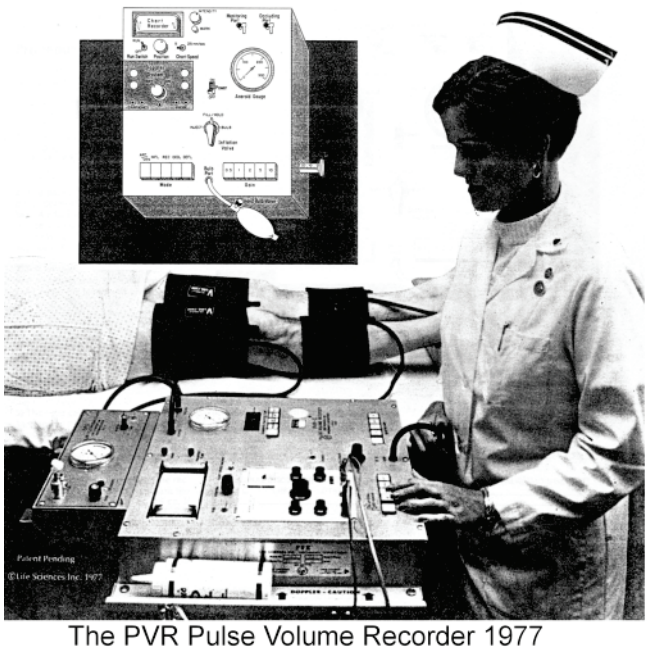
The Development of the VascuMAP®

Volume-Calibrated Air Plethysmography and Non-Invasive Blood Pressure In one instrument

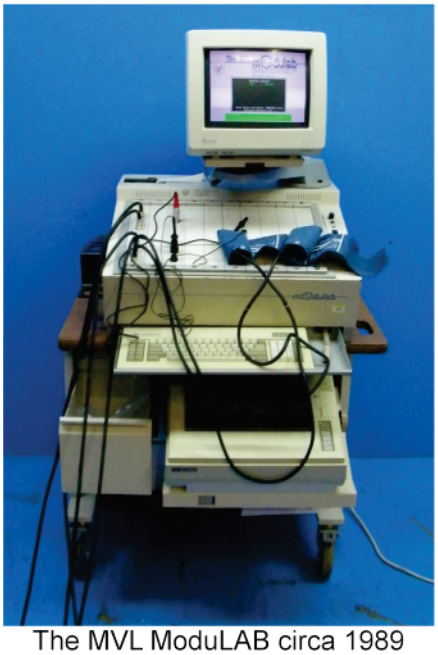
James Stewart Campbell, EE, MD. 2024

Introduction:

The year was 1988, the personal computer still ran under MS-DOS, and the very buggy Windows 3.0 was 2 years away. With the demise of Washington, DC-based Automated Diagnostic Systems from a self-caused flood and loss of grant funding, I was out of a job and desperate to cover expenses. After an extensive search, the only job offer I got was with Life Sciences, Inc. in West Lebanon, New Hampshire. I was to be their "Director of Clinical Services", teaching classes on how to operate their venerable PVR Pulse Volume Recorder and their latest development, the MVL "ModuLAB", which accommodated modules for CW Doppler, 4-cuff air plethysmography (PVR), ocular pneumoplethysmography (OPG), photoplethysmography (PPG), venous impedance plethysmography (IPG), and ultrasound imaging. The new MVL, however, was fraught with difficulties. The original designers of the ModuLAB had mistakenly mixed the low-noise analog grounds with the noisy digital grounds, making the noise-sensitive imaging module unusable. Also, by attempting to cram four separate PVR air channels into one thin MVL module, they had created a rats-nest of small-diameter tubing which could not support the 20-Hz pneumatic bandwidth required for human air-cuff plethysmography, thus "slurring" the pulse waveforms and reducing the important reflected pulse waves. In addition, the IPG module didn't work reliably if at all. Another electrical engineer hired along with me freaked out when he learned of the problems, demanding that the MVL be taken off the market until the problems were solved. The outcome? The MVL stayed, he left, and I was tasked with cleaning up the problems. My education in non-invasive vascular diagnosis had begun.



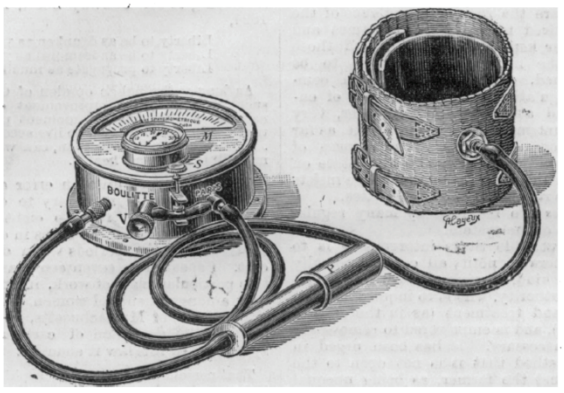
The PVR Pulse Volume Recorder 1977

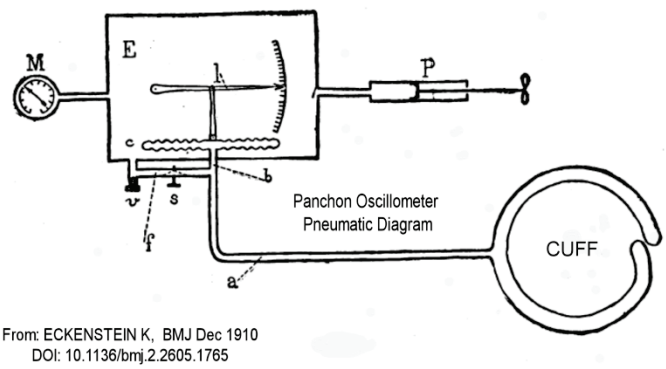


The MVL ModuLAB circa 1989

History:

Perhaps the first clinical instrument to detect the pulse volume in an arm cuff at various cuff pressures was the Panchon Oscillometer, manufactured by Mr. G. Boulitte in Paris, France around 1900. This was a mechanical instrument with no electric power required. A manual pump (P) increased the pressure in an enclosure (E) and the cuff. A meter (M) measured this pressure in cm of mercury (cmHg). A restrictive orifice (S) in combination with the enclosure volume acted as a low-pass filter so that the pressure in the enclosure changed very little with the arterial pulse. The pulse wave was instead transmitted into the aneroid bellows (C) where it could be observed on the larger meter scale (l), albeit as a non-calibrated needle fluctuation. By raising the cuff pressure above systolic pressure, the deflection of the pulse wave ceased. The pressure was then released about 1 cmHg (10 mmHg) at a time. Where the pulse fluctuations returned was the systolic pressure. These pulse fluctuations increased to a maximum value as the pressure was lowered (fluctuations would be greatest at the mean arterial pressure), then decreased. Where the pulse fluctuations ceased was considered the diastolic pressure. The Panchon Oscillometer was a direct competitor to the palpation blood pressure detection method of Dr. Riva-Rocci in Italy and the auscultatory method of Dr. Korotkoff in Russia (which is in common use today). Later the Panchon instrument was used to detect low pulse fluctuations distal to arterial blockages. A cuff pressure of 4 cmHg (40 mmHg) was often used for these determinations. The Panchon Oscillometer provided the pneumatic principles on which later electronic devices would be built.





