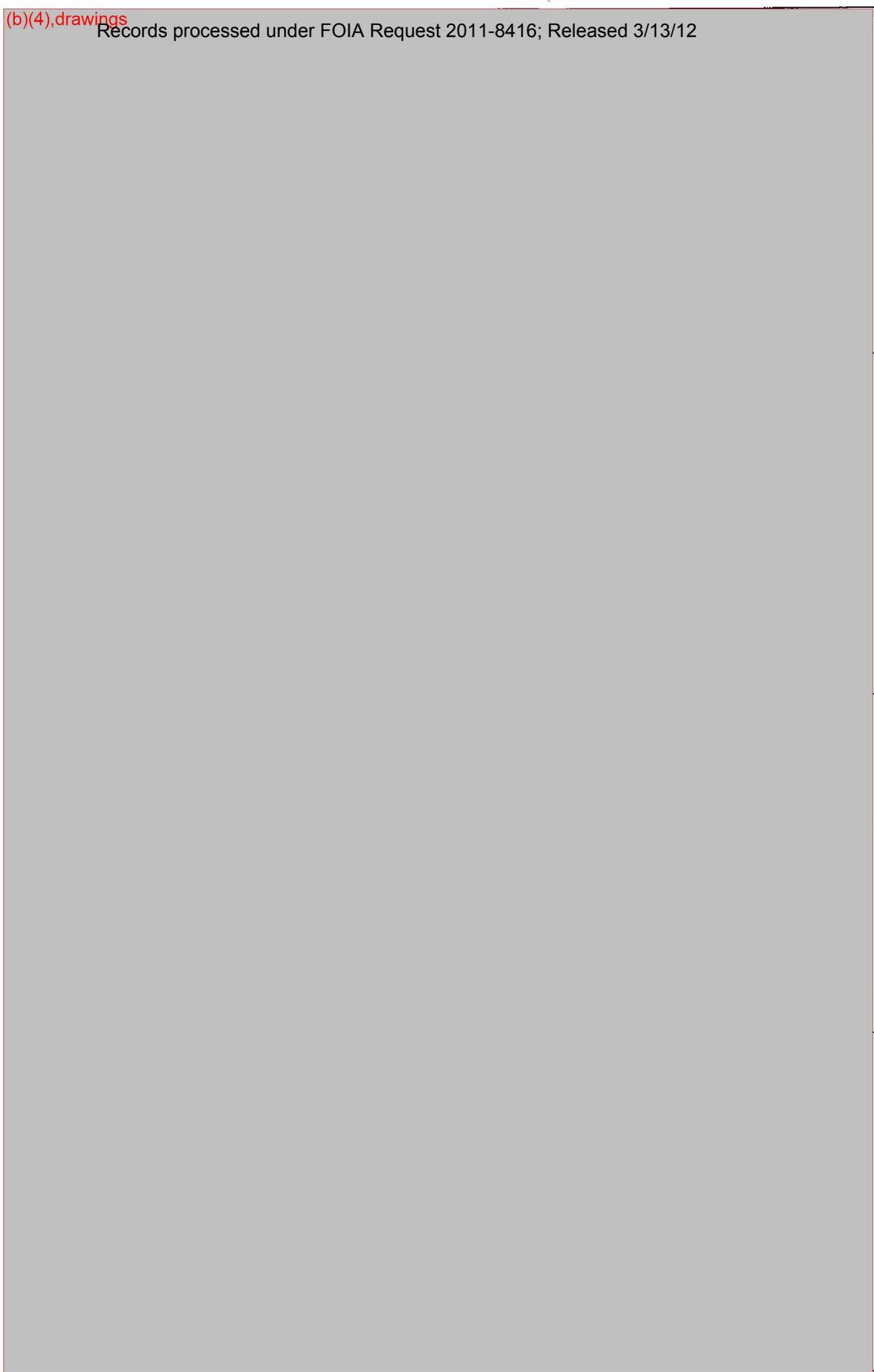
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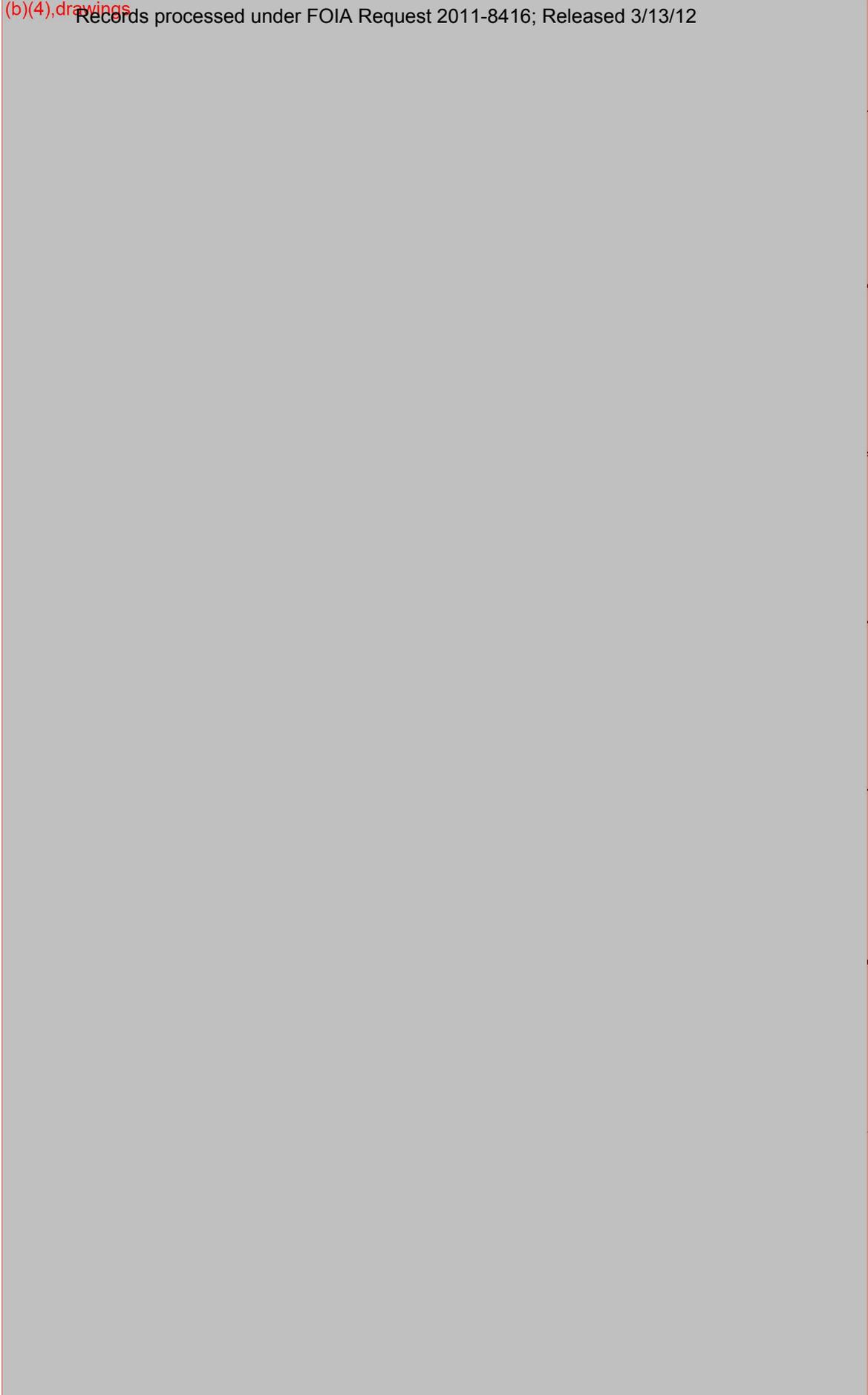
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Wound Dressing Drawings

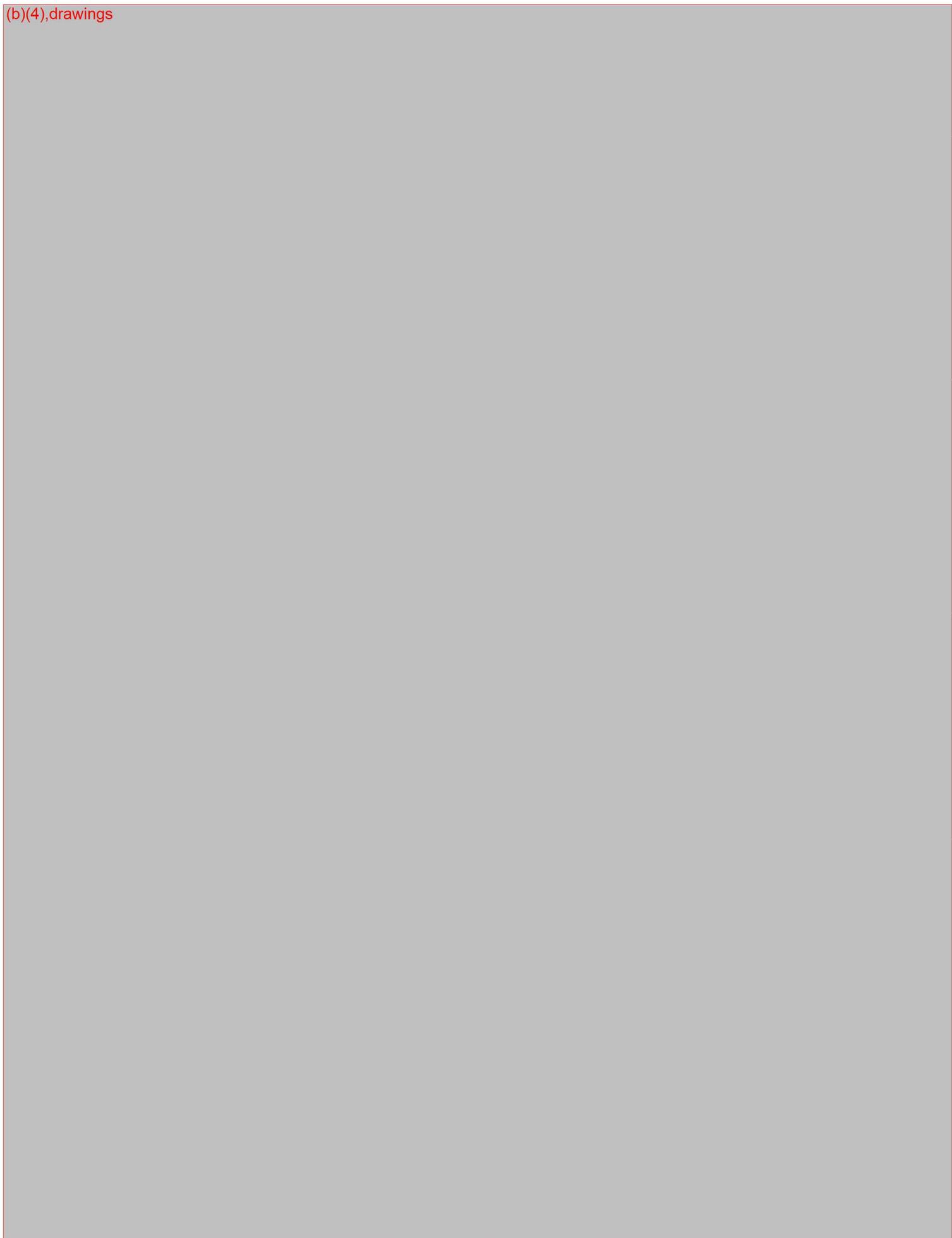
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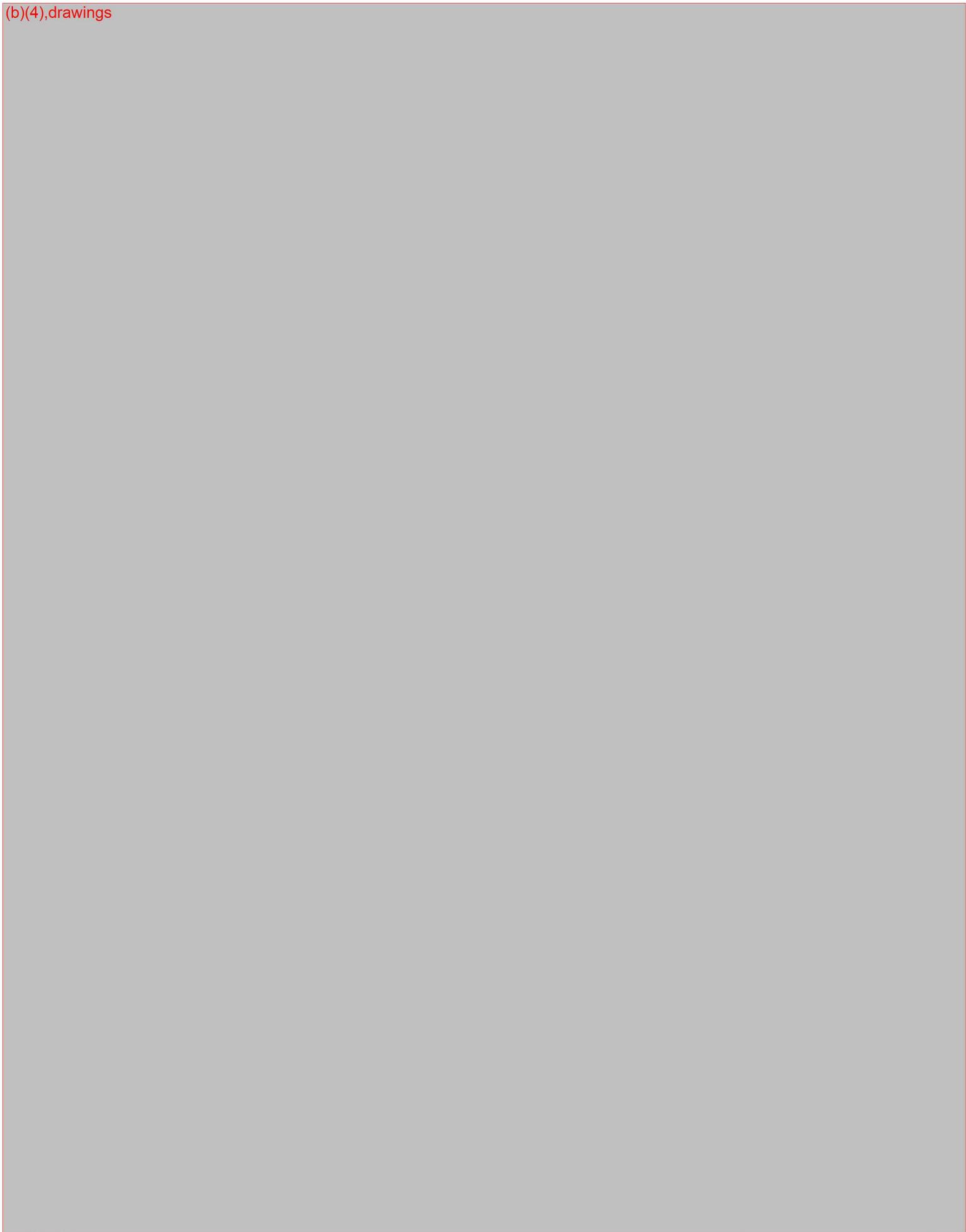
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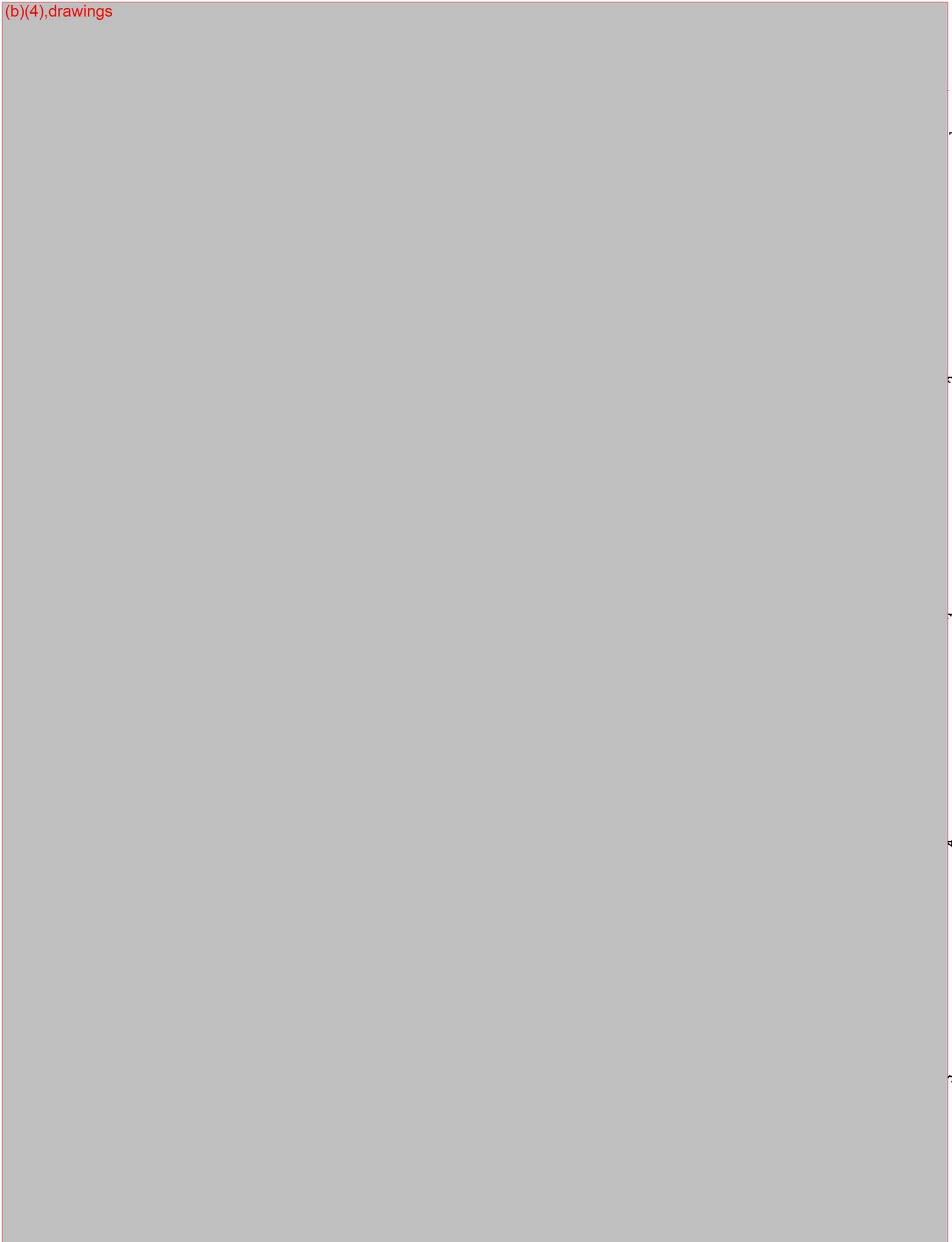
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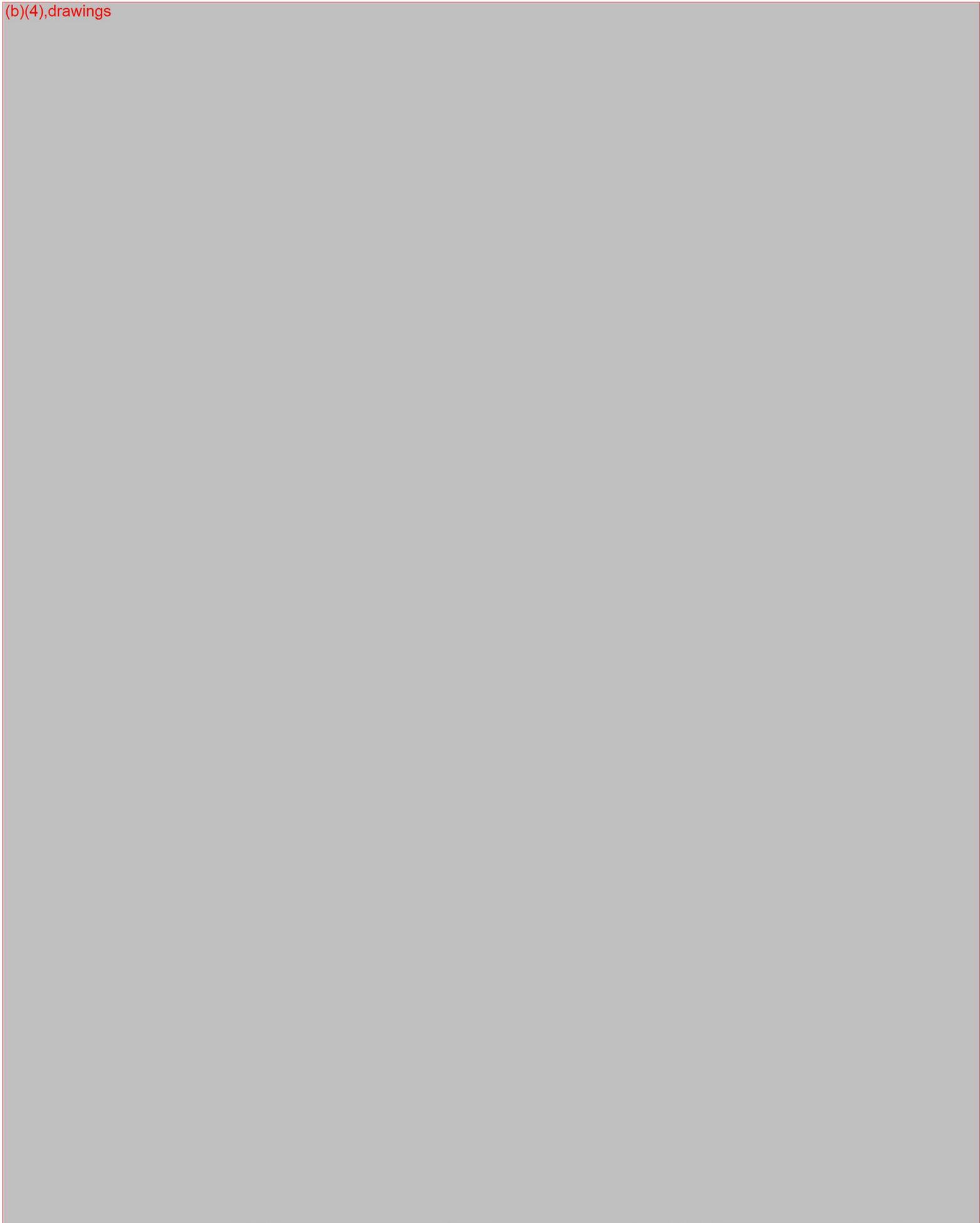
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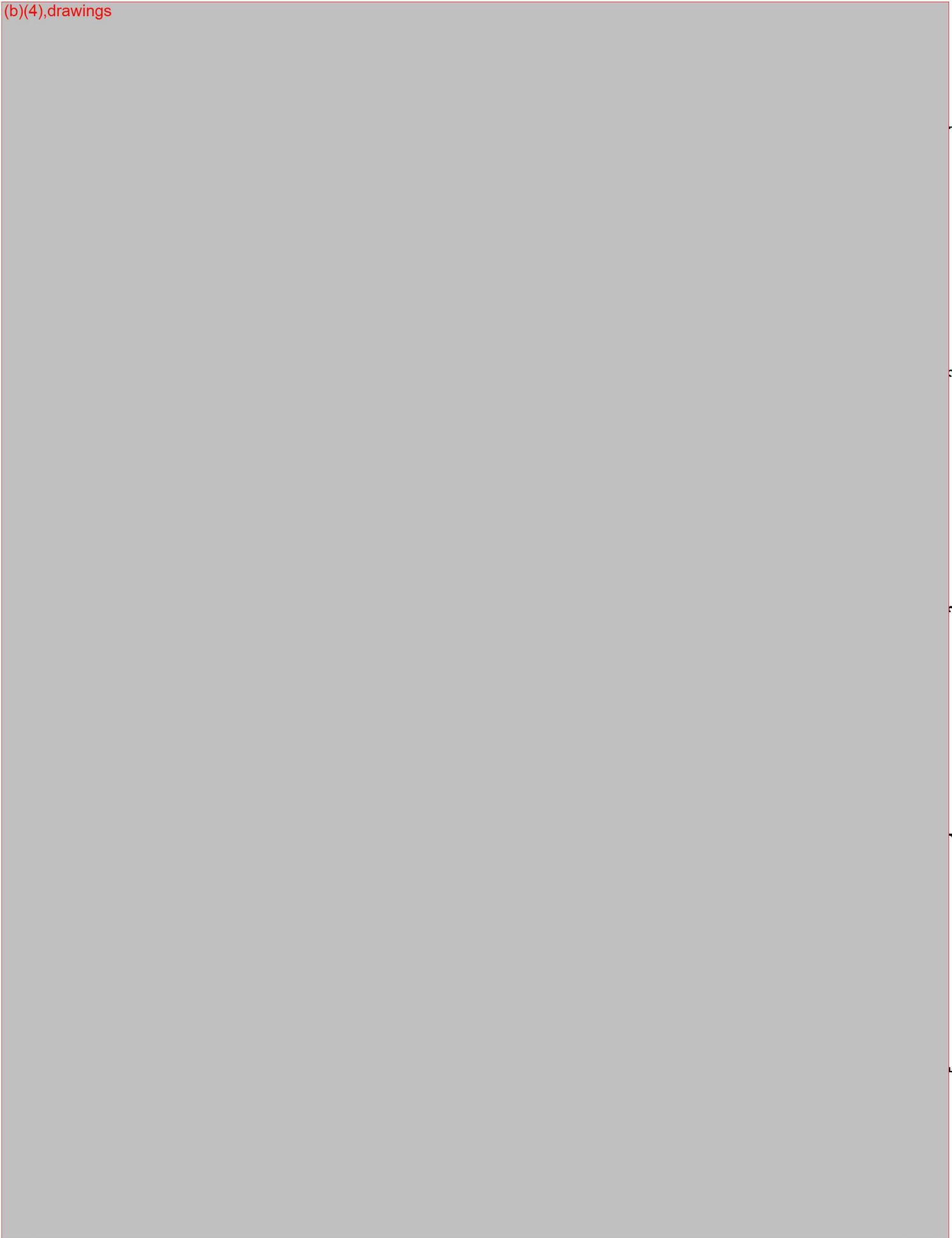
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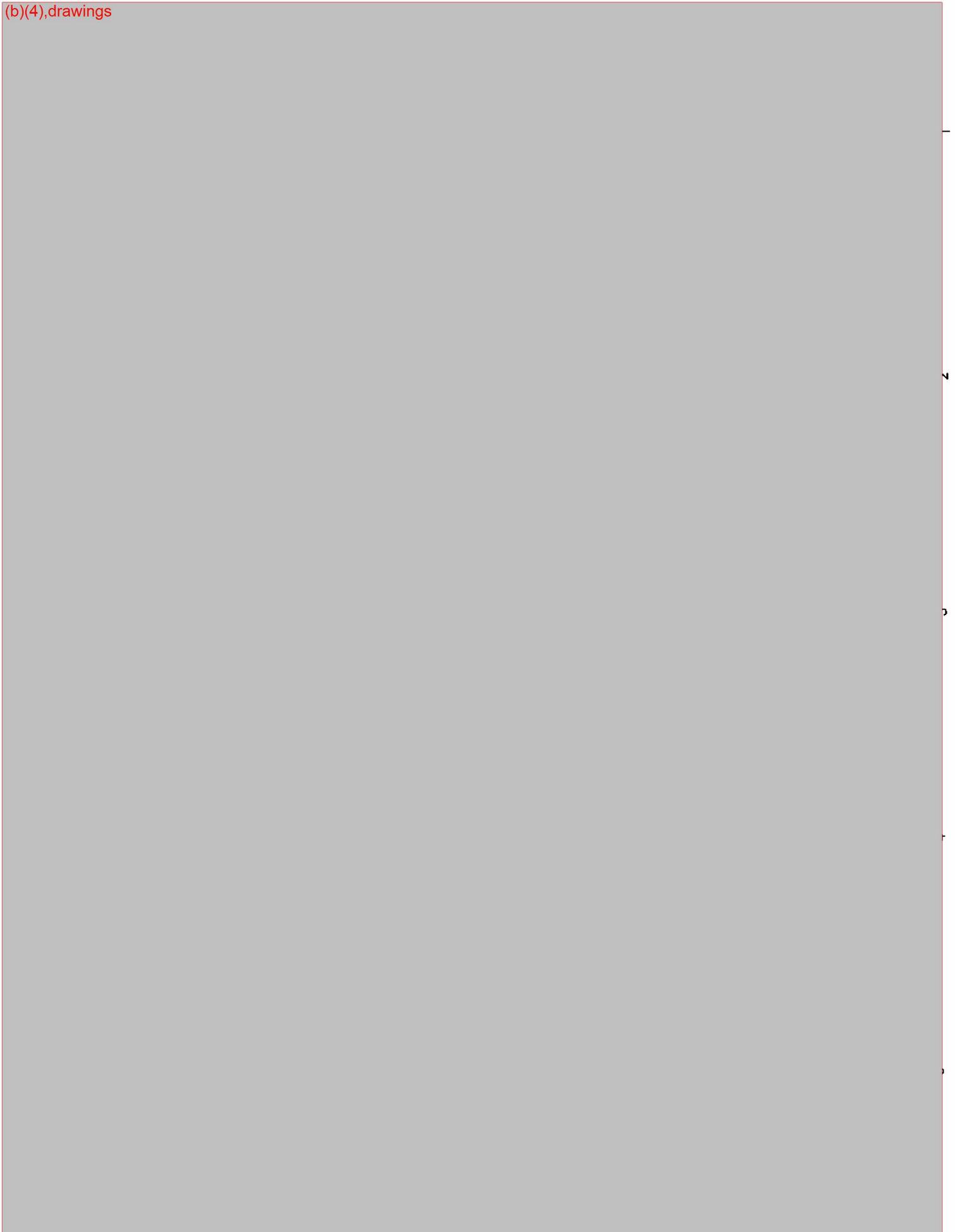
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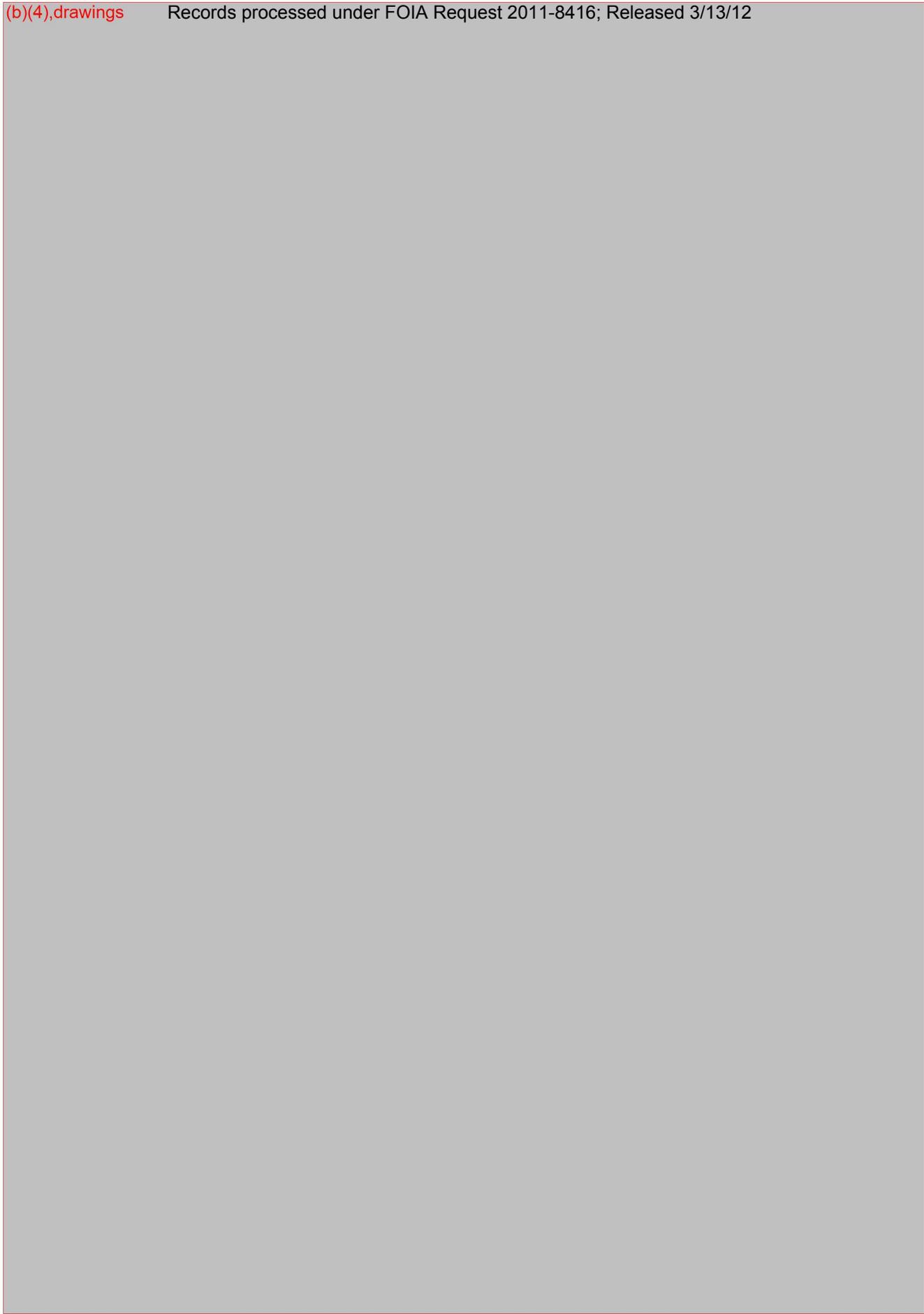


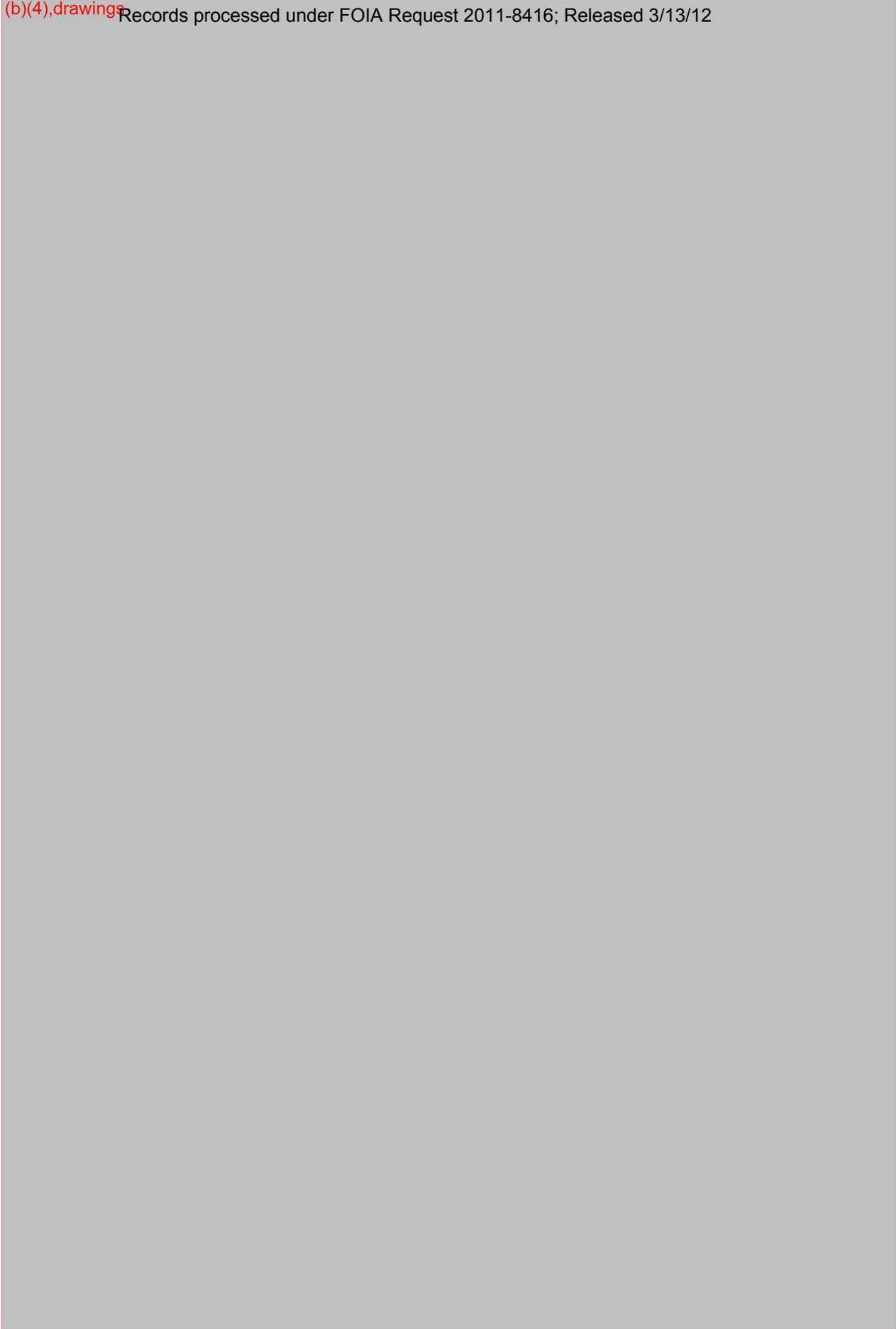
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Appendix 2: Device Labels and Instructions for Use

Control Unit Label

NPD 1000 Control Unit
Negative Pressure Wound
Therapy Device

Manufactured for:
IASIS Medical, Inc.
6393 Oakgreen Ave. S.
Hastings, MN 55033




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

SN:000000 Manufactured: MM/YYYY
P/N:50001 Rev A 11/07 4.5VDC / 1.0A / 4.5VA

Continuous Therapy Pump Module Label

NPD 1000c Pump Module

Manufactured for:
IASIS Medical, Inc.
6393 Oakgreen Ave. S.
Hastings, MN 55033



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

SN:000000 Manufactured: MM/YYYY
P/N:50003 Rev A 11/07

Intermittent Therapy Pump Module Label

NPD 1000i Pump Module

Manufactured for:
IASIS Medical, Inc.
6393 Oakgreen Ave. S.
Hastings, MN 55033



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

SN:000000 Manufactured: MM/YYYY
P/N:50002 Rev A 11/07

Wound Dressing Label

**IASIS Medical Negative Pressure Wound Therapy
50 CC Dressing
w/ SureSeal gasket technology**

For use only with the NPD 1000 Negative Pressure
Therapy Device

Re-Order #: xxxxxxxxxxxxxxxx

P/N 50000 Rev A 11/07



SINGLE USE ONLY

LATEX FREE

STERILE

Do not use if package is open or damaged.



Caution: Consult the NPD 1000 Instructions for Use for directions
on the safe use of this dressing.

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

LOT

xxxxxxxxxx



YYYY-MM

Manufactured for
IASIS Medical, Inc.
6393 Dalgreen Ave.
Hastings, MN 55033
1-800-xxx-xxxx
www.iasismedical.com

Bar Code Here



The NPD-1000, certain accessories and methods
are subject US Patent applications as follows: xxxxx

Assembled in the USA

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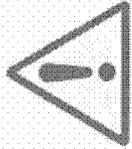
Instruction for Use

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IASIS Medical NPD 1000
Negative Pressure Wound Therapy System

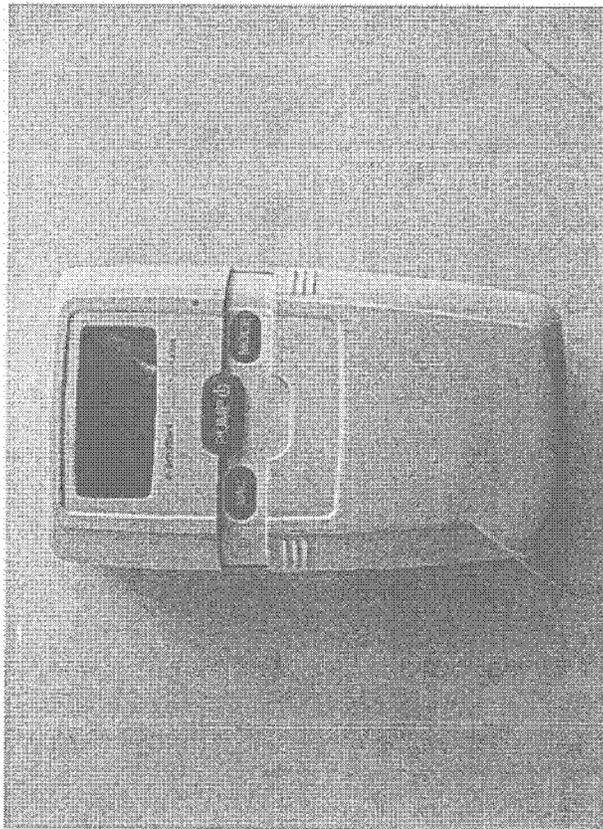
Instructions for Use

WARNING



Important Safety Information accompanies this device. Indications, Contraindications, Warnings, Precautions and other Safety Information are included in these Instructions for Use (IFU). To reduce risk of serious or fatal injury, all caregivers and patients must carefully read and follow all user instructions and safety information that accompany IASIS Medical, Inc. products.

If there are questions contact IASIS Medical, Inc. immediately. See back cover of this IFU for specific contact information.



P/N 50004 Rev A 11/07

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 - b. Dressing
7. Applying the Dressing
8. Programming the Pump
9. Connecting the Pump to the Dressing and Initiating Therapy
10. Troubleshooting
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 - b. Leaks
 - c. Low Battery
11. Course of Negative Pressure Therapy with the NPD 1000
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Glossary

	Refer to the Instructions for Use (IFU)
	Single use only. Do not reuse.
	Date of Manufacture
	Manufacturing Lot Number
	Type B, Applied Part. Internally powered electrical device.
	Keep Dry
	Warning, consult accompanying documents
	Product sterilized by ionizing radiation
	Not protected against harmful effects of water
	Use by date
	Serial Number
	ON/OFF (Vacuum Pump power)
	Part Number
	Low Battery
	Negative Pressure Therapy Pump system is operating
	System Pressure Leak
	Medical Equipment classified with respect to Electrical Shock, Fire and Mechanical Hazards Only in accordance with UL 60601-1 and to CAN/CSA C22.2 No. 601.1 Standards, including JIS amendment by Underwriters Laboratory Inc.

Product Description

The NPD 1000 Negative Pressure Wound Therapy System is comprised of a battery-operated system controller, an attachable electromechanical pump and proprietary wound dressing that uses controlled negative pressure (vacuum) under the wound dressing to create an environment that promotes wound healing by bringing the wound edges together, reducing edema, promoting granulation tissue formation and perfusion, and by removing wound fluids and infectious material.

The pump device (depending on the model purchased) can provide negative pressure therapy in two modes, "continuous" and "intermittent", in pressure ranges from -40mmHg to -125 mmHg. In "continuous" mode the pump holds the pressure inside the dressing at the prescribed programmed level during the entire period the negative pressure dressing is worn and the pump is connected to the dressing and therapy is turned ON. In intermittent mode, the pump cycles between the programmed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. This cycle continues from the time therapy is initiated until the pump is turned OFF.

Available Models

The NPD 1000 Negative Pressure Wound Therapy device is available in two configurations utilizing the universal system controller, the NPD 1000i Intermittent Therapy pump and the NPD 1000c Continuous Negative Pressure therapy pump.

CAUTION: Both devices are designed to work with all IASIS Negative Pressure bandages and are not compatible with other negative pressure bandage systems.

The NPD 1000i is an assembly of the NPD 1000 system controller and the 1000i pump module. It is capable of providing both "intermittent" and "continuous" modes of therapy over the specified pressure range. Additionally, this assembly can be used by multiple patients.

The NPD 1000c is an assembly of the NPD 1000 system controller and the 1000c pump module. It is capable of providing only the "continuous" mode of therapy over the specified pressure range. Additionally, this assembly should only be used by one patient. Note: The system controller can be used by multiple patients but the pump assembly is single patient use only.

Indications for Use

The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Contraindications

Do not use the NPD 1000 Negative Pressure Wound Therapy System for --

1. Application to wounds where there is evidence of
 - a. Exposed arteries or veins in wound
 - b. Fistula – unexplored
 - c. Fistula - non enteric
 - d. Osteomyelitis, untreated
 - e. Malignancy in the wound
 - f. Necrotic tissue with eschar
- NOTE:** After debridement of necrotic tissue and complete removal of eschar, the NPD 1000 Negative Pressure Wound Therapy System may be used.
2. Emergency Airway Aspiration
 3. Pleural, mediastinal or chest tube drainage. These applications require a device that provides specific low suction levels and an underwater seal.
 4. Surgical Suction
 5. Do not apply the NPD 1000 Wound Dressings directly to exposed blood vessels, organs, or nerves.
 6. Sensitivity to silver (NPD 1000 Silver Dressing only).

Warnings, Cautions and Adverse Reactions

Warnings

With or without using NPD 1000 Therapy, certain patients are at high risk of bleeding complications. The following types of patients are at increased risk of bleeding, which, if uncontrolled, could be potentially fatal.

- Patients who have weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to:
 - Suturing of the blood vessel (native anastomoses or grafts)/organ
 - Infection
 - Trauma
 - Radiation
- Patients without adequate wound hemostasis
- Patients who have been administered anticoagulants or platelet aggregation inhibitors
- Patients who do not have adequate tissue coverage over vascular structures.

If NPD 1000 Therapy is prescribed for patients who have an increased risk of bleeding complications, they should be treated and monitored in a care

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setting deemed appropriate by the treating physician. If active bleeding develops suddenly or in large amounts during NPD 1000 Therapy, or if frank (bright red) blood is seen in the dressing, immediately stop NPD 1000, leave dressing in place, take measures to stop the bleeding, and seek immediate medical assistance.

All exposed or superficial vessels and organs in or around the wound must be completely covered and protected prior to the administration of NPD 1000 therapy. Always ensure that NPD 1000 Dressings do not come in direct contact with vessels or organs.

Cautions

- Wound Dressings are single patient use only and should be disposed of in accordance with local rules and practices regarding infectious waste.
- Use of clean technique is the responsibility of the health care professional directly responsible for patient care.
- Use only alkaline or NiMH rechargeable AA cells.
- Safe Performance: Even in fault conditions, the NPD 1000 will not exceed 175 mmHg of suction.
- Do not use the NPD 1000 Wound therapy system in the presence of flammable anesthetics.

- To reduce the risk of transmission of bloodborne pathogens, apply standard precautions for infection control with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. In addition to gloves, use gown and goggles if exposure to body fluids is likely.
- To minimize the risk of bradycardia, the NPD 1000 Negative Pressure Wound Therapy System must not be placed in proximity to the vagus nerve.
- Consider use of a skin preparation product to protect periwound skin. Do not allow foam to overlap onto intact skin. Protect fragile/friable periwound skin with a breathable polyurethane tape, hydrocolloid, or other transparent film.
- If any signs of irritation or sensitivity to the drape, foam, or tubing assembly appear, discontinue use and consult a physician.
- To avoid trauma to the periwound skin, do not pull or stretch the dressing during application.
- Extra caution should be used for patients with neuropathic etiologies or circulatory compromise.
- When using the NPD 1000 Silver Dressing, do not use topical solutions or agents that may have adverse interactions with silver. For example, saline solutions may compromise the effectiveness of the NPD 1000 Silver Dressing.

- Do not allow the NPD 1000 Silver Dressing to come in contact with EKG or other electrodes or conductive gels during electronic monitoring or when taking electronic measurements.
- The NPD 1000 Silver Dressing contains metallic silver that may impair visualization with certain imaging modalities.

Adverse Reactions

- Excessive bleeding is a serious risk associated with the application of suction to wounds which may result in death or serious injury. Careful patient selection, in view of the above stated contraindications, warnings and precautions, is essential. Carefully monitor the wound and collection circuit for any evidence of a change in the blood loss status of the patient. Notify the Physician of any sudden or abrupt changes in the volume or the color of exudate.

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Product Overview

Negative Pressure Pump

The NPD Negative Pressure Wound Therapy Pump Device contains a microprocessor-controlled pump and pressure sensor working in feedback fashion to control the pressure under the dressing at the programmed setting (Fig. 1).

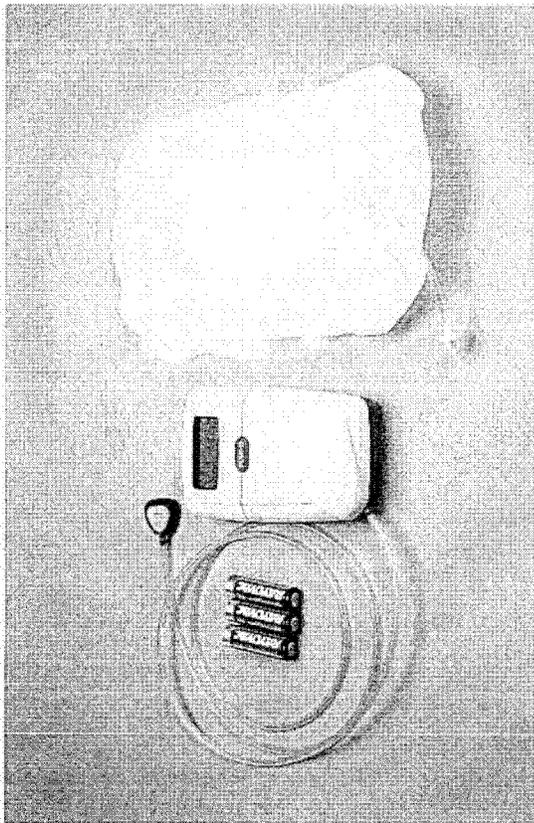


Fig. 1. Iasis Negative Pressure Wound Therapy Device and accessories

It has a user interface of three buttons to control the treatment mode, pressure setting and turn the device ON/OFF. It is powered by 3 AA batteries, either alkaline or NiMH rechargeable cells.

Additionally, it has 6 ft. of tubing with a pressure fitting between the pump and the dressing.

The pump applies controlled suction adjustable by the user in the vacuum range (negative pressure) from 40 mmHg to 125 mmHg. The pump operates in continuous and intermittent modes. For therapy status notification, it has a proprietary leak detection system, a low battery indicator and therapy proceeding indication.

Assembling the Pump

CAUTION: Be careful when assembling device to not pinch your fingers between the two parts.

The NPD 1000 Negative Pressure Pump device is shipped in two pieces, Fig. 2, a system controller and one of two pump housings, either continuous (NPD 1000c) or intermittent (NPD 1000i).

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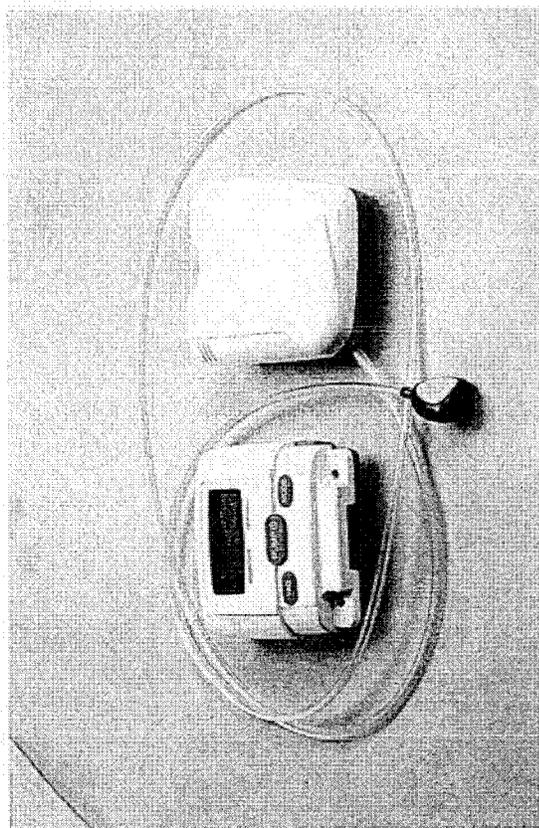


Fig. 2 Iasis Negative Pressure Pump subassemblies
Both pump housings can provide continuous therapy. However, the NPD 1000i housing is the only one that can perform intermittent therapy. Neither the system controller nor the pump housings are provided sterile and do not need to be sterilized between subsequent patients.

To assemble the two pieces into a functioning negative pressure wound therapy device, fit the two subassemblies together by matching the male and female connector housings and pressing them together, Fig. 3a.

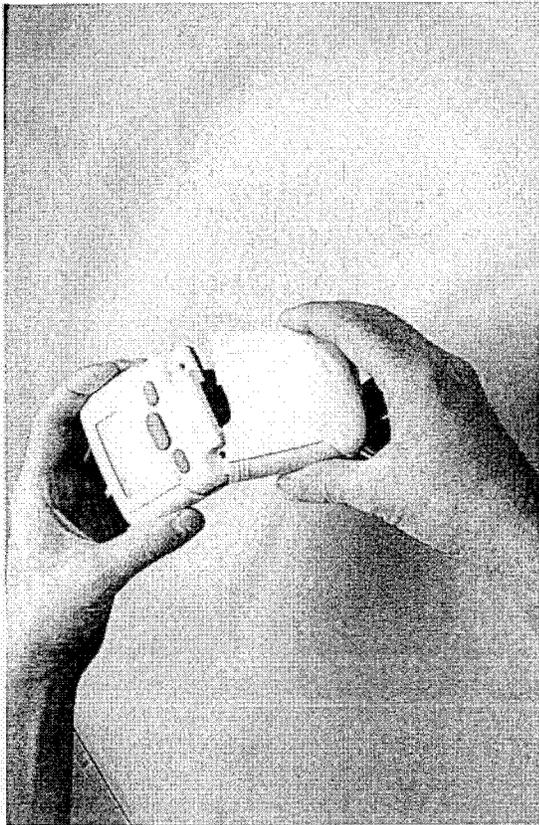


Fig. 3a Assembling the control and pump modules
Insert accompanying screws into pump housing a tighten to point of resistance, Fig. 3b. DO NOT overtighten.

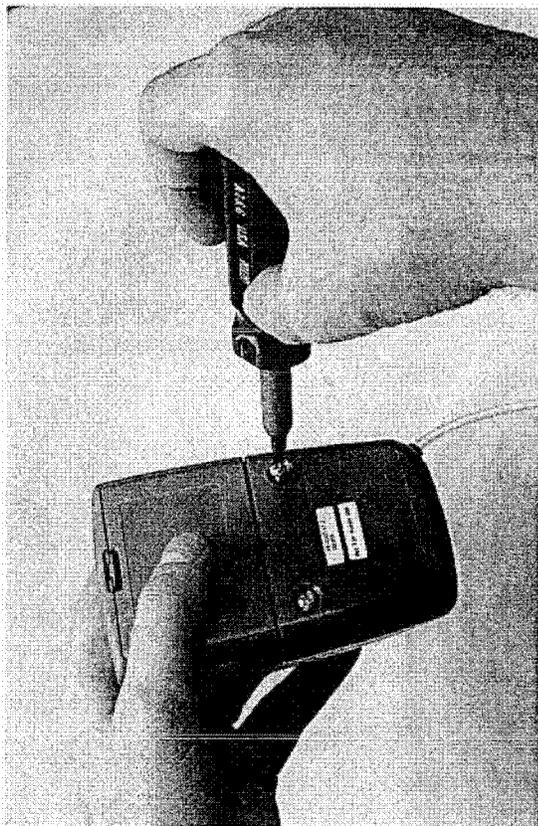


Fig. 3 Inserting screws to secure control and pump Modules

This will secure the device and prevent the modules from separating. The system controller automatically recognizes whether a continuous or intermittent pump has been attached.

NPD 1000 Negative Pressure Wound Therapy Dressing

The NPD 1000 Dressing Technology is a state-of-the-art product that delivers the benefits of negative pressure therapy without the need for a canister attached to the pump.

Applying the Dressing

Carefully inspect the wound and treat per the order of the patient's physician and according to the institution's protocol and standards of practice for wound care. This should include proper hand washing and gloving practices. Appropriate skin prep should be used to preserve the wound margins and prevent epithelial stripping.

1. Prior to application of the cover, ensure that the skin around the wound is clean, dry and shaven. This will ensure proper adherence and sealing of the thin film dressing.
2. Use of a skin preparation layer may protect peri-wound skin and promote and prolong cover adhesion.
3. Remove the NPD 1000 dressing consumables from the sterile package.
4. Remove the release liner from the dressing exposing the adhesive side of the dressing and the sealing gasket, Fig. 5.

It is comprised (See Fig. 4) of a semi-occlusive outer layer that maintains the negative pressure (1), a pressure port with an in-line hydrophobic, anti-bacterial filter to which the NPD Pump system is attached(2), a hydrogel gasket to seal the wound area(3), a super-absorbing non-woven polymer matrix to absorb exudates(4) and a non-stick wound contact layer(5). The dressing also has three windows near the pressure port (6) to monitor if the dressing is nearing its exudates capacity.

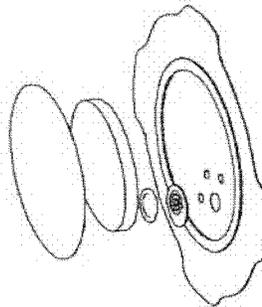


Fig. 4 Components of IASIS Negative Pressure Dressing



Fig. 5 Removing the dressing release liner.

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- 5. Carefully place the dressing on the wound, taking care to minimize folds and wrinkles, Fig. 6.
- 6. Do not force the wound dressing into cavity wounds. For cavity wounds a standard wound filler such as gauze or foam must be used.



Fig. 6 Applying the dressing over a wound

- 6. Run your finger along the perimeter of the gasket to secure the gasket material to the skin and increase the dressing seal, Fig. 7.

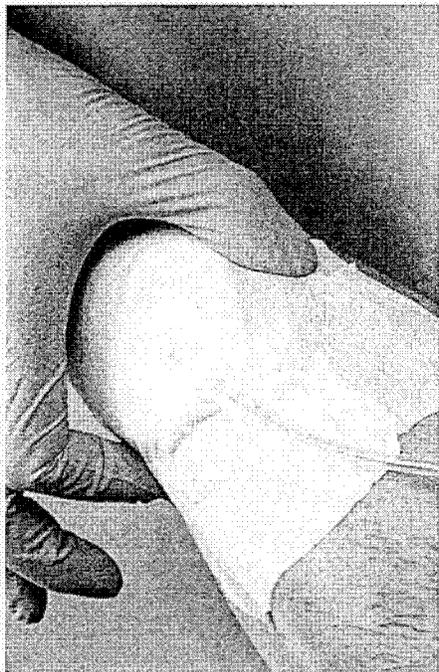


Fig. 7 Securing sealing gasket to skin

- 7. Attach provided pigtail tubing to the port on the top of the dressing, Fig. 8.

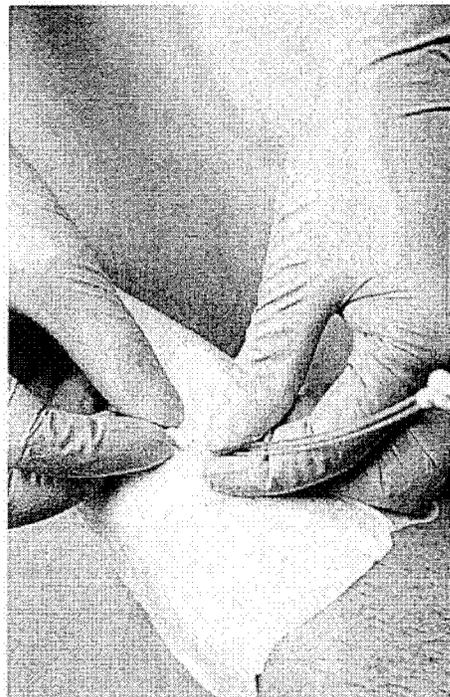


Fig. 8 Attach pigtail tubing to dressing

The dressing is now ready for application of negative pressure.

Programming the Pump

CAUTION: When programming the pump system, make sure that the settings match exactly those specified by the physician. Not following the negative pressure therapy prescription, could result in sub-optimal therapeutic results.

Before attaching the pump device to the patient's dressing, the clinician should set the device to the appropriate treatment settings in the following way:

1. Slide the bottom cover down to expose the programming, labeled "VAC" and "MODE", buttons, Fig. 9.

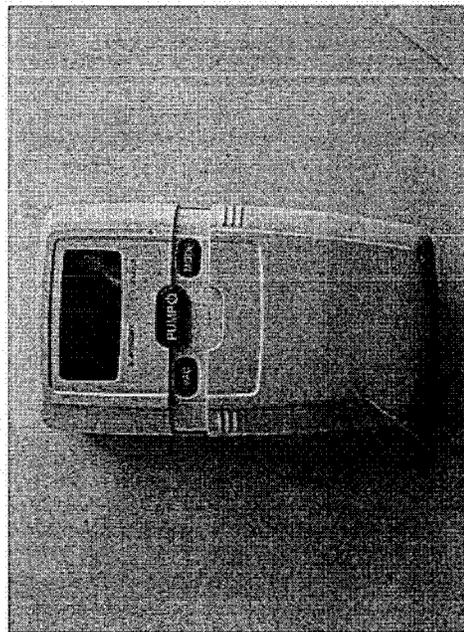


Fig. 9 Negative Pressure Wound Therapy Pump programming buttons

2. Depress and hold the "VAC" and "MODE" buttons simultaneously, while also pressing the power button, for one second.
3. Release the buttons and the device will beep twice and the pressure setting on the screen will blink, indicating the device is in programming mode.
4. Depress the "MODE" button to toggle the device between "continuous" and "intermittent" therapy, according to the placement of the tic mark on the display. For a description of "continuous" and "intermittent" therapy, see the **Product Description** section of this IFU.
5. Next depress the "VAC" button to set the pressure. The system cycles down 15 mmHg for each button push. The available settings are 40, 50, 65, 80, 95, 110 and 125 mmHg. The default setting of the device is 125mmHg of vacuum.
6. After setting the device to the prescribed therapy, press the power button briefly,  to exit setup mode.
7. Slide the bottom cover back into place to protect the buttons.

Connecting the Pump to the Dressing and Initiating Therapy

1. Trim pump tubing to appropriate length with a scissors, Fig 10. When determining the tube length, take into consideration where and how the patient will carry the device during mobile use and how the device will be placed during stationary use.

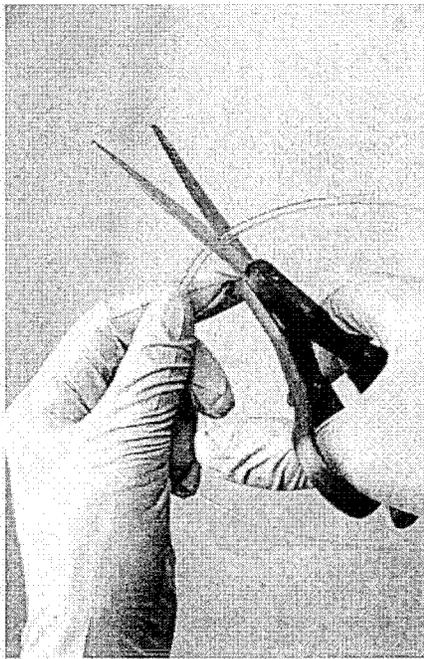


Fig. 10 Trimming pump tubing to length

2. Attach proprietary connector to newly trimmed tubing. Push the end of the tubing entirely over the hose barb at the end of the connector.
3. Attach the pump to the dressing by mating the connector on the pump tubing to the connector on the dressing tubing, Fig. 11.

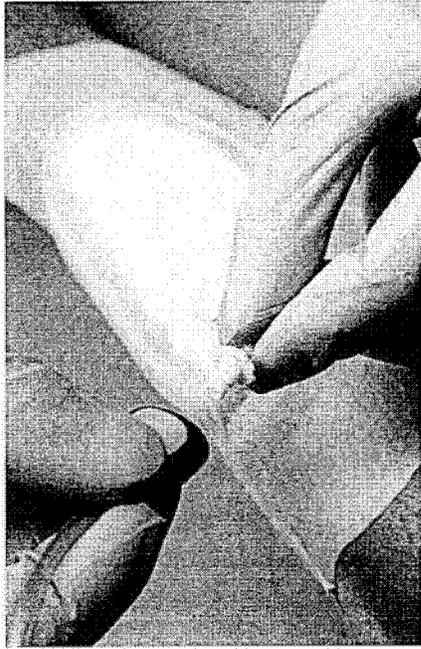


Fig. 11 Connecting the pump to the dressing

4. Depress the ON/OFF button for one second and release. The pump should turn on and the dressing should begin to contract under the application of negative pressure. Additionally the therapy preceding icon  should appear in the upper left hand corner of the screen. The device can be shut off by pressing the ON/OFF button again for 1 second and releasing.
5. After the pump has shut off, watch the device for a 2-3 minutes to be certain of the quality of the seal on the dressing. If the leak icon  does not appear, The pump should only run very briefly every 30 seconds to 5 minutes (depending on the quality of the dressing seal) once the therapy has started.

In the RUN mode, the user may not even hear the pump when it is operating.

6. The patient can know that the system is operating as needed by looking at the screen and finding the therapy proceeding icon  in the upper left hand corner.
7. If the user or clinician notices, either an audible beep from the device or visual indicator on the screen, either the low battery indicator icon  or the leak icon , during setup or during therapy, proceed to the troubleshooting section of this IFU.

Troubleshooting

The following are the alarm states for the NPD 1000 Negative Pressure Wound Therapy Pump signaled by an audible beep from the device or a visual indication on the LCD display.

1. All LCD Segments Flashing –

This condition indicates a system fault. Turn off the device, remove the batteries for 30 seconds, replace and turn the device on again. If the condition is repeated after this process, the device will not function properly. Interrupt therapy and call your clinician for guidance.

2. Leak Balloon Icon On –

 If the leak icon is present, the system has a leak in the dressing, the tubing or the device. Depending on the source of the leak, the user may or may not be able to fix it. The most likely source of a system leak is the dressing so troubleshooting should start there.

Bandage Leaks - First, run your fingers along the perimeter of the gasket applying gentle pressure. Also, smooth out any wrinkles in the semi-occlusive dressing outside the gasket. Wait for 2 to 3 minutes to see if the alarm condition goes away. For a new dressing, the gasket may take a few minutes to seat itself properly to provide a good seal.

If the leak icon does not disappear after two attempts to seat the gasket, then the leak may be in the tubing or the device.

Tubing Leaks - First, make sure the tubing is securely attached to all of the fittings, including the pressure port on the dressing and the quick connect fittings that connect the pump device to the dressing. The connection should be firm enough to withstand a firm tug on the tubing.

If after verifying that the tubing connections are good, the leak icon is still present, a existing dressing should be removed and disposed of in accordance with local regulations. Apply a second dressing and attempt to achieve a good seal (follow directions found in the "Applying the Dressing" section of this IFU). If the dressing has been applied in accordance with the instructions and a leak still exists, it is likely that the leak is in the pump itself. Call your clinician for guidance. Clinicians having this problem should call their IASIS representative for instructions as the device may need servicing that can only be done in the factory.

3. **Low Battery Icon On** –

 If you see the low battery indicator, replace the batteries. First, turn off the device by pressing the ON/OFF button for one second.

NOTE: If the batteries are low in the middle of therapy, there is no need to disconnect the pump unit from the bandage.

Remove the battery door and remove the batteries. Place new batteries in the battery holder in the orientation found in the battery holder. Replace the battery door. Turn on the device by pressing the ON/OFF switch for one second. The device will return to the therapy

mode in place when the device was turned off.

4. **Disabling the Audible Alarm** –

The audible alarm warns the user of the presence of a performance problem with the device. These alarms are also displayed on the LCD display. For many reasons, the user may wish to disable the audible alarm for a few minutes.

The alarm sound can be temporarily disabled by pressing any of the three blue buttons briefly. This will disable the alarm for 5 minutes. After which time, it will sound again if the alarm state still exists.

Course of Therapy with the NPD 1000

Dressings should be changed per the standard protocol for negative pressure wound therapy, every two to three days or when the dressing is full, whichever is sooner. The patient/clinician can tell if the dressing is full by monitoring the three windows near the pressure port. If they appear discolored (as in exudate is being absorbed in the pad near the pressure source, the dressing should be changed.

Disposal of Dressing and Pump

The NPD 1000 dressing is not constructed with any hazardous materials. Subsequently, after use it can be disposed of in the normal medical waste stream for wound care dressings.

The NPD 1000 Negative Pressure Wound Therapy Pump System is an electromechanical device powered by non-integral batteries. The batteries and device should be recycled according to the local regulations governing such products.

Care and Service of the Pump Device

The outside case of both the system controller and pump housings can be cleaned off with a water dampened cloth. No solvents should be used. Do not open either device as proper operation can not be assured once this has happened. These devices are tested to an IPX0 rating. Thus, they can not be immersed in water or subject to large volumes of water spray such as in the shower.

1. There are no user serviceable components inside the IASIS NPD 1000 Wound Therapy System Pump.
2. Contact your IASIS representative for return/replacement of damaged pumps.
3. Do not open the NPD 1000 pump or attempt to service it yourself.

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Product Specifications

Dimensions	3.2" W x 5.1" H x 1.3" D
Weight	8 oz.
Pressure Options	-40 to -125 mmHg
Therapy Delivery Modes	Continuous and Intermittent
Battery Type	Alkaline or Rechargeable NIMH
Battery Life	3 weeks or more
Patient Enclosure Leakage Current	N/A (Battery powered device)
Storage Conditions	
- Temperature Range	-20 °C to +60 °C
- Relative Humidity Range	0 to 95% non-condensing
Operating Conditions	
- Temperature Range	+5 °C to +40 °C
- Relative Humidity Range	0 to 95% non-condensing
Altitude Range	
- Operating	-1000 ft to +10,000 ft
- Storage	-1000 ft to +18,000 ft
IEC Classification	Medical Equipment Equipment not suitable for use in the presence of flammable anesthetic mixture Type B, Applied Part Class II IPX0

Specifications subject to change without notice.

IASIS Medical, Inc. Contact Information

IASIS Medical, Inc.
6393 Oakgreen Ave.
Hastings, MN 55033
www.iasismedical.com
1-651-331-0420

Appendix 3: Sterilization Validation Protocol and Packaging and Shelf Life Validation Protocol

Sterilization Validation Protocol

836

Packaging and Shelf Life Validation Protocol

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Draft Protocol for
Package Integrity and Shelf Life Validation for the
NPD 1000 Negative Pressure Dressing

January 30, 2008

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Appendix 4: Biocompatibility Reports

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Indications for Use

510(k) Number (if known): _____

Device Name: NPD 1000 Negative Pressure Wound Therapy System

Indications for Use:

The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 – 510(k) Summary

Submitter:	IASIS Medical, Inc. 6393 Oakgreen Avenue Hastings, MN 55033
Contact Person:	John Buan, Vice President of Product Development Phone (612) 703-1204, Fax (763) 287-3836
Date Prepared:	January 31, 2008
Trade Name:	NPD 1000 Negative Pressure Wound Therapy System
Classification:	Powered Suction Pump Class II 21 CFR 878.4780
Product Code:	BTA
Predicate Device(s):	The subject device is equivalent to the following devices: <ul style="list-style-type: none"> o V.A.C. Therapy Systems-ActiV.A.C. Therapy Unit M: K063692 o Boehringer Laboratories Suction Pump System: K060277
Device Description:	The NPD 1000 Negative Pressure Wound Therapy System includes a small, portable battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing.
Intended Use:	The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.
Functional and Safety Testing:	To verify that device design met its functional and performance requirements, representative samples of the device underwent functional and mechanical testing, EMC testing in accordance with IEC 60601-1-2:2001 and electrical safety testing in accordance with UL 60601-1:2006.
Conclusion:	IASIS Medical, Inc. considers the NPD 1000 Negative Pressure Wound Therapy System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, and indications for use.

Section 10 – Executive Summary

Device Description

The NPD 1000 Negative Pressure Wound Therapy System is a small, compact portable system comprised of a battery operated electromechanical pump with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing. This is achieved by bringing the wound edges together, reducing edema, promoting granulation tissue formation and perfusion, and by removing wound fluids and infectious material.

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting. The dressing has 3 windows near the pressure port to monitor when the dressing is nearing its exudate capacity.

The NPD1000 dressing is comprised of the following:

- semi-occlusive outer layer that maintains the negative pressure,
- pressure port with an in-line hydrophobic, anti-bacterial 0.2 μm filter and fitting to which the NPD pump system is attached via PVC tubing,
- hydrogel gasket to seal the wound area,
- super absorbent non-woven polymer matrix to absorb exudates, and
- non-stick Silverlon[®] wound contact layer.

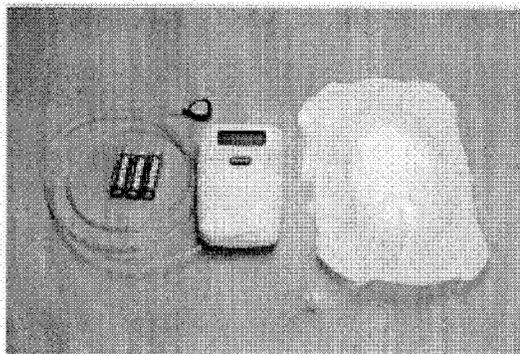


Figure 1: The NPD 1000 Negative Pressure Wound Therapy System

Indications for Use

The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Substantial Equivalence

IASIS Medical, Inc. believes that the NPD 1000 Negative Pressure Wound Therapy System is substantially equivalent to the devices listed below:

- V.A.C. Therapy Systems-ActiV.A.C. Therapy Unit M: K063692
- Boehringer Laboratories Suction Pump System: K060277

Similarities

The basic design (pump/ control unit/ tubing/ collection device), the pump/ control unit operating principle, the therapy delivery modes, the pump pressure, the sterilization method, the use of safety alarms and indicators, the power source, the bandage components and the indication for use of the subject device are equivalent to those of the predicate device(s).

Differences

The differences in dimensions, weight, battery type, collection device type, exudate collection volume, specific safety alarms, and bandage construction do not raise any new questions of safety and effectiveness over the predicate devices. The information demonstrates that the subject device is substantially equivalent to the predicate devices.

A comparison of the subject device to the predicate device(s) is provided in the table below. The information provided demonstrates the subject device is substantially equivalent to the predicate devices.

Table 1: Comparison to Predicate Devices

	IASIS Medical, Inc. NPD 1000 Negative Pressure Wound Therapy System	V.A.C. [®] Therapy Systems- ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam [®] Dressing)	Boehringer Laboratories Suction Pump System
510(k) Number	N/A	K063692	K060277
Decision Date		06/07/2007	03/03/2006
Manufacturer	IASIS Medical, Inc.	KCI USA, Inc	Boehringer Laboratories
Classification	Class II	Class II	Class II
Product Code	BTA	JCX	JCX
Regulation	878.4780	878.4780	878.4780
Indications for Use	The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.	The V.A.C. [®] Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	The Boehringer Laboratories Suction Pump System is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.
Device Design	The device consists of a suction pump/control unit, tubing and bandage assembly.	The device consists of a suction pump/control unit, collection canister, and canister tubing. The dressing is not included with the therapy unit.	The device consists of a suction pump/control unit, collection canister, tube attachment device, wound cover and wound dressing.
Dimensions	3.2" W x 5.1" H x 1.3" D	7.6" W x 6" H x 2.5" D	Unknown (larger than V.A.C. and IASIS)
Pump Pressure	40-125 mm Hg	25-200 mm Hg	30-75 mm Hg
Therapy Delivery	Intermittent and continuous	Intermittent and continuous	Intermittent and continuous
Weight	8 oz	2.4 lbs	5 lbs

Table 1: Comparison to Predicate Devices

	IASIS Medical, Inc. NPD 1000 Negative Pressure Wound Therapy System	V.A.C.® Therapy Systems- ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)	Boehringer Laboratories Suction Pump System
Power; Battery Life	Alkaline or rechargeable NiMH battery; 3 weeks or more battery life	Lithium ion rechargeable battery; 14 hour average battery life	12.0V DC rechargeable battery; up to 16 hour battery life
Storage Temperature	-20°C to 60°C	-20°C to 40°C	-18°C to 46°C
Storage Humidity	0-95% non-condensing	0-95% non-condensing	0-95% non-condensing
Operating Temp.	5°C to 40°C	5°C to 40°C	10°C to 38°C
Operating Humidity	0-95% non-condensing	0-95% non-condensing	0-95% non-condensing
Storage Alt. Range	-1000 to 18,000 feet -1000 to 10,000 feet	0 to 14,000 feet 0 to 8000 feet	Unknown
Operating Alt. Range	-1000 to 18,000 feet -1000 to 10,000 feet	0 to 14,000 feet 0 to 8000 feet	Unknown
Safety	Alarms for system fault, pressure leak, and low battery. Indicator icons for pressure leak and low battery	Alarms for low pressure, tubing blockage, full or missing canister, inactive therapy, low battery, leak in dressing seal, system error	Alarms for high leak rate, tubing blockage, full canister, discharged battery or no hours left on pump. Indicator lights for all alarm conditions and low level leak with adequate suction and normal operation
IEC Classification	Type B, Class II	Type B, Class II	Type B, Class II
Collection Device	50 cc absorbent wound dressing	300 cc collection canister	500 cc collection canister
Bandage	One multilayer assembly: wound contact layer, superabsorber pad, filter, fitting, cover assembly, release liner, tubing, and quick connect fitting	Separate components: polyurethane foam dressing, drape, and pad/tubing/connector	Separate components: Bio-dome™ wound dressing, wound cover, and Opti-Flo™ tube attachment device
Sterility	Only bandage provided sterile	Only bandage provided sterile	All components, except the pump, provided sterile
Sterilization Method	Radiation	Radiation	Radiation

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Performance Testing

Verification and validation testing was performed according to the Verification Test Procedures document DP-0001-84-0. This document details the individual tests and the acceptance criteria. No Animal Testing was performed to verify the design of this device. The testing included is listed in the table below. All testing passed the acceptance criteria except the Pressure Loss Prevention test. This is non-critical open issue (does not affect patient safety) possibly leading to false leak detect errors and reduced battery life. The position of a check valve in the pump plumbing will be moved and the Pressure Loss Prevention test will be repeated to address this issue. The Therapy Duration test is still in progress and will be completed in mid March 2008. The packaging integrity and shelf life validation testing is in progress and will be completed beginning April 2008.

Table 2: Verification and Validation Summary

Test	Acceptance Criteria (System Requirement Number Reference)	Summary of Results
Functional Tests		
Power on Self Tests	SYSREQ 54681, 54688, 57195, 54795	Pass
Therapy Mode Selection	SYSREQ 54686, 54751, 54691, 54675, 54728	Pass
Continuous Mode	SYSREQ 54639	Pass
Intermittent Mode	SYSREQ 54744, 54640, 64795	Pass
Therapy Duration: 4 pressure sensors and 4 therapy devices (2 continuous, 2 intermittent))	SYSREQ 54643, 54644, 54746	In Progress ¹
Vacuum Pressure	SYSREQ 54794, 54795, 54746, 54643, 54743, 54644, 54730, 54674	Pass
Pressure Loss Prevention	SYSREQ 54725	Fail ²
Parameter Retention and Autostart	SYSREQ 84690, 57537	Pass
Device Calibration: document review and inspection only	SYSREQ 54764	Pass
Multiple Bandages: 2 pressure sensors, 2 bandage kits	SYSREQ 54637, 54801	Pass
Device and Bandage Disposal: document review and inspection only	SYSREQ 54716, 54715, 54717, 54646	Pass
Software Upgrade	SYSREQ 55853, 57195	Pass
Reverse Polarity	SYSREQ 57243	Pass
Low Battery	SYSREQ 54799, 54750, 54684, 54729, 55903, 57609, 54728	Pass
Leak Detected	SYSREQ 54799, 54683, 54760, 54729, 54800, 55903, 55904, 57671, 57672, 54728	Pass
System Fault	SYSREQ 54685, 54799, 54795, 54729, 55903, 57673, 57675, 54794, 54728	Pass

Table 2: Verification and Validation Summary

User Interface Tests		
Audible Annunciation	SYSREQ 54550, 54802	Pass
Programming Controls	SYSREQ 54727	Pass
UI Display	SYSREQ 54676, 54678, 54677, 54726, 55903, 54537	Pass
Pump On/Off Control	SYSREQ 54687, 54665, 54798, 54671, 54728	Pass
Hardware Interface Tests		
External Interface Connections	SYSREQ 54539	Pass
Control Unit to Pump Unit Connection	Verify pump runs as expected and verify actual results are as expected	Pass
Stress and Robustness Tests		
Simulated User Evaluation	No expected outputs or pass/fail criteria	Pass
Continuous Pump Life: 6 pumps	SYSREQ 54672	Pass
Intermittent Pump Life: 6 pumps	SYSREQ 54745	Pass
Quick Connect Tubing Cycle Life	SYSREQ 54803	Pass
Environmental Tests		
Operating Conditions: document review and inspection only	SYSREQ 54693, 54694, 54695, 54696, 54660, 54658, 54659, 54781, 54657	Pass
Storage Conditions: document review and inspection only	SYSREQ 54755, 54756, 54757, 54758, 54754, 54753	Pass
Unpackaged Drop and Vibration: document review and inspection only (3 devices)	SYSREQ 54697, 54766, 54777	Pass
Packaged Shock and Vibe: document review and inspection only	SYSREQ 54752	Pass
Fluid Ingress: document review and inspection only	SYSREQ 54673	Pass
EMC: document review and inspection only	SYSREQ 54734, 54735	Pass
Shelf Life (Bandage Only): document review and inspection only	SYSREQ 54719	Pass
Cleaning	SYSREQ 54648, 547862	Pass
Quality, Regulatory and Safety Tests		
Product Safety: document review and inspection only	SYSREQ 54541, 54780	Pass
Device Classification: document review and inspection only	SYSREQ 54541	Pass
Quality Approval: document review and inspection only	SYSREQ 54778, 54779	Test Removed ³
Biocompatibility: document review and inspection only	SYSREQ 54788, 54785, 54543	Pass

Table 2: Verification and Validation Summary

Physical And Mechanical Tests		
Physical	SYSREQ 54773, 54776, 54774, 54767, 54775, 54548, 54711, 54710, 54655, 54692, 54797, 54723, 54549	Pass
Mechanical	SYSREQ 54765, 54782, 54748, 54747, 57244, 54803	Pass
Unit and Integration Tests		
Unit and Integration	SYSREQ 54689, 54681, 54795	Pass
IASIS Medical Testing		
Instruction for Use, Tubing Set, Bandage	SYSREQ 54789, 54783, 54654, 54641, 54797, 54647, 54712, 54713, 54653, 54709, 54703, 54704, 54705, 54706, 54707, 54700, 54699, 54663, 54701, 54708, 54702, 54892	Pass ⁴

¹ The Therapy Duration testing is in progress and will be completed in mid March 2008.

² The Pressure Loss Prevention test does not meet the acceptance criteria that the device's loss of vacuum pressure is no more than 10 mmHg/hour (averaged over 5 hours) when the pump is in the off state.

³ The test was removed because issues were not created in the Capricorn Issue Tracking project. An Open Issues Report was created and attached to the end of the Verification Report.

⁴ The packaging integrity and shelf life testing is in progress and will be completed beginning April 2008.

Section 11 – Device Description

Intended Use

The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Models and Accessories

The NPD 1000 Negative Pressure Wound Therapy System consists of the following components.

Table 3: Component Model Numbers

Component	Subassembly	Model	Part No.
Electromechanical Pump	System controller	NPD 1000 Control Unit	50001
	Intermittent pump housing	NPD 1000i Pump Module	50002
	Continuous pump housing	NPD 1000c Pump Module	50003
Wound Dressing	N/A	N/A	N/A

Device Description

The NPD 1000 Negative Pressure Wound Therapy System is comprised of a small, compact portable battery operated electromechanical pump and a wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing. This is achieved by bringing the wound edges together, reducing edema, promoting granulation tissue formation and perfusion, and by removing wound fluids and infectious material. The pump components are manufactured by Minnetronix (FDA registration Number 2133810), a contract manufacturer located in St. Paul, MN. The wound dressing is manufactured by TapeMark Co. (FDA Registration Number 2182681), a contract manufacturer located in West St. Paul, MN.

NPD 1000 Pump

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting in the dressing.

The NPD 1000 pump is shipped in 2 pieces, a system controller and 1 of 2 pump housings, either continuous or intermittent. Both pump housings can provide continuous therapy, but only the intermittent housing can provide intermittent therapy. The user fits the 2 subassemblies together by matching the male and female connector housings. The system controller automatically recognizes whether a continuous or intermittent pump has been attached. Neither the system controller nor the pump housing is provided sterile. The system controller and the intermittent

pump housing are reusable and do not need to be sterilized between subsequent patients. The continuous pump housing is single use.

The NPD 1000 pump contains a microprocessor controlled pump and pressure sensor working in feed back fashion to control the pressure under the dressing at the physician programmed setting. It has a user interface of 3 buttons to control the power (on/off), treatment mode (intermittent or continuous), and pressure setting (40, 50, 65, 80, 95, 110, and 125 mmHg). The pump is powered by 3 AA batteries, either alkaline or NiMH rechargeable. There is 6 feet of tubing, with a pressure fitting between the pump and the dressing, which can be trimmed to the desired length. A proprietary quick connect fitting is placed in the tubing for easily disconnecting the dressing from the pump. For therapy status notification, the pump has a leak detection indicator icon, a low battery indicator icon and therapy proceeding indicator icon. An alarm buzzer will sound for a leak detection, low battery or system fault.

The Product Specifications for the pump are listed in the table below.

Table 4: Pump Specifications

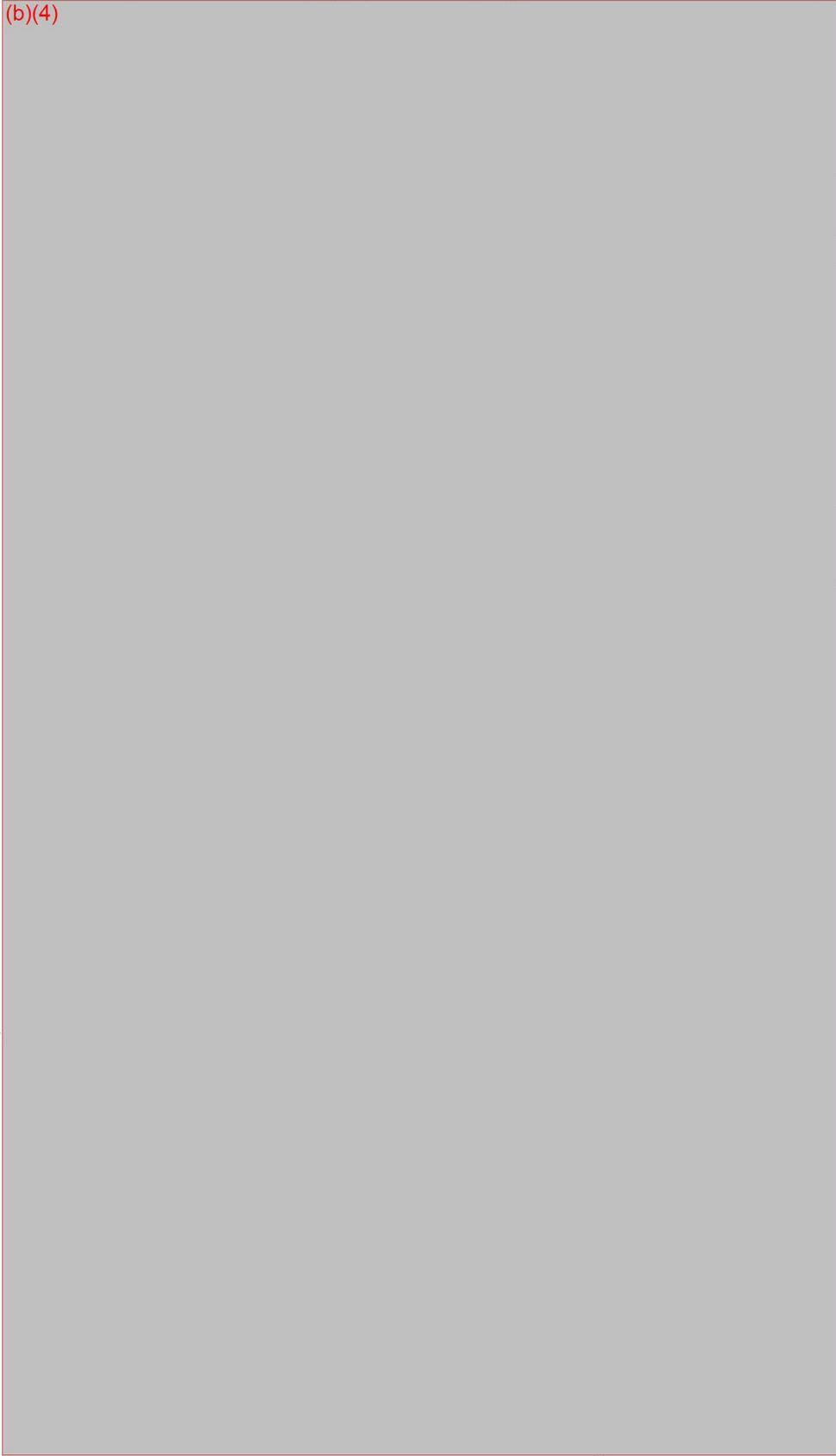
Parameter	Specification
Dimensions	3.2"W x 5.1" H x 1.3" D
Weight	8 ounces
Pressure Options	-40 to -125 mmHg
Therapy Delivery Modes	Continuous and Intermittent
Battery Type	Alkaline or Rechargeable NiMH
Battery Life	3 weeks or more
Storage Conditions	Temperature: -20°C to +60°C; Humidity: 0-95% non-condensing
Operating Conditions	Temperature: +5°C to +40°C; Humidity: 0-95% non-condensing
Altitude Range	Operating: -1000 ft. to +10,000 ft.; Storage: -1000 ft. to +18,000 ft.
IEC Classification	Medical Equipment; Equipment not suitable for use in the presence of flammable anesthetic mixture; Type B, Applied Part; Class II; IPXO

The materials for the pump are listed in the table below.

Table 5: Pump Component Materials

Pump Component	Materials
System Controller	GE Cycloy resin C6600
Controller Keypad	Silicone rubber
Continuous or Intermittent Pump Housing	GE Cycloy resin C6600
Tubing	PVC (Tygon R-3603) 55A
Quick Connect Fitting	Black ABS

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Appendix 5: System Software Design (b)(4)

Appendix 6: FMECA DP-0001-84-1 and Hazard Analysis DP-0001-83-7

FMECA DP-0001-84-1

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Hazard Analysis DP-0001-83-7

Appendix 7: System Requirements Specification DP-0001-84-2

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**Appendix 8: Verification and Validation Plan DP-0001-85-0,
Verification Test Procedures DP-000184-0, and NPD 1000 Negative
Pressure Dressing Verification and Validation Test Procedures QFM-
04-3b**

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FDA CDRH DMC

Verification and Validation Plan DP-000185-0

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Verification Test Procedures DP-0001-84-0

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**NPD 1000 Negative Pressure Dressing Verification and Validation Test
Procedures QFM-04-3b**

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**Appendix 9: Minnetronix Verification Report DR-0000-09-0 and NPD
1000 Negative Pressure Dressing Verification and Validation Test
Report QFM-04-3c**

Minnetronix Verification and Validation Report DR-0000-09-0

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Capricorn Verification Report

**Minnetronix[®] Document # DR-0000-09-0
Revision: 001-a**

January 25, 2008

**Prepared for:
Iasis Medical, Inc.
Hastings, MN**

**Prepared by:
Minnetronix[®], Inc.
St Paul, MN**

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1 Introduction

The purpose of this Verification Report is to summarize the verification activities for the Production release of the Iasis Medical Inc. Micro Negative Pressure Wound Therapy (NPWT) System (a.k.a. project Capricorn). The System consists of a control/display unit, two different pump units delivering continuous or intermittent therapy, and an inter-connected bandage. The verification activities performed are described in the Capricorn System Verification and Validation Plan; document DP-0001-85-0.

1.1 References and Applicable Documents

The type column below describes the source or document type for the listed description.

<u>Abbreviation</u>	<u>Description</u>	<u>Part Number</u>	<u>Type</u>
{SDP}	Capricorn System Development Plan	DP-0001-83-3	Word Doc
{VVP}	Capricorn System Verification & Validation Plan	DP-0001-85-0	Word Doc
{VTP}	Capricorn Requirement Verification Test Procedures	DP-0001-84-0	Caliber Doc
{HA}	Capricorn Hazard Analysis	DP-0001-83-7	Word Doc
{FMECA}	Capricorn Failure Modes and Effects Criticality Analysis	DP-0001-84-1	Caliber Doc
{CustRS}	Capricorn Customer Requirements Specification	DP-0001-84-5	Word Doc
{SysRS}	Capricorn System Requirements Specification	DP-0001-84-2	Caliber Doc
{UISpec}	Capricorn Usability Specification	DP-0001-84-7	Word Doc
{SysDD}	Capricorn System Design Specification	DP-0001-83-9	Word Doc
{SwDD}	Capricorn Software Design Document	DP-0001-84-3	Word Doc
{UIDD}	Capricorn User Interface Design Document	DP-0001-84-4	Word Doc
N/A	Minnetronix Glossary	DQ-0000-72-9	Word Doc
{ITDB}	Minnetronix Issue Tracking Database	N/A	Microsoft SQL
{DHF}	Minnetronix Design History File for Capricorn project	N/A	Microsoft Outlook, Paper file
N/A	Hardware Unit Testing Guideline	N/A	Word Doc
N/A	Traceability Matrix	N/A	Caliber Doc

2 Definitions, Acronyms, and Abbreviations

In addition to those listed here, reference the Minnetronix Glossary, document DQ-0000-72-9, for common definitions, acronyms, and abbreviations found in Minnetronix documentation.

Mntx	Minnetronix
MKS	MKS Integrity 2007, Build: 4.9.0.4414, Service Pack: 000-00 (configuration management tool)

3 Summary of Results

This is a summary of verification test results per execution of the Capricorn Requirement Verification Test Procedures (DP-0001-84-0).

3.1 Requirements Verification Test

This report covers the system requirements testing activities described in the System Verification and Validation Plan. All requirements were verified as described in paragraphs 6.5.5 (system verification test), 6.5.3 (inspection and unit testing), and/or 6.5.4 (integration testing). Of the verification activities listed herein that are the responsibility of Mntx, most have been completed, with one long duration test in progress, one test with a non-critical open issue, and one incomplete formal document review. See section 3.1.3 for test results. Test data/results of execution of verification tests are recorded in the marked up copy of the Capricorn Requirement Verification Test Procedures document as attached to this report.

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3.1.1 Test Environment & Equipment

~~All testing was performed using pre-production Control Units and Pump Units.~~ The specific test environment and test equipment used is captured as part of the recorded test results for each procedure or group of procedures.

3.1.2 Items tested

Verification testing was performed with the Capricorn hardware identified as AE-0000-83-2 (Control Unit top level assembly), as AE-0000-83-3 (Continuous Pump Unit top level assembly), and as AE-0000-83-4 (Intermittent Pump Unit top level assembly) and Capricorn software identified as SE-0000-17-0.

The following revisions of Capricorn Embedded Software were used during testing:

- Version 06, MKS checkpoint identified as "Version 06" (SE-0000-17-0 Rev. 001-a; ECO 5699, status Approved).
- Version 05, MKS checkpoint identified as "Version 05".

The following revisions of Capricorn PCBA hardware were used during testing:

Control Unit: Revisions of AP-0000-89-1 PCB Capricorn Control Unit hardware used were Rev. 002-a (ECO 5531, status Effective) and Rev. 003-a (ECO 5670, status Effective). Rev. 003-a incorporated pull-up/pull-down resistors per Pump Device issue #17.

Pump Units: Revision of AP-0000-89-3 PCB Capricorn Continuous Therapy Pump Module hardware used was Rev. 001-a (ECO 5422, status Effective) and revision of AP-0000-89-5 PCB Capricorn Intermittent Therapy Pump Module hardware used was Rev. 001-a (ECO 5422, status Effective).

The following hardware software combinations were used during testing:

Software version 05 was combined with hardware revisions Control Unit Rev. 002-a, Continuous Pump Module Rev. 001-a, and Intermittent Pump Module Rev. 001-a.

Software version 06 was combined with hardware revisions Control Unit Rev. 003-a, Continuous Pump Module Rev. 001-a, and Intermittent Pump Module Rev. 001-a.

3.1.2.1 Changes from previous Document Baseline to the current baseline

None, this is the initial VTP execution.

3.1.2.2 Test Procedures re-executed

None, this is the initial VTP execution.

3.1.3 Test results

Capricorn Requirement Verification Test Procedures document has been baselined in Caliber (VTP Rev. .02-a labeled "ECO 5596 (12/20/07) - 510(k) Documentation" and VTP Rev. 001-a labeled "ECO 5699 (1/25/08) - Release to Production"). The details of the requirements verification testing is contained in the table below.

The result of execution of the {VTP} included some test failures. Three of the tests were either not executed or had testing in progress at the time this report was issued. When a test failure occurs, it is recorded in {ITDB}. All test failures are reviewed by testers, developers, and the Mntx project leader. Any test failure(s) remaining were deemed acceptable for this release. The table represents a summary of test pass/fail status, plus any anomalies and corrective action encountered during the execution of the {VTP}. The software version listed is the version under test in which the anomaly was first identified.

The following is a list of the SYSTSTs and the version(s) of software that the SYSTST was executed against. Note that SYSTST is a Caliber requirement type and the 5-digit number is a unique identifier within the Caliber database.

SYSTST	Test Name	Software Version	Software Version	Pass/Fail & Issues / Comments
55788	Power On Self Tests	05	06	Passed on 05. Passed on 06.

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SYSTST	Test Name	Software Version	Software Version	Pass/Fail & Issues / Comments
55807	Therapy Mode Selection	05		Passed.
55816	Continuous Mode	05		Passed.
55817	Intermittent Mode	05		Passed.
55818	Therapy Duration	-	06	6 week test in progress at this time of this report. Interface issue #56 opened, currently Unresolved.
55811	Vacuum Pressure	05		Passed.
55822	Pressure Loss Prevention	05		Failed step 1 (pressure loss is > 10 mmHg/hr with the Continuous Pump Module). Pump Device issue #19 opened, currently Unresolved.
55821	Parameter Retention & Autostart	05		Passed.
55775	Device Calibration	05		Passed.
55824	Multiple Bandages	05		Passed.
55782	Device & Bandage Disposal	05		Passed.
55854	Software Upgrade	05		Passed.
57540	Reverse Polarity	05		Passed.
55813	Low Battery	05	06	Passed on 05. Passed on 06.
55814	Leak Detected	05		Passed.
55815	System Fault	05	06	Passed. History: Failed steps 2b, 7b, and 10b on 05 (Backlight did not turn on, see Interface issue #46). Failed steps 14 and 15 on 05 (System fault did not occur, see Interface issue # 51). Regression tested and Passed on 06 (steps 2-5, 7, 10, and 13-14 only).
55786	Audible Annunciation	05		Passed with requirements updates (see Interface issue #47).
55808	Programming Controls	05		Passed.
55810	UI Display	05		Passed.
55801	Pump On/Off Control	05		Passed.
55825	External Interface Connections	05		Passed.
55826	Control Unit to Pump Unit Connection	05		Passed.
55540	Simulated User Evaluation	05	06	Passed on 05. Passed on 06.
55819	Continuous Pump Life	n/a		Passed.
55820	Intermittent Pump Life	n/a		Passed.
56068	Quick Connect Tubing Cycle Life	05		Passed.
55541	Operating Conditions	05		Passed.
55542	Storage Conditions	05		Passed.
55543	Unpackaged Drop and Vibration	05		Passed.
55544	Packaged Shock and Vibe (ie. Shipping)	05		Passed.
55545	Fluid Ingress	n/a		Passed.
55546	EMC	emc		Passed.
55547	Shelf Life (Bandage only)	-		Responsibility of Iasis Medical Inc. (see Interface issue #54).
55548	Cleaning	n/a		Passed.
55581	Product Safety	05		Passed with 'draft' revision of Product Safety report.

SYSTST	Test Name	Software Version	Software Version	Pass/Fail & Issues / Comments
55582	Device Classification	05		Passed.
55779	Quality Approval	-	-	Test case deleted per Interface issue #53.
55787	Biocompatibility	n/a		Passed (steps 2 and 3 only) per redlines (see Interface issue #54). Step 1 is the responsibility of Iasis Medical Inc..
55776	Physical	n/a		Passed with requirements updates (see Interface issue #55).
55777	Mechanical	n/a		Passed.
55535	Unit and Integration Tests	n/a		Passed. See Unit and Integration Test section below for reference list of verification by unit or integration test.
55536	Iasis Medical Inc. Tests	n/a		Responsibility of Iasis Medical Inc.

There are several open issues in the Minnetronix Issue tracking system for the Capricorn NPWT System. Customer approval to leave these issues open will be via signoff of the ECO which releases this report. A closed issues list is not included with this report.

3.1.3.1 Attached Documentation

Test Results Data Sheets (129) pages. These pages contain the equipment list, test data and results of execution of Rev. .02-a of the VTP.

Test Results Data Sheets (17) pages. These pages contain the regression test list, equipment list, test data and results of regression execution of Rev. 001-a of the VTP.

Open/Future Issues Report (1) page. Includes Capricorn Interface 'Open' issues 56 and 58 and Capricorn Pump Device 'Open' issues 19 and 20. There are no 'Future' issues for the Capricorn project.

3.2 Other Verification Activities

3.2.1 System Development Plan

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-83-3. Per the System V&V Plan, the document should be reviewed by Iasis Medical Inc., Minnetronix Technical and QA personnel.

