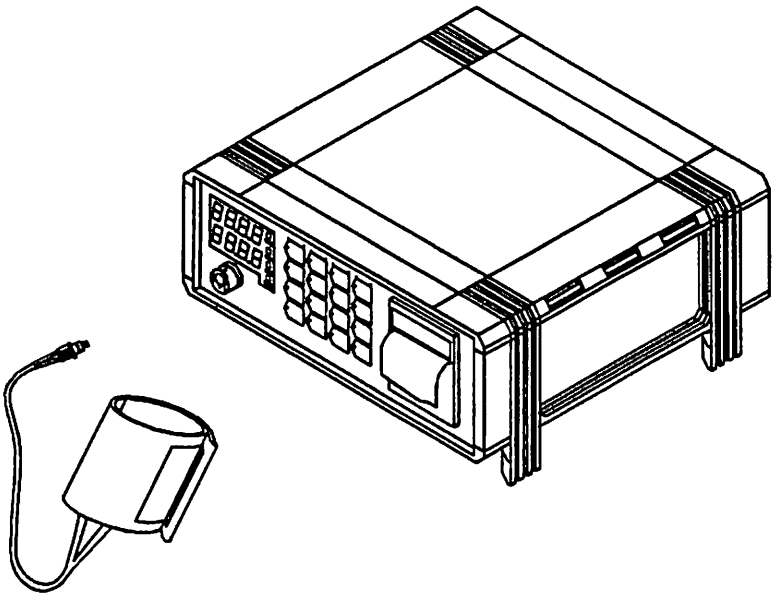
Operator's Handbook
VascuMAP®-Medical Air Plethysmograph
Covers Models AP102, AP102R, AP102V

CAROLINA MEDICAL ELECTRONICS, INC.
P.O. BOX 307 157 Industrial Drive King, North Carolina 27021 USA

VASCUMAP®

NONINVASIVE VASCULAR DIAGNOSTIC SYSTEM

OPERATOR'S MANUAL



Carolina Medical

VascuMAP® Operator's Manual
revision of March 1996
for software release 2.00

Edited by James. S. Campbell, EE, MD.

Contents

STATEMENT OF INTENDED USE

The VascuMAP Medical Air Plethysmograph is designed and intended for measurement of Blood 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.

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

AAMI's Standard, Electronic or Automated Sphygmomanometers (SP10), was utilized in obtaining and providing the proper labeling, safety, and performance requirements for the VascuMAP Medical Air Plethysmograph.

INTRODUCING THE VascuMAP

The **VascuMAP Medical Air Plethysmograph** is a multi-purposed diagnostic instrument. The technology of the VascuMAP is based upon high-resolution, high-bandwidth air plethysmography. The VascuMAP can perform automatic and repetitive blood pressure measurements in humans and animals, and can also acquire and display volume calibrated arterial waveform patterns and venous changes. The patient's only contact with the VascuMAP is through blood pressure cuffs. Different sized cuffs, disposable cuffs, volumetric cuffs, and other special-purpose cuffs can be used with the VascuMAP. Two tubes connect the VascuMAP to the cuff. One tube fills and deflates the cuff under microprocessor command, while the other smaller tube connects to the sensitive pressure sensor within the instrument. A special coaxial pneumatic connector attaches the cuff to the VascuMAP.

The VascuMAP is controlled by a microprocessor which automatically and repetitively performs blood pressure measurements through the oscillometric method and provides tracings of the pulse waveform detected in the cuff. The microprocessor interprets oscillometric tracings to determine mean arterial pressure (MAP) and computes the systolic and diastolic endpoints using a software algorithm developed by Carolina Medical, Inc.

Two four-digit LED displays exhibit the systolic, diastolic, and mean pressures, and the pulse rate. Four other lights labeled SYS, DIAS, MAP, and RATE indicate which values are being displayed. These values are also printed by the chart recorder (if installed), along with arterial waveform tracings, pulse amplitude variation data (useful in assessing the validity of BP measurements), volume calibration data, time and date from the internal real-time clock, and the patient's identification number (if entered). If the chart recorder is not functioning, the VascuMAP will continue to operate and show results through the LED display. This numeric display also shows actual cuff pressure, cuff target pressure, time and date, chart recorder gain and speed, interval between repeat tests (in minutes), warning limits for all pressure and pulse readings, the patient's ID number, and special error messages.

The VascuMAP is operated by a 16-button keypad on the front panel. The operator can select the test to be performed (BLOOD PRESSURE, VASCULAR, VENOUS, or MANUAL) and the time interval (INT) between tests such as repetitive blood pressure measurements.

The VascuMAP's settings (maximum pressure, warning limits, interval settings, mode, gain, speed, and the ID number) are stored in memory when the VascuMAP is turned off. When turned on again, the previous setup is ready for use as soon as the GO button is pressed.

The lights of the keypad are colored LEDs beside each key. Each light is separate and under microprocessor control. During operation of the VascuMAP, these LEDS light or flash to prompt the operator for the next needed input, or to indicate what the instrument is doing. For instance, the "UP" and "DOWN" Arrow keys light up when the "MAX-P" key is pressed, as these raise or lower the pressure value shown on the display. The function(s) of each key are described fully in this manual.

To insure long-term accuracy, a manual calibration should be performed yearly to check and adjust the VascuMAP's pressure readout against a known standard such as a mercury-column manometer. Please see the CALIBRATION section in this manual for detailed instructions.

Below is a list of some of the selectable features of the VascuMAP:

1. High and Low Warning limits for Systolic, Diastolic, Mean Arterial Pressure (MAP), and Pulse Rate during repetitive measurements

2. Specialized clinical test formats (BP, VASC, VEN, or MAN)

3. Adjustable maximum cuff inflation pressure (MAX-P)

4. Patient's ID number entry (up to 20 digits).

5. Date and Time record from internal quartz clock.

6. Keypad Lockout Feature for unattended use.

7. Volume-Calibrated waveform tracings (AP-102V)

The VascuMAP series includes the following three models:

1. AP-102 (no chart recorder included)

2. AP-102R (includes chart recorder)

3. AP-102V (includes chart recorder and positive displacement volume calibrator)

WARNINGS

TO PREVENT DAMAGE TO THE VASCUMAP OR INCIDENTAL INJURY TO THE PATIENT, OBSERVE THE FOLLOWING WARNINGS:

WARNING:
This device is capable of causing damage to nerves, blood vessels, and body tissues if improperly used (such as leaving the cuff inflated at high pressure too often or for too long). Provide proper supervision of device operation when used on debilitated, unresponsive, anesthetized, or otherwise compromised subjects. If symptoms or signs of nerve, vessel, muscle, skin, or other tissue damage appear, discontinue use of this device immediately.

WARNING:
Medical device for use only by or under the direction of a physician or other properly trained practitioner. This device is designed and calibrated to be used only as described in this operator's manual.

WARNING:
Do not leave patient unattended until certain that the VascuMAP is set up and functioning properly.

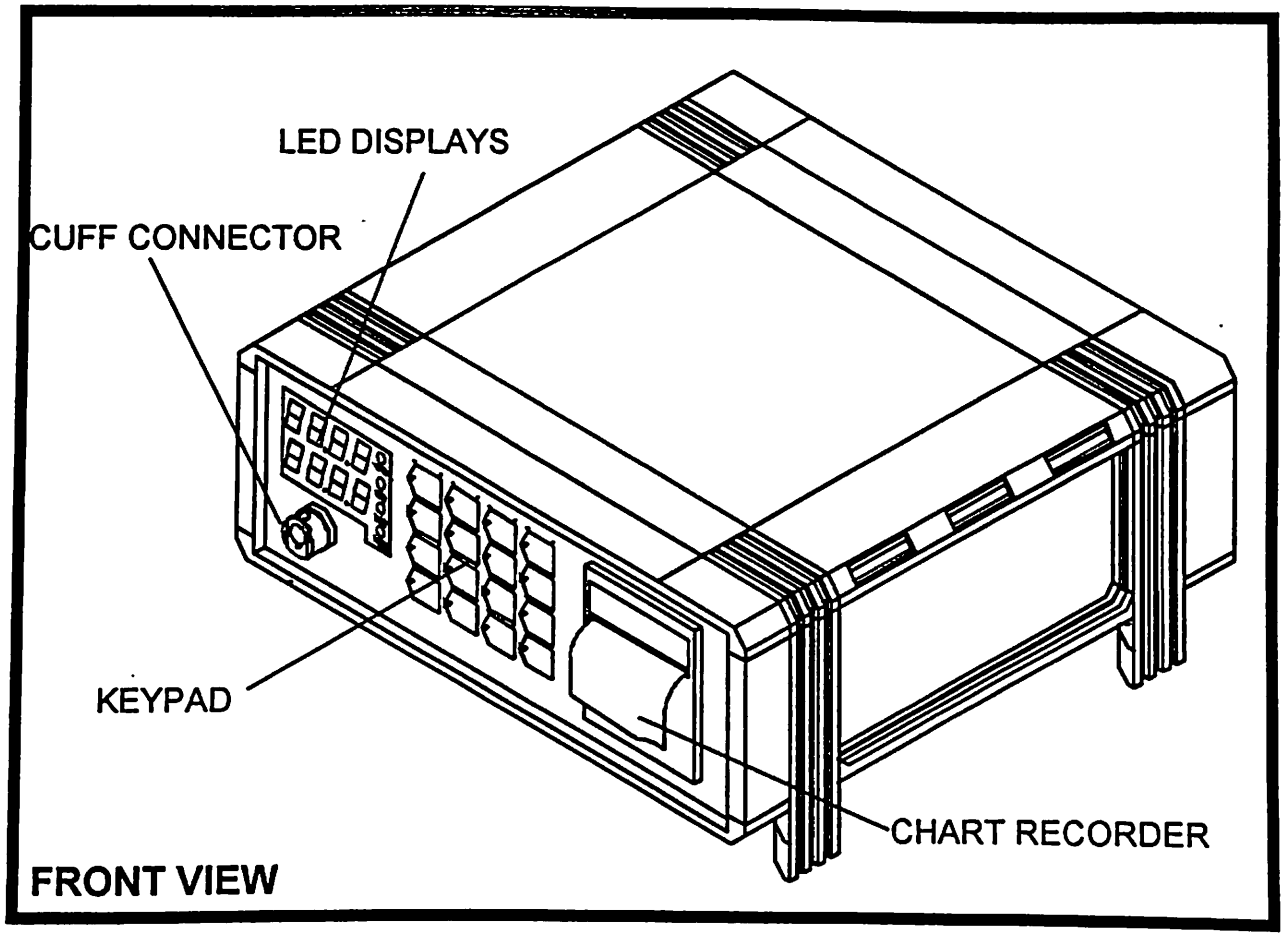
WARNING:
This device must be plugged into a hospital grade receptacle to achieve proper grounding.

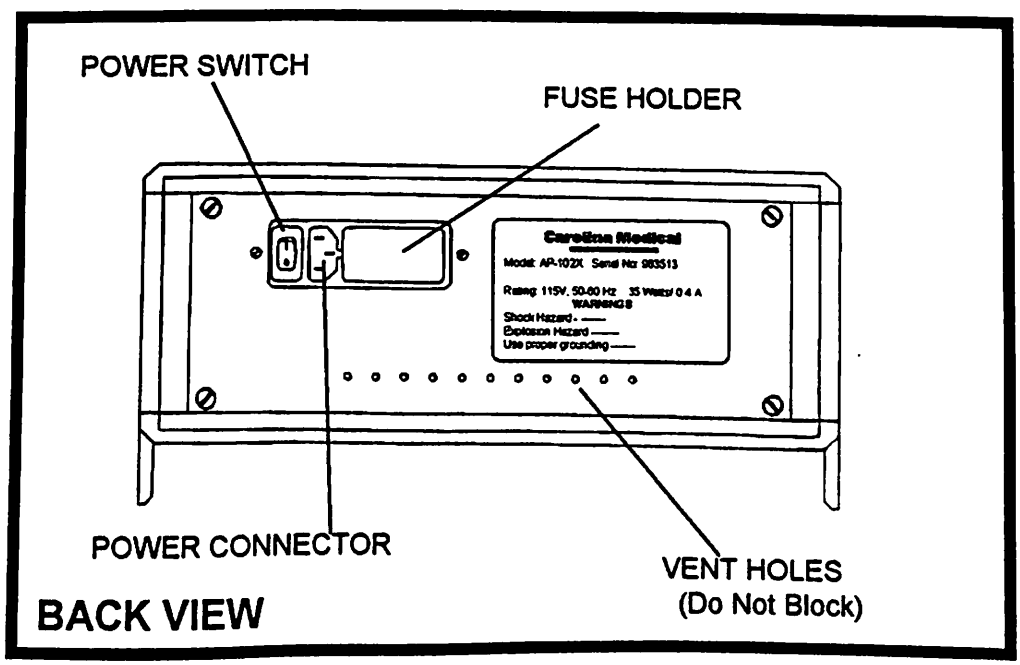
WARNING:
Do not use this device in the presence of flammable anesthetics.

NOTE:
This device is not intended for neonatal use or pediatric use.

NOTE:
Carolina Medical, Inc. is not responsible for injury to the patient as a result of use of the VascuMAP.

The Medical Device Reporting Law requires Carolina Medical, Inc. to report patient injuries and equipment malfunctions with potential for causing injury. Please report experiences of incidental injury to the patient or experiences that might have caused injury to CAROLINA MEDICAL, Inc., P.O. Box 307, King, NC 27021, or call: (910) 983-5132 or (800) 334-4531.


LED DISPLAYS
CUFF CONNECTOR
KEYPAD
CHART RECORDER
FRONT VIEW


POWER SWITCH
FUSE HOLDER
POWER CONNECTOR
VENT HOLES
(Do Not Block)
BACK VIEW

UNPACKING AND SETTING UP THE VascuMAP

The VascuMAP is shipped completely assembled. Unpack the main unit carefully and check for any shipping damage. Notify Carolina Medical, Inc. and the shipper immediately if damage is found.

The following accessories are included with the VascuMAP:

(1) Hospital-Grade Power Cord
(2) One Patient Cuff
(3) One Test Adaptor (for calibration purposes)
(4) One roll of chart paper (if unit is equipped with recorder)
(5) One Operator's Manual

If any of the items listed above are missing, please notify Carolina Medical, Inc.

Place the VascuMAP on a firm, flat surface. Be sure a source of properly grounded AC power is available.

Before plugging in or operating the VascuMAP, READ THIS INSTRUCTION MANUAL. This manual contains explanations of the oscillometric blood pressure measurement method performed by this instrument, instructions on how to perform the four basic tests (BP, VASC, VEN, and MAN), complete listing of all operator controls, troubleshooting information, error messages, and specifications.

AFTER READING THIS OPERATOR'S MANUAL, the operator is ready to connect the VascuMAP to power and turn it on. First, be sure the unit is switched OFF by checking the power switch located on the BACK PANEL. This is done by pressing in on the "O" side of the switch (see back panel diagram on the previous page). Now connect the POWER CORD to the instrument. The special "IEC" connector will fit only one way. WARNING: DO NOT SUBSTITUTE OTHER POWER CORDS, EVEN THOUGH THEY MAY HAVE MATCHING CONNECTORS. Other cords may not be made to "Hospital Grade" specifications and may affect patient or operator safety. Plug the other end of the cord into a properly grounded wall outlet (120V, 50-60 Hz).

If your unit is equipped with a CHART RECORDER, be sure the recorder is loaded with thermal paper and that the paper is threaded correctly. See the section on CHART RECORDER OPERATION for more details.

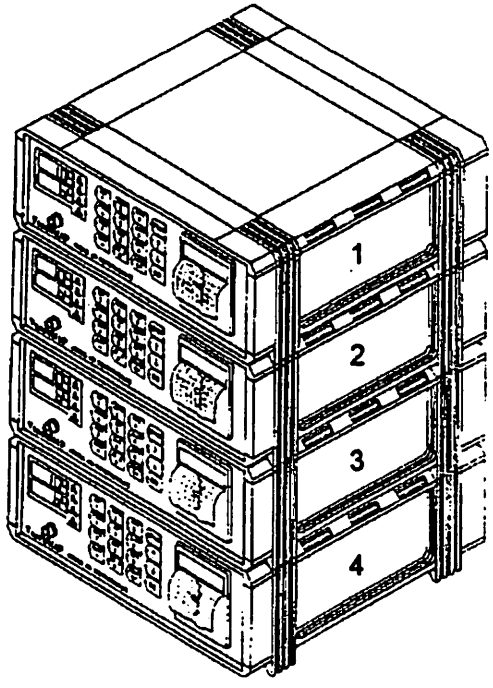
ADJUSTING THE CASE TILT

The VascuMAP has specially designed feet that can be extended to tilt the unit either backward or forward or, if all four legs are extended, to raise the unit about 3/4 of an inch. To extend the feet, SHUT OFF THE POWER, then turn the unit over to expose the bottom side. With a flat instrument such as a small screwdriver or a nail file, the feet can be easily pulled out. Fully extend the feet and lock them into place by pushing them up into the short case leg. To tilt the unit backward, extend the front feet. To tilt the VascuMAP forward, extend the back feet.

If further tilt capability is desired, the optional VascuMAP Carrying Handle/Support Stand (part #19851) may be easily mounted on the case. Contact the factory for details.

STACKING VascuMAPs

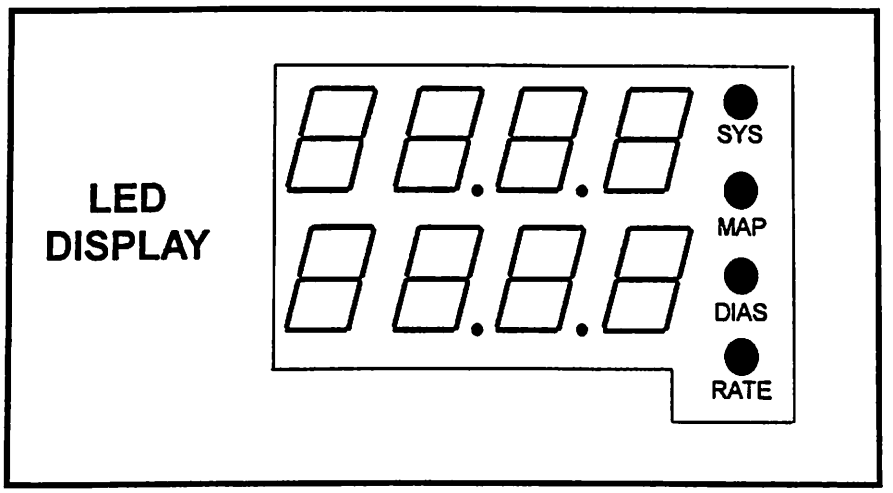
Up to four VascuMAPs can be stacked together to save space. A four-channel testing setup may be created with a minimum of space and expense. To stack units, BE SURE THE TILT LEGS ARE NOT EXTENDED. Place the units one on top of the other, fitting the legs of the upper unit into the special indentations of the unit below. If stacking units on a mobile cart, it is suggested that a strap be used to tighten the units down to the cart for safety.



FOUR-CHANNEL TESTING SETUP

STARTUP ROUTINE

Watch the FRONT PANEL as the VascuMAP IS TURNED ON. The two sets of numbers above the Cuff Connector should flash ***"88.8 .8"*** (First the upper set, then the lower). The MAP, RATE, SYS, and DIAS lights will also flash. At the same time, the lights under each key will flash in sequence. At the end of this startup routine, the audio beeper will sound once, signalling that the VascuMAP is ready. This process takes about five seconds. If the operator wishes to see the display repeated, shut the power OFF for **five seconds**, then turn it ON again. The VascuMAP should go through the startup routine again as described above. If the instrument is equipped with a chart recorder, a title sheet will be printed. The version of operating software appears on this title sheet.



VascuMAP Model AP-102V
Volume Calibrated
Medical Air Plethysmograph

Designed and Manufactured by:
CAROLINA MEDICAL inc
PO Box 307, King, NC 27021
Phone: (910) 983-5132
FAX: (910) 983-8992

15 Mar 1996 11:35 am
Software Revision level 2.00

CHART RECORDER PRINTOUT---TITLE SHEET

CAUTION : If the VascuMAP display lights up, but DOES NOT GO THROUGH THE STARTUP SEQUENCE as described previously, turn the power OFF for **five full seconds**, then turn it ON again. If the Startup Routine still does not occur properly, DO NOT USE THE VascuMAP. See the TROUBLESHOOTING section of this manual for further instruction.