From: ECKENSTEIN K, BMJ Dec 1910
DOI: 10.1136/bmj.2.2605.1765

Fifty years and two world wars later, Doctor Travis Winsor, working in Los Angeles, California, studied the principles of air-cuff plethysmography and went on to develop an electronic Segmental Plethysmograph that calibrated the volume displacement caused by the pulse wave in cubic centimeters. To accomplish this, Winsor used a "Standardization Chamber", a calibrated bellows device that would *decrease* the volume of the pneumatic system (cuff plus device) by 1.0cc when activated by a button press. Decreasing the enclosed volume *increased* the internal pressure in the system. This increase in pressure could be visualized on a tracing of the pulse wave, and the pulse volume could then be related to this known volume/pressure change independent of cuff pressure or enclosed air volume. As in the Panchon Oscillometer, the pulse wave was detected by a separate "Differential Chamber", while the cuff pressure was shown on a standard pressure gage. As shown in Figure 2, below, the differential chamber was configured to be a capacitor whose capacitance changed with the pulse-induced motion of a metal diaphragm. This change in capacitance changed the frequency of an electronic oscillator. A frequency-to-voltage converter circuit could then develop a voltage signal which varied linearly with the pulse wave. A calibrated panel meter (on the left side of the instrument in Figure 1) displayed the pulse displacement in cubic centimeters, and a chart recorder made a hard copy of the pulse wave and calibration standard (Figure 4).

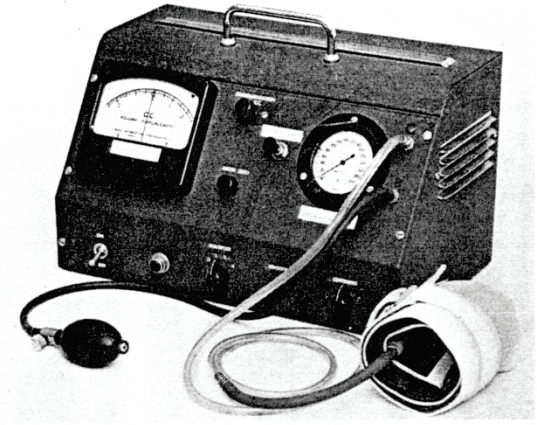


FIG. 1. Appearance of the segmental plethysmograph

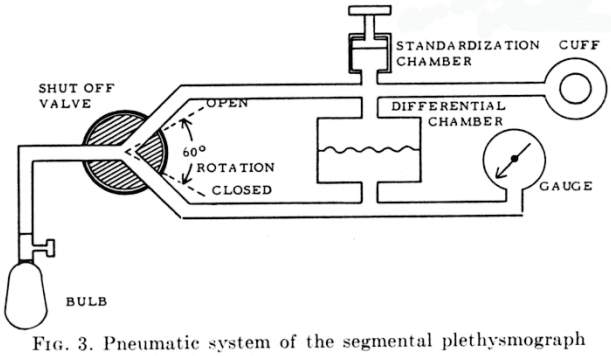


FIG. 3. Pneumatic system of the segmental plethysmograph

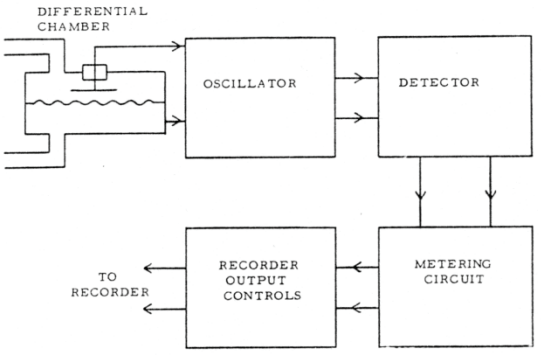


FIG. 2. Electronic circuit of the segmental plethysmograph

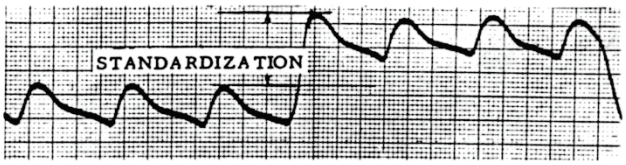
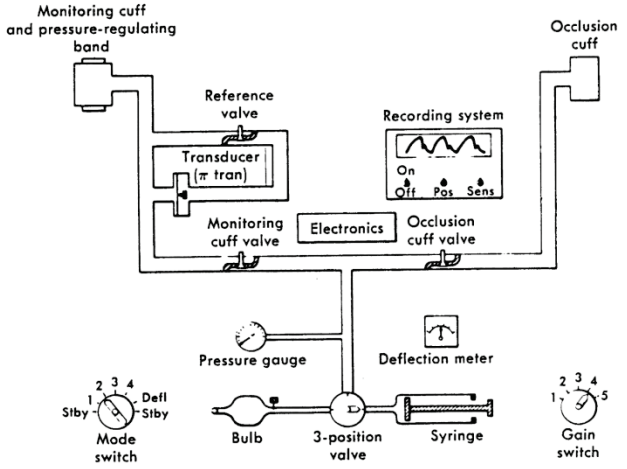


FIG. 4. Typical standardization in which the pneumatic system was decreased by a volume of 1 cc and the gain adjusted so that the stylus moved 15 mm.

Illustrations from:
Winsor, T: The Segmental Plethysmograph: A Description of the Instrument. Angiology 8: 87-101, 1957 https://doi.org/10.1177/000331975700800109

Twenty years after Dr. Winsor's work on pulse recording, Dr. Jeffrey Raines sought to calibrate pulse volumes by injecting a known amount of air into the cuff so that it reached a pressure of about 40 mmHg. At this pressure, cuff compliance becomes fairly stable, so that a normal/abnormal pulse volume change can be made by observing the amplitude of the pulse pressure wave.

"The pulse volume recorder (PVR) was introduced by Raines almost 40 years ago in a thesis based on graduate work conducted at the Massachusetts Institute of Technology (MIT), Harvard Medical School and Massachusetts General Hospital. The work was sponsored by the National Institutes of Health. The work built on earlier pioneering efforts by investigators such as T.Winsor and E. Strandness. The research took advantage of major recent advances in electronics, specifically in the area of pressure transducer design." (Excerpt from Pulse Volume Recording in the Diagnosis of Peripheral Vascular Disease by Jeffrey K. Raines, Jose I. Almeida. Chapter 23 of Noninvasive Vascular Diagnosis, AF AbuRahma, ed., Springer International Pub., 2017).



System diagram of PVR.

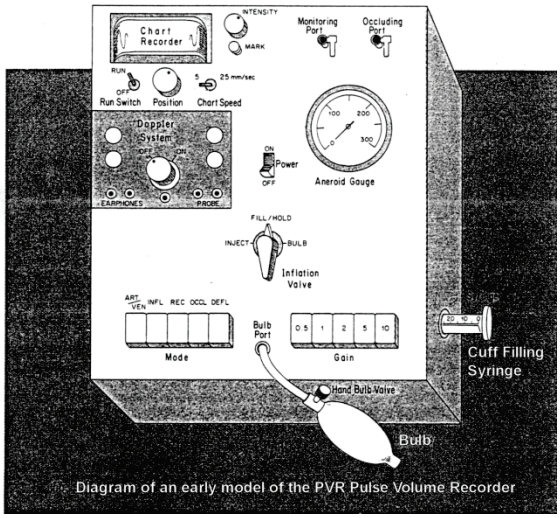


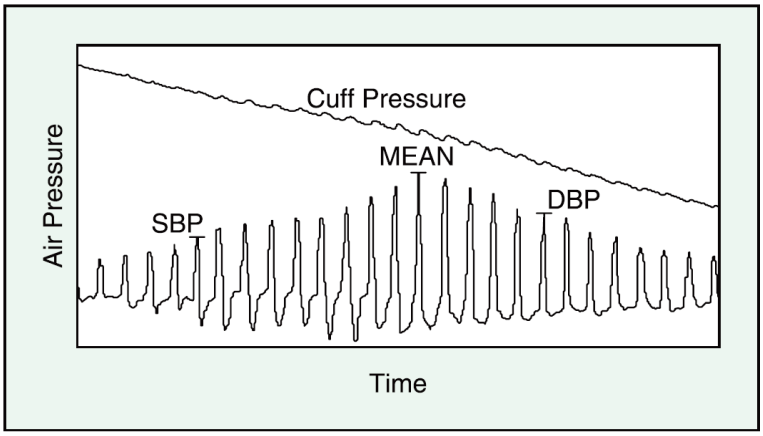
Diagram of an early model of the PVR Pulse Volume Recorder

The pulse volume via PVR is not calibrated in cubic centimeters, however, but in "millimeters of chart height". A PVR Chart Height of 15mm at the ankle indicates good perfusion (PVR Category 1 or 2), while a Chart Height less than 5mm indicates poor arterial perfusion (PVR Cat 4). This lack of true volumetric calibration is also compromised by the inability to inflate the cuff (especially the larger cuffs) to the required pressure with the limited air volume injected, thus reducing the observed pulse pressure change. To obtain the required volume-pressure results, the vascular technician would have to tighten the cuff around the limb using excessive, painful traction. Techs often cheated on these requirements (pressures and volumes are not recorded by the device) thus delivering erroneous recordings to the interpreting physician (Personal observation while accompanying technicians on Dr. Raines' service at Miami Heart Institute, 1988).

