

K042616
Page 1 of 5

OCT 12 2004

510(K) Summary of Safety and Effectiveness

General Information

Submitter's Name: BioMedix, Inc.
Address: 4205 White Bear Parkway
St. Paul, MN 55110
Telephone: 651-762-4010
Contact Person: Will Rogers or Dick Magnuson
Date Prepared: July 23, 2004
Registration Number: 2134492

Device

Name: PADnet Lab
Trade Name: PADnet Lab
Common Name: Plethysmograph
Classification Name: Blood Flow Monitor
Product Code: JOM
Class: II
Regulation Number: 870.2780

Identification of Legally Marketed Devices

Name: Flostat Vascular Lab

K Number: K973644

Date Cleared: December 23, 1997

Description of the Device

The BioMedix PADnet Lab is a non invasive cardiovascular blood flow monitor. It is intended for use in the early detection of peripheral vascular disease. The PADnet Lab has been tested to the following standards.

- EN60601-1 Electrical Safety
- EN60601-1-2 EMC
- ISO 10993-1 Biological evaluation

The BioMedix PADnet Lab is a non invasive cardiovascular blood flow monitor. It is intended for use by trained medical professionals in a hospital or clinic. It is not to be operated in an explosive atmosphere nor in the proximity to any equipment that has the potential to generate a sufficiently large electromagnetic field as to interfere in any manner with the operation of the PADnet Lab.

The BioMedix PADnet Lab is a Prescription Device, **not** life supporting or life sustaining, not an implant, supplied **non-sterile** with pressure cuffs. It requires a Personal Computer with the following requirements:

- Windows 2000 Operating System or higher
- 128 MB RAM
- 20 GB Free Hard Disk Space
- 600 MHz Processor or higher

Intended Use Statement

The BioMedix PADnet Lab is a non invasive device used to gauge the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures to assist in the identification of vascular disease. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

Components/ Part Numbers

Description	BioMedix Part Number
1- USB cable	100-1600
1- Cuff kit	7200
BioMedix PADnet Lab Software Program CD ROM	400-210
1-AC Power Cord	350-215
1- PADnet Lab Operators Manual	10650

Table of Comparisons

The following summary table of comparisons compares the new device (PADnet Lab) to the predicate device: Flowstat Vascular Lab.

#	Area	New Device: PADnet Lab	Predicate Device: Flowstat Vascular Lab	Same	Different
1	Pulse Volume Recording	Plethysmograph	Plethysmograph	X	
2	Segmental Pressure flow sensor	Oscillometric	Distal Flow Sensor		X
3	Patient Population	Male/Female Adult	Male/Female Adult	X	
4	Environment	Hospital or Clinic	Hospital or Clinic	X	
5	Power Source	AC converted to DC	AC converted to DC	X	
6	Weight	4 lbs.	26 lbs.		X
7	Data acquisition	Single site	Bilateral		X
8	Software Controls	Operator initiated	Operator initiated	X	
9	Size	12 1/2" W X 10" D X 3 " H	20 1/2" W X 17 3/4 " D X 7" H		X
10	Cuff Deflation Rate	3-5 mm Hg/Sec	3-5 mm Hg/Sec	X	

11	Operating Environment	0 to +40°C 15 - 90%	0 to +40°C 15 - 90%	X	
12	Storage Environment	-40 to +50° C 5-95%	-40 to +50° C 5-95%	X	
3	Safety Standards	Yes	Yes	X	
14	EMC	Yes	Yes	X	
15	Prescription Device	Yes	Yes	X	
16	Cuff Bladder Deflation	Automatic	Automatic	X	
17	Inflation Method	Automatic	Automatic	X	
18	Cuff Sizes	Multiple	Multiple	X	
19	Clinical Reports	Yes	Yes	X	
20	Printed Reports	Yes	Yes	X	
21	Supplied Non-Sterile	Yes	Yes	X	

Discussion of Similarities and Differences

The PADnet Lab and the Flowstat Lab have the following similarities:

- Pulse Volume Recording
- Patient Population
- Environment
- Power Source
- Software Controls
- Cuff Deflation Rate
- Operating Environment
- Storage Environment
- Safety Standards
- EMC
- Prescription Device
- Cuff Bladder Deflation
- Inflation Method
- Cuff Sizes
- Clinical Reports
- Printed Reports
- Supplied Non-Sterile

The differences, with comments, are the following:

- Segmental Pressure flow sensor – The PADnet Lab uses Oscillometric not distal flow sensor.
- Weight – PADnet Lab is significantly less.
- Data acquisition – PADnet Lab is single site not bilateral.
- Size – PADnet Lab is significantly smaller.

Thus, even though the PADnet Lab is not identical to the Flowstat Vascular Lab, we at BioMedix believe it should be granted substantial equivalence because:

- It has the same intended use as the predicate device.
- It has the same technical characteristics as the predicate device and does not raise any new types of safety or effectiveness concerns.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2004

Biomedix, Inc.
c/o Ms. Laura Danielson
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K042616

Trade Name: Biomedix PADnet Lab
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, pneumatic, or photoelectric plethysmographs
Regulatory Class: Class II (two)
Product Code: JOM
Dated: September 22, 2004
Received: September 23, 2004

Dear Ms. Danielson:

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.

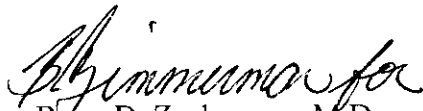
Page 2 – Ms. Laura Danielson

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Biomedix PADnet Lab

Indications for Use:

The BioMedix PADnet Lab is a non invasive device used to record physiological data from the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures for use by the Physician in the identification of vascular pathology. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

User Profile:

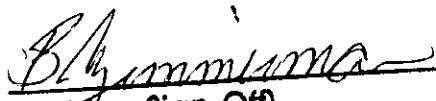
Patient Population: Male/Female, Adults

Environment of Use: Hospitals or Clinics

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042616

Page __ of __

(Posted November 13, 2003)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850**

OCT 12 2004

Biomedix, Inc.
c/o Ms. Laura Danielson
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K042616

Trade Name: Biomedix PADnet Lab
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, pneumatic, or photoelectric plethysmographs
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Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

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User Profile:

Patient Population: Male/Female, Adults

Environment of Use: Hospitals or Clinics

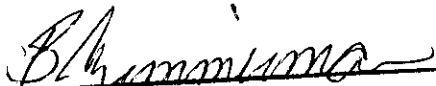
Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

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

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042616

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(Posted November 13, 2003)

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

September 24, 2004

BIOMEDIX, INC.
c/o TUV AMERICA, INC.
1775 OLD HIGHWAY 8
NEW BRIGHTON, MN 55112
ATTN: LAURA DANIELSON

510(k) Number: K042616
Received: 23-SEP-2004
Product: BIOMEDIX PADNET LAB

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

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

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 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.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

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

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Cover Letter FDA	K042616 TÜV PRODUCT SERVICE IQ
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Date: September 22, 2004

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

RE: Premarket Notification

To Whom It May Concern:

Enclosed in duplicate is the following information:

A. Purpose of Submission: New Device

B. Name and Address of the Third Party:

TÜV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

C. Name and Address of the Manufacturer:

BioMedix, Inc.
4205 White Bear Parkway
St. Paul, MN 55110

D. Name of Device

Trade Name: PADnet Lab

Common Name: Blood Flow Monitor

FDA Classification Name: Plethysmograph

E. Classification Regulation Number: 21 CFR 892.2780

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891
Telephone: 612-631-2487

Form: FDA_F_09.06L, Revision 1
Author: Jackson
Developed: 10. May, 1996 / Released: 30. September, 1996
Page 1 of 2

File: FDA_F_09.06L, Revision 1, Effective 30. November, 1996

Cover Letter FDA



F. Recommendation: Substantially Equivalent

G. Date TÜV Product Service Received the 510(k): July 27, 2004

We have also enclosed the following additional material:

H. Manufacturer's Authorization Letter (FDA_F_09.07)

I. Complete 510(k)

J. Review of the 510(k) (FDA_F_09.01, FDA_F_09.02, FDA_F_09.05 and all other correspondence and documents related to the review.)

K. Certification (FDA_F_18.05)

If you should have any questions regarding this submission, please contact me at 651-604-3380 or fax 651-633-5286. When completed, please fax the substantially equivalent letter to TÜV Product Service.

Sincerely,

A handwritten signature in black ink, appearing to read "Laura Danielson".

Laura Danielson
Responsible Third Party Official
510(k) Program Manager

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891
Telephone: 612-631-2487

Form: FDA_F_09.06L, Revision 1
Author: Jackson
Developed: 10. May, 1996 / Released: 30. September, 1996
Page 2 of 2

File: FDA_F_09.06L, Revision 1, Effective 30. November, 1996

26

Indications for Use

510(k) Number (if known): _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page of

(Posted November 13, 2003)

510(K) Summary of Safety and Effectiveness

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Submitter's Name: BioMedix, Inc.

Address: 4205 White Bear Parkway
St. Paul, MN 55110

Telephone: 651-762-4010

Contact Person: Will Rogers or Dick Magnuson

Date Prepared: July 23, 2004

Registration Number: 2134492

Device

Name: PADnet Lab

Trade Name: PADnet Lab

Common Name: Plethysmograph

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Product Code: JOM

Class: II

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21	Supplied Non-Sterile	Yes	Yes	X	

Discussion of Similarities and Differences

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- It has the same intended use as the predicate device.
- It has the same technical characteristics as the predicate device and does not raise any new types of safety or effectiveness concerns.

**FDA Certification (Qualifications, Truthful/Accurate,
Review on 510(k), False Information)**



1. I certify that TÜV Product Service continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by the FDA;
2. In addition, I state that TÜV Product Service believes that statements made in the review are true and accurate to the best knowledge of TÜV Product Service;
3. That TÜV Product Service review is based on the 510(k) that is attached with the review; and
4. TÜV Product Service understands that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 33(q).

Laura Danielson

Name of Third Party Official

A handwritten signature in black ink, appearing to be "Laura Danielson", written over a horizontal line.

Signature of Third Party Official

Date: **September 22, 2004**

TÜV Product Service
1775 Old Highway 8 Suite 104
New Brighton, MN 55112-1891
Telephone: (651)631-2487

File: FDA_F_18.05L, Revision 2, Effective March 15, 2001

Form: FDA_F_18.05L, Revision 2
Author: Mark Job
Developed: 10. May, 1996 / Released: 30. September, 1996
Page 1 of 1

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**COI Declaration and Certification
For Specific 510(k) Review**

**COI Declaration and Certification
for**

Manufacturer: BioMedix, Inc.
Device: PADnet Lab

Initials

CN I have read and understand TÜV's COI/Confidentiality Procedure (FDA_P_18.02), regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.

CN I was not employed within the last two years by the manufacturer (identified above) who submitted the 510k for review;

CN I did not charge fees contingent or based upon the recommendation for initial classification (SE decision).

CN I have not performed testing in connection with this specific device 510(k).

Signed:

Cheryl Norton

Printed Name: Cheryl Norton

Date: September 22, 2004

Please return signed original to 510(k) Program Manager.

TÜV PRODUCT SERVICE

1775 Old Highway 8 NW
New Brighton, MN 55412-1891
Telephone: (651)631-2487

COI Declaration and Certification
For Specific 510(k) Review
Author: Mark Job
Developed: 27.Feb.2001
Page 1 of 1

File: FDA_F_09_12, Revision: 1, Effective: 4 January 2002



Third Party "Substantial Equivalence" (SE) Decision Making Documentation

- 510(k) Holder's Name: BioMedix, Inc.

- Primary Third Party Reviewer:

Cheryl Norton
 Signature
Cheryl Norton
 Print Name

September 22, 2004
 Date

- Responsible Third Party Official:

[Signature]
 Signature
Laura Danielson, 510(k) Program Manager
 Print Name and Title
 TÜV PRODUCT SERVICE

September 22, 2004
 Date

	Yes*	No*	
1. Is product a device?	X		If NO= Stop
2. Is device subject to 510(k)?	X		If NO= Stop
3. Same indication statement?	X		If YES=Go to 5
4. Do differences alter the effect or raise new issues of safety or effectiveness?			If YES=Stop NE
5. Same technological characteristics?		X	If YES=Go to 7
6. Could the new characteristics affect safety or effectiveness?	X		If YES=Go to 8
7. Descriptive characteristics precise enough?			If NO=Go to 10 If YES=Stop SE
8. New types of safety or effectiveness questions?		X	If YES=Stop NE
9. Accepted scientific methods exist?	X		If NO=Stop NE
10. Performance data available?	X		If NO=Request Data
11. Data demonstrate equivalence?	X		Final Decision:SE

*Note: "yes" responses to questions 4,6,8, and 11, and every "no" response requires an explanation. Document the decision path by marking the arrows followed on the FDA flowchart.



Third Party "Substantial Equivalence" (SE) Decision Making Documentation

Company Name: BioMedix, Inc.

Device Name: PADnet Lab

Contact: William Rogers

Phone: 651-762-4010

Fax: 651-762-4014

E-Mail: wrogers@biomedix.com

I. Purpose

The purpose of this document is to explain the substantial equivalence determination for the new device BioMedix PADnet Lab compared to the BioMedix Flostat Vascular Lab.

BioMedix has authorized TÜV America to be the Third Party Reviewer for this 510(k).

The Truthful and Accurate statement is located in tab 26 of the submission.

The 510(k) Summary of Safety and Effectiveness is found in tab 24 of the submission.

II. Device Description

A. Intended Use/Indications for Use

The BioMedix PADnet Lab is a non-invasive device used to record physiological data from the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures for use by the Physician in the identification of vascular disease. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

The Indications for Use statement is located with the Additional Information received on 8/13/04.

B. Summary

Life-supporting or life-sustaining?	☐ Yes	☒ No
Implant?	☐ Yes	☒ No
Sterile?	☐ Yes	☒ No
Single use?	☐ Yes	☒ No
Prescription use?	☒ Yes	☐ No
Home use or portable?	☒ Yes (portable)	☒ No (Home Use)

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891
Telephone: (651) 631-2487



Third Party "Substantial Equivalence" (SE) Decision Making Documentation

Drug or biological combination product?	☐ Yes	☒ No
Kit?	☐ Yes	☒ No
Software driven?	☒ Yes	☐ No
Electrically Operated?	☒ Yes	☐ No

C. Materials/Biocompatibility

The only part of the device which is in contact with the patient is the blood pressure cuff. The blood pressure cuffs specified for use with the PADnet Lab are D.E. Hokanson, Inc., part numbers SC10, SC12, and DC2.5 cleared in K041689.

D. Design/Specifications

Physical Description:

The PADnet Lab device weighs 4 lb. and measures 12.5" x 10" x 3". The PADnet Lab Test software is loaded on a computer with minimum operating specifications stated by BioMedix. A USB cable is used to connect the PADnet Lab device to the computer. BioMedix provides a kit with various sizes of blood pressure cuffs for use with the device. Photographs of the device are found in tab 2D.

Theory of Operation:

The PADnet Lab is able to perform two different measurements: segmental pressure and pulse volume recording (PVR). The PADnet Lab takes pressure readings at various body locations. The cuff is inflated to a pressure higher than the patient's systolic pressure. The PADnet Lab uses a procedure similar to the oscillometric method to estimate a pressure value that matches the predicate device pressure reading. The pressure in the cuff is gradually released and the oscillations in the cuff are recorded and amplified. Pressure and amplitude are calculated according to the algorithm described in the document "PADnet Pressure Calculation" found with the Additional Information received 9/20/04.

E. Sterilization/Reuse

The PADnet Lab is not sterilized.

F. Labeling

The draft Operators Manual is found in tab 6E. It includes adequate instructions for use, a list of approved accessories, the minimum computer specifications, cautions, the intended use of the device, and the required prescription statement.

Additional device labels and shipping labels are also found in tab 6.



Third Party "Substantial Equivalence" (SE) Decision Making Documentation

The promotional literature for the PADnet Lab is contained with the Additional Information received 9/20/04. This proposed advertising is consistent with the information in the rest of the submission and no additional claims are made.

G. Comparative Specifications

BioMedix has provided a comparison table for the PADnet Lab and the predicate Flostat Vascular Lab on page 16 of the submission. The comparison includes patient population, environment, standards compliance, and functionality.

The intended use of the PADnet Lab and Flostat Vascular Lab are the same since both are non-invasive devices used to record physiological data using pulse volume recordings and segmental pressures for use by healthcare professionals in a hospital or clinic to identify vascular disease. The predicate device also includes an ultrasound modality which is not part of the PADnet Lab.

The PADnet Lab is smaller and lighter than the predicate. The PADnet Lab only measures pressure at one site at a time but the predicate was able to acquire data from multiple sites. The pulse volume recording is the same for both devices but the segmental pressure is different since the predicate used a distal flow sensor and the PADnet Lab uses the oscillometric method.

H. Performance Testing

BioMedix has performed testing to show substantially equivalent pressure readings between the PADnet Lab and the predicate device. Tab 4 contains the raw data of nine samples comparing both PVR (Pulse Volume Recording) amplitude and pressure at various locations on both sides of the body. The largest difference in amplitude was 1 with an average difference less than 1. The largest difference in pressure readings between the devices was 3 mmHg with an average difference less than 1 mmHg.

I. Animal Testing

Animal testing was not performed and is not required.

J. Clinical Testing

Clinical trials (IDE) were not performed. Non-clinical data was sufficient to determine substantial equivalence.

K. Software



Third Party "Substantial Equivalence" (SE) Decision Making Documentation

The Level of Concern of the software is Moderate since PADnet Lab provides diagnostic information which could result in non-serious injury prior to mitigation.

The software description is found on page 11 of the submission. PADnet Lab has two software components. The PADnet Lab Test software is application software which provides the user interface on the computer for entering patient data and controlling the PADnet Lab Diagnostic Test Unit (DTU) firmware. The PADnet DTU firmware works with the hardware to gather the blood pressure data.

A "top down" Hazard Analysis for the PADnet Lab is found in tab 13A. A risk index was determined from the estimated severity, probability of occurrence, and risk management method effectiveness for each identified hazard. All risks were found acceptable without further mitigation. BioMedix also performed a Design FMEA on the PADnet Lab Diagnostic Test Unit (DTU) to identify potential single fault failures at the functional block level. A Risk Priority Number was determined for each failure mode based on criticality, probability of occurrence, and probability of detection. All risks were ranked as minor.

The Software Requirements Specifications are found in tab 11 (PADnet Lab DTU software) and tab 12 (PADnet Test software). These documents include a list of all software functional requirements identified with the unique numbers "Rxxx".

The Architecture Design (including charts) for the PADnet Test software is explained on pages 5-9 of the PADnet Test Design Specification in tab 15. The Architecture Design (including charts) for the DTU Firmware is shown on pages 5-8 of the PADnet DTU Firmware Design Specification in tab 16. These documents also contain design specifications which explain the steps for how the software will perform each feature of the software including security and communications.

A Traceability Analysis is found in tab 17. This document links the requirements, design specifications, hazard analysis, and validation testing of the PADnet Lab.

The BioMedix Software Development Lifecycle is described on pages 12-13 of the submission. BioMedix used the Waterfall Model which included System Conceptualization, System Analysis, System Design, Coding, and Testing. The tool CVS (Concurrent Version System) was used for the configuration management system to control changes to the software. The tool Eventum was used for tracking defects.

Verification testing of the Hardware is found in tab 20A and 20B of the submission. Validation testing for the PADnet Test software is contained in tab 18 and validation testing for the PADnet DTU firmware is found in tab 19. These documents contain



Third Party "Substantial Equivalence" (SE) Decision Making Documentation

pass/fail criteria and actual test results.

The software Revision Level History as of 7/6/04 is contained in tab 21 for the PADnet Test Software. Information linking the specific software version and date is found with the Additional Information received 9/20/04.

Unresolved anomalies (bugs) are described in the Certificate of Known Defects in tab 22. None of these known issues are related to the safety of the device.

The planned software release version number for the PADnet DTU Firmware is (b) (4)
The planned software release version number for the PADnet Test Software is (b) (4)

The PADnet Lab uses off-the-shelf software as documented in tab 23. The PADnet Lab Test application software uses the Microsoft XP Operating System, Microsoft MSDE Database, and Microsoft GUI. The PADnet DTU software uses Nilsen Elektronik's NESOS RTOS and KPIT GNU toolset.

L. Environmental Testing

Electrical and Mechanical Safety:

The PADnet Lab is in compliance with IEC 60601-1 (1998) according to the testing performed by TUV Rheinland of North America located in Newtown, CT. The test report is found in tab 9 of the submission.

Electromagnetic Compatibility:

The PADnet Lab is in compliance with EN 60601-1-2 (2001) for both emissions and immunity according to the testing performed by International Certification Services, Inc. in Glencoe, MN. The test reports are found in tabs 7 (emissions) and 8 (immunity) of the submission. The worst case margin is 3.7 dB for radiated emissions and 5.6 dB for conducted emissions. The device continued to operate properly during application of immunity tests without manual intervention or system degradation.

M. Certifications/Statements/Standards Met

510(k) Statement	-	no
510(k) Summary	-	yes
Class III Certification	-	no
Class III Summary	-	no
Truthful and Accurate Statement	-	yes
Indications for Use	-	yes



Third Party "Substantial Equivalence" (SE) Decision Making Documentation

N. Predicate Devices

The predicate device is the BioMedix Flostat Vascular Lab (K973644). This device was cleared by the Radiology branch under CFR 892.1540 (Nonfetal ultrasonic monitor). The predicate device's intended use does include a plethysmography function in addition to the doppler ultrasound function which is why it is used as a predicate device.

III. Correspondence

All phone, e-mail, and fax communications are documented. The following is a brief summary of all correspondence related to this submission.

- The 510(k) was received by TUV from BioMedix on 7/27/04.
- TUV had numerous e-mail and phone conversations with FDA between 8/4/04 and 8/12/04 trying to determine if the device qualified for Third Party review.
- TUV received revised information from BioMedix on 8/13/04 which allowed TUV to accept the 510(k) for Third Party review on 8/16/04 after another discussion with FDA.
- TUV sent a deficiency letter to BioMedix on 9/17/04.
- BioMedix responded to the questions on 9/20/04.
- TUV asked one follow-up question on 9/21/04 which was answered by BioMedix the same day.
- TUV is recommending substantial equivalence based on this review memo.

IV. Substantial Equivalence

The BioMedix PADnet Lab is substantially equivalent to the BioMedix Flostat Vascular Lab according to the decision path on the attached FDA flowchart and summarized on page 1 of this document.

V. Recommendation

Based upon the content of this document, a substantially equivalent decision is recommended.



Third Party "Substantial Equivalence" (SE) Decision Making Documentation

Explanations To "Yes" and "No" Answers to Questions On Page 1 As Needed.

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:

The PADnet Lab measures pressure differently compared to the predicate device.

- 6: Explain how new characteristics could or could not affect safety or effectiveness:

The pressure data from the PADnet Lab is ultimately used by a physician for diagnosis so the effectiveness of the device could be affected. The new characteristics do not affect safety.

- 7: Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

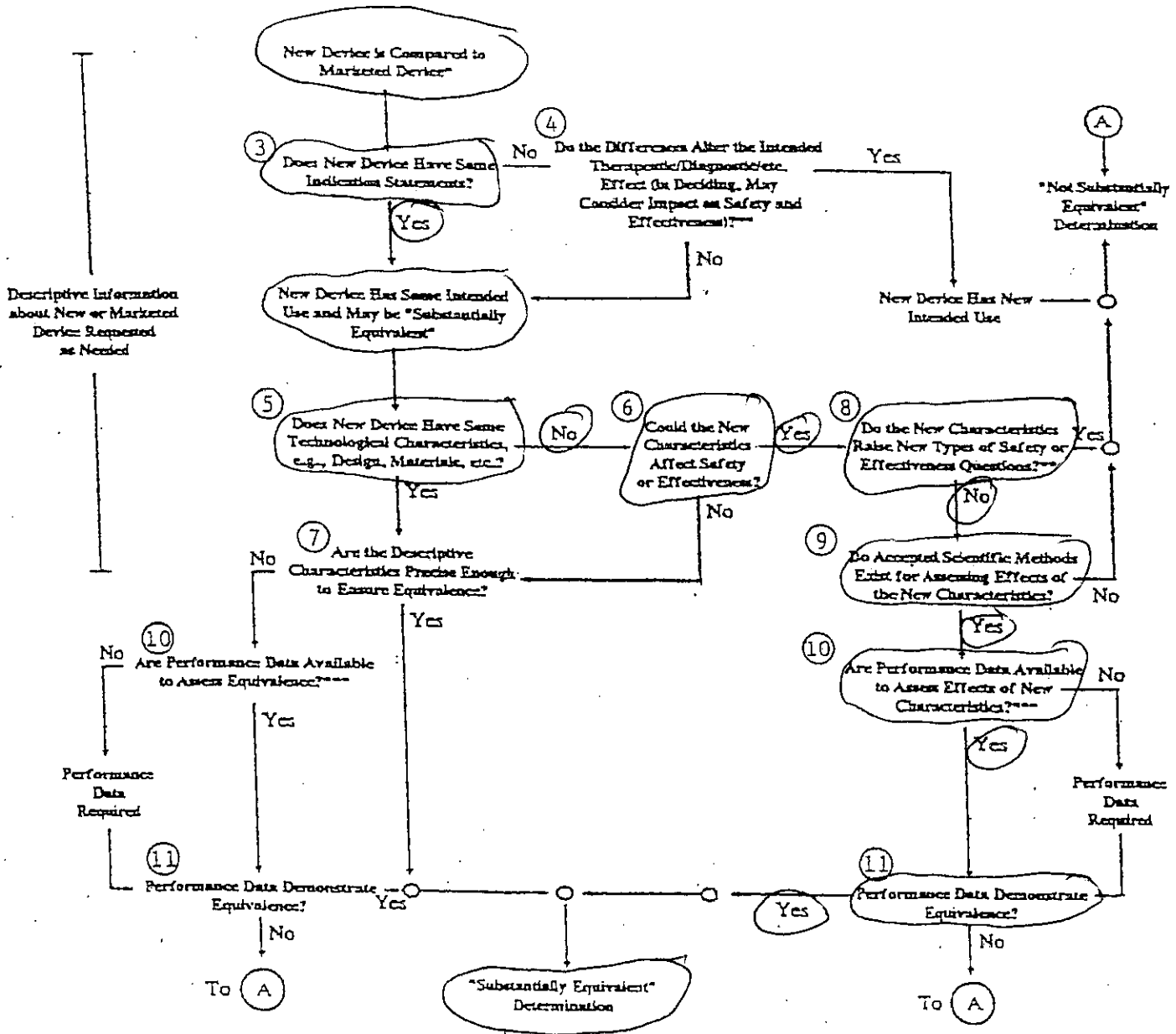
The question of effectiveness is not new since accurate pressure measurements were already design considerations for the device.

9. Explain why existing scientific methods cannot be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

Performance data demonstrates that the device is substantially equivalent since the average pressure variation compared to the predicate device was less than 1 mmHg.

BioMedix PADnet Lab

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



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

*** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Norton Cheryl

From: Will Rogers [rogersw@biomedix.com]
Sent: Tuesday, September 21, 2004 12:33 PM
To: Norton Cheryl
Cc: 'Dick Magnuson'; 'John Romans'
Subject: RE: one follow-up question

Cheryl,

(b) (4)



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

From: Norton Cheryl [mailto:CNorton@tuvam.com]
Sent: Tuesday, September 21, 2004 10:04 AM
To: Will Rogers
Cc: Dick Magnuson
Subject: one follow-up question

Will,
Please see the attached letter acknowledging receipt of the Additional Information.

<<ACKNOW3.DOC>>

(b) (4)



Regards,

Cheryl Norton
Lead NB Auditor/ Compliance Engineer/ Third Party 510(k) Reviewer TUV
America Inc.
Product Service
P: 651-638-0294
F: 651-638-0295

FACSIMILE TRANSMISSION

510(k) Program Dept.
Phone: 651 638-0294
Fax: 651 638-0295

Total of 1 page

TO: Will Rogers, BioMedix
cc: Richard Magnuson, BioMedix

Fax: 651-762-4014

FROM: Cheryl Norton

DATE: September 21, 2004

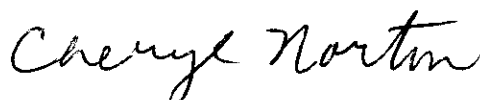
SUBJECT: 510(k) Notification for the PADnet Lab

Dear Mr. Rogers,

This letter is to acknowledge that on September 20, 2004, TÜV Product Service received Additional Information for the BioMedix PADnet Lab 510(k).

If you have any questions please contact me at 651-638-0294.

Sincerely,



Cheryl Norton
Third Party 510(k) Reviewer



BioMedix, Inc.

Memo

RECEIVED
SEP 20 2004

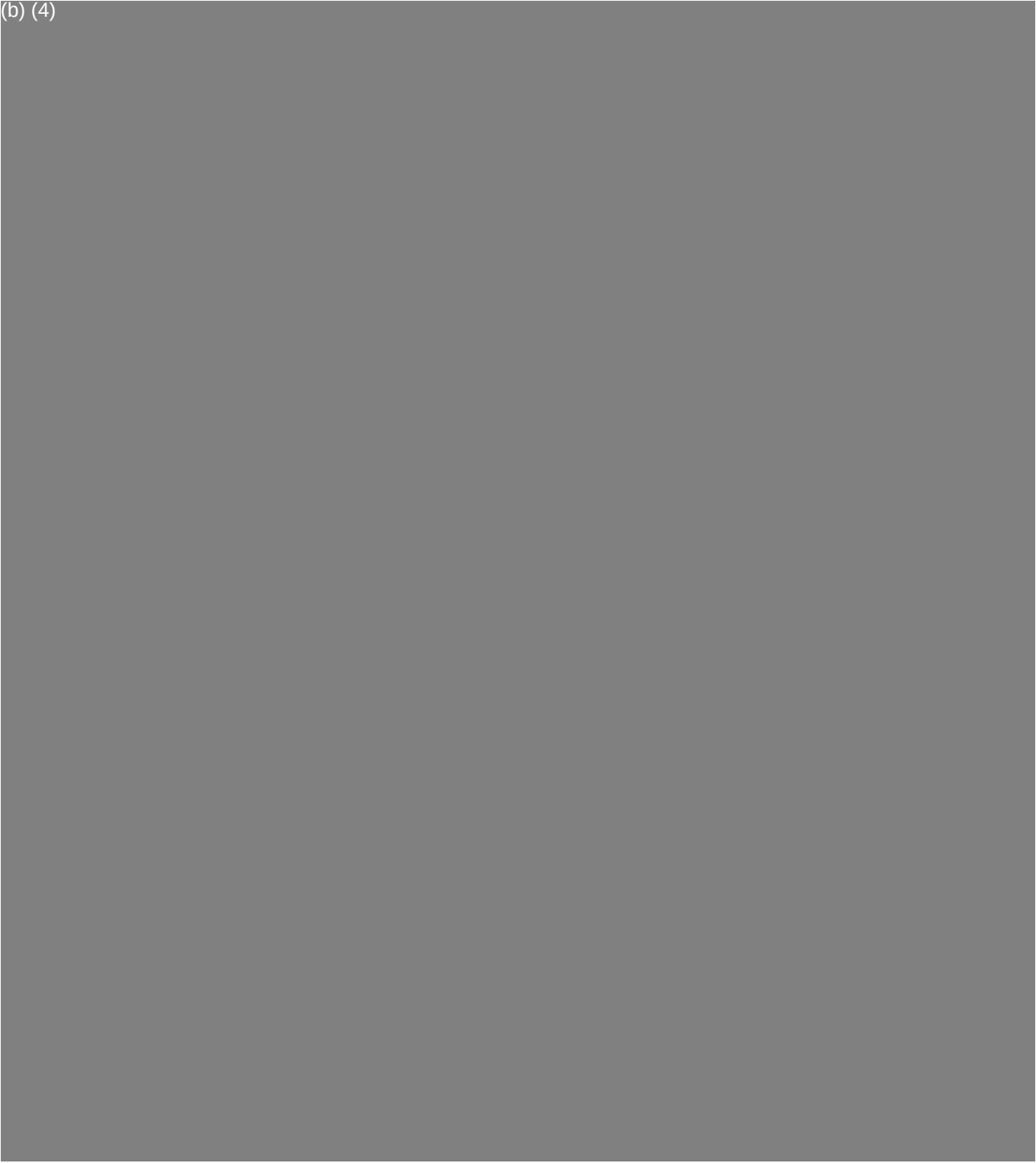
To: Cheryl Norton, TUV Product Services
From: Will Rogers
CC: D. Magnuson, J. Romans
Date: September 20, 2004
Re: Substantive Review Questions

Please find attached a detailed response to your inquiry of 9-17-04.

(b) (4)



(b) (4)



(b) (4)



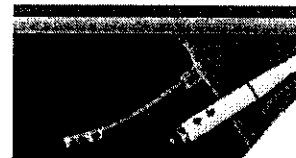
(b) (4)



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SEARCH

GO



Straight Segmental Cuffs

[< back](#)

Standard Hokanson straight cuffs come complete with a cover and bladder, and a plastic female luer fitting. Replacement bladders are also available.

[Enlarge Image](#)[Request Information](#)

Cuff Name	Overall cuff size	Applications
SC10	11 x 85 cm	Upper arm and lower leg for segmental pressure measurements and pulse volume recordings, four cuff method.
SC12	13 x 85 cm	Upper arm and lower leg for segmental pressure measurements and pulse volume recordings, four cuff method.
SC12L	13 x 124 cm	Upper thigh for segmental pressure measurements and pulse volume recordings, four cuff method on large patients.
SC5	6 x 83 cm	Arm or leg tourniquet cuff.
TMC7	7.5 x 40 cm	Metatarsus or wrist.

See also:

[S300 Aneroid Sphygmomanometer](#) | [TD312 Calculating Cuff Inflator](#)

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SEARCH

GO

Digit and Penile Cuffs

[< back](#)

Digit and penile cuffs are well constructed of latex rubber on a Velcro backing. Disposable penile cuffs are made of PVC. All cuffs are packaged individually and come with a plastic female luer fitting.

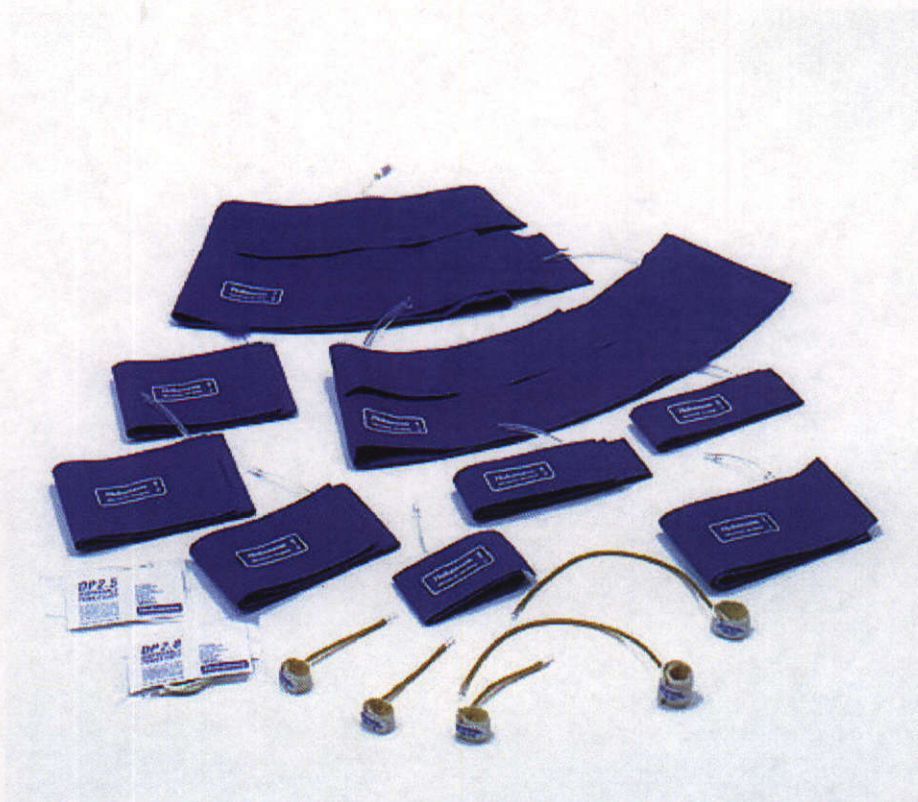
[Enlarge Image](#)[Request Information](#)

Cuff Name	Overall Cuff Size	Applications
DC1.6	1.6 x 9 cm	Small toes and fingers.
DC1.9	1.9 x 9 cm	Middle toes and fingers.
DC2.5	2.5 x 9 cm	Large fingers and middle toes.
PC2.5	2.5 x 12 cm	Large toe or penis.
PC3.3	3.3 x 12 cm	Very large toe or penis.
DP2.0	2.1 x 12.1 cm	Large toe or penis (disposable).
DP2.5	3.0 x 12.1 cm	Large toe or penis (disposable).

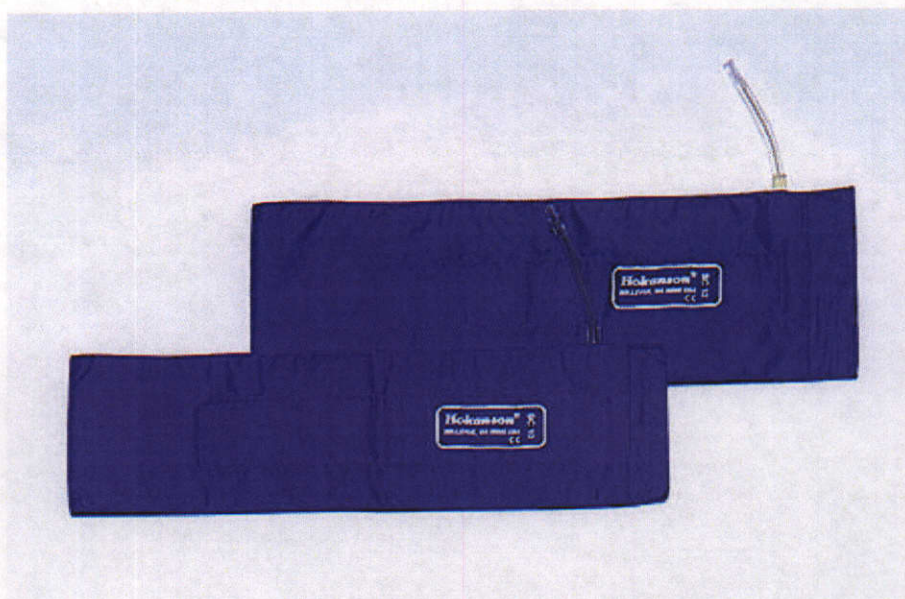
See also:

[TD312 Calculating Cuff Inflator | S300
Aneroid Sphygmomanometer](#)

[ABOUT HOKANSON](#) | [CONTACT HOKANSON](#) | [HOKANSON PRIVACY STATEMENT](#)
[RESOURCE CENTER](#) | [FAQS](#) | [CUSTOMER SERVICE](#) | [SITE MAP](#)
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(B)

		
Model	PADnet Lab	
SN		
Product	PADnet Lab	
Voltage	115/230 VAC	
Frequency	50-60 Hz	
Amperage	1.2 – 0.7Amp	St. Paul, MN 55110 Made in USA
		 0086
Caution : Federal Law restricts this device to sale by or on the order of a Physician		
Draft Product Label This label will be located on the lower right corner of the back panel of the device.		

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D

- ▶ Ankle Brachial Indices (ABI)
- ▶ Pulse Volume Waveforms (PVR)
- ▶ Study transfer via web

System

OVERVIEW:

- ▶ BioMedix™ PADnet Lab
- ▶ Dell Latitude™ D505
- ▶ Ergotron™ Medical Cart
- ▶ Complete Cuff Kit & Sensing Devices

SOFTWARE:

- ▶ Windows XP
- ▶ PADnet Test software
- ▶ Includes video tutorial

HARDWARE:

- ▶ Test unit
- ▶ Laptop PC- 1.40hz Pentium Dell
- ▶ Medical grade cart as shown
- ▶ Color Inkjet printer
- ▶ Pressure Cuff kit

Support

Installation and in-service training is provided for clinical staff

Laptop

PROCESSOR

Intel® Pentium® M

CPU SPEED

1.40 GHz

MEMORY

256 MB RAM

CHIPSET

Intel 855GM Integrated

UMA Graphics

DISPLAY SIZE & TYPE

14" TFT

VIDEO MEMORY

65 MB

FLOPPY DRIVE

NO

HARD DRIVE

30GB

CD ROM

24XCD, COMBO Included

INTERNAL SPEAKERS

YES

INTERNAL MICROPHONE

YES

MODEM

56K Fax Modem

LAN

10/100

AC ADAPTER

65W

I/O PORTS

3 - USB 2.0 MAX

1 PS/2

VGA OUT

Yes

AUDIO (IN/OUT)

YES/YES

S-VIDEO(IN/OUT)

NO/YES

DOCKING/PORT REP

USB

FIREWIRE(1394)

YES

TYPE II/TYPE III

1/0

POINTING DEVICE

TOUCH

BATTERY

Latitude D505 (6 CELL)

DIMENSION (WxDxH)

12.0x10.0x1.0

WEIGHT (w/batt.)

5.50

OPERATING SYSTEM

WIN XP

CERTIFICATIONS

FCC,UL

WARRANTY

2 years



BioMedix
VASCULAR LABORATORY SYSTEMS

www.biomedix.com

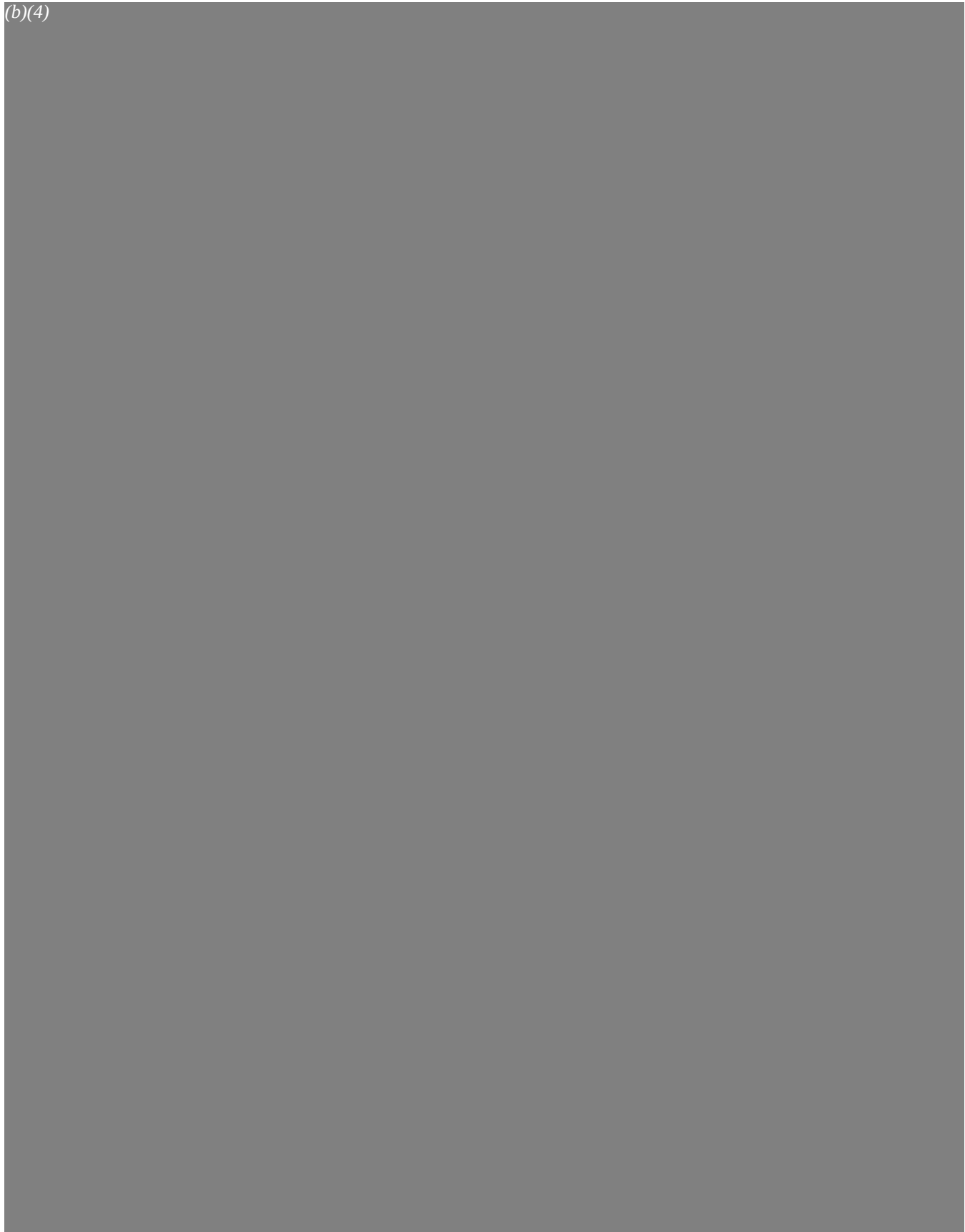
BioMedix® PCs use genuine Microsoft® Windows®
www.microsoft.com/piracy/howtotell

Equipment configuration may vary from that shown, depending on availability of components. In these cases, a functional equivalent will be provided
©2004. All copyright and trademarks are the property of their respective

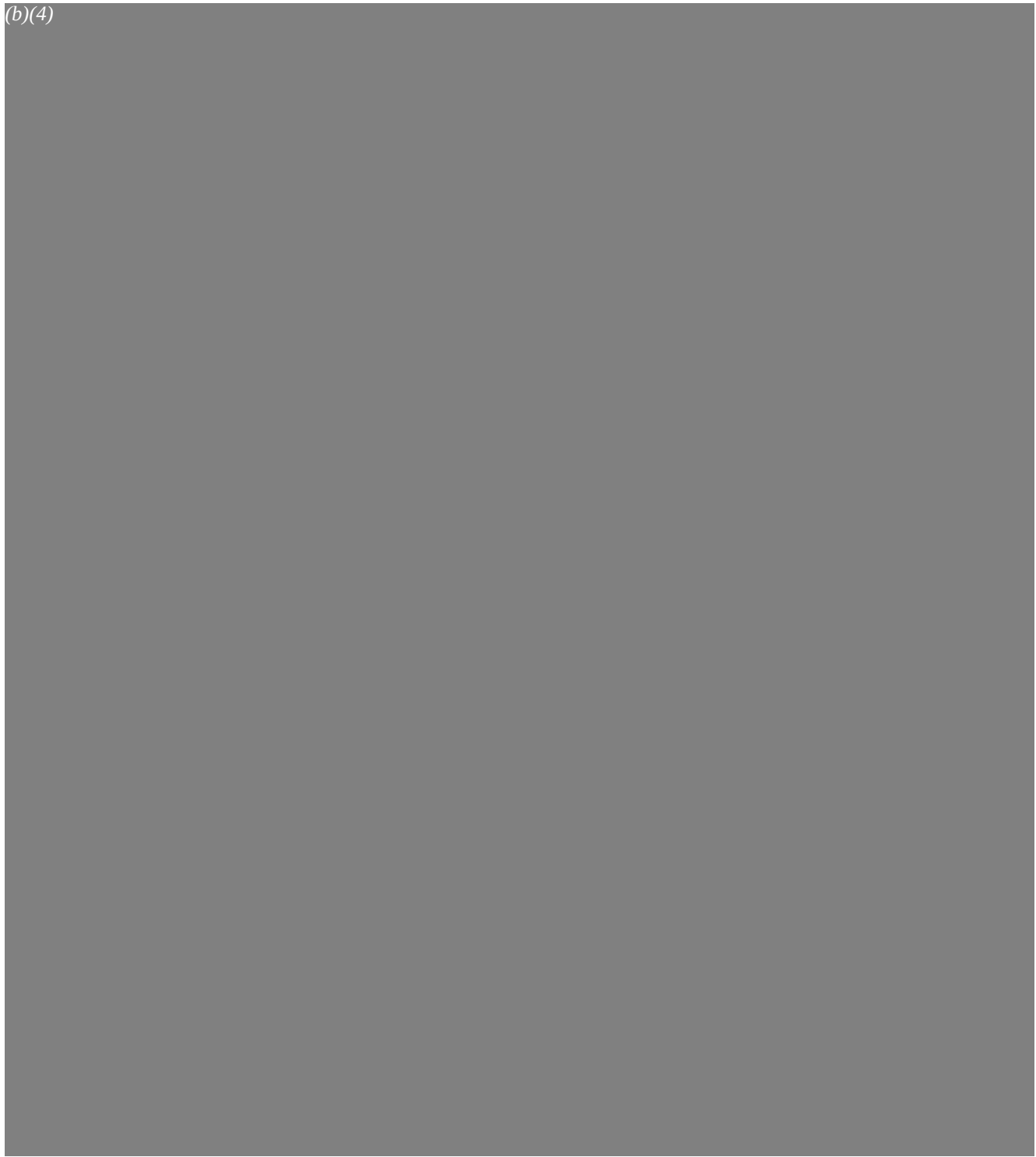
55

PADNet Pressure Calculation

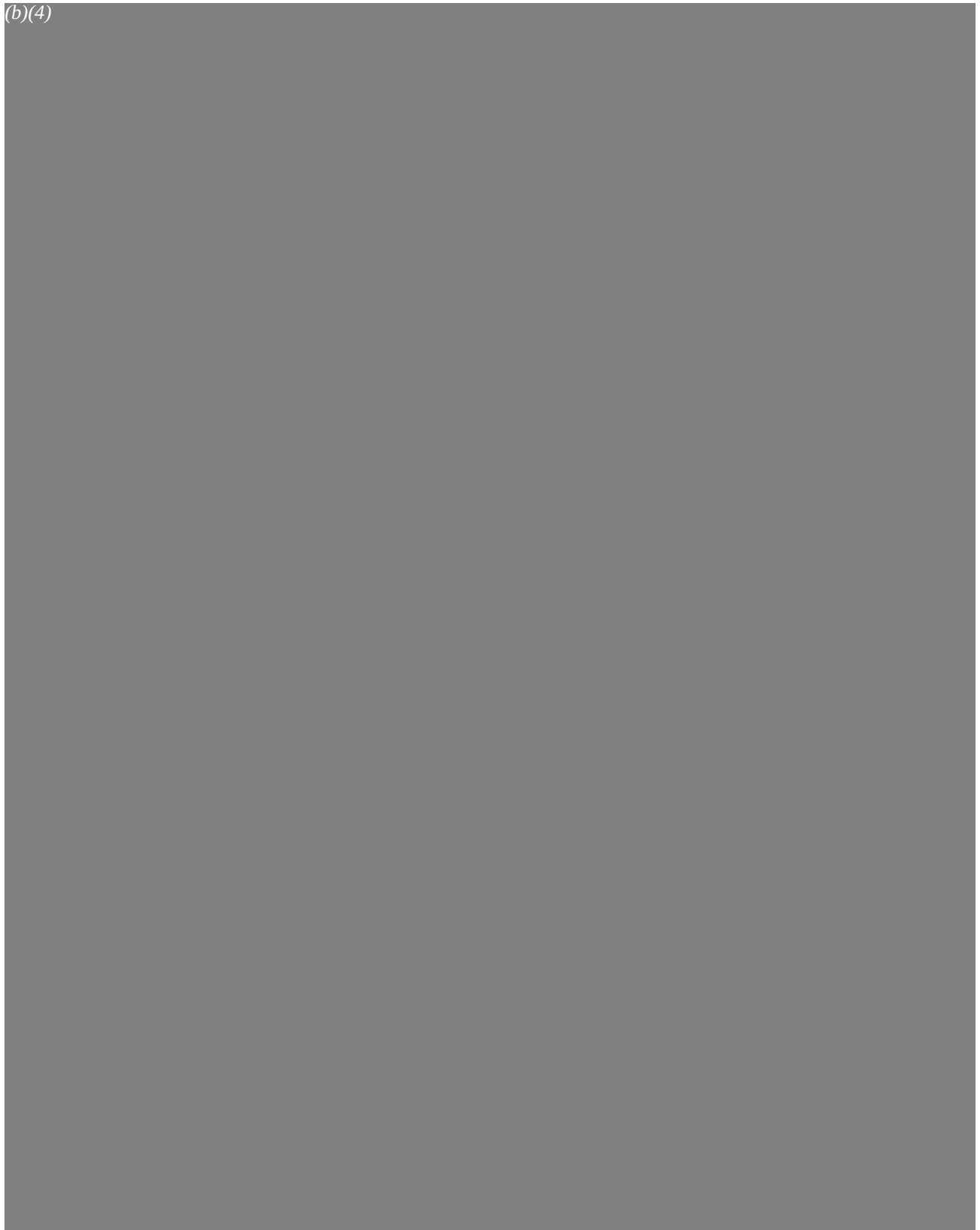
(b)(4)



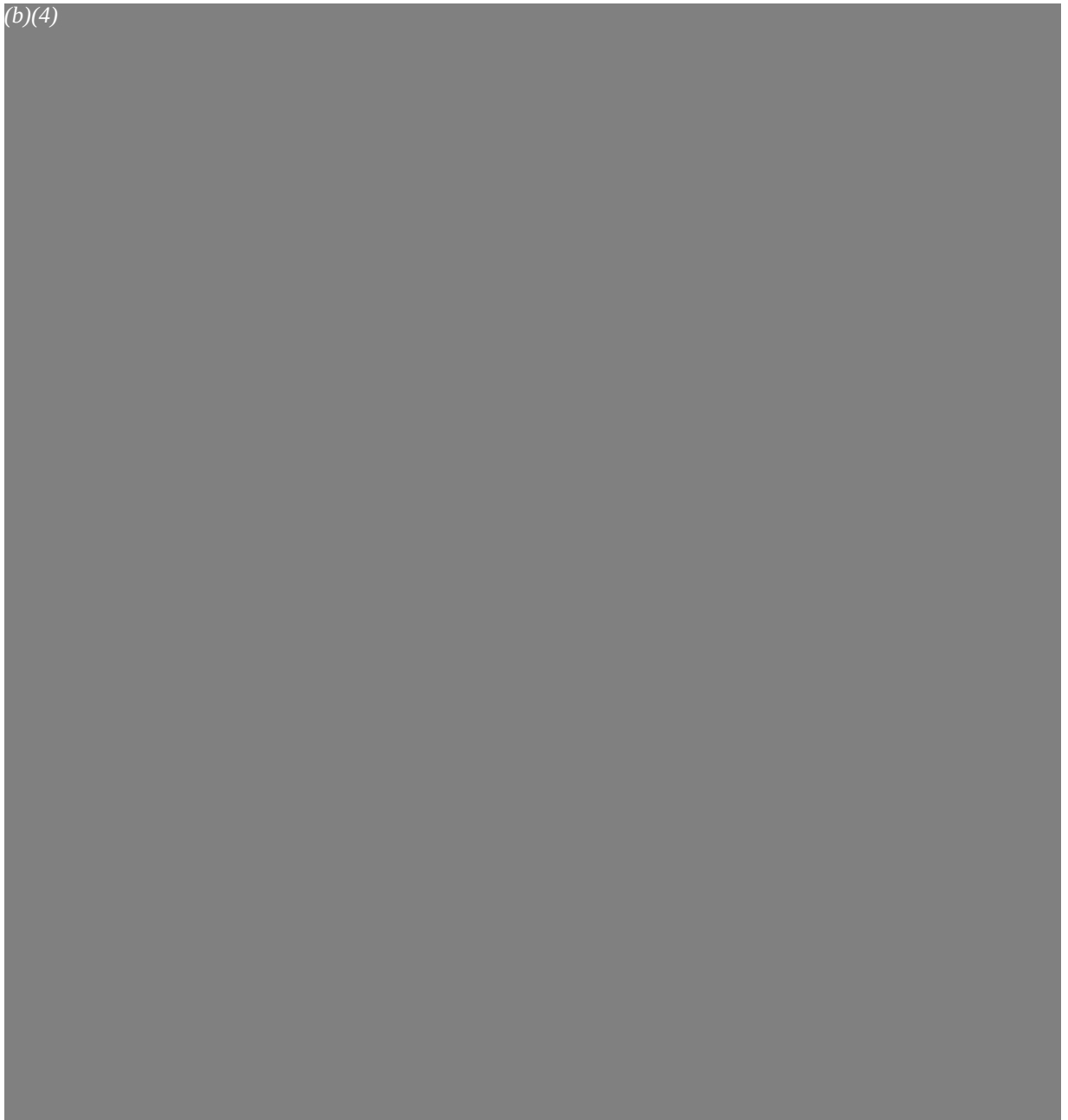
(b)(4)



(b)(4)



(b)(4)



(b)(4)



60



COMMUNICATION LOG FOR CHERYL NORTON

CONTACT:	<u>Will Rogers</u>	COMPANY:	<u>FDA</u>
TEL. NO.:	<u>651-762-4010</u>	FAX NO.:	<u>N/A</u>
DATE:	<u>September 20, 2004</u>	TIME:	<u>9:15 a.m.</u>
SUBJECT:	<u>510(k) Notification for PADnet Lab</u>		

NOTES:

(b) (4)

A large, solid grey rectangular box covers the majority of the page, redacting the content of the notes section. It starts below the "NOTES:" header and extends nearly to the bottom of the page.

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

FACSIMILE TRANSMISSION

510(k) Program Dept.
Phone: 651 638-0294
Fax: 651 633-5286

Total of 3 pages

TO: Will Rogers, BioMedix
cc: Richard Magnuson, BioMedix

Fax: 651-762-4014

FROM: Cheryl Norton

DATE: September 17, 2004

SUBJECT: 510(k) Notification for the PADnet Lab

Dear Mr. Rogers:

TÜV Product Service has completed the substantive review. We have found items that are missing or require clarification. These deficiencies are described in the attached Record of Deficiencies. Upon receipt of your written responses, TÜV Product Service will continue the review process.

If you have any questions please contact me at 651-638-0294.

Sincerely,



Cheryl Norton
Third Party 510(k) Reviewer

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**Third Party "Substantial Equivalence" (SE)
Decision Making Documentation**



Record of Deficiencies (from Substantive Review)

Model: PADnet Lab

Date: September 17, 2004

Describe in detail the additional information that is required:

(b)(4)



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**Third Party "Substantial Equivalence" (SE)
Decision Making Documentation**



IQ

(b)(4)

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64

TÜV PRODUCT SERVICE
1775 Old Highway 8 NW, Suite 104
New Brighton MN 55112-1891
United States of America

Phone 651 631 2487
Fax 651 638 0295
email info@tuvps.com
http www.tuvglobal.com



FACSIMILE TRANSMISSION

510(k) Program Dept.
Phone: 651 638-0294
Fax: 651 638-0295

Total of 1 page

TO: Will Rogers, BioMedix
cc: Richard Magnuson, BioMedix

Fax: 651-762-4014

FROM: Cheryl Norton

DATE: August 16, 2004

SUBJECT: 510(k) Notification for the PADnet Lab

Dear Mr. Rogers,

This letter is to acknowledge that on August 13, 2004, TÜV Product Service received Additional Information for the BioMedix PADnet Lab 510(k). The administrative review using the 27 item checklist for acceptance is complete. All required items are present and the substantive review will now begin. You will be advised as the review progresses.

If you have any questions please contact me at 651-638-0294.

Sincerely,

A handwritten signature in cursive script that reads 'Cheryl Norton'.

Cheryl Norton
Third Party 510(k) Reviewer

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Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Part I)



IQ

4. Device Name: PADnet Lab
Trade or Proprietary: PADnet Lab
Classification Name: Plethysmograph
5. CFR Classification Citation: 21 CFR 892.2780
(see 21 CFR 862 through 892)
6. Classification Panel: Cardiovascular
7. Based on my completion of pages 1 and 2 of FDA-F_09.01 and pages 1 through 5 of FDA_F_09.02, I recommend that this 510(k):
☒ Be accepted for substantive review and I have notified the 510(k) owner using FDA_F_09.09.
☐ Not be accepted for substantive review and I have listed the deficiencies on FDA_F_09.03
8. Primary Third Party Reviewer:
Cheryl Norton
Signature
August 16, 2004
Date
Cheryl Norton
Print Name
9. Responsible Third Party Official
[Signature]
Signature
August 16, 2004
Date
Laura Danielson
Print Name
FDA 510(k) Program Manager
Print Title

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55412-1891
Telephone: (612)631-2487

Form: FDA_F_09.01L, Revision 2
Author: Jackson
Developed: 10. May, 1996 / Released: 30. September, 1996
Page 2 of 2

File: FDA_F_09.01L, Revision 2, Effective 15. October, 1997

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Third Party Premarket Notification Checklist for Acceptance (Part II)

Part II - Checklist	YES	NO	Instructions
1 a). Is the device one that FDA has determined as being acceptable for third party review?	√		If NO, telephone DSMA for instructions. --STOP REVIEW--
1 b). Have you confirmed that the manufacturer has not engaged in forum shopping?	√		If NO, telephone DSMA for instructions. --STOP REVIEW--
2. Is the device trade or proprietary name included?	√		If NO, note deficiency on FDA_F_09.03.
3. Is the device common or usual name included?	√		If NO, note deficiency on FDA_F_09.03.
4. Is the device classification name, class of the device, and regulation number (21 CFR 870.2780) included?	√		If NO, note deficiency on FDA_F_09.03.
5. Is the classification panel included?	√		If NO, note deficiency on FDA_F_09.03.
6. Has the applicant complied with Section 514 of the Act? (Section 514 relates to performance standards for class II devices. At this time, there are no 514 standards. Therefore, your answer should be yes.)	√ (N/A)		If NO, note deficiency on FDA_F_09.03.
7. Does the submission include proposed labels, labeling, and advertisements (if available) that describe the device, its intended use, and directions for use (ODE Guidance Memorandum #G91-1)?	√		If NO, note deficiency on FDA_F_09.03.
8. Does the submission contain the "Indications for Use" form?	√		If YES, indicate page number <u>section 25</u> . If NO, note deficiency on FDA_F_09.03.

TÜV Product Service
1775 Old Highway 8 NW
New Brighton, MN 55412-1891
Telephone: (651)631-2487

Form: FDA_F_09.02L, Revision 2

Author: Job

Developed: 10. May, 1996 / Released: 30. September, 1996

Page 1 of 5

File: FDA_F_09.02L, Revision 2, Effective 15. March, 2001

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Third Party Premarket Notification Checklist for Acceptance (Part II)

Part II - Checklist	YES	NO	Instructions
9. Does the submission contain an acceptable <u>510(k) Summary of Safety and Effectiveness</u> (per 21 CFR 807.92) OR an acceptable <u>510(k) Statement</u> (per 21 CFR 807.93) that safety and effectiveness information will be made available to any person upon request?	✓		If YES, indicate page number <u>section 24</u> . If NO, note deficiency on FDA_F_09.03.
10. Does the submission contain photographs of the device if applicable?	✓ (N/A)		If NO, note deficiency on FDA_F_09.03.
11. Does the submission contain drawings for the device with dimensions and tolerances if applicable?	✓ (N/A)		If NO, note deficiency on FDA_F_09.03.
12. Does the submission identify the device to which equivalence is claimed?	✓		If NO, note deficiency on FDA_F_09.03.
13. If the answer to question 12 is YES, did the applicant identify: a. Predicate device (referred to as marketed device)? b. Legally marketed device (referred to as marketed device)? Note: A predicate device is a device that was legally in commercial distribution in the U.S. on or before May 28, 1976 (referred to as a pre-amendments device) or a device that was marketed after May 28, 1976 (referred to as a post amendments device) that was reclassified from class III to class I or II. A marketed device can be a predicate device but is most often a device that FDA has	✓	✓	<u>K973644</u>

TUV Product Service
1775 Old Highway 8 NW
New Brighton, MN 55412-1891
Telephone: (651)631-2487

Form: FDA_F_09.02L, Revision 2

Author: Job

Developed: 10. May, 1996 / Released: 30. September, 1996

Page 2 of 5

File: FDA_F_09.02L, Revision 2, Effective 15. March, 2001



Third Party Premarket Notification Checklist for Acceptance (Part II)

Part II - Checklist	YES	NO	Instructions
13. (con't) determined is SE to another marketed device (21 CFR 807.92(a)3). <u>IT IS YOUR RESPONSIBILITY TO MAKE SURE THAT THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE IDENTIFIED IS LEGITIMATE.</u> If it is not, the review must STOP. Telephone DSMA for assistance.			
14. Does the submission contain information about the marketed device(s) identified in questions 12 and 13 above to which equivalence is claimed, including labeling and a description of the device?	√		If NO, note deficiency on FDA_F_09.03.
15. Does the submission contain a statement/comparison of similarities and/or differences between the new device and the marketed device? (The new device that is the subject of this 510(k) can be either a new device or a modification to the existing device.)	√		If NO, note deficiency on FDA_F_09.03.
16. Does the submission contain the Truthful and Accurate Statement (per 21 CFR 807.87(j))?	√		If YES, indicate page number <u>section 26</u> . If NO, note deficiency on FDA_F_09.03.
17. Does the submission contain the submitter's name, address, contact person, telephone number, and fax number?	√		If NO, note deficiency on FDA_F_09.03.

TÜV Product Service
1775 Old Highway 8 NW
New Brighton, MN 55412-1891
Telephone: (651)631-2487

File: FDA_F_09.02L, Revision 2, Effective 15. March, 2001

Form: FDA_F_09.02L, Revision 2
Author: Job
Developed: 10. May, 1996 / Released: 30. September, 1996
Page 3 of 5

[illegible]

Form: FDA_F_09.02L, Revision 2
Author: Job
06 / Released: 30. September, 1996
Page 4 of 5



Third Party Premarket Notification Checklist for Acceptance (Part II)

Part II - Checklist	YES	NO	Instructions
24. If the device is labeled as sterile, does the submission contain sterilization data?	√ (N/A)		If NO, note deficiency on FDA_F_09.03.
25. Does the device incorporate a computer or computer software?	√		
a. If YES, is there information about the hardware?	√		
b. If YES, is there information about the software?	√		
26 a). Is there a specific guidance document for this type of device? Title: _____ _____ _____ _____		√	If YES, continue review with checklist from the specific guidance document and return to question 27. If NO, proceed to question 26 b).
26 b). Contact the appropriate ODE Branch Chief to obtain information for reviewing this type of device. Has a summary of this discussion been documented?	√		If YES, answer question 27. If NO, do not proceed to question 27; stop review until summary completed.
27. Is this 510(k) sufficiently complete to allow substantive review?	√		If YES, continue review using specific guidance document or if no specific guidance document, continue the review using documentation forms. If NO, note deficiency on FDA_F_09.03.

TÜV Product Service
1775 Old Highway 8 NW
New Brighton, MN 55412-1891
Telephone: (651)631-2487

File: FDA_F_09.02L, Revision 2, Effective 15. March, 2001

Form: FDA_F_09.02L, Revision 2
Author: Job
Developed: 10. May, 1996 / Released: 30. September, 1996
Page 5 of 5

Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Part I)



Part I - Acceptance / Non-Acceptance

1. Third Party:

Name: TÜV Product Service
Address: 1775 Old Highway 8 N.W., Suite 104
New Brighton, MN 55112-1891
Contact: Laura Danielson
Telephone No: 651-604-3380 Fax No: 651-633-5286

2. For Foreign Third Parties, Specify A Domestic Correspondent:

Name: N/A
Address: _____

Contact: _____
Telephone No: _____ Fax No: _____

3. 510(k) Owner (could be manufacturer, specifications developer, or other person preparing the 510(k)):

Name: BioMedix, Inc.
Address: 4205 White Bear Parkway
St. Paul, MN 55110
Contact: William Rogers
Telephone No: 651-762-4010 Fax No: 651-762-4014

STOP!

Before completing items 4 through 9 below, complete part II checklist questions 1 through 29 beginning on page 1 of FDA_F_09.02.

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55412-1891
Telephone: (612)631-2487

Form: FDA_F_09.01L, Revision 2
Author: Jackson
Developed: 10. May, 1996 / Released: 30. September, 1996
Page 1 of 2

File: FDA_F_09.01L, Revision 2, Effective 15. October, 1997



COMMUNICATION LOG FOR CHERYL NORTON

CONTACT:	<u>Dr. Charles Ho</u>	COMPANY:	<u>FDA</u>
TEL. NO.:	<u>301-443-8517, x179</u>	FAX NO.:	<u>N/A</u>
DATE:	<u>August 16, 2004</u>	TIME:	<u>12:30 p.m.</u>
SUBJECT:	<u>510(k) Notification for PADnet Lab</u>		

NOTES:

Cheryl called Charles to explain that Biomedix had revised their 510(k) and Cheryl wanted to know whether the revisions would allow Third Party review. Cheryl explained that the indications for use were revised to state that the device collects physiological data only and reference to diagnosis was removed. The Operators Manual was also revised to remove reference to diagnosis using the SBI. Charles emphasized again that the device must only give "a number" (data) and there must be no hint of how to interpret the data. If this condition is met, then the submission qualifies for Third Party review. Charles also mentioned that the data must be measured correctly; Cheryl stated that performance data was included in the submission. Cheryl stated that she planned to now accept this 510(k) for Third Party review and reminded Charles that all conversations with FDA are recorded in phone logs or e-mail messages as a record of information provided to FDA in order to reach this determination.

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

RECEIVED
AUG 13 2004

August 13, 2004

Cheryl Norton

TUV Product Service
1775 Old Highway 8 NW
Suite 104
New Brighton, MN 55112

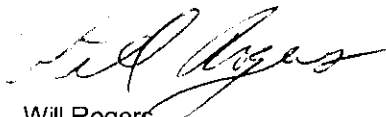
Dear Cheryl:

This letter is to acknowledge the fax and e-mail received on August 12th, 2004. After our phone conversation I would like to reiterate that the PADnet Lab was never intended to provide a diagnosis. It is only intended to provide physiological testing data to a qualified Physician to allow him to assess the status of the peripheral arterial system of the lower extremity. The following details were changed to reflect this intension.

- Indications for use statement located in section 25 and in the Premarket Notification document.
- The Operators Manual pgs. 3, 28-29 and 32-33.

Copies of these changed documents have been left at your office front desk to your attention. If you have any additional questions, please feel free to contact me.

Sincerely,



Will Rogers
Vice President Customer Service
Chief Technology Officer

BioMedix, Inc.

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CONFIDENTIAL

PREMARKET NOTIFICATION

FOR

BIOMEDIX'S
PADnet Lab

FOR REVIEW BY

Circulatory support and Prosthetics Devices Branch
Within

Division of Cardiovascular and Respiratory Devices (DCRD)

By

William Rogers
Vice President Customer Service / Chief Technology Officer
BioMedix, Inc.

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I. Administrative

A. Application Date:

B. Name/Address of Manufacturer/Applicant

BioMedix, Inc.
4205 White Bear Parkway
St. Paul, MN 55110
Phone - 651-762-4010
Fax - 651-762-4014

C. Contact Person

William Rogers, VP Customer Service / Chief Technology Officer
E-mail - wrogers@biomedix.com
651-762-4010

Or

Dick Magnuson, CFO
E-mail - dmagnuson@biomedix.com
651-762-4010

D. FDA Registration Number

FDA Registration Number - 2134492
Owner / Operator Number - 9032550

E. Sterilization Site Statement

Not Applicable; PADnet Lab is supplied non-sterile

F. Packaging Facilities

The PADnet Lab is manufactured, assembled and packaged at BioMedix, Inc. facilities or contract manufacturer. The address is the same as company address.

II. Device ID

A. Product Information

Proprietary Name - BioMedix PADnet Lab
Common Name - Blood Flow Monitor - Plethysmograph
Classification - Cardiovascular Blood Flowmeter
Class - Class II (two)
Panel Code - JOM
Regulation Number - 870.2100

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Model – Series 1

B. Miscellaneous

Previously Submitted: The BioMedix PADnet Lab has not been previously submitted to the Food and Drug Administration (FDA). This is a new Premarket Notification [510(K)].

Under Review: This submission is not being reviewed by DCRD or any other branch within ODE.

Previously Cleared: This submission has not been previously cleared for different indications.