NOTE: If NOTHING happens when the VascuMAP is turned on, make sure that the power cord is plugged in properly and that power is available at the wall outlet. If power is available, and the cord is correctly attached, see the section on TROUBLESHOOTING in this manual for instructions on how to check the fuse.

After the STARTUP ROUTINE, the NUMERIC DISPLAY above the Cuff Connector will show the last eight digits of the PATIENT ID NUMBER (if any) and the GO and ID# buttons will also be lit. Pressing GO will accept the Patient ID number as shown, and the last test mode that was used will be entered (BP, VASC, VEN, or MAN). See the description of the ID NUMBER ENTRY later in this manual for more information.

PUSH-BUTTON CONTROLS

The VascuMAP is operated through 16 momentary-contact, tactile push-buttons. Only one button may be pressed at a time. Each button has an LED which may be lit, flashed, or extinguished under software control independent of the other lights.

THE KEY LIGHTS FLASH WITH THE FOLLOWING CODE:

LIT STEADILY: Button is active if pressed.

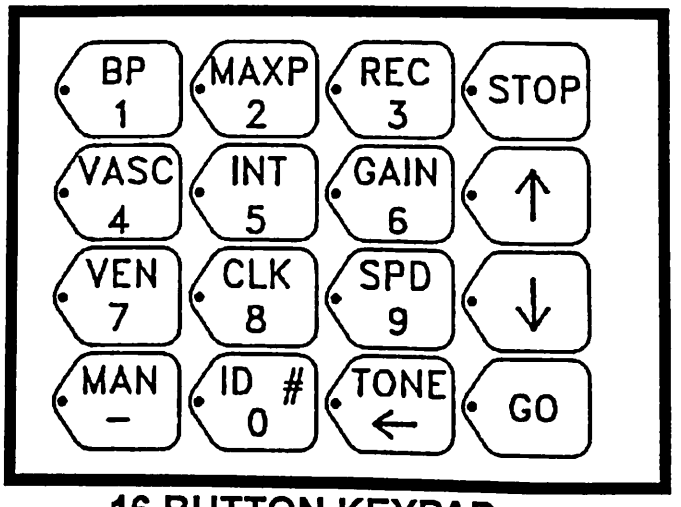
NOT LIT: Pressing the button will have no effect.

FAST FLASH: (10 per second) indicates the present function.

SLOW FLASH: (1 per second) indicates the function is running in the background.

TRIPLE FLASH: The ID# Button flashes in a pattern of three flashes to indicate that Keypad Lockout is ON.

OCCASIONAL FLASH: The TONE button flashes when a pulse is detected (BLOOD PRESSURE and VASCULAR modes).

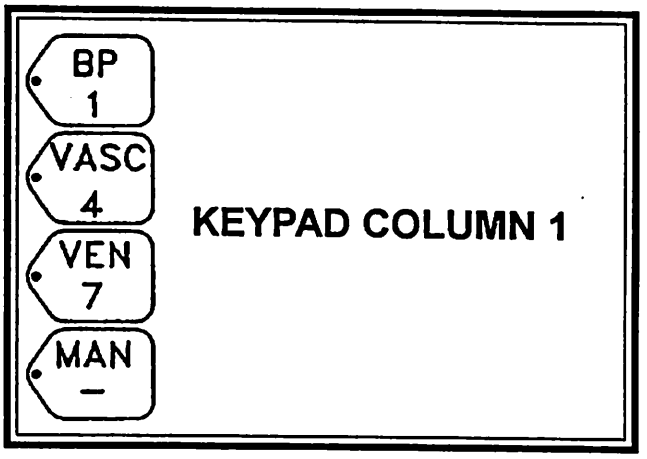


16 BUTTON KEYPAD

There are two levels of keypad functioning. The second or "upper" level is entered when the ID# button is pressed, and when entering Segmental Index data. This turns the keypad into a numeric keypad with an added **"Dash" (-) Key, Backspace/Erase Key, and Forward and Backward Scroll Keys.** Press the "STOP" or "GO" button to return the keypad to first level functioning.

FIRST COLUMN CONTROLS

(MODE BUTTONS)



BP (BLOOD PRESSURE)
Enters the BP Mode, which is used for obtaining oscillometric blood pressures automatically and repetitively. In second level functioning the BP key enters a "1".

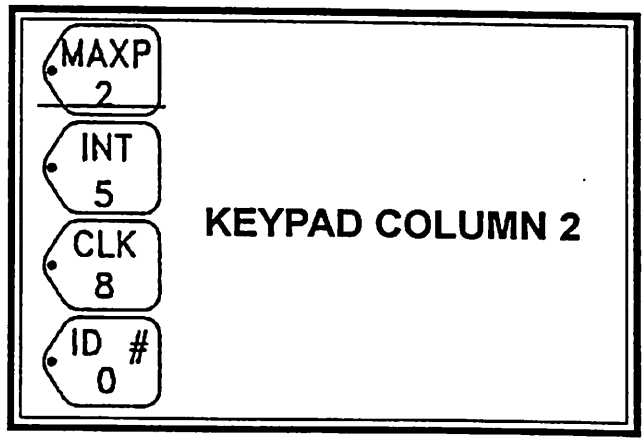
VASC (VASCULAR)
Provides blood pressure, mean arterial pressure (MAP), pulse rate, and pulse waveform tracings taken at the MAP automatically and repetitively in any limb segment. In second level functioning the VASC key enters a "4".

VEN (VENOUS)
Enables the operator to do venous volume studies such as VENOUS OCCLUSION PLETHYSMOGRAPHY, VENOUS RESPIRATORY WAVE STUDY, and VENOUS REFLUX TESTING. In second level functioning the VEN key enters a "7".

MAN (MANUAL)
Sets up the VascuMAP as a Manual Air Plethysmograph to obtain arterial and venous waveforms at operator selectable intervals, gains, and chart speeds. In second level functioning the MAN key enters a dash (-).

NOTE: In-depth descriptions of the four testing modes -- BP, VASC, VEN and MAN--can be found in further sections of this Operator's Manual.

SECOND COLUMN CONTROLS



THE MAXIMUM PRESSURE (MAX-P) BUTTON

Use the UP and DOWN Arrows to raise or lower the MAX-P value which appears on the upper numeric display in mmHg. In MANUAL (MAN) mode, the target pressure (shown on the lower display) cannot be higher than the value of MAX-P. During MAN repeat (INT>0) functioning, the MAX-P value is the pressure at which the chart tracing will automatically be made. Each Test Mode (BP, VASC, VEN, and MAN) has its own value of MAX-P. Press the STOP or GO button to exit the MAX-P function.

THE INTERVAL (INT) BUTTON

In BP, VASC or MAN Modes, the INT (INTERVAL) button sets the interval between repetitive measurements in minutes. There is only ONE INT value for BP, VASC, and MAN, which is not affected by changing modes. The UP and DOWN arrows change the interval value. Intervals may be any value from 1 through 60 minutes. If the interval is decreased to zero (0), the test will not be repeated. The interval timing (INT value in minutes) is measured from the start of one test to the start of the next. There is a 15-second minimum time between tests. The INT button flashes once a second when active, indicating the test will be repeated.

If an INT value other than zero is chosen when in the BP or VASC modes, the numeric display will prompt for high and low pressure warning limits, and the Pulse Rate warning limits. These warning limits are stored in non-volatile memory and are NOT erased by setting the INT value to zero (0).

When in **VEN Mode**, the INT Button sets the chart baseline level in millimeters above the bottom of the trace grid. 0 is the bottom and 40 is the top. Venous tests are not automatically repeatable.

SETTING THE PRESSURE AND PULSE WARNING LIMITS

To set the warning limits, first enter the desired mode (see First Column Controls). INT (INTERVAL) must then be set greater than 0 to adjust the warning limits. In BP and VASC Modes, pressure limits are "requested" in order by first lighting the "SYS" LED and displaying an "H" (high) and the present systolic high limit value. This may be changed in 5 mmHg increments using the UP and DOWN Arrows. Press GO to accept the displayed value. A low Systolic pressure limit is then displayed. This value may be changed with the ARROW buttons. Pressing GO accepts this value and changes the LED to "DIAS". The Diastolic High and Low limits are set with the same technique as for Systolic. Similarly, the MAP and RATE levels are set. When the Low RATE level is entered with "GO", this function is exited and the new warning limits are stored in non-volatile memory. Pressing STOP at any time during this procedure exits the function and restores all the previous warning limits. NOTE that to change any warning limits, all must be reviewed. To change the warning limits, or to review them, press the INT button to re-enter the interval setting function again and proceed as above.

Warning limits are not available in Manual (MAN) mode or Venous (VEN) mode.

During repetitive BP or VASC measurements, if the pressures or pulse rate are outside the set limits, a pulsing warning beep will sound (if the TONE is turned ON) until the STOP or GO buttons are pressed. The-out-of-range value is identified by flashing of the appropriate lamp (SYS, DIAS, MAP, or RATE), flagging the out-of-range numeric value with an "H" or "L", and, if present, the chart recorder indicates the out-of-range value(s) with a warning message such as SYS HIGH, RATE LOW, etc.

AVAILABLE WARNING LIMITS

HIGH AND LOW LIMITS
OF
SYSTOLIC, DIASTOLIC,
MEAN ARTERIAL PRESSURE,
AND PULSE RATE

THE CLOCK (CLK) BUTTON

If the CLK button is pressed ONCE, the time, day, and month are shown on the numeric LED display, with the decimal point between hours and minutes flashing once per second. The CLK Key flashes also. Time display is in "military" 24 hour format. The clock display may be exited by pressing STOP or GO, either of which will exit to the previously selected Test Mode (BP, VASC, VEN, or MAN). Or, by pressing the CLK button again, the clock setting function is started (see the separate section below on how to set the clock).

SETTING THE CLOCK

By pressing the CLK button a second time while the clock is displayed, the clock setting function is started. **NOTE:** the values of date and time must all be reviewed if any are to be changed.

The CLK button flashes at the fast rate and the ARROW, STOP, and GO keys are lit. STOP will exit this function at any step, leaving the time and date unchanged from its previous value and returning to the clock display. The time is shown on the upper numeric display, with the decimal point lit steadily between hours and minutes to indicate that the display is now frozen. The item to be changed appears flashing. The ARROW keys first change the hours. When the hour is set correctly, press GO. Then the ARROW keys change the minutes. Pressing GO accepts the minutes and flashes the month, which is shown along with the day on the lower numeric display. Using the ARROW keys and GO, the month and then the day are changed as needed. Accepting the day with the GO button moves the month and day information to the upper display and the year appears flashing on the lower display. When the year is accepted by GO, the setting function is finished, the ARROW LEDs go out, the CLK button continues flashing, and the new time, month, and day are displayed with the decimal point flashing (i.e., the display returns to the clock display). Pressing GO a second time ends the clock display and returns to the test mode chosen previously.

ID# (IDENTIFICATION NUMBER) BUTTON

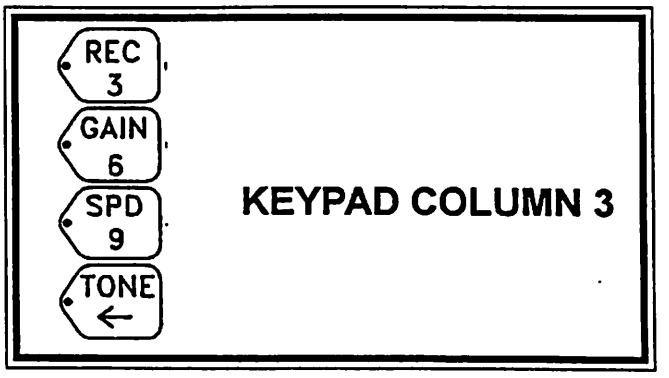
To enter or change the patient's Identification Number, press the ID# Key. The ID# button will flash and the keypad becomes a numeric keypad. Press the correct buttons to enter in the patient's ID. Use the MAN key (dash -) to separate number sequences in the entry. Up to 20 numbers can be entered. Use the TONE/BACKSPACE key to erase the ID# if it has been entered incorrectly. The ARROW Keys can be used to scroll backwards or forwards through the number to check it. When the ID# is entered correctly, press the GO button to accept the ID# and switch the program into the last used testing Mode—BP, VASC, MAN, or VEN.

The ID Number may be changed while a test is in progress as long as the STOP Button is not pressed.

NOTE: Placing a DASH in the last (20th) place of the ID Number field will put the VascuMAP in Keypad Lockout. For more information, see the chapter on the Keypad Lockout Feature in this manual.

POSSIBLE CHOICES FOR THE ID NUMBER	
SOCIAL SECURITY NUMBER	222-33-2000
LICENSE NUMBER	198800119
TELEPHONE NUMBER	910-983-5132

THIRD COLUMN CONTROLS



RECORD
Press the RECORD button to turn the chart recorder ON or OFF when in the MANUAL or VENOUS testing modes. In the VASCULAR mode, pressing the RECORD button records the peak cuff pressure of the preceding pulse wave as "Psys via operator input". Using REC to stop a tracing will print pressure (and volume) scales **without** deflating the cuff.

GAIN
To raise or lower the GAIN of a waveform tracing, press the GAIN key. Use the UP and DOWN Arrows to select the appropriate GAIN value. If the chart recorder is running, the new gain value is used immediately. Press GO to make this value permanent. The GAIN can be set from 0.01 to 20.0 cm/mmHg. The GAIN cannot be changed while the recorder is running in VENOUS Mode.

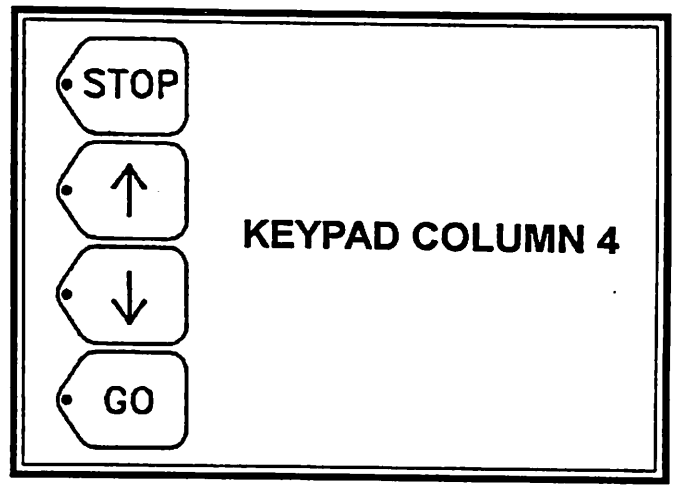
NOTE: When running auto-repeating MANUAL tests, the GAIN setting sets the time delay in seconds from the point of stopping cuff inflation to the time the tracing is recorded. This is to allow for thermal settling when using smaller cuffs. Actual recorder gain is automatic in this mode.

SPEED
Press the SPEED key to change the speed of a waveform tracing. The speed can be adjusted from 1 to 50 mm/sec. Select the appropriate SPEED value using the UP and DOWN Arrows. If the recorder is running, speed change will be immediate. Press GO to make the new SPD value permanent. The SPEED setting also works in VASC Mode.

TONE BUTTON
The TONE button is used to toggle the audio beeper ON and OFF. When the TONE button is turned ON, the key is lit up. When the TONE button is OFF, the LED flashes to indicate when a "beep" would otherwise sound. In the AP-102V, the TONE button starts a volume-calibration sequence when running a MAN or VEN test.

In second level functioning, the TONE key is the BACKSPACE AND ERASE key.

FOURTH COLUMN CONTROLS



THE STOP BUTTON

The STOP button is the red button on the keypad. Pressing the STOP key while running any test immediately deflates the air cuff and stops the test. If a function has been started, such as MAX-P, CLK, INT, etc., STOP exits without saving any of the new values (the old values from memory are used instead). In Second Level functioning (numeric keypad), pressing the STOP button returns the program to First Level functioning without changing the number in memory.

THE UP AND DOWN ARROW KEYS

The two yellow UP and DOWN arrow keys light up when a numeric value is to be adjusted. Such functions include MAX-P, INT, GAIN, and CLK. Pressing the UP Arrow raises the value, pressing the DOWN Arrow lowers the value. In Second Level Functioning (numeric keypad), the UP Arrow scrolls to the beginning of the entered number without erasing and the DOWN Arrow scrolls to the end of the entered number.

In the VENOUS testing mode, the DOWN Arrow speeds up the recorder to 10 mm/sec and starts the volume calibration sequence (AP-102V).

THE GO BUTTON

The GO button is used to accept a number shown on the numeric display or to start a test. The GO button lights when a number may be accepted or when a test is ready to run. The GO button also flashes when the cuff pressure is being adjusted up or down by the microprocessor. Pressing GO while a test is in progress will restart the test.

In second level functioning, the GO button will enter the displayed ID# into non-volatile memory. The ID number will then remain in memory even if the unit is shut off.

KEYPAD LOCKOUT FEATURE

The KEYPAD LOCKOUT FEATURE **disables the VascuMAP keypad** except for the STOP and GO keys. This allows the unit to be set up for a certain testing routine by the operator. The keypad can then be "locked out" so that inadvertent button presses will not change the testing routine. **The STOP and GO buttons always remain functional** so that the test may be stopped or restarted at any time.

To ENABLE the KEYPAD LOCKOUT, first set up the test to be performed including the interval and warning limits and the Patient ID Number, if desired. Run one or two tests to make sure the VascuMAP is programmed correctly. Once it is sure that the setup is correct, Press **ID#** and insert a string of dashes after the ID number so that there is **a DASH in the last (20th) place of the ID number** (the beep will sound when the 20th place is full). On pressing **GO** to accept this modified ID number, the KEYPAD LOCKOUT is ENABLED.

To verify that LOCKOUT is ENABLED, look at the keypad lights. The ID# light blinks repeatedly with THREE FLASHES when LOCKOUT is ENABLED. In addition, the selected test mode button flashes, and the STOP and GO buttons are lit. Pressing any button except for STOP or GO will have no effect.

To DISABLE the KEYPAD LOCKOUT, it is necessary to TURN THE POWER **OFF** to the VascuMAP. Wait five seconds, then turn the power back **ON.** After the short startup routine, the GO and ID# keys will be lit. **PRESS ID#** to bring up the standard ID# Number Routine. Then **PRESS TONE/BACKSPACE** to remove the dash from the last place in the ID Number. On pressing **GO** to accept this new ID Number, the KEYPAD LOCKOUT will be DISABLED, and the VascuMAP Keypad will return to full function.

NOTE: pressing GO first on power-up will start the pre-set testing routine and keep the VascuMAP in KEYPAD LOCKOUT.

HINT: The VascuMAP operator should instruct the other hospital or clinic personnel to press the GO button on the VascuMAP to restart testing if the power to the unit is interrupted for any reason. Also, the STOP button should be pressed if necessary to cancel a test and deflate the cuff.