Though the PVR device as manufactured was not truly volume-calibrated, it advanced the field of vascular diagnosis by incorporating a continuous-wave (CW) Doppler as championed by Dr. Eugene Strandness, allowing the operator to use two separate modalities to estimate limb perfusion. Indeed, the vascular surgeons who used the PVR were less interested in true volume calibration, preferring a simple good/bad number that told them the state of the arterial flow to the limb. The PVR also incorporated a

separate port for an “occlusion cuff” which allowed testing for post-occlusive reactive hyperemia (PORH) and determination of the limb systolic pressure using the Doppler to determine the distal pulse return as the occlusion cuff pressure was lowered. With the clout of the NIH, MIT, Harvard, and Massachusetts General, the PVR was a huge success. Dr. Winsor’s pioneering work in pulse calibration faded into history.

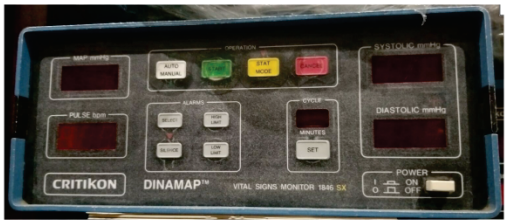
With all of the pulse volume detection instruments above, including the Panchon Oscillometer, it was noted that as the cuff pressure decreased below the systolic pressure (Psys) the pulse amplitude would increase to a maximum, then decrease as the diastolic pressure was approached. With the electronic devices, this could be recorded on a pen chart recorder for study. The unique shape of these pulse pressure recordings as the cuff pressure was slowly lowered became known as the *Oscillometric Curve*. Dr. Leslie Geddes and others examined these tracings and noted that the maximum pulse wave occurred at the Mean Arterial Pressure (MAP) (Cardiovasc Res Cent Bull 1969 Jul-Sep;8:15-25). Further characterization of the oscillometric curve by Dr. Geddes, et.al, revealed the pulse height ratio to the MAP pulse height could, on average, determine the systolic and diastolic pressures (Annals of Biomedical Engineering 1982, volume 10, pp. 271–280). A ratio of 0.5 determined Psys, and a ratio of 0.8 determined Pdias. Further work determined that these ratios could vary from patient to patient. The pulse pressure (i.e., Psys minus Pdias) was shown to alter these ratios.



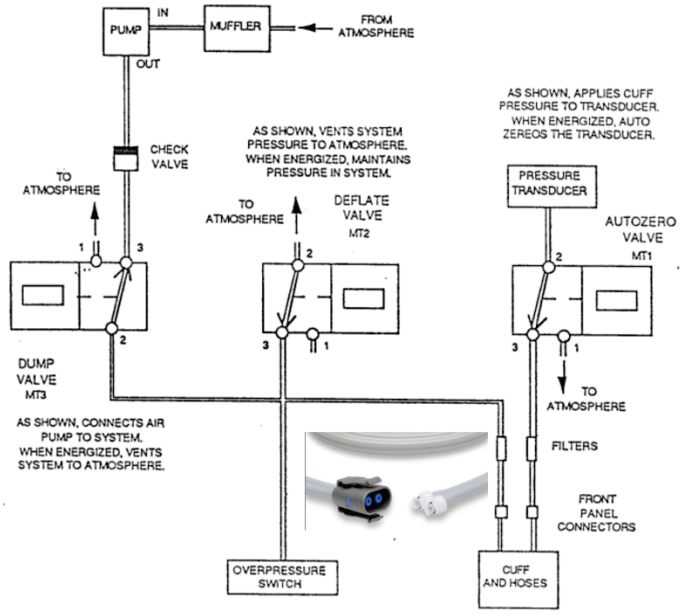
Generation of the Oscillometric Curve (Diagram by Meir Nitzan 2011)

Building on the work of Dr. Geddes and aided by the advance in integrated circuit microprocessors and solid-state memory (oscillometry requires memory for analysis), Dr. Maynard Ramsey III developed the DINAMAP® blood pressure monitor in 1976. The first instrument displayed the Mean Arterial Pressure (MAP) only. Later devices computed Psys and Pdias using the fixed ratios determined by Dr. Geddes. In addition, the pulse rate was computed and displayed. The DINAMAP soon became the standard computerized Non-Invasive Blood Pressure (NIBP) device. Dr. Ramsey also made a major improvement in air plethysmography by using two separate tubes between the instrument and the cuff. One tube was used for filling and deflating the cuff, while the other tube directly monitored the cuff pressure, unaffected by any pressure changes caused by air flow in the fill/deflate tube.

This early DINAMAP Instrument showed Mean Arterial Pressure (MAP) only.



The later DINAMAP 1846-SX showed Systolic, Mean, and Diastolic pressures as well as the pulse rate.

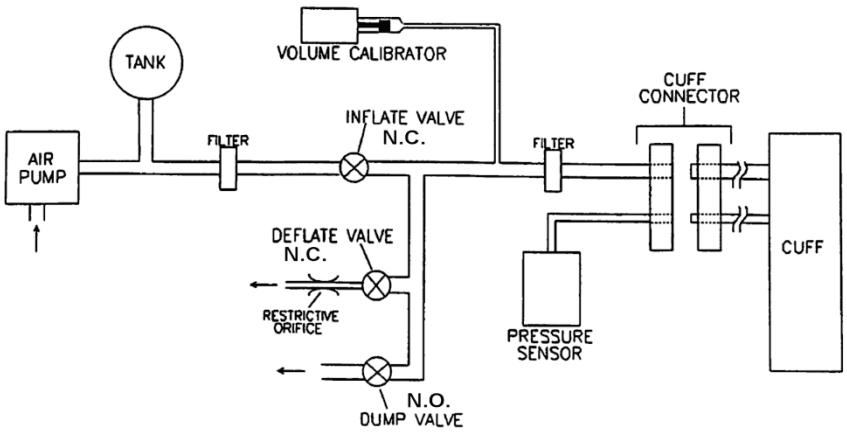


As I slowly acquired the knowledge of the various instruments shown above (there was no internet or Google in 1989), I realized the deficiencies of the PVR and MVL devices. I also realized that, with the advancing capabilities of microprocessors, a single instrument could be made that would, by running different software routines, perform both volume-calibrated pulse recordings using the method of Dr. Winsor, and non-invasive blood pressures using the oscillometric method of Dr. Geddes. I approached Dr. Manfred Asrican, president of Life Sciences, about phasing out the old PVR and developing a totally new, automatic device. He turned down the project, not wanting to "rock the boat" and admit to the PVR's deficiencies. I thus started to look for another company that would help with this project. By October 1989 I was working for Carolina Medical Electronics in King, NC, developing what would become the VascuMAP®.