Current Status:

Document has been formally reviewed. Changes to this document since review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

References:

{ITDB} Meeting ID#1601, name Formal Review of Capricorn System Development Plan, dated 6/26/07.

3.2.2 System Verification & Validation Plan

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-85-0. Per the System V&V Plan, the document should be reviewed by Iasis Medical Inc., Minnetronix Technical and QA personnel.

Current Status:

Document has been formally reviewed. Changes to this document since review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

References:

{ITDB} Meeting ID#1598, name Formal Review of Capricorn System V&V Plan, dated 6/27/07.

3.2.3 Hazard Analysis

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-83-7. Per the System V&V Plan, the document should be reviewed by Iasis Medical Inc., Minnetronix Technical and QA personnel.

Current Status:

Document has been formally reviewed. Changes to this document since formal review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

References:

{ITDB} Meeting ID#1599, name Formal Review of Capricorn Hazard Analysis document, dated 6/26/07.

3.2.4 FMECA

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-84-1. Per the System V&V Plan, the document should be reviewed by Iasis Medical Inc., Minnetronix Technical and QA personnel.

Current status:

Document has been formally reviewed. Changes to this document since formal review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

References:

{ITDB} Meeting ID#1801, name Capricorn FMECA Formal Review, dated 12/14/07.

3.2.5 Customer Requirements Specification

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-84-5. Per the System V&V Plan, the document should be reviewed by Iasis Medical Inc., Minnetronix Technical and QA personnel.

Current status:

Document has been formally reviewed. Changes to this document since formal review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

References:

{ITDB} Meeting ID#1602, name Formal Review of Iasis Customer Requirements Specification, dated 6/26/07.

3.2.6 System Requirements Specification

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-84-2. Per the System V&V Plan, the document should be reviewed by Iasis Medical Inc., Minnetronix Technical and QA personnel.

Current status:

Document has been formally reviewed. Changes to this document since formal review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

References:

{ITDB} Meeting ID#1671, name Capricorn System Requirements Updates, dated 8/23/07.

{ITDB} Meeting ID#1603, name Formal Review of Capricorn System Requirements Specification, dated 6/26/07.

3.2.7 Usability Specification

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-84-7. Per the System V&V Plan, the document should be reviewed by Iasis Medical Inc., Minnetronix Technical and QA personnel.

Current status:

Document has not been formally reviewed. Capricorn -- Interface issue #58 opened, currently Unresolved.

3.2.8 Design Documentation

This documentation is controlled by Mntx developers and includes system design documentation. Per the System V&V Plan, the System Design Specification, identified as Mntx P/N: DP-0001-83-9, and the User Interface Design document, identified as Mntx P/N: DP-0001-84-4, should be reviewed by Iasis Medical Inc., Minnetronix Technical and QA personnel. Per the System V&V Plan, the Software Design document, identified as Mntx P/N: DP-0001-84-3 does not require formal review.

Current status:

Document has been formally reviewed. Changes to this document since formal review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

References:

Design documents:

{ITDB} Meeting ID#1688, name Capricorn Software Design Review, dated 9/5/07.

{ITDB} Meeting ID#1589, name Capricorn System Design Spec -- Internal Review, dated 7/2/07.

{ITDB} Meeting ID#1600, name Formal Review of Capricorn System Design Specification, dated 6/27/07.

{ITDB} Meeting ID#1584, name Formal Review of Capricorn UI Design Doc, dated 6/26/07.

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Source Code reviews and walkthroughs:

- {ITDB} Meeting ID#1779, name Capricorn EEPROM and Parmas Modules Code Review, dated 11/15/07.
- {ITDB} Meeting ID#1771, name Capricorn Op Module Code Review, dated 11/6/07.

PCBs, Schematics, and Enclosures:

- {ITDB} Meeting ID#1842, name Capricorn Controller Rev 002-a PCB Design Review, dated 1/21/08.
- {ITDB} Meeting ID#1773, name Capricorn Pump & Controller Rev 001-a PCB Design Review, dated 11/08/07.
- {ITDB} Meeting ID#1753, name Pump Module Rev .02-a Schematic Review, dated 11/1/07.
- {ITDB} Meeting ID#1754, name Control Unit Rev .02-a Schematic Review, dated 11/1/07.
- {ITDB} Meeting ID#1700, name Capricorn Pump & Controller PCB Design Review, dated 9/12/07.
- {ITDB} Meeting ID#1691, name Capricorn Formal Enclosure Design Review – Part 2, dated 9/6/07.
- {ITDB} Meeting ID#1680, name Capricorn Formal Enclosure Design Review, dated 8/29/07.
- {ITDB} Meeting ID#1647, name Control Unit Rev .01-a Schematic Review, dated 8/15/07.
- {ITDB} Meeting ID#1648, name Pump Module Rev .01-a Schematic Review, dated 8/15/07.

3.2.9 Unit and Integration Test

This documentation is controlled by Mntx developers. Unit testing is performed per Mntx document Hardware Unit Testing Guideline and Software Testing Guideline. Requirements that are deferred to Unit and/or Integration test are identified in the {VTP}.

Current Status:

Unit and integration tests have been completed.

References:

Normal Unit Test (NUT) and Heavy Unit Test (HUT):

- {DHF} See email titled “3-hour bandage top-off test procedure and results when pump is not connected to pressure sensor” dated 1/15/08, author Greg Ludewig.
- {DHF} See MKS file \$Capricorn\Hardware\Beta Pre-Production Board Test.xls, author Michael Tvedt. Note: MKS is a configuration management tool and file repository.
- {DHF} See email titled “Alpha Unit Testing Results” dated 11/12/07, author Michael Tvedt.
- {DHF} See MKS file \$Capricorn\Hardware\Alpha Board Test.xls, author Michael Tvedt.
- {DHF} See engineering notebook #397 (software), author Greg Ludewig.
- {DHF} See engineering notebook #404 (hardware), author Michael Tvedt.

Requirements Deferral to Unit and/or Integration Test:

- {DHF} See email titled “Capricorn SW Verification Tests by Developer” dated 1/25/08, author Greg Ludewig (contains testing for the following 4 requirements: SYSREQs 54681, 54689, 54795 and 57675).

3.2.10 Requirements Verification Test Procedures

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-84-0. Per the System V&V Plan, the document should be reviewed by Iasis Medical Inc., Minnetronix Technical and QA personnel.

Current status:

Document has been formally reviewed. Changes to this document since formal review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

References:

- {ITDB} Meeting ID#1804, name Capricorn VTP Formal Review, dated 12/19/07.

3.2.11 Traceability

3.2.11.1 Requirements

Traceability between system requirements and verification tests has been entered into the Caliber requirements management database. Traceability has been independently reviewed by QA personnel.

References:

- {DHF} See email titled “Capricorn Traceability Audit Results” dated 1/25/08, author Loren Berg.

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3.2.11.2 Design

Traceability between requirements and design is not required for the Capricorn NPWT System per the System V&V Plan.

3.2.11.3 FMECA

Traceability between failure modes and requirements has been entered into the Caliber requirement management database.

References:

{DHF} See email titled "Capricorn Traceability Audit Results" dated 1/25/08, author Loren Berg.

3.2.11.4 Risk Assessment / Hazard Analysis

Traceability between Hazard Analysis and system requirements has been entered and exists in the Hazard Analysis document. Traceability has been independently reviewed by QA personnel.

References:

{ITDB} Interface issue #40, added traceability. Issue closure required QA verification/review.

3.2.12 Issue/Discrepancy Handling

All issues in the Minnetronix Issue Tracking Database have been addressed and closed with the exceptions noted in the attached Open/Future issue lists.

3.2.13 Configuration and Data Control

Configuration management has been performed in accordance with {SDP}, {VVP} and Minnetronix SOPs.

3.2.14 Supplier Issues

All vendors have been qualified as required by Mntx SOPs.

3.2.15 Tool Qualification

Capricorn System V&V Plan states that all development and verification tools will be qualified for use. The following development and verification tools were required for or used on the Capricorn NPWT System:

<u>Description</u>	<u>Part Number/Identifier</u>	<u>Qualification Information</u>
IAR Embedded Workbench	Version EWVAR v3.20C	See section 4.2 "Tool Qualification" of the Capricorn Software Design document, DP-0001-84-3 Rev. .01-a (ECO 5587).
AVR Studio	Version 4.13	See section 4.2 "Tool Qualification" of the Capricorn Software Design document, DP-0001-84-3 Rev. .01-a (ECO 5587).
PCAD (used for board layouts and schematics)	Version 2002, Build 17.01.22	Qualified through use. Boards are designed, ordered, tested for opens/shorts, stuffed, in-circuit tested, and unit and integration tested. Lastly, boards are integration tested at a system level.
Capricorn Pump Life Test Fixture	AT-0000-30-7 Rev. .01-a	AT fixture released on ECO 5423. See See part specification on Mntx Intranet for calibration/qualification information.

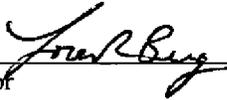
4 Recommendations

Capricorn hardware, Mntx part numbers AE-0000-83-2 (Control Unit), AE-0000-83-3 (Continuous Pump Module) and AE-0000-83-4 (Intermittent Pump Module), and software, Mntx part number SE-0000-17-0 (Embedded Software), are acceptable for Production release to the customer.

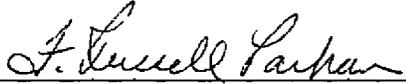
Release Capricorn NPWT System to Iasis Medical, Inc.

- 1170

5 Approvals


Author

1/05/08
Date


Reviewed By

1/25/2008
Date

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Test Result Data Sheets
for Initial Execution (Rev. .02-a)
(129 pages, excluding this one)

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Test Equipment

ALL CONTROL UNITS PROGRAMMED WITH VERSION 05 SOFTWARE,

Capricorn DP-0001-84-0

AB	Stork Twin City Testing Project # 30160 08-90995 1/22/08				
A	DC Power Supply	Topward	3306D	S/N 7148 49	NO Cal Required 365
B	↓	↓	↓	746673	↓ 815
C	VDC	Meterman	37XR		4/6/08 372
D	VDC	Amprobe	37XR-A		9/14/08 839
E	Timer	Hanhart	Delta E100		9/6/08 662
F	↓	↓	↓		9/10/08 362
G	↓	↓	↓		9/6/08 822
H1	db meter	SPer Scientific	840015	S/N 049386	8/30/08 826
H	db meter	Extech	46740	S/N M052650	4/10/08 75
I	Pressure Transducer	Utah Medical	650-900	S/N 1072090-001	1/2/09 893
J	↓	↓	↓	1072090-003	11/14/08 889
K	↓	↓	↓	1062138-007	2/14/08 718
L	Control	AE-0000-83-2	S/N 000013		
M	↓	↓	S/N 000014		
N	Pump	CONTINUOUS	AE-0000-83-3	S/N 000008	
O	↓	↓	↓	S/N 000010	
P	↓	INTERMITTENT	AE-0000-83-4	S/N 000005	
Q	Control	AE-0000-83-2	S/N 000018		
R	Microscope	Bausch & Lomb	31-35-47		
S	Pump	CONTINUOUS	AE-0000-83-3	S/N 000011	
T	Scale	48"	100612304	4/4/11	785
U	Scale	6"	MITUTOYO 182P1	4/11/08	208
V	Calipers			4/11/08	760
W	Weight Scale	Francotyp-Postalia	FP-15	S/N 1228163	
X	IASYS Medical	NPD1000	T/N 50004	Rev A	11/07
Y	UV Report Draft	IASYS	EXXXXXX-A1	Draft	2008-01-18
Z	EMR Intertek	3139960MIN-001	Rev 01		
AA	Questions Contact FDA/CDRH/Office of Radiation Control at 301-796-8118 2513				

Test Result Data Sheets

(b)(4)

A large rectangular area of the document is redacted with a solid grey fill. The redaction covers the majority of the page's content.

(17 pages, excluding this one)

1302

**NPD 1000 Negative Pressure Dressing Verification and Validation Test
Report QFM-04-3c**

1322

NPD 1000 Negative Pressure Dressing Verification and Validation Test Report

**Iasis Document #QFM-04-3c
Revision: A**

**Prepared by:
John Buan**

1323

1 h General Instructions

Status: Accepted Requirement Version: 3.0

This is the Verification Test Procedures (VTP) document for the Iasis Medical Inc. Negative Pressure Wound Therapy (NPWT) System Dressing (bandage). The entire system consists of a Control Unit, a Pump Unit (continuous or intermittent), disposable batteries, a custom Bandage, and a tube set to connect the Pump Unit to the Bandage.

All traceable requirements will be verified via execution of the test cases within this plan.

Note: SYSREQs are driven out of the Minnetronix Quality system for the Negative Pressure Wound Therapy project.

Record formal test results on Test Results Data Sheets (TRDS). Acceptable TRDS are hardcopy pages of the VTP

Record tester's name or initials, date of test execution, and revision of the Capricorn System Requirements Specification being tested against.

Positively identify all tools and equipment used. Include the following:

- Record all IDs and serial numbers of hardware in use (this includes UUTs, test equipment, etc.).
- Record calibration date(s) of all test equipment.
- In the case of Minnetronix developed test tools, record MKS label and revision, and include a pointer to qualification information.

Note: Deviations to the test procedures will be documented on the TRDS or in the Verification Report.

Note: Unless otherwise noted, all timing and performance requirements shall have a tolerance of +/- 10%.

Reference: \\Mxcaliber\caliberreferences\$\Capricorn\TestResults\DataSheet.doc

This requirement traces from:

1.1 h References (SYSTST55526)

Status: Accepted Requirement Version: 2.0

The following documents were used as references when creating this document:

Minnetronix Documentation

- DQ-0000-21-0 Minnetronix Design Verification and Validation SOP
- DP-0001-83-7 Capricorn Hazard Analysis
- DP-0001-85-0 Capricorn System Verification and Validation Plan
- DP-0001-84-2 Capricorn System Requirements Specification
- DP-0001-84-1 Capricorn FMECA

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External Documentation

- FDA General Principles of Software Validation; Final Guidance for Industry and FDA Staff (January 11, 2002)
- FDA Guidance Document for Powered Suction Pump 510(k)s (September 30, 1998)

2 h Standard Test Setup

The standard setup/configuration used for Capricorn NPWT dressing testing is as follows:

- One complete and finished Control unit with all parts (housing, PCB, UI display, batteries, etc.) and software ECO released
- One complete and finished Continuous and/or one complete and finished Intermittent pump unit with all parts (housing, PCB, pump motor, etc.) ECO released
- One set of bandage to pump tubing
- One bandage or 60cc syringe, Iasis P/N 4002
- One reservoir to hold test fluids

With the batteries installed in the control unit (device automatically On), connect the control unit to the pump unit. Seal the bandage to the appropriate test surface or use the syringe and connect the tubing from the bandage to the pump. Turn the pump on at the default pressure setting.

Note: The Control unit displays the negative pressure setpoint in absolute value (ie. does not display the negative symbol). So an increase in displayed value is actually a decrease in pressure. Likewise, a decrease in displayed value is actually an increase in pressure.

Note: The default unit under test (UUT) sample size is one (1) unless specified otherwise in each individual test case.

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3 h Functional Tests

The following functionality of the Capricorn NPWT dressing will be tested within this section of the test plan:

- Fluid Uptake (Bandage Capacity)
- Bandage Durability
- Bandage Interconnect System
- Bandage Full Condition
- Bandage Adhesion
- Bandage IPX rating

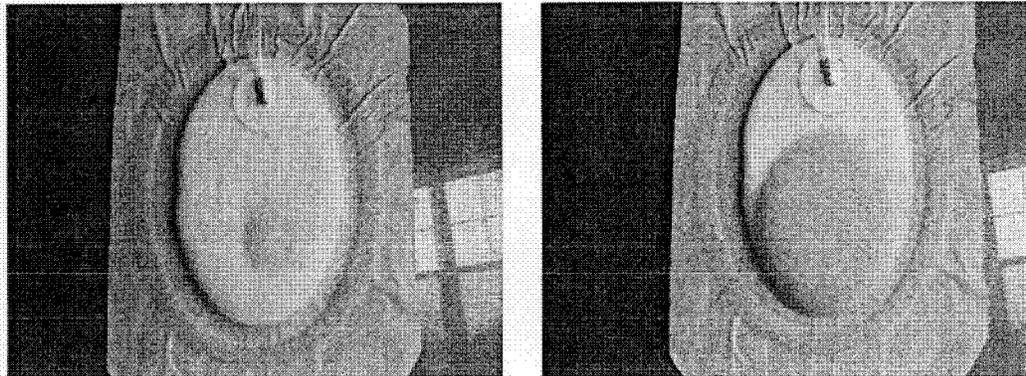
3.1 Fluid Uptake (SYSREQ54709)

This test will verify . . .

The NPD 1000 Negative Pressure Dressing maintains its therapeutic fluid capacity, when used with the NPD 1000 Negative Pressure Wound Therapy Device, the 1000 Negative Pressure Dressing shall be capable of holding 50 cc of fluid +/- 10%.

Results (Data taken from engineering notebook of John Buan, tests on 1/7/08 and 1/08/08)

Test Pictures (typical)



Bandage #	Volume of Absorbed Fluid
1	47 ml
2	67 ml
3	60 ml
4	51 ml
5	48 ml
6	60 ml

The average absorbed fluid for the bandages tested is 55.6 ml

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The dressing PASSES the requirement of 25 ml. of fluid capacity.

3.2 Bandage Durability (SYSREQ54699)

The Micro NPWT bandage shall be able to allow for the delivery of V.A.C. therapy for up to three days, or until it reaches bandage type fluid handling capacity

Results (Data taken from engineering notebook of John Buan, tests from 1/15/08 and 1/21/08)

Bandage #	Volume of Absorbed Fluid
1	44 ml
2	56 ml
3	60 ml

The average absorbed fluid for the bandages tested is 53.3 ml

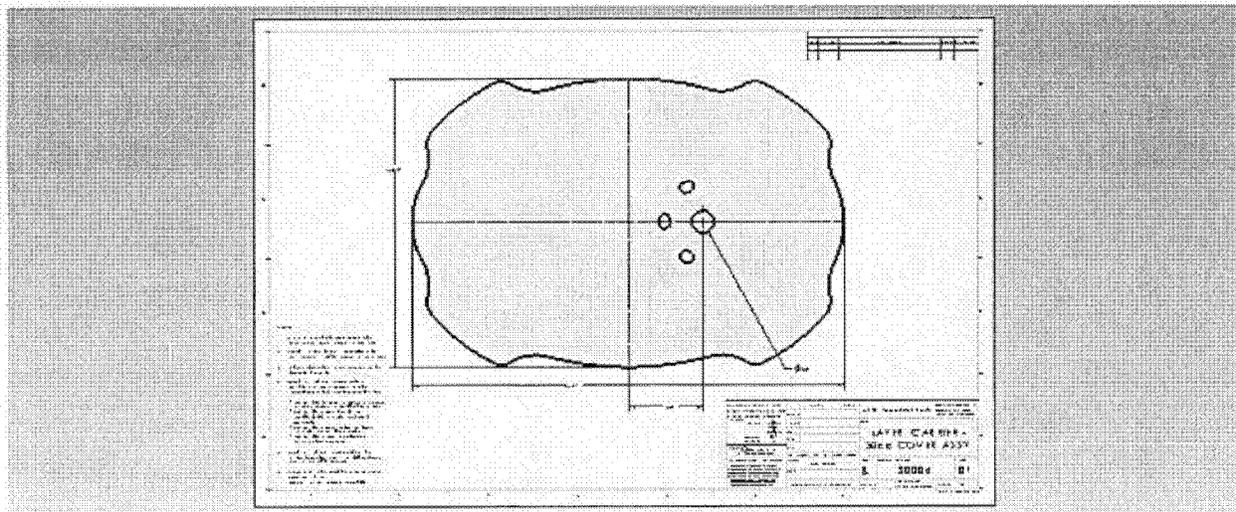
The dressing PASSES the requirement of 25 ml. of fluid capacity after being worn for three days.

3.3 Bandage Full Condition(SYSREQ54663)

This procedure will that the NPD 1000 dressing has a design feature to allow the user to detect if the dressing has reached its fluid capacity during treatment.

Results

Inspection of Iasis P/N 30004 indicates the presence of windows in the dressing so as to detect exudates near the pressure port, thereby indicating that the bandage is nearing capacity

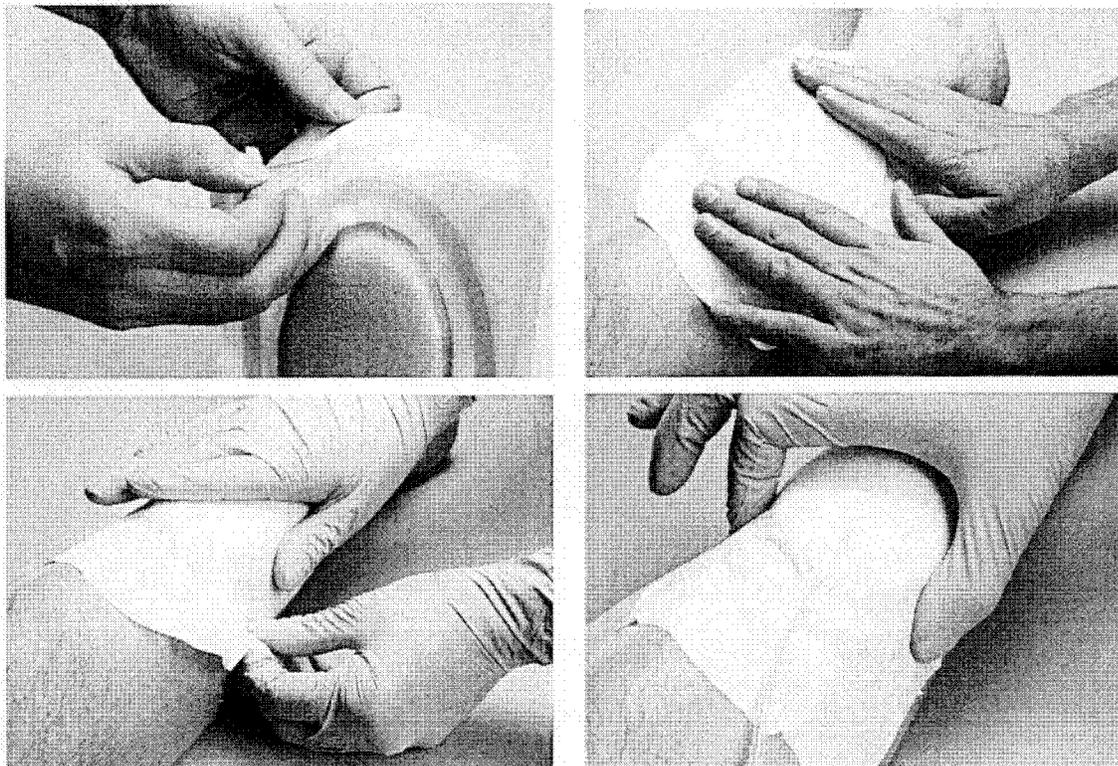


The dressing DOES allow the user to detect the presence of fluid in the dressing and that the dressing is nearing capacity.

3.4 Bandage Adhesion(SYSREQ54701)

This procedure that the NPD 1000 dressing shall adhere to the healthy skin at the perimeter of the wound such that it remains in place for at least three days.

Results



Dressings have been worn for three days throughout the project, in both fall and winter conditions with varying activity levels. No adhesion failures reported.

3.5 Bandage IPX Rating (SYSREQ54700)

This procedure will verify that the NPD 1000 dressing has an IPX rating of IPX0.

Results

Page 15 of the NPD 1000 Negative Pressure Wound Therapy System in the Product Specification table rates the entire system at IPX0 - PASS

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4 h Labeling

4.1 IFU Warning for Ag(silver) content in dressing (SYSREQ54789)

This procedure will verify the presence in the NPD 1000 IFU of the warning of the presence of Ag in the Negative Pressure Dressing and the possibility exists for an allergic reaction.

Results

In the Contraindications section of the IFU the following verbage is included

“Sensitivity to silver (NPD 1000 Silver Dressing only).”

PASSES

4.2 Device Maintenance and Cleaning (SYSREQ54792)

This procedure will the verify the IFU for the NPD 1000 system shall include user instructions detailing necessary device maintenance and cleaning.

Results

The following is the “Care and Service” section of the NPD 1000 System IFU

Care and Service of the Pump Device

The outside case of both the system controller and pump housings can be cleaned off with a water dampened cloth. No solvents should be used. Do not open either device as proper operation can not be assured once this has happened. These devices are tested to an IPX0 rating. Thus, they can not be immersed in water or subject to large volumes of water spray such as in the shower.

1. There are no user serviceable components inside the IASIS NPD 1000 Wound Therapy System Pump.
2. Contact your IASIS representative for return/replacement of damaged pumps.
3. Do not open the NPD 1000 pump or attempt to service it yourself.

PASSES

4.3 Single Patient Treatment (SYSREQ54797)

This procedure will the verify the IFU for the NPD 1000 system shall include user instructions that the device is intended for single patient treatment.

Test Setup

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Results

The following text is found on page 3 of the NPD 1000 IFU.

"Note: The system controller can be used by multiple patients but the pump assembly is single patient use only."

PASSES

4.4 Use in Magnetic Fields (SYSREQ54783)

This procedure will the verify the IFU for the NPD 1000 system shall include user instructions of proper device operation in proximity to strong magnetic fields .

Results

The following is an excerpt of the "CAUTIONS" section of the NPD 1000 system IFU

- Operation of the NPD 1000 in the presence of high magnetic fields, such as those produced by an MRI (magnetic resonance imager), has not been tested and is not recommended. Incorrect operation could result.

PASSES

4.5 Reuse of Control Unit (SYSREQ54647)

This procedure will the verify the IFU for the NPD 1000 system shall include user instructions that the control unit is reusable between patients .

Results

The following text is found on page 3 of the NPD 1000 IFU.

"Note: The system controller can be used by multiple patients but the pump assembly is single patient use only."

PASSES

5 h Usability

5.1 Shelf Life (Bandage only) (SYSTST55547)

Introduction

This test will verify . . .

- a. The Micro NPWT bandage shall have a minimum shelf life of 1 year.

Test Setup

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1. Document review and inspection only.

Test Procedures and Expected Results

1. Inspect Accelerated Aging test report and insure that a copy exists in the design history file.

Note: Accelerated Aging to be performed per ASTM F1980 "Standard Guide for Accelerated Aging of Sterile Medical Device Packages." A separate Accelerated Aging test procedure shall be created which defines the test parameters and includes pass/fail acceptance criteria.

P/F a. Verify the bandage packaging, bandage and bandage components pass the defined acceptance criteria after undergoing accelerated age testing simulating a minimum of a 1 year shelf life / storage.

IN PROCESS

5.2 Bandage Interconnect System (SYSREQ54712)

This procedure will verify that the bandage shall be connectable to a tubing set in less than 30 seconds.
Note: tubing set to be used with the Micro NPWT system is: 3/32 inch I.D. tubing.

Results

Attach tubing set to port of dressing



Attachment of pigtail to dressing takes less than 2 seconds

PASSES

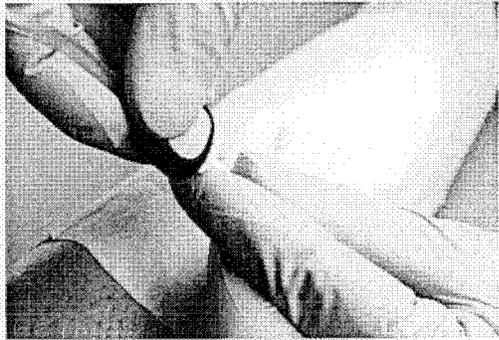
5.3 Pump Module/Tubing interface (SYSREQ54713)

This procedure will verify that the NPD pump module shall be connectable to a tubing set in less than 30 seconds.

Results

Attach pump tubing connector to dressing pigtail

1330



Procedure takes less than 2 seconds

PASSES

<END OF DOCUMENT>

1351



COVER SHEET MEMORANDUM

From: Reviewer Name
Subject: 510(k) Number
To: The Record

Suzanne Malli **DK**
K080275/S2
October 6, 2008
SE

Please list CTS decision code

- Refused to accept (Note: this is considered the first review cycle. - See Screening Checklist. http://eroom.fda.gov/RoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%202007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary / 510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacem/morechoices/fdaforms/FDA-3654.pdf)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/RoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients age <= 21		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days < 2 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child (2 years < 12 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Adolescent (12 years < 18 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group; different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Nanotechnology		<input type="checkbox"/>	<input checked="" type="checkbox"/>

Is this device subject to Section 522-Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		✓

Regulation Number: 21 CFR 878.4780 Class*: II Product Code: JCX
 (*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Daniel Krone PRSB 10/9/2008
 (Branch Chief) (Branch Code) (Date)

Final Review: Neil R. J. ... 10/9/08
 (Division Director) (Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification 510(k) Review
Traditional
K080275/S2**

Date: October 6, 2008
To: The Record
From: Suzanne Malli
Branch: Plastic and Reconstructive Surgery Branch
Division: Division of General, Restorative, and Neurological Devices
Office: Office of Device Evaluation

510(k) Holder: Kalypto Medical
Device Name: NPD 1000 Negative Pressure Wound Therapy System
Contact: John Buan
Phone: (612)-703-1204
Fax: (763)-287-3836
Email: jbuan@iasismedical.com

I. Purpose of Submission

The 510(k) holder would like to introduce the following device into interstate commerce. **NPD 1000 Negative Pressure Wound Therapy System**

II. Document History

This is the first pre-market submission for this product and this company. The company changed their name after the original submission. Initially, their name was Iasis Medical and now they are called Kalypto Medical. NPD refers to (Negative Pressure Dressing).

III. Recommendation: Substantially Equivalent

Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: proposed JCX

*I. Concur
D. A. K. here
10/7/2008*

IV. Administrative Requirements

	YES	NO	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are cleaning instructions included for the end user?	X		

V. Device Description

The NPD 1000 Negative Pressure Wound Therapy System by IASIS Medical Inc includes a small, portable battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing by removing wound exudate and collecting the exudate in the wound dressing.

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting. The dressing has 3 windows near the pressure port to monitor when the dressing is nearing its exudate capacity.

The NPD 1000 accessory wound dressing is comprised of the following:

- Semi-occlusive outer layer that maintains the negative pressure,
- Pressure port with an in-line hydrophobic, anti-bacterial 0.2um filter and fitting to which the NPD pump system is attached via PVC tubing,
- Hydrogel gasket to seal the wound area,
- Super absorbent non-woven polymer matrix to absorb exudates—see biocompatibility data
- Silverlon wound contact layer— K023210 this is an already cleared silver wound dressing

Kalypto Negative Pressure bandages
NPD 1000i Intermittent Therapy Pump
NPD 1000c Continuous Therapy Pump

VI. Indications for Use

Old version

The NPD 1000 Negative Pressure Wound Therapy System is a compact portable device indicated for patients who would benefit from suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Final version:

The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.

Predicate Device - K060277

The Boehringer Laboratories Suction Pump System is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.

Predicate Device - K063692

The V.A.C.® Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The V.A.C.® GranuFoam® Silver™ Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types.

Discussion of whether the intended use/indications are the same
--

The company changed the IFU statement to the following:

The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.

The IFU statement can now be considered substantially equivalent to the predicate device.

VII. Predicate Device Technological Comparison

The NPD 1000 Negative Pressure Wound Therapy System is comprised of a small, compact portable battery operated electromechanical pump and a wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing.

The NPD 1000 pump is shipped in 2 pieces, a system controller and 1 of 2 pump housings, either continuous or intermittent. Both pump housings can provide continuous therapy, but only the intermittent housing can provide intermittent therapy.

The NPD 1000 pump contains a microprocessor controlled pump and pressure sensor working in feedback fashion to control the pressure under the dressing at the physician programmed setting. The pump is powered by 3 AA batteries, either alkaline or NiMH rechargeable. For therapy status notification, the pump has a leak detection indicator icon, a low battery indicator icon and therapy proceeding indicator icon. An alarm buzzer will sound for a leak detection, low battery or system fault.

	Subject Device	K063692	K060277
Weight	8 oz.	2.4 lbs	5 lbs.
Pump Pressure	40-125	25-200	30-75
Dimensions	3.2W x 5.1H x 1.3D	7.6W x 6H x 2.5D	3.2W x 5.1H x 1.3D
Battery	Alkaline or rechargeable	Lithium	12V rechargeable
Dressing	Occlusive dressing	Polyurethane foam	none
Collection	50ml	300ml	500ml

This device is technologically different than the predicate device based on the weight, dimensions, collection volume. Further, there appears to be no packing of the wound bed. With the predicate devices this is done to create an area to draw the exudate into and thus it is unclear how the wound bed would be affected by a constant airflow and no protective covering to prevent desiccation of the wound. Because of these differences we asked the company to conduct performance testing to show that the vacuum pulled by the subject device is equivalent to predicate devices. The company has demonstrated that the subject device is able to maintain the noted pump pressure settings at the wound in a continuous and intermittent mode. The company provided bandage fluid capacity performance testing.

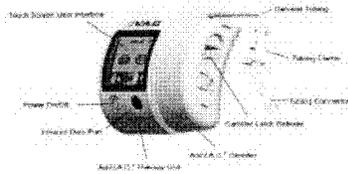
Predicate Device Boehringer Laboratories Suction Pump System

The Boehringer Laboratories Suction Pump System consists of a powered suction pump for the application of low flow suction. A rigid disposable canister for the collection of fluids is included as an accessory.

Predicate Device Description

ActiV.A.C. Therapy unit delivers software controlled negative pressure to the wound site. The open cells of the foam dressings provide distribution of suction across the surface of the wound as

exudate is drained into the canister. The pump can deliver between 25-200mmHG in 25mm increments. The ActiVAC measures 6 x 7.6 x 2.5 inches and weighs 2.4 pounds. The device is curved to fit against the patient's body. The device uses a lithium ion battery and is housed in powder-coated magnesium. The canister holds 300ml of fluid.



VIII. Labeling

Package Insert: Attachement Q2

The package insert contains:

- * A description of the device and materials
- * Indications and Contraindications
- * Storage and Handling Instructions
- * Warnings, Precautions and Possible Adverse Effects
- * The name, address and telephone number of the sponsor

In supplement 2, the company provided a revised instructions for use which is acceptable and provides adequate labeling for this product. The company developed and test patient labeling so that patients can use the instructions and obtain the desired outcome.

Package Labels:

The package label contains:

- * The device name and size
- * Quantity and Lot #
- * Expiration date
- * Two indicators as described in the Packaging section and explanations of the indicators
- **The** name address and telephone # of the sponsor

Claims:

Reducing edema	Tissue perfusion
Promoting granulation	Tissue formation

The company has stated that they have removed the above claims from their labeling but the below claims exist. The company was queried regarding these claims and in supplement 2 these claims were removed:

“This approach to wound care is believed to create an environment that promotes wound healing by bring the wound edges together (with negative pressure)” page 6 indications for use.

“pressure sensor working in feedback fashion to control the pressure under the wound.”

IX. Sterilization/Shelf Life/Reuse

Stability Studies Shelf: The company is claiming (submission page 35) a 12-month shelf life; they have provided stability data to support their claim. Product and Package Validation testing is found in Attachment Q1.

The company states that the stability validation will consist of accelerated aging to one year, seal integrity testing, bubble leak testing, and seal strength testing. ASTM F 1980-02, ASTM F 2096-04, ASTM F 88-07. All testing met the acceptance criteria. See attachment Q1 for testing summaries.

The company conducted a cleaning validation and the report can be found in Attachment Q9.

The following functional testing were be performed:

- achieving and maintaining vacuum integrity over the full range of therapeutic pressures: 40-125mmHG—persistent vacuum integrity testing
- Achieving set pressure in less than 3 minutes - - bandage pump down time testing
- Verifying the therapeutic fluid capacity of 50ml is not impacted by aging - - bandage fluid capacity testing

1. Sterilant:	
a. Sterilization method description (e.g., Steam, EtO, Radiation):	Electron Beam
c. Sterilant Dose	25kGy
2. A description of the Validation Method for the sterilization cycle (not data): (Citation of an FDA recognized standard is acceptable (e.g..))	ISO 11137: 2006
Assurance level (SAL): 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}
4. Is it labeled "Pyrogen Free"?	No
If so, a description of the method: (e.g., LAL (<i>Limulus</i> Amebocyte Lysate test))	None provided
5. A description of the packaging (not including package integrity test data):	Polyester/foil laminate pouch layers include PET, LDPE, aluminum foil, Surlyn sealant layer

X. Biocompatibility

The subject device was tested for biocompatibility,

(b)(4)

Test	Results
Cytotoxicity: ISO Agarose Overlay Method	Showed Grade 2 (mild) cytotoxicity
Irritation	No irritation
Sensitization	No sensitization

Non-Woven Polymer Matrix

The company provided biocompatibility testing on their non-woven polymer matrix. They described the chemical composition of this material. It is a cross-linked acrylate copolymer in fiber form. The polymer is very low acute toxicity and is not mutagenic. This material is used in the food industry to absorb fluids in food trays (fluid absorber for food contact materials). An Material Safety Data Sheet was provided. The biocompatibility data was provided in the addendum to supplement 2, dated August 20, 2008. The company states that this material will not come in contact with the wound as the Silverlon wound dressing (previously cleared product) will be in contact with the wound. The non-woven polymer matrix will serve as a fluid absorber outside the wound bed. The testing evaluated acute toxicity, mutagenicity, sensitization, irritation, cytotoxicity in both intact and abraded skin with the dry and water swollen versions of the product. No adverse effects were noted in any of the above tests. The product was found to be non-cytotoxic, non mutagenic, non-skin irritating and slightly irritating to the eyes and non-sensitizing to the skin.

XI. Software see attached software review from Steven Pelham, software engineer OSEL

The company has addressed Steven Pelham's review questions.

XII. Electromagnetic Compatibility/Electrical, Mechanical and Thermal Safety

See attached review from electrical engineer Sajjad Sayed.

XIII. Performance Testing – Bench

The company has shown that the pressure can be maintained for up to 60minutes

Additionally, the subject device is comparable to the predicate device ActiVAC in the scaling up

the pressure and

- achieving and maintaining vacuum integrity over the full range of therapeutic pressures: 40-125mmHG
- Achieving set pressure in less than 3 minutes

XIV. Performance Testing – Animal

None provided

XV. Substantial Equivalence Discussion

NPD 100 Negative Pressure Wound Therapy Device is substantially equivalent to the predicate devices identified above, which have been cleared with product code JCX, in terms of product indications, technology, sterility, biocompatibility and other factors.

	YES	NO	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		x	If YES = Stop NSE
3. Same Technological Characteristics?		x	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	x		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?	x		If NO = Request Data
9. Data Demonstrate Equivalence?	x		Final Decision: SE

XVI. Deficiencies from initial submission:

1. Please provide a completed Traceability Analysis which links together your product 1) hardware and software design requirements, 2) software design specifications, and 3) testing requirements. It should also provide a means of tying together 4) identified hazards with the 5) mitigations and 6) subsequent testing to validate the mitigation. It is requested that you submit for review explicit traceability among these activities and associated documentation because they are essential to effective product development and to our understanding of product design, development, testing, and hazard mitigations. The Traceability Analysis commonly consists of a matrix with line items for requirements, specifications and tests, and pointers to hazard mitigations.

The traceability analysis was provided. This is an acceptable response.

2. Please provide the test results for the Therapy Duration and Pressure Loss prevention tests. For any modifications made in response to failed tests, please provide the results of the regression testing performed to verify and validate those modifications to show that the modifications were effective, as well as a description of any tests that failed. Please ensure that the Traceability Analysis effectively links these activities and results to your design requirements and specifications.

The traceability analysis was provided and the information was linked to the design requirements and specifications. This is an acceptable response.

3. Please provide the history of software revisions generated during the course of product development. This typically takes the form of a line-item tabulation of the major changes to the software made during the development cycle, including date, version number, and a brief description of the changes in the version relative to the previous version. The last entry in the list should be the final version number/designation and date which will be incorporated in the released device. This entry should also briefly describe any differences between the tested version of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.

A software revision history was provided. This is an acceptable response.

4. Please provide a list of all unresolved software anomalies. For each anomaly, please indicate the 1) problem, 2) impact on device performance, 3) any plans or time frames for correcting the problem (where appropriate). Please annotate each item with an explanation of the impact of the anomaly on device safety or effectiveness, including operator usage and human factors issues. In all instances where it is practical to do so, please include any mitigation or possible work-around for unresolved anomalies. If there are no unresolved software anomalies, as written statement declaring such should be submitted.

A list of unresolved software anomalies was provided. The company stated that no unresolved anomalies were listed. This is an acceptable response.

5. Please provide the final software version number and release date for this device.

The company provided the final software version number and release date.

6. In your submission you have provided EMC and safety test results. The Agency believes that IEC 60601-1-2 and IEC 60601-1 testing should be performed on a final finished, production ready unit, to fully certify that the device design is correct. Please verify for us if all the testing was performed on a final finished, production ready unit.

The company stated the IEC 60601-1-2 and IEC 60601-1 testing was done on the final finished device. This is an acceptable response.

7. You have indicated that the subject device can be used in a home-care setting. However, you have not submitted patient labeling to coincide with the subject device. Please develop and test patient labeling to be used with the subject device. Additionally, please demonstrate use of the subject device when used according to the Patient and Physician Labeling and the Instructions for Use that you plan to provide with the proposed device for the proposed Indications for Use. Usability testing is needed to assess the adequacy of the Patient and Physician labeling developed for the home care use of the subject device. Please submit usability testing consistent with the patient labeling guidance <http://www.fda.gov/cdrh/ohip/guidance/1128.html> (appendix F).

The company submitted usability testing but the patient labeling was not entirely clear on the patient responsibilities. A follow-up deficiency will be sent.

8. You proposed a 12-month shelf life but did not provide supporting data for this shelf-life claim. Please be advised that conformance to a standard is not sufficient to obtain a shelf-life claim. Your stability data should support the proposed shelf life (i.e., subject device meets product specifications over the proposed shelf life). Please provide stability testing on real-time or validated accelerated aged samples to support your proposed 12-month shelf life for the subject device.

The company provided stability testing to support their 12-month shelf life. This is an acceptable response.

9. Please be advised claims such as reducing edema, promoting granulation tissue formation and perfusion (page 27 of 55) should be supported by data.

The company has removed these claims. This is an acceptable response.

10. Your labeling should contain a precaution that the device should not be used once wound exudate is no longer present in the wound.

The company has added this precaution to their instruction for use. This is an acceptable response.

S1 Deficiencies

1. On April 29, 2008, FDA requested performance testing to demonstrate equivalence of the subject device to a legally marketed predicate device. You submitted bandage integrity testing demonstrating final pressure and pump down time. The submitted testing is not sufficient to determine that the subject device is substantial equivalent to the predicate device based on how negative pressure is effectively administered to the wound bed resulting in the removal of wound exudate. In all predicate devices the negative pressure is administered to the dressings placed in the wound bed. You stated that negative pressure will be administered to a wound dressing that is external to the wound. You have not demonstrated that the pressure created by this external negative pressure will result in effective removal of exudate from the wound. Please provide performance testing that demonstrates negative pressure administered (continuously and intermittently) to the wound over an extended period of time results in wound exudate effectively removed from the wound bed and contained in the occlusive wound dressing. Please be aware the model used P080299 is not a relevant physiological model.

The company responded that system is intended to treat surface wounds. The dressing does not fill the wound bed but lies on top of the wound bed. The company states that the application of negative pressure pulls the exudate away from the wound into the wound dressing accessory and is the same principle of operation as the predicate device. A series of photos provided in attachment Q1, demonstrates the performance of the subject device administering negative pressure to the wound bed and the resultant exudate being collected into the accessory wound dressing. The wound dressing capacity is more than 50ml of fluid. The company demonstrated that the device performs intermittent and continuous modes in attachment Q3. I have no further questions. This is an adequate response.

2. Please explain this statement found in your labeling: "For cavity wounds a standard wound filler such as gauze or foam must be used". Please submit performance data to demonstrate how your device will function with gauze or foam present in the wound.

The company responded that this statement has been removed from the product labeling. This is an acceptable response.

3. You state the following on page 10 of the indications for use: "...pressure sensor working in feedback fashion to control the pressure under the wound." Please identify the testing you completed on your Proprietary Leak Detection System that demonstrates a feedback mechanism to control the pressure under the wound. You have testing that identifies the presence of a leak but this statement infers that the device will identify a leak and then compensate the pressure. Please identify the testing or remove this claim from your labeling.

The company explained that the system can detect a leak when the pressure continues to try to compensate for the leak for a set amount of time. At that time, an alarm will sound. This is an acceptable response. See Feedback Loop flowchart Attachment Q3.

4. Please provide the data you have to support the following claim:

“This approach to wound care is believed to create an environment that promotes wound healing by bring the wound edges together (with negative pressure)” found on page 6 indications for use.

The company responded that this statement has been removed from the product labeling. This was an acceptable response.

5. Predicate devices advise users on specific measures to take to isolate major vessels that may be present in a wound bed. Please explain how you will isolate vessels in the wound bed.

The company responded by adding a warning to labeling regarding protecting any major vessels in the wound bed. This is an acceptable response.

6. Please clarify this statement “do not use topical solutions or agents that may have adverse interactions with silver. For example, saline solutions may compromise the effectiveness of the silver dressing”. Please outline what effectiveness you expect from the silver dressing. Please explain how you have determined that Silverlon is a non-stick layer.

The company will be advised not to make any antimicrobial claims regarding the use of silverlon in their product. The company has changed their non-stick to non-adherent based on the K981299 clearance. This is an acceptable response.

7. You listed a device component as a “Super absorbent non-woven polymer matrix”. Your biocompatibility refers to this product as (b)(4). This does not appear to be a previously cleared 510(k) product for (b)(4). Please characterize this material based on the chemical composition. Please identify how this product has been evaluated for toxic effects and potential leaching effects. Additionally, you have shown that this polymer matrix can be squeezed to release fluid. Please demonstrate how this polymer matrix will not release fluid back into the wound. Lastly, please demonstrate how will negative pressure be administered to the wound in the presence of this polymer matrix.

Please see the biocompatibility section. The non-woven polymer matrix passed the biocompatibility tests and can be considered biocompatible based on the submitted testing. This is an acceptable response.

8. Please modify your Indications for Use statement to read as follows:

"The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing."

The company modified their IFU statement to read as noted above. This is an acceptable response.

- 9. You have stated that the device should be wiped down with a damp cloth. These measures will not allow safe repeat use of the pump unit between patients. Please outline how the device should be disinfected to prevent cross-contamination from multiply uses.

The company completed a cleaning protocol validation. They determined the appropriate measures to be taken to prevent cross-contamination between patients. This is an acceptable response. Please see Attachment Q9. This is an acceptable response.

- 10. You state at the beginning of the patient labeling that a patient does not need to touch the device, yet you explain several points throughout the labeling for what measures the patient can take to manipulate the device. You are not consistent in your advice to the patient. Please explain why the patient would need to change the batteries on this device or disable the alarm. These do not seem like functions that should be required by patients. Please review the FDA patient labeling guidance and ensure that your patient labeling is consistent with this guidance.
<http://www.fda.gov/cdrh/ohip/guidance/1128.html>

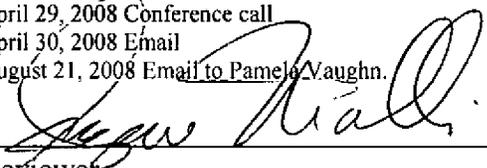
The patient labeling was revised to more explicitly describe the patient responsibilities to observe the displayed information, disable alarms when necessary, check if a leak is present and change battery if necessary. The patient labeling is found in Q2. This patient is labeling is much improved from the last supplement.

- 11. Your NPD dressing is labeled as follows: "Arm or Leg". Your IFU does not restrict the use with the arm or leg. Please explain this discrepancy.

The IFU and label were revised to indicate that it should be used on a surface where the dressing can achieve the appropriate vacuum seal. Please see attachment Q11. This is an acceptable response.

XVII. Contact History

March 26, 2008 Email sent to Mr. John Buan
April 29, 2008 Conference call
April 30, 2008 Email
August 21, 2008 Email to Pamela Vaughn.



Reviewer

10/07/08

Date

Branch Chief

Date

Reviewer

Date

Branch Chief

Date

MEMO OF EMC REVIEW

510(K): K080275

FROM: Sajjad Syed, Software Engineer (CDRH General Hospital Devices Branch), 240-276-3712, sajjad.syed@fda.hhs.gov

TO: Suzanne Malli (CDRH\ODE\DGRND\PRSB)

DATE: Friday March 14th, 2008

SUBJECT: EMC Review (CON081467) of K080275 Powered Suction Pump

Name of the Device: Model npd 1000 negative pressure wound therapy system
Applicant: Iasis Medical, Inc.

General description of device:

The NPD 1000 Negative Pressure Wound Therapy System is comprised of a small, compact portable battery operated electromechanical pump and a wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing.

The NPD 1000 pump is shipped in 2 pieces, a system controller and 1 of 2 pump housings, either continuous or intermittent. Both pump housings can provide continuous therapy, but only the intermittent housing can provide intermittent therapy.

The NPD 1000 pump contains a microprocessor controlled pump and pressure sensor working in feedback fashion to control the pressure under the dressing at the physician programmed setting. The pump is powered by 3 AA batteries, either alkaline or NiMH rechargeable. For therapy status notification, the pump has a leak detection indicator icon, a low battery indicator icon and therapy proceeding indicator icon. An alarm buzzer will sound for a leak detection, low battery or system fault.

Intended Use:

The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Consultant Comments and description about EMC:

The sponsor has stated that to meet the safety requirements, sample devices were subjected to testing according to the IEC 60601-1 and IEC 60601-1-2. The sponsor has signed a declaration of conformity form and has identified specific tests from the standards that were used for testing. The sponsor submitted the subject device to Intertek (third party lab) to perform both EMC and Electrical Safety testing. The lab performed the following tests according to the standard on both Intermittent and Continuous versions of the device:

Immunity Test
Emissions Test
Radiated RF Immunity Test
Magnetic Immunity Test
ESD Immunity Test

The third party lab (Intertek) has stated that during the test no deviation was detected to the sample devices. The lab provided a certificate stating that the device met with the requirements of the standard.

Under the conditions outlined in these tests, the device emits levels of electromagnetic radiation that is below established upper limit threshold of acceptable emissions and according to the lab, operates without error in the presence of electromagnetic radiation.

The sponsor also conducted testing according to the IEC 60601-1 standard. Some of the tests performed are:

Enclosures and Protective Covers
Fire Prevention
Interruption and restoration of power not resulting in a safety hazard
Conductors and connectors secured and/or insulated
Excessive Temperatures

The device passed all the IEC 60601-1 applicable tests, meeting the criteria for electrical safety. The IEC 60601-1-2 tests were conducted when the device was both in Continuous and Intermittent modes.

In my opinion the sponsor has done a sufficient job of verifying that their device is electrically safe and not susceptible to RF, magnetic fields interferences. I have only one question that I want the sponsor to verify. It is stated below:

1. In your submission you have provided EMC and safety test results. The Agency believes that IEC 60601-1-2 and IEC 60601-1 testing should be performed on a final finished, production ready unit, to fully certify that the device design is correct. Please verify for us if all the testing was performed on a final finished, production ready unit.

Sajjad Syed

Memorandum of a Software Review

K080275

February 21, 2008

From: Steven Pelham; OSEL-DESE (WO62-4229); (301) 796-2589
To: Suzanne Malli, ODE-DGRND-PRSD (HFZ-410), (240) 276-3632
Subject: Software review of NPD 1000 Negative Pressure Wound Therapy System by IASIS Medical Inc.

Succinct Conclusion: Additional Information

The information contained within this submission is insufficient to meet the software concerns as described in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005, and it is recommended that, from a software standpoint, this submission be considered **Additional Information**.

Summary

The NPD 1000 Negative Pressure Wound Therapy System by IASIS Medical Inc includes a small, portable battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing. The NPD 1000 is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressure.

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting. The dressing has 3 windows near the pressure port to monitor when the dressing is nearing its exudate capacity.

The NPD 1000 dressing is comprised of the following:

- Semi-occlusive outer layer that maintains the negative pressure,
- Pressure port with an in-line hydrophobic, anti-bacterial 0.2 um filter and fitting to which the NPD pump system is attached via PVC tubing,
- Hydrogel gasket to seal the wound area,
- Super absorbent non-woven polymer matrix to absorb exudates, and

- Non-stick Silverlon wound contact layer.

This software review does not cover the correctness of the underlying algorithms or their appropriateness or applicability to the indicated use of this device, as such evaluation is beyond the scope of this review. This is a MAJOR Level of Concern device.

1. Software Description [ok]

The firm provided an acceptable overview of the device features that are controlled by software, and a description of the intended operational environment. [Appendix 5, System Software Design, DP-0001-84-3 Section 2]

2. Device (including Software) Hazard Analysis [ok]

The firm provided an acceptable description of the hazards presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards. [Appendix 6, FMECA DP-0001-84-1 and Hazard Analysis DP-0001-83-7]

3. Software Requirements Specifications (SRS) [ok]

The firm provided a copy of their software requirements specification document, which clearly documented their functional, performance, interface, design, and development requirements. [Appendix 7, System Requirements Specification DP-0001-84-2]

4. Architecture Design [ok]

The firm provided an acceptable description of the software system partitioned into its functional subsystems. [Appendix 5, System Software Design, DP-0001-84-3, Sections 3 & 5]

5. Software Design Specification (SDS) [ok]

The firm provided an acceptable design specification document, which describes what the program does and how it does it. [Appendix 5, System Software Design, DP-0001-84-3 Section 2]

6. Traceability Analysis [not ok]

The firm **failed to provide** their traceability matrix, which provided the links between the hazards, requirements, validation and testing.

7. Software Development Environment Description [ok]

The firm submitted a summary of their software development life cycle plan, describing the processes that have been put into place to manage the various software development life cycle activities, including a summary of the configuration management and maintenance activities. [Appendix 5, System Software Design, DP-0001-84-3, Sections 4 & 5]

8. Verification and Validation (including Testing) [not ok]

The firm provided an acceptable description of their systematic process of life cycle activities, including analysis, evaluation, assurance, and testing of the software, and supporting documentation. HOWEVER, the firm **has not finished testing the device**, specifically the Therapy Duration tests

and the Pressure Loss Prevention test. [Appendix 8, V&V Plan DP-0001-85-0, Verification Test Procedures DP-0001-84-0, NPD 1000 Negative Pressure Dressing V&V Test Procedures QFM-04-3b and Appendix 9, Minnetronix Verification Report DR-0000-09-0, NPD 1000 Negative Pressure Dressing V&V Test Report QFM-04-3c]

9. Revision Level History [not ok]

The firm **failed to provide** the revision history log, documenting all major changes to the software during its development cycle.

10. Unresolved Anomalies (bugs) [not ok]

The firm **failed to provide** a list of all unresolved software anomalies, indicating the problem, the impact on device performance, and plans and time frames for correcting each problem.

11. Release Version Number [not ok]

The firm **failed to provide** an acceptable description of the version numbers and dates.

Recommendation

Additional Information

The firm has **failed to provide** acceptable documentation demonstrating that they carried out an appropriate complete validation process as well as other missing documents as detailed above.

These procedures provide the foundation for assuring, to the extent possible, that the software will operate in a manner described in the specifications, and in no other predictable way. It is recommended that, from a software standpoint, this submission should be considered **Additional Information**.

Please provide a written response to the following questions:

- a. Please provide a completed Traceability Analysis which links together your product 1) hardware and software design requirements, 2) software design specifications, and 3) testing requirements. It should also provide a means of tying together 4) identified hazards with the 5) mitigations and 6) subsequent testing to validate the mitigation. It is requested that you submit for review explicit traceability among these activities and associated documentation because they are essential to effective product development and to our understanding of product design, development, testing, and hazard mitigations. The Traceability Analysis commonly consists of a matrix with line items for requirements, specifications and tests, and pointers to hazard mitigations.
- b. Please provide the test results for the Therapy Duration and Pressure Loss prevention tests. For any modifications made in response to failed tests, please provide the results of the regression testing performed to verify and validate those modifications to show that the modifications were effective, as well as a description of any tests that failed. Please ensure that the Traceability Analysis effectively links these activities and results to your design requirements and specifications.
- c. Please provide the history of software revisions generated during the course of product development. This typically takes the form of a line-item tabulation of the major changes to the software made during the development cycle, including date, version number, and a brief description of the changes in the version relative to the previous version. The last entry in the list

should be the final version number/designation and date which will be incorporated in the released device. This entry should also briefly describe any differences between the tested version of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.

- d. Please provide a list of all unresolved software anomalies. For each anomaly, please indicate the 1) problem, 2) impact on device performance, 3) any plans or timeframes for correcting the problem (where appropriate). Please annotate each item with an explanation of the impact of the anomaly on device safety or effectiveness, including operator usage and human factors issues. In all instances where it is practical to do so, please include any mitigations or possible work-around for unresolved anomalies. If there are no unresolved software anomalies, a written statement declaring such should be submitted.
- e. Please provide the final software version number and release date for this device.

Since a 510(k) submission relies on objective evidence that all V&V tests have passed as well as other safety and effectiveness evidence, it is appropriate that all testing be completed and documented before a final determination of substantial equivalence can be made.

IASIS (KALYPTO) – FDA Telecom Meeting Minutes

RE: K080275 NPD1000 Negative Pressure Wound Therapy System

Minutes prepared by: Pamela Vaughan, Alquest, Principal Project Manager

Date and Time of Telecom Meeting: April 29, 2008 at 1:30 PM -2:00PM CDT

FDA Attendees:

024

David Krause, Branch Chief, Plastic and Reconstructive Surgery Branch
Suzanne Malli, Plastic and Reconstructive Surgery Devices Branch

Sponsor Attendees:

John Buan, V.P. Marketing and Product Development, IASIS Medical, Inc.
Philip Vierling, President/CEO, IASIS Medical, Inc.
Pamela Vaughan, Principal Project Manager, Alquest, Inc.
Mark DuVal, J.D. Regulatory Consultant, DuVal & Associates
Marcia Palma, Principal Consultant, Alquest (not introduced)

Ms. Vaughan opened the meeting by introducing IASIS/KALYPTO attendees and verifying FDA attendees on telecom.

She requested FDA to correct an administrative error in the April 17, 2008 deficiency letter- the correct predicate 510(k) number should be K063692, not K063642.

Ms. Vaughan then reiterated the Sponsor comments stated in Item #1 on the Agenda (attached), emphasizing that IASIS contends that the NPD1000 NPWT System is substantially equivalent to the KCI ActiVac, K063692. She then asked FDA questions presented in Item #2 on the Agenda:

1. Since these devices have somewhat different technological characteristics, do they raise for the Agency unanswered questions of safety and effectiveness? If so, what precisely are they?

FDA Responses and Questions:

FDA (Ms. Malli) agreed that the intended use of the devices is the same. She then listed the significant technological differences that raise concerns by FDA:

- NPD1000 weighs significantly less than the proposed predicate devices
(8oz vs 2.5 pounds)
- NPD1000 capacity is 50mL; minimum predicate volume capacity is 300mL
- NPD1000 is battery powered only, not both battery and/or AC

Ms. Malli then asked the following questions about the NPD1000 (in *italics*), which were answered by John Buan.

How can it hold the vacuum? Does the device “pack” the wound?

As recommended by Mark DuVal, John Buan explained the design and functionality of the NPD1000 NPWT System, and how the vacuum is accomplished through the dressing seal properties and the attached vacuum source. He explained how the fluids are drawn into the dressing, away from the wound. Although we’ve recorded briefly his answers to questions below, John’s answers were lengthy and quite detailed and satisfied the FDA.

How has IASIS shown that the bandage can draw 125 Hg vacuum? John Buan described the bench data, which was provided in the 510(k) submission. He described the uncomplicated deployment of the dressing and how the negative pressure is maintained.

How does it prevent wound desiccation? Once the fluid is in the bandage, it binds molecularly to the dressing material, so it does not “evaporate” or desiccate the wound site.

Will the device be applied to the wound continuously? Per standard NPWT, the device will be in place for 24 hours per day for the 2-3 days between placement of the dressing and removal. However, it is likely that the dressing will be removed (or treatment suspended) in the hour or two before the patient’s appointment to change dressings so that the patient may take care of personal hygiene considerations, (bathing, showering etc.).

Will the “semi occlusive” wound dressing cause maceration? No. First, all negative pressure wound therapy dressings are “semi-occlusive”, meaning that they can hold vacuum for some time with the assistance of a mechanical pump. For wounds to be treated with the Kalypto dressing, the fluids will be drawn away from the wound into a super-absorbent non-woven material. Once in the non-woven, the fluid is molecularly bonded to a super-absorbing polymer fiber that is one of the constituent fibers of the non-woven “pad”.. Thus, up to the capacity of the dressing, there are no free fluids (water) to sit on the tissue and cause maceration. Additionally, the pressure under the bandage is uniform, so no squeezing of fluid, from the material will occur due to a mechanical force generated by a pressure imbalance or gradient. “Additionally, company testing has shown that for fluid absorption at levels 40% beyond the design capacity, substantial external mechanical forces (from outside the dressing) will not “free” fluid from the non-woven material so that they could potentially cause maceration of the healthy tissues around the wound.”

Is the dressing a closed system? Yes. There is a 0.2µm (b)(4) layer at the connection of the vacuum tubing, to prevent bacteria and water from getting into the tubing.

Can fluid get into the pump? No. The (b)(4) prevents water/fluids from getting into the tubing, so it cannot get into the pump. The (b)(4) material has a water ingress pressure of 14 psi, well above the (negative) maximum pressure applied by the device.

Mark DuVal asked if there were impediments to clearance due to proposed labeling.

Dr. Krause then expressed his concern about the differences in this device, and predicate devices under the same regulation for powered suction pumps, 21CFR Part 878.4780, which was intended for larger suction pumps and the NPD1000 System is “awfully small” for the regulation. The devices in this class have “morphed” over time in design and intended uses. Historically, FDA has seen other incremental, but less significant changes to predicates than is seen with the new NPD1000 System. Especially, that it is much smaller, and only holds 50mL of exudate. This limited capacity (to differentiate from predicates) needs to be clear in the labeling of this device. He proposed a new intended use statement to read:

Portable, low powered, battery operated suction pump to remove a small amount of exudate (such as infectious agents) from wounds.

FDA (Dr. Krause) verified that this new intended use would then permit IASIS to use the ActiVAC (K063692) as an adequate predicate.

Dr. Krause then suggested that the 50mL capacity was a “mega step” for substantial equivalence compared to the other pumps on the market. Most are 300mL canisters. He thought the 50mL capacity needed to be clearly stated in the instructions for use; and to “be careful” of claims such as wound healing. IASIS needs to be sure they can support the claims with bench data.

Dr. Krause stated that side by side data with the NPD and predicate device must be collected. IASIS questioned why this was necessary. David responded- to show substantial equivalence. IASIS agreed to collect this data (comparison of negative pressures achieved in bench testing).

Mark DuVal asked Dr. Krause to comment on the acceptability of the “promotes wound healing” claim. Dr. Krause said that this claim was accepted years ago in the original predicate, but was stated at that time as “may promote wound healing”, a benefit that was due to removal of infectious materials. But, the use of the “promotes wound healing” claim now has different interpretations by manufacturers. He said he felt that he couldn’t stop us from using “may promote wound healing” since the predicate has it, but to state “promotes wound healing” would require clinical substantiation. The claim should be qualified by stating that the device “may promote wound healing, due to removal of infectious materials”, and clarify that use of device itself does not directly promote wound healing.

Ms. Vaughan then asked the FDA how IASIS should provide the new information to FDA? Dr. Krause verified with Ms. Malli that the 510(k) review was “on hold”. He suggested that we submit the following information to the 510(k) file:

- side by side bench testing data (predicate vs NPD1000)
- modify the indication for use (as stated above)
- provide a more detailed description of the dressing materials and how they function to wick and retain the fluids (and include brief description of principles of NPWT)
- provide wound contact material biocompatibility data (already submitted)
- revised labeling
- revised Summary of Safety and Indications for posting on FDA website

NOTE: The additional questions in Agenda Item #2 and Item #3 were not discussed, as they were no longer relevant.

At the closing of the meeting, Ms. Malli stated that FDA had some additional deficiencies related to device software. She said she would send those to IASIS tomorrow (4/30/08). When asked, John Buan verified that IASIS had utilized the FDA Guidance document on Software Validation during software validation.

Lastly, Dr. Krause stated that most of the adverse events they have seen with marketed suction pump devices have occurred in the home use setting, although he didn't expect it to be a problem with our smaller, portable pump. He still recommended that IASIS provide FDA with patient labeling and results of usability testing.

Ms. Vaughan thanked FDA for taking time to discuss these issues with IASIS, and that we appreciated their assistance to resolve these issues. The meeting closed at 2:05PM CDT.

IASIS MEDICAL, INC. (now Kalypto Medical, Inc.)

**MEETING AGENDA for Telecom with FDA, CDRH,
Plastic and Reconstructive Surgery Branch**

Meeting Purpose:

Discuss deficiency letter dated April 17, 2008 regarding IASIS Medical, Inc. 510(k) submission K080275

Date and Time: April 29, 2008 at 1:30 PM CDT

Dial (763) 287-3830, request connection to Bridge Line #657

Planned FDA Attendees:

David Krause, Branch Chief, Plastic and Reconstructive Surgery Branch
Suzanne Malli, Plastic and Reconstructive Surgery Devices Branch

Planned Sponsor Attendees:

John Buan, VP Marketing and Product Development, IASIS Medical, Inc.
Philip Vierling, President/CEO, IASIS Medical, Inc.
Pamela Vaughan, Principal Project Manager, Alquest, Inc.
Mark DuVal, J.D. Regulatory Consultant, DuVal & Associates

Discussion Topics and Questions:

- Both the Iasis NPD1000 and the ActiV.A.C. (K063692) are intended to promote healing by removing infectious materials and fluids (exudate) from wounds by vacuum-assisted drainage (negative pressure). Both devices include a powered suction pump, to create the negative pressure. Both the IASIS NPD1000 and the ActiV.A.C. dressings/bandage materials provide a bacterial barrier and transmit the negative pressure from the suction pump to the wound site. Both devices remove the exudate from the wound and store it safely away from the wound. In the case of the NPD1000, the dressing acts as the exudate collection device; the bandage provides a dry barrier on the wound side and prevents the exudate from remaining in contact with the wound. In the case of the ActiV.A.C., the exudate is stored in a canister. The only real difference between the two devices is that, in the case of the NPD1000, the dressing is, in effect, the holding canister.

TABLE:

Claim	IASIS NPD1000	ActiV.A.C.
Promotes healing	Yes	Yes
Removes infectious materials	Yes	Yes

Provides bacterial barrier	Yes	Yes
Negative Pressure	Yes – vacuum assisted	Yes – vacuum-assisted
Exudate removed from wound site	Yes – stored in bandage	Yes – stored in canister

3. We believe the NPD1000 is substantially equivalent to the chosen predicate because it is unequivocally the same intended use and the technological characteristics, while somewhat different, are functionally the same. Since these devices have somewhat different technological characteristics, do they raise for the Agency unanswered questions of safety and effectiveness? If so, what precisely are they? And what kind of evidence might the Agency want to see to address them? Are the Agency's requested information and studies relevant to the substantial equivalence determination?

4. If these unanswered questions of safety and effectiveness are relevant to the SE determinations and can be addressed, using least burdensome principles, does FDA agree that the ActiV.A.C. (K063692) is an adequate predicate?



COVER SHEET MEMORANDUM

From: Reviewer Name Suzanne Malli
 Subject: 510(k) Number 6080245/S1
 To: The Record

A1 June 19, 2008 EMAIL sent

- Please list CTS decision code A1
- Refused to accept (Note: this is considered the first review cycle. See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%20202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____ see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff -- MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/odel/guidance/1216.html)			
Is this device Intended for pediatric use only?			
Is this a prescription device? (if both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of Clinical Trials.gov Data Bank? (if not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <= 21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days - < 2 years old)			
Child (2 years - < 12 years old)			
Adolescent (12 years - < 18 years old)			
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification 510(k) Review
Traditional
K080275/S1**

Date: June 19, 2008
To: The Record
From: Suzanne Malli
Branch: Plastic and Reconstructive Surgery Branch
Division: Division of General, Restorative, and Neurological Devices
Office: Office of Device Evaluation

510(k) Holder: Kalypto Medical
Device Name: NPD 1000 Negative Pressure Wound Therapy System
Contact: John Buan
Phone: (612)-703-1204
Fax: (763)-287-3836
Email: jbuan@iasismedical.com

I. Purpose of Submission

The 510(k) holder would like to introduce the following device into interstate commerce. **NPD 1000 Negative Pressure Wound Therapy System**

II. Document History

This is the first pre-market submission for this product and this company. The company changed their name during the original submission and the supplement one submission. Initially, they were called Iasis Medical and now are called Kalypto Medical. NPD appears to refer to (Negative Pressure Dressing).

III. Recommendation: Additional Information

Regulation Number: proposed 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: proposed JCX

IV. Administrative Requirements

	YES	NO	N/A
Indications for Use page (Indicate if: <u>Prescription</u> or OTC)	X		
Truthful and Accuracy Statement	X		
<u>510(k) Summary</u> or 510(k) Statement	X		
Standards Form			X
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?	X		

V. Device Description

The NPD 1000 Negative Pressure Wound Therapy System by IASIS Medical Inc includes a small, portable battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing. The NPD 1000 is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressure.

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting. The dressing has 3 windows near the pressure port to monitor when the dressing is nearing its exudate capacity.

The NPD 1000 dressing is comprised of the following:

- Semi-occlusive outer layer that maintains the negative pressure,
- Pressure port with an in-line hydrophobic, anti-bacterial 0.2um filter and fitting to which the NPD pump system is attached via PVC tubing,
- Hydrogel gasket to seal the wound area,
- Super absorbent non-woven polymer matrix to absorb exudates—**how has this been studied**
- Non-stick Silverlon wound contact layer— K023210 this is an already cleared silver wound dressing **how do they know this is a non stick layer?**

Kalypto Negative Pressure bandages
NPD 1000i Intermittent Therapy Pump
NPD 1000c Continuous Therapy Pump

VI. Indications for Use

Old version

The NPD 1000 Negative Pressure Wound Therapy System is a compact portable device indicated for patients who would benefit from suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Suggested new version

The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.

Predicate Device - K060277

The Boehringer Laboratories Suction Pump System is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.

Predicate Device - K063692

The V.A.C.® Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The V.A.C.® GranuFoam® Silver™ Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types.

Discussion of whether the intended use/indications are the same
--

The IFU proposed by the company need to be modified and a additional deficiency is being sent out.

VII. Predicate Device Technological Comparison

The NPD 1000 Negative Pressure Wound Therapy System is comprised of a small, compact portable battery operated electromechanical pump and a wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing.

The NPD 1000 pump is shipped in 2 pieces, a system controller and 1 of 2 pump housings, either continuous or intermittent. Both pump housings can provide continuous therapy, but only the intermittent housing can provide intermittent therapy.

The NPD 1000 pump contains a microprocessor controlled pump and pressure sensor working in feedback fashion to control the pressure under the dressing at the physician programmed setting. The pump is powered by 3 AA batteries, either alkaline or NiMH rechargeable. For therapy status notification, the pump has a leak detection indicator icon, a low battery indicator icon and therapy proceeding indicator icon. An alarm buzzer will sound for a leak detection, low battery or system fault.

	Subject Device	K063692	K060277
Weight	8 oz.	2.4 lbs	5 lbs.
Pump Pressure	40-125	25-200	30-75
Dimensions	3.2W x 5.1H x 1.3D	7.6W x 6H x 2.5D	3.2W x 5.1H x 1.3D
Battery	Alkaline or rechargeable	Lithium	12V rechargeable
Dressing	Occlusive dressing	Polyurethane foam	none
Collection	50ml	300ml	500ml

This device is technologically different than the predicate device based on the weight, dimensions, collection volume. Further, there appears to be no packing of the wound bed. With the predicate devices this is done to create an area to draw the exudate into and thus it is unclear how the wound bed would be affected by a constant airflow and no protective covering to prevent desiccation of the wound. Because of these differences we asked the company to conduct performance testing to show that the vacuum pulled by the subject device is equivalent to predicate devices. The company has not demonstrated that the subject device is able to maintain the noted pump pressure settings at the wound in a continuous and intermittent mode.

The published literature had two studies with the following conclusions for alternatives to NPWT:

"For routine wounds that are small and have a contour that is not complex, use of a cotton bolster dressing is clinically as effective as NPWT and substantially more cost effective."

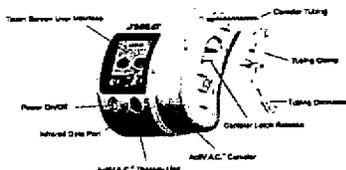
"The use of a simple suction drain is a cheap and safe alternative to commercial VAC dressings for the treatment of lower limb split skin grafts. Length of hospital stay and cost are superior to VAC, with no diminished clinical outcome."

Predicate Device Boehringer Laboratories Suction Pump System

The Boehringer Laboratories Suction Pump System consists of a powered suction pump for the application of low flow suction. A rigid disposable canister for the collection of fluids is included as an accessory.

Predicate Device Description

ActiV.A.C. Therapy unit delivers software controlled negative pressure to the wound site. The open cells of the foam dressings provide distribution of suction across the surface of the wound as exudate is drained into the canister. The pump can deliver between 25-200mmHG in 25mm increments. The ActiVAC measures 6 x 7.6 x 2.5 inches and weighs 2.4 pounds. The device is curved to fit against the patient’s body. The device uses a lithium ion battery and is housed in powder-coated magnesium. The canister holds 300ml of fluid.



VIII. Labeling

Package Insert:

The package insert contains:

- * A description of the device and materials
- * Indications and Contraindications
- * Storage and Handling Instructions
- * Warnings, Precautions and Possible Adverse Effects
- * The name, address and telephone number of the sponsor

Package Labels:

The package label contains:

- * The device name and size
- * Quantity and Lot #
- * Expiration date
- * Two indicators as described in the Packaging section and explanations of the indicators
- **The name address and telephone # of the sponsor**

Claims:

Reducing edema	Tissue perfusion
Promoting granulation	Tissue formation

The company has stated that they have removed the above claims from their labeling but the below claims exist. The company will be queried regarding these claims:

“This approach to wound care is believed to create an environment that promotes wound healing by bring the wound edges together (with negative pressure)” page 6 indications for use.

“pressure sensor working in feedback fashion to control the pressure under the wound.”

IX. Sterilization/Shelf Life/Reuse

Stability Studies Shelf: The company is claiming (submission page 35) a 12-month shelf life; but they have not provided stability data to support their claim. A deficiency needs to be sent to the company regarding their claim of a 12-month shelf life and the need for stability data to support any expiration dating.

The company states that the stability validation will consist of accelerated aging to one year, seal integrity testing, and seal strength testing. ASTM F 1980-02, ASTM F 2096-04, ASTM F 88-07.

The following functional testing were be performed:

- achieving and maintaining vacuum integrity over the full range of therapeutic pressures: 40-125mmHG
- Achieving set pressure in less than 3 minutes
- Verifying the therapeutic fluid capacity of 50ml is not impacted by aging

1. Sterilant:	
a. Sterilization method description (e.g., Steam, EtO, Radiation):	Electron Beam
c. Sterilant Dose	25kGy
2. A description of the Validation Method for the sterilization cycle (not data): (Citation of an FDA recognized standard is acceptable (e.g.,))	ISO 11137: 2006
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}
4. Is it labeled "Pyrogen Free"?	No
If so, a description of the method: (e.g., LAL (<i>Limulus</i> Amebocyte Lysate test))	None provided
5. A description of the packaging (not including package integrity test data):	Polyester/foil laminate pouch layers include PET, LDPE, aluminum foil, Surlyn sealant layer

X. Biocompatibility

The subject device was tested for biocompatibility,

Test	Results
Cytotoxicity: ISO Agarose Overlay Method	Showed Grade 2 (mild) cytotoxicity
Irritation	No irritation
Sensitization	No sensitization

XI. Software see attached software review from Steven Pelham, software engineer OSEL

The company has addressed Steven Pelham's review questions. The responses appear to be adequate but I will ask Steven Pelham to review the company's responses.

XII. Electromagnetic Compatibility/Electrical, Mechanical and Thermal Safety

See attached review from electrical engineer Sajjad Sayed.

XIII. Performance Testing – Bench

The company has shown that the pressure can be maintained for up to 60minutes

That the subject device is comparable to the predicate device ActiVAC in the scaling up the pressure and

XIV. Performance Testing – Animal

None provided

XV. Substantial Equivalence Discussion

Additional information required, an AI letter will sent.

	YES	NO	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		x	If YES = Stop NSE
3. Same Technological Characteristics?		x	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	x		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		x	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		x	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

XVI. Deficiencies to be sent once correct predicate is defined:

1. Please provide a completed Traceability Analysis which links together your product 1) hardware and software design requirements, 2) software design specifications, and 3) testing requirements. It should also provide a means of tying together 4) identified hazards with the 5) mitigations and 6) subsequent testing to validate the mitigation. It is requested that you submit for review explicit traceability among these activities and associated documentation because they are essential to effective product development and to our understanding of product design, development, testing, and hazard mitigations. The Traceability Analysis commonly consists of a matrix with line items for requirements, specifications and tests, and pointers to hazard mitigations.
2. Please provide the test results for the Therapy Duration and Pressure Loss prevention tests. For any modifications made in response to failed tests, please provide the results of the regression testing performed to verify and validate those modifications to show that the modifications were effective, as well as a description of any tests that failed. Please ensure that the Traceability Analysis effectively links these activities and results to your design requirements and specifications.
3. Please provide the history of software revisions generated during the course of product development. This typically takes the form of a line-item tabulation of the major changes to the software made during the development cycle, including date, version number, and a

brief description of the changes in the version relative to the previous version. The last entry in the list should be the final version number/designation and date which will be incorporated in the released device. This entry should also briefly describe any differences between the tested version of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.

4. Please provide a list of all unresolved software anomalies. For each anomaly, please indicate the 1) problem, 2) impact on device performance, 3) any plans or time frames for correcting the problem (where appropriate). Please annotate each item with an explanation of the impact of the anomaly on device safety or effectiveness, including operator usage and human factors issues. In all instances where it is practical to do so, please include any mitigation or possible work-around for unresolved anomalies. If there are no unresolved software anomalies, as written statement declaring such should be submitted.
5. Please provide the final software version number and release date for this device.
6. In your submission you have provided EMC and safety test results. The Agency believes that IEC 60601-1-2 and IEC 60601-1 testing should be performed on a final finished, production ready unit, to fully certify that the device design is correct. Please verify for us if all the testing was performed on a final finished, production ready unit.
7. You have indicated that the subject device can be used in a home-care setting. However, you have not submitted patient labeling to coincide with the subject device. Please develop and test patient labeling to be used with the subject device. Additionally, please demonstrate use of the subject device when used according to the Patient and Physician Labeling and the Instructions for Use that you plan to provide with the proposed device for the proposed Indications for Use. Usability testing is needed to assess the adequacy of the Patient and Physician labeling developed for the home care use of the subject device. Please submit usability testing consistent with the patient labeling guidance <http://www.fda.gov/cdrh/ohip/guidance/1128.html> (appendix F).
8. You proposed a 12-month shelf life but did not provide supporting data for this shelf-life claim. Please be advised that conformance to a standard is not sufficient to obtain a shelf-life claim. Your stability data should support the proposed shelf life (i.e., subject device meets product specifications over the proposed shelf life). Please provide stability testing on real-time or validated accelerated aged samples to support your proposed 12-month shelf life for the subject device.
9. Please be advised claims such as reducing edema, promoting granulation tissue formation and perfusion (page 27 of 55) should be supported by data.

The company has removed these claims. This is an acceptable response.

10. Your labeling should contain a precaution that the device should not be used once wound exudate is no longer present in the wound.

The company has added this precaution to their instruction for use. This is an acceptable response.

S1 Deficiencies

1. On April 29, 2008, FDA requested performance testing to demonstrate equivalence of the subject device to a legally marketed predicate device. You submitted bandage integrity testing demonstrating final pressure and pump down time. The submitted testing is not sufficient to determine that the subject device is substantial equivalent to the predicate device based on how negative pressure is effectively administered to the wound bed resulting in the removal of wound exudate. In all predicate devices the negative pressure is administered to the dressings placed in the wound bed. You stated that negative pressure will be administered to a wound dressing that is external to the wound. You have not demonstrated that the pressure created by this external negative pressure will result in effective removal of exudate from the wound. Please provide performance testing that demonstrates negative pressure administered (continuously and intermittently) to the wound over an extended period of time results in wound exudate effectively removed from the wound bed and contained in the occlusive wound dressing. Please be aware the model used P080299 is not a relevant physiological model.
2. Please explain this statement found in your labeling: "For cavity wounds a standard wound filler such as gauze or foam must be used". Please submit performance data to demonstrate how your device will function with gauze or foam present in the wound.
3. You state the following on page 10 of the indications for use: "...pressure sensor working in feedback fashion to control the pressure under the wound." Please identify the testing you completed on your Proprietary Leak Detection System that demonstrates a feedback mechanism to control the pressure under the wound. You have testing that identifies the presence of a leak but this statement infers that the device will identify a leak and then compensate the pressure. Please identify the testing or remove this claim from your labeling.
4. Please provide the data you have to support the following claim:

"This approach to wound care is believed to create an environment that promotes wound healing by bring the wound edges together (with negative pressure)" found on page 6 indications for use.
5. Predicate devices advise users on specific measures to take to isolate major vessels that may be present in a wound bed. Please explain how you will isolate vessels in the wound bed.
6. Please clarify this statement "do not use topical solutions or agents that may have adverse interactions with silver. For example, saline solutions may compromise the effectiveness of the silver dressing". Please outline what effectiveness you expect from

the silver dressing. Please explain how you have determined that Silverlon is a non-stick layer.

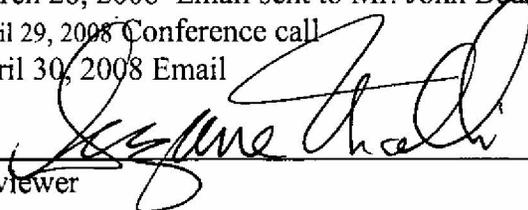
- 7. You listed a device component as a "Super absorbent non-woven polymer matrix". Your biocompatibility refers to this product as (b)(4). This does not appear to be a previously cleared 510(k) product for (b)(4). Please characterize this material based on the chemical composition. Please identify how this product has been evaluated for toxic effects and potential leaching effects. Additionally, you have shown that this polymer matrix can be squeezed to release fluid. Please demonstrate how this polymer matrix will not release fluid back into the wound. Lastly, please demonstrate how will negative pressure be administered to the wound in the presence of this polymer matrix.
- 8. Please modify your Indications for Use statement to read as follows:

"The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing."

- 9. You have stated that the device should be wiped down with a damp cloth. These measures will not allow safe repeat use of the pump unit between patients. Please outline how the device should be disinfected to prevent cross-contamination from multiply uses.
- 10. You state at the beginning of the patient labeling that a patient does not need to touch the device, yet you explain several points throughout the labeling for what measures the patient can take to manipulate the device. You are not consistent in your advice to the patient. Please explain why the patient would need to change the batteries on this device or disable the alarm. These do not seem like functions that should be required by patients. Please review the FDA patient labeling guidance and ensure that your patient labeling is consistent with this guidance.
<http://www.fda.gov/cdrh/ohip/guidance/1128.html>
- 11. Your NPD dressing is labeled as follows: "Arm or Leg". Your IFU does not restrict the use with the arm or leg. Please explain this discrepancy.

XVII. Contact History

March 26, 2008 Email sent to Mr. John Buan
April 29, 2008 Conference call
April 30, 2008 Email



Reviewer

06/19/08
Date

I concur
David Krane
Branch Chief

June 20, 2006
Date

MEMO OF EMC REVIEW

510(K): K080275

FROM: Sajjad Syed, Software Engineer (CDRH General Hospital Devices Branch), 240-276-3712, sajjad.syed@fda.hhs.gov

TO: Suzanne Malli (CDRH\ODE\DGRND\PRSB)

DATE: Friday March 14th, 2008

SUBJECT: EMC Review (CON081467) of K080275 Powered Suction Pump

Name of the Device: Model npd 1000 negative pressure wound therapy system
Applicant: Iasis Medical, Inc.

General description of device:

The NPD 1000 Negative Pressure Wound Therapy System is comprised of a small, compact portable battery operated electromechanical pump and a wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing.

The NPD 1000 pump is shipped in 2 pieces, a system controller and 1 of 2 pump housings, either continuous or intermittent. Both pump housings can provide continuous therapy, but only the intermittent housing can provide intermittent therapy.

The NPD 1000 pump contains a microprocessor controlled pump and pressure sensor working in feedback fashion to control the pressure under the dressing at the physician programmed setting. The pump is powered by 3 AA batteries, either alkaline or NiMH rechargeable. For therapy status notification, the pump has a leak detection indicator icon, a low battery indicator icon and therapy proceeding indicator icon. An alarm buzzer will sound for a leak detection, low battery or system fault.

Intended Use:

The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Consultant Comments and description about EMC:

The sponsor has stated that to meet the safety requirements, sample devices were subjected to testing according to the IEC 60601-1 and IEC 60601-1-2. The sponsor has signed a declaration of conformity form and has identified specific tests from the standards that were used for testing. The sponsor submitted the subject device to Intertek (third party lab) to perform both EMC and Electrical Safety testing. The lab performed the following tests according to the standard on both Intermittent and Continuous versions of the device:

Immunity Test
Emissions Test
Radiated RF Immunity Test
Magnetic Immunity Test
ESD Immunity Test

The third party lab (Intertek) has stated that during the test no deviation was detected to the sample devices. The lab provided a certificate stating that the device met with the requirements of the standard.

Under the conditions outlined in these tests, the device emits levels of electromagnetic radiation that is below established upper limit threshold of acceptable emissions and according to the lab, operates without error in the presence of electromagnetic radiation.

The sponsor also conducted testing according to the IEC 60601-1 standard. Some of the tests performed are:

Enclosures and Protective Covers
Fire Prevention
Interruption and restoration of power not resulting in a safety hazard
Conductors and connectors secured and/or insulated
Excessive Temperatures

The device passed all the IEC 60601-1 applicable tests, meeting the criteria for electrical safety. The IEC 60601-1-2 tests were conducted when the device was both in Continuous and Intermittent modes.

In my opinion the sponsor has done a sufficient job of verifying that their device is electrically safe and not susceptible to RF, magnetic fields interferences. I have only one question that I want the sponsor to verify. It is stated below:

1. In your submission you have provided EMC and safety test results. The Agency believes that IEC 60601-1-2 and IEC 60601-1 testing should be performed on a final finished, production ready unit, to fully certify that the device design is correct. Please verify for us if all the testing was performed on a final finished, production ready unit.

Sajjad Syed

Memorandum of a Software Review

K080275

February 21, 2008

From: Steven Pelham; OSEL-DESE (WO62-4229); (301) 796-2589
To: Suzanne Malli, ODE-DGRND-PRSD (HFZ-410), (240) 276-3632
Subject: Software review of NPD 1000 Negative Pressure Wound Therapy System by IASIS Medical Inc.

Succinct Conclusion: Additional Information

The information contained within this submission is insufficient to meet the software concerns as described in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005, and it is recommended that, from a software standpoint, this submission be considered **Additional Information**.

Summary

The NPD 1000 Negative Pressure Wound Therapy System by IASIS Medical Inc includes a small, portable battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing. The NPD 1000 is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressure.

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting. The dressing has 3 windows near the pressure port to monitor when the dressing is nearing its exudate capacity.

The NPD 1000 dressing is comprised of the following:

- Semi-occlusive outer layer that maintains the negative pressure,
- Pressure port with an in-line hydrophobic, anti-bacterial 0.2 um filter and fitting to which the NPD pump system is attached via PVC tubing,
- Hydrogel gasket to seal the wound area,
- Super absorbent non-woven polymer matrix to absorb exudates, and
- Non-stick Silverlon wound contact layer.

This software review does not cover the correctness of the underlying algorithms or their appropriateness or applicability to the indicated use of this device, as such evaluation is beyond the scope of this review. This is a MAJOR Level of Concern device.

1. Software Description [ok]

The firm provided an acceptable overview of the device features that are controlled by software, and a description of the intended operational environment. [Appendix 5, System Software Design, DP-0001-84-3 Section 2]

2. Device (including Software) Hazard Analysis [ok]

The firm provided an acceptable description of the hazards presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards. [Appendix 6, FMECA DP-0001-84-1 and Hazard Analysis DP-0001-83-7]

3. Software Requirements Specifications (SRS) [ok]

The firm provided a copy of their software requirements specification document, which clearly documented their functional, performance, interface, design, and development requirements. [Appendix 7, System Requirements Specification DP-0001-84-2]

4. Architecture Design [ok]

The firm provided an acceptable description of the software system partitioned into its functional subsystems. [Appendix 5, System Software Design, DP-0001-84-3, Sections 3 & 5]

5. Software Design Specification (SDS) [ok]

The firm provided an acceptable design specification document, which describes what the program does and how it does it. [Appendix 5, System Software Design, DP-0001-84-3 Section 2]

6. Traceability Analysis [not ok]

The firm **failed to provide** their traceability matrix, which provided the links between the hazards, requirements, validation and testing.

7. Software Development Environment Description [ok]

The firm submitted a summary of their software development life cycle plan, describing the processes that have been put into place to manage the various software development life cycle activities, including a summary of the configuration management and maintenance activities. [Appendix 5, System Software Design, DP-0001-84-3, Sections 4 & 5]

8. Verification and Validation (including Testing) [not ok]

The firm provided an acceptable description of their systematic process of life cycle activities, including analysis, evaluation, assurance, and testing of the software, and supporting documentation. HOWEVER, the firm **has not finished testing the device**, specifically the Therapy Duration tests and the Pressure Loss Prevention test. [Appendix 8, V&V Plan DP-0001-85-0, Verification Test Procedures DP-0001-84-0, NPD 1000 Negative Pressure Dressing V&V Test Procedures QFM-04-3b]

and Appendix 9, Minnetronix Verification Report DR-0000-09-0, NPD 1000 Negative Pressure Dressing V&V Test Report QFM-04-3c]

9. Revision Level History [not ok]

The firm **failed to provide** the revision history log, documenting all major changes to the software during its development cycle.

10. Unresolved Anomalies (bugs) [not ok]

The firm **failed to provide** a list of all unresolved software anomalies, indicating the problem, the impact on device performance, and plans and time frames for correcting each problem.

11. Release Version Number [not ok]

The firm **failed to provide** an acceptable description of the version numbers and dates.

Recommendation

Additional Information

The firm has **failed to provide** acceptable documentation demonstrating that they carried out an appropriate complete validation process as well as other missing documents as detailed above.

These procedures provide the foundation for assuring, to the extent possible, that the software will operate in a manner described in the specifications, and in no other predictable way. It is recommended that, from a software standpoint, this submission should be considered **Additional Information**.

Please provide a written response to the following questions:

- a. Please provide a completed Traceability Analysis which links together your product 1) hardware and software design requirements, 2) software design specifications, and 3) testing requirements. It should also provide a means of tying together 4) identified hazards with the 5) mitigations and 6) subsequent testing to validate the mitigation. It is requested that you submit for review explicit traceability among these activities and associated documentation because they are essential to effective product development and to our understanding of product design, development, testing, and hazard mitigations. The Traceability Analysis commonly consists of a matrix with line items for requirements, specifications and tests, and pointers to hazard mitigations.
- b. Please provide the test results for the Therapy Duration and Pressure Loss prevention tests. For any modifications made in response to failed tests, please provide the results of the regression testing performed to verify and validate those modifications to show that the modifications were effective, as well as a description of any tests that failed. Please ensure that the Traceability Analysis effectively links these activities and results to your design requirements and specifications.
- c. Please provide the history of software revisions generated during the course of product development. This typically takes the form of a line-item tabulation of the major changes to the software made during the development cycle, including date, version number, and a brief description of the changes in the version relative to the previous version. The last entry in the list should be the final version number/designation and date which will be incorporated in the released device. This entry should also briefly describe any differences between the tested version

of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.

- d. Please provide a list of all unresolved software anomalies. For each anomaly, please indicate the 1) problem, 2) impact on device performance, 3) any plans or timeframes for correcting the problem (where appropriate). Please annotate each item with an explanation of the impact of the anomaly on device safety or effectiveness, including operator usage and human factors issues. In all instances where it is practical to do so, please include any mitigations or possible work-around for unresolved anomalies. If there are no unresolved software anomalies, as written statement declaring such should be submitted.
- e. Please provide the final software version number and release date for this device.

Since a 510(k) submission relies on objective evidence that all V&V tests have passed as well as other safety and effectiveness evidence, it is appropriate that all testing be completed and documented before a final determination of substantial equivalence can be made.

IASIS (KALYPTO) – FDA Telecom Meeting Minutes

RE: K080275 NPD1000 Negative Pressure Wound Therapy System

Minutes prepared by: Pamela Vaughan, Alquest, Principal Project Manager

Date and Time of Telecom Meeting: April 29, 2008 at 1:30 PM -2:00PM CDT

FDA Attendees:

David Krause, Branch Chief, Plastic and Reconstructive Surgery Branch
Suzanne Malli, Plastic and Reconstructive Surgery Devices Branch

Sponsor Attendees:

John Buan, V.P. Marketing and Product Development, IASIS Medical, Inc.
Philip Vierling, President/CEO, IASIS Medical, Inc.
Pamela Vaughan, Principal Project Manager, Alquest, Inc.
Mark DuVal, J.D. Regulatory Consultant, DuVal & Associates
Marcia Palma, Principal Consultant, Alquest (not introduced)

Ms. Vaughan opened the meeting by introducing IASIS/KALYPTO attendees and verifying FDA attendees on telecom.

She requested FDA to correct an administrative error in the April 17, 2008 deficiency letter- the correct predicate 510(k) number should be K063692, not K063642.

Ms. Vaughan then reiterated the Sponsor comments stated in Item #1 on the Agenda (attached), emphasizing that IASIS contends that the NPD1000 NPWT System is substantially equivalent to the KCI ActiVac, K063692. She then asked FDA questions presented in Item #2 on the Agenda:

1. Since these devices have somewhat different technological characteristics, do they raise for the Agency unanswered questions of safety and effectiveness? If so, what precisely are they?

FDA Responses and Questions:

FDA (Ms. Malli) agreed that the intended use of the devices is the same. She then listed the significant technological differences that raise concerns by FDA:

- NPD1000 weighs significantly less than the proposed predicate devices (8oz vs 2.5 pounds)
- NPD1000 capacity is 50mL; minimum predicate volume capacity is 300mL
- NPD1000 is battery powered only, not both battery and/or AC

Ms. Malli then asked the following questions about the NPD1000 (in *italics*), which were answered by John Buan.

How can it hold the vacuum? Does the device “pack” the wound?

As recommended by Mark DuVal, John Buan explained the design and functionality of the NPD1000 NPWT System, and how the vacuum is accomplished through the dressing seal properties and the attached vacuum source. He explained how the fluids are drawn into the dressing, away from the wound. Although we’ve recorded briefly his answers to questions below, John’s answers were lengthy and quite detailed and satisfied the FDA.

How has IASIS shown that the bandage can draw 125 Hg vacuum? John Buan described the bench data, which was provided in the 510(k) submission. He described the uncomplicated deployment of the dressing and how the negative pressure is maintained.

How does it prevent wound desiccation? Once the fluid is in the bandage, it binds molecularly to the dressing material, so it does not “evaporate” or desiccate the wound site.

Will the device be applied to the wound continuously? Per standard NPWT, the device will be in place for 24 hours per day for the 2-3 days between placement of the dressing and removal. However, it is likely that the dressing will be removed (or treatment suspended) in the hour or two before the patient’s appointment to change dressings so that the patient may take care of personal hygiene considerations, (bathing, showering etc.).

Will the “semi occlusive” wound dressing cause maceration? No. First, all negative pressure wound therapy dressings are “semi-occlusive”, meaning that they can hold vacuum for some time with the assistance of a mechanical pump. For wounds to be treated with the Kalypto dressing, the fluids will be drawn away from the wound into a super-absorbent non-woven material. Once in the non-woven, the fluid is molecularly bonded to a super-absorbing polymer fiber that is one of the constituent fibers of the non-woven “pad”. Thus, up to the capacity of the dressing, there are no free fluids (water) to sit on the tissue and cause maceration. Additionally, the pressure under the bandage is uniform, so no squeezing of fluid, from the material will occur due to a mechanical force generated by a pressure imbalance or gradient. “Additionally, company testing has shown that for fluid absorption at levels 40% beyond the design capacity, substantial external mechanical forces (from outside the dressing) will not “free” fluid from the non-woven material so that they could potentially cause maceration of the healthy tissues around the wound.”

Is the dressing a closed system? Yes. There is a 0.2µm (b)(4) PTFE layer at the connection of the vacuum tubing, to prevent bacteria and water from getting into the tubing.

Can fluid get into the pump? No. The (b)(4) prevents water/fluids from getting into the tubing, so it cannot get into the pump. The (b)(4) material has a water ingress pressure of 14 psi, well above the (negative) maximum pressure applied by the device.

Mark DuVal asked if there were impediments to clearance due to proposed labeling.

Dr. Krause then expressed his concern about the differences in this device, and predicate devices under the same regulation for powered suction pumps, 21CFR Part 878.4780, which was intended for larger suction pumps and the NPD1000 System is “awfully small” for the regulation. The devices in this class have “morphed” over time in design and intended uses. Historically, FDA has seen other incremental, but less significant changes to predicates than is seen with the new NPD1000 System. Especially, that it is much smaller, and only holds 50mL of exudate. This limited capacity (to differentiate from predicates) needs to be clear in the labeling of this device. He proposed a new intended use statement to read:

Portable, low powered, battery operated suction pump to remove a small amount of exudate (such as infectious agents) from wounds.

FDA (Dr. Krause) verified that this new intended use would then permit IASIS to use the ActiVAC (K063692) as an adequate predicate.

Dr. Krause then suggested that the 50mL capacity was a “mega step” for substantial equivalence compared to the other pumps on the market. Most are 300mL canisters. He thought the 50mL capacity needed to be clearly stated in the instructions for use; and to “be careful” of claims such as wound healing. IASIS needs to be sure they can support the claims with bench data.

Dr. Krause stated that side by side data with the NPD and predicate device must be collected. IASIS questioned why this was necessary. David responded- to show substantial equivalence. IASIS agreed to collect this data (comparison of negative pressures achieved in bench testing).

Mark DuVal asked Dr. Krause to comment on the acceptability of the “promotes wound healing” claim. Dr. Krause said that this claim was accepted years ago in the original predicate, but was stated at that time as “may promote wound healing”, a benefit that was due to removal of infectious materials. But, the use of the “promotes wound healing” claim now has different interpretations by manufacturers. He said he felt that he couldn’t stop us from using “may promote wound healing” since the predicate has it, but to state “promotes wound healing” would require clinical substantiation. The claim should be qualified by stating that the device “may promote wound healing, due to removal of infectious materials”, and clarify that use of device itself does not directly promote wound healing.

Ms. Vaughan then asked the FDA how IASIS should provide the new information to FDA? Dr. Krause verified with Ms. Malli that the 510(k) review was “on hold”. He suggested that we submit the following information to the 510(k) file:

- side by side bench testing data (predicate vs NPD1000)
- modify the indication for use (as stated above)
- provide a more detailed description of the dressing materials and how they function to wick and retain the fluids (and include brief description of principles of NPWT)
- provide wound contact material biocompatibility data (already submitted)
- revised labeling
- revised Summary of Safety and Indications for posting on FDA website

NOTE: The additional questions in Agenda Item #2 and Item #3 were not discussed, as they were no longer relevant.

At the closing of the meeting, Ms. Malli stated that FDA had some additional deficiencies related to device software. She said she would send those to IASIS tomorrow (4/30/08). When asked, John Buan verified that IASIS had utilized the FDA Guidance document on Software Validation during software validation.

Lastly, Dr. Krause stated that most of the adverse events they have seen with marketed suction pump devices have occurred in the home use setting, although he didn't expect it to be a problem with our smaller, portable pump. He still recommended that IASIS provide FDA with patient labeling and results of usability testing.

Ms. Vaughan thanked FDA for taking time to discuss these issues with IASIS, and that we appreciated their assistance to resolve these issues. The meeting closed at 2:05PM CDT.

IASIS MEDICAL, INC. (now Kalypto Medical, Inc.)

**MEETING AGENDA for Telecom with FDA, CDRH,
Plastic and Reconstructive Surgery Branch**

Meeting Purpose:

Discuss deficiency letter dated April 17, 2008 regarding IASIS Medical, Inc. 510(k) submission K080275

Date and Time: April 29, 2008 at 1:30 PM CDT

Dial (763) 287-3830, request connection to Bridge Line #657

Planned FDA Attendees:

David Krause, Branch Chief, Plastic and Reconstructive Surgery Branch
Suzanne Malli, Plastic and Reconstructive Surgery Devices Branch

Planned Sponsor Attendees:

John Buan, VP Marketing and Product Development, IASIS Medical, Inc.
Philip Vierling, President/CEO, IASIS Medical, Inc.
Pamela Vaughan, Principal Project Manager, Alquest, Inc.
Mark DuVal, J.D. Regulatory Consultant, DuVal & Associates

Discussion Topics and Questions:

- Both the Iasis NPD1000 and the ActiV.A.C. (K063692) are intended to promote healing by removing infectious materials and fluids (exudate) from wounds by vacuum-assisted drainage (negative pressure). Both devices include a powered suction pump, to create the negative pressure. Both the IASIS NPD1000 and the ActiV.A.C. dressings/bandage materials provide a bacterial barrier and transmit the negative pressure from the suction pump to the wound site. Both devices remove the exudate from the wound and store it safely away from the wound. In the case of the NPD1000, the dressing acts as the exudate collection device; the bandage provides a dry barrier on the wound side and prevents the exudate from remaining in contact with the wound. In the case of the ActiV.A.C., the exudate is stored in a canister. The only real difference between the two devices is that, in the case of the NPD1000, the dressing is, in effect, the holding canister.