OSCILLOMETRIC BLOOD PRESSURE BASICS

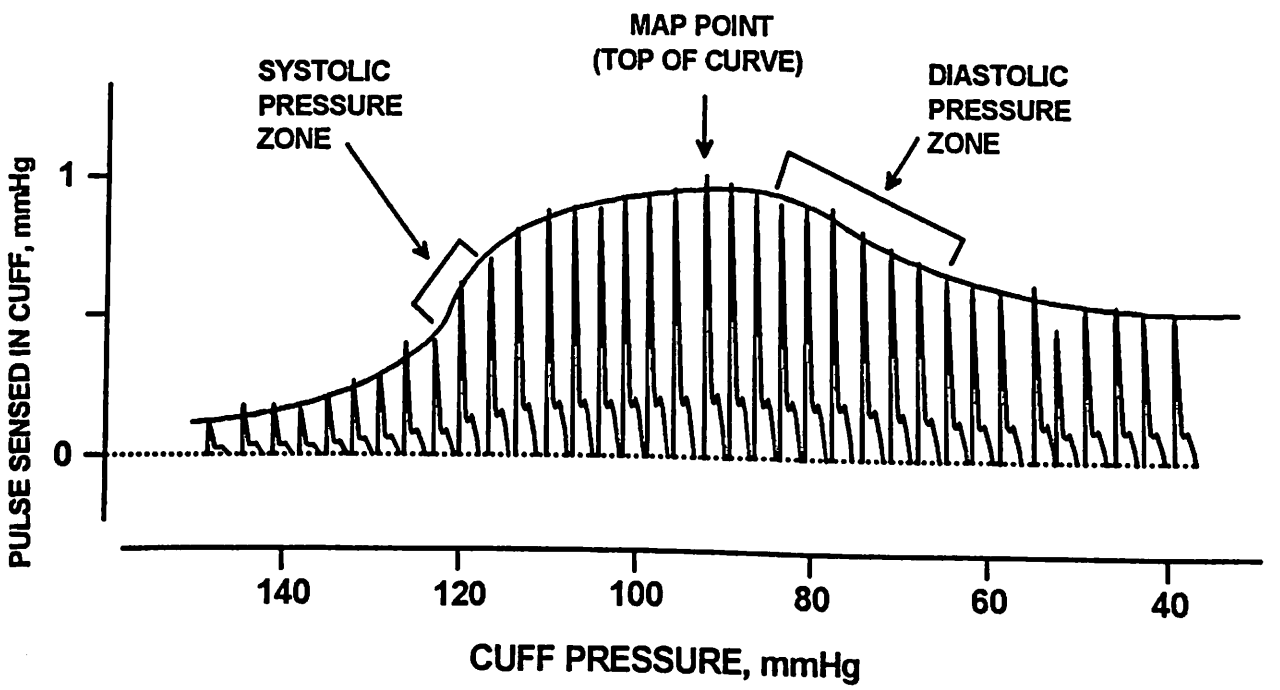
The VascuMAP uses the Oscillometric method to determine blood pressures in the BLOOD PRESSURE and VASCULAR Modes. Through animal and human studies and mathematical models, it has been shown that the largest pulses detected in a cuff occur when the cuff pressure equals the Mean Arterial Pressure (MAP) in the limb under test if the proper sized cuff is used. Systolic and Diastolic pressures are then found by choosing points on the Oscillometric Curve corresponding to fractions of the MAP pulse height. These fractional amounts change slightly depending on segmental tissue composition (bony, muscular, fatty, etc.), arterial status (flexible vs. hardened), cuff compliance (elasticity), and other factors. These variations are slight, however, and Oscillometric pressure results have been shown to be equal in accuracy to standard methods of obtaining blood pressures.

To collect the data required to determine the Oscillometric Curve (see diagram on the following page), the VascuMAP first inflates the cuff to the MAX-P pressure, which should have been set 15 mmHg above the subject's Systolic pressure. Then the cuff pressure is reduced automatically in 10 mmHg steps, and sample pulses are obtained. If the individual pulse heights vary, the VascuMAP collects more samples, trying to get pulses which match. This takes longer, and in cases of marked pulse height differences, the test may take over 180 seconds (3 minutes). This will cause the instrument to end the test because the test took too long.

Because the Oscillometric method relies on the height of the pulse waves detected in the cuff, it is very important that the stroke volume output of the heart remain as constant as possible during the test period (30-60 seconds, usually). Stroke output is strongly influenced by respiratory movements, especially the Valsalva maneuver, coughing, talking, and labored breathing. To reduce respiratory effects, the patient should be as quiet and as still as possible during the test. Cardiac Arrhythmia, especially atrial fibrillation, will also affect stroke output and can confuse pressure readings taken by the VascuMAP. In addition, subjects with a marked tremor such as found in Parkinson's Disease or other conditions may be poor candidates for Oscillometric blood pressure determination, and alternate methods should be used. To warn the operator that excessive variations have occurred in the pulses detected during the test period, the VascuMAP determines the Pulse Height Variation as a percentage figure, and reports both average and maximum values. Lower values of Pulse Height Variation (<12% average or <25% maximum) generally indicate a reliable pressure determination.

It is extremely important that the **correct sized cuff** be used for accurate blood pressure measurement. The ratio of cuff width to limb circumference is the most critical factor. Too narrow a cuff will give a pressure reading higher than actual, and too wide a cuff will give a low reading. For use on human and animal (mammalian) limbs, the correct cuff width is 40% of the limb circumference. When testing animal tail sites, the correct cuff width is 20% of the tail circumference. Please refer to the table of cuff sizes in the Appendix of this manual for recommended cuff width to limb circumference values.

Position of the cuff site in relation to the level of the heart is also important when comparing pressure readings throughout the body. Remember that a change of one foot in the height of the cuff will change the arterial pressure at that point by about 22 mmHg. Thus the arterial pressure measured at the ankle may be 66 mmHg higher while sitting as compared to the same site measured with the subject laying flat, due to the three foot change in vertical position of the ankle between the two readings.



TYPICAL OSCILLOMETRIC CURVE

VOLUME CALIBRATION INFORMATION (AP-102V)

PRINCIPLE OF OPERATION:
The AP-102V VascuMAP is equipped with a 0.5 cc positive-displacement volume calibrator which consists of a precision bellows, a strong solenoid, and associated driving electronics, case, and software.

On command from the VascuMAP microprocessor, the solenoid pulls the bellows back to draw 0.5 cc of air OUT of the cuff under test. After 2/10 of a second, a return spring pushes forward again, forcing the 0.5 cc of air back into the cuff, thus completing one calibration pulse. This process is repeated four times a second, with the microprocessor checking each result for validity. A minimum of three valid calibration cycles are needed for averaging and comparison before a volume scale can be computed. The VascuMAP will cycle the volume calibrator up to sixteen times to obtain these three valid results. If valid results cannot be computed from the maximum sixteen attempts, an error message will appear on the printout to alert the interpreter to compare the computed volume scale with the height of the 0.5 cc calibration pulses visible on the tracing. These pulses may be checked on the volume-calibrated tracing to confirm the accuracy of the computed volume scale. To alert the observer to the location of the Volume Calibration pulses on a tracing, a gray line appears in the bottom margin of the chart recording during the calibration routine.

In addition to providing tracings calibrated in Cubic Centimeters (cc's), the VascuMAP Model AP-102V can also give tracings scaled in TISSUE VOLUME PERCENT (cc per 100cc of tissue) when using optional CME. Volume-Calibrated Cuffs (see illustration). To perform this measurement, the total cuff volume is read from the scale on the cuff and is keyed into the VascuMAP before the test is begun (a "Travelling Dash" display prompts for this entry). On accepting this cuff volume value with the GO button, the cuff is automatically inflated to 150 mmHg and a volume calibration routine performed to determine the volume of air in the cuff. Then the cuff pressure adjusts to perform the test requested (VASC, MAN, or VEN). Tracing results are accompanied by three scales - Pressure (mmHg), Volume (cc's), and Tissue Volume Percent (%).

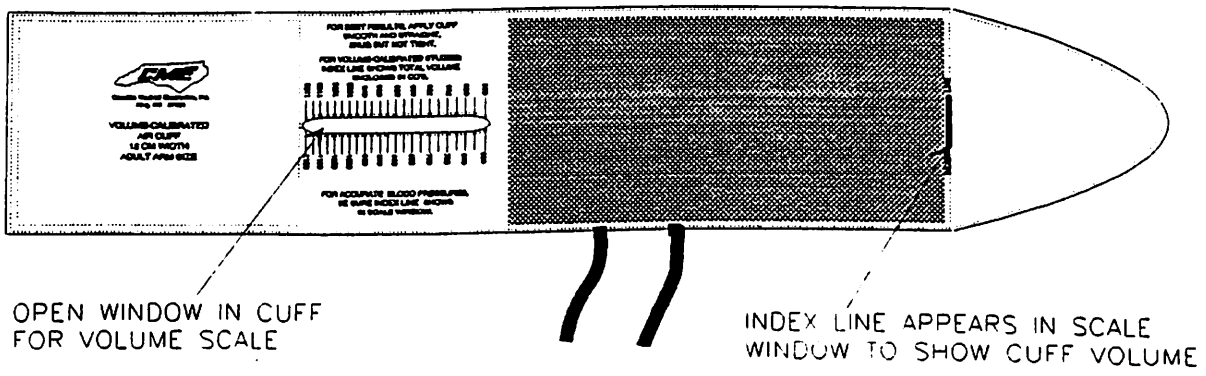
NOTE: If Tissue Volume Percent studies are not wanted, press GO without entering any numbers (not even zero) at the "Travelling Dash" prompt.

Volume calibration is available in VASC, VEN, and MAN Modes as outlined below:

VASCULAR (VASC) VOLUME CALIBRATION:

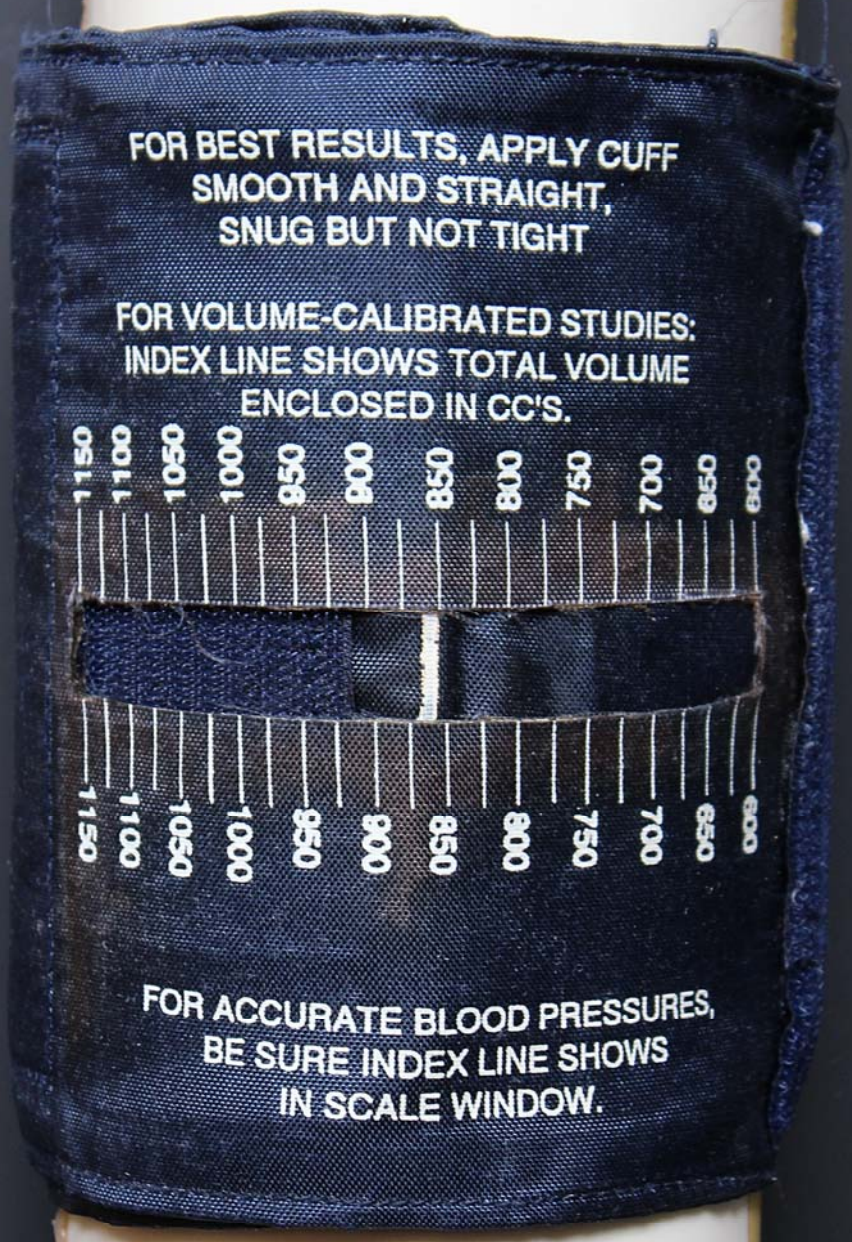
Volume calibration is entirely automatic in VASC Mode with the AP-102V. After determining the mean arterial pressure (MAP), the instrument will fill the cuff to the MAP point. Then the Volume Calibrator will "snap" up to 16 times, after which four seconds of vascular waveform are recorded into memory (be sure the subject under test remains quiet during this short time). Following this, the cuff deflates and the results are printed with a volume scale in cc's following the pressure scale. To aid the interpreter in evaluating pulse volume accuracy, the waveform during volume calibration appears at the beginning of the waveform tracing. Any warnings concerning the volume calibration appear at the bottom of the text printout.

When running VASC in repeating mode (INT > 0), Volume Calibration is done automatically on each test run as described above UNLESS the TONE button is turned OFF.



C.M.E. VOLUME-CALIBRATED CUFF FOR TISSUE VOLUME PERCENT STUDIES

Carolina Medical Electronics
King, NC



VascuMAP 12 cm Cuff for Tissure Volume Percent Measurements.

Original Prototype shown.
jscmd2023

VOLUME CALIBRATION (AP-102V)

Principle of Operation:

The AP-102V VascuMAP is equipped with a 0.5 cc positive-displacement volume calibrator which consists of a precision bellows, a strong solenoid, and associated driving electronics, case, and software.

On command from the VascuMAP microprocessor, the solenoid pulls the bellows back to draw 0.5 cc of air OUT of the cuff under test. After 2/10 of a second, a return spring pushes forward again, forcing the 0.5 cc of air back into the cuff, thus completing one calibration pulse. This process is repeated four times a second, with the microprocessor checking each result for validity. A minimum of three valid calibration cycles are needed for averaging and comparison before a volume scale can be computed. The VascuMAP will cycle the volume calibrator up to sixteen times to obtain these three valid results. If valid results cannot be computed from the maximum sixteen attempts, an error message will appear on the printout to alert the interpreter to compare the computed volume scale with the height of the 0.5 cc calibration pulses visible on the tracing. Check these pulses on the volume-calibrated tracing to confirm the accuracy of the computed volume scale. To alert the observer to the location of the Volume Calibration pulses on a tracing, a gray line appears in the bottom margin of the chart recording during the calibration routine.

NOTE: Tissue Volume Percent studies are no longer available with version 2.0 software. If these studies are desired, contact the factory for version 1.08r1 research software and special-purpose cuffs.

Volume calibration is available in VASC, VEN, and MAN Modes as outlined below:

VASCULAR (VASC) VOLUME CALIBRATION:

Volume calibration is entirely automatic in VASC Mode. After determining the mean arterial pressure (MAP), the instrument will fill the cuff to the approximate MAP pressure. Then the Volume Calibrator will "snap" up to 16 times, after which four seconds of vascular waveform are recorded into memory (be sure the subject under test remains quiet during this short time). Following this, the cuff deflates and the results are printed with a volume scale in cc's following the pressure scale. To aid the interpreter in evaluating pulse volume accuracy, the volume calibration waveform appears at the beginning of the waveform tracing. Any warnings concerning the volume calibration appear at the bottom of the text printout.

VENOUS (VEN) MODE VOLUME CALIBRATION:

While recording waveforms in VENOUS Mode, the volume calibration routine may be started at any time by pressing the TONE Button. Trace recording will continue normally after the volume calibration has ended. On stopping the recorder by either the REC or STOP Buttons, a volume scale will be printed just after the pressure scale is printed. If more than one Volume Calibration is done during a tracing (by pressing the TONE Button again after a calibration is completed), only the results of the LAST calibration will be printed on stopping the trace.

NOTE: If TONE or DOWN ARROW is **not** pressed during venous recording, no volume scale will appear.

When performing Venous Occlusion Plethysmography, Volume Calibration will be performed automatically on pressing the DOWN ARROW (see the section on Venous Testing in this manual for more details). If Volume Calibration has already been done via the TONE button, the results will be erased from memory and the new results (from the DOWN ARROW command) will appear on the scale at the end of the tracing.

MANUAL (MAN) MODE VOLUME CALIBRATION:

When running MANUAL Mode for **single tests** (INT = 0), pressing TONE while the recorder is running will start the Volume Calibration routine. After the calibration is complete, pressing TONE again will repeat the Volume Calibration if the recorder is still running. When a REC or STOP command is given to stop the recorder, the results of the last calibration will be displayed as a volume scale printed just after the pressure scale.

NOTE: If TONE is not pressed during MANUAL recording, no volume scale will appear.

Volume Calibration during **automatically-repeating** MANUAL Mode tracing operates as follows: At the proper interval, the cuff is inflated to the MAX-P pressure. Then the VascuMAP pauses for the GAIN setting in seconds (20 sec, max.). Volume Calibration is then performed and four seconds of waveform are recorded in memory. The cuff then deflates and the chart recorder prints the date and time and the complete tracing in memory, including the Volume Calibration tracing and waveform along with pressure and volume scales. The chart recorder then stops and the VascuMAP waits for the next interval signal to repeat the tracing.

BLOOD PRESSURE MODE

PERFORMING SINGLE TESTS:

1) Press GO once, then STOP several times to clear any other mode or function.
2) Press the BP key to enter the BLOOD PRESSURE test routine.
3) Press the MAX-P button to check and adjust the maximum cuff pressure.
   Use the UP and DOWN Arrows to choose the appropriate MAX-P value. This value should be 15 mmHg above the patient's systolic pressure.
4) Press the GO button to accept the MAX-P value.
5) Make sure that the cuff is securely placed and ready.
6) Press the GO button again to start the test.
   The cuff will inflate up to the set Maximum Pressure. Then the cuff pressure will decrease in 10 mmHg steps. After the cuff deflates, the Blood Pressure reading will be shown on the display and chart recorder.

   NOTE: If the Maximum Pressure was not set high enough for the patient, the VascuMAP will increase the MAX-P by 40 mmHg and repeat the test in 15 seconds. If the MAX-P was set too high, it is automatically lowered for patient comfort (without repeating the test).

7) Press GO to repeat the test if desired.

USING THE AUTOMATIC REPEATING BP METHOD:

The BLOOD PRESSURE test can be done in interval mode (automatically repeating).

1) Enter BP Mode as shown in steps 1 through 5 above.
2) Press the INT key to enter into the INTERVAL function.
3) Use the UP and DOWN Arrows to select the MINUTES between tests.
4) Press GO when the desired time interval is selected.
   Now use the UP and DOWN Arrows to enter the warning limits for HIGH and LOW Systolic, Diastolic, Mean Arterial Pressure, and Pulse Rate. After each value is chosen, press GO to accept the value and to go on the next. Press STOP at any time to exit and leave the warning limits unchanged.

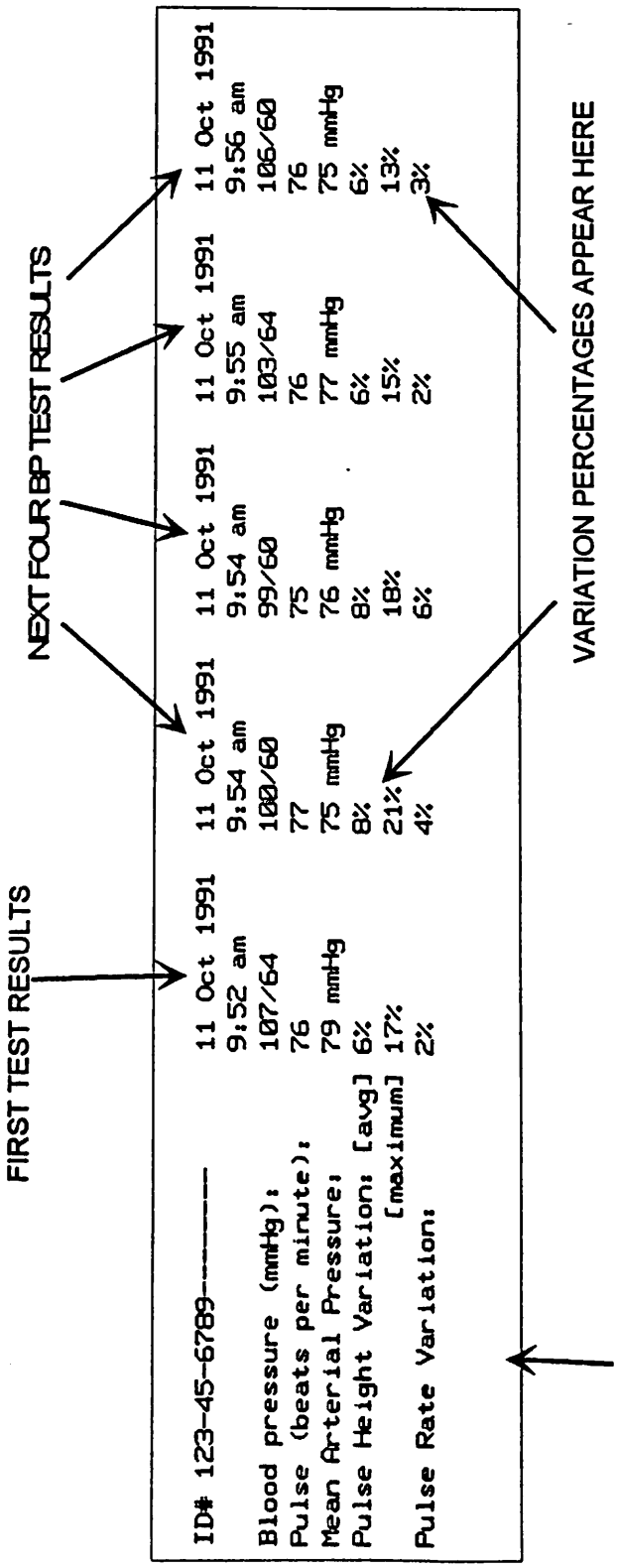
   NOTE: To turn the warning limits "OFF," set the "H" values as HIGH as they can go (255), and the "L" values as LOW as they can go (15).