The VascuMAP Project:
Carolina Medical Electronics (CME, later known as Carolina Medical, Inc.) was in a small, windowless industrial building that housed the instrument assembly area, a quality assurance room, service department, parts and shipping, sales office, staff conference room, president and VP offices, and a separate area for the engineering department. The facility was tight, but adequate. Money was also tight; the VascuMAP budget was bare bones – actually there was no budget. I would have to work with the staff and equipment on hand. CME had developed the first medical electromagnetic flow meters, but that market was being overtaken by transit-time flowmeters. The engineering department was hard at work completing an ultrasound imager for carotid artery examination. That huge device produced low-quality images and froze up frequently during exams. It was nicknamed "The Beast". Such a large engineering project was simply too much to undertake for a small firm like CME. The VascuMAP, being smaller, simpler, and more straightforward to design, would be a much more realistic project.

I was pretty good at analog engineering, but knew little about digital design. Luckily the other engineers could design the digital circuitry while I concentrated on the pneumatic design, the analog "front end" and the functioning of the device. Standard Baumanometer® blood pressure cuffs were specified because they had two tubes into the air bladder. Flexible and small dual-lumen tubing designed originally for dental instruments was chosen to separate the cuff pressure monitor line from the pressure variations in the fill-deflate line. Tests were done to assure that the tubing, which is analogous to an electronic transmission line, did not "ring". Such ringing, even if not audible, could introduce noise into the pressure sensing system and produce false readings, especially on the fast Volume Calibrator signal.

Perhaps the most important component of the pneumatic system, as far as the clinical operator is concerned, is the air connector for the cuffs. The Dinamap used separate screw connectors for the two tubes, making cuff changes clumsy and slow. Cuff changes would be frequent in a non-invasive vascular laboratory. A single, quick, dual-lumen connector would be necessary for the VascuMAP. After much searching, a semi-custom connector pair from Colder Products Co. fit the bill. It turned out to be a good choice – inexpensive, rugged, and bubble-tight while allowing quick, one-handed cuff changes.



VascuMAP Pneumatic Diagram

The pneumatic system was designed to be as simple as possible. The three electromagnetic valves are all the same type (Clippard EVO-3-12), which can be pneumatically configured as normally open (N.O.) or normally closed (N.C.). Note that the Dump valve which deflates the cuff rapidly is connected N.O. That means if the power fails, the Dump valve will open and deflate the cuff to prevent injury to the patient. All three valves are used in variable pulse width mode, a feature that allowed controlled filling and deflation of large thigh cuffs (18 cm wide) as well as small finger cuffs (2cm wide).

The Analog Design

The Honeywell 17PC05DF pressure sensor is a piezoresistive bridge linear from 0 to 5 PSI (0 ~ 300 mmHg) which, when scaled for a 16-bit analog-to-digital converter (ADC), is capable of resolving a 0.02 mmHg pressure change in about one millisecond, limited primarily by the 4 LSB noise level at the ADC output. The pneumatic line running from the cuff connector to the internal pressure sensor was made as short and low-volume as possible to increase the sensing bandwidth. Since there would be no net air flow in or out of the sensor, no filter was needed in that line. With such a pneumatic front end, no valves or separate signal paths for cuff pressure and pulse pressure were necessary. The low-noise sensor detects both the cuff pressure and the pulse wave simultaneously. After digitization it is up to software routines to separate them and produce the oscillometric curve for analysis.

A major problem occurred right at the start of the project. Available 16-bit ADCs were all power-hungry, large, and expensive modules. We forged ahead on our low budget, constructing a 16-bit ADC by using an inexpensive but fast 16-bit Digital-to-Analog (DAC) converter combined with a fast voltage comparator. Software would rapidly increase the DAC output voltage until the comparator flipped. The software count at that time was the ADC output; then the cycle repeated. We just got this scheme up and working when news of a novel 16-bit ADC chip was released – the AD7701, a low-power, small, and stable sigma-delta ADC from Analog Devices. The AD7701, however, could deliver only a 10-Hz bandwidth at the recommended clock speed of 5 MHz; we needed a 20-Hz bandwidth. To get that speed, we took a chance by running the chip at 10 MHz - luckily none of the samples blew up or glitched. They ran just fine! Later, talking to the chip manufacturer, we learned that the maximum clock speed of 5 MHz only applied in really cold or hot conditions. The AD7701 has proven to be a rugged and successful design. It is still in production over 30 years later and the original chips are still running in my VascuMAP prototypes.

AD7701

The output settling of the AD7701 in response to a step input change is shown in Figure 12. The Gaussian response has fast settling with no overshoot, and the worst-case settling time to ±0.0007% (±0.5 LSB) is 125 ms with a 4.096 MHz master clock frequency.

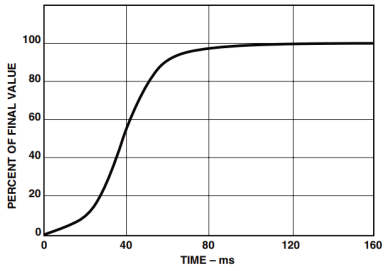


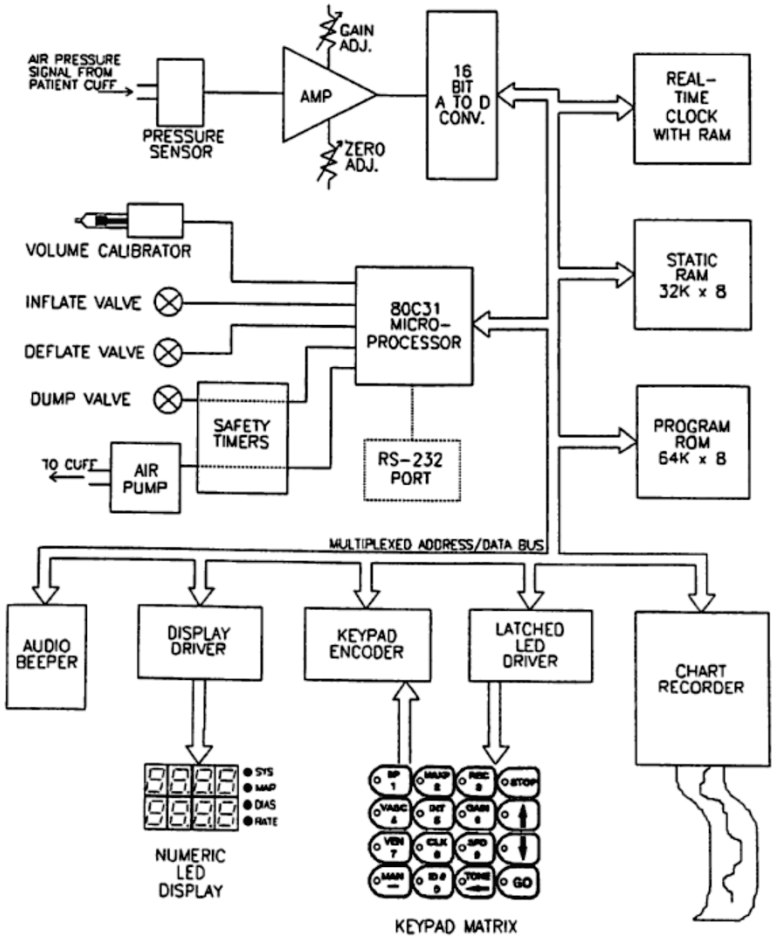
Figure 12. AD7701 Step Response

ADC settling time with a 10MHz clock is about 40ms.

Conditioning the low-voltage differential signal coming from the pressure sensor required amplification and manual offset adjustment in an instrument amplifier and manual gain adjustment and a 20-Hz low-pass filter via an additional op-amp. The filter prevented any ADC aliasing which might occur in the AD7701. The 16-bit digital output from the converter was broken into two 8-bit bytes for the microprocessor.