III. Device Description

A. Intended Use

The BioMedix PADnet Lab is a non invasive device used to record physiological data from the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures for use by the Physician in the identification of vascular disease. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

B. Written Description

A. Written Description – The BioMedix PADnet Lab is a non invasive cardiovascular blood flow monitor. It is intended for use in the early detection of peripheral vascular disease. The PADnet Lab has been tested to the following standards.

- EN60601-1 Electrical Safety
- EN60601-1-2 EMC
- ISO 10993-1 Biological evaluation

User Profile:

Patient Population: Male/Female, Adults

Environment of Use: Hospitals or Clinics

The BioMedix PADnet Laboratory Product Specification can be found in section 1 to assist the reviewer(s) in understanding the system.

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C. Schematics

The schematic drawings show a detailed layout of the DTU (Diagnostic Test Unit) electric, electronic, and pneumatic organization. Schematics can be found in section 2A.

D. Block Diagram

The block diagram shows the logical layout of PADnet Lab DTU. This includes power, motor, pneumatic, and electronic items with their respective connectors. Please see Section 2B for details. The Block Diagram can be found in section 2B.

E. Drawings

The schematic drawings show a detailed layout of the DTU electric, electronic, and pneumatic organization. The Drawing can be found in section 2C.

F. Photographs

Section 2D contains photos of the front, back and sides of the device as well as all cuffs.

G. Special Controls/ Performance Standards

- EN 60601-1 Electrical Safety
- EN 60601-1-2 EMC
- ISO 10993-1 Biological Evaluation
- EN 980 Symbols
- ISO 13485:1996/1998 Medical Devices
- ISO 9001:2000 Quality Systems Standard
- 93/42/EEC- Medical Device Directive
- 21 CFR Part 801 Labeling
- 21 CFR Part 820 Quality System Regulation
- ISO 14971 Risk Analysis
- EN 1441 Risk Analysis

The BioMedix PADnet Lab conforms with all of the above standards and controls. The Blood Pressure Cuffs used with the BioMedix PADnet Labs do not require 510(k) clearance as they are considered a pre-amendment device. Section 3 contains copies of the manufacturer's certification of its pre-amendment status and CE Certificates.

H. BP Algorithm

The BioMedix PADnet Lab uses the well known "Oscillometric" Blood Pressure Algorithm to estimate the required systolic segmental pressure values for the arm, ankle and digit. Additional details describing the use of these oscillometric pressure values as compared to a predicate device can be found in section 4.

I. Interaction with Patient

The product is intended for use by trained medical personnel. The results are for the physician's use only.

The user manual in section 6 describes the software installation, connection of the segmental cuffs to the device, choosing the correct cuff, placing the cuff, the user interface, conducting a test, prompts/warnings/errors and troubleshooting, calibration, cleaning, care/maintenance, specifications, warranty and service.

IV. Materials

A. Specific Materials

(b) (4)



B. Biocompatibility

Section 5 contains applicable biocompatibility information for the specific materials coming in contact with the patient (segmental cuffs). This information has been deemed adequate by BioMedix, Inc.

V. Labeling

A. Box Label

Section 6A contains an example of this Label.

B. Product Labels

Section 6B contains an example of this Label.

C. CD-ROM Label

Section 6C contains an example of this Label.

D. Promotional Literature

Section 6D contains an example of all promotional literature.

E. Prescription Device

Section 6E page 2 of the draft operator's manual contains a copy of the prescription statement.

F. Symbols

Section 6F page 2 of the draft operator's manual contains examples of all symbols used on this device.

G. Draft Users Manual

Section 6G contains a copy of the draft operator's manual.

H. Predicate User Manual

Section 6H contains a copy of the Flowstat Vascular Lab User Manual

I. Predicate Marketing Literature

Section 6I contains a copy of the Flowstat Vascular Lab Marketing Literature.

VI. Testing

A. Electrical Safety

Section 9 contains a copy of the 60601-1 Safety Testing

B. Emissions

Section 7 contains a copy of the 60601-1-2 EMC Emissions

C. Immunity

Section 8 contains a copy of the 60601-1-2 EMC Immunity

D. Device Life

The device life shall be a minimum of 100,000 cycles. Section 9 contains a copy of the IEC601-1 Test Report. Please see page 22, of the referenced report.

E. Clinical Study

The clinical data is not required to support substantial equivalence to the predicate device.

VII. Software Information

A. Software Version

PADnet DTU Firmware: (b) (4)

PADnet Test Software: (b) (4)

B. Level of Concern

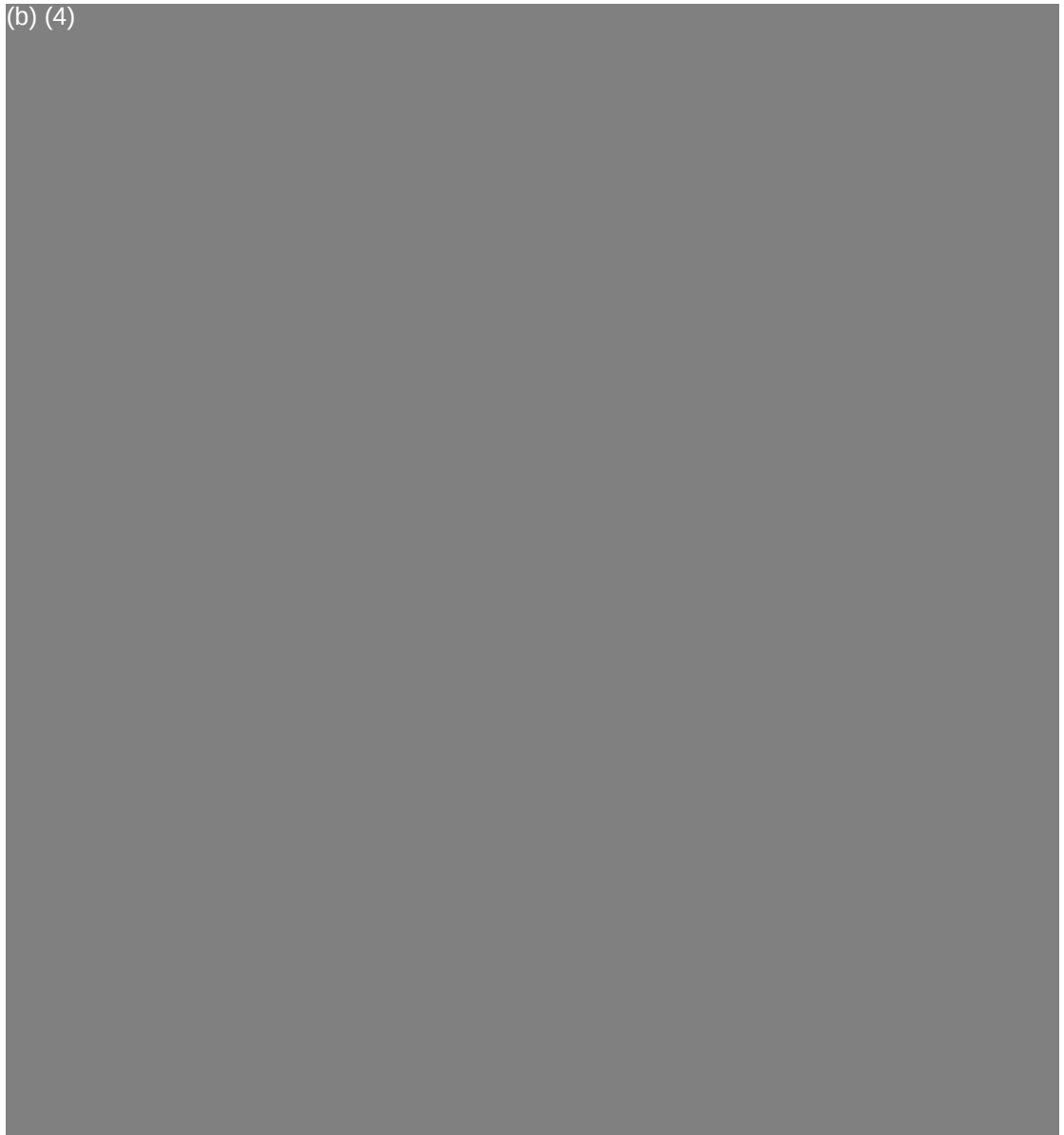
PADnet is a testing device used in series with other methods of testing to detect cardiovascular disease by collecting blood flow ratios on bodily extremities.

PADnet is a lower than moderate level of concern for the following reasons. It does not control life supporting or life sustaining functions, it does not deliver potential harmful energy, and it does not control treatment delivery.

A series of external misdiagnosed tests along with possible PADnet software failure may result in serious injury through the failure to detect need of treatment. Also failure of safety overrides on patient cuff inflation may result in injury and classifies this device to be of moderate concern.

The Following flow chart depicts Level of Concern:

(b) (4)



C. Software / Hardware Description

PADnet is a patient vascular acquisition system divided into two major components, one being a hardware component used to pneumatically gather blood pressure data and other PC software used to store and display information acquired.

PADnet Lab consists of the PADnet Test Lab computer application and the firmware controlled PADnet DTU (Diagnostic Test Unit). PADnet Lab Test provides a user interface to step the user through the process of gathering patient information in an office visit. PADnet Test controls PADnet DTU hardware.

Section 10 contains PADnet Lab Hardware Requirements Specification, Revision (b) 06/08/04

Section 11 contains PADnet Lab DTU Requirements Specification, Revision (b) 06/30/04

Section 12 contains PADnet Test Requirements Specification, Revision (b) 06/30/04

D. Hazard Analysis

Hazards are documented in an external hazards analysis document in accordance with BioMedix Hazard Analysis procedure DP04-04. That document takes into account all device hazards associated with the product's intended use, hardware and software. The document addresses: hazardous event, level of concern of the hazard, cause(s) of hazard, method of control, and corrective measures taken. The current version of the document is “

Section 13A contains PADnet Lab Preliminary Hazard Analysis”, v (b) dated 7/8/2004,

Section 13B also contains PADnet Lab DTU FMEA Analysis”, (b) , dated 05/25/2004.

Section 14 contains the BioMedix Hazard Analysis procedure DP04-04

E. Software Requirements Specifications

The requirements are documented in external requirements documents. The titles of the documents are “PADnet Test Requirements Specification” and “DTU Requirements Specification”. The documents list both functional (general, and by kind of user) and non-functional (general, security, and performance) requirements. In addition, the DTU (Diagnostic Test Unit) firmware requirements are described in the DTU Requirements Specification.

Section 11 contains PADnet Lab DTU Requirements Specification, Revision (b)(4), 06/30/04

Section 12 contains PADnet Test Requirements Specification, Revision (b)(4), 06/30/04

F. Architecture Design Chart and Software Design

The architecture and software design are documented in an external design documents. The documents are composed of an architectural design section, a component design section, a design use-case section, and a requirements mapping section. The architecture section contains a conceptual model (including a diagram), design patterns, an analysis model, an application architecture (including a diagram), and a components description section. The component design contains component descriptions and component interfaces. The use case section contains use-cases for both normal and expected-error event sequences. The requirements mapping section maps the use-cases in the document to the list of requirements in the requirements document.

Section 15 contains PADNet Test Design Specification, Revision (b)(4) 07/01/04

Section 16 contains PADNet DTU Firmware Design Specification, Revision (b)(4) 07/01/04

G. Trace-ability Analysis

The requirements are linked to the design and code in the “PADNet Test Design Specification” document. The requirements and use cases are linked to the testing in the “PADNet Test Validation Plan” document. The hazards are described and linked to the software in the “PADNet Hazards Description”. The hazards document is currently being prepared according to the DP04-04 document template. Determining where a particular item is tested, and the status of the test can be found by reviewing the validation document. Determining if a particular hazard has been identified, and where and how it is removed or mitigated can be found by reviewing the hazards document.

Section 17 contains the BioMedix PADnet Lab Trace-ability Analysis, Revision (b)(4) and dated 07/08/04

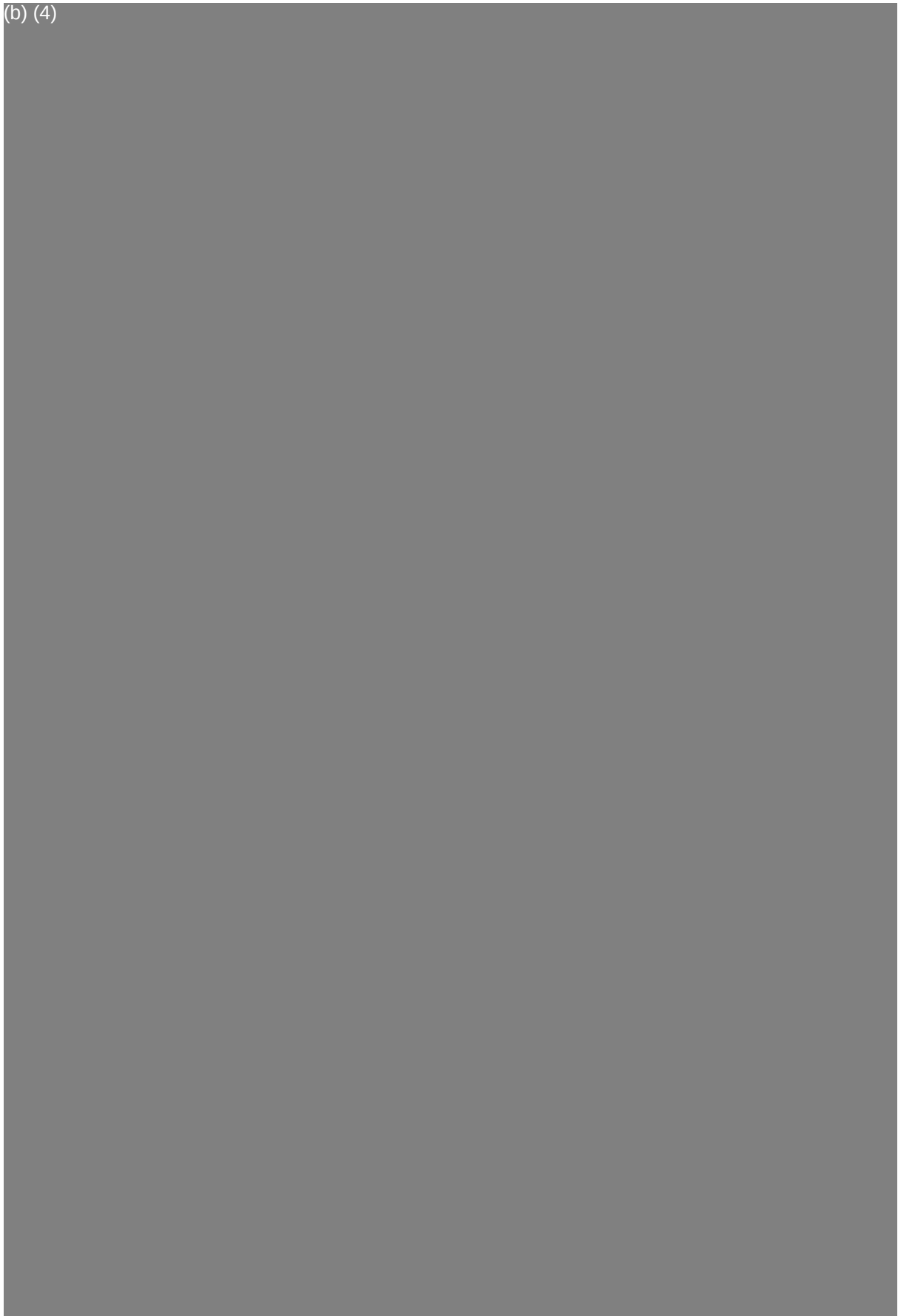
H. Software Development Life Cycle

(b)(4)



86

(b) (4)



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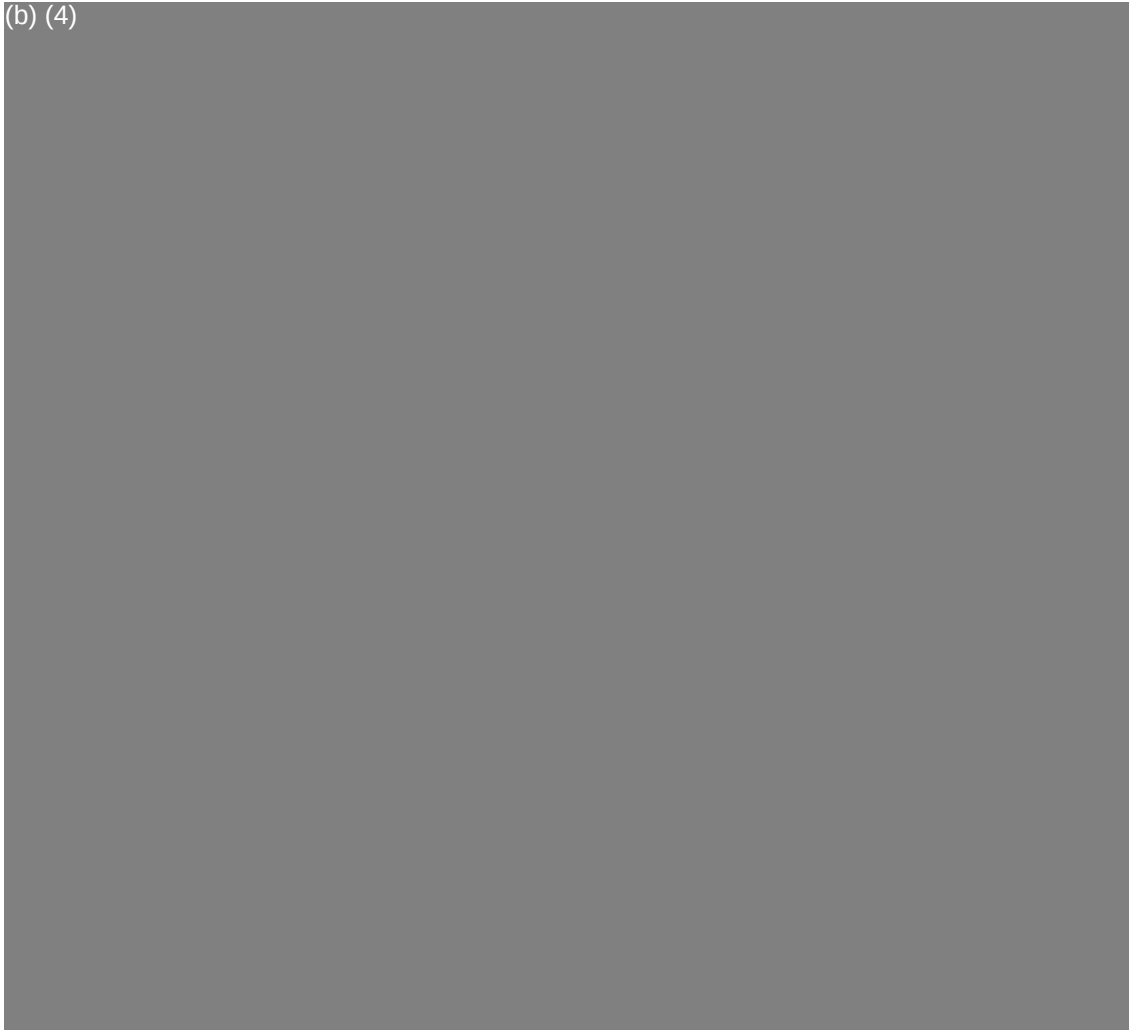
I. Hardware / Software Verification/Validation

(b) (4)



J. Revision History

(b) (4)



K. Certificate of Known Bugs

A "Certificate of Known Bugs" will be prepared and made available. This will be all unresolved software anomalies. For each anomaly, it will indicate the problem, the impact on device correctness and/or performance and, if communicated to the user in labeling, how that labeling will be performed. This list will be prepared from the issue tracking database using the Eventum tool described above.

Section 22 contains BIOMEDIX PADnet Lab Certificate of Known Defects
Version (b) (4)

L. OTS Software

(b) (4)



VIII. Comparative Performance Evaluations and Clinical Performance Evaluations/Data

A. Comparative Performance Evaluations

A comparative performance evaluation for the PADnet Lab and Flostat Vascular Lab can be found in appendix section 4.

B. Clinical Performance Evaluations/Data

Clinical data is not required to support substantial equivalence for the PADnet Lab.

IX. Substantial Equivalence Information

A. 510(k) of Predicate

The legally marketed predicate for the PADnet Lab is the BioMedix Flostat Vascular Lab (K973644). Appendix XX contains information on the BioMedix Flostat Vascular Lab, the Legally Marketed Predicate.

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B. Summary Table of Comparisons

The following summary table of comparisons compares the new device (PADnet Lab) to the predicate device: Flowstat Vascular Lab.

#	Area	New Device: PADnet Lab	Predicate Device: Flowstat Vascular Lab	Same	Different
1	Pulse Volume Recording	Plethysmograph	Plethysmograph	X	
2	Segmental Pressure flow sensor	Oscillometric	Distal Flow Sensor		X
3	Patient Population	Male/Female Adult	Male/Female Adult	X	
4	Environment	Hospital or Clinic	Hospital or Clinic	X	
5	Power Source	AC converted to DC	AC converted to DC	X	
6	Weight	4 lbs.	26 lbs.		X
7	Data acquisition	Single site	Bilateral		X
8	Software Controls	Operator initiated	Operator initiated	X	
9	Size	12 1/2"W X 10" D X 3 " H	20 1/2" W X 17 3/4 " D X 7" H		X
10	Cuff Deflation Rate	3-5 mm Hg/Sec	3-5 mm Hg/Sec	X	
11	Operating Environment	0 to +40°C 15 - 90%	0 to +40°C 15 - 90%	X	
12	Storage Environment	-40 to +50° C 5-95%	-40 to +50° C 5-95%	X	
13	Safety Standards	Yes	Yes	X	
14	EMC	Yes	Yes	X	
15	Prescription Device	Yes	Yes	X	
16	Cuff Bladder Deflation	Automatic	Automatic	X	
17	Inflation Method	Automatic	Automatic	X	
18	Cuff Sizes	Multiple	Multiple	X	
19	Clinical Reports	Yes	Yes	X	
20	Printed Reports	Yes	Yes	X	
21	Supplied Non-Sterile	Yes	Yes	X	

C. Discussion of Similarities/Differences

The PADnet Lab and the Flowstat Lab have the following similarities:

- Pulse Volume Recording
- Patient Population
- Environment
- Power Source
- Software Controls
- Cuff Deflation Rate
- Operating Environment
- Storage Environment
- Safety Standards
- EMC
- Prescription Device
- Cuff Bladder Deflation

90

- Inflation Method
- Cuff Sizes
- Clinical Reports
- Printed Reports
- Supplied Non-Sterile

The differences, with comments, are the following:

- Segmental Pressure flow sensor – The PADnet Lab uses Oscillometric not distal flow sensor.
- Weight – PADnet Lab is significantly less.
- Data acquisition – PADnet Lab is single site not bilateral.
- Size – PADnet Lab is significantly smaller.

Thus, even though the PADnet Lab is not identical to the Flowstat Vascular Lab, we at BioMedix believe it should be granted substantial equivalence because:

- It has the same intended use as the predicate device.
- It has the same technical characteristics as the predicate device and does not raise any new types of safety or effectiveness concerns.

X. 510(k) Summary / Statement

A. 510(k) Summary

A 510 (k) Summary in conformance with 21 CFR Part 807.92 is located in Section 24 and behind the front cover.

B. 510(k) Statement

A 510 (k) Statement is not necessary, as a 510 (k) Summary is included.

XI. Miscellaneous

A. Indications for Use Form

An Indication for Use Form is included as Section 25.

B. Truthful/Accurate Statement

A Truthful / Accurate Statement can be found in Section 26.

C. Financial Certification

A Form 3454 is not required as a “covered” clinical study was not required or conducted on the PADnet Lab to demonstrate substantial equivalence.

D. Financial Disclosure

A Form 3455 is not required as there was no clinical investigation required demonstrate substantial equivalence

E. Class III Certification

Blood Flowmeters are Class II devices, not Class III. Therefore, Class III Certification is not required.

F. Kit Certification Statement

The BioMedix PADnet Lab does not come as a kit; therefore kit certification is not required.

G. 510 (k) Decision Making Chart

Section 27 contains a 510 (k) Decision Making Chart with the path BioMedix believes the PADnet Lab has taken to be determined "substantially equivalent."

XII. Appendices

Section 1:	BioMedix PADnet Laboratory Product Specification.
Section 2A:	Schematics
Section 2B:	Block Diagram
Section 2C:	Drawings
Section 2D:	Photographs
Section 3:	Cuff Manufacturer's certification of its pre-amendment status and CE Section
Section 4:	Comparative performance evaluation to a predicate device
Section 5:	Biocompatibility
Section 6:	Labeling
Section 7:	Emissions
Section 8:	Immunity
Section 9:	Test Report IEC 60601-1
Section 10:	PADnet Lab Hardware Requirements Specification
Section 11:	PADnet Lab DTU Requirements Specification
Section 12:	PADNet Test Requirements Specification
Section 13:	PADNet Lab Preliminary Hazard Analysis / DTU FMEA Analysis
Section 14:	BioMedix Hazard Analysis procedur()
Section 15:	PADNet Test Design Specification
Section 16:	PADNet DTU Firmware Design Specification
Section 17:	BioMedix PADnet Lab Trace-ability Analysis
Section 18:	PADNet Test Validation Plan and Test Results
Section 19:	PADnet DTU Firmware Validation Plan and Test Results
Section 20:	PADnet Lab Hardware Design Verification and Test Results
Section 21:	PADNet Lab Revision History
Section 22:	BIOMEDIX PADnet Lab Certificate of Known Defects
Section 23:	OTS Software
Section 24:	510K Summary
Section 25:	Indications for use
Section 26:	Truth/Accurate Statement
Section 27:	Decision Making Chart

Indications for Use

510(k) Number (if known): _____

Device Name: Biomedix PADnet Lab

Indications for Use:

The BioMedix PADnet Lab is a non invasive device used to record physiological data from the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures for use by the Physician in the identification of vascular disease. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

User Profile:

Patient Population: Male/Female, Adults

Environment of Use: Hospitals or Clinics

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

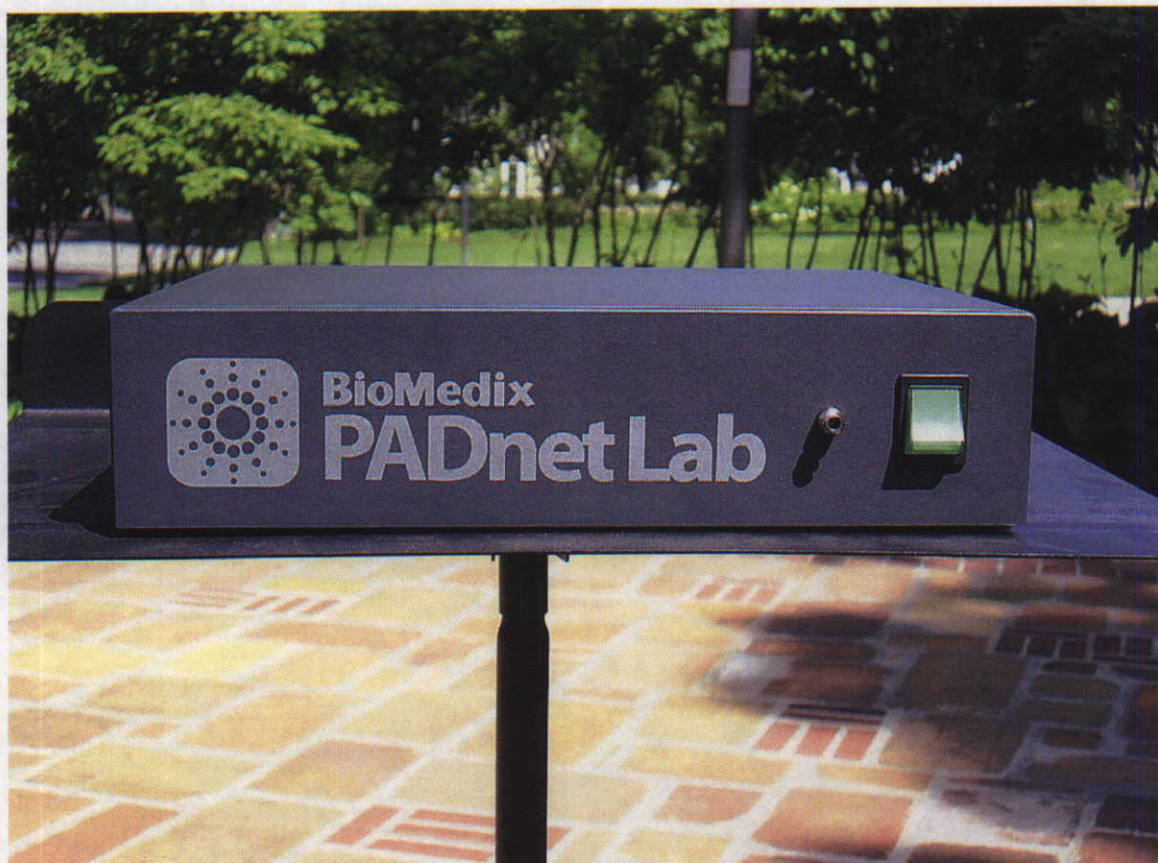
Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of __

(Posted November 13, 2003)



PADnet Lab Operators Manual (DRAFT)

L-XXX, Rev.X

REF – Bio 10600

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Symbols

1.  Type BF Applied Parts
2.  Attention, consult accompanying documents
3. **IPXO** - No Protection against Ingress of Water
4.  Volts AC (Alternating Current Voltage)
5. I / O Main Power Switch. I = On and O = off.

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

Class1, type BF  applied parts, not suitable for use with flammable anesthetics, and continuous operation.

Caution

This equipment has been tested and found to comply with Medical Equipment Standard: EN60601-1-2, 2001. This unit was tested to IEC 60601-1:1988 + A1:1991 + A2:1995 and UL 60601-1:2003. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one of the following measures:

- ◆ **Reorient or relocate the devices**
- ◆ **Increase the separation between the devices**
- ◆ **Connect the equipment to an outlet on a different circuit**
- ◆ **Consult the manufacturer or field service technician for help**

Computers or Printers should be tested and approved per EN 60601-1-1 or equivalent standards prior to placing system into service.

This system is **NOT FOR FETAL USE.**

Introduction

Thank you for your interest in the BioMedix PADnet Lab. This Operators Manual will help you perform tests using the BioMedix PADnet Lab. Whether you're a first time user, or have experience with the device, this manual is designed to answer your questions and show you just how easy the BioMedix PADnet Lab is to use.

The BioMedix PADnet Lab is a highly sophisticated device for use in the testing of vascular pathology. Using plethysmography (the change in limb circumference as a reflection of blood volume changes), the PADnet Lab can assess vascular blood supply simply and non-invasively.

This manual and the PADnet Lab itself were designed to make vascular assessment as easy as possible for all levels of computer users. The PADnet Lab works with your IBM Compatible personal computer to draw waveforms in real time, archive patient history and test data onto the hard drive, and much more. It is, however, beyond the scope of this manual to provide significant education on the clinical uses of the data generated by the PADnet Lab.

This manual and the PADnet Lab software described in it are copyrighted, with all rights reserved. Under the copyright laws, this manual or the software may not be copied, in whole or in part, without the written consent of BioMedix, Inc., except in the normal use of the software or to make backup copies of the software. The same proprietary and copyright notices must be affixed to any permitted copies as were affixed to the original. This exception does not allow copies to be made for others, whether or not sold, but all of the material purchased (with all backup copies) may be sold, given, or loaned to another person. Under the law, copying includes translating into another language or format.

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Section 1

Set up

Loading your PADnet Lab Version X.0 Software:

The PADnet Lab is very easy to set up. PADnet Lab software loads easily into your personal computer (PC). While we cannot guarantee compatibility with every PC clone or operating system, we will help you find a solution that ensures you are able to use your PC with the PADnet Lab.

Review the table below to ensure your system meets the **Minimum Operating Specifications** for PADnet Lab operation.

Minimum Computer Specifications for Operation (Only computers meeting IEC60950 or equivalent should be used)

IBM PC or Compatible
Pentium III Processor (or Above)
600 MHz Minimum Processor Speed
One Free USB port
SVGA or greater Monitor or Display (set for 800 X 600 or 1024 X 768)
One 3.5" Floppy Disk Drive
One 16X CD Drive
One Printer Port or USB for Printer
One Mouse Port and Mouse
128 MB RAM or Higher
Windows XP
Any Windows Compatible Printer

Minimum Computer Settings

Screen / Display Set to 800 X 600 or 1024 X 768 Resolution
Fonts Set to Small Font Size
Color set to High Color (32 bit)

Set Up Continued

Loading your PADnet Lab Version X.0 Software

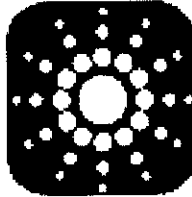
NOTE: If you purchase your computer package from BioMedix, your software will be pre-loaded. If your PC was provided by BioMedix, you can skip over these instructions. These instructions are provided if you switch computers or need to load a software upgrade later on.

1. To install the software, close all programs on your Windows desktop.
2. Place the CD-ROM into your CD drive.
3. The setup program will lead you through the steps to complete setup.
4. If the set up program does not appear onscreen, click on ***start***, then click on ***run***.
5. Type **D: setup** or if D is not the correct drive for your computer, replace D with the drive letter that does correspond to the CD-ROM drive on your computer.
6. Press **Enter** & follow the instructions of the setup wizard.
7. Once the software is installed, you will need to restart the computer.
8. A desktop icon named PADnet Lab should appear on your desktop and on the START menu.

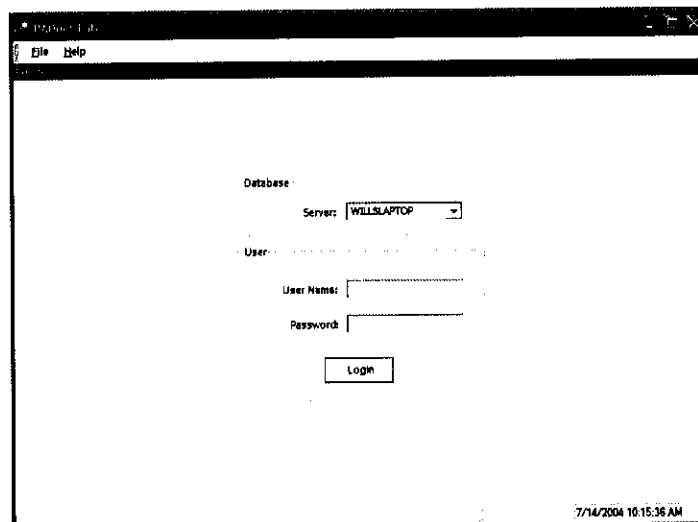
If you have any questions about the software installation, please call our technical support staff at **651-762-4010**.

Set up Continued

1. To access the program, from the Windows desktop double click on the PADnet Lab icon.

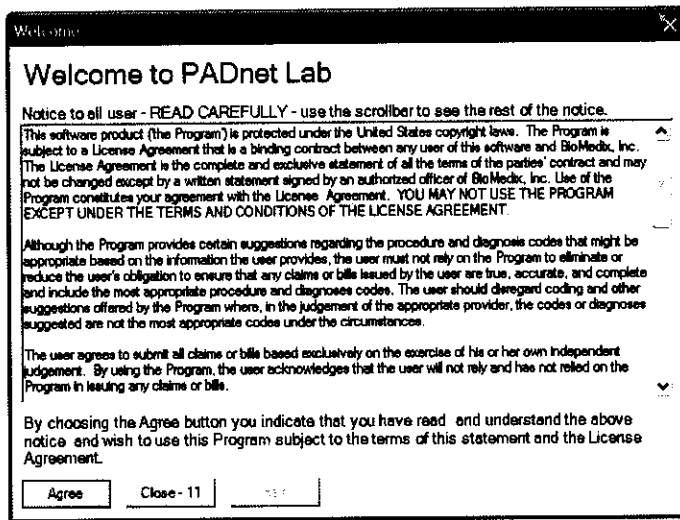


2. This leads you to the PADnet Lab Sign On screen.

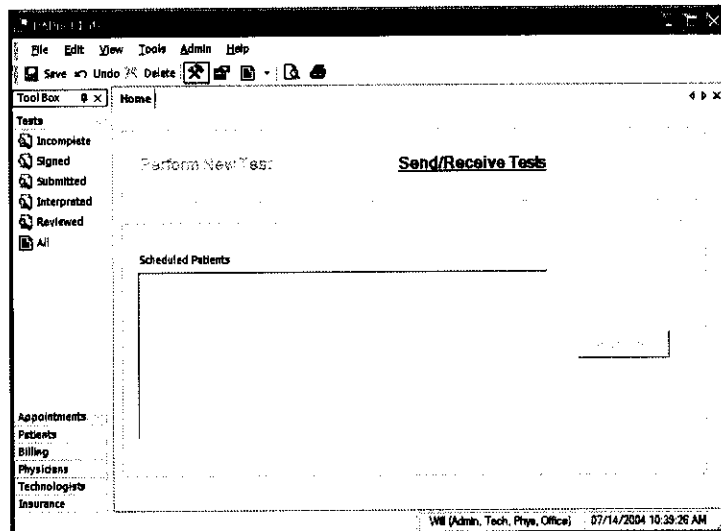


2. From here, you will need to enter your user name and password. This will take you to the licensing screen. You need to read and agree to the licensing prior to proceeding to the main menu. **If you do not agree to the licensing within 30 seconds the program will return to the log in screen.**

Set up Continued



3. After agreeing to the licensing you will come to the PADnet Lab main menu.



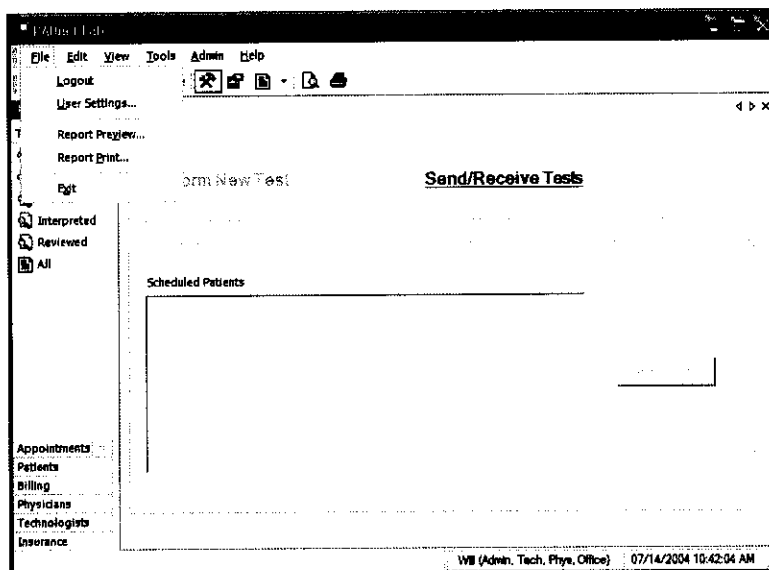
4. There are tabs across the top and down the left side of the main menu. The tabs at the top will open drop down menus for additional functions. The tabs on the left side enable the user to open selected functions for use to manage database tables and functions, such as scheduling appointments, adding physicians or updating insurance company information.

Set up Continued

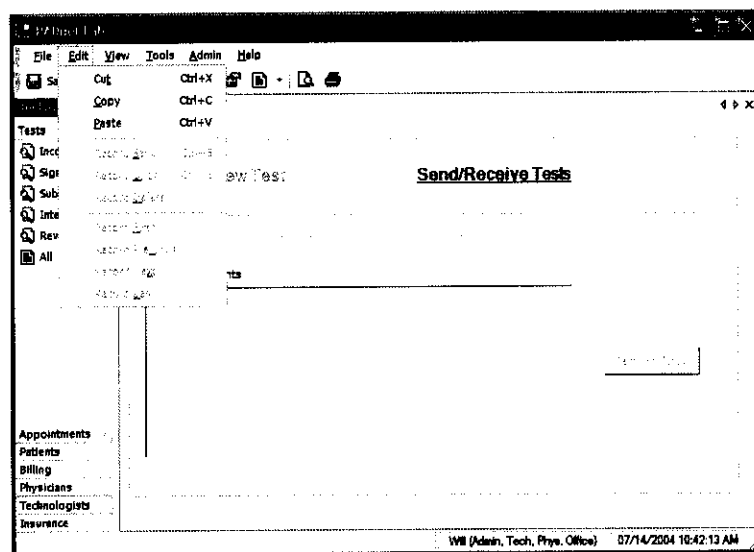
Main Menu Selections:

Tabs at top of page

1. **File** - This selection allows the user to log out of the software, edit user settings, print preview the patient report, print the patient report or exit from the program.

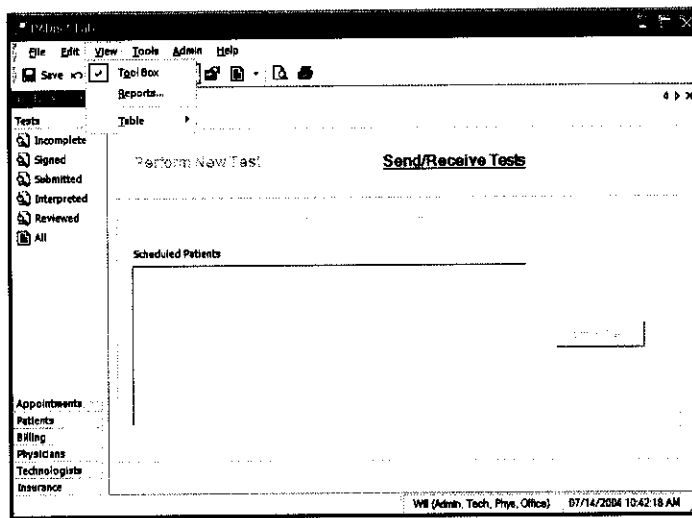


2. **Edit**- This selection allows editing functions such as copy and paste. The user may also edit records and review records.

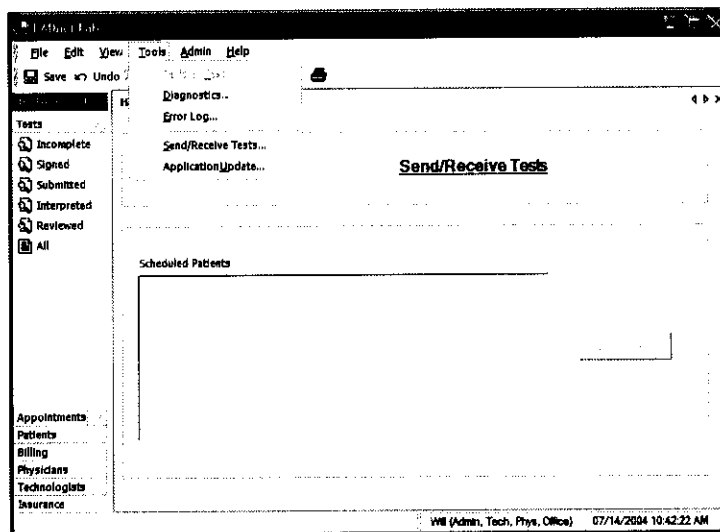


Set up Continued

4. **View-** Selecting this tab allows the user to view toolbox selections, available reports and tables.

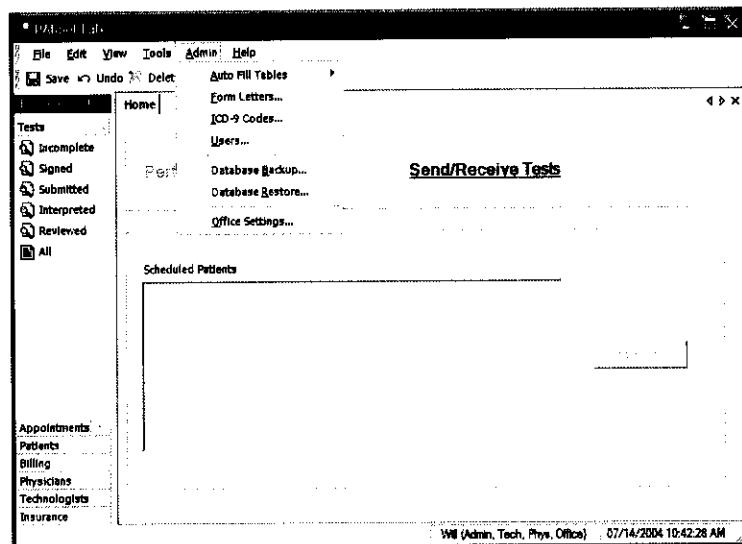


5. **Tools-** These selections allow the user to perform test on selected patient, go to system diagnostic screen (only available to administrators), review error log if any exist or send and receive data from the reading center. The user can also get application updates from the web site.

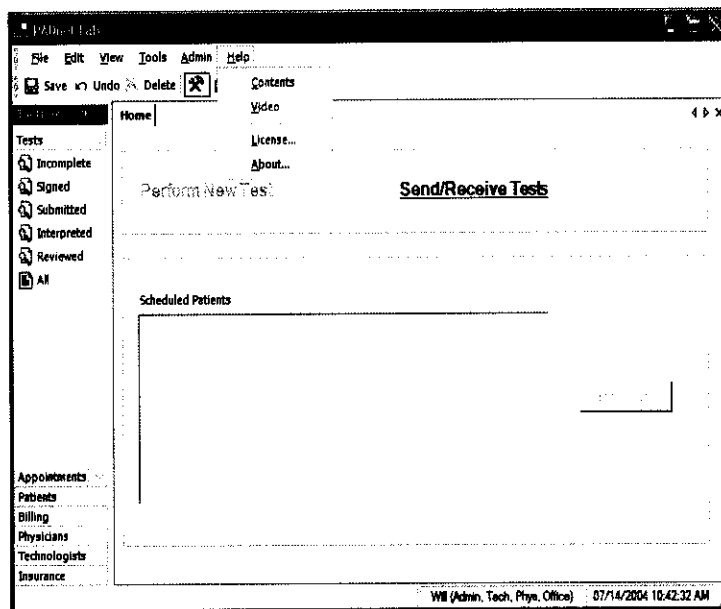


6. **Admin** – Selecting this tab allows the user to perform various administrative functions. Most of these functions may only be accessed by a system administrator.

Set up Continued



1. **Help-** This menu allows the user access to various help functions such as the help menu, the video tutorial, the license agreement and the about information.

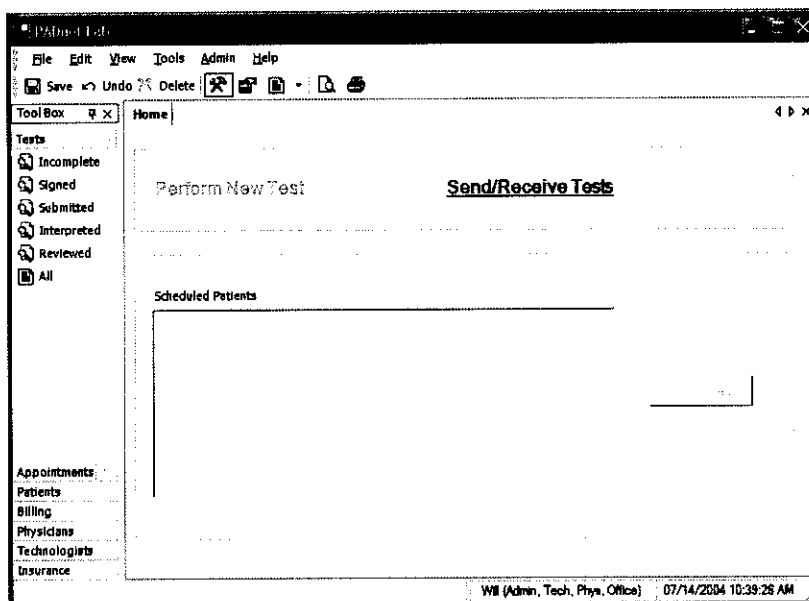


Set up Continued

Main Menu Selections:

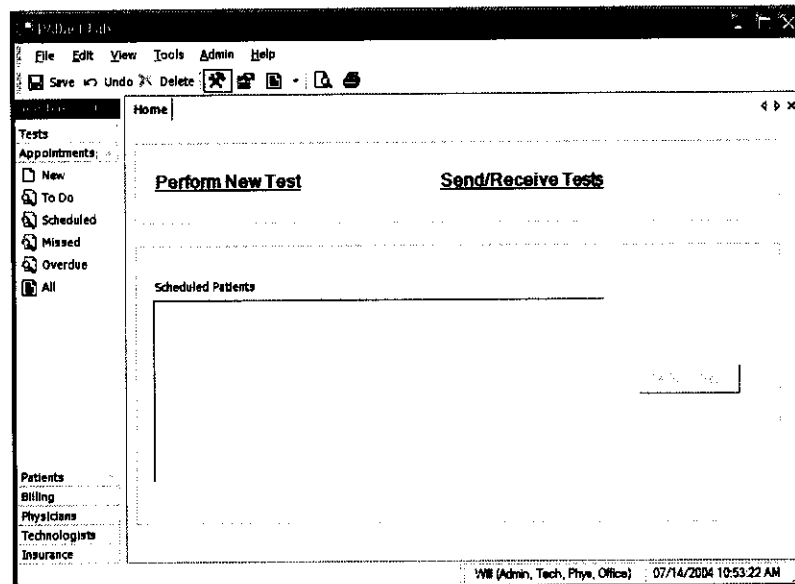
Tabs at left of page

2. **Tests** – This selection will allow the user access to several types of patient list. To access any of these options simply click on the desired selection.

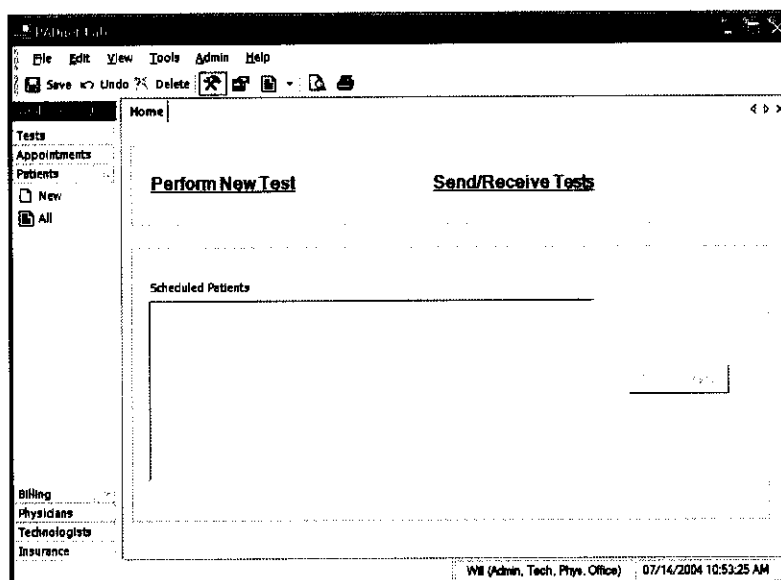


3. **Appointments** – This tab allows the user to select various lists of appointments.

Set up Continued

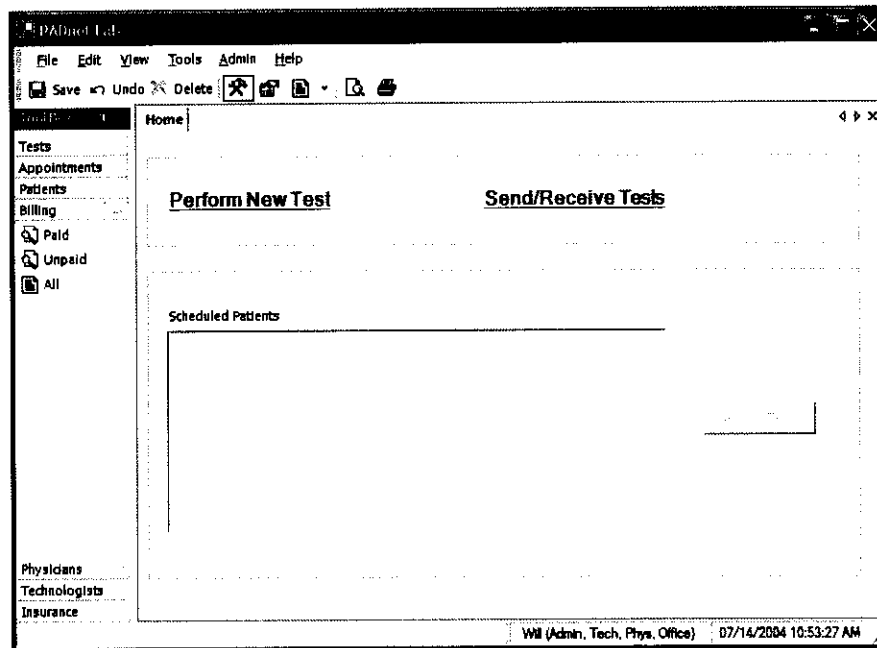


4. **Patients** – This selection allows the user to enter a new patient or view a list of patients already in the database.

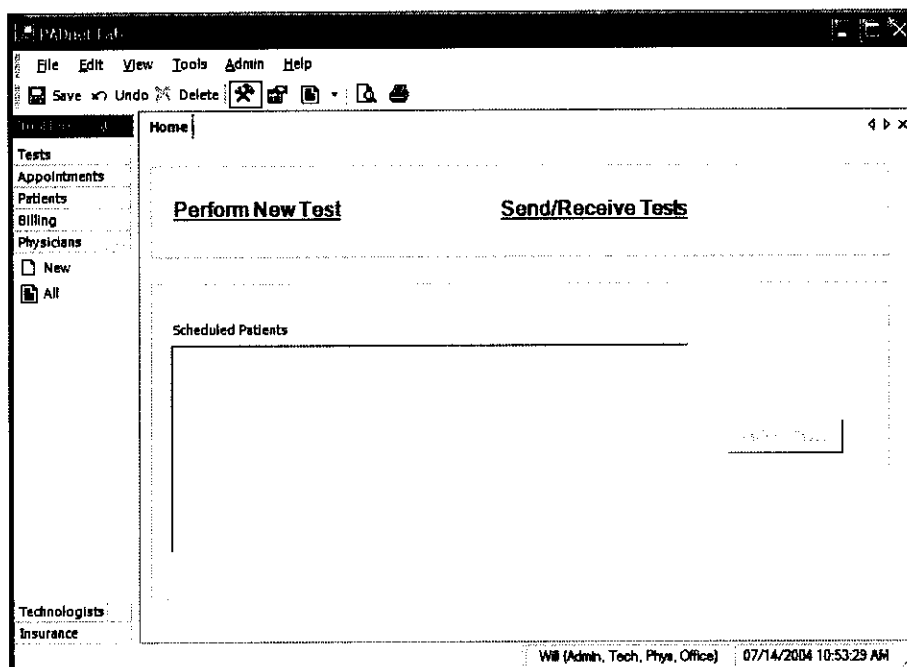


Set up Continued

5. **Billing** - This tab will enable the user to view and print lists of billing status.

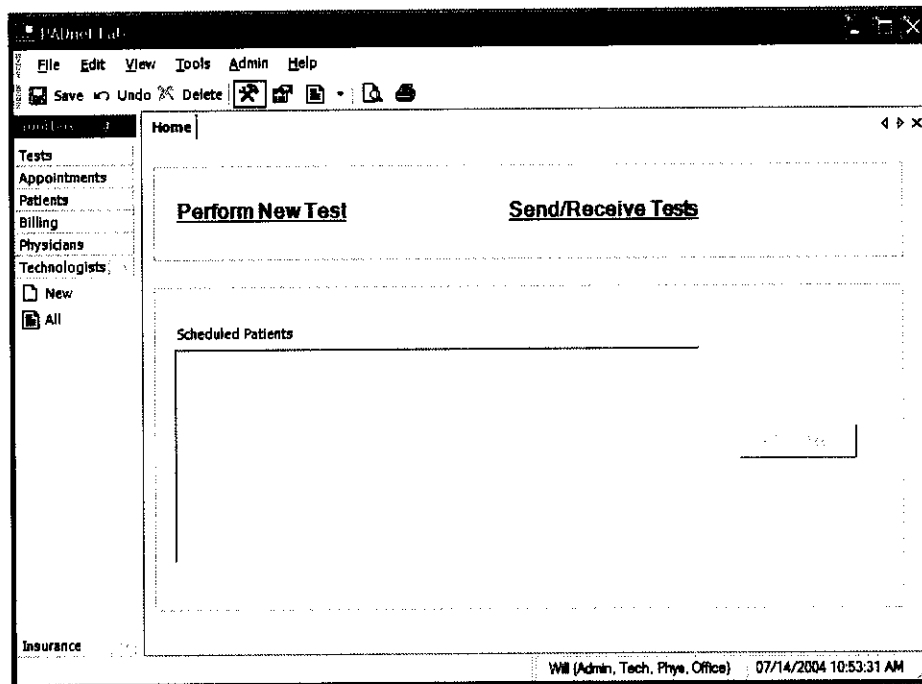


6. **Physicians** – The user may use this selection to add or view a list of Physicians entered into the database.

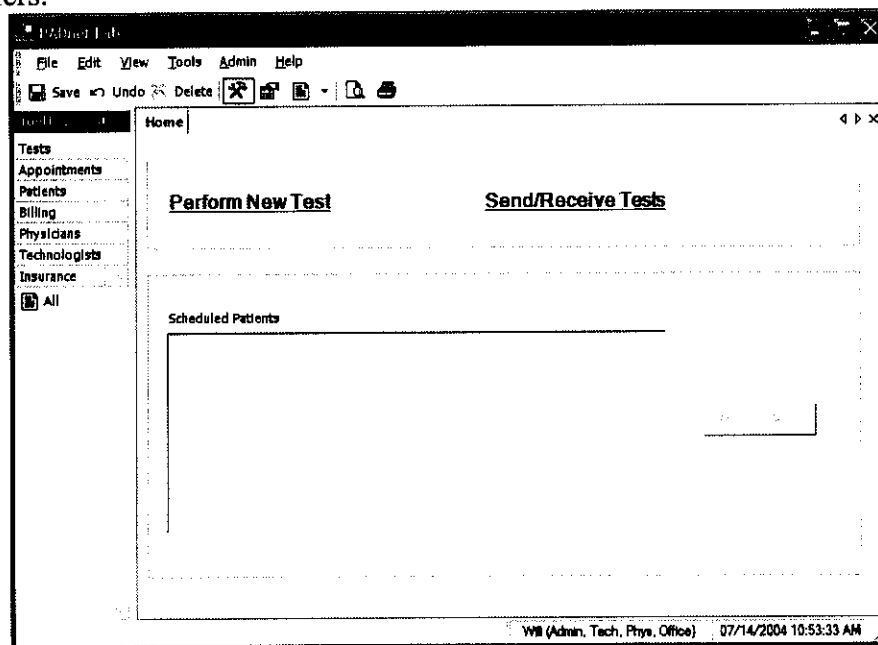


Set up Continued

7. **Technologist** – This tab will allow the user to enter or view a list of Technologist entered into the database.



8. **Insurance** – This selection will allow the user to enter or view a list of insurance carriers.



Front Panel Layout and Description

The Front Panel of the BioMedix PADnet Lab is designed for simplicity and ease of use. The numbers of controls have been minimized, with internal circuitry and software conducting many of the operations that are performed manually on other systems.

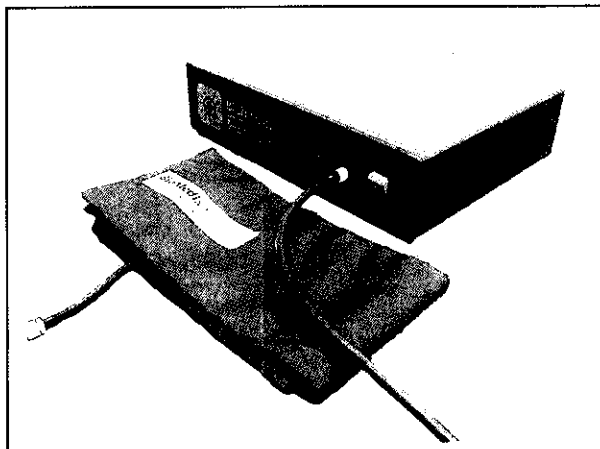


Switches

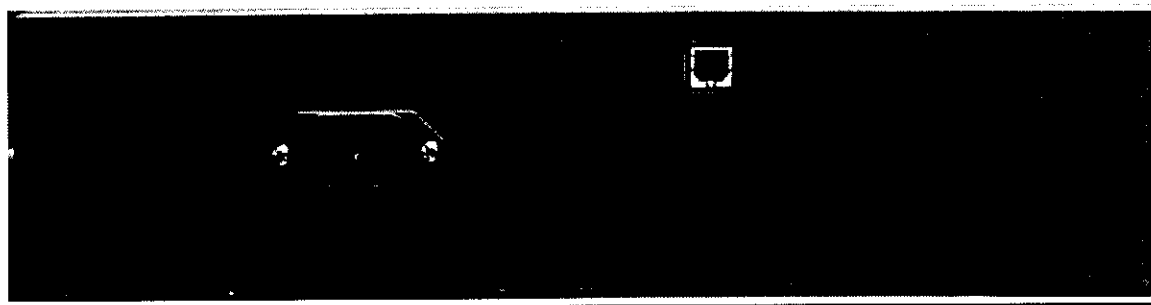
On/Off: This green colored switch with a I and O symbol, located on the right of the front of the unit is illuminated when on. When the switch is in the I position, the unit is powered on. When the switch is in the O position, it is powered off.

Connectors

Cuff Connector: Found to the left of the power switch, cuffs are connected to the PADnet Lab here. Insert the plastic connector on the cuff tube into the connector on the front panel. **Twist it gently in a clockwise direction until it locks. Do not over tighten. Please see diagram below:**



Rear Panel Layout and Description



AC Input: The AC power supply is plugged in here. Use **only a factory-supplied power cord to run the PADnet Lab.**

USB: The USB connector is plugged in here. This is the **main data connection point** between your computer and the PADnet Lab.

Label: The Serial label is located in the lower right corner of the rear panel, and appears as below.

		BioMedix
		PADnet Lab
Model	PADnet Lab	
SN		
Product	PADnet Lab	
Voltage	115/230 VAC	
Frequency	50-60 Hz	
Amperage	1.2 – 0.7Amp	St. Paul, MN 55110
Made in USA		
		 0086

Rear Panel Hook-up

Power Supply

The power cord is plugged into a **100-240 VAC, 47-63 Hz electrical outlet**. Connect the power cord to the PADnet Lab by pushing the connector into the **AC input** connector.

USB Cable (Computer to PADnet Lab Connection)

The PADnet Lab comes with a **USB** connector cable. One end of the cable is **connected to the PADnet Lab at the connector**. The other end of the cable **plugs into the USB port on your computer**.

Now your BioMedix PADnet Lab is properly configured and you are ready to begin vascular testing.

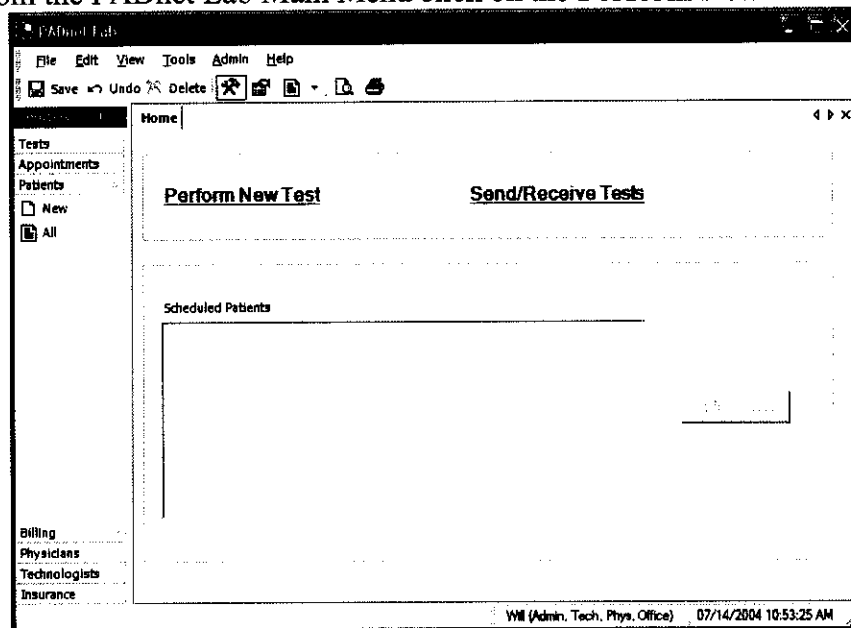
Component List

Description	BioMedix Part Number
1- USB cable	100-1600
1- Cuff kit	7200
1- BioMedix PADnet Lab Software Program CD ROM	400-210
1-AC Power Cord	350-215
1- PADnet Lab Operators Manual	10650

**Please only use components approved by BioMedix for use
with the PADnet Lab. Use of other Manufacturers' accessories
with the PADnet Lab could void your warranty.**

Patient Data Entry

From the PADnet Lab Main Menu click on the **Perform New Test** field.



This leads you to the Patient Data Entry Screen

This tab allows the user to enter all relevant patient demographic data. All fields that must have data entered into them have a ! or [mark] next to them. Fields with this mark ! must be completed prior to any attempted data transfer. Fields with this mark [mark] must be completed prior to saving or going to any other tabs. After completing all necessary fields on this tab user should move to the next tab **Insurance**. The following fields will appear.

Patient Data Entry Continued

The screenshot shows the PADnet Lab software window. The menu bar includes File, Edit, View, Tools, Admin, and Help. Below the menu is a toolbar with icons for Save, Undo, Delete, and others. A 'Tool Box' on the left contains icons for New, Incomplete, Signed, Submitted, Interpreted, Reviewed, and All. The main window has tabs for Patient, Insurance, History, Indications, Test, Interpretation, and Report. The 'Insurance' tab is active, showing fields for Primary and Secondary Policy information. Each policy section includes First Name, Last Name, Carrier, Policy Number, Group Number, Address, City, State, and ZIP. The status bar at the bottom indicates 'WHL (Admin, Tech, Phys. Office)' and the date/time '07/14/2004 10:59:58 AM'.

This screen is where all insurance information needed for patient billing is entered. After completing this screen, you should click on the next tab **History**. The following screen will appear.

The screenshot shows the PADnet Lab software window with the 'History' tab active. The main window has tabs for Patient, Insurance, History, Indications, Test, Interpretation, and Report. The 'History' tab is active, showing fields for Risk Factors and Associated Diseases. Each section includes a list of conditions with dropdown menus for 'None'. The status bar at the bottom indicates 'WHL (Admin, Tech, Phys. Office)' and the date/time '07/14/2004 11:00:12 AM'.

Patient Data Entry Continued

The History tab is divided into three sub tabs Risk factors, Vascular Procedures and Notes.

1. Risk Factors – This is where Vascular Risk Factors and Associated Diseases are listed along with there severity.
2. Vascular Procedures – This is where prior Vascular Surgery or other procedures may be listed.
3. Notes – This area is for entry of any additional information the testing site would like the reading site to be aware of.

After completing the History tab information the user should select the **Indications** tab. The following screen will appear.

The screenshot displays the PADnet Lab application window. The main menu includes File, Edit, View, Tools, Admin, and Help. Below the menu is a toolbar with icons for Save, Undo, Delete, and others. On the left is a 'Tool Box' with a 'Tests' section containing icons for New, Incomplete, Signed, Submitted, Interpreted, Reviewed, and All. Below this are sections for Appointments, Patients, Billing, Physicians, Technologists, and Insurance. The main window has tabs for Patient, Insurance, History, Indications, Test, Interpretation, and Report. The 'Indications' tab is active, showing a 'Referral' section with a 'Referring Physician' dropdown menu (labeled 'New') and a 'Referral #' field. To the right is a list of checkboxes for various indications: Claudication, Rest pain, Extremity ulceration, Extremity gangrene, Extremity trauma, Embolic discoloration of toes or foot, and Pulseless. Each checkbox is followed by a 'Side' dropdown menu. At the bottom right, there is an 'Other' text area. The status bar at the bottom indicates 'Will (Admin, Tech, Phys. Office)' and the date/time '07/14/2004 11:00:17 AM'.

This tab is where the Referring Physician information and Indications for testing are documented. There is an additional area to enter other indications for testing. Upon completion of these fields the user should select the **Test** tab. The following screen will appear.

Patient Data Entry Continued

This screen is used to access the testing screens by selecting the Perform button on the left side of the screen. The tester should also select their name from the drop down menu at the end of the field labeled Technologist. After they have completed patient testing the tester should review testing results and then sign the test by placing a check in the Test Signed box. All tests must be signed prior to data transfer. Upon completion of testing when exit is selected from the test screen you will return to this screen and all acquired testing data will populate the appropriate fields. When patient testing data has been returned from the reading location the Interpretation tab the following screen will appear.

Patient Data Entry Continued

The testing facility can review the interpretation of the reading location from this screen. To print Patient reports click on the **Report** tab. The following screen will appear.

The screenshot displays a software window titled "Patient Data Entry". The interface includes a menu bar (File, Edit, View, Tools, Admin, Help) and a toolbar with icons for Save, Undo, Delete, and Print. A "ToolBox" on the left lists various test statuses: New, Incomplete, Signed, Submitted, Interpreted, Reviewed, and All. The main area is divided into three sections: "Print Selection", "Status", and "Coding/Billing". The "Print Selection" section has checkboxes for Summary and PVR, each with a "View..." button, and a "Print..." button. The "Status" section has fields for "Sent for Interpretation", "Current Status", and "Interpretation received". The "Coding/Billing" section has fields for "CPT code", "CPT modifier(s)", "Reimbursable ICD-9 code(s)", and "ICD-9 code(s)", along with an "ICD9 Check..." button. A sidebar on the left lists "Appointments", "Patients", "Billing", "Physicians", "Technologists", and "Insurance". The bottom status bar shows "Will (Admin, Tech, Phys, Office)" and the date/time "07/14/2004 11:05:28 AM".

The Report tab is divided into three areas Print Selection, Status and Coding/Billing.

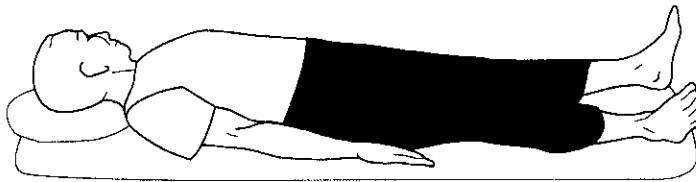
1. **Print Selection** – This area contains check box selections for Summary, PVR, Bill and Letter. It also has view and modify buttons, used to preview reports or modify them prior to printing. The Print button on the upper left side of the screen will print all selected reports.
2. **Status** – This area contains fields for Sent for interpretation, Current status and Interpretation received. There is also a button used to resend test data back to the reader for additional review.
3. **Coding/Billing** – This area contains fields for CPT code, CPT modifiers, reimbursable ICD-9 codes and ICD-9 codes. There is also a button to recheck ICD-9 codes.

Patient Testing

Prior to beginning any testing on a patient, you should do several things:

- Introduce yourself and explain why this test is being performed and how long it should take.
- Explain the various procedures performed during the exam.
- Respond to any issues or concerns of the patient.
- Be prepared to answer questions the patient may have concerning the exam.
- Refer any specific diagnostic, treatment or prognosis questions to the patient's physician.
- Patient should be allowed to rest for several minutes before any testing data is acquired to allow the patient to return to a normal resting state.
- Patient should lay supine with the heart at approximately the same level as the extremities as shown below.

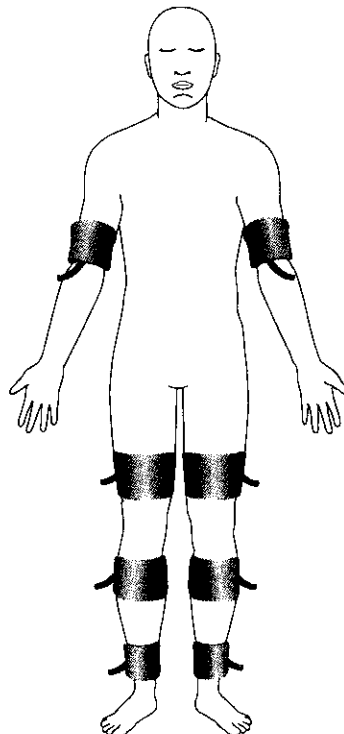
Patient Positioning



Patient lies supine on the bed, as flat as possible.