5) Press GO to start testing.
   The VascuMAP will repeatedly perform BP tests as in step #6 shown above.

WARNING: NEVER LEAVE A PATIENT UNATTENDED UNTIL YOU MAKE SURE THE VascuMAP IS WORKING PROPERLY!

6) Press STOP to end the repeating tests.
   NOTE: To **cancel** the repeating tests, press INT, then lower the INT value to zero (0) and press GO.

BLOOD PRESSURE TEST RESULTS
AUTOMATICALLY REPEATING TESTS SHOWN



VASCULAR (VASC) MODE

The Vascular (VASC) test gives complete arterial pressure and waveform information in a single automatic test. The Vascular test can be done at any practical cuff site. In the VASC mode, the arterial blood pressure is determined oscillometrically, the pulse rate is computed, and the arterial waveform at the MAP (Mean Arterial Pressure) is displayed. The MAP waveform is the largest wave detected (by definition), and it is the closest to the actual intra-arterial waveform in shape (as determined by mathematical models).

Doppler Systolic Pressure Recording Feature:

The VASC test examines pulses at every 10 mmHg drop in pressure. This makes it possible for the operator to determine the Systolic pressure by observing **distal pulse return** using a hand-held Doppler or other detection instrument. The peak cuff pressure of the Systolic return point is entered on the chart record by pressing the **REC button** just after the pulse return is detected. This pressure is labeled **"Psys via operator input"** on the strip chart. Psys values determined this way are recommended in penile artery studies (where oscillometric pressure values may be in error), when the Psys in a single selected artery needs to be determined, and when the VascuMAP cannot determine Psys oscillometrically because the pulse is too small (E-PL or "Pulseless Limb" errors) or the patient has a persistent tremor.

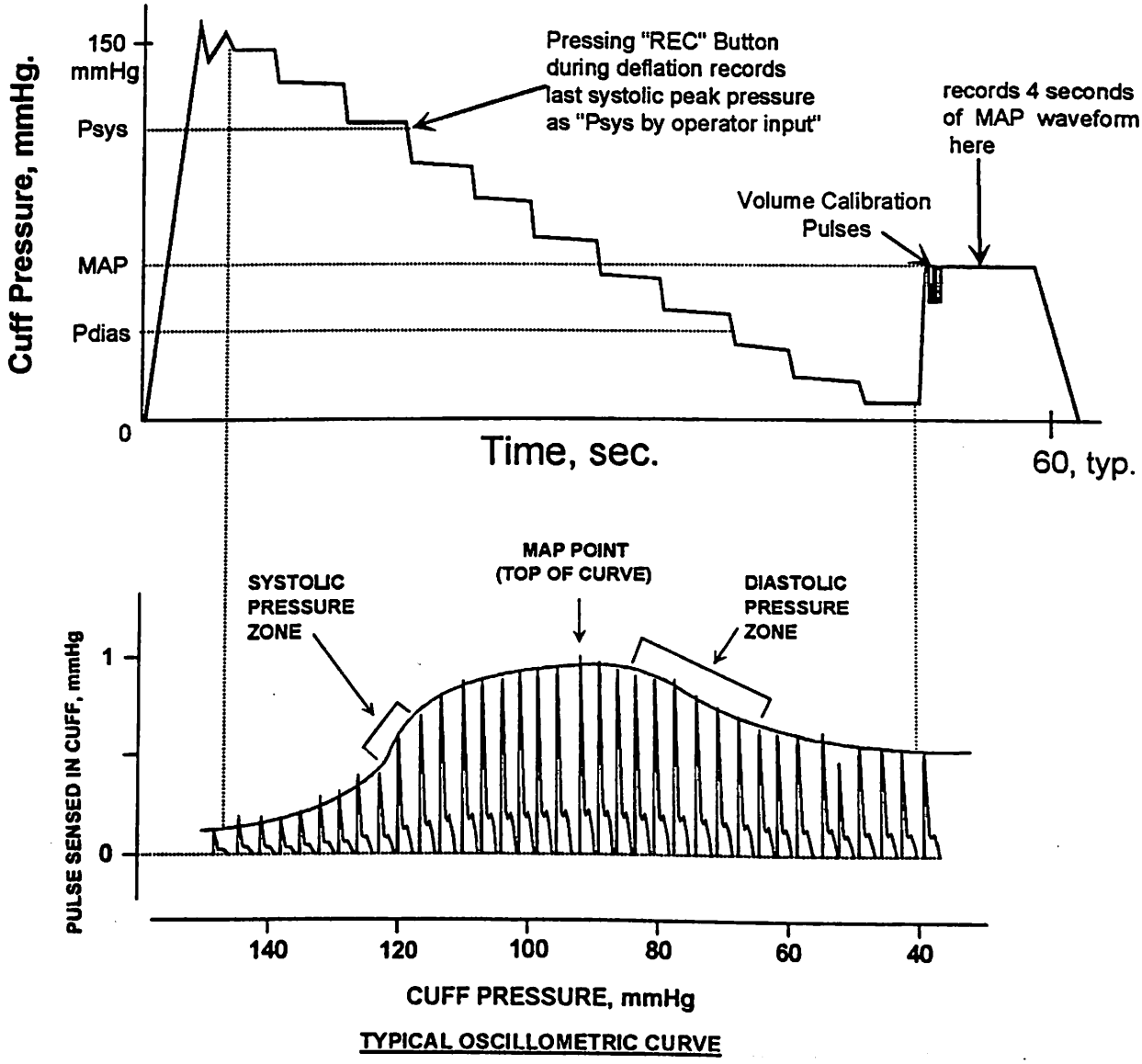
NOTE: REC may be pressed more than once during a test, in which case only the last Psys value will appear on the record.

Segmental Index Computation Feature:

Segmental Index values such as the Ankle-Brachial index are important in vascular diagnosis and prognosis. The VascuMAP computes the Segmental Index and prints it on the output chart if the **Brachial Systolic Pressure** is entered when the **"SEG-" prompt** appears on the LED display at the start of a VASC Test. Only Brachial pressure values between 40 and 325 are accepted to reduce accidental number entry. Numbers entered outside of this acceptance range are shown as zeroes on the LED display when starting subsequent VASC Tests.

If the operator-entered systolic pressure feature (Psys by operator input) is used (i.e., the REC button is pushed during the VASC test), it will be used to compute the Segmental Index, otherwise the automatic Oscillometric Psys is used. The actual pressure values used to compute the Segmental Index are shown on the printout for evaluation by the interpreting physician.

TYPICAL VascuMAP "VASC" MODE CUFF PRESSURE CYCLE



TYPICAL OSCILLOMETRIC CURVE

PERFORMING VASC TESTS

For vascular testing, best results are obtained if the patient is supine. The patient should be relaxed and warm. A cuff of proper size is placed around the limb segment under test (see the Appendix for cuff size recommendations), or several cuffs can be placed on a limb and tests run in rapid succession.

NOTE: It is convenient to perform VASCULAR testing with the INTERVAL (INT Button) set to 60 min (see AUTOMATIC REPEATING METHOD, below). Then, if the VASC test cannot give waveform results due to possible "Pulseless Limb" error (E-PL), the operator can quickly enter the MANUAL Mode (press MAN Button) and press GO to obtain an automatic 4-second "snapshot" of the arterial waveform. See MANUAL MODE for more details.

SINGLE TEST METHOD:

1) Press GO once, then STOP several times to clear any other mode or function.
2) Press the VASC key to enter the VASCULAR test routine.
3) Press the MAX-P button to check and adjust the maximum cuff pressure.
   Use the UP and DOWN Arrows to choose the appropriate MAX-P value. This value should be 15 mmHg above the patient's systolic pressure.
4) Press the GO button to accept the MAX-P value.
5) Make sure that the cuff is securely placed and ready.
6) Press the GO button - "SEG-" will appear on the LED display.
   Enter the Brachial Psys using the keypad if Segmental Index computation is desired. Otherwise go to step 7.
   (insonate a distal artery with a Doppler if Psys confirmation is desired)*
7) Press GO to start the test.
   The cuff will inflate up to the set Maximum Pressure. Then the cuff pressure will decrease in 10 mmHg steps to below diastolic pressure.
   *(press REC when arterial flow return is heard with the Doppler)
   The cuff will inflate again to the approximate MAP pressure and record a 4-second long sample of the arterial waveform. (With the VascuMAP AP-102V, volume calibration is done automatically at this point). Then the cuff deflates and the results are printed on the LED display and the chart recorder.

   NOTE: If the Maximum Pressure was not set high enough for the patient, the VascuMAP will increase the MAX-P by 40 mmHg and repeat the test in 15 seconds. If the MAX-P was set too high, it is automatically lowered for patient comfort (without repeating the test).

8) Press GO to repeat the test if desired.

AUTOMATIC REPEATING VASC TESTING:

The VASCULAR test can be done in interval mode (automatically repeating).

1) Enter VASC Mode as shown in steps 1 through 5 on the previous page.
2) Press the INT key to enter the INTERVAL function.
3) Use the UP and DOWN Arrows to select the **minutes** between tests.
4) Press GO when the desired time interval is selected.
   Now use the UP and DOWN Arrows to enter the **warning limits** for HIGH and LOW Systolic, Diastolic, Mean Arterial Pressure, and Pulse Rate. When each value is correct on the LED display, press GO to accept the value and to go on the next. Press STOP at any time to exit and leave the warning limits unchanged.
   If the PRESSURES or PULSE are outside of the chosen values after any test, the alarm will trigger and show the operator which value is out of range.

   NOTE: To turn the warning limits "OFF," set the "H" values as HIGH as they can go (255), and the "L" values as LOW as they can go (!5).

5) Press GO after entering all the Warning Limits
   "**SEG-**" will appear on the LED display.
   Enter the Brachial Psys using the keypad if Segmental Index computation is desired. This value will be used for all following Segmental Index computations until STOP is pushed.
   (insonate a distal artery with a Doppler if Psys confirmation is desired)*
6) Press GO to start testing.
   The VascuMAP will repeatedly perform timed VASC tests as described on the previous page.
   *(press REC when arterial flow return is heard with the Doppler)

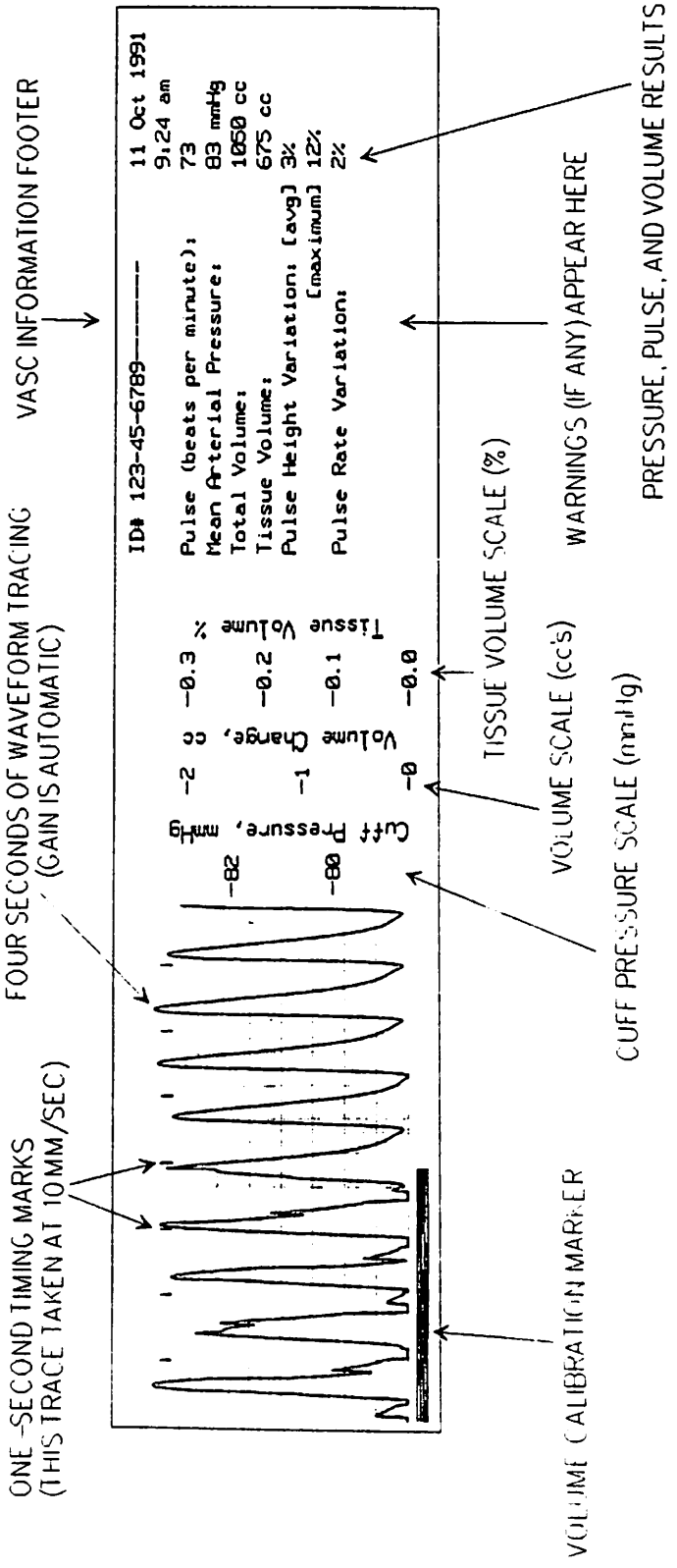
   NOTE: To repeat a test before the time interval is up, press GO at any time.

WARNING: NEVER LEAVE A PATIENT UNATTENDED UNTIL YOU MAKE SURE THE VascuMAP IS WORKING PROPERLY!

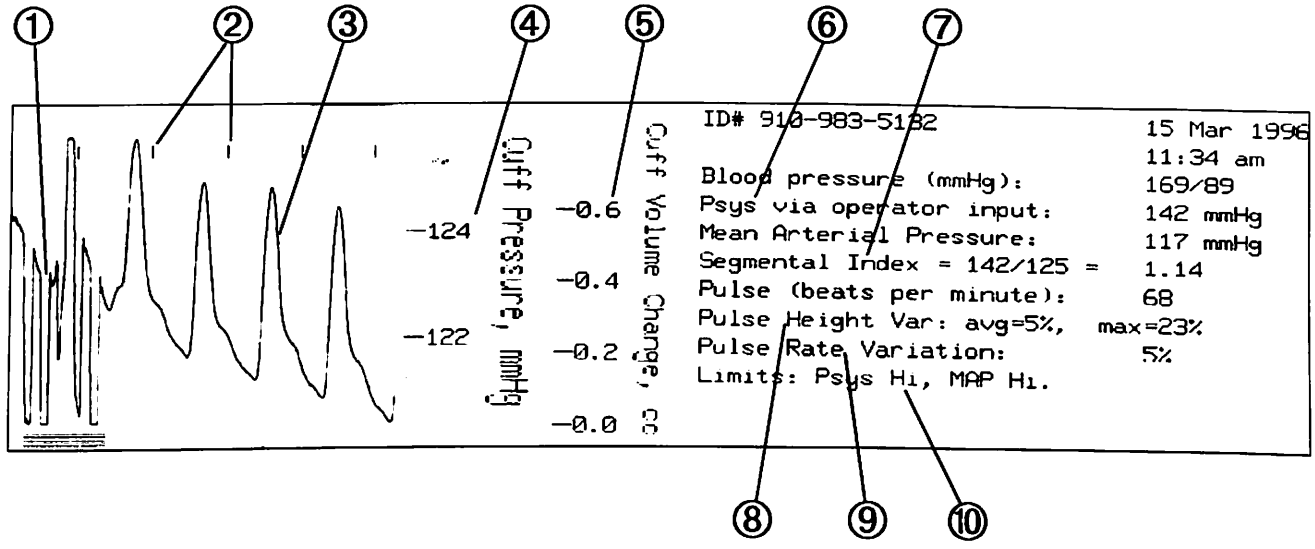
6) Press STOP to end the repeating tests.
   Pressing GO will start repeat testing again.

   NOTE: To **cancel** the repeating tests, press INT, then lower the INT value to zero (0) and press GO.

VASCULAR TESTING OUTPUT EXAMPLE:



VASCULAR TEST RESULTS EXAMPLE



① 0.5 cc. Volume Calibration routine takes place here (3 to 16 pulses).

② One second timing marks.

③ Four second tracing of arterial waveform recorded at approximate mean arterial pressure.

④ Scale showing actual cuff pressure in millimeters of mercury (mmHg).

⑤ Volume Calibration scale in cubic centimeters (cc.) derived from ①.

⑥ Psys line printed if REC button was pushed to record systolic return (detected by Doppler or other method).

⑦ Segmental Index printed if Brachial Psys is entered at the "SEG-" prompt.

⑧ High pulse height variation (avg>12% or max>25%) indicates blood pressure results are in question; results will appear in parentheses ( ).

⑨ High pulse rate variation (>12%) indicates an irregular pulse.

⑩ BP and pulse rate results outside of the operator-entered warning limits are printed here (during auto-repeating tests [INT>0] only).

MANUAL MODE

The Manual Test Mode turns the VascuMAP into a manually-controlled Air Plethysmograph which allows the operator to control cuff pressure, volume calibration, and recorder status (on-off, gain, speed). Also, by setting the INTERVAL for repeat testing, MANUAL MODE will automatically record 4-second "snapshots" of the arterial waveform at any desired cuff pressure, providing quick and convenient arterial monitoring for long periods with minimal discomfort to the patient.

SINGLE TEST METHOD (FULLY MANUAL):

1) Press GO once, then STOP several times to clear any other mode or function.
2) Press the MAN key to enter the MANUAL MODE test routine.
3) Press the INT key to be sure the INTERVAL setting is zero (0).
   Press the DOWN arrow to reduce INT to zero if necessary.
4) Press GO to accept the INTERVAL value of zero.
5) Press the MAX-P button to adjust the maximum allowable cuff pressure.
   Use the UP and DOWN Arrows to choose the appropriate MAX-P value. This value must be at or above the desired cuff pressure.
6) Press the GO button to accept the MAX-P value.
7) Use the UP and DOWN arrows to adjust the desired cuff "target" pressure on the LED display.
8) Make sure that the cuff is securely placed and ready.
9) Press the GO button to inflate the cuff to the displayed target pressure.
   The cuff will inflate up to the set pressure, then settle slowly.
   Repeat pressing of GO will "top up" the cuff pressure to the target pressure shown on the LED display.
10) Once the desired cuff pressure is reached, press REC to record the tracing.
   Press SPD to adjust the chart speed with the UP and DOWN arrows.
   Press GAIN to adjust the tracing size to fit the recording strip.

   NOTE: If the tracing drifts off the strip chart, it is automatically re-centered.