Though the analog front end and the AD7701 make up the most critical analog circuitry in the VascuMAP, the audio beeper driven by a dual analog R-C timer should also be discussed. The "beep" tone could have been generated directly in software, but this was found to be very difficult in a machine that was busy servicing frequent interrupts for other services such as the sampling clock and the chart recorder. Thus the addition of the venerable 556 dual-timer chip. Now the software only had to send a short zero pulse to trigger the *beep length* monostable timer section which turned on the *beep tone* astable timer section for a set time – the beep! The schematic diagram can be seen in the VascuMAP Maintenance Manual.

Another important analog chore is driving the three valves which required 50mA at 12Vdc to operate. An output from the microprocessor could only supply a few milliamps at 5V. Each valve would also generate a large "kickback" voltage when suddenly turned off. This surge is best shunted back across the coil terminals by a power diode. In the end a 10KΩ resistor, an MPSA13 NPN Darlington transistor, and a 1N4007 diode did the trick and has proven very rugged over the years.



VascuMAP Electronics Block Diagram

The Digital Design

To anchor the digital circuitry, an 8031 8-bit microprocessor was chosen because it was small, easy to program, and inexpensive. Unfortunately it was also power hungry, and would have required a fan to cool the unit. As this was to be a bedside instrument, fan noise was undesirable. The CMOS version of the processor, the 80C31, came out just in time. It would use much less power, a fan would not be needed, and it could run the same code and libraries as the popular 8031. With a 20MHz clock, a 64 Kbyte program ROM, and a 32 Kbyte "scratchpad" SRAM, computing power was limited but adequate for the device (though the project eventually used up ALL the ROM space).

Design of the Software Routines

At this point I must introduce the software engineer that made the VascuMAP work. Greg Reid was finishing his senior year in Computer Science at NC State and available for work on weekends. He brought with him the latest computing techniques including "fuzzy logic". During the week I would work on the hardware design. The first prototype was built on a large plugboard and was constantly changing, requiring a lot of erasures on the hand-drawn mylar schematic. On the weekend, Greg and I would put in two 8-hour days of development. Greg had set up a PROM emulator so he could make quick program upgrades directly from his computer. No slow programming of a ROM chip was necessary. Sometimes we could test and make changes right away, saving a lot of development time. The next week I would carefully test the prototype running the latest code, writing notes for necessary changes that Greg would make the next weekend. Greg, on his end, was developing professional-grade code, beginning with a startup routine, a main loop, and all the subroutines written as separate sections of the C-code. Here is a selection of the major algorithms we needed to develop.

The Cuff-Filling Algorithm

As the VascuMAP would have to quickly inflate and deflate a wide range of air cuff sizes, a robust but sensitive fill/deflate algorithm was required. The cuff pressure algorithm would attempt to hit a set "target pressure", but this is difficult to achieve when the actual cuff pressure is fluctuating with a pulse wave of several mmHg. In addition to this pulsatile "noise", significant thermal pressure settling occurs for 2 to 3 seconds after a cuff pressure change. As a gas is compressed, its temperature goes up instantly. When the compression is complete, this higher temperature begins to equilibrate with the surroundings, slowly dropping the gas pressure. The opposite effect occurs on cuff deflation to a lower target pressure; a rise in pressure occurs at the end of the deflation. Both the pulse waves and the thermal pressure settling would have to be addressed in the algorithm.

In addition, pressure changes caused by movement of the subject must be dealt with. Contracting a muscle located under a cuff will increase the cuff pressure. Stretching the muscle will decrease the pressure. Such muscle movement may suddenly cause the cuff pressure to be higher, or lower, than the target pressure. Thus the cuff-filling algorithm would have to be flexible enough to go from inflate to deflate quickly if necessary to adjust for muscle movement.

As there was no electronic, mechanical, or manual input to the VascuMAP to delineate which cuff was attached to the air connector, the instrument would have to determine the cuff filling characteristics by seeing how fast the pressure increased when the inflate valve was opened. The range of cuffs that needed to be accommodated was very large, the smallest finger cuff required ~5mL of air; the large thigh cuff required ~1000mL – a 200x difference. With only one inflate valve to work with, a special and untried fill-deflate algorithm would be necessary.

Though not supported by Clippard at that time, we decided to use pulse-width modulation to control the air input and cuff deflation valves. This would subject the valves to millions of open-close cycles. Could they take it? We had to try as this was our only viable cuff-filling solution. Fortunately the valves turned out to be much more rugged than the manufacturer stated. Perhaps encouraged by experience with the VascuMAP, Clippard has since revised the data sheet to state that the valves can cycle over one billion

times. The valves have run in my prototypes for almost 30 years without developing leaks or other problems.

It takes 5 to 10 milliseconds to open the air valve and another 10ms or so for the pressure change to reach the sensor. To accommodate this delay, we decided to pulse the valve open every 40 ms, increasing the pulse width slightly with every pulse until the desired rate of pressure change in the cuff was met. For the large cuffs, the inflate valve would ramp up the on-time until the valve stayed open, then close when the "target pressure" was reached. At this point thermal settling would begin.

Thermal settling in the VascuMAP was found to take about 3 seconds, fairly independent of the cuff selection and pressure change. Thus the algorithm "Topped Up" the pressure once per second thrice if the cuff pressure was over 0.5mmHg different from the target pressure. At that point the thermal settling would be small compared to a healthy pulse wave. When the cuff-filling procedure ends, the valve pulse timing parameters are retained in memory as it can be assumed that the attached cuff will not be changed during the test. Now the pulse detection and measurement algorithm can begin.

The Pulse Detection Algorithm

Detecting a pulse by palpating an artery is easy for a human, but how can an 80C31 microprocessor reliably detect when a cardiac pulse occurs in a timed string of incoming 16-bit numbers? It is here that Greg Reid's fuzzy logic training came to the rescue. First, only a rise in cuff pressure greater than the electronic noise level (>4LSB) would be examined by the algorithm. Then this detected rise was evaluated for magnitude (in mmHg), rise time from trough to peak (in ms), and time from the previous detected pulse (in ms). Using values taken from a clinically normal pulse wave as a comparative reference, these three measurements were each given a "weight". These weighting factors, which today could be determined by artificial intelligence, were estimated by the variability of each measurement and then tweaked to improve device performance. Pulse rise time was the most stable parameter so it got the greatest weight. The pulse amplitude was also fairly stable. Pulse timing was most variable. Using this algorithm, the little 80C31 was able to take these measurements off the stream of pressure numbers, weight them, add the results, and declare when a true pulse was detected well before the next pulse wave occurred.

The results of this fuzzy logic pulse detector were impressive. In a BP cuff on a normal and quiet individual it would reliably detect pulses close to 100% of the time. Slight movement or talking had no effect. Blood pressure tests on subjects with the irregular pulse of atrial fibrillation would take longer as the algorithm had to detect more pulses, which were then averaged to give a fairly accurate result. Even trying to confuse pulse detection by tapping on the cuff had little effect except to slow the pulse detection a bit. The only non-artifact condition that could totally confuse the machine was the tremor of Parkinson's disease. The VascuMAP would "think" that the rhythmic muscle contractions under the cuff were pulse waves. The true pulse waves were smaller in amplitude than the muscular contraction "noise" which drowned them out.

The Keypad Layout and Basic Routines

So now we had a device with a reliable cuff fill-deflate algorithm as well as an automatic pulse detector. What application programs should be incorporated into the VascuMAP? We decided on four basic routines: an arterial NIBP function with calibrated pulse tracings taken at the MAP point ("VASC" Test); a non-invasive blood pressure (NIBP) monitor (no pulse tracings); a Venous function optimized for very low cuff pressures (5-10 mmHg) and slow chart recording speeds to record venous volume changes; and a Manual function where the cuff target pressure, chart speed, and recorder gain could be selected by the operator.

In addition to selecting these four basic applications, additional controls for cuff pressure, interval between repeat tests, setting the clock, and entering an identification number were added. Entering an ID number means being able to enter numbers, other selections can be performed with up-down controls. A chart record toggle with gain and speed adjustments is necessary. And the beeper must have a mute control.

