Carolina Medical Electronics, Inc.
P.O. Box 307 • King, NC 27021 USA • 919-983-5132 • TLX 80-6442 • FAX 919-983-8992

September 18, 1991

Attention: Division of Cardiovascular Devices
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

RE: 510(k) Notification for the VascuMAP Medical Air Plethysmograph Series

Dear Sirs:

Please find enclosed two copies of the 510(k) Premarket Notification for the VascuMAP Medical Air Plethysmograph Series submitted in accordance with 21 CFR 807, Subpart E.

Carolina Medical Electronics, Inc., is informing the Center for Devices and Radiological Health of its intent to market the VascuMAP Medical Air Plethysmograph Series. The contents of this 510(k) submission are confidential commercial information. We ask that the maximum protection provided by law be given this notification.

If you require further information, please contact me.

Sincerely,

James S. Campbell MD

James S. Campbell, EE, MD
Director of Clinical Services
Official FDA Correspondent

Enclosure

VASCUMAP MEDICAL AIR PLETHYSMOGRAPH

RE: 510(k) Premarket Notification

This 510(k) Premarket Notification has been prepared in accordance with "21 CFR 807 Subpart E-Premarket Notification Procedures".

CLASSIFICATION NAME:

Non-invasive Blood Pressure Measurement System (21 CFR 870.1130)

Oscillometer (21 CFR 870.2675)

Pneumatic Plethysmograph (21 CFR 870.2780)

COMMON/UNUSUAL NAME:

Segmental Air Plethysmograph

Oscillometric Non-Invasive Blood Pressure Instrument

PROPRIETARY NAME: VascuMAP Medical Air Plethysmograph

Models: AP-102 (no chart recorder included)

AP-102R (includes chart recorder)

AP-102V (includes chart recorder and volume calibrator)

ESTABLISHMENT REGISTRATION NUMBER: 1017913

C. ROGER JONES, PRESIDENT
Carolina Medical Electronics, Inc.

JAMES. S. CAMPBELL, EE, MD., DIRECTOR OF CLINICAL SERVICES
Official FDA Correspondent

510(k) APPLICATION

VascuMAP
MEDICAL AIR PLETHYSMOGRAPH

MODELS: AP-102, AP-102R, AP-102V

CAROLINA MEDICAL ELECTRONICS, INC.
P.O. BOX 307
157 INDUSTRIAL DRIVE
KING, NC 27021

PRESIDENT: C. ROGER JONES
OFFICIAL FDA CORRESPONDENT: JAMES S. CAMPBELL, EE, MD.

STATEMENT OF INTENDED USE

The VascuMAP Medical Air Plethysmograph was designed and intended to be used for measurement of Brachial Blood Pressures and Pulse Rates in adults, for obtaining Mean Arterial Pressures and Pulse Rates at peripheral vascular sites in adults, and for obtaining volume calibrated arterial and venous waveforms at peripheral vascular sites in adults. The VascuMAP Medical Air Plethysmograph is a diagnostic instrument, but as with any non-invasive diagnostic procedure, the results should be confirmed by a physician.

PERFORMANCE STANDARDS:

None Established under Section 514 of Federal Food, Drug, and Cosmetic Act.

Carolina Medical Electronics, Inc., designed the VascuMAP Medical Air Plethysmograph to comply with the electrical, fire, and mechanical safety guidelines in Underwriters Laboratories Standard for Safety, Medical and Dental Equipment, UL544.

The American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI SP10), developed by the Association for the Advancement of Medical Instrumentation was also utilized in obtaining the proper labeling, safety, and performance requirements for the VascuMAP Medical Air Plethysmograph.

The Sections of this 510(k) Notification are as follows:

Attachment A: Operator's Manual and other labeling

Attachment B: Substantial Equivalence to Predicate Devices

Attachment C: Clinical Data

Attachment D: Software Assurance

Attachment E: References

SUMMARY OF DEVICE SAFETY, EFFECTIVENESS, AND ADVERSE EFFECTS:
Pursuant to Section 513i(3) (A) AND (B):

1) SAFETY

The VascuMAP Medical Air Plethysmograph Series has been developed in accordance with and meets the criteria as stated in Underwriters Laboratory Standard UL544 for Medical and Dental Equipment for direct patient use. The only item contacting the patient is a standard pneumatic blood pressure cuff.

The VascuMAP Device is an instrument that may be set to acquire blood pressures and waveforms in automatically timed repeating modes without operator intervention, so additional safety features were deemed necessary and were incorporated into the design from its inception. See the SPECIFICATIONS Section of the VascuMAP Operator's Manual for more information.

Carolina Medical Electronics, Inc. will provide VascuMAP safety information available to any interested party or individual.