TABLE:

Claim	IASIS NPD1000	ActiV.A.C.
Promotes healing	Yes	Yes
Removes infectious materials	Yes	Yes

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Provides bacterial barrier	Yes	Yes
Negative Pressure	Yes – vacuum-assisted	Yes – vacuum-assisted
Exudate removed from wound site	Yes – stored in bandage	Yes – stored in canister

3. We believe the NPD1000 is substantially equivalent to the chosen predicate because it is unequivocally the same intended use and the technological characteristics, while somewhat different, are functionally the same. Since these devices have somewhat different technological characteristics, do they raise for the Agency unanswered questions of safety and effectiveness? If so, what precisely are they? And what kind of evidence might the Agency want to see to address them? Are the Agency's requested information and studies relevant to the substantial equivalence determination?

4. If these unanswered questions of safety and effectiveness are relevant to the SE determinations and can be addressed, using least burdensome principles, does FDA agree that the ActiV.A.C. (K063692) is an adequate predicate?

Malli, Suzanne M

From: Malli, Suzanne M
Sent: Thursday, June 19, 2008 3:46 PM
To: 'jbuan@iasismedical.com'
Subject: K080275

Dear Mr. Buan:

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

1. On April 29, 2008, FDA requested performance testing to demonstrate equivalence of the subject device to a legally marketed predicate device. You submitted bandage integrity testing demonstrating final pressure and pump down time. The submitted testing is not sufficient to determine that the subject device is substantial equivalent to the predicate device based on how negative pressure is effectively administered to the wound bed resulting in the removal of wound exudate. In all predicate devices the negative pressure is administered to the dressings placed in the wound bed. You stated that negative pressure will be administered to a wound dressing that is external to the wound. You have not demonstrated that the pressure created by this external negative pressure will result in effective removal of exudate from the wound. Please provide performance testing that demonstrates negative pressure administered (continuously and intermittently) to the wound over an extended period of time results in wound exudate effectively removed from the wound bed and contained in the occlusive wound dressing. Please be aware the model used P080299 is not a relevant physiological model.
2. Please explain this statement found in your labeling: "For cavity wounds a standard wound filler such as gauze or foam must be used". Please submit performance data to demonstrate how your device will function with gauze or foam present in the wound.
3. You state the following on page 10 of the indications for use: "...pressure sensor working in feedback fashion to control the pressure under the wound." Please identify the testing you completed on your Proprietary Leak Detection System that demonstrates a feedback mechanism to control the pressure under the wound. You have testing that identifies the presence of a leak but this statement infers that the device will identify a leak and then compensate the pressure. Please identify the testing or remove this claim from your labeling.
4. Please provide the data you have to support the following claim:

"This approach to wound care is believed to create an environment that promotes wound healing by bring the wound edges together (with negative pressure)" found on page 6 indications for use.
5. Predicate devices advise users on specific measures to take to isolate major vessels that may be present in a wound bed. Please explain how you will isolate vessels in the wound bed.
6. Please clarify this statement "do not use topical solutions or agents that may have adverse interactions with silver. For example, saline solutions may compromise the effectiveness of the silver dressing". Please outline what effectiveness you expect from the silver dressing. Please explain how you have determined that Silverlon is a non-stick layer.

7. You listed a device component as a "Super absorbent non-woven polymer matrix". Your biocompatibility refers to this product as (b)(4). This does not appear to be a previously cleared 510(k) product for (b)(4). Please characterize this material based on the chemical composition. Please identify how this product has been evaluated for toxic effects and potential leaching effects. Additionally, you have shown that this polymer matrix can be squeezed to release fluid. Please demonstrate how this polymer matrix will not release fluid back into the wound. Lastly, please demonstrate how will negative pressure be administered to the wound in the presence of this polymer matrix.
8. Please modify your Indications for Use statement to read as follows:

"The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing."

9. You have stated that the device should be wiped down with a damp cloth. These measures will not allow safe repeat use of the pump unit between patients. Please outline how the device should be disinfected to prevent cross-contamination from multiply uses.
10. You state at the beginning of the patient labeling that a patient does not need to touch the device, yet you explain several points throughout the labeling for what measures the patient can take to manipulate the device. You are not consistent in your advice to the patient. Please explain why the patient would need to change the batteries on this device or disable the alarm. These do not seem like functions that should be required by patients. Please review the FDA patient labeling guidance and ensure that your patient labeling is consistent with this guidance. <http://www.fda.gov/cdrh/ohip/guidance/1128.html>
11. Your NPD dressing is labeled as follows: "Arm or Leg". Your IFU does not restrict the use with the arm or leg. Please explain this discrepancy.

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

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

Suzanne Malli
Plastic and Reconstructive Surgery Devices Branch
Division of General, Restorative, and Neurological Devices

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Office of Device Evaluation
Center for Devices and Radiological Health
U.S. Food and Drug Administration
1090 Corporate Blvd.
Bethesda, MD 20850
240.276.3621 office
240.276.3733 fax
suzanne.malli@fda.hhs.gov

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COVER SHEET MEMORANDUM

From: Reviewer Name Suzanne Malli
Subject: 510(k) Number K080275
To: The Record April 17, 2008

Please list CTS decision code AI 15
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/Screening Checklist](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ScreeningChecklist))
 Hold (Additional Information) or Telephone Hold.
 Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III? If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABB_REVIATED_STANDARDS_DATA_FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		

Regulation Number Class* Product Code

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: David Kane PRSD April 16, 2008
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see <u>H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC</u>)			✓
2. Is the device exempt from 510(k) by regulation (Please see <u>http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC</u> or subject to enforcement discretion (No regulation - See 510(k) Staff)?			✓
3. Does this device type require a PMA by regulation? (Please see management.)			✓
Questions 4-8 are intended to help you start your review:		YES	NO
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, <u>http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc</u>)			✓
5. a. Did the firm request expedited review? (See management.)		NA	
b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , <u>http://www.fda.gov/cdrh/mdufma/guidance/108.html</u>)			✓
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		✓
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		✓
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> <u>http://www.fda.gov/cdrh/mdufma/guidance/1215.html</u>)			✓



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification 510(k) Review
Traditional
K080275**

Date: April 15, 2008
To: The Record
From: Suzanne Malli
Branch: Plastic and Reconstructive Surgery Branch
Division: Division of General, Restorative, and Neurological Devices
Office: Office of Device Evaluation

510(k) Holder: Iasis Medical
Device Name: NPD 1000 Negative Pressure Wound Therapy System
Contact: John Buan
Phone: (612)-703-1204
Fax: (763)-287-3836
Email: jbuan@iasismedical.com

I. Purpose of Submission

The 510(k) holder would like to introduce the following device into interstate commerce. **NPD 1000 Negative Pressure Wound Therapy System**

II. Document History

This is the first pre-market submission for this product.

III. Recommendation: Additional Information

Regulation Number: unclassified
Regulation Name: proposed 21 CFR 878.4780
Regulatory Class: II
Product Code: proposed JCX

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IV. Administrative Requirements

	YES	NO	N/A	MISC
Indications for Use page (Indicate if: Prescription or OTC)	x			
Truthful and Accuracy Statement	x			
510(k) Summary or 510(k) Statement	x			
Standards Form			x	

V. Device Description

The NPD 1000 Negative Pressure Wound Therapy System by IASIS Medical Inc includes a small, portable battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing. The NPD 1000 is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressure.

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting. The dressing has 3 windows near the pressure port to monitor when the dressing is nearing its exudate capacity.

The NPD 1000 dressing is comprised of the following:

- Semi-occlusive outer layer that maintains the negative pressure,
- Pressure port with an in-line hydrophobic, anti-bacterial 0.2um filter and fitting to which the NPD pump system is attached via PVC tubing,
- Hydrogel gasket to seal the wound area,
- Super absorbent non-woven polymer matrix to absorb exudates, and
- Non-stick Silverlon wound contact layer.

	YES	NO	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?	X		

VI. Indications for Use

The NPD 1000 Negative Pressure Wound Therapy System is a compact portable device indicated for patients who would benefit from suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Predicate Device - K060277

The Boehringer Laboratories Suction Pump System is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.

Predicate Device - K063692

The V.A.C.® Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

The V.A.C.® GranuFoam® Silver™ Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types.

VII. Predicate Device Comparison

	Subject Device	K063692	K060277
Weight	8 oz.	2.4 lbs	5 lbs.
Pump Pressure	40-125	25-200	30-75
Dimensions	3.2W x 5.1H x 1.3D	7.6W x 6H x 2.5D	3.2W x 5.1H x 1.3D
Battery	Alkaline or rechargeable	Lithium	12V rechargeable
Dressing	Occlusive dressing	Polyurethane foam	none
Collection	50ml	300ml	500ml

This device is technologically different than the predicate device. This is based on the weight, dimensions, collection volume. Further, there appears to be no packing of the wound bed. With the predicate devices this is done to create an area to draw the exudate into and thus it is unclear how the wound bed would be affected by a constant airflow and no protective covering to prevent desiccation of the wound. From the submitted information, the subject device wound dressing is completely different and has never been seen before in the predicate devices. The company has not demonstrated that the subject device is able to maintain the noted pump pressure settings at the wound in a continuous and intermittent mode.

VIII. Labeling

Claims:

Reducing edema	Tissue perfusion
Promoting granulation	Tissue formation

IX. Sterilization/Shelf Life/Reuse

Stability Studies Shelf: The company is claiming (submission page 35) a 12-month shelf life; but they have not provided stability data to support their claim. A deficiency needs to be sent to the company regarding their claim of a 12-month shelf life and the need for stability data to support any expiration dating.

The company states that the stability validation will consist of accelerated aging to one year, seal integrity testing, and seal strength testing. ASTM F 1980-02, ASTM F 2096-04, ASTM F 88-07.

The following functional testing will be performed (data not submitted):

- achieving and maintaining vacuum integrity over the full range of therapeutic pressures: 40-125mmHG
- Achieving set pressure in less than 3 minutes
- Verifying the therapeutic fluid capacity of 50ml is not impacted by aging

1. Sterilant:	
a. Sterilization method description (e.g., Steam, EtO, Radiation):	Electron Beam
c. Sterilant Dose	25kGy
2. A description of the Validation Method for the sterilization cycle (not data): (Citation of an FDA recognized standard is acceptable (e.g.,))	ISO 11137: 2006
3. Sterility assurance level (SAL): (e.g., 10 ⁻⁶ for all devices (except 10 ⁻³ for devices that contact intact skin))	10⁻⁶
4. Is it labeled "Pyrogen Free"?	no
If so, a description of the method: (e.g., LAL (<i>Limulus</i> Amebocyte Lysate test))	None provided
5. A description of the packaging (not including package integrity test data):	Polyester/foil laminate pouch layers include PET, LDPE, aluminum foil, Surlyn sealant layer

X. **Biocompatibility**

The subject device was tested for biocompatibility,

Biocompatibility was not done on final finished device.

Test	Results
Cytotoxicity: ISO Agarose Overlay Method	Showed Grade 2 (mild) cytotoxicity

XI. **Software** see attached software review from Steven Pelham, software engineer OSEL

XII. **Electromagnetic Compatibility/Electrical, Mechanical and Thermal Safety**

See attached review from electrical engineer Sayed.

XIII. **Performance Testing – Bench**

XIV. **Performance Testing – Animal**

None provided

Performance Testing –

Predicate Device

XV. **Substantial Equivalence Discussion**

Additional information required, an AI letter will sent.

	YES	NO	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	x		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?			If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?			If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

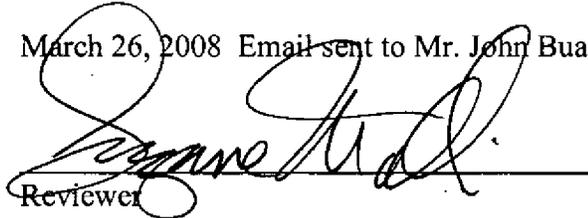
XVI. Deficiencies to be sent once correct predicate is defined:

1. Please provide a completed Traceability Analysis which links together your product 1) hardware and software design requirements, 2) software design specifications, and 3) testing requirements. It should also provide a means of tying together 4) identified hazards with the 5) mitigations and 6) subsequent testing to validate the mitigation. It is requested that you submit for review explicit traceability among these activities and associated documentation because they are essential to effective product development and to our understanding of product design, development, testing, and hazard mitigations. The Traceability Analysis commonly consists of a matrix with line items for requirements, specifications and tests, and pointers to hazard mitigations.
2. Please provide the test results for the Therapy Duration and Pressure Loss prevention tests. For any modifications made in response to failed tests, please provide the results of the regression testing performed to verify and validate those modifications to show that the modifications were effective, as well as a description of any tests that failed. Please ensure that the Traceability Analysis effectively links these activities and results to your design requirements and specifications.
3. Please provide the history of software revisions generated during the course of product development. This typically takes the form of a line-item tabulation of the major changes to the software made during the development cycle, including date, version number, and a brief description of the changes in the version relative to the previous version. The last entry in the list should be the final version number/designation and date which will be incorporated in the released device. This entry should also briefly describe any differences between the tested version of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.
4. Please provide a list of all unresolved software anomalies. For each anomaly, please indicate the 1) problem, 2) impact on device performance, 3) any plans or timeframes for correcting the problem (where appropriate). Please annotate each item with an explanation of the impact of the anomaly on device safety or effectiveness, including operator usage and human factors issues. In all instances where it is practical to do so, please include any mitigation or possible work-around for unresolved anomalies. If there are no unresolved software anomalies, as written statement declaring such should be submitted.
5. Please provide the final software version number and release date for this device.
6. In your submission you have provided EMC and safety test results. The Agency believes that IEC 60601-1-2 and IEC 60601-1 testing should be performed on a final finished, production ready unit, to fully certify that the device design is correct. Please verify for us if all the testing was performed on a final finished, production ready unit.

7. You have stated that the device components will include approximately 6 feet of tubing—patients have tripped what will they do with the tubing?
8. Outline benefits of negative pressure without the need for a canister attached to a pump
9. Patient labeling and usability testing
10. NPD silver does that need 510k
11. Dressing does not pack into wound to provide a negative pressure chamber. Please provide a rationale for how the subject device can be compared to the predicate devices when the dressing is not packed into the wound.
12. How is possible that pump can maintain pressure over time? The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes.

XVII. Contact History

March 26, 2008 Email sent to Mr. John Buan



Reviewer

04/15/08
Date



Branch Chief

April 16, 2008
Date

MEMO OF EMC REVIEW

510(K): K080275

FROM: Sajjad Syed, Software Engineer (CDRH General Hospital Devices Branch), 240-276-3712, sajjad.syed@fda.hhs.gov

TO: Suzanne Malli (CDRH\ODE\DGRND\PRSB)

DATE: Friday March 14th, 2008

SUBJECT: EMC Review (CON081467) of K080275 Powered Suction Pump

Name of the Device: Model npd 1000 negative pressure wound therapy system
Applicant: Iasis Medical, Inc.

General description of device:

The NPD 1000 Negative Pressure Wound Therapy System is comprised of a small, compact portable battery operated electromechanical pump and a wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing.

The NPD 1000 pump is shipped in 2 pieces, a system controller and 1 of 2 pump housings, either continuous or intermittent. Both pump housings can provide continuous therapy, but only the intermittent housing can provide intermittent therapy.

The NPD 1000 pump contains a microprocessor controlled pump and pressure sensor working in feedback fashion to control the pressure under the dressing at the physician programmed setting. The pump is powered by 3 AA batteries, either alkaline or NiMH rechargeable. For therapy status notification, the pump has a leak detection indicator icon, a low battery indicator icon and therapy proceeding indicator icon. An alarm buzzer will sound for a leak detection, low battery or system fault.

Intended Use:

The NPD 1000 Negative Pressure Wound Therapy System is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

Consultant Comments and description about EMC:

The sponsor has stated that to meet the safety requirements, sample devices were subjected to testing according to the IEC 60601-1 and IEC 60601-1-2. The sponsor has signed a declaration of conformity form and has identified specific tests from the standards that were used for testing. The sponsor submitted the subject device to Intertek (third party lab) to perform both EMC and Electrical Safety testing. The lab performed the following tests according to the standard on both Intermittent and Continuous versions of the device:

Immunity Test
Emissions Test
Radiated RF Immunity Test
Magnetic Immunity Test
ESD Immunity Test

The third party lab (Intertek) has stated that during the test no deviation was detected to the sample devices. The lab provided a certificate stating that the device met with the requirements of the standard.

Under the conditions outlined in these tests, the device emits levels of electromagnetic radiation that is below established upper limit threshold of acceptable emissions and according to the lab, operates without error in the presence of electromagnetic radiation.

The sponsor also conducted testing according to the IEC 60601-1 standard. Some of the tests performed are:

Enclosures and Protective Covers
Fire Prevention
Interruption and restoration of power not resulting in a safety hazard
Conductors and connectors secured and/or insulated
Excessive Temperatures

The device passed all the IEC 60601-1 applicable tests, meeting the criteria for electrical safety. The IEC 60601-1-2 tests were conducted when the device was both in Continuous and Intermittent modes.

In my opinion the sponsor has done a sufficient job of verifying that their device is electrically safe and not susceptible to RF, magnetic fields interferences. I have only one question that I want the sponsor to verify. It is stated below:

1. In your submission you have provided EMC and safety test results. The Agency believes that IEC 60601-1-2 and IEC 60601-1 testing should be performed on a final finished, production ready unit, to fully certify that the device design is correct. Please verify for us if all the testing was performed on a final finished, production ready unit.

Sajjad Syed

Memorandum of a Software Review

K080275

February 21, 2008

From: Steven Pelham; OSEL-DESE (WO62-4229); (301) 796-2589
To: Suzanne Malli, ODE-DGRND-PRSDB (HFZ-410), (240) 276-3632
Subject: Software review of NPD 1000 Negative Pressure Wound Therapy System by IASIS Medical Inc.

- 727

Succinct Conclusion: Additional Information

The information contained within this submission is insufficient to meet the software concerns as described in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005, and it is recommended that, from a software standpoint, this submission be considered **Additional Information**.

Summary

The NPD 1000 Negative Pressure Wound Therapy System by IASIS Medical Inc includes a small, portable battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing. The NPD 1000 is a compact, portable device indicated for patients who would benefit from a suction device, particularly as the device use may promote wound healing, including for patients who would benefit from vacuum-assisted drainage and removal of infectious materials or other fluids from wounds under the influence of continuous and/or alternating suction pressure.

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting. The dressing has 3 windows near the pressure port to monitor when the dressing is nearing its exudate capacity.

The NPD 1000 dressing is comprised of the following:

- Semi-occlusive outer layer that maintains the negative pressure,
- Pressure port with an in-line hydrophobic, anti-bacterial 0.2 um filter and fitting to which the NPD pump system is attached via PVC tubing,
- Hydrogel gasket to seal the wound area,
- Super absorbent non-woven polymer matrix to absorb exudates, and
- Non-stick Silverlon wound contact layer.

This software review does not cover the correctness of the underlying algorithms or their appropriateness or applicability to the indicated use of this device, as such evaluation is beyond the scope of this review. This is a MAJOR Level of Concern device.

1. Software Description [ok]

The firm provided an acceptable overview of the device features that are controlled by software, and a description of the intended operational environment. [Appendix 5, System Software Design, DP-0001-84-3 Section 2]

2. Device (including Software) Hazard Analysis [ok]

The firm provided an acceptable description of the hazards presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards. [Appendix 6, FMECA DP-0001-84-1 and Hazard Analysis DP-0001-83-7]

3. Software Requirements Specifications (SRS) [ok]

The firm provided a copy of their software requirements specification document, which clearly documented their functional, performance, interface, design, and development requirements. [Appendix 7, System Requirements Specification DP-0001-84-2]

4. Architecture Design [ok]

The firm provided an acceptable description of the software system partitioned into its functional subsystems. [Appendix 5, System Software Design, DP-0001-84-3, Sections 3 & 5]

5. Software Design Specification (SDS) [ok]

The firm provided an acceptable design specification document, which describes what the program does and how it does it. [Appendix 5, System Software Design, DP-0001-84-3 Section 2]

6. Traceability Analysis [not ok]

The firm **failed to provide** their traceability matrix, which provided the links between the hazards, requirements, validation and testing.

7. Software Development Environment Description [ok]

The firm submitted a summary of their software development life cycle plan, describing the processes that have been put into place to manage the various software development life cycle activities, including a summary of the configuration management and maintenance activities. [Appendix 5, System Software Design, DP-0001-84-3, Sections 4 & 5]

8. Verification and Validation (including Testing) [not ok]

The firm provided an acceptable description of their systematic process of life cycle activities, including analysis, evaluation, assurance, and testing of the software, and supporting documentation. **HOWEVER**, the firm **has not finished testing the device**, specifically the Therapy Duration tests and the Pressure Loss Prevention test. [Appendix 8, V&V Plan DP-0001-85-0, Verification Test Procedures DP-0001-84-0, NPD 1000 Negative Pressure Dressing V&V Test Procedures QFM-04-3b and Appendix 9, Minnetronix Verification Report DR-0000-09-0, NPD 1000 Negative Pressure Dressing V&V Test Report QFM-04-3c]

9. Revision Level History [not ok]

The firm **failed to provide** the revision history log, documenting all major changes to the software during its development cycle.

10. Unresolved Anomalies (bugs) [not ok]

The firm **failed to provide** a list of all unresolved software anomalies, indicating the problem, the impact on device performance, and plans and time frames for correcting each problem.

11. Release Version Number [not ok]

The firm **failed to provide** an acceptable description of the version numbers and dates.

Recommendation

Additional Information

The firm has **failed to provide** acceptable documentation demonstrating that they carried out an appropriate complete validation process as well as other missing documents as detailed above.

These procedures provide the foundation for assuring, to the extent possible, that the software will operate in a manner described in the specifications, and in no other predictable way. It is recommended that, from a software standpoint, this submission should be considered **Additional Information**.

Please provide a written response to the following questions:

- a. Please provide a completed Traceability Analysis which links together your product 1) hardware and software design requirements, 2) software design specifications, and 3) testing requirements. It should also provide a means of tying together 4) identified hazards with the 5) mitigations and 6) subsequent testing to validate the mitigation. It is requested that you submit for review explicit traceability among these activities and associated documentation because they are essential to effective product development and to our understanding of product design, development, testing, and hazard mitigations. The Traceability Analysis commonly consists of a matrix with line items for requirements, specifications and tests, and pointers to hazard mitigations.
- b. Please provide the test results for the Therapy Duration and Pressure Loss prevention tests. For any modifications made in response to failed tests, please provide the results of the regression testing performed to verify and validate those modifications to show that the modifications were effective, as well as a description of any tests that failed. Please ensure that the Traceability Analysis effectively links these activities and results to your design requirements and specifications.
- c. Please provide the history of software revisions generated during the course of product development. This typically takes the form of a line-item tabulation of the major changes to the software made during the development cycle, including date, version number, and a brief description of the changes in the version relative to the previous version. The last entry in the list should be the final version number/designation and date which will be incorporated in the released device. This entry should also briefly describe any differences between the tested version of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.
- d. Please provide a list of all unresolved software anomalies. For each anomaly, please indicate the 1) problem, 2) impact on device performance, 3) any plans or timeframes for correcting the problem (where appropriate). Please annotate each item with an explanation of the impact of the anomaly on device safety or effectiveness, including operator usage and human factors issues. In all instances where it is practical to do so, please include any mitigations or possible work-around for unresolved anomalies. If there are no unresolved software anomalies, as written statement declaring such should be submitted.
- e. Please provide the final software version number and release date for this device.

Since a 510(k) submission relies on objective evidence that all V&V tests have passed as well as other safety and effectiveness evidence, it is appropriate that all testing be completed and documented before a final determination of substantial equivalence can be made.

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

June 10, 2008

IASIS MEDICAL, INC.
6393 OAKGREEN AVENUE
HASTINGS, MN 55033
ATTN: JOHN BUAN

510(k) Number: K080275
Product: MODEL NPD 1000
NEGATIVE
PRESSURE WOUND
THERAPY SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. 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



K080275/S

June 4, 2008

Received JUN 9 2008 FDA CDRH DMC

Office of Device Evaluation
Document Mail Center (HFZ401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: K080275: Additional Information for the NPD 1000 Negative Pressure Wound Therapy System

Enclosed are one original and two copies of additional information to K080575: 510(k) PreMarket Notification for the NPD 1000 Negative Pressure Wound Therapy System. Per our discussion with FDA on April 29, 2008 and the e-mail letter requesting additional information received April 29, 2008, Kalypto Medical is submitting the following information.

This submission contains our response to the email request for additional information, followed by the revisions to the 510(k) submission. The revisions to the 510(k) include:

- revised information for Section 2: Form FDA 3514 with new company name (Kalypto Medical), and revised indication
- revised Indications for Use form, with revised indication
- revised proposed IFU and labeling
- revised information relevant to Section 5: 510(k) Summary with new company name, revised indication, and revised device description
- revised information relevant to Section 10: Executive Summary with new company name, revised indication, revised device description and revised performance testing
- revised information relevant to Section 11: Device Description with revised indication, device description and expanded description of dressing
- revised information relevant to Section 12: Substantial Equivalence section with new company name, revised indication, revised device description and revised predicate
- new Section 18: Performance Testing – Bench with the revised performance testing and additional side by side testing with predicate

This submission contains technical, commercial and confidential trade secret information, and Kalypto Medical respectfully requests the maximum protection provided by law, in accordance with 21 CFR § 807.95.

Sincerely,

John Buan, Vice President of Product Development

Kalypto Medical Responses to Request for Additional Information

K080275

Responses to FDA Request for Additional Information dated April 29, 2008

1. Please provide a completed Traceability Analysis which links together your product 1) hardware and software design requirements, 2) software design specifications, and 3) testing requirements. It should also provide a means of tying together 4) identified hazards with the 5) mitigations and 6) subsequent testing to validate the mitigation. It is requested that you submit for review explicit traceability among these activities and associated documentation because they are essential to effective product development and to our understanding of product design, development, testing, and hazard mitigations. The Traceability Analysis commonly consists of a matrix with line items for requirements, specifications and tests, and pointers to hazard mitigations.

Response: The Traceability Matrix linking the System Requirements, Hazard Analysis results, FMECA analysis, and System Requirements Specifications and/or Tests is provided in Attachment 1. This spreadsheet links the 1) hardware and software design requirements, 2) software design specifications, and 3) testing requirements; 4) identified hazards with the 5) mitigations and 6) subsequent testing to validate the mitigation.

Since all data could not be printed on a single spreadsheet, the following subordinate spreadsheets are also provided: Hazard Descriptions Spreadsheet; spreadsheet linking Identified Hazards (Hazard Analysis) to the Systems Requirements; spreadsheet linking FMECA Results to System Requirements; and spreadsheet linking System Requirements to FMECA Results to System Requirements Verification Test Procedures.

2. Please provide the test results for the Therapy Duration and Pressure Loss prevention tests. For any modifications made in response to failed tests, please provide the results of the regression testing performed to verify and validate those modifications to show that the modifications were effective, as well as a description of any tests that failed. Please ensure that the Traceability Analysis effectively links these activities and results to your design requirements and specifications.

Response:

As can be seen from the Traceability Matrix (Attachment 1) the activities and results are linked via an Excel spreadsheet to the design requirements and specifications.

A copy of the testing report for the Therapy Duration Testing and Pressure Loss Testing is provided in Attachment 2 (Capricorn Verification Report, DR-0000-09-0; Rev. 002-a).

A summary of the results of the Therapy Duration testing, which was in process at the time of submission on 1/31/08 is provided in the Table below. Verification testing passed on both version 06 and version 08.

Kalypto Medical Responses to Request for Additional Information

K080275

The Pressure Loss testing, retested due to failure in the initial testing, is also provided below. Prior to repeat testing on version 08, the position of a check valve in the pump plumbing was moved to address this issue. Results in the following Table show that the pressure loss prevention testing passed after changing the position of the check valve. This repeat testing was conducted on software version 08, the version intended for market release.

Test	Software Version	Results
Therapy Duration: 4 pressure sensors and 4 therapy devices (2 continuous, 2 intermittent))	06 and 08	Passed
Pressure Loss Prevention	08	Passed

As can be seen from these results, revision 08 successfully passed all applicable tests.

3. Please provide the history of software revisions generated during the course of product development. This typically takes the form of a line-item tabulation of the major changes to the software made during the development cycle, including date, version number, and a brief description of the changes in the version relative to the previous version. The last entry in the list should be the final version number/designation and date which will be incorporated in the released device. This entry should also briefly describe any differences between the tested version of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.

Response: The software revision history was provided on page 50 of the original submission. Two revisions (07 and 08) have been made to the software since the submission date 1/31/08. The updated table listing the additional revisions is provided below. Revision 08 is the final software version. Revisions 07 and 08 are software enhancements and have no effect on the safety and effectiveness of the device and do not require additional verification testing.

SW Version	Date	Description of Changes from Previous Version
01	08/28/07	Initial version.
02	10/12/07	Demo version for use at Wound Therapy Conference. Continuous mode only implemented. No notifications implemented.
03	11/15/07	Implemented intermittent mode, implemented leak and low battery notifications, implemented power-save functionality, added ability to automatically restart therapy after a power cycle, added SW version screen.
(b)(4)		

Kalypto Medical Responses to Request for Additional Information

K080275

SW Version	Date	Description of Changes from Previous Version
(b)(4)	(b)(4)	(b)(4)
		3) Test of solenoid valve added as an aid to manufacturing test.
07	03/06/08	Enable 5V to drive solenoid valve (vs. previous 3V) to solve sticky valve issue. Update pressure sensor check algorithm to reduce the number of nuisance system faults. Added new low voltage threshold specifically for the intermittent pump module. Supplements existing threshold which is now specific to the continuous pump module.
08	03/07/08	Correct potential for ADC timeout when stopping therapy while pump is running.

4. Please provide a list of all unresolved software anomalies. For each anomaly, please indicate the 1) problem, 2) impact on device performance, 3) any plans or time frames for correcting the problem (where appropriate). Please annotate each item with an explanation of the impact of the anomaly on device safety or effectiveness, including operator usage and human factors issues. In all instances where it is practical to do so, please include any mitigation or possible work-around for unresolved anomalies. If there are no unresolved software anomalies, a written statement declaring such should be submitted.

Response: There are no unresolved anomalies on software version 08. This statement was also made on page 50 of the original submission 1/31/08 for software version 06.

5. Please provide the final software version number and release date for this device.

Response: The final software version is 08 and was released 3/07/08. Please refer to the response to item #3.

6. In your submission you have provided EMC and safety test results. The Agency believes that IEC 60601-1-2 and IEC 60601-1 testing should be performed on a final finished, production ready unit, to fully certify that the device design is correct. Please verify for us if all the testing was performed on a final finished, production ready unit.

Kalypto Medical Responses to Request for Additional Information

K080275

Response: The devices tested for EMC and electrical safety testing were final, production ready devices with all electrical systems included in the devices.

7. You have indicated that the subject device can be used in a home-care setting. However, you have not submitted patient labeling to coincide with the subject device. Please develop and test patient labeling to be used with the subject device. Additionally, please demonstrate use of the subject device when used according to the Patient and Physician Labeling and the Instructions for Use that you plan to provide with the proposed device for the proposed Indications for Use. Usability testing is needed to assess the adequacy of the Patient and Physician labeling developed for the home care use of the subject device. Please submit usability testing consistent with the patient labeling guidance <http://www.fda.gov/cdrh/ohip/guidance/1128.html> (appendix F).

Response: The Instructions for Use was revised to include Patient and Physician labeling and the new company name. The device labels were also revised with the new company name. The revised Instructions for Use and labels are provided in Attachment 3.

Usability testing was performed to assess the adequacy of the Patient and Physician labeling developed for the home care use of the NPD 1000. Fourteen potential users (7 males and 7 females), average age of 65 years, reviewed the IFU, completed a Questionnaire about the IFU, and attempted to fix a leak and change the battery. The testing session was videotaped, and the results compiled.

The results of the testing are summarized in the table below.

Usability Test	Results Acceptable
14 Potential Users tested to verify that Users know:	
If the system is operating properly	14/14
Whether to clean the device	14/14
When to change the batteries	9/14
If the dressing is properly sealed	12/14
If the dressing has reached maximum fluid capacity	12/14
When to call wound care provider for assistance	14/14
What to do with device when treatment is no longer needed	14/14
How to replace the batteries	13/14
How to detect (and fix) a leak	14/14

Based on the testing results, the Instructions for Use were revised to better explain the following: 1) a full dressing condition ("If the dressing has reached maximum fluid capacity"), visual cues that the system is operating as expected ("If the dressing is properly sealed"), and adding a reference to the audible beep that is sounded upon appearance of the low battery icon ("When to change batteries"). These three changes are reflected in the revised IFU provided in Attachment 3.

Kalypto Medical Responses to Request for Additional Information

K080275

The Usability Testing Questionnaire and Report are provided in Attachment 4.

8. You proposed a 12-month shelf life but did not provide supporting data for this shelf-life claim. Please be advised that conformance to a standard is not sufficient to obtain a shelf-life claim. Your stability data should support the proposed shelf life (i.e., subject device meets product specifications over the proposed shelf life). Please provide stability testing on real-time or validated accelerated aged samples to support your proposed 12-month shelf life for the subject device.

Response: Accelerated aging, package integrity and strength testing and performance testing after aging were performed by DDL, Inc. in Eden Prairie, MN.

One year accelerated aging was performed on one shipper for 38 days in accordance with Q10 Theory ASTM F1980-07: *Guide for Accelerated Aging of Sterile Medical Device Packages*. The cycle of accelerated aging equivalent to one year of real time is outlined in the table below.

Condition	Start	End	Days
55° / <20%RH	Feb. 18 / 2:00 PM	Mar. 27 / 2:00 PM	38

Thirty (30) single barrier foil/foil pouches were bubble leak tested after aging based on ASTM F 2096-04: *Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)* and DDL SOP #6047. The test method is designed to detect open pathways, channels, or voids across the seal area intended as a primary sterile barrier and to detect pinholes in non-porous materials. All package configurations tested passed.

Thirty (30) single barrier foil/foil pouches were seal strength tested based on ASTM F88-07a: *Seal Strength of Flexible Barrier Materials* and DDL SOP #6008. Samples from 4 designated locations on the single barrier foil/foil pouch were tested. There was no seal separation in any samples tested, therefore all seals tested passed.

Eight (8) bandages were functionality tested after aging for Persistent Vacuum Integrity according to the Protocol for Packaging Integrity and Shelf Life Validation provided in Attachment 5 and as a draft in Appendix 3 of the original submission. This test was designed to verify the NPD 1000 dressing could achieve and maintain vacuum pressures of 40 mmHg and 125 mmHg for a minimum of one hour. No system faults occurred during the test period; therefore, all devices tested passed.

Seven (7) bandages were functionality tested after aging for Bandage Pump Down Time according to the Protocol for Packaging Integrity and Shelf Life Validation. This test was designed to verify the continuous pump could achieve a set pressure in less than 3 minutes. The average pump down time for the bandages ranged from 28 seconds to 1 minute 27 seconds; therefore, all devices tested passed.

Kalypto Medical Responses to Request for Additional Information

K080275

Fifteen (15) bandages were functionality tested after aging for Dressing Fluid Capacity according to the Protocol for Packaging Integrity and Shelf Life Validation. This test was designed to verify the NPD 100 dressing maintains its therapeutic capacity at the end of its shelf life. The Instruction for Use claims a capacity of 50cc. The measured capacity of the bandages ranged from 71.8g to 92.7g; therefore, all devices tested passed.

The final report, Product and Package Validation Testing, is provided in Attachment 5.

9. Please be advised claims such as reducing edema, promoting granulation tissue formation and perfusion (page 27 of 55) should be supported by data.

Response: These claims were removed from the Executive Summary (see revised Executive Summary section 10) and the Device Description (see revised Device Description section 11).

10. Your labeling should contain a precaution that the device should not be used once wound exudate is no longer present in the wound.

Response: The Instructions for Use was revised to include this precaution. See revised Instructions for Use included in Attachment 3 of this submission.

Traceability Matrix
Hazards to System Requirements
to Verification Test Plan
to Verification Test Reports

0421

Hazard Analysis (DP-0001-03-7 Rev. 001-a)		Failure Modes & Effects Criticality Analysis (DP-0001-04-1 Rev. 001-a)		System Requirements Specification (DP-0001-04-2 Rev. 002-a)		Verification Test Procedures (DP-0001-04-0 Rev. 000)								
Control Number	Potential Hazard	Hazard Cause(s) of System Level Effects	Mitigation	Potential Failure Mode	Mitigation	HERARCHY	TAG	NAME	PRIORITY	TRACE TAG	TRACE NAME	TRACE VERSION	PRIORITY	TRACE
1						1	SYSREQ03776	h Introduction	Section Heading	SYSREQ03778	h Scope	5.1	Section Heading	
2						1	SYSREQ03776	h Introduction	Section Heading	SYSREQ03777	h References	10	Section Heading	
3						1	SYSREQ03776	h Introduction	Section Heading	SYSREQ03780	h Conventions	2.2	Section Heading	
4						1	SYSREQ03776	h Introduction	Section Heading	SYSREQ03778	h Glossary	5	Section Heading	
5						1.1	SYSREQ03777	h References	Section Heading					
6						1.2	SYSREQ03778	h Scope	Section Heading					
7						1.3	SYSREQ03779	h Glossary	Section Heading					
8						1.3.1	SYSREQ03781	h Historical Background	Section Heading					
9						1.4	SYSREQ03780	h Conventions	Section Heading					
10						2	SYSREQ03781	h System Overview	Section Heading	SYSREQ03784	h Use Venues	4.1	Section Heading	
11						2	SYSREQ03781	h System Overview	Section Heading	SYSREQ03785	h Key Assumptions	4.1	Section Heading	
12						2	SYSREQ03781	h System Overview	Section Heading	SYSREQ03786	h Basic System Configuration	4	Section Heading	
13						2	SYSREQ03781	h System Overview	Section Heading	SYSREQ03783	h Product Philosophy	5.1	Section Heading	
14						2	SYSREQ03781	h System Overview	Section Heading	SYSREQ03782	h General Description	5.1	Section Heading	
15						2	SYSREQ03781	h System Overview	Section Heading	SYSREQ03787	h Historical Background	3.1	Section Heading	
16						2.1	SYSREQ03782	h General Description	Section Heading					
17						2.2	SYSREQ03783	h Product Philosophy	Section Heading					
18						2.3	SYSREQ03784	h Use Venues	Section Heading					
19						2.4	SYSREQ03785	h Key Assumptions	Section Heading					
20						2.5	SYSREQ03786	h Basic System Configuration	Section Heading					
21						3	SYSREQ04533	h Product Requirements	Section Heading	SYSREQ04547	h Physical Requirements	1.1	Section Heading	
22						3	SYSREQ04533	h Product Requirements	Section Heading	SYSREQ04560	h Manufacturing Requirements	2.1	Section Heading	
23						3	SYSREQ04533	h Product Requirements	Section Heading	SYSREQ04559	h Validation Requirements	3.1	Section Heading	
24						3	SYSREQ04533	h Product Requirements	Section Heading	SYSREQ04557	h Quality and Reliability Requirements	1.2	Section Heading	
25						3	SYSREQ04533	h Product Requirements	Section Heading	SYSREQ04553	h Environmental Requirements	1.1	Section Heading	
26						3	SYSREQ04533	h Product Requirements	Section Heading	SYSREQ04561	h Service Requirements	2.1	Section Heading	
27						3	SYSREQ04533	h Product Requirements	Section Heading	SYSREQ04546	h Power Requirements	2.1	Section Heading	
28						3	SYSREQ04533	h Product Requirements	Section Heading	SYSREQ04540	h Regulatory and Safety Requirements	1.1	Section Heading	
29						3	SYSREQ04533	h Product Requirements	Section Heading	SYSREQ04536	h Other Interface Requirements	1.1	Section Heading	
30						3	SYSREQ04533	h Product Requirements	Section Heading	SYSREQ04535	h User Interface Functional and Performance Requirements	2.1	Section Heading	
31						3.1	SYSREQ04534	h Functional and Performance Requirements	Section Heading	SYSREQ04534		1.1	Section Heading	
32						3.1.1	SYSREQ04529	h System Unit Requirements	Section Heading					
33						3.1.1.1	SYSREQ04746	Set Point Pressure Tolerance	Traceable Requirement	SYSTS15811	Test Case FT004 - Vacuum Pressure	20	Traceable Requirement	

58	Degraded/determin-ation of the end of life of the medical device	Failure to deliver appropriate therapy	Design criteria will have MTBF that device will have one patient therapy cycle reliability.	3.1.2.3	SYSREQ054672	Continuous Pump Operational Period	Traceable Requirement	SYSTST55819	Test Case SR002 - Continuous Pump Life	6	Traceable Requirement
59	Degradation	Reduced therapy benefit to patient	Reliability and pump life cycle testing will be performed to determine performance margins.	3.1.2.4	SYSREQ054745	Intermittent Pump Operation Period	Traceable Requirement	SYSTST55820	Test Case SR003 - Intermittent Pump Life	5	Traceable Requirement
60	Inability of system to maintain appropriate vacuum level	Degradation of pump performance	Pump selection criteria, life cycle test to achieve pump life expectancy exceeding single patient use.	3.1.2.4	SYSREQ054745	Intermittent Pump Operation Period	Traceable Requirement	SYSTST55820	Test Case SR003 - Intermittent Pump Life	5	Traceable Requirement
61	Degraded system performance	Failure to deliver appropriate therapy	Design criteria will have MTBF that device will have one patient therapy cycle reliability.	3.1.2.4	SYSREQ054745	Intermittent Pump Operation Period	Traceable Requirement	SYSTST55820	Test Case SR003 - Intermittent Pump Life	5	Traceable Requirement
62	Degraded system performance	Failure to deliver appropriate therapy	Design criteria will have MTBF that device will have one patient therapy cycle reliability.	3.1.2.4	SYSREQ054745	Intermittent Pump Operation Period	Traceable Requirement	SYSTST55820	Test Case SR003 - Intermittent Pump Life	5	Traceable Requirement
63	Wrong dressing for anatomical site	Inappropriate therapy	Section on bandage in IFU will address use of the 50cc bandage, and no other manufacturer's dressings, used by trained wound care provider.	3.1.3.10	SYSREQ054705	Bandage Types III	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
64	Inability of system to maintain appropriate vacuum level	Wound desiccation, reduced battery life	Ergonomic design of bandages relative to intended use and leak detection.	3.1.3.10	SYSREQ054705	Bandage Types III	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
65	Inability of system to maintain appropriate vacuum level	Wound desiccation, reduced battery life	Ergonomic design of bandages relative to intended use and leak detection.	3.1.3.11	SYSREQ054706	Bandage Types IV	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
66	Inability of system to maintain appropriate vacuum level	Wound desiccation, reduced battery life	Ergonomic design of bandages relative to intended use and leak detection.	3.1.3.11	SYSREQ054706	Bandage Types IV	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement

65	29	Wrong dressing for anatomical site	Inappropriate therapy	Section on bandage in IFU will address the multiple bandage styles available.	3.1.3.12	SYSREQ54707	Bandage Types V	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
66	58	Inability of system to maintain appropriate vacuum level	Wound desiccation, reduced battery life detection.	Ergonomic design of bandages relative to intended use and leak detection.	3.1.3.12	SYSREQ54707	Bandage Types V Bandage Fluid Handling Capacity	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
67					3.1.3.13	SYSREQ54709	Ortheses Accommodation	Traceable Requirement Design	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
68					3.1.3.14	SYSREQ54639	Duration of Application	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
69					3.1.3.2	SYSREQ54699	Bandage Water Resistance	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
70	42	Development of leak mid-therapy	Ineffective or reduced therapy	Secondary sealing means beyond bandage	3.1.3.4	SYSREQ54701	Adhesion Requirement	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
71	26	Inappropriate size setting of the bandage on the wound	Causes leak in bandage.	Step-wise description of bandage application in IFU, and leak detection notification in hardware.	3.1.3.5	SYSREQ54708	Bandage Sealing Requirement	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
72	42	Development of leak mid-therapy	Ineffective or reduced therapy	Secondary sealing means beyond bandage dressing.	3.1.3.5	SYSREQ54708	Bandage Sealing Requirement Bandage Tubing Connector Pull Force	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests Test Case PM002 - Mechanical	15	Traceable Requirement
73	41	Failure to read actual pressure at bandage	Ineffective or reduced therapy	Kink resistant tubing and strain relieved connection to the bandage.	3.1.3.6	SYSREQ54747		Traceable Requirement	SYSTST55777		10.1	Traceable Requirement
74	29	Wrong dressing for anatomical site	Inappropriate therapy	Section on bandage in IFU will address use of the 50cc bandage, and no other manufacturer's dressings, used by trained wound care provider.	3.1.3.7	SYSREQ54748	Bandage Tubing Connector Strain Relief	Traceable Requirement	SYSTST55777	Test Case PM002 - Mechanical	10.1	Traceable Requirement
75	58	Inability of system to maintain appropriate vacuum level	Wound desiccation, reduced battery life detection.	Ergonomic design of bandages relative to intended use and leak detection.	3.1.3.8	SYSREQ54703	Bandage Types I	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
					3.1.3.8	SYSREQ54703	Bandage Types I	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement
					3.1.3.9	SYSREQ54704	Bandage Types II	Traceable Requirement	SYSTST55536	Iasis Medical Inc. Tests	15	Traceable Requirement

65	Inappropriate functioning attributed to battery degradation.	Failure to deliver appropriate therapy.	IFU will call out that device is not field serviceable except for battery replacement.	3.1.3	SYSREQ54792	System Maintenance	Traceable Requirement	SYSTST55536	Istis Medical Inc. Tests	15	Traceable Requirement
66	Degraded system performance.	Failure to deliver appropriate therapy.	Design criteria will have MTBF that device will have one patient therapy cycle reliability level.	3.1.3	SYSREQ54792	System Maintenance	Traceable Requirement	SYSTST55536	Istis Medical Inc. Tests	15	Traceable Requirement
83	Inappropriate setting or pressure setting.	Ineffective/reduced therapy.	Write IFU to 6 th grade level.	3.2	SYSREQ54635	h User Interface	Traceable Requirement	SYSTST55536	Istis Medical Inc. Tests	15	Traceable Requirement
25	Inability of system to maintain appropriate vacuum level.	Ineffective therapy.	Design with window indicator when bandage is full, label against highly exuding wounds.	3.2.1	SYSREQ54654	Ease of Use Requirement	Traceable Requirement	SYSTST55536	Istis Medical Inc. Tests	15	Traceable Requirement
61	Bandage full - indicate with fluid level.	Ineffective therapy.	Redundant audio and visual display, buttons have tactile feel.	3.2.2	SYSREQ54663	Bandage Full Detection	Traceable Requirement	SYSTST55536	Istis Medical Inc. Tests	15	Traceable Requirement
96	Bandage full - indicate with fluid level.	Ineffective therapy.	Redundant audio and visual display, buttons have tactile feel.	3.2.3	SYSREQ54664	h User Controls	Traceable Requirement	SYSTST55536	Istis Medical Inc. Tests	15	Traceable Requirement
57	Inefficient visibility, reduced visual acuity, hearing or dexterity.	Ineffective or reduced therapy.	Redundant audio and visual display, buttons have tactile feel.	3.2.3.1	SYSREQ54728	Display Backlighting Requirement	Traceable Requirement	SYSTST55810	Test Case UI003 - UI Display Reliability	5.2	Traceable Requirement
98	Inefficient visibility, reduced visual acuity, hearing or dexterity.	Ineffective or reduced therapy.	Redundant audio and visual display, buttons have tactile feel.	3.2.3.1.1	SYSREQ55903	Backlight Operation	Traceable Requirement	SYSTST55813	Test Case SN001 - Low Reliability	17	Traceable Requirement
99	Inefficient visibility, reduced visual acuity, hearing or dexterity.	Ineffective or reduced therapy.	Redundant audio and visual display, buttons have tactile feel.	3.2.3.1.1	SYSREQ55903	Backlight Operation	Traceable Requirement	SYSTST55814	Test Case SN002 - Leak Detected	19	Traceable Requirement
100	Inefficient visibility, reduced visual acuity, hearing or dexterity.	Ineffective or reduced therapy.	Redundant audio and visual display, buttons have tactile feel.	3.2.3.1.1	SYSREQ55903	Backlight Operation	Traceable Requirement	SYSTST55815	Test Case SN003 - System Fault	27	Traceable Requirement
101	Inefficient visibility, reduced visual acuity, hearing or dexterity.	Ineffective or reduced therapy.	Redundant audio and visual display, buttons have tactile feel.	3.2.3.1.1	SYSREQ55903	Backlight Operation	Traceable Requirement	SYSTST55910	Test Case UI003 - UI Display On/Off Control	5.2	Traceable Requirement
102	Inefficient visibility, reduced visual acuity, hearing or dexterity.	Ineffective or reduced therapy.	Redundant audio and visual display, buttons have tactile feel.	3.2.3.2	SYSREQ54665	Pump On/Off Control	Traceable Requirement	SYSTST55801	Test Case UI004 - Pump On/Off Control	2.1	Traceable Requirement
103	Inefficient visibility, reduced visual acuity, hearing or dexterity.	Ineffective or reduced therapy.	Redundant audio and visual display, buttons have tactile feel.	3.2.3.3	SYSREQ54674	Vacuum Pressure Selection	Traceable Requirement	SYSTST55811	Test Case FT004 - Vacuum Pressure	20	Traceable Requirement
104	Inability of system to maintain appropriate vacuum level.	Ineffective therapy.	A pressure sensor check will be performed after a set time if the pump is inactive. Pressure sensors will be inspected in manufacturing prior to install in product.	3.2.3.4	SYSREQ54675	Therapy Mode Selection	Traceable Requirement	SYSTST55807	Test Case FT002 - Therapy Mode Selection	12.1	Traceable Requirement
59	Pressure sensor failure.	Ineffective therapy.	IFU and Hardware lockout. Software lockout controls.	3.2.3.5	SYSREQ54727	Patient Lock Out	Traceable Requirement	SYSTST55808	Test Case UI002 - Programming Controls	11	Traceable Requirement
105	Manually changing clinician's setting.	Ineffective/reduced therapy.	IFU and Hardware lockout. Software lockout controls.	3.2.4	SYSREQ54670	h User Feedback	Traceable Requirement	SYSTST55808	Test Case UI002 - Programming Controls	11	Traceable Requirement
106	Pressure sensor failure.	Ineffective therapy.	IFU and Hardware lockout. Software lockout controls.	3.2.4	SYSREQ54670	h User Feedback	Traceable Requirement	SYSTST55808	Test Case UI002 - Programming Controls	11	Traceable Requirement
57	Insufficient visibility, reduced visual acuity, hearing or dexterity.	Ineffective or reduced therapy.	Redundant audio and visual display, buttons have tactile feel.	3.2.4.1	SYSREQ54676	Control Unit Character Size	Traceable Requirement	SYSTST55910	Test Case UI003 - UI Display	5.2	Traceable Requirement

125	26	Inappropriate sealing of the bandage on the wound	• inadequate specification of pre-use checks	Causes leak in bandage	Step-wise description of bandage application in IFU, and leak detection notification in hardware. Failure open will trigger a leak notification that is handled by the system (pump running continuously after valve activation). Failure closed will trigger a system notification that is handled by the system (no pressure change after valve activation). Check valves will be inspected in manufacturing prior to install in a robot.	FMECA56382	Solenoid Valve Stuck Opened	Inability to form vacuum pressure at the wound site	User is notified of a leak if the target pressure is not reached.	3.2.4.5.1.3	SYSREQ054683	Leak Detection Indication	Traceable Requirement SYSYST155814	Test Case SN002 - Leak Detected	19	Traceable Requirement
126	63	Inability of system to maintain appropriate vacuum level	Check valve failure	Ineffective therapy	Ergonomic design of bandages relative to included use and leak detection parameters. Sill sealing prevents therapy tube fittings and leak detection notification in the hardware.	FMECA56382	Solenoid Valve Stuck Opened	Inability to form vacuum pressure at the wound site	User is notified of a leak if the target pressure is not reached.	3.2.4.5.1.3	SYSREQ054683	Leak Detection Indication	Traceable Requirement SYSYST155814	Test Case SN002 - Leak Detected	19	Traceable Requirement
127	38	Inability of system to maintain appropriate vacuum level	ill-fitting bandage or leak in system plumbing	Wound desiccation / reduced battery life	Ergonomic design of bandages relative to included use and leak detection parameters. Sill sealing prevents therapy tube fittings and leak detection notification in the hardware.	FMECA56382	Solenoid Valve Stuck Opened	Inability to form vacuum pressure at the wound site	User is notified of a leak if the target pressure is not reached.	3.2.4.5.1.3	SYSREQ054683	Leak Detection Indication	Traceable Requirement SYSYST155814	Test Case SN002 - Leak Detected	19	Traceable Requirement
128	37	Incorrect connection of system tubing	inadequate specification of pre-use checks	Causes leak in system	Ergonomic design of bandages relative to included use and leak detection parameters. Sill sealing prevents therapy tube fittings and leak detection notification in the hardware.	FMECA57033	Solenoid Valve Stuck Opened	Inability to form vacuum pressure at the wound site	User is notified of a leak if the target pressure is not reached.	3.2.4.5.1.3	SYSREQ054683	Leak Detection Indication	Traceable Requirement SYSYST155814	Test Case SN002 - Leak Detected	19	Traceable Requirement
129					EEPROM data is CRC checked when it is loaded during POST. Power on sequence failure will disable the device and user is notified of a system fault.		Corrupted EEPROM	EEPROM data storing device parameters becomes corrupted		3.2.4.5.10	SYSREQ054689	N/RAW Error Checks	Traceable Requirement SYSYST155535	Unit and Integration Tests	9	Traceable Requirement
130										3.2.4.5.11	SYSREQ057195	Software Version Number	Traceable Requirement SYSYST155788	Test Case F7001 - Power On Self Tests	11	Traceable Requirement
131										3.2.4.5.11	SYSREQ057195	Software Version Number	Traceable Requirement SYSYST155854	Test Case F7009 - Software Upgrade	6.1	Traceable Requirement
132	57	Inefficient visibility, reduced visual acuity, hearing or ability and dexterity	Patient has reduced visual acuity, hearing and dexterity	Ineffective or reduced therapy	Redundant audio and visual display, buttons have tactile feel.	FMECA57031	LCD Failure	One or more pressure sensor segments stuck on or off or no power to LCD	POST turns all segments on and off for the user to check. Redundant audible notification.	3.2.4.5.2	SYSREQ04729	Audible Notifications	Traceable Requirement SYSYST155813	Test Case SN001 - Low Battery	17	Traceable Requirement
133							LCD Alarm Indicators Failure	Alarm indicators fail to activate in the event of an actual alarm condition	POST turns all segments on and off for the user to check. Redundant audible notification.	3.2.4.5.2	SYSREQ04729	Audible Notifications	Traceable Requirement SYSYST155815	Test Case SN003 - System Fault	27	Traceable Requirement
134										3.2.4.5.2	SYSREQ04729	Audible Notifications	Traceable Requirement SYSYST155814	Test Case SN002 - Leak Detected	19	Traceable Requirement
135	5	Excessive pressure level, including acoustic pressure and vibration	Extremely high dB from speaker, Excessive pressure and vibration	No direct hazard for vibration or noise	Design of device precludes any issues for acoustic and vibration. Alarm buzzer will not create hazard region for vibration or noise.	SYSREQ054682	Audible Notification Volume Level	Audible Notification Volume Level	Test Case U001 - Audible Announcement	3.2.4.5.2.1	SYSREQ054682	Audible Notification Volume Level	Traceable Requirement SYSYST155786	Test Case U001 - Audible Announcement	6	Traceable Requirement

45	pressure	21	<p>Going too negative in vacuum.</p> <p>pressure via pump signal failure. Too positive a pressure is a possibility as well for pumps that run in both directions.</p> <p>Too negative of pressure causes ineffective therapy. The bandage could be "blown off" disrupting therapy in the case of too positive a bandage pressure.</p> <p>(in Swine, Annela Pias Surg 2001: 475-475-51).</p> <p>A pressure sensor check will be performed after a set time if the pump is inactive.</p> <p>Pressure sensors will be inspected prior to manufacturing in product.</p>	FMECA56626	Pump Fails to Activate	<p>Pump fails to activate</p> <p>User is notified of a system fault (if the pressure does not change when the pump is turned on) or of a leak detected (if unable to reach the set pressure).</p>	3.2.4.5.5	SYSREQ54794	Loss of Pump Control	Traceable Requirement	SYSTST55811	Test Case FT004 - Vacuum Pressure	20	Traceable Requirement	
146	<p>Ability of system to maintain appropriate vacuum level.</p> <p>Pressure sensor failure</p>	29	<p>Pressure sensors will be inspected prior to manufacturing in product.</p>	FMECA56382	Solenoid Valve Stuck Opened	<p>Inability to form vacuum pressure at the wound site</p> <p>Solenoid Valve continuously turned on - inability to create a vacuum</p> <p>Solenoid Valve continuously turned off - inability to release vacuum</p>	<p>User is notified of a leak if the target pressure is not reached.</p> <p>* User is notified of a leak if the target pressure is not reached.L</p> <p>* Product safety testing of Solenoid Valve</p>	3.2.4.5.5	SYSREQ54794	Loss of Pump Control	Traceable Requirement	SYSTST55815	Test Case SN003 - System Fault	27	Traceable Requirement
147				FMECA56383	Solenoid Valve Switch Stuck On	<p>Pressure reading stuck above setpoint - bandage will not reach setpoint pressure - pump will continue to run</p>	<p>* User is notified of a leak if the pressure does not reach the setpoint due to the pump running continuously for more than 1 minute.L</p> <p>* User Training: user must determine that pump is continuously running even though they have verified no leaks in system and bandage has grown down.</p>	3.2.4.5.5	SYSREQ54794	Loss of Pump Control	Traceable Requirement	SYSTST55815	Test Case SN003 - System Fault	27	Traceable Requirement
148				FMECA57025	Pressure Sensor Stuck High			3.2.4.5.6	SYSREQ54688	Improper Therapy Mode	Traceable Requirement	SYSTST55807	Test Case FT002 - Therapy Mode Selection	12.1	Traceable Requirement
149								3.2.4.5.7	SYSREQ54751	Attempted Improper Therapy Mode	Traceable Requirement	SYSTST55807	Test Case FT002 - Therapy Mode Selection	12.1	Traceable Requirement
150								3.2.4.5.8	SYSREQ54687	Missing Pump Monitor	Traceable Requirement	SYSTST55801	Test Case U004 - Pump On/Off Control	2.1	Traceable Requirement
				FMECA56378	Pressure Button Stuck On	<p>Pressure "VAC" Button stuck in the "ON" position or inadvertently pressed. Loss of ability to adjust pressure to adjust pressure setpoint.</p> <p>Pressure "VAC" button stuck test done during POST, power on sequence failure will disable the device and user is notified of a system fault.L. Pressure setpoint can only be changed in program mode.L Buttons are recessed and covered.L. Button presses are debounced.</p>	<p>Pressure "VAC" button stuck test done during POST, power on sequence failure will disable the device and user is notified of a system fault.L. Pressure setpoint can only be changed in program mode.L Buttons are recessed and covered.L. Button presses are debounced.</p>	3.2.4.5.9	SYSREQ54638	POST Failure	Traceable Requirement	SYSTST55788	Test Case FT001 - Power On Self Tests	11	Traceable Requirement

217	18	Design such that only this product's system components will be compatible.	No hazard		3.7.2	SYSREQ57244	Mated Connectors	Traceable Requirement	Traceable Requirement	10.1	Traceable Requirement
218	28	Wrong dressing (Non-Kalypto Medical) intended to be used with other devices	Inappropriate therapy	Use of mated fittings to connect Kalypto Medical components.	3.7.2	SYSREQ57244	Mated Connectors	Traceable Requirement	Traceable Requirement	10.1	Traceable Requirement
219	38	Wrong dressing (Non-Kalypto Medical) intended to be used with other devices	Inappropriate therapy	Pump/bandage connections proprietary to Kalypto Medical will be marketed	3.7.2	SYSREQ57244	Mated Connectors	Traceable Requirement	Traceable Requirement	10.1	Traceable Requirement
220	68	loss of electrical/mechanical integrity	Ineffective therapy or device failure	environmental and shipping/vibration testing per relevant standards. Note: these traces are to the section headings that contain the environmental requirements for the operational, storage, and shipping conditions.	3.8.1	SYSREQ54554	h Operating Conditions	Section Heading	Section Heading	1.2	Traceable Requirement
221	69	inadequate packaging (contamination and/or deterioration of the medical device)	Ineffective therapy or device failure	environmental and shipping/vibration testing per relevant standards. Note: these traces are to the section headings that contain the environmental requirements for the operational, storage, and shipping conditions.	3.8.1	SYSREQ54554	h Operating Conditions	Section Heading	Section Heading	1.2	Traceable Requirement
222					3.8.1.1	SYSREQ54656	h Altitude Operating Conditions	Section Heading	Section Heading		Traceable Requirement
223					3.8.1.1.1	SYSREQ54657	Minimum Operating Altitude (electronics)	Traceable Requirement	Traceable Requirement	4	Traceable Requirement
224					3.8.1.1.2	SYSREQ54658	Minimum Operating Altitude (bandage)	Traceable Requirement	Traceable Requirement	4	Traceable Requirement
225					3.8.1.1.3	SYSREQ54660	Maximum Operating Altitude Requirement (electronics)	Traceable Requirement	Traceable Requirement	4	Traceable Requirement
226					3.8.1.1.4	SYSREQ54659	Maximum Operating Altitude Requirement (bandage)	Traceable Requirement	Traceable Requirement	4	Traceable Requirement
227					3.8.1.2	SYSREQ54663	Minimum Operating Temperature	Traceable Requirement	Traceable Requirement	4	Traceable Requirement
228					3.8.1.3	SYSREQ54694	Maximum Operating Humidity Requirement	Traceable Requirement	Traceable Requirement	4	Traceable Requirement
229					3.8.1.4	SYSREQ54695	Maximum Operating Humidity Requirement	Traceable Requirement	Traceable Requirement	4	Traceable Requirement
230					3.8.1.5	SYSREQ54696	h Operational Drop and Vibration	Traceable Requirement	Traceable Requirement	4	Traceable Requirement
230					3.8.1.6	SYSREQ54729	h Operational Drop and Vibration	Traceable Requirement	Traceable Requirement	4	Traceable Requirement

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221	19	accidental mechanical damage	dropped, plastic enclosure may break with jagged edges	Patient may experience injury.	Drop and vibration testing will be conducted.	3.8.1.6.1	SYSREQ54687	Drop Requirements	Traceable Requirement	SYSTST55543	Test Case EV003 - Unpackaged Drop and Vibration	6	Traceable Requirement
222	19	accidental mechanical damage	LCD display may cause glass shards if dropped. Plastic enclosure may break with jagged edges	Patient may experience injury.	Test to 601-1 product safety.	3.8.1.6.2	SYSREQ54777	Vibration	Traceable Requirement	SYSTST55543	Test Case EV003 - Unpackaged Drop and Vibration	6	Traceable Requirement
223	15	susceptibility to magnetic interference emissions of electronic devices	Internal electronics function disrupted by external EM radiation	Disruption of therapy.	Test to 601-1.2.	3.8.1.7	SYSREQ54735	Electrostatic Discharge (ESD) Requirements	Traceable Requirement	SYSTST55546	Test Case EV006 - EMC	2.1	Traceable Requirement
224	15	emissions of electronic devices	Internal electronics radiating at undesirable levels	Disruption of external devices, e.g. pacemakers	Test to 601-1.2 shipping/vibration testing per relevant standards.	3.8.1.B	SYSREQ54734	EMC/Immunity Requirements	Traceable Requirement	SYSTST55546	Test Case EV006 - EMC	2.1	Traceable Requirement
225	68	loss of electrical/mechanical integrity	Inappropriate shipping or handling.	Ineffective therapy or device failure	Note: these traces are to the section headings that contain the environmental requirements for the operational, storage, and shipping conditions.	3.8.2	SYSREQ54555	h Storage and Transport Conditions	Section Heading				
226	69	inadequate packaging (contamination and/or deterioration of the medical device)	Inappropriate shipping or handling.	Ineffective therapy or device failure	Note: these traces are to the section headings that contain the environmental requirements for the operational, storage, and shipping conditions.	3.8.2	SYSREQ54555	h Storage and Transport Conditions	Section Heading				
227	236				shipping/vibration testing per relevant standards.	3.8.2.1	SYSREQ54718	h Shelf Life Requirements	Section Heading				
228	237				shipping/vibration testing per relevant standards.	3.8.2.1.1	SYSREQ54718	Bandage Shelf Life	Traceable Requirement	SYSTST55536	Tests Medical Ins. Tests	15	Traceable Requirement
229	238				shipping/vibration testing per relevant standards.	3.8.2.1.1	SYSREQ54718	Bandage Shelf Life	Traceable Requirement	SYSTST55547	Test Case EV007 - Shelf Life (Bandage only)	4	Traceable Requirement
230	239				shipping/vibration testing per relevant standards.	3.8.2.1.2	SYSREQ54720	Display/Control Unit Shelf Life	Design Guideline				
240	240				shipping/vibration testing per relevant standards.	3.8.2.1.3	SYSREQ54721	Pump Module Shelf Life	Design Guideline				
241	241				shipping/vibration testing per relevant standards.	3.8.2.1.4	SYSREQ54722	Batteries Shelf Life	Design Guideline				
242	242				shipping/vibration testing per relevant standards.	3.8.2.2	SYSREQ54753	Minimum Storage Temperature	Traceable Requirement	SYSTST55542	Test Case EV002 - Storage Conditions	2.1	Traceable Requirement
243	243				shipping/vibration testing per relevant standards.	3.8.2.3	SYSREQ54754	Maximum Storage Temperature	Traceable Requirement	SYSTST55542	Test Case EV002 - Storage Conditions	2.1	Traceable Requirement

Question ID	Question Text	Requirement ID	Requirement Description	Test Case	Traceability	Requirement ID	Requirement Description	Test Case	Traceability
245		3.8.2.3		Test Case EV002 - Storage Conditions	Traceable Requirement	SYSTST55542	Traceable Requirement	Test Case EV002 - Storage Conditions	Traceable Requirement
246		3.8.2.6		Minimum Storage Humidity	Traceable Requirement	SYSTST55542	Traceable Requirement	Test Case EV002 - Storage Conditions	Traceable Requirement
247		3.8.2.7		Maximum Storage Humidity	Traceable Requirement	SYSTST55542	Traceable Requirement	Test Case EV002 - Storage Conditions	Traceable Requirement
248	68	3.8.3		Package integrity / Shipping	Traceable Requirement	SYSTST55544	Traceable Requirement	Test Case EV004 - Packaged Shock and Vibe (ie. Shipping)	Traceable Requirement
249		3.8.3		Package integrity / Shipping	Traceable Requirement	SYSTST55544	Traceable Requirement	Test Case EV004 - Packaged Shock and Vibe (ie. Shipping)	Traceable Requirement
250	69	3.8.3	Environmental and shipping/vibration testing per relevant standards.	Package integrity / Shipping	Traceable Requirement	SYSTST55544	Traceable Requirement	Test Case EV004 - Packaged Shock and Vibe (ie. Shipping)	Traceable Requirement
251		3.8.4		h Disposal Requirements	Traceable Requirement	SYSTST55782	Traceable Requirement	Test Case FT008 - Device & Bandage Disposal	Traceable Requirement
252	70	3.8.4.1	Inadequate packaging (contamination and/or deterioration of the medical device).	Battery Disposal Requirements	Traceable Requirement	SYSTST55782	Traceable Requirement	Test Case FT008 - Device & Bandage Disposal	Traceable Requirement
253		3.8.4.2	Inadequate packaging (contamination and/or deterioration of the medical device).	Device Electronics Disposal U.S.	Traceable Requirement	SYSTST55782	Traceable Requirement	Test Case FT008 - Device & Bandage Disposal	Traceable Requirement
254		3.8.4.3	Inadequate packaging (contamination and/or deterioration of the medical device).	Bandage Disposal Requirement	Traceable Requirement	SYSTST55782	Traceable Requirement	Test Case FT008 - Device & Bandage Disposal	Traceable Requirement
255		3.8.4.4	Inadequate packaging (contamination and/or deterioration of the medical device).	WEEE Certification	Traceable Requirement	SYSTST55782	Traceable Requirement	Test Case FT008 - Device & Bandage Disposal	Traceable Requirement
256		3.8.4.5	Inadequate packaging (contamination and/or deterioration of the medical device).	RoHS Certification	Traceable Requirement	SYSTST55782	Traceable Requirement	Test Case FT008 - Device & Bandage Disposal	Traceable Requirement
257		3.9		h Validation Requirements	Traceable Requirement	SYSTST55828	Traceable Requirement	Test Case HI002 - Central Unit to Pump Unit Connection	Traceable Requirement
258		4		Potential Product Enhancements	Traceable Requirement	SYSTST55828	Traceable Requirement	Test Case SR001 - Stimulated User Evaluation	Traceable Requirement

Hazards Descriptions

Traceability Matrix- Hazards to System Requirements

Traceability Matrix- FMECA to System Requirements

Capricorn Verification Report

**Minnetronix® Document # DR-0000-09-0
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1 Introduction

The purpose of this Verification Report is to summarize the verification activities for the Production re-release of the Kalypto Medical, Inc. Micro Negative Pressure Wound Therapy (NPWT) System (a.k.a. project Capricorn). The System consists of a control/display unit, two different pump units delivering continuous or intermittent therapy, and an inter-connected bandage. The verification activities performed are described in the Capricorn System Verification and Validation Plan; document DP-0001-85-0. Note: Kalypto Medical, Inc. was formerly known as Iasis Medical, Inc.

This report is intended to supplement verification information as found in the following previously released verification report:

- "Capricorn Verification Report, DR-0000-09-0 Rev. 001-a", dated 1/25/08, and released on ECO 5699 (status Effective).

1.1 References and Applicable Documents

The type column below describes the source or document type for the listed description.

<u>Abbreviation</u>	<u>Description</u>	<u>Part Number</u>	<u>Type</u>
{SDP}	Capricorn System Development Plan	DP-0001-83-3	Word Doc
{VVP}	Capricorn System Verification & Validation Plan	DP-0001-85-0	Word Doc
{VTP}	Capricorn Requirement Verification Test Procedures	DP-0001-84-0	Caliber Doc
{HA}	Capricorn Hazard Analysis	DP-0001-83-7	Word Doc
{FMECA}	Capricorn Failure Modes and Effects Criticality Analysis	DP-0001-84-1	Caliber Doc
{CustRS}	Capricorn Customer Requirements Specification	DP-0001-84-5	Word Doc
{SysRS}	Capricorn System Requirements Specification	DP-0001-84-2	Caliber Doc
{UISpec}	Capricorn Usability Specification	DP-0001-84-7	Word Doc
{SysDD}	Capricorn System Design Specification	DP-0001-83-9	Word Doc
{SwDD}	Capricorn Software Design Document	DP-0001-84-3	Word Doc
{UIDD}	Capricorn User Interface Design Document	DP-0001-84-4	Word Doc
N/A	Minnetronix Glossary	DQ-0000-72-9	Word Doc
{ITDB}	Minnetronix Issue Tracking Database	N/A	Microsoft SQL
{DHF}	Minnetronix Design History File for Capricorn project	N/A	Microsoft Outlook, Paper file
N/A	Hardware Unit Testing Guideline	N/A	Word Doc
N/A	Traceability Matrix	N/A	Caliber Doc

2 Definitions, Acronyms, and Abbreviations

In addition to those listed here, reference the Minnetronix Glossary, document DQ-0000-72-9, for common definitions, acronyms, and abbreviations found in Minnetronix documentation.

Mntx	Minnetronix, Inc.
MKS	MKS Integrity 2007; Build: 4.9.0.4414, Service Pack: 000-00 (configuration management tool)
PCBA	Printed Circuit Board Assembly

3 Summary of Results

This is a summary of verification test results per regression execution of the Capricorn Requirement Verification Test Procedures (DP-0001-84-0). See section 3.1.2.2 for a list of completed or re-executed test procedures.

3.1 Requirements Verification Test

This report covers the system requirements testing activities described in the System Verification and Validation Plan. All requirements were verified as described in paragraphs 6.5.5 (system verification test), 6.5.3 (inspection and unit testing), and/or 6.5.4 (integration testing). Any on-going verification activities are documented in the open issues and in section 3.1.3. See section 3.1.3 for test results. Test data/results of execution of verification tests are recorded in the marked up copy of the Capricorn Requirement Verification Test Procedures document as attached to this report (see section 3.1.3.1).

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3.1.1 Test Environment & Equipment

All testing was performed using pre-production Control Units and Pump Units. The specific test environment and test equipment used is captured as part of the recorded test results for each procedure or group of procedures.

3.1.2 Items tested

Verification testing was performed with the Capricorn hardware identified as AE-0000-83-2 (Control Unit top level assembly), as AE-0000-83-3 (Continuous Pump Unit top level assembly), and as AE-0000-83-4 (Intermittent Pump Unit top level assembly) and Capricorn software identified as SE-0000-17-0.

The following revision of Capricorn Embedded Software was used during testing:

- Version 08, MKS checkpoint identified as "Version 08" (SE-0000-17-0 Rev. 002-a; ECO 5933, status Effective). Note: Changes from Version 06 are the addition of a new low battery voltage threshold specifically for the Intermittent pump module per Interface issue #60, correction of an ADC timeout system failure per Interface issue #62, and removal of nuisance pressure sensor system faults per Interface issue #59.

The following revisions of Capricorn hardware were used during testing:

Control Board: Revision of AP-0000-89-1 PCBA Capricorn Control Unit hardware used was Rev. 005-a (ECO 5933, status Effective). Note: The difference between Rev. 003-a and Rev. 005-a is the structuring of software to the board and the incorporation/programming of revision 08 software.

Pump Boards: Revision of AP-0000-89-3 PCBA Capricorn Continuous Therapy Pump Module hardware used was Rev. 001-a (ECO 5422, status Effective). Note: No change from the previous verification report. Revision of AP-0000-89-5 PCBA Capricorn Intermittent Therapy Pump Module hardware used was Rev. 002-a (ECO 5883, status Effective) and Rev. 003-a (ECO 5884, status Effective). Note: The difference between Rev. 001-a and Rev. 002-a is the addition of a cut, jump, and diode to control/drive the solenoid valve with a higher voltage per Pump Device issue #21. The difference between Rev. 002-a and 003-a is the addition of a cut and jump to power U4 with a lower voltage per Pump Device issue #23.

Assembled Units: Revision of AE-0000-83-2 Assembly Capricorn Control Unit hardware used was Rev. .04-a (ECO 5614, status Effective). Revision of AE-0000-83-3 Assembly Capricorn Continuous Therapy Pump Module hardware used was Rev. .04-a (ECO 5614, status Effective). Revision of AE-0000-83-4 Assembly Capricorn Intermittent Therapy Pump Module hardware used was Rev. .04-a (ECO 5614, status Effective). Note: For both the Continuous and Intermittent Pump Module assemblies, the check valve was relocated to the output port of the associated pump per Pump Device issue #19.

3.1.2.1 Changes from previous Document Baseline to the current baseline

System Requirements Specification, DP-0001-84-2, was updated and re-released at Rev. 002-a (ECO 5990, status Approved). System Design Specification, DP-0001-83-9, was updated and re-released at Rev. 001-a (ECO 5973, status Approved). Hazard Analysis, DP-0001-83-7, was updated and re-released at Rev. 001-a (ECO 5814, status Approved). Failure Modes and Effects Criticality Analysis, DP-0001-84-1, was updated and re-released at Rev. 001-a (ECO 5814, status Approved). User Interface Design document, DP-0001-84-4, was updated and re-released at Rev. 002-a (ECO 5990, status Approved). Verification Test Procedures, DP-0001-84-0, was updated and re-released at Rev. 002-a (ECO 5990, status Approved).

3.1.2.2 Test Procedures re-executed or completed

Completed

Test Case FT003 – Therapy Duration (SYSTST55818)

Re-executed

Test Case FT001 – Power On Self Tests (SYSTST55788, steps 1-3 only)

Test Case FT002b – Intermittent Mode (SYSTST55817)

Test Case FT003 – Therapy Duration (SYSTST55818)

Test Case FT004a – Pressure Loss Prevention (SYSTST55822)

Test Case SN001 – Low Battery (SYSTST55813)

Test Case SN003 – System Fault (SYSTST55815)

Test Case SR001 – Simulated User Evaluation (SYSTST55540)

Test Case UI004 – Pump On/Off Control (SYSTST55801)

3.1.3 Test results

Capricorn Requirement Verification Test Procedures document has been baselined in Caliber (VTP Rev. 002-a labeled "ECO 5990 (4/8/08) - SRS and VTP Only"). The details of the requirements verification testing is contained in the table below.

The result of regression execution of the {VTP} was all executed tests passed. One test, Therapy Duration, is in progress at the time of this report. When a test failure occurs, it is recorded in {ITDB}. All test failures are reviewed by testers, developers, and the Mntx project leader. Any test failure(s) remaining were deemed acceptable for this release. The table represents a summary of test pass/fail status, plus any anomalies and corrective action encountered during the executions of the {VTP}. The software version listed is the version under test in which the anomaly was first identified.

The following is a list of the SYSTSTs and the version(s) of software that the SYSTST was executed against. Note that SYSTST is a Caliber requirement type and the 5-digit number is a unique identifier within the Caliber database. The SYSTSTs listed cover testing for all requirements as specified in the {SysRS}.

SYSTST	Test Name	for report Rev. 001-a	for report Rev. 001-a	for this report	Pass/Fail & Issues / Comments
		Software Version	Software Version	Software Version	
55788	Power On Self Tests	05	06	08	Passed on 05. Passed on 06. Passed on 08 (steps 1-3 only).
55807	Therapy Mode Selection	05			Passed.
55816	Continuous Mode	05			Passed.
55817	Intermittent Mode	05		08	Passed on 05. Passed on 08
55818	Therapy Duration	-	06	08*	Passed on 06. Interface issue #56 closed. * 6 week test in progress on 08 at the time of this report. Interface issue #63 opened, currently Unresolved.
55811	Vacuum Pressure	05			Passed.
55822	Pressure Loss Prevention	05		08	Passed on 08. Pump Device issue #19 closed. History: Failed step 1 on 05 (pressure loss is > 10 mmHg/hr with the Continuous Pump Module, see Pump Device issue #19).
55821	Parameter Retention & Autostart	05			Passed.
55775	Device Calibration	05			Passed.
55824	Multiple Bandages	05			Passed.
55782	Device & Bandage Disposal	05			Passed.
55854	Software Upgrade	05			Passed.
57540	Reverse Polarity	05			Passed.
55813	Low Battery	05	06	08	Passed on 05. Passed on 06. Passed on 08.
55814	Leak Detected	05			Passed.
55815	System Fault	05	06	08	Passed. History: Failed steps 2b, 7b, and 10b on 05 (Backlight did not turn on, see Interface issue #46). Failed steps 14 and 15 on 05 (System fault did not occur, see Interface issue # 51). Regression tested and Passed on 06 (steps 2-5, 7, 10, and 13-14 only).

SYSTST	Test Name	for report Rev. 001-a	for report Rev. 001-a	for this report	Pass/Fail & Issues / Comments
		Software Version	Software Version	Software Version	
					Passed on 08 per redlines (see Interface issue #64).
55786	Audible Annunciation	05			Passed with requirements updates (see Interface issue #47).
55808	Programming Controls	05			Passed.
55810	UI Display	05			Passed.
55801	Pump On/Off Control	05		08	Passed on 05. Passed on 08.
55825	External Interface Connections	05			Passed.
55826	Control Unit to Pump Unit Connection	05			Passed.
55540	Simulated User Evaluation	05	06	08	Passed on 05. Passed on 06. Passed on 08.
55819	Continuous Pump Life	n/a			Passed.
55820	Intermittent Pump Life	n/a			Passed.
56068	Quick Connect Tubing Cycle Life	05			Passed.
55541	Operating Conditions	05			Passed.
55542	Storage Conditions	05			Passed.
55543	Unpackaged Drop and Vibration	05			Passed.
55544	Packaged Shock and Vibe (ie. Shipping)	05			Passed.
55545	Fluid Ingress	n/a			Passed.
55546	EMC	emc			Passed.
55547	Shelf Life (Bandage only)	-			Responsibility of Kalypto Medical, Inc. (see Interface issue #54).
55548	Cleaning	n/a			Passed.
55581	Product Safety	05			Passed with 'draft' revision of Product Safety report.
55582	Device Classification	05			Passed.
55779	Quality Approval	-	-	-	Test case deleted per Interface issue #53.
55787	Biocompatibility	n/a			Passed (steps 2 and 3 only) per redlines (see Interface issue #54). Step 1 is the responsibility of Kalypto Medical, Inc..
55776	Physical	n/a			Passed with requirements updates (see Interface issue #55).
55777	Mechanical	n/a			Passed.
55535	Unit and Integration Tests	n/a			Passed. See Unit and Integration Test section below for reference list of verification by unit or integration test.
55536	Kalypto Medical Inc. Tests	n/a			Responsibility of Kalypto Medical, Inc.

There are two (2) open issues in the Minnetronix Issue tracking system for the Capricorn NPWT System. Customer approval to leave these issues open will be via signoff of the ECO which releases this report. A closed issues list is not included with this report.

3.1.3.1 Attached Documentation

Test Results Data Sheets	(11) pages. These pages contain the equipment list, test data and results for the completion of execution of Rev. 001-a of the VTP. More specifically, completion of the Therapy Duration test.
Test Results Data Sheets	(25) pages. These pages contain the regression test list, equipment list, test data and results of regression execution of Rev. 002-a of the VTP.
Open Issues Report	(1) page. Includes Capricorn Interface 'Open' issues 58 and 63. There are no 'Future' issues for the Capricorn project.

3.2 Other Verification Activities

3.2.1 System Development Plan

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-83-3. Per the System V&V Plan, the document was reviewed by Kalypto Medical Inc., Minnetronix Technical and QA personnel.

Current Status:

DP-0001-83-3, Rev .02-a, no changes for this release.

3.2.2 System Verification & Validation Plan

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-85-0. Per the System V&V Plan, the document was reviewed by Kalypto Medical Inc., Minnetronix Technical and QA personnel.

Current Status:

DP-0001-85-0, Rev .02-a, no changes for this release.

3.2.3 Hazard Analysis

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-83-7. Per the System V&V Plan, the document was reviewed by Kalypto Medical Inc., Minnetronix Technical and QA personnel.

Current Status:

Document has been formally reviewed. Changes to this document since formal review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

DP-0001-83-7, Rev 001-a, updated for this release.

References:

ECO 5814 (status Approved)

{ITDB} Interface issues #59 and #61, updated hazard items #003, #059 and #062.

3.2.4 FMECA

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-84-1. Per the System V&V Plan, the document was reviewed by Kalypto Medical Inc., Minnetronix Technical and QA personnel.

Current status:

Document has been formally reviewed. Changes to this document since formal review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

DP-0001-84-1, Rev 001-a, updated for this release.

References:

ECO 5814 (status Approved)

{ITDB} Interface issues #59 and #61, updated FMECAs 57025, 57026, 56378, 56380, 57026, 56626, and 56318.

{ITDB} Pump Device issue #20, updated FMECA 57117.

3.2.5 Customer Requirements Specification

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-84-5. Per the System V&V Plan, the document was reviewed by Kalypto Medical Inc., Minnetronix Technical and QA personnel.

Current status:

DP-0001-84-5, Rev 001-a, no changes for this release. Note: Change from .01-a to 001-a was just a revision change for Production release (see ECO 5694, status Effective).

3.2.6 System Requirements Specification

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-84-2. Per the System V&V Plan, the document was reviewed by Kalypto Medical Inc., Minnetronix Technical and QA personnel.

Current status:

Document has been formally reviewed. Changes to this document since formal review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

DP-0001-84-2, Rev 002-a, updated for this release.

References:

ECO 5990 (status Approved)

{ITDB} Pump Device issues #19, #20 and #22, updated SYSREQs 54725, 53786, 54672 and 54745.

3.2.7 Usability Specification

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-84-7. Per the System V&V Plan, the document should be reviewed by Kalypto Medical Inc., Minnetronix Technical and QA personnel.

Current status:

Document has not been formally reviewed. Capricorn – Interface issue #58 opened, currently Unresolved.

3.2.8 Design Documentation

This documentation is controlled by Mntx developers and includes system design documentation. Per the System V&V Plan, the System Design Specification, identified as Mntx P/N: DP-0001-83-9, and the User Interface Design document, identified as Mntx P/N: DP-0001-84-4, were reviewed by Kalypto Medical Inc., Minnetronix Technical and QA personnel. Per the System V&V Plan, the Software Design document, identified as Mntx P/N: DP-0001-84-3 does not require formal review.

Current status:

Document has been formally reviewed. Changes to this document since formal review have been tracked utilizing Outlook {DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

DP-0001-83-9, Rev 001-a, updated for this release.

DP-0001-84-3, Rev 001-a, no changes for this release. Note: Change from .01-a to 001-a was just a revision change for Production release (see ECO 5694, status Effective).

DP-0001-84-4, Rev 002-a, updated for this release.

References:

Design documents:

System Design Spec:

ECO 5973 (status Approved)

{ITDB} Pump Device issue #20, updated block diagram, power budget, battery life calculations, and design options/decisions.

UI Design:

ECO 5990 (status Approved)

{ITDB} Interface issue #59, updated for changes to pump and pressure sensor checks.

Source Code reviews and walkthroughs:

No changes for this release.

PCBs, Schematics, and Enclosures:

{ITDB} Meeting ID#1883, name Capricorn Pump Module Rev 002-a PCB Design Review, dated 3/06/08.

{ITDB} Meeting ID#1882, name Pump Module Rev 002-a Schematic Review, dated 3/05/08.

3.2.9 Unit and Integration Test

This documentation is controlled by Mntx developers. Unit testing is performed per Mntx document Hardware Unit Testing Guideline and Software Testing Guideline. Requirements that are deferred to Unit and/or Integration test are identified in the {VTP}.

Current Status:

Unit and integration tests have been completed.

References:

Normal Unit Test (NUT) and Heavy Unit Test (HUT):

{DHF} Engineering Notebook #397 pages 39-41, author Greg Ludwig (covers Interface issues #59, #60 and #62).

{DHF} See Mntx Internal Memo titled "Stuck Solenoid Valves in Pre-Production Build v03" dated 3/06/08, author Michael Tvedt as attached to Pump Device issue #21.

{DHF} See Mntx Internal Memo titled "Leaky Pumps in Pre-Production Build v01.doc" dated 3/11/08, author Michael Tvedt as attached to Pump Device issue #19.

Requirements Deferral to Unit and/or Integration Test:

No changes for this release.

3.2.10 Requirements Verification Test Procedures

This documentation is controlled by Mntx, and identified as Mntx P/N: DP-0001-84-0. Per the System V&V Plan, the document was reviewed by Kalypso Medical Inc., Minnetronix Technical and QA personnel.

Current status:

Document has been formally reviewed. Changes to this document since formal review have been tracked utilizing Outlook

{DHF} and/or the Minnetronix Issue Tracking Database {ITDB}.

DP-0001-84-0, Rev 002-a, updated for this release.

References:

ECO 5990 (status Approved)

{ITDB} Interface issues #59 and #60, updated SYSTSTs 55813 (Low Battery) and 55815 (System Fault).

{ITDB} Pump Device issues #19 and #22, updated SYSTSTs 55822 (Pressure Loss Prevention), 55819 (Continuous Pump Life) and 55820 (Intermittent Pump Life).

3.2.11 Traceability**3.2.11.1 Requirements**

Traceability between system requirements and verification tests has been entered into the Caliber requirements management database. Traceability has been independently reviewed by QA personnel.

References:

No changes since last release. Note: Updates to {SysRS} and {VTP} did not affect traces.

3.2.11.2 Design

Traceability between requirements and design is not required for the Capricorn NPWT System per the System V&V Plan.

3.2.11.3 FMECA

Traceability between failure modes and requirements has been entered into the Caliber requirement management database.

References:

No changes since last release. Note: Updates to {FMECA} did not affect traces.

3.2.11.4 Risk Assessment / Hazard Analysis

Traceability between Hazard Analysis and system requirements has been entered and exists in the Hazard Analysis document.

Traceability has been independently reviewed by QA personnel.

References:

No changes since last release. Note: Updates to {HA} did not affect traces.

3.2.12 Issue/Discrepancy Handling

All issues in the Minnetronix Issue Tracking Database have been addressed and closed with the exceptions noted in the attached Open/Future issue lists.

3.2.13 Configuration and Data Control

Configuration management has been performed in accordance with {SDP}, {VVP} and Minnetronix SOPs.

3.2.14 Supplier Issues

All vendors have been qualified as required by Mntx SOPs.

3.2.15 Tool Qualification

Capricorn System V&V Plan states that all development and verification tools will be qualified for use.

No new software tools were used since the Rev. 001-a verification report was issued. See the previous verification report for a complete list of qualified tools.

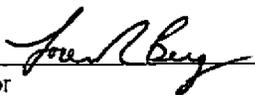
4 Recommendations

All requirements as specified by {SysRS} have been met. The remaining open issues have been reviewed and are deemed acceptable for this release.

Capricorn hardware, Mntx part numbers AE-0000-83-2 (Control Unit), AE-0000-83-3 (Continuous Pump Module) and AE-0000-83-4 (Intermittent Pump Module), and software, Mntx part number SE-0000-17-0 (Embedded Software), are acceptable for Production release to the customer.

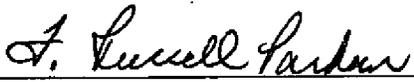
Release updated Capricorn NPWT System documentation to Kalypto Medical, Inc.

5 Approvals



Author

4/24/08
Date



Reviewed By

4/24/2008
Date

Test Result Data Sheets
for the
completion of execution of Rev. 001-a of the VTP

(11 pages, excluding this one)

Requirement Detail Report

Requirement Detail

Project: Capricorn

Date: 4/1/2008

3.3		Test Case FT003 - Therapy Duration		SYSTST55818
Details				
Owner:	lberg	Version:	7.1	Status: Accepted
Type:	System Test (SYSTST)	Priority:	Traceable Requirement	
Description:	<p>Introduction This test will verify . . .</p> <p>a. The Micro NPWT device shall be able to achieve and maintain a vacuum pressure down to 40 mmHg for 6 weeks of therapy, regardless of therapy mode. b. The Micro NPWT device shall be able to achieve and maintain a vacuum pressure up to 125 mmHg for 6 weeks of therapy, regardless of therapy mode. Note: clinically proven nominal therapy pressure is 125 mmHg. c. The tolerance of all set pressures in the Micro NPWT device shall be +/- 10% unless otherwise specified.</p> <p>Note: The duration of this test is 6 weeks.</p> <p>Test Setup</p> <ol style="list-style-type: none"> Standard setup. Stopwatch. Two (2) complete Continuous therapy devices and two (2) complete Intermittent therapy devices. One of each therapy type set to 40 mmHg and the other set to 125 mmHg. Four (4) independent pressure sensors hooked up to a data acquisition unit. Connect pressure sensors in-line with the bandage tubing. Incorporate an artificial leak rate of 10 mmHg/hour per SYSREQs 54672 and 54745. <p>Test Procedures and Expected Results</p> <ol style="list-style-type: none"> Start this test with all device batteries removed. Place new batteries in each control unit, allowing each device to power up and complete self tests. <ul style="list-style-type: none"> <input checked="" type="checkbox"/> P/F a. Verify that all of the devices power up successfully with no user notifications present. Turn all the pumps on. Start the stopwatch (record the date and time) and allow the devices to run for 6 weeks. Note: if a leak occurs, correct the leak and continue the test. Note: if a low battery notification occurs, record the date and time of battery replacement and continue therapy. If necessary, extend the test run time to compensate for time lost to leaks or time lost to low or dead batteries. <ul style="list-style-type: none"> <input checked="" type="checkbox"/> P/F a. Verify that two of the pumps (one of each therapy type) turn on and deliver negative pressure wound therapy at 40 mmHg +/- 10%. <input checked="" type="checkbox"/> P/F b. Verify that two of the pumps (one of each therapy type) turn on and deliver negative pressure wound therapy at 125 mmHg +/- 10%. <input checked="" type="checkbox"/> P/F c. Verify that all of the devices achieve 6 weeks of therapy run time at either 40 mmHg +/- 10% or at 125 mmHg +/- 10% respectively. <input checked="" type="checkbox"/> P/F d. Verify that all of the devices achieve 6 weeks of therapy run time without 			

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3/31/08

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Requirement Detail Report

suffering from a system fault (see SYSREQ54795 for system fault definitions).