- The pressure cuffs should be applied to the patient as shown below.

PVR Cuff Positions



Patient Testing **Continued**

All Patient testing is performed from a testing summary screen. When the user selects **perform** from the test tab the following screen appears.

Click a button to begin testing at that site. Normal test sequence is indicated by the numbers displayed on the buttons.

Click on the anatomical location you wish to start testing.

Right		Left	
9	Sys	Sys	10
	Mean	Mean	
	Dia	Dia	
1	PVR	PVR	5
2	PVR	PVR	6
3	PVR	PVR	7
11	Sys	Sys	12
4	PVR	PVR	8
13	Sys	Sys	14

Exit

To begin testing select the test and anatomical location you wish to start from. Click on the box of the location you wish to start testing. The usual testing routine begins with the Brachial Pressure. When a pressure location is selected the following screen will appear.

Right Arm

240
200
160
120
80
40
0

Systolic
Mean
Diastolic

1 Start 6 Next 7 Exit



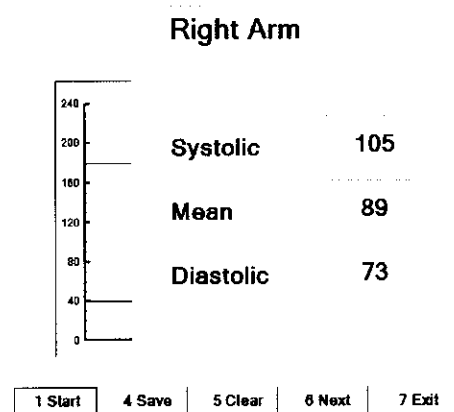
Caution: please verify anatomical location prior to recording any Patient data!

Patient Testing

Continued

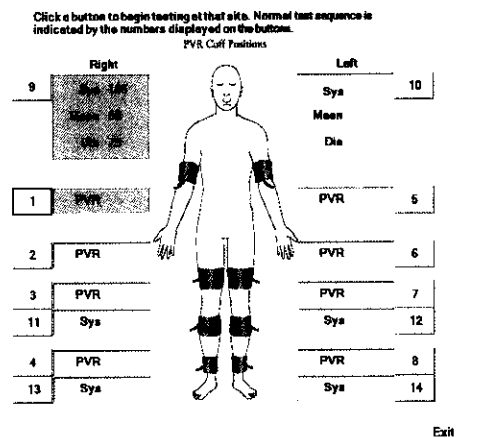
Segmental Pressure – Testing

1. To begin testing make sure hose from cuff is attached to connector on faceplate of PADnet Lab.
2. User may click on **Start** or press the number **1** key on the computer keyboard.
3. The pump will begin to inflate the cuff to the indicated fill pressure which is the top solid line. This setting may be adjusted by clicking on the line and dragging it to the desired level.
4. When the cuff is inflated the pump will shut off and the cuff will begin to deflate. When the pressure has been detected the system will dump any remaining air out of the cuff and the pressure value will be displayed on the right side of the screen as depicted below.



5. If the values are acceptable to the tester than the tester should click on **Save** or press the **4** key on the computer to save the test data. If not acceptable than the tester should click on **Clear** or press the **5** key on the computer to clear the existing data and retest the location.
6. The tester may than click on next to move to the next testing location. This sequence of testing should be repeated for each pressure location. The normal testing locations are arms and ankles. Toes may need to be tested on patients with non – compressible vessels at the ankle level.
7. When data is stored the testing summary screen is updated with the pressure values and will appear as below.

Patient Testing Continued



Segmental Pressure – Basics

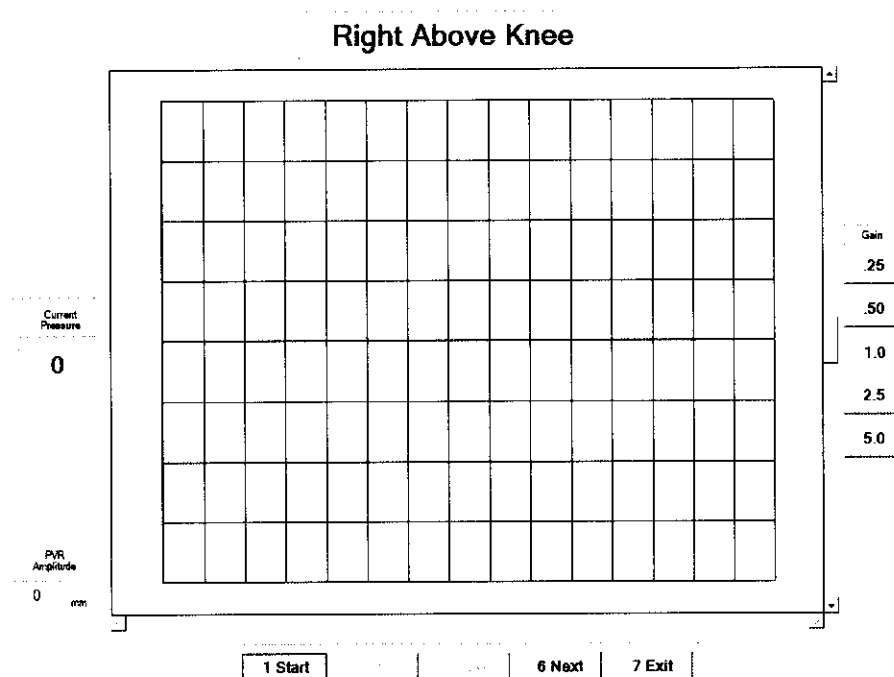
Segmental pressures are simply systolic blood pressures recorded at various sites on the limb. They are taken by using blood pressure cuffs. Segmental pressure taking is similar to taking a brachial pressure, with the exception that the Cuff replaces the stethoscope in its ability to detect the disappearance and return of flow. It may be helpful to think of the Cuff as a high-tech stethoscope. Segmental pressures and the resulting Segmental Brachial Indices (SBI) are of crucial diagnostic value.

If an increase in pressure is noticed in the pressures down the limb, they are usually due to the calcification of the vessels. This calcification causes them to be harder to compress with the cuff. In the presence of calcified vessels a digit pressure is indicated. A normal digital pressure will be 60% of the ankle pressure.

Patient Testing **Continued**

PVR Testing

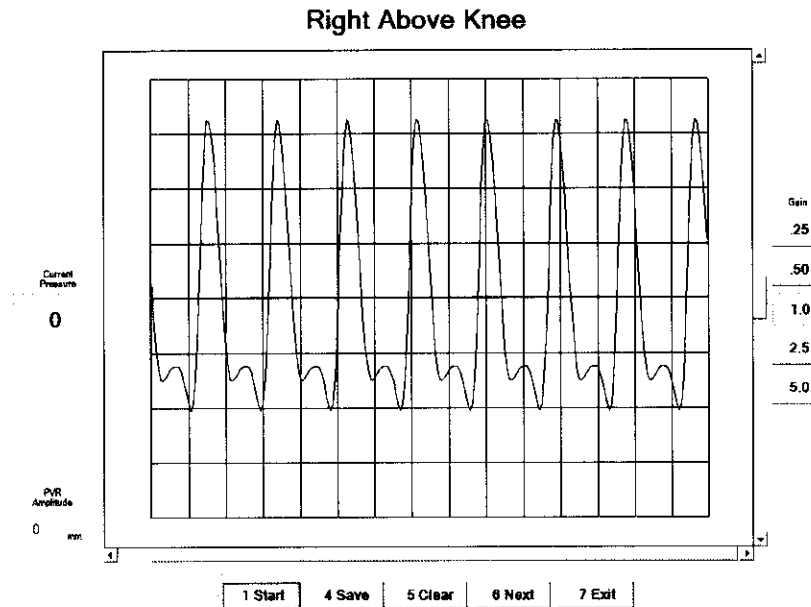
From the testing summary screen an anatomical location for PVR testing is selected. The following test screen will appear.



Caution: please verify anatomical location prior to recording any Patient data!

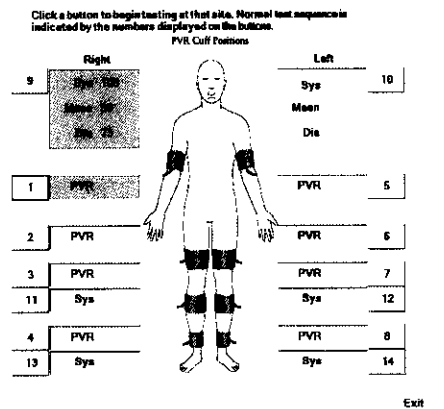
1. To begin testing make sure hose from cuff is attached to connector on faceplate of PADnet Lab.
2. User may click on **Start** or press the number **1** key on the computer keyboard.
3. The pump will begin to inflate the cuff to the indicated fill pressure (65mmHg). When this pressure is achieved the PVR waveforms will scroll across the graph from right to left.
4. The tester should allow the graph to fill with PVR waveforms and then click on **Stop** or press the **1** key on the computer.

Patient Testing **Continued**



5. The tester may now position the tracings using the scroll bars. The scroll bar below the graph will move the tracing back and forth. The scroll bar to the right of the graph will move the tracings up or down on the graph. The tester may also change the overall gain by clicking on the Gain settings on the far right of the screen.
6. To measure the amplitude of the PVR tracing the tester should click on the base and then the peak of a selected PVR waveform. The measured value will be displayed in a window on the left side of the screen.
7. If the values and PVR waveforms are acceptable to the tester then the tester should click on **Save** or press the **4** key on the computer to save the test data. If not acceptable then the tester should click on **Clear** or press the **5** key on the computer to clear the existing data and retest the location.
8. The tester may then click on next to move to the next testing location. This sequence of testing should be repeated for each PVR location. The normal testing locations are thigh, calf and ankles. Toes may need to be tested on patients with non – compressible vessels at the ankle level.
9. When data is stored the testing summary screen is updated with the pressure values and will appear as below.

Patient Testing **Continued**



Pulse Volume Recording: Basics

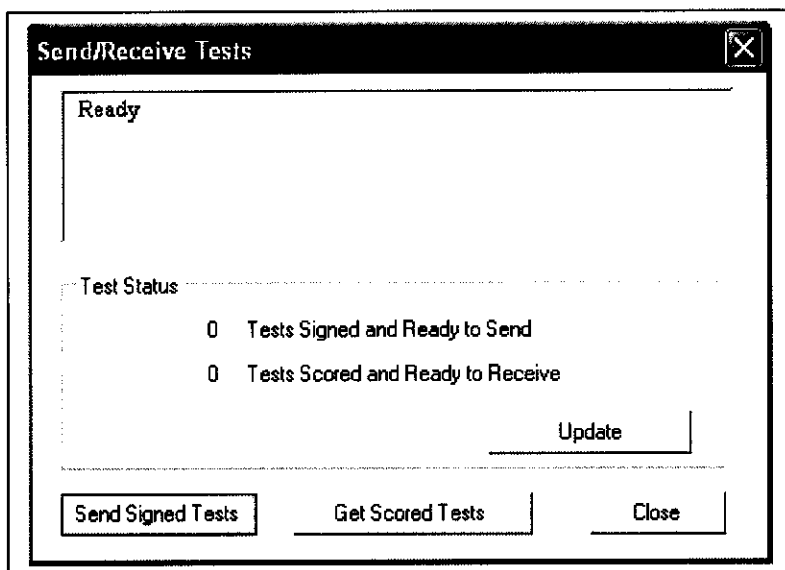
Pulse volume recording (PVR) or air plethysmography is perhaps the easiest and least technician dependent test you can perform. In arterial studies the plethysmograph reflects volume changes in the extremity underneath the cuff. Each waveform corresponds to a complete cardiac cycle. Said another way, PVR captures the changes in pressure in an air filled cuff wrapped around an extremity, and provides important diagnostic data on the functional aspect of the patient's limb.

The tracings derived from PVR are only minimally affected by application technique. The BioMedix PADnet Lab tracings are calibrated to a standard. Once the cuff is inflated, and a trace is obtained, the characteristics of that tracing (i.e., morphology) can be compared with specific diagnostic criteria and placed into a category.

Data Transfer From Tester to Reader

PADnet Lab sends collected test data to PADnet Read via Web Services. Web Services operates as a service that interfaces to the PADnet Lab read database. The PADnet web service will only transfer data using a secure, encrypted data channel (SSL). It will authenticate the requesting application before handling any requests. The PADnet Lab user drives all transfer of data, both sending and receiving test data from the PADnet Read database. Once test information is send to PADnet Read, an interpreting Physician can interpret the test information from a web page, connected to the PADnet Read database. Interpreted tests are made available for download, back to PADnet Lab.

To navigate to send or receive test data, select Tools, Send/Receive tests or select the Send/Receive hyper text link on the Home page. The following diagram will be displayed.



The topmost window displays status of the connection to the Internet. Click "Update" to update Test Status. If Test Status shows tests are ready to send, click the "Send Signed Tests" to send those tests to PADnet Read. If Test Status shows tests are ready to receive from PADnet Read, click "Get Scored Tests" to retrieve tests.

Printing Patient Reports

Printing Patient Reports is done from the report tab screen. A Summary, PVR and Billing report is able to be selected for printing. The tester may also create a follow up letter and have it printed at the same time. This screen is as seen below.



Reports can be previewed prior to printing by (1) selecting the print preview button from the tool bar or (2) by selecting File then Report Preview from the menu or (3) by selecting the Preview button within the report dialog. The report dialog is viewed by selecting View, then selecting Reports...

Guidance on Preventative Inspection and Maintenance

Note: The PADnet Lab does not contain parts that require preventative maintenance

1. **Never** store the PADnet Lab near an air conditioning or heating ventilator.
2. Clean the exterior of the PADnet Lab with alcohol and a cloth only... and **ONLY** with the unit **UNPLUGGED** from the **AC WALL SOCKET**.
3. Leave the PADnet Lab **"OFF"** when not in use.
4. The Cuffs should only be cleaned with mild soap and water. They should never be cleaned with alcohol.
5. **NEVER PLACE LIQUID CONTAINERS** on top of or near the PVL.
6. The PADnet Lab should **NEVER** be opened regardless of circumstances. There are no user serviceable parts inside.  **Shock hazard could result if opened.**

NOTE: UNAUTHORIZED SERVICING OF THE UNIT WILL VOID YOUR FACTORY WARRANTY. ONLY AUTHORIZED SERVICE PERSONNEL CAN SERVICE THIS DEVICE. FOR FURTHER INFORMATION PLEASE CONTACT BIOMEDIX AT 651-762-4010.

Note: For disposal of the device at the end of its useful life, please contact BioMedix for proper disposal.

Specifications

Class 1, type BF  applied parts

Storage / Transport Temperature Range = -40°C to +50°C

Storage / Transport Humidity Range = 5% to 95%

Operational Temperature Range = 0°C to +40°C

Operational Humidity Range = 15% to 90%

Only computers that meet IEC 60950 should be connected to this device.

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1775 Old Highway 8 NW, Suite 104
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United States of America

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Fax 651 638 0295
email info@tuvps.com
http www.tuvglobal.com



FACSIMILE TRANSMISSION

510(k) Program Dept.
Phone: 651-638-0294
Fax: 651-638-0295

Total of 1 page

TO: Will Rogers
BioMedix

Fax: 651-762-4014

FROM: Cheryl Norton

DATE: August 12, 2004

SUBJECT: 510(k) Notification for the PADnet Lab

Dear Mr. Rogers,

This letter is to acknowledge that on July 27, 2004, TÜV Product Service received a 510(k) for the PADnet Lab. The administrative review using the 27 item checklist for acceptance is complete.

After discussions with the FDA required by pilot program devices with a guidance document, it is clear that clinical data is needed for this submission due to claims of diagnosis. TÜV America is unable to accept this submission for further review. 510(k)s with clinical data must be sent directly to FDA since Third Parties are not allowed to review 510(k)s with clinical data. We ask that you please either withdraw your submission from Third Party review or revise the submission so that clinical studies are not required.

The specific details which caused the determination that a clinical study is required are:

(b)(4)

A large rectangular area of the document is redacted with a solid grey fill, obscuring the specific details mentioned in the preceding sentence.

If you have any questions, please contact me at 651-638-0294.

Sincerely,

A handwritten signature in cursive script that reads 'Cheryl Norton'.

Cheryl Norton
510(k) Third Party Reviewer

Norton Cheryl

From: Ho, Charles S. [CBH@CDRH.FDA.GOV]
Sent: Thursday, August 12, 2004 3:10 PM
To: Norton Cheryl
Cc: Mallis, Elias; Ho, Charles S.
Subject: RE: Third Party 510(k) for Biomedix

Hello Ms. Norton:

As we discussed a few minutes ago, the last page of the attachment clearly indicates a clinical claim by the device-- that the SBI index can be used to diagnose the degree of stenosis in a blood vessel. Hence, I believe that a clinical study is needed to substantiate this claim, and that the submittal should not be reviewed by a third-party reviewer.

Thanks for the discussion!

Regards,

Charles Ho, Ph.D.

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

From: Norton Cheryl [mailto:CNorton@tuvam.com]
Sent: Thursday, August 12, 2004 2:12 PM
To: CBH@CDRH.FDA.GOV
Cc: EYM@CDRH.FDA.GOV
Subject: FW: Third Party 510(k) for Biomedix

Dr. Ho,

This is a duplicate of the e-mail I sent on Friday Aug. 6 which you may not have received. Please see e-mail below with further questions.

My office phone is 651-638-0294.

Sincerely,

Cheryl Norton

Lead NB Auditor/ Compliance Engineer/ Third Party 510(k) Reviewer

TUV America Inc.

Product Service

P: 651-638-0294

F: 651-638-0295

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

From: Norton Cheryl
Sent: Friday, August 06, 2004 11:01 AM
To: 'Ho, Charles S.'
Cc: Mallis, Elias
Subject: RE: Third Party 510(k) for Biomedix

Dr. Ho,

I appreciate your assistance on this matter. I am still unable to proceed

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

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based on your response. Please consider the following information about the device:

The Indications for Use is "The BioMedix PADnet Lab is a non invasive device used to gauge the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures to assist in the identification of vascular disease. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin."

The Operators Manual (draft) states: "The BioMedix PADnet Lab is a highly sophisticated device for use in the diagnosis of vascular pathology."

I have also attached 4 pages scanned from the Operators Manual (draft) related to interpretation of data using the Segmental Brachial Indices (SBI). I am concerned that this information would be considered by FDA as diagnosis and require clinical studies. I understand that Third Parties are not allowed to review 510(k)s with clinical data.

Please let me know if any of this informaton would need to be removed or changed by BiomMedix in order for the device to be reviewed by a Third Party.

Regards,
Cheryl Norton

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

From: Ho, Charles S. [mailto:CBH@CDRH.FDA.GOV]
Sent: Thursday, August 05, 2004 5:32 PM
To: Norton Cheryl
Cc: Mallis, Elias; Ho, Charles S.
Subject: RE: Third Party 510(k) for Biomedix

Hello Ms. Norton:

Based on the information provided by you, I believe that if the subject device is claimed to be able to diagnose any disease, including contributing to the diagnosis of the disease, FDA will probably require a clinical study on the device. This will remove the device from the third party review arena.

However, if the device's intended use is for measuring blood flow or blood volume in a peripheral vessel only, without attaching any clinical significance to the recorded data, there is a chance that the device can remain in the third part arena.

Further, the review at FDA may involve the Peripheral Vascular Devices Branch of DCD, in addition to my present Branch of CEMB.

Regards,

Charles Ho, Ph.D.

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

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

From: Norton Cheryl [mailto:CNorton@tuvam.com]
Sent: Thursday, August 05, 2004 10:54 AM
To: CBH@CDRH.FDA.GOV
Subject: Third Party 510(k) for Biomedix

Dr. Ho,
See attached additional information as requested. These documents were supplied by Biomedix. The first document is a printout from the FDA database for a predicate device in the Cardiovascular branch (K801291). The second document is a paper on pneumoplethysmography. The third document is an article on pulse volume recorders (segmental pressure). <<K801291.pdf>> <<air plethysmography.pdf>> <<pulse volume recorder.pdf>>

Please let me know if this is enough information to determine whether this 510(k) qualifies for Third Party review.

Sincerely,
Cheryl Norton
Lead NB Auditor/ Compliance Engineer/ Third Party 510(k) Reviewer
TUV America Inc.
Product Service
P: 651-638-0294
F: 651-638-0295



COMMUNICATION LOG FOR CHERYL NORTON

CONTACT:	<u>Will Rogers</u>	COMPANY:	<u>FDA</u>
TEL. NO.:	<u>651-762-4010</u>	FAX NO.:	<u>N/A</u>
DATE:	<u>August 12, 2004</u>	TIME:	<u>3:10 p.m.</u>
SUBJECT:	<u>510(k) Notification for PADnet Lab</u>		

NOTES:

Cheryl called Will to explain the determination that TÜV America cannot accept the BioMedix 510(k) for review due to claims of diagnosis which require clinical studies. Third Parties are not allowed to review 510(k)s with clinical data. Cheryl pointed out specific issues from the Indications for Use and labeling which led to the decision by FDA. She promised to send a written letter today explaining the options for BioMedix. Will stated that he would be willing to remove the SBI from the Operators Manual if it would allow TÜV America to perform a Third Party review.

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891



COMMUNICATION LOG FOR CHERYL NORTON

CONTACT:	<u>Dr. Charles Ho</u>	COMPANY:	<u>FDA</u>
TEL. NO.:	<u>301-443-8517, x179</u>	FAX NO.:	<u>N/A</u>
DATE:	<u>August 12, 2004</u>	TIME:	<u>2 and 3 p.m.</u>
SUBJECT:	<u>510(k) Notification for PADnet Lab</u>		

NOTES:

Cheryl called Charles to ask if he received her e-mail from August 6 and whether he had a response. Charles responded that he never received the e-mail. Cheryl said she would send it again.

Charles called Cheryl after he reviewed Cheryl's e-mail and responded that clinical studies would definitely be required based on the last page of the e-mail attachment (Operators Manual page with diagnosis based on the SBI). He explained that clinical studies would not be required if the device only gives the user a number and does not try to interpret the data. Cheryl asked if the Indications for Use was also an issue. Charles stated that Biomedix would need to "tone it down".

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Norton Cheryl

From: Norton Cheryl
Sent: Thursday, August 05, 2004 9:54 AM
To: 'CBH@CDRH.FDA.GOV'
Subject: Third Party 510(k) for Biomedix

Dr. Ho,

See attached additional information as requested. These documents were supplied by Biomedix. The first document is a printout from the FDA database for a predicate device in the Cardiovascular branch (K801291). The second document is a paper on pneumoplethysmography. The third document is an article on pulse volume recorders (segmental pressure).



K801291.pdf



air
plethysmography.pdf



pulse volume
recorder.pdf

Please let me know if this is enough information to determine whether this 510(k) qualifies for Third Party review.

Sincerely,

Cheryl Norton

Lead NB Auditor/ Compliance Engineer/ Third Party 510(k) Reviewer

TUV America Inc.

Product Service

P: 651-638-0294

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510(k) Premarket Notification Database

Device Classification Name	<u>Plethysmograph, Photoelectric, Pneumatic Or Hydraulic</u>
510(K) Number	<u>K801291</u>
Regulation Number	<u>870.2780</u>
Device Name	<u>EC-4 PLETHYSMOGRAPH</u>
Applicant	<u>WA</u> <u>D. E. HOKANSON, INC.</u>
Product Code	<u>JOM</u>
Date Received	<u>06/02/1980</u>
Decision Date	<u>07/08/1980</u>
Decision	<u>Substantially Equivalent (SE)</u>
Classification Advisory Committee	<u>Cardiovascular</u>
Review Advisory Committee	<u>Cardiovascular</u>
Statement/Summary/Purged Status	<u>Purged, No Summary Or Statement</u>
Type	<u>Traditional</u>
Reviewed By Third Party	<u>No</u>

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Center for Devices and Radiological Health / CDRH

CHAPTER 23

Air plethysmography in arterial and venous disease

Plethysmography is derived from two Greek words: *plethysmos* (to increase) and *graphien* (to write). It indicates an instrument that records an increase in volume.

A number of methods have been used to measure volume changes: water, air, electrical impedance, mercury in rubber strain gauge, and photoelectric plethysmography. Air plethysmography has recently been developed for quantitative clinical use by calibrating the instrument to measure volume changes of the whole leg in absolute units (ml). It has found a place in both arterial inflow measurements and the assessment of chronic venous insufficiency.

PULSE VOLUME RECORDER

Jeffrey K. Raines

Segmental (limb and digit) plethysmographic recordings have proved to be important in the clinical evaluation of the peripheral arterial system. The segmental recordings are similar to the arterial pressure-pulse contour and reveal the degree of occlusive disease, an estimate of collateral circulation, anatomic localization of obstructive lesions, and indirectly, the level of perfusion. These measurements should not be confused with absolute blood flow, which segmental plethysmography does not measure. Plethysmographic data combined with clinical findings, segmental limb pressures, and treadmill exercise testing provide useful hemodynamic information necessary for the treatment of patients with peripheral disease.

The pulse volume recorder (PVR)* was developed through the combined efforts of the Massachusetts Institute of Technology and the Massachusetts General Hospital. It is a quantitative segmental plethysmograph designed for high sensitivity and clinical application.^{9,14,15} It provides pulse volume recordings and systolic pressure measurements of the extremities, is adaptable to arterial measurements taken before and after exercise, and is capable of producing permanent records for reference. It may also be used to diagnose deep vein thrombosis in major veins of the lower extremities and is now available with an attachment to measure ophthalmic systolic artery pressure. Chap-

ter 59 describes the practical clinical use of this instrument and gives examples of PVR recordings; the remainder of this section is devoted to describing the mechanics of the PVR.¹³

OPERATING PROCEDURE

With the PVR, appropriate blood pressure cuffs are placed on the extremity or digit and a measured quantity of air (75 ± 10 ml) is injected until a preset pressure (65 mm Hg) is reached. This procedure ensures that at a given pressure, the cuff volume surrounding the limb is constant from reading to reading. If this cuff setting (volume and pressure) is not met, the cuff must be reapplied at a slightly different tension. The PVR electronic package measures and records instantaneous pressure changes in the segmental monitoring cuff. Cuff pressure change reflects alteration in cuff volume, which in turn reflects momentary changes in limb volume. Cuffs are available in different sizes for all anatomic locations, including the digits. They have a neoprene bladder surrounded by a nonelastic nylon Velcro band that allows easy application.

The PVR method is simpler than making volume calibrations with application of the cuff, as has been done with other instruments.¹⁸ Similarly, it obviates mathematical corrections for volume and pressure changes and provides PVR recordings that can be visually compared with those previously obtained. PVR recordings are taken at a chart speed of 25 mm/sec.

The major components of the PVR are illustrated in Fig. 23-1. The electronic circuit includes a pressure-sensitive silicone NPN plantar transistor with its emitter-base junction mechanically coupled to a diaphragm.¹² A differential pressure applied to the diaphragm produces a large reversible change in the gain of the transistor, which has a uniform frequency response up to 150 kHz. Additional electronic components of the PVR include (1) a sample-and-hold circuit that operates in closed-loop fashion to maintain a proper operating point for the pressure sensor, (2) logic circuits that set solenoid valve configuration according to the mode selected by the operator, and (3) a dual-limit comparator that detects and corrects for excessive differential pressures applied to the sensor.

*Life Sciences, Inc. Greenwich, Conn.

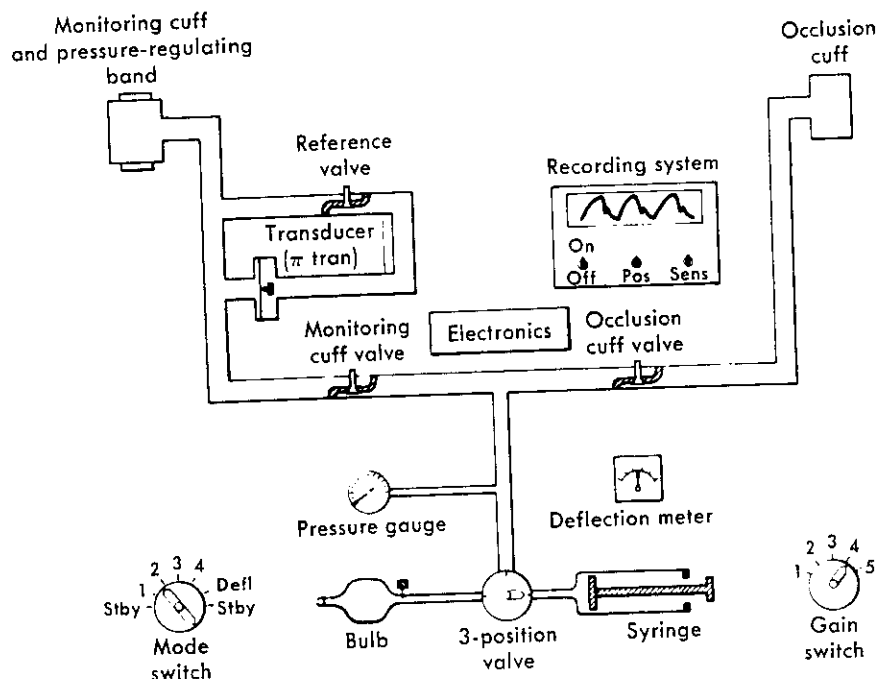


Fig. 23-1. System diagram of a PVR.

CALIBRATION

The PVR is calibrated so that a 1 mm Hg pressure change in the cuff provides a 20 mm chart deflection. If desired, maximum chart deflection may be translated (by means of cuff dynamics formulas) into volume change per cardiac cycle.

FREQUENCY RESPONSE

The frequency response of the complete device (cuff and electronic package) was tested by strapping a water-filled bladder around a rigid plastic cylinder, which in turn was encircled by an air-filled PVR monitoring cuff. A small piston-in-cylinder pump was then connected to the bladder to produce a sinusoidal pressure change in the monitoring cuff. The amplitude of these oscillations remained constant up to a pump frequency of 20 Hz, which is sufficient to evaluate the higher-frequency components of the human arterial pressure-pulse contour accurately.¹⁰

LINEARITY

The linearity of the system was tested by measuring cuff pressure changes as a function of cuff volume changes. This was studied over a range of mean cuff pressures varying from 20 to 200 mm Hg and with injected cuff volumes varying from 20 to 125 ml. Within the range studied, cuff pressure change was indeed a linear function of taking clinical readings at consistent cuff pressures and volumes.

CUFF DYNAMICS

It was important to understand how the pressure of the air in the cuff related to the arterial pressure and limb volume

changes to aid in the development of the PVR operating procedure and the interpretation of its recordings. A number of experiments and analyses were performed.¹³

For example, a constant mass of air in the cuff is at an absolute pressure p_c in a volume V_c . Furthermore, if it is assumed that the gas undergoes an isentropic process, the following equation may be written:

$$p_c V_c^\gamma = \text{Constant} \quad (1)$$

where γ is the ratio of specific heats (for air, γ is 1.4).

The pressure-measuring components of the PVR were connected to a rigid cylinder (50 ml volume) to test the validity of the isentropic assumption. Also included in the pneumatic circuit was a small piston-in-cylinder pump with a 1-ml stroke volume. The pump was used to oscillate the total volume of the system at various frequencies while measuring the pressure changes. It was found that at frequencies from 0.25 to 20 Hz (highest frequency tested), the pressure amplitude remained constant. The pressure amplitude increased approximately 34% gradually from zero frequency (isothermal) to 0.25 Hz. This experiment suggests that in the range of primary frequencies encountered in clinical use (0.5 to 1.5 Hz) the air in the cuff undergoes an isentropic process, changing from isothermal to isentropic between zero and 0.25 Hz. It can be shown that the identification of the process is not critical to the analysis, since its effect is combined with the elastic expansion of the cuff. Since the volume excursions in the cuff are a small fraction (2% maximum) of its mean volume, equation 1 can be differentiated to give:

$$\delta p_c = -\frac{\gamma p_c}{V_c} \delta V_c \quad (2)$$

where p_c and V_c have been replaced by their time-mean values $\bar{p}_c$ and $\bar{V}_c$, respectively. The time-mean volume $\bar{V}_c$ is also a function of cuff pressure and the injected air mass. If the initial volume of air injected at atmospheric pressure (P_{ATM}) is V_1 , the volume of air in the cuff is defined by equation 3:

$$\bar{V}_c = \frac{P_{ATM}}{\bar{p}_c} (V_1 + V_1 + V_2) - V_2 \quad (3)$$

Here V_1 is the tube volume from an internal shutoff valve in the PVR to the monitoring cuff; V_2 represents the tube volume from the shutoff valve to the syringe. V_1 and V_2 are 21 and 22 ml, respectively. The compression of the injected air is assumed to be isothermal, since it subsists for a long period of time, much longer than 4 seconds (0.25 Hz). Combining equations 2 and 3 results in:

$$\delta p_c = \frac{-\gamma \delta V_c \bar{p}_c}{(P_{ATM}/\bar{p}_c [V_1 + V_1 + V_2] - V_2)} \quad (4)$$

Another experiment was performed to investigate the validity of equation 4. The monitoring cuff was connected to the PVR electronics with a 1-ml syringe also in the pneumatic circuit. The syringe was used to change the total air volume in increments of 0.25 ml from 0.25 to 1 ml at different cuff pressures and initial injected volumes. Cuff gauge pressures at 20, 40, 60, 80, and 100 mm Hg were used with injected volumes of 25, 50, 75, and 100 ml. The results of this experiment indicated that the bladder constrained by the nylon Velcro band is not inextensible but instead expands with pressure over the monitoring cycle. The edges and corners of the bladder that are not constrained by the cuff may move and make additional volume available. The actual volume change of the air in the bladder δV_x resulting from the expansion of the cuff is defined by:

$$\delta V_x = \delta V - \delta V_c \quad (5)$$

where δV is the volume change applied to the cuff.

The ratio of $\delta V_x/\delta V$ varies with mean cuff pressures and injected volumes.¹³ The extrapolations of the measurements to $p_c \rightarrow 0$ lead to $\delta V_x = \delta V$, and even at high cuff pressures the expansion is still present but to a lesser degree as the bladder becomes stiffer. The fact that wrapping an inextensible band around the cuff does not change the results suggests that end effects, not the stretching of the bladder, are the dominant factors. This observation suggests that the sensitivity of the PVR may be considerably improved by designing a cuff that absorbs all the limb volume change.

Clinical practice has indicated that improved sensitivity is not necessary; slightly modified blood pressure cuffs are adequate. Including the results of the preceding experiment, equation 4 is rewritten as:

$$\delta p_c = \frac{-\gamma \delta V \left(1 - \frac{\delta V_x}{\delta V}\right)}{\left[\frac{(P_{ATM}/\bar{p}_c [V_1 + V_1 + V_2] - V_2)}{\bar{p}_c}\right]} \quad (6)$$

Equation 6 defines the relationship of limb volume change (δV) and cuff pressure change (δp_c).

It is of interest to continue the analysis and define the relationship of cuff pressure to arterial pressure. The volume changes of the limb caused by the passage of the pressure pulse are proportional to the changes in the arterial volume δV_a encompassed by the cuff. This has been shown to be true, even in the edematous limb. Therefore:

$$\delta V = \delta V_a = C_a \delta p_a \quad (7)$$

where $C_a = \delta V_a/\delta p_a$ is the compliance of the arterial section surrounded by the cuff and p_a denotes the arterial pressure. Combining equations 6 and 7:

$$\delta p_c = \frac{\gamma C_a \delta p_a \left(1 - \frac{\delta V_x}{\delta V}\right)}{\left[\frac{(P_{ATM}/\bar{p}_c [V_1 + V_1 + V_2] - V_2)}{\bar{p}_c}\right]} \quad (8)$$

Since $\delta V_x/\delta V$ is approximately independent of δV , it follows from equation 8 that if C_a remains constant, the variations in the cuff pressure are proportional to the variations in arterial pressure and the output of the pressure-sensitive transistor will yield a good representation of the arterial pressure-pulse contour. The critical experiment to test the accuracy of this analysis is the comparison with direct intraarterial measurements. This comparison has been made with excellent correlation and is provided in Chapter 59.

DIAGNOSTIC INDICES

A number of important diagnostic parameters are contained in the pulse volume recordings.

The amplitude of the pulse volume recording with a constant pneumatic and electronic gain is a function of local pulse pressure, segmental arterial compliance, and the number of arterial vessels in the segment under investigation. These are all affected by the development of arteriosclerotic disease. Reduced pulse pressure and obliterated arterial channels are major hemodynamic parameters that affect functional perfusion.

Because the pulse volume contour is linked to the pressure-pulse contour (equation 8), the shape of the pulse volume contour contains useful hemodynamic information. Contour alterations are largely the result of changes in terminal reflection coefficients, which are a function of peripheral resistance. Peripheral resistance changes to compensate for fixed arterial resistance caused by obstructive lesions. This phenomenon has been previously described.^{13,15}

CONCLUSION

This section has described the engineering development and mechanics of the PVR; its clinical application to arterial peripheral vascular disease is outlined in Chapter 59.

CHAPTER 59

The pulse volume recorder in peripheral arterial disease

JEFFREY K. RAINES

Recent advances in electronics, a more complete understanding of peripheral hemodynamics, and the vigorous development of clinical criteria have made the use of quantitative segmental plethysmography an important component in the routine evaluation of peripheral vascular disease.

After years of instrumentation development in the Fluid Mechanics Laboratory at the Massachusetts Institute of Technology¹⁰⁻¹² and clinical trials in the Vascular Laboratory, Massachusetts General Hospital,^{2,5,13} the pulse volume recorder (PVR)* has emerged. The PVR is basically a quantitative segmental plethysmograph that has been designed for high sensitivity and oriented toward clinical use (Fig. 59-1).

In the operation of the PVR, appropriate blood pressure cuffs are placed on the extremity or digit, and a measured quantity of air is injected until a preset pressure is reached. This procedure ensures that at a given pressure the cuff volume surrounding the limb is constant from reading to reading. The PVR electronic package measures and records instantaneous pressure changes in the segmental monitoring cuff. Cuff pressure change reflects alteration in cuff volume, which in turn reflects momentary changes in limb volume. PVR units are calibrated so that a 1 mm Hg pressure change in the cuff provides a 20 mm chart deflection.

During the design phase, the frequency response of the complete device (cuff/electronic system) was tested. The system has a flat response to 20 Hz, which is sufficient to evaluate the higher frequency components of the human arterial pressure pulse contour. Additional experiments were performed to verify that linearity is maintained over the full range of clinical interest. For arterial studies the output of the PVR electronics is AC coupled with a 1-second time constant.

Simultaneous PVR traces were compared with direct intraarterial pressure recordings taken at the same location to determine how closely the volume pulse contour resembles the pressure pulse contour. Fig. 59-2 shows a typical comparison in which mean cuff pressures were adjusted between 30 and 80 mm Hg in 10 mm Hg increments. The cuff pressure must be sufficiently high to allow adequate contact

between the cuff bladder and the limb segment. Since the cuff pressure will by necessity reduce the transmural pressure in the underlying arteries, distortion of the recorded pulse contour will result at higher cuff pressures. In clinical practice a cuff pressure of 65 mm Hg gives excellent pneumatic gain and surface contact and maintains the important contour characteristics.

PVR INDICES**PVR amplitude**

In clinical trials extending over 8 years, PVR amplitudes were found to remain highly reproducible in the same patient if constant cuff volumes and pressures were used.⁵ For example, the presence of limb edema does not influence the height or contour of the PVR recording. Significant changes were consistently correlated with alterations in the underlying vasculature. There were variations in amplitudes from patient to patient. Amplitude can be affected by ventricular stroke volume, blood pressure, vasomotor tone, and volume.

Pulse volume amplitudes, however, are universally affected by exercise. In normal subjects the amplitude increases following standard exercise tests. On the other hand, patients with occlusive arterial disease uniformly show a diminution in pulse volume at the ankle following exercise. In addition, there is a definite relationship between the degree of ischemia as determined by the maximum walking time and the relative fall in pulse volume amplitude. In some cases the recovery time required to establish preexercise pulse amplitudes is useful.

PVR contour

Indications of occlusive arterial disease as demonstrated by the PVR contour include (1) decrease in the rise of the anacrotic limb, (2) rounding and delay in the pulse crest, (3) decreased rate of fall of the catacrotic limb, and (4) absence of the reflected diastolic wave.

The reflected diastolic wave is of particular diagnostic significance; it is generally not seen in the presence of demonstrable occlusive disease. The hemodynamic principles of this phenomenon at rest and after exercise are described in detail by Raines.¹⁰ Examples of normal and abnormal PVR contours are shown in Fig. 59-3.

*Life Sciences, Inc., Greenwich, Conn.

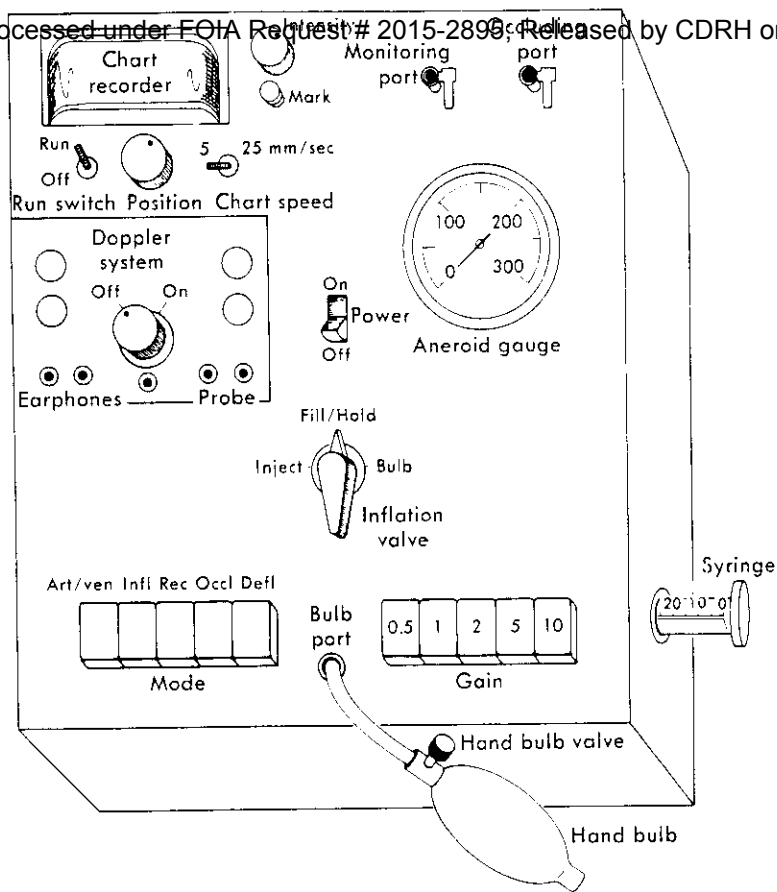


Fig. 59-1. Pulse volume recorder (PVR).

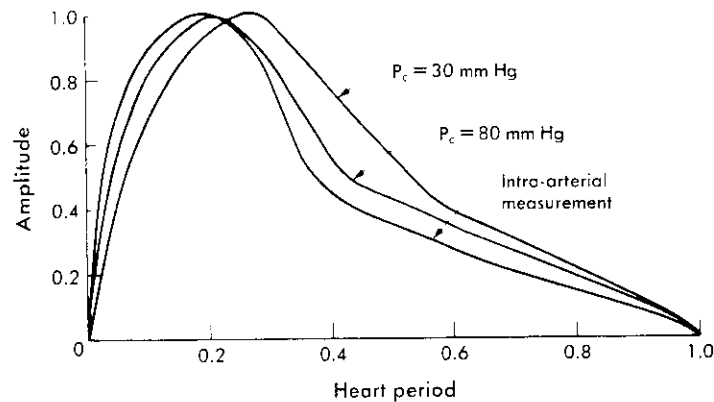


Fig. 59-2. PVR contours at different cuff pressures (P_c) compared with intraarterial measurement in the femoral artery.

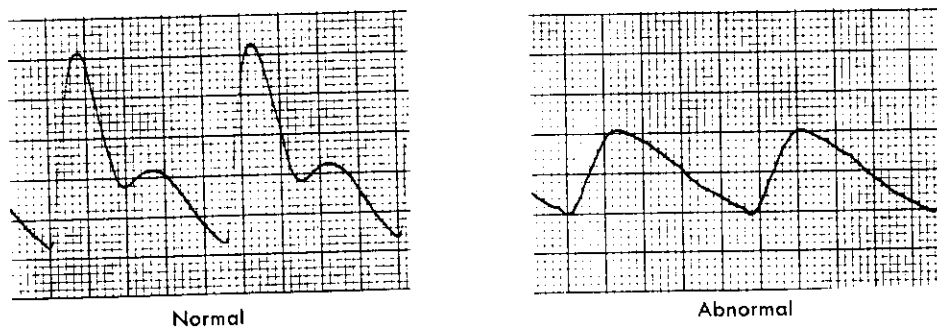


Fig. 59-3. Normal and abnormal pulse volume recordings taken at the ankle level. Cuff pressure, 65 mm Hg; cuff volume, 75 ml.

Limb pressures

In most cases the Doppler velocity detector can be used to measure limb systolic pressures. In addition, the PVR can be used to measure limb or digit systolic and diastolic pressures by placement of the occlusion cuff proximal to the monitoring cuff. Pressures are determined at the site of the occlusion cuff when its pressure obliterates the PVR recording in the distal monitoring cuff. As pressure is lowered in the occluding cuff, oscillations in the monitoring device increase in amplitude, with the maximum excursions occurring at the diastolic level. This method is reliable even at low pressures and does not require specific positioning over an artery, as does the Doppler ultrasonic velocity detector. This method may be the only applicable procedure to obtain a limb pressure when no Doppler signals are obtainable. The systolic and diastolic pressures obtained by the PVR have been compared with intraarterial pressures obtained by radial and femoral artery cannulation. The agreement is excellent for systolic pressure and always within 10 mm Hg for diastolic pressure determinations.

It has been shown that arterial occlusions or high-grade stenoses produce pressure differences in the limb at rest.^{5,10,14,16} However, less significant degrees of stenosis, particularly at the aortoiliac level, may not. The hemodynamic significance of such minor degrees of arterial narrowing and the functional capacity of the collateral circulation are best evaluated by resting PVR tracings and the response of PVR amplitudes and pressures after measured exercise.

The remainder of this chapter deals with procedures, techniques, and clinical criteria used in conjunction with the PVR.

EVALUATING ARTERIAL HEMODYNAMICS IN THE LOWER EXTREMITIES

Lower limb vascular laboratory examinations may be performed both before and after exercise and in the resting state. Examples of such examinations in the lower limbs at rest are PVR recordings and systolic pressure measurements at the thighs, calves, and ankles of both legs; Doppler velocity detection in the feet; documentation of pulses and bruits; and brachial blood pressure. Exercise testing is performed when history, clinical examination, and symptoms indicate the procedure to be necessary.

PVR cuffs are placed snugly around both thighs, calves, and ankles (six cuffs in all). The thigh cuff bladders are 36 × 18 cm, whereas the bladders in the cuffs for the calves and ankles are 22 × 12 cm.

Each recording is taken separately. The thigh cuff may be inflated using the hand bulb to a pressure of 65 mm Hg (air volume ≈ 400 ml). For the calf and ankle level the cuff pressure should also be 65 mm Hg with an injected volume of 75 ± 10 ml using the syringe. If this criterion is not met, the cuff must be reapplied at a slightly different tension. With practice, reapplication is rarely necessary. The PVR or the Doppler velocity detector may be used to obtain

Table 59-1. Definition of PVR categories

PVR category	Chart deflection (mm)	
	Thigh and ankle	Calf
1	>15*	>20*
2	>15†	>20†
3	5 to 15	5 to 20
4	<5	<5
5	Flat	Flat

From Raines JK et al: *Surgery* 79:21, 1976.

*With reflected wave.

†No reflected wave.

systolic pressure at the thigh, calf, and ankle of a lower extremity.

After completion of resting studies, exercise testing is performed and maximum walking time determined. If minimal or no symptoms occur, a 5-minute standard walking time is selected. Immediately after exercise, PVR recordings and pressures are measured at the ankle level and compared with resting values. In addition, postexercise brachial blood pressure is recorded.

When it is desirable to evaluate perfusion at the transmetatarsal or digital level, PVR recordings can be obtained. For transmetatarsal tracings a pediatric cuff (12 × 7 cm bladder) is used. The bladder is placed in contact with the anterior portion of the foot; 65 mm Hg is the desired cuff pressure, with an injected volume of 50 ± 10 ml.

For digital tracings, specifically designed cuffs⁹ are used (7 × 2 cm and 9 × 3 cm bladders); 40 mm Hg is the recommended cuff pressure, with an injected volume of approximately 5 ml.

PVR recordings are classified into five categories, as listed in Table 59-1, and are combined with pressure data to define various clinical states. The information given in Tables 59-1 to 59-6 was developed at the Vascular Laboratory of the Massachusetts General Hospital and represents experience gained from 4500 examinations.¹³ These tables establish objective criteria useful for the clinical management of peripheral vascular disease.

Rest pain

Table 59-2 summarizes data gathered to provide objective criteria for evaluation of patients with a complaint of rest pain.

Diabetics have significantly elevated ankle pressure, since they often have medical calcinosis of peripheral vessels. This has the effect of artificially elevating the measured ankle pressure.¹⁵ In fact, in at least 5% to 10% of patients with diabetes mellitus, ankle pressures cannot be determined at all because of incompressible vessels. In these patients the PVR tracings are the only measurable parameter, and it is especially important to be able to differentiate between primary neuropathic pain and primary ischemic pain.

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Table 59-2. Vascular laboratory criteria for evaluation of rest pain

	Unlikely	Probable	Likely
Ankle pressure (mm Hg)			
Nondiabetic	>55	35-55	<35
Diabetic	>80	55-80	<55
Ankle PVR category			
Nondiabetic and diabetic	1,2,3	3,4	4,5

From Raines JK et al: *Surgery* 79:21, 1976.**Table 59-3.** Vascular laboratory criteria for the prediction of lesion healing

	Unlikely	Probable	Likely
Ankle pressure (mm Hg)			
Nondiabetic	<55	55-65	>65
Diabetic	<80	80-90	>90
Ankle PVR category			
Nondiabetic and diabetic	4,5	3	1,2,3

From Raines JK et al: *Surgery* 79:21, 1976.

Foot lesions

Table 59-3 provides objective criteria for the evaluation of patients with foot lesions. In a recent study, patients with diabetes mellitus represented only 15% of patients in the rest pain group; 54% of those with necrosis had the disease. This emphasizes the clinically recognized fact that these patients are far more prone to develop traumatic lesions, perhaps because of the frequent incidence of peripheral neuropathy. They also frequently have artificially elevated pressures as a result of calcified vessels; this pressure difference is approximately 25 mm Hg. Furthermore, because of more distal small vessel involvement, a digital or forefoot lesion may develop or progress at a higher ankle pressure than in patients who do not have diabetes.

In predicting healing of foot lesions, determination of ankle pressure and PVR recordings at the ankle, transmetatarsal, and digital levels are again the most important measurements.

Below-knee amputation healing

In the patient with advanced arteriosclerotic peripheral vascular disease in whom arterial reconstruction is not possible and who comes to amputation, it is generally agreed that a below-knee amputation is preferable from the standpoint of rehabilitation. However, it is also recognized that significant morbidity and mortality are present in this group of patients, particularly those in whom a more distal amputation fails and who therefore require a second procedure.

Table 59-4. Vascular laboratory criteria for the primary healing of below-knee amputation

	Unlikely	Probable	Likely
Pressure (mm Hg)			
Calf	>65	>65	>65
Ankle	>30	>30	>30
PVR category			
Calf	4,5	4	1,2,3
Ankle	5	4	1,2,3,4

From Raines JK et al: *Surgery* 79:21, 1976.

Since the prediction of successful healing of a below-knee amputation on the basis of clinical or arteriographic information is often a difficult task requiring considerable experience, easily obtained and objective vascular laboratory measurements that prove helpful in this regard have been sought.

Table 59-4 summarizes current criteria developed to predict the chances of successful below-knee amputation. Similar criteria for transmetatarsal and digital amputations are also being derived. In these instances, distal PVR recordings play an important role. In fact, in the absence of sepsis and osteomyelitis a toe amputation will heal if a pulsatile PVR tracing is found at the base of the digit in question. In addition, for the same clinical presentation a transmetatarsal amputation will heal if a pulsatile PVR tracing is present at the transmetatarsal level.

Evaluation of claudication

In the patient with lower extremity pain or exertion, it is of utmost importance to distinguish symptoms caused by neurologic or orthopedic processes from those produced by vascular insufficiency. Both entities may coexist. If true claudication is present, it is also important to determine accurately the patient's degree of disability and to establish a quantitative baseline with which medical or surgical therapy can be compared. However, it is often difficult to accomplish this by history and physical examination alone; a vascular laboratory examination including treadmill exercise should be routine in the workup of such patients.

In evaluating the presence or absence of true claudication, the most important parameters are ankle pressure and ankle PVR recording after measured treadmill exercise. Patients are exercised until significant symptoms are produced. The treadmill time at which this level of pain is reached is the maximum walking time, which occurs sometime between the onset of symptoms and the point at which the patient develops disabling pain. The endpoint of the maximum walking time has been shown to be the most reliable.

Table 59-5 provides simple criteria for the laboratory evaluation of limiting claudication.

It should be pointed out that for maximum use of these tables, PVR and pressure measurements *must complement*

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each other; pressures are not always obtainable and, taken alone, may be misleading. PVR recordings are rarely misleading and are enhanced by pressure measurements. However, when pressures cannot be measured accurately, PVR recordings may be used alone to form sound impressions.

Anatomic localization

Anatomic localization of hemodynamically significant peripheral vascular lesions by noninvasive means is another important contribution to patient management. Table 59-6 is given here as a simple guide for localization. It is important to note that laboratory findings and physical findings must be combined to produce accurate localization. Looking at one parameter is generally not sufficient. The case of combined disease is by far the most challenging; in 5% to 10% of patients with combined disease, noninvasive analysis, although it may define the hemodynamics, cannot accurately localize the major contributing lesion. In these cases an invasive femoral artery pressure study may be indicated.¹ A study is currently in progress at the Miami Heart Institute

to define the accuracy and limitations of noninvasive testing in anatomic localization.

EVALUATING ARTERIAL HEMODYNAMICS IN THE UPPER EXTREMITIES

Occlusive arterial disease of the arteries supplying the upper extremities is rare when compared with the frequency of the disease in the lower extremities. However, arterial trauma and thrombosis following cardiac catheterization result in patients requiring evaluation of upper extremity arterial hemodynamics.

PVR cuffs (22 × 12 cm bladder) are placed snugly around the upper arm and forearm, and 100 ± 15 ml of air is injected with the syringe system into the upper cuff to produce a pressure of 65 mm Hg. This procedure is repeated for the forearm.

When the PVR is used to measure pressures, distal monitoring is obtained at the digital level using a digital cuff.

The upper extremity workup is completed by evaluating digital perfusion. This is done by taking PVR recordings at the base and tip of each digit, as well as digital systolic pressures. The larger digital cuff (9 × 3 cm bladder) is placed at the base of the digit and the smaller digital cuff (7 × 2 cm bladder) at the tip. PVR recordings are taken at these locations at a cuff pressure of 40 mm Hg; approximately 5 ml of atmospheric air is injected.

Systolic pressure at the base of the digits may be measured by using the PVR occlusion technique previously described.

EVALUATING VASOSPASTIC DISEASE

It is often important to differentiate digital small vessel disease from vasospastic disease. Vasospasm is character-

Table 59-5. Vascular laboratory criteria for limiting claudication

	Unlikely	Probable	Likely
Postexercise ankle pressure (mm Hg)	>50	>50	>50
Postexercise ankle PVR category	2,3	4	4,5

From Raines JK et al: *Surgery* 79:21, 1976.

Table 59-6. Anatomic localization

	ΔP_s			PVR			Postexercise		Exercise symptoms
	Arm-thigh	Thigh-calf	Calf-ankle	Thigh	Calf	Ankle	P, ankle† (mm Hg)	PVR category	
AI stenosis ODS	Yes	No	No	Abn	Abn	Abn	<50	5 (quick recovery)	Calf, thigh, buttocks
AI occlusion ODS	Yes	No	No	Abn	Abn	Abn	<20	5	Calf, thigh, buttocks
SFA occlusion (low) No AI disease*	No	Yes	Yes	Nor	Abn	Abn	20-50	4	Calf
SFA occlusion (high) No AI disease*	Yes	Yes	Yes	Abn	Abn	Abn	20-50	4	Calf, lower thigh
Combined disease AI + SFA	Yes	Yes	Yes	Abn	Abn	Abn	<10	5	Calf, thigh, buttocks
Tibial vessel disease	No	No	Yes	Nor	Nor	Abn	30-70	4	Foot, ankle, calf
Small vessel disease	No	No	No	Nor	Nor	Nor‡	—	—	—

AI, Aortoiliac; ODS, open distal system; SFA, superficial femoral artery; ΔP_s , systolic pressure difference; Abn, abnormal; Nor, normal; P, systolic pressure.

*No hemodynamically significant AI disease present.

†Values quoted are not absolute and are given as a guide.

‡PVR recordings at transmetatarsal region and/or digits reduced.

ized by loss of reflected wave, blunting, and reduced amplitude in the PVR recordings. When vasospasm first occurs, digital hemodynamics may be abnormal only when the patient is stressed, such as with cold or tension. Therefore such a patient should be studied at room temperature (a constant temperature room is not required) and also after digital immersion in iced water for 2 minutes. If the patient does not have nearly normal digital tip PVR recordings after 5 minutes at room temperature, vasospasm is probable.

In patients with more advanced vasospastic phenomena, abnormal PVR recordings will be present at room temperature at the digit tip level with near normal digital bases. With disease progression, the digit bases show abnormal recordings and systolic pressures.

In the further differentiation of vasospastic disease from occlusive disease and in predicting the effect of dorsal or lumbar sympathectomy, the study of digital perfusion with the PVR before and after nerve block has proved useful. If studies remain unchanged, sympathectomy may be of little help, and occlusive disease is suggested as a prime factor in the process. If perfusion is improved after block, the contribution resulting from vasospasm may be estimated and a basis for continued therapy established. Serial digital PVR studies also serve as a monitor for medical therapy.⁸ The chances of lesion healing are good if pulsatile PVR recordings can be determined at the tip level under normal conditions. This obviously is modified if sepsis is present.

EVALUATING COMPRESSION SYNDROMES

The PVR can be helpful in thoracic outlet syndromes and popliteal artery entrapment.^{3,6} Most researchers believe the pain associated with thoracic outlet syndromes is neurologic, secondary to nerve compression at the lowest trunk of the brachial plexus by a cervical or first rib. Since the subclavian artery and the lower trunk of the brachial plexus are in close proximity, the artery also undergoes compression that may be monitored by the PVR.

The patient is first asked to sit erect off the side of the examining table. A PVR monitoring cuff is placed on the upper arm to be evaluated and is inflated to 65 mm Hg. Recordings are taken in the following positions:

1. Erect, with hands in lap
2. Erect, with arm at a 90-degree angle in the same plane as the torso
3. Erect, with arm at a 120-degree angle in the same plane as the torso
4. Erect, with arm at a 90-degree angle in the same plane as the torso and with shoulders in extended military-type brace
5. Same position as in 4 but with head turned sharply toward the monitored arm
6. Same position as in 4 but with head turned sharply away from the monitored arm

In general, PVR amplitudes increase as the arm is elevated. Arterial compression is present if the PVR amplitude goes flat in any of the standard positions. Since the syndrome

is often bilateral, the other arm should always be studied. It should be noted that many individuals without symptoms (25% is a good estimate) compress arteries supplying the arm in some of the positions outlined. Therefore it is important to base therapy on symptoms, physical findings, history, and ulnar nerve conduction in addition to vascular laboratory data.

Ischemic pain with exercise may occur because of intermittent compression or entrapment of the popliteal artery by the medial head of the gastrocnemius muscle. In such instances the popliteal artery passes medial to or through fibers of the medial head of the gastrocnemius muscle, which may have an anomalous origin on the femur either cephalad or lateral to its normal position on the posterior face of the medial femoral condyle. Regardless of the anatomic or embryologic anomaly, however, the result is an episodic and functional occlusion of the popliteal artery that occurs with each plantar flexion. The significance of early detection and treatment of this abnormality is related to observations that progressive structural changes may occur in the arterial wall as a result of chronic and recurring trauma ultimately resulting in aneurysm formation, thrombosis, and loss of limb vitality. Less than 30 documented cases of the popliteal entrapment syndrome have been noted. Current review suggests that the syndrome may be characterized by (1) history of unilateral intermittent claudication in young men, (2) laboratory findings of diminution of ankle PVR recordings with sustained plantar flexion and/or passive dorsiflexion of the foot, and (3) angiographic findings of medial deviation of the popliteal artery.

In cases of suspected popliteal artery entrapment, it is extremely important to perform a standard lower extremity examination as well as PVR recordings at the ankle with sustained active plantar flexion and with passive dorsiflexion of the foot. Compression during any of these maneuvers is easily recognized.

With regard to entrapment in other clinical situations, the finding of normal PVR recordings in response to acute hip flexion and knee bending has been of help in advising patients who have had extraordinary, makeshift bypass grafts carried out for the treatment of sepsis or related problems. In many of these patients the grafts have been implanted lateral to the inguinal ligament, across the pubis, deep or superficial to muscle bellies and fascial bands, or around bony prominences at the knee. In such patients it is reassuring to know that the graft does not kink or become entrapped in varying limb positions.⁵

EVALUATING VASCULAR MALFORMATIONS

Pulse volume recordings taken on an extremity or digit over an area of suspected vascular malformation are helpful in differentiating the type of malformation and its extent. Doppler velocity detection over areas of suspected vascular malformation is also useful. Table 59-7 is presented as a simple guide.

In venous malformations, arterial hemodynamics are not

Table 59-7. Malformations

Malformation	Local PVR		Doppler abnormal superficial signals
	Amplitude	Reflected wave	
Venous	Normal	Present	Absent
Arteriovenous	Increased	Absent	Present

significantly affected. Therefore venous pressure remains within normal limits, and pulse volume is not increased. In addition, peripheral resistance is normal, and arterial reflected waves recorded by the PVR are present. In arteriovenous malformation the compliant venous conduits undergo abnormal pulsatile pressure transmitted through the malformation from the arterial system, resulting in increased pulse volume. Decreased local peripheral resistance results in loss of reflected wave.

INTRAOPERATIVE MONITORING

The PVR has been used extensively to monitor the results of reconstructive arterial surgery.⁵ It is acknowledged that experienced surgeons performing proximal arterial reconstructions in the presence of patent distal vessels can get a qualitative estimate of the excellence of revascularization by restoration of pedal pulses. However, pulses are not always restored and may be very difficult to appreciate in the operating room. The time to appreciate any operative misadventure is while in the operating room with the vessels exposed and not following a few hours of observation in the recovery room. Intraoperative monitoring is particularly valuable in the teaching setting and provides immediate objective evidence of technical success.

Intraoperative monitoring is essential in patients undergoing proximal arterial reconstruction in the presence of distal occlusive disease. This group of patients includes those with combined aortoiliac and femoropopliteal disease and those with femoropopliteal disease and associated tibial involvement. Absence of definable PVR amplitude in the limb segment immediately distal to the arterial reconstruction has invariably led to a successful search for a cause, whether an anastomotic stenosis, clamp injury, thrombosis, or embolus.

The PVR recording measured immediately following revascularization may be somewhat decreased. This is particularly true if the ankle is monitored following aortoiliac reconstruction in patients with known femoropopliteal occlusive disease. This may reflect several factors, including vasoconstriction, hypotension, and hypovolemia. Therefore with such patients, limb monitoring should be carried out as proximally as possible; the calf is ideal. In no recorded instance has there been a flat trace at the calf if the proximal reconstruction has been adequate. In cases where the pulse amplitude has not returned to more than 50% of its preoperative level, measurement of calf and ankle pressures

has been used to complement the PVR measurements and verify the adequacy of the reconstruction. In patients with patent distal vessels the initial response following clamp removal has been immediate return of the PVR amplitude, usually to normal.

Technical errors during femoropopliteal bypass procedures may account for 6% to 15% of early and 15% to 30% of late failures.⁴ Improperly constructed distal anastomoses with obstruction of the outflow tract, valvular or torsion defects with the vein graft, and distal thrombosis caused by intraoperative emboli are the principal causes of graft failure. Intraoperative arteriography has been suggested as a means of detection of these abnormalities. However, intraoperative arteriography is time-consuming, usually visualizes only one plane, and provides no physiologic information about the graft and distal runoff. In addition, the various angiographic techniques employed may lead to complications in themselves. The PVR provides physiologic information on (1) the distal runoff before insertion of the graft, (2) the condition and function of the distal and proximal anastomoses, and (3) the alignment of the saphenous vein.

Simulated pulse volume as monitored by the PVR has allowed correction of technical errors in the operating room, thus avoiding a repeat procedure. In this technique the PVR is connected to a monitoring cuff placed at the ankle; heparinized saline solution is "pulsed" by hand at the rate of ≈ 5 ml/sec at two stages: (1) through the popliteal arteriotomy by means of a Marx needle and (2) through the upper end of the graft following completion of distal anastomosis. After the proximal anastomosis is complete, the initial pulsatile blood flow propelled by the heart is also monitored. If abnormalities are found at any stage, reasons for hemodynamic defects are investigated.

RECOVERY ROOM MONITORING

Following peripheral arterial reconstruction in the presence of known distal occlusive disease, peripheral pulses may not be easily discernible, particularly in the early postoperative course. In addition, palpable pulses may disappear because of lower extremity edema later in the postoperative course. Noninvasive studies using the PVR have been of considerable value in following patients during this period.⁵ Nursing personnel are able to monitor arterial reconstructions in the recovery area effectively despite the absence of palpable pulses. By detecting failure early, the surgeon is often able to correct problems, thus salvaging the reconstruction.

In practice the recovery room nurses take PVR recordings at set intervals. PVR amplitudes invariably remain stable or increase during the early postoperative period in the presence of a successful reconstruction. Failing PVR amplitudes, often but not always associated with diminution of the ankle/brachial systolic pressure ratio, invariably mean a failing arterial reconstruction in our experience. These findings should prompt early reexploration of the arterial reconstruction.

CONCLUSION

Function is the most important consideration in evaluating lower extremity occlusive arterial disease. Evaluation such as described in this chapter can be done by means of non-invasive hemodynamic studies more precisely than by clinical examination or angiography. The overall functional accuracy of Tables 59-2 through 59-5 is greater than 95% when the clinical course is used as the standard. If disease is confined to a single level, these studies can anatomically localize (Table 59-6) the lesion in virtually 100% of cases. With bilevel disease, accuracy drops into a range of 90% to 95%.

The PVR (venous mode) in combination with its built-in Doppler system can perform lower and upper extremity noninvasive deep venous tree evaluations. This technique produces approximately 5% false-positive and 2% false-negative results.

Because of the flexibility of the transducer system in the PVR, it has been possible to build a simple attachment to the PVR for the measurement of ophthalmic artery pressure (ocular pneumoplethysmography—OPG*).⁷ The attachment is available in both unilateral and bilateral models. This measurement in combination with carotid audiofrequency analysis and cerebral Doppler evaluation has an overall accuracy of 94%.

Newest instrumentation

A small group of vascular laboratory directors, vascular surgeons, electrical engineers, mechanical design engineers, and computer software and hardware engineers combined their skills to produce the automated procedures laboratory (PVR/APL).^{*} The overall system is best described when its two major components are considered.

Measurement unit. The measurement unit (MU) (Fig. 59-4) provides the interface between the operator and the patient. In keeping with basic and validated systems, the MU contains menu-driven automated versions of the PVR, an advanced zero-crossing continuous wave Doppler system (3.5 to 9.2 MHz), a dual-channel OPG (OPG II/500), and a digital carotid phonoangiograph (CPA II). The probes and cuffs are conveniently stored in the MU for use in the vascular laboratory, in the operating room, or at the bedside. The unit has a minimum of buttons and controls, has the same floor space requirement as the current PVR, and is slightly taller. Its mobility also compares favorably.

The operator is prompted by a menu that appears on the cathode-ray tube (CRT) screen. Protocols for all standard vascular laboratory procedures are built in. The operator has control over the various steps in the protocols and may repeat any sequence as desired, such as the data stored (PVR tracings, limb pressures, ophthalmic artery pressures, or carotid phonoangiographic [CBA] data) and cuff inflation/deflation. To perform these functions, the operator uses a controller that fits in the palm of one hand and has one

*Life Sciences, Inc., Greenwich, Conn.

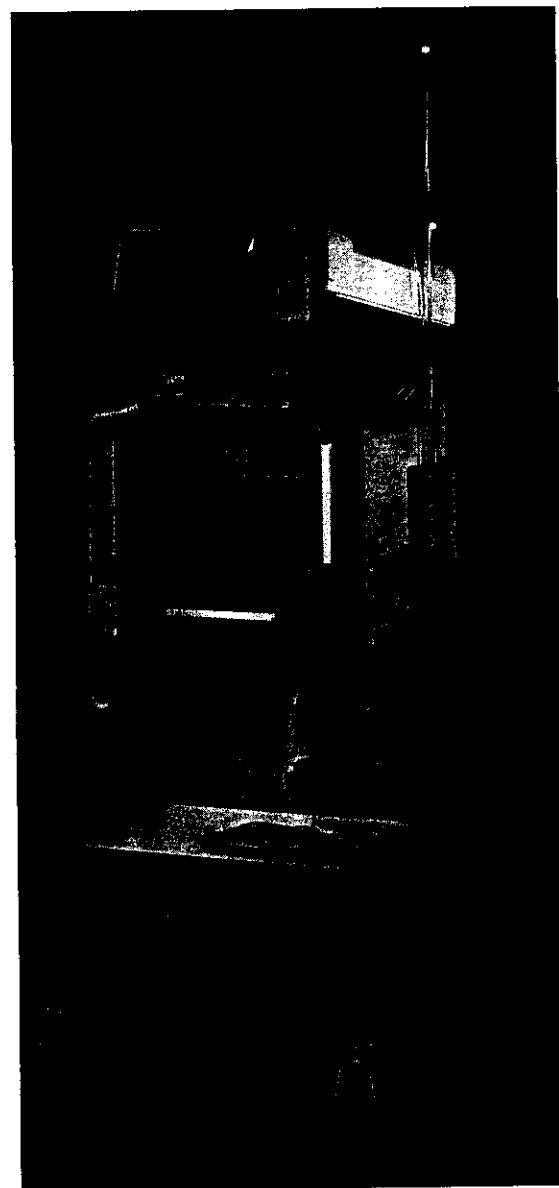


Fig. 59-4. Measurement unit (MU). (From Raines J: Vasc Lab Rev 1:10, 1983.)

button and two rocker switches. Patient data are stored on a floppy disk in the MU. At the completion of the tests the patient disk is removed for use in the analysis unit (AU).

Besides being able to perform the standard lower extremity arterial, extracranial arterial, and lower extremity venous evaluations in combination with the AU, the MU can perform these studies independently. It also has a built-in strip-chart recorder for independent hard copy. Capabilities for digital studies, penile studies, femoral artery studies, lesion healing prediction, and amputation healing predictions are also included.

The MU used with the AU also has a built-in teaching program that outlines step by step all the required procedures. Actual patient data are displayed for immediate comparison by the student.