With our restricted budget, fancy controls and touch-screen displays were too expensive (this was 1990, remember). We would have to settle for a 4x4 lit pushbutton matrix, with no other controls except for the power switch on the rear panel and the air cuff connector.

A Production VascuMAP Keypad in action, 2023

With 16 push buttons and 16 LEDs to work with, the question was how to squeeze all the required functions and feedback into the control matrix. The front panel was in design and the labels had to be specified. How to proceed?

I had to think this design out fully. It would be wasted money if the printed circuits or front-panel artwork had to be re-done. So after work one summer's day I went over to a creek near where I lived. There was a small sandy island in the creek. I checked that was the only person around before lighting up my cannabis pipe. I took several good tokes and then paced around and around the island in a walking meditation, picturing the device functions, buttons, and lights in my head, no paperwork required. By sunset the front panel layout was complete and I had worn a big circular groove in the sand.

The LED incorporated into each button would be ON if the button was active (pressing it would do something), OFF if the button was inactive (pressing it would do nothing), and BLINKING if the button's

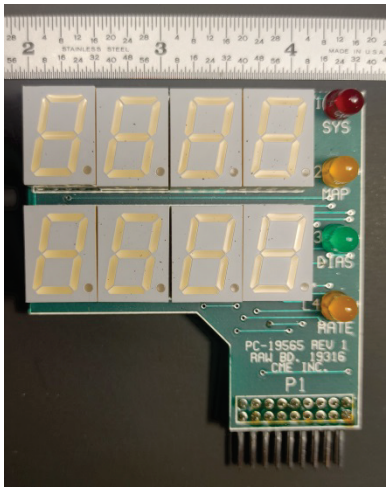
function was active (such as during a BP measurement). This scheme provided simple but effective feedback to the operator.

The keypad matrix was divided into four columns. The first (left hand) column chose one of the four routines to run. The second column added miscellaneous but necessary functions to the routine being performed. The third column provided chart recorder controls and toggled the "beep" function on or off. The fourth column controlled the basic function at hand: Stop and Go and Up and Down.

If a function such as entering a number in the Identification Number (ID#) was running, an "alternate" numeric keypad was enabled to enter, erase, or change the ID Number in memory. Accepting the entry by pressing GO returned the keypad to its regular function. Pressing STOP would return the keypad to its regular function without changing the original ID number.

The Numeric LED Display

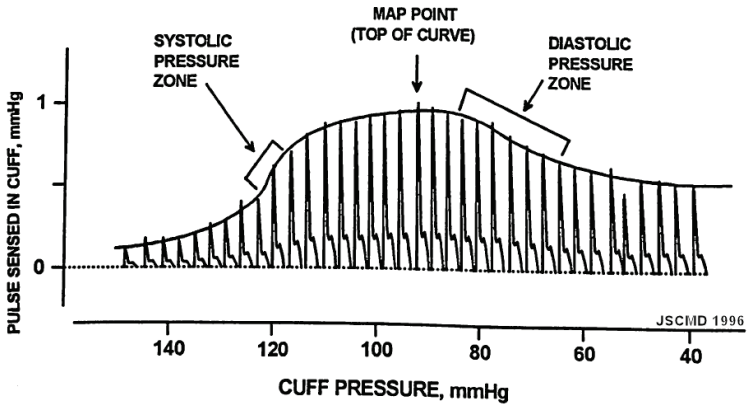
For the numeric and status display we used eight 7-segment (plus decimal point) red LEDs and four single LEDs to indicate what was being displayed – Psys (red) and Pdias (green) or Pmap and Pulse Rate (both yellow). The numeric LEDs were driven by an ICM7218D 8-Digit LED Display Driver chip selected to show digits 0 through 9 as well as E, H, L, P, Dash (-), and Blank (off). Limited to these characters, we decided to assign "E" to Error; "H" to High; "L" to Low; and "P" to Pulse. The Dash could be used in the patient ID entry (e.g. 123-456). If the VascuMAP was not sure of the numeric result, the display would flash the number in question. The ICM7218D chip turned out to be rugged and useful. It is still in production in 2024, though it is expensive, probably because it is a legacy chip and hard to replace.



The Numeric LED Display Board

Oscillometric Curve Generation

The VascuMAP is programmed to decrease the air cuff pressure in 10mmHg steps, thus the pulse pressure is sensed only at intervals, creating a discontinuous curve. In addition, each separate pulse is physiologically of different height, varying mainly with respiration and the beat-to-beat interval. Because of this incomplete pulse height data, filtering would be needed to reduce spurious results. First, we averaged the three or four valid pulses taken at each 10mmHg step. Then, taking these averaged pulse points, a Hann digital filter "smoothing" algorithm was performed to produce an oscillometric curve with only one maximum point (if possible). The mean, systolic, and diastolic pressures were then determined from this smoothed curve.



TYPICAL OSCILLOMETRIC CURVE

Determining the Systolic and Diastolic Pressures

As shown in earlier studies (see History section), a pulse height 50% of the MAP pulse amplitude has been used to determine Psys, and Pdias occurs at 80% of the MAP amplitude. Further work by Forster & Turney (1986) determined that these ratios could vary from patient to patient. The pulse pressure (i.e., Psys minus Pdias in mmHg) was shown to alter these ratios, especially for the Psys determination. We decided to include this pulse pressure in determining the Psys ratio.

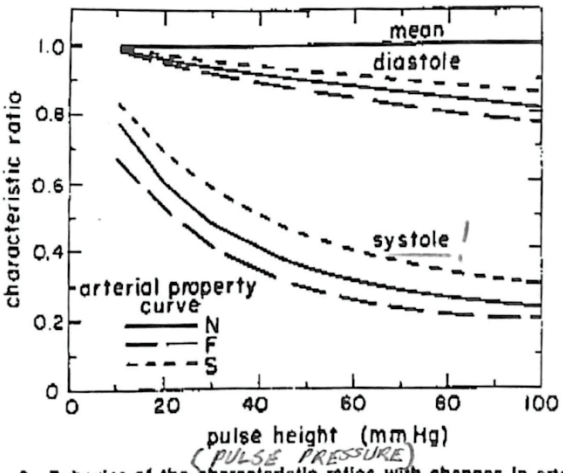


Fig. 8 Behavior of the characteristic ratios with changes in arterial pulse height and arterial compliance. $P_{ad} = 75$ mmHg, and SF = 0.42.

From: Forster FK & Turney D, J Biomech Eng, 1986, PMID: 3795883

This correction algorithm has to be an iterative procedure. Using the filtered oscillometric curve, the Pulse Pressure (PP) was calculated using the legacy 0.5/0.8 ratios (PP1), this PP was used to correct the Psys ratio (PP2). Now a third PP was calculated and the Psys ratio recalculated (PP3). We could have repeated this correction, but PP3 seemed to give good results, and we were concerned that too many iterations might cause measurement instability in certain conditions.