Traceability

	Backward	Suspect	Forward	Suspect
Minimum System Vacuum		TRUE		
Set Point Pressure Tolerance		TRUE		
Maximum System Vacuum		TRUE		

Capnicorn

sheet #1

DP-0001-84-0 Rev. 02-a

Step 6.2 SRO02 Continuous Pump Life

AE-0000-83-2 S/N 000012 Software 06 4 pull up

AE-0000-83-3 S/N 000011 Continuous

125 mmHg

BANDAGE

Monday

1/28/08 1:18P new batteries Intermittent #1

1/29/08 2:05P no problems

1/30/08 2:20P

Tue 1/31/08 10:32 AM

2/1/08 1:14 PM

2/4/08 11:38 AM

2/5/08 9:58 AM

2/6/08 1:53 PM

2/7/08 11:27 AM Low BATT DISPLAYED + SOUNDED

2/8/08 3:40 PM " " " "

DOWNTIME < NOT WORKING WHEN THERAPY STOPPED OVER THE WEEKEND

2/11/08 9:15 AM " " " " CAN NOT START THERAPY
CHANGED BATTERIES (9:20 AM)

2/12/08 3:23 PM No PROBLEMS

2/13/08 8:38 AM

2/14/08 9:35 AM (MT) Leak Alarm - unit top off every 5 seconds. Fixed leakage by pressing on bandage

2/15/08 11:38 AM Tue LEAK ALARM, FIXED LEAK

2/18/08 11:04 AM No PROBLEMS

2/19/08 4:34 PM

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CAPRICORN (CONTINUED)

Sheet #2

2/20/08	12:37 pm	NO PROBLEMS	
2/21/08	9:25 am	}	
2/22/08	9:22 am		
2/23/08	9:17 am	LOW BATTERY DISPLAYED + SUMMER	
2/24/08		" " " FREQUENT TSP OFFS	
2/25/08		SWITCHED TO BATTERY CONTINUOUS #3	
2/26/08	10:30 am	" " "	
2/27/08	10:02 am	" " "	
2/28/08	1:19 pm	" " " , SYSTEM RESET, PUMP OFF	
		REPLACED BATTERIES, RESTARTED PUMP	
2/29/08	9:50 am	NO PROBLEMS	
3/3/08	9:15 am	}	
3/4/08	10:35 am		
3/5/08	11:15 am		
3/6/08	10:58 am		
3/7/08	12:45 pm		
SCHEDULED END DATE → 3/10/08 MONDAY	10:38 am		
ADD 2 DAYS DUE TO DOWNTIME	3/11/08		11:34 am
	3/12/08		6:04 pm
	3/13/08		9:34 am
	3/14/08		3:14 pm
	3/17/08		4:00 pm
	3/18/08		11:38 am
END TEST	3/20/08		1:33 pm
TEST DURATION	> 7 WEEKS		

AE-0000-83-2 S/N 000012 CONTROL

AE-0000-83-3 S/N 000011 CONTINUOUS

Capricorn

sheet #1

DP-0001-84-0 Rev 02-a

Step 6.2 SRO02 Continuous Pump Life

AE-0000-83-2 s/n 000014 Software v6.4 full up

AE-0000-83-3 s/n 000010 Continuous

40 mmHg

1/28/08 1:35 P new batteries ^{BRIDGE} Intermittent #2

1/29/08 2:05 P no problems

1/30/08 2:20 P

2/1/08 10:22 Am

2/1/08 1:14 PM

2/4/08 11:39 Am

2/5/08 9:58 Am

2/6/08 1:53 PM

2/7/08 11:28 Am

2/8/08 3:40 PM

2/11/08 9:15 Am

2/12/08 3:24 PM

2/13/08 8:38 Am

2/14/08 9:35 AM (M)

2/15/08 1:21 PM 2/15

2/18/08 11:04 Am

2/19/08 4:34 PM

2/20/08 12:33 PM

2/21/08 9:25 Am

CAPRICORN (CONTINUED)

sheet #2

2/2	2/22/08	9:22 AM	NO PROBLEMS
	2/25/08	9:17 AM	
	2/26/08	10:30 AM	LOW BATTERY SWAPPED AND DISARMED
	2/27/08	10:02 AM	" " "
	2/28/08	1:18 PM	" " "
	2/29/08	9:50 AM	" " "
DOWN TIME NOT KNOWING WHEN THERAPY STOPPED OVER THE WEEKEND	3/3/08	9:12 AM	" " " PUMP OFF, RESTARTED, RESET, CHANGED BATTERIES
		9:15 AM	RESTARTED, NO PROBLEMS
	3/4/08	10:55 AM	}
	3/5/08	11:15 AM	
	3/6/08	10:58 AM	
	3/7/08	12:45 AM	
SCHEDULED END DATE	3/10/08	10:38 AM	
ADD 2 DAYS FOR DOWN TIME	3/11/08	11:34 AM	
	3/12/08	6:04 PM	
	3/13/08	9:37 AM	
	3/14/08	3:14 PM	
	3/17/08	4:00 PM	
	3/18/08	11:38 AM	
	3/20/08	1:34 PM	
	3/24/08	3:01 PM	
	3/31/08	2:56 PM	

TEST DURATION → 8 WEEKS

AE-0000-83-2 S/N 000014 Control

AE-0000-83-3 S/N 000010 Continuous

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Capnicorn

sheet #1

DP-0001-84-0 Rev. 02-a

Step 6.2 SRO02 Continuous Pump Life

AE-0000-83-2 S/N 000018 Software 06 4 pull up

AE-0000-83-4 S/N 000003 Intermittent
125 mm Hg

1/22/08 1:58P new batteries ^{BANDAGE} Intermittent #3

1/29/08 2:05P no problems

1/30/08 2:20P

708 1/31/08 10:32 AM

2/1/08 1:15 PM

2/4/08 11:39 AM

2/5/08 9:59 AM

2/6/08 1:54 PM

2/7/08 11:29 AM Low BATTERY DISPLAYED + SOUNDED

2/8/08 3:40 PM " " "

2/11/08 9:15 AM SYSTEM FAULT DISPLAYED, Cycled Power, ran o.k. (VENT OPENED)

2/11/08 5:05 PM SYSTEM FAULT DISPLAYED

2/11/08 5:16 PM Test Resumed Error Code 072

5:17 PM Not to pressure Major Leak alarm

Bandage seal checked - pump stopped

turning on ~ 1 per second now

could not fix leak moved to "Int #5" Bandage

System Fault 072 REPLACED SOLENOID VALVE 2/14/08

2/14/08 1:17 PM SYSTEM RESTARTED ~~NO PROBLEMS~~ ^{BANDAGE} Intermittent #3

CAPRICORN (CONTINUED)

sheet #2

	2/14/08	6:05 am	SYSTEM FAULT DISPLAYED, CYCLED POWER, CONTINUED TEST
Downtime	2/15/08	11:38 am	" / SYSTEM FAULT 72 SOLENOID VALVE FAILURE
	2/19/08	10:47 am	SYSTEM ABANDONED, LOW BATTERY DISPLAYED + SOUND
		11:43 am	SYSTEM FAULT DISPLAYED, SYSTEM FAULT 72 SOLENOID VALVE FAILURE INSPECTED PUMP MODULE, CYCLED POWER, RESTARTED THERAPY
		11:11 am	SYSTEM FAULT DISPLAYED, VERIFIED PUMP MODULE OPERATION ON TEST FIXTURE, RESTARTED THERAPY
	2/20/08	10:14 am	SYSTEM FAULT DISPLAYED, FAULT 72, LOW BATTERY
		6:03 pm	REPLACED BATTERIES, RESTARTED THERAPY, NO PROBLEMS
	2/21/08	9:24 am	}
	2/22/08	9:23 am	
	2/23/08	9:16 am	LOW BATTERY + LEAK DISPLAYED, FIXED LEAK
			SWITCH TO BATTERY CONTINUOUS #2
	2/26/08	10:30 am	LOW BATT DISPLAYED + SOUND
	2/27/08	10:02 am	" " "
	2/28/08	1:22 pm	SYSTEM FAULT DISPLAYED, CODE 72, CYCLED POWER AND RESTARTED PUMP
		5:16 pm	SYSTEM FAULT DISPLAYED, CODE 72, TURNED OFF DEVICE FOR SERVICE
Downtime	2/29/08	2:30 pm	REPLACED BATTERIES, RESTARTED THERAPY, NO PROBLEMS
	3/2/08	9:14 am	} AE-0000-83-2 S/N 000018 Control AE-0000-83-4 S/N 000003 Intermittent
	3/4/08	10:55 am	
	3/5/08	11:15 am	
	3/6/08	10:59 am	
	3/7/08	12:44 pm	
SCHEDULED END DATE	3/10/08	10:35 am	LOW BATTERY DISPLAYED + SOUND
ADD	3/11/08	11:35 am	" " "
	3/12/08	6:04 pm	" " "
	3/13/08	9:52 am	SYSTEM FAULT DISPLAYED, CODE 72, CYCLED POWER AND RESTARTED PUMP
		4:54 pm	" " " , CODE 72, REPLACED BATTERIES, RESTARTED THERAPY, NO PROBLEMS

CAPLICON (CONTINUED)

Sheet #2 #3

MS	3/14/08	3:14 Am	} NO PROBLEMS
	3/17/08	4:00 Am	
	3/18/08	11:39 Am	
	3/20/08	1:32 Am	

END TEST →
 MS
 TEST DURATION > 6 WEEKS

AE-0000-83-2	S/N 000018	Control
AE-0000-83-4	S/N 000003	Intermittent

Capricorn

Sheet #1

DT-0001-84-0 Rev. 02-a

STEP G.2 STROOK Continuous Pump Life

AE-0000-83-2 S/N 000015 Software 06

AE-0000-83-4 S/N 000005 Intermittent
40 mm Hg

Date	Time	Notes
1/28/08	2:04 P	new batteries ⁸⁰⁰⁰⁶ Continuous #1
1/29/08	2:05 P	no problems
1/30/08	2:20 P	}
1/31/08	10:33 AM	
2/1/08	1:15 PM	
2/4/08	11:39 AM	
2/5/08	9:59 AM	
2/6/08	1:54 AM	
2/7/08	11:30 AM	
2/8/08	3:40 PM	Low Battery Displayed
2/11/08	9:15 AM	" " " AND SOUNDED
2/10/08	3:24 PM	" " " "
2/13/08	8:39 AM	" " " "
2/14/08	9:35 AM	(MT) Therapy off - Low Battery Therapy restarted OK
2/15/08	11:39 AM	zab Therapy off - Low Battery, RESTARTED THERAPY
	11:44 AM	Therapy off, CAN NOT RESTART, REPLACED BATTERIES
2/18/08	11:05 AM	NO PROBLEMS
2/19/08	4:34 PM	}

CAPRICORN (CONTINUED)

sheet #2

	2/20/08	12:36 PM	NO PROBLEMS	
	2/21/08	9:24 AM	}	
	2/22/08	9:24 AM		
	2/25/08	9:16 AM		
	2/26/08	10:30 AM	LOW BATTERY DISPLAYED & SUCCESS	
	2/27/08	10:02 AM	" " "	
	2/28/08	1:18 PM	" " "	
	2/29/08	9:51 AM	" " "	
DOWNTIME NOT KNOWN WHEN THERAPY STOPPED OVER THE WEEKEND	3/3/08	9:12 AM	" " "	PUMP OFF, RESTARTED
	3/4/08	10:44 AM	" " "	PUMP OFF, RESTARTED, RESET, CHANGED BATTERIES
		10:55 AM		RESTARTED, NO PROBLEMS
	3/5/08	11:15 AM	}	
	3/6/08	10:59 AM		
	3/7/08	12:44 PM		
		12:51 PM	FAILED TEST BECAUSE OF LOW BATTERY → PUMP MOBILE DUE TO IT BEING A BREAKOUT MIXTURE. CUT JUNCTION ARE FOR 5V 2AB	
		1:06 PM	RESTARTED TEST, NO PROBLEMS	
SCHEDULED END DATE	→ 3/10/08	10:35 AM	}	
ADD 3 DAYS + 15 MINUTES FOR DOWN TIME	3/11/08	11:35 AM		AE-0000-83-2 S/N 000015 Control
	3/12/08	6:05 AM		AE-0000-83-4 S/N 000005 Intermittent
	3/13/08	9:33 AM		
	3/14/08	3:14 PM		
	3/17/08	10:46 AM	LOW BATTERY DISPLAYED & SUCCESS	
	3/18/08	11:39 AM	" " "	
	END TEST	2:30 PM	" " "	

TEST DURATION > 6 WEEKS

Test Result Data Sheets
for the
regression execution of Rev. 002-a of the VTP

(25 pages, excluding this one)

Test Equipment

Capricorn FT004a, FT002b, SR001, SN001, SN003

A	DC Power Supply Topward 3306D	S/N 746669	814
B	DC volt Meter max 37XR	Cal due 12/11/08	527
C	Timer Hanhart Delta E100	Cal due 9/6/08	662
D	Capricorn Control Units programmed with Version 08 Software		
E	Control	AE-0000-83-2 S/N 000023	
F	Pump Intermittent	AE-0000-83-4 S/N 000008-2	
G	Pump Continuous	AE-0000-83-3 S/N 000016	
H	Pressure Transducer Utah Medical Veri-Cal	650-900 S/N 1072090-003 1072090-007	
I		Cal due 11/14/09	889
		S/N 1072090-001	
		Cal due 1/2/09	893
J	Timer Hanhart Delta E100	Cal due 9/6/08	661
K	Capricorn Control	AE-0000-83-2 S/N 000025	
L	Pump Continuous	AE-0000-83-3 S/N 000015	
M	Control	AE-0000-83-2 S/N 000013	
N	Pump Continuous	AE-0000-83-3 S/N 000013	
O	Pump Intermittent	AE-0000-83-4 S/N 000008-1	
P	Control	AE-0000-83-2 S/N 000024	
Q	Pump Intermittent	AE-0000-83-4 S/N 000008-3	
R	DC Power Supply Topward 6303A	S/N 664541	140

EGJ
4/1/08

Requirement Detail Report

Requirement Detail

Project: Capricorn

Date: 4/4/2008

3.1		Test Case FT001 - Power On Self Tests	SYSTST55788
Details			
Owner:	Iberg	Version:	11.0
Status:	Accepted		
Type:	System Test (SYSTST)	Priority:	Traceable Requirement
Description:			
Introduction This test will verify . . .			
<p>a. The Micro NPWT device shall perform the following power on self test (POST) checks each time batteries are changed in the control/display unit:</p> <ul style="list-style-type: none"> • UI Display test • Audio test • ALU test (test via Unit Test) • RAM test (test via Unit Test) • Application CRC check (test via Unit Test) • Watchdog test (test via Unit Test) • Key Stuck test 			
<p>b. The Micro NPWT device shall notify the user if any of the power on self test checks failed, thus indicating that the device is unable to deliver therapy.</p>			
<p>c. The Micro NPWT device shall notify the user if a system fault occurs. Note: system faults consist of POST failures, NVRAM failures, loss of pump control, pump inoperable, and the inability to provide intermittent therapy. Note: if the ALU, RAM, CRC, or Watchdog portion of the POST tests fail, it may not be possible to inform the user because the processor and/or software is not functioning properly in those cases. (only POST failure tested here)</p>			
<p>d. When POST has successfully completed, the software shall place the software version number on the display for 2 seconds.</p>			
Test Setup			
<ol style="list-style-type: none"> 1. Standard setup. 2. Control unit set to Continuous therapy mode. 3. Stopwatch. 			
Test Procedures and Expected Results			
<ol style="list-style-type: none"> 1. Start this test with device batteries removed. Re-insert the batteries and allow power on self tests to complete. <ul style="list-style-type: none"> <input checked="" type="checkbox"/> a. Verify that a UI Display test occurred (all UI display screen elements are turned on, then off). <input checked="" type="checkbox"/> b. Verify that an audio test occurred (three beeps are sounded per the User Interface Design document, DP-0001-84-4). <input checked="" type="checkbox"/> c. Verify that power on self tests all pass and that no system faults occurred. <input checked="" type="checkbox"/> d. Verify after POST has completed, that the software version number is displayed for 2 seconds. <i>displayed "08"</i> 			
<ol style="list-style-type: none"> 2. Remove the device batteries. Press and hold the Pump On/Off key and re-insert the 			

*JAB
4/4/08
Step 1-3 only*

*AE-0000-03-2
S/N 000022*

*JAB
4/4/08
JAB
4/4/08
JAB
4/4/08
JAB
4/4/08*

Requirement Detail Report.

batteries. Allow power on self tests to complete. Repeat this step for the Mode and VAC keys.

*JAS
4/4/08*

P/F a. Verify that the power on self test for key stuck failed and that the device displays a system fault (all UI display screen elements are blinked multiple times).
SYSTEM FAULT FOR EACH OF THE 3 KEYS.

3. Attempt to start the pump (press the Pump On button) and deliver continuous therapy.

*JAS
4/4/08*

P/F a. Verify that the pump does not start and that it continues to display a system fault.

4. Repeat steps 2 and 3 with the Control unit set to Intermittent therapy mode.

P/F a. Verify results are as expected (1. power on self test for key stuck failed and system fault displayed. 2. pump does not start and continues to display a system fault).

Traceability

	Backward	Suspect	Forward	Suspect
Power On Self Test Check		TRUE		
System Fault Indication		TRUE		
POST Failure		TRUE		
Software Version Number		TRUE		

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Requirement Detail

Project: Capricorn

Date: 03/14/08

Test Case FT002b - Intermittent Mode

Details

Owner:	Iberg	Version:	13.0	Status:	Accepted
Type:	System Test (SYSTST)	Priority:	Traceable Requirement	Caliber ID:	SS817

Description: Introduction

This test will verify ...

a. The Micro NPWT system shall deliver intermittent V.A.C. therapy up to 125 mmHg.

Note: V.A.C. = vacuum assisted closure of wounds.

b. The intermittent mode cycle time of the Micro NPWT device shall be 5 minutes at the target negative pressure then 2 minutes at atmospheric pressure. Note: this cycle is repeated for the duration of the therapy.

c. The Micro NPWT device shall notify the user if a system fault occurs. Note: system faults consist of POST failures, NVRAM failures, loss of pump control, pump inoperable, and the inability to provide intermittent therapy. Note: if the ALU, RAM, CRC, or Watchdog portion of the POST tests fail, it may not be possible to inform the user because the processor and/or software is not functioning properly in those cases. (Note: only inability to provide Intermittent therapy tested here)

Test Setup

1. Standard setup (control unit w/Intermittent pump unit).
2. One independent pressure sensor connected in-line with the bandage tubing.
3. Stopwatch.
4. Jumper installed in-line with resistor R2 per the Capricorn Pump Module Schematic, Mntx part # DS-0000-70-5.

Test Equipment: C, H, P, Q, D

Test Procedures and Expected Results

1. Enter Configuration mode, press the VAC button until the vacuum pressure is set to 125 mmHg. Exit Configuration mode and turn the pump on. Wait at least 3 minutes per SYSREQ54730 for initial bandage negative pressure drawdown. Allow the unit to run for a minimum of 4 hours. Note: if a leak occurs, correct the leak and continue the test. If necessary, extend the test run time to compensate for time lost to the leak. Using the stopwatch, record the times when the pump starts up and when the purge valve opens. Calculate the average of these readings. These times are used to determine the Intermittent mode cycle times.

EGJ 3/26/08 PF a. Verify that no system fault notifications occur (ie. loss of pump control or pump inoperable) due to the inability of the system to deliver and maintain 125 mmHg of negative pressure Intermittent therapy over a 4 hour duration.

EGJ 3/26/08 PF b. Verify that the independent pressure sensors confirm the 125 mmHg negative pressure setpoint is achieved.

EGJ 3/26/08 PF c. Verify the Intermittent mode cycle times average 5 minutes at the target negative pressure and 2 minutes at atmospheric pressure. *see attachment*

2. With the device and pump still on, open the jumper at R2 and add a 10 kohm resistor on the U2 side of R2 to ground, thus removing control of the purge valve (ie. keeps it shut so it can not open and vent to atmosphere). Wait at least 10 minutes allowing the pump time to cycle 5

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Requirement Detail Report

min. at the pressure setpoint and 2 min. at atmosphere.

EG
3/26/08

PF a. Verify that the device notifies the user that the Intermittent pump module is unable to provide Intermittent therapy (ie. pressure sensor determines that it can not vent to atmosphere).

3. Remove the batteries from the device. Replace the jumper at R2. Replace the batteries and allow power on self tests to complete. Turn the pump on. Wait at least 10 minutes.

EG
3/26/08

PF a. Verify that no system fault notifications occur and that the Intermittent pump module is able to provide Intermittent therapy.

Traceability

	Backward	Suspect	Forward	Suspect
Intermittent Mode Requirement		TRUE		
Intermittent Mode Cycle Time		TRUE		
System Fault Indication		TRUE		

FT002b - Intermittent Mode
Capnicon

Caliber: 55817

Intermittent set to Intermittent 125mmHg

Time (1)			Time (2)		Time (3)	
start	hrs:min:sec	Pressure	hrs:min:sec	Pressure	hrs:min:sec	
06:40	0:00:00	125.7	1:06:48	3.5	4:12:45	1.9
3/26/08			1:08:45	117.6		
			1:18:40	3.6	4:15:20	pump on
06:48	0:00:00	121.9	1:15:37	121.5	4:16:08	leak
3/26/08	0:4:57	3.4	20:32	3.4	12:05	
	0:6:54	127.7	22:30	123.8	18:03	
	11:55	3.7	27:29	3.7	19:02	
	13:47	122.1	29:22	123.0	20:02	system fault
	18:41	3.6				removed batteries
	20:39	126.0	3:31:04	3.4		
	25:35	3.5	3:33:00	122.8	0:00	replaced batteries
	27:32	126.5	3:37:55	3.5	4:51	121.8
	32:26	3.5	3:39:54	125.5	6:49	3.6
	34:24	120.9	3:44:48	3.4	11:44	120.1
	39:20	3.5	3:46:44	123.1	13:41	3.4
	41:15	121.5	51:39	3.5		124.1
	46:11	3.3	53:36	121.5		
	48:08	126.2	58:31	3.4		
	53:03	3.6	4:00:28	126.2		
	55:02	127.5	2:25	3.5		
	0:59:55	3.5	7:22	128.0		
	1:01:53	126.0				

GGJ
3/26/08

Requirement Detail Report

Requirement Detail

Project: Capricorn

Date: 03/14/08

Test Case SR001 - Simulated User Evaluation

Details

Owner:	Iberg	Version:	2.1	Status:	Accepted
Type:	System Test (SYSTST)	Priority:	Traceable Requirement	CALIBER ID:	SS540

Description: Introduction
 This test will attempt to simulate actual user inputs and use conditions for the Capricorn NPWT System.

Test Setup

1. Standard setup.

Test Equipment: D, H, P, N, O

Test Procedures and Expected Outputs

1. Activate and deactivate the pump, change control unit parameters, remove and replace the device batteries (repeated power cycles), cause control unit faults to occur, cause multiple faults to occur, etc. Put the NPWT System hardware and software through its paces. Record any errors, failures, or anomalies found. If possible, record the condition(s) leading to the error, failure, or anomaly.

GGJ
3/25/08
 Traceability

P/F a. N/A (There are no expected outputs or pass/fail criteria associated with this test case).

see attachment

Backward

Suspect

Forward

Suspect

*FOCUS TEST ON TUNING
 OFF THERAPY WHILE
 THE PUMP IS RUNNING.
 REPEAT MULTIPLE TIMES.
 (PER INTERFACE ISSUE 62)
 SEE ME.*

SZ001 - Simulated User Evaluation
Capricorn

Caliber: 55540

CONTINUOUS 125mmHg

1) Pass ran 25 Times

~~Intermittent~~ set to ~~Intermittent~~ 125mmHg

1) Pass ran 25 Times

~~Intermittent~~ set to CONTINUOUS 125mmHg

1) Pass ran 25 Times

520

[Signature]
3/25/08

Requirement Detail Report

Requirement Detail

Project: Capricorn

Date: 3/21/2008

3.4.1 Test Case FT004a - Pressure Loss Prevention		SYSTST55822
Details		
Owner:	lberg	Version: 5.0
Type:	System Test (SYSTST)	Status: Accepted
Description:	Introduction This test will verify . . .	
	<p>a. The Micro NPWT device shall prevent a loss of vacuum pressure of no more than 100 mmHg/hour from a control volume of 60 cc to the pump when the pump is in the off state.</p> <p>Test Setup</p> <ol style="list-style-type: none"> 1. Standard setup. 2. One independent pressure sensor. 3. One 60 cc minimum syringe for use as a control volume. 4. One complete Intermittent therapy device and one complete Continuous therapy device. 5. Connect the independent pressure sensor in-line with the syringe tubing, then connect to the pump unit under test. Do not connect to a bandage. 6. Stopwatch. <p>Note: Pre-test all the tubing connections and the syringe for leaks prior to starting this test. Correct all leaks before continuing.</p> <p><i>Test Equipment: C, D, E, L, H</i></p> <p>Test Procedures and Expected Results</p> <p>Continuous Therapy Device</p> <ol style="list-style-type: none"> 1. Set the vacuum pressure to 125 mmHg. Turn the pump on. When the device achieves the vacuum pressure setpoint and the pump stops running, start the stopwatch. Record the pressure reading from the independent pressure sensor. Remove connector P1 (To Pump) per the Capricorn Pump Module Schematic, Mntx part # DS-0000-70-5. This will keep the pump from turning back on. Wait exactly 1 hour. Record the pressure reading from the independent pressure sensor. Calculate and record the delta pressure change between the two readings. Replace connector P1. Repeat this step 4 additional times and calculate the average of these delta pressure readings. <p><i>CG 3/19/08</i> PF a. Verify that the Continuous device's loss of vacuum pressure is no more than 100 mmHg/hour (averaged over 5 hours) when the pump is in the off state. <i>7.36 mmHg see attachment #1</i></p> <p><i>Test Equipment: J, D, K, F, I</i></p> <p>Intermittent Therapy Device</p> <ol style="list-style-type: none"> 2. Set the Intermittent device to Continuous mode. Set the vacuum pressure to 125 mmHg. Turn the pump on. When the device achieves the vacuum pressure setpoint and the pump stops running, start the stopwatch. Record the pressure reading from the independent pressure sensor. Remove connector P1 (To Pump) per the Capricorn Pump Module Schematic, Mntx part # DS-0000-70-5. This will keep the pump from turning back on. Wait exactly 1 hour. Record the pressure reading from the independent pressure sensor. Calculate and record the delta pressure change between 	

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FT004a - Pressure Loss Prevention
 Capricorn

attachment #1
 Caliber: 55822

Continuous 125 mm Hg

	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>
to min					
Start Time	00:00	0:00	0:00	0:00	0:00
Finish	1:05	1:00	1:00	1:00	1:00
Start mmHg	128.2	122.3	133.7	129.3	126.4
Finish	121.0	115.0	125.7	122.0	119.4
delta	128.2	122.3	133.7	129.3	126.4
pressure	-121.0	-115.0	-125.7	-122.0	-119.4
change	7.2	7.3	8.0	7.3	7.0

avg of
 delta pressure
 changes $7.2 + 7.3 + 8.0 + 7.3 + 7.0 = 36.8 / 5 = 7.36$

GG
 3/19/08

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FT004a - Pressure Loss Prevention
 Capricorn

attachment #2
 Caliber: 55822

Intermittent set to Continuous 125 mmHg

	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>
	hr min				
Start Time	00:00	0:00	0:00	0:00	0:00
Finish	1:04	1:05	1:06	1:00	1:00
Start mmHg	119.6	126.3	127.6	126.0	128.3
Finish	117.0	124.2	125.4	124.4	127.6
delta	119.6	126.3	127.6	126.0	128.3
pressure	-117.0	-124.2	-125.4	-124.4	-127.6
change	2.6	2.1	2.2	1.6	0.7

avg of
 delta pressure
 changes $2.6 + 2.1 + 2.2 + 1.6 + 0.7 = 9.2$
 $\frac{9.2}{5} = 1.84$

GGJ
 3/19/08

Requirement Detail

Project: Capricorn

Date: 03/17/08

Test Case SN001 - Low Battery

Details

Owner:	lberg	Version:	17.0	Status:	Accepted
Type:	System Test (SYSTST)	Priority:	Traceable Requirement	CALIBER ID:	SS013

Description: Introduction
This test will verify . . .

- a. The Micro NPWT device shall notify the user of a low battery condition.
- b. The Micro NPWT device shall double beep every 5 minutes at a remaining battery capacity of 25%-10% and triple beep every 30 seconds at a remaining battery capacity of <10%.
- c. The low battery indication shall be set inactive when the power source is disconnected (i.e. batteries are replaced) or when the battery voltage returns to a level above the notification threshold.
- d. The Micro NPWT display/control unit shall issue an audio beep tone at a periodic frequency to notify the user to a change in system status requiring their attention.
- e. The Micro NPWT device shall give the user the ability to mute or silence the Leak Detected audio notification. Note: System Fault and Low Battery notifications can not be silenced.
- f. The Micro NPWT display/control unit shall notify the user to changes in status via the pertinent icon.
- g. The backlight shall be turned on for 10 seconds after a button press and whenever a notification becomes active (Note: button presses tested elsewhere).

Test Setup

- 1. Standard setup.
- 2. Variable output DC power supply set to 4.5 VDC, simulating three (3) AA 1.5VDC batteries. Connect to the device under test in place of the 3 batteries using test point E1 (GND) and test point TP2 (Batt +) per the Capricorn Control Unit Schematic, Mntx part # DS-0000-70-3.
- 3. Stopwatch.
- 4. Digital Voltage Meter (DVM).

Test Procedures and Expected Results

- 1. Start this test with the Continuous pump module. Turn on the DC power supply (set to 4.5 VDC), allowing the device to power up and complete self tests. Turn the pump on.

EW

PF a. Verify that the device passes power on self tests and that no system faults occurred.
see attachment #1

Low Battery - Pump Not Running

- 2. Turn the pump off. Slowly reduce the DC power supply voltage until a low battery notification occurs. Record the voltage level which triggered the low battery condition. Note: this is 4.1 VDC for the Continuous pump module and 4.0 VDC for the Intermittent pump module as defined in the software.

EW

PF a. Verify that the low battery notification becomes active (ie. the low battery icon turns on solid, not blinking).

EW

PF b. Verify when the low battery notification becomes active, that the backlight is turned on for 10 seconds.

EW

PF c. Verify that the control unit sounds a double beep every 5 minutes.

see attachment #1

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Requirement Detail Report

Low Battery - Pump Running

3. Turn the pump on. Introduce a bandage leak as the pump motor must be actively running for the software to recognize this low battery condition. Slowly reduce the DC power supply voltage until a low battery notification occurs (25% remaining battery capacity). Remove the cause of the bandage leak. Record the voltage level which triggered the low battery condition. Note: this is 3.3 VDC as defined in the software. *see attachment #1*

EG PF a. Verify that the low battery notification becomes active (ie. the low battery icon turns on solid, not blinking).

EG PF b. Verify when the low battery notification becomes active, that the backlight is turned on for 10 seconds.

EG PF c. Verify that the control unit sounds a double beep every 5 minutes.

EG PF d. Verify that the pump remains on (ie. will run to repressurize if a leak is introduced).

4. Attempt to silence the Low Battery notification by pressing the mute button. *see attachment #1*

EG PF a. Verify that the device does not allow the user to silence/mute the audio notification (ie. double beep continues to sound).

EG PF b. Verify that the pump remains on (ie. will run to repressurize if a leak is introduced).

Critically Low Battery - Pump Running

5. Re-introduce the bandage leak. Continue to slowly reduce the DC power supply voltage until a critically low battery notification occurs (<10% remaining battery capacity). Remove the cause of the bandage leak. Record the voltage level which triggered the critically low battery condition. Note: this is 3.0 VDC as defined in the software. *see attachment #1*

EG PF a. Verify that the low battery notification remains active (ie. the low battery icon remains on solid, not blinking).

EG PF b. Verify when the critically low battery notification becomes active, that the backlight is turned on for 10 seconds.

EG PF c. Verify that the control unit sounds a triple beep every 30 seconds.

EG PF d. Verify that the pump remains on (ie. will run to repressurize if a leak is introduced).

6. Attempt to silence the Low Battery notification by pressing the mute button. *see attachment #1*

EG PF a. Verify that the device does not allow the user to silence/mute the audio notification (ie. triple beep continues to sound).

EG PF b. Verify that the pump remains on (ie. will run to repressurize if a leak is introduced).

Clearing Low Battery

7. Remove the cause of the low battery notification (ie. slowly increase the DC power supply voltage back to 4.5 VDC). *see attachment #1*

EG PF a. Verify that the low battery notification clears (ie. the low battery icon is turned off) when battery voltage rises above the low battery threshold.

EG PF b. Verify that the control unit no longer sounds a triple beep every 30 seconds.

EG PF c. Verify that the pump remains on (ie. will run to repressurize if a leak is introduced).

8. Remove the DC power supply. Install low batteries into the device. Allow the device to power up and complete self tests. Re-introduce the bandage leak and turn the pump on.

EG PF a. Verify that the device passes power on self tests and that no system faults occurred.

EG PF b. Verify that the low battery notification becomes active (ie. the low battery icon turns on solid, not blinking). *see attachment #1*

9. Remove the cause of the low battery notification (ie. replace the low batteries with fresh/new batteries). *see attachment #1*

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Requirement Detail Report

-  PF a. Verify that the device passes power on self tests and that no system faults occurred.
-  PF b. Verify after power cycling the device, that the low battery notification is no longer active (ie. the low battery icon is turned off).
-  10. Repeat steps 1 - 9 using the Intermittent pump module.
- PF a. Verify results are as expected. *see attachment #2*

Traceability

	Backward	Suspect	Forward	Suspect
Low Battery Indication		TRUE		
Beep Mute Capability		TRUE		
Low Battery Beep		TRUE		
Visual Notifications		TRUE		
Audible Notifications		TRUE		
Backlight Operation		TRUE		
Inactivate Low Battery		TRUE		

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SNOO1 - Low Battery
Capricorn

attachment #1
Caliber: 55813

Continuous 125mmHg

Test Equipment: A, B, J, I, M, N, D

1) a) Pass

2) 4.106VDC a) Pass b) Pass 10.2sec c) ^{MIN SEC} Pass 5.04

3) 3.310VDC a) Pass b) Pass 10.2sec
c) ^{MIN SEC} Pass 5.01 d) Pass

4) a) Pass b) Pass

5) 3.029VDC a) Pass b) Pass 9.82sec
c) Pass d) Pass

6) a) Pass b) Pass

7) a) Pass b) Pass c) Pass

8) a) Pass b) Pass

9) a) Pass b) Pass

GGJ
3/20/08 528

SNOO1 - Low Battery
Capricorn

attachment #2

Caliber: 55813

Intermittent set to Continuous

125mmHg

TEST Equipment: A, B, J, I, M, O, D

- 1) a) Pass
- 2) 3.990 vDC a) Pass b) Pass 10.1sec ^{MIN SEC} c) Pass 5.02 ^{MIN SEC}
- 3) 3.326 vDC a) Pass b) Pass 9.8sec c) Pass ^{MIN SEC} 5.02 d) Pass
- 4) a) Pass b) Pass
- 5) 3.033 vDC a) Pass b) Pass 9.8sec
- ~~6) a)~~ c) Pass d) Pass
- 6) a) Pass b) Pass
- 7) a) Pass b) Pass c) Pass
- 8) a) Pass b) Pass
- 9) a) Pass b) Pass
- 10) a) Pass

GGJ

3/20/06

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Requirement Detail Report

Requirement Detail

Project: Capricorn

Date: 3/21/2008

3.11.3		Test Case SN003 - System Fault		SYSTST55815
Details				
Owner:	Iberg	Version:	26.0	Status: Accepted
Type:	System Test (SYSTST)	Priority:	Traceable Requirement	
Description:				
Introduction This test will verify . . .				
<p>a. The Micro NPWT device shall notify the user when the pump module is unable to deliver therapy. Note: pump inoperable consist of solenoid valve failure, pressure sensor failure, and pump motor failure.</p> <p>b. The Micro NPWT device shall notify the user that the pump module is unable to reach the set pressure. Note: If pressure sensed is below the set point refer to SysReq 54683 (tested in SYSTST55811). If pressure sensed is above the set point refer to SysReq 54795.</p> <p>c. The Micro NPWT device shall turn the pump on and verify a pressure drop if the pump has not been activated in the last 3 hours. Note: Upon pump activation, if the pressure drops (ie. negative value goes up), then the device is o.k. If it does not drop, we signal a system fault as the pressure sensor is faulty (refer to SYSREQ54685). Note: 3 hr activation with device o.k. is tested via Unit test.</p> <p>d. The Micro NPWT device shall notify the user if a system fault occurs. Note: system faults consist of POST failures, NVRAM failures, loss of pump control, pump inoperable, and the inability to provide intermittent therapy. Note: if the ALU, RAM, CRC, or Watchdog portion of the POST tests fail, it may not be possible to inform the user because the processor and/or software is not functioning properly in those cases. (POST failures tested in SYSTST55788, NVRAM failures tested via Unit test)</p> <p>e. The system fault indication shall be set inactive when power is cycled to the device. Note: this means battery removal and replacement.</p> <p>f. The Micro NPWT display/control unit shall issue an audio beep tone at a periodic frequency to notify the user to a change in system status requiring their attention.</p> <p>g. The Micro NPWT device shall give the user the ability to mute or silence the Leak Detected audio notification. Note: System Fault and Low Battery notifications can not be silenced.</p> <p>h. The Micro NPWT display/control unit shall notify the user to changes in status via the pertinent icon.</p> <p>i. The backlight shall be turned on for 10 seconds after a button press and whenever a notification becomes active (Note: button presses tested elsewhere).</p>				
Test Setup				
<ol style="list-style-type: none"> Standard setup starting with an Intermittent pump unit connected. Stopwatch. One pressure transducer tester (such as Utah Medical Products, Inc. model Veri-Cal, Cal. I.D. 223) connected in-line with the bandage tubing. 				
Test Procedures and Expected Results				
<ol style="list-style-type: none"> Insert the batteries and allow the device to power up and complete self tests. Turn the pump on. 				

see attachment #1

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Requirement Detail Report

P/F a. Verify that the device passes power on self tests and that no system faults occurred.

Pump Motor Failure - At Atmosphere

2. Unplug connector P1 (pump) per the Capricorn Pump Module hardware schematic, Mntx document #DS-0000-70-5. Introduce a major bandage leak. Wait at least one minute.

P/F a. Verify that the system fault notification does not activate, but instead, the major leak detected notification activates. Note: this was changed from a system fault per Interface issue 59.

3. Plug in connector P1 (pump). Wait at least 1 minute.

P/F a. Verify after plugging in the pump (ie. clearing the failure) that the major leak detected notification deactivates.

Pump Motor Failure - At Setpoint

4. With the pump off and the bandage at the pressure setpoint, unplug connector P1 (pump) per the Capricorn Pump Module hardware schematic. Turn the pump on. Wait at least 1 minute.

P/F a. Verify that the system fault notification becomes active (ie. all LCD segments repeatedly blink on and off).

P/F b. Verify when the system fault notification becomes active, that the backlight is turned on for 10 seconds.

P/F c. Verify that the control unit sounds a one time sequence of 5 beeps in a row.

P/F d. Verify that the pump is turned off (ie. no longer runs to repressurize).

5. Attempt to silence the System Fault notification by pressing the mute button.

P/F a. Verify that the device does not allow the user to silence/mute the audio notification (ie. beeps continue to sound).

P/F b. Verify that the pump remains off.

6. Plug in connector P1 (pump). Wait at least 5 minutes.

P/F a. Verify after reconnecting the pump (ie. clearing the failure) that the system fault notification does not deactivate.

P/F b. Verify that the pump remains off.

7. Cycle device power.

P/F a. Verify that the device passes power on self tests and that no system faults occurred (ie. system fault was set inactive when power was cycled).

8. Take the side plate off the pump. Jam the pump motor. Turn the pump on.

P/F a. Verify that the system fault notification becomes active (ie. all LCD segments repeatedly blink on and off).

P/F b. Verify that the pump is turned off (ie. no longer runs to repressurize).

Solenoid Valve Failure

9. Unjam the pump motor and replace the side plate. Remove the major bandage leak. Cycle device power. Turn the pump on. Unplug connector P2 (solenoid valve) per the Capricorn Pump Module hardware schematic. Wait at least 7 minutes (ie. one intermittent cycle equals 5 minutes at pressure and 2 minutes at atmosphere).

P/F a. Verify that the system fault notification becomes active (ie. all LCD

Requirement Detail Report

segments repeatedly blink on and off) when the valve does not open to vent the bandage to atmosphere.

P/F b. Verify when the system fault notification becomes active, that the backlight is turned on for 10 seconds.

P/F c. Verify that the control unit sounds a one time sequence of 5 beeps in a row.

P/F d. Verify that the pump is turned off (ie. no longer runs to repressurize).

10. Plug in connector P2 (solenoid valve). Wait at least 5 minutes.

P/F a. Verify after reconnecting the solenoid valve (ie. clearing the failure) that the system fault notification does not deactivate.

P/F b. Verify that the pump remains off.

11. Cycle device power.

P/F a. Verify that the device passes power on self tests and that no system faults occurred (ie. system fault was set inactive when power was cycled).

USING A DC POWER SUPPLY, INPUT

Pressure Sensor Failure - At Atmosphere *To 1.6VDC and Ground*

12. With the pump off, vent the bandage to atmosphere, then reconnect. *Ground* resistor R11 (at the node between R10 and R11) *(per the Capricorn Control Unit hardware schematic, Mntx document #DS-0000-70-3)*. Turn the pump on. *Wait at least one minute. The pump will continue to operate and overpressure the transducer.*

P/F a. Verify that the system fault notification does not activate, but instead, the major leak detected notification activates. Note: this was changed from a system fault per Interface issue 59. *↑ GAINS NOTE, NOT REDLINE. 7/18*

P/F b. Verify that the pump continues to run.

13. *DISCONNECT THE DC POWER SUPPLY VOLTAGE TO GROUND* Remove the ground from R11. Wait at least 1 minute.

P/F a. Verify after removing the ground (ie. clearing the failure) that the major leak detected notification deactivates.

Pressure Sensor Failure - At Setpoint

14. With the pump off and the bandage at the pressure setpoint, ground resistor R11 (at the node between R10 and R11) per the Capricorn Control Unit hardware schematic. Turn the pump on. Wait at least one minute.

P/F a. Verify that the system fault notification becomes active (ie. all LCD segments repeatedly blink on and off).

P/F b. Verify when the system fault notification becomes active, that the backlight is turned on for 10 seconds.

P/F c. Verify that the control unit sounds a one time sequence of 5 beeps in a row.

P/F d. Verify that the pump is turned off (ie. no longer runs to repressurize).

15. Remove the ground from R11. Wait at least 5 minutes.

P/F a. Verify after removing the ground (ie. clearing the failure) that the system fault notification does not deactivate.

P/F b. Verify that the pump remains off.

16. Cycle device power.

P/F a. Verify that the device passes power on self tests and that no system faults occurred (ie. system fault was set inactive when power was cycled).

Pressure Sensor Failure - Three Hour Inactivity Check

*SET
REDLINES ARE
Interface Issue
#64
GG 4/2/08*

*REDLINES ARE
Interface Issue
#64
GG 4/2/08*

Requirement Detail Report

GROUND RESISTANCE RII (AT THE NODE BETWEEN R10 AND R11) PER THE CAPACITOR CONTROL UNIT HARDWARE SCHEMATIC.

Ground the junction of R10 and R11.

REQUIRES ANE Interface Issue #64 GGJ 4/2/08

17. Replace the bandage with a 60cc syringe. This should hold pressure for greater than three hours (ie. is leak proof). ~~Bypass pressure sensing of the line from the pump to the syringe and connect it to the pressure transducer tester (ie. Utah Medical Products Veri-Cal device). On the Veri-Cal, dial in the programmed pressure setpoint. Keep the motor tubing connected to the syringe. This setup should hold pressure for greater than three hours (ie. is leak proof).~~ Set the vacuum pressure to 40 mmHg, turn on the pump and start the stopwatch. Wait at least 3 hours. Stop the stopwatch when the pump activates. Note: When using the Intermittent Pump Module, set therapy mode to Continuous to prevent solenoid valve from opening.
 P/F a. Verify the inactivity check occurs after 3 hours of pump inactivity.
 P/F b. Verify that when the pump activates, the pressure does ~~not~~ change in the tubing connected to the sensor and a system fault notification occurs (pressure sensor is not working properly). ~~Note: pressure only changes in the tubing connected to the syringe.~~

REQUIRES ANE Interface Issue #64 GGJ 4/2/08

18. Replace the Intermittent pump unit with a Continuous pump unit and repeat steps 1 through 6, and 10 through 15. Do not repeat solenoid valve testing as this valve does not exist in the Continuous pump unit.
 P/F a. Verify results were as expected. *see attachment #2*

Traceability

	Backward	Suspect	Forward	Suspect
System Fault Indication		TRUE		
Pump Inoperable		TRUE		
Beep Mute Capability		TRUE		
Visual Notifications		TRUE		
Audible Notifications		TRUE		
Backlight Operation		TRUE		
Inactivate System Fault		TRUE		
Pump Inactivity Check		TRUE		
Loss of Pump Control		TRUE		

SNOO3 - System Fault
Capricorn

attachment #1
Caliber: 55815

Test Equipment: A, B, J, I, N, F, D, K, R

Intermittent set to Intermittent 125 mmHg

1) a) Pass

2) a) Pass

3) a) Pass

4) a) Pass b) Pass c) Pass d) Pass

5) a) Pass b) Pass

6) a) Pass b) Pass

7) a) Pass

8) a) Pass b) Pass

9) a) Pass b) Pass c) Pass d) Pass

10) a) Pass b) Pass

11) a) Pass

12) a) Pass b) Pass

13) a) Pass

14) a) Pass b) Pass c) Pass d) Pass

15) a) Pass b) Pass

16) a) Pass

Intermittent set to Continuous 40 mmHg

17) a) Pass b) Pass

hrs min sec
3:01:17

GG)

3/31/09

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CAPRICORN

SN003 - System Fault

attachment #2

Test Equipment: A, J, H, M, D, N, B, R

Caliber: 55815

CONTINUOUS 125mmHg

- 18) 1) a) Pass
- 2) a) Pass
- 3) a) Pass
- 4) a) Pass b) Pass c) Pass d) Pass
- 5) a) Pass b) Pass
- 6) a) Pass b) Pass
- 7) a) Pass
- 8) a) Pass b) Pass

- 12) a) Pass b) Pass
- 13) a) Pass
- 14) a) Pass b) Pass c) Pass d) Pass
- 15) a) Pass b) Pass
- 16) a) Pass

CONTINUOUS 40mmHg

- 18) 17) a) Pass hrs min sec
3:00:54
- b) Pass
- 18) a) Pass

GGJ

Requirement Detail

Project: Capricorn

Date: 4/21/2008

4.4		Test Case UI004 - Pump On/Off Control		SYSTST55801
Details				
Owner:	lberg	Version:	2.1	Status: Accepted
Type:	System Test (SYSTST)	Priority:	Traceable Requirement	
Description: Introduction This test will verify ...				
<p>a. The Micro NPWT device shall provide for a target population user an "on/off" function for the pump module.</p> <p>b. The Micro NPWT device shall provide a way for users not to inadvertently turn on/off the pump module.</p> <p>c. The Micro NPWT device shall ignore the pump on/off button if no pump module is installed in the display/control unit.</p> <p>d. The Micro NPWT device shall indicate to the user that the pump is on and operational.</p> <p>e. The Micro NPWT display/control unit shall notify the user to changes in status via the pertinent icon.</p>				
<p>Note: From the Capricorn User Interface Design document (DP-0001-84-4), to turn the pump on or off, press the Pump On/Off button for greater than 1 second.</p>				
<p>Test Setup</p> <p>1. Standard setup.</p> <p>2. Start with a Continuous ^{INTERMITTENT} pump unit attached to the control unit.</p>				
<p>PUMP MODULE : NPD 1000A LOT 000008 #4 CONTROL UNIT : AE-0000-83-2 S/N 000013 SOFTWARE REV. : 08</p>				
<p>Test Procedures and Expected Results</p> <p>1. Power on and inspect the NPWT device.</p>				
<p><i>STEP 7 ONLY.</i></p> <p><i>AS 4/24/08</i></p> <p><i>P/F</i> a. Verify that there is a Pump On/Off button used to turn the pump on or off.</p> <p><i>P/F</i> b. Verify that there is no indication of pump operational status (ie. pump is off).</p>				
<p>2. Press and release the Pump On/Off button in less than one second.</p> <p><i>P/F</i> a. Verify that the pump does not turn on. Shows that an inadvertent button press does not turn on the pump. <i>ICON OFF</i></p>				
<p>3. Press the Pump On/Off button for greater than 1 second.</p> <p><i>P/F</i> a. Verify that the pump turns on and that the pump enabled icon is displayed. <i>ICON ON</i></p>				
<p>4. Press and release the Pump On/Off button in less than one second.</p> <p><i>P/F</i> a. Verify that the pump does not turn off. Shows that an inadvertent button press does not turn off the pump. <i>ICON ON</i></p>				
<p>5. Press the Pump On/Off button for greater than 1 second.</p> <p><i>P/F</i> a. Verify that the pump turns off and that the pump enabled icon is no longer displayed. <i>ICON OFF</i></p>				
<p>6. Disconnect the pump unit from the control unit by removing the two screws.</p>				

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Attempt to turn on the pump.

PF a. Verify with no pump unit connected that the Pump On/Off button press is ignored.

BEEPS TWICE, TURNS ON BACKLIGHT, PUMP ICON OFF.

7. Power off the device. Attach an Intermittent pump unit to the control unit and repeat steps 1 - 8.6

PF a. Verify results are as expected.

Traceability

	Backward	Suspect	Forward	Suspect
Missing Pump Module		TRUE		
Pump On/Off Control		TRUE		
Pump Operational Status		TRUE		
Inadvertant Pump Off		TRUE		
Mitigation				
Visual Notifications		FALSE		

REPEATED TURNING PUMP ON/OFF MULTIPLE TIMES, OPERATES AS EXPECTED.

TAB 4/24/08

Open Issues

(1 page, excluding this one)

Open Issues Report.xls

Capricorn - Interface Subsystem	Issue Number	Description	Resolution	Approval	Status
Capricorn - Interface	58	Capricorn Usability Specification (DP-0001-84-7) has not been formally reviewed as required by Capricorn System V&V Plan and per Mntx Technical Review SOP.			Open
Capricorn - Interface	63	<p>Test Case FT003 - Therapy Duration (SYSTST55818) has a duration of 6 weeks and was in progress at the time the verification report was issued. Must complete test and report results.</p> <p>Note: This is retest due to Intermittent pump module hardware changes and software update to Rev. 08.</p> <p>This is a re-test of the hardware, to verify performance over 6 weeks of use.</p>			Open

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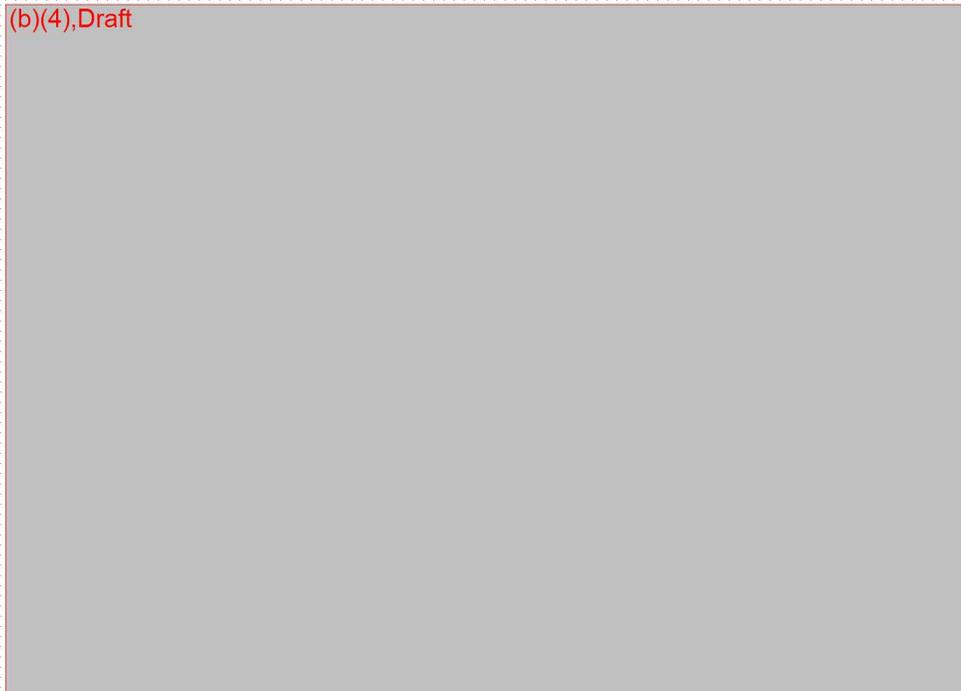
Instructions for Use

0540

K a l y p t o M e d i c a l

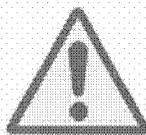
**NPD 1000™ Negative Pressure
Wound Therapy System –
Portable Negative Pressure Pump and Dressing**

(b)(4),Draft



Clinician and Patient
Instructions for Use

541



Important Safety Information accompanies this device. Indications for Use, Contraindications, Warnings, Precautions and other Safety Information are included in these Instructions for Use (IFU). To reduce risk of serious or fatal injury, all caregivers and patients must carefully read and follow all user instructions and safety information that accompany Kalypso Medical products.

If there are questions, please contact Kalypso Medical immediately at (877) 286-3740.
See back cover of this IFU for other Kalypso contact information.

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INTRODUCTION

The NPD 1000 Negative Pressure Wound Therapy System Instructions for Use (IFU) is intended to supply information to both the clinician and patient on the use of the device, application of the wound dressing, expectations for normal operation and troubleshooting system issues. While the system is designed to provide negative pressure wound therapy in a patient's home, the system should be set up and dressings applied by a qualified wound clinician. The patient should with the use of the IFU be able to competently troubleshoot any problems that appear during the normal course of use and know when it is appropriate to call their medical provider regarding issues with the system. Thus, the IFU is divided into three sections, 1) General information - including indications for use, contraindications, warnings and precautions, 2) Clinician - information needed by the clinician to use the device on a patient with a wound and 3) Patient – information needed by the patient to insure that the device continues to operate appropriately after leaving the direct care of their wound care professional.

GENERAL INFORMATION

	Refer to the Instructions for Use (IFU)
	Single use only. Do not reuse.
	Date of Manufacture
	Manufacturing Lot Number
	Type B, Applied Part. Internally powered electrical device.
	Keep Dry
	Warning, consult accompanying documents
	Product sterilized by ionizing radiation
IPX0	Not protected against harmful effects of water
	Use by date
SN	Serial Number
	ON/OFF (Vacuum Pump power)
P/N	Part Number
	Low Battery
	Negative Pressure Therapy Pump system is operating
	System Pressure Leak
	Medical Equipment classified with respect to Electrical Shock, Fire and Mechanical Hazards Only in accordance with UL 60601-1 and to CAN/CSA C22.2 No. 601.1 Standards, including JIS amendment by Underwriters Laboratory Inc.

The NPD 1000 Negative Pressure Wound Therapy System is comprised of a battery-operated system controller, with a portable electromechanical pump and proprietary wound dressing. The pump produces a controlled negative pressure (vacuum) under the wound dressing. This approach to wound care is believed to create an environment that promotes wound healing by bringing the wound edges together (with the negative pressure,) and by actively removing wound fluids and infectious material from the wound bed.

The pump device (depending on the model purchased) can provide negative pressure therapy in two modes, "continuous" and "intermittent", with pressure ranges from - 40mmHg to -125 mmHg. In "continuous" mode, the pump holds the pressure inside the dressing at the prescribed programmed level while the negative pressure dressing is worn, the pump is connected to the dressing and therapy is turned ON. In intermittent mode, the pump cycles between the programmed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. This cycle continues from the time therapy is initiated until the pump is turned OFF.

Available Models

The NPD 1000 Negative Pressure Wound Therapy device is available in two configurations utilizing the universal system controller, the NPD 1000i Intermittent Therapy Pump and the NPD 1000c Continuous Negative Pressure Therapy Pump.

CAUTION: Both devices are designed to only work with all Kalypto Negative Pressure bandages. They are not compatible with other negative pressure bandage systems.

The **NPD 1000i** is an assembly of the NPD 1000 system controller and the 1000i pump module. It is capable of providing both "intermittent" and "continuous" modes of therapy over the specified pressure range. This assembly can be used by multiple patients.

The **NPD 1000c** is an assembly of the NPD 1000 system controller and the 1000c pump module. It is capable of providing only the "continuous" mode of therapy

over the specified pressure range. This assembly should only be used by one patient. **NOTE:** The system controller can be used by multiple patients but the pump assembly is single patient use only.

Indications for Use

The NPD 1000 Negative Pressure Wound Therapy System, a portable, low powered, battery operated, negative pressure suction pump and wound dressing, is intended for the application of suction to remove a small amount of fluid from the wound bed, including wound exudates and infectious materials, which may promote wound healing.

Contraindications

Do not use the NPD 1000 Negative Pressure Wound Therapy System for --

1. Application to wounds where there is evidence of
 - Exposed arteries or veins in wound
 - Fistula - unexplored
 - Fistula - non enteric
 - Osteomyelitis, untreated
 - Malignancy in the wound
 - Necrotic tissue with eschar

NOTE: After debridement of necrotic tissue and complete removal of eschar, the NPD 1000 Negative Pressure Wound Therapy System may be used.

2. Emergency Airway Aspiration
3. Pleural, mediastinal or chest tube drainage. These applications require a device that provides specific low suction levels and an underwater seal.
4. Surgical Suction
5. Do not apply the NPD 1000 Wound Dressings directly to exposed blood vessels, organs, or nerves.
6. Sensitivity to silver (NPD 1000 Silver Dressing only).

WARNINGS, CAUTIONS & ADVERSE REACTIONS

Warnings

With or without using NPD 1000 Therapy, certain patients are at high risk of bleeding complications. The following types of patients are at increased risk of bleeding, which, if uncontrolled, could potentially be fatal.

- Patients who have weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to:

- Suturing of the blood vessel (native anastomoses or grafts)/organ
- Infection
- Trauma
- Radiation
- Patients without adequate wound hemostasis
- Patients who have been administered anticoagulants or platelet

aggregation inhibitors

- Patients who do not have adequate tissue coverage over vascular structures.

If NPD 1000 Therapy is prescribed for patients who have an increased risk of bleeding complications, they should be treated and monitored in a care setting deemed appropriate by the treating physician. If active bleeding develops suddenly or in large amounts during NPD 1000 Therapy, or if frank (bright red) blood is seen in the dressing, immediately stop NPD 1000, leave dressing in place, take measures to stop the bleeding.

Seek immediate medical assistance.

All exposed or superficial vessels and organs in or around the wound must be completely covered and protected prior to the administration of NPD 1000 therapy. Always ensure that NPD 1000 Dressings do not come in direct contact with vessels or organs.

Cautions

- Wound Dressings are single patient use only and should be disposed of in accordance with local rules and practices regarding infectious waste.
- The device should not be used once the wound is no longer producing exudates.
- Use of clean technique is the responsibility of the health care professional directly responsible for patient care.
- Use only alkaline or NiMH rechargeable AA batteries.

- If the patient needs to shower or bathe in between dressing changes, steps should be taken to prevent water from coming in contact with the dressing and to disconnect the pump from the dressing. However, It is advisable that as part of the care plan, personal hygiene matters, such as showering and bathing should be done immediately preceding the changing of the dressing, when the device can be detached from the patient until the application of the new dressing.
- the devices are designed to work with ~~50cc~~ Kalypto Negative Pressure bandage and are not compatible with other negative pressure bandage systems
 - Safe Performance: Even in fault conditions, the NPD 1000 will not exceed 250 mmHg of suction.
 - Do not use the NPD 1000 Wound Therapy System in the presence of flammable anesthetics.
 - To reduce the risk of transmission of bloodborne pathogens, apply standard precautions for infection control with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. In addition to gloves, use gown and goggles if exposure to body fluids is likely.
 - To minimize the risk of bradycardia, the NPD 1000 Negative Pressure Wound Therapy System must not be placed in proximity to the vagus nerve.
 - Consider use of a skin preparation product to protect periwound skin.
 - If any signs of irritation or sensitivity to the dressing or tubing assembly appear, discontinue use and consult a physician immediately.
 - To avoid trauma to the periwound skin, do not pull or stretch the dressing during application.
 - Extra caution should be used for patients with neuropathic etiologies or circulatory compromise.
 - When using the NPD 1000 Silver Dressing, do not use topical solutions or agents that may have adverse interactions with silver. For example, saline solutions may compromise the effectiveness of the NPD 1000 Silver Dressing.
 - Do not allow the NPD 1000 Silver Dressing to come in contact with EKG or other electrodes or conductive gels during electronic monitoring, or when taking electronic measurements.
 - The NPD 1000 Silver Dressing contains metallic silver that may impair visualization with certain imaging modalities.

- Operation of the NPD 1000 in the presence of high magnetic fields, such as those produced by an MRI (Magnetic Resonance Imager), has not been tested and is not recommended. Incorrect operation could result.

Adverse Reactions

- Excessive bleeding is a serious risk associated with the application of suction to wounds which may result in death or serious injury. Careful patient selection, in view of the above stated contraindications, warnings and precautions, is essential. Carefully monitor the wound and dressing for any evidence of a change in the blood loss status of the patient. Notify the Physician of any sudden or abrupt changes in the volume or the color of exudate.

CLINICIAN INFORMATION AND INSTRUCTION

PRODUCT OVERVIEW

Negative Pressure Pump

The NPD Negative Pressure Wound Therapy Pump Device contains a microprocessor-controlled pump and pressure sensor working in feedback fashion to control the pressure under the wound dressing. (Fig. 1).

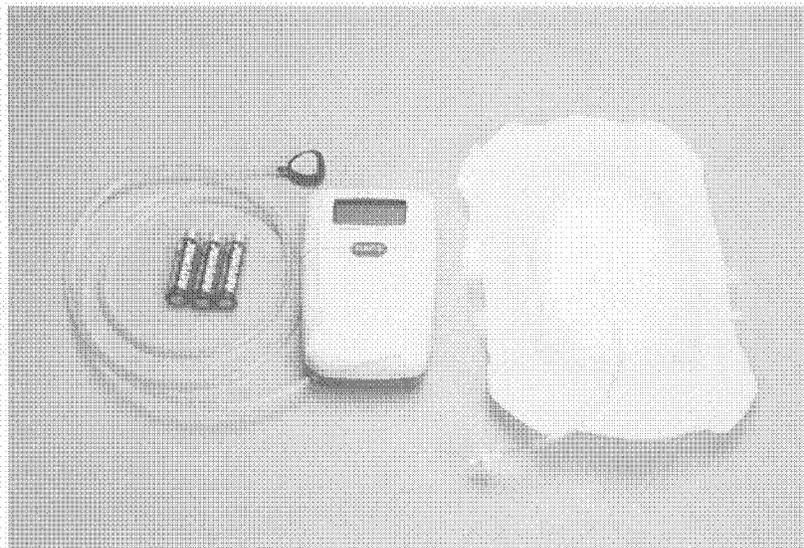


Fig. 1. Kalypto Negative Pressure Wound Therapy Device & Accessories

It has a user interface of three buttons to control the treatment mode, pressure setting and turn the device ON/OFF. It is powered by 3 AA batteries, either

alkaline or NiMH rechargeable cells. Additionally, it has 6 ft. of tubing with a pressure fitting between the pump and the dressing.

The pump applies controlled suction, adjustable by the user, in the vacuum range (negative pressure) from 40 mmHg to 125 mmHg. The pump operates in continuous and intermittent modes. For therapy status notification, it has a proprietary leak detection system, a low battery indicator and therapy proceeding indication.

ASSEMBLING THE PUMP

Assembling the Pump

CAUTION: Be careful when assembling device to not pinch your fingers between the two parts.

The NPD 1000 Negative Pressure Pump device consists of two pieces; a system controller and one of two pump housings – continuous (NPD 1000c) or intermittent (NPD 1000i). (See Fig. 2)

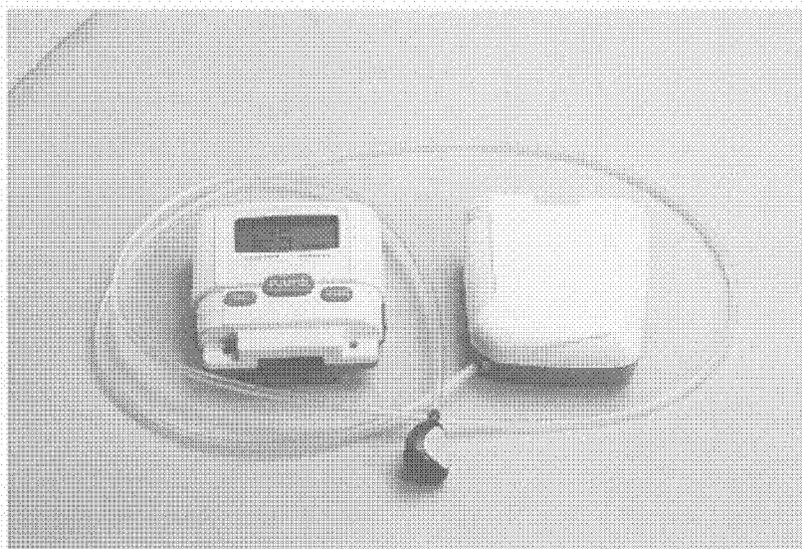


Fig. 2: Kalypto Negative Pressure Pump Subassemblies

Both pump housings can provide continuous therapy. However, the NPD 1000i housing is the only one that can perform intermittent therapy. Neither the system

controller nor the pump housings are provided sterile and do not need to be sterilized between subsequent patients.

To assemble the two pieces into a functioning negative pressure wound therapy device, fit the two subassemblies together by matching the male and female connector housings and pressing them together. (Fig. 3a)

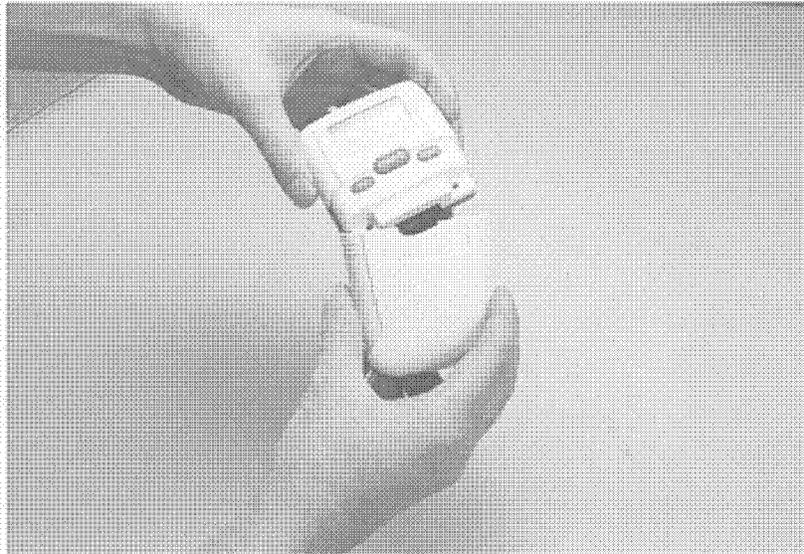


Fig. 3a Assembling the control and pump modules

Insert accompanying screws into pump housing, tighten to point of resistance, Fig. 3b. DO NOT overtighten.

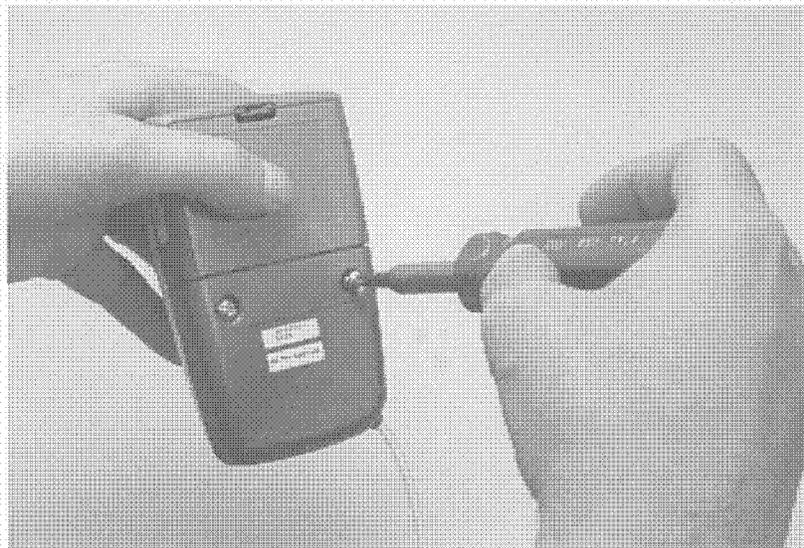


Fig. 3b: Inserting screws to secure control and pump

This will secure the device and prevent the modules from separating. The system controller automatically recognizes whether a continuous or intermittent pump has been attached.

NPD 1000 Negative Pressure Wound Therapy Dressing

The NPD 1000 Dressing Technology is a state-of-the-art product that delivers the benefits of negative pressure therapy with a disposable fluid absorbing dressing. It is comprised (See Fig. 4) of a semi-occlusive outer layer that maintains negative pressure (1), a pressure port (2a) with an in-line hydrophobic, anti-bacterial filter (2b) which attaches the NPD Pump system, a gasket to seal the wound area (3), a super-absorbing non-woven polymer matrix to absorb exudates (4) and a non-adherent stick wound contact layer (5). The dressing also has three windows near the pressure port (6) to monitor the level of exudate in the dressing.

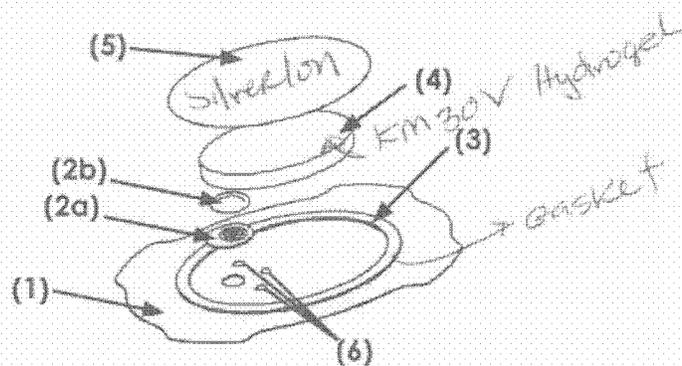


Fig. 4: Components of Kalypto Negative Pressure Dressing

Applying the Dressing

Carefully inspect the wound and treat per the order of the patient's physician and according to the institution's protocol and standards of practice for wound care. This should include proper hand washing and gloving practices. Appropriate skin prep should be used to preserve the wound margins and prevent epithelial stripping.

1. Prior to application of the cover, ensure that the skin that will be under the dressing the wound is clean, dry and shaven. This will ensure proper adherence and sealing of the thin film dressing.

2. Use of a skin preparation layer may protect peri-wound skin and promote and prolong cover adhesion.

3. Remove the NPD 1000 dressing consumables from the sterile package.

4. Remove the release liner from the dressing exposing the adhesive side of the dressing and the sealing gasket. (Fig. 5)



Fig. 5: Removing the dressing release liner

5. Carefully place the dressing on the wound, taking care to minimize folds and wrinkles. (Fig. 6). Do not force the wound dressing into cavity wounds. For cavity wounds a standard wound filler such as gauze or foam must be used.

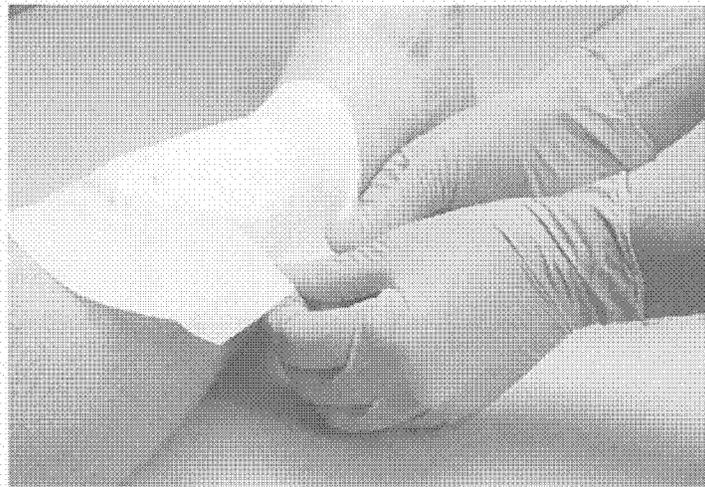


Fig. 6: Applying the dressing over a wound

6. Run your finger along the perimeter of the gasket to secure the gasket material to the skin and increase the dressing seal, Fig. 7.

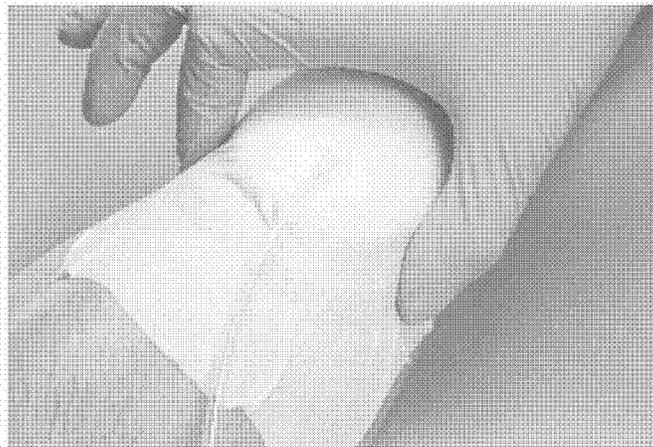


Fig. 7: Securing sealing gasket to skin

7. Attach provided pigtail tubing to the port on the top of the dressing. (Fig. 8)



Fig. 8 Attach pigtail tubing to dressing

The dressing is now ready for application of negative pressure.

PROGRAMMING THE PUMP

CAUTION: When programming the pump system, make sure that the settings match exactly those specified by the physician. Not following the negative pressure therapy prescription, could result in sub-optimal therapeutic results.

Before attaching the pump device to the patient's dressing, the clinician should set the device to the appropriate treatment settings in the following way:

1. Slide the bottom cover down to expose the programming, labeled "VAC" and "MODE", buttons, Fig. 9.

(b)(4), Draft

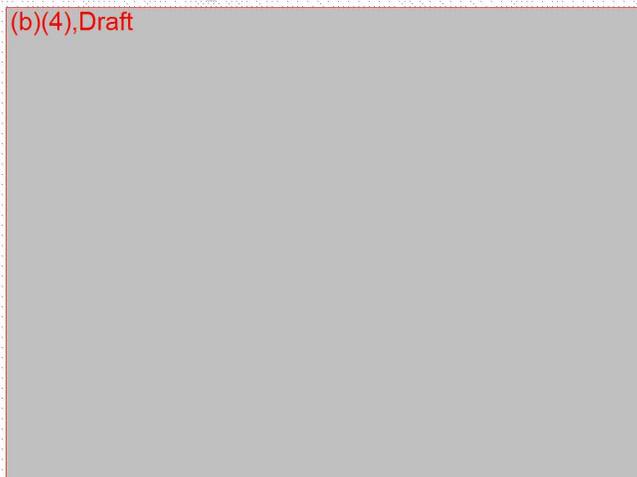


Fig. 9 Negative Pressure Wound Therapy Pump Programming Buttons

2. Depress and hold the "VAC" and "MODE" buttons simultaneously, while also pressing the power button,  for one second.

3. Release the buttons and the device will beep twice and the pressure setting on the screen will blink, indicating the device is in programming mode.

4. Depress the "MODE" button to toggle the device between "continuous" and "intermittent" therapy, according to the placement of the tic mark on the display. For a description of "continuous" and "intermittent" therapy, see the Product Description section of this IFU.

5. Next depress the "VAC" button to set the pressure. The system cycles down 15 mmHg for each button push. The available settings are 40, 50, 65, 80, 95, 110 and 125 mmHg. The default setting of the device is 125mmHg of vacuum.

6. After setting the device to the prescribed therapy, press the power button,  briefly, to exit setup mode.

7. Slide the bottom cover back into place to protect the buttons.

CONNECTING THE PUMP & INITIATING THERAPY

1. Trim pump tubing to appropriate length with a scissors, Fig 10. When determining the tube length, take into consideration where and how the patient will carry the device during mobile use and how the device will be placed during stationary use.

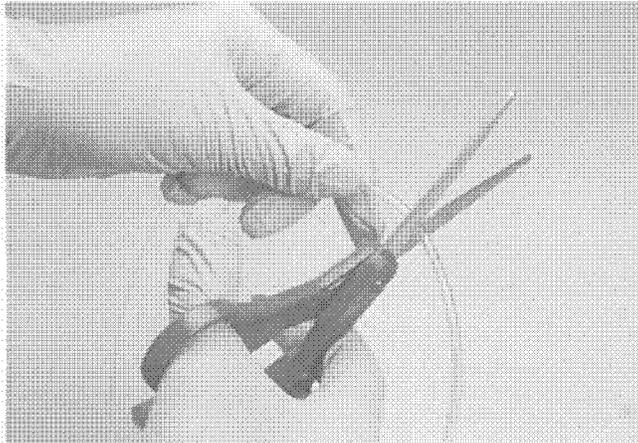


Fig. 10: Trimming pump tubing to length

2. Attach proprietary connector to newly trimmed tubing, black plastic piece with gray button and hose barb. Push the end of the tubing entirely over the hose barb at the end of the connector.

3. Attach the pump to the dressing by mating the connector on the pump tubing to the connector on the dressing tubing, Fig. 11.



Fig. 11: Connecting the pump to the dressing

4. Depress the ON/OFF button for one second and release. The pump should turn on and the dressing should begin to contract under the application of negative pressure. Additionally the therapy proceeding icon  should appear in the upper left hand corner of the screen.

5. As the air is removed underneath the dressing, the surface of the dressing will contract toward the surface of the wound. When the set therapeutic pressure is reached the pump will shut off.

6. After the pump has shut off, watch the device for 2-3 minutes to be certain of the quality of the seal on the dressing. If the leak icon  does not appear, The pump should only run very briefly every 30 seconds to 5 minutes (depending on the quality of the dressing seal) once the therapy has started. In the RUN mode, the user may not even hear the pump when it is operating.

7. The patient can know that the system is operating as needed by looking at the screen and finding the therapy proceeding icon  in the upper left hand corner.

8. If the user or clinician notices, either an audible beep from the device or visual indicator on the screen, either the low battery indicator icon  or the leak icon , during setup or during therapy, proceed to the troubleshooting section of this IFU.

TROUBLESHOOTING

The following are the alarm states for the NPD 1000 Negative Pressure Wound Therapy Pump signaled by an audible beep from the device or a visual indication on the LCD display.

All LCD Segments Flashing – This condition indicates a system fault. Turn off the device, remove the batteries for 30 seconds, replace and turn the device on again. If the condition is repeated after this process, the device will not function properly. Interrupt therapy and turn off the device. The clinician should contact their Kalypto Medical sales representative. The patient should call you're their clinician for guidance.

Leak Balloon Icon () On – If the leak icon is present, the system has a leak in the dressing, the tubing or the device. Depending on the source of the leak, the user may or may not be able to fix it. First, verify that the wound site was appropriately prepared; the periwound skin was cleaned and dried and the skin

under the dressing was shaved smooth. If this is the case, the most likely source of a system leak is the dressing so troubleshooting should start there.

Dressing Leaks – First, run your fingers along the perimeter of the gasket applying gentle pressure. Also, smooth out any wrinkles in the semi-occlusive dressing outside the gasket. Wait for 2 to 3 minutes to see if the alarm condition goes away. For a new dressing, the gasket may take a few minutes to seat itself properly to provide a good seal.

If the leak icon does not disappear after two attempts to seat the gasket, then the leak may be in the tubing or the device.

Tubing Leaks – First, make sure the tubing is securely attached to all of the fittings, including the pressure port on the dressing and the quick connect fittings that connect the pump device to the dressing. The connection should be firm enough to withstand a firm tug on the tubing.

No Dressing or Tubing Leak - If after verifying that the tubing connections are good, the leak icon is still present, a existing dressing should be removed and disposed of in accordance with local regulations. Apply a second dressing and attempt to achieve a good seal (follow directions found in the "Applying the Dressing" section of this IFU). If the second dressing has been applied in accordance with the instructions and a leak still exists, it is likely that the leak is in the pump itself. Call your clinician for guidance. Clinicians having this problem should call their Kalypto representative for instructions as the device may need servicing that can only be done in the factory.

Low Battery Icon  On – If you see the low battery indicator, replace the batteries. First, turn off the device by pressing the ON/OFF button for one second.

NOTE:

If the batteries are low in the middle of therapy, there is no need to disconnect the pump unit from the bandage.

Remove the battery door, pull upwards on the battery removal strap and remove the batteries. Place new batteries in the battery holder in the orientation found in the battery holder. Replace the battery door. Turn on the device by pressing the ON/OFF switch for one second. The device will return to the therapy mode in place when the device was turned off.

Disabling the Audible Alarm - The audible alarm warns the user of the presence of a performance problem with the device. These alarms are also displayed on the LCD display. For many reasons, the user may wish to disable the audible alarm for a few minutes.

The alarm sound can be temporarily disabled by pressing any of the three blue buttons briefly. This will disable the alarm for 5 minutes. After which time, it will sound again if the alarm state still exists.

COURSE OF THERAPY WITH THE NPD 1000

Dressings should be changed per the standard protocol for negative pressure wound therapy. The patient/clinician can monitor the level of fluid in the dressing by examining the three windows in the dressing near the pressure port. If they appear discolored (as in exudate is being absorbed in the pad near the pressure source), the pump and dressing should be monitored for signs that the dressing has reached capacity. These are 1) the pump has not turned on (to maintain the negative pressure in the dressing) for an extended period of time, 2) the dressing does not have the appearance (shriveled and firm to touch) of being under negative pressure as was evident at the application of the dressing. If the dressing and/or pump meets the above criteria, the wound care professional should consider changing the dressing.

CARE & SERVICE OF THE PUMP DEVICE

The outside case of both the system controller and pump housings can be cleaned off with a water dampened cloth. No solvents should be used. Do not open either device housing (except the battery door, as proper operation cannot be assured once this has happened).

These devices are tested to an IPX0 rating. Thus, they cannot be immersed in water or subject to large volumes of water spray such as in the shower.

1. There are no user serviceable components inside the Kalypto NPD 1000 Wound Therapy System Pump.

2. Contact your Kalypto representative for return/replacement of damaged pumps.
3. Do not open the NPD 1000 pump or attempt to service it yourself.

DISPOSAL OF DRESSING AND PUMP

The NPD 1000 dressing is not constructed with any hazardous materials. Subsequently, after use it can be disposed of in the normal medical waste stream for wound care dressings.

The NPD 1000 Negative Pressure Wound Therapy Pump System is an electromechanical device powered by non-integral batteries. The batteries and device should be recycled according the local regulations governing such products.

PRODUCT SPECIFICATIONS

Dimensions:	3.2" W x 5.1" H x 1.3" D
Weight:	8 oz.
Pressure Options:	-40 to -125 mmHg
Therapy Delivery Modes:	Continuous & Intermittent
Battery Type:	Alkaline or Rechargeable NIMH
Battery Life:	3 weeks or more
Patient Enclosure	
Leakage Current:	N/A (Battery powered device)
Storage Conditions:	Temperature Range -20 °C to +60 °C

	Relative Humidity Range 0 to 95% non-condensing
Operating Conditions:	Temperature Range +5 °C to +40 °C
	Relative Humidity Range 0 to 95% non-condensing
Altitude Range	Operating -1000 ft to +10,000 ft
	Storage -1000 ft to +18,000 ft
IEC Classification	<ul style="list-style-type: none"> - Medical Equipment - Equipment not suitable for use in the presence of flammable anesthetic mixture - Type B, Applied Part - Class II - IPX0

Specifications subject to change without notice.

PATIENT INFORMATION AND INSTRUCTION

PLEASE READ CAREFULLY

Overview of Negative Pressure Wound Therapy

Negative Pressure Wound Therapy (NPWT) is used to promote wound healing for a variety of wounds that are difficult to treat or having difficulty healing with the use of conventional wound dressings. It involves the use of a negative pressure pump (vacuum) and a special pressure sealing dressing. The wound dressing is placed over the wound and connected to the pump with medical tubing. The pump is turned on and the air under the dressing is removed. The removal of the air causes the dressing to exert a small mechanical force on the wound bed. Additionally, the negative pressure helps draw out various fluids produced by the body at the site of the wound. The pump removes these fluids from the tissues and they are stored in the dressing. The medical community believes that these small applied forces and the removal of the wound fluids help in the healing process of these difficult to treat wounds. The scientific evidence on the success in treatment with this technique is very strong. In fact, over 500,000 people in the US are treated annually with NPWT. The Kalypto Medical NPD 1000 Negative Pressure Wound Therapy system is a state-of-the-art medical device designed to deliver negative pressure wound therapy to wounds that may benefit from the application of such treatment. *references*

What to expect during treatment

After your wound care professional has determined that your wound is a candidate for NPWT, the NPD 1000 system was prescribed. The system includes a battery-operated negative pressure pump, a negative pressure wound dressing and medical tubing to connect the pump to the dressing. On the first day, the wound care professional will apply your wound dressing and connect the pump to the dressing and turn on the device. As the air is removed from underneath the dressing, the dressing will shrink and press down on your skin. You should feel a slight mechanical force under the dressing. At this point, barring a battery change, you should not have to touch the device until you see your wound care professional for a dressing change. Once therapy begins, the wound dressing should be changed every two to three days by your wound

care professional. Therapy will proceed in this fashion until the wound care professional determines that the NPWT treatment is no longer necessary.

Operation of the Device

Patient instructions for the operation of the device are as follows:

Negative pressure wound therapy is a 24 hour a day treatment. Once set up and turned "ON" by your healthcare professional, you should not need to touch the system other than to address an unusual, but possible, alarm or change the batteries. For directions with regards to these issues, see the Alarms and Troubleshooting section in the pages that follow.

The patient SHOULD NOT change or remove the dressing between visits with their wound care provider. The wound dressing is designed to meet the needs of the patient for the entire time between visits and should not be changed except by the clinician.

Full Dressing

In some cases, it may be possible that the wound is producing so much fluid that the dressing reaches its fluid absorption capacity. The patient can monitor the level of fluid in the dressing by examining the three clear windows in the dressing near the pressure port. **If they appear discolored, as wound fluid is being absorbed in the pad near the pressure source, the pump and dressing should be monitored for signs that the dressing has reached capacity.** Additionally the other signs of a full dressing are:

- 1) The pump has not turned on (to maintain the negative pressure in the dressing) for an extended period of time.
- 2) The dressing does not have the appearance (shriveled and firm to touch) of being under negative pressure as was evident at the application of the dressing.

If the dressing and/or pump meets the above criteria, you should contact your wound care professional.

Powering "ON" the Device

Note: This should only be necessary for the patient if the device was inadvertently turned OFF for some reason or the batteries needed to be changed.

Depress the ON/OFF  button for one second and release. The pump should turn on and the dressing should begin to contract under the application of negative pressure. Additionally the "pump operational" icon  should appear in the upper left hand corner of the LCD display indicating the system is working. The device can be shut off by depressing the ON/OFF button again for one second and releasing.

As the device is applying vacuum to the dressing, the dressing should appear to contract against the skin and become firm to the touch. After the dressing has reached the target pressure, **the pump will shut off**. If it continues to run, beyond 1 or 2 minutes, the seal of the dressing will need to be improved. Watch the device for 2-3 minutes to be certain of the quality of the seal on the dressing. If the leak icon  does not appear the seal is good. The pump should only run very briefly every 30 seconds to 5 minutes (depending on the quality of the dressing seal) once the therapy has started. In the RUN mode, the user may not even hear the pump when it is operating.

Maintenance and Care of the system

The patient is not responsible for the maintenance of the device. In fact, the device is designed to be maintenance free, meaning other than changing batteries in the pump, the patient should not have to service the device.

As for caring for the NPD 1000, take the following precautions with the device during use

- Keep away from open flames or high heat
- Do not immerse in water or expose to water sprays, or other liquids

- Be careful to not allow the device to drop onto hard surfaces, such as a floor
- Do not set anything on top of the pump
- Do not attempt to clean the device, leave that to the medical professional

Alarms and Troubleshooting

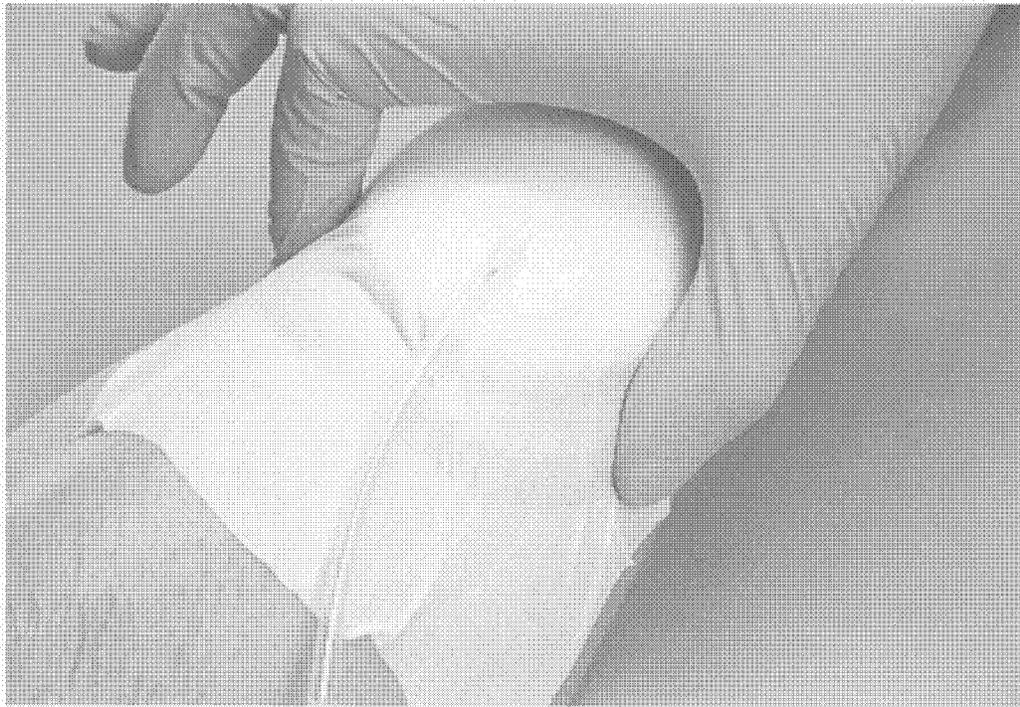
The NPD 1000 Negative Pressure Wound Therapy Pump has various alarms to let the user know of any system malfunctions. Some alarms are serviceable by the patient, others may require a call to your clinician. Under no circumstances should a patient try to service the device outside of the instructions provided below. All of the system malfunctions (or momentary problems) are signaled by an audible beep from the device and/or a visual indication on the LCD display. Each section below details the reasons for device alarms, the potential source of the problem and the possible fixes to be tried by the patient or home caregiver.

Audible Beep (alarm) heard – If the user hears an audible beep from the device, he/she should inspect the display on the pump to determine the nature of the problem. The user is notified of all problems with the device by the audible beeping sound. An audible beep will be produced by the device to notify the user of any problem, including LOW BATTERY and DRESSING LEAK.

All LCD Segments Flashing – This condition indicates a system fault. Turn off the device, remove the batteries for 30 seconds, replace and turn the device on again. If the condition is repeated after this process, the device will not function properly. Turn off the device. At this point, the patient should call their clinician for guidance.

Leak Balloon Icon (🎈) On – If the leak icon is present, the system has a leak in the dressing, the tubing or the device. Additionally, the dressing may feel soft or the pump is running continuously. Depending on the source of the leak, the patient may or may not be able to fix it.

Dressing Leaks – First, run your fingers along the perimeter of the gasket applying gentle pressure, see picture below. Also, smooth out any wrinkles in the dressing outside the gasket. Wait for 2 to 3 minutes to see if the alarm goes away. For a new dressing, the gasket may take a few minutes to seat itself properly to provide a good seal.



If the leak icon does not disappear after two attempts to seat the gasket, then the leak may be in the tubing or the device.

Tubing Leaks – First, make sure the tubing is securely attached to all of the fittings, including the pressure port on the dressing and the fittings that attach the pump device to the dressing. The connection should be strong enough to withstand a firm tug on the tubing.

No Dressing or Tubing Leak – If the leak icon is still present checking for dressing and tubing leaks, turn off the pump, by depressing the ON/OFF button for one second and contact your health care provider. The problem is not serviceable by the patient.

Low Battery Icon  **On** – If you see the low battery indicator, replace the batteries. First, turn off the device by pressing the ON/OFF button for one second.

NOTE:

If the batteries are low in the middle of therapy, there is no need to disconnect the pump unit from the bandage.

Remove the battery door, pull upwards on the battery removal strap and remove the batteries. Place new batteries in the battery holder in by following the +/- orientation found in the battery holder. Replace the battery door. Turn on the device by pressing the ON/OFF switch for one second. The device will return to the therapy mode as set when the device was turned off.

Disabling the Audible Alarm - The audible alarm warns the user of the presence of a performance problem with the device. These alarms are also displayed on the LCD display. For many reasons, the user may wish to disable the audible alarm for a few minutes.

The alarm sound can be temporarily disabled by pressing any of the three blue buttons briefly. This will disable the alarm for 5 minutes. After which time, it will sound again if the problem still exists.

End of Therapy and Returning the NPD 1000 device

As the negative pressure therapy proceeds, the healing of the wound will progress to a point at which the clinician will determine that the NPD 1000 system is no longer necessary. **DO NOT DISCONTINUE USE OF THE NEGATIVE PRESSURE WOUND THERAPY SYSTEM WITHOUT THE CONSENT OF YOUR WOUND CARE PROFESSIONAL.** Ask your clinician for guidance on the return of the pump. **DO NOT THROW THE PUMP IN THE TRASH.** It is likely that you will be returning the device to the clinician, the hospital or nursing facility or be required to call your home medical equipment provider. Your clinician will be able to tell you what to do once therapy has been terminated.

Kalypto Medical Contact Information

Kalypto Medical

1250 Northland Drive
Mendota Heights, MN 55120

Website:

www.kalyptomedical.com

Email:

info@kalyptomedical.com

Phone:

651.XXX.XXXX
877.286.3740

Fax:

651.XXX.XXXX

P/N 5004 Kalypto Medical 6/08

Labeling

NPD1000 Control Unit Label

NPD 1000 Control Unit Negative Pressure Wound Therapy Device

Manufactured for:
Kalypto Medical
1250 Northland Drive
Mendota Heights, MN
55120

 CLASSIFIED
UL US
3RTV


UL60601-1,
CAN/CSA
No.601.1



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

4.5VDC/ 1.0A/ 4.5V P/N 50001 Rev. A © Kalypto Medical 4/08

NPD 1000i Pump Module Label

NPD 1000i Pump Module

Manufactured for:
Kalypto Medical
1250 Northland Drive
Mendota Heights, MN 55120



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

P/N 50003 Rev. A © Kalypto Medical 5/08

NPD 1000c Pump Module Label

NPD 1000c Pump Module

Manufactured for:
Kalypto Medical
1250 Northland Drive
Mendota Heights, MN 55120



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

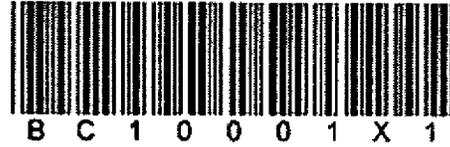
P/N 50005 Rev. A © Kalypto Medical 5/08

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**NPD 1000 Negative Pressure
Wound Therapy Dressing Label**

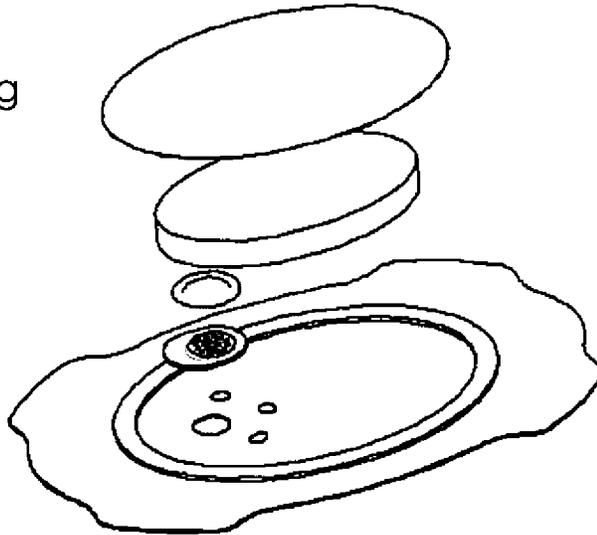
To re-order, consult your physician and refer to the Product Number below.

Product Number #: BC10001x1



NPD 1000 Negative Pressure Wound Therapy Dressing

Arm or Leg
50 CC Dressing
Latex-free



Patents pending on the NPD 1000 Negative Pressure System and accessories

 SINGLE USE ONLY

STERILE Do not use if package is open or damaged.

 **CAUTION:** Consult the NPD 1000 Instructions for Use for directions on the safe use of this dressing.

 **CAUTION:** Federal law restricts this device to sale by or on the order of a physician

LOT Lot Number listed on pouch below

 Manufacture Date listed on pouch below

 Keep Dry

 Use By Date listed on pouch below

Assembled in the USA



Manufactured for:
Kalypto Medical
1250 Northland Drive
Mendota Heights, MN 55120

Website:
www.kalyptomedical.com

P/N 50007 Rev. A © Kalypto Medical 4/08

Usability Testing Questionnaire

Kalypto

research questionnaire

Thank you for participating in this user research session. The following questions are designed to review the instructions for use of the Kalypto Negative Pressure Wound Therapy System. If you have any questions please do not hesitate to ask. Thank you again- the Kalypto R&D team

Questionnaire

(Circle the correct answer)

AGE _____

Male

Female

1) How do you know if the negative pressure wound system is working?

- a. You hear the pump.
- b. Display shows pump icon  in upper left corner.
- c. Display lights up.

2) Should you ever clean the device?

Yes

No

3) How do you know if the batteries need to be changed?

- a. Battery icon  appears on the display.
- b. Device beeps.
- c. Pump does not run.
- d. Both A and B.

4) How do you know if the dressing is not properly sealed?

- a. Dressing is not conformed to wound and firm to touch.
- b. Balloon icon  is shown on the display.
- c. Pump runs continuously.
- d. Any of the above.

- 5) Since the wound dressing is absorbing some wound fluid, how do you know if the dressing has reached its fluid capacity?
- a. Dressing windows near the pressure port are discolored.
 - b. Dressing is no longer firm to the touch.
 - c. Balloon icon  is shown on the display.
 - d. System beeps frequently.
 - e. Both A and B.
- 6) Under what circumstances should you call your wound care provider regarding your NPD1000 Negative Pressure Wound System?
- a. Unable to identify the cause of an alarm.
 - b. Unable to fix a dressing leak.
 - c. Display flashing even after replacing batteries.
 - d. Any of the above.
- 7) What do you do with your negative pressure pump, when your wound care provider has determined that you no longer need negative pressure therapy?
- a. Throw device in the trash.
 - b. Send device back to Kalypto Medical.
 - c. Talk to your wound care provider for guidance.
 - d. Do nothing.

Usability Testing Summary Report

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3

IFU User Group Study



IFU User Research Summary

May 2008

redgroup
product development

580

4

Que

IFU User Group Study

Kalypto
Medical

Overview of Research

redgroup
product development

581

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Purpose of User Research

- Confirm that potential users can understand the language used in the IFU.
- Confirm that potential users can answer some questions about the operation of the negative pressure wound care system.
- Observe that potential users can fix a simple bandage leak and replace the batteries.

Methodology of User Research

- Review of the current IFU
- Survey questionnaire about the IFU
- Test that potential users can fix a leak and replace the batteries
- (Sessions videotaped)



Survey Questionnaire

page 1

page 2

research questionnaire

Thank you for participating in this user research session. The following questions are designed to review the instructions for use of the Kalypto Negative Pressure Wound Therapy System. If you have any questions please do not hesitate to ask. Thank you again- the Kalypto R&D team

Questionnaire

(Circle the correct answer)

AGE _____

Male Female

- How do you know if the negative pressure wound system is working?
 - a. You hear the pump.
 - b. Display shows pump icon  in upper left corner.
 - c. Display lights up.
- Should you ever clean the device?
 - Yes No
- How do you know if the batteries need to be changed?
 - a. Battery icon  appears on the display.
 - b. Device beeps.
 - c. Pump does not run.
 - d. Both A and B.
- How do you know if the dressing is not properly sealed?
 - a. Dressing is not contacted to wound and firm to touch.
 - b. Balloon icon  is shown on the display.
 - c. Pump runs continuously.
 - d. Any of the above.

Kalypto

research questionnaire

- Since the wound dressing is absorbing some wound fluid, how do you know if the dressing has reached its fluid capacity?
 - a. Dressing windows near the pressure port are discolored.
 - b. Dressing is no longer firm to the touch.
 - c. Balloon icon  is shown on the display.
 - d. System beeps frequently.
 - e. Both A and B.
- Under what circumstances should you call your wound care provider regarding your NPWT 0000 Negative Pressure Wound System?
 - a. Unable to identify the cause of an alarm.
 - b. Unable to fix a gassing leak.
 - c. Display flashing even after replacing batteries.
 - d. Any of the above.
- What do you do with your negative pressure pump, when your wound care provider has determined that you no longer need negative pressure therapy?
 - a. Throw device in the trash.
 - b. Send device back to Kalypto Medical.
 - c. Talk to your wound care provider for guidance.
 - d. Do nothing.

Kalypto

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IFU User Group Study

Kalypto
Medical

Research Findings

redgroup
product development

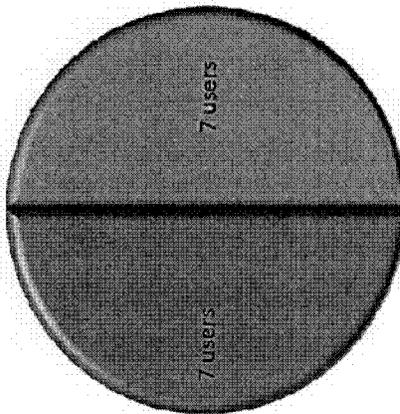
584

8



Purpose of User Research

Demographics



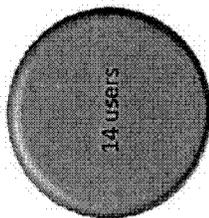
Male
 Female

- Total Users: 14
- Average Age: 65 years

Survey Questions

1) How do you know if the negative pressure wound system is working?

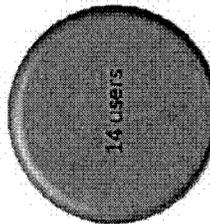
- A. You hear the pump.
- B. Display shows pump icon in upper left corner.
- C. Display lights up.



B.

2) Should you ever clean the device?

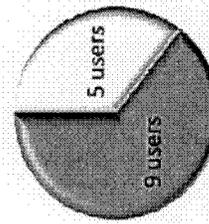
- Yes
- No



No

3) How do you know if the batteries need to be changed?

- A. Battery icon appears on the display.
- B. Device beeps.
- C. Pump does not run.
- D. Both A and B.



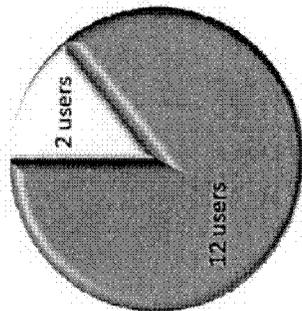
A.

D.

Survey Questions

4) How do you know if the dressing is not properly sealed?

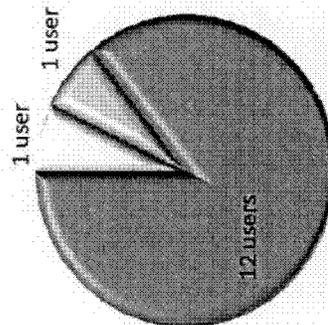
- A. Dressing is not conformed to wound and firm to touch.
- B. Balloon icon is shown on the display.
- C. Pump runs continuously.
- D. Any of the above.



- B.
- D.

5) Since the wound dressing is absorbing some wound fluid, how do you know if the dressing has reached its fluid capacity?

- A. Dressing windows near the pressure port are discolored.
- B. Dressing is no longer firm to the touch.
- C. Balloon icon is shown on the display.
- D. System beeps frequently.
- E. Both A and B.

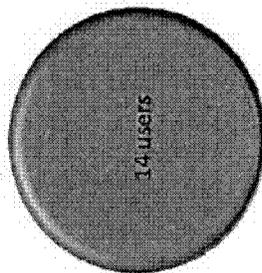


- A.
- B.
- E.

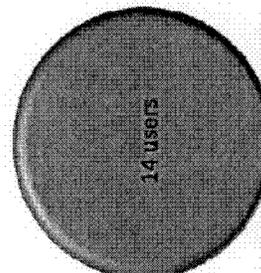


Survey Questions

- 6) Under what circumstances should you call your wound care provider regarding your NPD1000 Negative Pressure Wound System?
- A. Unable to identify the cause of an alarm.
 - B. Unable to fix a dressing leak.
 - C. Display flashing even after replacing batteries.
 - D. Any of the above.
- 7) What do you do with your negative pressure pump, when your wound care provider has determined that you no longer need negative pressure therapy?
- A. Throw device in the trash.
 - B. Send device back to Kalypto Medical.
 - C. Talk to your wound care provider for guidance.
 - D. Do nothing.



D.



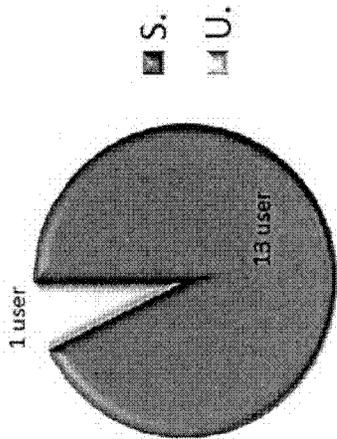
C.



Leak Test and Battery Change

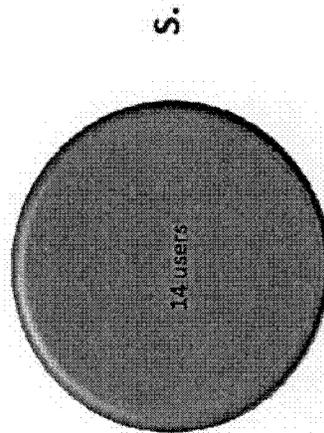
8. Potential user battery change:

- Successful
- Unsuccessful



9. Potential user leak test:

- Successful
- Unsuccessful

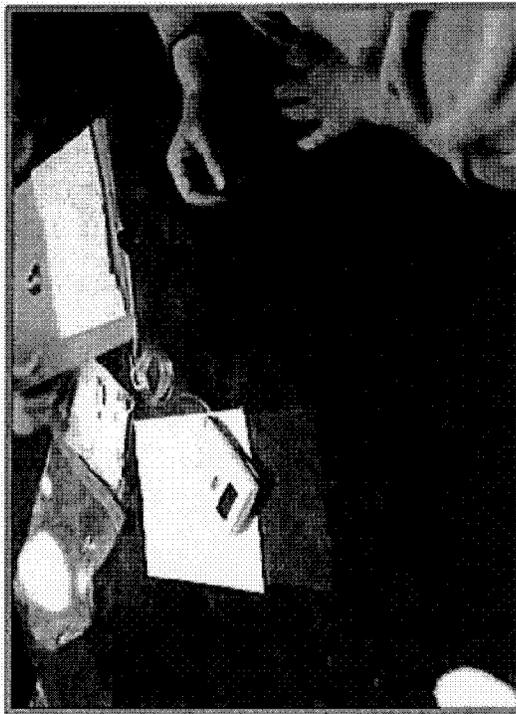


Leak Test and Battery Change Video

Potential user battery change:



Potential user leak test:

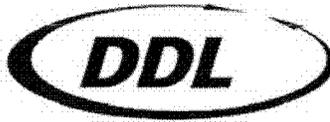


Summary

Based on the results of the focus group testing, the following changes should be made to the patient section of the Kalypto Medical NPD 1000 Instructions for Use

1. **Full Dressing Condition** - The visible signs on the dressing indicating the dressing has reached its fluid capacity should be highlighted (bolded)
2. In describing the appearance of the dressing after powering on the device, a more complete explanation should be given of the visual cues that the system is operating as expected.
3. In the "Low Battery" section of the Alarms and Troubleshooting an explicit reference to the presence of an audible beep upon the appearance of the low battery icon should be made.

Protocol for Packaging Integrity and Shelf Life Validation
(one Year Product and Package Evaluation)



Tested and Proven.

10200 Valley View Rd., #101
 Eden Prairie MN 55344
 952-941-9226
 Fax 952-941-9318
 1-800-229-4235

Test Protocol Title: <i>One Year Product and Package Evaluation</i>	
Test Type:	<i>Accelerated Aging, Product Functionality and Package Sterility Validation Tests</i>
Protocol Number: P080299	Revision: B
Approvals:	
Iasis Medical: _____	Date: _____
DDL, Inc Written By: <u>Alan Gale</u>	Alan M. Gale <small>Digitally signed by Alan M. Gale DN: CN = Alan M. Gale, C = US, O = DDL, Inc., OU = Operations Reason: I am the author of this document Date: 2008.04.31 07:29:11 -0500</small> Date: <u>Mar 31, 2008</u>
Approved By: <u>Patrick J. Nolan</u>	Date: _____
Package Tested: Single Barrier Foil/Foil Pouch	
Product Tested: NPD 1000 Negative Pressure Dressing	

1. Purpose

1.1. This document provides the test parameters required to perform accelerated aging, product functionality and package strength evaluation using physical strength methods, and product sterility validation testing using physical integrity detection methods.