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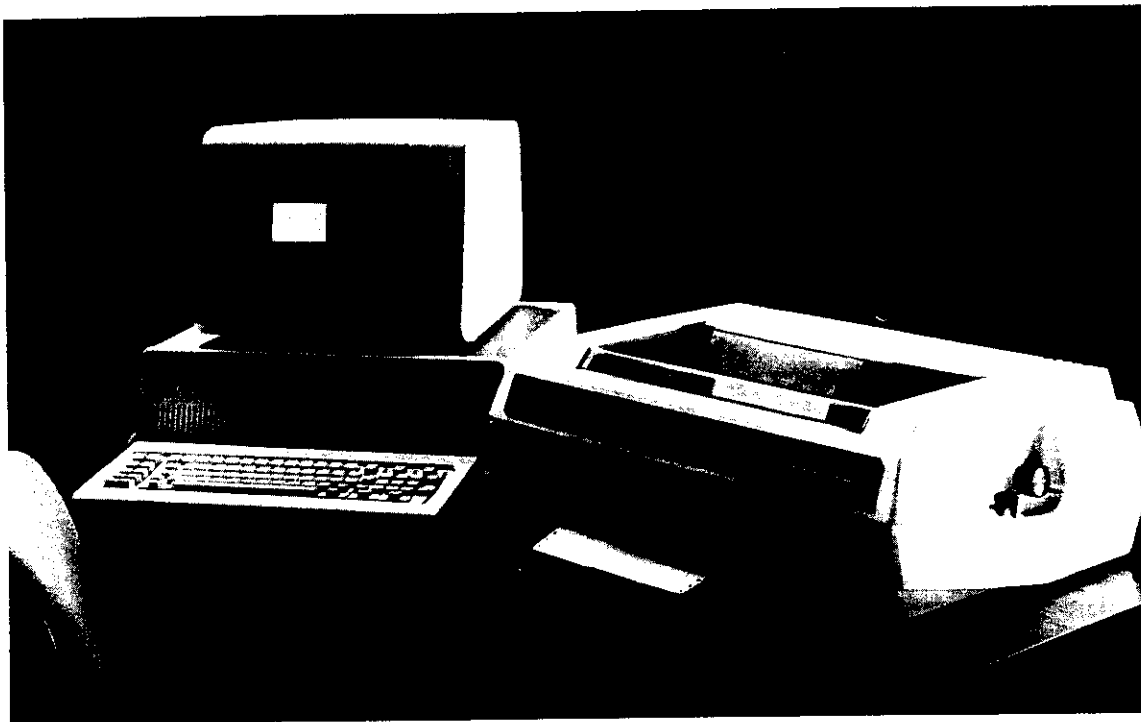


Fig. 59-5. Analysis unit (AU). (From Raines J: *Vasc Lab Rev* 1:10, 1983.)

Analysis unit. The AU (Fig. 59-5) is a combination of the most advanced, supported microcomputer, specifically designed software (an interface that allows the operator to communicate with the computer), and an advanced dot-matrix printer.

Patient data taken from the MU in disk form are displayed by the AU for analysis and final report printings. Reports may be generated after each patient examination or at another convenient time. The patient data are displayed on the CRT, and a menu-driven AU protocol guides the operator in entering the data. Final verification of the data is prepared by the operator with the help of the computer. When the patient data are complete, a quantitative interpretation is presented on the screen. This provides a firm diagnosis based on thousands of cases. The word processing capability of the system allows the operator or laboratory director to alter this interpretation. The operator can then instruct the AU to print the final clinical report. This report includes the history and physical examination information, the data that were measured including all tracings (PVR, OPG, and CPA), interpretation of the data, and a graphic display indicating the anatomic lesions of interest. Patient data are automatically stored on floppy disks in laboratory archives and entered into the peripheral vascular registry, which will be described.

Since the AU is also a powerful computer, a comprehensive office management system has been written for this equipment. The system generates patient logs, has complete office accounting files, includes automated billing, and prints insurance forms. In addition, IBM software for word processing, electronic spread sheet analysis, statistical analysis, and BASIC language is compatible. There are also more than 2000 software packages written for this system by independent programming firms.

Peripheral vascular registry. A peripheral vascular registry is desirable for a number of reasons. The registry can improve patient management by reviewing previous experiences, new certification requirements, regional vascular societies, and surgical/medical results and can generate interest in more automated research. This component has been built into the automated peripheral laboratory. It has been carefully designed to answer the maximum number of potential questions with the minimum of data entry and storage. In addition, most of the data obtained from the vascular laboratory studies are automatically placed in the registry. Extensive sorting, classification, and retrieval routines have been programmed into this system. This allows rapid clinical research on large patient populations. The hard disk in the IBM PC/XT can easily store more than 12,000 registry records for review. Since the registry is completely in soft-

ware form, changes can be made easily at minimal cost. Nine files can be accessed by this registry as follows:

1. Census data, history, and physical findings
2. Lower extremity arterial laboratory data
3. Cerebral laboratory data
4. Lower extremity venous data
5. Lower extremity arteriography
6. Cerebral arteriography
7. Lower extremity venography
8. Compact surgical record
9. Complete follow-up record

The peripheral vascular registry allows the maximal use of measured noninvasive data in temporal management of patients, as well as in clinical research and natural history studies.

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Norton Cheryl

From: Norton Cheryl
Sent: Wednesday, August 04, 2004 4:17 PM
To: 'wrogers@biomedix.com'
Cc: 'rmagnuson@biomedix.com'
Subject: PADnet Lab 510(k)

Hello Will,

I spoke again with my contact at FDA (Dr. Charles Ho from the FDA Division of Cardiovascular Devices) regarding your submission. In order to determine whether this device is eligible for Third Party review, he asked me to send (in writing via e-mail) a detailed description regarding the pneumoplethysmograph measurement (he still doesn't understand it after my verbal explanation). I am able to scan part of your 510(k) and send it to him if you could advise me where the best description is located. Also, Dr. Ho would like you to identify a predicate device from the Cardiovascular branch (not Radiology branch).

Regards,

Cheryl Norton

Lead NB Auditor/ Compliance Engineer/ Third Party 510(k) Reviewer

TUV America Inc.
Product Service
P: 651-638-0294
F: 651-638-0295



COMMUNICATION LOG FOR CHERYL NORTON

CONTACT:	<u>Dr. Charles Ho</u>	COMPANY:	<u>FDA</u>
TEL. NO.:	<u>301-443-8517, x179</u>	FAX NO.:	<u>N/A</u>
DATE:	<u>August 4, 2004</u>	TIME:	<u>4 p.m.</u>
SUBJECT:	<u>510(k) Notification for PADnet Lab</u>		

NOTES:

Cheryl called Charles to communicate additional information about the Biomedix device. She explained the two measurement modalities: pneumoplethysmograph and segmental pressure.

Charles stated that segmental pressure is "ordinary" but he still doesn't understand the pneumoplethysmograph measurement. Charles asked if Cheryl could forward a more detailed description from the manufacturer to him via e-mail. He also asked for a predicate device from the cardiovascular branch.

Cheryl agreed to send more information.

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891



COMMUNICATION LOG FOR CHERYL NORTON

CONTACT:	<u>Will Rogers</u>	COMPANY:	<u>FDA</u>
TEL. NO.:	<u>651-762-4010</u>	FAX NO.:	<u>N/A</u>
DATE:	<u>August 4, 2004</u>	TIME:	<u>3:30 p.m.</u>
SUBJECT:	<u>510(k) Notification for PADnet Lab</u>		

NOTES:

Cheryl called Will to gather more information about the device in order to communicate with FDA regarding whether the device can be accepted for Third Party review.

Cheryl asked Will to explain the theory of operation of the device. Will explained that the device has 2 measurement modalities and both use "old" (25+ year) technology.

- 1) Pneumoplethysmography (blood volume change with each cardiac cycle)
- 2) Segmental pressure (blood pressure using cuffs, technique similar to oscillometric)

Cheryl asked if only the pressure cuff is needed to make the measurements? Will said yes. Cheryl asked if the software algorithms are new or unique? Will said no.

Cheryl stated that a diagnosis claim may require clinical studies. Will responded that the doctor takes the data and makes a diagnosis but the device only provides raw data. Cheryl asked about the stenosis reference scale in the Operators Manual. Will explained that these are guidelines to determine the validity of the data.

Cheryl also made Will aware that FDA would need to discuss the submission with the Radiology branch due to the predicate device. Will explained that the predicate had Doppler.

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891



COMMUNICATION LOG FOR CHERYL NORTON

CONTACT:	<u>Dr. Charles Ho</u>	COMPANY:	<u>FDA</u>
TEL. NO.:	<u>301-443-8517, x179</u>	FAX NO.:	<u>N/A</u>
DATE:	<u>August 4, 2004</u>	TIME:	<u>2 p.m.</u>
SUBJECT:	<u>510(k) Notification for PADnet Lab</u>		

NOTES:

Charles called Cheryl in response to her e-mail with a 4 page description of the device operation. Charles stated that this information does not answer his question because he considers it general "public knowledge" information only. This description is just the normal response of a NIBP cuff.

Cheryl asked if the software algorithm was needed? Charles said yes he needs to understand how data is converted into blood flow volume with only a pressure cuff measurement. What other patient parameters are input? Cheryl asked if this information was needed in order to determine if Third Party review was possible and if clinical data might be needed? Charles said yes.

Charles verified with Cheryl that the predicate device is K973644 which was not cleared by the Cardiology branch. Cheryl stated this is correct; the predicate device was a "combination" device cleared by the Radiology branch. Charles stated that he would also need to talk to someone in the FDA division of radiology.

Charles asked what is claimed by the device? Cheryl read the Intended Use statement from the 510(k). Charles replied that if Biomedix is claiming to assist detection of disease then a clinical study is normally required to support a diagnosis claim.

Cheryl promised, again, to obtain further information from Biomedix regarding the theory of operation of the device.

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891



COMMUNICATION LOG FOR CHERYL NORTON

CONTACT:	<u>Dr. Charles Ho</u>	COMPANY:	<u>FDA</u>
TEL. NO.:	<u>301-443-8517, x179</u>	FAX NO.:	<u>N/A</u>
DATE:	<u>August 4, 2004</u>	TIME:	<u>12:15 p.m.</u>
SUBJECT:	<u>510(k) Notification for PADnet Lab</u>		

NOTES:

Charles called Cheryl in response to her e-mail and phone message to the Branch Chief, Elias Mallis. Charles asked for more information about the new device. How does it measure blood flow with only a pressure cuff? Cheryl read some information from the file:

- plethysmograph, blood flow monitor
- non-invasive device used to gauge the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures
- arm, ankle and digit

Charles asked how does the device control flow velocity and convert to volume? Different patients have different artery sizes so how is this accounted for? Cheryl said that according to the Operators Manual the patient's height and weight is entered.

Charles stated that based on his experience, this will not be an easy file to review since the theory is not "clear cut".

Charles gave Cheryl his direct phone number (301-443-8517, x179) and promised to also send an e-mail with his contact information. Cheryl stated that she would need to obtain further information from Biomedix in order to answer FDA questions.

TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Norton Cheryl

From: Norton Cheryl
Sent: Friday, July 30, 2004 9:28 AM
To: 'rmagnuson@biomedix.com'; 'wrogers@biomedix.com'
Subject: PADnet Lab 510(k)

Richard and Will,

I did receive your 510(k) on July 27. I believe the submission meets the Acceptance Checklist however before I can officially accept your 510(k) for review, I am required to speak to the applicable FDA Branch Chief. This is required for all Third Party reviews that are part of the pilot program where no guidance document is available. The appropriate Branch Chief is out of the office until Monday so I will try calling him again on Monday. I expect to send you a letter next week accepting the 510(k) for review.

Best Regards,

Cheryl Norton

Lead NB Auditor/ Compliance Engineer/ Third Party 510(k) Reviewer

TUV America Inc.

Product Service

P: 651-638-0294

F: 651-638-0295

RECEIVED
JUL 27 2004

July 26, 2004

TUV America
1775 Old Highway 8 NW
Suite 104
New Brighton, MN 55112-1891

Attention: Cheryl Norton

Re: Pre-market Notification for PADnet Labs

Cheryl,

The enclosed pre-market notification provides information to support the findings of the substantial equivalence of BioMedix's PADnet Lab. The information provided with this submission is in conformance to 21 CFR 807.87 and in accordance with the Safe Medical Devices Act (SMDA) of 1990.

In response to the requirements of 21 CFR Part 807, I am enclosing a 510(k) Summary of Safety and Effectiveness which can be found both behind the front cover and in Appendix Section 24. Also included is the Manufacturer's Authorization Letter required for 501(k) 3rd party review.

Sincerely,



Will Rogers
VP Customer Service/CTO

Enclosures: Three Copies of Complete Submission Information

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Manufacturer's Authorization Letter



Date:

TÜV Product Service
1775 Old Highway 8 NW
New Brighton, MN 55112-1891

RE: Authorization for Third Party Review

To Whom It May Concern:

Enclosed is the Premarket Notification 510(k) for the following product
PADnet Lab manufactured by BioMedix, Inc.

We at BioMedix, Inc. (name of manufacturer) hereby
authorize TÜV Product Service to submit the enclosed 510(k) to the Food
and Drug Administration (FDA) on our behalf, discuss its contents with
the FDA, and function as the Third Party Reviewer.

We certify that we have not contacted another Third Party Reviewer to
perform the review of this 510(k) submission.

Sincerely,

A handwritten signature in black ink, appearing to read 'Richard C. Magnuson'.

Officer of the Manufacturer
Name and Title

Richard C. Magnuson
CFO

TÜV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891
Telephone: 651 604 3381

Form: FDA_F_09.07L, Revision 2
Author: Mark Job
Developed: 10. May, 1996 / Released: 30. September, 1996
Page 1 of 1

File: FDA_F_09.07L, Revision 2, Effective November 1, 2001

510(K) Summary of Safety and Effectiveness

General Information

Submitter's Name: BioMedix, Inc.
Address: 4205 White Bear Parkway
St. Paul, MN 55110
Telephone: 651-762-4010
Contact Person: Will Rogers or Dick Magnuson
Date Prepared: July 23, 2004
Registration Number: 2134492

Device

Name: PADnet Lab
Trade Name: PADnet Lab
Common Name: Plethysmograph
Classification Name: Blood Flow Monitor
Product Code: JOM
Class: II
Regulation Number: 870.2780

Identification of Legally Marketed Devices

Name: Flostat Vascular Lab

K Number: K973644

Date Cleared: December 23, 1997

Description of the Device

The BioMedix PADnet Lab is a non invasive cardiovascular blood flow monitor. It is intended for use in the early detection of peripheral vascular disease. The PADnet Lab has been tested to the following standards.

- EN60601-1 Electrical Safety
- EN60601-1-2 EMC
- ISO 10993-1 Biological evaluation

The BioMedix PADnet Lab is a non invasive cardiovascular blood flow monitor. It is intended for use by trained medical professionals in a hospital or clinic. It is not to be operated in an explosive atmosphere nor in the proximity to any equipment that has the potential to generate a sufficiently large electromagnetic field as to interfere in any manner with the operation of the PADnet Lab.

The BioMedix PADnet Lab is a Prescription Device, **not** life supporting or life sustaining, not an implant, supplied **non-sterile** with pressure cuffs. It requires a Personal Computer with the following requirements:

- Windows 2000 Operating System or higher
- 128 MB RAM
- 20 GB Free Hard Disk Space
- 600 MHz Processor or higher

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Intended Use Statement

The BioMedix PADnet Lab is a non invasive device used to gauge the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures to assist in the identification of vascular disease. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

Components/ Part Numbers

Description	BioMedix Part Number
1- USB cable	100-1600
1- Cuff kit	7200
BioMedix PADnet Lab Software Program CD ROM	400-210
1-AC Power Cord	350-215
1- PADnet Lab Operators Manual	10650

Table of Comparisons

The following summary table of comparisons compares the new device (PADnet Lab) to the predicate device: Flowstat Vascular Lab.

#	Area	New Device: PADnet Lab	Predicate Device: Flowstat Vascular Lab	Same	Different
1	Pulse Volume Recording	Plethysmograph	Plethysmograph	X	
2	Segmental Pressure flow sensor	Oscillometric	Distal Flow Sensor		X
3	Patient Population	Male/Female Adult	Male/Female Adult	X	
4	Environment	Hospital or Clinic	Hospital or Clinic	X	
5	Power Source	AC converted to DC	AC converted to DC	X	
6	Weight	4 lbs.	26 lbs.		X
7	Data acquisition	Single site	Bilateral		X
8	Software Controls	Operator initiated	Operator initiated	X	
9	Size	12 1/2" W X 10" D X 3 " H	20 1/2" W X 17 3/4 " D X 7" H		X
10	Cuff Deflation Rate	3-5 mm Hg/Sec	3-5 mm Hg/Sec	X	

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11	Operating Environment	0 to +40°C 15 - 90%	0 to +40°C 15 - 90%	X	
12	Storage Environment	-40 to +50° C 5-95%	-40 to +50° C 5-95%	X	
13	Safety Standards	Yes	Yes	X	
14	EMC	Yes	Yes	X	
15	Prescription Device	Yes	Yes	X	
16	Cuff Bladder Deflation	Automatic	Automatic	X	
17	Inflation Method	Automatic	Automatic	X	
18	Cuff Sizes	Multiple	Multiple	X	
19	Clinical Reports	Yes	Yes	X	
20	Printed Reports	Yes	Yes	X	
21	Supplied Non-Sterile	Yes	Yes	X	

Discussion of Similarities and Differences

The PADnet Lab and the Flowstat Lab have the following similarities:

- Pulse Volume Recording
- Patient Population
- Environment
- Power Source
- Software Controls
- Cuff Deflation Rate
- Operating Environment
- Storage Environment
- Safety Standards
- EMC
- Prescription Device
- Cuff Bladder Deflation
- Inflation Method
- Cuff Sizes
- Clinical Reports
- Printed Reports
- Supplied Non-Sterile

The differences, with comments, are the following:

- Segmental Pressure flow sensor – The PADnet Lab uses Oscillometric not distal flow sensor.
- Weight – PADnet Lab is significantly less.
- Data acquisition – PADnet Lab is single site not bilateral.
- Size – PADnet Lab is significantly smaller.

Thus, even though the PADnet Lab is not identical to the Flowstat Vascular Lab, we at BioMedix believe it should be granted substantial equivalence because:

- It has the same intended use as the predicate device.
- It has the same technical characteristics as the predicate device and does not raise any new types of safety or effectiveness concerns.

CONFIDENTIAL

PREMARKET NOTIFICATION

FOR

**BIOMEDIX'S
PADnet Lab**

FOR REVIEW BY

**Circulatory support and Prosthetics Devices Branch
Within**

Division of Cardiovascular and Respiratory Devices (DCRD)

By

**William Rogers
Vice President Customer Service / Chief Technology Officer
BioMedix, Inc.**

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I. Administrative

A. Application Date: 27 July, 2004

B. Name/Address of Manufacturer/Applicant

BioMedix, Inc.
4205 White Bear Parkway
St. Paul, MN 55110
Phone - 651-762-4010
Fax - 651-762-4014

C. Contact Person

William Rogers, VP Customer Service / Chief Technology Officer
E-mail - wrogers@biomedix.com
651-762-4010

Or

Dick Magnuson, CFO
E-mail - dmagnuson@biomedix.com
651-762-4010

D. FDA Registration Number

FDA Registration Number - 2134492
Owner / Operator Number - 9032550

E. Sterilization Site Statement

Not Applicable; PADnet Lab is supplied non-sterile

F. Packaging Facilities

The PADnet Lab is manufactured, assembled and packaged at BioMedix, Inc. facilities or contract manufacturer. The address is the same as company address.

II. Device ID

A. Product Information

Proprietary Name - BioMedix PADnet Lab
Common Name - Blood Flow Monitor - Plethysmograph
Classification - Cardiovascular Blood Flowmeter
Class - Class II (two)
Panel Code - JOM
Regulation Number - 870.2100

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Model – Series 1

B. Miscellaneous

Previously Submitted: The BioMedix PADnet Lab has not been previously submitted to the Food and Drug Administration (FDA). This is a new Premarket Notification [510(K)].

Under Review: This submission is not being reviewed by DCRD or any other branch within ODE.

Previously Cleared: This submission has not been previously cleared for different indications.

III. Device Description

A. Intended Use

The BioMedix PADnet Lab is a non invasive device used to gauge the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures to assist in the identification of vascular disease. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

B. Written Description

A. Written Description – The BioMedix PADnet Lab is a non invasive cardiovascular blood flow monitor. It is intended for use in the early detection of peripheral vascular disease. The PADnet Lab has been tested to the following standards.

- EN60601-1 Electrical Safety
- EN60601-1-2 EMC
- ISO 10993-1 Biological evaluation

User Profile:

Patient Population: Male/Female, Adults

Environment of Use: Hospitals or Clinics

The BioMedix PADnet Laboratory Product Specification can be found in section 1 to assist the reviewer(s) in understanding the system.

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C. Schematics

The schematic drawings show a detailed layout of the DTU (Diagnostic Test Unit) electric, electronic, and pneumatic organization. Schematics can be found in section 2A.

D. Block Diagram

The block diagram shows the logical layout of PADnet Lab DTU. This includes power, motor, pneumatic, and electronic items with their respective connectors. Please see Section 2B for details. The Block Diagram can be found in section 2B.

E. Drawings

The schematic drawings show a detailed layout of the DTU electric, electronic, and pneumatic organization. The Drawing can be found in section 2C.

F. Photographs

Section 2D contains photos of the front, back and sides of the device as well as all cuffs.

G. Special Controls/ Performance Standards

- EN 60601-1 Electrical Safety
- EN 60601-1-2 EMC
- ISO 10993-1 Biological Evaluation
- EN 980 Symbols
- ISO 13485:1996/1998 Medical Devices
- ISO 9001:2000 Quality Systems Standard
- 93/42/EEC- Medical Device Directive
- 21 CFR Part 801 Labeling
- 21 CFR Part 820 Quality System Regulation
- ISO 14971 Risk Analysis
- EN 1441 Risk Analysis

The BioMedix PADnet Lab conforms with all of the above standards and controls. The Blood Pressure Cuffs used with the BioMedix PADnet Labs do not require 510(k) clearance as they are considered a pre-amendment device. Section 3 contains copies of the manufacturer's certification of its pre-amendment status and CE Certificates.

H. BP Algorithm

The BioMedix PADnet Lab uses the well known "Oscillometric" Blood Pressure Algorithm to estimate the required systolic segmental pressure values for the arm, ankle and digit. Additional details describing the use of these oscillometric pressure values as compared to a predicate device can be found in section 4.

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I. Interaction with Patient

The product is intended for use by trained medical personnel. The results are for the physician's use only.

The user manual in section 6E describes the software installation, connection of the segmental cuffs to the device, choosing the correct cuff, placing the cuff, the user interface, conducting a test, prompts/warnings/errors and troubleshooting, calibration, cleaning, care/maintenance, specifications, warranty and service.

IV. Materials

A. Specific Materials

(b) (4)

A large rectangular area of the document has been redacted with a solid grey box. The redaction covers several lines of text under the 'Specific Materials' section.

B. Biocompatibility

Section 5 contains applicable biocompatibility information for the specific materials coming in contact with the patient (segmental cuffs). This information has been deemed adequate by BioMedix, Inc.

V. Labeling

A. Box Label

Section 6A contains an example of this Label.

B. Product Labels

Section 6B contains an example of this Label.

C. CD-ROM Label

Section 6C contains an example of this Label.

D. Promotional Literature

Section 6D contains an example of all promotional literature.

E. Prescription Device

Section 6E page 2 of the draft operator's manual contains a copy of the prescription statement.

F. Symbols

Section 6E page 2 of the draft operator's manual contains examples of all symbols used on this device.

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G. Draft Users Manual

Section 6E contains a copy of the draft operator's manual.

H. Predicate User Manual

Section 6F contains a copy of the Flowstat Vascular Lab User Manual

I. Predicate Marketing Literature

Section 6G contains a copy of the Flowstat Vascular Lab Marketing Literature.

VI. Testing

A. Electrical Safety

Section 9 contains a copy of the 60601-1 Safety Testing

B. Emissions

Section 7 contains a copy of the 60601-1-2 EMC Emissions

C. Immunity

Section 8 contains a copy of the 60601-1-2 EMC Immunity

D. Device Life

The device life shall be a minimum of 100,000 cycles. Section 9 contains a copy of the IEC601-1 Test Report. Please see page 22, of the referenced report.

E. Clinical Study

The clinical data is not required to support substantial equivalence to the predicate device.

VII. Software Information

A. Software Version

PADnet DTU Firmware: (b) (4)

PADnet Test Software: (b) (4)

B. Level of Concern

PADnet is a testing device used in series with other methods of testing to detect cardiovascular disease by collecting blood flow ratios on bodily extremities.

PADnet is a lower than moderate level of concern for the following reasons. It does not control life supporting or life sustaining functions, it does not deliver potential harmful energy, and it does not control treatment delivery.

A series of external misdiagnosed tests along with possible PADnet software failure may result in serious injury through the failure to detect need of treatment. Also failure of safety overrides on patient cuff inflation may result in injury and classifies this device to be of moderate concern.

The Following flow chart depicts Level of Concern:

(b) (4)



C. Software / Hardware Description

PADnet is a patient vascular acquisition system divided into two major components, one being a hardware component used to pneumatically gather blood pressure data and other PC software used to store and display information acquired.

PADnet Lab consists of the PADnet Test Lab computer application and the firmware controlled PADnet DTU (Diagnostic Test Unit). PADnet Lab Test provides a user interface to step the user through the process of gathering patient information in an office visit. PADnet Test controls PADnet DTU hardware.

Section 10 contains PADnet Lab Hardware Requirements Specification, Revision (b) 06/08/04

Section 11 contains PADnet Lab DTU Requirements Specification, Revision (b) 06/30/04

Section 12 contains PADnet Test Requirements Specification, Revision (b) 06/30/04

D. Hazard Analysis

Hazards are documented in an external hazards analysis document in accordance with BioMedix Hazard Analysis procedure DP04-04. That document takes into account all device hazards associated with the product's intended use, hardware and software. The document addresses: hazardous event, level of concern of the hazard, cause(s) of hazard, method of control, and corrective measures taken. The current version of the document is “

Section 13A contains PADnet Lab Preliminary Hazard Analysis”, v (b) dated 7/8/2004,

Section 13B also contains PADnet Lab DTU FMEA Analysis”, v (b) dated 05/25/2004.

Section 14 contains the BioMedix Hazard Analysis procedure DP04-04

E. Software Requirements Specifications

The requirements are documented in external requirements documents. The titles of the documents are “PADnet Test Requirements Specification” and “DTU Requirements Specification”. The documents list both functional (general, and by kind of user) and non-functional (general, security, and performance) requirements. In addition, the DTU (Diagnostic Test Unit) firmware requirements are described in the DTU Requirements Specification.

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Section 11 contains PADnet Lab DTU Requirements Specification, Revision [REDACTED], 06/30/04

Section 12 contains PADnet Test Requirements Specification, Revision [REDACTED], 06/30/04

F. Architecture Design Chart and Software Design

The architecture and software design are documented in an external design documents. The documents are composed of an architectural design section, a component design section, a design use-case section, and a requirements mapping section. The architecture section contains a conceptual model (including a diagram), design patterns, an analysis model, an application architecture (including a diagram), and a components description section. The component design contains component descriptions and component interfaces. The use case section contains use-cases for both normal and expected-error event sequences. The requirements mapping section maps the use-cases in the document to the list of requirements in the requirements document.

Section 15 contains PADNet Test Design Specification, Revision [REDACTED], 07/01/04

Section 16 contains PADNet DTU Firmware Design Specification, Revision [REDACTED], 07/01/04

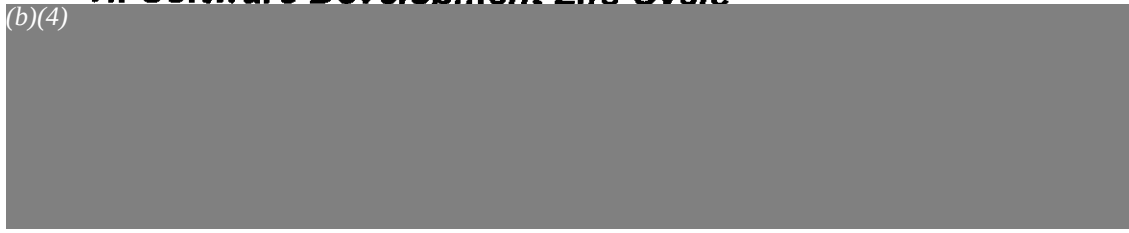
G. Trace-ability Analysis

The requirements are linked to the design and code in the "PADNet Test Design Specification" document. The requirements and use cases are linked to the testing in the "PADNet Test Validation Plan" document. The hazards are described and linked to the software in the "PADNet Hazards Description". The hazards document is currently being prepared according to the DP04-04 document template. Determining where a particular item is tested, and the status of the test can be found by reviewing the validation document. Determining if a particular hazard has been identified, and where and how it is removed or mitigated can be found by reviewing the hazards document.

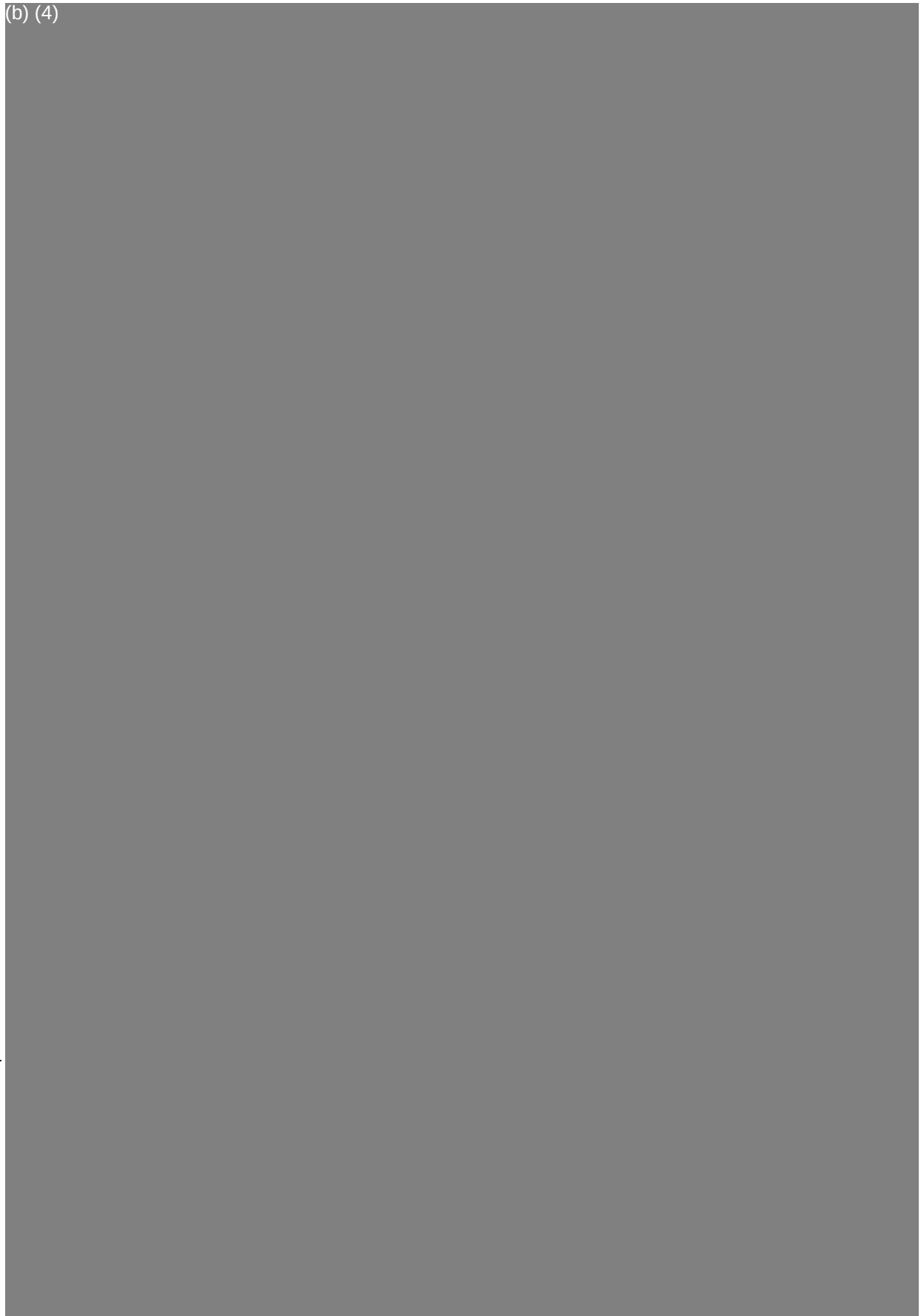
Section 17 contains the BioMedix PADnet Lab Trace-ability Analysis, Revision [REDACTED] and dated 07/08/04

H. Software Development Life Cycle

(b)(4)



(b) (4)



I. Hardware / Software Verification/Validation

(b) (4)



J. Revision History

(b) (4)



K. Certificate of Known Bugs

A “Certificate of Known Bugs” will be prepared and made available. This will be all unresolved software anomalies. For each anomaly, it will indicate the problem, the impact on device correctness and/or performance and, if communicated to the user in labeling, how that labeling will be performed. This list will be prepared from the issue tracking database using the Eventum tool described above.

Section 22 contains BIOMEDIX PADnet Lab Certificate of Known Defects
Version (b) (4)

L. OTS Software

(b) (4)



VIII. Comparative Performance Evaluations and Clinical Performance Evaluations/Data

A. Comparative Performance Evaluations

A comparative performance evaluation for the PADnet Lab and Flostat Vascular Lab can be found in appendix section 4.

B. Clinical Performance Evaluations/Data

Clinical data is not required to support substantial equivalence for the PADnet Lab.

IX. Substantial Equivalence Information

A. 510(k) of Predicate

The legally marketed predicate for the PADnet Lab is the BioMedix Flostat Vascular Lab (K973644). Appendix 4 contains information on the BioMedix Flostat Vascular Lab, the Legally Marketed Predicate.

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B. Summary Table of Comparisons

The following summary table of comparisons compares the new device (PADnet Lab) to the predicate device: Flowstat Vascular Lab.

#	Area	New Device: PADnet Lab	Predicate Device: Flowstat Vascular Lab	Same	Different
1	Pulse Volume Recording	Plethysmograph	Plethysmograph	X	
2	Segmental Pressure flow sensor	Oscillometric	Distal Flow Sensor		X
3	Patient Population	Male/Female Adult	Male/Female Adult	X	
4	Environment	Hospital or Clinic	Hospital or Clinic	X	
5	Power Source	AC converted to DC	AC converted to DC	X	
6	Weight	4 lbs.	26 lbs.		X
7	Data acquisition	Single site	Bilateral		X
8	Software Controls	Operator initiated	Operator initiated	X	
9	Size	12 1/2" W X 10" D X 3 " H	20 1/2" W X 17 3/4 " D X 7" H		X
10	Cuff Deflation Rate	3-5 mm Hg/Sec	3-5 mm Hg/Sec	X	
11	Operating Environment	0 to +40°C 15 - 90%	0 to +40°C 15 - 90%	X	
12	Storage Environment	-40 to +50° C 5-95%	-40 to +50° C 5-95%	X	
13	Safety Standards	Yes	Yes	X	
14	EMC	Yes	Yes	X	
15	Prescription Device	Yes	Yes	X	
16	Cuff Bladder Deflation	Automatic	Automatic	X	
17	Inflation Method	Automatic	Automatic	X	
18	Cuff Sizes	Multiple	Multiple	X	
19	Clinical Reports	Yes	Yes	X	
20	Printed Reports	Yes	Yes	X	
21	Supplied Non-Sterile	Yes	Yes	X	

C. Discussion of Similarities/Differences

The PADnet Lab and the Flowstat Lab have the following similarities:

- Pulse Volume Recording
- Patient Population
- Environment
- Power Source
- Software Controls
- Cuff Deflation Rate
- Operating Environment
- Storage Environment
- Safety Standards
- EMC
- Prescription Device
- Cuff Bladder Deflation

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- Inflation Method
- Cuff Sizes
- Clinical Reports
- Printed Reports
- Supplied Non-Sterile

The differences, with comments, are the following:

- Segmental Pressure flow sensor – The PADnet Lab uses Oscillometric not distal flow sensor.
- Weight – PADnet Lab is significantly less.
- Data acquisition – PADnet Lab is single site not bilateral.
- Size – PADnet Lab is significantly smaller.

Thus, even though the PADnet Lab is not identical to the Flowstat Vascular Lab, we at BioMedix believe it should be granted substantial equivalence because:

- It has the same intended use as the predicate device.
- It has the same technical characteristics as the predicate device and does not raise any new types of safety or effectiveness concerns.

X. 510(k) Summary / Statement

A. 510(k) Summary

A 510 (k) Summary in conformance with 21 CFR Part 807.92 is located in Section 24 and behind the front cover.

B. 510(k) Statement

A 510 (k) Statement is not necessary, as a 510 (k) Summary is included.

XI. Miscellaneous

A. Indications for Use Form

An Indication for Use Form is included as Section 25.

B. Truthful/Accurate Statement

A Truthful / Accurate Statement can be found in Section 26.

C. Financial Certification

A Form 3454 is not required as a “covered” clinical study was not required or conducted on the PADnet Lab to demonstrate substantial equivalence.

D. Financial Disclosure

A Form 3455 is not required as there was no clinical investigation required demonstrate substantial equivalence

E. Class III Certification

Blood Flowmeters are Class II devices, not Class III. Therefore, Class III Certification is not required.

F. Kit Certification Statement

The BioMedix PADnet Lab does not come as a kit; therefore kit certification is not required.

G. 510 (k) Decision Making Chart

Section 27 contains a 510 (k) Decision Making Chart with the path BioMedix believes the PADnet Lab has taken to be determined "substantially equivalent."

XII. Appendices

Section 1:	BioMedix PADnet Laboratory Product Specification.
Section 2A:	Schematics
Section 2B:	Block Diagram
Section 2C:	Drawings
Section 2D:	Photographs
Section 3:	Cuff Manufacturer's certification of its pre-amendment status and CE Section
Section 4:	Comparative performance evaluation to a predicate device
Section 5:	Biocompatibility
Section 6:	Labeling
Section 7:	Emissions
Section 8:	Immunity
Section 9:	Test Report IEC 60601-1
Section 10:	PADnet Lab Hardware Requirements Specification
Section 11:	PADnet Lab DTU Requirements Specification
Section 12:	PADNet Test Requirements Specification
Section 13:	PADNet Lab Preliminary Hazard Analysis / DTU FMEA Analysis
Section 14:	BioMedix Hazard Analysis procedure (b)(4)
Section 15:	PADNet Test Design Specification
Section 16:	PADNet DTU Firmware Design Specification
Section 17:	BioMedix PADnet Lab Trace-ability Analysis
Section 18:	PADNet Test Validation Plan and Test Results
Section 19:	PADnet DTU Firmware Validation Plan and Test Results
Section 20:	PADnet Lab Hardware Design Verification and Test Results
Section 21:	PADNet Lab Revision History
Section 22:	BIOMEDIX PADnet Lab Certificate of Known Defects
Section 23:	OTS Software
Section 24:	510K Summary
Section 25:	Indications for use
Section 26:	Truth/Accurate Statement
Section 27:	Decision Making Chart

BioMedix PADnet Laboratory Product Specification

Schematics / Block Diagrams / Drawings / Photographs

Cuff Manufacturer's Certification/Pre-Amendment Status / CE

Comparative Performance Evaluation to predicate device

Biocompatibility

Labeling

Emissions

Immunity

Test Report IEC 601-1

PADnet Lab Hardware Requirements Specification

PADnet Lab DTU Requirements Specifications

PADnet Test Requirements Specification

PADNetLab Preliminary Hazard and DTU FMEA Analysis

BioMedix Hazard Analysis Procedure DP04-04

PADNet Test Design Specification

PADNet DTU Firmware Design Specification

BioMedix PADnet Lab Trace-Ability Analysis

PADNet Test Validation Plan and Test Results

PADnet DTU Firmware Validation Plan and Test Results

PADnet Lab Hardware Design Verification and Test Results

PADnet Lab Revision History

BIOMEDIX PADnetLab Certificate of Known Defects

OTS Software

510K Summary

Indications for use

Truth/Accurate Statement

Decision Making Chart

K04/2616 VOL II

Table of Contents

1	BioMedix PADnet Laboratory Product Specification
2	Schematics / Block Diagrams / Drawings / Photogaphs
3	Cuff Manufacturer's Certification/Pre-Amendment Status / CE
4	Comparative Performance Evaluation to predicate device
5	Biocompatibility
6	Labeling
7	Emissions
8	Immunity
9	Test Report IEC 601-1
10	PADnet Lab Hardware Requirements Specification
11	PADnet Lab DTU Requirements Specifications
12	PADnet Test Requirements Specification
13	PADNetLab Preliminary Hazard and DTU FMEA Analysis
14	BioMedix Hazard Analysis Procedure DP04-04
15	PADNet Test Design Specification
16	PADNet DTU Firmware Design Specification
17	BioMedix PADnet Lab Trace-Ability Analysis
18	PADNet Test Validation Plan and Test Results
19	PADnet DTU Firmware Validation Plan and Test Results
20	PADnet Lab Hardware Design Verification and Test Results
21	PADnet Lab Revision History
22	BIOMEDIX PADnetLab Certificate of Known Defects
23	OTS Software
24	510K Summary
25	Indications for use
26	Truth/Accurate Statement
27	Decision Making Chart
28	
29	
30	
31	

RECEIVED
2004 SEP 23 PM 15
FDA/CDRH/OCE/PMO

PADNet Product Specification

Date 2004-February 26

Version (b) (4)

Author Will Rogers

1.0 Product Description

(b)(4)



2.0 Intended Use

(b)(4)



3.0 Market

(b)(4)



(b)(4)



5.0 Standards

(b)(4)



6.0 PADnet Lab Software Requirements

(b)(4)



PADnet Lab Hardware requirements

(b)(4)



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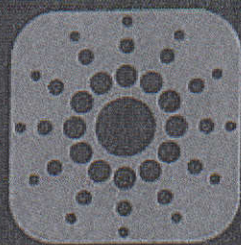
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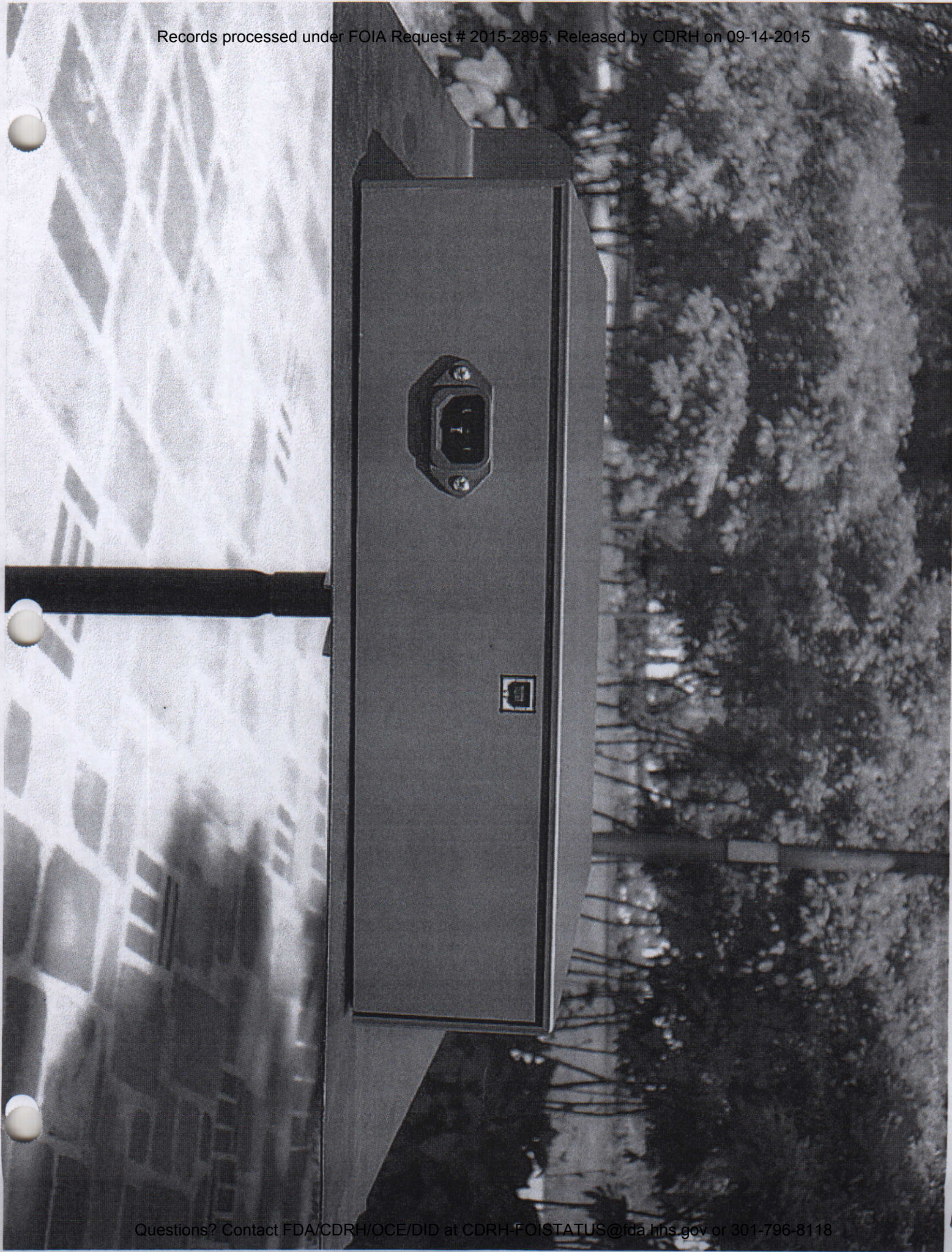
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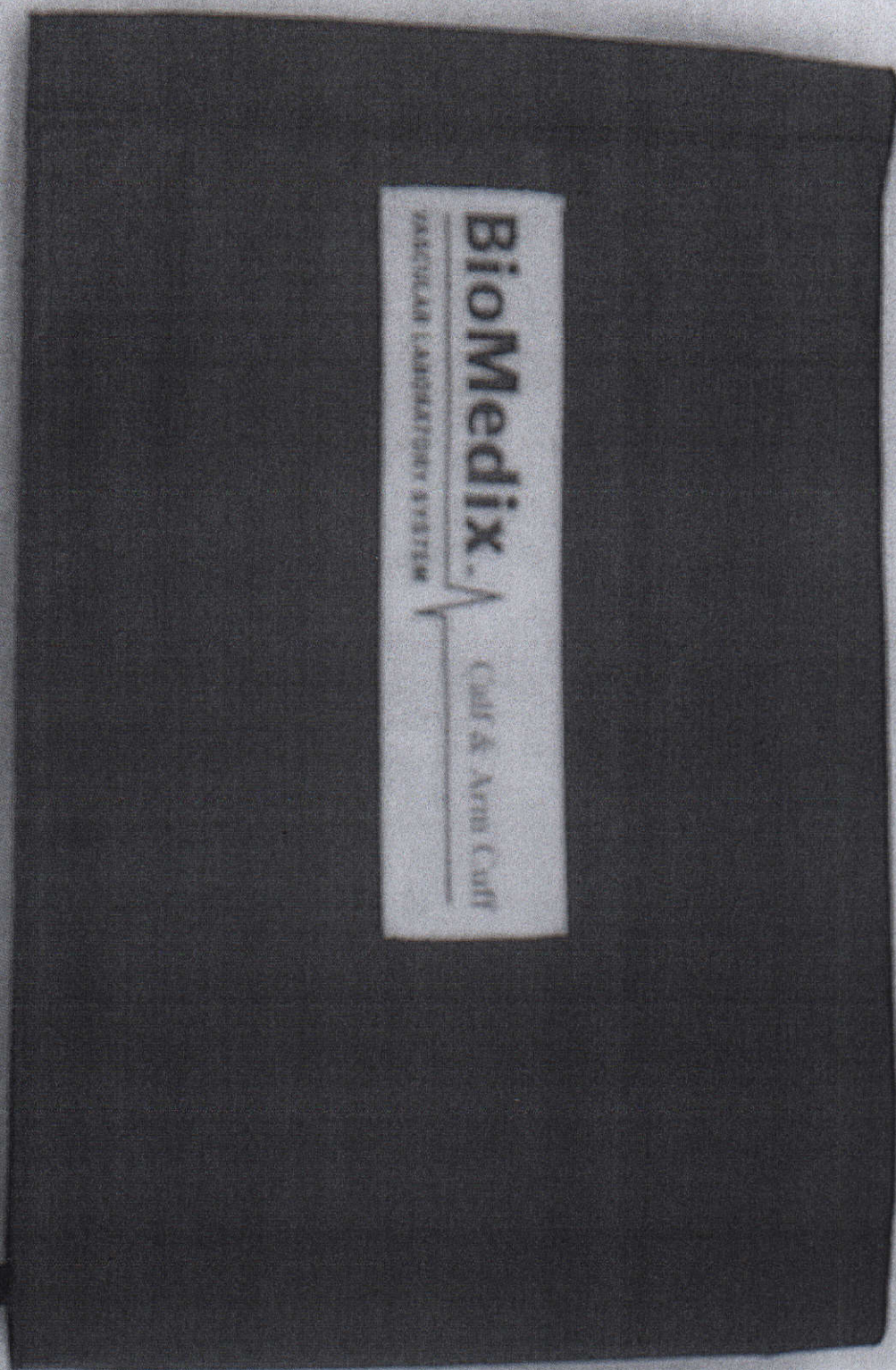
Records processed under FOIA Request # 2015-2895; Released by CDRH on 09-14-2015



BioMedix
PADnet Lab







BioMedix
VASCULAR LABORATORY SYSTEM

Ankle Cuff



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Health and
Human Services**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [CDRH A-Z Index](#) | [Contact CDRH](#)

510(k) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)

[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)

[New Search](#)[Back To Search Results](#)**510(k) Premarket Notification Database**

Device Classification Name	<u>Monitor, Ultrasonic, Nonfetal</u>
510(K) Number	K973644
Regulation Number	892.1540
Device Name	FLOSTAT VASCULAR LAB
Applicant	BIOMEDIX, INC. P.O. Box 1419 Camden, NJ 08105
Contact	David Lerner
Product Code	JAF
Date Received	09/24/1997
Decision Date	12/23/1997
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology
Statement/Summary/Purged Status	Statement Only
Statement	<u>Statement</u>
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 7/06/2004

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Center for Devices and Radiological Health / CDRH

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1997

David Lerner
Sr. Engineer
BioMedix, Inc.
P.O. Box 1419
Camden, NJ 08105

Re: K973644
FLOSTAT VASCULAR LAB
(Doppler Ultrasound/Plethysmograph)
Dated: September 11, 1997
Received: September 24, 1997
Regulatory Class: II
21 CFR 892.1540/Procode: 90 JAF

Dear Mr. Lerner:

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

This determination of substantial equivalence applies to the following transducers intended for use with the FLOSTAT VASCULAR LAB, as described in your premarket notification:

Transducer Model Number

8.0 MHz Peripheral Vascular
5.0 MHz Peripheral Vascular
8.0 MHz Ophthalmic Periorbital

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved

Page - 2 - Mr. David Lerner

levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

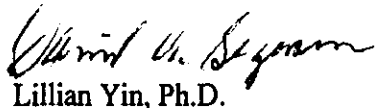
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Paul Gammell, Ph.D. at (301) 594-1212.

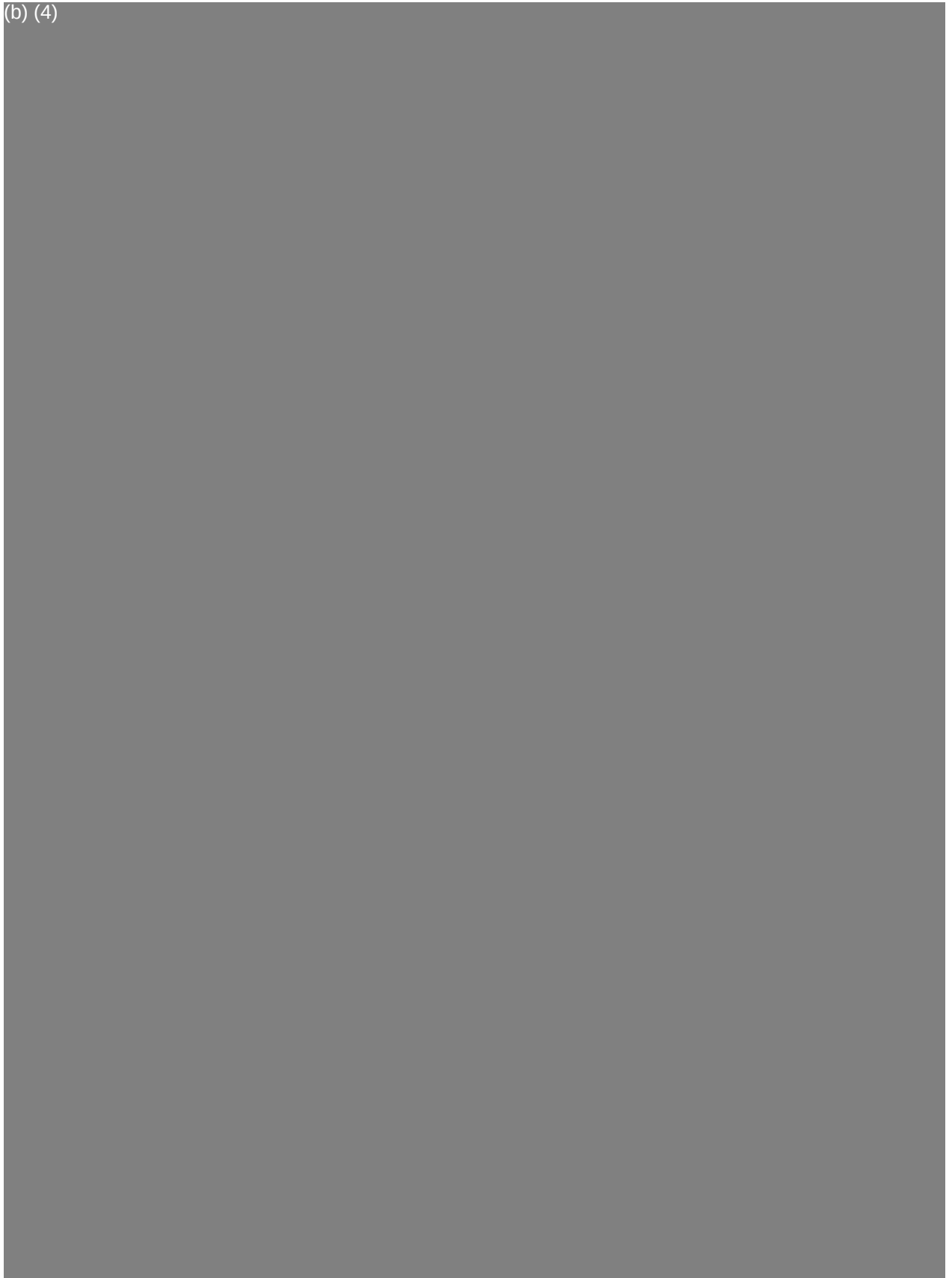
Sincerely yours,

for 
Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

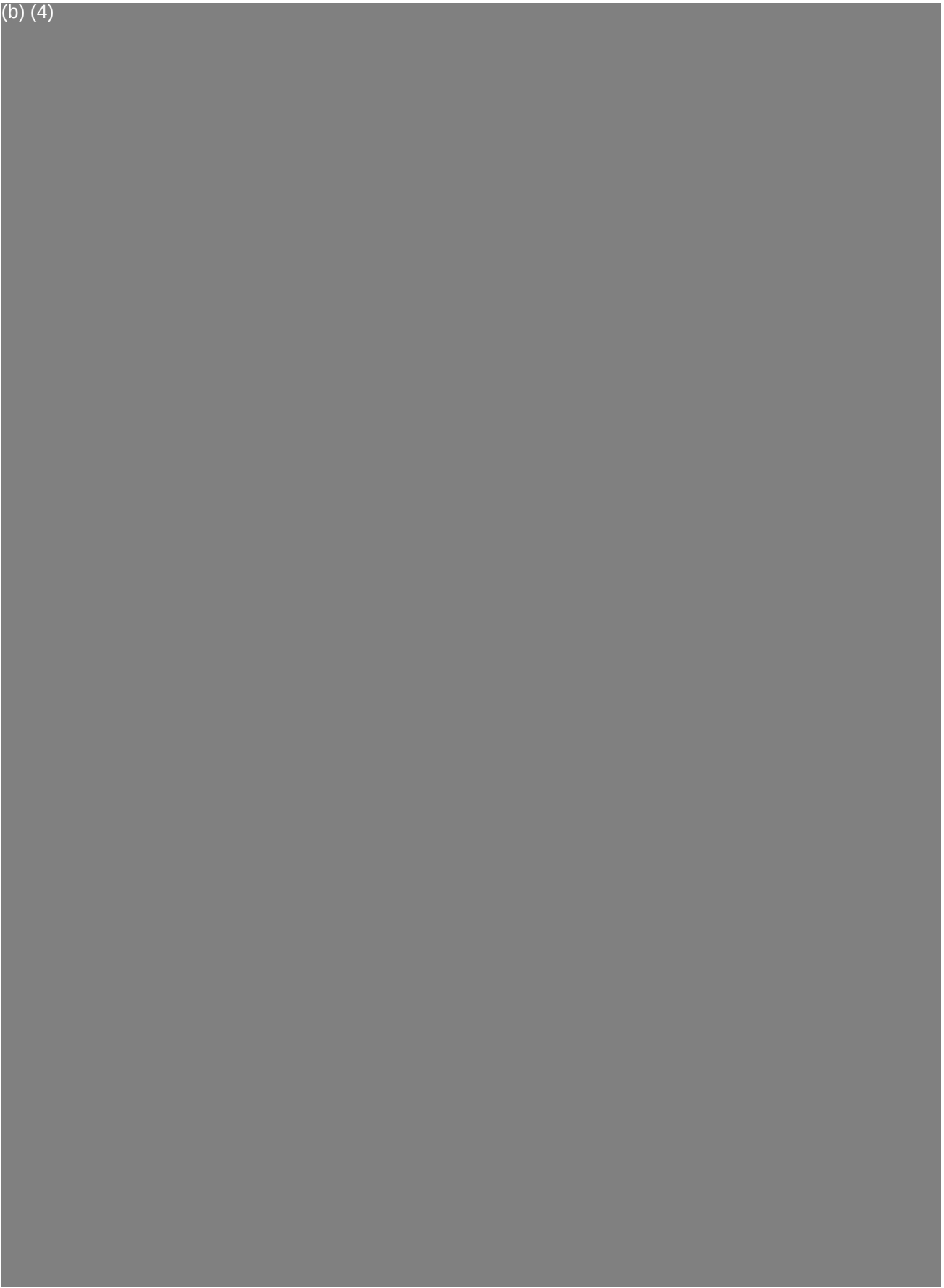
Enclosure

Comparative Performance Evaluation

(b) (4)



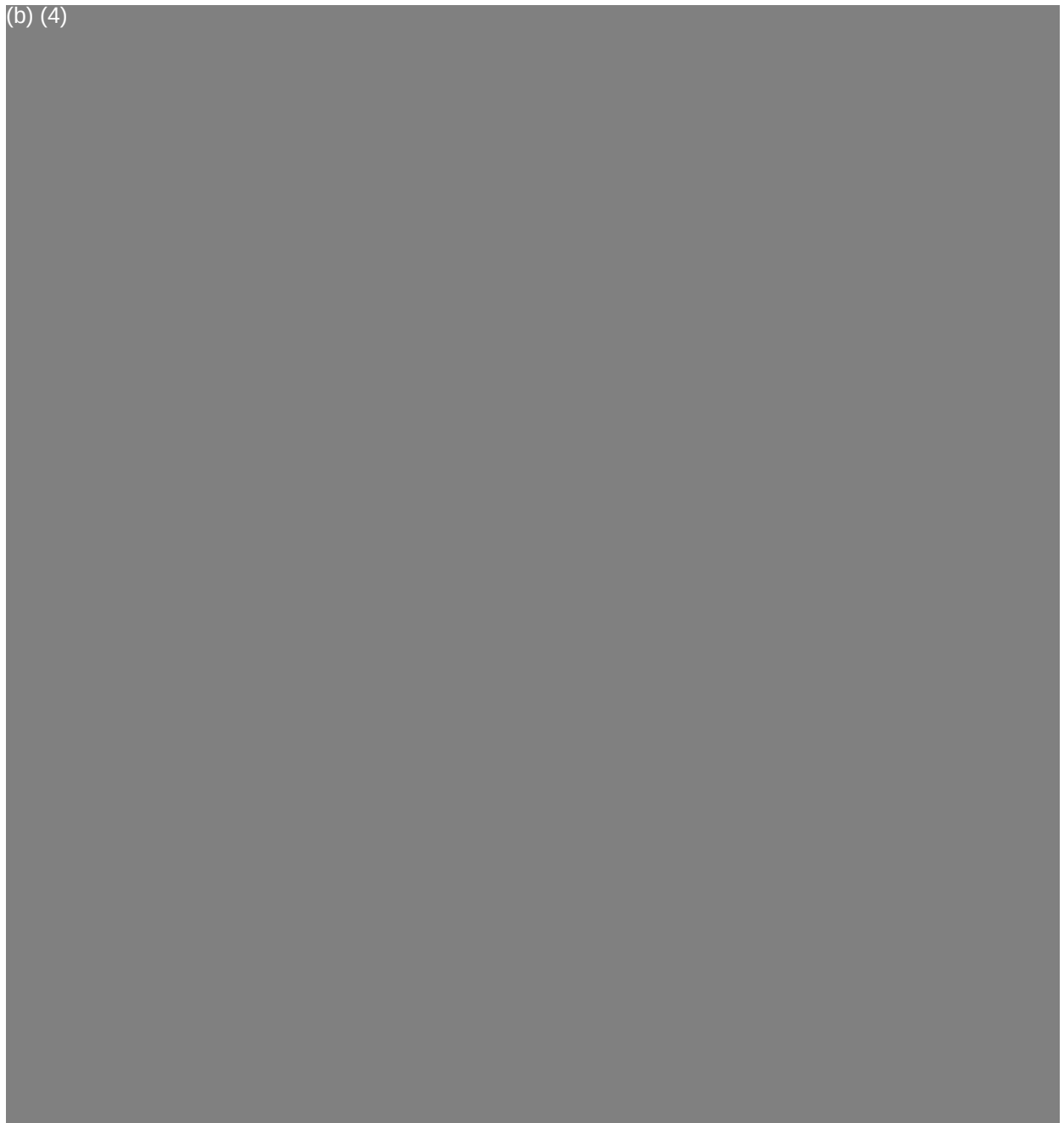
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PADnet Lab Box Label (A)

BioMedix, Inc.
4205 White Bear Parkway
St. Paul, MN. 55110
(651) 762-4010

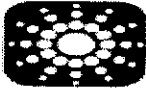
DRAFT
L-0XX



REF: PADnet Lab
Model: PADnet Lab
SN: YYYY-XXXX

Temperature Storage Range: -40 °C to 50 °C (-4 0°F to 122 °F)
Humidity Storage Range: 5% to 95% (Noncondensing)

(B)

 BioMedix PADnet Lab		
Model	PADnet Lab	
SN		
Product	PADnet Lab	
Voltage	115/230 VAC	
Frequency	50-60 Hz	
Amperage	1.2 – 0.7Amp	St. Paul, MN 55110
		Made in USA
		 0086
Draft Product Label This label will be located on the lower right corner of the back panel of the device.		



(Draft)

PADnet Lab

© 2004 BioMedix, Inc

Core Label

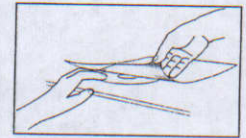
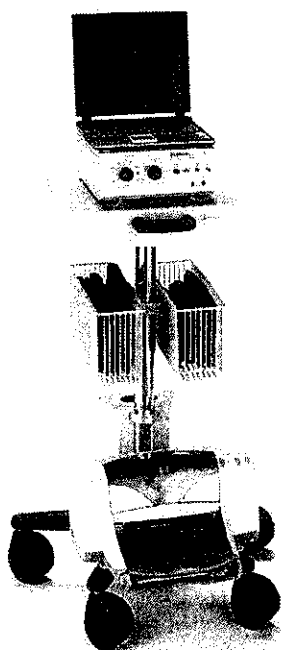


PHOTO QUALITY MATTE

Spine Labels



Core Label 234



PADnet

BioMedix
PADnet Lab



- ▶ Ankle Brachial Indices
- ▶ Pulse Volume Waveforms
- ▶ Study transfer via web

System

OVERVIEW:

- ▶ BioMedix™ PADnet Lab
- ▶ Dell Latitude™ D505
- ▶ Ergotron™ Medical Cart
- ▶ Complete Cuff Kit & Sensing Devices

SOFTWARE:

- ▶ Win XP
- ▶ PADnet Test software
- ▶ Includes video tutorial

HARDWARE:

- ▶ Test unit
- ▶ Laptop PC - 1.40hz Pentium Dell
- ▶ Medical grade cart as shown
- ▶ Color Inkjet printer
- ▶ Pressure Cuff kit
- ▶ Doppler and PPG probe

SUPPORT:

Installation and in-service training is provided for clinical staff.

Laptop

PROCESSOR

Intel® Pentium® M

CPU SPEED

1.40 GHz

MEMORY

256 MB RAM

CHIPSET

Intel® 855GM integrated

UMA graphics

DISPLAY SIZE & TYPE

14" TFT

VIDEO MEMORY

64 MB

FLOPPY DRIVE

NO

HARD DRIVE

30 GB

CD ROM

24X CD, COMBO

INTERNAL SPEAKERS

YES

INTERNAL

MICROPHONE

YES

MODEM

56K Fax Modem

LAN

10/100

AC ADAPTER

65 W

I/O PORTS

3 - USB 2.0 MAX

1 - PS/2

VGA OUT

YES

AUDIO (IN/OUT)

YES / YES

S-VIDEO (IN/OUT)

NO / YES

DOCKING / PORT REP

USB

FIREWIRE (1394)

YES

TYPE II / TYPE III

1 / 0

POINTING DEVICE

TOUCH

BATTERY

Latitude D505 (6 CELL)

DIMENSION (WxDxH)

12.0 X 10.0 X 1.0

WEIGHT (w/batt.)

5.50

OPERATING SYSTEM

WIN XP

CERTIFICATIONS

FCC, UL

WARRANTY

2 years

www.biomedix.com

BioMedix® PCs use genuine Microsoft® Windows®
www.microsoft.com/piracy/howtotell



PADnet Lab Operators Manual (DRAFT)

L-XXX, Rev.X

REF – Bio 10600

BioMedix, Inc.

4205 White Bear Parkway

St. Paul, MN 55110

Phone: 651-762-4010 Toll Free: 877-854-0012

Fax: 651-762-4014

<http://www.biomedix.com>

Authorized European Representative:

Advena Ltd.

PO Box 30

Leominster

Herefordshire

HR6 0ZQ, UK

CE
0086

Symbols

1.  Type BF Applied Parts
2.  Attention, consult accompanying documents
3. **IPXO** - No Protection against Ingress of Water
4.  Volts AC (Alternating Current Voltage)
5. I / O Main Power Switch. I = On and O = off.

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

Class1, type BF  applied parts, not suitable for use with flammable anesthetics, and continuous operation.

Caution

This equipment has been tested and found to comply with Medical Equipment Standard: EN60601-1-2, 2001. This unit was tested to IEC 60601-1:1988 + A1:1991 + A2:1995. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one of the following measures:

- ◆ Reorient or relocate the devices
- ◆ Increase the separation between the devices
- ◆ Connect the equipment to an outlet on a different circuit
- ◆ Consult the manufacturer or field service technician for help

Computers or Printers should be tested and approved per EN 60601-1-1 or equivalent standards prior to placing system into service.

This system is NOT FOR FETAL or PEDIATRIC USE. NOT FOR USE ON OR NEAR NON-INTACT SKIN.

Introduction

Thank you for your interest in the BioMedix PADnet Lab. This Operators Manual will help you perform diagnostic tests using the BioMedix PADnet Lab. Whether you're a first time user, or have experience with the device, this manual is designed to answer your questions and show you just how easy the BioMedix PADnet Lab is to use.

The BioMedix PADnet Lab is a highly sophisticated device for use in the diagnosis of vascular pathology. Using plethysmography (the change in limb circumference as a reflection of blood volume changes), the PADnet Lab can assess vascular blood supply simply and non-invasively.

This manual and the PADnet Lab itself were designed to make vascular assessment as easy as possible for all levels of computer users. The PADnet Lab works with your IBM Compatible personal computer to draw waveforms in real time, archive patient history and test data onto the hard drive, and much more. It is, however, beyond the scope of this manual to provide significant education on the clinical uses of the data generated by the PADnet Lab.

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Section1

Set up

Loading your PADnet Lab Version X.0 Software:

The PADnet Lab is very easy to set up. PADnet Lab software loads easily into your personal computer (PC). While we cannot guarantee compatibility with every PC clone or operating system, we will help you find a solution that ensures you are able to use your PC with the PADnet Lab.

Review the table below to ensure your system meets the **Minimum Operating Specifications** for PADnet Lab operation.

Minimum Computer Specifications for Operation

(Only computers meeting IEC60950 or equivalent should be used)

IBM PC or Compatible
Pentium III Processor (or Above)
600 MHz Minimum Processor Speed
One Free USB port
SVGA or greater Monitor or Display (set for 800 X 600 or 1024 X 768)
One 3.5" Floppy Disk Drive
One 16X CD Drive
One Printer Port or USB for Printer
One Mouse Port and Mouse
128 MB RAM or Higher
Windows XP
Any Windows Compatible Printer

Minimum Computer Settings

Screen / Display Set to 800 X 600 or 1024 X 768 Resolution
Fonts Set to Small Font Size
Color set to High Color (32 bit)

Set Up Continued

Loading your PADnet Lab Version X.0 Software

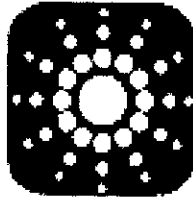
NOTE: If you purchase your computer package from BioMedix, your software will be pre-loaded. If your PC was provided by BioMedix, you can skip over these instructions. These instructions are provided if you switch computers or need to load a software upgrade later on.

1. To install the software, close all programs on your Windows desktop.
2. Place the CD-ROM into your CD drive.
3. The setup program will lead you through the steps to complete setup.
4. If the set up program does not appear onscreen, click on ***start***, then click on ***run***.
5. Type **D: setup** or if D is not the correct drive for your computer, replace D with the drive letter that does correspond to the CD-ROM drive on your computer.
6. Press **Enter** & follow the instructions of the setup wizard.
7. Once the software is installed, you will need to restart the computer.
8. A desktop icon named PADnet Lab should appear on your desktop and on the START menu.

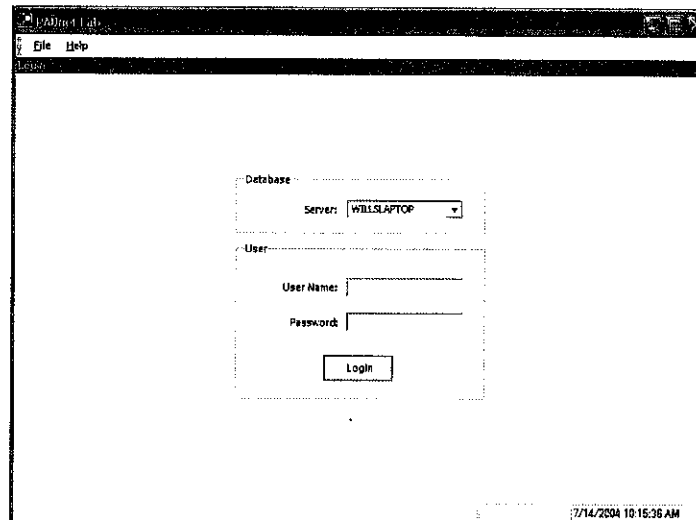
If you have any questions about the software installation, please call our technical support staff at **651-762-4010**.