   NOTE: Both GAIN and SPEED may be changed during the recording without stopping the recorder.

11) For **volume calibration** of the tracing segment (AP102V models), press **TONE**.
12) Press REC to **pause** the recording without cuff deflation.
   Press REC again to re-start the tracing.
   Date and time are printed at the start of each tracing segment.
13) Press STOP to **end** recording, deflate the cuff, and print the identification strip.

AUTOMATIC TIMED MANUAL TRACINGS:

The MANUAL test can be done in interval mode (automatically repeating) to record 4-second "snapshot" tracings at any desired cuff pressure.

1) Press GO once, then STOP several times to clear any other mode or function.
2) Press the MAN key to enter the MANUAL MODE test routine.
3) Press the INT key to enter into the INTERVAL function.
4) Use the UP and DOWN Arrows to select the **MINUTES between tests.**
5) Press GO when the desired time interval is selected.
6) Press SPD to set the chart speed (10 mm/sec is recommended).
7) Press GO when the chart speed is correct.
8) Press GAIN to set the **time delay in seconds** between inflation and recording.

   NOTE: This allows thermal settling to take place so that small pulses show up larger. Generally, use 1.0 for larger cuffs, and 10 or 20 for digital or penile cuffs. Actual tracing gain is automatically adjusted so the "snapshot" fits the strip chart.

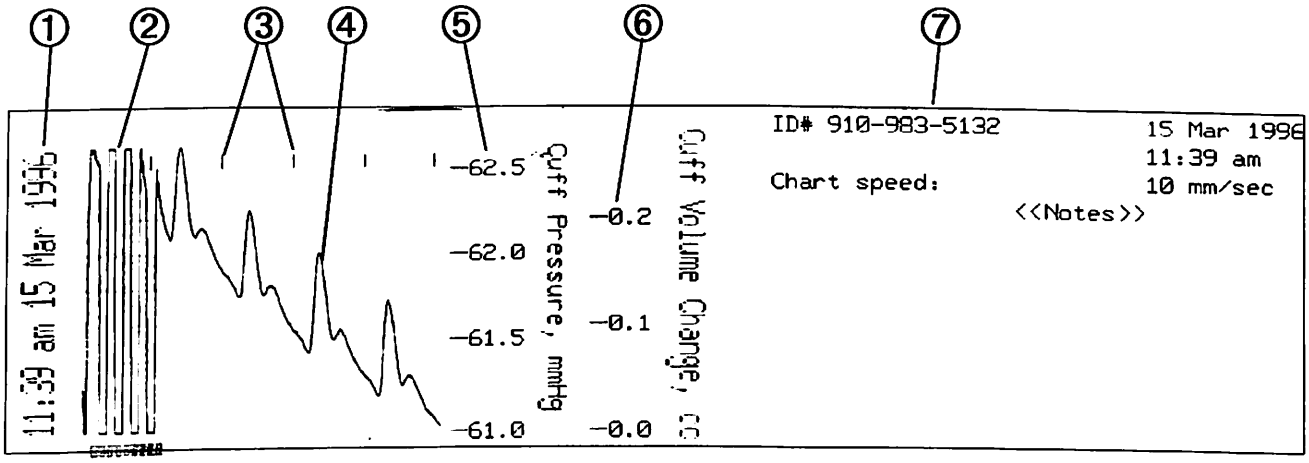
9) Press GO to accept the desired time delay.
10) Press MAX-P to set the cuff pressure where tracings will be taken.
    40, 65, and 90 mmHg are common "standard" tracing pressures.
11) Press GO to accept the desired MAX-P value.
12) Press GO to start the first automatic test.
    The VascuMAP will now repeatedly perform timed "snapshots" tests.
    Date and time is printed at the start of each strip.
    Volume Calibration (AP-102 Models) is automatic at the start of each tracing

WARNING: NEVER LEAVE A PATIENT UNATTENDED UNTIL YOU MAKE SURE THE VascuMAP IS WORKING PROPERLY!

13) Press STOP to end the repeating tests and print the Identification strip.
    Pressing GO will re-start automatic trace gathering.

    NOTE: To **cancel** the repeating tests, press INT, then lower the INT value to zero (0) and press GO.

MANUAL MODE TRACING EXAMPLE
AUTOMATIC TIMED INTERVAL TRACING SHOWN



① Date and time printed at the start of each tracing.

② 0.5 cc. Volume Calibration routine takes place here (3 to 16 pulses).

③ One second timing marks.

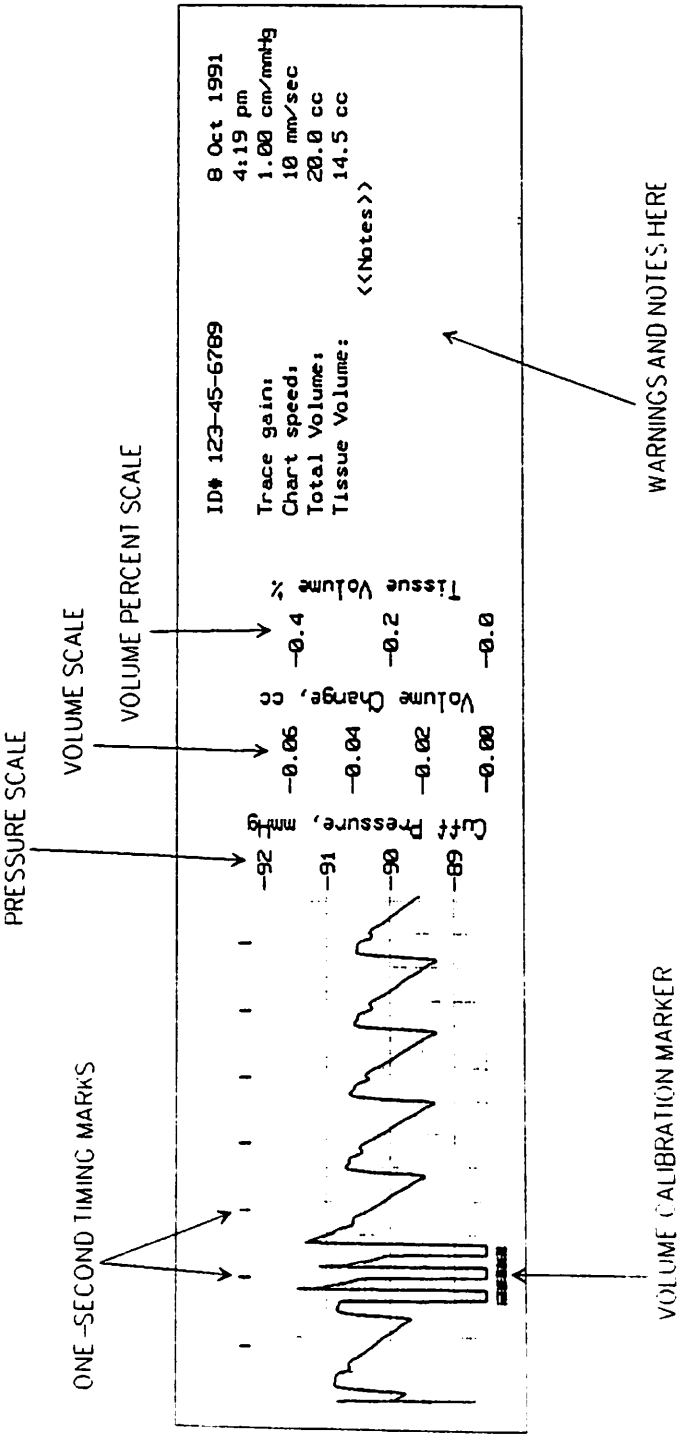
④ Four second tracing of arterial waveform at pressure entered for MAX-P.

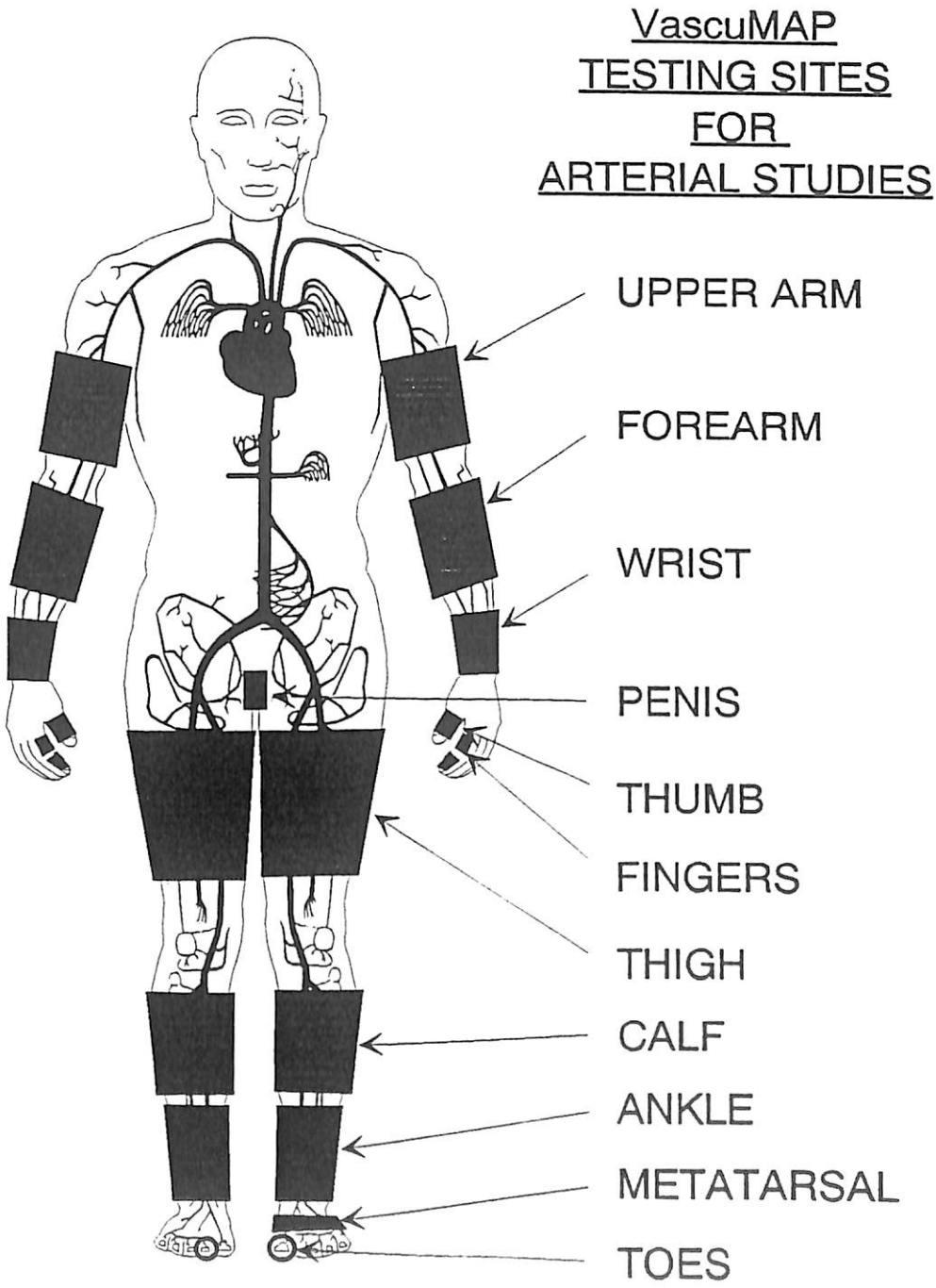
⑤ Scale showing actual cuff pressure in millimeters of mercury (mmHg).

⑥ Volume Calibration scale in cubic centimeters (cc.) derived from ①.②

⑦ Identification Header prints at end of testing (when STOP is pushed).

MANUAL MODE TRACING EXAMPLE:




VascuMAP
TESTING SITES
FOR
ARTERIAL STUDIES
UPPER ARM
FOREARM
WRIST
PENIS
THUMB
FINGERS
THIGH
CALF
ANKLE
METATARSAL
TOES

VENOUS TEST MODE

The VascuMAP Model AP-102V can perform both pressure-calibrated and volume-calibrated venous studies. These tests generally require that the cuff be placed over the calf or the forearm. Make sure that an appropriate sized cuff is used on the limb segment. As Venous pressures are much lower than arterial pressures, patient positioning during testing is very important because of gravitational effects.

NOTE: Keypad control for venous tests is slightly different than the other testing modes:

INT - The INTERVAL Key sets the venous **tracing Baseline Level** measured in millimeters above the bottom of the trace grid. Zero (0) is the bottom of the strip chart, twenty (20) is the middle, and forty (40) is the top. The available range is 5 to 35 mm.

DOWN ARROW - In Venous Mode, this key is used **to signal deflation of the occlusion cuff** when performing Venous Occlusion Plethysmography. It changes the chart SPEED to 10 mm/sec, and performs a Volume Calibration (AP-102V only). When the test footer is printed, information pertinent to Venous Occlusion Plethysmography is included.

MAX-P - The Maximum cuff inflation pressure cannot be set higher than 20 mmHg in Venous Mode.

Recorder SPEED and GAIN can only be changed when the chart recorder is stopped.

VENOUS Testing Mode has been designed to perform three basic venous studies which are outlined below. Because of the unique functioning of the VascuMAP, other test routines are also possible. It is beyond the scope of this manual to cover all possible venous testing routines.

VENOUS RESPIRATORY WAVE OBSERVATION

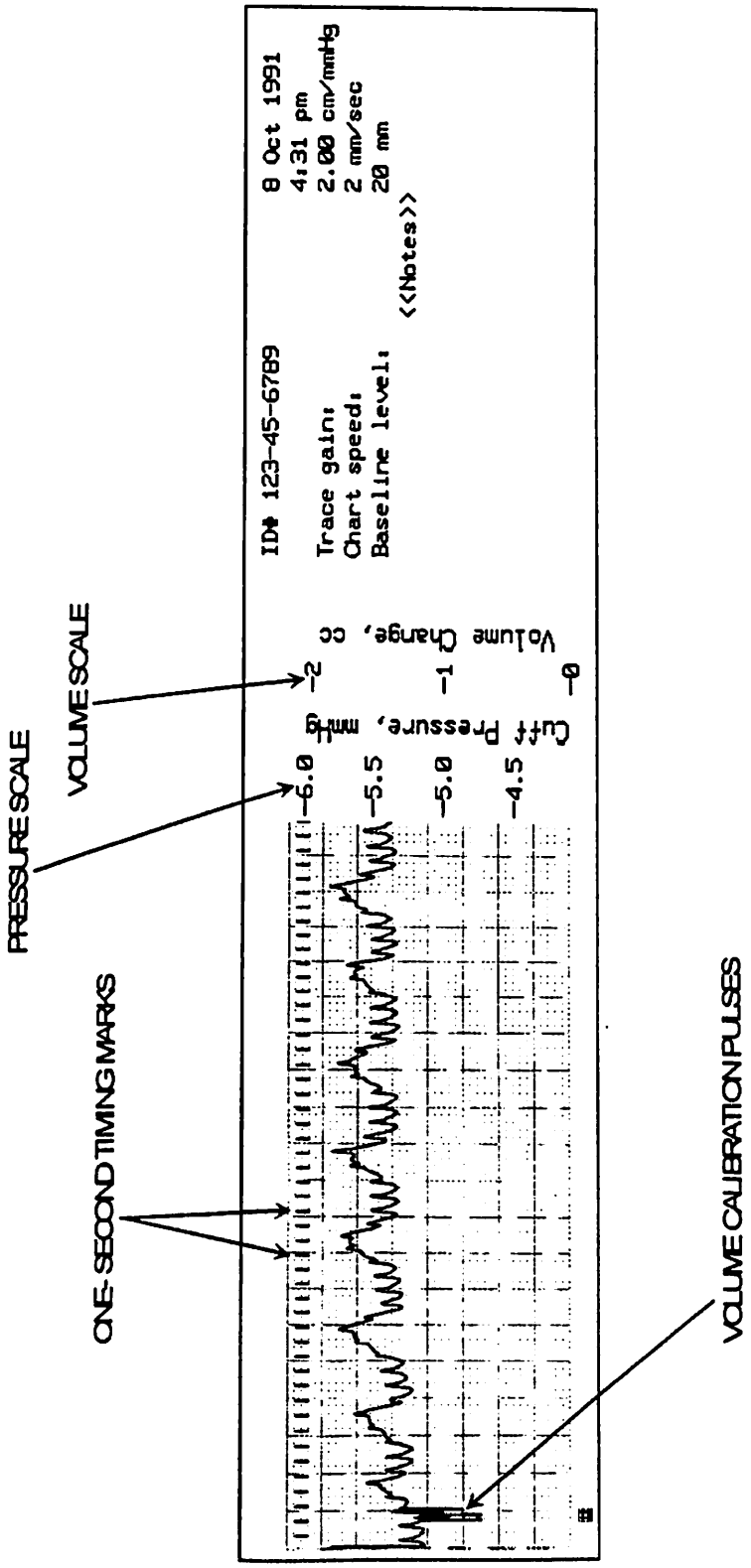
Observing respiratory fluctuations of venous volume in a limb segment indicates that a low-resistance path for venous blood exists between the monitoring cuff site and the central venous tree (Inferior or Superior Vena Cava). Occlusion of the returning veins between the cuff and the Vena Cavae by intravenous clot, venous sclerosis, or extravascular pressure (from tumor, enlarged lymph nodes, tight scar or clothing, etc.) will generally obliterate the respiratory wave pattern observed in the subject. Exaggerated respiratory action such as forced deep breathing or the Valsalva Maneuver, or conditions such as emphysema or obstructed airway may increase the amplitude of the observed respiratory waves where the veins are normal.

TEST PROCEDURE:
To perform a respiratory wave test, first place the subject supine. Loosen any restrictive clothing. Place a cuff lightly on the site to be tested (usually the calf or forearm) and connect it to the VascuMAP. Make sure that the limb is positioned such that the cuff does not touch the exam table or bed. Use pillows if necessary above and below the cuff. Enter the Venous (VEN) Program. Set INT to 20 (this places the tracing at the center of the strip chart.) Chart speed (SPD) is usually best at 2 or 5 mm/sec for this test. GAIN values are between 1 and 5 cm/mmHg. MAX-P (cuff pressure) should be within 5 to 7mmHg.

Once the VascuMAP is set up as outlined above, press GO to inflate the cuff to the MAX-P value. Once any cuff settling is complete, press REC to start the recorder. The patient should breathe normally as the record is taken. Deep breathing or the Valsalva maneuver may also be done to provide further information. Press REC to stop the trace without cuff deflation, or press STOP to deflate the cuff, print the title sheet, and end the test.

A sample tracing of Venous Respiratory Waves appears on the next page:

VENOUS RESPIRATORY WAVE SAMPLE TRACING:



VENOUS REFLUX TESTING

Venous reflux testing is performed to find the status of the venous valves and muscular pumping action in an extremity (usually the leg). When the venous valves are functioning properly, venous refilling occurs via flow through the capillary bed in the limb. This normal refilling is slow and controlled. In the presence of leaking venous valves (or arterio-venous malformation or fistula) refilling time is shortened considerably. Differential diagnosis of the site of venous incompetence may be performed with proper application of venous tourniquets. Remember that the VascuMAP is monitoring the total venous volume under the cuff, thus both deep and superficial venous systems are being measured unless tourniquets are used to block the superficial veins.