2. Scope

2.1. Completion of the work described in this protocol will provide documentation supporting the capabilities of the package under conditions of temperature. It will also determine the seal integrity of the packages and sterility maintenance.

2.2. The loss of sterility in a package is typically a dynamic event related incident rather than a time related phenomenon. Damage to a package may be caused by one or more of the following events:

- Loss of the seal integrity due to the effects of high temperature and humidity or shipping and handling events.
- Improper manufacturing and production processes.

2.3. By selecting products which have been processed through manufacturing and sterilization, and then subjecting those packages to accelerated aging, product functionality, package strength and package integrity tests, it can be determined if the production process and package design are adequate to maintain sterile conditions throughout the expected shelf life.

Test Protocol Title:	One Year Accelerated Aging Product and Package Evaluation
Test Type:	Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests
Protocol Number:	P080299
	Revision: B

3. References

- 3.1 ASTM F 1980-07, *Standard Guide for Accelerated Aging of Sterile Medical Device Packages.*
- 3.2 ASTM F 88-07a, *Standard Test Method for Seal Strength of Flexible Barrier Materials.*
- 3.3 ASTM F 2096-04, *Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak).*
- 3.4 Iasis Medical, *Bandage Integrity - Vacuum Pressure Test Protocol*
- 3.5 Iasis Medical, *Bandage Fluid Capacity Test Protocol*
- 3.6 Iasis Medical, NPD 1000 IFU (instructions for use)

4. Materials and Equipment

- 4.1. Temperature/Humidity Chamber meeting the requirements of ASTM D-4332, *Conditioning Containers, Packages, or Packaging Components for Testing.*
- 4.2. Material Test System meeting the requirements of ASTM F-88, *Standard Test Method for Seal Strength of Flexible Barrier Materials.*
- 4.3. Iasis Medical NPD 1000 Negative Pressure Wound Therapy Device
- 4.4. Iasis Medical Micro NPWT device
- 4.5. Ashcroft Vacuum pressure sensor gauge
- 4.6. Stopwatch
- 4.7. Syringe of 50 – 200 ml capacity
- 4.8. Beaker of 500 – 2000 ml capacity
- 4.9. Fluid as described in protocol – de-ionized, distilled, or tap water

5. Sample Description and Preparation

- 5.1. The test packages consist of a single barrier foil to foil pouch package.
- 5.2. Sample size will reflect the number of samples desired for the seal strength and integrity evaluation, and product functionality verifications.
- 5.3. Ninety (90) pouches will be used for this study. Sixty (60) of these pouches will contain **NO product** and will be designated for the Seal Strength and Bubble Leak testing. Thirty (30) of these pouches **WILL contain product** and be designated for the functionality testing. These packages have been produced under normal processing limits established in the process validation.
- 5.4. All samples will be clearly identified by Iasis Medical for testing requirements.

6. Test Procedure

The following test procedures will be performed per the test sequence described below.

6.1 Sterilization

All packages and product for the one year accelerated aging shelf life study have been Ebeam sterilized using the Iasis Medical standard operating procedures.

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6.2 Accelerated Aging Test Protocol

Ninety (90) pouches with product will be subjected to the environmental conditions described below and in accordance with ASTM F1980-07.

6.2.1 For one year of accelerated aging, each primary package will be subjected to the following sequence of conditions in accordance with the following equation:

$$\text{Accelerated Aging Rate (AAR)} = Q^{((\text{elevated temp.} - \text{ambient temp.})/10)}$$

where

$$Q = 2.0$$

$$\text{Ambient Temp.} = 22^{\circ}\text{C}$$

$$\text{Test Temp.} = 55^{\circ}\text{C}$$

$$\text{Accelerated Aging Time Duration (AATD)} = \text{Real Time}/\text{AAR}$$

$$\text{so... AAR} = 2^{((55-22)/10)}$$

$$\text{AAR} = 9.85$$

$$\text{AATD} = 365/9.85 = 38 \text{ Days}$$

The test sequence for the 1 Year study:

Test Temperature	1 Year
55°C +/-2 <20% RH	38 Days

The aging for this protocol will simulate **1 Year** of real time aging. A total of **38** days of conditioning is required to complete this segment of this validation.

6.2.2 Temperature selection will be based on the heat resistance of the packaging materials. If lower temperatures are required, then the conditioning time will be adjusted based on the Arrhenius thermodynamic temperature coefficient rule ("a rise in temperature of 10 °C will double the rate of chemical reaction").

6.2.3 Accelerated Aging Technical Note:

When conducting an accelerated aging program for establishing product and package shelf life or expiration dating claims, it must be recognized that the data obtained from the study is based on conditions that **simulate** the effects of aging on the materials. The resulting creation of an 'expiration date' or shelf life represents a conservative estimate of shelf life and is **tentative** until the results of real time aging studies are completed on the product or product/package combination.

Since the results of the study produce a **conservative estimate** of the actual shelf life of the materials, tolerances for the

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Test Protocol Title: <i>One Year Accelerated Aging Product and Package Evaluation</i>	
Test Type: <i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>	
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temperature and humidity are only provided to ensure that the chamber operates within a satisfactory range. Out of tolerance excursions for less than 6 hours in duration for either temperature or humidity are acceptable and do not adversely affect the estimate for shelf life.

Out of tolerance excursions may be caused by opening doors for sample transfer; inserting moist samples into a dry environment causing spikes in humidity; proximity of monitoring device to temperature and/or humidity source inlets.

6.3 Post Accelerated Aging Package Analysis

Sixty (60) empty pouches will be tested to determine the effects of accelerated aging on the seal strength and integrity of the production pouches. Thirty (30) empty pouches will be tested in accordance with ASTM F88-07a and thirty (30) empty pouches will be tested in accordance with ASTM F2096-04.

6.4 Post Accelerated Aging Product Analysis (Negative Pressure Integrity)

Fifteen (15) pouches with product inside will be opened to remove the NPD 1000 Negative Pressure Dressing from the pouch. Each dressing will be tested according to the Bandage Integrity - Vacuum Pressure Test Protocol. Within the protocol, two tests will be performed. A Persistent Vacuum Integrity test will be performed on eight (8) samples and a Bandage Pump Down Time test will be performed on seven (7) samples.

6.5 Post Accelerated Aging Product Analysis (Bandage/Dressing Fluid Capacity)

Fifteen (15) pouches with product inside will be opened to remove the NPD 1000 Negative Pressure Dressing from the pouch. Each dressing will be tested according to the Bandage Fluid Capacity Test Protocol.

6.6 Summary of Strength and Integrity Sample Size

	Post 1 Year. AA
Seal Strength	30 empty Pouches
Bubble Leak	30 empty Pouches

6.7 Summary of Accelerated Aging Product Analysis

	Post 1 Year. AA
Negative Pressure Integrity Testing	15 Product
Bandage/Dressing Fluid Capacity Testing	15 Product

Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>		
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7 Acceptance Criteria

- 7.1 Primary packages will be visually inspected while undergoing integrity testing for damages caused by accelerated age testing. Obvious mechanical damage such as seal failures, holes, tears and voids will be documented and lasis Medical will be notified.
- 7.2 Packages fail the test protocol if there is obvious physical damage to the primary package or the bubble leak test indicates any signs of leakage.
- 7.3 Acceptance criteria for all product functionality testing has been identified by lasis Medical.
 - 7.3.1 Tests that involved the Bandage Pump Down Time must able to achieve the set pressure in less than 3 minutes with each bandage/dressing.
 - 7.3.2 Tests that involved the Persistent Vacuum Integrity will have the pump and bandage system deliver and maintain 125 mmHg of negative pressure over the 1 hour duration.
 - 7.3.3 Tests that involved the Bandage/Dressing Fluid Capacity, the average Vcap calculated from the 15 samples shall be within 50cc +/- 10%.

8 Documentation

- 8.1 The accelerated aging will be documented using a NIST traceable temperature/humidity recorder and probe. The periodic readings will be retained as evidence that the proper temperature and humidity were maintained throughout the test duration.
- 8.4 The seal strength testing will be documented and all data will be compiled for average and standard deviation.
- 8.5 The bubble leak test will be documented on appropriate work sheets or laboratory notebook indicating a pass or fail.
- 8.6 The negative pressure integrity test will be documented on appropriate work sheets or a laboratory notebook. It will be used to record the equipment used and test results of performing the Bandage Integrity - Vacuum Pressure Test Protocol.
- 8.7 The bandage/dressing fluid capacity test will be documented on appropriate work sheets or a laboratory notebook. It will be used to record the equipment used and test results of performing the Bandage Fluid Capacity Test Protocol.
- 8.8 Gross irregularities found during inspection of samples prior to integrity testing will be documented and lasis Medical will be notified.
- 8.9 Records for this project will be archived at DDL for a duration of 5 years in accordance with DDL's record policy. At the completion of 5 years all records will be disposed of properly. A written request must be made by the customer, specifying a longer retention period before the 5 years is complete.

Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>		
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- 8.10 A single test report including the one year accelerated aging, seal strength, bubble leak and functionality tests will be issued to lasis Medical upon completion of testing.

Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
Protocol Number:	P080299
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APPENDIX A

Bandage Integrity - Vacuum Pressure Test Protocol

Introduction

This test will verify . . .

- The NPD 1000 Negative Pressure Dressing has vacuum integrity, when used with the NPD 1000 Negative Pressure Wound Therapy Device, over the full range of therapeutic pressures at the end of its labeled shelf life.
- The 1000 Negative Pressure Dressing shall be able to achieve and maintain a vacuum pressure down to 40 mmHg.
- The Micro NPWT device shall be able to achieve and maintain a vacuum pressure up to 125 mmHg.
- The tolerance of all set pressures in the Micro NPWT device shall be +/- 10% unless otherwise specified.
- The Micro NPWT device pump module shall be able to achieve the set pressure in less than 3 minutes with largest bandage designed.

Setting parameters on the NPD 1000 Negative Pressure Wound Therapy Device

To enter Configuration mode in order to change therapy mode or to modify the vacuum pressure setpoint, press and hold the Therapy Type (Mode) button and Pressure Setting (VAC) button simultaneously. While the Mode and VAC buttons are both held down, press and release the Pump On/Off button, then release the Mode and VAC buttons. Once in Configuration mode, to change therapy modes, press and release the Mode button. To change the vacuum pressure setpoint, press and release the VAC button. To exit Configuration mode, press and release the Pump On/Off button or wait 30 seconds from the last button press to time out and automatically exit.

Test Equipment

1. 15 NPD 1000 Negative Pressure Dressings*
2. NPD 1000 Negative Pressure Wound Therapy Device*
3. Negative pressure tubing and fittings*
4. One independent pressure sensor.
5. Smooth surface fiberglass board to accommodate mounting of bandage*
6. Stopwatch.

* Note: These items supplied by customer

Test Procedures and Expected Results

Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
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Persistent Vacuum Integrity (test performed with 8 bandages, serially)

1. Connect the control module and pump module according to the directions in the NPD 1000 IFU (instructions for use). Label the pumps, pump # 1 and pump # 2.



2. Start this test with device batteries (in control module) removed. Place the batteries in the control module, allowing the entire device to power up and complete self tests. Enter Configuration mode.

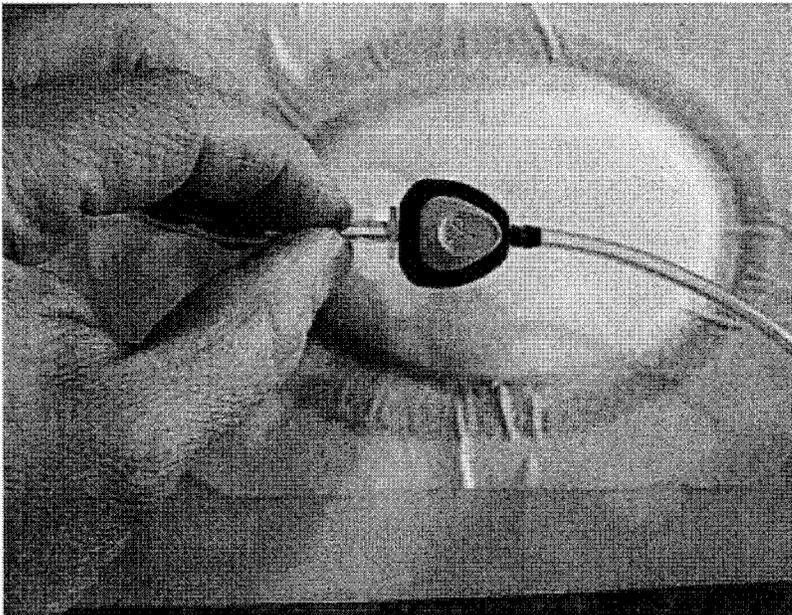


- Verify that the vacuum pressure setpoint display is active and flashing

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Test Protocol Title:	One Year Accelerated Aging Product and Package Evaluation
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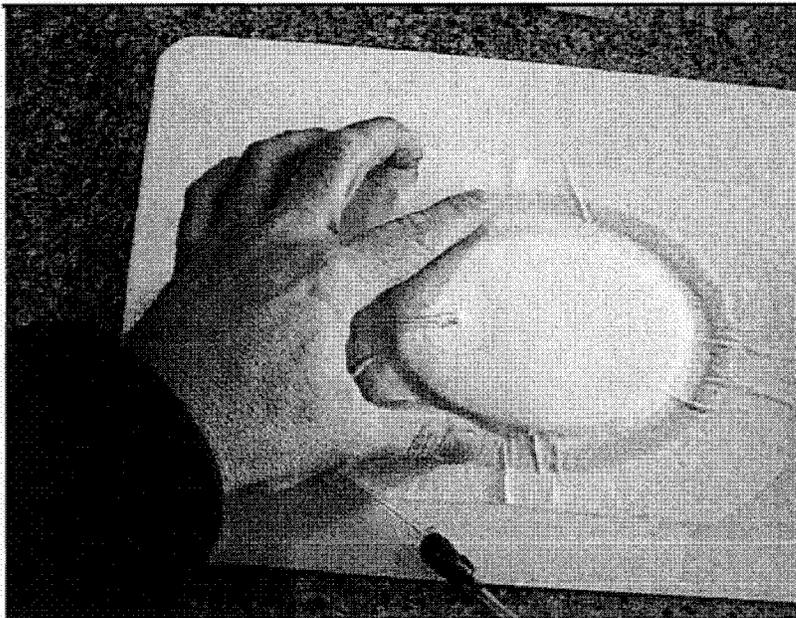
3. Press the VAC button until the vacuum pressure is set to 125 mmHg. Continue to press the VAC button, scrolling through all the vacuum pressure setpoints until 40 mmHg is reached. Stop at this value.
 - Verify the vacuum pressure setpoint display is active and flashing (signals a change in vacuum setting).
 - Exit Configuration mode
4. Mount the bandage securely to the test board
5. Connect the pump to the bandage with connectors, connectors on bandage and pump tubing. Add independent pressure gauge in-line with "tee" into pump tubing.



6. Turn the pump on by depressing the power button for > 1 second. Allow the unit to run for a minimum of 1 hour. Note: if a persistent leak occurs at start up (i.e. the pump never turns off), correct the leak by pressing the bandage gasket against the surface of the mounting board (see below) and continue the test.
 - Verify that the pump turns on and the bandage achieves the appropriate negative pressure at 40 mmHg +/- 10%.
 - Verify that no system fault notifications occur (ie. loss of pump control or pump inoperable) due to the inability of the system to deliver and maintain 40 mmHg of negative pressure continuous therapy over the 1 hour duration. "Inability" is defined as the bandage being unable to seal, such that the leak alarm (defined in the instructions for use booklet) persists throughout the test period. A balloon icon will appear if there is a seal fault. If the display has many pixels illuminated, there is a system fault.

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Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
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Revision:	B



7. Enter Configuration mode, press the VAC button until the vacuum pressure is set to 125 mmHg. Exit Configuration mode and turn the pump on. Allow the unit to run for a minimum of one hour. Note: if a leak occurs, correct the leak and continue the test.
- Verify that the pump turns on and the bandage achieves the appropriate negative pressure at 125 mmHg +/- 10%.
 - Verify that no system fault notifications occur (ie. loss of pump control or pump inoperable) due to the inability of the system to deliver and maintain 125 mmHg of negative pressure continuous therapy over the 1 hour duration.

Bandage Pump Down Time (seven bandages, one at a time)

1. Attach a new bandage to fixture.
2. Seal the dressing to the fixture by pressing gasket around the entire perimeter and smoothing the dressing corner as much as possible.
3. Configure the NPD 1000 Negative Pressure Wound Therapy Device to deliver 125 mmHg of continuous therapy.
4. Attach the bandage to the pump with the appropriate connectors.
5. Turn the pump on and start the stopwatch at the same time.
6. Stop the stopwatch when the pump stops pumping AND when the independent pressure sensor signals a negative pressure of 125 mmHg.
7. Record the elapsed time.
8. Repeat this process 10 times recording the pump down time each time.
9. Average the recorded elapsed times.
 - Verify that the Continuous pump is able to achieve the set pressure in less than 3 minutes with each bandage.

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Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
Protocol Number: P080299	Revision: B

APPENDIX B

Bandage Fluid Capacity Test Protocol

Introduction

This test will verify . . .

- The NPD 1000 Negative Pressure Dressing maintains its therapeutic fluid capacity, when used with the NPD 1000 Negative Pressure Wound Therapy Device, at the end of its labeled shelf life.
- The average fluid retention capacity, (Vcap) of the NPD 1000 Negative Pressure Dressing shall be capable of holding 50cc of fluid, +/- 10%.

Setting up the NPD 1000 Negative Pressure Wound Therapy Device

To enter Configuration mode in order to change therapy mode or to modify the vacuum pressure setpoint, press and hold the Therapy Type (Mode) button and Pressure Setting (VAC) button simultaneously. While the Mode and VAC buttons are both held down, press and release the Pump On/Off button, then release the Mode and VAC buttons. Once in Configuration mode, to change therapy modes, press and release the Mode button. To change the vacuum pressure setpoint, press and release the VAC button. To exit Configuration mode, press and release the Pump On/Off button or wait 30 seconds from the last button press to time out and automatically exit.

Test Setup

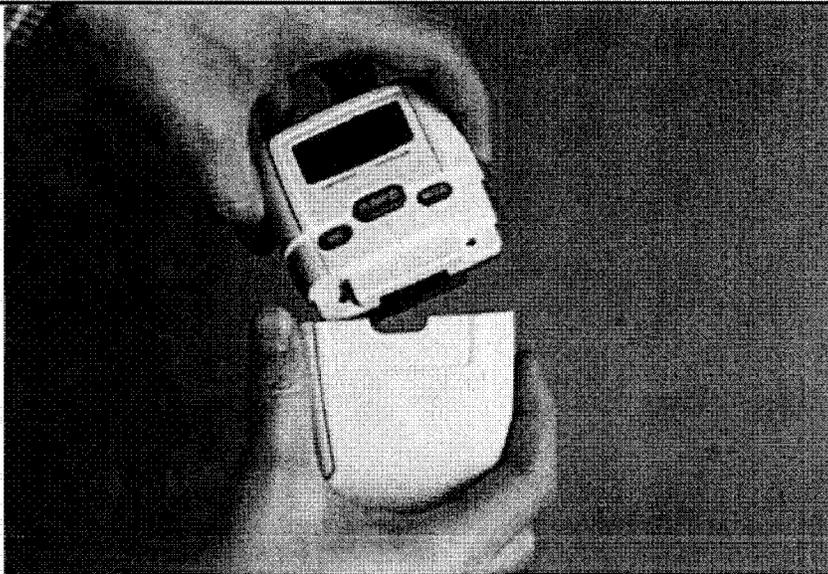
7. Fifteen (15) of the NPD 1000 Negative Pressure Dressings
8. One (1) NPD 1000 Negative Pressure Wound Therapy Device (control module w/ batteries and pump module)
9. Negative pressure tubing and fittings
10. Fiberglass board to accommodate mounting of bandage and introduction of fluid to bandage
11. One (1) Calibrated fluid syringe (50 – 200 ml capacity)
12. Test Fluid container with water and food coloring (for indication purposes)
13. Stopwatch.

Test Procedures and Expected Results

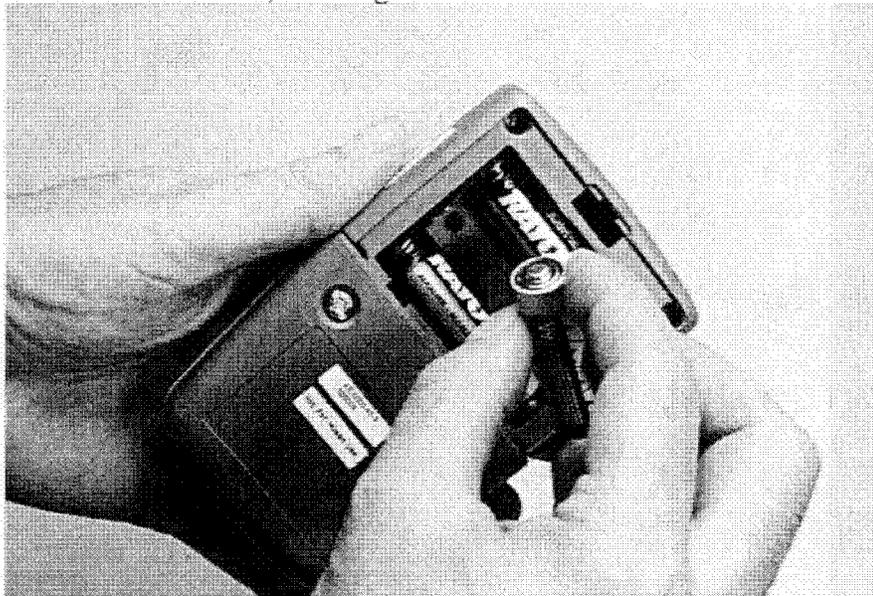
Bandage Fluid Capacity (test performed with 15 bandages, one at a time)

8. Connect the control module and pump module according to the directions in the NPD 1000 IFU (instructions for use).

Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
Protocol Number:	P080299
Revision:	B



9. Start this test with device batteries (in control module) removed. Place the batteries in the control module, allowing the entire



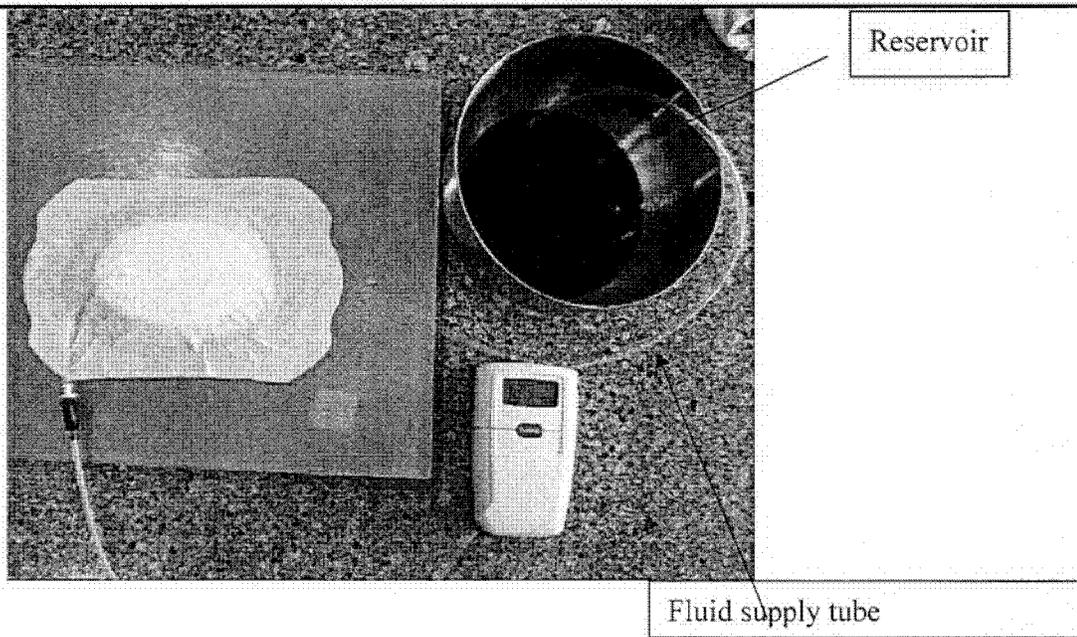
device to power up and complete self tests. Enter Configuration mode.

- Verify that the vacuum pressure setpoint display is active and flashing

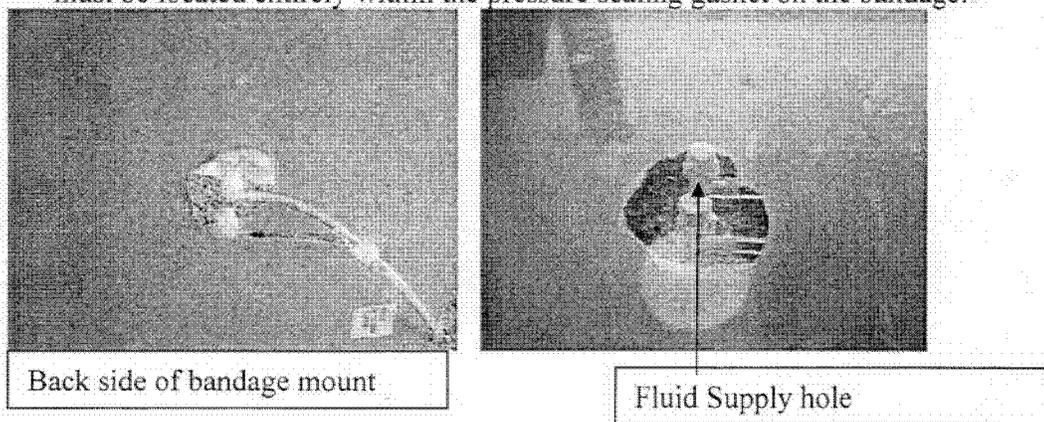
10. Press the VAC button until the vacuum pressure is set to 125 mmHg. Exit configuration mode.

11. Using syringe, measure 200 cc of colored fluid into test reservoir

Test Protocol Title:	One Year Accelerated Aging Product and Package Evaluation
Test Type:	Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests
Protocol Number:	P080299
Revision:	B



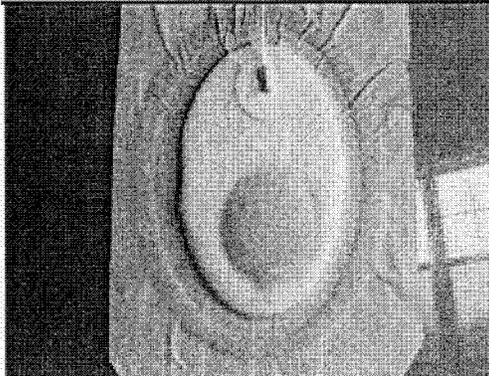
12. Place fluid supply tube, attached to bandage mounting board into the fluid
13. Mount bandage on board above fluid supply "hole". Note: The fluid supply hole must be located entirely within the pressure sealing gasket on the bandage.



14. Attach the NPD 1000 Negative Pressure Wound Therapy Device to the dressing with the supplied tubing.
15. Turn on the pump. Fluid will begin to flow from the reservoir to the bandage. The pump will turn off and on during this process. The bandage will fill in approximately 30-45 seconds.

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Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
Protocol Number: P080299	Revision: B

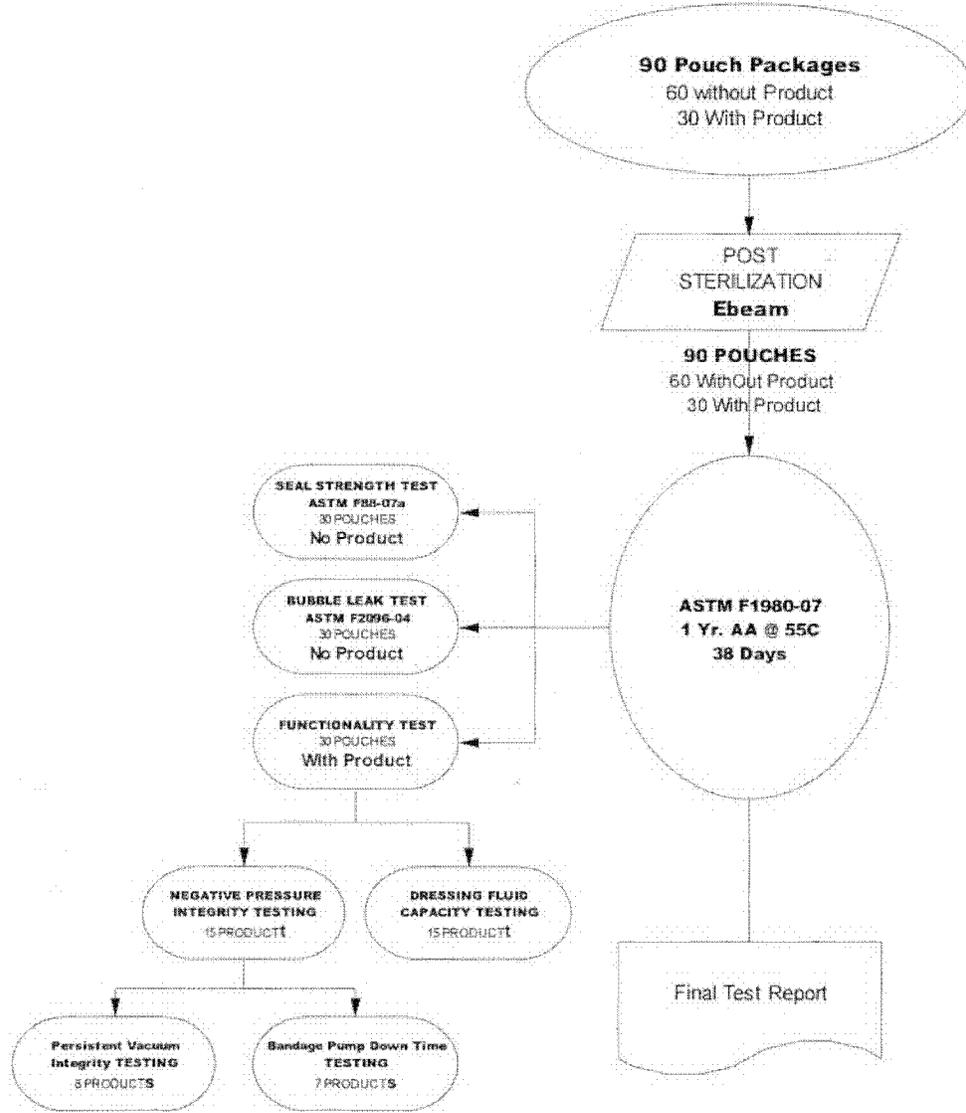


16. Five minutes after the pump has stopped cycling, turn off the pump and detach the tubing from the bandage.
17. Carefully remove the bandage from the fixture, taking care not to squeeze the absorbent pad.
18. Extract the absorbent pad from the dressing.
19. Place absorbent pad on flat surface and extract the "free" water from the pad by compressing the pad with a rigid roller applying 3 lbs. of force. Collect "squeezed" water into the original fluid reservoir.
20. Measure the non-absorbed fluid in the reservoir with the calibrated syringe, noting the remaining volume, Vrem. As an alternative, the volume of fluid can be measured using a scale capable of displaying grams.
21. Calculate the dressing fluid retention capacity, Vcap, by the following formula,
 1. $V_{cap} = 200 \text{ cc} - V_{rem}$
22. Repeat measurement for remaining dressings
23. Calculate the average of Vcap and S.D. of Vcap
24. The average of all fifteen (15) Vcaps must be within the 50cc +/- 10% tolerance or failure has occurred.

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Test Protocol Title:	One Year Accelerated Aging Product and Package Evaluation
Test Type:	Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests
Protocol Number:	P080299
Revision:	B

lasis Medical
1 Year Accelerated Aging Product and Package Evaluation
Single Foil / Foil Pouch Package
Product Name: NPD 1000 Negative Pressure Dressing
Protocol #: 080299



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Product Package and Validation Testing Report

Product and Package Validation Testing
for the
IASIS Medical, Inc.
NPD 1000 Negative Pressure Dressing

Report Number: 0802099
Protocol Number: P080299 Rev. B
PO Number: 1005
7 May 2008

Customer:
IASIS Medical, Inc.
Attn: John Buan
15912 69th Place North
Maple Grove, MN 55311

Testing Performed by



Tested and proven.

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INTRODUCTION

Objective

The objective of this project was to evaluate the capabilities of the NPD 1000 Negative Pressure Dressing package design and product for IASIS Medical, Inc. when exposed to accelerated aging. Testing was done under controlled laboratory conditions with equipment qualified to perform these tests.

Scope

This report documents accelerated aging, strength, integrity, and functionality testing on DDL, Inc. specimen number 100543 in accordance with the test methods stated in DDL, Inc. quote number 0802099 Rev. B and DDL, Inc. Protocol P080299 Rev. B located in Appendix A.

SUMMARY OF TESTED SPECIMENS

Specimen Number	Test Interval	Number of Specimens Tested
100543	One Year Accelerated Aging	1
100543	Bubble Leak Testing	30
100543	Seal Strength Testing	30
100543	Persistent Vacuum Integrity	8
100543	Bandage Pump Down Time	7
100543	Bandage Fluid Capacity	15

Table 1: Summary of tested specimens.

RESULTS SUMMARY

Acceptance Criteria

The acceptance criterion has been outlined in DDL, Inc. Protocol P080299 Rev. B located in Appendix A of this test report.

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Accelerated Aging

One year of accelerated aging was performed on one (1) shipper for thirty-eight (38) days in accordance with Q10 Theory ASTM F1980-07; *Guide for Accelerated Aging of Sterile Medical Device Packages*. The cycle of accelerated aging equivalent to one year of real time aging is outlined in the table below.

Condition	Start	End	Days
55°C / <20%RH	18-Feb-08 / 2:00 pm	27-Mar-08 / 2:00 pm	38

Table 2: One Year Accelerated Aging Timeline

Equipment used is kept in current calibration traceable to NIST. Operation of the test was done according to procedure and was monitored by both NIST traceable devices, and continuous monitoring devices.

All raw data for the accelerated aging test is located in Appendix B of this test report.

Package Integrity Testing

Bubble Leak Testing

Thirty (30) single barrier foil/foil pouches were bubble leak tested. All package configurations tested, passed. The raw data for the bubble leak test is located in Appendix C of this test report.

Specimen Number	Test Interval	Number of Specimens Tested	Pass	Fail
100543	Post Accelerated Aging	30	30	0

Table 3: Bubble leak test results.

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Package Strength Testing

Seal Strength Testing

Thirty (30) single barrier foil/foil pouches were seal strength tested. Samples from four (4) designated locations on the single barrier foil/foil pouch were prepared for testing. The standard deviation and average of the peak values were tabulated and are shown below. The raw data for all seal strength testing is located in Appendix D of this test report.

Specimen Number	Side A		Side B		Side C		Side D	
	Avg.	Std. Dev.						
100543	20.19	0.56	21.10	0.49	20.25	0.54	20.82	0.54

Table 4: Post one year accelerated aging seal strength results in lbs.

Functionality Testing

Persistent Vacuum Integrity Testing

Eight (8) bandages were persistent vacuum integrity tested. The pass/fail results are shown below.

The raw data for all persistent vacuum integrity testing is located in Appendix E of this test report.

Specimen Number	40 mmHg		125 mmHg	
	Pass	Fail	Pass	Fail
100543	8	0	8	0

Table 5: Post one year accelerated aging persistent vacuum integrity results.

Bandage Pump Down Time Testing

Seven (7) bandages were bandage pump down time tested. The average pump down time is shown below.

The raw data for all bandage pump down time testing is located in Appendix F of this test report.

Specimen Number	Average Time (min:sec)
100543	00:30

Table 6: Post one year accelerated aging bandage pump down time results.

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Dressing Fluid Capacity Testing

Fifteen (15) bandages were dressing fluid capacity tested. The standard deviation and average absorption was tabulated and are shown below.

The raw data for all dressing fluid capacity testing is located in Appendix G of this test report.

Specimen Number	Minimum	Maximum	Average	Std. Dev
100543	71.8	92.7	81.3	7.3

Table 7: Post one year accelerated aging dressing fluid capacity results in g.

RELATED DOCUMENTS

Standards
ASTM F 2096-04; <i>Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)</i>
ASTM F 88-07a; <i>Seal Strength of Flexible Barrier Materials</i>
ASTM F 1980-07; <i>Guide for Accelerated Aging of Sterile Medical Device Packages</i>
References
DDL, Inc. Quote # 0802099 Rev. B; <i>Product and Package Validation Testing</i>
DDL, Inc. Protocol # P080299 Rev. B; <i>One Year Product and Package Evaluation</i>
DDL, Inc. S.O.P. # 6011, Rel. 04; <i>Distribution Simulation Test</i>
DDL, Inc. S.O.P. # 6047, Rel. 05; <i>Bubble Leak Test for ASTM 2096</i>
DDL, Inc. S.O.P. # 6008, Rel. 05; <i>Procedure for Peel Seal Testing of Flexible Packages</i>

Table 8: Standards and References

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LOGISTICS

Specimen 100543 was received: 18 February 2008

One Year Accelerated Aging:

- Started: 18 February 2008
- Completed: 27 March 2008

Bubble Leak Testing:

- Started: 31 March 2008
- Completed: 31 March 2008

Seal Strength Testing:

- Started: 31 March 2008
- Completed: 2 April 2008

Persistent Vacuum Integrity Testing:

- Started: 31 March 2008
- Completed: 2 April 2008

Bandage Pump-Down Time Testing:

- Started: 2 April 2008
- Completed: 2 April 2008

Bandage Fluid Capacity Testing:

- Started: 3 April 2008
- Completed: 3 April 2008

Specimens picked up by IASIS Medical, Inc. on: 10 April 2008

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EQUIPMENT

The following equipment was used to complete these tests:

Equipment Name	Model No.	Serial No.	Calibration Due
T.M. Electronics Package Tester	BT-115	BT-465	25-Jan-09
DDL Tensile Test System	100P	0001064	11-Apr-09
Thermocouple Thermometer - Digital (4)	HH23	T-258666	17-Oct-08
Chamber 16 (N6)	W09318-01	96120203	13-Feb-09
Thermocouple Probe (D36)	TTSS-HH	D36	19-Jun-08
Temptale4 Sensor (110)	H4600-02-001	3710790574	2-May-08
Iasis Medical NPD 1000 Negative Pressure Wound Therapy Device	50001 Rev A	NA	NA
Pressure Sensor	Ashcroft	1022965	2-Jul-08
Stopwatch	3	001614	1-May-09
600g Scale	AND EK-6000	001065	10-Mar-09

Table 9: Equipment List

PRODUCT

Product

NPD 1000 Negative Pressure Dressing

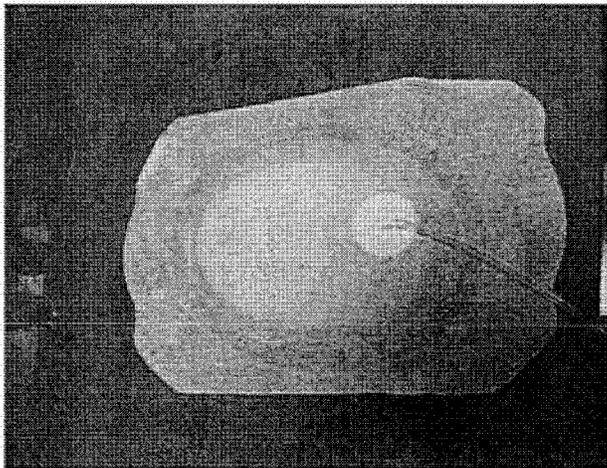


Figure 1: This is a photograph of the negative pressure dressing.

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PACKAGING SYSTEM

Sterile Barrier System

The sterile barrier system consisted of a foil to foil single barrier pouch.

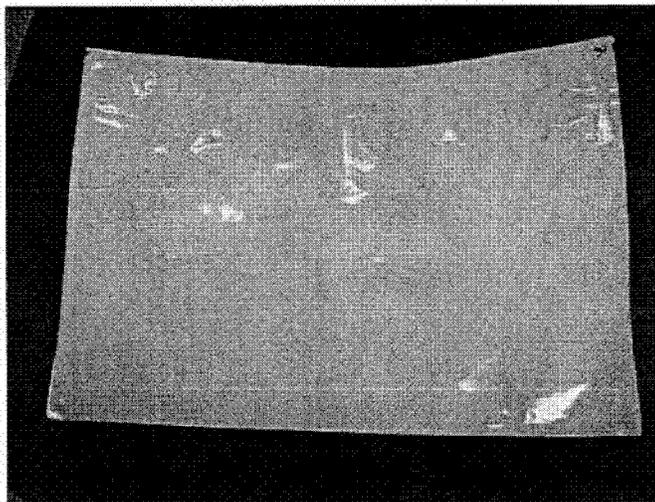


Figure 2: This is a photograph of the sterile barrier system.

TEST PROCEDURE

Accelerated Aging

One year of accelerated aging was performed on the shipping units in accordance with Q10 Theory ASTM F1980-07; *Guide for Accelerated Aging of Sterile Medical Device Packages*. The following cycle was performed once to simulate one year of real time aging.

Condition	Duration
55°C / <20%RH	38 days

Table 10: One Year Accelerated Aging Cycle

The following equation was used to calculate the test duration for a shelf life study equivalent to one year of real time aging:

Accelerated Aging Rate (AAR) = $Q_{10}^{((Elevated\ Temp. - Ambient\ Temp.) / 10)}$		
Q_{10}	2.0	$AAR = 2.0^{((55 - 22) / 10)} = 9.85$
Ambient Temp.	22°C	
Elevated Temp.	55°C	
Accelerated Aging Time Duration = Desired Real Time Aging / AAR		
365 days / 9.85 = 37.06 days		

Table 11: Accelerated Aging Time Duration Equation

The chamber conditions were monitored using a TempTaleH data logger. Periodic temperature measurements were made using a NIST traceable temperature probe. All data for this test can be found in Appendix B of this test report. A tabular summary of the results is presented in the results section of this test report.

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Accelerated Aging Technical Note:

When conducting an accelerated aging program for establishing product and package shelf life or expiration dating claims, it must be recognized that the data obtained from the study is based on conditions that simulate the effects of aging on the materials. The resulting creation of an 'expiration date' or shelf life represents a conservative estimate of shelf life and is tentative until the results of real time aging studies are completed on the product or product/package combination.

Since the results of the study produce a conservative estimate of the actual shelf life of the materials, tolerances for the temperature and humidity are only provided to ensure that the chamber operates within a satisfactory range. Out of tolerance excursions for less than 6 hours in duration for either temperature or humidity are acceptable and do not adversely affect the estimate for shelf life.

Out of tolerance excursions may be caused by opening doors for sample transfer; inserting moist samples into a dry environment causing spikes in humidity; proximity of monitoring device to temperature and/or humidity source inlets.

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Package Integrity Testing

Bubble Leak Test

This test was performed based on ASTM F 2096-04; *Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)* and DDL, Inc. S.O.P. #6047, Rel. 05.

The test method is designed to detect open pathways, channels, or voids across the seal area intended as a primary sterile barrier, and to detect pinholes in non-porous materials. The test may be used for flexible or rigid packages with porous or non-porous materials.

A set-up specimen was used to determine the set pressure by creating a 0.008 inch hole in the foil material. The test apparatus described in the 'materials and equipment' section was used for air pressure. The package was submerged in a water bath for at least five (5) seconds with no air pressure being applied to the single barrier foil/foil pouch. The pressure was then increased slowly until a steady flow of bubbles came from the 0.008 inch hole created in the foil. The packages were observed for any evidence of leakage in the form of a steady stream of bubbles emanating from the package.

All raw data can be found in Appendix C of this test report. A tabular summary of the results is presented in the results section of this test report.

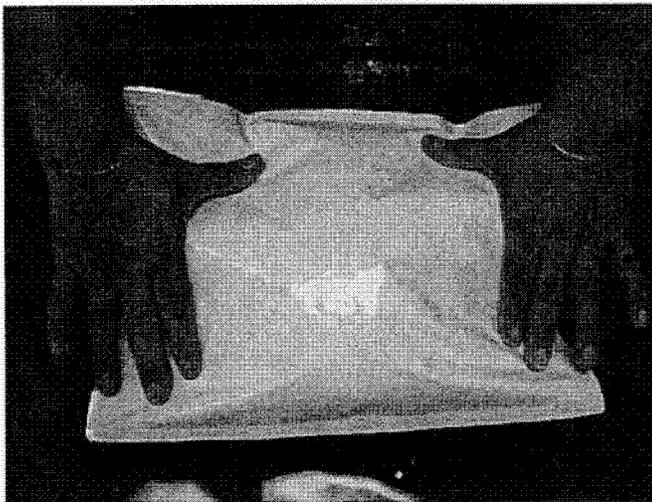


Figure 3: This is a photograph of the bubble leak test set-up.

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Package Strength Testing

Seal Strength Test

Seal strength testing was performed based on ASTM F88-07a; *Seal Strength of Flexible Barrier Materials* and DDL, Inc. S.O.P. #6008, Rel. 05. Specimens were prepared for testing by cutting one-inch by three-inch long strips from designated locations that were perpendicular to the seal on the package. A package sample cutter specifically designed for this task was used.

All raw data for the seal strength tests can be found in Appendix D of this test report. A tabular summary of the results is presented in the results section of this test report.

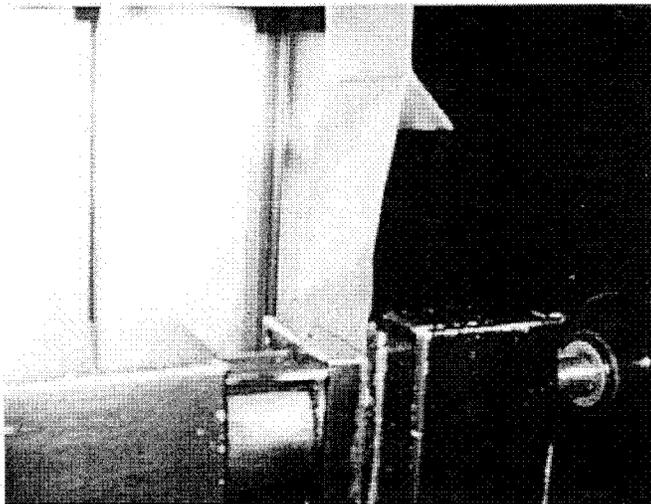


Figure 4: This is a photograph of the seal strength test set-up.

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Functionality Testing

Persistent Vacuum Integrity Test

This test was performed based on DDL Protocol: P0802099 Rev B.: *One Year Product and Package Evaluation*.

The test method is designed to verify the Negative Pressure Dressing will be able to achieve and maintain vacuum pressures of 40 mmHg and 125 mmHg for a minimum of one (1) hour.

A bandage was securely mounted to the test board supplied by Iasis Medical. The bandage was then connected to a pump and allowed to reach a pressure of 40 mmHg. The pump was allowed to run for a minimum of one (1) hour. The bandage passed if no system fault occurred during the test period.

This test procedure was repeated for a pressure of 125 mmHg for each bandage.

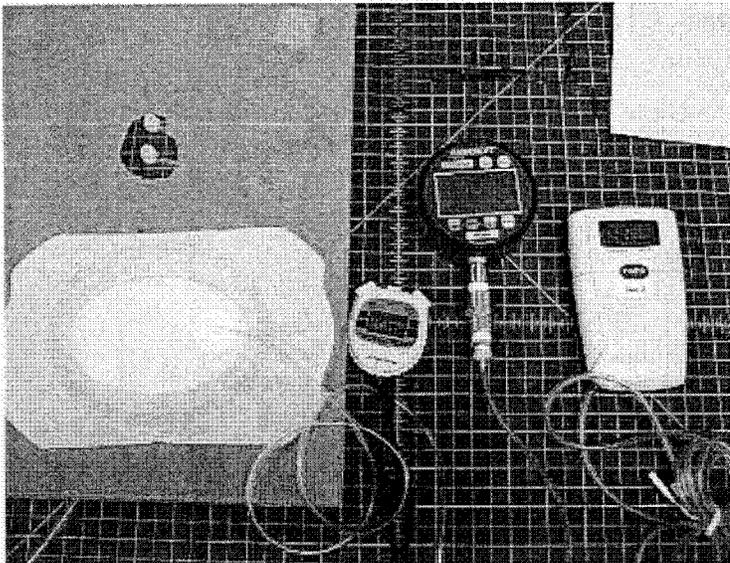


Figure 5: This is a photograph of the persistent vacuum integrity test set-up.

All raw data for the persistent vacuum integrity tests can be found in Appendix E of this test report. A tabular summary of the results is presented in the results section of this test report.

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Bandage Pump Down Time Test

This test was performed based on DDL Protocol: P0802099 Rev B.: *One Year Product and Package Evaluation*.

This test method was designed to verify the continuous pump is able to achieve a set pressure in less than three (3) minutes.

A bandage was securely mounted to the test board and connected to the NPD 1000 Negative Pressure Wound Therapy Device. The pump was set to a negative pressure of 125 mmHg. The pump was turned on and a stopwatch was started simultaneously. The stopwatch was stopped when the pump stopped pumping and the independent pressure sensor signaled a pressure of 125 mmHg. This process was repeated for a total of ten (10) times.

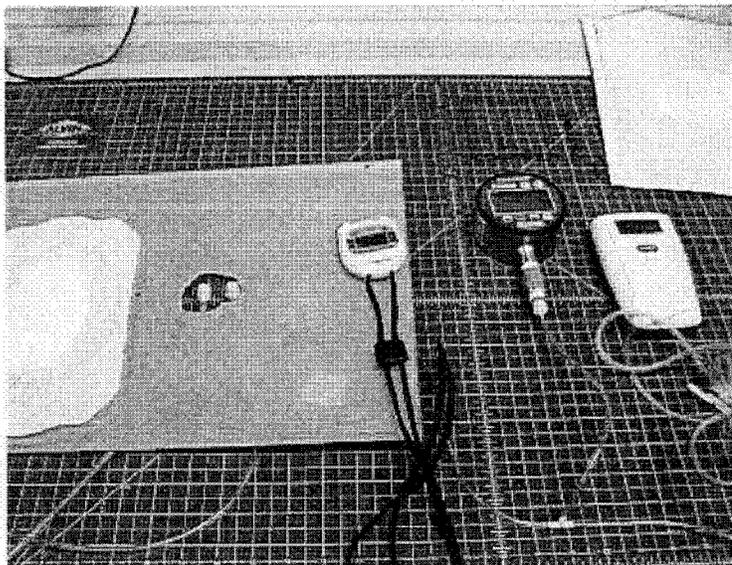


Figure 6: This is a photograph of the bandage pump down time test set-up.

All raw data for the bandage pump down time tests can be found in Appendix F of this test report. A tabular summary of the results is presented in the results section of this test report.

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Bandage Fluid Capacity Test

This test was performed based on DDL Protocol: P0802099 Rev B.: *One Year Product and Package Evaluation*.

This test method was designed to verify the NPD 1000 Negative Pressure Dressing maintains its therapeutic fluid capacity at the end of its labeled shelf life.

In a method approved by the customer a bandage was weighed dry and then securely mounted to the test board. The bandage was pumped with fluid and let set for five (5) minutes. The bandage was then reweighed. The excess fluid was then removed from the bandage using a three (3) pound roller and weighed a third time. The pad absorption was then calculated.

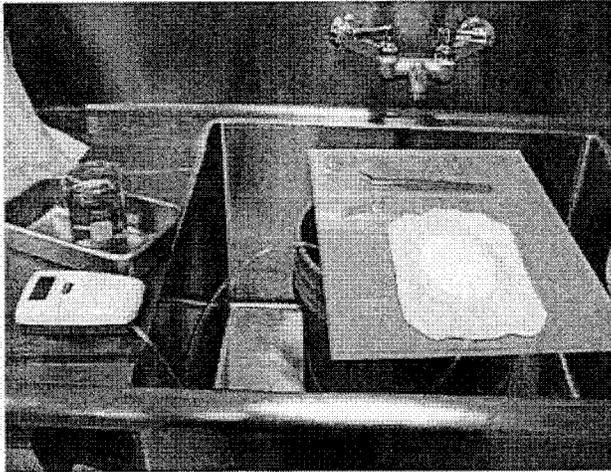


Figure 7: This is a photograph of the bandage fluid capacity test set-up.

All raw data for the bandage fluid capacity tests can be found in Appendix G of this test report. A tabular summary of the results is presented in the results section of this test report.

CONCLUSION

Upon completion of testing all specimens were returned to IASIS Medical, Inc. for further analysis.

- Thirty (30) of thirty (30) single barrier foil/foil pouches subjected to bubble leak testing, passed.
- Eight (8) of eight (8) bandages subjected to persistent vacuum integrity testing, passed.
- Seven (7) of seven (7) bandages subjected to bandage pump down time testing, passed.
- Fifteen (15) of fifteen (15) bandages subjected to bandage fluid capacity testing, passed.
- DDL, Inc. makes no claims as to the functionality of the product.

DISCLAIMER OF WARRANTIES

ALL WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY THAT THE PRODUCT OR PACKAGING TESTED IS MERCHANTABILITY, FIT FOR A PARTICULAR PURPOSE, OR IN COMPLIANCE WITH ANY FEDERAL, STATE OR LOCAL REGULATIONS, ARE DISCLAIMED. In no event shall DDL, Inc. liability exceed the total amount paid by **IASIS Medical, Inc.** for services rendered.

A Quality Assurance program should be in place to ensure that the manufacturing process produces products/packages of equivalent performance to those tested here. This is solely the responsibility of the manufacturer. DDL, Inc. takes no responsibility for the quality of products/packages produced hereafter, other than to certify the design of those physical test systems actually tested by DDL, Inc. DDL, Inc. takes no responsibility for the use, acceptance or non-acceptance of this data by government regulatory agencies.

In the event of future changes to the referenced test procedure(s), it is the responsibility of **IASIS Medical, Inc.** to determine whether additional testing or updating of this certification is necessary to verify that the product and/or packaging certified here remains in compliance with requirements.

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STATEMENT OF CONFORMITY

DDL, Inc. certifies that the above stated testing services have been performed in accordance to applicable standard good laboratory practices and/or standards identified within this report. Testing has been completed as described herein.

The following list of exceptions occurred during testing performed at DDL, Inc.:

- None

All materials, equipment, methods, and processes used to perform the described testing have been standardized, calibrated, and monitored in accordance with prescribed guidelines, standard operating procedures, and the supervision requirements of DDL, Inc. All raw data obtained from this testing by DDL, Inc. personnel is archived at DDL, Inc.

The signatures below are in compliance with 21 CFR Part 11.

Testing performed by: Jackie L. Vue, Colleen K. Bird, and Kathleen A. McDaniel

Digitally signed by Mike B. Woletz
 DN: CN = Mike B. Woletz, C = US, O = DDL, Inc., OU = Operations
 Reason: I am the author of this document
 Location: Eden Prairie, MN
 Date: 2008.05.07 13:55:19 -05'00'

Digitally signed by Amy J. Peterson
 DN: CN = Amy J. Peterson, C = US, O = DDL, Inc., OU = Operations
 Reason: I am the author of this document
 Location: Eden Prairie, MN
 Date: 2008.05.07 14:21:26 -05'00'

Mike B. Woletz **Amy J. Peterson**
 on

Report prepared by:

Mike B. Woletz & Amy J. Peterson
Project Managers

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 Date: 2008.05.07 14:40:12 -05'00'

Eric T. Borchardt

Technical Review by:

Eric T. Borchardt
Lab Manager

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Kimberly M. Pratt

Approved by:

Kim M. Pratt
Quality Assurance Manager

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 17 of 24
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**APPENDIX A: DDL, INC. PROTOCOL # P080299 REV. B; ONE
YEAR PRODUCT AND PACKAGE EVALUATION**

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 18 of 24
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Tested and Proven.

10200 Valley View Rd., #101
 Eden Prairie MN 55344
 952-941-9226
 Fax 952-941-9318
 1-800-229-4235

Test Protocol Title: <i>One Year Product and Package Evaluation</i>	
Test Type: <i>Accelerated Aging, Product Functionality and Package Sterility Validation Tests</i>	
Protocol Number: P080299	Revision: B
Approvals:	
Iasis Medical: <u><i>John A. [Signature]</i></u> Date: <u><i>3/05/08</i></u>	
DDL, Inc Written By: <u>Alan Gale</u> Alan M. Gale Approved By: <u>Patrick J. Nolan</u>	Digitally signed by Alan M. Gale DN: CN = Alan M. Gale, C = US, O = DDL, Inc., OU = Operations Reason: I am the author of this document Date: 2008.04.01 07:29:11 -0500 Date: <u>Mar 31, 2008</u> Date: _____
Package Tested: Single Barrier Foil/Foil Pouch Product Tested: NPД 1000 Negative Pressure Dressing	

1. Purpose

1.1. This document provides the test parameters required to perform accelerated aging, product functionality and package strength evaluation using physical strength methods, and product sterility validation testing using physical integrity detection methods.

2. Scope

- 2.1. Completion of the work described in this protocol will provide documentation supporting the capabilities of the package under conditions of temperature. It will also determine the seal integrity of the packages and sterility maintenance.
- 2.2. The loss of sterility in a package is typically a dynamic event related incident rather than a time related phenomenon. Damage to a package may be caused by one or more of the following events:
- Loss of the seal integrity due to the effects of high temperature and humidity or shipping and handling events.
 - Improper manufacturing and production processes.
- 2.3. By selecting products which have been processed through manufacturing and sterilization, and then subjecting those packages to accelerated aging, product functionality, package strength and package integrity tests, it can be determined if the production process and package design are adequate to maintain sterile conditions throughout the expected shelf life.

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3. References

- 3.1 ASTM F 1980-07, *Standard Guide for Accelerated Aging of Sterile Medical Device Packages.*
- 3.2 ASTM F 88-07a, *Standard Test Method for Seal Strength of Flexible Barrier Materials.*
- 3.3 ASTM F 2096-04, *Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak).*
- 3.4 Iasis Medical, *Bandage Integrity - Vacuum Pressure Test Protocol*
- 3.5 Iasis Medical, *Bandage Fluid Capacity Test Protocol*
- 3.6 Iasis Medical, NPD 1000 IFU (instructions for use)

4. Materials and Equipment

- 4.1. Temperature/Humidity Chamber meeting the requirements of ASTM D-4332, *Conditioning Containers, Packages, or Packaging Components for Testing.*
- 4.2. Material Test System meeting the requirements of ASTM F-88, *Standard Test Method for Seal Strength of Flexible Barrier Materials.*
- 4.3. Iasis Medical NPD 1000 Negative Pressure Wound Therapy Device
- 4.4. Iasis Medical Micro NPWT device
- 4.5. Ashcroft Vacuum pressure sensor gauge
- 4.6. Stopwatch
- 4.7. Syringe of 50 – 200 ml capacity
- 4.8. Beaker of 500 – 2000 ml capacity
- 4.9. Fluid as described in protocol – de-ionized, distilled, or tap water

5. Sample Description and Preparation

- 5.1. The test packages consist of a single barrier foil to foil pouch package.
- 5.2. Sample size will reflect the number of samples desired for the seal strength and integrity evaluation, and product functionality verifications.
- 5.3. Ninety (90) pouches will be used for this study. Sixty (60) of these pouches will contain **NO product** and will be designated for the Seal Strength and Bubble Leak testing. Thirty (30) of these pouches **WILL contain product** and be designated for the functionality testing. These packages have been produced under normal processing limits established in the process validation.
- 5.4. All samples will be clearly identified by Iasis Medical for testing requirements.

6. Test Procedure

The following test procedures will be performed per the test sequence described below.

6.1 Sterilization

All packages and product for the one year accelerated aging shelf life study have been Ebeam sterilized using the Iasis Medical standard operating procedures.

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6.2 Accelerated Aging Test Protocol

Ninety (90) pouches with product will be subjected to the environmental conditions described below and in accordance with ASTM F1980-07.

6.2.1 For one year of accelerated aging, each primary package will be subjected to the following sequence of conditions in accordance with the following equation:

$$\text{Accelerated Aging Rate (AAR)} = Q^{((\text{elevated temp.} - \text{ambient temp.})/10)}$$

where

$$Q = 2.0$$

$$\text{Ambient Temp.} = 22^{\circ}\text{C}$$

$$\text{Test Temp.} = 55^{\circ}\text{C}$$

$$\text{Accelerated Aging Time Duration (AATD)} = \text{Real Time}/\text{AAR}$$

$$\text{so... AAR} = 2^{((55-22)/10)}$$

$$\text{AAR} = 9.85$$

$$\text{AATD} = 365/9.85 = 38 \text{ Days}$$

The test sequence for the 1 Year study:

Test Temperature	1 Year
55°C +/-2 <20% RH	38 Days

The aging for this protocol will simulate **1 Year** of real time aging. A total of **38** days of conditioning is required to complete this segment of this validation.

6.2.2 Temperature selection will be based on the heat resistance of the packaging materials. If lower temperatures are required, then the conditioning time will be adjusted based on the Arrhenius thermodynamic temperature coefficient rule ("a rise in temperature of 10 °C will double the rate of chemical reaction").

6.2.3 Accelerated Aging Technical Note:

When conducting an accelerated aging program for establishing product and package shelf life or expiration dating claims, it must be recognized that the data obtained from the study is based on conditions that **simulate** the effects of aging on the materials. The resulting creation of an 'expiration date' or shelf life represents a conservative estimate of shelf life and is **tentative** until the results of real time aging studies are completed on the product or product/package combination.

Since the results of the study produce a **conservative estimate** of the actual shelf life of the materials, tolerances for the

Test Protocol Title: One Year Accelerated Aging Product and Package Evaluation	
Test Type:	Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests
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temperature and humidity are only provided to ensure that the chamber operates within a satisfactory range. Out of tolerance excursions for less than 6 hours in duration for either temperature or humidity are acceptable and do not adversely affect the estimate for shelf life.

Out of tolerance excursions may be caused by opening doors for sample transfer; inserting moist samples into a dry environment causing spikes in humidity; proximity of monitoring device to temperature and/or humidity source inlets.

6.3 Post Accelerated Aging Package Analysis

Sixty (60) empty pouches will be tested to determine the effects of accelerated aging on the seal strength and integrity of the production pouches. Thirty (30) empty pouches will be tested in accordance with ASTM F88-07a and thirty (30) empty pouches will be tested in accordance with ASTM F2096-04.

6.4 Post Accelerated Aging Product Analysis (Negative Pressure Integrity)

Fifteen (15) pouches with product inside will be opened to remove the NPD 1000 Negative Pressure Dressing from the pouch. Each dressing will be tested according to the Bandage Integrity - Vacuum Pressure Test Protocol. Within the protocol, two tests will be performed. A Persistent Vacuum Integrity test will be performed on eight (8) samples and a Bandage Pump Down Time test will be performed on seven (7) samples.

6.5 Post Accelerated Aging Product Analysis (Bandage/Dressing Fluid Capacity)

Fifteen (15) pouches with product inside will be opened to remove the NPD 1000 Negative Pressure Dressing from the pouch. Each dressing will be tested according to the Bandage Fluid Capacity Test Protocol.

6.6 Summary of Strength and Integrity Sample Size

	Post 1 Year. AA
Seal Strength	30 empty Pouches
Bubble Leak	30 empty Pouches

6.7 Summary of Accelerated Aging Product Analysis

	Post 1 Year. AA
Negative Pressure Integrity Testing	15 Product
Bandage/Dressing Fluid Capacity Testing	15 Product

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7 Acceptance Criteria

- 7.1 Primary packages will be visually inspected while undergoing integrity testing for damages caused by accelerated age testing. Obvious mechanical damage such as seal failures, holes, tears and voids will be documented and Iasis Medical will be notified.
- 7.2 Packages fail the test protocol if there is obvious physical damage to the primary package or the bubble leak test indicates any signs of leakage.
- 7.3 Acceptance criteria for all product functionality testing has been identified by Iasis Medical.
 - 7.3.1 Tests that involved the Bandage Pump Down Time must be able to achieve the set pressure in less than 3 minutes with each bandage/dressing.
 - 7.3.2 Tests that involved the Persistent Vacuum Integrity will have the pump and bandage system deliver and maintain 125 mmHg of negative pressure over the 1 hour duration.
 - 7.3.3 Tests that involved the Bandage/Dressing Fluid Capacity, the average Vcap calculated from the 15 samples shall be within 50cc +/- 10%.

8 Documentation

- 8.1 The accelerated aging will be documented using a NIST traceable temperature/humidity recorder and probe. The periodic readings will be retained as evidence that the proper temperature and humidity were maintained throughout the test duration.
- 8.4 The seal strength testing will be documented and all data will be compiled for average and standard deviation.
- 8.5 The bubble leak test will be documented on appropriate work sheets or laboratory notebook indicating a pass or fail.
- 8.6 The negative pressure integrity test will be documented on appropriate work sheets or a laboratory notebook. It will be used to record the equipment used and test results of performing the Bandage Integrity - Vacuum Pressure Test Protocol.
- 8.7 The bandage/dressing fluid capacity test will be documented on appropriate work sheets or a laboratory notebook. It will be used to record the equipment used and test results of performing the Bandage Fluid Capacity Test Protocol.
- 8.8 Gross irregularities found during inspection of samples prior to integrity testing will be documented and Iasis Medical will be notified.
- 8.9 Records for this project will be archived at DDL for a duration of 5 years in accordance with DDL's record policy. At the completion of 5 years all records will be disposed of properly. A written request must be made by the customer, specifying a longer retention period before the 5 years is complete.

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8.10 A single test report including the one year accelerated aging, seal strength, bubble leak and functionality tests will be issued to Iasis Medical upon completion of testing.

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APPENDIX A

Bandage Integrity - Vacuum Pressure Test Protocol

Introduction

This test will verify . . .

- The NPD 1000 Negative Pressure Dressing has vacuum integrity, when used with the NPD 1000 Negative Pressure Wound Therapy Device, over the full range of therapeutic pressures at the end of its labeled shelf life.
- The 1000 Negative Pressure Dressing shall be able to achieve and maintain a vacuum pressure down to 40 mmHg.
- The Micro NPWT device shall be able to achieve and maintain a vacuum pressure up to 125 mmHg.
- The tolerance of all set pressures in the Micro NPWT device shall be +/- 10% unless otherwise specified.
- The Micro NPWT device pump module shall be able to achieve the set pressure in less than 3 minutes with largest bandage designed.

Setting parameters on the NPD 1000 Negative Pressure Wound Therapy Device

To enter Configuration mode in order to change therapy mode or to modify the vacuum pressure setpoint, press and hold the Therapy Type (Mode) button and Pressure Setting (VAC) button simultaneously. While the Mode and VAC buttons are both held down, press and release the Pump On/Off button, then release the Mode and VAC buttons. Once in Configuration mode, to change therapy modes, press and release the Mode button. To change the vacuum pressure setpoint, press and release the VAC button. To exit Configuration mode, press and release the Pump On/Off button or wait 30 seconds from the last button press to time out and automatically exit.

Test Equipment

1. 15 NPD 1000 Negative Pressure Dressings*
2. NPD 1000 Negative Pressure Wound Therapy Device*
3. Negative pressure tubing and fittings*
4. One independent pressure sensor.
5. Smooth surface fiberglass board to accommodate mounting of bandage*
6. Stopwatch.

* Note: These items supplied by customer

Test Procedures and Expected Results

Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
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Persistent Vacuum Integrity (test performed with 8 bandages, serially)

1. Connect the control module and pump module according to the directions in the NPD 1000 IFU (instructions for use). Label the pumps, pump # 1 and pump # 2.



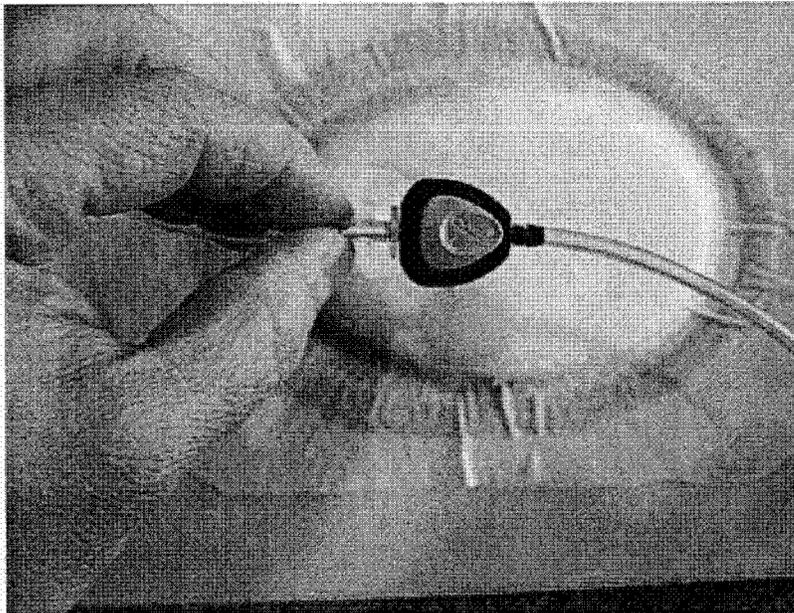
2. Start this test with device batteries (in control module) removed. Place the batteries in the control module, allowing the entire device to power up and complete self tests. Enter Configuration mode.



- Verify that the vacuum pressure setpoint display is active and flashing

Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
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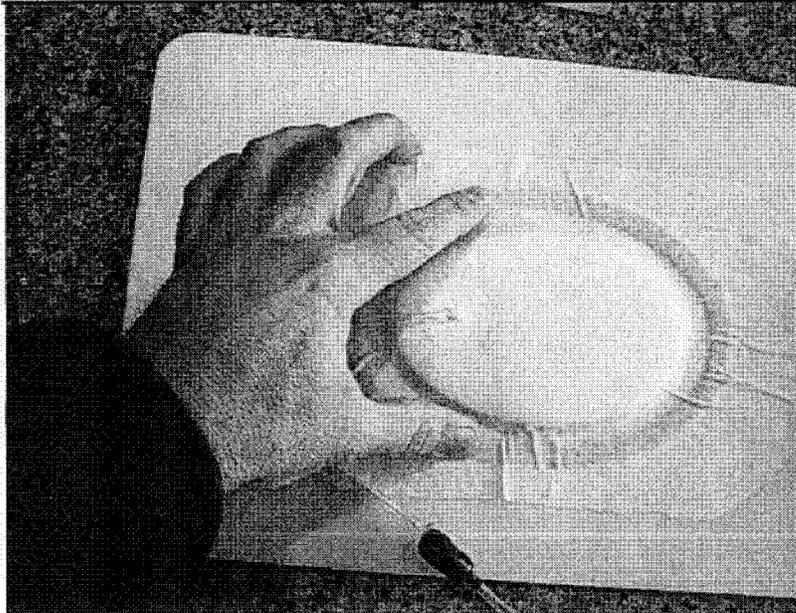
3. Press the VAC button until the vacuum pressure is set to 125 mmHg. Continue to press the VAC button, scrolling through all the vacuum pressure setpoints until 40 mmHg is reached. Stop at this value.
 - Verify the vacuum pressure setpoint display is active and flashing (signals a change in vacuum setting).
 - Exit Configuration mode
4. Mount the bandage securely to the test board
5. Connect the pump to the bandage with connectors, connectors on bandage and pump tubing. Add independent pressure gauge in-line with "tee" into pump tubing.



6. Turn the pump on by depressing the power button for > 1 second. Allow the unit to run for a minimum of 1 hour. Note: if a persistent leak occurs at start up (i.e. the pump never turns off), correct the leak by pressing the bandage gasket against the surface of the mounting board (see below) and continue the test.
 - Verify that the pump turns on and the bandage achieves the appropriate negative pressure at 40 mmHg +/- 10%.
 - Verify that no system fault notifications occur (ie. loss of pump control or pump inoperable) due to the inability of the system to deliver and maintain 40 mmHg of negative pressure continuous therapy over the 1 hour duration. "Inability" is defined as the bandage being unable to seal, such that the leak alarm (defined in the instructions for use booklet) persists throughout the test period. A balloon icon will appear if there is a seal fault. If the display has many pixels illuminated, there is a system fault.

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7. Enter Configuration mode, press the VAC button until the vacuum pressure is set to 125 mmHg. Exit Configuration mode and turn the pump on. Allow the unit to run for a minimum of one hour. Note: if a leak occurs, correct the leak and continue the test.
 - Verify that the pump turns on and the bandage achieves the appropriate negative pressure at 125 mmHg +/- 10%.
 - Verify that no system fault notifications occur (ie. loss of pump control or pump inoperable) due to the inability of the system to deliver and maintain 125 mmHg of negative pressure continuous therapy over the 1 hour duration.

Bandage Pump Down Time (seven bandages, one at a time)

1. Attach a new bandage to fixture.
2. Seal the dressing to the fixture by pressing gasket around the entire perimeter and smoothing the dressing corner as much as possible.
3. Configure the NPD 1000 Negative Pressure Wound Therapy Device to deliver 125 mmHg of continuous therapy.
4. Attach the bandage to the pump with the appropriate connectors.
5. Turn the pump on and start the stopwatch at the same time.
6. Stop the stopwatch when the pump stops pumping AND when the independent pressure sensor signals a negative pressure of 125 mmHg.
7. Record the elapsed time.
8. Repeat this process 10 times recording the pump down time each time.
9. Average the recorded elapsed times.
 - Verify that the Continuous pump is able to achieve the set pressure in less than 3 minutes with each bandage.

Test Protocol Title:	One Year Accelerated Aging Product and Package Evaluation
Test Type:	Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests
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APPENDIX B

Bandage Fluid Capacity Test Protocol

Introduction

This test will verify . . .

- The NPD 1000 Negative Pressure Dressing maintains its therapeutic fluid capacity, when used with the NPD 1000 Negative Pressure Wound Therapy Device, at the end of its labeled shelf life.
- The average fluid retention capacity, (Vcap) of the NPD 1000 Negative Pressure Dressing shall be capable of holding 50cc of fluid, +/- 10%.

Setting up the NPD 1000 Negative Pressure Wound Therapy Device

To enter Configuration mode in order to change therapy mode or to modify the vacuum pressure setpoint, press and hold the Therapy Type (Mode) button and Pressure Setting (VAC) button simultaneously. While the Mode and VAC buttons are both held down, press and release the Pump On/Off button, then release the Mode and VAC buttons. Once in Configuration mode, to change therapy modes, press and release the Mode button. To change the vacuum pressure setpoint, press and release the VAC button. To exit Configuration mode, press and release the Pump On/Off button or wait 30 seconds from the last button press to time out and automatically exit.

Test Setup

7. Fifteen (15) of the NPD 1000 Negative Pressure Dressings
8. One (1) NPD 1000 Negative Pressure Wound Therapy Device (control module w/ batteries and pump module)
9. Negative pressure tubing and fittings
10. Fiberglass board to accommodate mounting of bandage and introduction of fluid to bandage
11. One (1) Calibrated fluid syringe (50 – 200 ml capacity)
12. Test Fluid container with water and food coloring (for indication purposes)
13. Stopwatch.

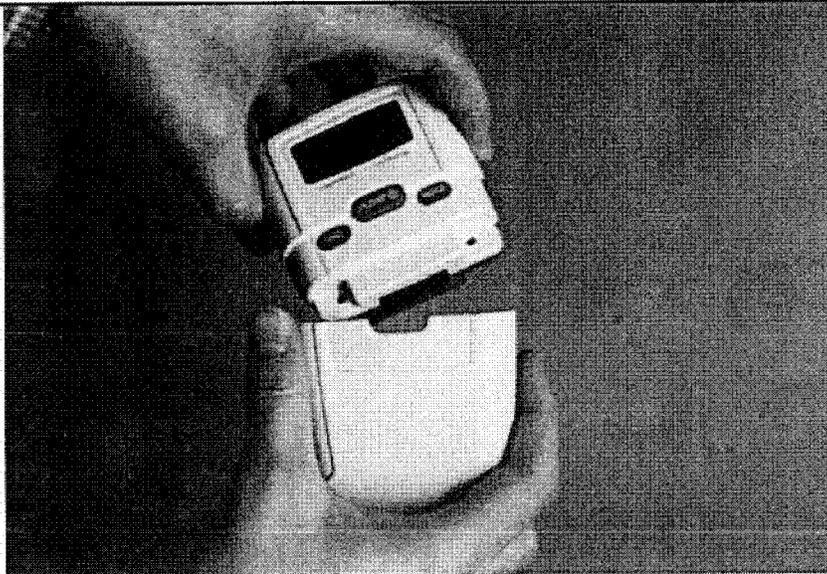
Test Procedures and Expected Results

Bandage Fluid Capacity (test performed with 15 bandages, one at a time)

8. Connect the control module and pump module according to the directions in the NPD 1000 IFU (instructions for use).

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Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
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9. Start this test with device batteries (in control module) removed. Place the batteries in the control module, allowing the entire



device to power up and complete self tests. Enter Configuration mode.

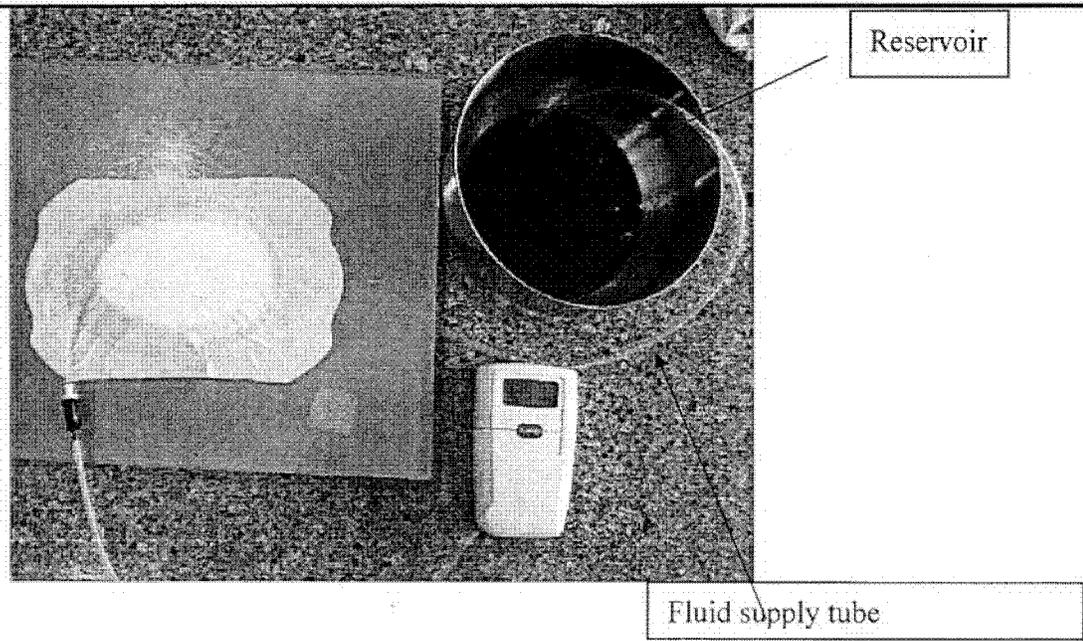
- Verify that the vacuum pressure setpoint display is active and flashing

10. Press the VAC button until the vacuum pressure is set to 125 mmHg. Exit configuration mode.

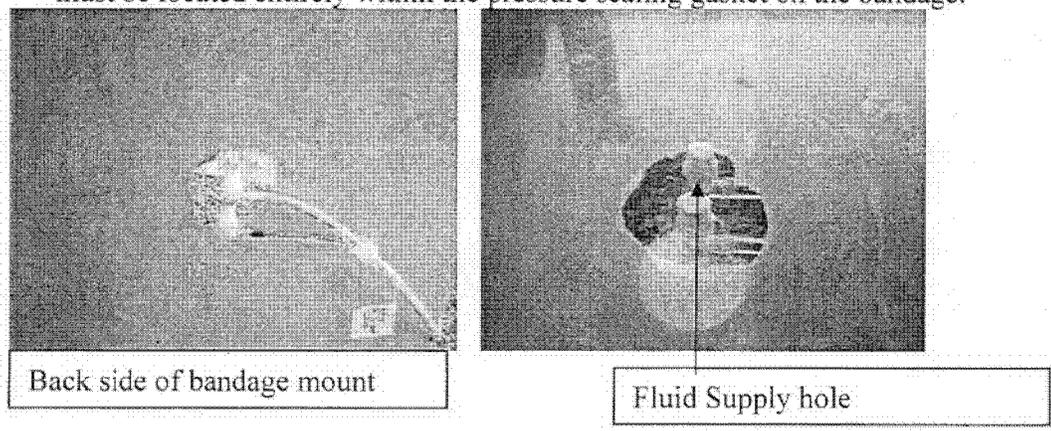
11. Using syringe, measure 200 cc of colored fluid into test reservoir

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Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
Protocol Number:	P080299
Revision:	B



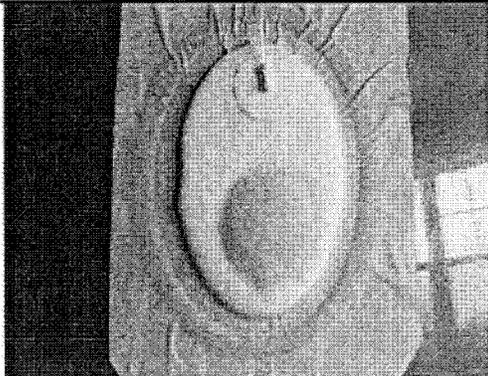
12. Place fluid supply tube, attached to bandage mounting board into the fluid
13. Mount bandage on board above fluid supply "hole". Note: The fluid supply hole must be located entirely within the pressure sealing gasket on the bandage.



14. Attach the NPD 1000 Negative Pressure Wound Therapy Device to the dressing with the supplied tubing.
15. Turn on the pump. Fluid will begin to flow from the reservoir to the bandage. The pump will turn off and on during this process. The bandage will fill in approximately 30-45 seconds.

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Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
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16. Five minutes after the pump has stopped cycling, turn off the pump and detach the tubing from the bandage.
17. Carefully remove the bandage from the fixture, taking care not to squeeze the absorbent pad.
18. Extract the absorbent pad from the dressing.
19. Place absorbent pad on flat surface and extract the "free" water from the pad by compressing the pad with a rigid roller applying 3 lbs. of force. Collect "squeezed" water into the original fluid reservoir.
20. Measure the non-absorbed fluid in the reservoir with the calibrated syringe, noting the remaining volume, V_{rem} . As an alternative, the volume of fluid can be measured using a scale capable of displaying grams.
21. Calculate the dressing fluid retention capacity, V_{cap} , by the following formula,

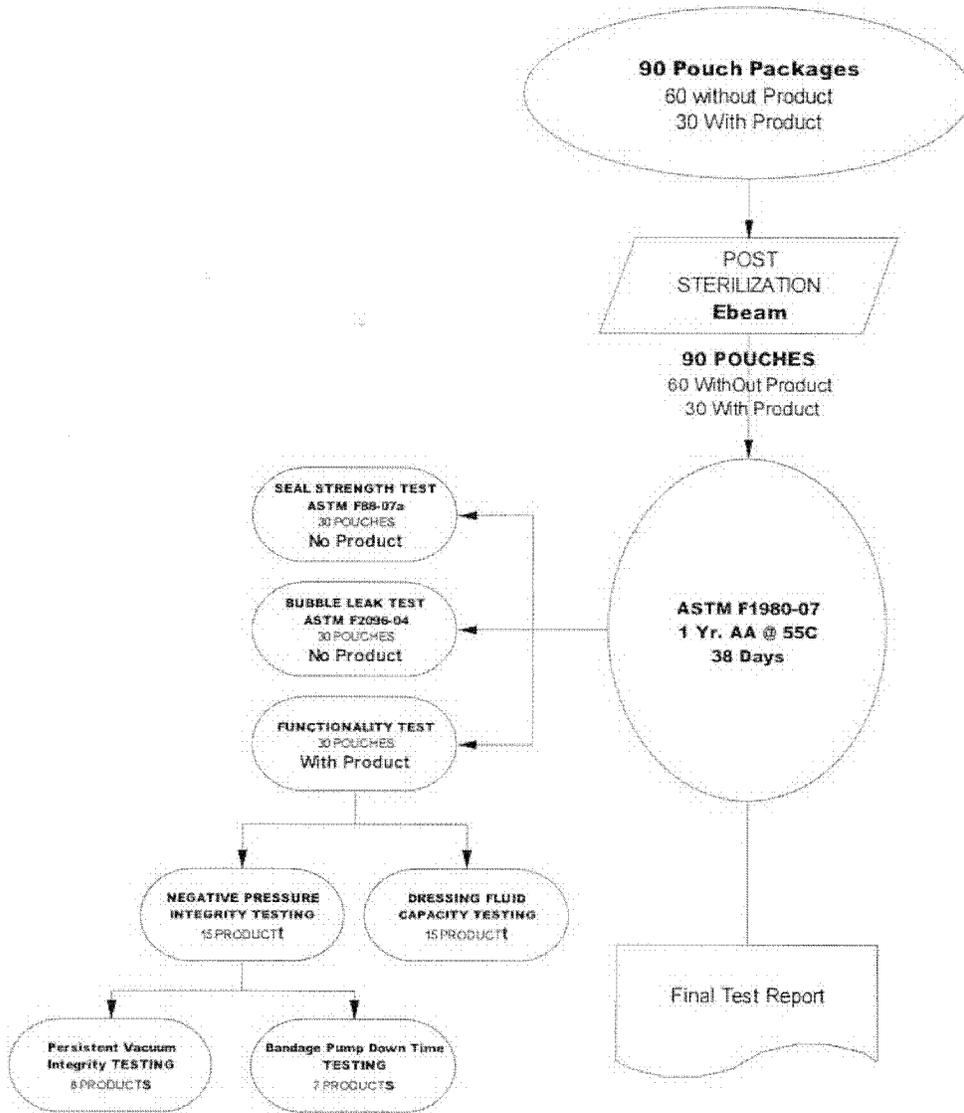
$$1. V_{cap} = 200 \text{ cc} - V_{rem}$$

22. Repeat measurement for remaining dressings
23. Calculate the average of V_{cap} and S.D. of V_{cap}
24. The average of all fifteen (15) V_{caps} must be within the 50cc +/- 10% tolerance or failure has occurred.

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Test Protocol Title: One Year Accelerated Aging Product and Package Evaluation
Test Type: Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests
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lasis Medical
1 Year Accelerated Aging Product and Package Evaluation
Single Foil / Foil Pouch Package
Product Name: NPd 1000 Negative Pressure Dressing
Protocol #: 080299



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APPENDIX B: ONE YEAR ACCELERATED AGING DATA

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 19 of 24
DDL, Inc. • 10200 Valley View Road, Suite 101 • Eden Prairie, MN 55344 • Tel: 952-941-9226 • Fax: 952-941-9318				



1 Year AA

Customer: Iasis Medical
Product: NPD 1000 Negative Pressure Dressing
Cust. PO: N/A
DDL JN: 0802099

MW 18-Feb-08
 Worksheet Approved By
Test: 1 Year AA @ 55 C
 55C @ <20% RH

Start Date: 18-Feb-08
Start Time: 2:00 PM

Chamber: 16

Date	Day	Nist Temp (C)	RH (%)	Remarks	Specimen Verification	Chamber Verification
Mon, 18-Feb-08	Start	54.9	L20	JW 55C / Low Humidity	JW	JW
Tue, 19-Feb-08	1	54.7	L20	JW 16-017		
Wed, 20-Feb-08	2	54.4	L20	JW		
Thu, 21-Feb-08	3	54.6	L20	JW		
Fri, 22-Feb-08	4	54.6	L20	JW		
Sat, 23-Feb-08	5	54.1	L20	YH		
Sun, 24-Feb-08	6	54.4	L20	LOH		
Mon, 25-Feb-08	7	54.5	L20	JW		
Tue, 26-Feb-08	8	54.5	L20	JW		
Wed, 27-Feb-08	9	54.4	L20	JW		
Thu, 28-Feb-08	10	54.3	L20	JW		
Fri, 29-Feb-08	11	54.5	L20	JW		
Sat, 01-Mar-08	12	54.3	L20	JW		
Sun, 02-Mar-08	13	54.2	L20	JW		
Mon, 03-Mar-08	14	54.2	L20	JW		
Tue, 04-Mar-08	15	54.1	L20	JW		
Wed, 05-Mar-08	16	54.3	L20	JW		
Thu, 06-Mar-08	17	54.5	L20	JW		
Fri, 07-Mar-08	18	54.5	L20	JW		
Sat, 08-Mar-08	19	55.2	L20	MW		
Sun, 09-Mar-08	20	—	—	—		
Mon, 10-Mar-08	21	54.3	L20	JW		
Tue, 11-Mar-08	22	54.6	L20	JW		
Wed, 12-Mar-08	23	54.5	L20	JW		
Thu, 13-Mar-08	24	54.6	L20	JW		
Fri, 14-Mar-08	25	54.7	L20	JW		
Sat, 15-Mar-08	26	54.6	L20	JW		
Sun, 16-Mar-08	27	55.7	L20	JW		
Mon, 17-Mar-08	28	54.4	L20	JW		
Tue, 18-Mar-08	29	54.5	L20	JW		
Wed, 19-Mar-08	30	54.9	L20	JW		
Thu, 20-Mar-08	31	54.7	L20	JW 16-018		
Fri, 21-Mar-08	32	54.6	L20	JW		
Sat, 22-Mar-08	33	55.1	L20	LOH		
Sun, 23-Mar-08	34	54.8	L20	MW		
Mon, 24-Mar-08	35	54.7	L20	JW		
Tue, 25-Mar-08	36	54.5	L20	JW		
Wed, 26-Mar-08	37	54.1	L20	JW		
Thu, 27-Mar-08	38	54.2	L20	JW moved to quarantine		
End of Test						

Overtemp Set Point: 57
 Overtemp Verification:

Specimens Removed: JW

Specimen(s): 100543

Probe(s): 034

Chart(s): 16-017, 16-018

MW 27-Mar-08
 Data Approved By

APPENDIX C: BUBBLE LEAK TESTING DATA

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Bubble Leak Test

Test Interval: Post 1 YR AA

Customer: Iasis Medical
 P.O.: 1005
 J/N: 0802099
 Package type: Single Barrier Foil/Foil Pouch
 Product: Empty Pouches

Worksheet Approval: JAS 28-Mar-08
 (Date)
 Test Technician: CKB
 Test Dates: 31-Mar-08 31-Mar-08
 (Start) (End)
 PM (initials): MBW

Equipment Used: TM ELECTRONICS / BURST TESTER

MODEL #: BT 115
 SERIAL #: BT 465
 Cal Due: 25-Jan-09

Machine Parameters

Flow Rate: open
 Pressure: .20
 Pressure Verification: CJA

DDL SOP#: 6047

Rel#: 05

Test Standard: ASTM F 2096

Notes
 Sample Prep CKB
 Validated with .008 pin gauge
 ① validation

Specimen	Sample	Results		Comments/Location	
100543	1	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	①
	2	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	3	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	4	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	5	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	6	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	7	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	8	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	9	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	10	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	11	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	12	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	13	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	14	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	15	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	16	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	17	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	18	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	19	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	20	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	21	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	22	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	23	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	24	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	25	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	26	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	27	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	28	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	29	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	
	30	<input checked="" type="checkbox"/>	Pass	<input type="checkbox"/> Fail	

pkg test photo
 pkg des. photo

Summary

Total	Passed	Failed
30	30	0

Reviewed By: MBW Date: 31-Mar-08

APPENDIX D: SEAL STRENGTH TESTING DATA

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 21 of 24
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DDL, Inc. • 10200 Valley View Road, Suite 101 • Eden Prairie, MN 55344 • Tel: 952-941-9226 • Fax: 952-941-9318

647



Seal Strength Test

Test Interval: Post 1 YR AA

Customer: Iasis Medical
 P.O.: 1005
 J/N: 0802099
 Package type: Single Barrier Foil/Foil Pouch
 Product: Empty Pouches

Compiled by: MBW 8-Apr-08
 (date)
 Test Technician(s): CKB
 Test Date(s): 31-Mar-08 2-Apr-08
 (start) / (end)

Equipment Used: DDL Universal Tensile Test System
 Model #: 100P Serial #: 0001064
 Load Cell: SMT1-56 Serial #: 602371
 Cal Due: 11-Apr-08

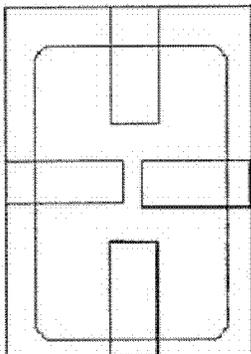
Machine Parameters
 Cross-Head Speed: 11 in/min
 Verified by: CKB

Load Cell Verification
 2lb wt. Serial #: C6845
 Measured wt.: 2.00 lbs

90° Un-supported Method: CKB

DDL SOP#: 6008 Rel#: 05
 Test Standard: ASTM F-88

Package Description



Notes

Sample Prep: CKB

The foil material tore prior to seal separation on all tested samples.

Specimen	Sample	Peak Value (lbs.)				Equipment set-up Approval		
		I	II	III	IV			
100543	31	19.58	21.14	19.99	21.36	CJA		
	32	20.74	21.40	19.68	21.27			
	33	20.17	20.41	20.04	20.55			
	34	19.97	21.82	20.74	21.27			
	35	20.04	21.20	20.91	20.45			
	36	19.99	21.57	21.01	20.39			
	37	19.94	21.60	21.31	20.88			
	38	20.00	21.07	19.83	21.43			
	39	21.22	21.32	19.87	20.49			
	40	20.46	20.87	20.04	21.11			
	41	20.18	21.00	20.20	21.32			
	42	19.75	20.96	20.74	21.23			
	43	21.19	20.92	20.59	21.05			
	44	19.10	21.25	20.45	20.91			
	45	20.01	20.44	18.93	20.56			
	46	20.22	20.89	19.69	19.82			
	47	20.15	22.11	20.10	19.43			
	48	21.08	20.92	20.01	20.54			
	49	20.09	20.54	20.14	20.87			
	50	19.62	21.17	19.89	21.25			
	51	20.48	21.30	20.27	21.21			
	52	20.30	21.91	20.37	21.28			
	53	19.56	20.65	20.86	20.53			
	54	20.70	21.24	19.98	20.14			
	55	19.79	20.75	20.51	21.55			
	56	19.31	21.83	19.71	20.91			
	57	20.23	20.43	19.59	20.55			
	58	20.18	19.92	20.47	20.31			
	59	21.55	21.24	21.34	21.60			
	60	20.08	20.98	20.33	20.56			
	St. Dev.		0.56	0.49	0.54		0.54	
	Average		20.19	21.10	20.25		20.82	

Reviewed By: TSP Date: 08 Apr 08

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APPENDIX E: PERSISTENT VACUUM INTEGRITY TESTING DATA

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 22 of 24
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Persistent Vacuum Integrity

Customer: Iasis Medical
 P.O.: 1005
 J/N: 0802099
 Product: NPD 1000 Negative Pressure Dressing

Compiled By: AJP
 Date: 2-Apr-08
 Test Tech: KAM
 Test Date: 31-Mar-08 2-Apr-08
 (start) (end)

Equipment:

Iasis Medical NPD 1000 Negative Pressure Wound Therapy Device
 PN #: 50001 Rev A Unit #: 2
 Pressure Sensor Ashcroft Vacuum Gauge
 Model #: 30 inHg Serial #: 1022965 Cal Due: 2-Jul-08
 Stopwatch Cole-Palmer
 Model #: 3 Serial #: 1614 Cal Due: 1-May-09

Test Approval: AJP
 Date: 31-Mar-08

Test Standard: DDL Protocol: P0802099 Rev B Appendix A Steps 1-7

Specimen	Iasis Medical Dressing Number	Step 6 Pressure Reading (inHg)	Results		Test Duration Time (min:sec)	Step 7 Pressure Reading (inHg)	Results		Test Duration Time (min:sec)	Comments
			Pass	Fail			Pass	Fail		
100543	1	1.57	X	-	60:01	4.80	X	-	60:23	-
	2	1.58	X	-	60:04	4.64	X	-	60:00	-
	3	1.56	X	-	60:17	4.86	X	-	-	1
	4	1.53	X	-	62:52	4.57	X	-	60:32	-
	5	1.63	X	-	61:06	4.68	X	-	61:26	-
	6	1.54	X	-	60:11	4.68	X	-	61:40	-
	7	1.65	X	-	60:08	4.59	X	-	65:32	-
	8	1.54	X	-	60:45	5.01	X	-	61:15	-
Total			8	0	Total			8	0	

Comments:

Pass if no system fault notification occurs during the test period.
 Fail if the leak alarm persists throughout the test period.

1 Forgot to start the timer. Test started between 7:05am and 7:10am test ended at 8:10am.

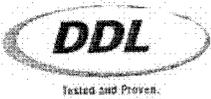
Reviewed By: [Signature]

Date: 2-Apr-08

650

APPENDIX F: BANDAGE PUMP DOWN TIME TESTING DATA

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 23 of 24
DDL, Inc. • 10200 Valley View Road, Suite 101 • Eden Prairie, MN 55344 • Tel: 952-941-9226 • Fax: 952-941-9318				



Customer: Iasis Medical
 P.O.: 1005
 JIN: 0802099
 Product: NPD 1000 Negative Pressure Dressing

Compiled By: AJP
 Date: 2-Apr-08
 Test Tech: KAM
 Test Date: 2-Apr-08 2-Apr-08
 (start) (end)

Equipment:

Iasis Medical NPD 1000 Negative Pressure Wound Therapy Device
 Model #: 50001 RevA Unit #: 2
 Pressure Sensor Ashcroft Vacuum Gauge
 Model #: 30 inHg Asset #: 1634 Cal Due: 2-Jul-08
 Stopwatch Cole-Parmer
 Model #: 3 Serial #: 1614 Cal Due: 1-May-09

Test Approval: AJP
 Date: 2-Apr-08

Test Standard: DDL Protocol: P0802099 Rev B Appendix A Steps 1-9

1. Attach new bandage to fixture
2. Seal the dressing to the fixture by pressing gasket around the entire perimeter and smoothing the dressing corner as much as possible.
3. Configure the NPD 1000 Negative Pressure Wound Therapy Device to deliver 125 mmHg of continuous therapy.
4. Attach the bandage to the pump with the appropriate connectors.
5. Turn the pump on and start the stopwatch at the same time.
6. Stop the stopwatch when the pump stops pumping AND when the independent pressure sensor signals a negative pressure of 125 mmHg
7. Record the elapsed time.
8. Repeat this process 10 times recording the pump down time each time.
9. Verify that the Continuous pump is able to achieve the set pressure in less than 3 minutes with each bandage.

Specimen	Iasis Medical Dressing Number	Elapsed Time (min:sec)										Average Time (min:sec)
		Run 1	Run 2	Run 3	Run 4	Run 5	Run 6	Run 7	Run 8	Run 9	Run 10	
100543	9	00:41	00:26	00:27	00:24	00:27	00:26	00:26	00:27	00:27	00:27	00:28
	10	00:38	00:27	00:27	00:27	00:28	00:26	00:28	00:29	00:28	00:27	00:29
	11	00:43	00:29	00:28	00:28	00:28	00:28	00:28	00:28	00:28	00:28	00:29
	12	00:50	00:30	00:30	00:30	00:30	00:30	00:30	00:30	00:30	00:30	00:31
	13 (1)	00:42	00:29	00:30	00:28	00:23	00:27	00:28	00:27	00:28	00:28	00:29
	14	00:49	00:31	00:30	00:31	00:32	00:30	00:31	00:30	00:31	00:31	00:33
	15	01:16	01:55	01:43	01:27	01:28	01:13	01:16	01:22	01:16	01:33	01:27

Comments:

(1) Low Battery signal at start of test, stopped and replaced batteries. Specimen then failed to seal properly, maximum pressure of 0.50 inHg was observed. John Buan came and fixed the seal near the pump tube. Specimen was then retested with proper seal and equipment.