2) EFFECTIVENESS

The VascuMAP Medical Air Plethysmograph Series of instruments has undergone thorough testing for effectiveness and accuracy in measuring waveform volumes and systolic, mean, and diastolic blood pressures and pulse rates in clinical patients. The VascuMAP has been found to be accurate and effective as shown in the clinical study reports accompanying this application (see attachment C). Carolina Medical Electronics, Inc. will make copies of these studies available to any interested party or individual.

3) ADVERSE HEALTH EFFECTS

To date, no adverse effects on health are documented from use of the VascuMAP. However, as stated in the WARNINGS Section of the VascuMAP Operator's Manual, improper use of the device is potentially capable of causing damage to body tissues. Possible improper use includes leaving a cuff inflated above arterial systolic pressure on a patient for a long period (over 30 minutes), thus causing tissue ischemia. The VascuMAP is programmed to keep cuffs inflated for no more than 180 seconds (3 minutes) for all automatic test modes. However, prolonged inflation IS possible in non-automatic MANUAL Mode. It is recommended that VascuMAP operation be observed for proper functioning before leaving the instument on an unattended patient.

ATTACHMENT B

SUBSTANTIAL EQUIVALENCE

to

PREDICATE DEVICES

SUBSTANTIAL EQUIVALENCE/PREDICATE DEVICE

The VascuMAP Medical Air Plethysmograph is substantially equivalent to the **Pulse Volume Recorder Models I, II, III, and IV and the MVL Modulab System**, all manufactured and marketed by Life Sciences, Inc., for obtaining Volume-Calibrated Venous and Arterial waveform tracings. The **Pulse Volume Recorder (PVR)** series was manufactured and initially marketed in 1975. The **MVL Modulab System** was marketed in 1988. The VascuMAP's Blood Pressure and Pulse Rate measurement method is substantially equivalent to the **Dinamap Vital Signs Monitor, Model 1846P** manufactured and marketed in 1983 by Critikon, Inc., and is also substantially equivalent to the standard Korotkoff Auscultatory method of measuring blood pressure manually and the standard clinical method of 15-second pulse palpation for determination of Pulse Rate.

MEDICAL DEVICE DIFFERENCES

The VascuMAP uses a **Displaced-Volume Technique** for performing Volume Calibration whereas the **PVR** and **MVL Systems** use a **Fixed-Volume Technique** (please see the Volume Calibration Section in the VascuMAP Operator's Manual and the study entitled "Volume-Calibrated Air Plethysmography, a Comparison of Two Methods" in attachment C for more information). With the VascuMAP system, a test can be done at any practical cuff volume and cuff pressure. With the **PVR** and **MVL Systems**, the cuff volume must be within a narrow range at a specific pressure. The **PVR System** has a relative volume scale, and the output is in "millimeters of chart height". The **VascuMAP** unit has an absolute volume scale which is in internationally accepted units of cc's (cubic centimeters of cuff displacement). The **Displaced-Volume Technique** for volume calibration is an accepted and well-studied method which has been used in other medical devices as shown in the attached Papers entitled "The Segmental Plethysmograph, A Description of the Instrument" by Travis Winsor, M.D. and "Air Plethysmography in Venous Disease: the Phleborheograph" by John J. Cranley (see attachment B). For information on the Fixed-Volume Method of Volume-Calibrated Segmental Plethysmography, see the information on the **PVR System** and the study " Mechanics of Air Plethysmography in Arterial Disease: the Pulse Volume Recorder" (both in attachment B). Also see the Clinical Data Section (attachment C) and the list of references (attachment E) for further information.

Continued Next Page:

For Blood Pressure measurement, the **VascuMAP System** uses the standard oscillometric method described by Geddes, Et. Al. (see attachment E for references), as does the **Dinamap Instrument.** The standard **Auscultatory Technique of Korotkoff** is generally performed manually in the clinical setting.

For Pulse Rate Determination, the **VascuMAP Instruments** use the inverse of the average pulse periods during a test to compute the pulse rate as does the **Dinamap Instrument.** Clinical pulse rates generally are determined manually by taking the number of pulses palpated over a timed period (usually 1/10, 1/6, or 1/4 of a minute) and multiplying this pulse quantity by the inverse of this time period to obtain the pulse rate in Beats per Minute.

ATTACHMENT D

VascuMAP SOFTWARE ASSURANCE

VascuMAP

SOFTWARE ASSURANCE

The VascuMAP is controlled by special software algorithms. The program is contained in a read-only memory chip inside the unit and is inaccessible to the operator. The operator cannot modify the software.