Set up Continued

1. To access the program, from the Windows desktop double click on the PADnet Lab icon.

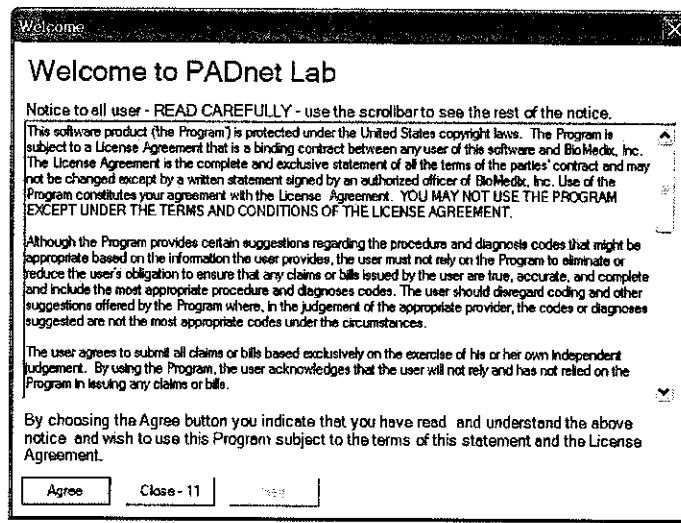


2. This leads you to the PADnet Lab Sign On screen.

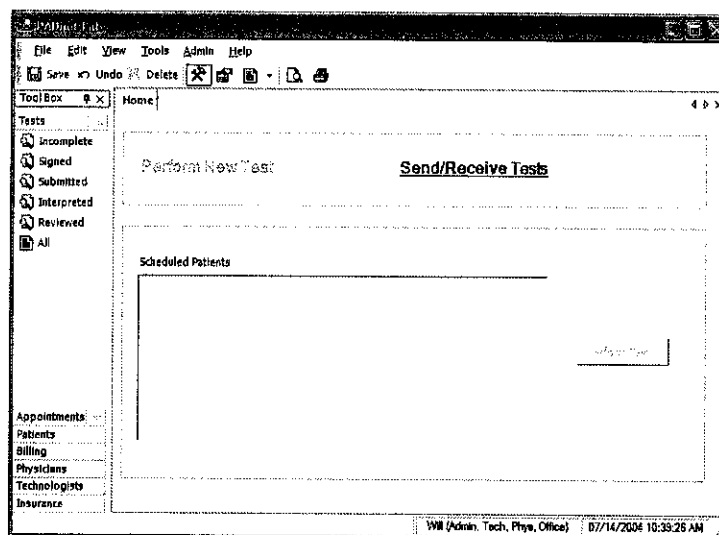


2. From here, you will need to enter your user name and password. This will take you to the licensing screen. You need to read and agree to the licensing prior to proceeding to the main menu. **If you do not agree to the licensing within 30 seconds the program will return to the log in screen.**

Set up Continued



3. After agreeing to the licensing you will come to the PADnet Lab main menu.



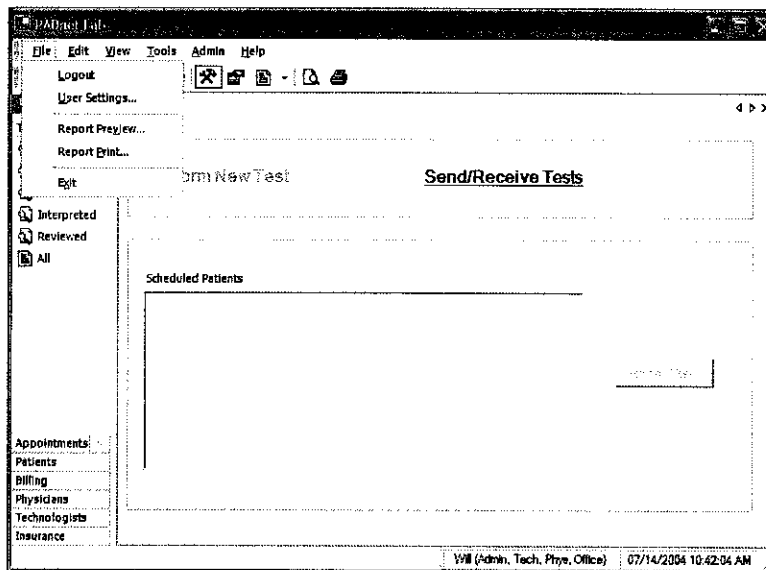
4. There are tabs across the top and down the left side of the main menu. The tabs at the top will open drop down menus for additional functions. The tabs on the left side enable the user to open selected functions for use to manage database tables and functions, such as scheduling appointments, adding physicians or updating insurance company information.

Set up Continued

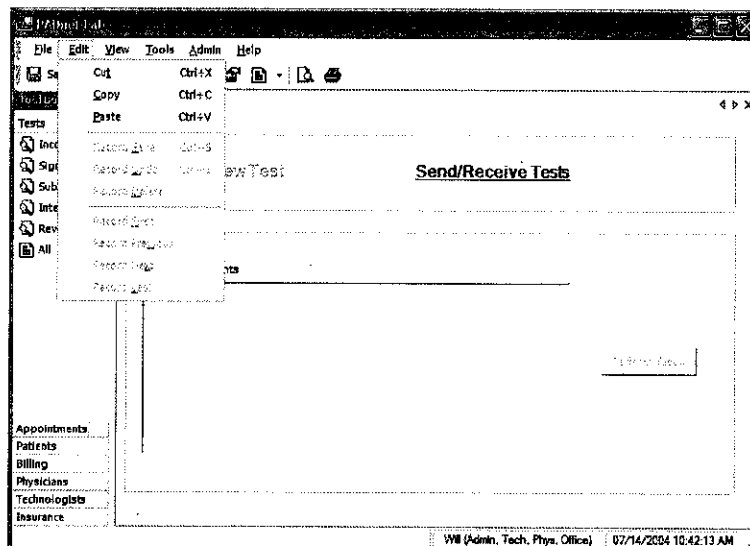
Main Menu Selections:

Tabs at top of page

1. **File** - This selection allows the user to log out of the software, edit user settings, print preview the patient report, print the patient report or exit from the program.

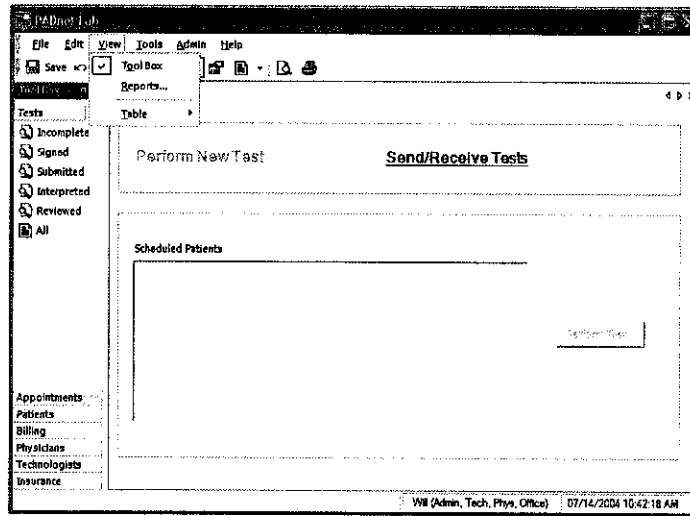


2. **Edit**- This selection allows editing functions such as copy and paste. The user may also edit records and review records.

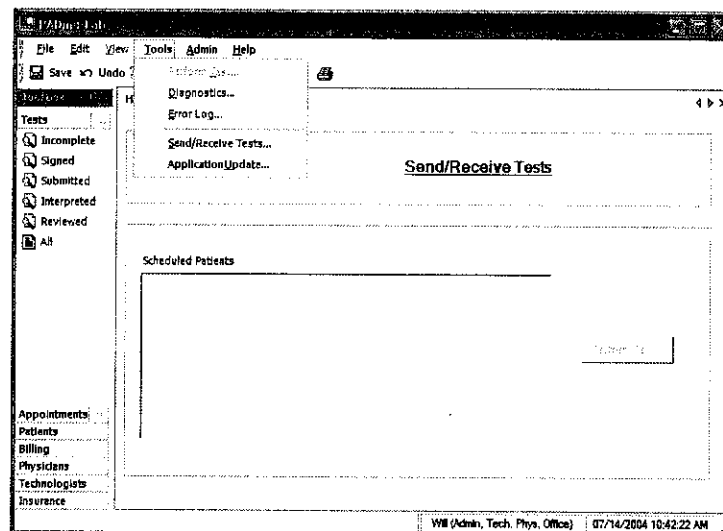


Set up Continued

4. **View-** Selecting this tab allows the user to view toolbox selections, available reports and tables.

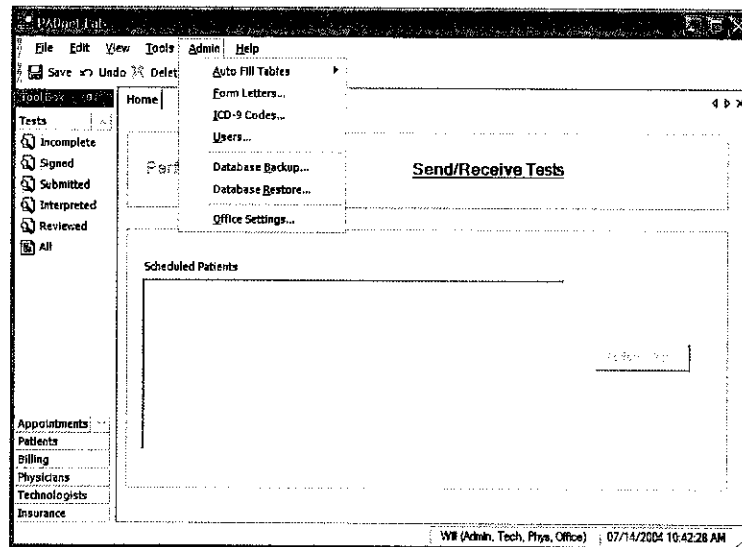


5. **Tools-** These selections allow the user to perform test on selected patient, go to system diagnostic screen (only available to administrators), review error log if any exist or send and receive data from the reading center. The user can also get application updates from the web site.

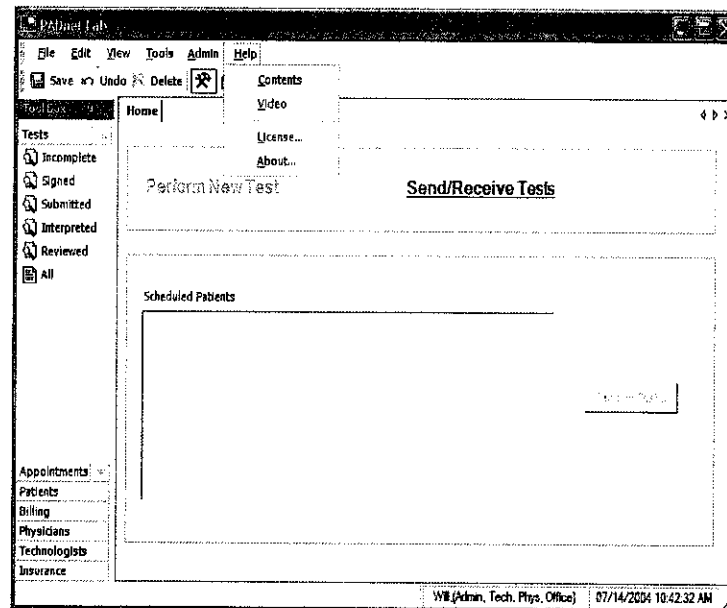


6. **Admin** – Selecting this tab allows the user to perform various administrative functions. Most of these functions may only be accessed by a system administrator.

Set up Continued



1. **Help**- This menu allows the user access to various help functions such as the help menu, the video tutorial, the license agreement and the about information.

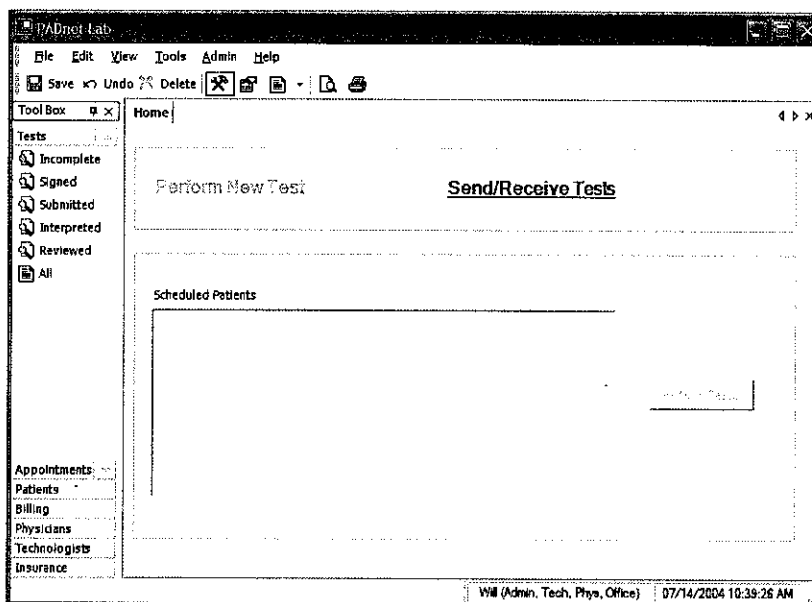


Set up Continued

Main Menu Selections:

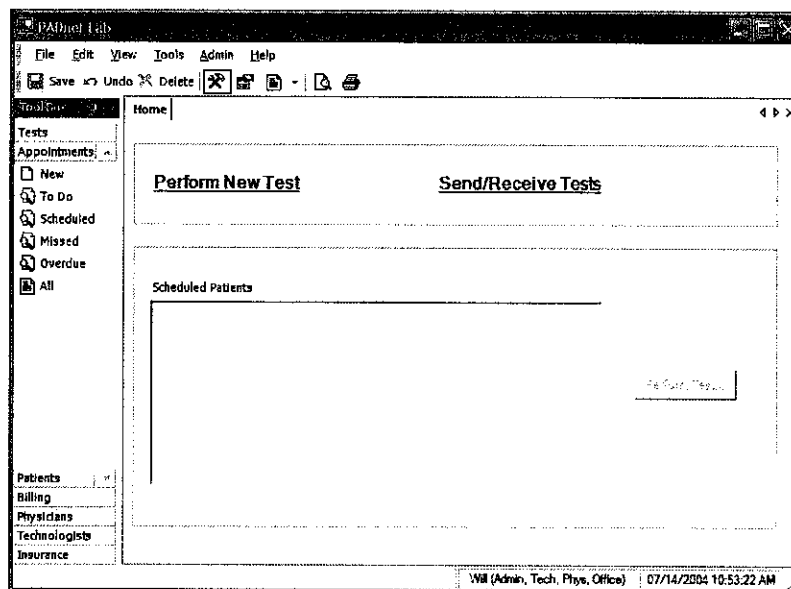
Tabs at left of page

2. **Tests** – This selection will allow the user access to several types of patient list. To access any of these options simply click on the desired selection.

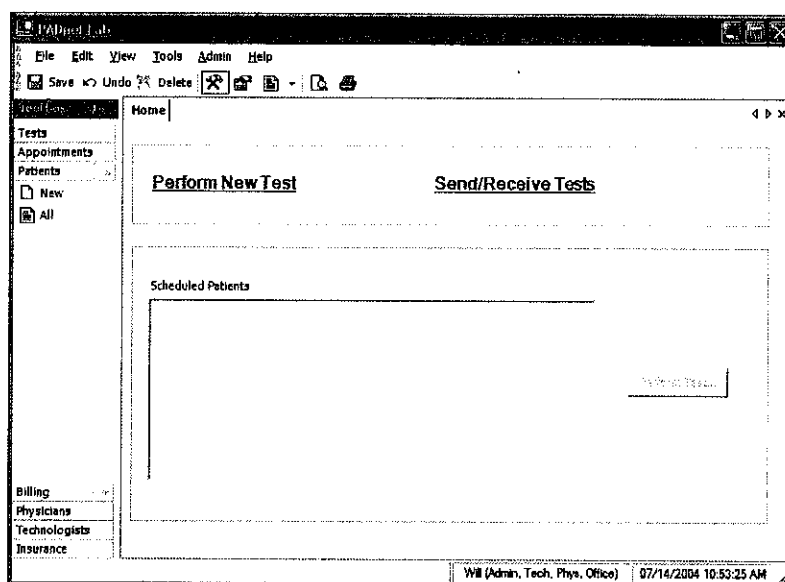


3. **Appointments** – This tab allows the user to select various lists of appointments.

Set up Continued

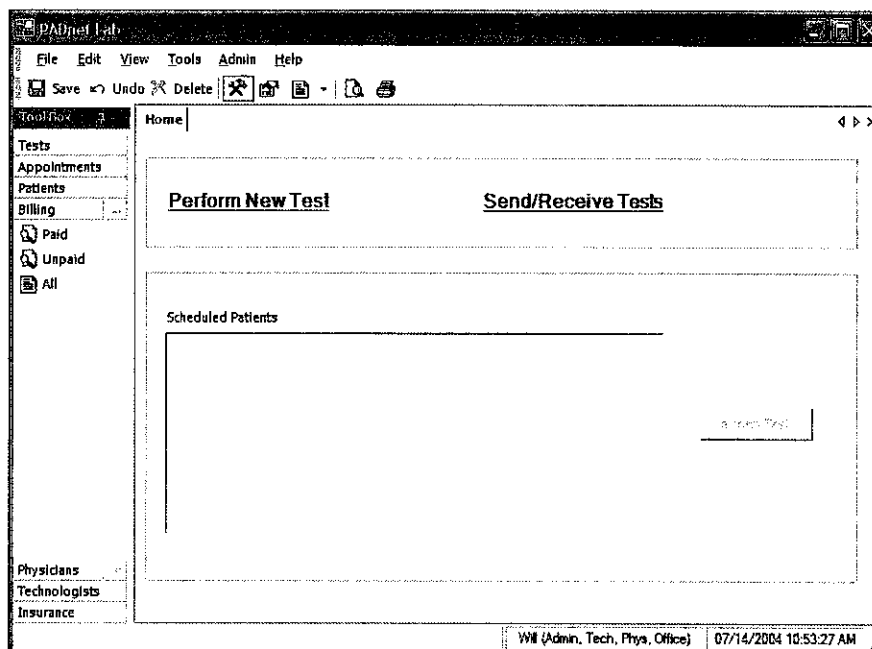


4. **Patients** – This selection allows the user to enter a new patient or view a list of patients already in the database.

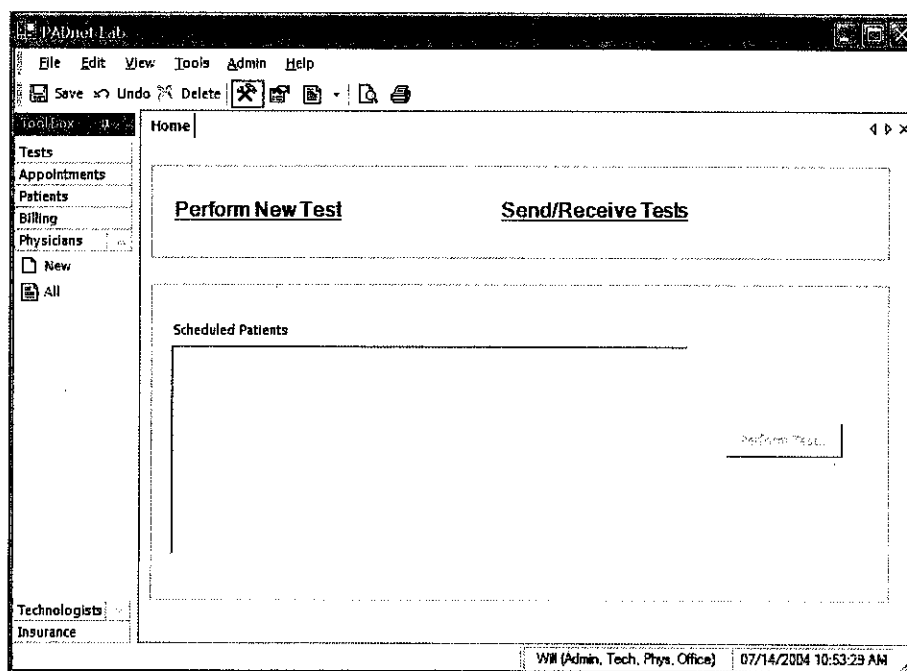


Set up Continued

5. **Billing** - This tab will enable the user to view and print lists of billing status.

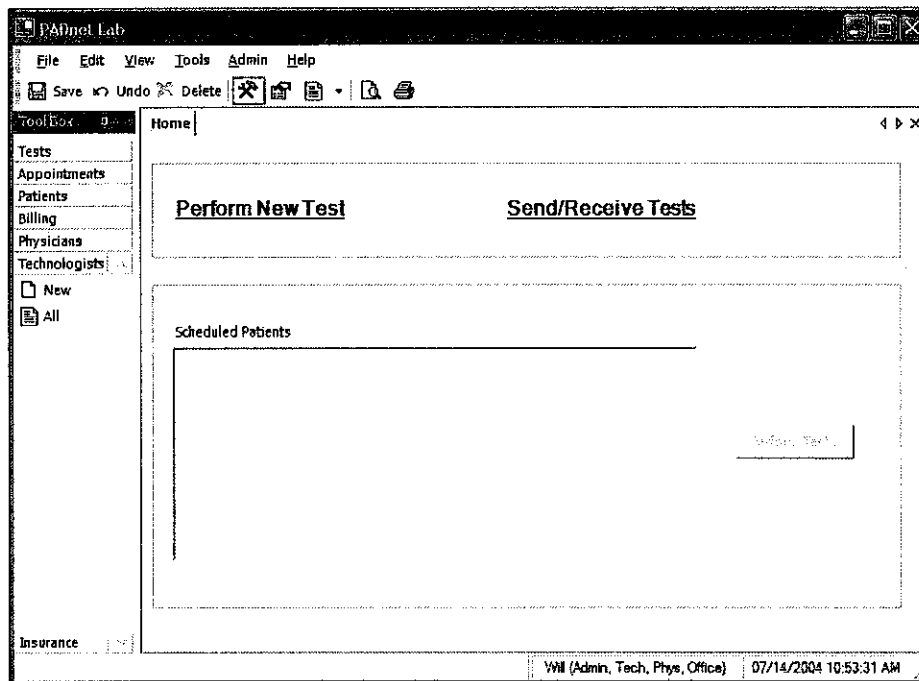


6. **Physicians** – The user may use this selection to add or view a list of Physicians entered into the database.

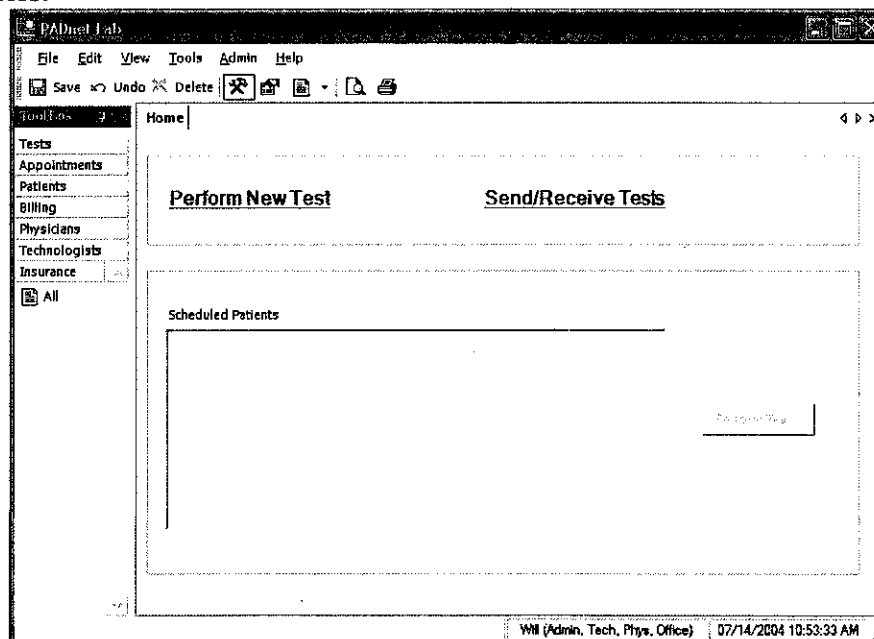


Set up Continued

7. **Technologist** – This tab will allow the user to enter or view a list of Technologist entered into the database.



8. **Insurance** – This selection will allow the user to enter or view a list of insurance carriers.



Front Panel Layout and Description

The Front Panel of the BioMedix PADnet Lab is designed for simplicity and ease of use. The numbers of controls have been minimized, with internal circuitry and software conducting many of the operations that are performed manually on other systems.



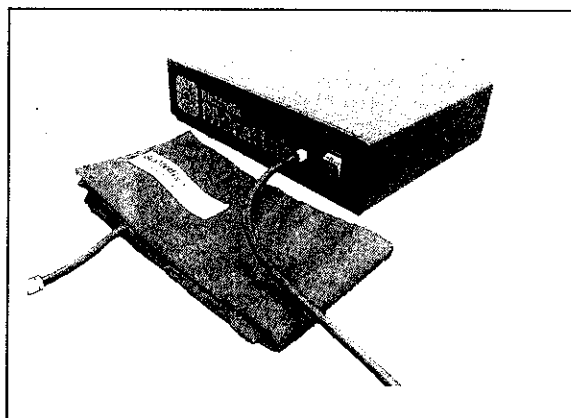
Switches

On/Off: This green colored switch with a I and O symbol, located on the right of the front of the unit is illuminated when on. When the switch is in the I position, the unit is powered on. When the switch is in the O position, it is powered off.

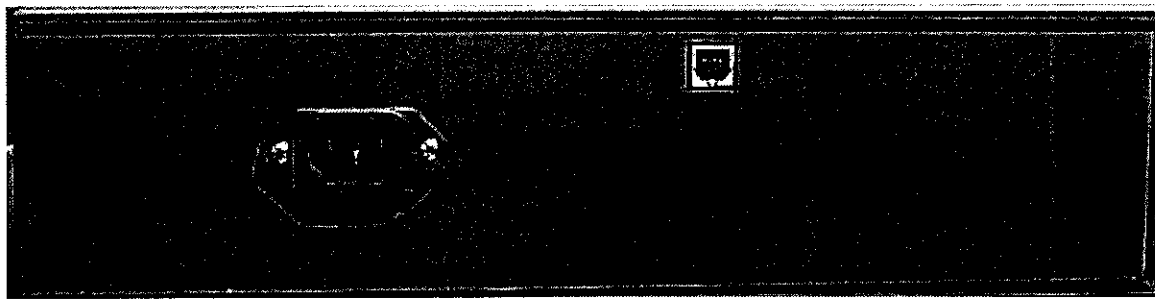
- **Switching off power results in automatic cuff deflation.**

Connectors

Cuff Connector: Found to the left of the power switch, cuffs are connected to the PADnet Lab here. Insert the plastic connector on the cuff tube into the connector on the front panel. **Twist it gently in a clockwise direction until it locks. Do not over tighten. Please see diagram below:**



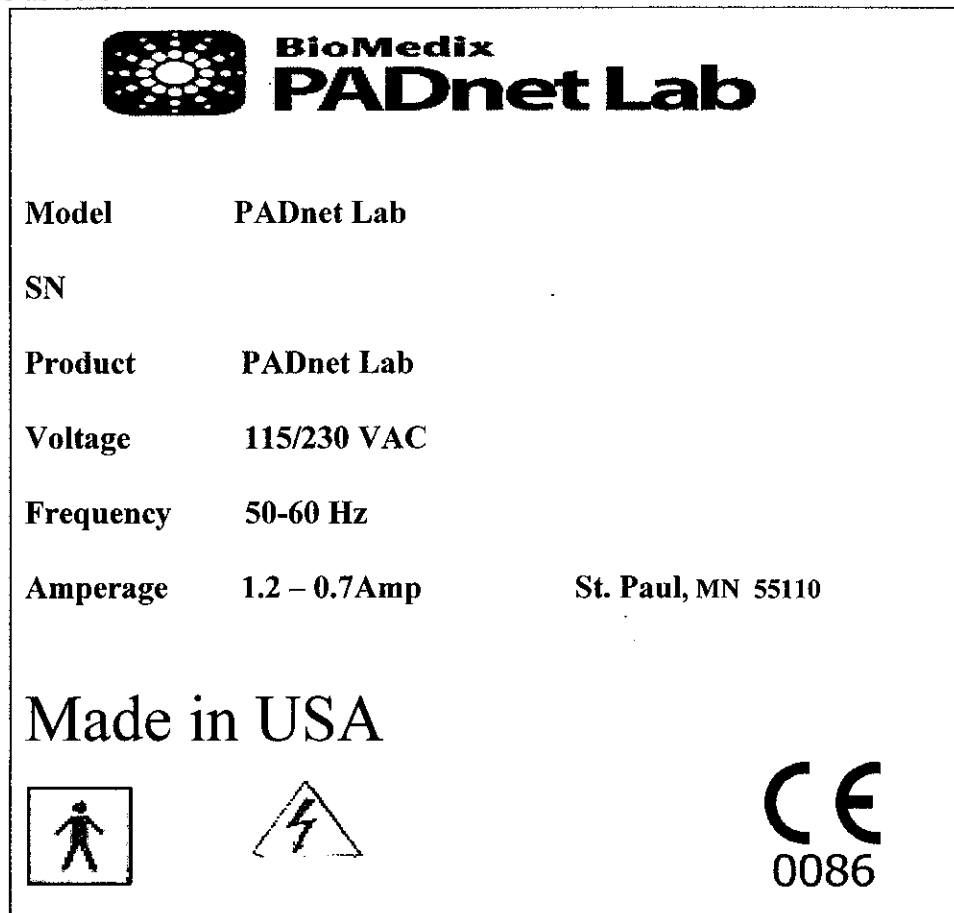
Rear Panel Layout and Description



AC Input: The AC power supply is plugged in here. Use only a factory-supplied power cord to run the PADnet Lab.

USB: The USB connector is plugged in here. This is the **main data connection point** between your computer and the PADnet Lab.

Label: The Serial label is located in the lower right corner of the rear panel, and appears as below.



Rear Panel Hook-up

Power Supply

The power cord is plugged into a **100-240 VAC, 47-63 Hz electrical outlet**. Connect the power cord to the PADnet Lab by pushing the connector into the **AC input** connector.

USB Cable (Computer to PADnet Lab Connection)

The PADnet Lab comes with a **USB** connector cable. One end of the cable is **connected to the PADnet Lab at the connector**. The other end of the cable plugs into the **USB port on your computer**.

Now your BioMedix PADnet Lab is properly configured and you are ready to begin vascular testing.

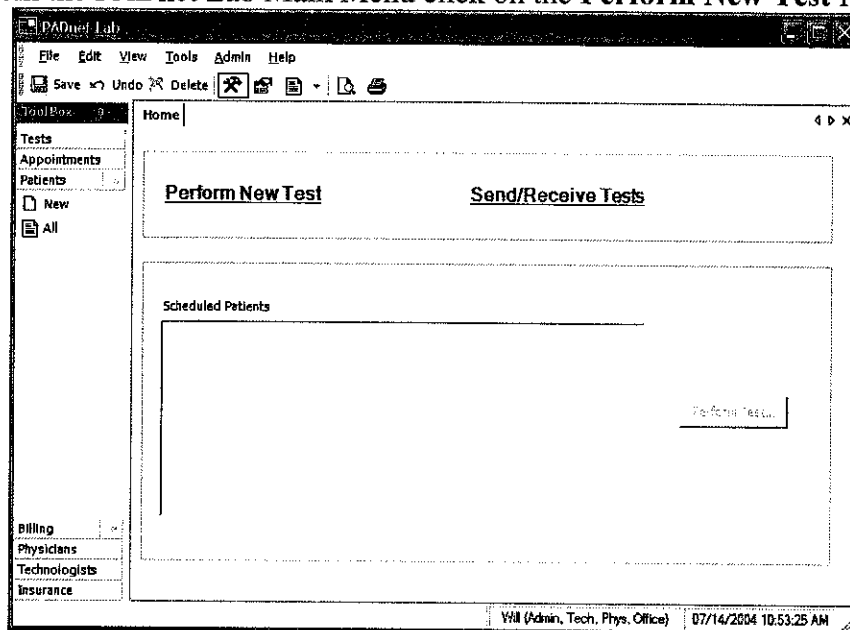
Component List

Description	BioMedix Part Number
1- USB cable	100-1600
1- Cuff kit	7200
1- BioMedix PADnet Lab Software Program CD ROM	400-210
1-AC Power Cord	350-215
1- PADnet Lab Operators Manual	10650

**Please only use components approved by BioMedix for use
with the PADnet Lab. Use of other Manufacturers' accessories
with the PADnet Lab could void your warranty.**

Patient Data Entry

From the PADnet Lab Main Menu click on the **Perform New Test** field.



This leads you to the Patient Data Entry Screen

This tab allows the user to enter all relevant patient demographic data. All fields that must have data entered into them have a ! or  next to them. Fields with this mark ! must be completed prior to any attempted data transfer. Fields with this mark  must be completed prior to saving or going to any other tabs. After completing all necessary fields on this tab user should move to the next tab **Insurance**. The following fields will appear.

Patient Data Entry Continued

The screenshot shows the 'Insurance' tab in the PADnet Lab software. The interface includes a menu bar (File, Edit, View, Tools, Admin, Help) and a toolbar with icons for Save, Undo, Delete, and other functions. A 'Tool Box' on the left lists various test categories: New, Incomplete, Signed, Submitted, Interpreted, Reviewed, and All. The main area is titled 'Test Details' and contains tabs for Patient, Insurance, History, Indications, Test, Interpretation, and Report. The 'Insurance' tab is active, showing two policy sections. The 'Primary Policy' section has fields for First Name, Last Name, Carrier, Policy Number, Group Number, Address, City, State, and ZIP. There are also checkboxes for 'Cardiogram/ECG' and 'Reprint Requested'. The 'Secondary Policy' section has similar fields. The status bar at the bottom shows 'Will (Admin, Tech, Phys, Office)' and the date/time '07/14/2004 10:59:58 AM'.

This screen is where all insurance information needed for patient billing is entered. After completing this screen, you should click on the next tab **History**. The following screen will appear.

The screenshot shows the 'History' tab in the PADnet Lab software. The interface includes a menu bar (File, Edit, View, Tools, Admin, Help) and a toolbar with icons for Save, Undo, Delete, and other functions. A 'Tool Box' on the left lists various test categories: New, Incomplete, Signed, Submitted, Interpreted, Reviewed, and All. The main area is titled 'Test Details' and contains tabs for Patient, Insurance, History, Indications, Test, Interpretation, and Report. The 'History' tab is active, showing 'Risk Factors' and 'Associated Diseases' sections. The 'Risk Factors' section has dropdown menus for 'Hypertension...', 'Tobacco...', 'Diabetes...', and 'Hyperlipidemia...'. The 'Associated Diseases' section has dropdown menus for 'Cardiac...', 'Carotid...', 'Pulmonary...', and 'Renal...'. The status bar at the bottom shows 'Will (Admin, Tech, Phys, Office)' and the date/time '07/14/2004 11:00:12 AM'.

Patient Data Entry Continued

The History tab is divided into three sub tabs Risk factors, Vascular Procedures and Notes.

1. Risk Factors – This is where Vascular Risk Factors and Associated Diseases are listed along with there severity.
2. Vascular Procedures – This is where prior Vascular Surgery or other procedures may be listed.
3. Notes – This area is for entry of any additional information the testing site would like the reading site to be aware of.

After completing the History tab information the user should select the **Indications** tab. The following screen will appear.

The screenshot displays the PADnet Lab application window. The title bar reads "PADnet Lab". The menu bar includes "File", "Edit", "View", "Tools", "Admin", and "Help". Below the menu bar is a toolbar with icons for "Save", "Undo", "Delete", and others. The main window has a tabbed interface with tabs for "Patient", "Insurance", "History", "Indications", "Test", "Interpretation", and "Report". The "Indications" tab is currently selected. On the left side, there is a "ToolBox" with a list of "Tests" including "New", "Incomplete", "Signed", "Submitted", "Interpreted", "Reviewed", and "All". Below the toolbox are links for "Appointments", "Patients", "Billing", "Physicians", "Technologists", and "Insurance". The main content area of the "Indications" tab is divided into two sections: "Referral" and "Other". The "Referral" section contains a "Referring Physician" field with a "New" button and a dropdown menu, and a "Referral #" field. The "Other" section is a large text area. To the right of the "Referral" section, there is a "Side" dropdown menu and a list of checkboxes for various indications: "Claudication", "Rest pain", "Extremity ulceration", "Extremity gangrene", "Extremity trauma", "Embofic discoloration of toes or foot", and "Pulseless". The status bar at the bottom right shows "WHL (Admin, Tech, Phys, Office)" and the date/time "07/14/2004 11:00:17 AM".

This tab is where the Referring Physician information and Indications for testing are documented. There is an additional area to enter other indications for testing. Upon completion of these fields the user should select the **Test** tab. The following screen will appear.

Patient Data Entry Continued

This screen is used to access the testing screens by selecting the Perform button on the left side of the screen. The tester should also select their name from the drop down menu at the end of the field labeled Technologist. After they have completed patient testing the tester should review testing results and then sign the test by placing a check in the Test Signed box. All tests must be signed prior to data transfer. Upon completion of testing when exit is selected from the test screen you will return to this screen and all acquired testing data will populate the appropriate fields. When patient testing data has been returned from the reading location the Interpretation tab the following screen will appear.

Patient Data Entry Continued

The testing facility can review the interpretation of the reading location from this screen. To print Patient reports click on the **Report** tab. The following screen will appear.

The screenshot displays the PAFnet Lab software interface. The main window has a menu bar (File, Edit, View, Tools, Admin, Help) and a toolbar with icons for Save, Undo, Delete, and others. Below the menu bar is a 'Tool Box' with a 'Tests' section containing icons for New, Incomplete, Signed, Submitted, Interpreted, Reviewed, and All. The main content area is divided into three tabs: Patient, Insurance, and History. The 'Report' tab is selected, showing three sub-sections: 'Print Selection', 'Status', and 'Coding/Billing'. The 'Print Selection' section has checkboxes for Summary, PVR, Bill, and Letter, each with a 'View...' button. The 'Status' section has fields for 'Sent for interpretation', 'Current Status', 'Interpretation received', and a 'Resend' button. The 'Coding/Billing' section has fields for 'CPT code', 'CPT modifier(s)', 'Reimbursable ICD-9 code(s)', and 'ICD-9 code(s)', along with an 'ICD9 Check...' button. A status bar at the bottom indicates 'HHS (Admin, Tech, Phys, Office)' and the date/time '07/14/2004 11:05:28 AM'.

The Report tab is divided into three areas Print Selection, Status and Coding/Billing.

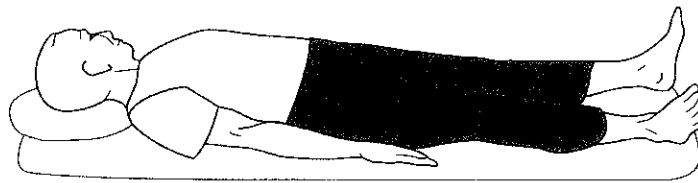
1. **Print Selection** – This area contains check box selections for Summary, PVR, Bill and Letter. It also has view and modify buttons, used to preview reports or modify them prior to printing. The Print button on the upper left side of the screen will print all selected reports.
2. **Status** – This area contains fields for Sent for interpretation, Current status and Interpretation received. There is also a button used to resend test data back to the reader for additional review.
3. **Coding/Billing** – This area contains fields for CPT code, CPT modifiers, reimbursable ICD-9 codes and ICD-9 codes. There is also a button to recheck ICD-9 codes.

Patient Testing

Prior to beginning any testing on a patient, you should do several things:

- Introduce yourself and explain why this test is being performed and how long it should take.
- Explain the various procedures performed during the exam.
- Respond to any issues or concerns of the patient.
- Be prepared to answer questions the patient may have concerning the exam.
- Refer any specific diagnostic, treatment or prognosis questions to the patient's physician.
- Patient should be allowed to rest for several minutes before any testing data is acquired to allow the patient to return to a normal resting state.
- Patient should lay supine with the heart at approximately the same level as the extremities as shown below.

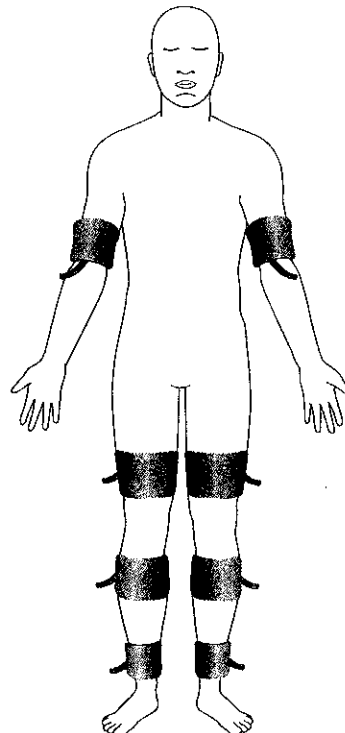
Patient Positioning



Patient lies supine on the bed, as flat as possible.

- The pressure cuffs should be applied to the patient as shown below.

PVR Cuff Positions



Patient Testing Continued

All Patient testing is performed from a testing summary screen. When the user selects **perform** from the test tab the following screen appears.

Click a button to begin testing at that site. Normal test sequence is indicated by the numbers displayed on the buttons.

Click to attach cable

Right		Left	
9	Sys	10	Sys
	Mean		Mean
	Dia		Dia
1	PVR	5	PVR
2	PVR	6	PVR
3	PVR	7	PVR
11	Sys	12	Sys
4	PVR	8	PVR
13	Sys	14	Sys

Exit

To begin testing select the test and anatomical location you wish to start from. Click on the box of the location you wish to start testing. The usual testing routine begins with the Brachial Pressure. When a pressure location is selected the following screen will appear.

Right Arm

240	Systolic
200	
160	Mean
120	
80	Diastolic
40	
0	

1 Start 6 Next 7 Exit



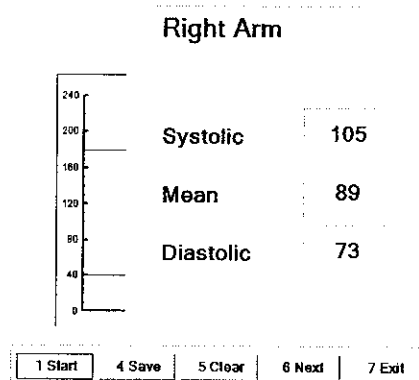
Caution: please verify anatomical location prior to recording any Patient data!

Patient Testing

Continued

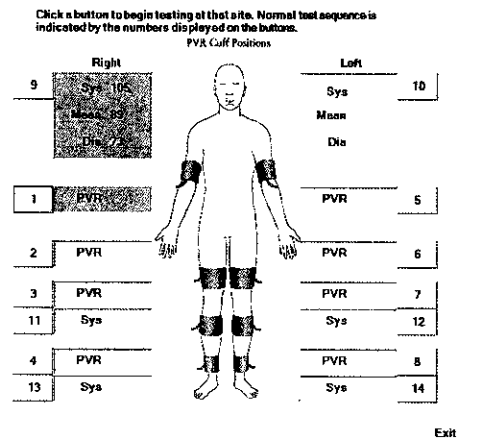
Segmental Pressure – Testing

1. To begin testing make sure hose from cuff is attached to connector on faceplate of PADnet Lab.
2. User may click on **Start** or press the number **1** key on the computer keyboard.
3. The pump will begin to inflate the cuff to the indicated fill pressure which is the top solid line. This setting may be adjusted by clicking on the line and dragging it to the desired level.
4. When the cuff is inflated the pump will shut off and the cuff will begin to deflate. When the pressure has been detected the system will dump any remaining air out of the cuff and the pressure value will be displayed on the right side of the screen as depicted below.



5. If the values are acceptable to the tester than the tester should click on **Save** or press the **4** key on the computer to save the test data. If not acceptable than the tester should click on **Clear** or press the **5** key on the computer to clear the existing data and retest the location.
6. The tester may than click on next to move to the next testing location. This sequence of testing should be repeated for each pressure location. The normal testing locations are arms and ankles. Toes may need to be tested on patients with non – compressible vessels at the ankle level.
7. When data is stored the testing summary screen is updated with the pressure values and will appear as below.

Patient Testing Continued



Segmental Pressure – Basics

Segmental pressures are simply systolic blood pressures recorded at various sites on the limb. They are taken by using blood pressure cuffs. Segmental pressure taking is similar to taking a brachial pressure, with the exception that the Cuff replaces the stethoscope in its ability to detect the disappearance and return of flow. It may be helpful to think of the Cuff as a high-tech stethoscope. Segmental pressures and the resulting Segmental Brachial Indices (SBI) are of crucial diagnostic value.

If an increase in pressure is noticed in the pressures down the limb, they are usually due to the calcification of the vessels. This calcification causes them to be harder to compress with the cuff. In the presence of calcified vessels a digit pressure is indicated. A normal digital pressure will be 60% of the ankle pressure.

Patient Testing

Continued

The following five tables can be used as a reference to assist in the interpretation of the arterial studies but care must be taken to remember to include clinical signs and symptoms in the decision and diagnosis process.

Table II Ischemic Rest Pain

	UNLIKELY	PROBABLE	LIKELY
Ankle Pressure - mmHg			
Non - Diabetic	>55	35 - 55	<35
Diabetic	>80	55 - 80	<55

Table III Foot Lesion Healing

	UNLIKELY	PROBABLE	LIKELY
Ankle Pressure - mmHg			
Non - Diabetic	<35	35 - 55	>55
Diabetic	<55	55 - 80	>80

Table IV Below Knee Amputation Healing

	UNLIKELY	PROBABLE	LIKELY
Pressure - mmHg			
Calf	<65	>65	>65
Ankle	<30	>30	>30

Table V Limiting Claudication

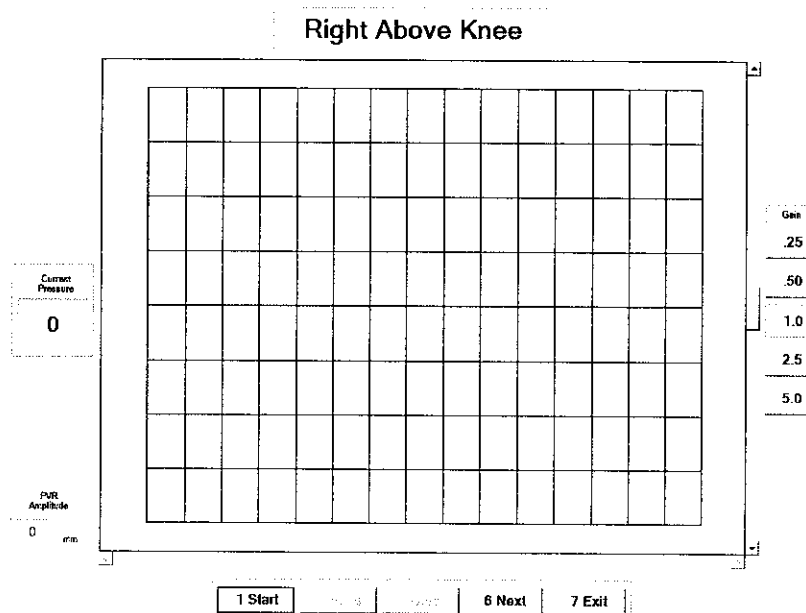
	UNLIKELY	PROBABLE	LIKELY
Post Exercise Ankle Pressure - mmHg			
	>50	>50	<50

Often in diabetics, the pressures in the lower extremity will be abnormally high, or the vessel will be non-compressible. Again, this is due to the medial calcinosis of the vessels, and you may need to refer to air plethysmograph tracings. These tracings may be the only accurate method available to evaluate the patient without imaging.

Patient Testing Continued

PVR Testing

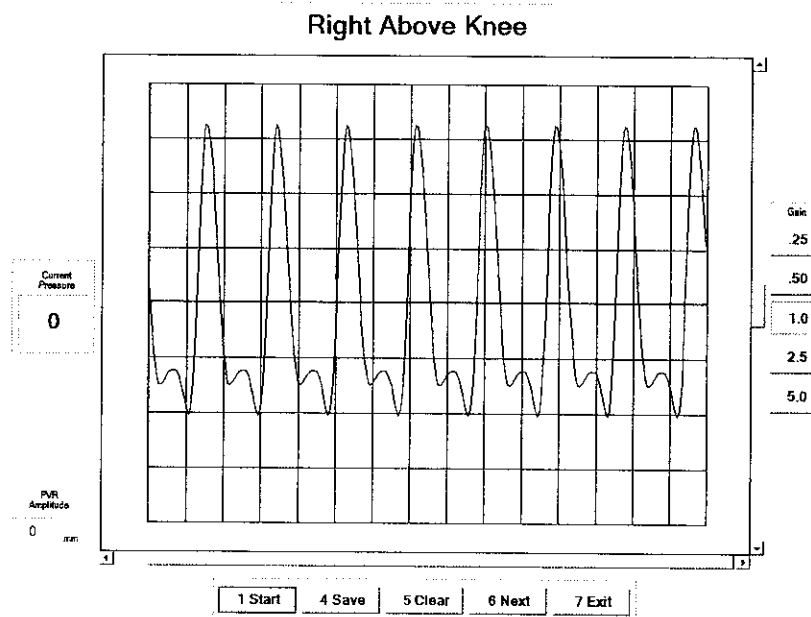
From the testing summary screen an anatomical location for PVR testing is selected. The following test screen will appear.



Caution: please verify anatomical location prior to recording any Patient data!

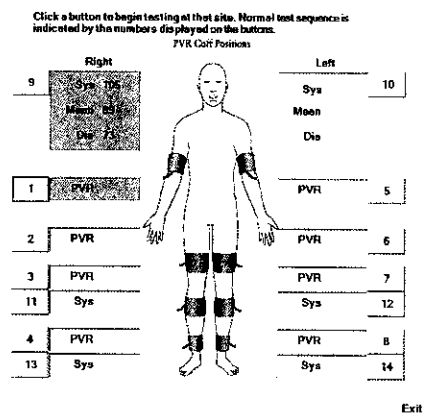
1. To begin testing make sure hose from cuff is attached to connector on faceplate of PADnet Lab.
2. User may click on **Start** or press the number **1** key on the computer keyboard.
3. The pump will begin to inflate the cuff to the indicated fill pressure (65mmHg). When this pressure is achieved the PVR waveforms will scroll across the graph from right to left.
4. The tester should allow the graph to fill with PVR waveforms and then click on **Stop** or press the **1** key on the computer.

Patient Testing Continued



5. The tester may now position the tracings using the scroll bars. The scroll bar below the graph will move the tracing back and forth. The scroll bar to the right of the graph will move the tracings up or down on the graph. The tester may also change the overall gain by clicking on the Gain settings on the far right of the screen.
6. To measure the amplitude of the PVR tracing the tester should click on the base and then the peak of a selected PVR waveform. The measured value will be displayed in a window on the left side of the screen.
7. If the values and PVR waveforms are acceptable to the tester than the tester should click on **Save** or press the **4** key on the computer to save the test data. If not acceptable than the tester should click on **Clear** or press the **5** key on the computer to clear the existing data and retest the location.
8. The tester may then click on next to move to the next testing location. This sequence of testing should be repeated for each PVR location. The normal testing locations are thigh, calf and ankles. Toes may need to be tested on patients with non – compressible vessels at the ankle level.
9. When data is stored the testing summary screen is updated with the pressure values and will appear as below.

Patient Testing **Continued**



Pulse Volume Recording: Basics

Pulse volume recording (PVR) or air plethysmography is perhaps the easiest and least technician dependent test you can perform. In arterial studies the plethysmograph reflects volume changes in the extremity underneath the cuff. Each waveform corresponds to a complete cardiac cycle. Said another way, PVR captures the changes in pressure in an air filled cuff wrapped around an extremity, and provides important diagnostic data on the functional aspect of the patient's limb.

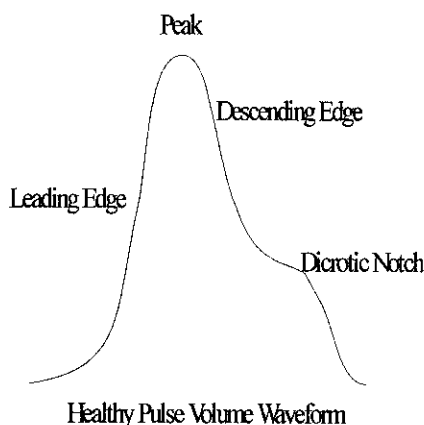
The tracings derived from PVR are only minimally affected by application technique. The BioMedix PADnet Lab tracings are calibrated to a standard. Once the cuff is inflated, and a trace is obtained, the characteristics of that tracing (i.e., morphology) can be compared with specific diagnostic criteria and placed into a category.

Diagnostic Criteria

In a healthy waveform as shown below, there should be a very sharp upstroke with a relatively sharp peak and a dicrotic notch or reflected wave on the descending edge.

Patient Testing

Continued



With the loss of the dicrotic notch and slight rounding of the peak you should suspect early arterial disease which could be classified as mild.

Sometimes a dicrotic notch will not be visible at the thigh or calf levels due to either severe obesity or severe muscle development. If the dicrotic notch reappears at the ankle level you may feel confident it was present at the levels above the ankle also as it would be very difficult to have disease above a normal waveform.

When interpreting air plethysmographic waveforms it is important to compare these waveforms down each limb as well as compare them side to side. In this manner, the limbs can be compared for side to side abnormalities as well as consistency down each limb. If any differences are noticed side to side or down the limb be sure to look carefully at the other modalities that were used to substantiate the diagnosis.

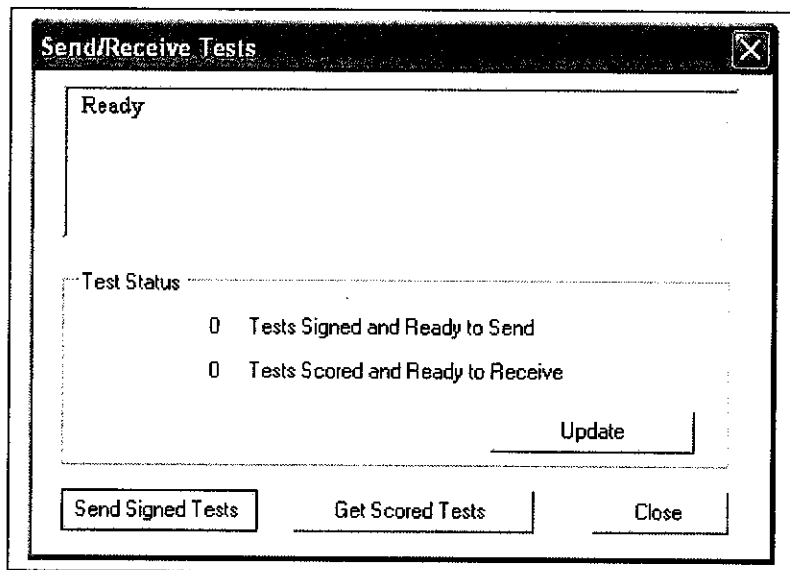
Normal and Abnormal SBI's

.97 to 1.25	=	Normal
.70 to .96	=	Mild Stenosis
.50 to .69	=	Moderate Stenosis, Claudication
.30 to .49	=	Severe Stenosis, Rest Pain, Single Site Occlusion
.29 or less	=	Gangrene, Probable Multiple Site Occlusion

Data Transfer From Tester to Reader

PADnet Lab sends collected test data to PADnet Read via Web Services. Web Services operates as a service that interfaces to the PADnet Lab read database. The PADnet web service will only transfer data using a secure, encrypted data channel (SSL). It will authenticate the requesting application before handling any requests. The PADnet Lab user drives all transfer of data, both sending and receiving test data from the PADnet Read database. Once test information is send to PADnet Read, an interpreting Physician can interpret the test information from a web page, connected to the PADnet Read database. Interpreted tests are made available for download, back to PADnet Lab.

To navigate to send or receive test data, select Tools, Send/Receive tests or select the Send/Receive hyper text link on the Home page. The following diagram will be displayed.



The topmost window displays status of the connection to the Internet. Click "Update" to update Test Status. If Test Status shows tests are ready to send, click the "Send Signed Tests" to send those tests to PADnet Read. If Test Status shows tests are ready to receive from PADnet Read, click "Get Scored Tests" to retrieve tests.

Printing Patient Reports

Printing Patient Reports is done from the report tab screen. A Summary, PVR and Billing report is able to be selected for printing. The tester may also create a follow up letter and have it printed at the same time. This screen is as seen below.

The screenshot displays the PADnet Lab software interface. The main window has a menu bar (File, Edit, View, Tools, Admin, Help) and a toolbar with icons for Save, Undo, Delete, and printing. The left sidebar contains a 'Tool Box' with options: New, Incomplete, Signed, Submitted, Interpreted, Reviewed, and All. Below this is a list of categories: Appointments, Patients, Billing, Physicians, Technologists, and Insurance. The main area is titled 'Test Details' and includes tabs for Patient, Insurance, History, Indications, Test, Interpretation, and Report. The 'Report' tab is active, showing a 'Print Selection' section with checkboxes for Summary, PVR, and Billing, each with a 'View...' button. A 'Status' section contains fields for 'Sent for interpretation', 'Current Status', 'Interpretation received', and a 'PRINTING' button. Below this is a 'Coding/Billing' section with fields for 'CPT code', 'CPT modifier(s)', 'Reimbursable ICD-9 code(s)', and 'ICD-9 code(s)', along with an 'ICD9 Check...' button. The bottom status bar shows 'Will (Admin, Tech, Phys, Office)' and the date/time '07/14/2004 11:00:28 AM'.

Guidance on Preventative Inspection and Maintenance

Note: The PADnet Lab does not contain parts that require preventative maintenance

1. **Never** store the PADnet Lab near an air conditioning or heating ventilator.
2. Clean the exterior of the PADnet Lab with alcohol and a cloth only... and **ONLY** with the unit **UNPLUGGED** from the **AC WALL SOCKET**.
3. Leave the PADnet Lab **"OFF"** when not in use.
4. The Cuffs should only be cleaned with mild soap and water. They should never be cleaned with alcohol.
5. **NEVER PLACE LIQUID CONTAINERS** on top of or near the PVL.
6. The PADnet Lab should **NEVER** be opened regardless of circumstances. There are no user serviceable parts inside.  **Shock hazard could result if opened.**

NOTE: *UNAUTHORIZED SERVICING OF THE UNIT WILL VOID YOUR FACTORY WARRANTY. ONLY AUTHORIZED SERVICE PERSONNEL CAN SERVICE THIS DEVICE. FOR FURTHER INFORMATION PLEASE CONTACT BIOMEDIX AT 651-762-4010.*

Note: For disposal of the device at the end of its useful life, please contact BioMedix for proper disposal.

Specifications

Class 1, type BF  applied parts

Storage / Transport Temperature Range = -40°C to +50°C

Storage / Transport Humidity Range = 5% to 95%

Operational Temperature Range = 0°C to +40°C

Operational Humidity Range = 15% to 90%

Only computers that meet IEC 60950 should be connected to this device.

BIBLIOGRAPHY

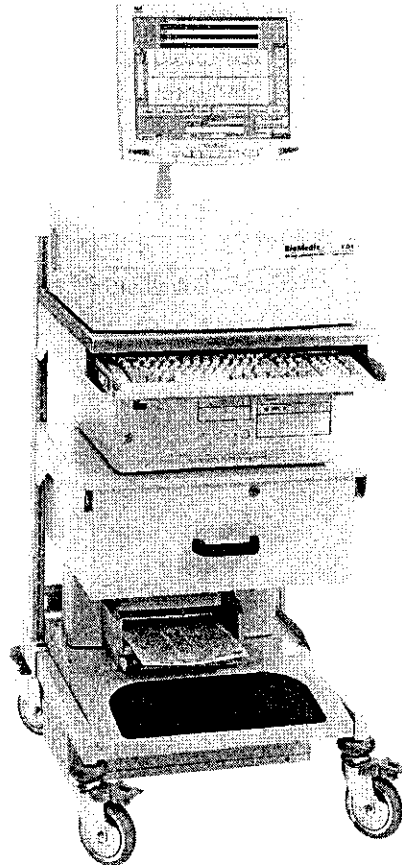
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BioMedix^{INC}

VASCULAR LABORATORY SYSTEMS

V D L

Vascular Diagnostic Lab



Vascular Diagnostic Laboratory (VDL) Operators Manual

L-016, Rev. F

REF - Bio 10800

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274



Preface

This manual assumes you have some understanding of the Windows environment of your computer. This manual has been written so even if you are not a computer expert you can install and operate the software to create reports generated by the BioMedix VDL.

If you encounter any problems during the installation or operations of this software please call BioMedix and one of our technical staff will be happy to help you. The office phone number is **651-762-4010**. Our office hours are **8:00 AM to 5:00 PM Central Time**.

Directory of Symbols



Type BF Applied Parts



Attention, consult accompanying documents

IPXO - No Protection against Ingress of Water



Volts DC (Direct Current Voltage)

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

Class1, type BF  applied parts, not suitable for use with flammable anesthetics, and continuous operation

This manual and the VDL software described in it are copyrighted, with all rights reserved. Under the copyright laws, this manual or the software may not be copied, in whole or in part, without the written consent of BioMedix, Inc., except in the normal use of the software or to make backup copies of the software. The same proprietary and copyright notices must be affixed to any permitted copies as were affixed to the original. This exception does not allow copies to be made for others, whether or not sold, but all of the material purchased (with all backup copies) may be sold, given, or loaned to another person. Under the law, copying includes translating into another language or format.

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Introduction

The BioMedix VDL is a highly sophisticated device for use in the diagnosis of vascular pathology. Using plethysmography (the change in limb circumference or light reflectance of skin as a reflection of blood volume changes), and Doppler ultrasound, the VDL can assess vascular blood supply simply and non-invasively.

This manual and the VDL itself were designed to make vascular assessment as easy as possible. The VDL works with a IBM Compatible personal computer to draw waveforms in real time, automatically analyze vascular flow, archive patient history and test data onto the hard drive, and much more. It is, however, beyond the scope of this manual to educate the user on the clinical uses of the data generated by the VDL. This is best learned through experience.

Notes of caution:

This equipment has been tested and found to comply with the limits for medical devices to IEC 601-1-2:1993 [or EN 60601-1-2: 1994 or Medical Device Directive 93/42/EEC]. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one of the following measures:

- ◆ Reorient or relocate the devices
- ◆ Increase the separation between the devices
- ◆ Connect the equipment to an outlet on a different circuit
- ◆ Consult the manufacturer or field service technician for help

Ultrasound is a safe and time-tested method of clinical diagnosis. However, one should always take care to limit patient exposure to all forms of Ultrasound by minimizing bodily contact with the probe.

This Doppler system is **NOT FOR FETAL USE.**

Computers and printers should be tested and approved per EN 60601-1-1 or equivalent standard prior to placing system into service.

The FDA seeks to minimize patient exposure to Ultrasound, thus, Any Doppler done near the eye should be performed in the Ophthalmic-8 MHz Mode, with the 8MHz probe. This mode lowers the Ultrasound energy to an acceptable level for the eye.

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Software Installation and Set up

1. From the Windows desktop please close all programs.
2. Insert CD disk into the CD disk drive.
3. Auto initiate should start the setup program. Please follow the install wizard to complete setup.
4. If the auto initiate doesn't start the install, Click on *start*, then click on *run*.
5. Type (drive letter): **setup**.
6. Press **Enter** & follow the instructions of the setup wizard.
7. Upon complete installation of the software, you will need to restart the computer.
8. A desktop icon named VDL should appear on your desktop.

Minimum Computer Settings

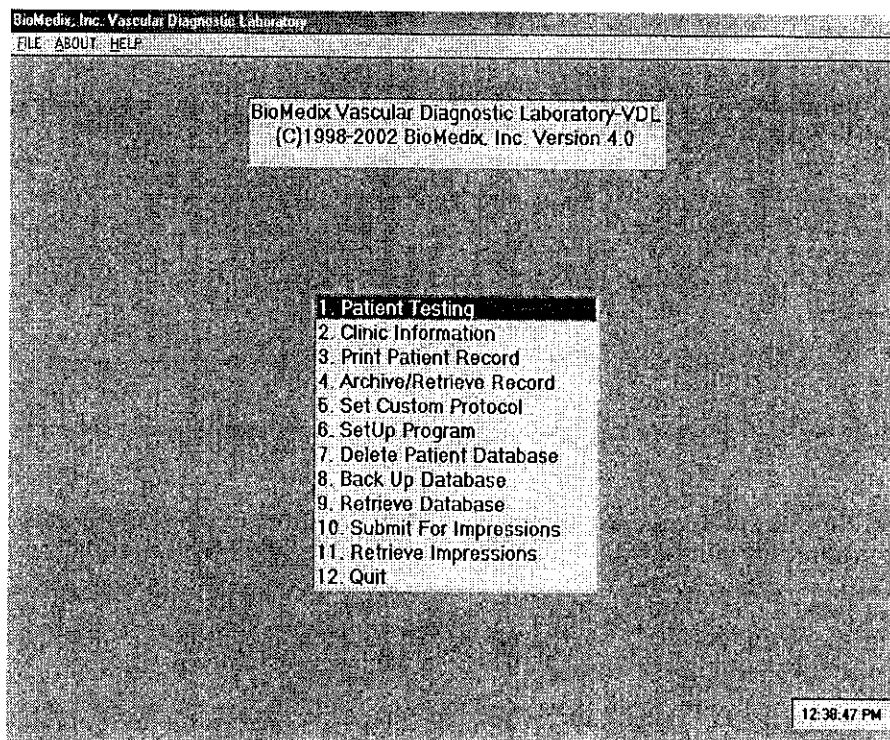
Screen / Display Set to 800 X 600
Fonts Set to Small Font Size

If you have any questions about the software installation, please call our technical support staff at 651-762-4010.

Software Start up

From the Windows desktop double click on the VDL icon.

You will now be at the VDL Main Menu.



From the VDL Main Menu you may choose one of the following by double clicking on the field or typing the number.

Note: For the purpose of the set up of the system for the first time, skip to the section labeled setup program or #6 and then to section #2 for Clinic Information. Once this information is entered, you will not have to return to them unless something changes with your facility or computer.

Software Start up Continued

Patient Testing- This selection will allow you to enter a new patient or recall a prior Patient for additional testing.

Last Name	First Name	Social Sec Number
DEMO2	PATIENT	122-22-2222
DEMO3	PATIENT3	345-34-5435

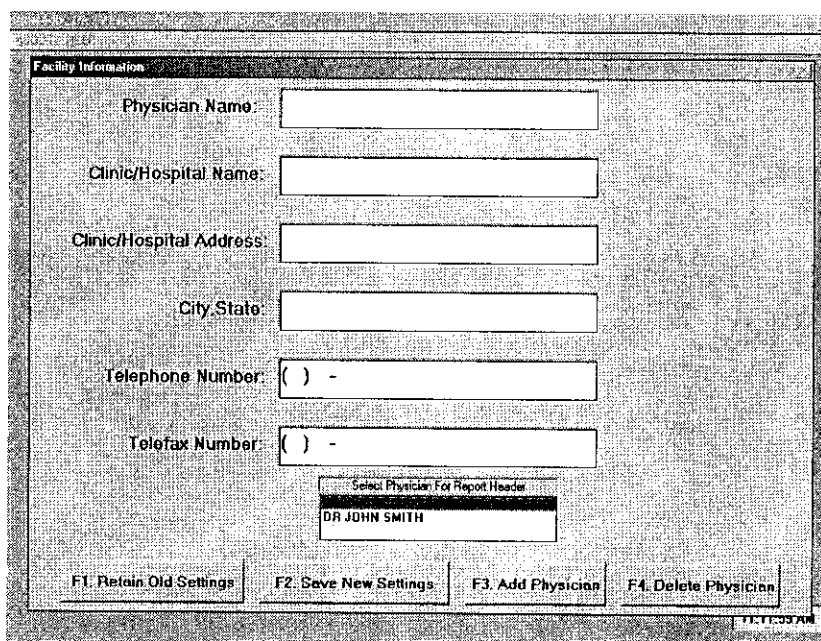
1. Add Patient 2. Edit Patient 3. Patient Test

4. Search 5. Delete 6. Exit

10:16:16 AM

The select Patient menu allows the user to perform several functions. To select a function double click on the field or type the number of the selection.

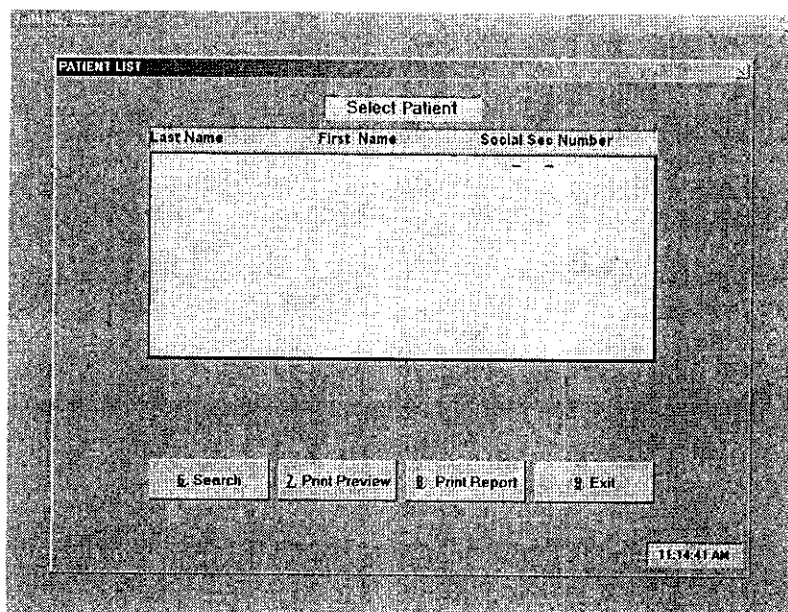
Software Start up Continued



The Facility Information screen contains several input fields for user data. At the bottom, there are four function key buttons: F1 Retain Old Settings, F2 Save New Settings, F3 Add Physician, and F4 Delete Physician. A timestamp in the bottom right corner reads 11:11:33 AM.

Physician Name:	
Clinic/Hospital Name:	
Clinic/Hospital Address:	
City/State:	
Telephone Number:	() -
Telefax Number:	() -
Select Physician For Report Header	
DR JOHN SMITH	
F1 Retain Old Settings F2 Save New Settings F3 Add Physician F4 Delete Physician	

Clinic Information- This selection will allow the user to insert clinic or site information in a Header that will appear at the top of printed pages. **This information only needs to be entered upon set up or if your Facility's information changes.** Type F1 to Exit and Retain old settings or F2 to Save New Settings.



The PATIENT LIST screen features a 'Select Patient' button at the top. Below it is a table with columns for Last Name, First Name, and Social Sec Number. The table area is currently empty. At the bottom, there are four buttons: 1 Search, 2 Print Preview, 3 Print Report, and 4 Exit. A timestamp in the bottom right corner reads 11:14:41 AM.

Select Patient		
Last Name	First Name	Social Sec Number
1 Search 2 Print Preview 3 Print Report 4 Exit		

Print Patient Record- This selection will allow the user to select a Patient Record for printing or preview. You may also search for a Patient using the search function.

Software Start up

Continued

Archive / Retrieve Record- This selection will allow the user to select a Patient Record to be archived to, or retrieved from a disk.

The screenshot shows a window titled "PATIENT LIST". Inside, there is a "Select Patient" button above a table with three columns: "Last Name", "First Name", and "Social Sec Number". The table is currently empty. Below the table is a "Target Drive:" label followed by a text input field containing "a:". At the bottom of the window are three buttons: "Archive Record", "Retrieve Record", and "Exit". A timestamp "11:14:54 AM" is visible in the bottom right corner.

Set Custom Protocol- This selection will allow the user to customize the Patient testing protocols in any format the user would choose to select.

The screenshot shows a window titled "Set Custom Protocol". It contains several dropdown menus: "SERIES" with "LOWER EXTREMITY ARTERIAL" selected, "MODE" with "PVR" selected, and "SITE" with "RIGHT UPPER THIGH" selected. Below these is a "Location Number" input field. A button "F5. Show Next Location" is present, along with a link "Click Here To Show The Mode/Location of the Next Test in the Protocol". The "Protocol Name" is set to "DEFAULT PROTOCOL". Below this is a "Protocol List" box containing "DEFAULT PROTOCOL". At the bottom are four buttons: "F1. Exit and Save", "F2. Add Protocol", "F3. Delete Protocol", and "F4. Save Location".

Software Start up Continued

The Default Protocol is pre set into the program. The user may choose to create a new protocol by clicking on **ADD PROTOCOL** or pressing the **F2** key. You should now type the name of the protocol into the name box. Select from the series drop down the series you would like to start with.