Reviewed By: [Signature]

Date: 3/14/08

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APPENDIX G: BANDAGE FLUID CAPACITY TESTING DATA

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 24 of 24
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DDL, Inc. • 10200 Valley View Road, Suite 101 • Eden Prairie, MN 55344 • Tel: 952-941-9226 • Fax: 952-941-9318

Project No. 0802099

Book No. 1062

94

TITLE FLUID CAPACITY OF BANDAGE

From Page No. 94

LAB COND 23.1°C @ 54% RH

TEST DATES START 3 APR 08 9:15 AM

CUSTOMER: IASIS MEDICAL

PO: 1005

JN: 0802099

PRODUCT: NPD 1000 NEGATIVE PRESSURE DRESSING

STANDARD/PROTOCOL: DDL P0802099 REV B: APPENDIX B STEPS 8-24

EQUIPMENT

IASIS MEDICAL 1000 NEGATIVE PRESSURE WOUND THERAPY DEVICE (PKM 125mmHg)

PN 50003 REV A UNIT #2

VACUUM GAUGE

ASHCROFT 30 in. Hg ASSET # 001634 CAL DUE 02 JUL 08

STOPWATCH

Cole-Palmer #3 ASSET # 001614 CAL DUE 01 MAY 08

600g SCALE

AND EK-6004 ASSET # 001065 CAL DUE 16 MAR 08 KAM 10 MAR 09

MATERIALS

RO WATER

BLUE DYE LOT 020408 Exp DATE 04 MAY 08 (FOR VISUAL AIDE ONLY -> CUSTOMER)

BEAKER; 250ml (113.3g) (RESERVOIR ONLY)

DIRECTIONS FOR MIXING RO + DYE 200g RO + 2g Blue Dye

TEST RESULTS ^{KAM 3 APR 08} 58.5g -> scale plate weights 59.3g

SAMPLE	PAD DRY (g)	Full after 5min. rest (g)	PAD AFTER SQUEEZE (g)	Δ FINAL - DRY (g)	PAD ABSORPTION
#16	78.3	170.8	152.9	74.6	153
#17	79.6	163.0	151.4	71.8	120
#18	78.4	156.1	150.2	71.8	120
#19	77.7	168.9	152.4	74.7	154
#20	77.7	159.1	151.2	73.5	142
#21	78.4	183.3	167.6	89.2	299
#22	78.1	180.1	157.7	79.6	200
#23	78.2	175.6	168.2	90.0	307
#24	78.2	175.7	170.9	92.7	339
#25	78.5	178.5	165.8	87.3	280
#26	77.7	169.6	159.3	81.6	220
#27	77.9	168.9	164.1	86.2	270
#28	78.1	175.5	165.0	86.9	270
#29	77.2	164.7	155.7	78.5	192
#30	78.3	168.5	162.7		

KAM 4 APR 08 9:25
To Page No. 97

Witnessed & Understood by me,

[Signature]

Date

7 APR 08

Invented by

kam

Recorded by

kam

Date

3 APR 08

654

TITLE FLUID CAPACITY OF BANDAGE

From Page No 94

TEST PROCEDURE

Mix FLUID

200g RO water

2g BLUE DYE

REMOVE BANDAGE FROM PACKAGE

REMOVE BOTH BACKING WRAPS FROM BANDAGE TAKING CARE NOT TO ^{REMOVE} ~~DISRUPT~~ ADHESIVE

WEIGH DRY PAD ON SCALE WITH USE OF A PLATE TO EXTEND ^{SCALE} SCALE SURFACE

RECORD AS DRY WEIGHT (g) * THIS WILL INCLUDE SUPPORT PLATE WEIGHT
POSITION ADHESIVE BANDAGE OVER NOZZLES ON MOUNTING PLATE, PROVIDED BY CUSTOMER, ENSURING THAT THE VACUUM TUBE IS AS FAR FROM THE NOZZLES AS POSSIBLE

ATTACH IASIS MEDICAL 1000 RELATIVE PRESSURE WOUND THERAPY DEVICE TO BANDAGE AS DESCRIBED IN DDL PROTOCOL P0802099

SET UNIT TO 125mmHg AND START PUMP.

LET PUMP CONTINUE UNTIL FLUID IS PUMPED TO SO THAT THE VACUUM VALUE IS COMPLETELY OCCLUSIVE

STOP DEVICE AND START TIMER: WAIT 5 MINUTES.

DETACH FROM BANDAGE TUBING TO DEVICE. MOUNTING ^{PLATE} ~~PLATE~~ CAREFULLY, REMOVE BANDAGE FROM ^{LOW} SUPPORT PLATE WITHOUT SQUEEZING OUT ANY FLUID

REWEIGH BANDAGE WITH ^{LOW} SUPPORT PLATE * THIS WILL INCLUDE SUPPORT PLATE WEIGHT

GENTLY PRY OFF PAD FROM BANDAGE AND PLACE IN FLAT PAIL

USING A 3lb. ROLLER ~~SEKAM~~ at an angle (gentle), slowly remove excess fluid from bandage

REPLACE PAD ONTO BANDAGE AND REWEIGH WITH SUPPORT PLATE

CALCULATE PAD ADSORPTION BY SUBTRACTING FROM THE FINAL WEIGHT

(^{LOW} PAD WEIGHT AFTER EXCESS FLUID WAS REMOVED (WF)) the DRY WEIGHT OF THE BANDAGE AND THE WEIGHT OF THE SUPPORTING PLATE

PAD ADSORPTION = ~~Pad~~ ^{LOW} ^{4 APR 08} BANDAGE (WEIGHT) - BANDAGE (DRY) - ^{LOW} ~~SUPPORTING PLATE~~ ^{4 APR 08}

To Page No. 95

Witnessed & Understood by me,

ASP

Date

7 APR 08

Invented by

Kam

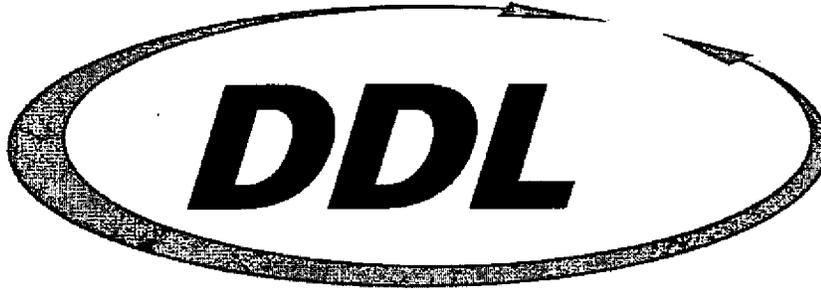
Recorded by

Kam

Date

7 Apr 08

655



Tested and proven.

Vision Statement

“DDL, Inc. will become America’s premier supplier of professional services in its chosen area of product, package, and material testing and consulting.”

Mission Statement

“DDL, Inc.’s mission is to provide our customers with the highest quality of testing and consulting services at a competitive price.”

“We serve our customers with integrity and professionalism. We strive to use our experience and insight as creative problem solvers...providing our customers with the professionalism they expect, and exceeding their expectations with exceptional personal service.”

DDL, Inc.
10200 Valley View Road, Suite 101
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Costa Mesa, CA 92626
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Fax 714-979-1721
1-800-229-4235

www.testedandproven.com

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

**Additional Information
510(k) K080275**

**for the
Kalypto Medical**

**NPD 1000 Negative Pressure
Wound Therapy System**

June 4, 2008

Contact:

John Buan, Vice President of Product Development
6393 Oakgreen Avenue
Hastings, MN 55033
Telephone (612) 703-1204
Fax 763-287-3836
jbuan@iasismedical.com

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Kalypto Medical

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CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.
--	---

Date of Submission June 4, 2008	User Fee Payment ID Number MD6034663-956733	FDA Submission Document Number (if known) K080275
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SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 35-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify)
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Kalypso Medical	Establishment Registration Number (if known)		
Division Name (if applicable)	Phone Number (including area code) (612) 703-1204		
Street Address 6393 Oakgreen Avenue	FAX Number (including area code) (763) 287-3836		
City Hastings	State / Province MN	ZIP/Postal Code 55033	Country USA
Contact Name John Buan			
Contact Title Vice President of Product Development		Contact E-mail Address jbuan@iasismedical.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)	Phone Number (including area code) ()		
Street Address	FAX Number (including area code) ()		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

FORM FDA 3514 (6/05)

Kalypso Medical

CONFIDENTIAL

Page 4 of 31

Additional Information for 510(k) K080275 for the NPD 1000

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SECTION D1 REASON FOR APPLICATION – PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

SECTION D2 REASON FOR APPLICATION – IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol – Feasibility <input type="checkbox"/> Protocol – Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		

SECTION D3 REASON FOR SUBMISSION – 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

FORM FDA 3514 (6/05)

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	JCX	2		
3		4		
5		6		

Information on devices to which substantial equivalence is claimed (if known)

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K063692	1 V.A.C. Therapy Systems-Acti-V.A.C. Therapy Unit M	1 KCI USA, Inc.
2 K060277	2 Boehringer Laboratories Suction Pump System	2 Boehringer Laboratories
3	3	3
4	4	4
5	5	5
6	6	6

SECTION F PRODUCT INFORMATION – APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Pump, Portable, Aspiration, (Manual or Powered)

Trade or Proprietary or Model Name for This Device	Model Number
1 NPD 1000 Negative Pressure Wound Therapy System	1 NPD 1000, NPD 1000i, NPD 1000c
	2
3	3
4	4
5	5

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

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

Data Included in Submission

- Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION – APPLICATION TO ALL APPLICATIONS

Product Code BTA	C.F.R. Section (if applicable) 21 CFR 878.4780	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)

The NPD 1000 Negative Pressure Wound Therapy System, a portable, low powered, battery operated, negative pressure suction pump and wound dressing, is intended for the application of suction to remove a small amount of fluid from the wound bed, including wound exudates and infectious materials, which may promote wound healing.

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

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 2133810	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer	<input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Minnetronix, Inc.		Establishment Registration Number 2133810	
Division Name (if applicable)		Phone Number (including area code) (651) 917-4060	
Street Address 1635 Energy Park Drive		FAX Number (including area code) ()	
City St. Paul		State / Province MN	ZIP/Postal Code 55108
		Country USA	
Contact Name		Contact Title	Contact E-mail Address

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer	<input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name TapeMark Co.		Establishment Registration Number 2182681	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address 1685 Marthaler Lane		FAX Number (including area code) ()	
City West St. Paul		State / Province MN	ZIP/Postal Code 55118
		Country USA	
Contact Name		Contact Title	Contact E-mail Address

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 1450662	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Sterilizer	<input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Steris Inc, Isomedix Services		Establishment Registration Number 1450662	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address 1880 Industrial Drive		FAX Number (including area code) ()	
City Libertyville		State / Province IL	ZIP/Postal Code 60048
		Country USA	
Contact Name		Contact Title	Contact E-mail Address

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Kalypto Medical

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Additional Information for 510(k) K080275 for the NPD 1000

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601	IEC	Medical Electrical Equipment- Part 1-2: General requirements for safety	2 nd Edition	2001
2	60601	UL	Medical Electrical Equipment- Part 1: General requirements for safety	1 st Edition	2006
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

FORM FDA 3514 (6/05)

Revised Indications for Use Statement

Indications for Use

510(k) Number (if known): K080275

Device Name: NPD 1000 Negative Pressure Wound Therapy System

Indications for Use:

The NPD 1000 Negative Pressure Wound Therapy System, a portable, low powered, battery operated, negative pressure suction pump and wound dressing, is intended for the application of suction to remove a small amount of fluid from the wound bed, including wound exudates and infectious materials, which may promote wound healing.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

Submitter:	Kalypto Medical 6393 Oakgreen Avenue Hastings, MN 55033
Contact Person:	John Buan, Vice President of Product Development Phone (612) 703-1204, Fax (763) 287-3836
Date Prepared:	June 4, 2008
Trade Name:	NPD 1000 Negative Pressure Wound Therapy System
Classification:	Powered Suction Pump Class II 21 CFR 878.4780
Product Code:	BTA
Predicate Device(s):	The subject device is equivalent to the following device: <ul style="list-style-type: none"> • V.A.C. Therapy Systems-ActiV.A.C. Therapy Unit M: K063692 • Boehringer Laboratories Suction Pump System: K060277
Device Description:	The NPD 1000 Negative Pressure Wound Therapy System includes a small, portable, low powered, battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to remove exudates, which may promote wound healing.
Intended Use:	The NPD 1000 Negative Pressure Wound Therapy System, a portable, low powered, battery operated, negative pressure suction pump and wound dressing, is intended for the application of suction to remove a small amount of fluid from the wound bed, including wound exudates and infectious materials, which may promote wound healing.
Functional and Safety Testing:	To verify that the device design met its functional and performance requirements, representative samples of the device underwent functional and mechanical testing, EMC testing in accordance with IEC 60601-1-2:2001 and electrical safety testing in accordance with UL 60601-1:2006.
Conclusion:	Kalypto Medical considers the NPD 1000 Negative Pressure Wound Therapy System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, and indications for use.

Revised Executive Summary

Device Description

The NPD 1000 Negative Pressure Wound Therapy System is a small, portable, low powered, battery operated system comprised of a battery operated electromechanical pump with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that may promote wound healing. This is achieved by removing small amounts of wound fluids and infectious material.

Negative Pressure Wound Therapy is designed to provide therapeutic negative pressure and wound fluid removal for the benefit of candidate wounds as determined by a wound care professional. All negative pressure wound therapy (NPWT) systems have a vacuum pump to provide negative pressure, an occlusive dressing to maintain the negative pressure over the wound bed, a means to remove and store wound exudates from the wound tissues and medical grade plastic tubing to communicate the negative pressure from the pump to the dressing. Standard operating parameters for NPWT devices include the ability to deliver consistent negative pressure from -40 mmHg to -125 mmHg in either a continuous or intermittent mode (5 minutes at pressure, 2 minutes at atmospheric pressure). The dressings for these devices are designed to be worn up to three days continuously with therapy occurring 24 hours per day between clinical visits. During each clinical visit, either at home, inpatient or outpatient (typically MWF schedule), the dressing is changed by a qualified wound care professional. After the dressing change, the patient will resume the daily activities appropriate with the level of care they are currently receiving, including remaining or returning home if they are being treated as an outpatient.

The NPD 1000 Negative Pressure Wound Therapy system (pump and dressing) is a new NPWT system that adheres to the basic principles of negative pressure wound therapy (negative pressure under an occlusive dressing and wound exudate removal), but does so in a way that the device is not a hindrance to the mobility of the patient, i.e. it is more portable than currently available technology.

A key component of this system is the occlusive dressing. The form and function of the dressing enable all of the key innovations of the NPD 1000 system. The components of this dressing are as follows: 1) a pressure port, 2) a (b)(4) anti-bacterial membrane, 3) an occlusive cover, 4) a superabsorbing nonwoven pad, 5) a sealing gasket and 6) a wound contact layer. The function of each of these components, starting from the surface of the wound, is:

Wound Contact Layer – The wound contact layer is an FDA cleared material, sold and cleared under the trade name Silverlon. This layer will cover the entirety of the wound bed to minimize adherence of the dressing to the wound tissues and providing a porous path for the negative pressure and the wound fluid.

Superabsorbing nonwoven pad – The nonwoven pad sits above the wound on top of the wound contact layer. It is a nonwoven material constructed of two constituent fibers made of medical rayon and superabsorbing polymer, respectively. The rayon fiber is extremely hydrophilic. Thus, it draws fluid into the pad by wicking fluid along the surface of the fiber. Once in the interior of

the pad, the free fluid is molecularly bonded by the superabsorbing fiber. The molecular forces binding the fluid are great. Thus the fluid in the pad cannot be removed even under application of large mechanical forces to the pad. Thus, it absorbs from but does not return fluid to the wound. This technology is identical to the function of modern diapers that absorb large amounts of urine, but do not cause maceration of the baby's skin. The wound dressing will absorb the wound fluid, but not cause maceration as maceration is caused by free liquids resident on tissues. The current design of the dressing allows for absorption in excess of 50 ml of fluid. Additionally, the nonwoven nature of the pad means that the pad is largely empty on a microscopic level, i.e. more air than fiber. As the pad absorbs fluid, the negative pressure continues to be communicated to the wound bed, because the pad does not occlude with fluid as it continues to absorb.

Sealing Gasket – The sealing gasket surrounds the non-woven pad and wound contact layer circumferentially, being attached to the occlusive dressing material. It is made of a hydrogel, used in products cleared for skin contact by the FDA. The gasket prevents lateral air leaks in the dressing, allowing the dressing to stay at pressure for substantially longer than current NPWT dressings without the assistance of a continuously running vacuum pump. This “low-leak” feature directly contributes to the dramatically reduced size of the pump and the use of long-life alkaline batteries for power.

Occlusive Dressing – The occlusive dressing is a bilayer of two (b)(4) wound cover materials. The base layer is a semi-occlusive polyurethane film which allows the dressing to hold the negative pressure. This film is laminated to a non-woven sheet that provides the mechanical integrity of the dressing and allows the dressing to be deployed like a conventional Band-Aid on a much larger scale.

Pressure Port and (b)(4) Membrane – The pressure port allows the pump device to be attached to the dressing with medical tubing. The port is a flared tube fitting sitting on top of a plastic flange. The tube fitting sticks up through a hole in the dressing, with the flange sealed to the dressing by the adhesive on the occlusive dressing. On the backside of the flange is a 0.2 micron anti-bacterial (b)(4) hydrophobic filter. This filter allows air to be removed from the dressing (to maintain negative pressure) but wound fluid and the accompanying bacteria stay in the dressing. Thus, the pump never comes in contact with fluid or bacteria and can be used on multiple patients without complex sterilization procedures. Additionally, in many instances of negative pressure wound therapy multiple wounds are treated with the same pump. The (b)(4) (b) membrane prevents spreading of surface infections from wound to wound.

Finally, the NPD 1000 Negative Pressure Wound Therapy system has a small portable vacuum pump as part of an electromechanical assembly that is driven by software and powered by AA alkaline batteries. The device can control the negative pressure under the dressing between -40 mmHg and -125 mmHg. It can do this either continuously or in an intermittent fashion. It has alarm modes to notify the user of low batteries, dressing leaks, full dressing or software system faults. The operation of this pump is completely equivalent to the commercially available pump systems. However, this pump will only work with the above described dressing technology.

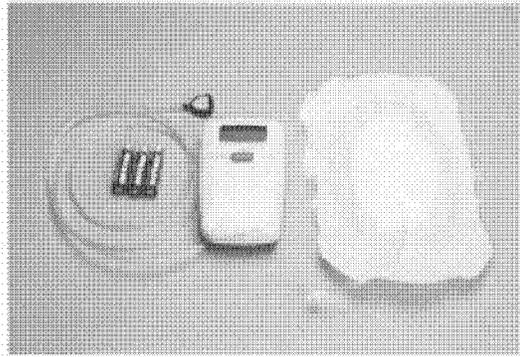


Figure 1: The NPD 1000 Negative Pressure Wound Therapy System

Indications for Use

The NPD 1000 Negative Pressure Wound Therapy System, a portable, low powered, battery operated, negative pressure suction pump and wound dressing, is intended for the application of suction to remove a small amount of fluid from the wound bed, including wound exudates and infectious materials, which may promote wound healing.

Substantial Equivalence

Kalypto Medical believes that the NPD 1000 Negative Pressure Wound Therapy System is substantially equivalent to the devices listed below:

- V.A.C. Therapy Systems-ActiV.A.C. Therapy Unit M: K063692
- Boehringer Laboratories Suction Pump System: K060277

Similarities

The Kalypto NPD 1000 and both predicates are intended to remove fluids (exudates) such as infectious materials. The Kalypto NPD 1000 and both predicates include a powered suction pump to create the negative pressure. The pressure range of the Kalypto NPD1000 (40-125 mm Hg) is within the pressure range of the predicates (25-200 mm Hg). The Kalypto NPD 1000 and both predicate dressing/bandage materials provide a bacterial barrier and transmit the negative pressure from the suction pump to the wound site. The Kalypto NPD 1000 and both predicates remove the exudate from the wound and store it safely away from the wound, thereby preventing the exudate from remaining in contact with the wound. The Kalypto NPD1000 dressing is a semi-occlusive multilayer dressing like the Boehringer Laboratories dressing.

Differences

The Kalypto NPD 1000 is smaller in dimension and lighter in weight than the predicates. The Kalypto NPD 1000 is powered only by battery, whereas the predicates can operate by battery or power supply. The Kalypto NPD1000 dressing does not include wound packing material like the V.A.C. ActiV.A.C.. The Kalypto NPD 1000 dressing is also the collection device, whereas the predicates have a separate collection canister. The Kalypto NPD 1000 exudate

collection volume is 50 cc, whereas the V.A.C. AvtiV.A.C. exudate collection volume is 300 cc, and the Boehringer Laboratories exudate collection volume is 500 cc.

Conclusion

We believe the NPD1000 is substantially equivalent to the predicates because it has the same intended use and the technological characteristics are functionally the same. We feel that any differences in technological characteristics do not raise any new questions of safety and effectiveness over the predicate device. The information demonstrates that the subject device is substantially equivalent to the predicate device.

A comparison of the subject device to the predicate devices is provided in the Table below. The information provided demonstrates the subject device is substantially equivalent to the predicate devices.

Table 1: Comparison to Predicate Devices

	Kalypto Medical NPD 1000 Negative Pressure Wound Therapy System	V.A.C.® Therapy Systems-ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)	Boehringer Laboratories Suction Pump System
510(k) Number	K080275	K063692	K060277
Decision Date	(not cleared)	06/07/2007	03/03/2006
Manufacturer	Kalypto Medical	KCI USA, Inc	Boehringer Laboratories
Classification	Class II	Class II	Class II
Product Code	BTA	JCX	JCX
Regulation	878.4780	878.4780	878.4780
Indications for Use	The NPD 1000 Negative Pressure Wound Therapy System, a portable, low powered, battery operated, negative pressure suction pump and wound dressing, is intended for the application of suction to remove a small amount of fluid from the wound bed, including wound exudates and infectious materials, which may promote wound healing.	The V.A.C. Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	The Boehringer Laboratories Suction Pump System is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.
Device Design	The device consists of a suction pump/control unit, tubing and bandage assembly.	The device consists of a suction pump/control unit, collection canister and tubing, and dressing.	The device consists of a suction pump/control unit, collection canister, tube attachment device, wound cover and wound dressing.
Dimensions	3.2" W x 5.1" H x 1.3" D	7.6" W x 6" H x 2.5" D	Unknown (larger than V.A.C. and NPD1000)
Pump Pressure	40-125 mm Hg	25-200 mm Hg	30-75 mm Hg

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Additional Information for 510(k) K080275 for the NPD 1000

Kalypto Medical

Table 1: Comparison to Predicate Devices

	Kalypto Medical NPD 1000 Negative Pressure Wound Therapy System	V.A.C.® Therapy Systems- ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)	Boehringer Laboratories Suction Pump System
Therapy Delivery	Intermittent and continuous	Intermittent and continuous	Intermittent and continuous
Weight	8 oz	2.4 lbs	5 lbs
Power; Battery Life	Alkaline or rechargeable NiMH battery; 3 weeks or more battery life	Lithium ion rechargeable battery; 14 hour average battery life	12.0V DC rechargeable battery; up to 16 hour battery life
Storage Temperature	-20°C to 60°C	-20°C to 40°C	-18°C to 46°C
Storage Humidity	0-95% non-condensing	0-95% non-condensing	0-95% non-condensing
Operating Temp.	5°C to 40°C	5°C to 40°C	10°C to 38°C
Operating Humidity	0-95% non-condensing	0-95% non-condensing	0-95% non-condensing
Storage Alt. Range	-1000 to 18,000 feet	0 to 14,000 feet	Unknown
Operating Alt. Range	-1000 to 10,000 feet	0 to 8000 feet	
Safety	Alarms for system fault, pressure leak, and low battery. Indicator icons for pressure leak and low battery	Alarms for low pressure, tubing blockage, full or missing canister, inactive therapy, low battery, leak in dressing seal, system error	Alarms for high leak rate, tubing blockage, full canister, discharged battery or no hours left on pump. Indicator lights for all alarm conditions and low level leak with adequate suction and normal operation
IEC Classification	Type B, Class II	Type B, Class II	Type B, Class II
Collection Device	50 cc absorbent wound dressing	300 cc collection canister	500 cc collection canister
Bandage	One multilayer assembly: wound contact layer, superabsorber pad, filter, fitting, cover assembly, release liner, tubing, and quick connect fitting	Separate components: polyurethane foam dressing, drape, and pad/tubing/connector	Separate components: Bio-dome™ wound dressing, wound cover, and Opti-Flo™ tube attachment device
Sterility	Only bandage provided sterile	Only bandage provided sterile	All components, except the pump, provided sterile
Sterilization Method	Radiation	Radiation	Radiation

Performance Testing

Verification and validation testing was performed according to the Verification Test Procedures document DP-0001-84-0. This document details the individual tests and the acceptance criteria. No Animal Testing was performed to verify the design of this device. The testing included is listed in the table below. All testing passed the acceptance criteria.

Table 2: Verification and Validation Summary

Test	Acceptance Criteria (System Requirement Number Reference)	Summary of Results
Functional Tests		
Power on Self Tests	SYSREQ 54681, 54688, 57195, 54795	Pass
Therapy Mode Selection	SYSREQ 54686, 54751, 54691, 54675, 54728	Pass
Continuous Mode	SYSREQ 54639	Pass
Intermittent Mode	SYSREQ 54744, 54640, 64795	Pass
Therapy Duration: 4 pressure sensors and 4 therapy devices (2 continuous, 2 intermittent)	SYSREQ 54643, 54644, 54746	Pass
Vacuum Pressure	SYSREQ 54794, 54795, 54746, 54643, 54743, 54644, 54730, 54674	Pass
Pressure Loss Prevention	SYSREQ 54725	Pass
Parameter Retention and Autostart	SYSREQ 84690, 57537	Pass
Device Calibration: document review and inspection only	SYSREQ 54764	Pass
Multiple Bandages: 2 pressure sensors, 2 bandage kits	SYSREQ 54637, 54801	Pass
Device and Bandage Disposal: document review and inspection only	SYSREQ 54716, 54715, 54717, 54646	Pass
Software Upgrade	SYSREQ 55853, 57195	Pass
Reverse Polarity	SYSREQ 57243	Pass
Low Battery	SYSREQ 54799, 54750, 54684, 54729, 55903, 57609, 54728	Pass
Leak Detected	SYSREQ 54799, 54683, 54760, 54729, 54800, 55903, 55904, 57671, 57672, 54728	Pass
System Fault	SYSREQ 54685, 54799, 54795, 54729, 55903, 57673, 57675, 54794, 54728	Pass
User Interface Tests		
Audible Annunciation	SYSREQ 54550, 54802	Pass
Programming Controls	SYSREQ 54727	Pass
UI Display	SYSREQ 54676, 54678, 54677, 54726, 55903, 54537	Pass
Pump On/Off Control	SYSREQ 54687, 54665, 54798, 54671, 54728	Pass

Table 2: Verification and Validation Summary

Hardware Interface Tests		
External Interface Connections	SYSREQ 54539	Pass
Control Unit to Pump Unit Connection	Verify pump runs as expected and verify actual results are as expected	Pass
Stress and Robustness Tests		
Simulated User Evaluation	No expected outputs or pass/fail criteria	Pass
Continuous Pump Life: 6 pumps	SYSREQ 54672	Pass
Intermittent Pump Life: 6 pumps	SYSREQ 54745	Pass
Quick Connect Tubing Cycle Life	SYSREQ 54803	Pass
Environmental Tests		
Operating Conditions: document review and inspection only	SYSREQ 54693, 54694, 54695, 54696, 54660, 54658, 54659, 54781, 54657	Pass
Storage Conditions: document review and inspection only	SYSREQ 54755, 54756, 54757, 54758, 54754, 54753	Pass
Unpackaged Drop and Vibration: document review and inspection only (3 devices)	SYSREQ 54697, 54766, 54777	Pass
Packaged Shock and Vibe: document review and inspection only	SYSREQ 54752	Pass
Fluid Ingress: document review and inspection only	SYSREQ 54673	Pass
EMC: document review and inspection only	SYSREQ 54734, 54735	Pass
Shelf Life (Bandage Only): document review and inspection only	SYSREQ 54719	Pass
Cleaning	SYSREQ 54648, 547862	Pass
Quality, Regulatory and Safety Tests		
Product Safety: document review and inspection only	SYSREQ 54541, 54780	Pass
Device Classification: document review and inspection only	SYSREQ 54541	Pass
Quality Approval: document review and inspection only	SYSREQ 54778, 54779	Test Removed ¹
Biocompatibility: document review and inspection only	SYSREQ 54788, 54785, 54543	Pass
Physical And Mechanical Tests		
Physical	SYSREQ 54773, 54776, 54774, 54767, 54775, 54548, 54711, 54710, 54655, 54692, 54797, 54723, 54549	Pass
Mechanical	SYSREQ 54765, 54782, 54748, 54747, 57244, 54803	Pass

Table 2: Verification and Validation Summary

Unit and Integration Tests		
Unit and Integration	SYSREQ 54689, 54681, 54795	Pass
Kalypto Medical Testing		
Instruction for Use, Tubing Set, Bandage	SYSREQ 54789, 54783, 54654, 54641, 54797, 54647, 54712, 54713, 54653, 54709, 54703, 54704, 54705, 54706, 54707, 54700, 54699, 54663, 54701, 54708, 54702, 54892	Pass

¹ The test was removed because issues were not created in the Capricorn Issue Tracking project. An Open Issues Report was created and attached to the end of the Verification Report.

Revised Device Description

Intended Use

The NPD 1000 Negative Pressure Wound Therapy System, a portable, low powered, battery operated, negative pressure suction pump and wound dressing, is intended for the application of suction to remove a small amount of fluid from the wound bed, including wound exudates and infectious materials, which may promote wound healing.

Models and Accessories

The NPD 1000 Negative Pressure Wound Therapy System consists of the following components.

Table 3: Component Model Numbers

Component	Subassembly	Model	Part No.
Electromechanical Pump	System controller	NPD 1000 Control Unit	50001
	Intermittent pump housing	NPD 1000i Pump Module	50002
	Continuous pump housing	NPD 1000c Pump Module	50003
Wound Dressing	N/A	N/A	N/A

Device Description

The NPD 1000 Negative Pressure Wound Therapy System is a small, portable, low powered, battery operated system comprised of a battery operated electromechanical pump with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that may promote wound healing. This is achieved by removing small amounts of wound fluids and infectious material. The pump components are manufactured by Minnetronix (FDA registration Number 2133810), a contract manufacturer located in St. Paul, MN. The wound dressing is manufactured by TapeMark Co. (FDA Registration Number 2182681), a contract manufacturer located in West St. Paul, MN.

Negative Pressure Wound Therapy is designed to provide therapeutic negative pressure and wound fluid removal for the benefit of candidate wounds as determined by a wound care professional. All negative pressure wound therapy (NPWT) systems have a vacuum pump to provide negative pressure, an occlusive dressing to maintain the negative pressure over the wound bed, a means to remove and store wound exudates from the wound tissues and medical grade plastic tubing to communicate the negative pressure from the pump to the dressing.

The dressing for this device is designed to be worn up to three days continuously with therapy occurring 24 hours per day between clinical visits. During each clinical visit, either at home, inpatient or outpatient (typically MWF schedule), the dressing is changed by a qualified wound care professional. After the dressing change, the patient will resume the daily activities appropriate with the level of care they are currently receiving, including remaining or returning home if they are being treated as an outpatient.

NPD 1000 Pump

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting in the dressing.

The NPD 1000 pump is shipped in 2 pieces, a system controller and 1 of 2 pump housings, either continuous or intermittent. Both pump housings can provide continuous therapy, but only the intermittent housing can provide intermittent therapy. The user fits the 2 subassemblies together by matching the male and female connector housings. The system controller automatically recognizes whether a continuous or intermittent pump has been attached. Neither the system controller nor the pump housing is provided sterile. The system controller and the intermittent pump housing are reusable and do not need to be sterilized between subsequent patients. The continuous pump housing is single use.

The NPD 1000 pump contains a microprocessor controlled pump and pressure sensor working in feed back fashion to control the pressure under the dressing at the physician programmed setting. It has a user interface of 3 buttons to control the power (on/off), treatment mode (intermittent or continuous), and pressure setting (40, 50, 65, 80, 95, 110, and 125 mmHg). The pump is powered by 3 AA batteries, either alkaline or NiMH rechargeable. There is 6 feet of tubing, with a pressure fitting between the pump and the dressing, which can be trimmed to the desired length. A proprietary quick connect fitting is placed in the tubing for easily disconnecting the dressing from the pump. For therapy status notification, the pump has a leak detection indicator icon, a low battery indicator icon and therapy proceeding indicator icon. An alarm buzzer will sound for a leak detection, low battery or system fault.

The Product Specifications for the pump are listed in the table below.

Table 4: Pump Specifications

Parameter	Specification
Dimensions	3.2"W x 5.1" H x 1.3" D
Weight	8 ounces
Pressure Options	-40 to -125 mmHg
Therapy Delivery Modes	Continuous and Intermittent
Battery Type	Alkaline or Rechargeable NiMH
Battery Life	3 weeks or more
Storage Conditions	Temperature: -20°C to +60°C; Humidity: 0-95% non-condensing
Operating Conditions	Temperature: +5°C to +40°C; Humidity: 0-95% non-condensing
Altitude Range	Operating: -1000 ft. to +10,000 ft.; Storage: -1000 ft. to +18,000 ft.
IEC Classification	Medical Equipment; Equipment not suitable for use in the presence of flammable anesthetic mixture;

	Type B, Applied Part; Class II; IPXO
--	--

The materials for the pump are listed in the table below.

Table 5: Pump Component Materials

Pump Component	Materials
System Controller	GE Cycology resin C6600
Controller Keypad	Silicone rubber
Continuous or Intermittent Pump Housing	GE Cycology resin C6600
Tubing	PVC (Tygon R-3603) 55A
Quick Connect Fitting	Black ABS

Figure 2: System Controller with Display Screen and Keypad

(b)(4), Draft

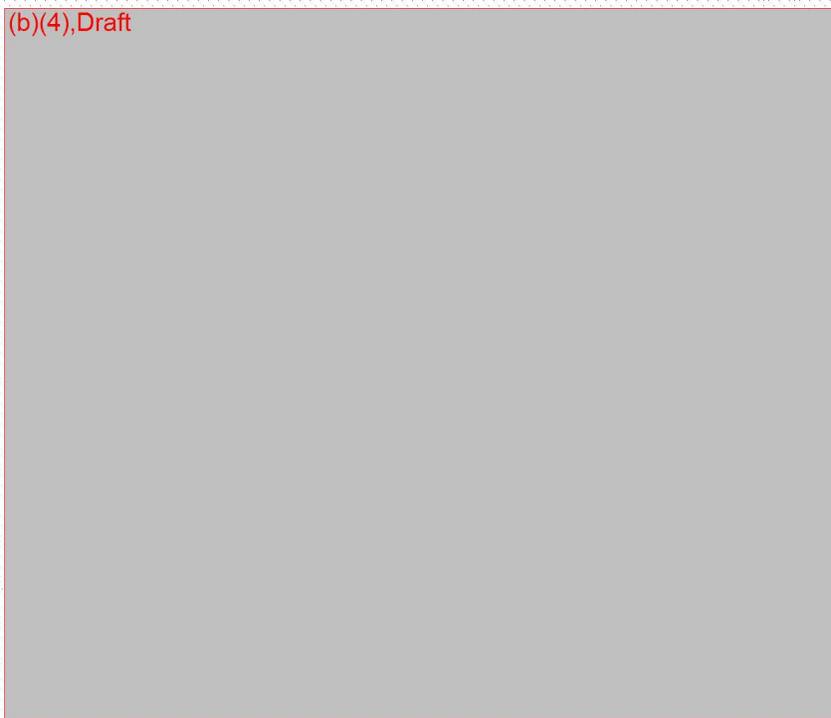


Figure 3: Interior of Pump Housing

(b)(4)

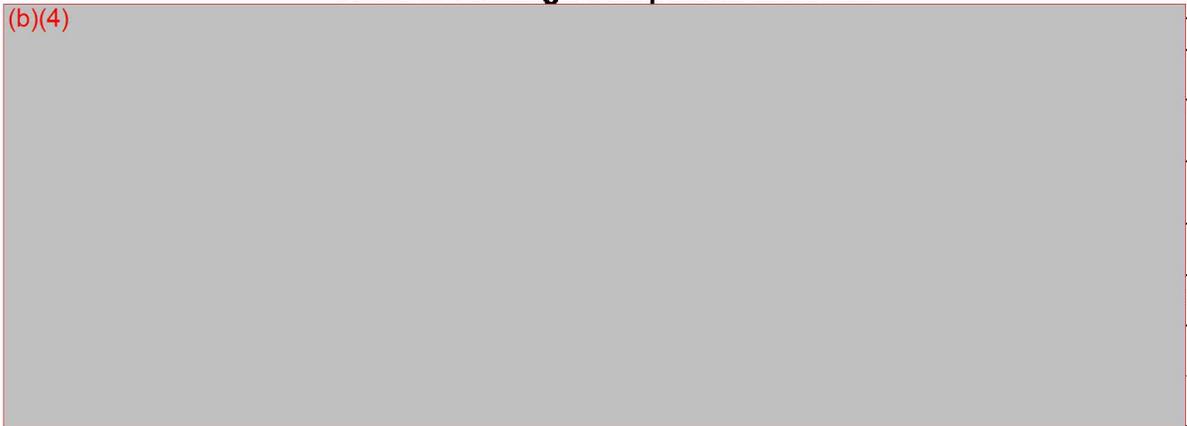


(b)(4)

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Table 6: Bandage Component Materials

(b)(4)

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Table 6: Bandage Component Materials

(b)(4)

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The tissue contacting materials are listed in the following table.

Table 7: Tissue Contacting Materials

(b)(4)

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Revised Substantial Equivalence Discussion

Kalypto Medical believes that the NPD 1000 Negative Pressure Wound Therapy System is substantially equivalent to the devices listed below:

- V.A.C. Therapy Systems-ActiV.A.C. Therapy Unit M: K063692
- Boehringer Laboratories Suction Pump System: K060277

Similarities

The Kalypto NPD 1000 and both predicates are intended to remove fluids (exudates) such as infectious materials. The Kalypto NPD 1000 and both predicates include a powered suction pump to create the negative pressure. The pressure range of the Kalypto NPD1000 (40-125 mm Hg) is within the pressure range of the predicates (25-200 mm Hg). The Kalypto NPD 1000 and both predicate dressing/bandage materials provide a bacterial barrier and transmit the negative pressure from the suction pump to the wound site. The Kalypto NPD 1000 and both predicates remove the exudate from the wound and store it safely away from the wound, thereby preventing the exudate from remaining in contact with the wound. The Kalypto NPD1000 dressing is a semi-occlusive multilayer dressing like the Boehringer Laboratories dressing.

Differences

The Kalypto NPD 1000 is smaller in dimension and lighter in weight than the predicates. The Kalypto NPD 1000 is powered only by battery, whereas the predicates can operate by battery or power supply. The Kalypto NPD1000 dressing does not include wound packing material like the V.A.C. AvtiV.A.C.. The Kalypto NPD 1000 dressing is also the collection device, whereas the predicates have a separate collection canister. The Kalypto NPD 1000 exudate collection volume is 50 cc, whereas the V.A.C. AvtiV.A.C. exudate collection volume is 300 cc and the Boehringer Laboratories exudate collection volume is 500 cc.

Conclusion

We believe the NPD1000 is substantially equivalent to the predicates because it has the same intended use and the technological characteristics are functionally the same. We feel that any differences in technological characteristics do not raise any new questions of safety and effectiveness over the predicate device. The information demonstrates that the subject device is substantially equivalent to the predicate device.

A comparison of the subject device to the predicate devices is provided in the Table below. The information provided demonstrates the subject device is substantially equivalent to the predicate devices.

Table 8: Comparison to Predicate Devices

	Kalypto Medical NPD 1000 Negative Pressure Wound Therapy System	V.A.C.® Therapy Systems- ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam® Dressing)	Boehringer Laboratories Suction Pump System
510(k) Number	K080275	K063692	K060277
Decision Date	(not cleared)	06/07/2007	03/03/2006
Manufacturer	Kalypto Medical	KCI USA, Inc	Boehringer Laboratories
Classification	Class II	Class II	Class II
Product Code	BTA	JCX	JCX
Regulation	878.4780	878.4780	878.4780
Indications for Use	The NPD 1000 Negative Pressure Wound Therapy System, a portable, low powered, battery operated, negative pressure suction pump and wound dressing, is intended for the application of suction to remove a small amount of fluid from the wound bed, including wound exudates and infectious materials, which may promote wound healing.	The V.A.C. Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	The Boehringer Laboratories Suction Pump System is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.
Device Design	The device consists of a suction pump/control unit, tubing and bandage assembly.	The device consists of a suction pump/control unit, collection canister and tubing, and dressing.	The device consists of a suction pump/control unit, collection canister, tube attachment device, wound cover and wound dressing.
Dimensions	3.2" W x 5.1" H x 1.3" D	7.6" W x 6" H x 2.5" D	Unknown (larger than V.A.C. and NPD1000)
Pump Pressure	40-125 mm Hg	25-200 mm Hg	30-75 mm Hg
Therapy Delivery	Intermittent and continuous	Intermittent and continuous	Intermittent and continuous

Kalypto Medical

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Additional Information for 510(k) K080275 for the NPD 1000

Table 8: Comparison to Predicate Devices

	Kalypto Medical NPD 1000 Negative Pressure Wound Therapy System	V.A.C. [®] Therapy Systems- ActiV.A.C. Therapy Unit M (with V.A.C. GranuFoam [®] Dressing)	Boehringer Laboratories Suction Pump System
Weight	8 oz	2.4 lbs	5 lbs
Power; Battery Life	Alkaline or rechargeable NiMH battery; 3 weeks or more battery life	Lithium ion rechargeable battery; 14 hour average battery life	12.0V DC rechargeable battery; up to 16 hour battery life
Storage Temperature	-20°C to 60°C	-20°C to 40°C	-18°C to 46°C
Storage Humidity	0-95% non-condensing	0-95% non-condensing	0-95% non-condensing
Operating Temp.	5°C to 40°C	5°C to 40°C	10°C to 38°C
Operating Humidity	0-95% non-condensing	0-95% non-condensing	0-95% non-condensing
Storage Alt. Range	-1000 to 18,000 feet	0 to 14,000 feet	Unknown
Operating Alt. Range	-1000 to 10,000 feet	0 to 8000 feet	
Safety	Alarms for system fault, pressure leak, and low battery. Indicator icons for pressure leak and low battery	Alarms for low pressure, tubing blockage, full or missing canister, inactive therapy, low battery, leak in dressing seal, system error	Alarms for high leak rate, tubing blockage, full canister, discharged battery or no hours left on pump. Indicator lights for all alarm conditions and low level leak with adequate suction and normal operation
IEC Classification	Type B, Class II	Type B, Class II	Type B, Class II
Collection Device	50 cc absorbent wound dressing	300 cc collection canister	500 cc collection canister
Bandage	One multilayer assembly: wound contact layer, superabsorber pad, filter, fitting, cover assembly, release liner, tubing, and quick connect fitting	Separate components: polyurethane foam dressing, drape, and pad/tubing/connector	Separate components: Bio-dome [™] wound dressing, wound cover, and Opti-Flo [™] tube attachment device
Sterility	Only bandage provided sterile	Only bandage provided sterile	All components, except the pump, provided sterile
Sterilization Method	Radiation	Radiation	Radiation

Additional information relevant to Section 18 – Performance Testing - Bench

Introduction

Representative samples of the NPD 1000 Negative Pressure Wound Therapy System were tested in accordance with the System Verification and Validation Plan (DP-0001-85-0) and the Verification Test Procedures (DP-0001-84-0), provided in Appendix 8 of the original submission. These documents detail the tests, methods and acceptance criteria to confirm that the hardware and software designs were implemented correctly and to ensure that the performance requirements of the device were met. The default unit under test (UUT) sample size is one (1) unless specified otherwise in each individual test. All timing and performance requirements had a tolerance of $\pm 10\%$ unless specified in the individual test.

The system verification and validation testing performed by Minnetronix included functional tests, user interface tests, hardware interface tests, stress and robustness tests, environmental tests, quality, regulatory and safety tests, physical and mechanical tests, and unit integration tests. The verification test results are summarized in Section 16, Table 14, of the original submission. Details of the Minnetronix test results are provided in the Verification Report, DR-0000-09-0, which is provided in Appendix 9 of the original submission.

Therapy Duration Testing

At the time of the original submission, there were two open items as a result of the Minnetronix verification testing. The Therapy Duration Testing was in progress, but has subsequently been completed. Verification testing on software version 06 passed. Regression testing on software version 08 has not yet been completed for the Therapy Duration testing. Only one item remains open for repeated verification testing on version 08, and no software changes have been made that are expected to influence the results.

Pressure Loss Prevention Testing

The Pressure Loss Prevention test which did not meet the acceptance criteria has been repeated. During verification testing on version 06 it was found that both the continuous and intermittent pumps have greatly different leak rates from pump to pump. Most intermittent pumps and half the continuous pumps meet the acceptance criteria. The others do not meet acceptance criteria which may lead to false leak detect errors and reduced battery life, both of which are non-critical and will not affect patient safety. The position of a check valve in the pump plumbing was moved and the Pressure Loss Prevention test was repeated to address this issue. Results show that the pressure loss prevention testing passed after changing the position of the check valve. This repeat testing was conducted on software version 08, the version intended for market release.

Side By Side Performance Testing With Predicate Device

Additional side by side performance testing has been performed and is now being submitted comparing the Kalypto NPD1000 Negative Pressure Dressing system and the KCI V.A.C. Advance dressing system. Ten (10) Kalypto bandages and 10 KCI bandages were matched with

their respective pumps and tested for vacuum pressure: a Bandage Pump Down Time Test and a Target Pressure Vacuum Integrity Test.

The acceptance criteria were that the Bandage Pump Down Time Test passed if the pump/dressing system was able to achieve the set pressure in less than 3 minutes, and there were no audible leaks in the dressing. The pump/dressing systems passed the Target Pressure Vacuum Integrity Test if the system achieved 125mm Hg of negative pressure (5 inches Hg).

The results showed that both the Kalypto and KCI pump/dressing systems met all acceptance criteria, and that they performed in an equivalent manner. The Kalypto system achieves the same level of negative pressure as the KCI V.A.C. Advanced Dressing System. The side by side testing protocol and (draft) report are provided in **Appendix II** of this submission. Note: No changes are to be made in the final report.

Usability Verification Testing

Some usability verification testing of the dressing, tubing and instructions for use was performed by IASIS Medical and presented in the original submission. A description of these tests and the results are summarized in Table 15 of the original submission. Details of the IASIS test results are provided in the NPD 1000 Negative Pressure Dressing Verification and Validation Test Report, QFM-04-3c, which is provided in Appendix 9 of the original submission.

Additional Usability Testing has been performed and is now being submitted to verify the adequacy of the Patient labeling developed for home care use of the subject device. The Instructions for Use has been revised to include separate Patient and Physician instruction sections. The usability testing is described in response # 7 of the "Responses to Request for Additional Information." The bandage package integrity and shelf life validation testing has been completed and is described in response #8 of the "Responses to Request for Additional Information."

Product Integrity Comparison
for
Kalypto Medical, Inc.
Kalypto NPD 1000 Negative Pressure Dressing vs. KCI V.A.C.
Advanced Dressing System

Report Number: 0805009 DRAFT
Protocol Number: P080597 Rev. A
P.O. Number: signed quote
3 June 2008

Customer:
Kalypto Medical, Inc.
Attn: John Buan
15912 69th Place North
Maple Grove, MN 55311

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Testing Performed by



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INTRODUCTION

Objective

The objective of this project was to compare the capabilities of the Kalypto NPD 1000 Negative Pressure Dressing vs. KCI V.A.C. Advanced Dressing System product functionality for Kalypto Medical, Inc. Testing was done off site with equipment qualified to perform these tests.

Scope

This report documents that the capabilities of the Kalypto NPD 1000 Negative Pressure Dressing System performs as well as the currently approved KCI V.A.C. Advanced Dressing system in accordance with the test methods stated in DDL, Inc. quote number 0805009 Rev. A and DDL, Inc. Protocol P080597 Rev. A located in Appendix A.

SUMMARY OF TESTED SPECIMENS

Due to the uniformity of the data collected during testing, the sample size was reduced to ten (10) from fifteen (15).

Specimen Type	Test Interval	Number of Specimens Tested
Kalypto NPD 1000 Negative Pressure Dressing	Persistent Vacuum Integrity	10
Kalypto NPD 1000 Negative Pressure Dressing	Bandage Pump Down Time	10
KCI V.A.C. Advanced Dressing System	Persistent Vacuum Integrity	10
KCI V.A.C. Advanced Dressing System	Bandage Pump Down Time	10

Table 1: Summary of tested specimens.

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RESULTS SUMMARY

Acceptance Criteria

The acceptance criterion has been outlined in DDL, Inc. Protocol P080597 Rev. A located in Appendix A of this test report.

Functionality Testing

Bandage Integrity Testing

Ten (10) bandages of each type were persistent vacuum integrity and bandage pump down time tested. The raw data for all integrity testing is located in Appendix B of this test report.

Kalypto NPD 1000 Negative Pressure Dressing	Final Pressure (in Hg)	Pump Down Time (sec)	Audible Leak
1	5.1	28:65	No
2	5.1	36:70	No
3	5.1	40:06	No
4	5.1	37:44	No
5	5.08	34:72	No
6	5.02	32:55	No
7	5.05	34:20	No
8	5.12	36:45	No
9	5.09	32:79	No
10	5.12	37:23	No
Average	5.09	35.08	-

Table 2: Bandage integrity results for Kalypto NPD 1000 Negative Pressure Dressing.

KCI V.A.C. Advanced Dressing System	Final Pressure (in Hg)	Pump Down Time (sec)	Audible Leak
1	5.02	6.04	No
2	5.04	5.30	No
3	5.03	7.81	No
4	5.02	6.78	No
5	5.03	5.97	No
6	5.02	7.09	No
7	5.06	4.43	No
8	5.02	8.10	No
9	5.02	7.54	No
10	5.03	7.37	No
Average	5.03	6.64	

Table 3: Bandage integrity results for KCI V.A.C. Advanced Dressing System.

RELATED DOCUMENTS

References
DDL, Inc. Quote # 0805009 Rev. A; Comparison Functionality Testing
DDL, Inc. Protocol # P080597 Rev. A; Product Integrity Comparison

Table 4: Standards and References

LOGISTICS

Persistent Vacuum Integrity Testing:

- Started: 21 May 2008
- Completed: 21 May 2008

Bandage Pump-Down Time Testing:

- Started: 21 May 2008
- Completed: 21 May 2008

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EQUIPMENT

The following equipment was used to complete these tests:

Equipment Name	Model No.	Serial No.	Calibration Due
KCI-INFO VAC	NA	VCOK02026	19-Sep-08
Kalypto NPD 1000 Negative Pressure Wound Therapy Device	50001 Rev A	AE-0000-83-4-000003	NA
Vacuum Gauge	Ashcroft	001447	05-May-09
Stopwatch	Cole-Palmer	001615	02-May-09

Table 5: Equipment List

PRODUCT

Product

Kalypto NPD 1000 Negative Pressure Dressing

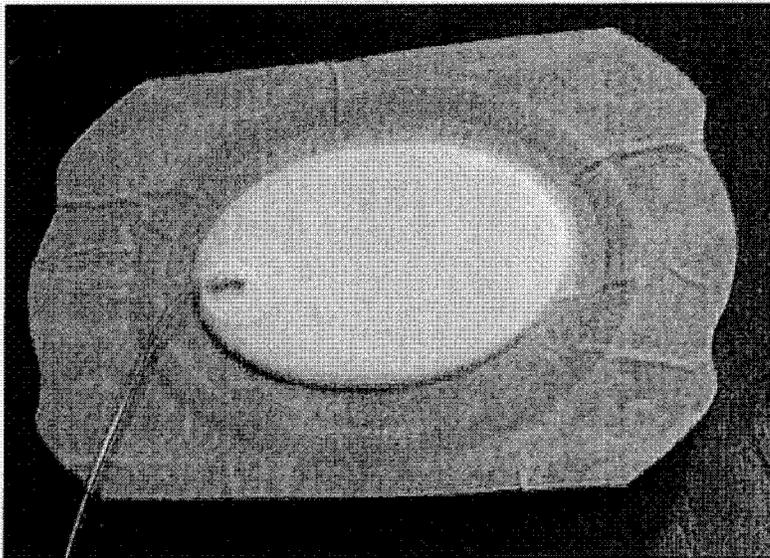


Figure 1: Kalypto NPD 1000 Negative Pressure Dressing.

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KCI V.A.C. Advanced Dressing System

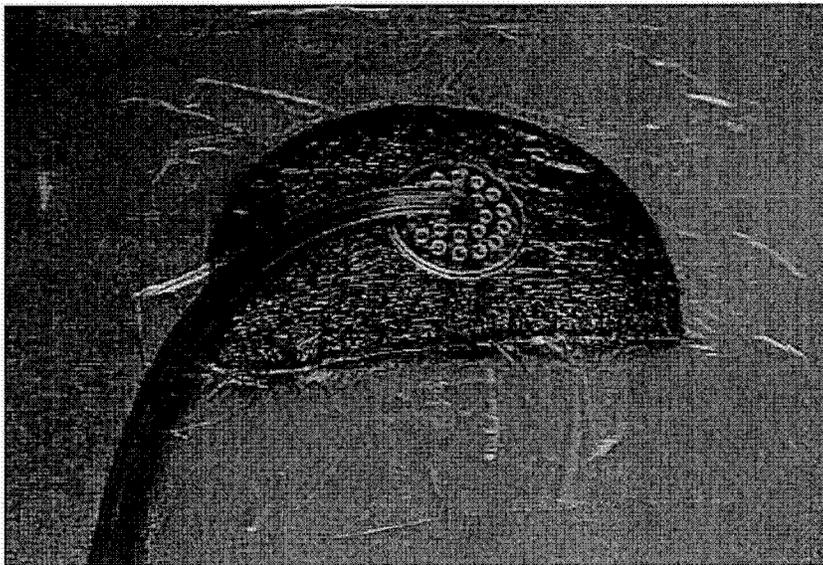


Figure 2: KCI Advanced Dressing System.

TEST PROCEDURE

Functionality Testing

Bandage Integrity Test

This test was performed based on DDL Protocol: P080597 Rev A.: *Product Integrity Comparison*.

The test method is designed to verify that the NPD 1000 Negative Pressure Dressing and the KCI VAC dressings have vacuum integrity, when used with respective manufacturer's pump systems and to further verify that each system (pump and dressing) can achieve a negative pressure of 125 mmHg when the control system in has a pressure set point of 125mmHg.

An independent calibrated pressure sensor was attached to the tubing on the back of the test fixture board. A dressing was then mounted onto the test board over the pressure ports. The pump was then connected to the dressing (Kalypto pump – Kalypto dressing, KCI pump – KCI dressing). The pump was then set to 125 mmHg per the manufacturer's instructions. A stopwatch was started when the pump was turned on to measure the time for the system to achieve a negative pressure of 125 mmHg.

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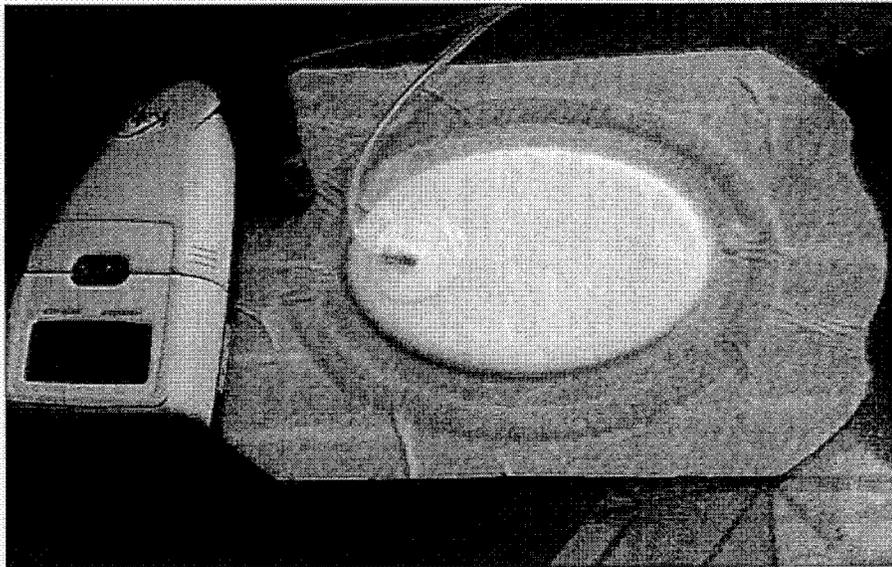


Figure 3: Typical bandage integrity test set-up for the Kalypto NPD 1000.

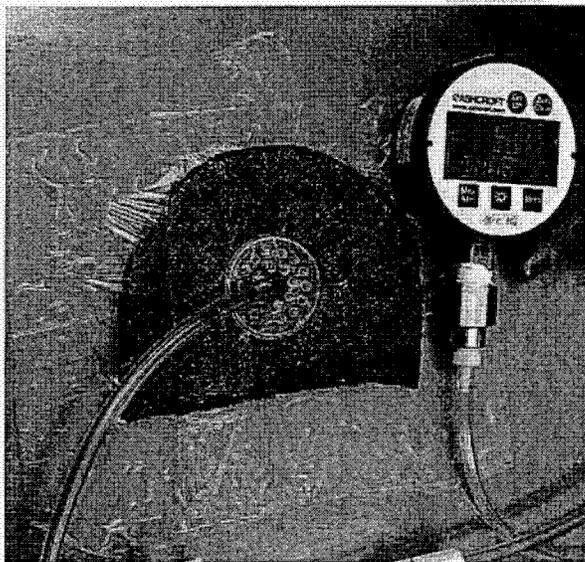


Figure 4: Typical bandage integrity test set-up for the KCI dressing.

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Figure 5: KCI pump used for testing KCI dressing.

All raw data for the bandage integrity tests can be found in Appendix B of this test report. A tabular summary of the results is presented in the results section of this test report.

CONCLUSION

The Kalypto NDP 1000 System achieves the same level of negative pressure as the KCI VAC System.

DISCLAIMER OF WARRANTIES

ALL WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY THAT THE PRODUCT OR PACKAGING TESTED IS MERCHANTABLE, FIT FOR A PARTICULAR PURPOSE, OR IN COMPLIANCE WITH ANY FEDERAL, STATE OR LOCAL REGULATIONS, ARE DISCLAIMED. In no event shall DDL, Inc. liability exceed the total amount paid by **Kalypto Medical, Inc.** for services rendered.

A Quality Assurance program should be in place to ensure that the manufacturing process produces products/packages of equivalent performance to those tested here. This is solely the responsibility of the manufacturer. DDL, Inc. takes no responsibility for the quality of products/packages produced hereafter, other than to certify the design of those physical test systems actually tested by DDL, Inc. DDL, Inc. takes no responsibility for the use, acceptance or non-acceptance of this data by government regulatory agencies.

In the event of future changes to the referenced test procedure(s), it is the responsibility of **Kalypto Medical, Inc.** to determine whether additional testing or updating of this certification is necessary to verify that the product and/or packaging certified here remains in compliance with requirements.

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STATEMENT OF CONFORMITY

DDL, Inc. certifies that the above stated testing services have been performed in accordance to applicable standard good laboratory practices and/or standards identified within this report. Testing has been completed as described herein.

The following list of exceptions occurred during testing:

- *None*

All materials, equipment, methods, and processes used to perform the described testing have been standardized, calibrated, and monitored in accordance with prescribed guidelines, standard operating procedures, and the supervision requirements of DDL, Inc. All raw data obtained from this testing by DDL, Inc. personnel is archived at DDL, Inc.

The signatures below are in compliance with 21 CFR Part 11.

Testing performed by: Kathleen A. McDaniel

Report prepared by:

Amy J. Peterson
Project Manager

Technical Review by:

Corey D. Hensel
Director of Operations

Approved by:

Kim M. Pratt
Quality Assurance Manager

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**APPENDIX A: DDL, INC. PROTOCOL # P080597 REV. A;
PRODUCT INTEGRITY COMPARISON**

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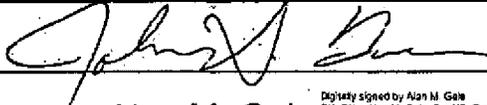
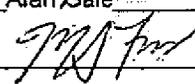
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Test Protocol Title: <i>Product Integrity Comparison</i>	
Test Type: <i>Product Functionality Tests</i>	
Protocol Number: <i>P080597</i>	Revision: <i>A</i>
Approvals:	
Kalypto Medical: 	Date: <i>5/20/08</i>
DDL, Inc: Written By: <i>Alan Gale</i>	Alan M. Gale <small>Digitally signed by Alan M. Gale DN: cn = Alan M. Gale, c = US, o = DDL, Inc., ou = Operations Reason: I am the author of this document Date: 2008.05.20 13:22:51 -0500</small>
Approved By: 	Date: <i>20 May 08</i>
Product Tested: NPD 1000 Negative Pressure Dressing and KCI V.A.C. Assisted Closure systems	

1. Purpose

1.1. This document provides the test parameters required to perform a comparison test of the Kalypto NPD 1000 Negative Pressure Dressing system and the KCI V.A.C. Advanced Dressing system. The testing will verify that both systems achieve therapeutic pressures under dressings constructed according to manufacturer's specifications on a bench test fixture.

2. Scope

2.1. Completion of the work described in this protocol will provide documentation supporting the capabilities of the Kalypto NPD 1000 Negative Pressure Dressing system to perform as well as the currently approved KCI V.A.C. Advanced Dressing system. Only the negative pressure characteristics of the systems will be tested. The ability of each dressing design to conduct fluid is not within the scope of this project.

3. References

- 3.1 Kalypto Medical, *Bandage Integrity - Vacuum Pressure Test Protocol*
- 3.2 Kalypto Medical, NPD 1000 IFU (instructions for use)
- 3.3 Clinical_Guidelines_VAC.pdf

4. Materials and Equipment

- 4.1. Kalypto Medical NPD 1000 Negative Pressure Wound Therapy Device
- 4.2. Kalypto Medical NPWT dressings
- 4.3. KCI V.A.C. Vacuum Assisted Closure system
- 4.4. Vacuum pressure sensor gauge
- 4.5. Stopwatch

Test Protocol Title:	Product Integrity Comparison		
Test Type:	Product Functionality Tests		
Protocol Number:	P080597	Revision:	A

4.6. T-connectors and miscellaneous hose fittings as necessary

5. Sample Description and Preparation

- 5.1. One currently manufactured NPD 1000 Negative Pressure Dressing system including the pump and dressings.
- 5.2. One currently manufactured KCI V.A.C. Vacuum Assisted Closure system including the pump and dressings.
- 5.3. Thirty (30) dressings will be used for this study. Fifteen (15) of these will be from the Kalypto NPD 1000 Negative Pressure Wound Therapy system. Fifteen (15) of these will be from the KCI V.A.C. Vacuum Assisted Closure system.
- 5.4. All samples will be clearly identified by Kalypto Medical for testing requirements.

6. Test Procedure

The following test procedures will be performed per the test sequence described below.

6.1 Kalypto NPD 1000 Negative Pressure Integrity Validation and Operation

Fifteen (15) Kalypto bandages will be matched with the Kalypto pump and each dressing will be tested according to the Bandage Integrity - Vacuum Pressure Test Protocol. The output of the device will be verified by a pressure gauge underneath the bandage. Within the protocol, two tests will be performed. A Bandage Pump Down test will be performed on each sample and a Target Pressure Vacuum Integrity test will be performed on the same sample afterwards.

6.2 KCI V.A.C. Negative Pressure Validation and Operation

Fifteen (15) KCI bandages will be matched with the KCI pump and each dressing will be tested in a manner similar to the Bandage Integrity - Vacuum Pressure Test Protocol. The output of the device will be verified by a pressure gauge underneath the bandage. The operator of the device will set-up the bandage system according to the manufactures instructions for actual use. Two tests will be performed. A Bandage Pump Down test will be performed on each sample and a Target Pressure Vacuum Integrity test will be performed on the same sample afterwards

7 Acceptance Criteria

7.1 Acceptance criteria for all product functionality testing has been identified by Kalypto Medical.

7.1.1 Pump/Dressing system will pass the Bandage Pump Down Time test if it is able to achieve the set pressure in less than 3 minutes with each bandage/dressing and there are no audible 700

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Test Protocol Title:	Product Integrity Comparison		
Test Type:	Product Functionality Tests		
Protocol Number:	P080597	Revision:	A

leaks in the dressing. Passing the Bandage Pump Down Time test for each dressing will be necessary to move to the Target Pressure Vacuum Integrity Test.

7.1.2 A Pump/Dressing system that passes the Target Pressure Vacuum Integrity test will achieve 125 mmHg of negative pressure at the dressing with statistical errors to be reported.

8 Documentation

- 8.1 The Product Integrity Comparison tests will be documented on appropriate work sheets or a laboratory notebook. It will be used to record the equipment used and test results of performing these tests.
- 8.2 Gross irregularities found during inspection of samples prior to integrity testing will be documented and Kalypto Medical will be notified.
- 8.3 Records for this project will be archived at DDL for a duration of 5 years in accordance with DDL's record policy. At the completion of 5 years all records will be disposed of properly. A written request must be made by the customer, specifying a longer retention period before the 5 years is complete.

Test Protocol Title:	Product Integrity Comparison		
Test Type:	Product Functionality Tests		
Protocol Number:	P080597	Revision:	A

APPENDIX A

Bandage Integrity - Vacuum Pressure Test Protocol

Introduction

These tests will verify . . .

- The NPD 1000 Negative Pressure Dressing and KCI VAC dressings have vacuum integrity, when used with respective manufacturers pump systems.
- The NPD 1000 Negative Pressure Wound Therapy System (pump and dressing) can achieve a negative pressure of 125 mmHg, when the control system in has a pressure setpoint of 125 mmHg.
- The KCI VAC system and dressing can achieve a negative pressure of 125 mmHg, when the control system in has a pressure setpoint of 125 mmHg.

Test Equipment

1. 15 NPD 1000 Negative Pressure Dressings*
2. NPD 1000 Negative Pressure Wound Therapy Device*
3. KCI VAC Dressing Materials and Tubing
4. KCI VAC Device
5. Negative pressure tubing and fittings*
6. Independent pressure sensor.
7. Smooth surface fiberglass board to accommodate mounting of bandage*
8. Stopwatch.

* Note: These items supplied by customer

Test Procedures and Expected Results

Bandage Pump Down Test and Vacuum Integrity Test (test performed with 15 bandages, serially, if dressing passes, proceed to Vacuum Pressure integrity Test for each dressing)

1. Attach one of the independent calibrated pressure sensors to the tubing on the back of the test fixture board. Make sure the second tube is occluded with at luer lock fitting
2. Attach the dressing to be tested to the test board over the pressure ports on the board (taking pictures after each dressing is attached)

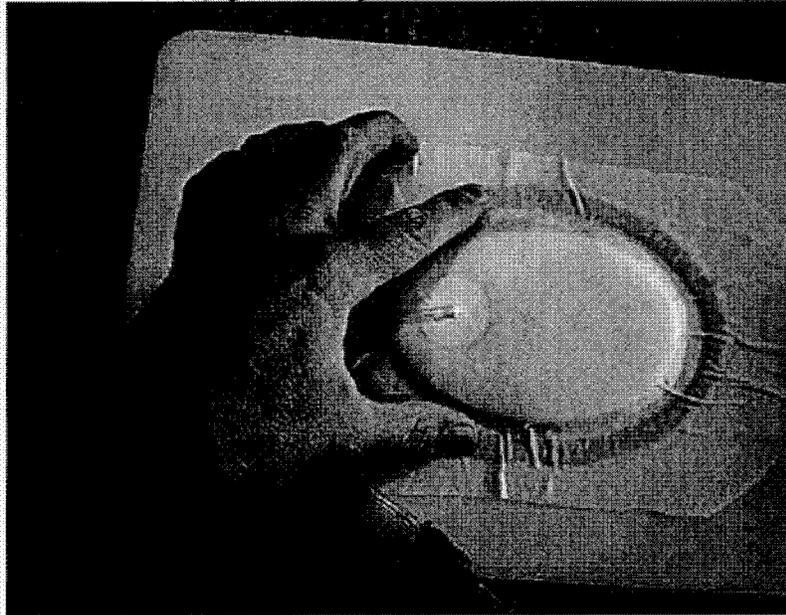
Test Protocol Title: *Product Integrity Comparison*

Test Type: *Product Functionality Tests*

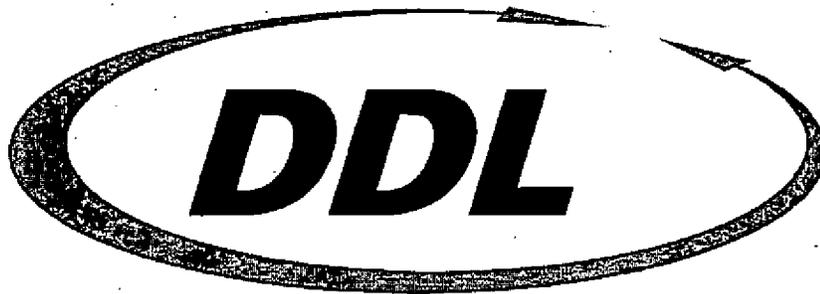
Protocol Number: P080597

Revision: A

- a. For the NPD 1000, seal the dressing gasket to the board, by running your fingers along the perimeter of the gasket (see picture below) and attach pigtail tubing to pressure port on dressing



- b. For the KCI dressing, prepare a 3x4x1/2 rectangle of foam. Place over pressure ports on fixture. Cover with 4x5 rectangle of cover material (remove all release liners). Cut small hole in cover material. Secure pressure tubing over hole on cover material and secure to the dressing.
3. Connect appropriate pump to dressing (Kalypto pump – Kalypto dressing, KCI pump – KCI dressing).
4. Set pump being tested to a setpoint of 125 mmHg, following manufacturers instructions.
5. Power on pump and start the stop watch.
6. Listen for leaks in the dressing by placing your ear close to the test fixture. If a leak is heard it must be patched.
7. Measure and record time for the system to achieve 125 mmHg.
8. Take a picture of dressing to corroborate that dressing has appropriate appearance per the IFU.
9. Repeat for 15 dressings for each manufacturer.



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Vision Statement

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APPENDIX B: BANDAGE INTEGRITY TESTING DATA

DRAFT

Report No.	0805009 DRAFT	Customer:	Kalypto Medical, Inc.	Page 11 of 11
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DDL, Inc. • 10200 Valley View Road, Suite 101 • Eden Prairie, MN 55344 • Tel: 952-941-9226 • Fax: 952-941-9318

TITLE NEG. PRESSURE DEVICE - PROTOCOL 0805097

From Page No. 5

EQUIPMENT

KALYPTO NPD 1000 s.n. AE-0000-834-000003

ASHCROFT VACUUM GAUGE (30 inHg) ASSET # 001447 CAL DUE 05 MAY 09

STOPWATCH (Cole-Palmer) ASSET # 001615 CAL DUE 02 MAY 2009

NPD 1000 DRESSING S/N N/A

PROTOCOL P0805097

PRESSURE SETTING 125 mmHg

DRESSING	FINAL PRESSURE (inHg)	PUMP DOWN TIME (SEC)	LEAK
#1	5.1	28.65	NO
#2	5.1	36.70	NO
#3	5.1	40.06	NO
#4	5.1	37.44	NO
#5	5.08	34.72	NO
#6	5.02	32.55	NO
#7	5.05	34.20	NO
#8	5.12	36.45	NO
#9	5.09	32.79	NO
#10	5.12	37.23	NO

Kam 23 MAY 08

To Page No. 5

Witnessed & Understood by me,

[Signature]

Date

23 May 08

Invented by

Recorded by

Kam

Date

23 May 08

707

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

August 15, 2008

IASIS MEDICAL, INC.
6393 OAKGREEN AVENUE
HASTINGS, MN 55033
ATTN: JOHN BUAN

510(k) Number: K080275
Product: MODEL NPD 1000
NEGATIVE
PRESSURE WOUND
THERAPY SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. 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



K080275/S2

August 14, 2008

Office of Device Evaluation
Document Mail Center (HFZ401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

FDA CDRH DMC
AUG 15 2008
Received

RE: K080275: Additional Information for the NPD 1000 Negative Pressure Wound Therapy System

Enclosed are one original and two copies of additional information to K080575: 510(k) PreMarket Notification for the NPD 1000 Negative Pressure Wound Therapy System. This additional information was requested by FDA in a letter dated June 19, 2008.

This submission contains technical, commercial and confidential trade secret information, and Kalypto Medical respectfully requests the maximum protection provided by law, in accordance with 21 CFR § 807.95.

If you have any questions, please contact me at (763) 551-8959, by Fax at (763) 287-3836, or by email at jbuan@kalyptomedical.com.

Sincerely,

Pamela Vaughan (for John Buan)

John Buan
Vice President of Product Development

K15

Kalypto Response to FDA Request for Additional Information	
Submission Index- Volume 1 of 1	
Cover Letter	
Additional Information	
Revised Form 3514	
Revised 510(k) Summary	
Revised Indications for Use Statement	
Attachments	
Product and Package Validation Testing (including Bandage Fluid Capacity Performance Testing) and Test System Photos	Attachment Q1
Revised Instructions for Use	Attachment Q2
Feedback Loop Flowchart	Attachment Q3
Verification Test Report DP-0001-84-0 (see relevant sections): <ul style="list-style-type: none"> -Test Case FT002a Continuous Mode -Test Case FT002b Intermittent Mode -Test Case FT003 Therapy Duration -Test Case FT004 Vacuum Therapy 	
Silverlon Instructions for Use	Attachment Q6
Silverlon 510(k) Summary (K981299)	
Hydrogel Biocompatibility Information	Attachment Q7
Superabsorbent Non-woven Polymer Matrix Information: <ul style="list-style-type: none"> -Chemical Composition -Technical Information 	
Superabsorbent Polymer Biocompatibility Information (b)(4) <ul style="list-style-type: none"> -Biocompatibility Test Information 	
Cleaning Validation Protocol and Report	Attachment Q9
Revised Dressing Label	Attachment Q11

Kalypto Medical Response to Request for Additional Information
K080275

Additional Information

1. In April 29, 2008, FDA requested performance testing to demonstrate equivalence of the subject device to a legally marketed predicate device. You submitted bandage integrity testing demonstrating final pressure and pump down time. The submitted testing is not sufficient to determine that the subject device is substantial equivalent to the predicate device based on how negative pressure is effectively administered to the wound bed resulting in the removal of wound exudate. In all predicate devices the negative pressure is administered to the dressings placed in the wound bed. You stated that negative pressure will be administered to a wound dressing that is external to the wound. You have not demonstrated that the pressure created by this external negative pressure will result in effective removal of exudate from the wound. Please provide performance testing that demonstrates negative pressure administered (continuously and intermittently) to the wound over an extended period of time results in wound exudate effectively removed from the wound bed and contained in the occlusive wound dressing. Please be aware the model used P080299 is not a relevant physiological model.

RESPONSE:

The tests that were performed during design verification and after accelerated aging and shipping simulation provide conclusive evidence that the NPD1000 Negative Pressure Wound Therapy System will effectively remove exudate from the wound bed. Bandage fluid capacity testing utilized a test board designed to simulate a flat surface, with a fluid source beneath the board. The fluid source was under the dressing distal to the negative pressure port of the dressing. A series of photos representative of the test setup are provided in Attachment Q1. These design verification studies showed that the negative pressure (applied at the dressing port) created a negative pressure across the surface of the dressing, and pulled the fluid into the dressing. Additionally, the wicking properties of the absorbent layer of the dressing insured even distribution of the fluid in the dressing.

This simulates the action of the system when applied to a tissue wound bed. The system is intended to treat surface wounds. The dressing does not "fill" the wound bed, but lies on top of the wound and conforms to the wound bed as a result of the application of negative pressure. The application of negative pressure across the dressing, which pulls liquid (exudate) away from the wound bed, is the same principle of operation as the predicate device.

The previously submitted design verification and validation report, Product and Package Validation Testing, is provided in Attachment Q1. The bandage capacity testing description is provided on page 15 of 24, and the results are provided on page 5 of 24 of the report. The average amount of fluid absorbed and held by the dressing (after removal of excess fluid) was 81.3 grams (mL). This data shows that the system creates negative pressure under and across the dressing, and will remove and hold more than 50cc of fluid (wound exudate) in the bandage (dressing).

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The performance testing conducted to verify that the system operates in both intermittent and continuous mode over an extend period of time is provided in the response to Question 3, below.

2. Please explain this statement found in your labeling: "For cavity wounds a standard wound filler such as gauze or foam must be used". Please submit performance data to demonstrate how your device will function with gauze or foam present in the wound.

RESPONSE:

This statement has been removed from the Instructions for Use (IFU). A copy of the revised IFU is provided in Attachment Q2. This particular change can be found on page 15 of the revised document.

3. You state the following on page 10 of the indications for use: "...pressure sensor working in feedback fashion to control the pressure under the wound." Please identify the testing you completed on your Proprietary Leak Detection System that demonstrates a feedback mechanism to control the pressure under the wound. You have testing that identifies the presence of a leak but this statement infers that the device will identify a leak and then compensate the pressure. Please identify the testing or remove this claim from your labeling.

RESPONSE:

Testing was conducted to verify proper operation and leak detection in continuous mode, in intermittent mode, throughout therapy duration, during vacuum application, and with multiple bandages (dressing changes). These tests showed that the feedback loop, designed to start or increase vacuum in response to a "leak" operated properly. The Feedback Loop Flowchart and the test reports for leak detection are provided in Attachment Q3.

It is important to note that various types of "leaks" can occur, and these are detected by the system as an increase (positive trend toward zero) in pressure. The "leaks" can be due to an incorrectly sealed dressing; a gradual increase in negative pressure due to diffusion through the dressing; loss of battery power; or other technical reasons. The negative pressure is measured once every second. If the pressure rises 10% above the setpoint (negative pressure value set by the clinician), the negative pressure pump activates to restore the negative pressure to the preset value. If the pump is activated more than 20 times in one minute in response to decreasing pressure, the system displays a leak warning; a leak icon appears on the device screen and an audible alarm sounds to alert the user.

Verification testing for Continuous and Intermittent Modes (Test Cases FT002a and FT002b) showed that the device will perform as expected over a 4 hour duration, and provide either continuous (125mmHG) or intermittent therapy (125mmHg for 5 minutes, then atmospheric pressure for 2 minutes), or notifies user that the system cannot provide the expected negative pressure therapy and/or vent to atmosphere in the intermittent mode.

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During testing of the feedback loop for Therapy Duration (Test Case FT003), an artificial leak was incorporated into the system (10mm Hg/hour), and the system was then tested for 6 weeks of continuous use, to verify that the system will maintain the desired negative pressure for the duration of therapy (6 weeks). The results showed that the pumps (in both continuous and intermittent mode) maintained negative pressure wound therapy at 40mmHg and 125mmHg, respectively, over the course of the 6 week simulated therapy.

During testing of the Vacuum Pressure (Test Case FT004), testing results showed that the system is able to achieve the set pressure in less than three (3) minutes after dressing changes. A massive leak was simulated, and the system notified the user, via the leak detector, that the pump was unable to reach set pressure (in both continuous and intermittent modes).

The Test Case Reports for operation and leak detection, as described above, are provided in Attachment Q3.

4. Please provide the data you have to support the following claim: "This approach to wound care is believed to create an environment that promotes wound healing by bring the wound edges together (with negative pressure)" found on page 6 indications for use.

RESPONSE:

This claim has been removed from page 6 of the revised IFU (see Attachment Q2).

5. Predicate devices advise users on specific measures to take to isolate major vessels that may be present in a wound bed. Please explain how you will isolate vessels in the wound bed.

RESPONSE:

The IFU has been revised to include advice on specific measures to take to isolate major vessels in the wound bed. See page 8 of Attachment Q2 for revisions to the IFU.

6. Please clarify this statement "do not use topical solutions or agents that may have adverse interactions with silver. For example, "saline solutions may compromise the effectiveness of the silver dressing". Please outline what effectiveness you expect from the silver dressing. Please explain how you have determined that Silverlon is a non-stick layer.

RESPONSE:

- a) The statements regarding interactions of solutions with silver are based upon the Caution section of the Silverlon Instructions for Use, which reads "Dressing effectiveness decreases if used with products containing saline, chlorine, potassium, iodine and hydrogen peroxide". A copy of the Silverlon Instruction for Use is provided in Attachment Q6. A change was made in page 10 of the IFU, Attachment Q2, to bring the caution statement in alignment with the instructions of the Silverlon manufacturer.

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- b) Effectiveness: The claims for anti-microbial activity are based upon claims in the Silverlon 510(k) Summary (K981299), "the silver provides effective protection of the dressing against microbial contamination" and, "The surface of the nylon fibers in Silverlon™ Contact Wound Dressings consists of a thin layer of metallic silver containing approximately 1% silver oxide that provides effective protection of the dressing against microbial contamination". Also, technical information on Silverlon dressings state that they permit "intact removal" of the dressing. A copy of the Silverlon 510(k) Summary is provided in Attachment Q6. Page 14 of the IFU, Attachment Q2, contains text in alignment with the manufacturer's description of the anti-microbial effectiveness of the Silverlon dressing material.
- c) Non-stick layer: This statement is based upon the Indication for Use of the Silverlon™ Contact Wound Dressings which states that they are "...non-adherent dressings intended for local management of partial thickness burns, incision, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure, and diabetic)" (K981299).

The IFU has been revised to in accordance with the above information. See Attachment Q2.

7. You listed a device component as a "Super absorbent non-woven polymer matrix". Your biocompatibility refers to this product as (b)(4). This does not appear to be a previously cleared 510(k) product for (b)(4). Please characterize this material based on the chemical composition. Please identify how this product has been evaluated for toxic effects and potential leaching effects. Additionally, you have shown that this polymer matrix can be squeezed to release fluid. Please demonstrate how this polymer matrix will not release fluid back into the wound. Lastly, please demonstrate how will negative pressure be administered to the wound in the presence of this polymer matrix.

RESPONSE:

Note: The (b)(4) product is the hydrogel component of the dressing, which is used to provide a vacuum seal against the healthy skin for the dressing around the periphery of the wound. It has no role in the absorbency of the dressing. The biocompatibility information for the hydrogel, provided in the original submission, is found in Attachment Q7.

Chemical Composition

(b)(4)
(b)(4). The chemical composition and technical information on this component are provided in Attachment O7. (b)(4)
(b)(4). It does not contact the wound surface. Only the Silverlon wound contact layer of the

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Kalypto Medical Response to Request for Additional Information
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dressing makes contact with the wound tissue. The superabsorbent material absorbs and retains the wound exudate.

How Negative Pressure Is Applied

As negative pressure is applied to the dressing pressure port, the dressing uniformly attains negative pressure within the sealing gasket. Fluid is drawn into the absorbent layer and molecularly absorbed by the fibers. Thus, the open space within the non-woven material is unaffected by the presence of the fluid and negative pressure continues to exist across the dressing. At the point at which the absorbent layer has reached saturation (i.e. the layer can no longer molecularly absorb or wick any wound exudates), fluid in the absorbent material accumulates below the pressure port hydrophobic filter on the dressing and occludes it. The pump will no longer provide negative pressure under the dressing. An alarm condition will activate and the dressing should be changed. See details in the IFU in Attachment Q2: page 20 of the clinician section and page 31 of the patient section. This provides an additional level of safety over the predicate device in the presence of accidental bleeding, in that once the dressing has reached its fluid capacity, negative pressure will NOT continue to draw blood out of the body of the patient.

Polymer Matrix Fluid Absorption

It is possible but unlikely that, if the fluid level in the dressing is at the design capacity, wound exudates previously wicked into the superabsorbent layer would re-cross the Silverlon layer back to the wound bed. This could only occur in the presence of extreme external mechanical pressure on the dressing, such as a patient fall onto the dressing. Based on the design verification data, the pressure would need to exceed 6 lbs of positive pressure per square inch for the fluid to cross over the dressing onto the wound. When negative pressure is no longer applied, the clinical situation would be similar to the patient having a conventional (not negative pressure) dressing that has reached its exudate saturation point.

Toxic Effects and Leeching Effects

(b)(4) has tested the super absorbent non-woven polymer matrix for biocompatibility in accordance with the Organisation for Economic Co-operation and Development OECD Guidelines and ISO-10993. Per ISO-10993, the device is a surface device that contacts breached or compromised surface (skin) for more than 30 days. Therefore, the superabsorbent non-woven polymer matrix was tested for Cytotoxicity, Sensitization, Irritation, Acute Toxicity, and Genotoxicity, as follows:

- ISO-10993 Part 5, Tests for *in vitro* cytotoxicity
- OECD 406 -Skin Sensitization (see ISO-10993 Part 10)
- OECD 404 -Acute Dermal Irritation on Abraded Skin (see ISO-10993 Part 10)
- OECD 401 -Acute Toxicity in rats (see ISO-10993 Part 11)
- OECD 471 -Mutagenicity using Salmonella Typhimurium (see ISO-10993 Part 3)

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All testing results passed, providing evidence that the super absorbent non-woven polymer matrix meets the requirements for biocompatibility for a compromised tissue contact product. The biocompatibility testing summary and an Authorization to Reference letter from (b)(4) regarding this testing are provided in Attachment Q7.

The (b)(4) biocompatibility test protocols and reports regarding cytotoxicity, sensitization and dermal irritation are also provided in Attachment O7. The (b)(4)

8. Please modify your Indications for Use statement to read as follows:

"The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing."

RESPONSE:

The Indications for Use statement has been modified to read:

The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing. See revised IFU, page 7, in Attachment Q2 and the revised Indications for Use Statement in this submission.

9. You have stated that the device should be wiped down with a damp cloth. These measures will not allow safe repeat use of the pump unit between patients. Please outline how the device should be disinfected to prevent cross-contamination from multiple uses.

RESPONSE:

The pump is the only reusable component in the system. The dressing is discarded when filled or at end of therapy. The vacuum tubing is discarded at the end of a patients therapy. When in use, the pump will be "stored" by the patient in a pocket, or attached to their belt, or on a bedside table, usually several feet away from the wound bed and dressing. There is a hydrophobic, antibacterial filter in every dressing in-line with the vacuum tubing connection to prevent microorganisms and liquid from traveling up the tubing to the pump. Therefore, the risk of contaminating the pump from the wound is very low.

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Although the pump may become "dirty" due to handling by the patient and wound care specialist, it does not contact open skin, and is therefore a low risk, non critical device. In accordance with FDA Guidance "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: For Reviewer Guidance", 1996, devices such as this, which do not contact open skin and are a low risk for transmission of pathogens, may be cleaned until visibly clean, and the device may be treated with a low level disinfectant.

The IFU, Attachment Q2, has been revised on page 23 of the clinician section to add cleaning and disinfection of the pump prior to re-use as follows.

Use cloth dampened with tap water and household dishwashing soap to clean the external surfaces. Wipe down until visibly clean.

Wipe the external surfaces again with a cloth dampened with water (no soap) to remove residual soap. Wipe until no longer "slippery", then allow to air dry.
--

Wipe external surface with 70% ethyl alcohol and allow to air dry.
--

Visually inspect for cleanliness.

The cleaning and disinfection procedure was validated by soiling the device with an artificial soil inoculated with microorganisms, as described in Cleaning Efficacy Study for Reusable Devices and the associated amendment (Planned Deviation), provided in Attachment Q9. The artificial soil was comprised of fetal calf serum, dry milk powder, rabbit blood, and saline. The artificial soil was inoculated with at least 10^5 CFU of *Geobacillus stearothermophilus* spore suspension, so that the cleaning and disinfection process could be evaluated for the ability to visibly clean the device, and to reduce microbial contamination. After soiling, the devices were cleaned and disinfected as described above. The results showed that the cleaning method results in visibly clean devices, and there was a 2 log reduction in the number of challenge microorganisms. This level of reduction is adequate for a device with a low risk of transmission of pathogens. The Cleaning Validation Report is also provided in Attachment Q9.

10. You state at the beginning of the patient labeling that a patient does not need to touch the device, yet you explain several points throughout the labeling for what measures the patient can take to manipulate the device. You are not consistent in your advice to the patient. Please explain why the patient would need to change the batteries on this device or disable the alarm. These do not seem like functions that should be required by patients. Please review the FDA patient labeling guidance and ensure that your patient labeling is consistent with this guidance.

<http://www.fda.gov/cdrh/ohip/guidance/1128.html>

Kalypto Medical Response to Request for Additional Information
K080275

RESPONSE:

The patient labeling has been revised to more explicitly describe the patient responsibilities to observe the displayed information, disable the alarms, check the dressing for leaks, and to change the battery if necessary. These changes are articulated throughout the patient section of the IFU starting on page 30, see Attachment Q2.

11. Your NPD dressing is labeled as follows: "Arm or Leg". Your IFU does not restrict the use with the arm or leg. Please explain this discrepancy.

RESPONSE:

The IFU and dressing label have been revised to indicate use on a body surface wherever the dressing can be applied and achieve the appropriate vacuum seal. See the revised Dressing Label in Attachment Q11, and the revised IFU, page 14, in Attachment Q2.

CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.		
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET				
Date of Submission August 14, 2008	User Fee Payment ID Number MD6034663-956733	FDA Submission Document Number (if known) K080275		
SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 35-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify)
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name Kalypso Medical		Establishment Registration Number (if known)		
Division Name (if applicable)		Phone Number (including area code) (612) 703-1204		
Street Address 6393 Oakgreen Avenue		FAX Number (including area code) (763) 287-3836		
City Hastings		State / Province MN	ZIP/Postal Code 55033	
Country USA				
Contact Name John Buan				
Contact Title Vice President of Product Development		Contact E-mail Address jbuan@iasismedical.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name				
Division Name (if applicable)		Phone Number (including area code) ()		
Street Address		FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	
Country				
Contact Name				
Contact Title		Contact E-mail Address		

FORM FDA 3514 (6/05)

Kalypso Medical

CONFIDENTIAL

Page 2 of 8

Additional Information for 510(k) K080275 for the NPD 1000

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

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SECTION D1 REASON FOR APPLICATION – PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (specify):

SECTION D2 REASON FOR APPLICATION – IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol – Feasibility <input type="checkbox"/> Protocol – Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
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Other Reason (specify):

SECTION D3 REASON FOR SUBMISSION – 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
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Other Reason (specify):

FORM FDA 3514 (6/05)

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	JCX	2		
5		6		

Information on devices to which substantial equivalence is claimed (if known)

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K063692	V.A.C. Therapy Systems-Acti-V.A.C. Therapy Unit M	KCI USA, Inc.
2 K060277	Boehringer Laboratories Suction Pump System	Boehringer Laboratories
3		
4		
5		
6		

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Pump, Portable, Aspiration, (Manual or Powered)

Trade or Proprietary or Model Name for This Device	Model Number
NPD 1000 Negative Pressure Wound Therapy System	1 NPD 1000, NPD 1000i, NPD 1000c
	2
	3
	4
	5

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

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

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code BTA	C.F.R. Section (if applicable) 21 CFR 878.4780	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)

The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.

FORM FDA 3514 (6/05)

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

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 2133810	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Minnetronix, Inc.		Establishment Registration Number 2133810
Division Name (if applicable)		Phone Number (including area code) (651) 917-4060
Street Address 1635 Energy Park Drive		FAX Number (including area code) ()
City St. Paul	State / Province MN	ZIP/Postal Code 55108
Country USA		
Contact Name	Contact Title	Contact E-mail Address

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name TapeMark Co.		Establishment Registration Number 2182681
Division Name (if applicable)		Phone Number (including area code) ()
Street Address 1685 Marthaler Lane		FAX Number (including area code) ()
City West St. Paul	State / Province MN	ZIP/Postal Code 55118
Country USA		
Contact Name	Contact Title	Contact E-mail Address

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 1450662	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Steris Inc, Isomedix Services		Establishment Registration Number 1450662
Division Name (if applicable)		Phone Number (including area code) ()
Street Address 1880 Industrial Drive		FAX Number (including area code) ()
City Libertyville	State / Province IL	ZIP/Postal Code 60048
Country USA		
Contact Name	Contact Title	Contact E-mail Address

FORM FDA 3514 (6/05)

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601	IEC	Medical Electrical Equipment- Part 1-2: General requirements for safety	2 nd Edition	2001
2	60601	UL	Medical Electrical Equipment- Part 1: General requirements for safety	1 st Edition	2006
3	ISO 10993-5	ISO	Biological evaluation of medical devices- Part 5, Test for in vitro cytotoxicity	2 nd Edition	1999
4	BS, EN, ISO 10993-5	BS, EN, ISO	Biological evaluation of medical devices- Part 5, Test for in vitro cytotoxicity	2 nd Edition	1999
5	ISO 10993- 10	ISO	Biological evaluation of medical devices- Part 10, Test for Irritation and Sensitization	1 st Edition	1995
6	OECD 404	OECD	Acute Dermal Irritation	----	May 1981
7	OECD 471	OECD	Genotoxicity, Mutagenicity	----	May 1981

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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FORM FDA 3514 (6/05)

SECTION I UTILIZATION OF STANDARDS- continued

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
8	OECD 406		OECD Guideline No. 406, Buehler Method, Skin Sensitization	----	May 1981
9	OECD 401	OECD	OECD Guideline No. 410, Acute Toxicity	----	May 1981
10	UK GLP Standards	OECD	OECD Principles on Good Laboratory Practice	----	1997
11					
12		OECD			

510(k) Summary

Submitter:	Kalypto Medical 6393 Oakgreen Avenue Hastings, MN 55033
Contact Person:	John Buan, Vice President of Product Development Phone (612) 703-1204, Fax (763) 287-3836
Date Prepared:	August 14, 2008
Trade Name:	NPD 1000 Negative Pressure Wound Therapy System
Classification:	Powered Suction Pump Class II 21 CFR 878.4780
Product Code:	BTA
Predicate Device(s):	The subject device is equivalent to the following device: <ul style="list-style-type: none"> • V.A.C. Therapy Systems-ActiV.A.C. Therapy Unit M: K063692 • Boehringer Laboratories Suction Pump System: K060277
Device Description:	The NPD 1000 Negative Pressure Wound Therapy System includes a small, portable, low powered, battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to remove exudates, which may promote wound healing.
Intended Use:	The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.
Functional and Safety Testing:	To verify that the device design met its functional and performance requirements, representative samples of the device underwent functional and mechanical testing, EMC testing in accordance with IEC 60601-1-2:2001 and electrical safety testing in accordance with UL 60601-1:2006.
Conclusion:	Kalypto Medical considers the NPD 1000 Negative Pressure Wound Therapy System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, and indications for use.

Indications for Use

510(k) Number (if known): K080275

Device Name: NPD 1000 Negative Pressure Wound Therapy System

Indications for Use:

The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

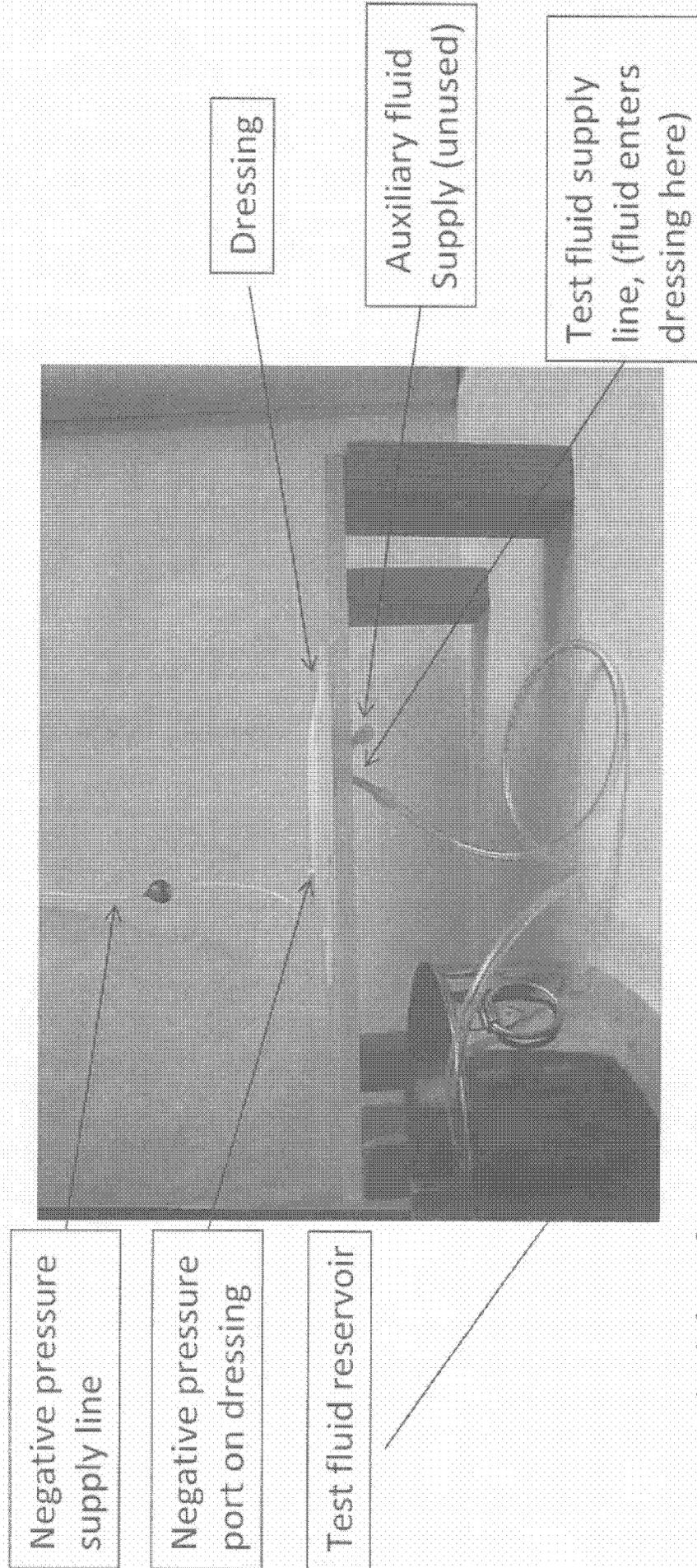
Concurrence of CDRH, Office of Device Evaluation (ODE)

0143

Test System Photos

Kalypto Medical

Negative Pressure Wound Therapy Dressing
Fluid Capacity Test Fixture



Negative pressure supply line

Negative pressure port on dressing

Test fluid reservoir

Dressing

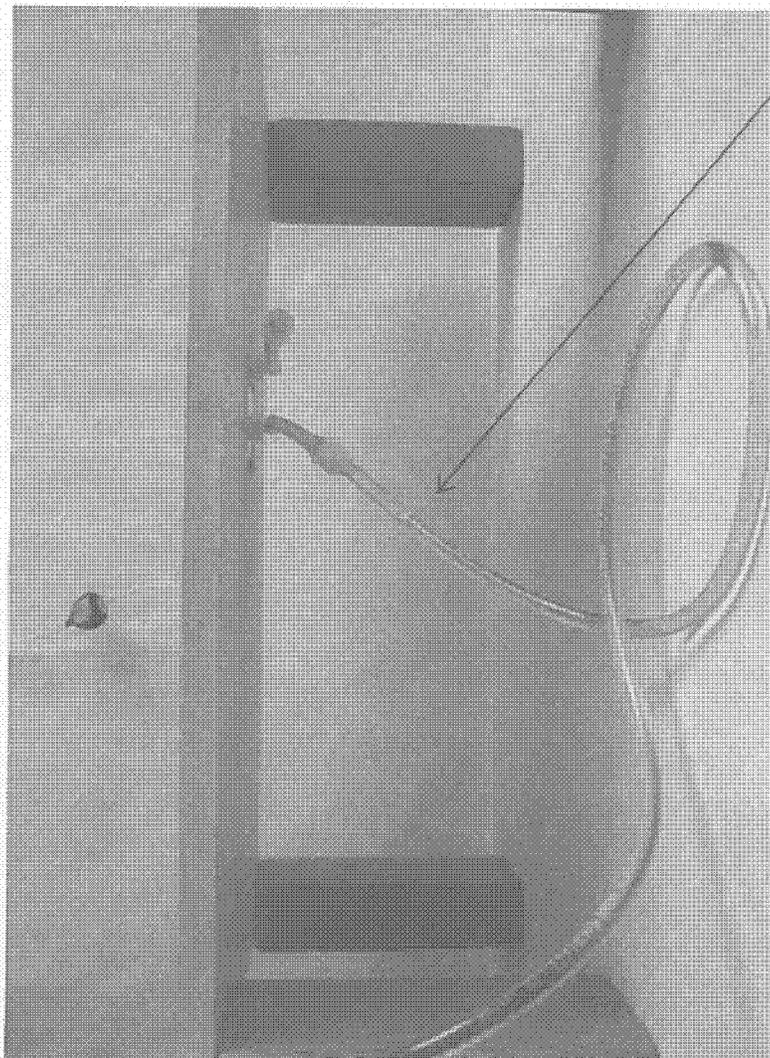
Auxiliary fluid Supply (unused)

Test fluid supply line, (fluid enters dressing here)

Principles of Operation:

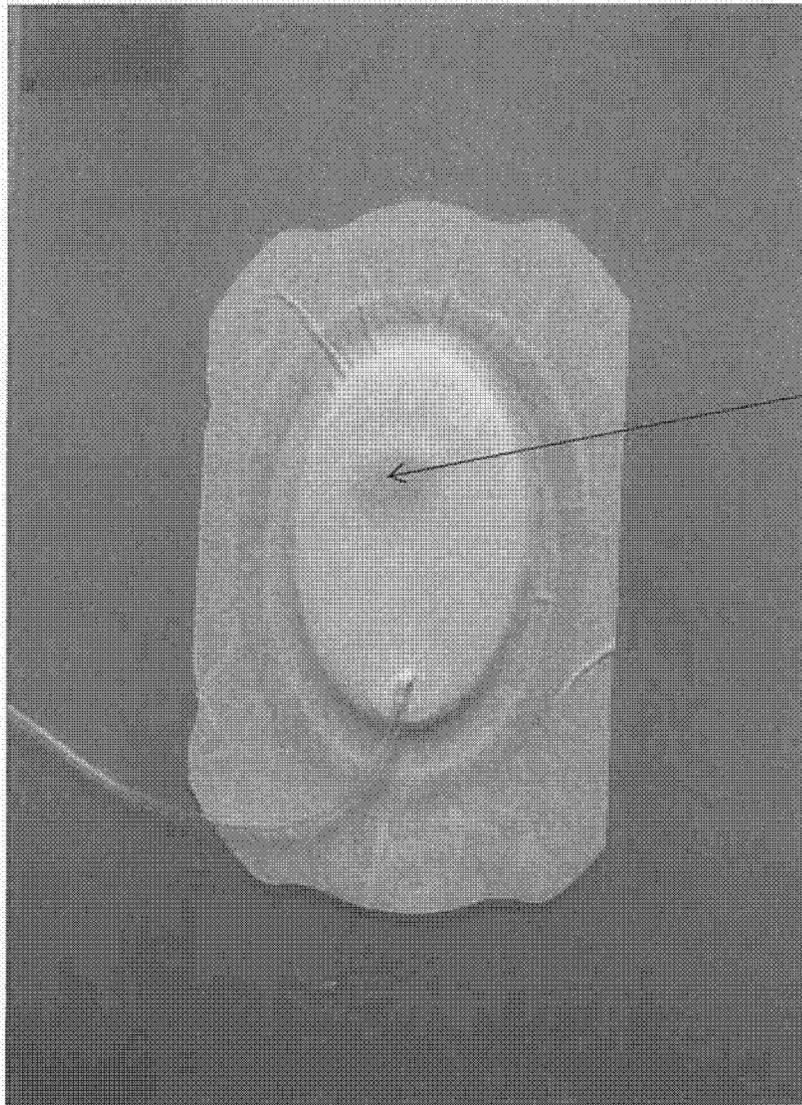
The Kalypto Negative Pressure Wound Therapy pump applies negative pressure under the semi-occlusive dressing, which draws fluid from the reservoir through the tube into the bottom of the dressing

Step 1 - Turn on the negative pressure pump



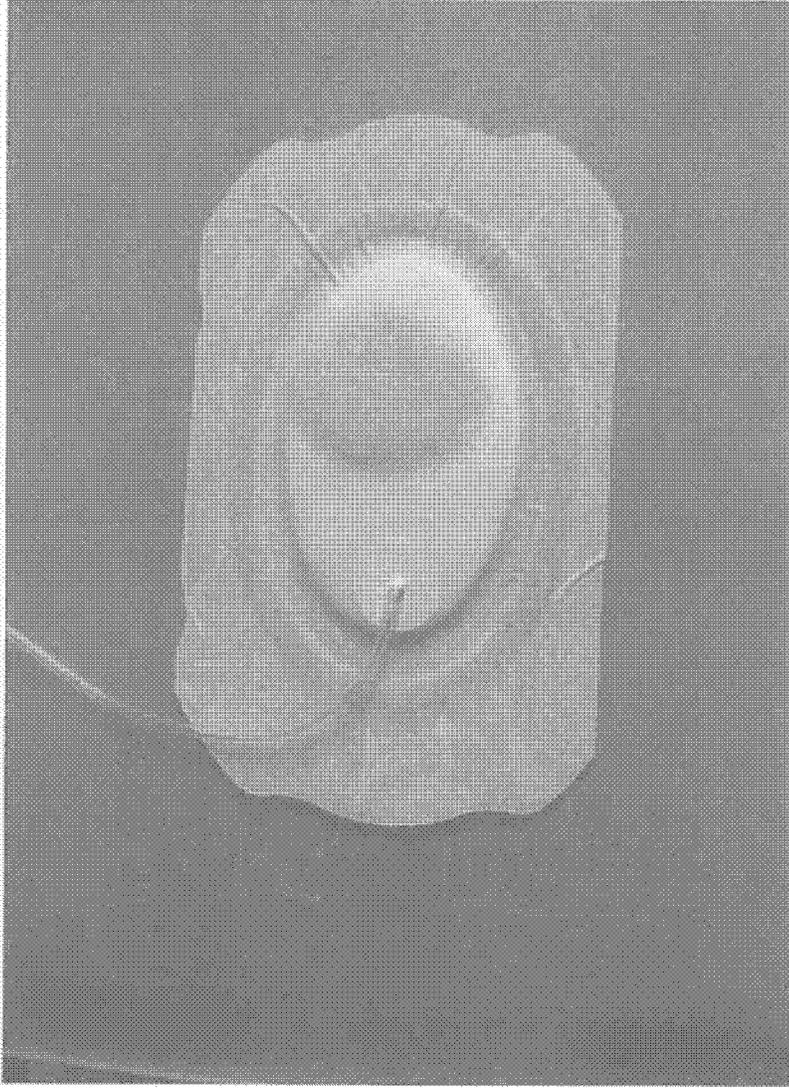
Note blue test fluid progressing
Along fluid supply line

Step 2 – Fluid passes through wound contact layer and enters absorbent layer



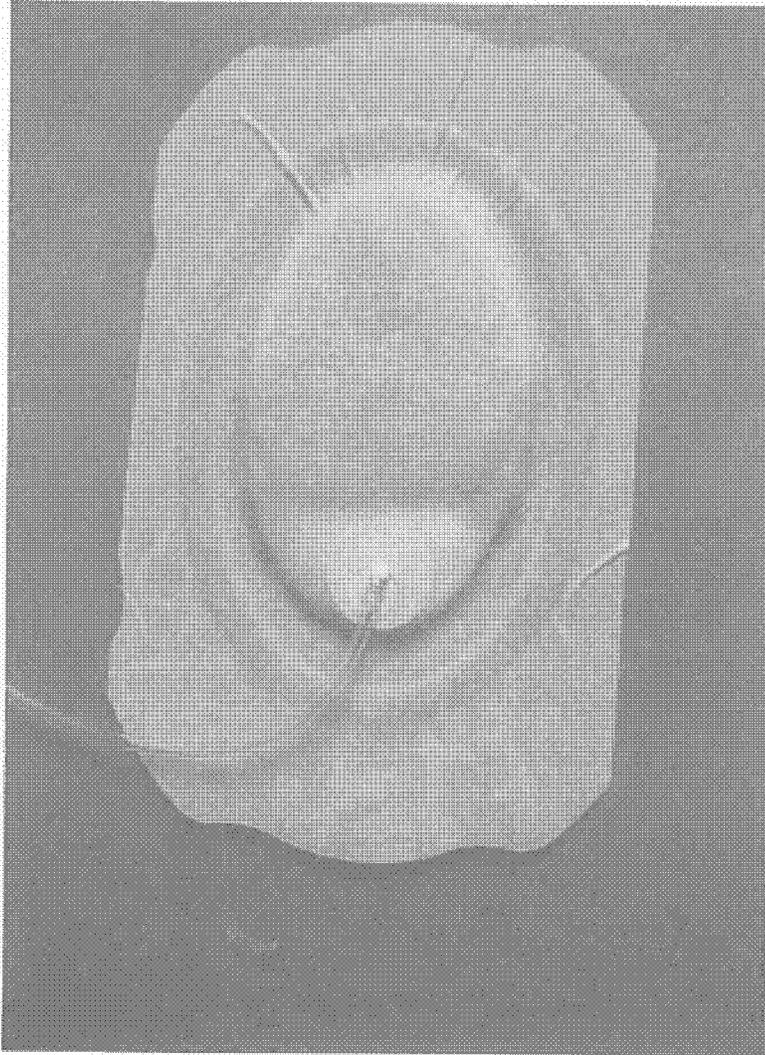
Note colored test fluid shows up in absorbent layer directly below the fluid supply line. It does not just wick along the test board surface to the source of negative pressure.

