701 COWARD'S CREEK ROAD
FRIENDSWOOD, TEXAS 77546

24 June 1977

Dear Bruce

Please read all of this, even the parts you have always ignored.

First the B.P. recorder. I have enough information to make some definite statements. Before that let's understand what I am trying to do at UTMB and things I can & can't do. First UTMB is a clinically oriented place, typical of the conservatives you sell to. Dr. John Wallace who I am working c is a professor of Med. in Cardiology. He spent a year c Lasagh in N.Y. probably the leading hypertension man in the U.S.. Wallace is established, aggressive and above all ethical - not a hot shot on the make. He publishes a good bit but c a reason more important than polishing his reputation He is re building a hypertension clinic which I am spending the day a week in and also a research effort which I will be even more active in.

For the B.P. recorder, we will first of all document what it will and won't do. I assume you will correct its basic defects of which there is at least one. After reaching a point that is

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(hopefully next week)

not embarrassing to the instrument, we will start a series to compare in a clinical fashion the present B.P. office visites, to one or more prolonged recordings on sufficient patients to provide a publication. You will of course receive the data as soon as gathered. After this initial break-in period I hope to get almost a record a day. This is your most basic need + application

After that ~~then~~ or concurrently with it I plan to integrate these BP results with other investigations (to be described). Also, you need time other preliminary basic studies on ~~[illegible]~~ 1) monitoring the effects of therapy + 2) monitoring suspected or at risk normals.

Bruce, this is and must be a part of a continuing effort and can't be a hit + run operation. The cost of this indirect BP program will be relatively small; supplies, running the records, etc. This is not a 'Mac special' sales paper effort. It will give you 1) the evaluation you need ~~not~~ from someone who understands the system 2) will provide sales info, new and the paper which takes time 3) a series of improvements & other devices to enhance the use of this. If you omission a quick squeeze for a few drops to suit your present fancy let me know now, for I must present it on a true basis for obvious reasons.

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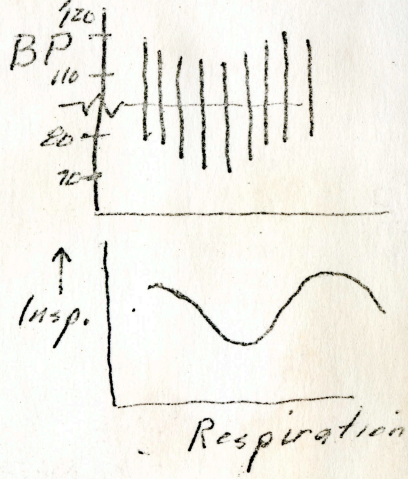
Now lets look briefly at what I know about the instrument:

1. It is a fine beginning - the pumping & control & pressure readout are all a big jump ahead
2. It appears to work (on the small sample seen) in hypertensives but <u>will not work on normals at rest</u> - sensing mechanism at fault
3. Its logic has faults some of which you have seen, most of which can probably be designed out (next model) - one fault not mentioned is that everyone has respiratory pseudop - a change of blood pressure c respiration - a beat of two will be heard at a higher pressure (one subject was 12 mm. or greater) & the potential for <u>apparent</u> error c instantaneous random ~~error~~ measurement is obvious.



4. It must be connected or (this is usually small) correlated c other objective indicators of the patients state to allow meaningful data to be collected - Criteria for hypertension is c the pt. <u>seated</u> - You will collect a mass of normals as hypertensives if you record c them standing, active etc. ~~This must be the~~ ~~way the microphone would trigger for you they~~ ~~are as~~ were active not resting.

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5. It currently is complicated by 4 bits & pieces & procedures which need a good systems analyses and design review.

I have enclosed ~~separately~~ to you (Cliff requested all verification data available which is enclosed) (#7 left) some detailed data & comments. According to Ray I will have the 2° unit here with a modified filter/trigger ckt in approx. a wk. & the presumably present unit will be returned. I would urge you to proceed slowly & elaborate production design and not to use a single fixed circuit board but rather use sub circuits on input, trigger & timing for the sensor/trigger will never be perfect & undoubtably want changes. ~~I~~ Logic can be greatly improved but this will be saved 'til July. There will be a need for a stand alone device which could have a small solid state memory and simple readout platter which will sell to many people who don't need the whole set up.

Because of your interests I became involved in this project ~~and~~ (BP research & development) and find that it is at an even more primitive state than electro-cardiology in the 50's - I can & will stay with this now and make contributions.

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While B.P. is the most significant or obvious element it is only one part of the effort. We can do each other a lot of good here. While I will do everything possible that is ethical to help your commercial efforts there has to be more to it than just getting a new device out by dept.

Talking first about the machine I have efforts to get data as soon as possible. If we get a quick fix on it, we should have 20-30 pts. run in 60-75 days from now and a decent report but this is the start of a program for us at UTMB for a good bit of effort will have been built around this. We can't build on hit and run nor should you choose your collaborators on such a basis - in short I need some sort of a commitment for a B.P. recorder for an indefinite period with readouts provided. no peoples salaries, etc. just the gear + supplies + maintenance support - M. S.