The software does not make diagnostic decisions. The clinician must exercise good judgment in interpreting the information and should have general training in use of the equipment to help him/her recognize incorrect or inaccurate device performance. In most cases the instrument will give an error or warning message if subject movement, cardiac arrhythmia, or other factors confuse the blood pressure, pulse rate, or volumetric determination algorithms. There is virtually no chance that software errors would lead to life threatening actions by the clinician.

The VascuMAP software program was written in the "C" language. Communication between the VascuMAP's microprocessor and the user is by high level command. Extensive use is made of interrupts to keep up with real-time events.

The microprocessor operates on real-time inputs and outputs. Inputs and outputs are hardware devices consisting of the A/D converter (for pressure measurement), the keypad, LED Display, Strip Chart Recorder, and pneumatic control circuits (pump and valves). If the microprocessor or the program are defective, "watchdog" timers are used to insure that the patient cuff will deflate rapidly.

Software development tools from prominent vendors were used for editing, assembling, linking, locating, emulating, and debugging the program.

The software development included the following major elements:

1. Software Operational Specification (a copy of which is attached to this document).

2. Software Design and Development

3. Software Verification Test Plan

4. Software Verification and Validation Report

5. Clinical Testing for Device Performance

SOFTWARE REQUIREMENTS SPECIFICATION

A comprehensive Software Requirements Specification was generated and copies given to the Software Engineer in charge of the software for the project and to the Director of the Engineering Department. This document lists the functions that the software must do. It also contains detailed hardware interface information generated by the hardware engineers which specify the control function definitions, addresses and timing requirements. This requirements specification was updated as changes were made during the development and testing process. This document will be controlled as it will be used to support the existing device and also to support planned evolution of the product in the future.

The code was written by an experienced, qualified, college trained computer software engineer. The code was reviewed by the Project Engineer and the Director of Engineering who were very knowledgeable about the specific hardware and software involved.

The software was tested by the Project Engineer to see that the functions were performing as intended. After the software was functioning as specified, the Director of Engineering, the company's applications training staff, and outside vascular technologists were asked to use the system to make sure that there was substantial evidence and opinion that the system was functioning properly during actual clinical operation of the VascuMAP.

CERTIFICATION

The VascuMAP software was developed following good quality assurance procedures. It has been tested both under laboratory conditions and in the hospital setting. Bench test and clinical test results show that the VascuMAP software is functioning properly and meets the design criteria. The software will be under change control so that future changes will be designed, tested, and reviewed to assure the integrity of the full software package. Please see the SOFTWARE OPERATIONAL SPECIFICATIONS DOCUMENT attached to this report.

VascuMAP
Models AP-102, AP-102R, and AP-102V

SOFTWARE OPERATIONAL SPECIFICATIONS
11 June 1991

Power-up Reset:
- Exercises all lights and annunciator
- Determines presence of Chart Recorder
- Determines presence of Volume Calibrator
- Calibrates A to D Converter
- Checks memory battery
- Checks ROM version against version stored in memory
- Enters operation mode in effect at power-down

Identification Number Entry:
- Stores up to 20 digits in non-volatile memory
- Numbers and dashes may be entered
- Number changeable via embedded keypad on front panel
- ID number retained in memory during power-down
- ID number printed on all tracing footer blocks

Clock Functions:
- On-board quartz time clock with 10 year lithium battery
- LED clock display in 24 hour format
- Time printed on all footer blocks in AM/PM format
- Clock settable via front panel keypad

Annunciator Tone:
- 0.1 second 500 Hz fixed volume tone
- Tone switchable on-off via front panel keypad
- TONE key flashes to signal tone when annunciator off

Interval (INT) Functioning:
- BP, VASC, and MAN Modes automatically repeat at Interval setting in minutes
- Tests repeatable at 2 to 60 minute intervals
- Repeat function may be turned off
- INT Button flashes slowly when activated

Parameter Warning Limits:
- Functional during Interval (INT) testing
- Systolic, Diastolic, Mean Pressure, and Pulse Rate warnings available in BP Mode
- Mean Arterial Pressure (MAP) and Pulse Rate warnings available in VASC Mode
- High and low limits adjustable independently for each parameter in each mode
- Warning limit settings retained in memory during power-down
- LEDs indicate out-of-range values with an "H" or "L"
- Printer documents out-of-range values as "H" or "L"
- Annunciator sounds if any value outside of set range

VascuMAP Software Specifications, continued:

Maximum Pressure (MAXP) Setting:
- Individually adjustable for each of four operating modes: BP, VASC, MAN, and VEN
- Sets maximum automatic cuff inflation pressure in BP, VASC, and repeating MAN Modes
- Limits maximum pressure obtainable via operator command in MAN and VEN Modes
- Self-adjusting if too low or too high in BP and VASC
- Settings retained in memory during power-down