Step 3 – Wicking throughout the absorbent layer



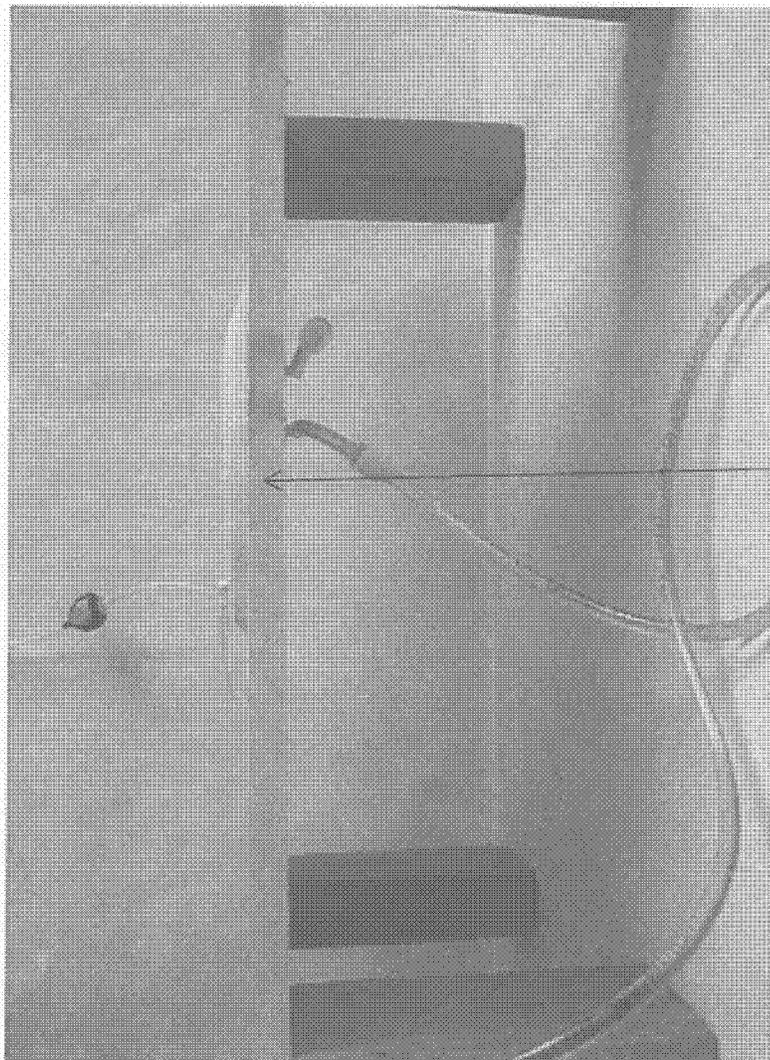
Note that even though the negative pressure should dictate the flow of the fluid toward the port, the wicking properties of the absorbent material create even distribution of the fluid in the absorbent layer

Step 4 Filling of absorbent pad



Pad does not fill preferentially on path between fluid source and pressure source

Step 5 - Full Dressing



Notice full distribution of fluid throughout absorbent layer

**Product Validation Testing
Protocol and Report**

Product and Package Validation Testing
for the
IASIS Medical, Inc.
NPD 1000 Negative Pressure Dressing

Report Number: 0802099
Protocol Number: P080299 Rev. B
PO Number: 1005
7 May 2008

Customer:
IASIS Medical, Inc.
Attn: John Buan
15912 69th Place North
Maple Grove, MN 55311

Testing Performed by



Tested and proven.

DDL, Inc.
10200 Valley View Road, Suite 101
Eden Prairie, MN 55344
952-941-9226
Fax 952-941-9318
1-800-229-4235



DDL West, Inc.
3303 Harbor Boulevard, Suite B9
Costa Mesa, CA 92626
714-979-1712
Fax 714-979-1721
1-800-229-4235

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www.testedandproven.com

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

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INTRODUCTION

Objective

The objective of this project was to evaluate the capabilities of the NPD 1000 Negative Pressure Dressing package design and product for IASIS Medical, Inc. when exposed to accelerated aging. Testing was done under controlled laboratory conditions with equipment qualified to perform these tests.

Scope

This report documents accelerated aging, strength, integrity, and functionality testing on DDL, Inc. specimen number 100543 in accordance with the test methods stated in DDL, Inc. quote number 0802099 Rev. B and DDL, Inc. Protocol P080299 Rev. B located in Appendix A.

SUMMARY OF TESTED SPECIMENS

Specimen Number	Test Interval	Number of Specimens Tested
100543	One Year Accelerated Aging	1
100543	Bubble Leak Testing	30
100543	Seal Strength Testing	30
100543	Persistent Vacuum Integrity	8
100543	Bandage Pump Down Time	7
100543	Bandage Fluid Capacity	15

Table 1: Summary of tested specimens.

RESULTS SUMMARY

Acceptance Criteria

The acceptance criterion has been outlined in DDL, Inc. Protocol P080299 Rev. B located in Appendix A of this test report.

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Accelerated Aging

One year of accelerated aging was performed on one (1) shipper for thirty-eight (38) days in accordance with Q10 Theory ASTM F1980-07; *Guide for Accelerated Aging of Sterile Medical Device Packages*. The cycle of accelerated aging equivalent to one year of real time aging is outlined in the table below.

Condition	Start	End	Days
55°C / <20%RH	18-Feb-08 / 2:00 pm	27-Mar-08 / 2:00 pm	38

Table 2: One Year Accelerated Aging Timeline

Equipment used is kept in current calibration traceable to NIST. Operation of the test was done according to procedure and was monitored by both NIST traceable devices, and continuous monitoring devices.

All raw data for the accelerated aging test is located in Appendix B of this test report.

Package Integrity Testing

Bubble Leak Testing

Thirty (30) single barrier foil/foil pouches were bubble leak tested. All package configurations tested, passed. The raw data for the bubble leak test is located in Appendix C of this test report.

Specimen Number	Test Interval	Number of Specimens Tested	Pass	Fail
100543	Post Accelerated Aging	30	30	0

Table 3: Bubble leak test results.

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Package Strength Testing

Seal Strength Testing

Thirty (30) single barrier foil/foil pouches were seal strength tested. Samples from four (4) designated locations on the single barrier foil/foil pouch were prepared for testing. The standard deviation and average of the peak values were tabulated and are shown below. The raw data for all seal strength testing is located in Appendix D of this test report.

Specimen Number	Side A		Side B		Side C		Side D	
	Avg.	Std. Dev.						
100543	20.19	0.56	21.10	0.49	20.25	0.54	20.82	0.54

Table 4: Post one year accelerated aging seal strength results in lbs.

Functionality Testing

Persistent Vacuum Integrity Testing

Eight (8) bandages were persistent vacuum integrity tested. The pass/fail results are shown below.

The raw data for all persistent vacuum integrity testing is located in Appendix E of this test report.

Specimen Number	40 mmHg		125 mmHg	
	Pass	Fail	Pass	Fail
100543	8	0	8	0

Table 5: Post one year accelerated aging persistent vacuum integrity results.

Bandage Pump Down Time Testing

Seven (7) bandages were bandage pump down time tested. The average pump down time is shown below.

The raw data for all bandage pump down time testing is located in Appendix F of this test report.

Specimen Number	Average Time (min:sec)
100543	00:30

Table 6: Post one year accelerated aging bandage pump down time results.

Dressing Fluid Capacity Testing

Fifteen (15) bandages were dressing fluid capacity tested. The standard deviation and average absorption was tabulated and are shown below.

The raw data for all dressing fluid capacity testing is located in Appendix G of this test report.

Specimen Number	Minimum	Maximum	Average	Std. Dev
100543	71.8	92.7	81.3	7.3

Table 7: Post one year accelerated aging dressing fluid capacity results in g.

RELATED DOCUMENTS

Standards
ASTM F 2096-04; <i>Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)</i>
ASTM F 88-07a; <i>Seal Strength of Flexible Barrier Materials</i>
ASTM F 1980-07; <i>Guide for Accelerated Aging of Sterile Medical Device Packages</i>
References
DDL, Inc. Quote # 0802099 Rev. B; <i>Product and Package Validation Testing</i>
DDL, Inc. Protocol # P080299 Rev. B; <i>One Year Product and Package Evaluation</i>
DDL, Inc. S.O.P. # 6011, Rel. 04; <i>Distribution Simulation Test</i>
DDL, Inc. S.O.P. # 6047, Rel. 05; <i>Bubble Leak Test for ASTM 2096</i>
DDL, Inc. S.O.P. # 6008, Rel. 05; <i>Procedure for Peel Seal Testing of Flexible Packages</i>

Table 8: Standards and References

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LOGISTICS

Specimen 100543 was received: 18 February 2008

One Year Accelerated Aging:

- Started: 18 February 2008
- Completed: 27 March 2008

Bubble Leak Testing:

- Started: 31 March 2008
- Completed: 31 March 2008

Seal Strength Testing:

- Started: 31 March 2008
- Completed: 2 April 2008

Persistent Vacuum Integrity Testing:

- Started: 31 March 2008
- Completed: 2 April 2008

Bandage Pump-Down Time Testing:

- Started: 2 April 2008
- Completed: 2 April 2008

Bandage Fluid Capacity Testing:

- Started: 3 April 2008
- Completed: 3 April 2008

Specimens picked up by IASIS Medical, Inc. on: 10 April 2008

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EQUIPMENT

The following equipment was used to complete these tests:

Equipment Name	Model No.	Serial No.	Calibration Due
T.M. Electronics Package Tester	BT-115	BT-465	25-Jan-09
DDL Tensile Test System	100P	0001064	11-Apr-09
Thermocouple Thermometer - Digital (4)	HH23	T-258666	17-Oct-08
Chamber 16 (N6)	W09318-01	96120203	13-Feb-09
Thermocouple Probe (D36)	TTSS-HH	D36	19-Jun-08
Temptale4 Sensor (110)	H4600-02-001	3710790574	2-May-08
Iasis Medical NPD 1000 Negative Pressure Wound Therapy Device	50001 Rev A	NA	NA
Pressure Sensor	Ashcroft	1022965	2-Jul-08
Stopwatch	3	001614	1-May-09
600g Scale	AND EK-6000	001065	10-Mar-09

Table 9: Equipment List

PRODUCT

Product

NPD 1000 Negative Pressure Dressing

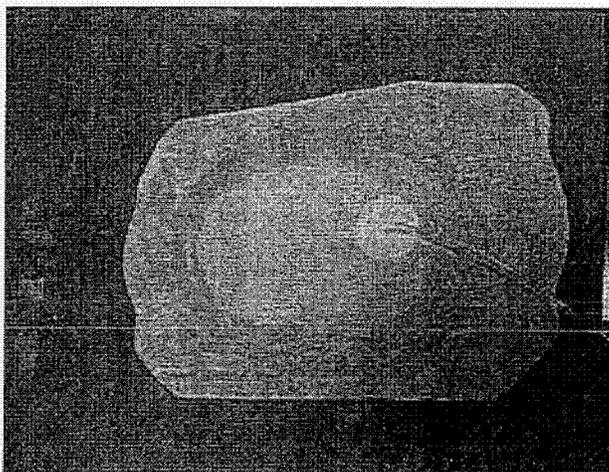


Figure 1: This is a photograph of the negative pressure dressing.

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PACKAGING SYSTEM

Sterile Barrier System

The sterile barrier system consisted of a foil to foil single barrier pouch.

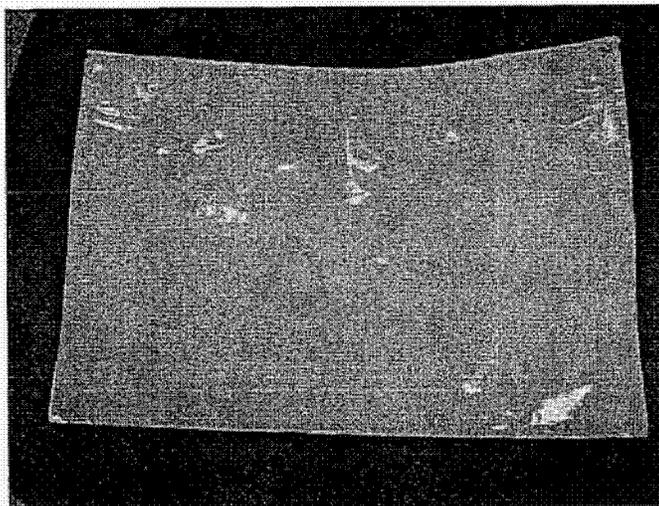


Figure 2: This is a photograph of the sterile barrier system.

TEST PROCEDURE

Accelerated Aging

One year of accelerated aging was performed on the shipping units in accordance with Q10 Theory ASTM F1980-07; *Guide for Accelerated Aging of Sterile Medical Device Packages*. The following cycle was performed once to simulate one year of real time aging.

Condition	Duration
55°C / <20%RH	38 days

Table 10: One Year Accelerated Aging Cycle

The following equation was used to calculate the test duration for a shelf life study equivalent to one year of real time aging:

Accelerated Aging Rate (AAR) = $Q_{10}^{((Elevated\ Temp. - Ambient\ Temp.) / 10)}$		
Q ₁₀	2.0	AAR = $2.0^{((55 - 22) / 10)} = 9.85$
Ambient Temp.	22°C	
Elevated Temp.	55°C	
Accelerated Aging Time Duration = Desired Real Time Aging / AAR		
365 days / 9.85 ≈ 37.06 days		

Table 11: Accelerated Aging Time Duration Equation

The chamber conditions were monitored using a TempTaleH data logger. Periodic temperature measurements were made using a NIST traceable temperature probe. All data for this test can be found in Appendix B of this test report. A tabular summary of the results is presented in the results section of this test report.

Accelerated Aging Technical Note:

When conducting an accelerated aging program for establishing product and package shelf life or expiration dating claims, it must be recognized that the data obtained from the study is based on conditions that simulate the effects of aging on the materials. The resulting creation of an 'expiration date' or shelf life represents a conservative estimate of shelf life and is tentative until the results of real time aging studies are completed on the product or product/package combination.

Since the results of the study produce a conservative estimate of the actual shelf life of the materials, tolerances for the temperature and humidity are only provided to ensure that the chamber operates within a satisfactory range. Out of tolerance excursions for less than 6 hours in duration for either temperature or humidity are acceptable and do not adversely affect the estimate for shelf life.

Out of tolerance excursions may be caused by opening doors for sample transfer; inserting moist samples into a dry environment causing spikes in humidity; proximity of monitoring device to temperature and/or humidity source inlets.

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 10 of 24
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Package Integrity Testing

Bubble Leak Test

This test was performed based on ASTM F 2096-04; *Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)* and DDL, Inc. S.O.P. #6047, Rel. 05.

The test method is designed to detect open pathways, channels, or voids across the seal area intended as a primary sterile barrier, and to detect pinholes in non-porous materials. The test may be used for flexible or rigid packages with porous or non-porous materials.

A set-up specimen was used to determine the set pressure by creating a 0.008 inch hole in the foil material. The test apparatus described in the 'materials and equipment' section was used for air pressure. The package was submerged in a water bath for at least five (5) seconds with no air pressure being applied to the single barrier foil/foil pouch. The pressure was then increased slowly until a steady flow of bubbles came from the 0.008 inch hole created in the foil. The packages were observed for any evidence of leakage in the form of a steady stream of bubbles emanating from the package.

All raw data can be found in Appendix C of this test report. A tabular summary of the results is presented in the results section of this test report.

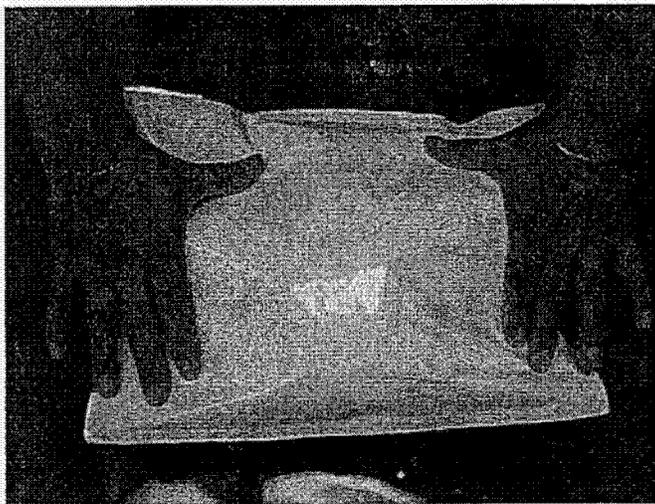


Figure 3: This is a photograph of the bubble leak test set-up.

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Package Strength Testing

Seal Strength Test

Seal strength testing was performed based on ASTM F88-07a; *Seal Strength of Flexible Barrier Materials* and DDL, Inc. S.O.P. #6008, Rel. 05. Specimens were prepared for testing by cutting one-inch by three-inch long strips from designated locations that were perpendicular to the seal on the package. A package sample cutter specifically designed for this task was used.

All raw data for the seal strength tests can be found in Appendix D of this test report. A tabular summary of the results is presented in the results section of this test report.

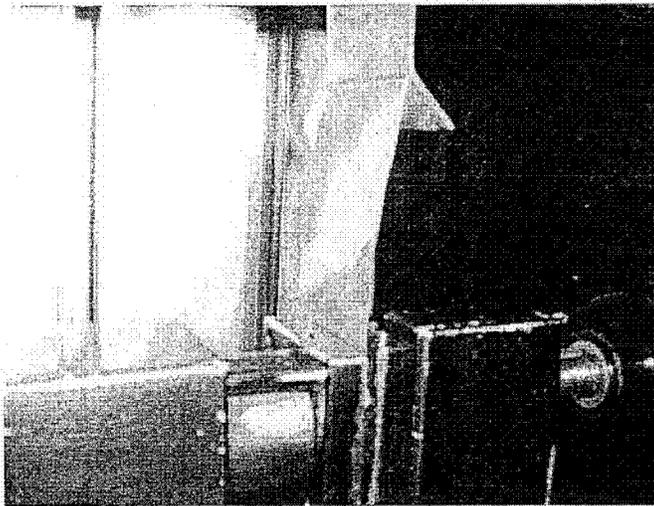


Figure 4: This is a photograph of the seal strength test set-up.

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Functionality Testing

Persistent Vacuum Integrity Test

This test was performed based on DDL Protocol: P0802099 Rev B.: *One Year Product and Package Evaluation*.

The test method is designed to verify the Negative Pressure Dressing will be able to achieve and maintain vacuum pressures of 40 mmHg and 125 mmHg for a minimum of one (1) hour.

A bandage was securely mounted to the test board supplied by Iasis Medical. The bandage was then connected to a pump and allowed to reach a pressure of 40 mmHg. The pump was allowed to run for a minimum of one (1) hour. The bandage passed if no system fault occurred during the test period.

This test procedure was repeated for a pressure of 125 mmHg for each bandage.



Figure 5: This is a photograph of the persistent vacuum integrity test set-up.

All raw data for the persistent vacuum integrity tests can be found in Appendix E of this test report. A tabular summary of the results is presented in the results section of this test report.

Bandage Pump Down Time Test

This test was performed based on DDL Protocol: P0802099 Rev B.: *One Year Product and Package Evaluation*.

This test method was designed to verify the continuous pump is able to achieve a set pressure in less than three (3) minutes.

A bandage was securely mounted to the test board and connected to the NPD 1000 Negative Pressure Wound Therapy Device. The pump was set to a negative pressure of 125 mmHg. The pump was turned on and a stopwatch was started simultaneously. The stopwatch was stopped when the pump stopped pumping and the independent pressure sensor signaled a pressure of 125 mmHg. This process was repeated for a total of ten (10) times.

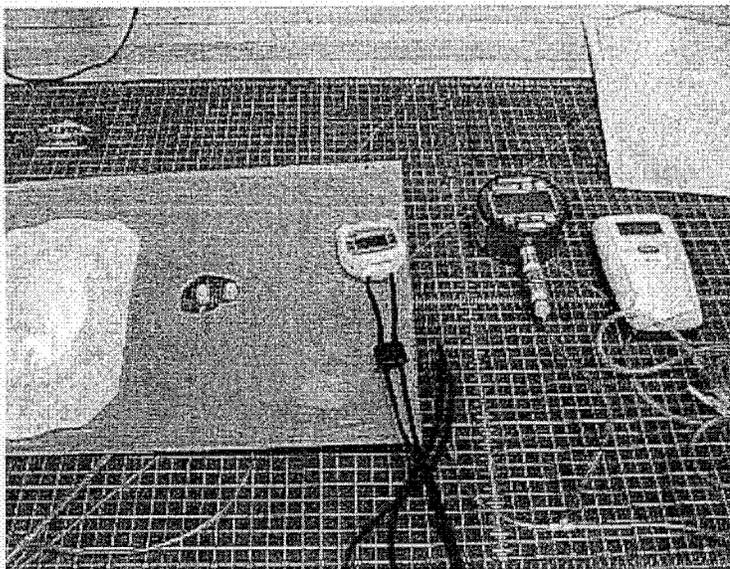


Figure 6: This is a photograph of the bandage pump down time test set-up.

All raw data for the bandage pump down time tests can be found in Appendix F of this test report. A tabular summary of the results is presented in the results section of this test report.

Bandage Fluid Capacity Test

This test was performed based on DDL Protocol: P0802099 Rev B.: *One Year Product and Package Evaluation*.

This test method was designed to verify the NPD 1000 Negative Pressure Dressing maintains its therapeutic fluid capacity at the end of its labeled shelf life.

In a method approved by the customer a bandage was weighed dry and then securely mounted to the test board. The bandage was pumped with fluid and let set for five (5) minutes. The bandage was then reweighed. The excess fluid was then removed from the bandage using a three (3) pound roller and weighed a third time. The pad absorption was then calculated.

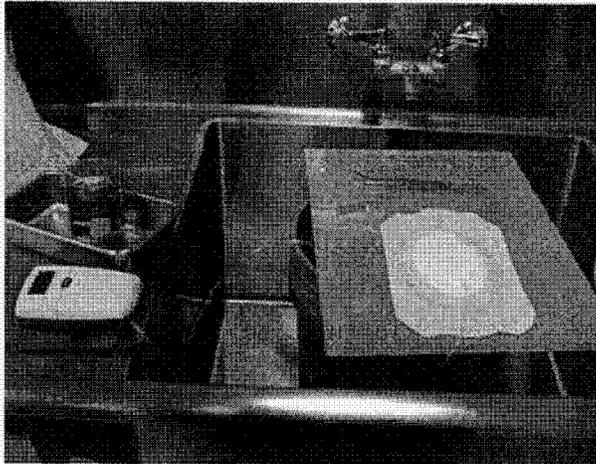


Figure 7: This is a photograph of the bandage fluid capacity test set-up.

All raw data for the bandage fluid capacity tests can be found in Appendix G of this test report. A tabular summary of the results is presented in the results section of this test report.

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CONCLUSION

Upon completion of testing all specimens were returned to IASIS Medical, Inc. for further analysis.

- Thirty (30) of thirty (30) single barrier foil/foil pouches subjected to bubble leak testing, passed.
- Eight (8) of eight (8) bandages subjected to persistent vacuum integrity testing, passed.
- Seven (7) of seven (7) bandages subjected to bandage pump down time testing, passed.
- Fifteen (15) of fifteen (15) bandages subjected to bandage fluid capacity testing, passed.
- DDL, Inc. makes no claims as to the functionality of the product.

DISCLAIMER OF WARRANTIES

ALL WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY THAT THE PRODUCT OR PACKAGING TESTED IS MERCHANTABLE, FIT FOR A PARTICULAR PURPOSE, OR IN COMPLIANCE WITH ANY FEDERAL, STATE OR LOCAL REGULATIONS, ARE DISCLAIMED. In no event shall DDL, Inc. liability exceed the total amount paid by **IASIS Medical, Inc.** for services rendered.

A Quality Assurance program should be in place to ensure that the manufacturing process produces products/packages of equivalent performance to those tested here. This is solely the responsibility of the manufacturer. DDL, Inc. takes no responsibility for the quality of products/packages produced hereafter, other than to certify the design of those physical test systems actually tested by DDL, Inc. DDL, Inc. takes no responsibility for the use, acceptance or non-acceptance of this data by government regulatory agencies.

In the event of future changes to the referenced test procedure(s), it is the responsibility of **IASIS Medical, Inc.** to determine whether additional testing or updating of this certification is necessary to verify that the product and/or packaging certified here remains in compliance with requirements.

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STATEMENT OF CONFORMITY

DDL, Inc. certifies that the above stated testing services have been performed in accordance to applicable standard good laboratory practices and/or standards identified within this report. Testing has been completed as described herein.

The following list of exceptions occurred during testing performed at DDL, Inc.:

- *None*

All materials, equipment, methods, and processes used to perform the described testing have been standardized, calibrated, and monitored in accordance with prescribed guidelines, standard operating procedures, and the supervision requirements of DDL, Inc. All raw data obtained from this testing by DDL, Inc. personnel is archived at DDL, Inc.

The signatures below are in compliance with 21 CFR Part 11.

Testing performed by: Jackie L. Vue, Colleen K. Bird, and Kathleen A. McDaniel

**Mike
B.
Woletz**

Digitally signed by Mike B. Woletz
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Reason: I am the author of this document
Location: Eden Prairie, MN
Date: 2008.05.07 13:55:19 -05'00'

**Amy J.
Peterson**

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Report prepared by:

Mike B. Woletz & Amy J. Peterson
Project Managers

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Date: 2008.05.07 14:40:12 -05'00'

Technical Review by:

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Lab Manager

**Kimberly
M. Pratt**

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Approved by:

Kim M. Pratt
Quality Assurance Manager

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**APPENDIX A: DDL, INC. PROTOCOL # P080299 REV. B; ONE
YEAR PRODUCT AND PACKAGE EVALUATION**

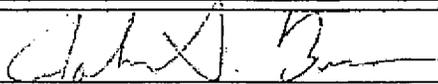
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Tested and Proven.

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 1-800-229-4235

Test Protocol Title: <i>One Year Product and Package Evaluation</i>	
Test Type: <i>Accelerated Aging, Product Functionality and Package Sterility Validation Tests</i>	
Protocol Number: P080299	Revision: B
Approvals:	
lasis Medical: 	Date: <i>3/05/08</i>
DDL, Inc Written By: <u>Alan Gale</u>	Alan M. Gale <small>Digitally signed by Alan M. Gale DN: cn = Alan M. Gale, c = US, o = DDL, Inc., ou = Operations Reason: I am the author of this document Date: 2008.04.01 07:28:11 -0500</small> Date: <u>Mar 31, 2008</u>
Approved By: <u>Patrick J. Nolan</u>	Date: _____
Package Tested: Single Barrier Foil/Foil Pouch	
Product Tested: NPD 1000 Negative Pressure Dressing	

1. Purpose

- 1.1. This document provides the test parameters required to perform accelerated aging, product functionality and package strength evaluation using physical strength methods, and product sterility validation testing using physical integrity detection methods.

2. Scope

- 2.1. Completion of the work described in this protocol will provide documentation supporting the capabilities of the package under conditions of temperature. It will also determine the seal integrity of the packages and sterility maintenance.
- 2.2. The loss of sterility in a package is typically a dynamic event related incident rather than a time related phenomenon. Damage to a package may be caused by one or more of the following events:
 - Loss of the seal integrity due to the effects of high temperature and humidity or shipping and handling events.
 - Improper manufacturing and production processes.
- 2.3. By selecting products which have been processed through manufacturing and sterilization, and then subjecting those packages to accelerated aging , product functionality, package strength and package integrity tests, it can be determined if the production process and package design are adequate to maintain sterile conditions throughout the expected shelf life.

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3. References

- 3.1 ASTM F 1980-07, *Standard Guide for Accelerated Aging of Sterile Medical Device Packages.*
- 3.2 ASTM F 88-07a, *Standard Test Method for Seal Strength of Flexible Barrier Materials.*
- 3.3 ASTM F 2096-04, *Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak).*
- 3.4 Iasis Medical, *Bandage Integrity - Vacuum Pressure Test Protocol*
- 3.5 Iasis Medical, *Bandage Fluid Capacity Test Protocol*
- 3.6 Iasis Medical, NPD 1000 IFU (instructions for use)

4. Materials and Equipment

- 4.1. Temperature/Humidity Chamber meeting the requirements of ASTM D-4332, *Conditioning Containers, Packages, or Packaging Components for Testing.*
- 4.2. Material Test System meeting the requirements of ASTM F-88, *Standard Test Method for Seal Strength of Flexible Barrier Materials.*
- 4.3. Iasis Medical NPD 1000 Negative Pressure Wound Therapy Device
- 4.4. Iasis Medical Micro NPWT device
- 4.5. Ashcroft Vacuum pressure sensor gauge
- 4.6. Stopwatch
- 4.7. Syringe of 50 – 200 ml capacity
- 4.8. Beaker of 500 – 2000 ml capacity
- 4.9. Fluid as described in protocol – de-ionized, distilled, or tap water

5. Sample Description and Preparation

- 5.1. The test packages consist of a single barrier foil to foil pouch package.
- 5.2. Sample size will reflect the number of samples desired for the seal strength and integrity evaluation, and product functionality verifications.
- 5.3. Ninety (90) pouches will be used for this study. Sixty (60) of these pouches will contain **NO product** and will be designated for the Seal Strength and Bubble Leak testing. Thirty (30) of these pouches **WILL contain product** and be designated for the functionality testing. These packages have been produced under normal processing limits established in the process validation.
- 5.4. All samples will be clearly identified by Iasis Medical for testing requirements.

6. Test Procedure

The following test procedures will be performed per the test sequence described below.

6.1 Sterilization

All packages and product for the one year accelerated aging shelf life study have been Ebeam sterilized using the Iasis Medical standard operating procedures.

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6.2 Accelerated Aging Test Protocol

Ninety (90) pouches with product will be subjected to the environmental conditions described below and in accordance with ASTM F1980-07.

6.2.1 For one year of accelerated aging, each primary package will be subjected to the following sequence of conditions in accordance with the following equation:

$$\text{Accelerated Aging Rate (AAR)} = Q^{((\text{elevated temp.} - \text{ambient temp.})/10)}$$

where

$$Q = 2.0$$

$$\text{Ambient Temp.} = 22^{\circ}\text{C}$$

$$\text{Test Temp.} = 55^{\circ}\text{C}$$

$$\text{Accelerated Aging Time Duration (AATD)} = \text{Real Time}/\text{AAR}$$

$$\text{so... AAR} = 2^{((55-22)/10)}$$

$$\text{AAR} = 9.85$$

$$\text{AATD} = 365/9.85 = 38 \text{ Days}$$

The test sequence for the 1 Year study:

Test Temperature	1 Year
55°C +/-2 <20% RH	38 Days

The aging for this protocol will simulate **1 Year** of real time aging. A total of **38** days of conditioning is required to complete this segment of this validation.

6.2.2 Temperature selection will be based on the heat resistance of the packaging materials. If lower temperatures are required, then the conditioning time will be adjusted based on the Arrhenius thermodynamic temperature coefficient rule ("a rise in temperature of 10 °C will double the rate of chemical reaction").

6.2.3 Accelerated Aging Technical Note:

When conducting an accelerated aging program for establishing product and package shelf life or expiration dating claims, it must be recognized that the data obtained from the study is based on conditions that **simulate** the effects of aging on the materials. The resulting creation of an 'expiration date' or shelf life represents a conservative estimate of shelf life and is **tentative** until the results of real time aging studies are completed on the product or product/package combination.

Since the results of the study produce a **conservative estimate** of the actual shelf life of the materials, tolerances for the

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temperature and humidity are only provided to ensure that the chamber operates within a satisfactory range. Out of tolerance excursions for less than 6 hours in duration for either temperature or humidity are acceptable and do not adversely affect the estimate for shelf life.

Out of tolerance excursions may be caused by opening doors for sample transfer; inserting moist samples into a dry environment causing spikes in humidity; proximity of monitoring device to temperature and/or humidity source inlets.

6.3 Post Accelerated Aging Package Analysis

Sixty (60) empty pouches will be tested to determine the effects of accelerated aging on the seal strength and integrity of the production pouches. Thirty (30) empty pouches will be tested in accordance with ASTM F88-07a and thirty (30) empty pouches will be tested in accordance with ASTM F2096-04.

6.4 Post Accelerated Aging Product Analysis (Negative Pressure Integrity)

Fifteen (15) pouches with product inside will be opened to remove the NPD 1000 Negative Pressure Dressing from the pouch. Each dressing will be tested according to the Bandage Integrity - Vacuum Pressure Test Protocol. Within the protocol, two tests will be performed. A Persistent Vacuum Integrity test will be performed on eight (8) samples and a Bandage Pump Down Time test will be performed on seven (7) samples.

6.5 Post Accelerated Aging Product Analysis (Bandage/Dressing Fluid Capacity)

Fifteen (15) pouches with product inside will be opened to remove the NPD 1000 Negative Pressure Dressing from the pouch. Each dressing will be tested according to the Bandage Fluid Capacity Test Protocol.

6.6 Summary of Strength and Integrity Sample Size

	Post 1 Year. AA
Seal Strength	30 empty Pouches
Bubble Leak	30 empty Pouches

6.7 Summary of Accelerated Aging Product Analysis

	Post 1 Year. AA
Negative Pressure Integrity Testing	15 Product
Bandage/Dressing Fluid Capacity Testing	15 Product

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7 Acceptance Criteria

- 7.1 Primary packages will be visually inspected while undergoing integrity testing for damages caused by accelerated age testing. Obvious mechanical damage such as seal failures, holes, tears and voids will be documented and Iasis Medical will be notified.
- 7.2 Packages fail the test protocol if there is obvious physical damage to the primary package or the bubble leak test indicates any signs of leakage.
- 7.3 Acceptance criteria for all product functionality testing has been identified by Iasis Medical.
- 7.3.1 Tests that involved the Bandage Pump Down Time must be able to achieve the set pressure in less than 3 minutes with each bandage/dressing.
- 7.3.2 Tests that involved the Persistent Vacuum Integrity will have the pump and bandage system deliver and maintain 125 mmHg of negative pressure over the 1 hour duration.
- 7.3.3 Tests that involved the Bandage/Dressing Fluid Capacity, the average Vcap calculated from the 15 samples shall be within 50cc +/- 10%.

8 Documentation

- 8.1 The accelerated aging will be documented using a NIST traceable temperature/humidity recorder and probe. The periodic readings will be retained as evidence that the proper temperature and humidity were maintained throughout the test duration.
- 8.4 The seal strength testing will be documented and all data will be compiled for average and standard deviation.
- 8.5 The bubble leak test will be documented on appropriate work sheets or laboratory notebook indicating a pass or fail.
- 8.6 The negative pressure integrity test will be documented on appropriate work sheets or a laboratory notebook. It will be used to record the equipment used and test results of performing the Bandage Integrity - Vacuum Pressure Test Protocol.
- 8.7 The bandage/dressing fluid capacity test will be documented on appropriate work sheets or a laboratory notebook. It will be used to record the equipment used and test results of performing the Bandage Fluid Capacity Test Protocol.
- 8.8 Gross irregularities found during inspection of samples prior to integrity testing will be documented and Iasis Medical will be notified.
- 8.9 Records for this project will be archived at DDL for a duration of 5 years in accordance with DDL's record policy. At the completion of 5 years all records will be disposed of properly. A written request must be made by the customer, specifying a longer retention period before the 5 years is complete.

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8.10 A single test report including the one year accelerated aging, seal strength, bubble leak and functionality tests will be issued to Iasis Medical upon completion of testing.

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APPENDIX A

Bandage Integrity - Vacuum Pressure Test Protocol

Introduction

This test will verify . . .

- The NPD 1000 Negative Pressure Dressing has vacuum integrity, when used with the NPD 1000 Negative Pressure Wound Therapy Device, over the full range of therapeutic pressures at the end of its labeled shelf life.
- The 1000 Negative Pressure Dressing shall be able to achieve and maintain a vacuum pressure down to 40 mmHg.
- The Micro NPWT device shall be able to achieve and maintain a vacuum pressure up to 125 mmHg.
- The tolerance of all set pressures in the Micro NPWT device shall be +/- 10% unless otherwise specified.
- The Micro NPWT device pump module shall be able to achieve the set pressure in less than 3 minutes with largest bandage designed.

Setting parameters on the NPD 1000 Negative Pressure Wound Therapy Device

To enter Configuration mode in order to change therapy mode or to modify the vacuum pressure setpoint, press and hold the Therapy Type (Mode) button and Pressure Setting (VAC) button simultaneously. While the Mode and VAC buttons are both held down, press and release the Pump On/Off button, then release the Mode and VAC buttons. Once in Configuration mode, to change therapy modes, press and release the Mode button. To change the vacuum pressure setpoint, press and release the VAC button. To exit Configuration mode, press and release the Pump On/Off button or wait 30 seconds from the last button press to time out and automatically exit.

Test Equipment

1. 15 NPD 1000 Negative Pressure Dressings*
2. NPD 1000 Negative Pressure Wound Therapy Device*
3. Negative pressure tubing and fittings*
4. One independent pressure sensor.
5. Smooth surface fiberglass board to accommodate mounting of bandage*
6. Stopwatch.

* Note: These items supplied by customer

Test Procedures and Expected Results

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Persistent Vacuum Integrity (test performed with 8 bandages, serially)

1. Connect the control module and pump module according to the directions in the NPD 1000 IFU (instructions for use). Label the pumps, pump # 1 and pump # 2.



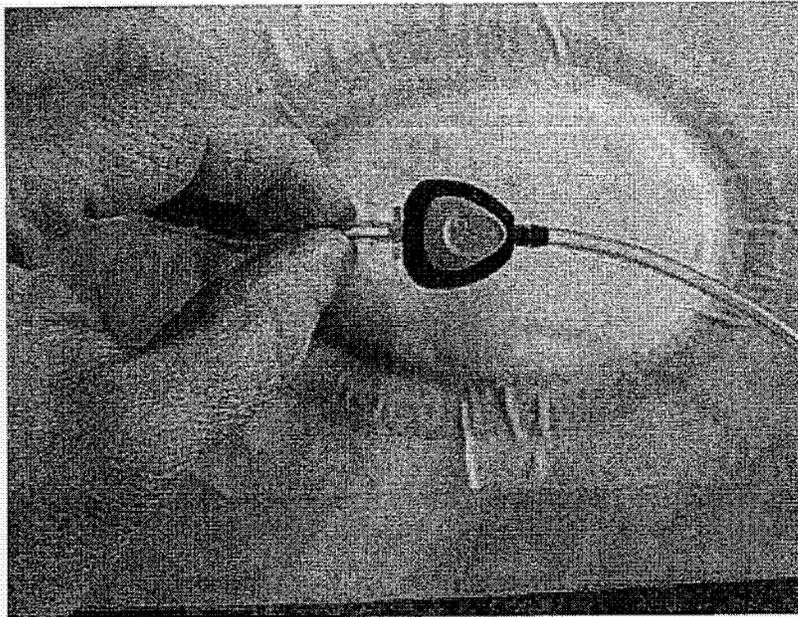
2. Start this test with device batteries (in control module) removed. Place the batteries in the control module, allowing the entire device to power up and complete self tests. Enter Configuration mode.



- Verify that the vacuum pressure setpoint display is active and flashing

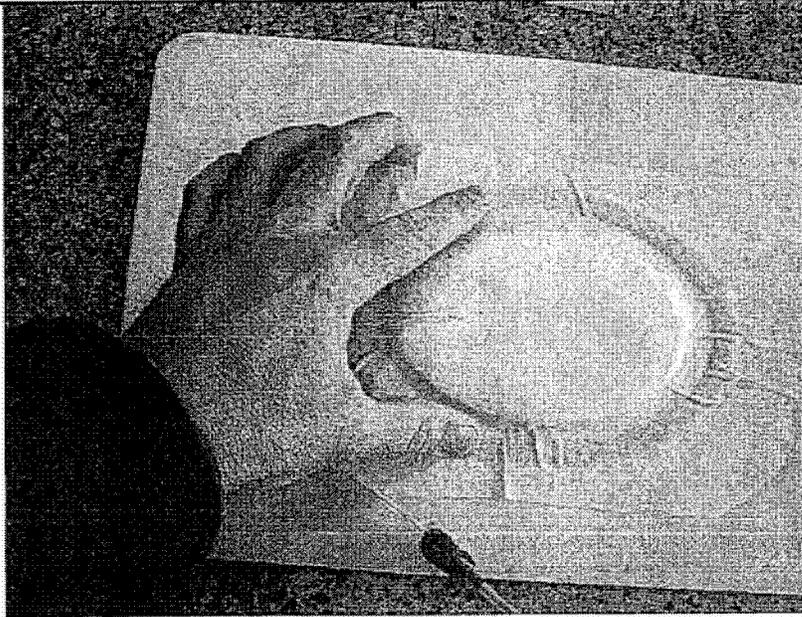
Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
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3. Press the VAC button until the vacuum pressure is set to 125 mmHg. Continue to press the VAC button, scrolling through all the vacuum pressure setpoints until 40 mmHg is reached. Stop at this value.
 - Verify the vacuum pressure setpoint display is active and flashing (signals a change in vacuum setting).
 - Exit Configuration mode
4. Mount the bandage securely to the test board
5. Connect the pump to the bandage with connectors, connectors on bandage and pump tubing. Add independent pressure gauge in-line with "tee" into pump tubing.



6. Turn the pump on by depressing the power button for > 1 second. Allow the unit to run for a minimum of 1 hour. Note: if a persistent leak occurs at start up (i.e. the pump never turns off), correct the leak by pressing the bandage gasket against the surface of the mounting board (see below) and continue the test.
 - Verify that the pump turns on and the bandage achieves the appropriate negative pressure at 40 mmHg +/- 10%.
 - Verify that no system fault notifications occur (ie. loss of pump control or pump inoperable) due to the inability of the system to deliver and maintain 40 mmHg of negative pressure continuous therapy over the 1 hour duration. "Inability" is defined as the bandage being unable to seal, such that the leak alarm (defined in the instructions for use booklet) persists throughout the test period. A balloon icon will appear if there is a seal fault. If the display has many pixels illuminated, there is a system fault.

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7. Enter Configuration mode, press the VAC button until the vacuum pressure is set to 125 mmHg. Exit Configuration mode and turn the pump on. Allow the unit to run for a minimum of one hour. Note: if a leak occurs, correct the leak and continue the test.
 - Verify that the pump turns on and the bandage achieves the appropriate negative pressure at 125 mmHg +/- 10%.
 - Verify that no system fault notifications occur (ie. loss of pump control or pump inoperable) due to the inability of the system to deliver and maintain 125 mmHg of negative pressure continuous therapy over the 1 hour duration.

Bandage Pump Down Time (seven bandages, one at a time)

1. Attach a new bandage to fixture.
2. Seal the dressing to the fixture by pressing gasket around the entire perimeter and smoothing the dressing corner as much as possible.
3. Configure the NPD 1000 Negative Pressure Wound Therapy Device to deliver 125 mmHg of continuous therapy.
4. Attach the bandage to the pump with the appropriate connectors.
5. Turn the pump on and start the stopwatch at the same time.
6. Stop the stopwatch when the pump stops pumping AND when the independent pressure sensor signals a negative pressure of 125 mmHg.
7. Record the elapsed time.
8. Repeat this process 10 times recording the pump down time each time.
9. Average the recorded elapsed times.
 - Verify that the Continuous pump is able to achieve the set pressure in less than 3 minutes with each bandage.

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Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
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APPENDIX B

Bandage Fluid Capacity Test Protocol

Introduction

This test will verify . . .

- The NPD 1000 Negative Pressure Dressing maintains its therapeutic fluid capacity, when used with the NPD 1000 Negative Pressure Wound Therapy Device, at the end of its labeled shelf life.
- The average fluid retention capacity, (Vcap) of the NPD 1000 Negative Pressure Dressing shall be capable of holding 50cc of fluid, +/- 10%.

Setting up the NPD 1000 Negative Pressure Wound Therapy Device

To enter Configuration mode in order to change therapy mode or to modify the vacuum pressure setpoint, press and hold the Therapy Type (Mode) button and Pressure Setting (VAC) button simultaneously. While the Mode and VAC buttons are both held down, press and release the Pump On/Off button, then release the Mode and VAC buttons. Once in Configuration mode, to change therapy modes, press and release the Mode button. To change the vacuum pressure setpoint, press and release the VAC button. To exit Configuration mode, press and release the Pump On/Off button or wait 30 seconds from the last button press to time out and automatically exit.

Test Setup

7. Fifteen (15) of the NPD 1000 Negative Pressure Dressings
8. One (1) NPD 1000 Negative Pressure Wound Therapy Device (control module w/ batteries and pump module)
9. Negative pressure tubing and fittings
10. Fiberglass board to accommodate mounting of bandage and introduction of fluid to bandage
11. One (1) Calibrated fluid syringe (50 – 200 ml capacity)
12. Test Fluid container with water and food coloring (for indication purposes)
13. Stopwatch.

Test Procedures and Expected Results

Bandage Fluid Capacity (test performed with 15 bandages, one at a time)

8. Connect the control module and pump module according to the directions in the NPD 1000 IFU (instructions for use).

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	Revision: B



9. Start this test with device batteries (in control module) removed. Place the batteries in the control module, allowing the entire



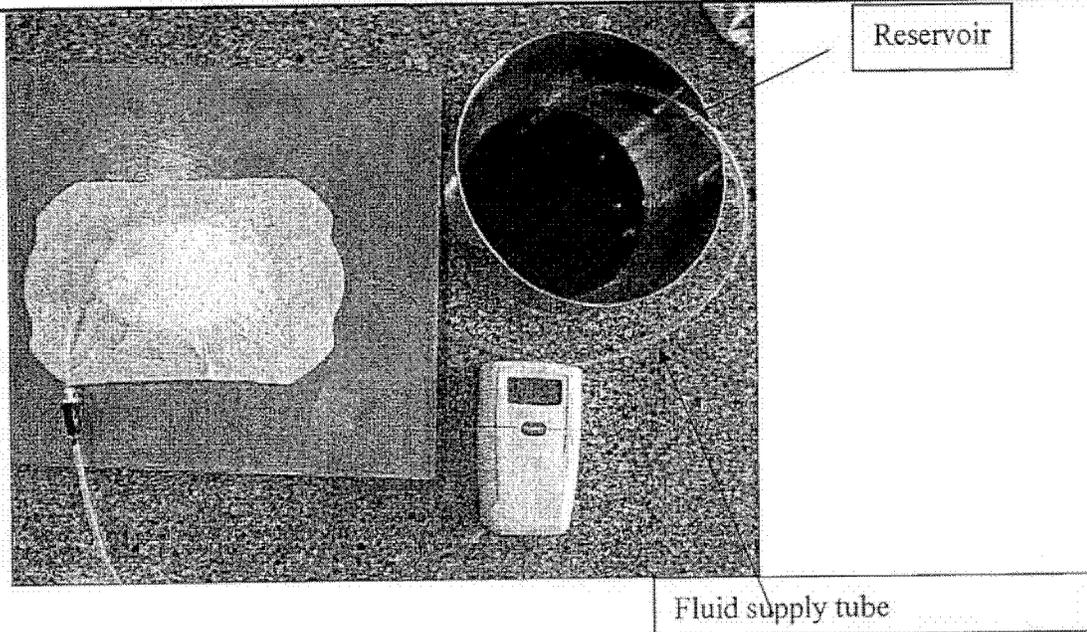
device to power up and complete self tests. Enter Configuration mode.

- Verify that the vacuum pressure setpoint display is active and flashing

10. Press the VAC button until the vacuum pressure is set to 125 mmHg. Exit configuration mode.

11. Using syringe, measure 200 cc of colored fluid into test reservoir

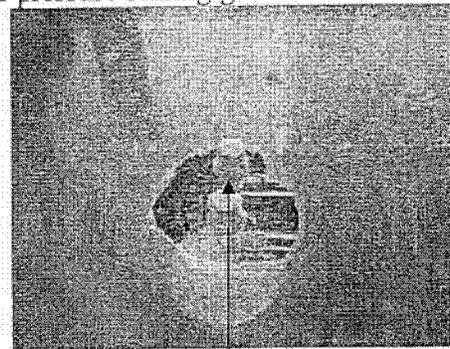
Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
Protocol Number:	P080299
Revision:	B



12. Place fluid supply tube, attached to bandage mounting board into the fluid
13. Mount bandage on board above fluid supply "hole". Note: The fluid supply hole must be located entirely within the pressure sealing gasket on the bandage.



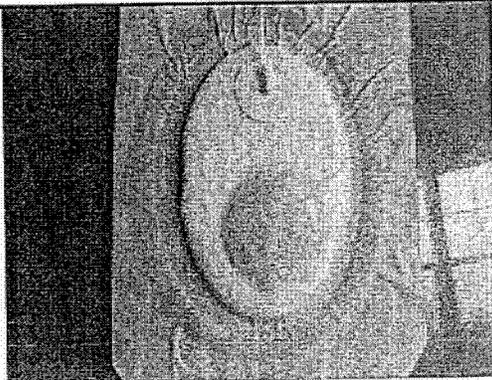
Back side of bandage mount



Fluid Supply hole

14. Attach the NPD 1000 Negative Pressure Wound Therapy Device to the dressing with the supplied tubing.
15. Turn on the pump. Fluid will begin to flow from the reservoir to the bandage. The pump will turn off and on during this process. The bandage will fill in approximately 30-45 seconds.

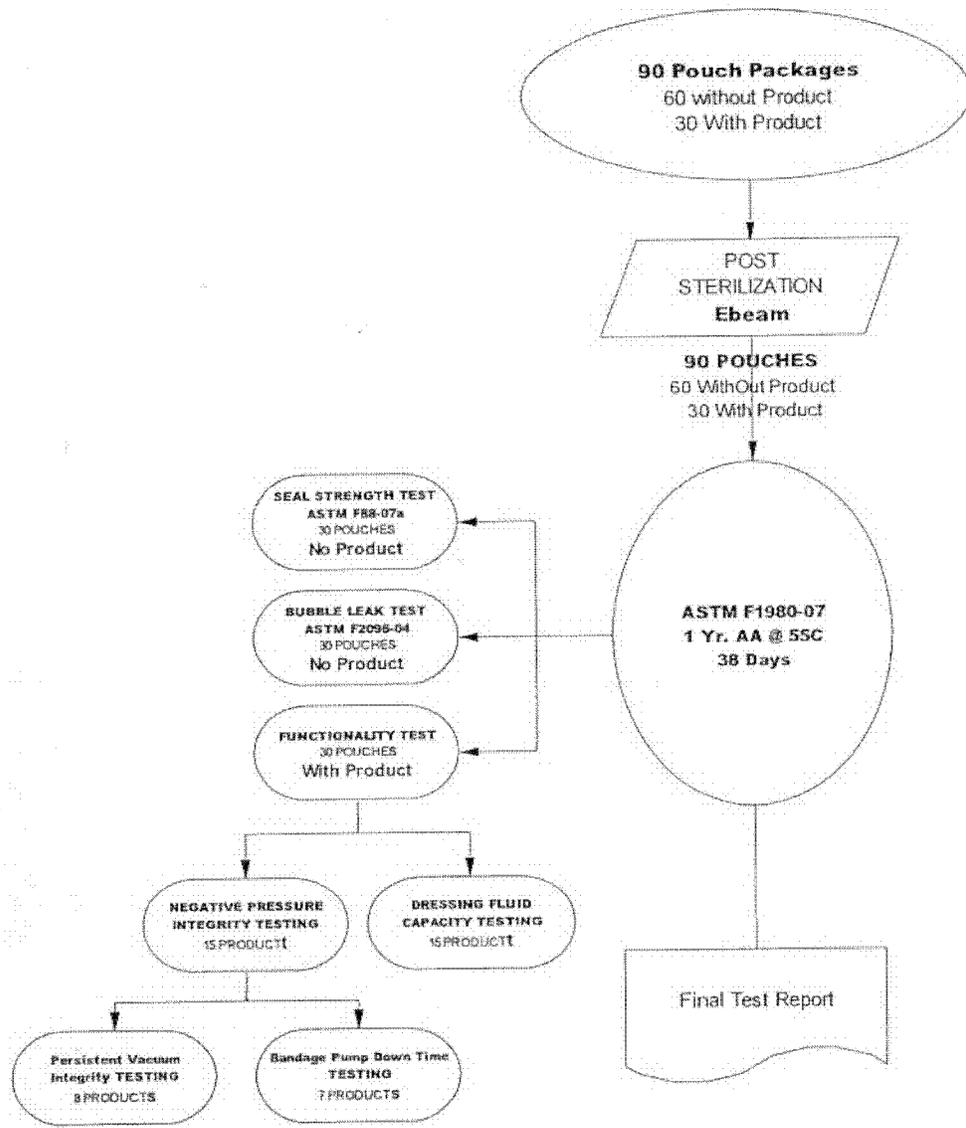
Test Protocol Title:	<i>One Year Accelerated Aging Product and Package Evaluation</i>
Test Type:	<i>Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests</i>
Protocol Number:	P080299
	Revision: B



16. Five minutes after the pump has stopped cycling, turn off the pump and detach the tubing from the bandage.
17. Carefully remove the bandage from the fixture, taking care not to squeeze the absorbent pad.
18. Extract the absorbent pad from the dressing.
19. Place absorbent pad on flat surface and extract the "free" water from the pad by compressing the pad with a rigid roller applying 3 lbs. of force. Collect "squeezed" water into the original fluid reservoir.
20. Measure the non-absorbed fluid in the reservoir with the calibrated syringe, noting the remaining volume, V_{rem} . As an alternative, the volume of fluid can be measured using a scale capable of displaying grams.
21. Calculate the dressing fluid retention capacity, V_{cap} , by the following formula,
 1. $V_{cap} = 200 \text{ cc} - V_{rem}$
22. Repeat measurement for remaining dressings
23. Calculate the average of V_{cap} and S.D. of V_{cap}
24. The average of all fifteen (15) V_{caps} must be within the 50cc +/- 10% tolerance or failure has occurred.

Test Protocol Title: One Year Accelerated Aging Product and Package Evaluation	
Test Type: Accelerated Aging, Product Functionality Testing and Package Sterility Validation Tests	
Protocol Number: P080299	Revision: B

lasis Medical
1 Year Accelerated Aging Product and Package Evaluation
Single Foil / Foil Pouch Package
Product Name: NPD 1000 Negative Pressure Dressing
Protocol #: 080299



APPENDIX B: ONE YEAR ACCELERATED AGING DATA

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 19 of 24
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DDL, Inc. • 10200 Valley View Road, Suite 101 • Eden Prairie, MN 55344 • Tel: 952-941-9226 • Fax: 952-941-9318



1 Year AA

Customer: Iasis Medical
 Product: NPD 1000 Negative Pressure Dressing
 Cust. PO: N/A
 DDL JN: 0802099

MW 18-Feb-08
 Worksheet Approved By
 Test: 1 Year AA @ 55 C
 55C @ <20% RH

Start Date 18-Feb-08
 Start Time 2:00 PM

Chamber: 16

Date	Day	Nist Temp (C)	RH (%)	Remarks	Specimen Verification	Chamber Verification
Mon, 18-Feb-08	Start	54.7	20	JW 55C / Low Humidity	JW	JW
Tue, 19-Feb-08	1	54.7	20	JW 16-017		
Wed, 20-Feb-08	2	54.4	20	JW		
Thu, 21-Feb-08	3	54.6	20	JW		
Fri, 22-Feb-08	4	54.6	20	JW		
Sat, 23-Feb-08	5	54.1	20	JW		
Sun, 24-Feb-08	6	54.4	20	JW		
Mon, 25-Feb-08	7	54.5	20	JW		
Tue, 26-Feb-08	8	54.5	20	JW		
Wed, 27-Feb-08	9	54.4	20	JW		
Thu, 28-Feb-08	10	54.3	20	JW		
Fri, 29-Feb-08	11	54.5	20	JW		
Sat, 01-Mar-08	12	54.3	20	JW		
Sun, 02-Mar-08	13	54.2	20	JW		
Mon, 03-Mar-08	14	54.2	20	JW		
Tue, 04-Mar-08	15	54.1	20	JW		
Wed, 05-Mar-08	16	54.3	20	JW		
Thu, 06-Mar-08	17	54.5	20	JW		
Fri, 07-Mar-08	18	54.5	20	JW		
Sat, 08-Mar-08	19	55.2	20	MW		
Sun, 09-Mar-08	20					
Mon, 10-Mar-08	21	54.3	20	JW		
Tue, 11-Mar-08	22	54.6	20	JW		
Wed, 12-Mar-08	23	54.5	20	JW		
Thu, 13-Mar-08	24	54.6	20	JW		
Fri, 14-Mar-08	25	54.7	20	JW		
Sat, 15-Mar-08	26	54.6	20	JW		
Sun, 16-Mar-08	27	55.7	20	JW		
Mon, 17-Mar-08	28	54.4	20	JW		
Tue, 18-Mar-08	29	54.5	20	JW		
Wed, 19-Mar-08	30	54.9	20	JW		
Thu, 20-Mar-08	31	54.7	20	JW 16-018		
Fri, 21-Mar-08	32	54.6	20	JW		
Sat, 22-Mar-08	33	55.1	20	JW		
Sun, 23-Mar-08	34	54.80	20	MW		
Mon, 24-Mar-08	35	54.7	20	JW		
Tue, 25-Mar-08	36	54.5	20	JW		
Wed, 26-Mar-08	37	54.1	20	JW		
Thu, 27-Mar-08	38	54.2	20	JW moved to quarantine		
				End of Test		

Overtemp Set Point: 57
 Overtemp Verification: ✓

Specimens Removed: JW

Specimen(s): 100543

Probe(s): D36

Chart(s): 16-017, 16-018

MW 27-Mar-08
 Data Approved By

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APPENDIX C: BUBBLE LEAK TESTING DATA

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 20 of 24
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Bubble Leak Test

Test Interval: Post 1 YR AA

Customer: Iasis Medical
 P.O.: 1005
 J/N: 0802099
 Package type: Single Barrier Foil/Foil Pouch
 Product: Empty Pouches

Worksheet Approval: JAS 28-Mar-08
(Date)
 Test Technician: CKB
 Test Dates: 31-Mar-08, 31-Mar-08
(Start) (End)
 PM (initials): MBW

Equipment Used: TM ELECTRONICS / BURST TESTER
 MODEL #: BT 115
 SERIAL #: BT 465
 Cal Due: 25-Jan-09

Machine Parameters
 Flow Rate: open
 Pressure: .30
 Pressure Verification: CJA

DDL SOP#: 6047 Rel#: 05
 Test Standard: ASTM F 2096

Notes
 Sample Prep CKB
 Validated with .008 pin gauge
 ① validation

Specimen	Sample	Results	Comments/Location
100543	1	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	①
	2	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	3	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	4	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	5	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	6	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	7	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	8	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	9	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	10	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	11	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	12	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	13	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	14	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	15	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	16	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	17	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	18	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	19	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	20	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	21	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	22	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	23	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	24	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	25	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	26	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	27	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	28	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	29	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	30	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	

pkg test photo
 pkg des. photo

Summary

Total	Passed	Failed
30	30	0

Reviewed By: MBW Date: 31-Mar-08

APPENDIX D: SEAL STRENGTH TESTING DATA

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 21 of 24
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



Seal Strength Test

Test Interval: Post 1 YR AA

Customer: Iasis Medical
 P.O.: 1005
 J/N: 0802099
 Package type: Single Barrier Foil/Foil Pouch
 Product: Empty Pouches

Compiled by: MBW 8-Apr-08
 (date)
 Test Technician(s): CKB
 Test Date(s): 31-Mar-08 2-Apr-08
 (start) / (end)

Equipment Used: DDL Universal Tensile Test System
 Model #: 100P Serial #: 0001064
 Load Cell: SMT1-56 Serial #: 602371
 Cal Due: 11-Apr-08

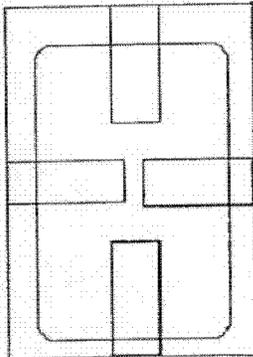
Machine Parameters
 Cross-Head Speed: 11 in/min
 Verified by: CKB

Load Cell Verification
 2lb wt. Serial #: C6845
 Measured wt.: 2.00 lbs

90° Un-supported Method: CKB

DDL SOP#: 6008 Ret#: 05
 Test Standard: ASTM F-88

Package Description



Notes

Sample Prep: CKB

The foil material tore prior to seal separation on all tested samples.

Specimen	Sample	Peak Value (lbs.)				Equipment set-up Approval
		I	II	III	IV	
100543	31	19.58	21.14	19.99	21.36	CJA
	32	20.74	21.40	19.68	21.27	
	33	20.17	20.41	20.04	20.55	
	34	19.97	21.82	20.74	21.27	
	35	20.04	21.20	20.91	20.45	
	36	19.99	21.57	21.01	20.39	
	37	19.94	21.60	21.31	20.88	
	38	20.00	21.07	19.83	21.43	
	39	21.22	21.32	19.87	20.49	
	40	20.46	20.87	20.04	21.11	
	41	20.18	21.00	20.20	21.32	
	42	19.75	20.96	20.74	21.23	
	43	21.19	20.92	20.59	21.05	
	44	19.10	21.25	20.45	20.91	
	45	20.01	20.44	18.93	20.56	
	46	20.22	20.89	19.69	19.62	
	47	20.15	22.11	20.10	19.43	
	48	21.08	20.92	20.01	20.54	
	49	20.09	20.54	20.14	20.87	
	50	19.62	21.17	19.89	21.25	
	51	20.48	21.30	20.27	21.21	
52	20.30	21.91	20.37	21.28		
53	19.56	20.65	20.86	20.53		
54	20.70	21.24	19.98	20.14		
55	19.79	20.75	20.51	21.55		
56	19.31	21.83	19.71	20.91		
57	20.23	20.43	19.59	20.55		
58	20.18	19.92	20.47	20.31		
59	21.55	21.24	21.34	21.60		
60	20.08	20.98	20.33	20.56		
St. Dev.		0.56	0.49	0.54	0.54	
Average		20.19	21.10	20.25	20.82	

Reviewed By: TSJ Date: 08-Apr-08

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APPENDIX E: PERSISTENT VACUUM INTEGRITY TESTING DATA

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 22 of 24
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Persistent Vacuum Integrity



Customer: Iasis Medical
 P.O.: 1005
 J/N: 0802099
 Product: NPD 1000 Negative Pressure Dressing

Compiled By: AJP
 Date: 2-Apr-08
 Test Tech: KAM
 Test Date: 31-Mar-08 2-Apr-08
 (start) (end)

Equipment:

Iasis Medical NPD 1000 Negative Pressure Wound Therapy Device
 PN #: 50001 Rev A Unit #: 2
 Pressure Sensor Ashcroft Vacuum Gauge
 Model #: 30 inHg Serial #: 1022965 Cal Due: 2-Jul-08
 Stopwatch Cole-Palmer
 Model #: 3 Serial #: 1614 Cal Due: 1-May-09

Test Approval: AJP
 Date: 31-Mar-08

Test Standard: DDL Protocol: P0802099 Rev B Appendix A Steps 1-7

Specimen	Iasis Medical Dressing Number	Step 6 Pressure Reading (inHg)	Results		Test Duration Time (min:sec)	Step 7 Pressure Reading (inHg)	Results		Test Duration Time (min:sec)	Comments
			Pass	Fail			Pass	Fail		
100543	1	1.57	X	-	60:01	4.80	X	-	60:23	-
	2	1.58	X	-	60:04	4.64	X	-	60:00	-
	3	1.56	X	-	60:17	4.86	X	-	-	1
	4	1.53	X	-	62:52	4.57	X	-	60:32	-
	5	1.63	X	-	61:06	4.68	X	-	61:26	-
	6	1.54	X	-	60:11	4.68	X	-	61:40	-
	7	1.65	X	-	60:08	4.59	X	-	65:32	-
	8	1.54	X	-	60:45	5.01	X	-	61:15	-
Total			8	0	Total		8	0		

Comments:

Pass if no system fault notification occurs during the test period.
 Fail if the leak alarm persists throughout the test period

1 Forgot to start the timer. Test started between 7:05am and 7:10am test ended at 8:10am.

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APPENDIX F: BANDAGE PUMP DOWN TIME TESTING DATA

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 23 of 24
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Customer: Iasis Medical
 P.O.: 1005
 J/N: 0802099
 Product: NPD 1000 Negative Pressure Dressing

Compiled By: AJP
 Date: 2-Apr-08
 Test Tech: KAM
 Test Date: 2-Apr-08 2-Apr-08
 (start) (end)

Equipment:

Iasis Medical NPD 1000 Negative Pressure Wound Therapy Device
 Model #: 50001 RevA Unit #: 2
 Pressure Sensor Ashcroft Vacuum Gauge
 Model #: 30 inHg Asset #: 1634 Cal Due: 2-Jul-08
 Stopwatch Cole-Palmer
 Model #: 3 Serial #: 1614 Cal Due: 1-May-09

Test Approval: AJP
 Date: 2-Apr-08

Test Standard: DDL Protocol: P0802099 Rev B Appendix A Steps 1-9

1. Attach new bandage to fixture
2. Seal the dressing to the fixture by pressing gasket around the entire perimeter and smoothing the dressing corner as much as possible.
3. Configure the NPD 1000 Negative Pressure Wound Therapy Device to deliver 125 mmHg of continuous therapy.
4. Attach the bandage to the pump with the appropriate connectors.
5. Turn the pump on and start the stopwatch at the same time.
6. Stop the stopwatch when the pump stops pumping AND when the independent pressure sensor signals a negative pressure of 125 mmHg
7. Record the elapsed time.
8. Repeat this process 10 times recording the pump down time each time.
9. Verify that the Continuous pump is able to achieve the set pressure in less than 3 minutes with each bandage.

Specimen	Iasis Medical Dressing Number	Elapsed Time (min:sec)										Average Time (min:sec)
		Run 1	Run 2	Run 3	Run 4	Run 5	Run 6	Run 7	Run 8	Run 9	Run 10	
100543	9	00:41	00:26	00:27	00:24	00:27	00:26	00:26	00:27	00:27	00:27	00:28
	10	00:38	00:27	00:27	00:27	00:28	00:26	00:28	00:29	00:28	00:27	00:29
	11	00:43	00:29	00:28	00:28	00:28	00:28	00:28	00:28	00:28	00:29	00:30
	12	00:50	00:30	00:30	00:30	00:30	00:30	00:30	00:30	00:30	00:31	00:32
	13 (1)	00:42	00:29	00:30	00:28	00:23	00:27	00:28	00:27	00:28	00:28	00:29
	14	00:49	00:31	00:30	00:31	00:32	00:30	00:31	00:30	00:31	00:31	00:33
	15	01:16	01:55	01:43	01:27	01:28	01:13	01:16	01:22	01:16	01:33	01:27

Comments:

(1) Low Battery signal at start of test, stopped and replaced batteries. Specimen then failed to seal properly, maximum pressure of 0.50 inHg was observed. John Buan came and fixed the seal near the pump tube. Specimen was then retested with proper seal and equipment.

Reviewed By: [Signature]

Date: 3 MAR 08

APPENDIX G: BANDAGE FLUID CAPACITY TESTING DATA

Report No.	0802099	Customer:	IASIS Medical, Inc.	Page 24 of 24
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Project No. 0802099

Book No. 1062

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TITLE FLUID CAPACITY OF BANDAGE

From Page No. 94

LAB COND 23.1°C @ 54% RH

TEST DATES START 3 APR 08 9:15 AM

CUSTOMER: IASIS MEDICAL

PO 1005

JN 0802099

PRODUCT NPD 1000 NEGATIVE PRESSURE DRESSING

STANDARD/PROTOCOL: DDL P0802099 REV B: APPENDIX B STEPS 8-24

EQUIPMENT

IASIS MEDICAL 1000 NEGATIVE PRESSURE WOUND THERAPY DEVICE (PUM 125mmHg)

PN 50003 REV A UNIT #2

VACUUM GAUGE

ASHCROFT 30 in. Hg ASSET # 001634 CAL DUE 02 JUL 08

STOPWATCH

COLE PALMER #3 ASSET # 001614 CAL DUE 01 MAY 08

600g SCALE

AND EK-6000 ASSET # 001065 CAL DUE 10 MAR 08 KAM 10 MAR 09

MATERIALS

RO WATER

BLUE DYE LOT 020408 EXP DATE 04 MAY 08 (FOR VISUAL AIDE ONLY -> CUSTOMER)

BEAKER, 250ml (113.3g) (RESERVOIR ONLY)

DIRECTIONS FOR MIXING RO + DYE 200g RO + 2g Blue Dye

TEST RESULTS ^{KAM 3 APR 08} 58.5g → scale plate weights 59.3g

SAMPLE	PAD DRY (g)	Full after 5min. rest (g)	PAD AFTER SQUEEZE (g)	PAD ABSORPTION Δ FINAL - DRY (g)
#16	78.3	170.8	152.9	74.6 <input type="checkbox"/>
#17	79.6	163.0	151.4	71.8 <input type="checkbox"/>
#18	78.4	156.1	150.2	71.8 <input type="checkbox"/>
#19	77.7	168.9	152.4	74.7 <input type="checkbox"/>
#20	77.7	159.1	151.2	73.5 <input type="checkbox"/>
#21	78.4	183.3	167.6	89.2 <input type="checkbox"/>
#22	78.1	180.1	157.7	79.6 <input type="checkbox"/>
#23	78.2	175.6	168.2	90.0 <input type="checkbox"/>
#24	78.2	175.7	170.9	92.7 <input type="checkbox"/>
#25	78.5	178.5	165.8	87.3 <input type="checkbox"/>
#26	77.7	169.6	159.3	81.6 <input type="checkbox"/>
#27	77.9	168.9	164.1	86.2 <input type="checkbox"/>
#28	78.1	175.5	165.0	86.9 <input type="checkbox"/>
#29	77.2	164.7	155.7	78.5 <input type="checkbox"/>
#30	78.3	168.5	162.7	

KAM 4 APR 08
To Page No. 95

Witnessed & Understood by me, 	Date <u>7 APR 08</u>	Invented by <u>KAM</u>	Date <u>3 APR 08</u>
		Recorded by <u>KAM</u>	<u>197</u>

TITLE FLUID CAPACITY OF BANDAGE

From Page No 94

TEST PROCEDURE

Mix FLUID

200g RO water

2g BLUE DYE

REMOVE BANDAGE FROM PACKAGE

REMOVE BOTH BACKING WRAPS FROM BANDAGE TAKING CARE NOT TO

~~REMOVE~~ ^{REMOVE} ADHESIVE

WEIGH DRY PAD ON SCALE WITH USE OF A PLATE TO EXTEND ^{SCALE} SCALE SURFACE

RECORD AS DRY WEIGHT (g) * THIS WILL INCLUDE SUPPORT PLATE WEIGHT

POSITION ADHESIVE BANDAGE OVER NOZZLES ON MOUNTING PLATE, PROVIDED

BY CUSTOMER, ENSURING THAT THE VACUUM TUBE IS AS FAR FROM THE

NOZZLES AS POSSIBLE

ATTACH IASIS MEDICAL 1000 RELATIVE PRESSURE WOUND THERAPY DEVICE TO

BANDAGE AS DESCRIBED IN DDL PROTOCOL P0802099

SET UNIT TO 125mm Hg AND START PUMP

LET PUMP CONTINUE UNTIL FLUID IS PUMPED TO SO THAT THE VACUUM VALUE

IS COMPLETELY INCLUSIVE

STOP DEVICE AND START TIMER: WAIT 5 MINUTES

DETACH FROM BANDAGE TUBING TO DEVICE: MOUNTING

PLATE ^{COM} CAREFULLY, REMOVE BANDAGE FROM SUPPORT PLATE WITHOUT

SQUEEZING OUT ANY FLUID

REWEIGH BANDAGE WITH ^{COM} SUPPORT PLATE * THIS WILL INCLUDE SUPPORT

PLATE WEIGHT

GENTLY PRY OFF PAD FROM BANDAGE AND PLACE IN FLAT PAN

USING A 3lb. ROLLER ~~stick~~ ^{stick} at an angle (gentle), SLOWLY REMOVE

EXCESS FLUID FROM BANDAGE

REPLACE PAD ONTO BANDAGE AND REWEIGH WITH SUPPORT PLATE

CALCULATE PAD ABSORPTION BY SUBTRACTING FROM THE FINAL WEIGHT

(^{COM} PAD WEIGHT AFTER EXCESS FLUID WAS REMOVED (WF)) the

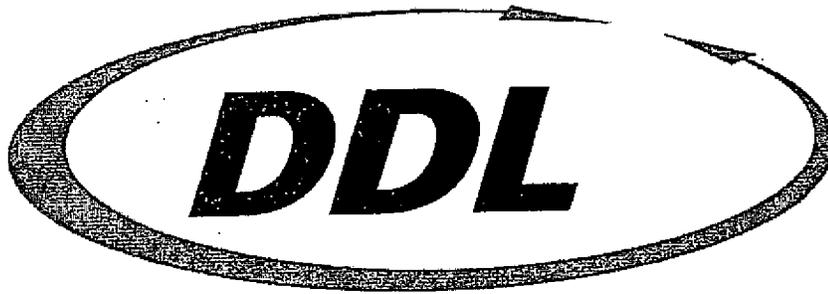
DRY WEIGHT OF THE BANDAGE AND THE WEIGHT OF THE SUPPORTING PLATE

$$\text{PAD ABSORPTION} = \frac{\text{COM}}{\text{PAD}} \times \text{APROB} \times (\text{BANDAGE (WEIGHT)} - \text{BANDAGE (DRY)} - \text{SUPPORTING PLATE})$$

^{COM}
APROB

To Page No 95

Witnessed & Understood by me, <u>ASP</u>	Date <u>7 APR 08</u>	Invented by <u>Kam</u>	Date <u>7 APR 08</u>
		Recorded by <u>Kam</u>	<u>198</u>



Tested and proven.

Vision Statement

"DDL, Inc. will become America's premier supplier of professional services in its chosen area of product, package, and material testing and consulting."

Mission Statement

"DDL, Inc.'s mission is to provide our customers with the highest quality of testing and consulting services at a competitive price."

"We serve our customers with integrity and professionalism. We strive to use our experience and insight as creative problem solvers...providing our customers with the professionalism they expect, and exceeding their expectations with exceptional personal service."

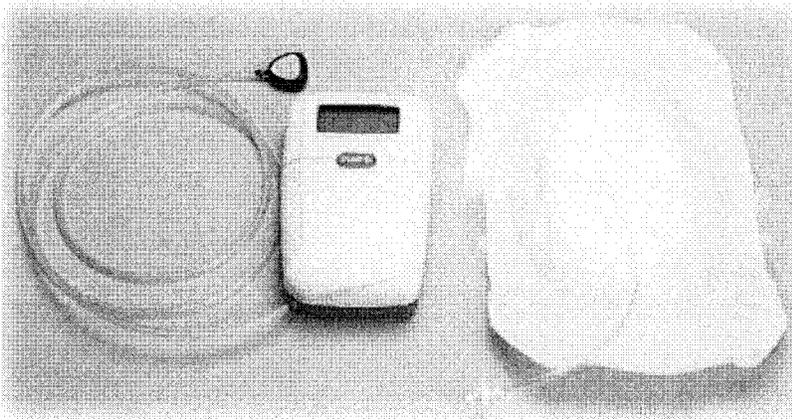
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K a l y p t o M e d i c a l

NPD 1000™ Negative Pressure Wound Care System

Portable Negative Pressure Pump & Dressing



Clinician & Patient Instructions for Use



Kalypto
Medical



Important Safety Information accompanies this device. Indications for Use, Contraindications, Warnings, Precautions and other Safety Information are included in these Instructions for Use (IFU). To reduce risk of serious or fatal injury, all caregivers and patients must carefully read and follow all user instructions and safety information that accompany Kalypto Medical products.

If there are questions, please contact Kalypto Medical immediately at (877) 286-3740.

See back cover of this IFU for other Kalypto contact information.

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GENERAL INFORMATION

CLINICIAN INFORMATION

PATIENT INFORMATION

GENERAL INFORMATION

INTRODUCTION

The NPD 1000 Negative Pressure Wound Therapy System Instructions for Use (IFU) is intended to supply information to both the clinician and patient on the use of the device, application of the wound dressing, expectations for normal operation and troubleshooting system issues. While the system is designed to provide negative pressure wound therapy in a patient's home, the system should be set up and dressings applied by a qualified wound clinician. The patient should with the use of the IFU be able to competently troubleshoot any problems that appear during the normal course of use and know when it is appropriate to call their medical provider regarding issues with the system. Thus, the IFU is divided into three sections, 1) General information - including indications for use, contraindications, warnings and precautions, 2) Clinician - information needed by the clinician to use the device on a patient with a wound and 3) Patient - information needed by the patient to insure that the device continues to operate appropriately after leaving the direct care of their wound care professional.

GLOSSARY OF SYMBOLS

	Refer to the Instructions for Use (IFU)
	Single use only. Do not reuse.
	Date of Manufacture
LOT	Manufacturing Lot Number
	Type B, Applied Part. Internally powered electrical device.
	Keep Dry
	Warning, consult accompanying documents
STERILE	Product sterilized by ionizing radiation
IPX0	Not protected against harmful effects of water
	Use by date
SN	Serial Number
	ON/OFF (Vacuum Pump power)
P/N	Part Number
	Low Battery
	Negative Pressure Therapy Pump system is operating
	System Pressure Leak
	Medical Equipment classified with respect to Electrical Shock, Fire and Mechanical Hazards Only in accordance with UL 60601-1 and to CAN/CSA C22.2 No. 601.1.

GENERAL INFORMATION

PRODUCT DESCRIPTION

The NPD 1000 Negative Pressure Wound Therapy System is comprised of a battery-operated system controller, with a portable electromechanical pump and proprietary wound dressing. The pump produces a controlled negative pressure (vacuum) under the wound dressing.

The pump device (depending on the model purchased) can provide negative pressure therapy in two modes, "continuous" and "intermittent", with pressure ranges from - 40mmHg to -125 mmHg. In "continuous" mode, the pump holds the pressure inside the dressing at the prescribed programmed level while the negative pressure dressing is worn, the pump is connected to the dressing and therapy is turned ON. In intermittent mode, the pump cycles between the programmed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. This cycle continues from the time therapy is initiated until the pump is turned OFF.

Available Models

The NPD 1000 Negative Pressure Wound Therapy device is available in two configurations utilizing the universal system controller, the NPD 1000i Intermittent Therapy Pump and the NPD 1000c Continuous Negative Pressure Therapy Pump.

CAUTION: Both devices are designed to only work with all Kalypto Negative Pressure bandages. They are not compatible with other negative pressure bandage systems.

The NPD 1000i is an assembly of the NPD 1000 system controller and the 1000i pump module. It is capable of providing both "intermittent" and "continuous" modes of therapy over the specified pressure range. This assembly can be used by multiple patients.

The NPD 1000c is an assembly of the NPD 1000 system controller and the 1000c pump module. It is capable of providing only the "continuous" mode of therapy over the specified pressure range. This assembly should only be used by one patient. **NOTE:** The system controller can be used by multiple patients but the pump assembly is single patient use only.

INDICATIONS FOR USE & CONTRAINDICATIONS

Indications for Use

The NPD 1000 Negative Pressure Wound Therapy System is a portable, low powered, battery operated, suction pump intended for the application of suction to remove a small amount of fluid from the wound bed, including wound exudate and infectious material, which may promote wound healing.

Contraindications

Do not use the NPD 1000 Negative Pressure Wound Therapy System for -

1. Application to wounds where there is evidence of
 - Exposed arteries or veins in wound
 - Fistula - unexplored
 - Fistula - non enteric
 - Osteomyelitis, untreated
 - Malignancy in the wound
 - Necrotic tissue with eschar

NOTE: After debridement of necrotic tissue and complete removal of eschar, the NPD 1000 Negative Pressure Wound Therapy System may be used.

2. Emergency Airway Aspiration
3. Pleural, mediastinal or chest tube drainage. These applications require a device that provides specific low suction levels and an underwater seal.
4. Surgical Suction
5. Do not apply the NPD 1000 Wound Dressings directly to exposed blood vessels, organs, or nerves.
6. Sensitivity to silver (NPD 1000 Silver Dressing only).

GENERAL INFORMATION

WARNINGS, CAUTIONS & ADVERSE REACTIONS

Warnings

With or without using NPD 1000 Therapy, certain patients are at high risk of bleeding complications. The following types of patients are at increased risk of bleeding, which, if uncontrolled, could potentially be fatal.

- Patients who have weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to:
- Suturing of the blood vessel (native anastomoses or grafts)/organ
- Infection
- Trauma
- Radiation
- Patients without adequate wound hemostasis
- Patients who have been administered anticoagulants or platelet aggregation inhibitors
- Patients who do not have adequate tissue coverage over vascular structures.

If NPD 1000 Therapy is prescribed for patients who have an increased risk of bleeding complications, they should be treated and monitored in a care setting deemed appropriate by the treating physician. If active bleeding develops suddenly or in large amounts during NPD 1000 Therapy, or if frank (bright red) blood is seen in the dressing, immediately stop NPD 1000, leave dressing in place, take measures to stop the bleeding. Seek immediate medical assistance.

Protect Vessels and Organs: All exposed or superficial vessels and organs in or around the wound must be completely covered and protected prior to the administration of negative pressure wound therapy with the NPD 1000 system.

Always ensure that the negative pressure dressing does not come in direct contact with vessels or organs. Use of a thick layer of natural tissue should provide the most effective protection. If a thick layer of natural tissue is not available or is not surgically possible, multiple layers of fine-meshed, non-adherent material, or bio-engineered tissue may be considered as an alternative, if deemed by the treating physician to provide a complete protective barrier. If using non-adherent materials, ensure that they are secured in a manner as to maintain their protective position throughout therapy. Consideration should also be given to the negative pressure setting and therapy mode used when initiating therapy.

WARNINGS, CAUTIONS & ADVERSE REACTIONS con't

Cautions

- Wound Dressings are single patient use only and should be disposed of in accordance with local rules and practices regarding infectious waste.
- The device should not be used once the wound is no longer producing exudates.
- Use of clean technique is the responsibility of the health care professional directly responsible for patient care.
- Use only alkaline AA batteries.
- If the patient needs to shower or bathe in between dressing changes, steps should be taken to prevent water from coming in contact with the dressing and to disconnect the pump from the dressing. However, It is advisable that as part of the care plan, personal hygiene matters, such as showering and bathing should be done immediately preceding the changing of the dressing, when the device can be detached from the patient until the application of the new dressing.
- The devices are designed to work with 50cc Kalypto Negative Pressure bandage and are not compatible with other negative pressure bandage systems
- Safe Performance: Even in fault conditions, the NPD 1000 will not exceed 250 mmHg of suction.
- Do not use the NPD 1000 Wound Therapy System in the presence of flammable anesthetics.
- To reduce the risk of transmission of bloodborne pathogens, apply standard precautions for infection control with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. In addition to gloves, use gown and goggles if exposure to body fluids is likely.
- To minimize the risk of bradycardia, the NPD 1000 Negative Pressure Wound Therapy System must not be placed in proximity to the vagus nerve.
- Consider use of a skin preparation product to protect periwound skin.
- If any signs of irritation or sensitivity to the dressing or tubing assembly appear, discontinue use and consult a physician immediately.
- To avoid trauma to the periwound skin, do not pull or stretch the dressing during application.
- Extra caution should be used for patients with neuropathic etiologies or circulatory compromise.

WARNINGS, CAUTIONS & ADVERSE REACTIONS con't

- When using the NPD 1000 Silver Dressing, do not use topical solutions or agents that may have adverse interactions with silver. Dressing effectiveness may decrease if used with products containing saline, chlorine, potassium, iodine and hydrogen peroxide.
- Do not allow the NPD 1000 Silver Dressing to come in contact with EKG or other electrodes or conductive gels during electronic monitoring, or when taking electronic measurements.
- The NPD 1000 Silver Dressing contains metallic silver that may impair visualization with certain imaging modalities.
- Operation of the NPD 1000 in the presence of high magnetic fields, such as those produced by an MRI (Magnetic Resonance Imager), has not been tested and is not recommended. Incorrect operation could result.

Adverse Reactions

- Excessive bleeding is a serious risk associated with the application of suction to wounds which may result in death or serious injury. Careful patient selection, in view of the above stated contraindications, warnings and precautions, is essential. Carefully monitor the wound and dressing for any evidence of a change in the blood loss status of the patient. Notify the Physician of any sudden or abrupt changes in the volume or the color of exudate.

PRODUCT OVERVIEW

PRODUCT OVERVIEW

Negative Pressure Pump

The NPD Negative Pressure Wound Therapy Pump Device contains a microprocessor-controlled pump and pressure sensor working in feedback fashion to control the pressure under the wound dressing. (Fig. 1).

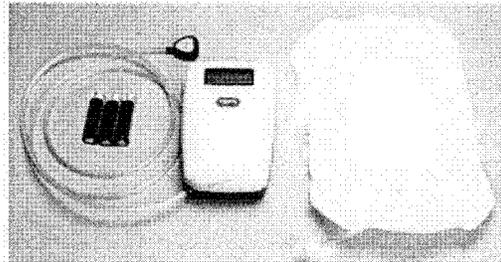


Fig. 1. Kalypto Negative Pressure Wound Therapy Device & Accessories

It has a user interface of three buttons to control the treatment mode, pressure setting and turn the device ON/OFF. It is powered by 3 AA alkaline batteries. Additionally, it has 6 ft. of tubing with a pressure fitting between the pump and the dressing.

The pump applies controlled suction, adjustable by the user, in the vacuum range (negative pressure) from 40 mmHg to 125 mmHg. The pump operates in continuous and intermittent modes. For therapy status notification, it has a proprietary leak detection system, a low battery indicator and therapy proceeding indication.

CLINICIAN INFORMATION

PRODUCT OVERVIEW- ASSEMBLING THE PUMP

ASSEMBLING THE PUMP

CAUTION: Be careful when assembling device to not pinch your fingers between the two parts.

The NPD 1000 Negative Pressure Pump device consists of two pieces: a system controller and one of two pump housings – continuous (NPD 1000c) or intermittent (NPD 1000i). (See Fig. 2)

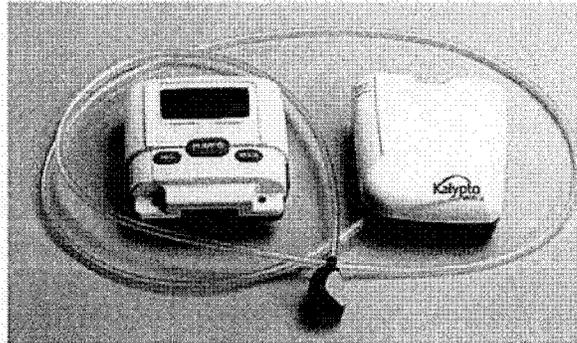


Fig. 2: Kalypto Negative Pressure Pump Subassemblies

CLINICIAN INFORMATION

Both pump housings can provide continuous therapy. However, the NPD 1000i housing is the only one that can perform intermittent therapy. Neither the system controller nor the pump housings are provided sterile and do not need to be sterilized between subsequent patients.

PRODUCT OVERVIEW- ASSEMBLING THE PUMP con't

To assemble the two pieces into a functioning negative pressure wound therapy device, fit the two subassemblies together by matching the male and female connector housings and pressing them together. (Fig. 3a)

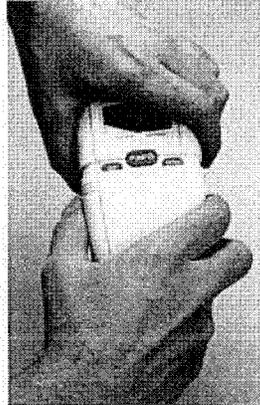


Fig. 3a Assembling the control and pump modules

Insert accompanying screws into pump housing, tighten to point of resistance, Fig. 3b. **DO NOT** overtighten.

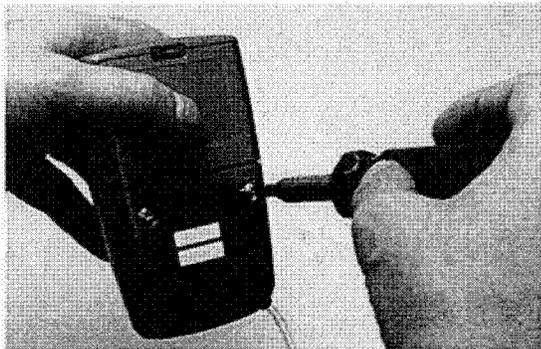


Fig. 3b: Inserting screws to secure control and pump

This will secure the device and prevent the modules from separating. The system controller automatically recognizes whether a continuous or intermittent pump has been attached.

CLINICIAN INFORMATION

PRODUCT OVERVIEW - APPLYING THE DRESSING

NPD 1000 Negative Pressure Wound Therapy Dressing

The NPD 1000 Dressing Technology is a state-of-the-art product that delivers the benefits of negative pressure therapy with a disposable fluid absorbing dressing. It is best used on wounds occurring on anatomical surfaces which will allow the dressing to seal appropriately when vacuum is applied. Highly curved surfaces such as those found below the ankle or on the hand may create difficulties in achieving an adequate vacuum seal.

It is comprised (See Fig. 4) of a semi-occlusive outer layer that maintains negative pressure (1), a pressure port (2a) with an in-line hydrophobic, anti-bacterial filter (2b) which attaches the NPD Pump system, a gasket to seal the wound area(3), a super-absorbing non-woven polymer matrix to absorb exudates(4) and a non-adherent silver-coated wound contact layer to provide effective protection against microbial contamination (5). The dressing also has three windows near the pressure port (6) to monitor the level of exudate in the dressing.

CLINICIAN INFORMATION

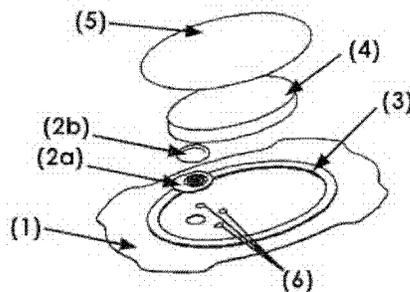


Fig. 4: Components of Kalypto Negative Pressure Dressing

Applying the Dressing

Carefully inspect the wound and treat per the order of the patient's physician and according to the institution's protocol and standards of practice for wound care. This should include proper hand washing and gloving practices. Appropriate skin prep should be used to preserve the wound margins and prevent epithelial stripping.

1. Prior to application of the cover, ensure that the skin that will be under the dressing the wound is clean, dry and shaven. This will ensure proper adherence and sealing of the thin film dressing.
2. Use of a skin preparation layer may protect peri-wound skin and promote and prolong cover adhesion.
3. Remove the NPD 1000 dressing consumables from the sterile package.

APPLYING THE DRESSING con't

4. Remove the release liner from the dressing exposing the adhesive side of the dressing and the sealing gasket. (Fig. 5)



Fig. 5: Removing the dressing release liner

5. Carefully place the dressing on the wound, taking care to minimize folds and wrinkles. (Fig. 6). Do not force the wound dressing into the wound. The application of negative pressure will cause the dressing to conform to the surface of the wound



Fig. 6: Applying the dressing over a wound

CLINICIAN INFORMATION

PRODUCT OVERVIEW - APPLYING THE DRESSING CONT

6. Run your finger along the perimeter of the gasket to secure the gasket material to the skin and increase the dressing seal, Fig. 7.

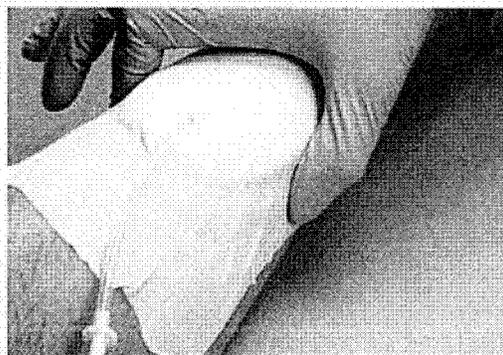


Fig. 7: Securing sealing gasket to skin

7. Attach provided pigtail tubing to the port on the top of the dressing. (Fig. 8)

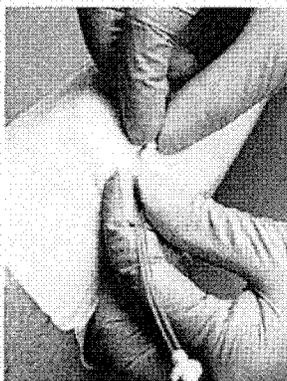


Fig. 8 Attach pigtail tubing to dressing

The dressing is now ready for application of negative pressure.

CLINICIAN INFORMATION

PROGRAMMING THE PUMP

PROGRAMMING THE PUMP

CAUTION: When programming the pump system, make sure that the settings match exactly those specified by the physician. Not following the negative pressure therapy prescription, could result in sub-optimal therapeutic results.

Before attaching the pump device to the patient's dressing, the clinician should set the device to the appropriate treatment settings in the following way:

1. Slide the bottom cover down to expose the programming, labeled "VAC" and "MODE", buttons, Fig. 9.

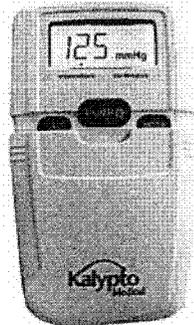


Fig. 9 Negative Pressure Wound Therapy Pump
Programming Buttons

2. Depress and hold the "VAC" and "MODE" buttons simultaneously, while also pressing the power button, for one second.
3. Release the buttons and the device will beep twice and the pressure setting on the screen will blink, indicating the device is in programming mode.
4. Depress the "MODE" button to toggle the device between "continuous" and "intermittent" therapy, according to the placement of the tic mark on the display. For a description of "continuous" and "intermittent" therapy, see the Product Description section of this IFU.
5. Next depress the "VAC" button to set the pressure. The system cycles down 15 mmHg for each button push. The available settings are 40, 50, 65, 80, 95, 110 and 125 mmHg. The default setting of the device is 125mmHg of vacuum.
6. After setting the device to the prescribed therapy, press the power button, briefly, to exit setup mode.
7. Slide the bottom cover back into place to protect the buttons.

CLINICIAN INFORMATION

CONNECTING THE PUMP & INITIATING THERAPY

CONNECTING THE PUMP & INITIATING THERAPY

1. Trim pump tubing to appropriate length with a scissors, Fig 10. When determining the tube length, take into consideration where and how the patient will carry the device during mobile use and how the device will be placed during stationary use.