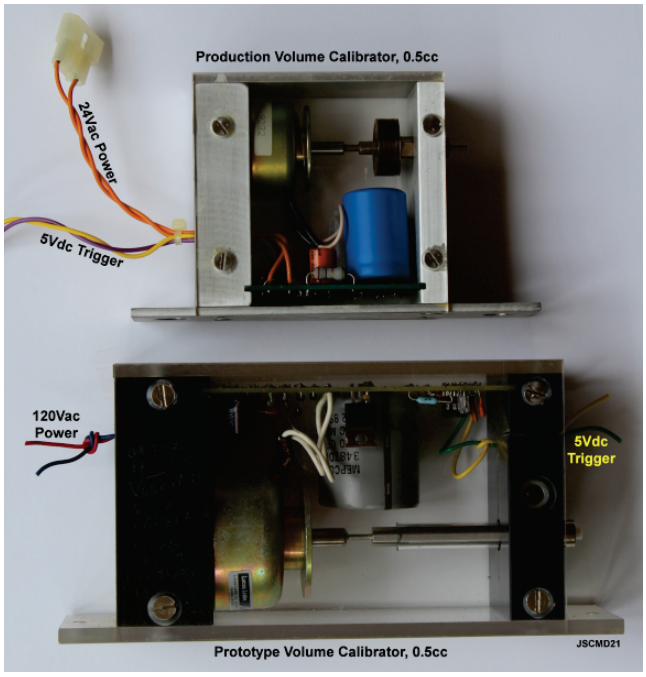
Testing of the VascuMAP on brachial cuff blood pressures was performed on over 100 sitting volunteer subjects ages 10 to 80. After checking manually for equal and simultaneous pulses in the wrists, similar air cuffs were place on both upper arms. The VascuMAP was placed out of view of the operator. While the instrument was running its BP routine on one arm, the operator took the pulse and determined the BP in the other arm using the standard Korotkoff method. The results of the study showed the VascuMAP to meet the ANSI/AAMI SP-10 Standard for Automated Sphygmomanometers (NIBP machines). The US FDA subsequently approved the VascuMAP application, granting 510(k) number K914200 in November 1991, two years after the project began.

The Volume Calibration Device and Algorithm

The Volume Calibrator was not part of the original design, but without it we only had what was known in the trade as a volume-uncalibrated "squiggle machine". With the basic VascuMAP instrument fully functional, we decided to add volume calibration for a complete vascular diagnostic unit. Dr. Winsor had used a bellows device to decrease the amount of air in the cuff system by 1.0 cc, observing the rise in the height of the pulse waves to determine the volume calibration of the tracing. As this method required waiting about a second (the pulse interval) to determine the chart height change, the results could be affected by significant thermal settling, i.e., the volume result would be quasi-isothermal (neither adiabatic nor fully isothermal). As such, these volume results would be dependent on the pulse rate, the pulse-to-pulse volume difference, and the ambient temperature. We decided instead to develop an *adiabatic* volume measurement system to avoid these inaccuracies. A sudden expansion or contraction of a gas is very nearly adiabatic.

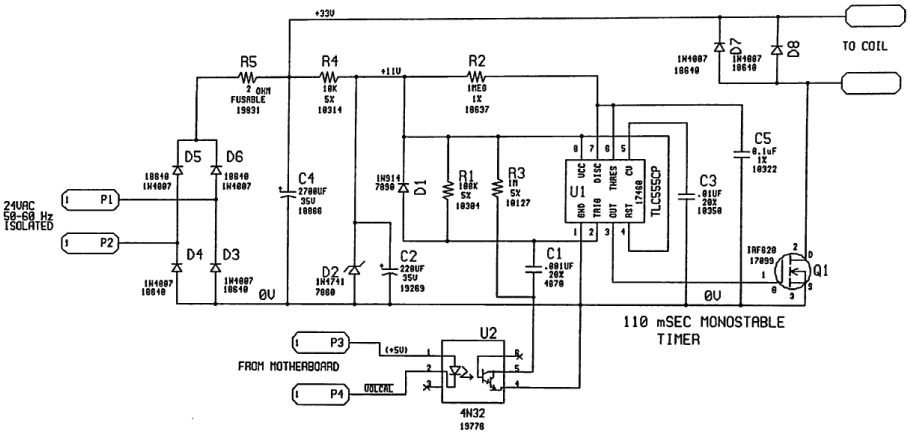
The original plan for the volume calibrator called for a strong solenoid to rapidly pull back on a precision syringe plunger, drawing 0.50cc of air *out* of the air cuff system. We obtained calibrated syringes from Hamilton Corp. to assure accurate volume changes. By drawing air out almost instantaneously, creating a high vacuum in the syringe, the maximum pressure difference created would be the cuff pressure (0 – 300 mmHg) plus the atmospheric pressure (~760 mmHg), or about 1060 mmHg (25psi), Maximum. This avoided the very high pressures that could cause damage if the solenoid pushed the syringe plunger down.

Unfortunately, the syringes proved too delicate for the sudden, powerful solenoid pull on the plunger, and, though they did produce enough data to show that the method worked for all our cuffs and cuff tubing lengths, they would not be reliable enough for a production VascuMAP. Taking a cue from Dr. Winsor, we decided to use a small metal bellows instead of a syringe mechanism. Robertshaw Corporation in Cookeville TN designed and made us small semi-custom bellows assemblies. Initially we specified that the bellows should be fully compressed (flat), with the solenoid pulling back suddenly to create the vacuum within the bellows. These units failed quickly, however, developing leaks after several hundred actuations. Robertshaw engineers advised that we revise the solenoid system so that the re-designed bellows was always in compression, even with the solenoid energized. That fix worked well, and bellows failures became a thing of the past.



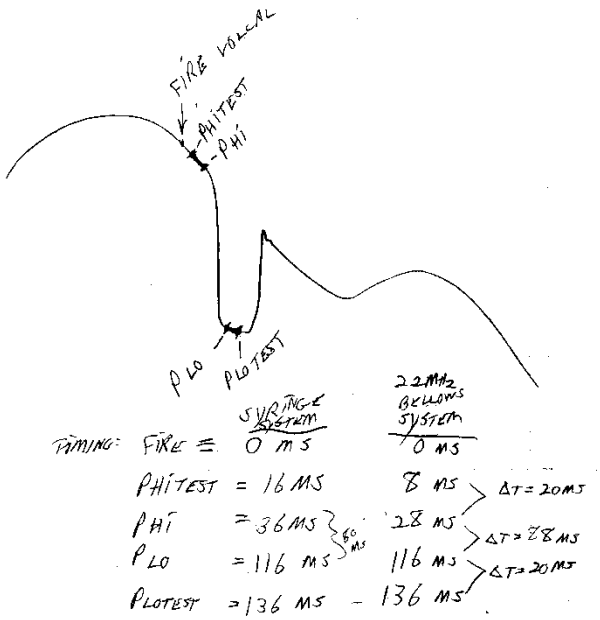
An unforeseen problem arose when it was discovered that the sudden volume (and pressure) change in the pneumatic system caused a “ring-down” effect. This ringing could cause errors in volume calibration and had to be eliminated. Since the ‘snap” of the solenoid could not be slowed down to prevent this ringing, a restrictive orifice in a threaded/barbed connector was used to connect the volume calibrator to the rest of the pneumatic system. The orifice size was determined experimentally by observing the VOLCAL pulses for the most rapid pressure response that did not ring. A 0.017-inch orifice did the trick.

To make it easier for the microprocessor when performing volume calibration, the software only had to trigger the Volume Calibrator electronics with a brief negative pulse to the VOLCAL line. This would then energize the solenoid for a fixed time. There would be no need for software to time the solenoid ON pulse; the return stroke of the solenoid was not used in the algorithm, so its timing was not critical. The 24Vac power for the VascuMAP was bridge-rectified to charge a large capacitor to 33Vdc. When the 555 timer was triggered via a 4N32 photo-Darlington isolator, the charge stored on the capacitor would power the solenoid for 110 milliseconds, pulling 0.5cc out of the air cuff system almost instantaneously – fast enough to be considered thermally adiabatic. After the calibration pulse, the capacitor would recharge through R5, a 2-Ohm fusible resistor. This safety resistor was needed to protect the solenoid coil from burnout should the solenoid stay energized for a long period. During software testing we burned out several of these resistors when rapidly repeating pulses occurred on the VOLCAL line, retriggering the 555 timer and holding the solenoid ON too long. No further failures occurred after the software was improved.