TEST PROCEDURE:

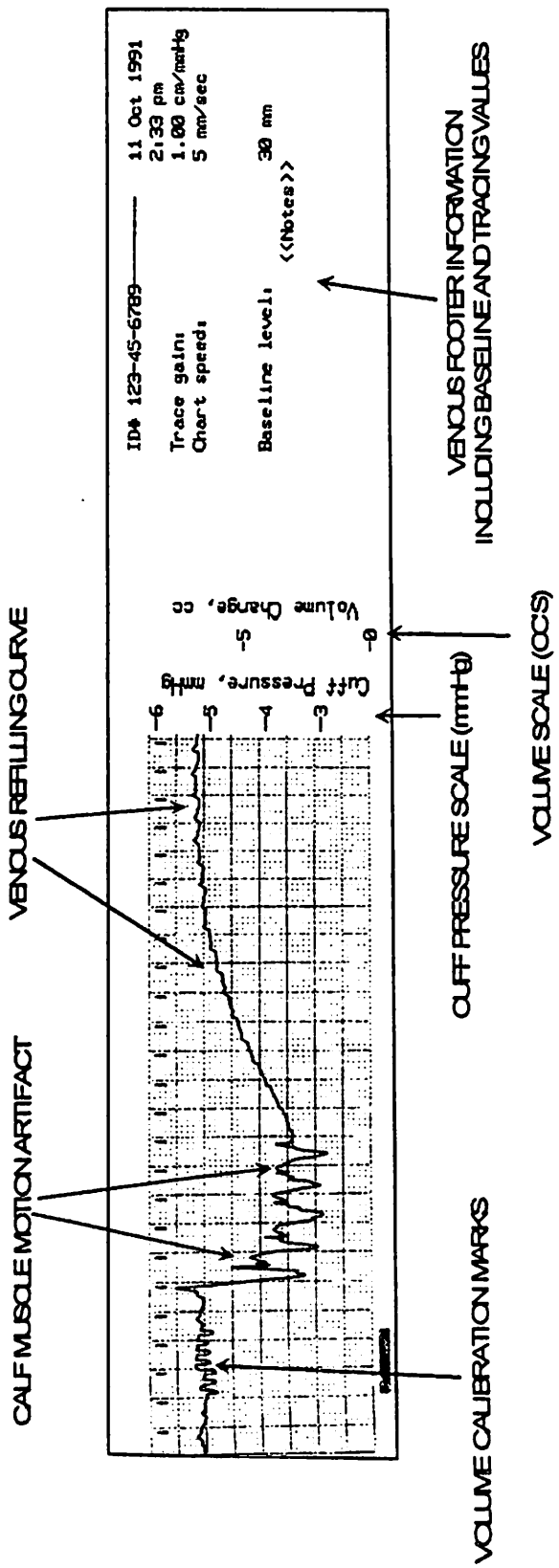
To use the VascuMAP to perform venous reflux testing in the lower extremities, have the subject stand or sit with the feet flat on the floor. Place a cuff of appropriate size lightly over the calf or ankle, and plug the cuff tubing into the VascuMAP. Tape the cuff to the leg to keep it from sliding down. Enter the Venous (VEN) program. Set the chart baseline near the top of the chart by adjusting the INT value to 30 or 35 (top of the chart is 40). Chart speed (SPD) is best at 2 or 5 mm/sec. GAIN will need to be adjusted to suit the individual case, but 1 cm/mmHg is a good starting value. MAX-P should be within 5 to 7 mmHg. Once the VascuMAP is set up as outlined above, press GO to inflate the cuff.

Press GO if needed to reset the baseline pressure to MAX-P. When the cuff pressure is stable, press REC to start the recording. Verify that the tracing is toward the top of the chart, then have the subject contract the calf muscle several times by pushing down with the toes and raising the heels off the floor. After this exercise, the tracing should be lower than the original baseline, as venous blood has been pumped out of the veins. The time it takes for the tracing to return to the baseline level determines venous reflux. As soon as a stable baseline is reached, the test may be repeated. If it is necessary to reset the baseline to the upper part of the chart, **press REC twice** to stop then re-start the recorder. To stop the test, deflate the cuff, and print the title sheet, press STOP.

If the tracing goes off the bottom of the chart after the exercise, the GAIN is **too high**. To change the GAIN, press REC to stop the recorder (the cuff will remain inflated). Change the GAIN, then re-start the tracing with REC. Be sure the subject's feet are at the same position on the floor before and after the exercise, as any change in resting length of the calf muscles produces an unwanted shift in baseline level.

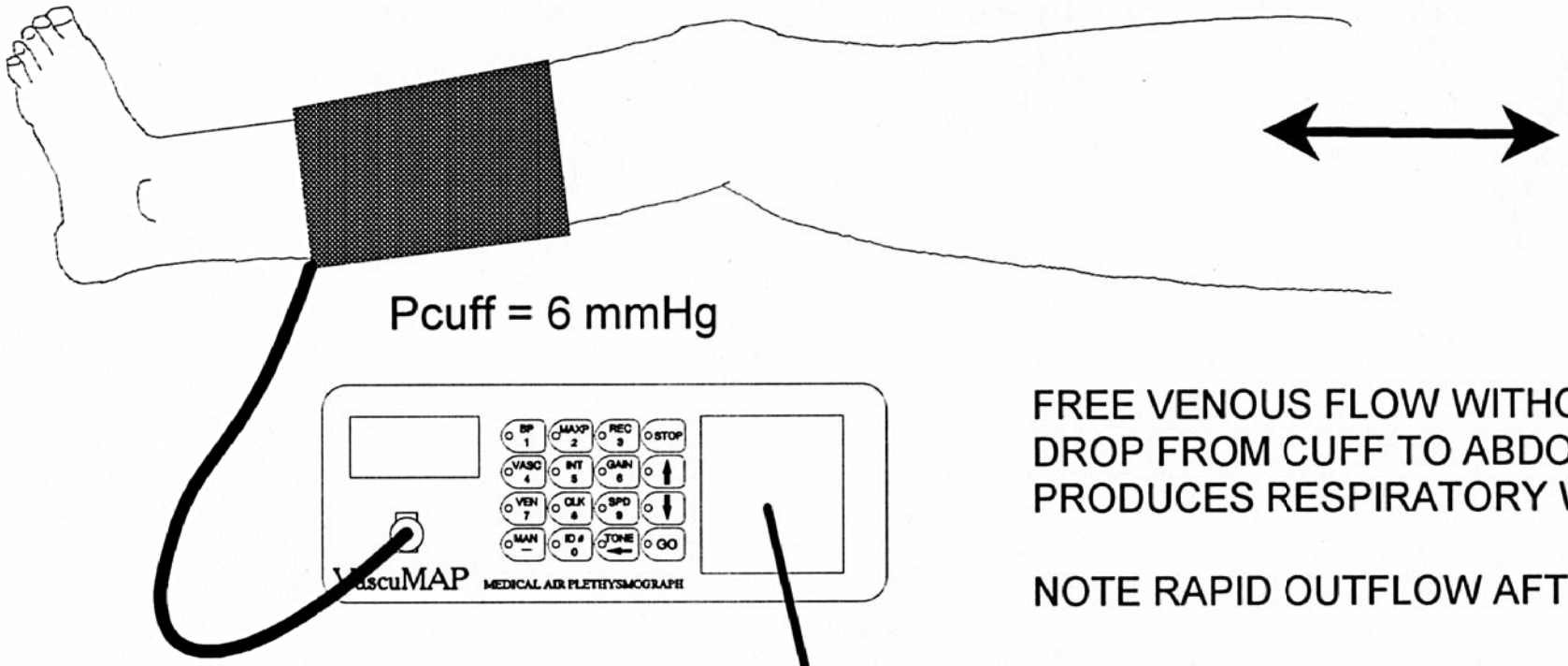
A sample tracing of Venous Reflux testing appears on the following page:

SAMPLE VENOUS REFLUX TESTING CURVE:



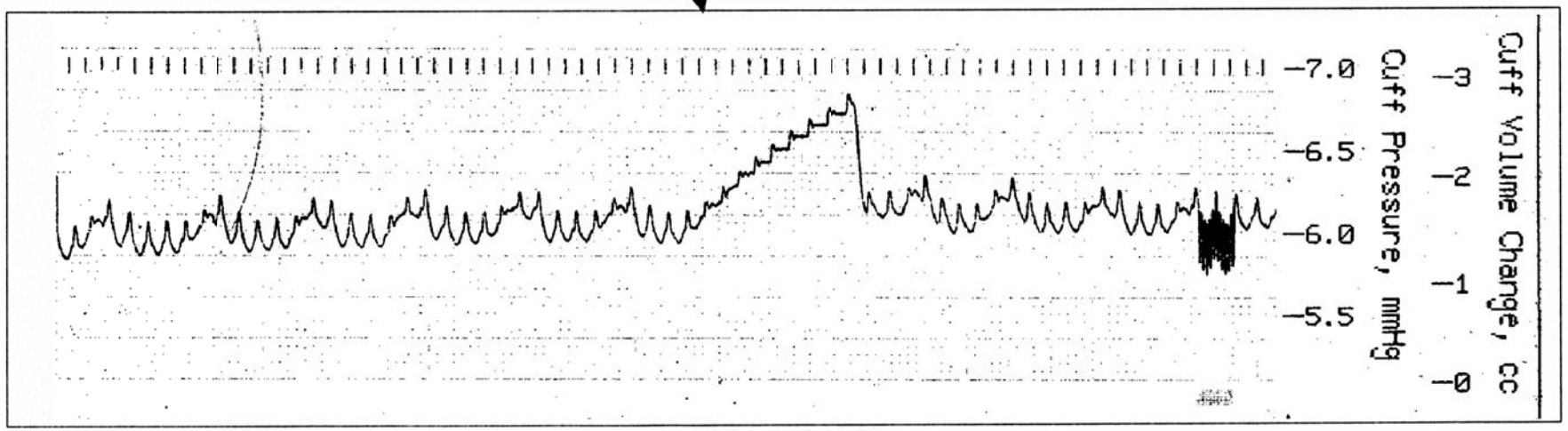
VENOUS RESPIRATORY WAVE MECHANISM IN THE LEG

NORMAL FLOW TRACING



FREE VENOUS FLOW WITHOUT PRESSURE DROP FROM CUFF TO ABDOMINAL CAVITY PRODUCES RESPIRATORY WAVES.

NOTE RAPID OUTFLOW AFTER VALSALVA.



VALSALVA

JSCMD21

VENOUS OCCLUSION PLETHYSMOGRAPHY

Venous Occlusion Plethysmography (VOP) may be performed by the VascuMAP when used with a Rapid Cuff Deflator. VOP may be used as a screening or follow-up test for deep venous obstruction in both the arm and leg. The test records venous filling in the calf or forearm when the venous return is blocked by a second air cuff placed more proximally on the limb. Speed of venous drainage can then be determined by observing the tracing as the second cuff is rapidly deflated, allowing the veins under the VascuMAP cuff to drain. Useful diagnostic parameters measured by this test are Segmental Venous Capacitance (SVC), which indicated the amount of patent, distensible venous channels present under the VascuMAP cuff, and the Maximum Venous Outflow (MVO) rate, which is useful in determining presence of venous obstruction in the veins draining the limb. The shape and timing of both the inflow and outflow curves may also provide diagnostic information to the trained observer.

TEST PROCEDURE:

To perform Venous Occlusion Plethysmography with the VascuMAP, first position the subject properly. Follow standard textbooks on proper positioning and cuff placement. Any restrictive clothing must be loosened. The limb to be tested should be at the same level as the heart, or slightly higher. For leg exams, the subject should be lying down flat on his/her back with the knee elevated and flexed and the hip externally rotated. Arm examination may be done supine with the wrist supported on the abdomen and the elbow resting on the exam table, or in the sitting position with the elbow and wrist supported by pillows on a small table such as a Mayo Stand. In any case, make sure the sensing cuff attached to the VascuMAP does not touch anything. Place the occlusion cuff loosely on the thigh or the upper arm, depending on the limb under test.

For VOP testing, press VEN to put the VascuMAP into Venous Mode. Place the baseline level near the bottom of the chart by setting INT to 5 (0 is the bottom of the chart). Chart speed SPD is usually 1, 2, or 5 mm/sec. GAIN may be set at 0.2 or 0.5 cm/mmHg initially. MAX-P should be 5 to 7 mmHg. Then inflate the sensing cuff by pressing GO. GO may be pressed as needed to adjust the cuff pressure back to MAX-P should cuff settling or limb movement affect it.

(Continued next page)

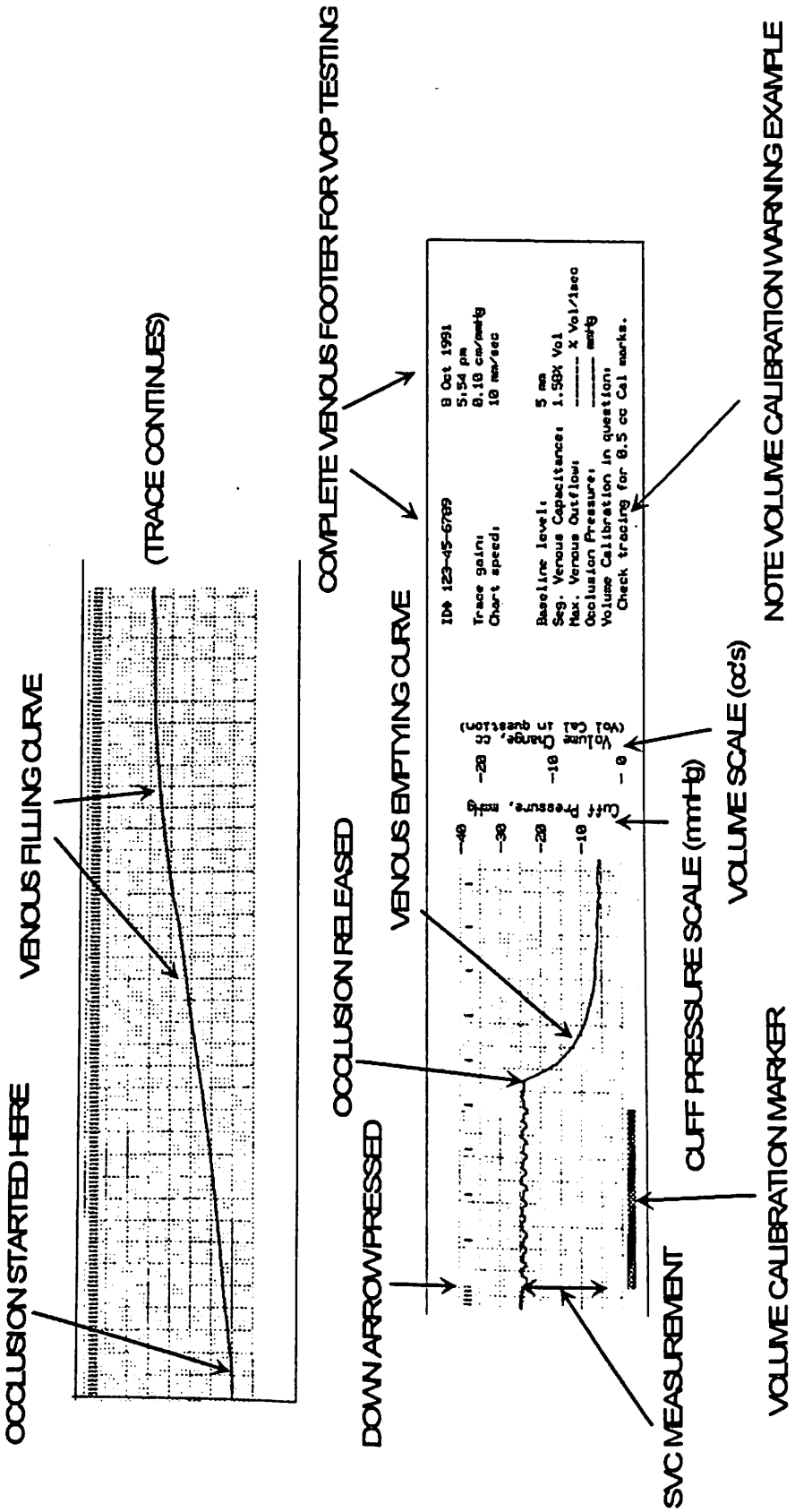
Once the cuff pressure is stable, press REC to start the recorder. The tracing should appear 5 mm above the bottom of the chart. Arterial pulsations and respiratory venous waves may be noted on the record. Now inflate the **occlusion cuff** to 55 mmHg pressure. This stops the venous blood return while allowing arterial flow to continue, thus the veins under the sensing cuff will begin to engorge, and the chart tracing will begin to rise slowly. Eventually, venous pressure will increase to the point that venous blood will begin to flow under the occlusion cuff. At this point, the tracing will stop rising (this is called the "plateau").

If the tracing goes off the top of the chart before the plateau is reached, the GAIN is too high. If the tracing does not reach the midpoint of the chart at the plateau, the GAIN is too low. The test must be started over to change the GAIN. Deflate the occlusion cuff and press REC to stop the recorder (the VascuMAP cuff will remain inflated). Then change the GAIN as needed and press REC to restart the recorder. Once a stable baseline is observed, the occlusion cuff may be re-inflated.

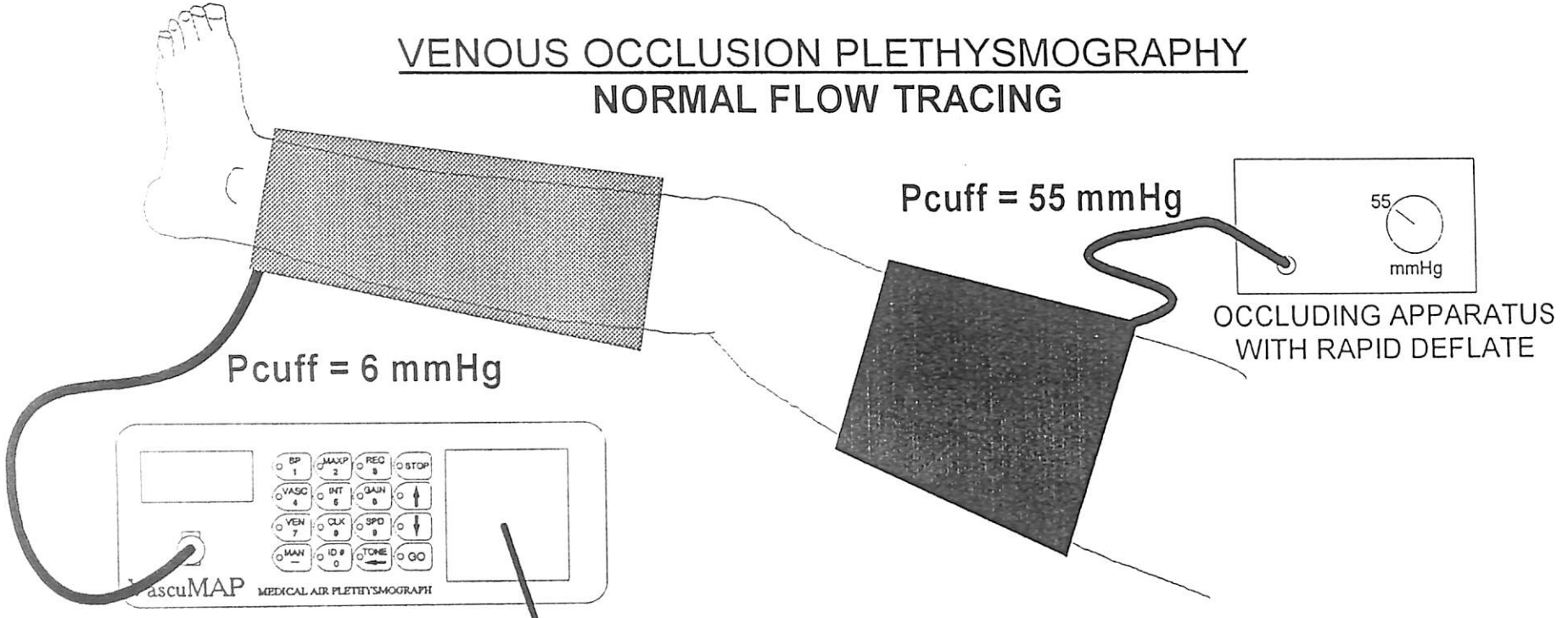
When the plateau is reached, press the **DOWN ARROW** key to change recorder speed to 10 mm/sec. A volume calibration will also be done automatically if using Model AP-102V VascuMAP. Then deflate the occlusion cuff rapidly. The outflow of the venous blood volume will be documented. When the original baseline is reached, the recorder may be stopped by pressing REC, and a full title sheet will be printed. The cuff will remain inflated until STOP is pressed, so that repeat testing is easy and rapid.