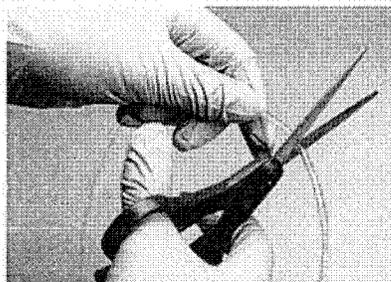


Fig. 10: Trimming pump tubing to length

2. Attach proprietary connector to newly trimmed tubing, black plastic piece with gray button and hose barb. Push the end of the tubing entirely over the hose barb at the end of the connector.
3. Attach the pump to the dressing by mating the connector on the pump tubing to the connector on the dressing tubing, Fig. 11.



Fig. 11: Connecting the pump to the dressing

4. Depress the ON/OFF button for one second and release. The pump should turn on and the dressing should begin to contract under the application of negative pressure. Additionally the therapy proceeding icon  should appear in the upper left hand corner of the screen.

CLINICIAN INFORMATION

CONNECTING THE PUMP & INITIATING THERAPY CONT

5. As the air is removed underneath the dressing, the surface of the dressing will contract toward the surface of the wound. When the set therapeutic pressure is reached the pump will shut off.
6. After the pump has shut off, watch the device for 2-3 minutes to be certain of the quality of the seal on the dressing. If the leak icon  does not appear, The pump should only run very briefly every 30 seconds to 5 minutes (depending on the quality of the dressing seal) once the therapy has started. In the RUN mode, the user may not even hear the pump when it is operating.
7. The patient can know that the system is operating as needed by looking at the screen and finding the therapy proceeding icon  in the upper left hand corner.
8. If the user or clinician notices, either an audible beep from the device or visual indicator on the screen, either the low battery indicator icon  or the leak icon , during setup or during therapy, proceed to the troubleshooting section of this IFU.

Wearing the Device

For the ambulatory patient, the pump may be carried in their pocket, purse, or any other convenient location. It does not need to be next to the wound.

For use in the home, pump can sit on a bedside table or any other convenient location within the 6 foot length of the negative pressure tubing.

CLINICIAN INFORMATION

TROUBLESHOOTING

TROUBLESHOOTING

The following are the alarm states for the NPD 1000 Negative Pressure Wound Therapy Pump signaled by an audible beep from the device or a visual indication on the LCD display.

All LCD Segments Flashing – This condition indicates a system fault indicating either a mechanical issue with the device or that the dressing has reached capacity.

First, check to see if the problem is a full dressing. Check the three window near the vacuum port on the dressing. If they are discolored, indicating the presence of exudate near the vacuum source and the pump is LCD is flashing, the dressing should be changed. Turn off the pump and disconnect the tubing.

If the dressing is not full, turn off the device, remove the batteries for 30 seconds, replace and turn the device on again. If the condition is repeated after this process, the device will not function properly. Interrupt therapy and turn off the device. The clinician should contact their Kalypto Medical sales representative. The patient should call you're their clinician for guidance.

CLINICIAN INFORMATION

Leak Balloon Icon () On – If the leak icon is present, the system has a leak in the dressing, the tubing or the device. Depending on the source of the leak, the user may or may not be able to fix it. First, verify that the wound site was appropriately prepared; the periwound skin was cleaned and dried and the skin under the dressing was shaved smooth. If this is the case, the most likely source of a system leak is the dressing so troubleshooting should start there.

Dressing Leaks – First, run your fingers along the perimeter of the gasket applying gentle pressure. Also, smooth out any wrinkles in the semi-occlusive dressing outside the gasket. Wait for 2 to 3 minutes to see if the alarm condition goes away. For a new dressing, the gasket may take a few minutes to seat itself properly to provide a good seal.

If the leak icon does not disappear after two attempts to seat the gasket, then the leak may be in the tubing or the device.

Tubing Leaks – First, make sure the tubing is securely attached to all of the fittings, including the pressure port on the dressing and the quick connect fittings that connect the pump device to the dressing. The connection should be firm enough to withstand a firm tug on the tubing.

No Dressing or Tubing Leak - If after verifying that the tubing connections are good, the leak icon is still present, a existing dressing should be removed and disposed of in accordance with local regulations. Apply a second dressing and attempt to achieve a good seal (follow directions found in the "Applying the Dressing" section of this IFU). If the second dressing has been applied in accordance with the instructions and a leak still exists, it is likely that the leak is in the pump itself. Call your clinician

TROUBLESHOOTING CONT

for guidance. Clinicians having this problem should call their Kalypto representative for instructions as the device may need servicing that can only be done in the factory.

Low Battery Icon () On – If you see the low battery indicator, replace the batteries. First, turn off the device by pressing the ON/OFF button for one second.

NOTE: If the batteries are low in the middle of therapy, there is no need to disconnect the pump unit from the bandage.

Remove the battery door, pull upwards on the battery removal strap and remove the batteries. Place new batteries in the battery holder in the orientation found in the battery holder. Replace the battery door. Turn on the device by pressing the ON/OFF switch for one second. The device will return to the therapy mode in place when the device was turned off.

Disabling the Audible Alarm - The audible alarm warns the user of the presence of a performance problem with the device. These alarms are also displayed on the LCD display. For many reasons, the user may wish to disable the audible alarm for a few minutes.

The alarm sound can be temporarily disabled by pressing any of the three blue buttons briefly. This will disable the alarm for 5 minutes. After which time, it will sound again if the alarm state still exists.

CLINICIAN INFORMATION

COURSE OF THERAPY WITH THE NPD 1000

COURSE OF THERAPY WITH THE NPD 1000

Dressings should be changed per the standard protocol for negative pressure wound therapy. The patient/clinician can monitor the level of fluid in the dressing by examining the three windows in the dressing near the pressure port. If they appear discolored (as in exudate is being absorbed in the pad near the pressure source), the pump and dressing should be monitored for signs that the dressing has reached capacity. These are 1) the pump has not turned on (to maintain the negative pressure in the dressing) for an extended period of time, 2) the dressing does not have the appearance (shriveled and firm to touch) of being under negative pressure as was evident at the application of the dressing. If the dressing and/or pump meets the above criteria, the wound care professional should consider changing the dressing.

CLINICIAN INFORMATION

SERVICE & CLEANING OF THE PUMP DEVICE

SERVICE AND CLEANING OF THE PUMP DEVICE

The NPD 1000 Negative Wound Therapy Pump is designed to have a service life of multiple patients. However, before the device can be given to a new patient, the external case of the pump must be cleaned and disinfected. (**Note:** the internal plumbing of the pump does not need to be cleaned as it is protected by anti-bacterial and fluid filters on each dressing.)

These devices are tested to an IPX0 rating. Thus, they cannot be immersed in water or subject to large volumes of water spray such as in the shower. The outside case of both the system controller and pump housings can be cleaned using the procedure articulated below. No solvents should be used. Do not open either device housing (except the battery door, as proper operation cannot be assured once this has happened.

SERVICE

1. There are no user serviceable components inside the Kalypto NPD 1000 Wound Therapy System Pump.
2. Contact your Kalypto representative for return/replacement of damaged pumps.
3. Do not open the NPD 1000 pump or attempt to service it yourself.

CLEANING

1. Use cloth dampened with tap water and household dishwashing soap to clean the external surfaces. Wipe down until visibly clean.
2. Wipe the external surfaces again with a cloth dampened with water (no soap) to remove the residual soap. Wipe until no longer "slippery", then allow to air dry.
3. Wipe external surface with 70% ethyl alcohol and allow to air dry.
4. Visually inspect for cleanliness.

DISPOSAL OF DRESSING AND PUMP

The NPD 1000 dressing is not constructed with any hazardous materials. Subsequently, after use it can be disposed of in the normal medical waste stream for wound care dressings.

The NPD 1000 Negative Pressure Wound Therapy Pump System is an electromechanical device powered by non-integral batteries. The batteries and device should be recycled according the local regulations governing such products.

CLINICIAN INFORMATION

PRODUCT SPECIFICATIONS

Dimensions:	3.2" W x 5.1" H x 1.3" D
Weight:	8 oz.
Pressure Options:	-40 to -125 mmHg or -.77 to -2.4 PSI -5.3 to -16.6 kPa
Therapy Delivery Modes:	Continuous & Intermittent
Battery Type:	Alkaline
Battery Life:	3 weeks or more
Patient Enclosure	
Leakage Current:	N/A (Battery powered device)
Storage Conditions:	Temperature Range -20 °C to +60 °C
	Relative Humidity Range 0 to 95% non-condensing
Operating Conditions:	Temperature Range +5 °C to +40 °C
	Relative Humidity Range 0 to 95% non-condensing
Altitude Range	Operating -1000 ft to +10,000 ft
	Storage -1000 ft to +18,000 ft
IEC Classification	- Medical Equipment - Equipment not suitable for use in the presence of flammable anesthetic mixture - Type B, Applied Part - Class II - IPX0

CLINICIAN INFORMATION

Specifications subject to change without notice.

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic Compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this user manual. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The NPD 1000 is intended for use in the electromagnetic environments specified below. The customer or the user of the NPD 1000 should assure it is used in such an environment.

Emissions Test	Compliance	Guidance
RF Emissions CISPR 11	Group 1	The NPD 1000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The NPD 1000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not Applicable	

CLINICIAN INFORMATION

ELECTROMAGNETIC COMPATIBILITY Con't

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The NPD 1000 is intended for use in the electromagnetic environments specified below. The customer or the user of the NPD 1000 should assure it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
Electrostatic Discharge IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/ Burst IEC 61000-4-4	Not Applicable	Not Applicable	The NPD 1000 has no connection to Mains
Surge IEC 61000-4-5	Not Applicable	Not Applicable	The NPD 1000 has no connection to Mains
Voltage Dips, Short Interrupts, & Variations on Power Supply Lines IEC 61000-4-11	Not Applicable	Not Applicable	The NPD 1000 has no connection to Mains
Power Frequency Magnetic Fields IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

CLINICIAN INFORMATION

ELECTROMAGNETIC COMPATIBILITY Con't

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The NPD 1000 is intended for use in the electromagnetic environments specified below. The customer or the user of the NPD 1000 should assure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>Not Applicable</p> <p>3 VRMS 80 MHz to 2.5 GHz</p>	<p>Not Applicable</p> <p>3V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the NPD 1000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ <p>(80 MHz to 800 MHz)</p> $d = 2.3\sqrt{P}$ <p>(800 MHz to 2.5 GHz)</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). b</p> <p>Filed strengths from fixed RF transmitters, as determined by an electromagnetic site survey, c should be less than the compliance level in each frequency range. d</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol</p>

CLINICIAN INFORMATION

con't next page

ELECTROMAGNETIC COMPATIBILITY Con't

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NPD 1000 is used exceeds the applicable RF compliance level above, the NPD 1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NPD 1000.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

CLINICIAN INFORMATION

ELECTROMAGNETIC COMPATIBILITY

Recommended separation distances between portable and mobile RF communications equipment and the NPD 1000

The NPD 1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NPD 1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NPD 1000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)
---	---

	150kHz to 80MHz	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	Not Applicable	0.12	0.23
0.1	Not Applicable	0.37	0.74
1	Not Applicable	1.2	2.3
10	Not Applicable	3.7	7.4
100	Not Applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CLINICIAN INFORMATION

PATIENT INFORMATION & INSTRUCTION

PATIENT INFORMATION AND INSTRUCTION

PLEASE READ CAREFULLY

Overview of Negative Pressure Wound Therapy

Negative Pressure Wound Therapy (NPWT) is used to promote wound healing for a variety of wounds that are difficult to treat or having difficulty healing with the use of conventional wound dressings. It involves the use of a negative pressure pump (vacuum) and a special pressure sealing dressing. The wound dressing is placed over the wound and connected to the pump with medical tubing. The pump is turned on and the air under the dressing is removed. The removal of the air causes the dressing to exert a small mechanical force on the wound bed. Additionally, the negative pressure helps draw out various fluids produced by the body at the site of the wound. The pump removes these fluids from the tissues and they are stored in the dressing. The Kalypto Medical NPD 1000 Negative Pressure Wound Therapy system is a state-of-the-art medical device designed to deliver negative pressure wound therapy to wounds that may benefit from the application of such treatment.

What to expect during treatment

After your wound care professional has determined that your wound is a candidate for NPWT, the NPD 1000 system was prescribed. The system includes a battery-operated negative pressure pump, a negative pressure wound dressing and medical tubing to connect the pump to the dressing. On the first day, the wound care professional will apply your wound dressing and connect the pump to the dressing and turn on the device. As the air is removed from underneath the dressing, the dressing will shrink and press down on your skin. You should feel a slight mechanical force under the dressing. At this point, barring a battery change or an unlikely mechanical issue, you should not have to adjust the device until you see your wound care professional for a dressing change. Once therapy begins, the wound dressing should be changed every two to three days by your wound care professional. Therapy will proceed in this fashion until the wound care professional determines that the NPWT treatment is no longer necessary.

PATIENT INFORMATION

PATIENT INFORMATION & INSTRUCTION con't

Operation of the Device

Patient instructions for the operation of the device are as follows:

Negative pressure wound therapy is a 24 hour a day treatment. Once set up and turned "ON" by your healthcare professional, you should not need to adjust the system other than to address an unusual, but possible, alarm or change the batteries. For directions with regards to these issues, see the Alarms and Troubleshooting section in the pages that follow.

For the ambulatory patient, the pump may be carried in their pocket, purse, or any other convenient location. It does not need to be next to the wound.

For use in the home, pump can sit on a bedside table or any other convenient location within the 6 foot length of the negative pressure tubing.

The patient SHOULD NOT change or remove the dressing between visits with their wound care provider. The wound dressing is designed to meet the needs of the patient for the entire time between visits and should not be changed except by the clinician.

Full Dressing

In some cases, it may be possible that the wound is producing so much fluid that the dressing reaches its fluid absorption capacity. The patient can monitor the level of fluid in the dressing by examining the three clear windows in the dressing near the pressure port . **If they appear discolored, as wound fluid is being absorbed in the pad near the pressure source, the pump and dressing should be monitored for signs that the dressing has reached capacity.** Additionally the other signs of a full dressing are:

- 1) The pump has not turned on (to maintain the negative pressure in the dressing) for an extended period of time.
- 2) All of the LCD icons are flashing on the pump screen, the numbers, the low battery icon() and the balloon icon 
- 3) The dressing does not have the appearance (shriveled and firm to touch) of being under negative pressure as was evident at the application of the dressing.

If the dressing and/or pump meets the above criteria, turn off the pump, and contact your woundcare professional. Do not remove dressing.

PATIENT INFORMATION

PATIENT INFORMATION & INSTRUCTION con't

Powering "ON" the Device

Note: This should only be necessary for the patient if the device was inadvertently turned OFF for some reason or the batteries needed to be changed.

Depress the ON/OFF  button for one second and release. The pump should turn on and the dressing should begin to contract under the application of negative pressure. Additionally the "pump operational" icon  should appear in the upper left hand corner of the LCD display indicating the system is working. The device can be shut off by depressing the ON/OFF button again for one second and releasing.

As the device is applying vacuum to the dressing, the dressing should appear to contract against the skin and become firm to the touch. After the dressing has reached the target pressure, **the pump will shut off**. If it continues to run, beyond 1 or 2 minutes, the seal of the dressing will need to be improved. Watch the device for 2-3 minutes to be certain of the quality of the seal on the dressing. If the leak icon  does not appear the seal is good. The pump should only run very briefly every 30 seconds to 5 minutes (depending on the quality of the dressing seal) once the therapy has started. In the RUN mode, the user may not even hear the pump when it is operating.

PATIENT INFORMATION & INSTRUCTION con't

Maintenance and Care of the system

The patient is not responsible for the maintenance of the device. In fact, the device is designed to be maintenance free, meaning other than changing batteries in the pump, the patient should not have to service the device.

If the device were to get dirty, clean the surface of the pump as follows:

- Do not immerse in water or expose to water sprays, or other liquids
- Use cloth dampened with tap water and household dishwashing soap to clean the external surfaces. Wipe down until visibly clean.
- Wipe the external surfaces again with a cloth dampened with water (no soap) to remove the residual soap. Wipe until no longer "slippery".

As for caring for the NPD 1000, take the following precautions with the device during use

- Keep away from open flames or high heat
- Be careful to not allow the device to drop onto hard surfaces, such as a floor
- Do not set anything on top of the pump

PATIENT INFORMATION

PATIENT INFORMATION & INSTRUCTION con't

Alarms and Troubleshooting

The NPD 1000 Negative Pressure Wound Therapy Pump has various alarms to let the user know of any system malfunctions. Some alarms are serviceable by the patient, others may require a call to your clinician. Under no circumstances should a patient try to service the device outside of the instructions provided below. All of the system malfunctions (or momentary problems) are signaled by an audible beep from the device and/or a visual indication on the LCD display. Each section below details the reasons for device alarms, the potential source of the problem and the possible fixes to be tried by the patient or home caregiver.

Audible Beep (alarm) heard – If the user hears an audible beep from the device, he/she should inspect the display on the pump to determine the nature of the problem. The user is notified of all problems with the device by the audible beeping sound. An audible beep will be produced by the device to notify the user of any problem, including LOW BATTERY and DRESSING LEAK.

All LCD Segments Flashing – This condition indicates a system fault. Turn off the device, remove the batteries for 30 seconds, replace and turn the device on again. If the condition is repeated after this process, the device will not function properly. Turn off the device. At this point, the patient should call their clinician for guidance.

Leak Balloon Icon () On – If the leak icon is present, the system has a leak in the dressing, the tubing or the device. Additionally, the dressing may feel soft or the pump is running continuously. Depending on the source of the leak, the patient may or may not be able to fix it.

Dressing Leaks – First, run your fingers along the perimeter of the gasket applying gentle pressure, see picture below. Also, smooth out any wrinkles in the dressing outside the gasket. Wait for 2 to 3 minutes to see if the alarm goes away. For a new dressing, the gasket may take a few minutes to seat itself properly to provide a good seal.



If the leak icon does not disappear after two attempts to seat the gasket, then the leak may be in the tubing or the device.

PATIENT INFORMATION & INSTRUCTION con't

Tubing Leaks – First, make sure the tubing is securely attached to all of the fittings, including the pressure port on the dressing and the fittings that attach the pump device to the dressing. The connection should be strong enough to withstand a firm tug on the tubing.

No Dressing or Tubing Leak – If the leak icon is still present checking for dressing and tubing leaks, turn off the pump, by depressing the ON/OFF button for one second and contact your health care provider. The problem is not serviceable by the patient.

Low Battery Icon () On – If you see the low battery indicator, replace the batteries. First, turn off the device by pressing the ON/OFF button for one second.

NOTE: If the batteries are low in the middle of therapy, there is no need to disconnect the pump unit from the bandage.

Remove the battery door, pull upwards on the battery removal strap and remove the batteries. Place new batteries in the battery holder in by following the +/- orientation found in the battery holder. Replace the battery door. Turn on the device by pressing the ON/OFF switch for one second. The device will return to the therapy mode as set when the device was turned off.

Disabling the Audible Alarm - The audible alarm warns the user of the presence of a performance problem with the device. These alarms are also displayed on the LCD display. For many reasons, , including inconvenient location, church, movie, etc., the user may wish to disable the audible alarm for a few minutes.

The alarm sound can be temporarily disabled by pressing any of the three blue buttons briefly. This will disable the alarm for 5 minutes. After which time, it will sound again if the problem still exists.

End of Therapy and Returning the NPD 1000 device

As the negative pressure therapy proceeds, the healing of the wound will progress to a point at which the clinician will determine that the NPD 1000 system is no longer necessary. **DO NOT DISCONTINUE USE OF THE NEGATIVE PRESSURE WOUND THERAPY SYSTEM WITHOUT THE CONSENT OF YOUR WOUND CARE PROFESSIONAL.** Ask your clinician for guidance on the return of the pump. **DO NOT THROW THE PUMP IN THE TRASH.** It is likely that you will be returning the device to the clinician, the hospital or nursing facility or be required to call your home medical equipment provider. Your clinician will be able to tell you what to do once therapy has been terminated.

PATIENT INFORMATION

KALYPTO MEDICAL CONTACT INFORMATION



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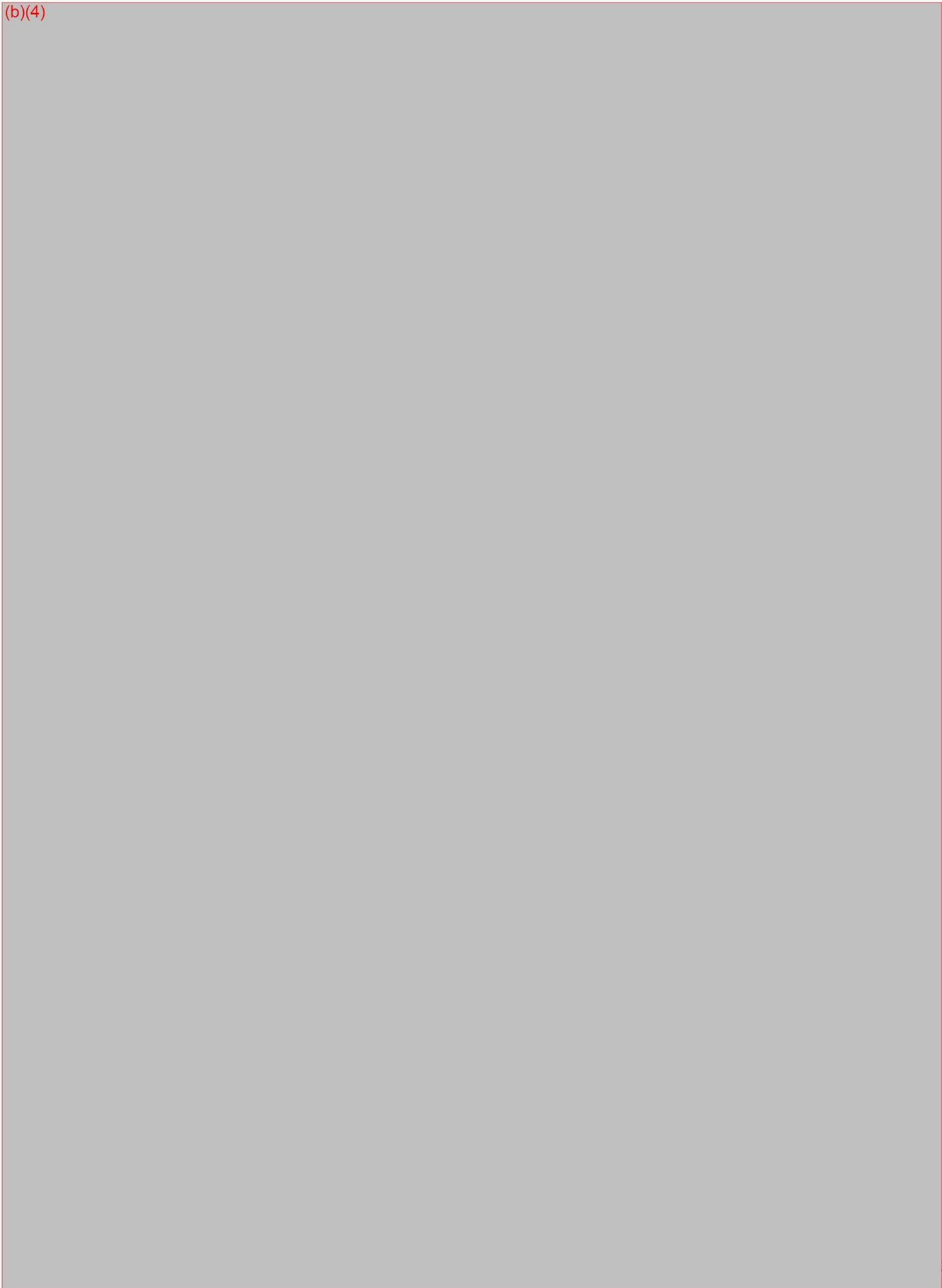
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P/N 50000 Rev. A © Kalypto Medical 8/08

Feedback Loop Flow Chart

(b)(4)



DP-0001-84-0

Verification Test Procedure Test Results Data Sheets

(Note: Pages 24-74 were intentionally omitted)

For Complete Report see Vol. 2 of 2, Appendix 9, pages 13-116
of the Original 510(k) Submission

Capricorn Verification Test Procedures

Minnetronix[®] Document # DP-0001-84-0
Revision: .02-a

Exported from Caliber
December 20, 2007

*TEST RESULT DATA
SHEETS.*

ZAB 1/21/08

Prepared for:
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Hastings, MN

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1 h General Instructions (SYSTST55525)*Status: Accepted Requirement Version: 2.0*

This is the Verification Test Procedures (VTP) document for the Iasis Medical, LLC Micro Negative Pressure Wound Therapy (NPWT) System (project name: Capricorn). The system consists of a Control Unit, a Pump Unit (continuous or intermittent), disposable batteries, a custom Bandage, and a tube set to connect the Pump Unit to the Bandage.

All traceable requirements will be verified via execution of the test cases within this plan.

Record formal test results on Test Results Data Sheets (TRDS). Acceptable TRDS are hardcopy pages of the VTP as exported via Document Factory from Caliber-RM, hardcopy individual test cases as printed from Caliber-RM, and filled in/completed test result data sheet form(s). Note: Applicable test result data sheet form(s) may be found in the References tab.

Record tester's name or initials, date of test execution, and revision of the Capricorn System Requirements Specification being tested against.

Positively identify all tools and equipment used. Include the following:

- Record all IDs and serial numbers of hardware in use (this includes UUTs, test equipment, etc.).
- Record calibration date(s) of all test equipment.
- In the case of Minnetronix developed test tools, record MKS label and revision, and include a pointer to qualification information.

Note: Deviations to the test procedures will be documented on the TRDS or in the Verification Report.

Note: Unless otherwise noted, all timing and performance requirements shall have a tolerance of +/- 10%.

Reference: \\Mxcaliber\caliberreferences\Capricorn\TestResultsDataSheet.doc

This requirement traces from:

1.1 h References (SYSTST55526)*Status: Accepted Requirement Version: 2.0*

The following documents were used as references when creating this document:

Minnetronix Documentation

- DQ-0000-21-0 Minnetronix Design Verification and Validation SOP
- DP-0001-83-7 Capricorn Hazard Analysis
- DP-0001-85-0 Capricorn System Verification and Validation Plan
- DP-0001-84-2 Capricorn System Requirements Specification
- DP-0001-84-1 Capricorn FMECA

External Documentation

- FDA General Principles of Software Validation; Final Guidance for Industry and FDA Staff (January 11, 2002)
- FDA Guidance Document for Powered Suction Pump 510(k)s (September 30, 1998)

This requirement traces from:

2 h Standard Test Setup (SYSTST55527)

Status: Accepted Requirement Version: 4.0

The standard setup/configuration used for Capricorn NPWT System testing is as follows:

- One complete and finished Control unit with all parts (housing, PCB, UI display, batteries, etc.) and software ECO released
- One complete and finished Continuous and/or one complete and finished Intermittent pump unit with all parts (housing, PCB, pump motor, etc.) ECO released
- One set of bandage to pump tubing
- One bandage or 60cc syringe
- One variable output DC Power Supply
- One Digital Multimeter (DMM)
- One Oscilloscope
- One Stopwatch

With the batteries installed in the control unit (device automatically On), connect the control unit to the pump unit. Seal the bandage to the appropriate test surface or use the syringe and connect the tubing from the bandage to the pump. Turn the pump on at the default pressure setting.

Note: The Control unit displays the negative pressure setpoint in absolute value (ie. does not display the negative symbol). So an increase in displayed value is actually a decrease in pressure. Likewise, a decrease in displayed value is actually an increase in pressure.

Note: The default unit under test (UUT) sample size is one (1) unless specified otherwise in each individual test case.

This requirement traces from:

3 h Functional Tests (SYSTST55528)

Status: Accepted Requirement Version: 3.1

The following functionality of the Capricorn NPWT System will be tested within this section of the test plan:

- Therapy Delivered (continuous or intermittent) and Duration
- Vacuum Pressure
- Fault Monitoring (system fault, low battery and leak detected)
- Fault Response (audible and visual)
- Calibration
- Parameter Retention
- Use with Multiple Bandages
- Disposal of System Components
- Software Upgrade

For a complete listing of specific requirements see Capricorn System Requirements Specification document (DP-0001-84-2).

This requirement traces from:

3.1 Test Case FT001 - Power On Self Tests (SYSTST55788)

Status: Accepted Requirement Version: 10.1

Introduction

This test will verify . . .

a. The Micro NPWT device shall perform the following power on self test (POST) checks each time batteries are changed in the control/display unit:

- UI Display test
- Audio test
- ALU test (test via Unit Test)
- RAM test (test via Unit Test)
- Application CRC check (test via Unit Test)
- Watchdog test (test via Unit Test)
- Key Stuck test

b. The Micro NPWT device shall notify the user if any of the power on self test checks failed, thus indicating that the device is unable to deliver therapy.

c. The Micro NPWT device shall notify the user if a system fault occurs. Note: system faults consist of POST failures, NVRAM failures, loss of pump control, pump inoperable, and the inability to provide intermittent therapy. (only POST failure tested here)

d. When POST has successfully completed, the software shall place the software version number on the display for 2 seconds.

Test Setup

1. Standard setup.
2. Control unit set to Continuous therapy mode.
3. Stopwatch.

TEST EQUIPMENT: A, F, I, M, P

Test Procedures and Expected Results

1. Start this test with device batteries removed. Re-insert the batteries and allow power on self tests to complete.

- GGJ
1/3/08
- P/F a. Verify that a UI Display test occurred (all UI display screen elements are turned on, then off).
 - P/F b. Verify that an audio test occurred (three beeps are sounded per the User Interface Design document, DP-0001-84-4).
 - P/F c. Verify that power on self tests all pass and that no system faults occurred.
 - P/F d. Verify after POST has completed, that the software version number is displayed for 2 seconds.

2. Remove the device batteries. Press and hold the Pump On/Off key and re-insert the batteries. Allow power on self tests to complete. Repeat this step for the Mode and VAC keys.

- GGJ
1/3/08
- P/F a. Verify that the power on self test for key stuck failed and that the device displays a system fault (all UI display screen elements are blinked multiple times).

3. Attempt to start the pump (press the Pump On button) and deliver continuous therapy.

- GGJ
1/3/08
- P/F a. Verify that the pump does not start and that it continues to display a system fault.

4. Repeat steps 2 and 3 with the Control unit set to Intermittent therapy mode.

- GGJ
1/3/08
- P/F a. Verify results are as expected (1. power on self test for key stuck failed and system fault displayed. 2. pump does not start and continues to display a system fault).

This requirement traces from:

SYSREQ54681: Power On Self Test Check
SYSREQ54688: POST Failure
SYSREQ57195: Software Version Number
SYSREQ54795: System Fault Indication

3.2 Test Case FT002 - Therapy Mode Selection (SYSTST55807)

Status: Accepted Requirement Version: 12.1

Introduction

This test will verify . . .

- a. The Micro NPWT device shall allow the health care professional to set the therapy mode to either continuous or intermittent.
- b. The Micro NPWT device shall notify the user when a therapy mode is selected that does not match the capabilities of the pump module attempting to be installed. Note: this requirement handles the scenario when the clinician is attempting to swap pump modules on a display/control unit that is already programmed for a specific therapy mode.
- c. The Micro NPWT device shall prevent the user from selecting a therapy mode that does not match the capabilities of the pump module installed. Note: this requirement handles the scenario when the pump module is already attached and the clinician wants to change the therapy mode.
- d. The control unit of the Micro NPWT device shall detect which pump module is attached before therapy can begin.
- e. The Micro NPWT display/control unit shall notify the user to changes in status via the pertinent icon.

Note: From the Capricorn User Interface Design document (DP-0001-84-4), to enter Configuration mode in order to change therapy mode or to modify the vacuum pressure setpoint, press and hold the Therapy Type (Mode) button and Pressure Setting (VAC) button simultaneously. While the Mode and VAC buttons are both held down, press and release the Pump On/Off button, then release the Mode and VAC buttons. Once in Configuration mode, to change therapy modes, press and release the Mode button. To change the vacuum pressure setpoint, press and release the VAC button. To exit Configuration mode, press and release the Pump On/Off button or wait 30 seconds from the last button press to time out and automatically exit.

Test Setup

- 1. Standard setup.
- 2. Both Continuous and Intermittent pump units.

Test Equipment: A, B, I, J, L, N, M, P

Test Procedures and Expected Results

- 1. Attach the Continuous pump unit to the control unit. Turn the pump on.
 - P/F a. Verify that the pump turns on and delivers Continuous mode therapy (Continuous is the default therapy type).
 - P/F b. Verify only the Continuous therapy icon/tickmark is active.

2. Turn the pump off. Remove the Continuous pump unit and attach the Intermittent pump unit. Turn the pump on.

EGJ
1/3/08
EGJ
1/3/08

GGJ
1/3/08 P/F a. Verify that the pump turns on and delivers Continuous mode therapy (Intermittent pump unit can deliver both Continuous mode therapy and Intermittent mode therapy).

P/F b. Verify that the Continuous therapy icon/tickmark remains active.

3. Turn the pump off. Enter Configuration mode, press the Mode button until the therapy type is set to Intermittent.

GGJ
1/3/08 P/F a. Verify that the vacuum pressure setpoint display is active and flashing (signals that the device is in configuration mode).

P/F b. Verify that the control unit allows the user to set the therapy type to Intermittent.

P/F c. Verify only the Intermittent therapy icon/tickmark is active and on solid (switch from Continuous tickmark signals a change in therapy mode).

4. Exit Configuration mode and turn the pump on.

GGJ
1/3/08 P/F a. Verify that the pump turns on and delivers Intermittent mode therapy (Intermittent pump unit can deliver both Continuous mode therapy and Intermittent mode therapy).

P/F b. Verify that the Intermittent therapy icon/tickmark remains active.

5. Turn the pump off. Remove the Intermittent pump unit and attach the Continuous pump unit. Attempt to turn the pump on.

GGJ
1/3/08 P/F a. Verify that the pump does **not** turn on and does **not** deliver Intermittent mode therapy (Continuous pump unit can not deliver Intermittent mode therapy).

P/F b. Verify that the Intermittent therapy icon/tickmark remains active.

6. Enter Configuration mode, press the Mode button and attempt to set the therapy type to Intermittent.

GGJ
1/3/08 P/F a. Verify with the Continuous pump unit attached that the control unit does **not** allow user to set the therapy type to Intermittent mode.

7. Enter Configuration mode, press the Mode button until the therapy type is set to Continuous.

GGJ
1/3/08 P/F a. Verify that the control unit allows the user to set the therapy type to Continuous.

P/F b. Verify only the Continuous therapy icon/tickmark is active and on solid (signals a change in therapy mode).

This requirement traces from:

SYSREQ54686: Improper Therapy Mode
SYSREQ54751: Attempted Improper Therapy Mode
SYSREQ54691: Pump Presence Detect
SYSREQ54675: Therapy Mode Selection
SYSREQ54728: Visual Notifications

3.2.1 Test Case FT002a - Continuous Mode (SYSTST55816)

Status: Accepted Requirement Version: 8.1

Introduction

This test will verify . . .

a. The Micro NPWT system shall deliver continuous V.A.C. therapy up to 125 mmHg. Note: V.A.C. = vacuum assisted closure of wounds.

Test Setup

1. Standard setup (control unit w/Continuous pump unit).
2. One independent pressure sensor connected in-line with the bandage tubing.
3. Stopwatch.

TEST EQUIPMENT: A, E, I, L, E

Test Procedures and Expected Results

1. Enter Configuration mode, press the VAC button until the vacuum pressure is set to 125 mmHg. Exit Configuration mode and turn the pump on. Wait at least 3 minutes per SYSREQ54730 for initial bandage negative pressure drawdown. Allow the unit to run for a minimum of 4 hours. Note: if a leak occurs, correct the leak and continue the test. If necessary, extend the test run time to compensate for time lost to the leak.

GG
1/3/06

PF a. Verify that no system fault notifications occur (ie. loss of pump control or pump inoperable) due to the inability of the system to deliver and maintain 125 mmHg of negative pressure Continuous therapy over a 4 hour duration.

GG
1/3/06

PF b. Verify that the independent pressure sensors confirm the 125 mmHg negative pressure setpoint is achieved.

This requirement traces from:
SYSREQ54639: Continuous Mode Requirement

3.2.2 Test Case FT002b - Intermittent Mode (SYSTST55817)

Status: Accepted Requirement Version: 11.1

Introduction

This test will verify . . .

- a. The Micro NPWT system shall deliver intermittent V.A.C. therapy up to 125 mmHg. Note: V.A.C. = vacuum assisted closure of wounds.
- b. The intermittent mode cycle time of the Micro NPWT device shall be 5 minutes at the target negative pressure then 2 minutes at atmospheric pressure. Note: this cycle is repeated for the duration of the therapy.
- c. The Micro NPWT device shall notify the user if a system fault occurs. Note: system faults consist of POST failures, NVRAM failures, loss of pump control, pump inoperable, and the inability to provide intermittent therapy. (Note: only inability to provide Intermittent therapy tested here)

Test Setup

- 1. Standard setup (control unit w/Intermittent pump unit).
- 2. One independent pressure sensor connected in-line with the bandage tubing.
- 3. Stopwatch.
- 4. Jumper installed in-line with resistor R2 per the Capricorn Pump Module Schematic, Mntx part # DS-0000-70-5.

TEST Equipment: B, F, J, M, P

Test Procedures and Expected Results

1. Enter Configuration mode, press the VAC button until the vacuum pressure is set to 125 mmHg. Exit Configuration mode and turn the pump on. Wait at least 3 minutes per SYSREQ54730 for initial bandage negative pressure drawdown. Allow the unit to run for a minimum of 4 hours. Note: if a leak occurs, correct the leak and continue the test. If necessary, extend the test run time to compensate for time lost to the leak. Using the stopwatch, record the times when the pump starts up and when the purge valve opens. Calculate the average of these readings. These times are used to determine the Intermittent mode cycle times.

GG
1/3/06

P/F a. Verify that no system fault notifications occur (ie. loss of pump control or pump inoperable) due to the inability of the system to deliver and maintain 125 mmHg of negative pressure Intermittent therapy over a 4 hour duration.

GG
1/3/06

P/F b. Verify that the independent pressure sensors confirm the 125 mmHg negative pressure setpoint is achieved.

GG
1/3/06

P/F c. Verify the Intermittent mode cycle times average 5 minutes at the target negative pressure and 2 minutes at atmospheric pressure.

and add a 10K Ω resistor from U2 pin 4 to ground,

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Capricorn Verification Test Procedures

DP-0001-84-0 Rev. .02-a

2. With the device and pump still on, open the jumper at R2 thus removing control of the purge valve (ie. keeps it shut so it can not open and vent to atmosphere). Wait at least 10 minutes allowing the pump time to cycle 5 min. at the pressure setpoint and 2 min. at atmosphere.

See attachment See Interface Issue #52 (REDLINES)

GG
1/4/08

P/F a. Verify that the device notifies the user that the Intermittent pump module is unable to provide Intermittent therapy (ie. pressure sensor determines that it can not vent to atmosphere).

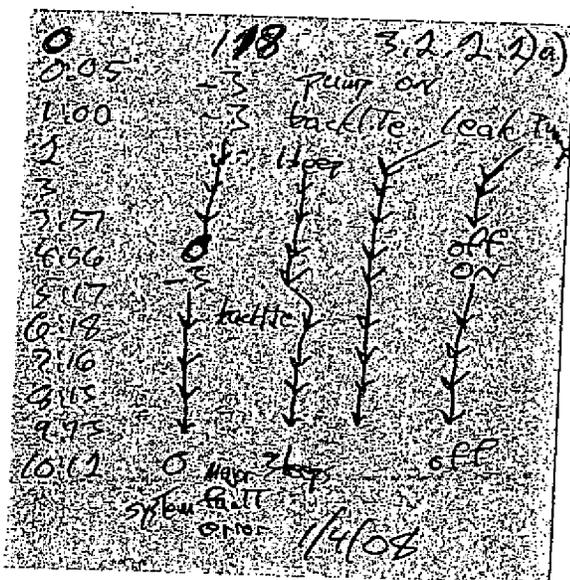
3. Remove the batteries from the device. Replace the jumper at R2. Replace the batteries and allow power on self tests to complete. Turn the pump on. Wait at least 10 minutes.

GG
1/4/08

P/F a. Verify that no system fault notifications occur and that the Intermittent pump module is able to provide Intermittent therapy.

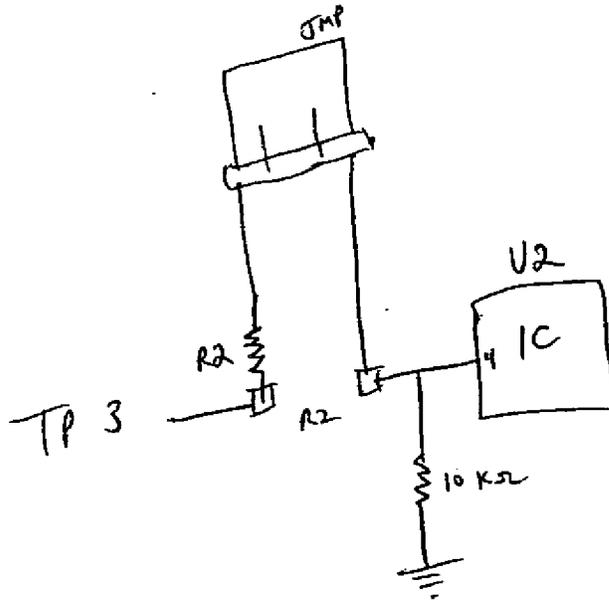
This requirement traces from:

- SYSREQ54744: Intermittent Mode Cycle Time
- SYSREQ54640: Intermittent Mode Requirement
- SYSREQ54795: System Fault Indication

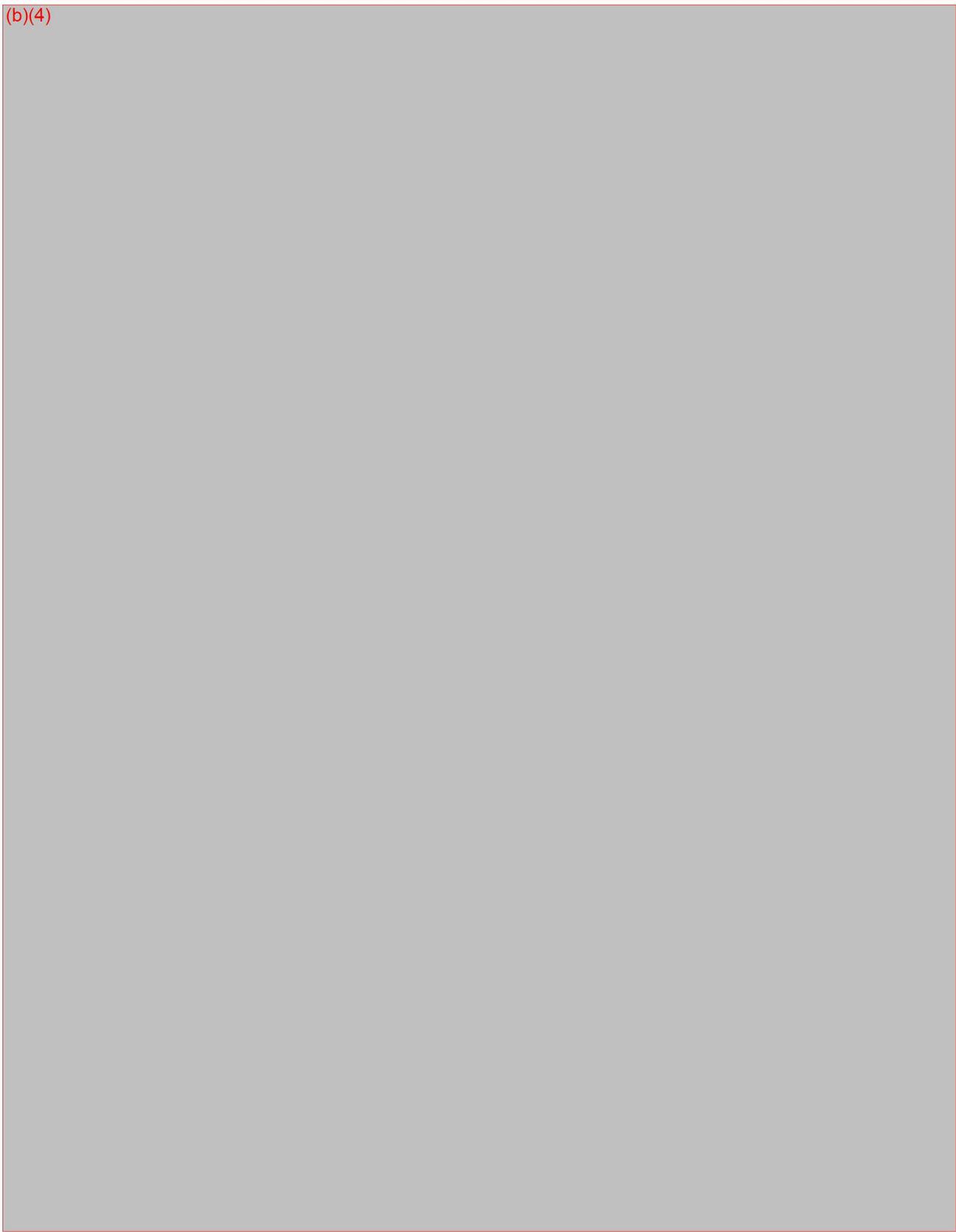


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STEP 3.2.2.2 FT ~~app~~ b



(b)(4)



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(b)(4)



(b)(4)



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(b)(4)



3J
1/10/08

P/F a. Verify that the Continuous pump is able to achieve the set pressure in less than 3 minutes with the largest bandage designed (ie. for the calf).

See attachment

6. Disconnect the bandage tubing quick connector, thus simulating a massive leak in the system. Allow three minutes per SYSREQ54730 for initial bandage negative pressure drawdown. Delay five additional minutes while observing the pressure sensor.

66J
1/11/08

P/F a. Verify that the device notifies the user (via leak detected) that the Continuous pump module is unable to reach the set pressure.

TEST EQUIPMENT: E, F, J, M, P

7. Remove the Continuous pump unit and replace with an Intermittent pump unit. Repeat step 6.

66J
1/11/08

P/F a. Verify that the device notifies the user (via leak detected) that the Intermittent pump module is unable to reach the set pressure.

1:00 leak
5:00 system fault, pump off

8. Turn the pump off. Disconnect the bandage tubing quick connector, thus allowing the bandage to vent to atmosphere. Replace the bandage with a new never before used bandage. Reconnect the bandage tubing quick connector. Set the vacuum pressure to 125 mmHg. Turn the pump on and start the stopwatch at the same time. Stop the stopwatch when the pump stops pumping and when the independent pressure sensor signals a negative pressure of 125 mmHg. Record the elapsed time. Repeat this step 10 times and average the recorded elapsed times. Repeat this step on 4 additional (a total of 5) new never before used bandages.

3J
1/14/08

P/F a. Verify that the Intermittent pump is able to achieve the set pressure in less than 3 minutes with the largest bandage designed (ie. for the calf).

See attachment

This requirement traces from:

- SYSREQ54794: Loss of Pump Control
- SYSREQ54795: System Fault Indication
- SYSREQ54746: Set Point Pressure Tolerance
- SYSREQ54643: Minimum System Vacuum
- SYSREQ54743: Default System Vacuum Pressure
- SYSREQ54644: Maximum System Vacuum
- SYSREQ54730: Time to Set Vacuum Pressure
- SYSREQ54674: Vacuum Pressure Selection

TEST EQUIPMENT: M, P, F, J

9. REPEAT STEP 3 USING AN INTERMITTENT PUMP UNIT WITH VACUUM PRESSURE SET TO 40 mmHg AND THERAPY MODE SET TO CONTINUOUS. (4 HOUR TEST) USED INTERMITTENT BANDAGE #2

7AS
1/12/08

P/F a.

P/F b.

RAN TEST FOR 4:48:52 (11:00:55).

10. REPEAT STEP 4. SET VACUUM PRESSURE TO 125 mmHg. (10 MINUTE TEST)

USED INTERMITTENT BANDAGE #2

7AS
1/12/08

- P/F a.
- P/F b.
- P/F c.
- P/F d.

RAN TEST FOR 13:23 (AMISS).

See Interface Issue #52 (REDLINES)

DP-0001-84-0 Rev. 02-a
 Step 3.4 FT004 Vacuum Pressure

5) Continuous

	<u>#1</u>	<u>#2</u>	<u>#3</u>	<u>#4</u>	<u>#5</u>
1	0:29	0:35	0:32	0:42	0:38
2	0:23	0:25	0:27	0:29	0:25
3	0:24	0:22	0:24	0:28	0:27
4	0:31	0:23	0:24	0:32	0:28
5	0:24	0:21	0:24	0:28	0:26
6	0:26	0:23	0:23	0:29	0:24
7	0:23	0:22	0:24	0:28	0:24
8	0:22	0:21	0:22	0:30	0:23
9	0:21	0:21	0:22	0:27	0:24
10	0:21	0:22	0:22	0:29	0:26
	<u>244</u> <u>10</u>	<u>235</u> <u>10</u>	<u>244</u> <u>10</u>	<u>302</u> <u>10</u>	<u>265</u> <u>10</u>
	0:24.4 sec	23.5 sec	24.4 sec	30.2 sec	26.5 sec

Gary J

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 Step 3.4 FT004 Vacuum Pressure

B) Intermittent

Bandage ^e	#1	#2	#3	#4	#5
1	0:30	0:28	0:32	1:33	0:28
2	0:20	0:24	0:22	0:20	0:22
3	0:28	0:21	0:22	0:18	0:22
4	0:21	0:21	0:23	0:19	0:28
5	0:21	0:21	0:21	0:20	0:21
6	0:22	0:20	0:21	0:18	0:20
7	0:21	0:21	0:21	0:18	0:20
8	0:23	0:21	0:20	0:18	0:19
9	0:22	0:21	0:20	0:19	0:20
10	0:22	0:21	0:20	0:18	0:20
	<u>230</u> 10	<u>219</u> 10	<u>222</u> 10	<u>301</u> 10	<u>220</u> 10
	23.0 sec	21.9 sec	22.2 sec	30.1 sec	22.0 sec

Bandage #1 had a slow leak around the disk

Bandage #4 is Brown & had a slow leak around the disk

Gary J. 258
 1/14/88

3.4.1 Test Case FT004a - Pressure Loss Prevention (SYSTST55822)

Status: Accepted Requirement Version: 4.1

Introduction

This test will verify . . .

a. The Micro NPWT device shall prevent a loss of vacuum pressure of no more than 10 mmHg/hour from a control volume of 60 cc to the pump when the pump is in the off state.

Test Setup

1. Standard setup.
2. One independent pressure sensor.
3. One 60 cc minimum syringe for use as a control volume.
4. One complete Intermittent therapy device and one complete Continuous therapy device.
5. Connect the independent pressure sensor in-line with the syringe tubing, then connect to the pump unit under test. Do not connect to a bandage.
6. Stopwatch.

Note: Pre-test all the tubing connections and the syringe for leaks prior to starting this test. Correct all leaks before continuing.

TEST Equipment: A, E, J, L, N
Test Procedures and Expected Results

Continuous Therapy Device

1. Set the vacuum pressure to 125 mmHg. Turn the pump on. When the device achieves the vacuum pressure setpoint and the pump stops running, start the stopwatch. Record the pressure reading from the independent pressure sensor. Remove connector P1 (To Pump) per the Capricorn Pump Module Schematic, Mntx part # DS-0000-70-5. This will keep the pump from turning back on. Wait exactly 1 hour. Record the pressure reading from the independent pressure sensor. Calculate and record the delta pressure change between the two readings. Replace connector P1. Repeat this step 4 additional times and calculate the average of these delta pressure readings.

RF a. Verify that the Continuous device's loss of vacuum pressure is no more than 10 mmHg/hour (averaged over 5 hours) when the pump is in the off state. See attachment

TEST Equipment: B, E, I, M, P
Intermittent Therapy Device ^{FML} see Interface Issue #19

2. Set the Intermittent device to Continuous mode. Set the vacuum pressure to 125 mmHg. Turn the pump on. When the device achieves the vacuum pressure setpoint and the pump stops running, start the stopwatch. Record the pressure reading from the independent pressure sensor. Remove connector P1 (To Pump) per the Capricorn Pump Module Schematic, Mntx part # DS-0000-70-5. This will keep the pump from turning back on. Wait exactly 1 hour. Record the pressure reading from the independent pressure

sensor. Calculate and record the delta pressure change between the two readings. Replace connector P1. Repeat this step 4 additional times and calculate the average of these delta pressure readings.

1/19/08

PF a. Verify that the Intermittent device's loss of vacuum pressure is no more than 10 mmHg/hour (averaged over 5 hours) when the pump is in the off state.

See attachment

This requirement traces from:
SYSREQ54725: Pressure Loss Mitigation Requirement

DP-0001-84-0 Rev. 02-a

STEP 3.4.1 FTOO4a Pressure Loss Prevention

Cont S/N 000013

125

INT (cont) 000014

0:00	118.3				0:00	122.8	
0:21	system fault				38:30	115.5	system fault
Step 3.4.1.1							
0:00	122.6				0:00	123.4	
0:00	122.8				28:23	115.4	backlight -- 1 beep response
0:00	120.8	0:00	123.9	Leak	1:00:00	113.5	Δ 9.9
1:05	114.4	system fault	109.8	Leak	0:00	124.0	
5:00	95.8	Δ 25.0	5:00	98.1	51.3	113.6	system fault
10:00	75.0	Δ 20.8	10:00	78.8	1:00:00	114.3	Δ 9.7
17:00	51.1		15:00	62.07	0:00	124.7	
00	43.1	Δ 31.9	20:00	48.2	1:00:00	116.0	Δ 8.7
25:00	32.1	Δ 11.0	25:00	37.2	0:00	123.8	
30:00	23.4	Δ 8.7	30:00	28.3	1:00:00	115.7	Δ 8.1
35:00	16.8	Δ 6.6	55:00	21.4	0:00	123.8	
40:00	11.9	Δ 4.9	40:00	15.8	1:00:00	115.8	Δ 8
45:00	8.3	Δ 3.6	45:00	11.6	0:00	124.8	
50:00	5.7	Δ 2.6	50:00	8.3	1:00:00	117.3	Δ 7.5
55:00	3.9	Δ 1.8	55:00	5.9	0:00	124.1	

* used a different syringe 55:57 115.3 system fault
 on 1/9/08 1:00:00 114.6 Δ 9.5
 * 2nd pass had a system fault 0:00 127.1
 1:00:00 116.6 Δ 10.5
 * powered down & waited 5 min (system fault)

Gann 261

1/9/08

3.5 Test Case FT005 - Parameter Retention & Autostart (SYSTST55821)

Status: Accepted Requirement Version: 10.0

Introduction

This test will verify . . .

- a. The Micro NPWT device shall retain the user's setup parameters when power is lost or removed.
- b. The Micro NPWT device shall restart therapy when power is lost or removed in the middle of an active therapy session.

Note: From the Capricorn User Interface Design document (DP-0001-84-4), to enter Configuration mode in order to change therapy mode or to modify the vacuum pressure setpoint, press and hold the Therapy Type (Mode) button and Pressure Setting (VAC) button simultaneously. While the Mode and VAC buttons are both held down, press and release the Pump On/Off button, then release the Mode and VAC buttons. Once in Configuration mode, to change therapy modes, press and release the Mode button. To change the vacuum pressure setpoint, press and release the VAC button. To exit Configuration mode, press and release the Pump On/Off button or wait 30 seconds from the last button press to time out and automatically exit. To turn the pump on or off, press the Pump On/Off button for greater than 1 second.

Test Setup

- 1. Standard setup.
- 2. Control unit set to Continuous therapy mode at 125 mmHg with connected Intermittent pump unit.
- 3. Variable output DC power supply set to 4.5 VDC, simulating three (3) AA 1.5VDC batteries.
- 4. Test lead connected to Pin 8 (RESET) of connector J1 (JTAG) per the Capricorn Control Unit Schematic, Mntx part # DS-0000-70-3.

TEST EQUIPMENT: A, C, E, I, L, N

Test Procedures and Expected Results

- 1. Power on the NPWT device with batteries and allow POST to complete. Turn on the pump.
 - PF a. Verify that the device delivers Continuous therapy at the 125 mmHg pressure setpoint.
- 2. Turn off the pump. Enter configuration mode and change therapy mode to Intermittent and modify vacuum pressure to 110 mmHg. Exit configuration mode. Turn on the pump.
 - PF a. Verify that the device delivers Intermittent therapy at the 110 mmHg pressure setpoint.

Remove Batteries

- 3. Remove the device batteries. Wait 30 seconds. Re-insert device batteries and allow POST to complete.
 - PF a. Verify that therapy automatically restarts after power on as the pump was on (ie. therapy was active) when the batteries were removed.

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1/4/08

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1/4/08

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1/1/08

GG 1/4/08 P/F b. Verify that the device delivers Intermittent therapy at the 110 mmHg pressure setpoint. This shows that programmable parameters are stored in non-volatile memory.

4. Turn off the pump. Remove the device batteries. Wait 30 seconds. Re-insert device batteries and allow POST to complete.

GG 1/4/08 P/F a. Verify that therapy does not automatically restart after power on as the pump was off (ie. therapy was inactive) when the batteries were removed.

Microprocessor Reset

5. Temporarily ground Pin 8 to force the microprocessor to reset. Allow POST to complete.

GG 1/4/08 P/F a. Verify that therapy does not automatically restart after a reset occurs as the pump was off (ie. therapy was inactive).

6. Enter configuration mode and change therapy mode to Continuous and modify vacuum pressure to 40 mmHg. Exit configuration mode. Turn on the pump. Temporarily ground Pin 8 to force the microprocessor to reset. Allow POST to complete.

GG 1/4/08 P/F a. Verify that therapy automatically restarts after a reset occurs as the pump was on (ie. therapy was active).

GG 1/4/08 P/F b. Verify that the device delivers Continuous therapy at the 40 mmHg pressure setpoint. This shows that programmed parameters are retained (NVM) and reused after a reset occurs.

Brownout Simulation

7. Turn off the pump. Remove the device batteries and connect the DC power supply using test point E1 (GND) and test point TP2 (Batt +) per the Capricorn Control Unit Schematic, Mntx part # DS-0000-70-3. Allow POST to complete. Introduce a bandage leak and turn on the pump. Slowly decrease the DC power supply voltage until low battery notification occurs. Remove the bandage leak and continue to slowly decrease the DC power supply voltage until a brownout occurs (ie. device shuts down as not enough power is available). Slightly increase the voltage, stop when the device powers up. Allow POST to complete.

GG 1/4/08 P/F a. Verify that therapy automatically restarts after a brownout occurs as the pump was on (ie. therapy was active).

GG 1/4/08 P/F b. Verify that the device delivers Continuous therapy at the 40 mmHg pressure setpoint. This shows that programmed parameters are retained (NVM) and reused after a brownout occurs.

This requirement traces from:

SYSREQ54690: Non-Volatile RAM Requirements
SYSREQ57537: Therapy Restart

3.6 Test Case FT006 - Device Calibration (SYSTST55775)

Status: Accepted Requirement Version: 3.1

Introduction

This test will verify . . .

- a. NPWT device calibration during manufacturing shall not be required.

Test Setup

- 1. Document review and inspection only.

Test Procedures and Expected Results

- 1. Inspect Mntx manufacturing assembly procedures and test procedures. Record the Mntx part numbers.
- P/F a. Verify after reviewing the procedures that the NPWT device does not require calibration at any point during or after manufacturing.

See attachment

*66
1/21/08*

This requirement traces from:
SYSREQ54764: Device Calibration

3.7 Test Case FT007 - Multiple Bandages (SYSTST55824)

Status: Accepted Requirement Version: 5.1

Introduction

This test will verify . . .

- a. The Micro NPWT system shall provide users the ability to interface the pump with up to two bandages.
- b. The Micro NPWT system shall be able to deliver up to 125 mmHg of negative pressure to two bandages simultaneously, regardless of therapy mode. Note: therapy mode could be either continuous or intermittent.

SUPPLIERS: HANHAT DELTA E700 CAL IDS: 662 AND 362

Test Setup

- 1. Standard setup.
- 2. Two independent pressure sensors. *VERI-CAL CAL IDS: 889 AND 893*
- 3. Two complete bandage kits and one accessories kit (contains double bandage "Y" adapter).
- 4. Connect the independent pressure sensors in-line with the bandage tubing, then connect to the "Y" adapter and finally, connect to the pump unit under test.

*CONTINUOUS AND INTERMITTENT DEVICES
(USED BACK-UP UNITS FOR BOTH)*

Test Procedures and Expected Results

DP-0001-84-0 Rev. 02-a
 3.6.1 Device Calibration FT-006
Control Continuous Intermittent

Assembly	DA-0001-59-3 Rev 01-a	DA-0001-59-1 Rev 01-a	DA-0001-59-2 Rev 01-a
BOM Assembly		AM-0001-06-0	
	AE-0000-83-2 Rev 03-a Rev 04-a	AE-0000-83-3 Rev 03-a Rev 04-a	AE-0000-83-4 Rev 03-a Rev 04-a
PCB Assembly	AP-0000-89-1 Rev 002-a	AP-0000-89-3 Rev 001-a	AP-0000-89-5 Rev 001-a
Drawing	DA-0001-57-5 Rev 002-a	DA-0001-57-6 Rev 001-a	DA-0001-57-6 Rev 001-a
KogP Assembly		^{KogP} AM-0001-06-0 Rev 001-a	^{Cast} AM-0001-06-1 Rev 001-a
Drawing KogP		^{KogP} DA-0001-62-5 Rev 001-a	^{Solenoid} AM-0001-06-2 Rev 001-a
Label	ML-0000-27-9 Rev 01-a	Label ML-0000-28-0 Rev 01-a	^{Solenoid Assembly} DA-0001-62-6 Rev 001-a
			^{Cast Assembly} DA-0001-62-4 Rev 001-a
			Label ML-0000-28-1 ^{Rev 01-a}

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 1/21/08

Continuous Pump

1. On the control unit, set the vacuum pressure to 125 mmHg and turn the pump on. Allow the unit to run for a minimum of 4 hours. Note: if a leak occurs, correct the leak and continue the test.

START 10:04 AM

STOP 2:18 PM

ELAPSED 04:14 (H:M:SS)

FAB
1/4/08

P/F a. Verify that the pump unit interfaces with one or two bandages.

P/F b. Verify that no system fault notifications occur (ie. loss of pump control or pump inoperable) due to the inability of the system to deliver and maintain 125 mmHg of negative pressure Continuous therapy over a 4 hour duration.

P/F c. Verify that the independent pressure sensors confirm the 125 mmHg negative pressure setpoint is achieved.

-118.6 mmHg

±10% = 12.5 mmHg (112.5 mmHg to 137.5 mmHg)
RANGE

-121.4 mmHg

-122.2 mmHg

-124.9 mmHg

Intermittent Pump

1. On the control unit, set the therapy type to Intermittent, set the vacuum pressure to 125 mmHg, and turn the pump on. Allow the unit to run for a minimum of 4 hours. Note: if a leak occurs, correct the leak and continue the test.

FAB
1/4/08

P/F a. Verify that the pump unit interfaces with one or two bandages.

P/F b. Verify that no system fault notifications occur (ie. loss of pump control or pump inoperable) due to the inability of the system to deliver and maintain 125 mmHg of negative pressure Intermittent therapy over a 4 hour duration.

P/F c. Verify that the independent pressure sensors confirm the 125 mmHg negative pressure setpoint is achieved.

-120.5 mmHg

START 10:37 AM

-123.2 mmHg

STOP 2:45 PM

-121.8 mmHg

ELAPSED 04:08 (H:M:SS)

-121.3 mmHg

This requirement traces from:

- SYSREQ54637: Bandage Accommodation
- SYSREQ54801: Multiple Bandage Interface

Silverlon
Antimicrobial Wound Contact Dressing
Instructions for Use

SILVERLON



Argentum Medical, LLC

Antimicrobial Wound Contact Dressing

CONTENTS: 1 DRESSING - 8" x 4" (20.32 cm x 10.16 cm)

Product Code: 16C04

Indications

Applicable to partial thickness burns, excisions, wet grafts, donor sites, lacerations, abrasions, slightly draining or non-exudative ulcers, pressure and surgery.

Directions

- To open, separate the seams at its corner and peel down.
- Peel dressing with sterile water - **DO NOT USE SALINE.**
- Apply in direct contact with wound, covering wound margins 1 or 2 cm.
- Cover dressing with conventional techniques.
- Change dressing based on exudate build up and wound condition.
- For optimal results, maintain dressing in moist condition.

Caution

- For external use only, remove prior to MRI scanning.
- Do Not use on patients with known sensitivity to silver or nylon.
- Store at room temperature. Avoid temperatures above 122°F (50°C).
- Dressing effectiveness decreases if used with products containing saline, glucose, povidone, iodine, hydrogen peroxide.

Indications and appearance may vary.

Toll free: 866-968-6322



**Silverlon Contact Wound Dressing
510(k) Summary**

**K981299
September 23, 1998**

Argentum International LLC **K981299**

510(k) Premarket Notification
Silverlon™ Contact Wound Dressing
K981299

SEP 25 1998

September 23, 1998

10. 510(K) SUMMARY

10.1 Summary Information

10.1.1 Submitter's Name and Address

Argentum International LLC
Post Office Box 429
Lakemont, GA 30552

Contact person and telephone number:

A. Bart Flick, M.D., Research Director
Telephone: (706) 782-6700
Telefax: (706) 782-3903

Date summary was prepared:

September 23, 1998

10.1.2 Name of Device

Trade Name: Silverlon™ Contact Wound Dressing
(1- and 4-Layer)
Common Name: Silver-nylon contact wound dressing
Classification Name: Contact wound dressing

10.1.3 Identification of predicate device to which substantial equivalence is being claimed

Silverlon™ Contact Wound Dressings are substantially equivalent in function and intended use to the following cleared contact wound dressings: Arglaes Film Dressing (K970566), Acticoat Silver Coated Dressing (K955453), and Tegapore™ Wound Contact Material (K890354).

Argentum International LLC

510(k) Premarket Notification
Silverlon™ Contact Wound Dressing
K981299

September 4, 1998

10.1.4 Device Description

Explanation of how the device functions: Silverlon™ Contact Wound Dressings are designed to intimately contact the wound as a primary dressing and permit the passage of fluids. The silver provides effective protection of the dressing against microbial contamination.

Basic scientific concepts that form the basis for the device: The nylon fabric permits the passage of oxygen and fluids to and from the wound. The surface of the nylon fibers in Silverlon™ Contact Wound Dressings consists of a thin layer of metallic silver containing approximately 1% silver oxide that provides effective protection of the dressing against microbial contamination.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: Silverlon™ Contact Wound Dressings are made of flexible, sterile, non-adherent fabric consisting of 1 or 4 layers of a knitted continuous nylon fiber substrate with a metallic silver surface containing approximately 1% silver oxide.

10.1.5 Statement of the intended use of the device, including general description of the conditions the device will mitigate and the patient population for which the device is intended

Silverlon™ Contact Wound Dressings are external wound dressings that are designed as an interface between the wound and a conventional occlusive dressing. Silverlon™ Contact Wound Dressings are sterile, non-adherent dressings intended for local management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure, and diabetic).

Argentum International LLC

510(k) Premarket Notification
Silverlon™ Contact Wound Dressing
K981299

September 4, 1998

10.1.6 Statement of how the technological characteristics of the device compare to those of the predicate device

The technological characteristics of the device such as flexible primary contact wound dressing, permeability to oxygen and fluids, and protection against microbial contamination of the dressing that are substantially equivalent to the predicate devices cited.

10.2 Assessment of Performance Data

Silverlon™ 1-Layer and 4-Layer Contact Wound Dressings were subjected to standard *in vitro* and *in vivo* biocompatibility tests including cytotoxicity, sensitization, acute intracutaneous reactivity, acute systemic toxicity, and tissue compatibility (muscle implantation study). All tests were performed in accordance with Part-10993 of the International Standard Organization (ISO) Standard (*Biological Evaluation of Medical Devices*) by North American Science Associates, Inc. (NAmsA), Northwood, Ohio. The studies indicated that Silverlon™ 1-Layer and 4-Layer Contact Wound Dressings are safe for their intended use.

Argentum International LLC

510(k) Premarket Notification
Silverlon™ Contact Wound Dressing
K981299

K981299

August 10, 1998

2. INDICATIONS FOR USE

510(k) Number (if known): K981299

Device Name: Silverlon™ Contact Wound Dressing

Indications for Use:

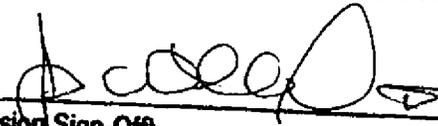
Silverlon™ Contact Wound Dressings are sterile, non-adherent dressings intended for local management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure, and diabetic).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

OR

Over-The-Counter Use _____



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981299

(b)(4)

Biocompatibility Information

(b)(4)

(b)(4)

Biocompatibility Data

Cytotoxicity Testing Protocol and Report

(b)(4)

Testing Protocol and Report

**Cleaning Efficacy Study
for Reusable Devices**

**WuXi AppTec
Protocol # KYP071408cln.01**

7705140294

APPT-EC



PROTOCOL TITLE: Cleaning Efficacy Study for Reusable Devices

SPONSOR / CLIENT: Kalypto Medical, Inc.
1250 Northland Drive
Mendota Heights, MN, 55120

PROTOCOL NUMBER: KYP071408cln.01

PRODUCT: NPD 1000 Negative Pressure Wound Therapy Device

PERFORMING LABORATORY: WuXi AppTec, Inc.
1265 Kennestone Circle
Marietta, GA 30066

ISSUE DATE: July 15, 2008

PROPRIETARY INFORMATION

THIS DOCUMENT IS PROVIDED WITH THE UNDERSTANDING THAT THE RECIPIENT SHALL RECOGNIZE IT CONTAINS WUXI APPTEC, INC. PROPRIETARY INFORMATION, THAT IT SHALL BE KEPT CONFIDENTIAL BY THE PERSON AND / OR COMPANY TO WHOM IT WAS ADDRESSED, AND THAT IT SHALL BE USED FOR NO OTHER PURPOSE THAN ASSESSING AND APPROVING THE DESCRIBED SERVICES TO BE PERFORMED BY WUXI APPTEC, INC. OR FOR THE PURPOSE OF REGULATORY SUBMISSION.



Protocol Number: KYP071408cln.01

Kalypto Medical, Inc.
Page 2 of 7

1.0 PURPOSE / SCOPE

The purpose of this study is to demonstrate the efficacy of the cleaning procedure that is specified by Kalypto Medical, Inc. for cleaning the NPD 1000 Negative Pressure Wound Therapy Device by the non-professional user (Consumer) in the home. These reusable devices are manufactured by or for Kalypto Medical, Inc. and are supplied to the user with cleaning instructions.

Note: A neutralization study per ASTM E 2314 will not be a part of this protocol.

2.0 SPONSOR / CLIENT: Kalypto Medical, Inc.
1250 Northland Drive
Mendota Heights, MN, 55120

3.0 TEST FACILITY: WuXi AppTec, Inc.
1265 Kennestone Circle
Marietta, GA 30066

4.0 SCHEDULING / DISCLAIMER

4.1 Initiation of the study is generally within 10 working days after receipt of the test article and a signed protocol or request form. Verbal results will be available upon completion of the study with the written report to follow approximately 7 working days after completion of the study.

4.2 If some portion of the study must be repeated due to failure by WuXi AppTec, Inc. to adhere to specified procedures, failure of internal controls, or failure by WuXi AppTec, Inc. to meet specified responsibilities, that portion of the study will be repeated free of charge.

4.3 If the test article fails the study and the Sponsor / Client requests a repeat test, or some portion of the study requires modifications due to complexity or difficulty of testing, additional charges will apply.

4.4 Neither the WuXi AppTec, Inc. name nor those of its employees are to be used in advertising or other promotions without written consent from WuXi AppTec, Inc.

4.5 The Sponsor / Client is responsible for reviewing the protocol and final report for format, pagination, etc. WuXi AppTec, Inc. will make reasonable changes deemed necessary by the Sponsor, without altering the technical data.

5.0 PRODUCT IDENTIFICATION

The test article is the NPD 1000 Negative Pressure Wound Therapy Device.

Protocol Number: KYP071408ch.01

Kalypto Medical, Inc.
Page 3 of 7**WuXi AppTec****6.0 RESPONSIBILITIES****6.1 Sponsor / Client is responsible for:**

- 6.1.1 Reviewing and approving the protocol
- 6.1.2 Providing the required quantities of test articles
- 6.1.3 Providing the cleaning instructions
- 6.1.4 Conducting any materials compatibility and functionality studies after cleaning

6.2 WuXi AppTec, Inc. is responsible for:

- 6.2.1 Writing the protocol based on client input
- 6.2.2 Performing the inoculation and cleaning of the test articles
- 6.2.3 Providing the appropriate cleaning materials, if necessary
- 6.2.4 Performing the post-cleaning testing of the test articles
- 6.2.5 Reporting and interpreting test results and writing a final report

7.0 EXPERIMENTAL DESIGN

This cleaning efficacy study will be based on inoculating sample devices with a specified level of challenge organism, cleaning the devices per client instructions, and testing the cleaned devices for the quantity of inoculated organisms that remain. The log reduction of the cleaning process will then be calculated based on the difference in the organism count on the inoculated devices prior to cleaning and after cleaning.

8.0 MATERIALS / EQUIPMENT

- 8.1 Lab materials and equipment will be used as listed in the specified WuXi AppTec, Inc. SOPs.
- 8.2 Cleaning materials will be provided by WuXi AppTec, Inc. and will be as follows: Household Dishwashing Soap and 70% Ethyl Alcohol.

Protocol Number: KYP071408cln.01

Kalypto Medical, Inc.
Page 4 of 7**9.0 SAMPLE REQUIREMENTS / SPECIFICATIONS**

- 9.1 The samples that are used in this study will be representative of the actual product to be cleaned.

Note: Rejected or damaged product may be used if it does not affect the validity of the study in any way.

- 9.2 A total of eighteen (18) sample devices will be provided for this study. These eighteen devices will be used in each cleaning run as shown in Table 1. The devices will be cleaned prior each cleaning run per Section 11.1.1.

Table 1: Test Sample Requirements

	1 st cleaning run	2 nd cleaning run	3 rd cleaning run	Total samples tested in 3 runs
Test Samples	3	3	3	9
Positive Controls	3	3	3	9
Total samples	6	6	6	18

10.0 CLEANING INSTRUCTIONS / SPECIFICATIONS

The cleaning instructions / specifications to be used in this study are as specified by the client as detailed in Section 11.2.1 of this protocol.

11.0 TEST PROCEDURE**11.1 PRODUCT INOCULATION**

11.1.1 Prior to inoculation for each cleaning run, the devices will be cleaned per client instructions by use of a cloth dampened with water and household dishwashing soap to clean external surface, followed with wiping of external surface with 70% Ethyl Alcohol.

11.1.2 The effectiveness of the cleaning procedure will be evaluated by inoculating the device with a spore suspension.

11.1.3 Each device will be inoculated with at least 10^5 colony-forming units (CFU) of a *Geobacillus stearothermophilus* spore suspension. The population of the spore suspension inoculum will be confirmed at the time of inoculation.

Note: In this study, the term "tag spores" will be used to refer to the *G. stearothermophilus* spores that are inoculated onto the device.

11.1.4 Six devices per cleaning run, three test devices and three positive controls, will each be directly inoculated with tag spores.

11.1.5 The location of the tag spores will be:

On the external surface of the device.

11.1.6 The inoculated devices will be allowed to dry in a contamination-controlled environment for 2-3 hours.

- Proprietary Information -



Protocol Number: KYP071408cln.01

Kalypto Medical, Inc.
Page 5 of 7

11.1.7 After drying, three of the inoculated devices will go through the cleaning procedure as outlined in 11.2. The three remaining inoculated devices will not be cleaned (positive controls), but will be tested as outlined in 11.3 to determine the tag spore count present on the inoculated devices.

11.2 CLEANING PROCEDURE

11.2.1 Clean the three inoculated devices using the following 3 steps:

Table 2: Cleaning Procedure

STEP	Time	Cleaning criteria
1	As needed	Use cloth dampened with tap water and household dishwashing soap to clean external surface
2	As needed	Wipe external surface with 70% Ethyl Alcohol.
3	As needed	Visually inspect

Note: Water used by WuXi AppTec, Inc. is acceptable per USP standards.

11.2.2 Allow cleaned devices to air dry in a contamination-controlled environment for approximately 15 minutes before testing.

11.3 TEST PROCEDURE

11.3.1 The devices from each cleaning run will be tested for the tag spore count using WuXi AppTec, Inc. SOP MA204SOP. The test parameters will be based on the size, configuration and nature of the device, and will be specified in the WuXi AppTec, Inc. Client Technical Procedure (CTP) for Kalypto Medical, Inc.'s NPDP 1000 Negative Pressure Wound Therapy Device.

11.3.2 All plates will be incubated aerobically at 55-60 °C for 2-3 days, the optimum culture conditions for *G. stearothermophilus*.

11.3.3 After incubation, plates will be enumerated for the tag spore colonies using procedures as outlined in WuXi AppTec, Inc. SOP ML223SOP.

11.3.4 The procedures in 11.1 through 11.3 will be repeated two more times for the 2nd and 3rd cleaning runs.

11.3.5 Final results for each cleaning run will be reported as:
a) the average of the log₁₀ CFU for the positive controls
b) the average of the log₁₀ CFU for the cleaned devices, and
c) the log reduction determined by subtracting b) from a).



Protocol Number: KYP071408cln.01

Kalypto Medical, Inc.
Page 6 of 7

12.0 ACCEPTANCE CRITERIA

The acceptance criteria for this study are:

- 12.1 Confirmation of the *G. stearo*thermophilus spore suspension inoculum at $\geq 10^5$ CFU.
- 12.2 Average tag spore counts $\geq 10^3$ CFU/device for the positive controls in each cleaning run.
- 12.3 Documentation for each cleaning run that each step of the cleaning procedure was performed according to the steps and criteria outlined in Table 2.

13.0 CONCLUSION / INTERPRETATION OF DATA

If the acceptance criteria specified in Section 12.0 are met, and the average tag spore counts on the cleaned devices show a reduction from the average tag spore counts on the positive controls for each cleaning run, then the cleaning method specified in Table 2 for the NPD 1000 Negative Pressure Wound Therapy Device will have been proven effective.

14.0 AMENDMENTS / REVISIONS / DEVIATIONS

If it becomes necessary to make changes in the approved protocol, the revisions and reasons for changes will be documented, reported to the sponsor / client, signed and dated, and maintained with the protocol. If an event occurs that may have an effect on the validity of the study, the sponsor will be notified as soon as is practical.

15.0 REPORTING

A written report will be prepared by WuXi AppTec, Inc. The report will include, but not be limited to, the dates of the study, the purpose of the study, any changes to the protocol, any deviations in the study, and a summary of the results.

16.0 RECORDS / RECORD RETENTION

WuXi AppTec, Inc. will retain all records involving the study including, but not limited to: the signed testing protocol, amendments, any written communication concerning the conduct of the study, raw data worksheets, test reports, and the final report.

17.0 INFORMATIVE REFERENCES

- 17.1 AAMI TIR 12 – 2004, *Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers* (AAMI TIR 12).
- 17.2 AAMI/CDV-1 TIR 30 (2003-02-14), *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.*
- 17.3 ASTM E 2314 – 03, *Standard Test Method for Determination of the Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)* (ASTM E 2314)

- Proprietary Information -



Protocol Number: KYP071408cln.01

Kalypto Medical, Inc.
Page 7 of 7

18.0 TEST ARTICLE DISPOSITION

All test articles will be returned to the client following study completion unless otherwise requested by Sponsor.

19.0 APPROVAL / SIGNATURES

SPONSOR / CLIENT:

NAME: John S. Buan (please print) TITLE: VP of Prod. Dev.

SIGNATURE: [Signature] DATE: 7/23/08

PHONE: (612) 703-1204 FAX: _____

EMAIL: jbuana@kalyptomedical.com

WUXI APPTec, INC.:

NAME: Shelley Green TITLE: Manager of Specialized Studies

SIGNATURE: [Signature] DATE: 07-16-08

NAME: Julia Taylor TITLE: Project Coordinator- Specialized Studies

SIGNATURE: [Signature] DATE: 07-15-08

Protocol Number: KYP071408cln.01
Deviation: 1

Kalypto Medical, Inc.
Page 1 of 2



DEVIATION

Cleaning Efficacy Study for Reusable Devices: NPD 1000 Negative Pressure Wound Therapy Device

1.0 PURPOSE:

The purpose of this study is to demonstrate the efficacy of the cleaning procedure that is specified by Kalypto Medical, Inc. for cleaning the NPD 1000 Negative Pressure Wound Therapy Device. These devices are manufactured by or for Kalypto Medical, Inc.

2.0 **SPONSOR:** Kalypto Medical, Inc.
1250 Northland Drive
Mendota Heights, MN 55120

3.0 **TEST FACILITY:** WuXi AppTec, Inc.
1265 Kennestone Circle
Marietta, GA 30066

4.0 DEVIATION

Section 11.1.2 of the study protocol states that the effectiveness of the cleaning procedure will be evaluated by inoculating the device with a spore suspension. The Client has elected to evaluate the effectiveness of the cleaning procedure by incorporating artificial soil that has been inoculated with a spore suspension. This artificial soil simulates the type of contamination that is expected to be on the devices after use. The formula for the simulated blood / serum artificial soil (Miles) is shown in Table 1.

Table 1: Formula for Artificial Soil

Ingredient	Amount
Fetal calf serum	10 mL
Dry milk powder	6 g
Rabbit blood	1 mL
0.9% saline	1 mL

Section 11.2.1, Table 2 of the study protocol outlines the cleaning procedure for Kalypto Medical, Inc.'s NPD 1000 Negative Pressure Wound Therapy Device. The Client has elected to change the cleaning procedure to the method described in Table 2 of KYP071408cln.01, Deviation 1.

Table 2: Cleaning Procedure

STEP	Time	Cleaning criteria
1	As needed	Use cloth dampened with tap water and household dishwashing soap to clean external surfaces. Wipe until visibly clean.
2	As needed	Wipe the external surfaces again with a cloth dampened with water (no soap) to remove residual soap. Wipe until no longer "slippery", then allow to air dry.
3	As needed	Wipe external surface with 70% ethyl alcohol and allow to air dry
4	As needed	Visually inspect

360

Protocol Number: KYP071408cln.01
Deviation: 1

Kalypto Medical, Inc.
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Section 12.0 of the study protocol outlines the acceptance criteria of the study. The Client has elected to add "Section 12.4 External surfaces of the cleaned device must be visibly clean" to the acceptance criteria.

5.0 DEVIATION APPROVAL SIGNATURES

SPONSOR: *Entellus Medical, Inc.*

NAME: *Pamela Vaughan*

TITLE: *Principal Project Mgr*

SIGNATURE: *Pamela Vaughan*

DATE: *8-4-08*

PHONE: *651-753-0004* FAX: *763-287-3836*

EMAIL: *pamela.v@alquest.com*

WUXI APPTec, INC.

NAME: *Julia Taylor*
Project Coordinator - Specialized Studies

SIGNATURE: *Julia Taylor*

DATE: *08-01-08*

**Cleaning Efficacy Study
for Reusable Devices**

Final Study Report

WuXi AppTec



FINAL STUDY REPORT

STUDY TITLE: Cleaning Efficacy Study for Reusable Devices

PROTOCOL NUMBER: KYP071408cln.01

PRODUCT: NPD 1000 Negative Pressure Wound Therapy Device

SPONSOR / CLIENT: Kalypto Medical, Inc.
1250 Northland Drive
Mendota Heights, MN, 55120

PERFORMING LABORATORY: WuXi AppTec, Inc.
1265 Kennestone Circle
Marietta, GA 30066

1.0 PURPOSE / SCOPE

The purpose of this study was to demonstrate the efficacy of the cleaning procedure that is specified by Kalypto Medical, Inc. for cleaning the NPD 1000 Negative Pressure Wound Therapy Device by the non-professional user (Consumer) in the home.

2.0 SPONSOR / CLIENT: Kalypto Medical, Inc.
1250 Northland Drive
Mendota Heights, MN, 55120

3.0 TEST FACILITY: WuXi AppTec, Inc.
1265 Kennestone Circle
Marietta, GA 30066

4.0 SCHEDULING

DATE SAMPLES RECEIVED: July 14, 2008
STUDY INITIATION DATE: August 08, 2008
STUDY COMPLETION DATE: August 11, 2008

5.0 PRODUCT IDENTIFICATION

The test article was the NPD 1000 Negative Pressure Wound Therapy Device.

6.0 EXPERIMENTAL DESIGN

This cleaning efficacy study was based on inoculating sample devices with a specified level of challenge organism in a simulated soil solution, cleaning the devices per client instructions, and testing the cleaned devices for the quantity of inoculated organisms that remain. The log reduction of the cleaning process was calculated based on the difference in the organism count on the devices prior to cleaning and after cleaning.

7.0 PROCEDURE**7.1 INOCULATION WITH ARTIFICIAL SOIL**

7.1.1 The devices for each of the three cleaning runs were cleaned per client instructions by using a cloth dampened with water and Dawn, a household dishwashing soap, to clean external surface then wiping the external surfaces again with a cloth dampened with water (no soap) to remove residual soap and until no longer "slippery", then allow to air dry followed with wiping of external surface with 70% Ethyl Alcohol.

- 7.1.2 Artificial soil was prepared as shown in Table 1. The soil solution was inoculated with a spore suspension of *Geobacillus stearothermophilus* (tag spores).

Table 1: Formula for Artificial Soil

Ingredient	Amount
Fetal calf serum	10 mL
Dry milk powder	6 g
Rabbit blood	1 mL
0.9% saline	1 mL

- 7.1.3 One-gram portions of the soil solution were each inoculated with 10^5 colony-forming units (CFU) of a *Geobacillus stearothermophilus* spore suspension. The population of the inoculum was confirmed and results are shown in Table 2. Refer to Attachment A for the population confirmation.

Table 2: Inoculation information

Organism	ATCC #	Lot Number	Cleaning Run	Inoculum confirmation
<i>Geobacillus stearothermophilus</i>	7953	AR350	1	2.0×10^5
			2	2.0×10^5
			3	1.4×10^5

- 7.1.4 After inoculation, the devices were allowed to dry in a contamination-controlled environment for 2-3 hours.
- 7.1.5 After drying, the three positive controls were tested to determine the tag spore count. The three remaining samples were cleaned according to the procedure stated in the deviation of the protocol.

7.2 CLEANING PROCEDURE

- 7.2.1 The three soiled samples from each cleaning run were cleaned using the following 4 steps:

Table 2: Cleaning Procedure

STEP	Time	Cleaning criteria
1	As needed	Use cloth dampened with tap water and household dishwashing soap to clean external surfaces. Wipe until visibly clean.
2	As needed	Wipe the external surfaces again with a cloth dampened with water (no soap) to remove residual soap. Wipe until no longer "slippery", then allow to air dry.
3	As needed	Wipe external surface with 70% ethyl alcohol and allow to air dry
4	As needed	Visually inspect

- 7.2.2 The cleaned devices were dried in a contamination-controlled environment for approximately 15 minutes before testing.

7.3 TEST PROCEDURE

- 7.3.1** The six devices from each cleaning run were tested for the tag spore count using WuXi AppTec, Inc. procedure MA204SOP. Test parameters are shown in the corresponding WuXi AppTec, Inc. Client Technical Procedure (CTP).
- 7.3.2** Plates were incubated at 55°-60°C for 2-3 days and enumerated according to WuXi AppTec, Inc. procedure ML223SOP.
- 7.3.3** Final results for each cleaning run were reported as the average for the cleaned devices, the average for the positive controls and the log reduction.

8.0 ACCEPTANCE CRITERIA

All acceptance criteria specified in Section 12.0, and on the deviation, of the protocol were met during the course of this study, as shown in Table 4.

Table 4: Acceptance Criteria Results

Acceptance criteria	Run 1	Run 2	Run 3
Tag spore inoculum at $\geq 10^5$	Criteria met	Criteria met	Criteria met
Positive control tag spore count at $\geq 10^3$	Criteria met	Criteria met	Criteria met
Cleaning procedure performed as specified	Criteria met	Criteria met	Criteria met
Confirmation of no visible soil present on each device following cleaning procedure	Criteria met	Criteria met	Criteria met

Reference attachments B, C, and D for reports on cycles 1, 2, and 3 respectively.

9.0 RESULTS / CONCLUSION

This cleaning study was successful in showing a reduction in the tag spore counts for each cleaning run, as shown in Table 5. This provides evidence that the Kalypto Medical, Inc. NPD 1000 Negative Pressure Wound Therapy Device can be cleaned effectively using the instructions provided.

Table 5: Test Results

Cleaning Run	Uncleaned controls Avg. CFU	Cleaned devices Avg. CFU	Log Reduction
Run # 1	4.9×10^4	7.9×10^2	1.8
Run # 2	5.2×10^4	3.4×10^2	2.1
Run # 3	1.1×10^5	1.1×10^3	2.0
Average Log Reduction			2.0

10.0 AMENDMENTS / DEVIATIONS

Refer to Attachment E for deviations to the protocol.

Protocol Number: KYP071408cln.01

Kalypto Medical, Inc.
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11.0 RECORDS / RECORD RETENTION

An official copy of all documents associated with this study and the raw data pertinent to the study will be retained according to WuXi AppTec, Inc. standard operating procedures for archival.

12.0 APPROVALS / SIGNATURES

SPONSOR / CLIENT:

NAME: Pamela Vaughan
(please print)

TITLE: Principal Proj. Mgr

SIGNATURE: Pamela Vaughan

DATE: 08-14-08

WUXI APPTec, INC.:

NAME: Shelley Green

TITLE: Manager of Specialized Studies

SIGNATURE: Shelley Green

DATE: 08-14-08

NAME: Julia Taylor

TITLE: Project Coordinator- Specialized Studies

SIGNATURE: Julia Taylor

DATE: 08-14-08

Appendix A



Test Facility:
1265 Kennestone Circle
Marietta, GA 30066

This report is confidential. No part may be used for advertising or public announcement without written permission. Results apply only to the sample(s) tested.

*** VAL ***

Report Number
774240
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WuXi AppTec, Inc.
1265 Kennestone Circle
Marietta, GA 30066-6037

April 22, 2008
P.O. # QA

Attn: QA Department

MICROBIAL ASSAYS TEST REPORT

Sample Information: SPSmedical, *Geobacillus stearothermophilus* Spore Suspension, ATCC 7953, Lot# AR350, Exp. May 5, 2009, 2.1 x 10E8/mL, D-value: 1.9, Rec'd 02-27-08

Date in Test: April 16, 2008
Date Completed: April 18, 2008

Test Information: Test Code: 120200
USP Total Viable Spore Count
Procedure #: MA225SOP

Sample ID	Average CFU/ 0.1 mL
1	6.9 x 10 ⁷

ORIGINAL SIGNED

Reviewed: _____

369

Testing conducted in accordance with current Good Manufacturing Practices.

Appendix B



Test Facility:
1265 Kennestone Circle
Marietta, GA 30066

This report is confidential. No part may be used for advertising or public announcement without written permission. Results apply only to the sample(s) tested.

* VAL *

Report Number
783664
Page 1 of 1

Kalypto Medical, Inc.
1250 Northland Drive
Mendota Heights, MN 55120

August 13, 2008
P.O. #: 1013

Attn: John Buan

MICROBIAL ASSAYS TEST REPORT

Sample Information: NPД 1000 Negative Pressure Wound Therapy Device, Cleaning Efficacy Study, Cycle 1

Date Received: July 14, 2008
Date in Test: August 07, 2008
Date Completed: August 09, 2008

Test Information: Test Codes: 1902100, 180116, 160210
 Protocol #: KYP071408cln.01
 Procedure #: MA204KYP.201
 Artificial Soil: Miles (Simulated Blood / Serum)
 Tag Organism: *Geobacillus stearothermophilus* ATCC 7953

PRODUCT SOILING / INOCULATION & CLEANING	
Organism Lot #	AR350
Expiration Date	May 5, 2009
Inoculum Level	2.0 x 10 ⁵ CFU/device

A total of 6 devices were soiled. Cleaning was performed on 3 test samples. The remaining 3 devices were not subjected to the cleaning process and were used as the positive control(s).

Test Sample ID	Total Count – Recovered CFU / device	Log
1	3.6 x 10 ²	2.6
2	1.0 x 10 ³	3.0
3	1.0 x 10 ³	3.0
Average	7.9 x 10 ²	2.9

Positive Control	Total Count – Recovered CFU / device	Log
1	4.3 x 10 ⁴	4.6
2	4.0 x 10 ⁴	4.6
3	6.5 x 10 ⁴	4.8
Average	4.9 x 10 ⁴	4.7

Log Reduction	1.8
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ORIGINAL SIGNED

Reviewed: _____ 371

Appendix C



Test Facility:
1265 Kennestone Circle
Marietta, GA 30066

This report is confidential. No part may be used for advertising or public announcement without written permission. Results apply only to the sample(s) tested.

* VAL *

Report Number
783672
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Kalypto Medical, Inc
1250 Northland Drive
Mendota Heights, MN 55120

August 13, 2008
P.O. # 1013

Attn: John Buan

MICROBIAL ASSAYS TEST REPORT

Sample Information: NPD 1000 Negative Pressure Wound Therapy Device, Cleaning Efficacy Study, Cycle 2

Date Received: July 14, 2008
Date in Test: August 07, 2008
Date Completed: August 09, 2008

Test Information: Test Codes: 1902100, 180116, 160210
Protocol #: KYP071408cln.01
Procedure #: MA204KYP.201
Artificial Soil: Miles (Simulated Blood / Serum)
Tag Organism: *Geobacillus stearothermophilus* ATCC 7953

PRODUCT SOILING / INOCULATION & CLEANING	
Organism Lot #	AR350
Expiration Date	May 5, 2009
Inoculum Level	2.0 x 10 ⁵ CFU/device

A total of 6 devices were soiled. Cleaning was performed on 3 test samples. The remaining 3 devices were not subjected to the cleaning process and were used as the positive control(s).

Test Sample ID	Total Count – Recovered CFU / device	Log
1	4.5 x 10 ²	2.6
2	1.9 x 10 ²	2.3
3	3.8 x 10 ²	2.6
Average	3.4 x 10 ²	2.5

Positive Control	Total Count – Recovered CFU / device	Log
1	7.0 x 10 ⁴	4.8
2	6.5 x 10 ⁴	4.8
3	2.0 x 10 ⁴	4.3
Average	5.2 x 10 ⁴	4.6

Log Reduction	2.1
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ORIGINAL SIGNED

Reviewed: _____

373

Appendix D



Test Facility:
1265 Kennestone Circle
Marietta, GA 30066

This report is confidential. No part may be used for advertising or public announcement without written permission. Results apply only to the sample(s) tested.

*** VAL ***

Report Number
784725
Page 1 of 1

Kalypto Medical, Inc.
1250 Northland Drive
Mendota Heights, MN 55120

August 13, 2008
P.O. #: 1013

Attn: John Buan

MICROBIAL ASSAYS TEST REPORT

Sample Information: NPD 1000 Negative Pressure Wound Therapy Device, Cleaning Efficacy Study, Cycle 3

Date Received: July 14, 2008

Date in Test: August 08, 2008

Date Completed: August 11, 2008

Test Information: Test Codes: 180116, 180115, 160210
Protocol #: KYP071408cln.01
Procedure #: MA204KYP.201
Artificial Soil: Miles (Simulated Blood / Serum)
Tag Organism: *Geobacillus stearothermophilus* ATCC 7953

PRODUCT SOILING / INOCULATION & CLEANING	
Organism Lot #	AR350
Expiration Date	May 5, 2009
Inoculum Level	1.4 x 10 ⁵ CFU/device

A total of 6 devices were soiled. Cleaning was performed on 3 test samples. The remaining 3 devices were not subjected to the cleaning process and were used as the positive control(s).

Test Sample ID	Total Count – Recovered CFU / device	Log
1	1.6 x 10 ³	3.2
2	8.1 x 10 ²	2.9
3	9.0 x 10 ²	3.0
Average	1.1 x 10 ³	3.0

Positive Control	Total Count – Recovered CFU / device	Log
1	7.5 x 10 ⁴	4.9
2	1.4 x 10 ⁵	5.1
3	1.1 x 10 ⁵	5.0
Average	1.1 x 10 ⁵	5.0

Log Reduction	2.0
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ORIGINAL SIGNED

Reviewed: _____ 375

Appendix E

Protocol Number: KYP071408cln.01
Deviation: 1

Kalypto Medical, Inc.
Page 1 of 2



DEVIATION

Cleaning Efficacy Study for Reusable Devices: NPD 1000 Negative Pressure Wound Therapy Device

1.0 PURPOSE:

The purpose of this study is to demonstrate the efficacy of the cleaning procedure that is specified by Kalypto Medical, Inc. for cleaning the NPD 1000 Negative Pressure Wound Therapy Device. These devices are manufactured by or for Kalypto Medical, Inc.

2.0 SPONSOR: Kalypto Medical, Inc.
1250 Northland Drive
Mendota Heights, MN 55120

3.0 TEST FACILITY: WuXi AppTec, Inc.
1285 Kennestone Circle
Marietta, GA 30066

4.0 DEVIATION

Section 11.1.2 of the study protocol states that the effectiveness of the cleaning procedure will be evaluated by inoculating the device with a spore suspension. The Client has elected to evaluate the effectiveness of the cleaning procedure by incorporating artificial soil that has been inoculated with a spore suspension. This artificial soil simulates the type of contamination that is expected to be on the devices after use. The formula for the simulated blood / serum artificial soil (Miles) is shown in Table 1.

Table 1: Formula for Artificial Soil

Ingredient	Amount
Fetal calf serum	10 mL
Dry milk powder	6 g
Rabbit blood	1 mL
0.9% saline	1 mL

Section 11.2.1, Table 2 of the study protocol outlines the cleaning procedure for Kalypto Medical, Inc.'s NPD 1000 Negative Pressure Wound Therapy Device. The Client has elected to change the cleaning procedure to the method described in Table 2 of KYP071408cln.01, Deviation 1.

Table 2: Cleaning Procedure

STEP	Time	Cleaning criteria
1	As needed	Use cloth dampened with tap water and household dishwashing soap to clean external surfaces. Wipe until visibly clean.
2	As needed	Wipe the external surfaces again with a cloth dampened with water (no soap) to remove residual soap. Wipe until no longer "slippery", then allow to air dry.
3	As needed	Wipe external surface with 70% ethyl alcohol and allow to air dry
4	As needed	Visually Inspect

Protocol Number: KYP071408clin.01
Deviation: 1

Kalypto Medical, Inc.
Page 2 of 2



Section 12.0 of the study protocol outlines the acceptance criteria of the study. The Client has elected to add "Section 12.4 External surfaces of the cleaned device must be visibly clean" to the acceptance criteria.

5.0 DEVIATION APPROVAL SIGNATURES

SPONSOR: Entellus Medical, Inc.

NAME: Pamela Vaughan

TITLE: Principal Project Mgr

SIGNATURE: Pamela Vaughan

DATE: 8-4-08

PHONE: 651-753-0004 FAX: 763-287-3836

EMAIL: pamelav@alquest.com

WUXI APPTEC, INC.

NAME: Julia Taylor
Project Coordinator - Specialized Studies

SIGNATURE: Julia Taylor

DATE: 08-01-08

- Proprietary Information -

To re-order, consult your physician and refer to the Product Number below.

Product Number #: B1-08x12-S

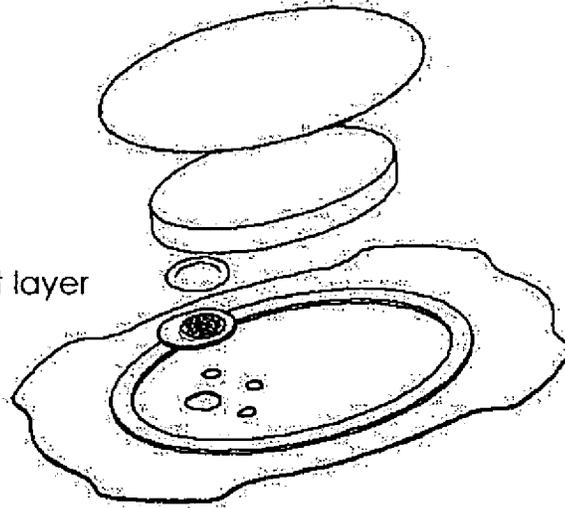


NPD 1000 Negative Pressure Wound Therapy Dressing

50cc Dressing

Latex-free

8 cm x 12 cm oval dressing with silver (Ag) wound contact layer



Patents pending on the NPD 1000 Negative Pressure System and accessories

 SINGLE USE ONLY.

STERILE Do not use if package is open or damaged.

 **CAUTION:** Consult the NPD 1000 Instructions for Use for directions on the safe use of this dressing.

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

LOT Lot Number listed at the bottom of the pouch.

 Manufacture Date listed at the bottom of the pouch.

 Keep Dry.

 Use by 1 year from the date of manufacture at the bottom of the pouch.

Assembled in the USA



Manufactured for:
Kalypto Medical
1250 Northland Drive
Mendota Heights, MN 55120
Phone: 877.286.3740

Website:
www.kalyptomedical.com

P/N 50007 Rev. A © Kalypto Medical 8/08