Set Custom Protocol

SERIES

LOWER EXTREMITY ARTERIAL

LOWER EXTREMITY ARTERIAL

LOWER EXTREMITY VENOUS

UPPER EXTREMITY ARTERIAL

UPPER EXTREMITY DIGIT

LOWER EXTREMITY DIGIT

CEREBROVASCULAR

UROLOGY

F9: Show Next Location

Click Here To Show The Mode/Location of the Next Test in the Protocol

Protocol Name: DEFAULT PROTOCOL

Protocol List

DEFAULT PROTOCOL

F1. Exit and Save F2. Add Protocol F3. Delete Protocol F4. Save Location

You can now select the mode of testing you would like to start with. Choose this from the mode drop down.

Set Custom Protocol

SERIES

LOWER EXTREMITY ARTERIAL

MODE

PVR

PVR

DOPPLER

SEG. PRESS.

POST EX. SEG. PRESS.

POST EX. PVR

POST PROCEDURE SEG. PRESS.

POST PROCEDURE PVR

Protocol Name: DEFAULT PROTOCOL

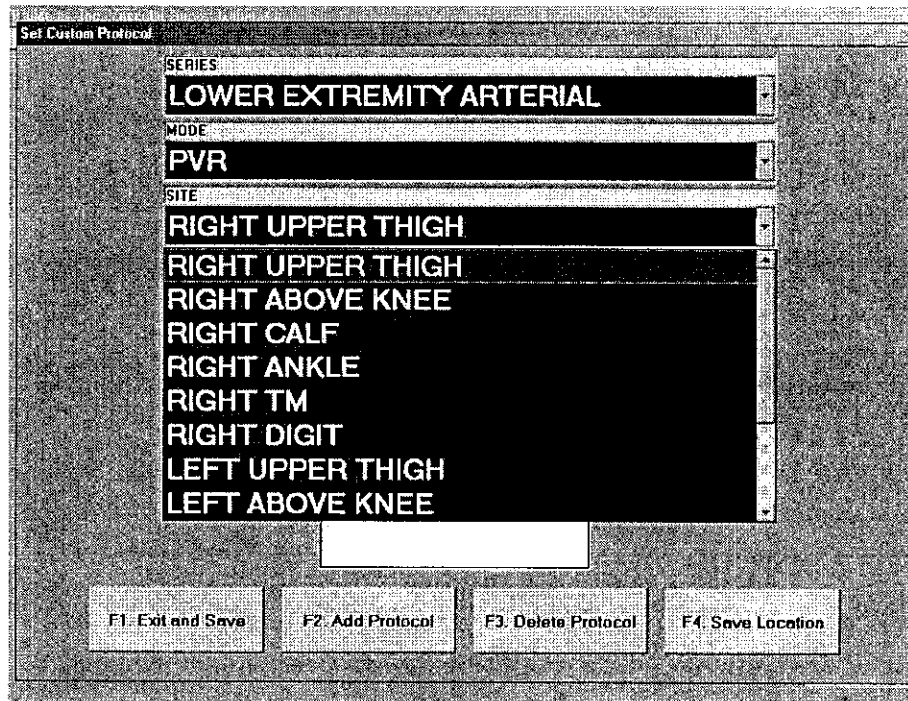
Protocol List

DEFAULT PROTOCOL

F1. Exit and Save F2. Add Protocol F3. Delete Protocol F4. Save Location

Software Start up Continued

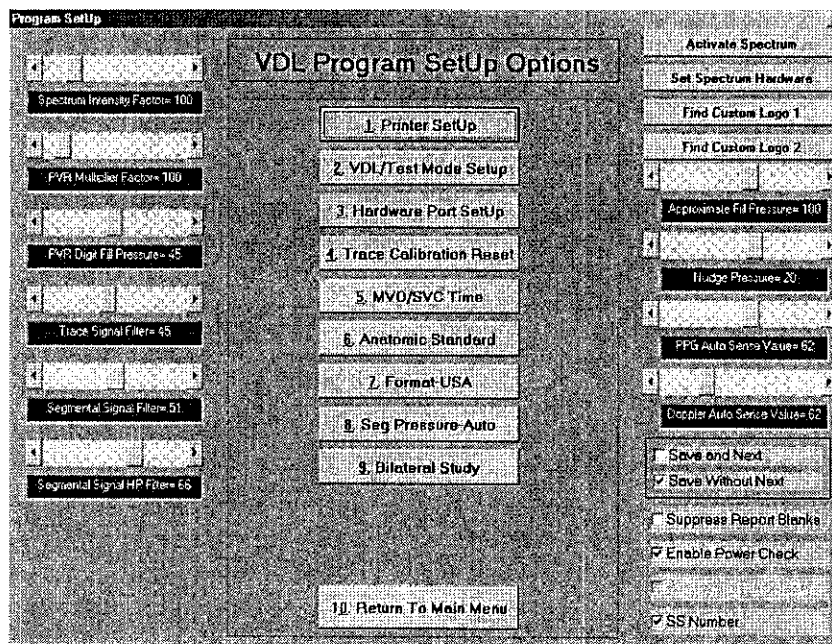
You can now choose the site to begin with from the site drop down menu.



After completing the selection of the series, mode and site to begin the custom protocol, you should click on save location. To complete the creation of your custom protocol, continue to make selections and click on save location after each selection. When you have created all the series, mode and site choices you want click on exit and save or **F1** and your newly created protocol will become the selected protocol used for patient testing. You may create numerous protocols. To change protocols simply double click on the protocol you desire from the list of saved protocols and exit.

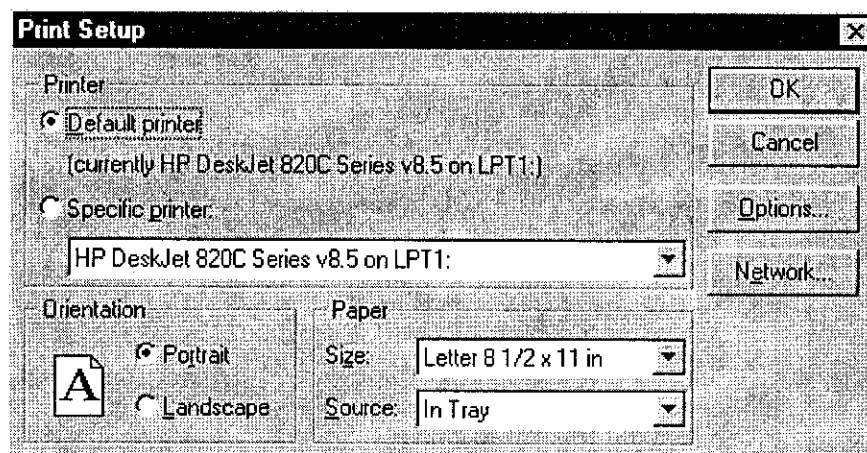
Software Start up Continued

Setup Program- This selection will allow the user to select functions used in the setup of the VDL.



The Program Setup menu allows the user to perform several functions. To select a function double click on the field or type the number of the selection.

1.Printer Setup- This selection will allow you to set up a printer. The software will default to the selected Printer in Windows unless an alternative printer is selected prior to printing.



Software Start up Continued

2.VDL Test Mode Setup- This selection will allow the user to change to the VDL Test Mode. This mode should only be used by authorized service personnel.

Program Setup

VDL Program Setup Options

1. Center Setup

2. **VDL Test Mode Setup**

3. Hardware Port Setup

4. Hardware Port Setup

5. MVR/VLC Time

6. Analogous Setup

7. Setup VDL

8. Setup Pressure Auto

9. Filter Setup

VDL Mode
Test Mode

10. Hardware Port Setup

Activate Spectrum

Set Spectrum Hardware

Find Custom Logo 1

Find Custom Logo 2

Approximate Filter Pressure=100

Hydro Pressure=20

PPG Auto Sense Value=62

Doppler Auto Sense Value=62

Save and Next

Save Without Next

Suppress Report Blanks

Enable Power Check

SS Number

3. Hardware Port Setup- This selection will allow the user to select the hardware port the VDL connects to. The default selection is pre-set. This setting should be retained unless a different device is using that port.

Program Setup

VDL Program Setup Options

1. Center Setup

2. VDL Test Mode Setup

3. **Hardware Port Setup**

4. Hardware Port Setup

5. MVR/VLC Time

6. Analogous Setup

7. Setup VDL

8. Setup Pressure Auto

9. Filter Setup

10. Hardware Port Setup

Activate Spectrum

Set Spectrum Hardware

Find Custom Logo 1

Find Custom Logo 2

Approximate Filter Pressure=100

Hydro Pressure=20

PPG Auto Sense Value=62

Doppler Auto Sense Value=62

Save and Next

Save Without Next

Suppress Report Blanks

Enable Power Check

SS Number

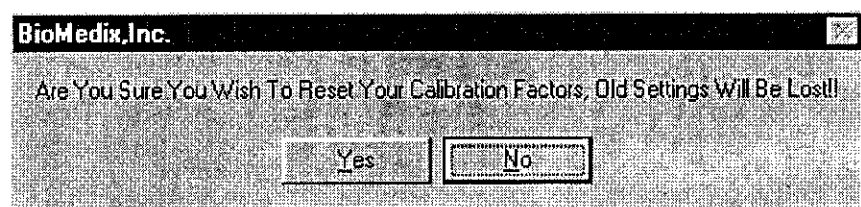
Port Address

Port One: 278

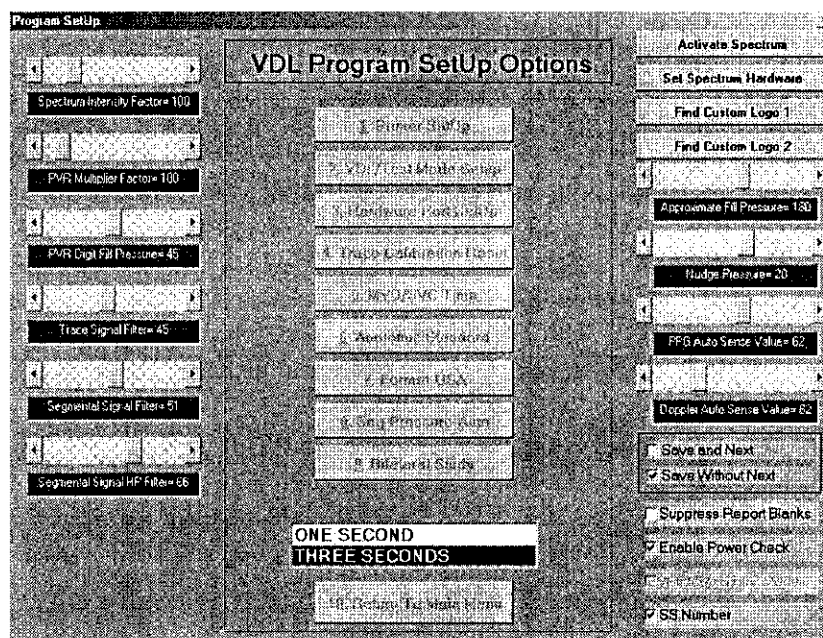
Port Two: 278

Software Start up Continued

4.Trace Calibration Reset- This selection will allow the user to re-calibrate the trace scrolling speed. The initial calibration is done the first time the waveform scrolling is started. This selection only needs to be done if there is a monitor change after the initial calibration.



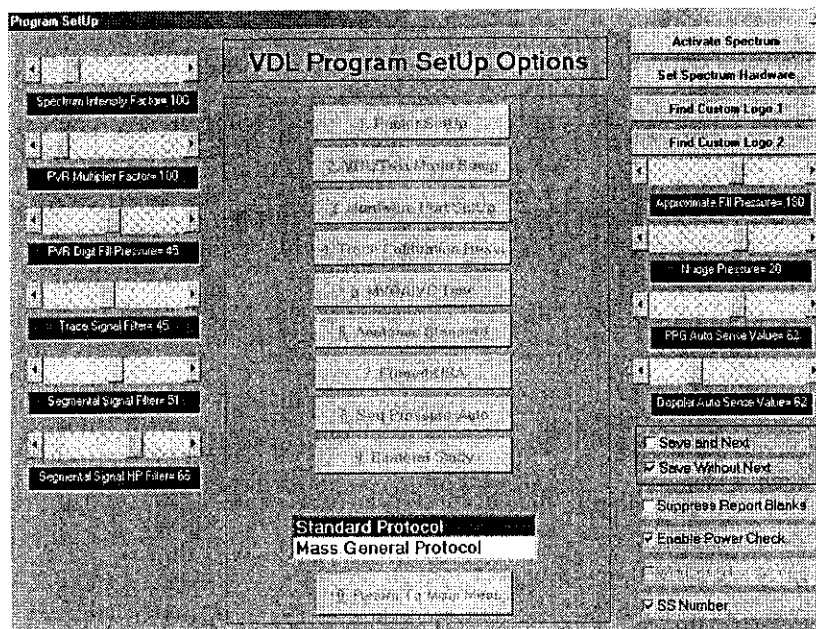
5.MVO/SVC Time- This selection will allow the user to select the MVO duration time for calculations. The standard is 1 second. The user may choose 3 seconds if that is the standard at their facility.



To change a selection, simply double click on the new selection.

Software Start up Continued

6. Anatomic Standard- This selection will allow the user to select anatomic location labels. The Standard protocol or the Mass General protocol. The Mass General protocol consists of only one thigh PVR and Pressure and a site called Popliteal Space.



The default selection is Standard Protocol. To change the selection, simply double click on the new selection.

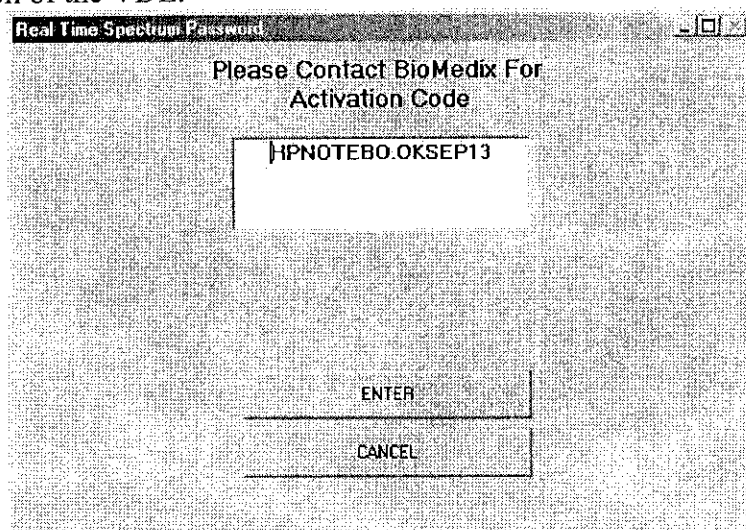
7.Format- USA- This selection will allow the user to select between US measurement standards and International measurement standards.

8.Segmental Pressure- Auto- This selection will allow the user to select between Auto sensing of segmental pressure return and Manual sensing of segmental pressure return.

9.Bilateral Study- This selection will allow the user to select between bilateral or unilateral testing mode.

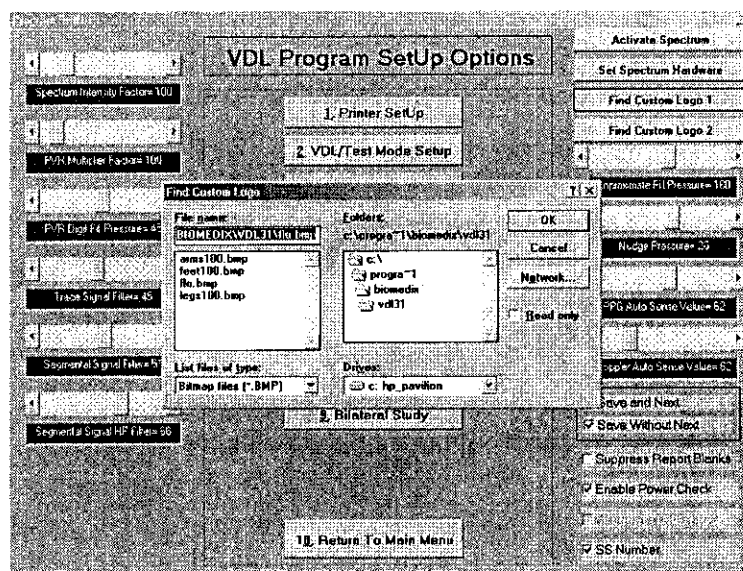
Software Start up Continued

Activate Spectrum- This selection will allow the user to activate the real-time spectrum frequency option of the VDL.



Set Spectrum Hardware- This selection will allow the software to control the functions of the sound card in the PC.

Find Custom Logo 1 and 2 – These selections will allow you to import logos into the patient demographics report pages.



Software Start up

Continued

Slide Adjustments

Approximate Fill Pressure- This will set the default fill pressure for the cuffs in the segmental pressure mode.

Nudge Pressure- This will set the additional pressure added to the cuff when the nudge function button is clicked during the segmental pressure mode.

PPG Auto Sense Value- This will adjust the sensitivity of the PPG sensing of return of signal in the segmental pressure mode.

Doppler Auto Sense Value- This will adjust the sensitivity of the Doppler sensing of return of signal in the segmental pressure mode.

Signal Filter- This will adjust the amount of filtering of the signal in the Doppler, PVR and PPG mode.

Check Boxes

Save and Next - This selection will set the program software so that when the operator clicks on the save button during patient testing the software will also move to the next location.

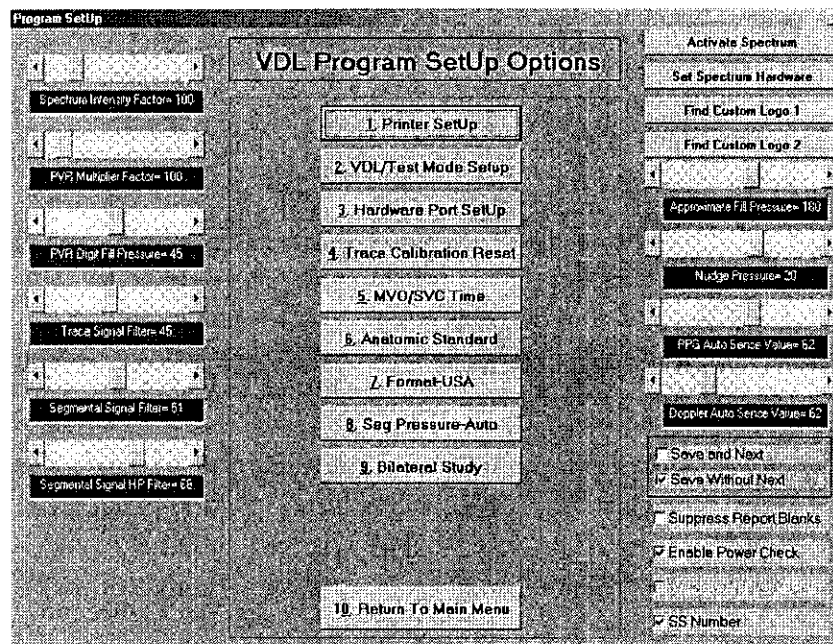
Save Without Next - This selection will set the program software so that when the operator clicks on the save button during patient testing the software save the acquired data but not move to the next location.

Suppress Report Blanks - This selection will prevent any non-answered entries in the patient demographics section from printing on the final report.

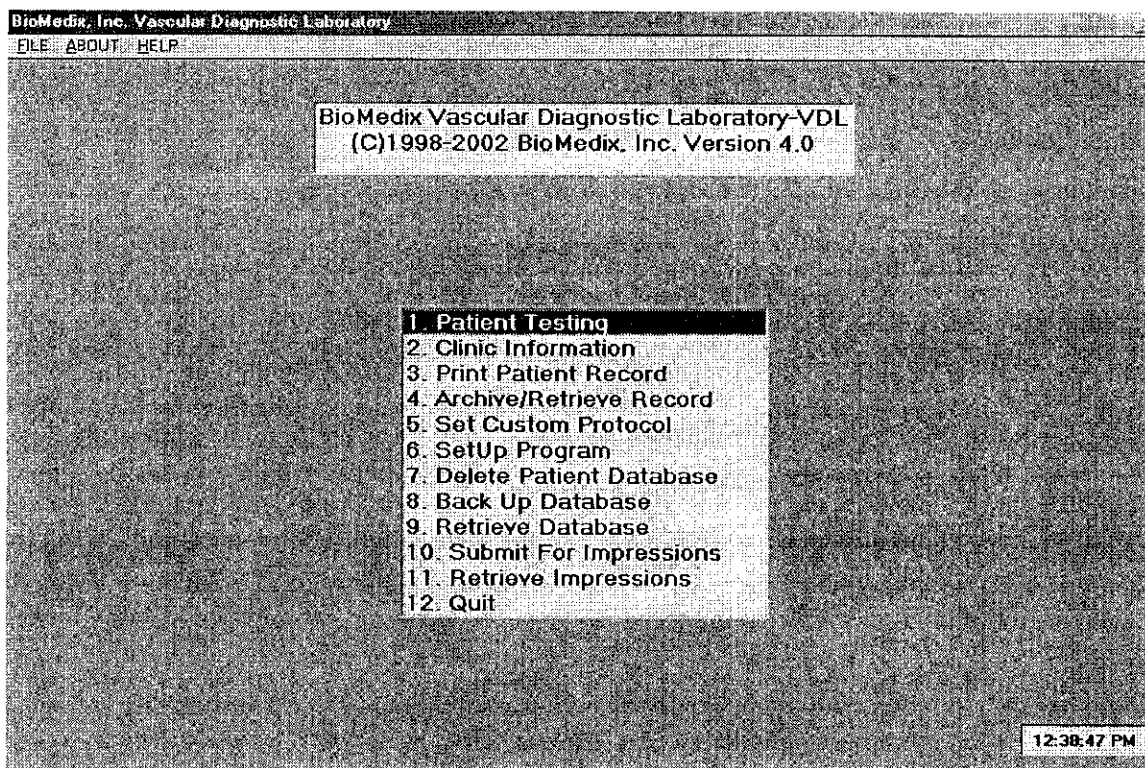
SS Number – Checking this box will identify which number will display in lists with the patient names. If unchecked the ID number will display and become mandatory if check the social security number will be required and display. If you do not use social security numbers at your facility, make sure this is unchecked.

Enable Power Check – This will enable to software to sense if the power to the VDL unit is on or if the IEEE cables are properly connected.

Software Start up Continued



10.Return to Main Menu- This selection will allow the user to return to the Main Menu after the Setup options have been entered. This selection will also save all changes made.



Software Start up Continued

7.Delete Patient Database- This selection will allow the user to delete the entire Patient Database. This function is password protected. A password will need to be established prior to completion of this function.  **Caution: This function will erase the entire Patient Database, you may be unable to retrieve the data after it is deleted.**

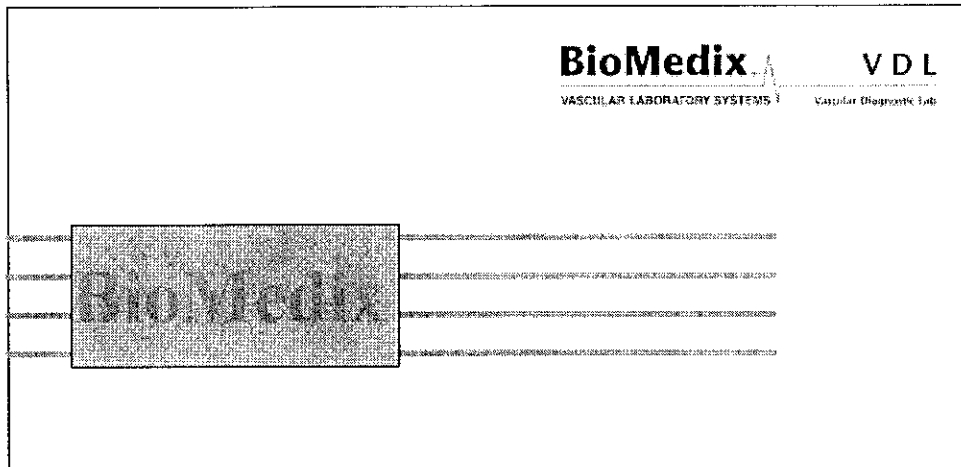
8.Back up Database- This function will allow the user to back up the entire Patient Database.

9. Retrieve Database- This function will allow you to retrieve the entire Patient Database.

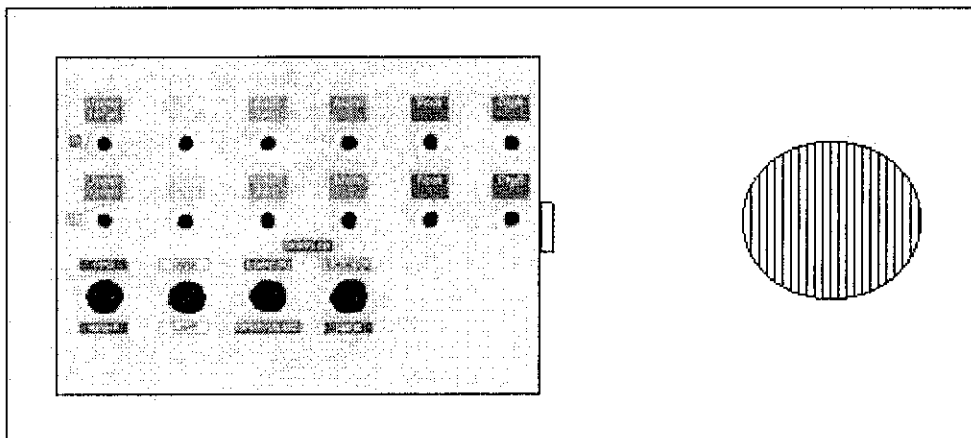
10.Quit- This function will allow the user to exit the VDL software program and return to the VDL start up screen.

Front Panel Layout

The Front Panel of the BioMedix VDL is as shown below.



Side Panel Layout and Description



Connectors

Cuff Connectors: The appropriate blood pressure cuff is connected to the VDL at this point. Insert the plastic connector on the cuff tube into the connector on the front panel. Twist it in a clockwise direction until it locks.

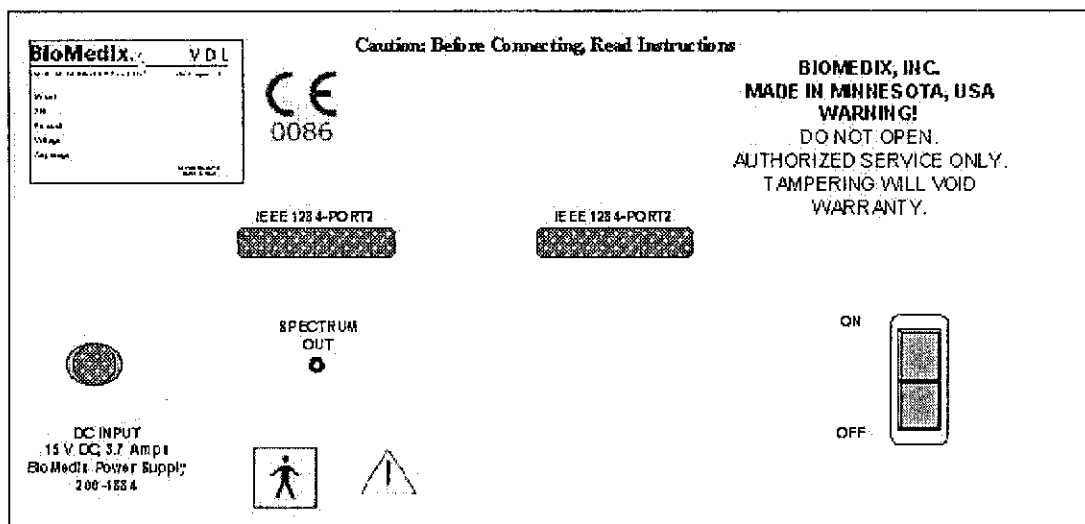
Doppler Probe Connectors: The Doppler probes are connected here by turning the connector on the probe until you can push and snap it into place. The probe is removed by pushing the button on top of the probe connector and gently yet firmly pulling the connector out of the socket.

Side Panel Layout and Description

Continued

PPG Probe Connector: Located on the lower right side of the front panel. The PPG (Photocell) probe is **connected here by turning the connector on the probe until you can push and snap it into place.** The probe is removed by pushing the button on top of the probe connector and gently yet firmly pulling the connector out of the socket.

Rear Panel Layout and Description



DC Input: The DC power supply is plugged in here. **Use only a factory-supplied power pack to run the VDL.**

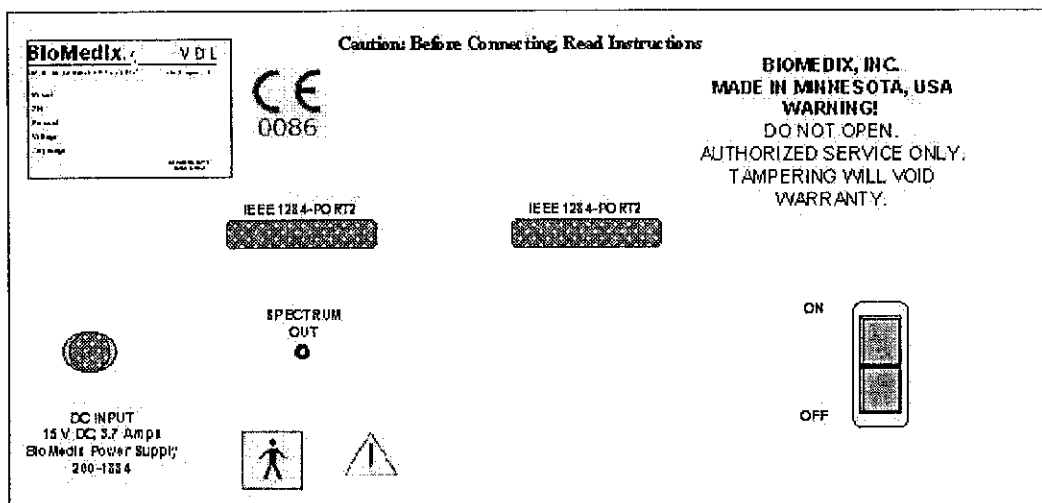
IEEE 1284 Cable Connectors: The IEEE 1284 cable connector is plugged in here. This is the **main data connection point** between your computer and the VDL.

Spectrum Out Connector: The spectrum cable connector is plugged in here.

Power On / Off Switch: This is the power on and off switch for the VDL unit.

The Unit Label: The serial number of the VDL unit is located on this label.

Rear Panel Hook-up



Power Pack Supply

The power pack is plugged into a **100-240 VAC, 47-63 Hz electrical outlet**. Connect the pack to the VDL by pushing the connector into the **DC input** jack. Any **electrical circuit problem or spikes** on your power system, **will trip, the breakers, shutting off the power pack**. The pack will automatically reset.

If the breaker trips again, **please unplug everything and call the factory immediately**.

IEEE 1284 Cable Connectors

The VDL comes with two IEEE 1284 serial connector cables. One end of the cable is **connected to the VDL at the IEEE 1284 cable connectors**. Push the cables **IEEE 1284 cable connectors** and screw the two cable clamps down. The **other end of the cable plugs into the computer**.

Spectrum Frequency Port

The VDL has Spectrum Frequency capability. The Spectrum Frequency connector cable **plugs into the Spectrum Frequency connector located on the back panel**. The other end of the cable plugs into the Line In jack of the sound card in the computer.

Now your BioMedix VDL is properly configured and you are ready to begin vascular testing.

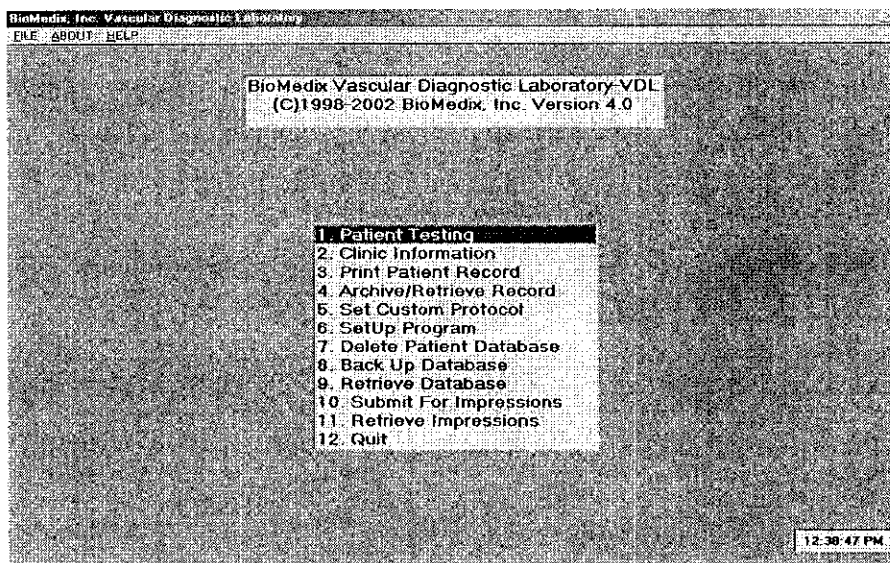
Components

Description	BioMedix Part Number
1- VDL Accessory Kit	500-310
2- PPG Probe (Photocell)	350-204
1- VDL Operators Manual	Bio 10800
2- Cuff Kit w/Straps	7200
1- Roll Double Stick Tape	200-1914
1- Acoustic Coupling Gel	200-1892
1- Spectrum Cable	100-1566
1- Headphone	200-1893
1- Desktop Computer	ACC-6
1- Monitor	ACC-4
1- Printer	ACC-2
1- Remote Wireless Mouse	350-218
1- Surge Protector	ACC-7
1- 8 MHz Doppler Probe – VDL	200-1885
1- BioMedix VDL CD Versior ^{(b) (4)}	400-300

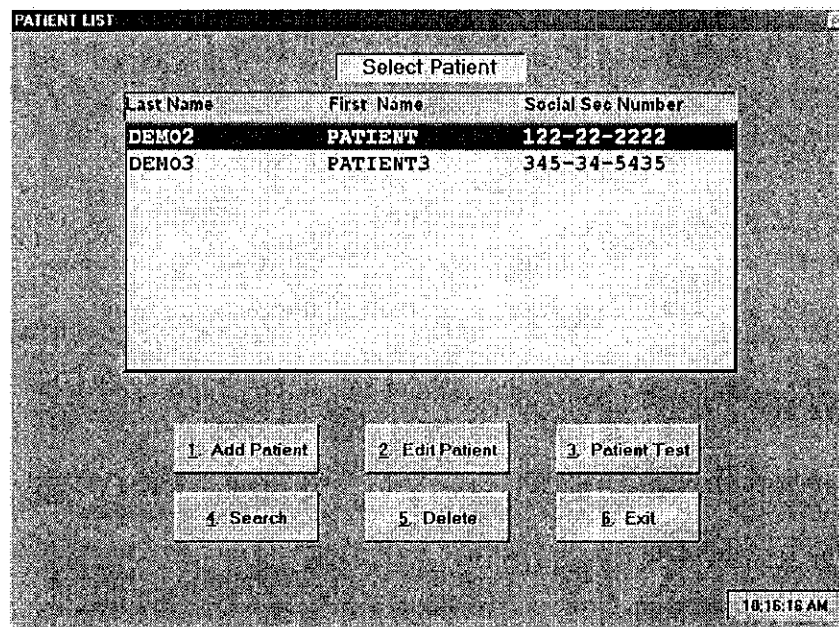
User should only use components approved by the Manufacturer

Patient Data Entry

From the VDL Main Menu double click on the Patient Testing Field or type 1.



This will bring you to the Select Patient Screen



From this screen you will have several options. You will see a Patient list mid-screen. This should be blank the first time you start the software. If you have completed some test, there will be a list of Patient names.

Patient Data Entry

Continued

PATIENT LIST

Select Patient

Last Name	First Name	Social Sec Number
DEMO2	PATIENT	122-22-2222
DEMO3	PATIENT3	345-34-5435

1. Add Patient 2. Edit Patient 3. Patient Test

4. Search 5. Delete 6. Exit

10:16:16 AM

The option buttons located below the Patient list will allow the user to choose different functions. To choose a function, click on the button or type the number.

Add Patient: This function will allow the user to enter data on a new Patient. Selecting this function will bring you to the Patient Demographics Screen.

PATIENT DEMOGRAPHIC INFORMATION

Last Name: Address:

First Name: City, State:

Patient I.D. Medication:

Referring Dr. Height: Ft In: Weight(lbs):

Attending Dr. Sex: Age:

Patient Location:

Date Of Birth: Soc Sec Number

F1-SAVE ENTRIES F2-ESCAPE F3-PREV CONDITIONS F4-IMPRESSIONS F5-SYMPTOMS F6-PHYSICAL SIGNS

Patient Data Entry

Continued

You may now enter the Patient information into the Patient record. Use the Enter key to move from field to field. You must enter the following fields; Name, **Date of Birth using a four-digit year ex: 1955** and Social Security Number.

After completing this screen, you may choose to add additional information by selecting one of the function buttons at the bottom of the screen.

Save Entries – This selection **will save** all the data you have entered on this Patient. You will return to the Select Patient screen. The new patient just entered will be at the bottom of the Patient list and will be highlighted. To begin Patient testing, click on the Patient Testing button.

Escape – This selection will exit the Patient Demographics screen **without** saving the data.

Prev Conditions – This selection will allow the user to enter additional data on the patient.

The screenshot shows a screen titled "DIAGNOSED CONDITIONS". It contains two columns of checkboxes for various medical conditions. The left column includes: Diabetes, Hypertension, Hyperlipidemia, Angina, Stroke/TIA, Heart Disease, Previous Vascular Intervention, and Previous Vascular Exam. The right column includes: Years (two instances), Family History, Syncope, Varicose Veins, and Bruit. At the bottom center, there is a button labeled "F1: TO PREVIOUS SCREEN".

Data may be entered into fields using Y or N for these entries. Certain fields will expand to additional fields if a Y is entered in those fields. Upon completion of this page, Press F1 to return to the Patient Demographics Screen.

Patient Data Entry

Continued

Impressions- This selection will allow the user to enter any additional comments or impressions.

To save all data entered on this screen and return to the Patient Demographics screen press F1.

IMPRESSIONS

This study is within normal limits. No abnormalities were noted in the PVR waveforms, Doppler waveforms or segmental pressures.

Interpreted By: Dr. Johnson

F1: TO PREVIOUS SCREEN

Symptoms- This selection will allow the User to enter additional data on the Patients.

CURRENT SYMPTOMS

Extremity Weakness: ☐	Ulceration: ☐	Rubor: ☐
Alcoholism: ☐	Limb Hair Loss: ☐	Gangrene: ☐
Headaches: ☐	Dizziness: ☐	Siasis Dermatitis: ☐
Edema: ☐	Vertigo: ☐	Trophic Nails: ☐
Obese: ☐	Cellulitis: ☐	Paresthesia: ☐

Risk Factors

Cigarette/Tobacco Use: ☐	Sedentary: ☐
Pack Years: ☐	

F1: TO PREVIOUS SCREEN

Patient Data Entry

Continued

Data may be entered into fields using Y or N for these entries. Press F1 to return to the Patient Demographics Screen.

Physical Signs- This selection will allow the User to enter additional data on the Patient.

PHYSICAL SIGNS AND SYMPTOMS		
	RIGHT	LEFT
Rest Pain:	☐	☐
Claudication	☐	☐
Swollen Ankle	☐	☐
Cold Foot	☐	☐
Phlebitis	☐	☐
Vein Problems	☐	☐
Pain Location		
	RIGHT	LEFT
Thigh/Buttock	☐	☐
Calf	☐	☐
Arch	☐	☐
Toe	☐	☐
Pain Relieved By:		
Rest	☐	☐
Exercise	☐	☐
Legs Elevated	☐	☐
Legs Down	☐	☐
F1. TO PREVIOUS SCREEN		

Data may be entered into fields using Y or N for these entries. Press F1 to return to the Patient Demographics Screen.

PATIENT DEMOGRAPHIC INFORMATION					
Last Name:			Address:		
First Name:			City, State:		
Patient I.D.			Medication:		
Referring Dr.			Height:	F1	In:
Attending Dr.			Weight(lb):		
Patient Location:			Sex:		Age:
Date Of Birth:			Soc Sec Number		
F1-SAVE ENTRIES F2-ESCAPE F3-PREV CONDITIONS F4-IMPRESSIONS F5-SYMPTOMS F6-PHYSICAL SIGNS					

Patient Data Entry

Continued

You should at this point click on F1 to save all the data entered on the new Patient. This will return you to the Select Patient Screen.

The screenshot shows a window titled "PATIENT LIST". At the top center is a button labeled "Select Patient". Below it is a table with three columns: "Last Name", "First Name", and "Social Sec Number". The table contains two rows of data:

Last Name	First Name	Social Sec Number
DEMO2	PATIENT	122-22-2222
DEMO3	PATIENT3	345-34-5435

Below the table are six buttons arranged in two rows of three:

- 1. Add Patient
- 2. Edit Patient
- 3. Patient Test
- 4. Search
- 5. Delete
- 6. Exit

In the bottom right corner, there is a timestamp: 10:16:16 AM.

Edit Patient- This selection will allow the user to edit data on a Patient. The Patient Demographic screen will appear and any changes can be entered.

Patient Test- This selection will allow the user to enter the Patient-testing screen. All Patient testing is done from this screen.

Search- This selection will allow the user to search for Patient Records. Searching may be done by any of several fields.

Delete- This selection will allow the user to delete Patient Records. This function is password protected. A password will need to be created upon the first use. This password should be recorded and placed in a safe place. If your password is lost or forgotten please call the technical support staff for assistance.

Exit- This selection will return the user to the VDL Main Menu.

Patient Testing

All Patient testing is done from the Patient Test Screen. This selection is made from the Select Patient Menu. Make sure the Patient you wish to test is highlighted in the Patient List. Click on the Patient Test Button or Type 3.

Last Name	First Name	Social Sec Number
DEMO2	PATIENT	122-22-2222
DEMO3	PATIENT3	345-34-5435

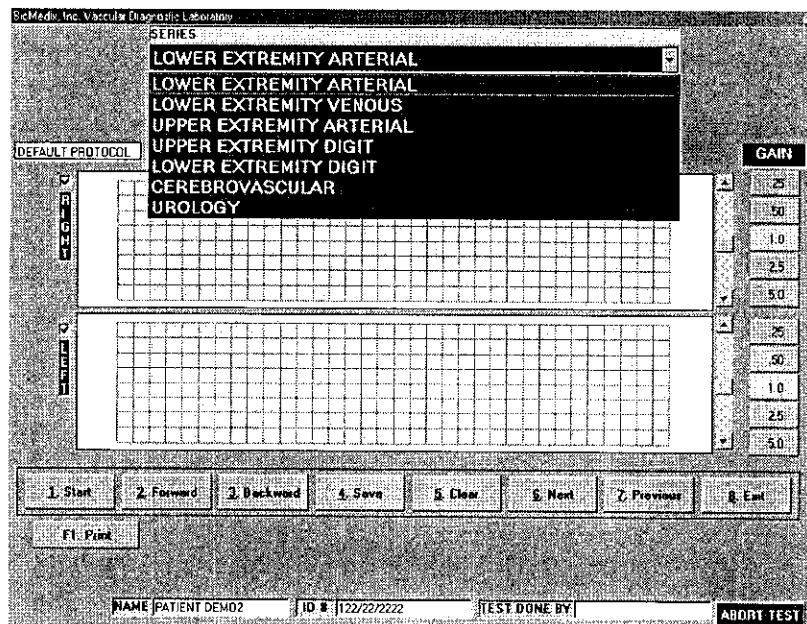
This selection will bring you to the Patient Test Screen.

Patient Testing

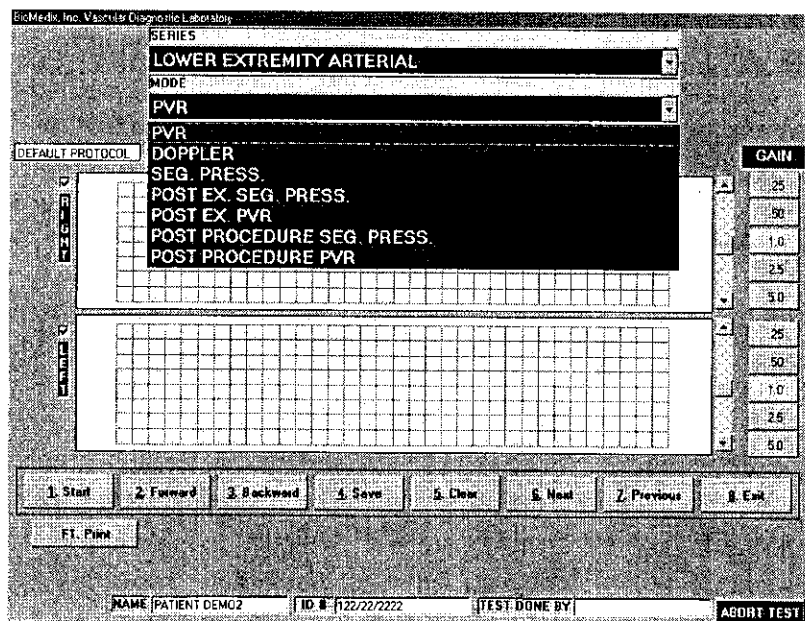
Continued

You will see three fields located at the top of the screen labeled **Series**, **Mode** and **Site**.

Series- This selection will allow the user to choose the type of Vascular Exam to be performed. To change the Series selection click on the arrow located on the right side of the field. A list of options will appear. Click on the type of test you wish to perform.

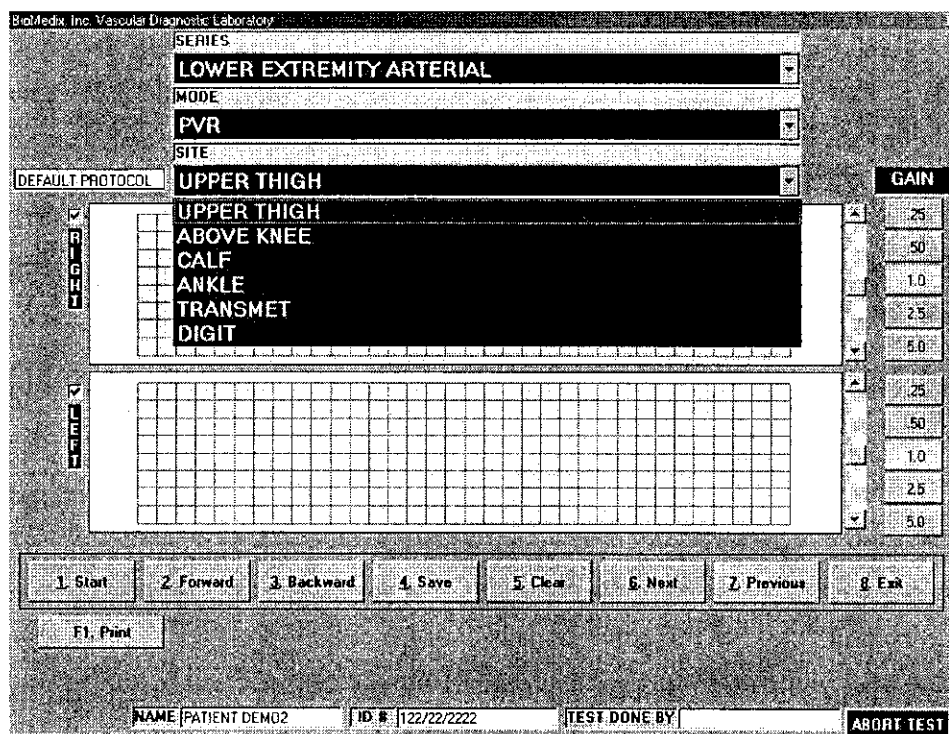


Mode- This selection will allow the user to choose the mode of testing they would like to perform. To change the Mode selection click on the arrow located on the right side of the field. A list of options will appear. Click on the mode of testing you wish to perform.



Patient Testing Continued

Site- This selection will allow the user to choose the site of testing they would like to perform. To change the Site selection click on the arrow located on the right side of the field. A list of options will appear. Click on the Site of testing you wish to perform.



Located on the right side of the screen are the **Gain Control Buttons**. The default **Gain setting is 1**. To change the Gain setting click on the setting button you wish to change to. You may also, press the **G** key on the keyboard and the gain will cycle through the settings. **Gain settings may be changed during or after waveform acquisition.**

Located to the right of the waveform graph is the **Trace position control**. To change the trace position on the waveform graph, simply position the scroll bar using the up or down arrows. **Trace position may be changed during or after waveform acquisition.**

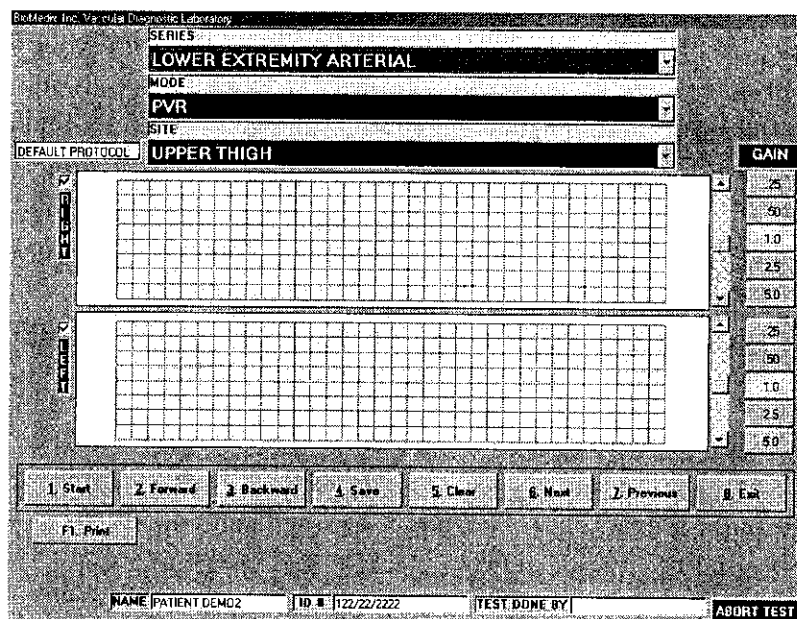
Located to the left of the waveform graph is the **Signal Strength Indicator**. This bar will fluctuate during testing.

Located below the waveform graph are the **Function Control Buttons**. These buttons are described below.

Start- This button will begin the testing function or start the waveform scrolling across the waveform graph. When the waveforms start to scroll across the graph this button will change to **STOP**. To stop waveform scrolling, click on this button. The operator may click on this button or type the **1** key on the keyboard.

Patient Testing

Continued



Forward- This button is used to scroll a stopped waveform forward. The operator may click on this button or type and hold the 2 key on the keyboard.

Backward- This button is used to scroll a stopped waveform backward. The operator may click on this button or type and hold the 3 key on the keyboard.

Save- This button is used to **save a stored waveform into the patient record**. Once the waveform is stored a list of stored waveforms will be seen below the function buttons. The operator may click on this button or type the 4 key on the keyboard.

Clear- This button is used to **clear the waveform graph of a stopped or saved waveform**. Please, be sure you really want to clear a waveform before using this function. The operator may click on this button or type the 5 key on the keyboard.

Next- This button is used to **advance to the next testing location**. The operator may click on this button or type the 6 key on the keyboard.

Exit- This button is used to **exit from the Patient Testing screen** and return to the Select Patient Screen.

Print- This button is used to exit from the Patient testing screen and **go to the print patient records screen**.

Abort Test- This button is used to **dump any air volume from any cuff attached to the VDL unit**.

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Patient Testing

Continued

Print Menu - This button may be used upon completion of patient testing to go directly to the print patient record functions without having to go back to the main menu first.

Physical Exam - This button will display a screen that will allow you to enter patient pulse and Bruit information as shown below.

The screenshot shows a window titled "Physical Exam". Inside, there are three sections for data entry:

- Pulses-0, 1, 2, 3**: A table with columns for "Femoral", "Popliteal", "Dor Pedis", and "Post Tibial". Each column has two rows for "Right" and "Left", each with an empty checkbox.
- Breathals**: A table with columns for "Radial" and "Ulnar". Each column has two rows for "Right" and "Left", each with an empty checkbox.
- Bruit-Y, N**: A table with columns for "Carotid" and "Femoral". Each column has two rows for "Right" and "Left", each with an empty checkbox.

At the bottom of the form is a button labeled "FL TO PREVIOUS SCREEN".

Test Done By - This field is a place for the operator to enter their name or initials to indicate whom acutely preformed the patient test.

Protocol Setting - This box will display which protocol has been selected, default or a customized protocol.

Lower Extremity Arterial Testing

The screenshot shows the BotMedix Vascular Diagnostic Laboratory software interface. At the top, the title bar reads "BotMedix, Inc. Vascular Diagnostic Laboratory". The main window has a menu bar with "SERIES", "MODE", "SITE", and "DEFAULT PROTOCOL". Below the menu bar, the "SERIES" dropdown is set to "LOWER EXTREMITY ARTERIAL", "MODE" is set to "PVR", and "SITE" is set to "UPPER THIGH". The "DEFAULT PROTOCOL" dropdown is also set to "UPPER THIGH". To the right of the main window is a "GAIN" control with a vertical slider and numerical values: 25, 50, 1.0, 2.5, and 5.0. The main window contains two large grid areas for data recording. Below the grids is a row of buttons: "1. Start", "2. Forward", "3. Backward", "4. Save", "5. Clear", "6. Next", "7. Previous", and "8. Exit". Below these buttons is a button labeled "F1. Print". At the bottom of the window, there is a status bar with fields for "NAME" (PATIENT DEMO2), "ID # 122/22/2222", "TEST DONE BY", and an "ABORT TEST" button.

The PVR measures the change in pressure of an inflated blood pressure cuff in order to gauge blood volume changes. It studies volume changes in a limb segment rather than an individual blood vessel.

Arterial studies may be performed with the PVR on Lower extremities (including the digits), the upper extremities, the toes and the Penis with the appropriate cuff. Included in the VDL package are cuffs for each purpose.

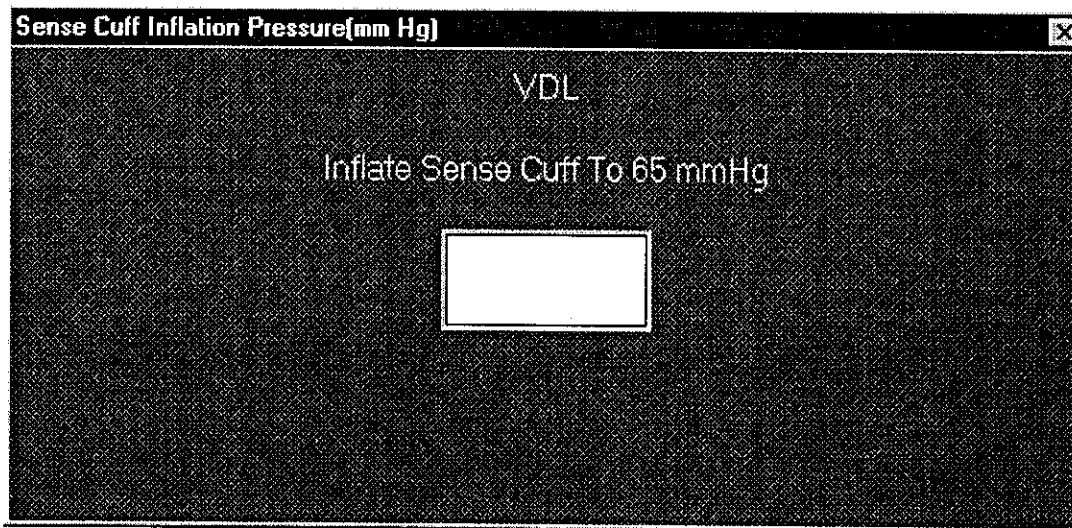
 **Caution: Please verify anatomical location prior to recording any Patient data!**

PVR Data

1. Position the Patient for examination.
2. **Select Mode of testing.** The default is PVR.
3. **Select Site of testing.** The default location is Upper Thigh.
4. Apply cuffs to the Patient.
5. Connect cuffs to cuff connectors on the right side panel of the VDL as follows: Upper Thigh to Port 1, Above knee to Port 2, Calf to Port 3, Ankle to Port 4, Transmetatarsal to Port 5 and Digit to Port 6.
6. Click on **Start** or type 1 on the keyboard. The following screen will appear:

Lower Extremity Arterial Testing

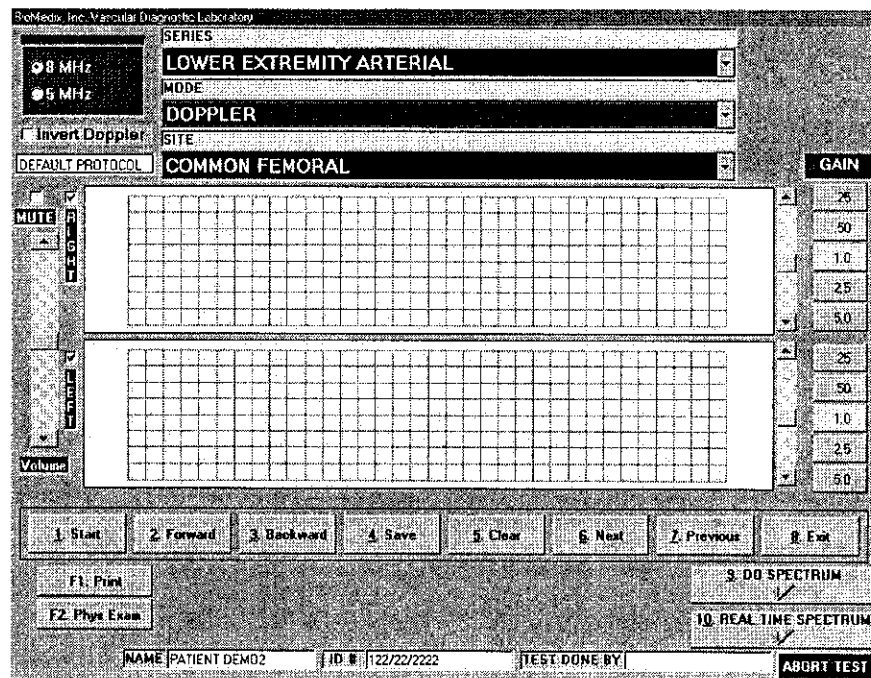
Continued



7. Waveforms will start to scroll across the waveform graph. **When the waveforms fill the graph click on STOP or type 1.**
8. You may now edit the waveforms prior to saving them. Position may be change by scrolling the waveform. Waveform size may be changed by the gain selection.
9. You may obtain the PVR amplitude measurement by using the pointer and clicking on the base then the peak of the PVR waveform. This measurement will be shown to the left of the waveform graph and recorded on the waveform print out page.
10. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
11. When the waveform is edited, **remember the left half of the waveform graph is what is saved for the report**, click on **Save** or type 4.
12. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**.
13. Continue to obtain all required PVR data this way.
14. As PVR testing data is saved a list of saved locations will appear in the lower center of the screen below the function buttons.

Lower Extremity Arterial Testing

Continued



⚠ Warning Doppler Ultrasound: Not for Fetal or Ophthalmic use.
Never perform a Doppler study on the eye in the Doppler mode. Use only the Ophthalmic 8.0 MHz mode for this purpose.

A Doppler device emits a stream of Ultrasound, of a particular frequency, and directs it, via a probe, toward a blood vessel. The Ultrasound is reflected off moving red blood cells, and returns to the probe. The frequency of the reflected Ultrasound changes in direct proportion to the blood velocity according to the Doppler effect. The different frequency of Ultrasound is conveyed to an amplifier and speaker so one can hear the flow.

Arterial sound is a strong pulsatile sound.

Venous sound is a soft blowing sound.

In addition to the audio output, Doppler output is also conveyed to your monitor and displayed. The waveform display is Proportional to blood velocity.

Different frequencies of Ultrasound are used for examining vessels at different depths in the body. High frequency is used to look at superficial vessels. An 8 MHz probe is recommended for this use. Low frequency Ultrasound is used to look at deeper vessels. A 5 MHz probe is recommended for this use. An important feature of a Doppler is its ability

Lower Extremity Arterial Testing

Continued

to sense the direction as well as the magnitude of blood velocity. The ability to sense retrograde or negative blood flow can be very important for diagnosis of certain pathological conditions.

Note: Never hold the probe on the body longer than is necessary. While ultrasound is very safe, any device which produces energy, should be used with caution and for as short a time as possible.

Hints for Doppler use

Hold the probe at about a 45° angle with respect to the area of interest.

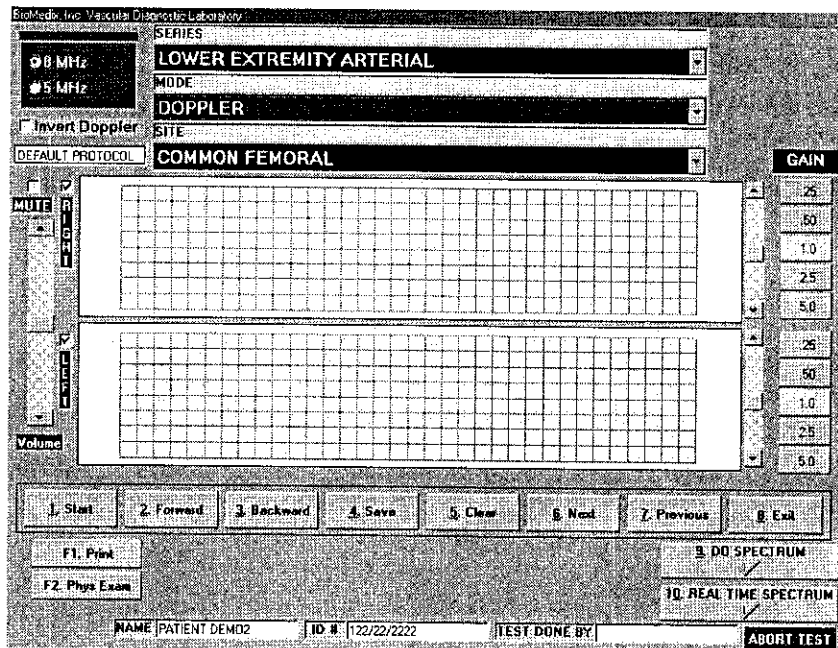
Put the acoustic coupling gel on the skin not on the probe itself, otherwise excessive noise will result.

Hold the probe like a pencil.

Do not press too hard.

Lower Extremity Arterial Testing

Continued



 **Caution:** Please verify anatomical location prior to recording any Patient data!

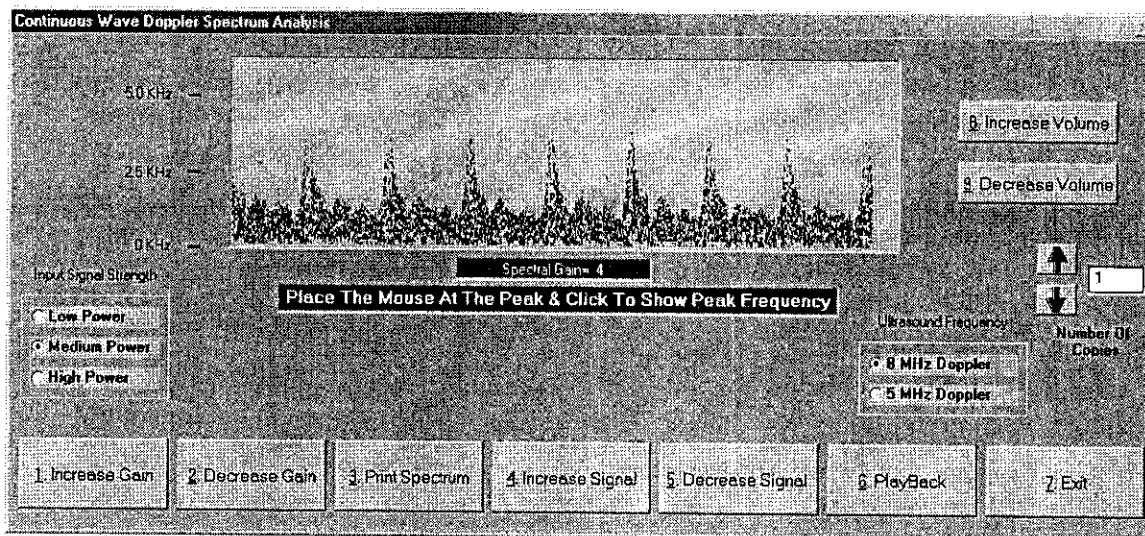
Doppler Waveforms

1. Position the Patient for Examination.
2. **Select Mode of testing.** The default is **Doppler**.
3. **Select site of testing.** The default is **Right Common Femoral**.
4. Apply acoustic gel to site of examination.
5. **Acquire audio Doppler signal** on site of choice. **Click on Start** or type 1.
6. Waveforms will start to scroll across the graph. **When the waveforms fill the graph Click on Stop** or type 1.
7. You may now **edit the waveforms** prior to saving them. Position may be change by scrolling the waveform. Waveform size may be changed by the gain selection.
8. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
9. When the waveform is edited, **remember the left half of the waveform graph is what is saved for the report**, click on the **Save button** or type 4.
10. The operator may now **move to the next location** for testing by clicking on the **Next button** or by **selecting it from the Site Window**.
11. Continue to obtain all required Doppler data this way.
12. As Doppler-testing data is saved **a list of saved locations will appear in the lower center of the screen** below the function buttons.

Lower Extremity Arterial Testing

Continued

13. The user may also choose to **do Spectrum Analysis** on any Doppler signal saved. This function is selected by clicking on **Due Spectrum** button or by typing **8** on the keyboard. The following screen will appear.



This screen will allow the user to edit and print the spectrum data from the Doppler waveform. This spectral signal is post processed from the Doppler waveform. This allows for editing the signal power levels, Signal levels and gain settings. **A unique feature is the Audio playback. This will allow the user to playback the Doppler audio after storing for review at a latter time.**

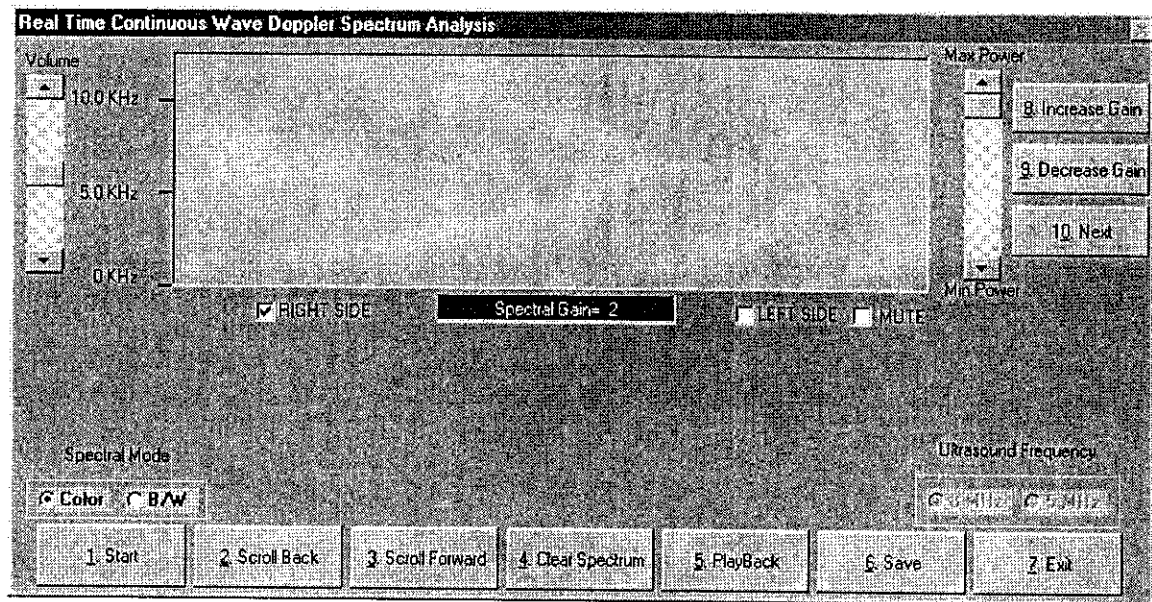
To create your measurements simply click on the peak of a waveform to measure the peak systolic velocity/Frequency and click on the lowest portion at the end of the same waveform to measure the end diastolic velocity/frequency.

In this version of software you will now be able to perform, Real Time Spectrum instead of just post processed. This provides you the ability to really see what you are collecting while you are collecting the data. Playback of the saved data can still be performed.

If you select Real Time Spectrum, you will see the following screen.

Lower Extremity Arterial Testing

Continued



The controls are similar to the Doppler trace screen but details of each follow.

Start – The start button will begin the data scrolling live from left to right in the window. This will change to Stop once the data has begun scrolling. You may begin the data acquisition by clicking the **Start** button or type **1**. To stop the data acquisitions click the **Stop** button or type **1**.

Scroll Back – This button will allow you to scroll the spectral data back in time to allow capture of the exact data desired. To select function click the **Scroll Back** button or type **2**.

Scroll Forward – This selection will allow the movement of the spectral data forward in time again allowing the correct selection of data. To select function click the **Scroll Forward** button or type **3**.

Clear Spectrum – This function will clear all captured data so the acquisition can be repeated. Be sure you really want to obtain new data prior to clicking this function. To select this function click the **Clear Spectrum** button or type **4**.

Playback – This function will playback the data just collected. To select this function click the **Playback** button or type **5**.

Lower Extremity Arterial Testing Continued

Save – This function will save the spectral data for this location. To save the data click the **Save** button or type 6.

Exit – This function will exit from the Real time spectrum and return you to the testing menu. To select this function click on the **Exit** button or type 7.

This Real Time Spectrum screen has some additional controls, which will be described.

There are two sets of radio button selections. The one on the left center of the screen allows change of the spectral data to be changed from Color, which is our default to black and white. Simply click on the option desired will change the display. The radio button set located at the right center of the screen will allow selection of the proper Doppler frequency. The options are either 8MHz or 5MHz. To select click on the desired frequency.

To the right and left of the data window are scroll bars. The one on the left is to increase or decrease the volume you are hearing and the one to the right is to increase or decrease the power level of the Doppler. Scrolling either will effect the change.

There are three additional functions available on this screen and they are located on the upper right side of the data window. Explanations of them follow.

Increase Gain – This will increase the gain or sensitivity of the Doppler. This can be selected by clicking on the **Increase Gain** button or typing 8.

Decrease Gain – This will decrease the gain of the Doppler. This can be selected by clicking on the **Decrease Gain** button or typing 9.

Next – This function will move to the next location in the list of vessels once you have saved the data on the current vessel. To select this function click on the **Next** button or type 0.

To perform measurements on the spectral data simply click on the peak of the waveform to be measured and the data will be seen below the spectral data screen as seen in the post processed section above.

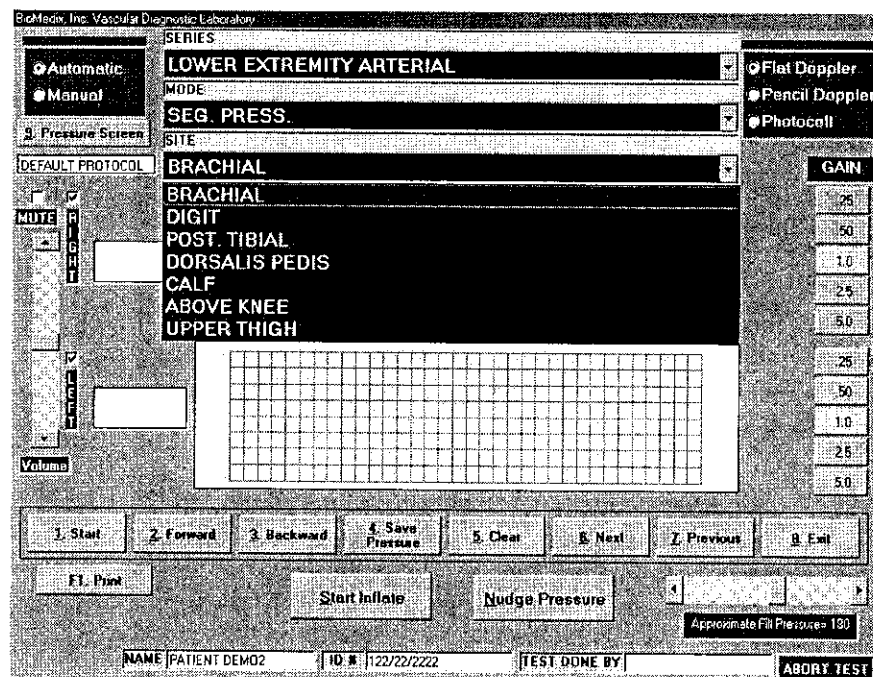
Rise time can also be measured with the real time spectrum by clicking the beginning of the waveform or end of the previous waveform and then the peak of the waveform being measured. Post processing of this data can also be performed as is done with all data collected from Doppler's with this system.