Blood Pressure (BP) Mode:
- Inflates cuff to MAXP-BP pressure value
- Obtains pulse samples at pressures decreasing in 10mmHg steps
- Deflates cuff when diastolic pressure reached
- LEDs display Systolic/Diastolic pressures and Mean Arterial Pressure/Pulse Rate alternately
- LEDs flash if results may be inaccurate
- Printer output contains
  - ID Number
  - Date and Time
  - Systolic/Diastolic Blood Pressure
  - Pulse Rate per minute
  - Mean Arterial Pressure (MAP)
  - Percent Average and Maximum pulse height variation from a smooth oscillometric curve
  - Error warning messages (if any)
- Printer output is in condensed form if multiple tests are run without changing ID number

Vascular (VASC) Mode:
- Inflates cuff to MAXP-VASC pressure value
- Obtains pulse samples at pressures decreasing in 5 mmHg steps
- After determining MAP, cuff re-inflates to MAP pressure and obtains waveform sample (Volume-calibrated automatically if Model AP-102V)
- Systolic pressure value recordable on operator command
- LEDs display Mean Arterial Pressure and Pulse Rate
- LEDs flash if results may be inaccurate
- Printer output contains
  - Waveform tracing and pressure scale at MAP point (also volume scale if AP-102V)
  - ID Number
  - Date and Time
  - Mean Arterial Pressure (oscillometric)
  - Pulse Rate per minute
  - Systolic Pressure via operator input
  - Percent Average and Maximum pulse height variation from a smooth oscillometric curve
  - Error warning messages (if any)

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VascuMAP Software Specifications, continued:

Manual (MAN) Mode:

- LEDs display actual cuff pressure and target pressure simultaneously
- Target pressure is operator-adjustable up to MAXP-MAN value
- Tracing Gain is manually adjustable
- Tracing Speed is manually adjustable
- REC button turns recorder on and off
- STOP button turns recorder off and deflates cuff
- TONE button triggers volume calibration in AP-102V
- Tracing automatically re-centers if it goes off scale
- Printer output contains:
  - real-time tracing of cuff pressure waveform with one second timing marks and pressure scale (and volume scale if AP-102V)
  - ID Number
  - Date and Time
  - Tracing Gain and Speed
  - Space for operator's notes

Venous (VEN) Mode:

- LEDs display actual cuff pressure and target pressure simultaneously
- Target pressure is operator-adjustable up to MAXP-VEN value
- Initial Tracing Gain is manually adjustable
- Initial Tracing Speed is manually adjustable
- Gain and Speed are fixed while recorder running
- Tracing does NOT re-center if off scale
- INT Button adjusts Zero Baseline above bottom of trace grid (measured in mm.)
- REC Button starts recorder and resets elapsed time
- REC Button stops recorder and prints pressure scale
- STOP Button stops recorder, deflates cuff, and gives complete footer
- TONE button triggers Volume Calibrator (AP-102V)
- DOWN ARROW Button changes recorder speed to 25 mm/sec and prints elapsed time since last REC command (also triggers volume calibration in AP-102V)
- Complete footer contains:
  - Identification number
  - Time and date
  - Tracing Gain
  - Initial Chart Speed
  - Zero Baseline level (in mm.)
  - Segmental Venous Capacitance (SVC) *
  - Space for Maximum Venous Outflow in mm/1sec *
  - Space for Occlusion Pressure in mmHg *
  - Space for operator's notes

*printed only if DOWN ARROW command given

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ATTACHMENT E

REFERENCES

REFERENCES

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19. Cranley, J.J.: Air Plethysmography in Venous Disease: the Phleborheograph. Chap. 16 in Noninvasive Diagnostic Techniques in Vascular Disease, Third Edition. E.F. Bernstein, MD, editor. C. V. Mosby Co, St Louis, MO, 1985.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

NOV 7 1991

Re: K914200
VascuMAP Medical Air Plethysmograph
Dated: September 18, 1991
Received: September 19, 1991
Regulatory Class: II

James S. Campbell, EE, M.D.
Director of Clinical Services
Carolina Medical Electronics, Inc.
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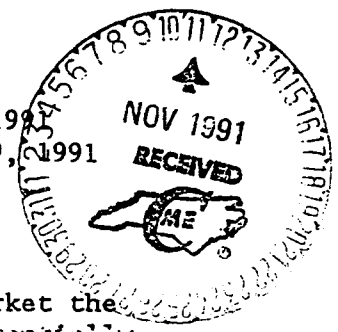

Dear Dr. Campbell:

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

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

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Abhijit Acharya, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health