VascuMAP Volume Calibrator Electronic Schematic for 24Vac Power

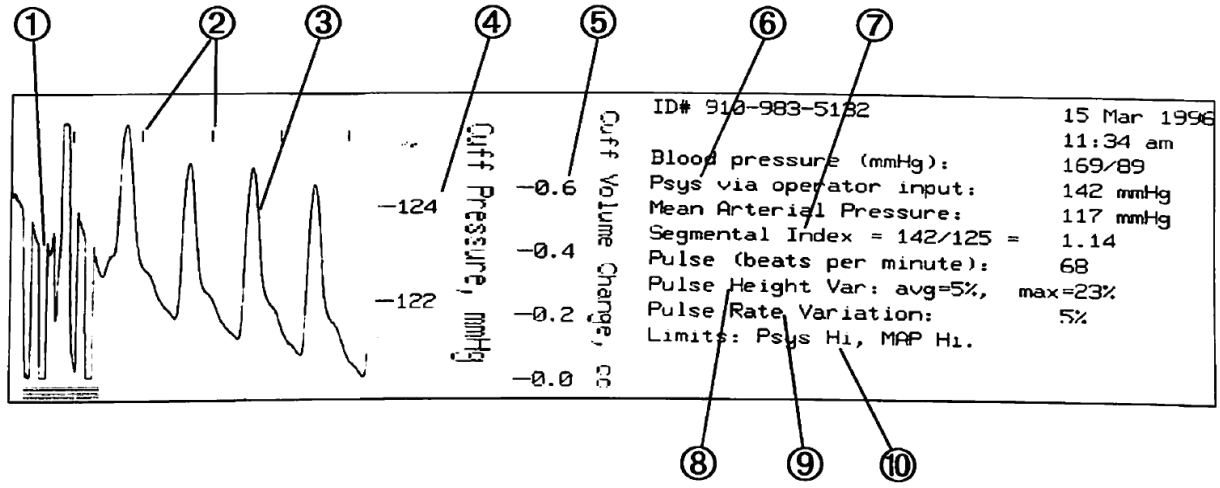
So now we had a device that would rapidly yet smoothly suck 0.5 cc of air out of the pneumatic system. How would software be able to detect this volume change and use it to draw a volume scale next to the pulse wave tracing? Complicating matters, this 0.5cc change could be swamped by the patient's arterial pulse wave, which could be a 2 or 3cc volume change. As there was no practical way to time the VOLCAL pulse to occur between the arterial pulses, an algorithm was devised to detect and correct for the slope of the pulse wave at the time of the VOLCAL pulse.



Timing Points for Determining Adiabatic Volume Change on a Noisy Background
(Drawing from lab notebook of JSCMD)

Since software fired the volume calibrator, the start of the VOLCAL air pulse could be established by taking the fairly stable tubing and A/D-converter delays into account. Pressure measurements could then be taken 20ms apart before the negative pressure pulse began. 88ms later, at the bottom of the air pulse, two more pressure measurements were taken 20 ms apart. The pressure "slope" of the first pair of readings (Phitest minus Phi) could then be compared to the slope of the second pair of readings (Plo minus Plotest). If these two slopes did not match closely, the reading was discarded. If they did match, it meant that the arterial pulse wave did not change much during the VOLCAL pulse and the "raw" volume data (Phi minus Plo) could be corrected for the background slope (see diagram). This corrected measurement was found to be quite accurate. To be sure of the result, a minimum of three valid VOLCAL pulses were obtained and averaged. The VascuMAP could fire the VOLCAL up to 16 times in rapid succession to try to get the three valid results. If three valid pulses were still not obtained, the 16 results were averaged and displayed with a warning message that the pulse volume may be in error. This averaged result turned out to be quite accurate, even when 16 pulses had to be averaged. The algorithm also provided the VascuMAP operator with audible feedback on the magnitude of the pulse waves in the air cuff. Three VOLCAL "snaps" meant that the pulse wave was of low volume, sixteen snaps meant a robust pulse wave under the cuff.

Printing Pressure *and* Volume Calibrated Pulse Waves



1. The Volume Calibrator 0.5 cc pulses
2. Time marks (in seconds)
3. Pulse Waveform
4. Cuff Pressure scale in mmHg
5. Cuff Volume Change in cc. Derived from the VOLCAL pulses (1)
6. The pressure in mmHg of the last recorded pulse peak is recorded as Psys when the operator detects the systolic pulse return and presses the TONE button.
7. The Segmental Index is computed if the higher brachial Psys is entered at the **SEG**- prompt.
8. The Pulse Height Variation average and maximum provide information on test reliability.
9. The Pulse Rate Variation percent (now called Heart Rate Variability) detects atrial fibrillation and skipped heartbeats.
10. If limits have been set previously, this line will flag any high or low outside of these limits.

After a VASC Test run, the AR-42 chart recorder had to display a lot of varied information in a compact form. Displaying the pulse waveform and VOLCAL pulses, along with the two scales (pressure and volume) and all the other data in text format was a challenge. Greg wrestled with the obtuse programming instructions for the recorder, finally succeeding in coming up with the display format shown above.

To display the pulse wave with the most accuracy, we decided to print the waves so that the greatest pressure encountered would be at the top of the display space, and the least pressure (including the negative VOLCAL pulses, would be at the bottom. To determine the cuff pressure change that this represented, the operator could look at the adjacent Cuff Pressure scale. This “automatic gain” function turned out to be a sales anathema, however, as the old PVR instrument was calibrated in “mm of chart height” of the pulses, and vascular lab personnel had been trained with this in mind. To look at a pressure or volume scale was confusing to them. Instead of learning a new and improved pulse display, they rejected the VascuMAP and kept their old, uncalibrated systems. You can lead people to knowledge, but you cannot make them think.

So the VascuMAP was never a sales success. Perhaps 20 units were produced before the project was shelved by the new owner of Carolina Medical. Having no experience with medical devices, he was intent on developing a "desktop" ultrasound imager, an undertaking that was too big and complicated for a small company. We simply could not compete with companies such as Phillips or General Electric, which were developing state-of –the-art imagers with their engineering departments that were bigger than all of Carolina Medical. When I told him my concerns about getting into such a project, he retaliated by shelving the entire VascuMAP project. I resigned several months later and went back into the practice of general medicine, taking three VascuMAP devices with me in lieu of my salary, which the company could no longer afford to pay me. Carolina Medical dissolved as a corporation several years later. Because I was the main designer and manual writer for the VascuMAP project, I feel that any copyrights have reverted back to me. I thus am publishing the operator's manual, maintenance manual, and other pertinent materials about the project so that others can use them to perhaps develop improved designs in the future.

Future Improvements to the VascuMAP

Of course, no complicated biomedical design is every really finished. There are always improvements or changes to be made as time progresses. Here are a few suggestions for design improvement of any future VascuMAP:

1. The "VASC" test button was poorly named. It starts a routine that examines the volumes and pressures in the *arteries*. Renaming the button "ART" for *arterial testing* is a good choice.
2. One of the major problems that arose as the VascuMAP design got older was the battery failure of the Dallas DS1287 real-time clock chip after about 10 years. Unfortunately, the DS1287 went obsolete during that time, and no replacement or alternative clock chips are available. In a future design it is advised that any clock battery must be easily replaceable. Silver Oxide coin batteries are best in that they do no corrode and ruin any nearby circuitry.
3. Add a pneumatic foot switch for "Psys by Operator Input". It is difficult for an operator to press a button while simultaneously holding a Doppler probe to detect systolic flow return. A foot switch wired in parallel with the REC Button would be very useful. Using a pneumatically-operated switch eliminates any electrical hazards that might occur with a wired switch.
4. Integrate a 5Mz directional Doppler into any new design of the VascuMAP. We were working on a NIST-qualified Doppler named VascuDOP when the VascuMAP project was shelved. Besides using the Doppler to detect Psys, it could also display and print the arterial flow waveform on the VascuMAP output.
5. Upgrade the numeric display and Graphical User Interface (GUI) to graphic touchscreen and tracing displays. Much of the control and display chores could be offloaded to a personal computer or even a smartphone via a wired or wireless USB connection.
6. Make the device portable with a rechargeable battery. This would require an efficient DC air pump and valves.