Lower Extremity Arterial Testing

Continued

Segmental Pressure

The systolic pressure in the limb segments can be evaluated with the Doppler system. It is much like taking a brachial pressure. The Doppler probe replaces the stethoscope allowing the disappearance and return of flow to be heard. These pressures and the resulting Segmental Brachial Indices (SBI) are of crucial diagnostic value.



⚠ **Caution: Please verify anatomical location prior to recording any Patient data!**

Segmental Pressure

1. Position the Patient for Examination.
2. **Select Mode of testing.** The default is **Segmental Pressure**.
3. **Select site of testing.** The default is **Brachial**.
4. Apply acoustic gel to site of examination.
5. Apply cuffs on sites to be examined.
6. Connect cuffs to cuff ports on plate on right side of VDL.
7. **Acquire audio Doppler signal** on site of choice. **Click on Start** or type 1. The Doppler waveform will scroll across the graph.
8. **Inflate** the cuff using the start button. all arterial audio **signal should be obliterated**.
9. The pressure in the cuff will start to bleed off.

Continued

10. When return of **flow is heard** click on **Stop** or **type 1**. If the auto sensing is used when the computer senses the return of flow a cursor will appear on the graph showing the waveform sensed. To select a different waveform, simply click on that waveform and the pressure will be adjusted.
11. The operator should then click on the **Save Pressure button** or **type 9** on the keyboard.
12. If the operator would like to **edit the pressures**, click on the **Show Pressure Button** or **type 8** on the keyboard. The following screen will appear.

Lower Extremity Arterial Segmental Pressure Screen

Segmental Pressure Values (in mmHg.)

Right Brachial		Left Brachial	
Right Digit		Left Digit	
Right Ankle (Post Tibial)		Left Ankle (Post Tibial)	
Right Ankle (Dors Pedis)		Left Ankle (Dors Pedis)	
Right Calf		Left Calf	
Right Above Knee		Left Above Knee	
Right Upper Thigh		Left Upper Thigh	
Right ABI	N/A	Left ABI	N/A

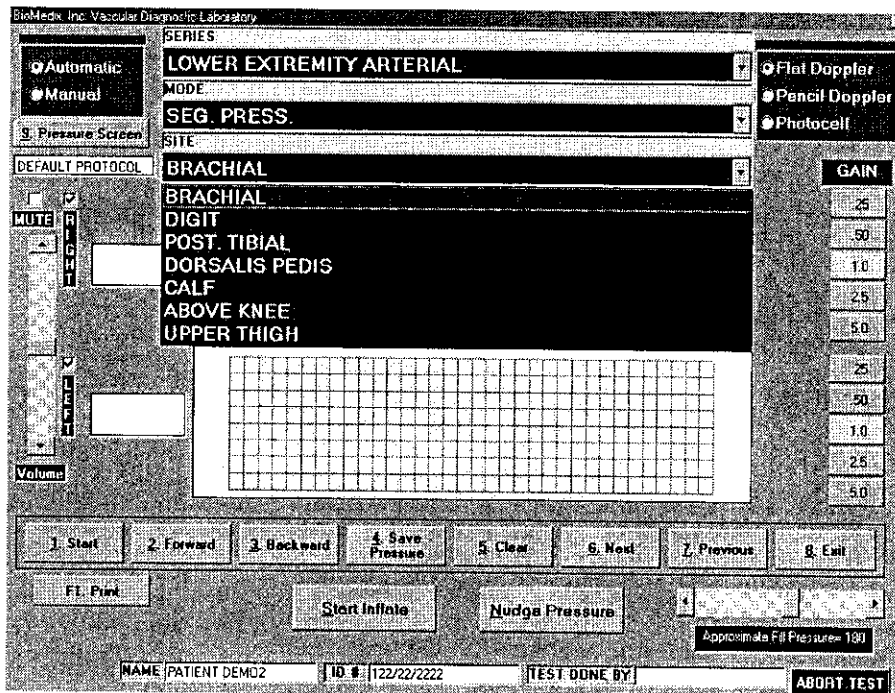
Post. Tibial/Dorsalis Pedis Doppler Assessment

☒ Use Post Tibial For ABI Values ☐ Use Post Tibial For ABI Values

☐ Use Dor Pedis For ABI Values ☐ Use Dor Pedis For ABI Values

F1 Save Pressure Values

13. The user may now enter or edit pressures using enter to move from field to field.
14. The operator should select the vessel to be used to calculate the ABI values by clicking in the box in front of the selected vessel.
15. The user may also enter comments about the selected vessel in the comment area. These comments will be saved and recorded on the graphics page above the brachial pressures.
16. To return to the Patient Testing Screen, click on the Save Pressure Values button or type F1 on the keyboard.



17. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
18. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**.
19. Continue to obtain all required Pressure data this way.
20. Please review all Pressure data prior to exiting.

The ratio of the Segmental Systolic Pressure to the Brachial Systolic Pressure is defined as the Segmental Brachial Index (SBI).

.97 to 1.25	=	Normal
.70 to .96	=	Mild Stenosis
.50 to .69	=	Moderate Stenosis, Claudication
.30 to .49	=	Severe Stenosis, Rest Pain, Single Site Occlusion
.29 or less	=	Gangrene, Probable Multiple Site Occlusion

Lower Extremity Arterial Testing

Continued

Toe Studies

Toe/Brachial Index

Normal = .75 and Greater

Abnormal = Less than .75

Penile Studies

Penile/Brachial Index

.75 and Greater

Less than .75

Finger Studies

Finger/Brachial Index

Normal = .8 and Greater

Abnormal = Less than .8

Difference in Pressure (dP) Between Fingers

Less than 15

Greater than 15

Pressure Interpretation Guidelines

Difference in pressure (dP)

Arms: Segmentally and bilaterally not more than 10

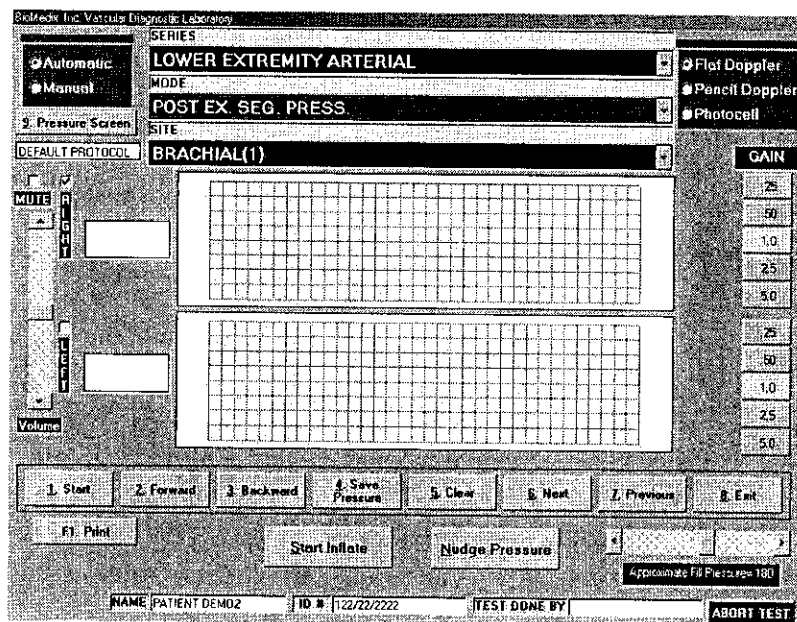
Fingers: Not more than 15

Legs: Segmentally not more than 30 mm/Hg
Bilaterally not more than 15 mm/Hg

Toes: Not more than 15 mm/Hg

Lower Extremity Arterial Testing

Continued



⚠ **Caution: Please verify anatomical location prior to recording any Patient data!**

Post Ex. Segmental Pressure

1. Prepare Patient following institutional guidelines on exercise.
2. Perform Post Exercise Pressure testing like any other pressure measurement.
3. The Operator may store up to five sets of post exercise pressure data.
4. Please review all pressure values prior to exiting the program.

Lower Extremity Arterial Testing

Continued

Bioscience, Inc. Vascular Diagnostic Laboratory

SERIES: LOWER EXTREMITY ARTERIAL

MODE: POST EX. PVR

SITE: ANKLE(1)

DEFAULT PROTOCOL: ANKLE(1)

GAIN: 0.25, 0.50, 1.0, 2.5, 5.0

1. Start 2. Forward 3. Backward 4. Save 5. Clear 6. Next 7. Previous 8. Exit

F1. Print F2. Exit Routine

NAME: PATIENT DEMO2 ID #: 122/22/2222 TEST DONE BY: ABORT TEST

 **Caution: Please verify anatomical location prior to recording any Patient data!**

Post. Ex. PVR

1. Prepare Patient following institutional guidelines on exercise.
2. Perform Post Exercise PVR testing like any other PVR measurement.
3. The Operator may store up to five sets of post exercise pressure data.
4. Please review all waveforms prior to exiting the program.

Lower Extremity Venous Testing

MVO/SVC

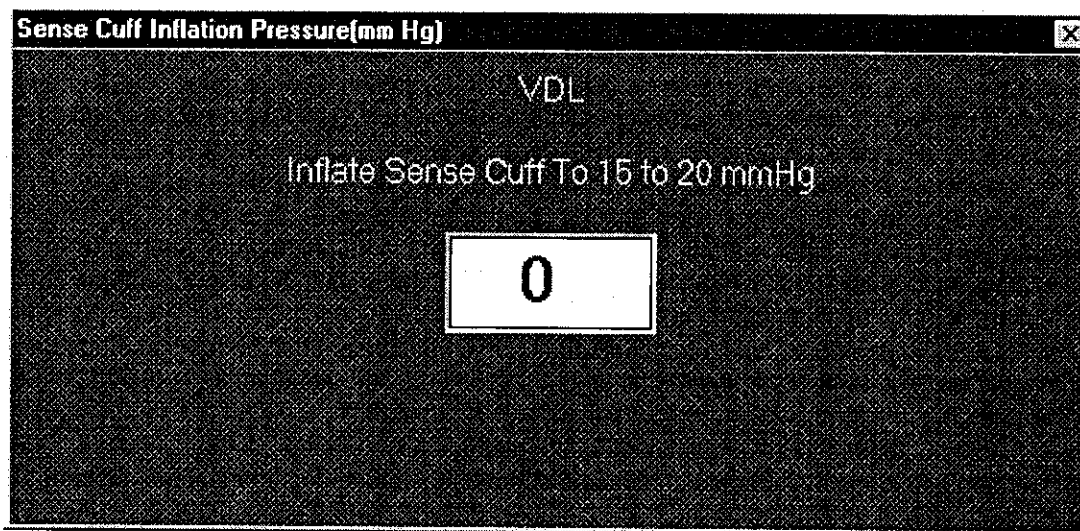
The goal of the MVO (Maximum Venous Outflow)/SVC (Segmental Venous Capacitance) test is to gauge the patency of the Patients Deep Venous System. The MVO test evaluates the presence of Deep Venous Thrombosis (DVT) by determining the speed of blood out flow in the studied limb. This test is most often done on the leg at the level of the calf by wrapping the distal cuff around he area to be examined. A comparison is made of the ratio between the Venous Capacitance (the height of the waveform baseline) and the Venous Out Flow (the blood volume change over time).

⚠ **Caution: Please verify anatomical location prior to recording any Patient data!**

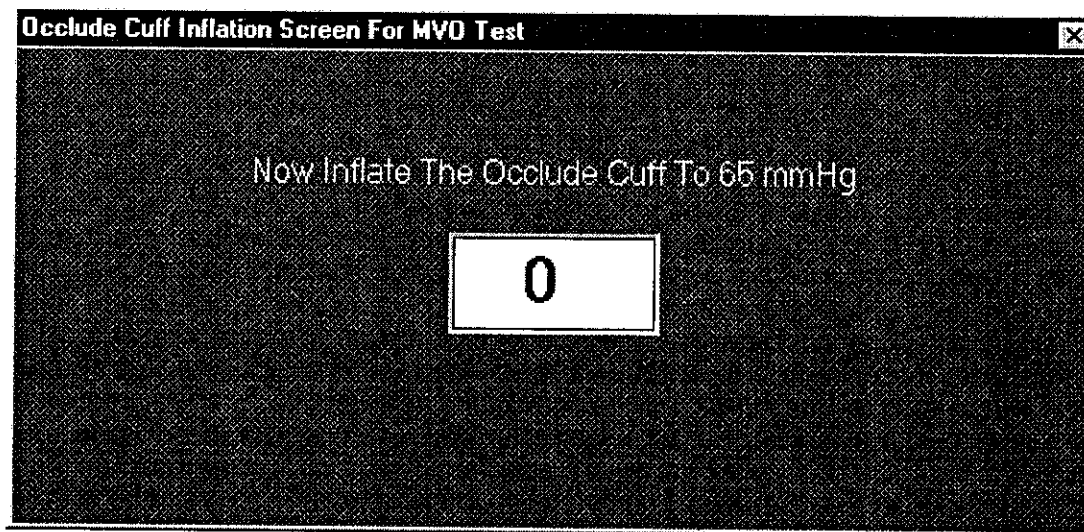
1. Position the Patient for Examination.
2. **Select Mode of testing.** The default is **MVO/SVC**
3. **Select site of testing.** The default is **Right Calf (1)**
4. **Apply the cuffs** to the patient. One on the calf and one on the thigh.
5. Connect the **calf cuff to the cuff port 3** and the **thigh cuff to cuff port 1**.
6. Click on the **Start button** or **type 1 on the keyboard**. The following screen will appear.

Lower Extremity Venous Testing

Continued



7. **Inflate the sense cuff (calf)** to the directed pressure.



Lower Extremity Venous Testing

Continued

8. **Inflate the Occlude cuff** (Thigh) to the directed pressure.
9. The Venous waveform will scroll across the graph. When **the waveform reaches a plateau click on the yellow instruction box in the lower left corner of the screen.** The waveform will start slopping downward. When the **waveform stops dropping, click on Stop or type 1 on the keyboard.**
10. Click on the **origin** of the base line and **at the peak.** This will calculate the **MVO/SVC Ratio.**
11. If this waveform is **acceptable** click on the **Save** button or **type 4** on the keyboard.
12. To **repeat** this test, click on the **Clear** button or **type 5** on the keyboard.
13. The MVO/SVC exam allows the user to store **three exams per site tested.**
14. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window.**
15. Continue to obtain all required MVO/SVC data this way.
16. As MVO/SVC data is saved **a list of saved locations will appear in the lower center of the screen** below the function buttons.
17. Please **review all waveforms prior to exiting** the program.

Understanding MVO/SVC Graphs

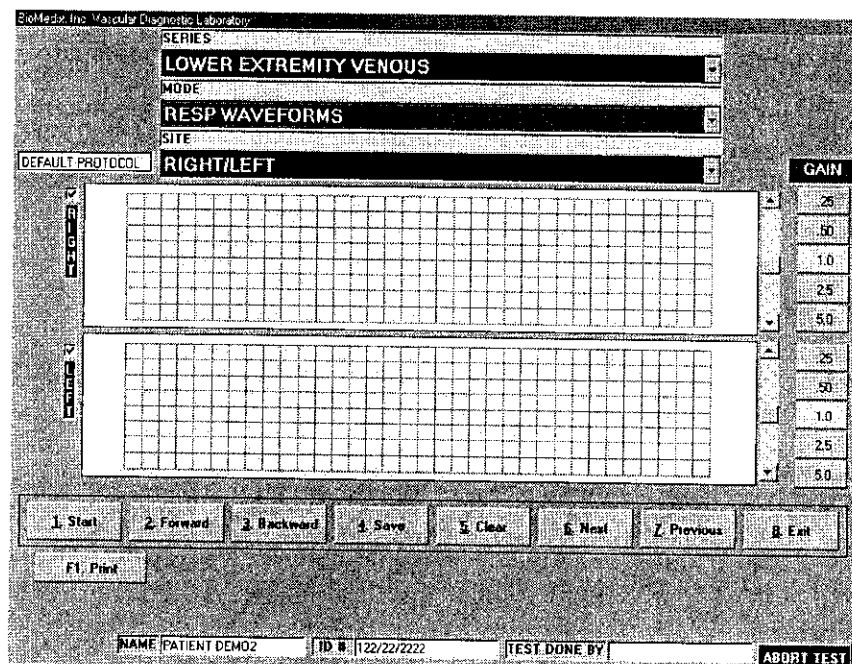
The distal cuff (calf) is inflated to 5-10mm/Hg. The Waveform will represent a steady state venous blood volume. The proximal cuff (thigh) is inflated to 60mm/Hg. This is low enough to allow arterial inflow and high enough to occlude venous outflow. The distal blood volume will start to pool and the waveform will start to rise. At the point the waveform stops rising and flattens out, full venous capacity has been reached. The proximal cuff is instantaneously deflated by unplugging it from the Occlude Port of the VDL. The waveform suddenly drops as the Patients venous system encourages venous return. Inadequate venous return due to an obstruction will result in the waveform taking longer to return to the baseline.

Lower Extremity Venous Testing

Continued

Respiratory Waves

Respiratory waves are a measurement of patency of the Deep Venous System. These tests are suggested to accompany MVO/SVC testing.



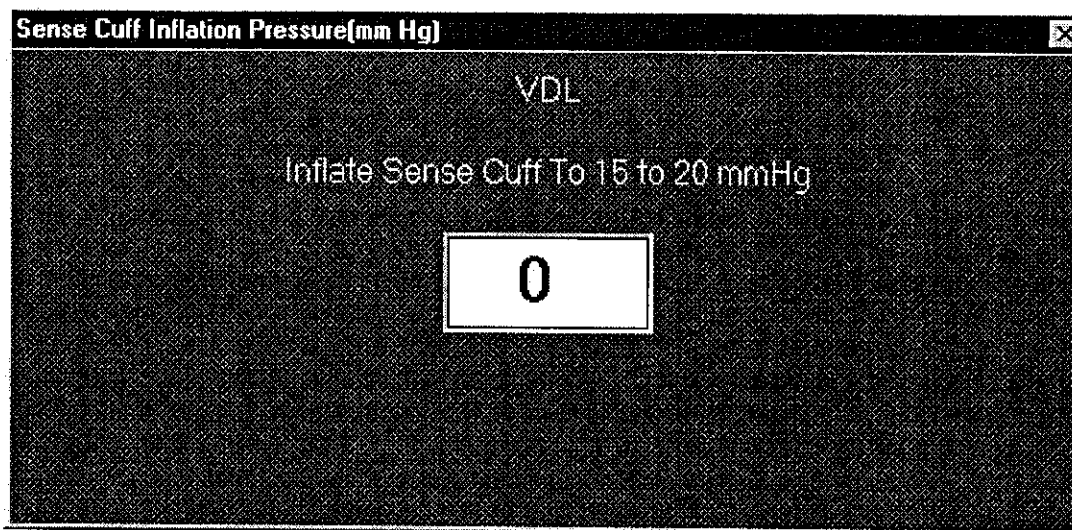
⚠ **Caution: Please verify anatomical location prior to recording any Patient data!**

1. Position the Patient for Examination.
2. **Select Mode of testing.** The default is Respiratory Waveforms.
3. **Select site of testing.** The default is **Right**.
4. **Apply the cuffs** to the patient. One on each calf.
5. Connect the **calf cuff to the #3 cuff port**.
6. Click on **the Start button or type 1 on the keyboard**. The following screen will appear.

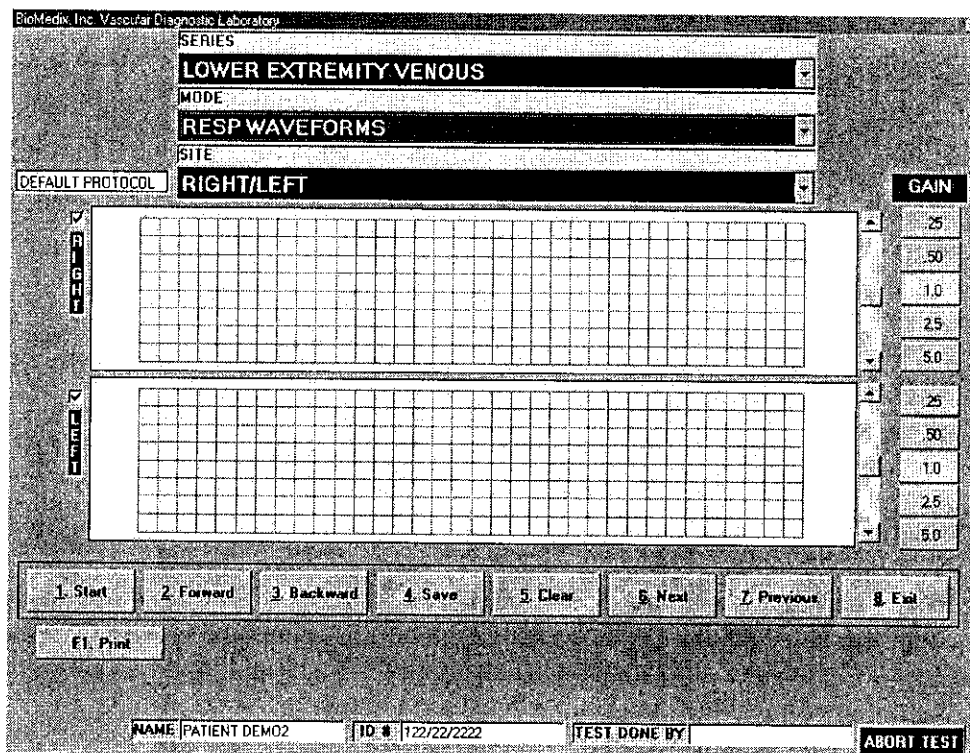
325

Lower Extremity Venous Testing

Continued



7. The following screen will appear.

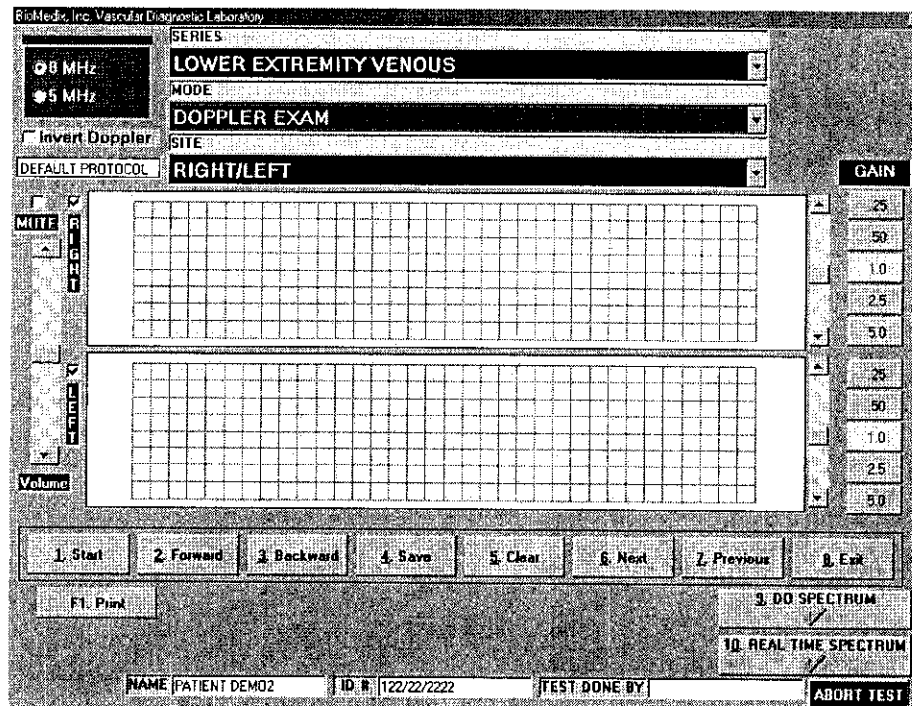


Lower Extremity Venous Testing

Continued

8. The venous waveform will scroll across the graph. Have the Patient perform forced inspiration and expiration maneuvers. The venous waveform will drift upwards and downwards. This will look like a hill-like baseline. If there is a three-mm drift of the baseline, this is a normal response. This is indicative of an open Deep Venous System.
9. If this waveform is **acceptable** click on the **Save** button or **type 4** on the keyboard.
10. To **repeat** this test, click on the **Clear** button or **type 5** on the keyboard.
11. The operator may now **move to the next location** for testing by clicking on the **Next** button or by **selecting it from the Site Window**.
12. Continue to obtain all required Resp. Waveform data this way.
13. As Respiratory Waveform data is saved a **list of saved locations** will appear in the **lower center of the screen** below the function buttons.
14. Please **review all waveforms prior to exiting** the program.

Venous Doppler



The Doppler can be used to listen to venous flow at various junctures in the venous system (popliteal vein, posterior tibial vein, etc.). Normal venous Doppler signals, sound like a soft blowing wind.

Lower Extremity Venous Testing

Continued

Change in the sound with inspiration and expiration is normal. If the sound is pulsatile, this could indicate high venous pressure.

By performing compression on the limb proximal and distal to the Doppler probe, assessments of the valvular system are possible.

While listening to the venous flow, if compression is done proximal to the probe, the sound should not be augmented. Augmented sound indicates valve incompetence. When the proximal compression is released, there should be augmented sound indicative of no occlusion between the site of compression and the Doppler probe.

If while listening to the venous flow, compression is done distal to the probe, a loud blowing sound, indicative of venous patency, should be heard. When the distal compression is released, no sound should be heard for a while indicating valve competence.

Summary of Venous Doppler Maneuvers

Compression		
	Distal to Probe	Proximal to Probe
Normal	Augmented sounds Vein Patent	No Flow Sounds Valve competent
Abnormal	No sound / reduced sound Obstruction	Flow sounds Incompetent valves
Release		
	Distal to Probe	Proximal to Probe
Normal	No augmented sound Valve Competent	Augmented sound Competent valve
Abnormal	Flow sound Incompetent valves	No sound Incompetent valves

Lower Extremity Venous Testing

Continued

Venous Doppler

The screenshot shows the Biomedix, Inc. Vascular Diagnostic Laboratory software interface. At the top, the title bar reads "Biomedix, Inc. Vascular Diagnostic Laboratory". The main window contains several fields and controls:

- SERIES:** LOWER EXTREMITY VENOUS
- MODE:** DOPPLER EXAM
- SITE:** RIGHT/LEFT
- DEFAULT PROTOCOL:** RIGHT/LEFT
- Frequency:** 8 MHz (selected) and 5 MHz (unselected).
- Invert Doppler:** A checkbox that is currently unchecked.
- MUTE:** A checkbox that is currently checked.
- Volume:** A vertical slider control.
- GAIN:** A vertical slider control with a scale from 25 to 5.0.
- Buttons:** 1. Start, 2. Forward, 3. Backward, 4. Save, 5. Clear, 6. Next, 7. Previous, 8. Exit, F1. Print, 9. DO SPECTRUM, 10. REAL TIME SPECTRUM, and ABORT TEST.
- Patient Information:** NAME: PATIENT DEMO2, ID #: 122/22/2222, TEST DONE BY: (blank).

 **Warning Doppler Ultrasound: Not for Fetal or Ophthalmic use.**
Never perform a Doppler study on the eye in the Doppler mode. Use only the Ophthalmic 8.0 MHz mode for this purpose.

Note: Never hold the probe on the body longer than is necessary. While ultrasound is very safe, any device, which produces energy, should be used with caution and for as short a time as possible.

 **Caution: Please verify anatomical location prior to recording any Patient data!**
Venous Doppler

1. Position the Patient for Examination.
2. **Select Mode of testing.** The default is **Doppler Exam.**
3. **Select site of testing.** The default is **Right.**
4. Apply acoustic gel to site of examination.
5. **Acquire audio Doppler signal** on site of choice. **Click on Start** or type 1.

Lower Extremity Venous Testing

Continued

6. Waveforms will start to scroll across the graph. Perform any compression maneuver indicated. **When the waveforms fill the graph Click on Stop or type 1.**
7. You may now **edit the waveforms** prior to saving them. Position may be change by scrolling the waveform. Waveform size may be changed by the gain selection.
8. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
9. When the waveform is edited, **remember the left half of the waveform graph is what is saved for the report**, click on the **Save** button or type 4.
10. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**.
11. Continue to obtain all required Doppler data this way.
12. As Doppler-testing data is saved **a list of saved locations will appear in the lower center of the screen** below the function buttons.

Venous Refill

The goal of the Venous refill test is to gauge the superficial venous system filling time as a reflection of venous valvular competence in the lower extremity. This testing is done with, and without, tourniquets. To evaluate, the source of any incompetence.

The screenshot shows the Sonimedix Inc. Vascular Diagnostic Laboratory software interface. At the top, the title bar reads "Sonimedix Inc. Vascular Diagnostic Laboratory". Below this, there are several dropdown menus: "SERIES" set to "LOWER EXTREMITY VENOUS", "MODE" set to "VENOUS REFILL", and "SITE" set to "LOWER EXTREMITY". A "DEFAULT PROTOCOL" dropdown is also set to "LOWER EXTREMITY". To the right of these menus is a "GAIN" control with a vertical slider and numerical values (25, 50, 1.0, 2.5, 5.0) for two channels. The main display area consists of two large grid graphs, one for "RIGHT" and one for "LEFT" (indicated by a vertical label on the left). Below the graphs is a row of function buttons: "1. Start", "2. Forward", "3. Backward", "4. Save", "5. Clear", "6. Next", "7. Previous", and "8. Exit". Below these buttons is an "F1. Print" button. At the bottom of the screen, there are fields for "NAME" (PATIENT DEMO2), "ID #:" (122/22/2222), and "TEST DONE BY:". An "ABORT TEST" button is located in the bottom right corner.

Lower Extremity Venous Testing

Continued



Caution: Please verify anatomical location prior to recording any Patient data!

1. Position the Patient for Examination.
2. **Select Mode of testing.** The default is **Venous Refill**.
3. **Select site of testing.** The default is **Right**.
4. **Apply the PPG probes** to the patient. One on each lower extremity. Located posterior and proximal to the medial malleolus.
5. Click on **the Start button or type 1 on the keyboard.**
6. Have the **Patient Dorsiflex the foot 3-5 times.** This will cause the waveform scrolling across the graph to stair-step down the graph. If this effect is not seen, reposition the PPG probe and try again.
7. When the **waveform has returned to a baseline, click on Stop or type the 1 key** on the keyboard.
8. To edit this waveform, click on the waveform at the end of the dorsiflex maneuver and where the waveform crosses the original baseline.
9. This will calculate the Refill time.
10. If this waveform **is acceptable** click on the **Save** button or **type 4** on the keyboard.
11. To **repeat** this test, click on the **Clear** button or **type 5** on the keyboard.
12. The Venous Refill exam allows the user to store data with and without tourniquets.
13. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window.**
14. Continue to obtain all required Venous Refill data this way.
15. As Venous Refill data is saved **a list of saved locations will appear in the lower center of the screen** below the function buttons.
16. Please **review all waveforms prior to exiting** the program.

Normal venous refill time is greater than 20 seconds. Abnormally quick filling time could indicate venous backflow and incompetent venous valves.

NOTE: Excess fingerprints or hair on the tape used to secure the PPG probe can impair the probes ability to emit and receive light. Distorting the test results. Hold the tape on the ends, beyond the probes viewing area. Remove excess hair from the test site.

NOTE: Allow the temperature of the PPG probe face to equilibrate to the Patients skin temperature by attaching 2-3 minutes prior to beginning the test.

Upper Extremity Arterial Testing

Caution: Please verify anatomical location prior to recording any Patient data!
PVR Data

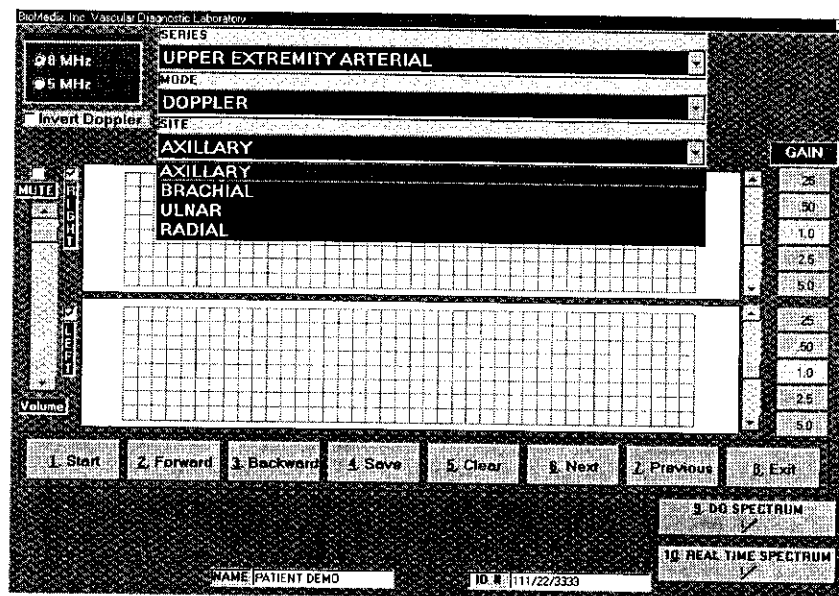
1. Position the Patient for examination.
2. **Select Mode of testing.** The default is PVR.
3. **Select Site of testing.** The default location is Right Upper Arm.
4. Apply cuffs to Patient.
5. Connect cuff to cuff connector on the right side panel of the VDL.
6. Click on **Start** or type 1 on the keyboard. The following screen will appear:

Upper Extremity Arterial Testing

Continued

7. Press Enter.
8. Waveforms will start to scroll across the waveform graph. **When the waveforms fill the graph click on STOP or type 1.**
9. You may now edit the waveforms prior to saving them. Position may be change by scrolling the waveform. Waveform size may be changed by the gain selection.
10. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
11. When the waveform is edited, **remember the left half of the waveform graph is what is saved for the report**, click on **Save** or type 4.
12. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**.
13. Continue to obtain all required PVR data this way.
14. As PVR testing data is saved a list of saved locations will appear in the lower center of the screen below the function buttons.

Doppler Waveforms



Warning Doppler Ultrasound: Not for Fetal or Ophthalmic use.
Never perform a Doppler study on the eye in the Doppler mode. Use only the Ophthalmic 8.0 MHz mode for this purpose.

Note: Never hold the probe on the body longer than is necessary. While ultrasound is very safe, any device, which produces energy, should be used with caution and for as short a time as possible.

Upper Extremity Arterial Testing

Continued

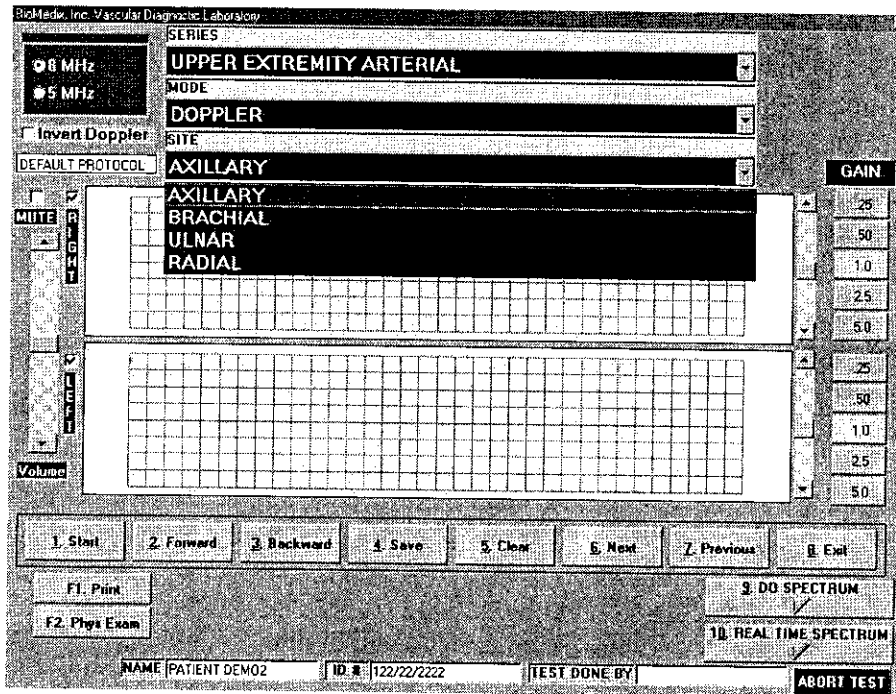
Hints for Doppler use

Hold the probe at about a 45° angle with respect to the area of interest.

Put the acoustic coupling gel on the skin not on the probe itself, otherwise excessive noise will result.

Hold the probe like a pencil.

Do not press too hard.



⚠ **Caution: Please verify anatomical location prior to recording any Patient data!**

Doppler Waveforms

1. Position the Patient for Examination.
2. **Select Mode of testing.** The default is **Doppler**.
3. **Select site of testing.** The default is **Right Axillary**.
4. Apply acoustic gel to site of examination.
5. **Acquire audio Doppler signal** on site of choice. **Click on Start** or type 1.
6. Waveforms will start to scroll across the graph. **When the waveforms fill the graph Click on Stop** or type 1.

Upper Extremity Arterial Testing

Continued

7. You may now **edit the waveforms** prior to saving them. Position may be change by scrolling the waveform. Waveform size may be changed by the gain selection.
8. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
9. When the waveform is edited, **remember the left half of the waveform graph is what is saved for the report**, click on the **Save** button or type 4.
10. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**.
11. Continue to obtain all required Doppler data this way.
12. As Doppler-testing data is saved a **list of saved locations will appear in the lower center of the screen** below the function buttons.

Segmental Pressure

The screenshot shows the 'SEG. PRESS.' screen of the Biomedix, Inc. Vascular Diagnostic Laboratory software. The interface includes a 'SERIES' field set to 'UPPER EXTREMITY ARTERIAL', a 'MODE' dropdown set to 'SEG. PRESS.', and a 'SITE' dropdown set to 'DIGIT #2'. Below the 'SITE' dropdown is a list of available sites: 'DIGIT #2', 'WRIST-RADIAL ARTERY', 'WRIST-ULNAR ARTERY', 'FOREARM', 'UPPER ARM', and 'BRACHIAL (POST EXERCISE)'. To the left of the site list are checkboxes for 'RIGHT' and 'LEFT' limbs. To the right of the site list is a 'GAIN' control with a vertical slider and numerical values (25, 50, 1.0, 25, 50, 25, 50, 1.0, 25, 50). Below the site list is a large grid area for waveform display. At the bottom of the screen are several function buttons: '1. Start', '2. Forward', '3. Backward', '4. Save Pressure', '5. Clear', '6. Next', '7. Previous', and '8. Exit'. There are also buttons for 'F1 Print', 'Start Inflate', and 'Nudge Pressure'. At the very bottom, there are fields for 'NAME' (PATIENT DEM02), 'ID #' (122/22/2222), 'TEST DONE BY', and an 'ABORT TEST' button. A status bar at the bottom right indicates 'Approximate Fill Pressure=180'.

 **Caution: Please verify anatomical location prior to recording any Patient data!**

1. Position the Patient for Examination.
2. **Select Mode of testing.** The default is **Segmental Pressure**.
3. **Select site of testing.** The default is **Right Brachial**.
4. Apply acoustic gel to site of examination.

Upper Extremity Arterial Testing

Continued

5. Apply cuff on site to be examined.
6. Connect cuff to cuff port on right side plate of VDL.
7. **Acquire audio Doppler signal** on site of choice. **Click on Start** or type 1. The Doppler waveform will scroll across the graph.
8. **Inflate the cuff using the start inflation button** until all arterial audio **signal is obliterated**.
9. The pressure in the cuff will start to bleed off.
10. When return of **flow is heard** click on **Stop** or **type 1**. If the auto sensing is used when the computer senses the return of flow a cursor will appear on the graph showing the waveform sensed. To select a different waveform, simply click on that waveform and the pressure will be adjusted.
11. The operator should then click on the **Save Pressure button** or **type 9** on the keyboard.
12. If the operator would like to **edit the pressures**, click on the **Show Pressure Button** or **type 8 on the keyboard**. The following screen will appear.

Segmental Pressure(In mm Hg.)	
Right Digit #2	Left Digit #2
Right Wrist(Radial Artery)	Left Wrist(Radial Artery)
Right Wrist(Ulnar Artery)	Left Wrist(Ulnar Artery)
Right Forearm	Left Forearm
Right Upper Arm	Left Upper Arm
Rt Brachial(Post Exercise)	Lt Brachial(Post Exercise)

F1 Save Pressure Values

13. The user may now enter or edit pressures using enter to move from field to field.
14. To return to the Patient Testing Screen, click on the Save Pressure Values button or type F1 on the keyboard.
15. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
16. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**.
17. Continue to obtain all required Pressure data this way.
18. Please review all Pressure data prior to exiting.

Upper Extremity Arterial Testing

Continued

The ratio of the Segmental Systolic Pressure to the Brachial Systolic Pressure is defined as the Segmental Brachial Index (SBI).

Normal and Abnormal SBI's

SBI

.97 to 1.25	=	Normal
.70 to .96	=	Mild Stenosis
.50 to .69	=	Moderate Stenosis, claudication
.30 to .49	=	Severe Stenosis, Rest Pain, Single site occlusion
.29 or less	=	Gangrene, Probable multiple site occlusion

Finger Studies

Finger/Brachial Index

Normal = .8 and Greater

Abnormal = Less than .8

Difference in Pressure (dP) Between Fingers

Less than 15 mm/Hg

Greater than 15 mm/Hg

Pressure Interpretation Guidelines

Difference in pressure (dP)

Arms:	Segmentally and bilaterally not more than 10 mm/Hg
Fingers:	Not more than 15 mm/Hg
Legs:	Segmentally not more than 30 mm/Hg Bilaterally not more than 15 mm/Hg
Toes:	Not more than 15 mm/Hg

Upper Extremity Digit Testing

BioMedix, Inc. Vascular Diagnostic Laboratory

SERIES: UPPER EXTREMITY DIGIT

MODE: PPG EXAM

SITE: DIGIT #1

DEFAULT PROTOCOL: DIGIT #1

DIGIT #1
DIGIT #2
DIGIT #3
DIGIT #4
DIGIT #5

GAIN: 25, 50, 1.0, 2.5, 5.0

1. Start 2. Forward 3. Backward 4. Save 5. Clear 6. Next 7. Previous 8. Exit

F1. Print

NAME: PATIENT DEMO2 ID #: 122/22/2222 TEST DONE BY: ABORT TEST

 **Caution: Please verify anatomical location prior to recording any Patient data!**

PPG Exam

1. Position the Patient for examination.
2. Connect the PPG connector to the right side plate of the VDL.
3. Place the PPG probe on the distal digit.
4. **Select Mode of testing.** The default is PPG Exam.
5. **Select Site of testing.** The default location is Right Digit 1.
6. Click on **Start** or type 1 on the keyboard to start waveform scrolling.
7. Waveforms will start to scroll across the waveform graph. **When the waveforms fill the graph click on STOP or type 1.**
8. You may now edit the waveforms prior to saving them. Position may be change by scrolling the waveform. Waveform size may be changed by the gain selection.
9. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
10. When the waveform is edited, **remember the left half of the waveform graph is what is saved for the report**, click on **Save** or type 4.
11. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**. Continue to obtain all required PPG data this way.
12. As PPG testing data is saved a list of saved locations will appear in the lower center of the screen below the function buttons.

Upper Extremity Digit Testing

Continued

 **Caution: Please verify anatomical location prior to recording any Patient data!**

Segmental Pressure

1. Position the Patient for Examination.
2. Connect the PPG connector to the right side plate of the VDL.
3. Place the PPG probe on the distal digit.
4. **Select Mode of testing.** The default is **Segmental Pressure**.
5. **Select site of testing.** The default is **Digit 1**.
6. Apply cuff on site to be examined.
7. Connect cuff to sense cuff port on right side plate of VDL.
8. **Acquire PPG signal** on site of choice. **Click on Start** or type 1. The PPG waveform will scroll across the graph.
9. Click on the Start Inflation button. The cuff should occlude the PPG signal being generated.
10. The pressure in the cuff will start to bleed off.
11. When return of **flow is seen** click on **Stop** or type 1. If the auto sensing is used when the computer senses the return of flow a cursor will appear on the graph showing the waveform sensed. To select a different waveform, simply click on that waveform and the pressure will be adjusted.
12. The operator should then click on the **Save Pressure** button or type 9 on the keyboard.

Upper Extremity Digit Testing

Continued

13. If the operator would like to **edit the pressures**, click on the **Show Pressure Button** or **type 8 on the keyboard**. The following screen will appear.

The screenshot shows a software window titled "Upper Extremity Digit Segmental Pressure Screen". Inside, the heading "Segmental Pressure(In mm Hg.)" is centered. Below this, there are two columns of input fields. The left column is labeled "Right" and the right column is labeled "Left". Each column contains six fields: "Brachial", "Digit #1", "Digit #2", "Digit #3", "Digit #4", and "Digit #5". At the bottom center of the window is a button labeled "F1. Save Pressure Values".

Segmental Pressure(In mm Hg.)	
Right Brachial	Left Brachial
Right Digit #1	Left Digit #1
Right Digit #2	Left Digit #2
Right Digit #3	Left Digit #3
Right Digit #4	Left Digit #4
Right Digit #5	Left Digit #5

F1. Save Pressure Values

14. The user may now enter or edit pressures using enter to move from field to field.
15. To **return to the Patient Testing Screen**, click on the **Save Pressure Values button** or **type F1 on the keyboard**.

Upper Extremity Digit Testing

Continued

16. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
17. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**.
18. Continue to obtain all required Pressure data this way.
19. Please review all Pressure data prior to exiting.

Lower Extremity Digit Testing

BioMedix, Inc. Vascular Diagnostic Laboratory

SERIES
LOWER EXTREMITY DIGIT

MODE
PPG EXAM

SITE
DIGIT #1

DEFAULT PROTOCOL

GAIN
25
50
1.0
2.5
5.0

1. Start 2. Forward 3. Backward 4. Save 5. Clear 6. Next 7. Previous 8. Exit

F1. Print

NAME: PATIENT DEMO2 ID #: 122/22/2222 TEST DONE BY: ABORT TEST



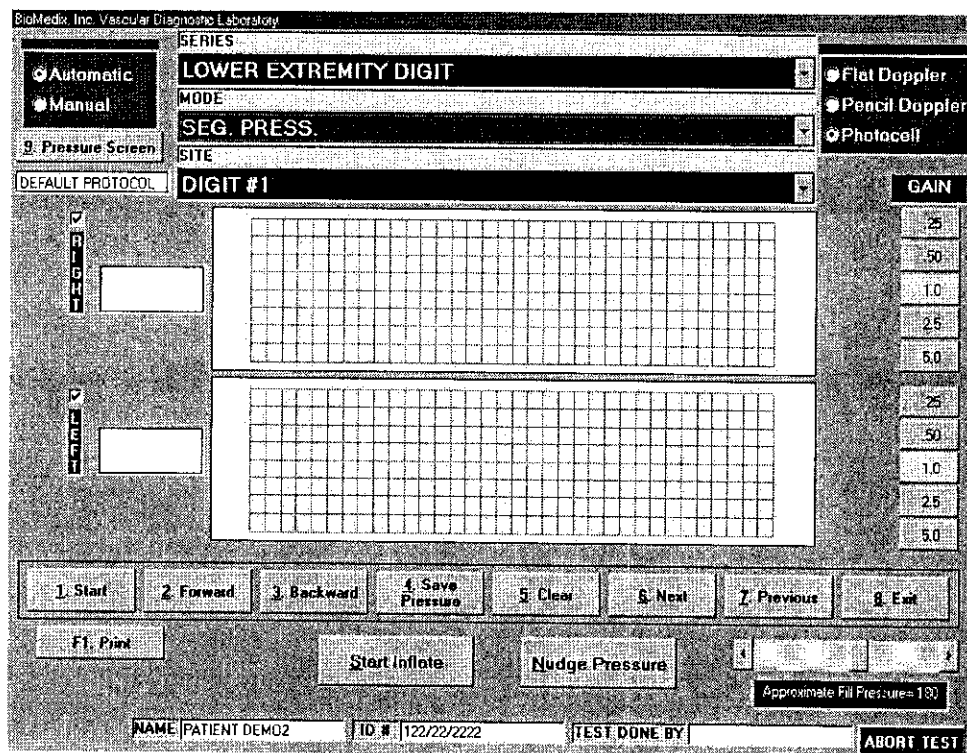
Caution: Please verify anatomical location prior to recording any Patient data!

PPG Exam

1. Position the Patient for examination.
2. Connect the PPG connector to the right side plate of the VDL.
3. Place the PPG probe on the distal digit.
4. **Select Mode of testing.** The default is PPG Exam.
5. **Select Site of testing.** The default location is Right Digit 1.
6. Click on **Start** or type 1 on the keyboard to start waveform scrolling.
7. Waveforms will start to scroll across the waveform graph. **When the waveforms fill the graph click on STOP or type 1.**
8. You may now edit the waveforms prior to saving them. Position may be change by scrolling the waveform. Waveform size may be changed by the gain selection.
9. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
10. When the waveform is edited, **remember the left half of the waveform graph is what is saved for the report**, click on **Save** or type 4.
11. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**. Unplug the cuff from the connector and attach the next cuff.
12. Continue to obtain all required PPG data this way.
13. As PPG testing data is saved a list of saved locations will appear in the lower center of the screen below the function buttons.

Lower Extremity Digit Testing

Continued



 **Caution: Please verify anatomical location prior to recording any Patient data!**

Segmental Pressure

1. Position the Patient for Examination.
2. Connect the PPG connector to the right side plate of the VDL.
3. Place the PPG probe on the distal digit.
4. **Select Mode of testing.** The default is **Segmental Pressure**.
5. **Select site of testing.** The default is **Digit 1**.
6. Apply cuff on site to be examined.
7. Connect cuff to sense cuff port on right side plate of VDL.
8. **Acquire PPG signal** on site of choice. **Click on Start** or type 1. The PPG waveform will scroll across the graph.
9. **Inflate the cuff using the start inflation button** until all arterial PPG signal is obliterated.
10. The pressure in the cuff will start to bleed off.
11. When return of **flow is seen** click on **Stop** or type 1. If the auto sensing is used when the computer senses the return of flow a cursor will appear on the graph showing the waveform sensed. To select a different waveform, simply click on that waveform and the pressure will be adjusted.
12. The operator should then click on the **Save Pressure button** or type 9 on the keyboard.

Lower Extremity Digit Testing

Continued

13. If the operator would like to **edit the pressures**, click on the **Show Pressure Button** or **type 8 on the keyboard**. The following screen will appear.

The screenshot displays a software window titled "Lower Extremity Digits-Segmental Pressure Screen". Inside the window, the text "Segmental Pressure(In mm Hg.)" is centered at the top. Below this, there are two columns of input fields. The left column is labeled "Right" and the right column is labeled "Left". Each column contains six input fields: "Brachial", "Digit #1", "Digit #2", "Digit #3", "Digit #4", and "Digit #5". At the bottom center of the window is a button labeled "F1: Save Pressure Values".

14. The user may now enter or edit pressures using enter to move from field to field.
15. To **return to the Patient Testing Screen**, click on the **Save Pressure Values button** or **type F1 on the keyboard**.

Lower Extremity Digit Testing Continued

BioMedix Inc. Vascular Diagnostic Laboratory

SERIES LOWER EXTREMITY DIGIT

MODE SEG. PRESS.

SITE DIGIT #1

DEFAULT PROTOCOL

RIGHT

LEFT

GAIN

25
50
1.0
2.5
5.0

25
50
1.0
2.5
5.0

1. Start 2. Forward 3. Backward 4. Save Pressure 5. Clear 6. Next 7. Previous 8. Exit

F1. Print

Start Inflate Nudge Pressure

Approximate Fill Pressure= 130

NAME PATIENT DEM02 ID # 122/22/2222 TEST DONE BY

ABORT TEST

16. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
17. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**.
18. Continue to obtain all required Pressure data this way.
19. Please review all Pressure data prior to exiting.

Cerebrovascular Testing

BioMedix, Inc. Vascular Diagnostic Laboratory

SERIES: CEREBROVASCULAR
MODE: DOPPLER
SITE: COMMON CAROTID ARTERY

8 MHz
5 MHz
Invert Doppler
DEFAULT PROTOCOL

MUTE
Volume

25
50
1.0
2.5
5.0

25
50
1.0
2.5
5.0

1. Start 2. Forward 3. Backward 4. Save 5. Clear 6. Next 7. Previous 8. Exit

F1. Print F2. Phys Exam

9. DO SPECTRUM
10. REAL TIME SPECTRUM

NAME: PATIENT DEMO2 ID #: 122/22/2222 TEST DONE BY: ABORT TEST

 **Caution:** Please verify anatomical location prior to recording any Patient data!
Doppler

 **Warning Doppler Ultrasound:** Not for Fetal or Ophthalmic use.
Never perform a Doppler study on the eye in the Doppler mode. Use only the Ophthalmic 8.0 MHz mode for this purpose.

Note: Never hold the probe on the body longer than is necessary. While ultrasound is very safe, any device, which produces energy, should be used with caution and for as short a time as possible.

Hints for Doppler use

Hold the probe at about a 45° angle with respect to the area of interest.

Put the acoustic coupling gel on the skin not on the probe itself, otherwise excessive noise will result.

Hold the probe like a pencil.

Do not press too hard.

Cerebrovascular Testing

Continued

BioMedix, Inc. Vascular Diagnostic Laboratory

SERIES: CEREBROVASCULAR
MODE: DOPPLER
SITE: COMMON CAROTID ARTERY
DEFAULT PROTOCOL: COMMON CAROTID ARTERY

8 MHz
5 MHz
Invert Doppler
MUTE
Volume

25 50 1.0 2.5 5.0
25 50 1.0 2.5 5.0

1. Start 2. Forward 3. Backward 4. Save 5. Clear 6. Next 7. Previous 8. Exit

F1. Print F2. Phys Exam

NAME: PATIENT DEMO2 ID #: 122/22/2222 TEST DONE BY: 3. DO SPECTRUM 10. REAL TIME SPECTRUM ABORT TEST

⚠ **Caution: Please verify anatomical location prior to recording any Patient data!**

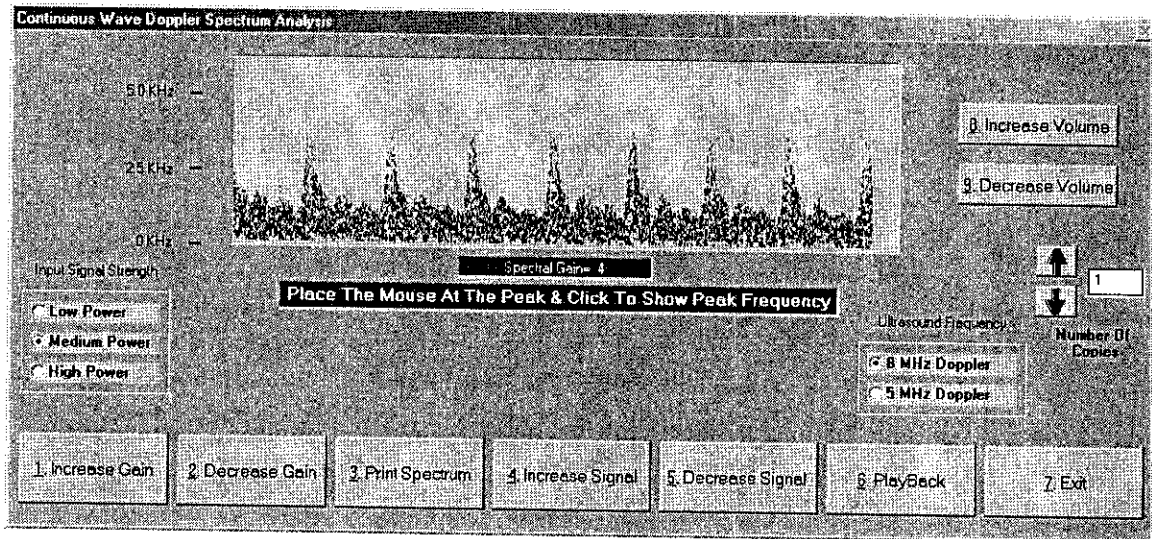
Doppler Waveforms

1. Position the Patient for Examination.
2. **Select Mode of testing.** The default is **Doppler**.
3. **Select site of testing.** The default is **Right Common Carotid Artery**.
4. Apply acoustic gel to site of examination.
5. **Acquire audio Doppler signal** on site of choice. **Click on Start** or type 1.
6. Waveforms will start to scroll across the graph. **When the waveforms fill the graph Click on Stop or type 1.**
7. You may now **edit the waveforms** prior to saving them. Position may be change by scrolling the waveform. Waveform size may be changed by the gain selection.
8. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
9. When the waveform is edited, **remember the left half of the waveform graph is what is saved for the report**, click on the **Save button** or type 4.

Cerebrovascular Testing

Continued

10. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**.
11. Continue to obtain all required Doppler data this way.
12. As Doppler-testing data is saved a **list of saved locations will appear in the lower center of the screen** below the function buttons.
13. The user may also choose to **do Spectrum Analysis** on any Doppler signal saved. This function is selected by clicking on **Due Spectrum** button or by typing **8** on the keyboard. The following screen will appear.

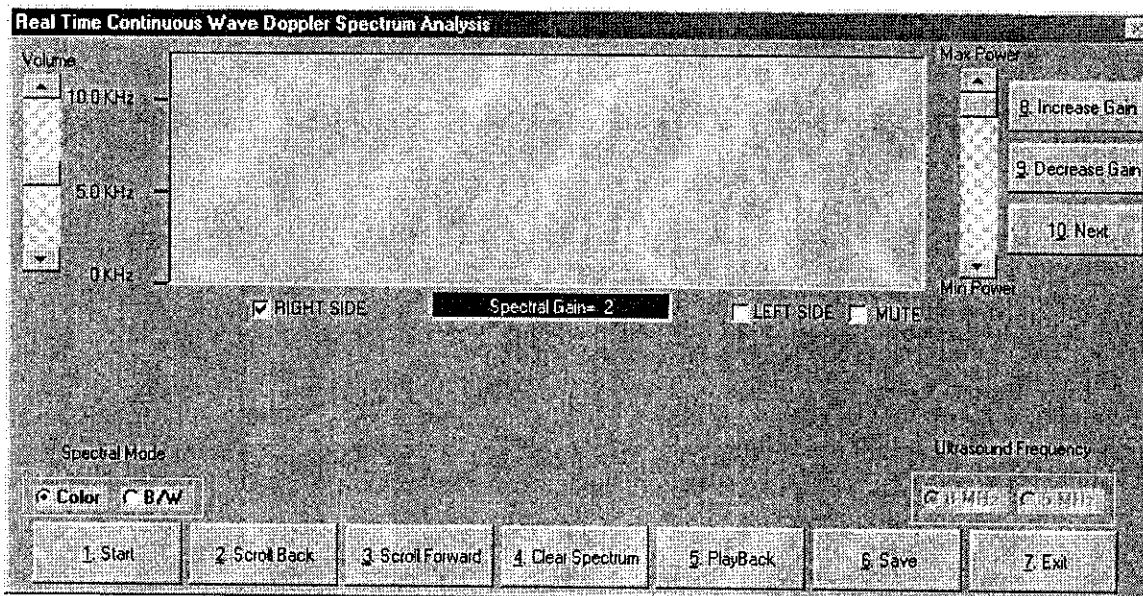


This screen will allow the user to edit and print the spectrum data from the Doppler waveform. This spectral signal is post processed from the Doppler waveform. This allows for editing the signal power levels, Signal levels and gain settings. **A unique feature is the Audio playback. This will allow the user to playback the Doppler audio after storing for review at a latter time.**

Cerebrovascular Testing

Continued

Real Time Spectrum is also **optionally** available with this version of the software. The real time Spectrum screen looks as depicted below.



The controls are similar to the Doppler trace screen but details of each follow.

Start – The start button will begin the data scrolling live from left to right in the window. This will change to Stop once the data has begun scrolling. You may begin the data acquisition by clicking the **Start** button or type **1**. To stop the data acquisition click the **Stop** button or type **1**.

Scroll Back – This button will allow you to scroll the spectral data back in time to allow capture of the exact data desired. To select function click the **Scroll Back** button or type **2**.

Scroll Forward – This selection will allow the movement of the spectral data forward in time again allowing the correct selection of data. To select function click the **Scroll Forward** button or type **3**.

Clear Spectrum – This function will clear all captured data so the acquisition can be repeated. Be sure you really want to obtain new data prior to clicking this function. To select this function click the **Clear Spectrum** button or type **4**.

Cerebrovascular Testing

Continued

Playback – This function will playback the data just collected. To select this function click the **Playback** button or type 5.

Save – This function will save the spectral data for this location. To save the data click the **Save** button or type 6.

Exit – This function will exit from the Real time spectrum and return you to the testing menu. To select this function click on the **Exit** button or type 7.

This Real Time Spectrum screen has some additional controls, which will be described.

There are two sets of radio button selections. The one on the left center of the screen allows change of the Spectral data to be changed from Color, which is our default to black and white. Simply click on the option desired will change the display. The radio button set located at the right center of the screen will allow selection of the proper Doppler frequency. The options are either 8MHz or 5MHz. To select click on the desired frequency.

To the right and left of the data window are scroll bars. The one on the left is to increase or decrease the volume you are hearing and the one to the right is to increase or decrease the power level of the Doppler. Scrolling either will effect the change.

There are three additional functions available on this screen and they are located on the upper right side of the data window. Explanations of them follow.

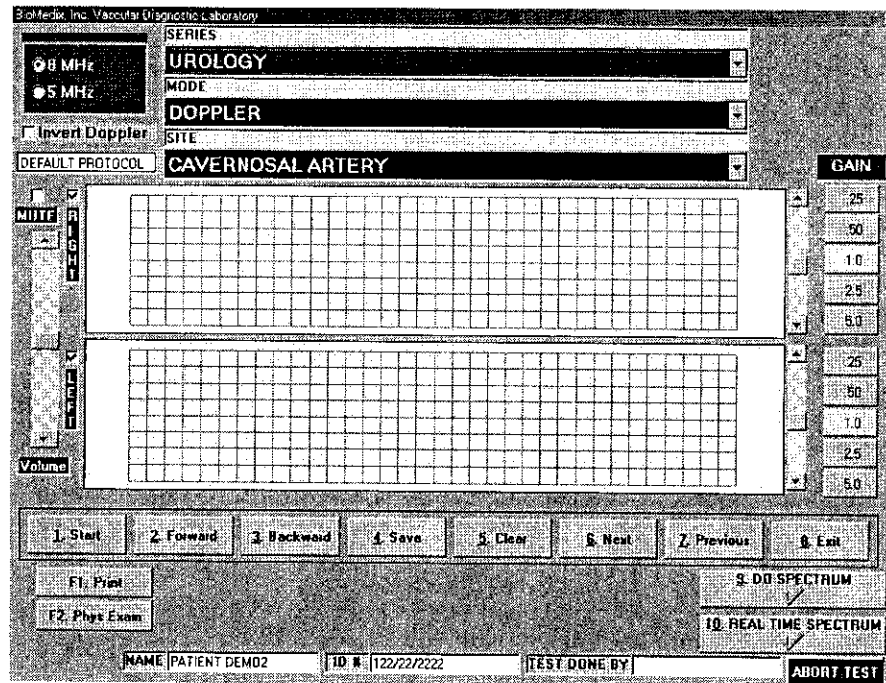
Increase Gain – This will increase the gain or sensitivity of the Doppler. This can be selected by clicking on the **Increase Gain** button or typing 8.

Decrease Gain – This will decrease the gain of the Doppler. This can be selected by clicking on the **Decrease Gain** button or typing 9.

Next – This function will move to the next location in the list of vessels once you have saved the data on the current vessel. To select this function click on the **Next** button or type 0. Post processing of this data can also be performed as is done with all data collected from Doppler's with this system.

Ultrasound studies of the periorbital and ophthalmic region can be performed when the 8 MHz Doppler probe is plugged into the ophthalmic Doppler probe connector. Instructions for use at this setting are the same as for the Doppler setting. Plug the 8 MHz probe into the Doppler jack on the side panel of the VDL.

Urology Testing



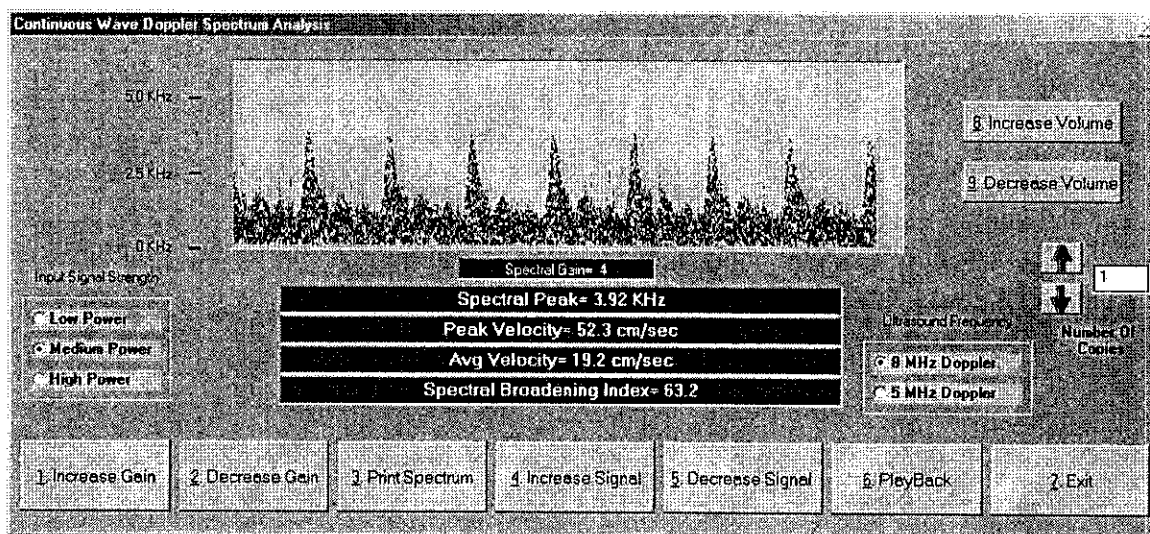
 **Caution: Please verify anatomical location prior to recording any Patient data!**

Doppler Waveforms

1. Position the Patient for Examination.
2. **Select Mode of testing.** The default is **Doppler**.
3. **Select site of testing.** The default is **Right Cavernosal Artery**.
4. Apply acoustic gel to site of examination.
5. **Acquire audio Doppler signal** on site of choice. **Click on Start** or type 1.
6. Waveforms will start to scroll across the graph. **When the waveforms fill the graph Click on Stop** or type 1.
7. You may now **edit the waveforms** prior to saving them. Position may be change by scrolling the waveform. Waveform size may be changed by the gain selection.
8. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
9. When the waveform is edited, **remember the left half of the waveform graph is what is saved for the report**, click on the **Save button** or type 4.
10. The operator may now **move to the next location** for testing by clicking on the **Next button** or **by selecting it from the Site Window**.
11. Continue to obtain all required Doppler data this way.
12. As Doppler-testing data is saved **a list of saved locations will appear in the lower center of the screen** below the function buttons.
13. The user may also choose to **do Spectrum Analysis** on any Doppler signal saved. This function is selected by clicking on **Due Spectrum button** or by **typing 8 on the keyboard**. The following screen will appear.

Urology Testing

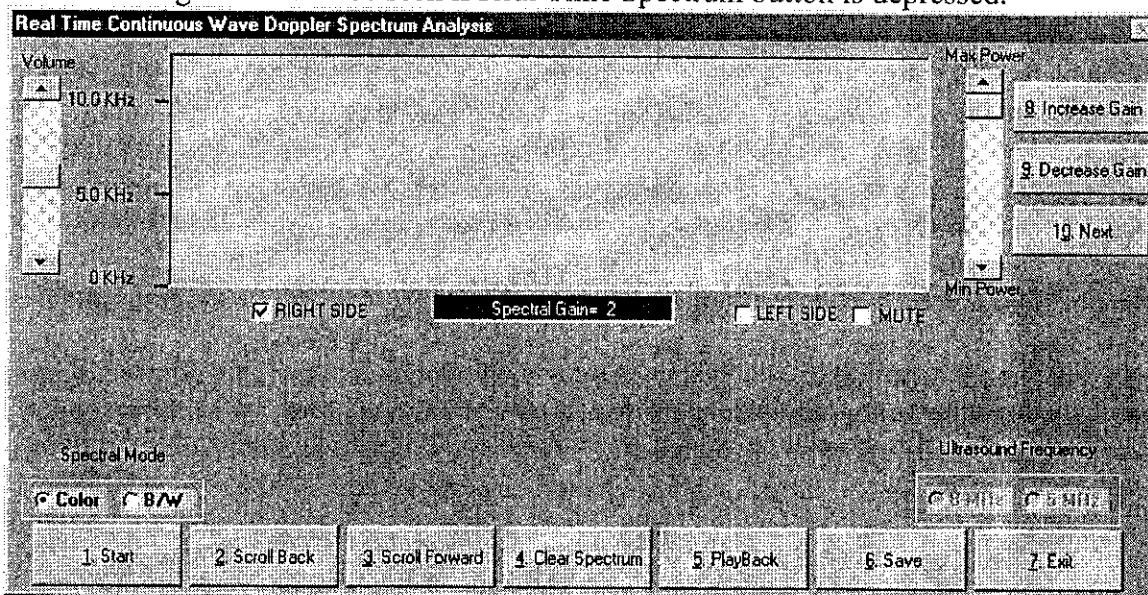
Continued



This screen will allow the user to edit and print the spectrum data from the Doppler waveform. This spectral signal is post processed from the Doppler waveform. This allows for editing the signal power levels, Signal levels and gain settings. **A unique feature is the Audio playback.** This will allow the user to playback the Doppler audio after storing for review at a latter time.

As with all other testing capabilities in Doppler, Real Time Spectrum is also available at this location.

The following screen will be seen if Real Time Spectrum button is depressed.



Urology Testing

Continued

The real time spectrum has been updated to allow for post injection studies to be performed with samples every five- (5) minutes post injection. Measuring can be done by Left clicking on the peak of the waveform of choice and right clicking on the end of the waveform being measured.

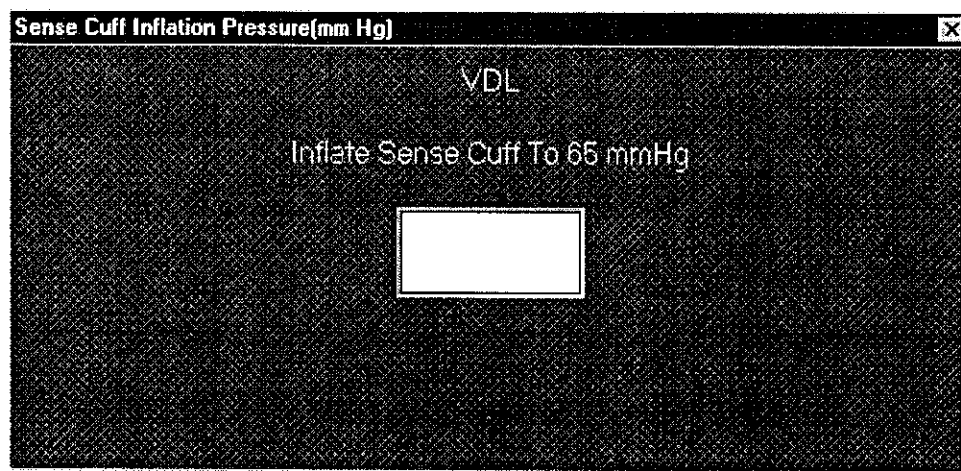
 **Caution: Please verify anatomical location prior to recording any Patient data!**

PVR Data

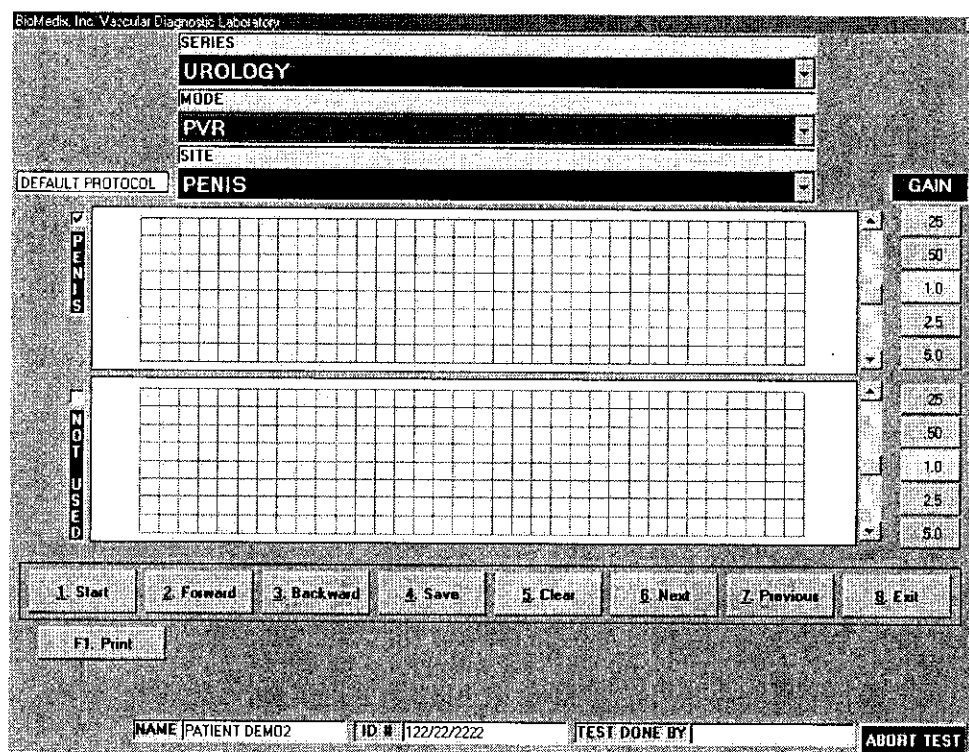
1. Position the Patient for examination.
2. **Select Mode of testing.** The default is PVR.
3. **Select Site of testing.** The default location is Penis.
4. Apply cuff to Patient
5. Connect cuff to Cuff connector on the right side panel of the VDL.
6. Click on **Start** or type 1 on the keyboard. The following screen will appear:

Urology Testing

Continued



7. Press Enter.



8. Waveforms will start to scroll across the waveform graph. **When the waveforms fill the graph click on STOP or type 1.**

Urology Testing

Continued

9. You may now edit the waveforms prior to saving them. Position may be change by scrolling the waveform. Waveform size may be changed by the gain selection.
10. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
11. When the waveform is edited, **remember the left half of the waveform graph is what is saved for the report**, click on **Save** or type 4.
12. As PVR testing data is saved a list of saved locations will appear in the lower center of the screen below the function buttons.

PPG Exam

BioMedex, Inc. Vascular Diagnostic Laboratory

SERIES: **UROLOGY**

MODE: **PPG**

SITE: **PENIS**

DEFAULT PROTOCOL: **PENIS**

GAIN: 25, 50, 1.0, 2.5, 5.0

1. Start 2. Forward 3. Backward 4. Save 5. Clear 6. Next 7. Previous 8. Exit

F1. Print

NAME: PATIENT DEMO2 ID #: 122/22/2222 TEST DONE BY: ABORT TEST

 **Caution: Please verify anatomical location prior to recording any Patient data!**

1. Position the Patient for examination.
2. Connect the PPG connector to the right side plate of the VDL.
3. Place the PPG probe on the distal digit.
4. **Select Mode of testing.** The default is PPG Exam.
5. **Select Site of testing.** The default location is Penis.
6. Click on **Start** or type 1 on the keyboard to start waveform scrolling.

Urology Testing

Continued

7. Waveforms will start to scroll across the waveform graph. **When the waveforms fill the graph click on STOP or type 1.**
8. You may now edit the waveforms prior to saving them. Position may be change by scrolling the waveform. Waveform size may be changed by the gain selection.
9. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
10. When the waveform is edited, **remember the left half of the waveform graph is what is saved for the report**, click on **Save** or type 4.
11. Continue to obtain all required PPG data this way.
12. As PPG testing data is saved a list of saved locations will appear in the lower center of the screen below the function buttons.

Segmental Pressure

SigMedix Inc. Vascular Diagnostic Laboratory

SERIES: UROLOGY

MODE: PENILE PRESSURE

SITE: BRACHIAL

3. Pressure Screen

DEFAULT PROTOCOL: BRACHIAL

BRACHIAL

PENILE PRESSURE

GAIN: 25, 50, 1.0, 2.5, 5.0

1. Start 2. Forward 3. Backward 4. Save Pressure 5. Clear 6. Next 7. Previous 8. Exit

F1. Print Start Inflate Nudge Pressure

Approximate Fill Pressure= 180

NAME: PATIENT DEMO2 ID #: 122/22/2222 TEST DONE BY: ABORT TEST

 **Caution: Please verify anatomical location prior to recording any Patient data!**

1. Position the Patient for Examination.
2. Apply acoustic gel to site of examination.
3. Apply cuff on site to be examined.
4. Connect cuff to cuff port on right side plate of VDL.
5. **Select Mode of testing.** The default is **Segmental Pressure**.

Urology Testing

Continued

6. **Select site of testing.** The default is **Right Brachial**.
7. **Acquire audio Doppler signal** on site of choice. **Click on Start** or type 1. The Doppler waveform will scroll across the graph.
8. **Inflate the cuff using the Start inflation button** until all arterial Doppler **signal is obliterated**.
9. The pressure in the cuff will start to bleed off.
10. When return of **flow is seen or heard** click on **Stop** or type 1. If the auto sensing is used when the computer senses the return of flow a cursor will appear on the graph showing the waveform sensed. To select a different waveform, simply click on that waveform and the pressure will be adjusted.
11. The operator should then click on the **Save Pressure button** or type 9 on the keyboard.
12. If the operator would like to **edit the pressures**, click on the **Show Pressure Button** or type 8 on the keyboard. The following screen will appear.

Penile Pressure Entry Screen

Segmental Pressure(In mm Hg.)

Right Brachial

Left Brachial

Penile Pressure

Penile Brachial Index(PBI)

F1: Save Pressure Values

13. The user may now enter or edit pressures using enter to move from field to field.
14. To **return to the Patient Testing Screen**, click on the **Save Pressure Values button** or type F1 on the keyboard.

Urology Testing

Continued

BioMedix, Inc. Vascular Diagnostic Laboratory

SERIES
UROLOGY

MODE
PENILE PRESSURE

SITE
BRACHIAL

BRACHIAL
PENILE PRESSURE

RIGHT
[Empty Box]

LEFT
[Empty Box]

GAIN
25
50
1.0
2.5
5.0

1. Start 2. Forward 3. Backward 4. Save Pressure 5. Clear 6. Next 7. Previous 8. Exit

F1. Print Start Inflate Nudge Pressure

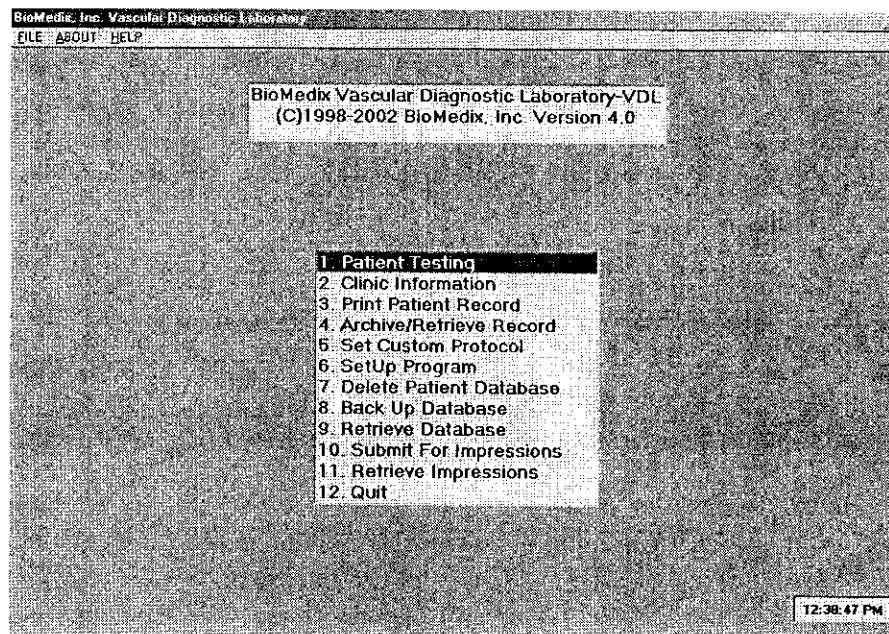
Approximate Fill Pressure: 180

NAME: PATIENT DEM02 ID #: 122/22/2222 TEST DONE BY: [Empty Box] ABORT TEST

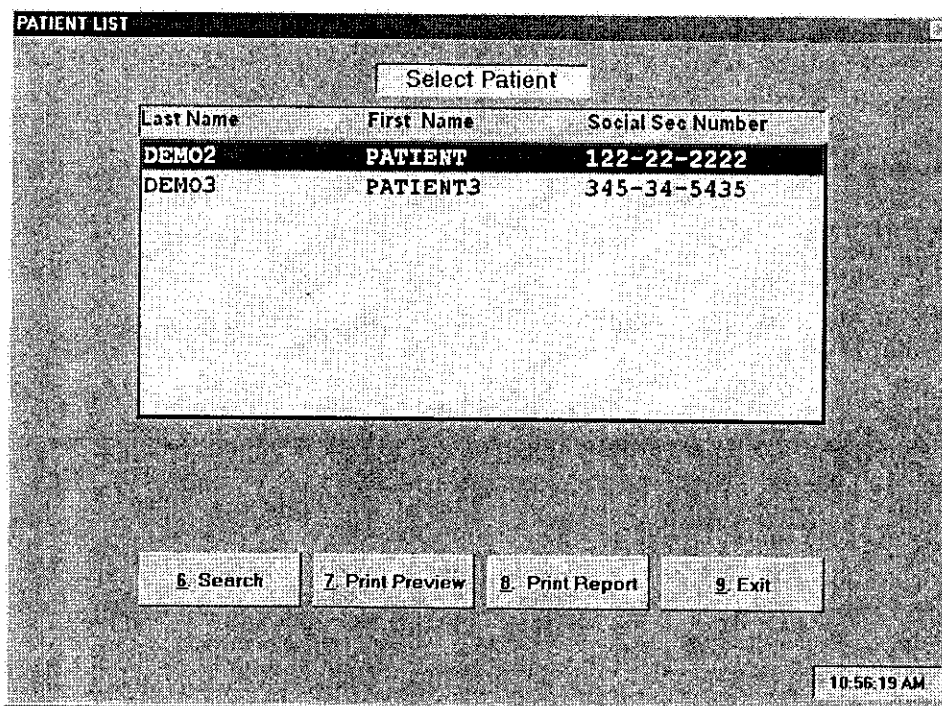
15. If you would like to **repeat the test** click on **Clear** or type 5. You may now repeat the test.
16. The operator may now **move to the next location** for testing by clicking on the **Next** button or **by selecting it from the Site Window**.
17. Continue to obtain all required Pressure data this way.
18. Please review all Pressure data prior to exiting.

Printing Patient Reports

Printing Patient Reports is done from the VDL Main Menu.



Click on Print Patient Record of type 3 on the keyboard. The following screen will appear.



Printing Patient Reports

Continued

There are several functions the user may select from this screen:

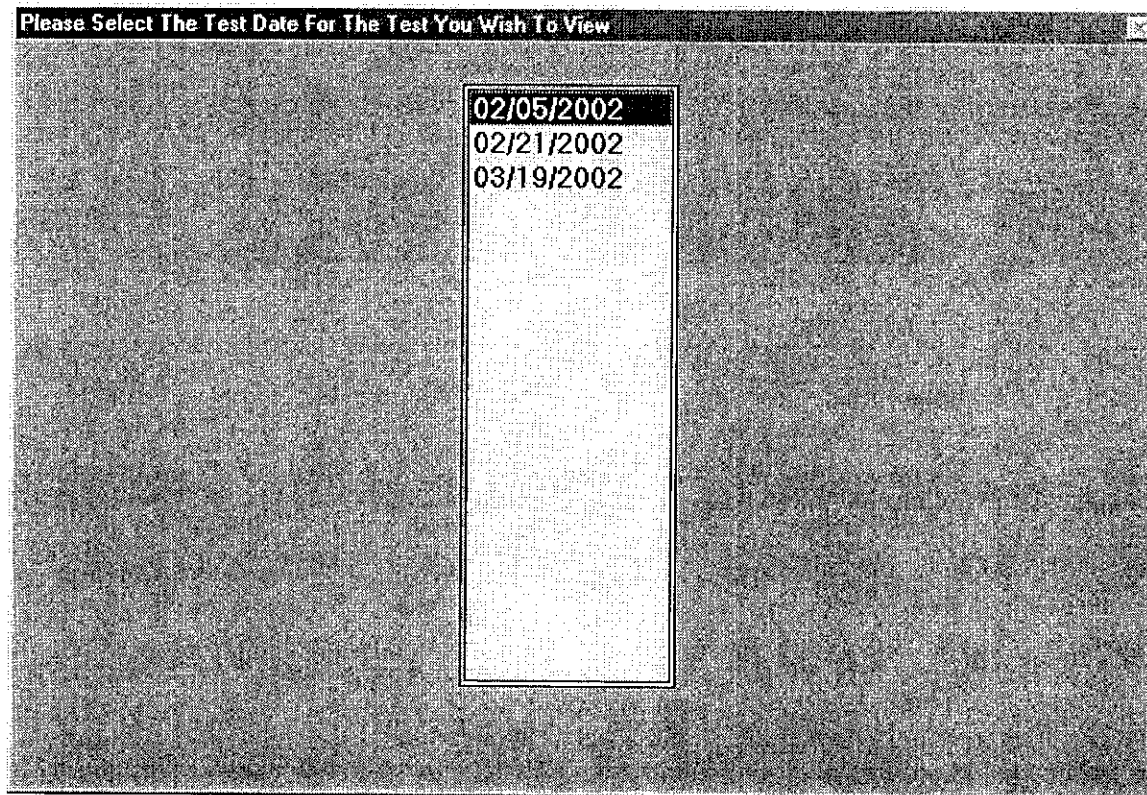
Print Preview- This selection will allow the operator to preview on screen the Patient Demographic and History data.

Print Report- This selection will allow the user to Print Reports on the Patient highlighted on the Patient list.

Exit- This selection will take the operator back to the VDL Main Menu.

To Print a Patient Report click on the Print Report button or type 8 on the keyboard.

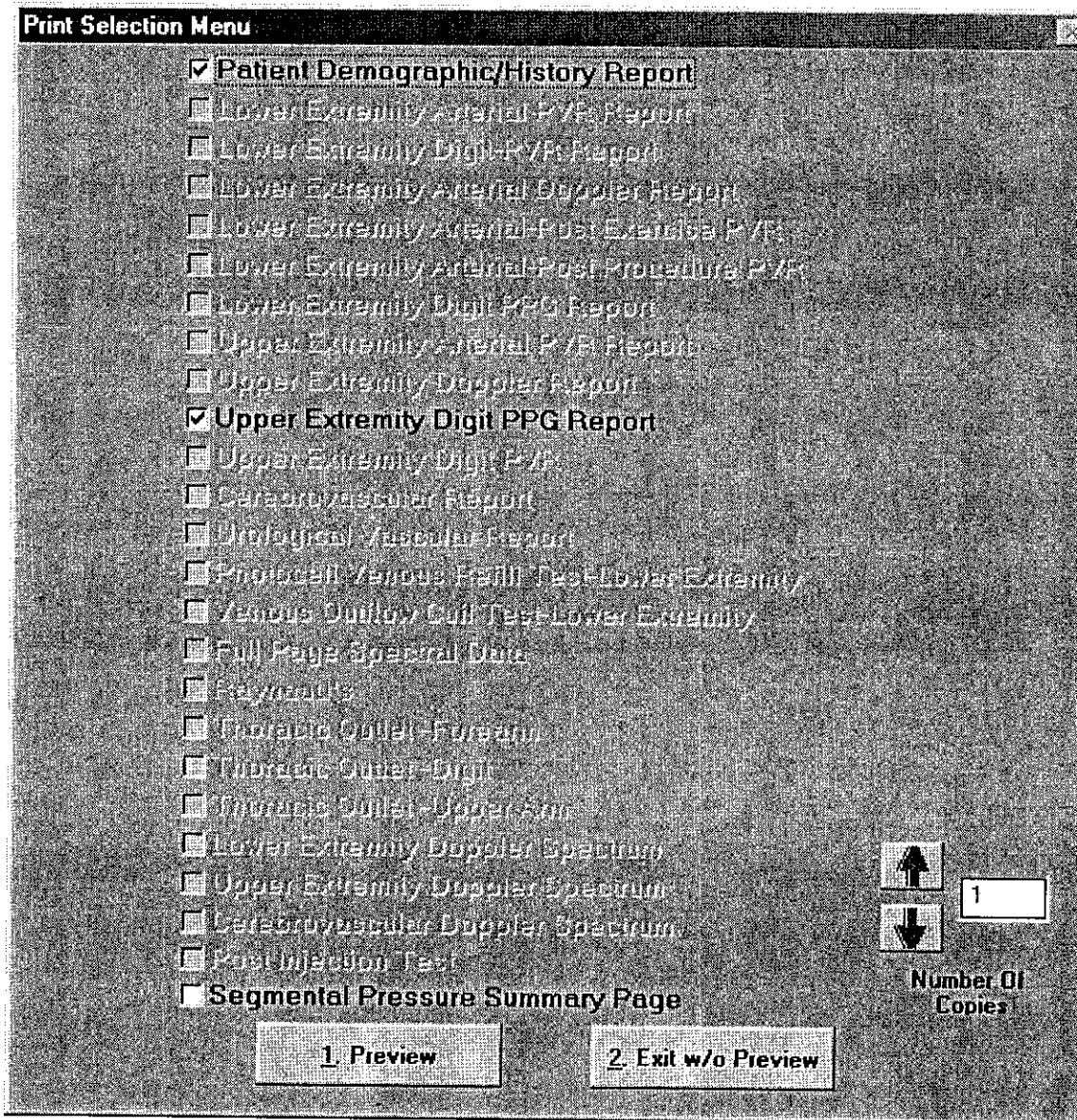
The following screen will appear:



The operator may **select the date of exam that they wish to print by clicking on that date**. The following screen will appear.

Printing Patient Reports

Continued

A screenshot of a software window titled "Print Selection Menu". The window contains a list of medical reports with checkboxes. The first two items, "Patient Demographic/History Report" and "Upper Extremity Digit PPG Report", are checked. The rest are unchecked. At the bottom right, there are up and down arrow buttons, a text box containing the number "1", and the label "Number Of Copies". At the bottom center, there are two buttons: "1. Preview" and "2. Exit w/o Preview".

Print Selection Menu

- ☒ Patient Demographic/History Report
- ☐ Lower Extremity Arterial P/R Report
- ☐ Lower Extremity Digit P/R Report
- ☐ Lower Extremity Arterial Doppler Report
- ☐ Lower Extremity Arterial Post Exercise P/R
- ☐ Lower Extremity Arterial Post Procedure P/R
- ☐ Lower Extremity Digit PPG Report
- ☐ Upper Extremity Arterial P/R Report
- ☐ Upper Extremity Doppler Report
- ☒ Upper Extremity Digit PPG Report
- ☐ Upper Extremity Digit P/R
- ☐ Cerebrovascular Report
- ☐ Diagonal Vascular Report
- ☐ Phlebostatic Venous Flow Test-Lower Extremity
- ☐ Venous Outflow Cuff Test-Lower Extremity
- ☐ Full Page Spectral Data
- ☐ Raynolds
- ☐ Thoracic Outlet-Forearm
- ☐ Thoracic Outlet-Digit
- ☐ Thoracic Outlet-Upper Arm
- ☐ Lower Extremity Doppler Spectrum
- ☐ Upper Extremity Doppler Spectrum
- ☐ Cerebrovascular Doppler Spectrum
- ☐ Post Injection Test
- ☐ Segmental Pressure Summary Page

Number Of Copies: 1

1. Preview 2. Exit w/o Preview

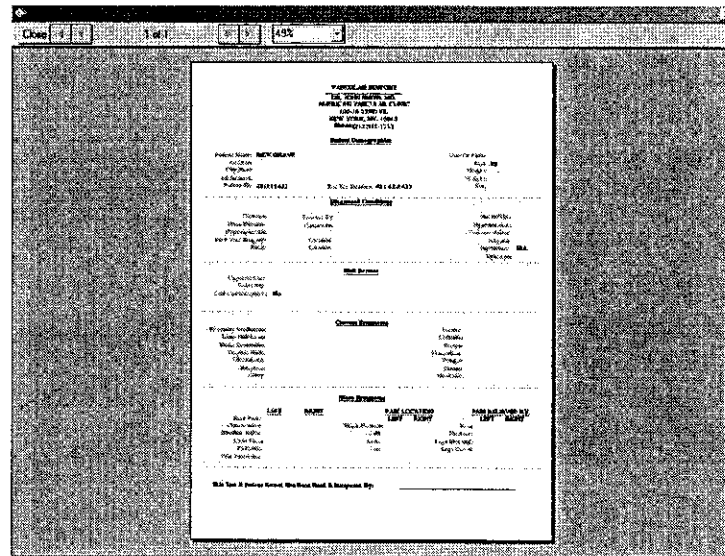
The user may select or unselect any report for printing by clicking on that selection. All selections with a check in the box will be printed.

The following screen will appear if you choose print preview.

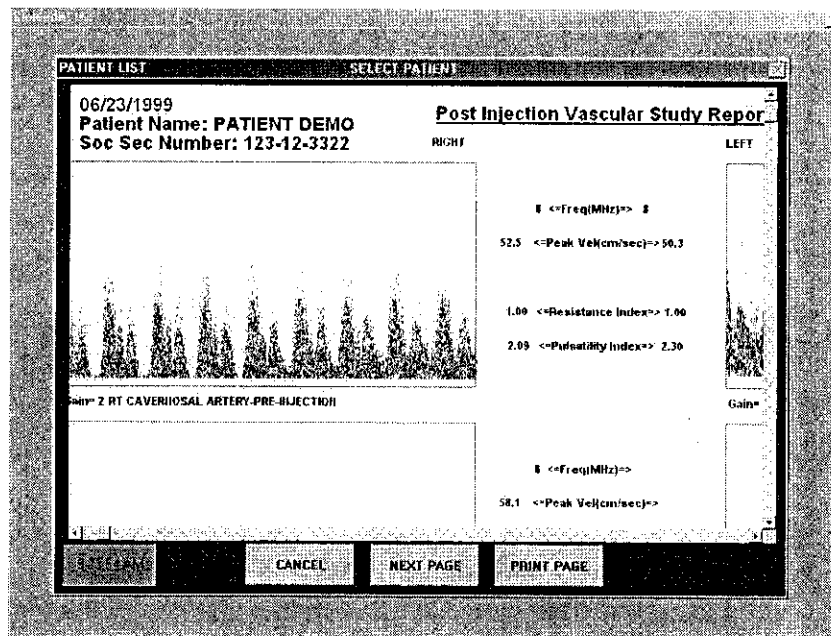
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Printing Patient Reports

Continued



While on this screen the user may zoom in on the report for better viewing in the following manner. Double Left mouse clicks will enlarge the image seen and each time the user double clicks with the left mouse button it will continue to get larger and larger. Double right mouse clicks will reduce the size in the same manner. If the user clicks and holds the left mouse button the cursor will change to a four-point arrow and allow movement of the entire report around in the window. Below is a sample of one of the many possible reports in a zoomed mode of the print preview.



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Printing Patient Reports

Continued

To Print a Patient Report Click on the Print button or type 1 on the keyboard. The Reports will then print on the selected Printer or the default printer set by Windows.

To Exit Without Printing, Click on that button or type 2 on the keyboard.

Guidance on Preventative Inspection and Maintenance

The VDL contains no parts, which require preventative maintenance

1. **Never** store the VDL near an air conditioning or heating ventilator.
2. Only clean the exterior of the VDL with alcohol and a cloth... and **ONLY** with the unit **UNPLUGGED** from the **AC WALL SOCKET**.
3. Leave the VDL **"OFF"** when not in use.
4. The Cuffs should only be cleaned with mild soap and water. They should never be cleaned with alcohol.
5. **NEVER PLACE LIQUID CONTAINERS** on top of or near the VDL.
6. Use only Ultrasound acoustic coupling gel with the Doppler probes. Please consult your sales person or the factory for replacement probes.
7. Doppler probes should be cleaned with transducer cleaning fluid. Please consult your sales person for supplies.
8. The VDL should **NEVER** be opened regardless of circumstances. There are no user serviceable parts inside.  **Shock hazard could result if opened.**

NOTE: *UNAUTHORIZED SERVICING OF THE UNIT WILL VOID YOUR FACTORY WARRANTY. ONLY AUTHORIZED SERVICE PERSONNEL CAN SERVICE THIS DEVICE. FOR FURTHER INFORMATION PLEASE CONTACT BioMedix AT 651-762-4010.*

Note: For disposal of the device at the end of its useful life, please contact BioMedix for proper disposal.

Instructions for Transducer Care

The Doppler ultrasound transducer provided with the VDL unit is an instrument that should be treated with care. One should be careful to clean the transducer after each use. After a time, acoustic-coupling gel could build up on the probe if regular (after every Patient) is not employed. The purpose of this procedure is to CLEAN the transducer and not to disinfect or sterilize it.

***  **WARNING*** NEVER CLEAN TRANSDUCER PROBE WITH THE PROBE PLUGGED IN.**

***  **WARNING*** NEVER USE ANY CLEANING FLUID OTHER THAN PARKER LABS TRANSEPTIC.**

1. Disconnect Transducer from the VDL unit.
2. Use Transeptic Cleaning fluid and a piece of sterile gauze.
3. Apply the cleaning solution to the sterile gauze pad.
4. Insure that the entire probe head (surface) and the cylindrical wall are completely covered with the cleaning fluid.
5. Use a second sterile gauze pad to wipe off and dry the excess cleaning fluid.
6. Once the cleaning fluid has been completely wiped off the transducer probe may be reconnected to the VDL and used again.

Specifications

Class 1, type BF  applied parts

Storage / Transport Temperature Range = -40°C to +50°C

Storage / Transport Humidity Range = 5% to 95%

Operational Temperature Range = 0°C to +40°C

Operational Humidity Range = 15% to 90%

Only computers that meet IEC 60950 should be connected to this device.

Doppler Sensitivity Measurements – 11.4 dB @ 2.90 cm @ 160 cm/sec

The “in-situ” intensity calculations are based on the measured center frequency of the acoustic signal (f, MHz) and the distance from the transducer under test to the hydrophone (d, cm) using the derating factor $e^{-0.069 \times f \times d}$.

5MHz CW Probe:	In-water SpTa 278.3 mW/ cm ²
	Derated SpTa 268.4 mW/ cm ²

8MHz CW Probe:	In-water SpTa 264.1 mW/ cm ²
	Derated SpTa 221.6 mW/ cm ²

8MHz CW Reduced Pwr:	In-water SpTa 14.2 mW/ cm ²
	Derated SpTa 13.5 mW/ cm ²

Doppler Frequency (Velocity) Accuracy = 90%

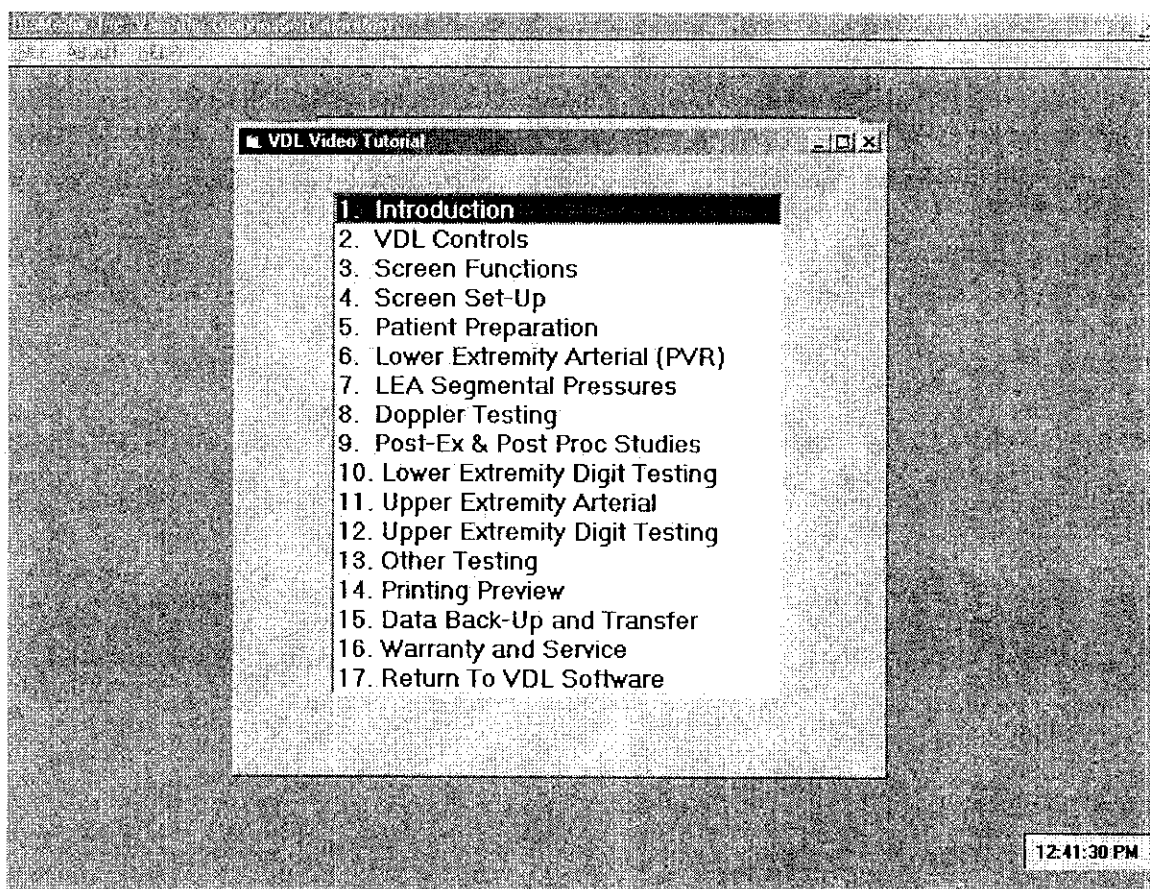
Segmental Pressure Accuracy = 95%

SBI/ABI/TBI Accuracy = 93%

Resistance Index Accuracy = 85%

Video Tutorial

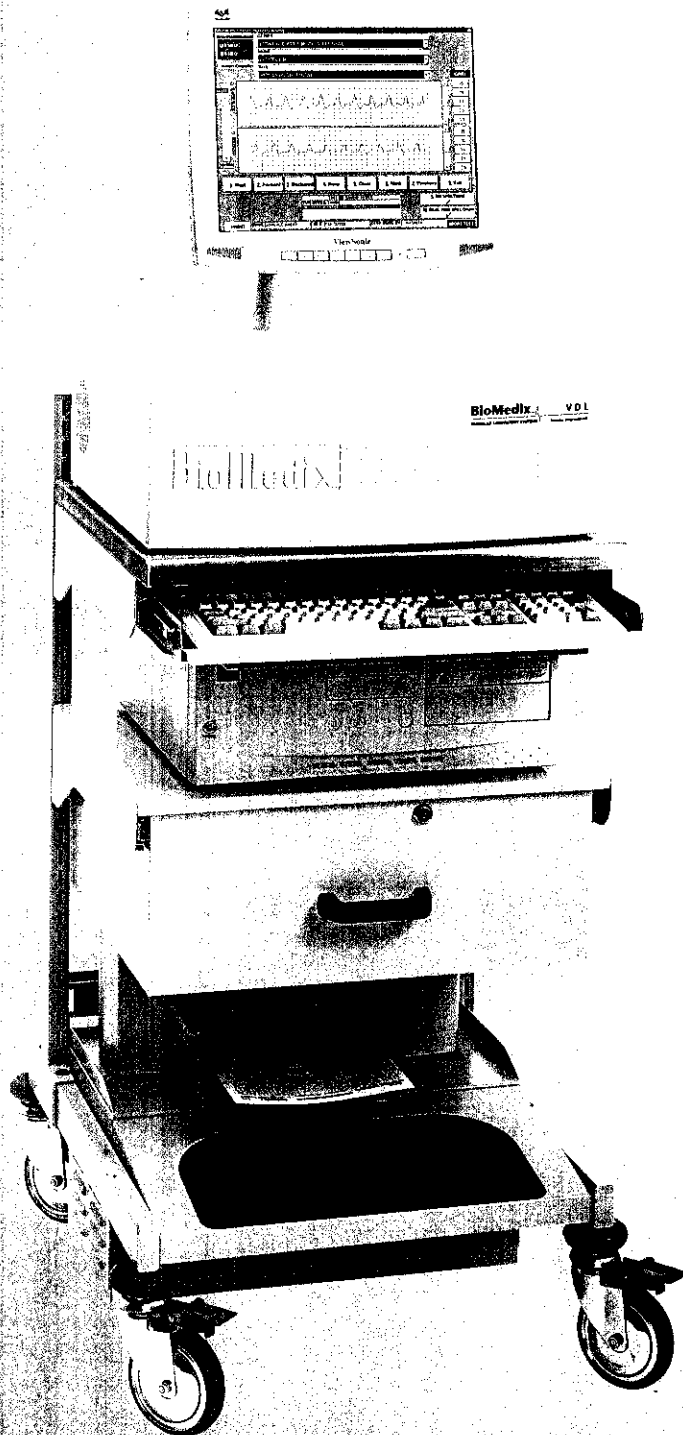
The VDL software employs a unique video tutorial system to provide the clinician with real time assistance in the performance of related diagnostic procedures. Throughout most of the software, one can press the F3 key to bring up a video table of contents.



One can start the video clip by double clicking on the selected topic. A few seconds after double clicking, the clip will start and the volume can be adjusted by moving the volume slider control with the mouse. The video can be stopped by clicking on the close button (the X on the top right of the screen).

The BioMedix Vascular Diagnostic Lab: the most comprehensive system available

- > This innovative system provides full bilateral, simultaneous testing, featuring an advanced design Doppler for segmental pressures with real time and post-process spectrum frequency capabilities.



TECHNOLOGY THAT FITS YOUR PRACTICE

The most comprehensive diagnostic system available, the VDL is suitable if you perform 11 or more tests per week.

PROCESSING POWER

Full-size desktop computer, flat panel display and printer are on custom cart. Complete studies, including audio, are saved for review or additional analysis at a later time.

HIGH QUALITY DIAGNOSTIC INFORMATION

Advanced design uses two Doppler circuits: phase locked loop Doppler technology. Bilateral simultaneous Doppler for segmental pressures.

FOR ADMINISTRATORS

A reimbursable and cost-effective diagnostic tool that addresses a serious health problem.

FOR TECHNICIANS

Easy to use and information-rich, it makes good use of your time and skills. Digital input enables you to manipulate data to arrive at meaningful post-procedure outputs.

FOR DOCTORS

Physiologic tests provide information about function and hemodynamic significance that not even sophisticated imaging systems can provide.

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BioMedix

VASCULAR LABORATORY SYSTEMS

The "top of the line" is even more impressive when it's the best line. What sets BioMedix apart:

ACCURATE WAVE FORMS MEAN ACCURATE DIAGNOSIS
Waveforms are never inflated to "fill the graph."

REAL-TIME WAVE FORMS ON AN EASY-TO-READ SCREEN
It's never been easier to visualize success.

RICH DATA FOR BETTER DIAGNOSIS
Color spectrum analysis, accurate audio capture and playback, and full color reports with optimized CPT and ICD-9 codes.

VERSATILITY

All diagnostic technologies (PVR, Doppler, Spectral Frequency Analysis PPG, and Segmental Pressures)

ONE-STOP ANALYSIS

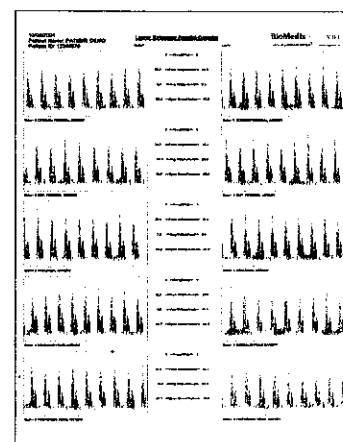
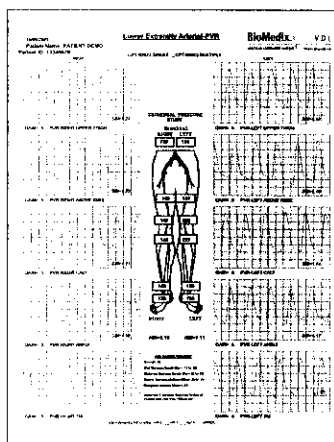
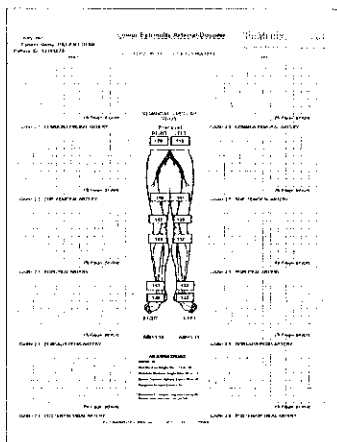
Entire testing procedure from one screen, with automated studies.

TESTING TECHNOLOGY THAT MAKES HOUSE CALLS

Because it is network and web-enabled, physicians can review results on their schedule.

Easy to Read Reports

These charts show PVR, Doppler waveforms and segmental pressures, plus Spectral Frequency Analysis.



VASCULAR DIAGNOSTIC LAB PRODUCT SPECIFICATIONS

Supplied Computer Specifications

- 500 MHz processor or greater
- Minimum 64 MB RAM or greater
- Minimum 20 GB hard drive
- 1.4MB 3.5" floppy disk drive
- CD-ROM Drive

Photoplethysmography (PPG)

- 2-independent PPG Channels

Sensor Type

- Solid-state photo transmitter and receiver

Doppler System

- 5 MHz continuous wave
- 8 MHz continuous wave
- 128 point FFT frequency spectrum analysis with color display
- Spectrum frequency in real time or post processed formats
- Post procedure audio playback

User Interface

- Microsoft Windows 95, 98, ME
- Operation via keyboard or wireless mouse

Display

- High resolution 15" or greater flat panel display

Main Power Supply

- 100-240 VAC, 47-63 Hz, 1.3 Amps
- Outputs via integral isolation transformer (optional)

BIOMEDIX, INC.

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HORSHAM WEST SUSSEX RH12 2BT

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TEST REPORT

(b)(4)



**FOOD AND DRUG ADMINISTRATION
EMC EMISSIONS REQUIREMENTS**

(b)(4)



TEST DATE: 17 MAY, 2004

(b)(4)



Records processed under FOIA Request # 2015-2895; Released by CDRH on 09-14-2015

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PADnet Lab Hardware Requirements Specification

Date 2004-Jul-08

Version (b) (4)

Tester (b) (6)

Records processed under FOIA Request # 2015-2895; Released by CDRH on 09-14-2015

PADnet Lab DTU **Hardware Requirements Specification**

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Records processed under FOIA Request # 2015-2895; Released by CDRH on 09-14-2015

PADNet Lab DTU Requirements Specification

Date 2004-Jul-06

Version (b) (4)

Tester (b) (6)

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Date 2004-Jul-30

Version (b) (4)

Author (b) (6)

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Records processed under FOIA Request # 2015-2895; Released by CDRH on 09-14-2015

Preliminary Hazard Analysis

PADnetLab

Project: PADnet

Version	Date	Author	Description
(b) (4)			

Table 1: Document Revision History

Records processed under FOIA Request # 2015-2895; Released by CDRH on 09-14-2015

Records processed under FOIA Request # 2015-2895; Released by CDRH on 09-14-2015

Records processed under FOIA Request # 2015-2895; Released by CDRH on 09-14-2015

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Version (b)(4)

Date: 2004-Jul-08

Version: (b)(4)

Author: (b)(6)

Rev Level	Approval Date	Checked By	Revision Description
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PADnetLab

Trace-ability Analysis

Version (b) (4)

Date: 2004-Jul-08

Version: (b) (4)

Author: (b) (6)

Rev Level	Approval Date	Checked By	Revision Description
(b) (4)			

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PADNet Lab Test

Validation Plan & Test Results Version (b) (4)

Date 2004-Jul-09

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PADnet Lab DTU Firmware

Validation Plan & Test Results

Version (b)(4)

Date: 2004-Jul-08

Version: (b)(4)

Tester:

(b)(6)

Rev Level	Approval Date	Checked By	Revision Description
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PADnet Lab Hardware Design Verification

Rev Level	Approval Date	Checked By	Revision Description
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PADNet Lab

Revision History as of 07/06/04

The following report of revision history shows all changes made to the software from the beginning of the project to the current date. Each day is listed in reverse chronological order showing changes made by each developer.

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BioMedixPADnetLab
[PRC-BIOMEDIX-01]REV
(b)(4)

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BIOMEDIX PADnetLab**Certificate of Known Defects****Version** (b)(4)**Date:** 2004-Jul-08**Version:** (b)(4)**Author:** (b)(6)

Rev Level	Approval Date	Checke d By	Revision Description
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(b)(4)

Table 1: Document Revision Data

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510(K) Summary of Safety and Effectiveness

General Information

Submitter's Name: BioMedix, Inc.
Address: 4205 White Bear Parkway
St. Paul, MN 55110
Telephone: 651-762-4010
Contact Person: Will Rogers or Dick Magnuson
Date Prepared: July 23, 2004
Registration Number: 2134492

Device

Name: PADnet Lab
Trade Name: PADnet Lab
Common Name: Plethysmograph
Classification Name: Blood Flow Monitor
Product Code: JOM
Class: II
Regulation Number: 870.2780

Identification of Legally Marketed Devices

Name: Flostat Vascular Lab

K Number: K973644

Date Cleared: December 23, 1997

Description of the Device

The BioMedix PADnet Lab is a non invasive cardiovascular blood flow monitor. It is intended for use in the early detection of peripheral vascular disease. The PADnet Lab has been tested to the following standards.

- EN60601-1 Electrical Safety
- EN60601-1-2 EMC
- ISO 10993-1 Biological evaluation

The BioMedix PADnet Lab is a non invasive cardiovascular blood flow monitor. It is intended for use by trained medical professionals in a hospital or clinic. It is not to be operated in an explosive atmosphere nor in the proximity to any equipment that has the potential to generate a sufficiently large electromagnetic field as to interfere in any manner with the operation of the PADnet Lab.

The BioMedix PADnet Lab is a Prescription Device, **not** life supporting or life sustaining, not an implant, supplied **non-sterile** with pressure cuffs. It requires a Personal Computer with the following requirements:

- Windows 2000 Operating System or higher
- 128 MB RAM
- 20 GB Free Hard Disk Space
- 600 MHz Processor or higher

Intended Use Statement

The BioMedix PADnet Lab is a non invasive device used to gauge the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures to assist in the identification of vascular disease. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

Components/ Part Numbers

Description	BioMedix Part Number
1- USB cable	100-1600
1- Cuff kit	7200
BioMedix PADnet Lab Software Program CD ROM	400-210
1-AC Power Cord	350-215
1- PADnet Lab Operators Manual	10650

Table of Comparisons

The following summary table of comparisons compares the new device (PADnet Lab) to the predicate device: Flowstat Vascular Lab.

#	Area	New Device: PADnet Lab	Predicate Device: Flowstat Vascular Lab	Same	Different
1	Pulse Volume Recording	Plethysmograph	Plethysmograph	X	
2	Segmental Pressure flow sensor	Oscillometric	Distal Flow Sensor		X
3	Patient Population	Male/Female Adult	Male/Female Adult	X	
4	Environment	Hospital or Clinic	Hospital or Clinic	X	
5	Power Source	AC converted to DC	AC converted to DC	X	
6	Weight	4 lbs.	26 lbs.		X
7	Data acquisition	Single site	Bilateral		X
8	Software Controls	Operator initiated	Operator initiated	X	
9	Size	12 1/2" W X 10" D X 3 " H	20 1/2" W X 17 3/4 " D X 7" H		X
10	Cuff Deflation Rate	3-5 mm Hg/Sec	3-5 mm Hg/Sec	X	

11	Operating Environment	0 to +40°C 15 - 90%	0 to +40°C 15 - 90%	X	
12	Storage Environment	-40 to +50° C 5-95%	-40 to +50° C 5-95%	X	
13	Safety Standards	Yes	Yes	X	
14	EMC	Yes	Yes	X	
15	Prescription Device	Yes	Yes	X	
16	Cuff Bladder Deflation	Automatic	Automatic	X	
17	Inflation Method	Automatic	Automatic	X	
18	Cuff Sizes	Multiple	Multiple	X	
19	Clinical Reports	Yes	Yes	X	
20	Printed Reports	Yes	Yes	X	
21	Supplied Non-Sterile	Yes	Yes	X	

Discussion of Similarities and Differences

The PADnet Lab and the Flowstat Lab have the following similarities:

- Pulse Volume Recording
- Patient Population
- Environment
- Power Source
- Software Controls
- Cuff Deflation Rate
- Operating Environment
- Storage Environment
- Safety Standards
- EMC
- Prescription Device
- Cuff Bladder Deflation
- Inflation Method
- Cuff Sizes
- Clinical Reports
- Printed Reports
- Supplied Non-Sterile

The differences, with comments, are the following:

- Segmental Pressure flow sensor – The PADnet Lab uses Oscillometric not distal flow sensor.
- Weight – PADnet Lab is significantly less.
- Data acquisition – PADnet Lab is single site not bilateral.
- Size – PADnet Lab is significantly smaller.

835

Thus, even though the PADnet Lab is not identical to the Flowstat Vascular Lab, we at BioMedix believe it should be granted substantial equivalence because:

- It has the same intended use as the predicate device.
- It has the same technical characteristics as the predicate device and does not raise any new types of safety or effectiveness concerns.

Indications for Use

510(k) Number (if known): _____

Device Name: Biomedix PADnet Lab

Indications for Use:

The BioMedix PADnet Lab is a non invasive device used to gauge the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures to assist in the identification of vascular disease. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

User Profile:

Patient Population: Male/Female, Adults

Environment of Use: Hospitals or Clinics

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)

Page ___ of ___

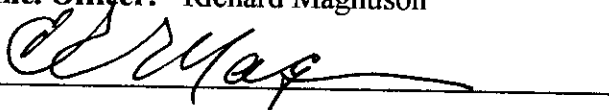
(Posted November 13, 2003)

**Premarket Notification
Truthful and Accurate Statement
[As required by 21 CFR 807.87(k)]**

I certify that, in my capacity as CFO of BioMedix, 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.

Name of BioMedix, Inc. Officer: Richard Magnuson

Signature: _____



Title: CFO

Company Name: BioMedix, Inc.

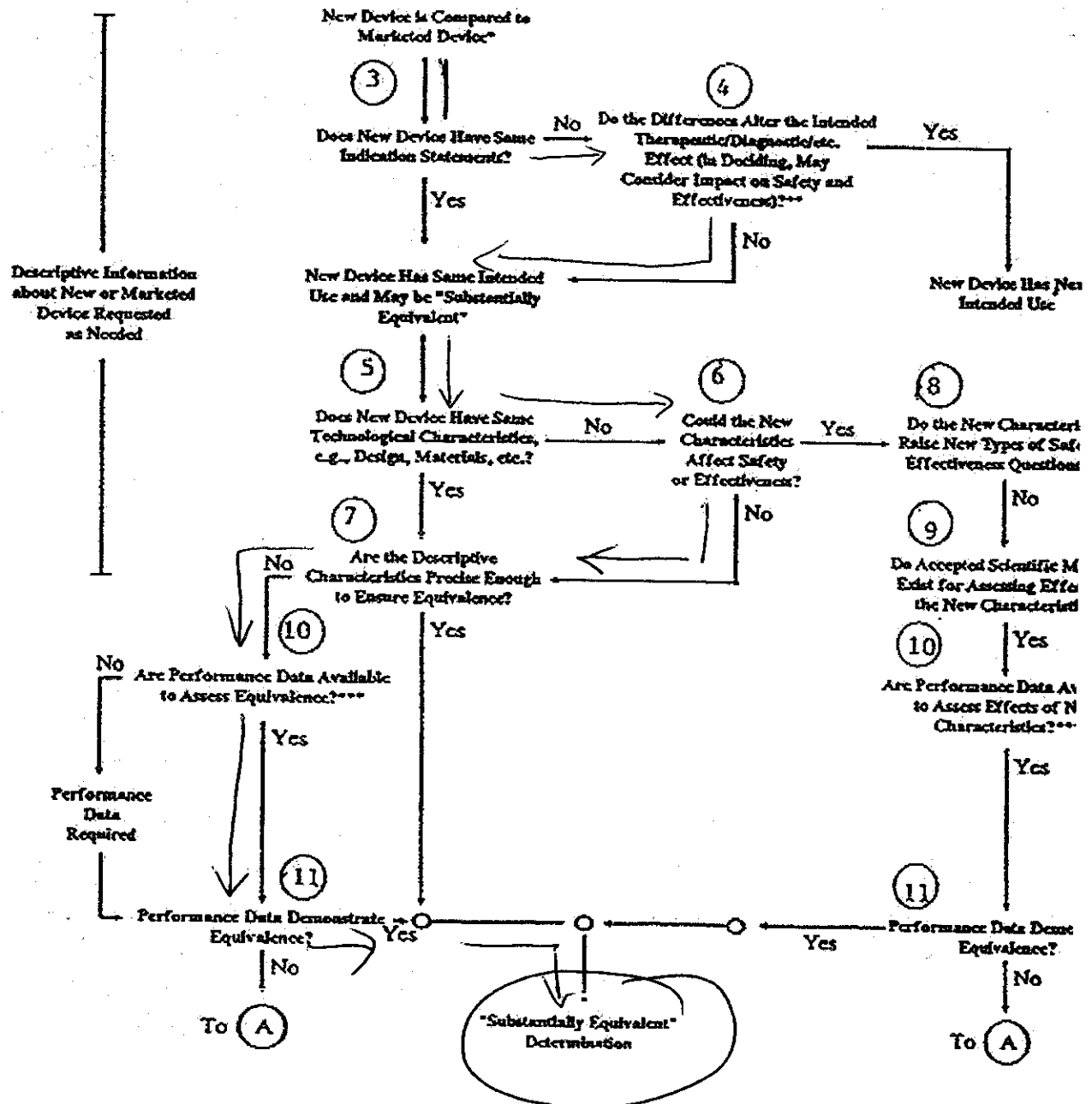
Date of Signature: _____

26 July 2004
Day/Month/Year

K Number (if known):

838

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



- * 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Frank Lacy

Subject: 510(k) Number K042616

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?

☐ YES ☒ NO

Is this device subject to the Tracking Regulation?

☐ YES ☒ NO

Was clinical data necessary to support the review of this 510(k)?

☐ YES ☒ NO

Is this a prescription device?

☒ YES ☐ NO

Was this 510(k) reviewed by a Third Party?

☒ YES ☐ NO

Special 510(k)?

☐ YES ☒ NO

Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers

☐ YES ☒ NOTruthful and Accurate Statement ☐ Requested ☒ Enclosed☒ A 510(k) summary OR ☐ A 510(k) statement☐ The required certification and summary for class III devices N/A☒ The indication for use formCombination Product Category (Please see algorithm on H drive 510k/Boilers) NAnimal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

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

74 JOM (Class II)Review: [Signature]

(Branch Chief)

CEMB

(Branch Code)

10/07/09

(Date)

Final Review: [Signature]

(Division Director)

10/8/09

(Date)

4

REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 042616

Reviewer: Frank Lacy

Division/Branch: DCD/CEMB

Device Name: PADnet Lab

Product To Which Compared (510(K) Number If Known): K973644

YES NO

1.	Is Product A Device	☒		If NO = Stop
2.	Is Device Subject To 510(k)?	☒		If NO = Stop
3.	Same Indication Statement?	☒		If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5.	Same Technological Characteristics?		☒	If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?	☒		If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?		☒	If YES = Stop NE
9.	Accepted Scientific Methods Exist?	☒		If NO = Stop NE
10.	Performance Data Available?	☒		If NO = Request Data
11.	Data Demonstrate Equivalence?	☒		Final Decision:

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

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1. Intended Use: *see 3rd party review*
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

see 3rd party review

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

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

see 3rd party review

I N T E R O F F I C E M E M O R A N D U M

Date: October 7, 2004

From: Frank Lacy, Electrical Engineer, ODE/DCD/CEMB

To: The Record, K042616 **(THIRD PARTY REVIEW)**

Subject: Review of Premarket Notification For Substantial
 Equivalence Decision

Reason for Submission: *This 510(k) is being submitted for a new Plethysmograph (or blood flow monitor).*

THIS IS A THIRD PARTY REVIEW.

Intended Use:

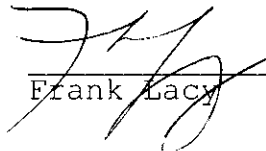
According to the manufacturer, the "Indications for Use" are stated to be "The BioMedix PADnet Lab is a non-invasive device used to record physiological data from the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures for use by the Physician in the identification of vascular pathology. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non-intact skin."

Comments: I generally concur with the assessment, by the Third Party reviewer, that the file is substantially equivalent to the predicate devices. The review caused this reviewer to perform a quick review of the documentation in the file (not just the review memo) to confirm that the information was well documented in a concise manner. There was an exchange/dialogue between me and the 3rd party reviewer (Cheryl Norton at TUV Services) during the week of October 4, 2004. On Monday, October 4, 2004, I contacted Cheryl about some concerns regarding her review memo dated September 22, 2004. It appeared that the Indications for Use were different than the predicate since the predicate was a Radiology device, section N of her review memo (page 7 of 8) was providing too much information that confused the technology used for this device, and that there was mention of a term called ABI (Ankle Brachial Indices) which appeared as a new claim. After several discussions on Tuesday, October 5, 2004, I asked Cheryl to approach the sponsor and ask them to identify the particular part of the Indications for Use (from the predicate) that was a subset used for this current device. She revised section N of her review memo to remove the statement that the predicate device included the Doppler ultrasound function when it is not found on

the subject device. Also, it was determined that the device (predicate and current) were not making any claims of diagnosis since the device is only reporting the raw data with regard to ABI; both reporting a calculated value from two measured values. According to 21 CFR 892.1540 (predicate Radiology device), the device projects a continuous high-frequency sound wave into the body (other than the fetus) to determine the frequency changes (Doppler shift) in the reflected wave and **intended for use in investigation of non-fetal blood flow** and other non-fetal body tissues in motion. According to 21 CFR 870.2780, the device **estimates blood flow** in a region of the body using hydraulic, **pneumatic**, or photoelectric measurement techniques. Both are blood flow monitors that are not intended for pediatric and fetal use. The predicate device used pneumoplethysmography, photoplethysmography, and continuous wave Doppler ultrasound velocity waveform measurements while the subject device used pneumoplethysmography. Finally, the intended use of the predicate device used for vascular pathology. Finally, I asked Cheryl to explain to the manufacturer that it appeared that the Indications for Use was growing when they used the terms "identification of vascular disease" instead of vascular pathology. The terms were changed by the manufacturer in the labeling and Indications for Use statement. This appeared to resolve all issues that were found with the review/documentation provided by TUV Services in their 3rd party assessment and review.

Recommendation:

I believe that enough information has been obtained from Biomedix, Inc. and reviewed by the Third Party reviewer (TUV Product Services) to determine if this 510(k) is substantially equivalent to the predicate devices. I recommend that the Third Party reviewer and the manufacturer be advised that no additional information is needed from the manufacturer. Hence, we believe that the file is SE to predicate devices.

 10/7/04
Frank Lacy (date)

Lacy, Frank

From: Norton Cheryl [CNorton@tuvam.com]
Sent: Monday, October 04, 2004 5:22 PM
To: fxl@cdrh.fda.gov
Subject: K042616 (Third Party Review, Biomedix Padnet Lab)

Dear Mr. Lacy,

(b) (4)



Sincerely,

Cheryl Norton

Third Party 510(k) Reviewer

TUV America Inc.
Product Service
P: 651-638-0294
F: 651-638-0295

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

From: Will Rogers [mailto:rogersw@biomedix.com]
Sent: Monday, October 04, 2004 3:57 PM
To: Norton Cheryl
Subject: ABI questions

Cheryl,

(b) (4)



(b) (4)



If you have any additional questions, please contact me.

Will Rogers

11

10/7/2004

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

12/12/97 FRI 12:40 FAX 301 480 4224

CDRH DRAERO

0003

Page ____ of ____

510(k) Number (if known): K973644

Device Name: FloSTAT Vascular Lab.

Indications For Use: See Attached

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Gerald L. Nigam
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K973644

Prescription Use ☒
(Per 2 CFR 301.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)

Intended Use

The BioMedix, Inc. Flostat Vascular Lab is a device for the use in the diagnosis of the etiology and extent of vascular pathology primarily in the peripheral vasculature and, in a more restricted sense, in the central vasculature (periorbital region ONLY). These tasks are accomplished via three separate modalities, each of which can be used to test either the arterial or venous system. The three modalities are 1) Pneumoplethysmography (blood pressure cuff air inflation), 2) Photoplethysmography (change in infrared light reflectance on skin as a reflection of larger branches) and 3) Simple continuous wave doppler ultrasound velocity waveform measurement. NONE of these testing modalities are intended for FETAL USE and the devices and instruction manuals are so labelled.

The air pump Pneumoplethysmograph and infrared Photoplethysmograph are for use in studying the PERIPHERAL VASCULATURE ONLY.

The 5 MHz. continuous wave doppler ultrasound velocity meter and the 8 MHz. continuous wave doppler ultrasound velocity meter are for use in studying the PERIPHERAL VASCULATURE ONLY.

There is a separate control setting labelled clearly on the FLOSTAT VASCULAR LAB - 'Ophthalmic-8 MHz.' doppler which is intended for periorbital doppler studies ONLY. The 'Ophthalmic-8 MHz.' mode is an 8 MHz. continuous wave doppler ultrasound velocity meter exactly the same as the 8 MHz. continuous wave doppler velocity meter except that the 'Ophthalmic-8 MHz.' doppler has substantially lower acoustic output which conforms to the safety standards for periorbital studies specified by the Food and Drug Administration (FDA). Through medical studies performed by the scientists at the FDA, it has been determined that ultrasound acoustic levels as rated by various figures of merit (eg. ISPTA; etc.) are safe for different areas of the body.

For this reason, DO NOT EVER PERFORM PERIORBITAL STUDIES WITH THE DOPPLER IN ANY MODE OTHER THAN THE 'Ophthalmic-8 MHz.' MODE. Labels will also be placed on the doppler transducer that they are NOT FOR FETAL USE and specifying the correct frequency (5 MHz or 8 MHz).

The doppler section is intended to generate velocity waveforms and values for study and audio output for physician analysis of the arterial and venous system.

The Ultrasonic Doppler device at 5 MHz. and 8 MHz. applies ultrasound energy through the extremities of the subject to assess blood velocity, blood velocity waveform morphology, spectrum analysis, pressure, and patency of PERIPHERAL VESSELS.

The Ultrasonic Ophthalmic-8 MHz. device applies ultrasound energy to the periorbital region to assess blood velocity, blood velocity waveform morphology, and spectrum analysis in this area.

The Pneumoplethysmograph is used to gauge the arterial system through volume pulse recording studies and is used to gauge the venous system through maximum venous outflow studies.

The Photoplethysmograph is used to gauge the arterial system through pulse waveform analysis and is used to gauge the venous system through venous reflux time tests. Full clinical information is provided in the Operators Instruction Manual(enclosed herein).

Lacy, Frank

From: Norton Cheryl [CNorton@tuvam.com]
ent: Tuesday, October 05, 2004 11:13 AM
to: fxl@cdrh.fda.gov
Subject: indications for use, K042616



Indications for Use
comparison...

Dear Mr. Lacy,

Attached is the Indications for Use of the predicate device (Flostat Vascular Lab, K973644) with text circled to show how the new device (PADnet Lab, K042616) has similar indications for use. The new device has indications for use which are a subset of the predicate device's indications for use. This information was provided by the manufacturer, Biomedix. <<Indications for Use comparison.pdf>>
Please let me know if you need any further information.

Best Regards,
Cheryl Norton
Third Party 510(k) Reviewer
TUV America Inc.
Product Service
P: 651-638-0294
F: 651-638-0295

Intended Use

The BioMedix, Inc. Flostat Vascular Lab is a device for the use in the diagnosis of the etiology and extent of vascular pathology primarily in the peripheral vasculature and, in a more restricted sense, in the central vasculature (periorbital region ONLY). These tasks are accomplished via three separate modalities, each of which can be used to test either the arterial or venous system. The three modalities are 1) Pneumoplethysmography (blood pressure cuff air inflation), 2) Photoplethysmography (change in infrared light reflectance on skin as a reflection of larger branches) and 3) Simple continuous wave doppler ultrasound velocity waveform measurement. NONE of these testing modalities are intended for PETAL USE and the devices and instruction manuals are so labelled.

The air pump Pneumoplethysmograph and infrared Photoplethysmograph are for use in studying the PERIPHERAL VASCULATURE ONLY.

The 5 MHz. continuous wave doppler ultrasound velocity meter and the 8 MHz. continuous wave doppler ultrasound velocity meter are for use in studying the PERIPHERAL VASCULATURE ONLY.

There is a separate control setting labelled clearly on the FLOSTAT VASCULAR LAB - 'Ophthalmic-8 MHz.' doppler which is intended for periorbital doppler studies ONLY. The 'Ophthalmic-8 MHz.' mode is an 8 MHz. continuous wave doppler ultrasound velocity meter exactly the same as the 8 MHz. continuous wave doppler velocity meter except that the 'Ophthalmic-8 MHz.' doppler has substantially lower acoustic output which conforms to the safety standards for periorbital studies specified by the Food and Drug Administration (FDA). Through medical studies performed by the scientists at the FDA, it has been determined that ultrasound acoustic levels as rated by various figures of merit (eg. ISPTA, etc.) are safe for different areas of the body.

For this reason, DO NOT EVER PERFORM PERIORBITAL STUDIES WITH THE DOPPLER IN ANY MODE OTHER THAN THE 'Ophthalmic-8 MHz.' MODE. Labels will also be placed on the doppler transducer that they are NOT FOR PETAL USE and specifying the correct frequency (5 MHz or 8 MHz).

The doppler section is intended to generate velocity waveforms and values for study and audio output for physician analysis of the arterial and venous system.

The Ultrasonic Doppler device at 5 MHz. and 8 MHz. applies ultrasound energy through the extremities of the subject to assess blood velocity, blood velocity waveform morphology, spectrum analysis, pressure, and patency of PERIPHERAL VESSELS.

The Ultrasonic Ophthalmic-8 MHz. device applies ultrasound energy to the periorbital region to assess blood velocity, blood velocity waveform morphology, and spectrum analysis in this area.

The Pneumoplethysmograph is used to gauge the arterial system through volume pulse recording studies and is used to gauge the venous system through maximum venous outflow studies.

The Photoplethysmograph is used to gauge the arterial system through pulse waveform analysis and is used to gauge the venous system through venous reflux time tests. Full clinical information is provided in the Operators Instruction Manual(enclosed herein).

Lacy, Frank

From: Norton Cheryl [CNorton@tuvam.com]
Sent: Tuesday, October 05, 2004 12:10 PM
o: fxl@cdrh.fda.gov
Subject: RE: indications for use, K042616



Indications for Use
K042616 .d...

Mr. Lacy,
Biomedix has agreed to change the wording (b)(4) Draft
Please see the revised Indications for Use form (attached). <<Indications for Use K042616.doc>>
Regards,
Cheryl Norton

> -----Original Message-----
> From: Norton Cheryl
> Sent: Tuesday, October 05, 2004 10:13 AM
> To: 'fxl@cdrh.fda.gov'
> Subject: indications for use, K042616
>
> Dear Mr. Lacy,
> Attached is the Indications for Use of the predicate device (Flostat
> Vascular Lab, K973644) with text circled to show how the new device
> (PADnet Lab, K042616) has similar indications for use. The new device
> has indications for use which are a subset of the predicate device's
> indications for use. This information was provided by the
> manufacturer, Biomedix. << File: Indications for Use comparison.pdf
>> Please let me know if you need any further information. Best
> Regards, Cheryl Norton Third Party 510(k) Reviewer TUV America Inc.
> Product Service
> P: 651-638-0294
> F: 651-638-0295
>
>
>

Indications for Use

510(k) Number (if known): _____

Device Name: Biomedix PADnet Lab

Indications for Use:

The BioMedix PADnet Lab is a non invasive device used to record physiological data from the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures for use by the Physician in the identification of vascular pathology. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

User Profile:

Patient Population: Male/Female, Adults

Environment of Use: Hospitals or Clinics

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)

Page of

(Posted November 13, 2003)

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THIRD PARTY REVIEW CHECKLIST

1. Is this 510(k) eligible for third party review, i.e.:		
a. Is the device on the list of eligible devices?*	Yes	No
b. Can a determination of substantial equivalence be made without clinical data?	Yes	No
c. Are you aware of the 510(k) holder being the subject of an Integrity Investigation?	Yes	No

IF THE ANSWER IS "NO" TO A or B above, or "YES" to C above, PLEASE BRING THE SUBMISSION TO POS IMMEDIATELY.

Are the following elements included in the submission:

2. A cover letter signed by the third party's official correspondent clearly identifying:		
a. The purpose of the submission	Yes	No
b. The name and address of the third party	Yes	No
c. The name and address of the 510(k) holder	Yes	No
d. The name of the device (trade name, common or usual name, and FDA classification name)	Yes	No
e. The third party's recommendation with respect to the substantial equivalence of the device	Yes	No
f. The date the third party first received the 510(k) from the 510(k) holder	Yes	No

3. A letter signed by the 510(k) holder authorizing the third party to submit the 510(k) on its behalf and to discuss its contents with FDA.	Yes	No
--	-----	----

4. The complete 510(k) conforming to FDA's established requirements relating to content and form of such submissions.	Yes	No
---	-----	----

5. A complete review of the 510(k), signed by all personnel who conducted the third party review and by an individual within the third party responsible for supervising third party reviews, with a recommendation concerning the substantial equivalence of the device.	Yes	No
---	-----	----

Page 2 - Third Party Review Checklist

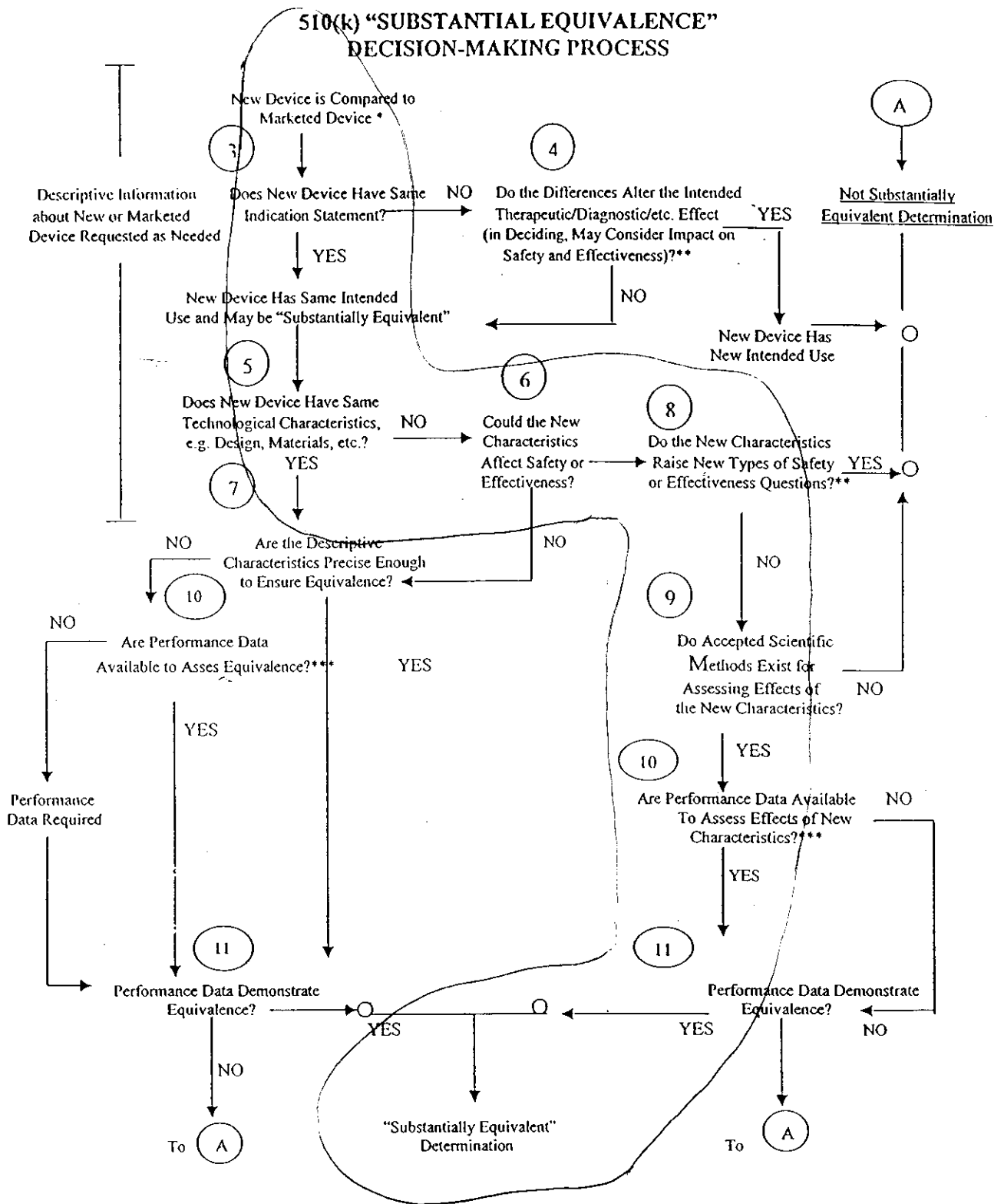
6. A certification that:		
a. The third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA	Yes	No
b. Statements made in the third party's review are true and accurate to the best knowledge of the third party	Yes	No
c. The third party's review is based on the 510(k) that it is submitting with the review	Yes	No
d. The third party understands that the submission to the government of false information is prohibited	Yes	No

7. Are the following forms included in the submission as discussed in the Center's guidance document entitled Third Party Review-An Instruction Manual for Conducting Reviews of Premarket Notifications:		
a. Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Parts I and II)	Yes	No
b. Record of Deficiencies, if applicable (attachment 1a)	Yes	No
c. Indications for Use Form	Yes	No
d. 510(k) Summary or Statement (attachment 1c)	Yes	No
e. 510(k) Truthful and Accurate Statement (attachment 1d)	Yes	No
f. Third Party "Substantial Equivalence" (SE) Decision Making Documentation (attachment 2)	Yes	No

IF ANY OF THE ABOVE INFORMATION IS NOT INCLUDED WITH THE THIRD PARTY'S SUBMISSION OR IS NOT ADEQUATE, CONTACT THE THIRD PARTY AND ATTEMPT TO RESOLVE THE DEFICIENCY. PLEASE INCLUDE A MEMORANDUM TO THE RECORD OF THE TELEPHONE CALL. WHEN THE INFORMATION IS RECEIVED PLEASE REVISE THIS CHECKLIST OR COMPLETE A NEW ONE.

COMMENTS: _____

*If the third party incorrectly classified the device and it is not a device type eligible for third party review please bring to POS.



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

5