A sample tracing of Venous Occlusion Plethysmography appears on the following page:

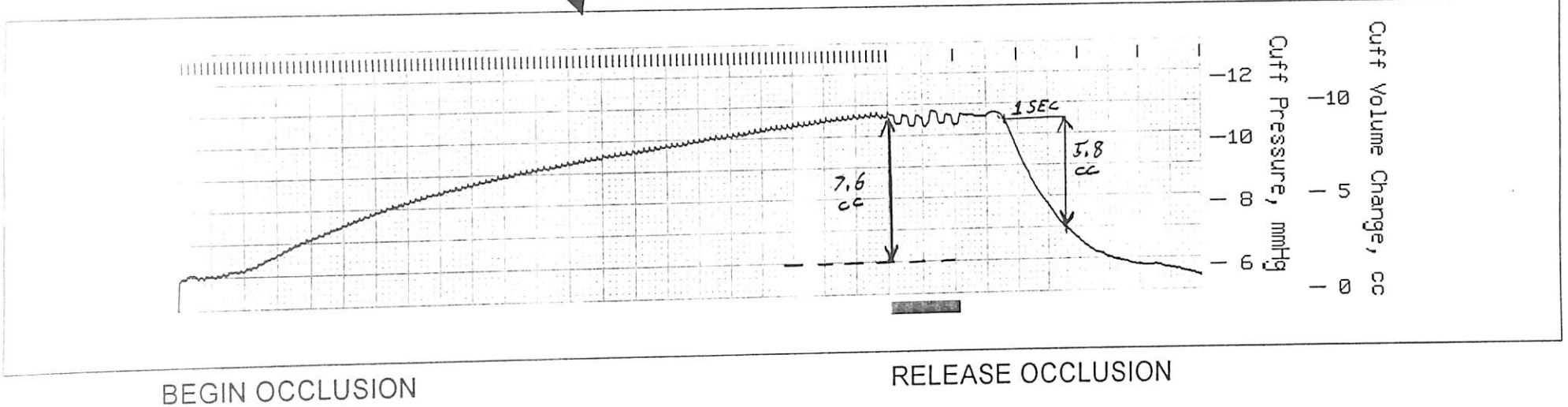
SAMPLE OF VENOUS OCCLUSION PLETHYSMOGRAPHY:



VENOUS OCCLUSION PLETHYSMOGRAPHY
NORMAL FLOW TRACING



RULE OF THUMB: OVER HALF OF THE VENOUS BLOOD SHOULD FLOW OUT WITHIN ONE SECOND.



BEGIN OCCLUSION

RELEASE OCCLUSION

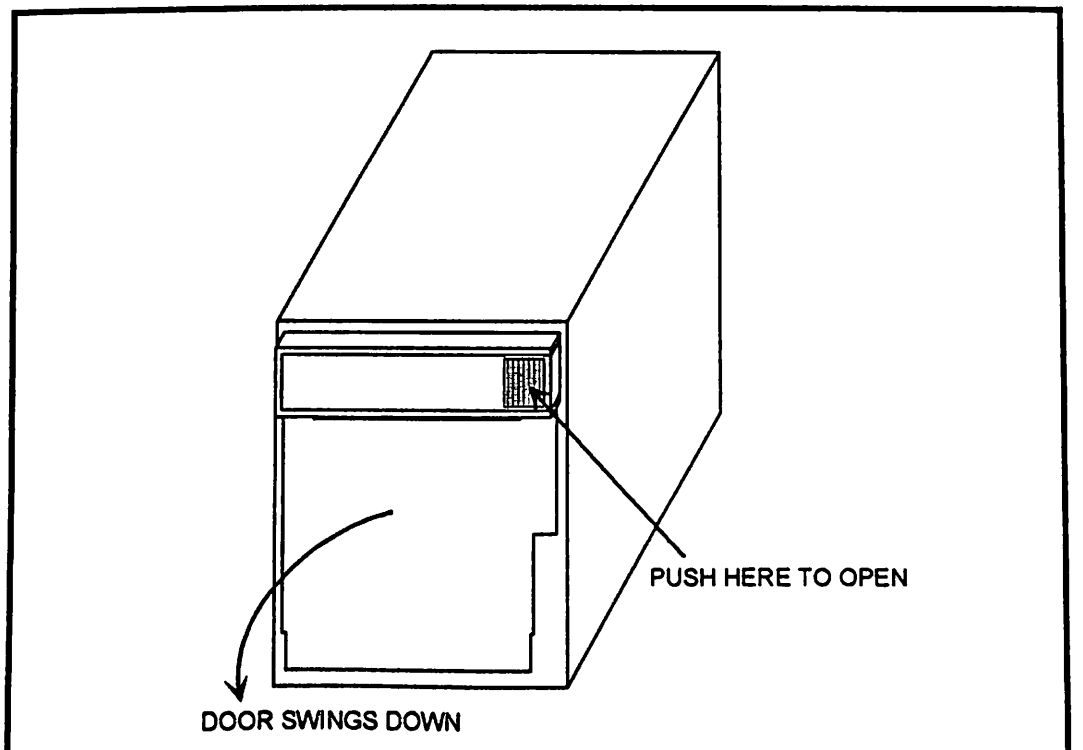
THE CHART RECORDER

The compact, lightweight thermal array recorder in the VascuMAP can print waveforms and text. Mechanically, the recorder is designed for easy servicing.

The paper drive is located inside the recorder. When the door at the front of the unit is open, it tilts forward revealing a curved paper tray. The paper is loaded between two round tabs of the paper holder (see diagram).

Thermal papers can vary considerably in thermal sensitivity and abrasiveness. Use a proper thermal paper to insure that the print quality will be acceptably dark and to reduce print head wear. A quality paper is available from Carolina Medical.

CLEANING THE RECORDER AND PRINT HEAD:
If the chart recorder print head becomes dirty, streaks or light areas will appear on the chart output. In this case, clean the print head using a cotton swab and alcohol. The print head is a spring-loaded plastic assembly located just inside the upper lip of the paper access door. Similarly clean the large rubber roller in the door that presses the paper against the print head when the door is closed. The front surface of the recorder may be cleaned by wiping with a moist (not saturated) cloth.



VASCUMAP CHART RECORDER

LOADING CHART PAPER

1. Open the door at the front of the chart recorder unit by pressing the paper eject button. The door tilts open.

2. Gently pull out the empty spool of the previous chart paper roll.

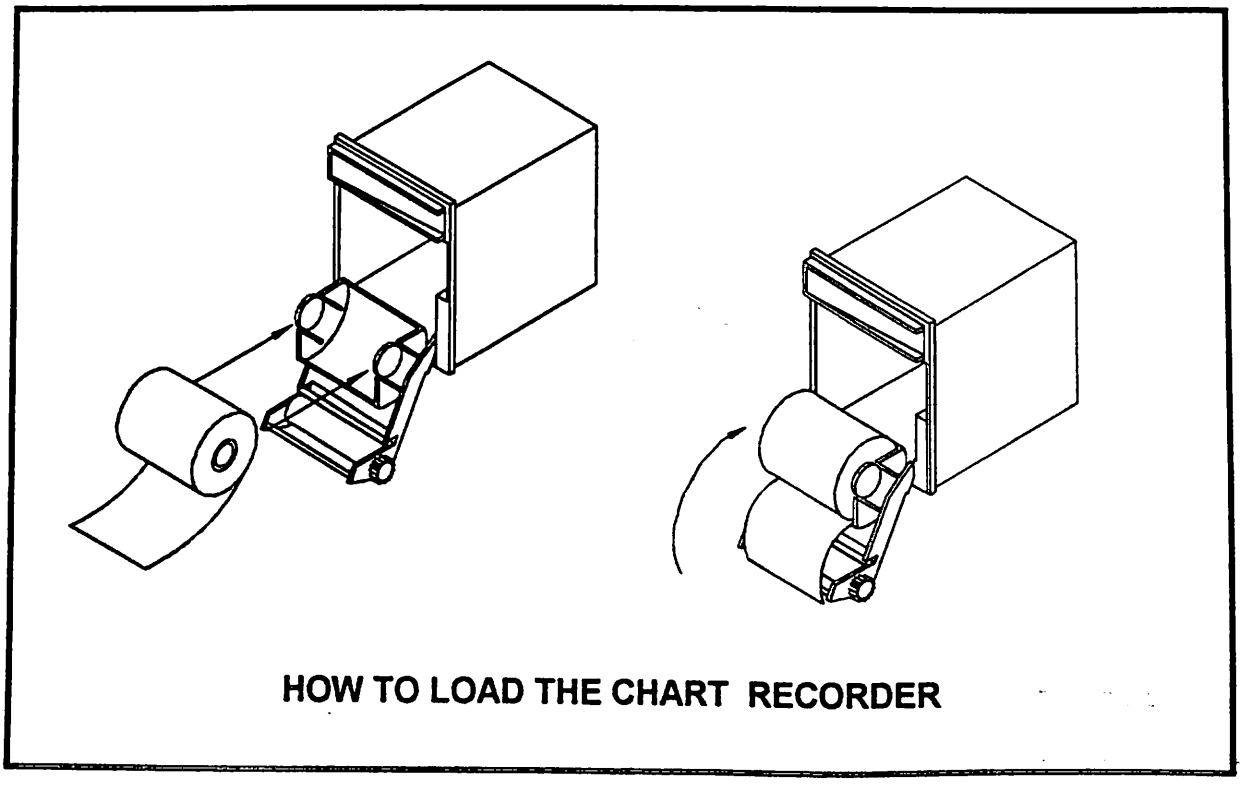
3. Insert a new roll between the two round tabs of the paper holder, so that the inner side of the thermal paper is facing the printhead at the top of the recorder.

4. Pull the paper forward until approximately 4 inches of the paper has been unrolled. **LAY THE PAPER OVER BOTH THE SMALL METAL ROLLER AND THE RUBBER ROLLER.** Then close the recorder door.

5. To insure that the paper is aligned in the slot and has not been pinched in the door, pull the loose edge until a few inches of paper is showing.

6. The chart recorder is now ready to print.

NOTE: When tearing off chart recordings, be careful not to wrinkle and jam the paper.



HOW TO LOAD THE CHART RECORDER

CUFF AND CONNECTOR CARE

1. The connector, tubing, and cuffs are critical for proper VascuMAP operation. Do not alter the cuff assemblies in any way, including changing the tubing length.

2. Always store the patient cuffs in a cool dry place.

3. Never pull on the cuff tubing.

4. Never let fluid get into the connector or the VascuMAP. If fluid does get into the unit, do not operate the VascuMAP until it is properly checked out by a qualified technician or Biomedical Engineer or returned to Carolina Medical for service.

5. Keep the connector plugged in while cleaning the unit to prevent fluid from entering the system.

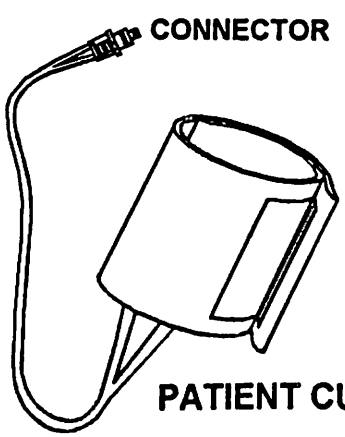
6. Always press the flat metal lever down to connect or unplug the cuff (see diagram below).

7. Clean the connector with a tissue or cotton applicator if needed. Leaks may occur from particles on the black "O" rings.

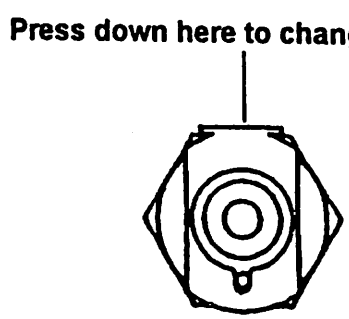
8. The non-disposable cuffs can be washed in mild soap and water after removing the internal bladder. CAUTION: the hook-and-loop fasteners will pick up lint if not protected.

9. Cuffs can be sterilized with ethylene oxide, but it will reduce the life of the cuff.

10. Never steam sterilize the cuffs, tubing, or connector.



PATIENT CUFF



VascuMAP
PNEUMATIC CONNECTOR

TECHNIQUES TO PREVENT CUFF CONTAMINATION

Many VascuMAP cuffs are intended for multiple patient use in the clinical setting. In order to keep the cuffs clean and suitable for re-use, follow these suggestions:

APPLYING CUFFS OVER UNBROKEN SKIN:
First place a single layer of standard food-grade plastic wrap (such as Saran Wrap) over the cuff site. The plastic wrap should be several inches wider than the cuff. Then place the VascuMAP cuff over the plastic wrap snugly but not tightly. Proceed with testing as usual. After the test, discard the plastic wrap as medical waste.

APPLYING CUFFS OVER BROKEN SKIN:
At times it is necessary to perform tests over open sores such as venous stasis ulcers or over recent surgical incision sites. To protect both the site and the cuff from contamination, the following protocol is suggested:

First, all bulky bandages must be removed from the cuff placement site so that the test results will be accurate. Seek help from the nursing or physician staff for bandage removal if you are not trained or authorized to perform this task.

Once the site has been exposed, cover any broken skin, ulcer, or incision site with a THIN sterile dressing such as a Telfa gauze pad. Use a "gentle" adhesive tape such as paper tape to hold the gauze in place if necessary. Keep any bulk to a minimum so as not to affect the VascuMAP results.

Then wrap food-grade plastic wrap around the cuff site and thin dressings as explained above. Apply the cuff over the plastic wrap snugly but not tightly. Proceed with the test as usual.

After testing, remove the cuff gently. Discard the plastic wrap as contaminated medical waste. The temporary dressings may be replaced with more suitable dressings if needed. Consult the nursing or physician staff for help with replacing dressings if you are not trained or authorized to apply fresh dressings. Discard the temporary dressings (if removed) as contaminated medical waste.

PENILE TESTING:
VascuMAP cuffs may be used over a non-lubricated latex condom when performing penile testing. Ultrasound-conductive gel may be used inside the condom and on the outside surface if Psys by Doppler is to be recorded during VASC tests. Alternatively, a VascuMAP "single patient use" cuff may be used and then discarded after the test.

PRESSURE CALIBRATION PROCEDURE

It is highly recommended that the VascuMAP be calibrated at least annually to insure accurate pressure readings. This is done in Manual Mode. In this mode, the upper display shows the pressure reading of the pressure transducer constantly to 0.1 mmHg. By applying known pressures (about 10 mmHg and 245 mmHg) the two ends of the pressure scale are checked for accuracy and adjusted if necessary.

Equipment Needed:

Medium Phillips Screwdriver
Small insulated flat blade screwdriver
CME VascuMAP Test Adaptor or Test Canister
Calibrated Pressure Standard with male Luer connector
(mercury manometer or other standard)

To perform calibration it is necessary to open the top of the instrument case. Follow the step-by-step instructions below:

WARNING -- SHOCK HAZARD! DANGEROUS VOLTAGES INSIDE. THIS PROCEDURE SHOULD BE DONE BY PROPERLY TRAINED PERSONNEL ONLY.

CAUTION -- STATIC-SENSITIVE ELECTRONICS INSIDE. USE ANTISTATIC PROCEDURES WHENEVER WORKING INSIDE THE VascuMAP CASE.

1. Unplug the unit.

2. Using a phillips screwdriver, remove the four screws that hold down the top of the case. These screws are located under four small ribbed plastic inserts. With a flat bladed screwdriver, pry up the edge of each insert which will hinge outward, exposing the screws (see diagram).

3. Remove the top of the case by lifting it straight up.

4. Look in the case and locate the two adjustments labeled ZERO ADJ and GAIN ADJ. These are found on the main circuit board near the cuff connector at the front of the unit.

5. Plug in and turn on the unit. SEE WARNING ABOVE!

6. After the Start-up Routine, press GO and then MAN to begin the Manual Test Mode.

7. Now plug the Test Adaptor into the Cuff Connector. Attach the calibrated pressure standard.

8. Using the Arrow keys, adjust the Target Pressure to 8 mmHg. Press GO. The pressure will increase and then stabilize (settle) over 20-30 seconds. You may have to press GO several times to obtain a stable reading between 5 and 10 mmHg . **NOTE: If settling continues and will not stop, check all tubing connections for leaks (see the Troubleshooting section).**

9. Using the small insulated screwdriver, turn the ZERO ADJ control so that the pressure reading on the display reads the same as the reading on the pressure standard.

10. Using the UP Arrow key, now set the Target Pressure (seen on the lower display) to 245 mmHg. Note: Be sure the value of MAX-P is 245 mmHg or greater, as the Target Pressure cannot be set higher than MAX-P.

11. Press GO. The pump will start, and the indicated pressure will rise and then partially settle (due to thermal settling). You may have to press GO several times to get a stable reading above 240 mmHg on the pressure standard.

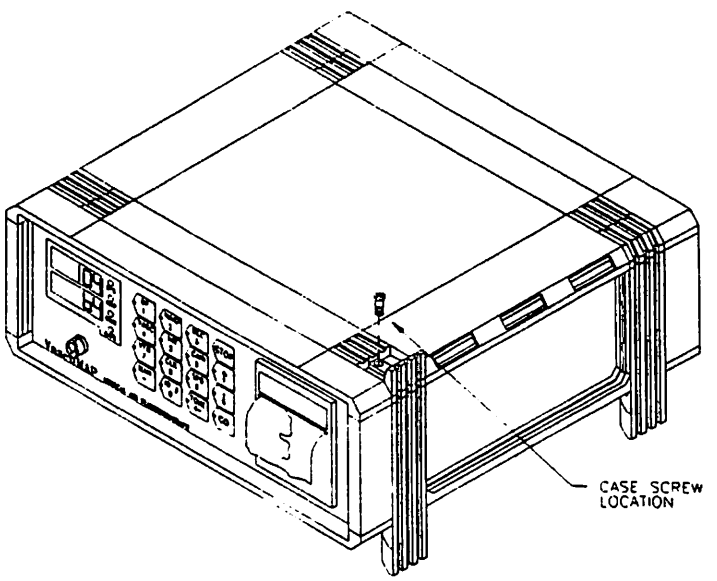
12. When a stable reading above 240 mmHg is obtained, check to see if the reading on the upper display of the VascuMAP reads the same as the pressure standard. If the readings are different, slowly turn the GAIN ADJ control using an insulated tool until the readings match.

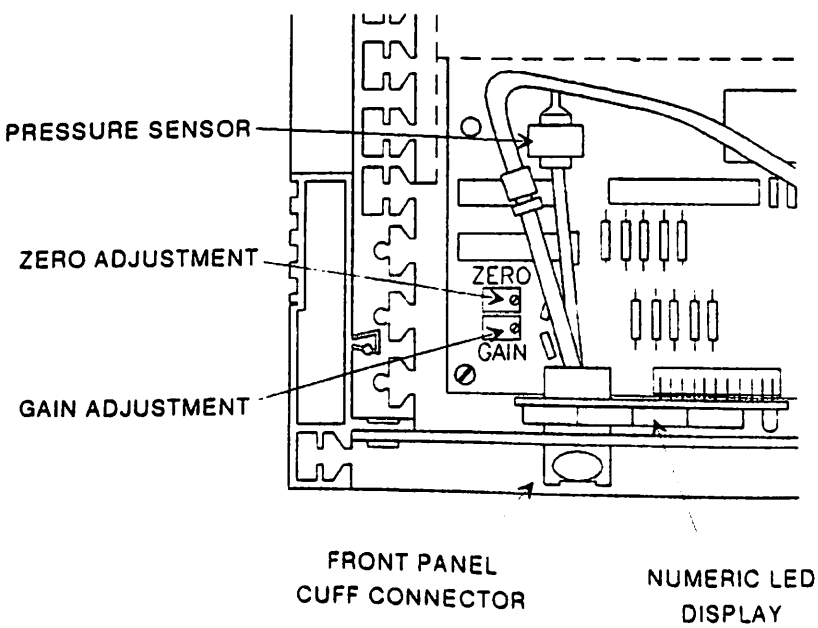
13. Decrease the Target Pressure back to 8 mmHg and press GO. When the pressure is stable between 5 and 10 mmHg, check to see if the VascuMAP's display pressure is the same as that shown on the pressure standard. If not, use the ZERO ADJ control to make the two equal.

14. Increase the Target Pressure back to 245 mmHg and press GO. When the pressure is stable again above 240 mmHg, compare the displayed pressure to that shown on the pressure standard. It should be very close. If needed, use the GAIN ADJ control to make the two readings the same.

15. If the VascuMAP is equipped with a Chart Recorder, a record of this calibration may be obtained if desired. Set the recorder GAIN to 20 cm/mmHg and the SPEED to 10mm/sec. Start the recorder by pressing REC. After 2 to 3 seconds, press REC again to stop the recorder and automatically record the pressure scale and footer information. Write the pressure shown on the pressure standard in the section of the footer labeled "Notes". Then lower the Target Pressure to 8 mmHg, press GO and, when the pressure is stable between 5 and 10 mmHg, proceed as above to obtain a record of the low pressure adjustment.

16. Finally, unplug the unit for safety and replace the top cover with the four screws removed earlier. The VascuMAP is now calibrated and ready to return to service. **Be sure to store the Test Adaptor and a copy of this Calibration Procedure in a safe place for future use.**





TROUBLESHOOTING

CONDITION: VascuMap will not operate, and the keypad will not light up.

NO POWER AT WALL OUTLET.
Make sure that power is available at the wall outlet. Check for presence of power by plugging a known good appliance (lamp, etc), into the outlet.

POWER CORD NOT ATTACHED.
Make sure that both ends of the power cord are properly connected.

POWER SWITCH "OFF".
Make sure that the unit's POWER SWITCH is in the "ON" position.

VASCUMAP FUSE BLOWN.
Make sure that the unit's fuse is not blown. CAUTION! ELECTRIC SHOCK HAZARD. DISCONNECT POWER BEFORE REMOVING FUSE. Pry out the small plastic panel near the power connector to check the fuse. Replace if necessary. Use only same size and rating fuse for replacement. (1 Amp/ 250 volt, slow-blow). If fuse continues to blow, return unit for servicing.

CONDITION: VascuMAP keypad lights up but will not function.

KEYPAD LOCKOUT ENABLED.
See section on Keypad Lockout Feature for instructions on disabling the lockout.

INTERNAL MALFUNCTION IN THE VASCUMAP UNIT.
Return unit for service.

CONDITION: VascuMAP will operate, but the patient cuff will not fill to pressure.

NO CUFF CONNECTED.
Make sure that the cuff connector is fully inserted and locked in place.

WRONG CUFF CONNECTED.
Make sure that the correct cuff is plugged into the VascuMAP unit.

CONNECTOR O-RING MISSING.
Make sure that the two O-rings on the cuff connector are properly located in their grooves.

LARGE CUFF LEAK.
Check cuff and tube carefully during inflation for a hissing sound indicating a large leak. Replace cuff if leak is found.

AIR LEAK WITHIN THE VASCUMAP UNIT.
Return unit for service.

INFLATE SYSTEM IN VASCUMAP UNIT DEFECTIVE.
Return unit for service.

CONDITION: VascuMAP will operate, but the patient cuff will not hold pressure during testing.

AIR LEAK IN CUFF CONNECTOR.
Make sure that the two black O-rings on the cuff connector are properly located in their grooves, and that they are in good condition. The O-rings should show no signs of damage or fraying. Replace cuff set if necessary. Also check the inside the plastic bore of the panel side of the cuff connector. It should be smooth without signs of deep scratches or other damage. If the panel connector is damaged, return unit for servicing.

AIR LEAK IN TUBING OR CUFF.
Check cuff and tube carefully during inflation. Wipe tubing and cuff bladder with mild soap-and-water solution checking for formation of bubbles (indicating a possible leak in the cuff or tubing). Replace cuff or tubing if leak is found.

AIR LEAK WITHIN VASCUMAP UNIT.
Return unit for service.

CONDITION: VascuMAP will operate, but the chart recorder will not function.

CHART RECORDER DOOR AJAR.
Make sure that the chart recorder door is properly closed.

NO PAPER IN RECORDER.
Make sure that the chart recorder is loaded with thermal paper.

PAPER JAMMED IN RECORDER.
Make sure that the paper is not jammed or mis-threaded in the chart recorder.

INTERNAL MALFUNCTION IN VASCUMAP UNIT.
Return to Carolina Medical for service.

CONDITION: Chart recorder operates, but the paper comes out blank.

PAPER INSERTED INCORRECTLY.
Make sure that the paper roll is inserted right side up. Note: only the inner surface of the thermal paper is sensitive.

NON-THERMAL PAPER IN RECORDER.
Be sure to always use fine-grade thermal paper in the chart recorder.

INTERNAL MALFUNCTION IN VASCUMAP UNIT.
Return unit for service.

CONDITION: No Volume Scales Appear on the printout. (AP-102V)

VOLUME CALIBRATION WAS NOT REQUESTED.
The TONE button must be pressed when doing MAN or VEN tracings. TheTONE button may be turned off during repeat MAN tracings.

IMPROPER CUFF OR TUBING ATTACHED TO CUFF PORT.
Use only CME VascuMAP cuffs and tubing sets for proper functioning.

INTERNAL MALFUNCTION IN VASCUMAP UNIT.
(Volume Calibrator does not snap and no calibration marks appear on tracing.)
Return unit for service.

PRINTER ERRORS:

PE 1: Bad command sent to printer. (Indicates a problem internal to the VascuMAP, if recurrent, return unit for servicing).

PE 2: Printer out of paper.

PE 4: Printer door is open

PE 16: Thermal print head voltage out of range. If the power line voltage is too low (brownout conditions) or too high, this message may appear. Otherwise, PE 16 Indicates a problem internal to the VascuMAP, in which case, return the unit for servicing.

PE 1000: Non-specified printer error. Check to see if printer door is ajar.

PROCESSOR ERRORS:

EEEE:
Number to be displayed on LED display is greater than 9999.

VOLUME CALIBRATION WARNINGS:
(These appear on the chart recorder only).

"Volume Calibration in Question: Check tracing for 0.5cc calibration marks"
Because of fast-changing baseline levels (due to patient movement, high-volume pulse waves, high pulse rate, etc.), the accuracy of the volume scale generated by the microprocessor may be in error. By checking the known 0.5cc volume change pulses, the volume scale may be verified by the interpreter.

"Volume Calibration in Question: Calibration Pulse Goes Negative"
This occurs when performing Volume Calibration at low pressures with very small cuffs.

ELECTRICAL AND MECHANICAL SPECIFICATIONS

Pneumatic System:
Maximum Pressure: 7.5 PSI, typ., limited by pump design
Flow Rate: 0.2 CFM (5 Liters/min) at 100 mmHg, typ.
Accumulator Tank Volume: 100 cc., max.
Tank Bursting Pressure: 100 PSI, min.
Deflate Rate: Deflates 200 cc volume from 250 to 20 mmHg in less than 4 seconds.

Safety Features:
Automatic cuff deflation if power fails
Automatic pump stop if microprocessor fails
Automatic cuff deflation if microprocessor fails
Automatic cuff deflation on overpressure of 10 seconds duration
Automatic pump stop if no cuff connected
Maximum cuff inflation pressure is user selectable
Coaxial pneumatic connector prevents connection error

Pressure Sensing System:
Separated from fill/deflate system with two-tube design
Range: 0 to 325 mmHg
Zero Offset: adjustable to less than +/- 0.1 mmHg.
Full-Scale Gain: adjustable to less than +/- 0.1 mmHg.
Linearity: +/- 0.5% of full scale (+/- 1.3 mmHg, worst case)
Drift over Operating Temperature: +/- 0.5 mmHg, max.
System Bandwidth (cuff to recorder output): 0 to 20 Hz, min.
Sensitivity: 0.005 mmHg, min, limited by LSB size
Zero Offset and Gain adjustments for field calibration

Analog to Digital Conversion:
16-Bit A to D Converter with no missing codes.
Conversion Factor: 1 bit = 0.005 mmHg pressure
Sampling Rate: 256 samples/sec.
Total System Noise: 2 LSB RMS Noise, Max., measured over 30 seconds.

Operator Controls:
4 by 4 custom lighted push-button matrix
Power Switch on rear panel
Replaceable Fuse
Coaxial Cuff Connector

Digital Circuitry:
CPU: 80C31 Microprocessor running at 22 MHz
Field-Replaceable program ROM for software updates
Socketed clock chip with integral 10-year battery for time setting storage

Display Output:
Two rows of four 0.5 inch 7-Segment Light Emitting Diodes (LEDs) with trailing decimal points on middle digits
Character Set: 0,1,2,3,4,5,6,7,8,9,E,H,L,P,-, and Off.
Four discrete LEDs labeled "SYS", "DIAS", "MAP", and "RATE"

Chart Recorder Output (AP-102R and AP-102V):
Recorder Location: internal, front panel mounted
Paper: 2 inch (48 mm) thermal roll type
Trace Resolution: 200 dots/inch (8 dots/mm), min.
Character Set: 137 characters including standard ASCII set
Print Speeds: 1, 2, 5, 10, 25, and 50 mm/sec
Vertical Gain: 0.01,0.02, 0.05, 0.1, 0.2, 0.5, 1.0, 2.0, 5.0, 10, and 20 cm/mmHg
Trace Grid: printed real-time during trace printing
Data Output Format: includes testing date and time from internal real-time clock, 20-digit patient ID number (if entered), full alphanumeric test results and warning messages, and tracing of the cuff waveform with pressure data

Positive-Displacement Volume Calibrator (AP-102V only):
Displacement Volume: 0.500 cc +/- 2.5%
Displacement Output Rate: 4 pulses per second up to 16 total

Cuff Set:
Twenty-four cuff types presently available, all with Velcro fasteners
Cuff widths available: 2.0 through 21 cm (fits digit to thigh sizes)
Cuffs use dual-lumen connection tube and coaxial connector.

Power Requirements:
Voltage: 105 to 125 Volts, AC only. (220 volt operation also available as option)
Frequency: 50 to 60 Hz.
Supply Current: less than 0.4 amp at 60Hz./ 120 Vac
Power Consumption: 35 Watts, Max. with pump running
Power Connector: Standard 3-conductor IEC recessed male
Fuse: 1 AMP, slow blow

Environmental Requirements (Operating):
Temperature: +10 to +38 Degrees, Centigrade (50 to 100F)
Humidity: 20 to 90% RH, noncondensing
Shock and Vibration: Withstands normal clinical and transportation conditions

Storage Conditions:
Temperature: -20 to+45 Degrees, Centigrade (-5 to +115 F)
Humidity: 5 to 90% RH, noncondensing

Electrical Safety (measured per UL-544)
Breakdown Voltage, line to ground: 1500Vrms, min.
AC Leakage Current: 100 microamps, Max @ 60 Hz.
DC Leakage Current: 50 microamps, max.
Chassis to Protective Ground Resistance: 0.1 Ohm, max.
Electrical Connection to Patient: None

Mechanical Specifications:
Case Size: 12.7"W by 5"H by 11.9"D
Weight: Approx. 13 Lb. (15 Lb for AP-102V)
Case Material: Aluminum and High-Density Plastic
Flammability Rating (case): UL-94V-0

APPENDIX A

VascuMAP **CUFF SIZE RECOMMENDATIONS** for Oscillometric Measurement of Arterial Pressure:

CUFF WIDTH	HUMAN LIMB CIRCUMFERENCE for 5% accuracy*
2.0 cm	4 - 6 cm
2.5	5 - 7.5
3.8 cm	7.5 - 11 cm
4.4	8.8 - 13
5.1	10 - 15
6.0 cm	12 - 17.5 cm
7.6	15.2 - 22.5
9.0 cm	18 - 26.5 cm
12	24 - 35
15	30 - 44
18	36 - 53
21	42 - 62

* as determined by the method of LA Geddes and SJ Whistler, Am Heart J., 96, 4-8, July 1978.

APPENDIX B

Typical **PULSE VOLUMES** at various cuff locations on a healthy 70 Kg man in a warm room, brachial blood pressure 120/92/80. Cuff sizes used are shown on parentheses (..).

CUFF SITE	PULSE VOLUME, cc. at MAP	at 65 mmHg	at 40 mmHg
Brachial (12cm)	1.5	1.1	0.4
Forearm (12 cm)	1.5	1.2	0.4
Wrist (9 cm)	0.75	0.5	0.2
Thumb (2.5 cm)	0.04	0.02	0.02
Index Finger (2.5 cm)	0.050	0.035	0.025
Little Finger (2.0 cm)	0.015	0.012	0.010
Thigh (18 cm)	6.0	4.0	2.5
Calf (15 cm)	3.0	2.5	1.1
Ankle (12 cm)	1.0	0.65	0.32
Trans-Metatarsal (9 cm)	0.35	0.28	0.19
Great Toe (2.5 cm)	0.035	0.030	0.018
Second Toe (2.0 cm)	0.010	0.007	0.003
Small Toe (2.0 cm)	0.0025	0.0025	0.002
Penis (2.5 cm)	0.006	0.004	0.001

ANKLE-BRACHIAL INDEX STUDY

See back of page for study interpretation.

Senior Care, PA 147 Columbine Drive
Winston-Salem, NC 27106
(336) 777-1200

PATIENT: _____ **DATE:** _____

RIGHT BRACHIAL TRACING:

MEDesign

Use ARTERIAL("Vasc") Mode for these tests. Use recorder speed of 10 mm/sec.

Plug properly sized cuff on **RIGHT ARM** into VascuMAP.

Erase any numbers at the "SEG" prompt on the VascuMAP display.

Press GO to begin test.

LEFT BRACHIAL TRACING:

Plug properly sized cuff on **LEFT ARM** into VascuMAP.

Do not enter a number at the "SEG" prompt on the VascuMAP display for the arm tests.

Press GO to begin test.

RIGHT ANKLE TRACING:

Plug cuff on **RIGHT ANKLE** into VascuMAP.

Enter the **higher** of the arm systolic pressures (see above) at the "SEG" prompt on the VascuMAP display.

Raise **MAXP** to 40 mmHg above arm Psys. **Press GO** to begin test.

The right ABI will be printed at the end of the test.

LEFT ANKLE TRACING:

Plug cuff on **LEFT ANKLE** into VascuMAP.

Leave the higher of the arm systolic pressures entered at the "SEG" prompt.

Check to be sure **MAXP** is still about 40 mmHg above arm Psys. **Press GO** to begin test.

The LEFT ABI will be printed at the end of the test.

VascuMAP® LOWER EXTREMITY ARTERIAL EVALUATION

CPT CODE: 93921

PATIENT I.D.# _____ DATE: _____

PATIENT NAME: _____ REFERRING PHYSICIAN: _____

BIRTH DATE: _____ AGE: _____ INTERPRETATION BY: _____

WEIGHT: _____ LB KG SEX: M F TEST DONE BY: _____

PATIENT HISTORY: ☐ DIABETES. ☐ HYPERTENSION. ☐ HYPERLIPIDEMIA. ☐ SEDENTARY.
☐ TOBACCO SMOKER. ☐ VASCULAR DISEASES. ☐ VASC. INJURY. ☐ PREVIOUS VASC. SURGERY.
EXPLAIN: _____

MEDICATIONS: _____

PRESENT SYMPTOMS: ☐ LEG PAIN AT REST. ☐ LEG PAIN ON EXERCISE. ☐ COLD FOOT / TOE.
☐ MALE IMPOTENCE. EXPLAIN: _____

PHYSICAL FINDINGS: ☐ SKIN ULCER. ☐ GANGRENE.
☐ TROPHIC NAILS. ☐ EDEMA. ☐ SKIN CHANGES / SCARS.
EXPLAIN: _____

PULSE EVALUATION

FEMORAL	R:	L:
POPLITEAL	R:	L:
POST. TIBIAL	R:	L:
DORSALIS PED.	R:	L:

INTERPRETATION:

BRACHIAL TRACING

R L

UPPER ARM TRACING
(USE ARM WITH HIGHER PRESSURE READING)

RIGHT THIGH TRACING

RIGHT CALF TRACING

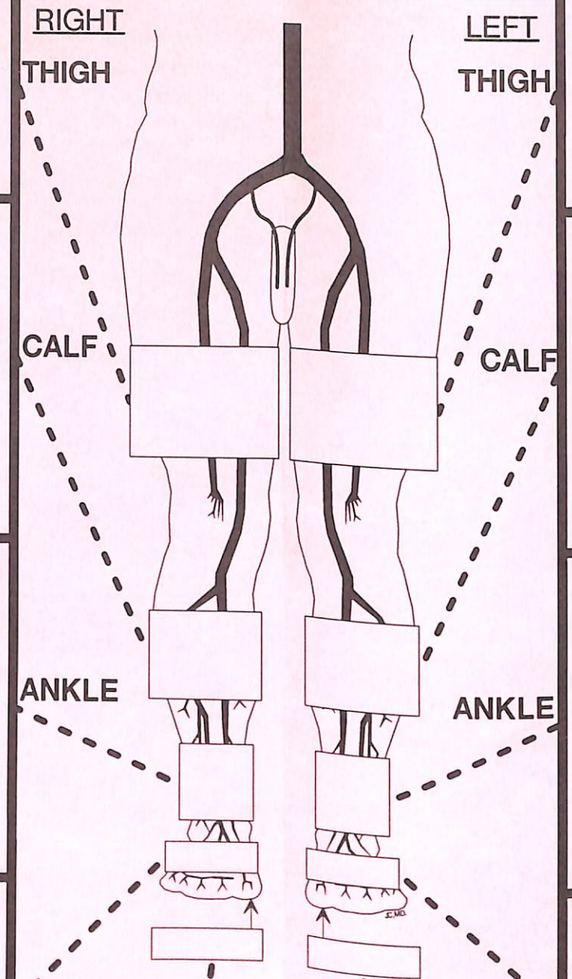
RIGHT ANKLE TRACING

RIGHT METATARSAL TRACING

RIGHT GREAT TOE TRACING

PATIENT:

NUMBER: DATE:



NOTES:

BRACHIAL PRESSURE = _____ mmHg

SEGMENTAL INDEX = SEGMENTAL PRESSURE / BRACHIAL PRESSURE

VascuMAP®

LOWER EXTREMITY ARTERIAL EVALUATION

Carolina Medical Inc

REORDER # 19992

(800) 334-4531

LEFT THIGH TRACING

LEFT CALF TRACING

LEFT ANKLE TRACING

LEFT METATARSAL TRACING

LEFT GREAT TOE TRACING

POST-EXERCISE TRACINGS:

NOTES

ANKLE-BRACHIAL INDEX (A.B.I.)= $\frac{\text{ANKLE PRESSURE}}{\text{BRACHIAL PRESSURE}}$

RIGHT ANKLE **A.B.I.=** _____	RIGHT ANKLE TRACING AFTER LEG EXERCISE OR REACTIVE HYPEREMIA (IF INDICATED)
LEFT ANKLE **A.B.I.=** _____	LEFT ANKLE TRACING AFTER LEG EXERCISE OR REACTIVE HYPEREMIA (IF INDICATED)

PENILE TRACINGS:

NOTES

PENILE-BRACHIAL INDEX (P.B.I.)= $\frac{\text{PENILE PRESSURE}}{\text{BRACHIAL PRESSURE}}$

PRE EXER-CISE: **P.B.I.=** _____	PENILE TRACING BEFORE LEG EXERCISE (IF INDICATED)
POST EXER-CISE: **P.B.I.=** _____	PENILE TRACING AFTER LEG EXERCISE (IF INDICATED)

Aegis Family Practice Clinic, 624 West Main Street, Yadkinville, NC 27055, (910) 679-6700

VENOUS REFLUX TEST REPORT

MEDICAL DESIGN

PATIENT_____ DATE_____

CLINICAL PROBLEM / INDICATIONS_____

INTERPRETATION_____

RECOMMENDATIONS_____

SIGNED_____

RIGHT CALF REFLUX CURVE, NO TOURNIQUET:

RIGHT CALF REFLUX CURVE, ABOVE KNEE TOURNIQUET:

RIGHT CALF REFLUX CURVE, BELOW KNEE TOURNIQUET:

Aegis Family Practice Clinic, 624 West Main Street, Yadkinville, NC 27055, (910) 679-6700

VENOUS REFLUX TEST REPORT - page 2

MEDICAL DESIGN

PATIENT_____ DATE_____

NOTES:

LEFT CALF REFLUX CURVE, NO TOURNIQUET:

LEFT CALF REFLUX CURVE, ABOVE KNEE TOURNIQUET:

LEFT CALF REFLUX CURVE, BELOW KNEE TOURNIQUET: