BIOCONTROL TECHNOLOGY INC. **INTEROFFICE MEMORANDUM**

DATE: 06 Feb 97

TO: Dave Purdy

FROM: Rich Wiggins

RE: Review of meeting on research projects

CC: Dave McMurry, John Maliszewski

The core projects in research are those reported on in my 08 Jan 97 "Status of Research Memo." In addition the following projects were discussed and action items were created as noted.

#	Project	Action Item
1	Littrow Spectrograph	Research will finish testing 2/14/97, create a comparative test report and supply design to Engineering.
2	Holographic Spectrograph	Research will finish testing 3/14/97, create a comparative test report and supply design to Engineering.
3	Multiplexing	Engineering project. No Research action.
4	Tuning for chopper.	Engineering will assist Research as needed. No date set.
5	Ge Detector	Project Management project. No Research action.
6	Differential Probe	Project Management project. Research might run skin tests after project is completed.
7	IR Source	Might form team Rapach+Wiggins. Wiggins will investigate what information is available by 2/14/97.
8	Delta-Reverse	Engineering project. No Research action.
9	Ultrasonic skin disruption	Research will conduct literature search. Project Management will find ultrasonics consultant.
10	Improved algorithm	Research is not involved in algorithm development. No action.
11	Improved homogenizer	Research will obtain parts, construct, test, prepare report by 3/21/97.

BIOCONTROL TECHNOLOGY, INC.

Interoffice Memorandum

DATE: February 25, 1996

TO: Rich Wiggins

FROM: Mark DiFrancesco

RE: The future of the non-invasive glucose sensor

We are blindly racing down the path to failure. None of our tests with the Beta-2 have measured glucose non-invasively. There is no reason to expect that the D-1000 will measure glucose.

Optimistic information and misinformation has been propagated to promote the future of Biocontrol. However, this misinformation has also been used for planning and development. In particular, spurious calibration results have been propagated to promote optimism. These are then used to estimate future performance. Therefore all estimates of future performance are spurious.

Furthermore, a large investment in infrastructure (manufacturing capability, inventory, networking, the D-1000 box etc.) has been made both for appearance and on the basis of the spurious calibration results. Because the employees at Biocontrol have been told that these infrastructure activities are the highest priorities, work on actually measuring glucose has gone from sluggish to stopped.

These challenges can be overcome only if they are faced. A list of the standard misconceptions are shown below.

1. We must be measuring glucose because the error grid analysis shows good results.

   No. When we restrict our prediction range to our calibration range we eliminate most of the error grid forbidden zone. Random chance will typically assign 90% of the results to the A and B zones and 70% to the A zone.

   No. All of our analysis is retrospective. We change the rules until the prediction sets pass. A clear indication of this is our rejection of the same percentages at calibration, follow-up, and evaluation. We manipulate our data rejection criteria until prediction works.

2. Maybe we cannot predict, but our calibrations prove that we are measuring.

   No. We fail all of the standard tests for calibration.

   No. We have calibrated equally well on scrambled data.

3. We have successfully measured glucose-in-water on the Beta-2, we should be able to measure glucose in skin.

   No. Our glucose-in-water measurements at best have ±25 [mg/dl] error under ideal conditions. However, glucose-in-skin has a concentration 5 times lower than glucose

   in water. Our best case error corresponds to a ±125 [mg/dl] error in a human measurement.

   No. Model simulations are consistent with these results.

4. The D-1000 is significantly more stable than the Beta 2G. The improved stability will allow us to measure.

   No. Identical stability tests on the Beta-2 and the D-1000 give identical results.

   No. Instrumental stability is small compared to skin noise. Total skin noise is 20 [mAU]. Drift removal reduces this to 2 [mAU]. Clustering reduces this to 200 [uAU]. Random instrumental noise is only 20 [uAU].

5. We can improved the D-1000 results by removing baseline drift.

   No. Removing baseline drift makes no improvement in the noise of individual channels beyond 5 seconds. This is intrinsic to the 0.2 [Hz] 1/f knee in the noise.

6. The D-1000 will reference faster so we will have less drift.

   No.. The reference rate is limited by the time required to sample skin. The time required to sample skin is determined by transients that are the same in the two instruments.

7. Because the D-1000 will be able to do more skin measurements we will be able to average more.

   No. The rate limit on Beta-2 measurements is not connected to the dither mechanism or the data processing speed. Rather that rate was set by delays that are needed to eliminate transient effects in both the skin and the instrument. All of these transients remain the same in the D-1000.

   No. Even in the Beta-2 the dithering is not giving a representative sample of daily skin variation. Tests show that the D-1000 is even worse.

8. The FTIR experiments showed that with small improvements our instrument will be sensitive enough to measure glucose.

   No. The calibration on the FTIR skin data predicted the mean only. There was no actual calibration.

9. Improvements in the calibration method can extract meaningful results from our data. We see real improvements by orthogonalizaiton, by extrapolating drift, and by using single beam data.

   No. Theory and experiment (glucose in water) agree in showing that our measurement performance is not good enough to measure glucose. No post treatment can improve this bad data.

   No. The single beam calibrations seem to improve because they retain more drift. That makes spurious time-based calibration easier.

   No. Drift follows a 1/f characteristic that cannot be extrapolated.

   No. Orthogonalization only offers improvement once a calibration has been achieved.

R. Wiggins 15 Apr 97

Research Project Status Update

(Most priority 1 projects have been completed. Focus shifted to priorty 2 projects.)

Research Projects from Improved D-1000 Project Listing

#	Project	Priority	Status
1	Littrow Spectrograph	Elder **complete**	Awaiting spectrograph team feedback, holographic results.
2	Holographic Spectrograph	Elder-1 **complete**	Awaiting spectrograph team feedback, holographic results.
4	Tuning fork chopper	Wiggins-7	Awaiting instrument team feedback.
6	Differential Probe Skin Testing	Wiggins-8 Elder-3	As probe engineering is likely to continue into 4Q97 research skin tests will not occur this year. Project suspended.
7	IR Source	Wiggins-6	Awaiting probe team feedback.
9	Ultrasound research	DiFrancesco 3	Literature search complete. Order of papers halted by purchase freeze. Project on hold.
11	Improved homogenizer	Wiggins-5	Research awaiting parts, input from spectrograph team Time shortage. Project delayed +6 weeks beyond 21 Mar 97.

Fundamental Research Projects

#	Project	Priority	
1	Short wavelength range D-1000 tests	Wiggins-2 Elder-2	Awaiting D-1000U; anticipated < 30 Apr 97. Characterized 30 May 97. Converted 30 Jun 97. Optimized 15 Aug 97. Clinical complete 15 Sep 97. Data analyzed 30 Nov 97. Elder loss may create delay.
2a	System characterization Signal to Noise	DiFrancesco 1a **complete**	Study of S/N in measurement complete. Report published.

2b	System characterization Figure-of-merit	DiFrancesco 1b	Analytical determination stalled because of lack of information. Synthetic estimate begun. Dec 97
2c	System characterization Calibration Anomalies	DiFrancesco 1c **complete**	Research finished. Writeup in progress.
2d	System characterization Detectivity	DiFrancesco 1d	Estimation and simulation of glucose absorption detectivity. 13 May 97.
2e	System characterization Glucose volume	DiFrancesco 1e	Estimation and simulation of glucose volume from observations on diabetics. 13 Jul 97.
2f	System characterization Spectro-photometer behavior	Wiggins-1 **complete**	Observation of spectrophotometer interaction with calibration process. +30 May 97. Derive non-clinical method for spectrophotometer evaluation. 30 Jun 97.
2g	System characterization Obtain parametric data	Wiggins-3 Elder-3 DiFrancesco 2	Skin measurements with 6500. +5 Jul 97. Other TBD. May be delayed by Dave Elder's leaving
3	Spectro-photmeter error budget	Wiggins-4 Elder-4	Derive spectrophotometer error propagation and create error budget. +Dec 97.
4	Consolidation of know data	Wiggins-9	On-hold because of freeze on paper ordering. Glucose papers ~150. Biolgical papers ~50.
5	Alternative technology tracking	Wiggins-10 DiFrancesco 4	On-hold because of freeze on paper ordering.

Cratta has Bio effects paper
Glucose [illegible] [illegible] [illegible]

BIOCONTROL TECHNOLOGY INC.

INTEROFFICE MEMORANDUM

DATE: 30 April 97

TO: Dave Purdy

FROM: Rich Wiggins

RE: D-1000 spin-offs

Dave:

A certain way to start generating income from the glucose sensor development in the next three months would be to sell versions of sub-components into the scientific instrument market. Many of these would require packaging only. While the potential income is small compared to the glucose sensor potential, these products could be used to take up excess production capacity and inventory.

I include a table of possibilities below.

As you know, I am considering setting up my own scientific instrument business, and I would be interested in selling choppers, fiber-bundles, and homogenizers for BICO if there was any interest in this idea.

Component	Unit price $	Sales $/yr	Comment
Chopper	$1000	$50,000	Would require development of control, package.
Fiber bundles	$200	$20,000	Would require a few standard lengths and fittings.
Homogenizer	$500	$50000	Would probably be OEM, lower profit.
NIR Spectrophotometer	$30,000	$1,500,000	This would be a downgraded version of the glucose sensor with a non-fiber probe. Would require packaging.
Littrow spectrograph	$1000	$500,000	Would require repackaging to fit standard silicon array detectors.
IR array detectors systems	$10,000	$150,000	Would require packaging, software. Could be Beta-2D electronics.

Rich

BIOCONTROL TECHNOLOGY, INC.

MEMORANDUM

TO: Dave
FROM: Rich
DATE: 14 Gun 95
RE: Advanced Concepts Glucose Sensor

Dave,

I am considering initiating a design project that would combine many of the exotic R&D research efforts with some advanced engineering refinements into an Advanced Concepts Glucose Sensor that could easily be transferred to engineering and production. Much of the component and systems research that we have been doing is reaching the point at which design specifications are resulting. It is probably time to begin research on advanced components and systems.

There is a good possibility that the Advanced Concepts Glucose Sensor would not function properly. However, part of the function of R&D is to test radical changes far in advance of engineering application. In addition, there is reasonable expectation that the system would function. Even in the event of failure, several cost / performance advances should result.

Development of this advanced concepts spectrometer would be concurrent with the current experimentation on its sub-systems. (I assume that all subsystems would work.) The advanced concept glucose sensor would combine the following.

Item	Quantity cost
Bulb with integral molded plastic reflector	10
Brushless chopper	75
Molded light-pipe illuminator/probe/collection optics	20
Concave corrected holographic grating f/1 spectrometer	120
On chip lock-in / multiplexer 128 element PbS detector (assembled at BICO)	400
Probe self-referencing at 4 Hz	0
Single microcontroller electronics	100
3" x 8.5" x 11" case with carbon composite base	75
Total parts cost	800

Estimated assembly and test time for a unit would be 3 hours.

Much of the development would involve negotiating the design and purchase of special parts. I estimate the development man-hours as shown on the table on the next page;

Item	Time [man-months]
Bulb with integral molded plastic reflector	1
Brushless chopper	4
Molded light-pipe illuminator/probe/collection optics	4
Concave corrected holographic grating f/1 spectrometer	3
On chip lock-in / multiplexer 128 element PbS detector (assembled at BICO)	12
Probe self-referencing at 4 Hz	3
Single microcontroller electronics	3
3" x 8.5" x 11" case with carbon composite base	6

The calendar time would depend upon the number of people who can be found to work on the project, and upon the availability of the many custom parts that would be needed for the project. Ideally, I would want to hire two to three more low-level optical engineers and one to two additional electrical engineers to work on this project. In addition, I would suspend work on the Delta-1 for six months and use Ralf, Kathy, and Mike on the project during those six months. Finally, there are several critical design numbers that will not be computed for 4 to 6 weeks, and I would not commence the project until they are available.

This project would use many custom components and development expenses would be large. These expenses are difficult to estimate without obtaining quotations. My best guess is below.

Item	Development cost (k$)
Bulb with integral molded plastic reflector	3
Brushless chopper	2
Molded light-pipe illuminator/probe/collection optics	25
Concave corrected holographic grating f/1 spectrometer	8
On chip lock-in / multiplexer 128 element PbS detector (assembled at BICO)	25
Probe self-referencing at 4 Hz	0
Single microcontroller electronics	3
3" x 8.5" x 11" case with carbon composite base	15
Total capital cost	81,000

The advanced concepts glucose sensor would be designed to measure glucose in a single 30 second measurement without dithering. If dithering was necessary it would be achieved by having the patient slide their arm across a slippery probe surface. The currently observed biological variation would be eliminated by the self-referencing probe.

Although this instrument would work with an individual calibration, I believe that the instrument would work better (10 mg/dl) with a universal calibration. However, developing a calibration transfer method would be much more ambitious than the project described here.

What do you think?

BIOCONTROL TECHNOLOGY INC. **INTEROFFICE MEMORANDUM**

DATE: 26 Jun 96

TO: Mark DiFrancesco, Gary Fletcher, Dave Purdy

FROM: Rich Wiggins

RE: Skin Noise on the Differential Probe

Abstract

One of the two objectives behind the differential probe project was reducing skin contact noise. Recent experiments with the standard probe have suggested that contact noise is not significant; the significant noise originates in water change in the stratum corneum. The measured behavior of the differential probe is in agreement with this model. No decrease in skin noise is observed with the differential probe. ***In fact, the differential probe has 3 times worse skin noise than the standard probe. This is in agreement with our new understanding of the skin.***

Theory

Skin noise seems to originate in differences in the papillary ridges. In the standard probe this noise after filtering by the probe can be written as

$$\text{Noise} = k * \text{Ridge-noise} * \text{SQRT}(A_p^{-1} + A_i^{-1})$$

where A_p is the area of the pickup fibers and A_i is the area of the illumination fibers.

This formula originates in the averaging that the probe performs.

In the differential probe the pick-up is common path and the A_p term vanishes. Unfortunately, the illumination area of the differential probe is considerably smaller than the area of the standard probe. We can write

$$\text{Noise(differential)}/ \text{Noise(standard)} = \text{SQRT}((1/2.82) / (1/0.31+1/12)) = 0.3$$

where 2.82 is the differential probe illumination area, 0.31 is the pick-up area, and 12 is the standard probe illumination area.

Experiment

Skin spectra taken with the differential probe show 14 [mAU] of skin noise in the 1100-1900 [nm] band, about the same as recent results on the D-1000. Unfortunately, the apparent equality is because of a hidden scale factor. The differential absorbance signal is about 3 times lower than the standard probe signal. The corrected differential noise is 3 times higher as anticipated by theory.

BIOCONTROL TECHNOLOGY, INC.

MEMORANDUM

TO: Dean, Ralf, Mark, Todd, Jeff
FROM: Rich
DATE: 07 July 94
RE: Review of Beta-4 meeting

The Beta-4 was defined as the next evolutionary improvement of the Beta-2. The intent is to improve the noise / drift of the Beta-2 from a nominal 15-50 [uAU] to < 1 [uAU]. At the same time, manufactureability, interchangeability, and universal calibration must not be ignored.

The Beta-4 is a parallel project with the Diasensor 1000. The Diasensor 1000 will provide important information on stability issues in a plastic case. The Beta-4 will provide a path for Diasensor improvement.

The milestones and manpower requirements of the Diasensor 1000 were discussed as a context for the Beta-4 development.

Diasensor work will fully consume the electronics development resources until November. At or before that time, specialized electronics for the Beta-4 can be constructed. The Beta-4 must be fully defined before that date.

An initial definition was created. The Beta-4 will combine the new scanning optical system with the DSP based data collection. The housing will initially be the Beta-2 style. However it should be remembered that the intent is to commercialize. It would be wise to examine the problem of interchangeability of machines.

Noise was discussed. The Beta-2 and Diasensor 1000 are now operating in a quasi single beam manner. Although drift limits the utility of integration to 2 seconds, the reference is not switched in for 30 seconds. The Beta-4 offers fast reference switching, but there are tradeoffs between detector memory effects and drift elimination.

A second Beta-4 meeting is scheduled for July 28. The intent of the meeting is to examine the noise and drift in the Beta-2 and to propose optimized methods of reducing these within the Beta-4.

BIOCONTROL TECHNOLOGY, INC.

MEMORANDUM

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FROM: Rich
DATE: 14 Jun 95
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What do you think?

Rich

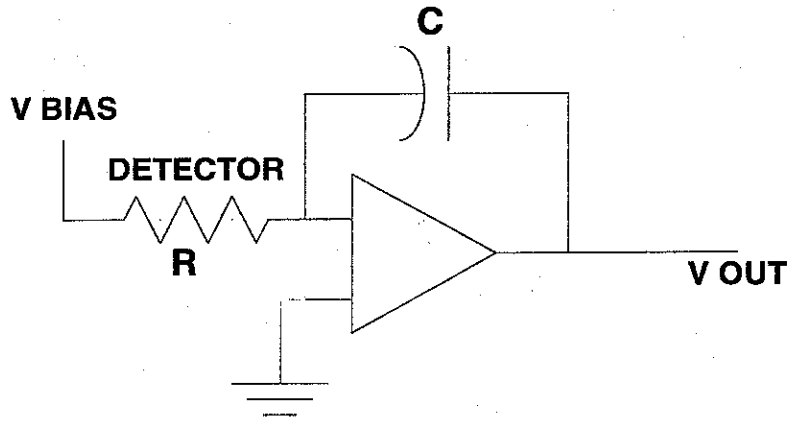
BIOCONTROL TECHNOLOGY, INC.

MEMORANDUM

TO: **Rich, Augustyn, Wei Jian, Dan**
FROM: **Mark DiFrancesco**
DATE: **26 January 1996**
RE: **Noise out of the Integrator**

For what it's worth, presented here is my assessment of the noise out of the integrator intended for the Beta 4. Assumed is operation under the proposed synchronous AC bias scheme.

At the input of the Reticon MUX chip we have a rather traditional integrator:



In this scenario, the current through the detector, I, is integrated such that Vout is:

$$Vout(t) = -\frac{1}{C}\int_0^t I(t')dt' \tag{1}$$

But, since we can write the time-averaged current as:

$$\bar{I} = \frac{1}{t}\int_0^t I(t')dt', \tag{2}$$

we can express Vout as:

$$Vout = -\frac{t}{C}\bar{I}. \tag{3}$$

Time-averaging results in a noise equivalent bandwidth, NEBW, of

$$NEBW = \frac{1}{\sqrt{t}} \quad \text{[square root Hz]}. \tag{4}$$

Noise in the output voltage can be expressed as

$$\sigma(Vout) = \frac{t}{C}\,\sigma(\bar{I}) \quad \text{[Volts rms]}. \tag{5}$$

Knowing the noise density for the current, N(I) [Amps/root Hz], we can now write the voltage noise as,

$$\sigma(Vout) = \frac{t}{C} N(I) * NEBW = \frac{\sqrt{t}}{C} N(I), \tag{6}$$

where equation 4 was used to substitute for NEBW. The signal-to-noise, SNR, can then be written,

$$SNR = \frac{Vout}{\sigma(Vout)} = \sqrt{t}\,\frac{\bar{I}}{N(I)}. \tag{7}$$

Note that the SNR increases as the square root of the integration time.

Let us now apply some plausible numbers to these equations. My memo of 24 January reviewed a means of estimating the current noise density of PbS using basic parameters. In that memo, I applied numbers for detectors approximating those put under test by Rapach. Let us now apply numbers more suitable for the detectors created for the Beta 4, i.e. **R = 100 MegOhms, Vbias = 10 Volts,** and **Area = 0.01 cm x 0.2 cm = 0.002 sq. cm.** Currently, I have no estimate of the **time constant** of these detectors, so I will assume a value of **500 microseconds**. Other parameters involved in calculating the G-R noise component are assumed to be equal to those used in the previous memo. Again, we assume that G-R noise dominates, so the **noise density** expected comes out to **~ 150 fA/rtHz.**

Plugging this noise density into equation 6, using the specified feedback capacitance in the Reticon chip inputs of 15 pF, and assuming an integration time of one full shutter cycle (¼ second), we get **Vout noise** of some **5 mV rms**.

If we accumulate, in ¼ second, enough charge on C to have a Vout of 10V, our SNR is only about 2000. If we want a SNR of about 100000, we would need to average to increase SNR by a factor of 50. This would require further averaging for 2500 shutter cycles or 625 seconds (10 minutes).

Have I missed something? Please look this over and give me your impressions.

Thank you.

THIS ESTIMATE SHOULD HAVE BEEN MADE EARLIER.

BIOCONTROL TECHNOLOGY, INC.

MEMORANDUM

TO: **Rich, Augustyn, Wei Jian, Dan**
FROM: **Mark DiFrancesco**
DATE: **26 January 1996**
RE: **Noise in PbS**

From my research report of 4 April 1995, the noise power density contributed by a PbS detector can be expressed as:

$$\langle i^2 \rangle = 4 I_{dc}^{\,2}(1+B)^2 / Adp\left(1+(\omega\tau)^2\right) + CI_{dc}^{\,2} / f^{\alpha} Ad + 2qI_{dc} / nL + 4kT / R .$$

Where:

- τ is the time constant
- I_{dc} is the dark current
- B is a constant (see 4 April 95 report by MD)
- A is the detector area
- d is the detector thickness
- p is the mean dark concentration of charge carriers
- ω is the noise radial frequency
- C is a constant
- f is the noise frequency
- q is the electron charge
- n is the number of crystallite barriers per unit length
- k is Boltzmann's constant
- T is the detector temperature
- R is the detector resistance

The first term is generation-recombination (G-R) noise. It is brought on by random fluctuations in the interaction of the PbS with background radiation and lattice phonons. In other words, it involves the interaction of the detector with thermal energy in its environment. Note that is has a roll-off at $1/\tau$ and has a dependence on the square of the current. The photo-conductive gain provides the additional factor of I as well as the dependence on the time constant.

The second term is flicker or 1/f noise. It too has a dependence on the square of the current.

The third term is shot noise manifested by the discrete nature of charge carriers which, in this case, are popping through a multitude of barriers comprising the PbS film. It has the usual dependence to the first power of current. Note, however, that it is scaled by the number of barriers encountered by charge carriers in traversing the detector.

Essentially, each crystallite is viewed as a current noise source which are added in parallel across the width of the film. After expressing as voltage sources, they are then added along the direction of current flow, along the detector's length.

The fourth and last term is Johnson noise having no dependence on the current.

How do the magnitudes of these sources compare? Using results of measurement and model fitting described in the 4 April '95 report, I come up with the following:

G-R noise: Neglecting the roll-off (say we're on the response plateau) and using τ = 500 microseconds, R of 20 megOhms, bias V of 30 volts, B of 0.2, A of 0.004 sq. cm, d of 2 microns, and p of 3e15: **about 33 microvolts/root Hz.**

1/f: assume that we are working at around 500 Hz where 1/f is presumed not to be a factor.

Shot noise: assuming a crystallite size of about 1 micron, we have on the order of 10000 barriers along the length of one of our detectors. This results in shot noise of **about 0.14 microvolts/root Hz.**

Johnson noise: at room temperature this comes out to **0.6 microvolts/root Hz.**

Clearly, G-R noise dominates and, in fact, agrees here rather well with measurements made by Rapach under similar conditions. Roll-off would reduce this calculation a bit and I'm not aware of specific time constant values for Rapach's measurements.

BIOCONTROL TECHNOLOGY, INC.

MEMORANDUM

TO: **Rich Wiggins and Augustyn Waczynski**
FROM: **Mark DiFrancesco**
DATE: **05 February 1996**
RE: **Beta 4 Modeled Operating Conditions**

The following pages summarize the outcome of a spreadsheet calculation of the optical power flow through the entire Beta 4 system. The conditions modeled are given in the first page. The graphs on the following three pages show what is expected as output from the device when applied to skin. Not all information regarding the model is given in these few pages. In addition, not all model parameters are well known or ideal (i.e., I am using the Beta 2 Czerny-Turner spectrograph as a model for the one to be used in the Beta 4, a single-element holographic design.)

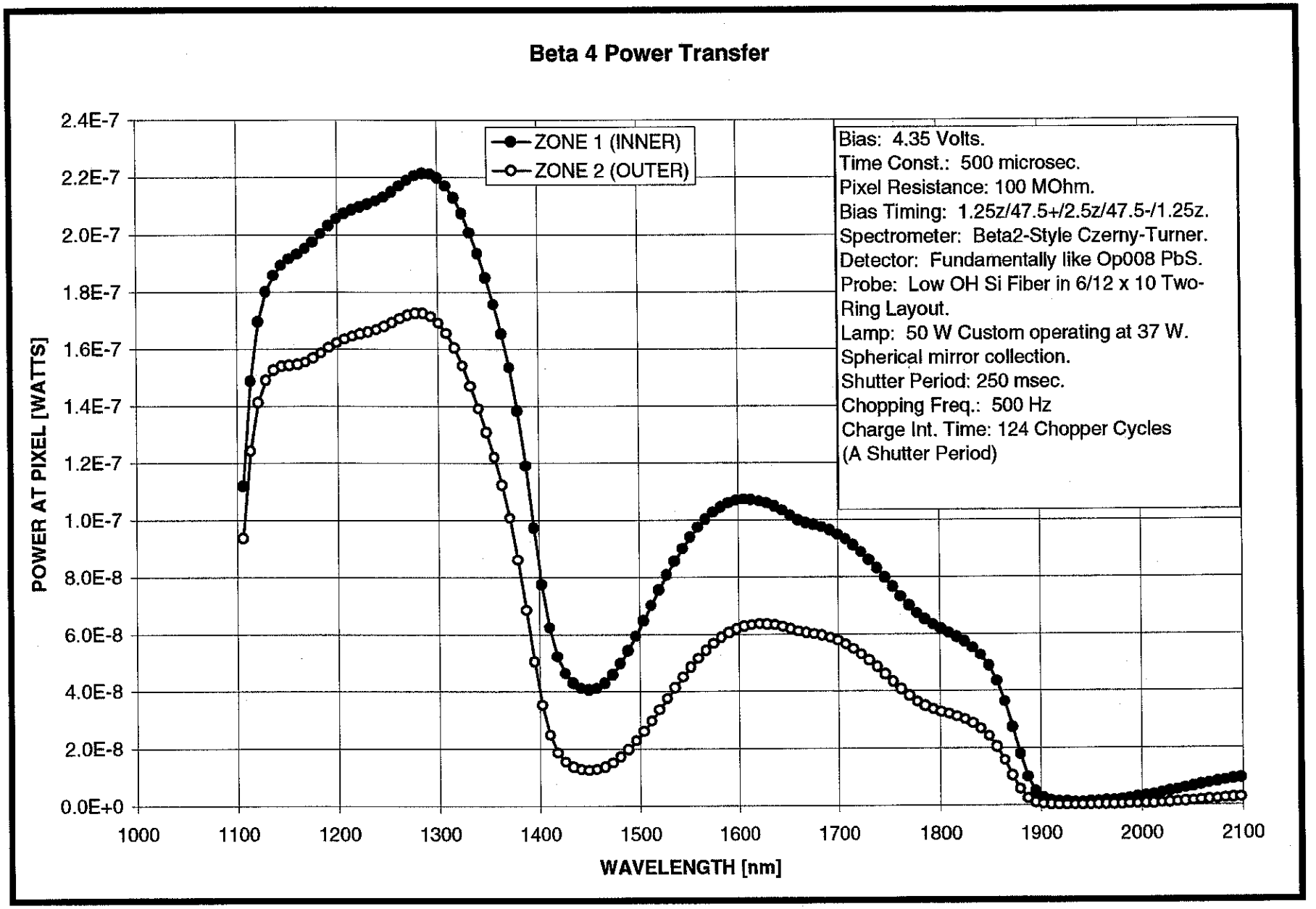
The first four pages referred to a model in which charge is integrated for half of a shutter period (the time during which light is applied through one or the other zone of the differential probe). That is, over 124 chopper cycles. This allows us over 2/3 of the A/D range as headroom. Integrating over fewer chopper cycles per digitization results in limitations on the optical signal which can fit within the available headroom. If we digitize every chopper cycle, we are limited to 150 mV of optical signal, or 10 bits, or a dynamic range of 1000.
A graph showing the relationship of dark headroom to optical signal for integration times of 1, 10, and 124 chopper cycles is included at the end of this memo.

As usual, if you have questions my hands are ready to wave!

printed: 2/6/96 12:06 PM

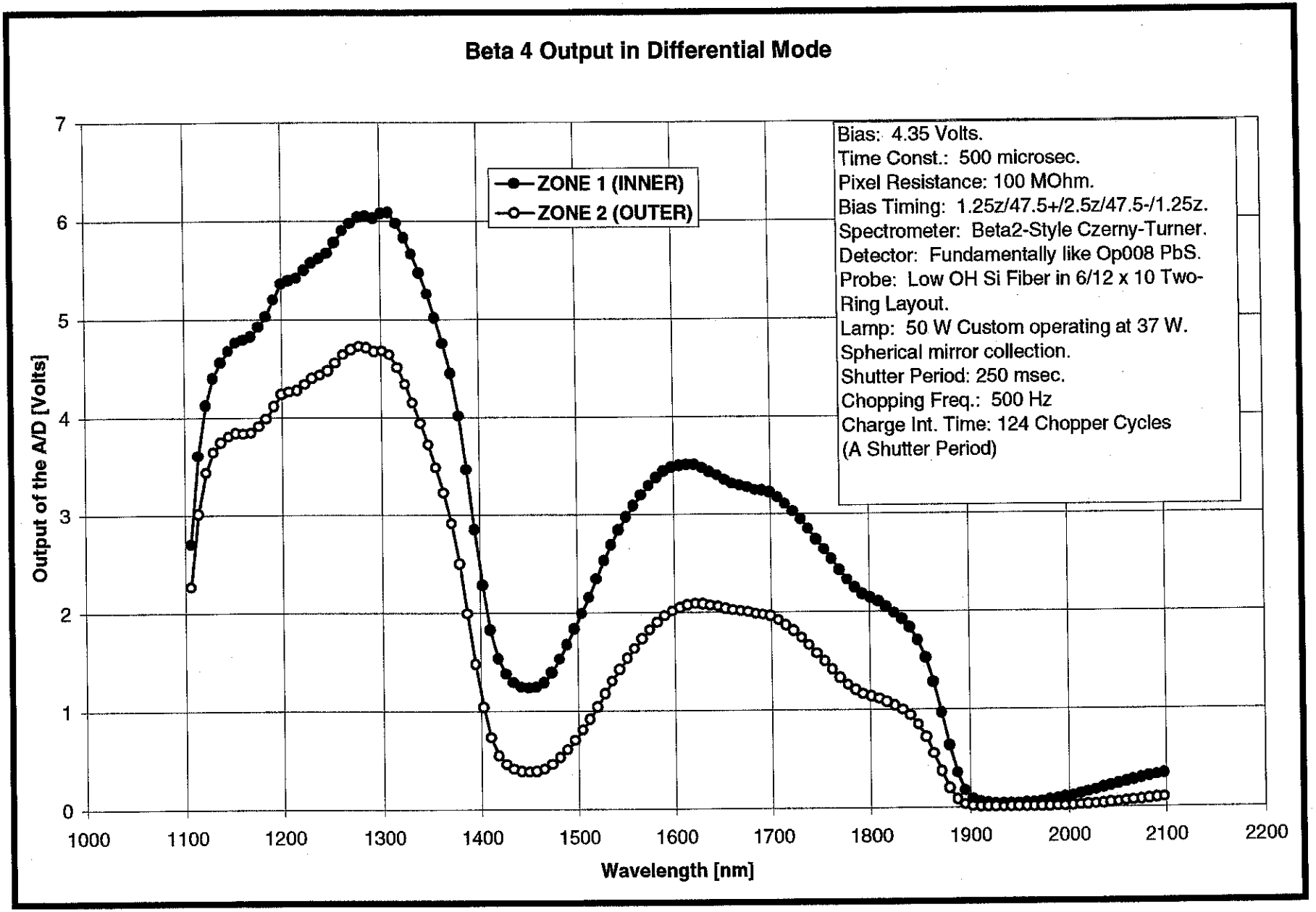
B4SYS3.XLS B4 POWER AT PIXEL

by: Mark DiFrancesco



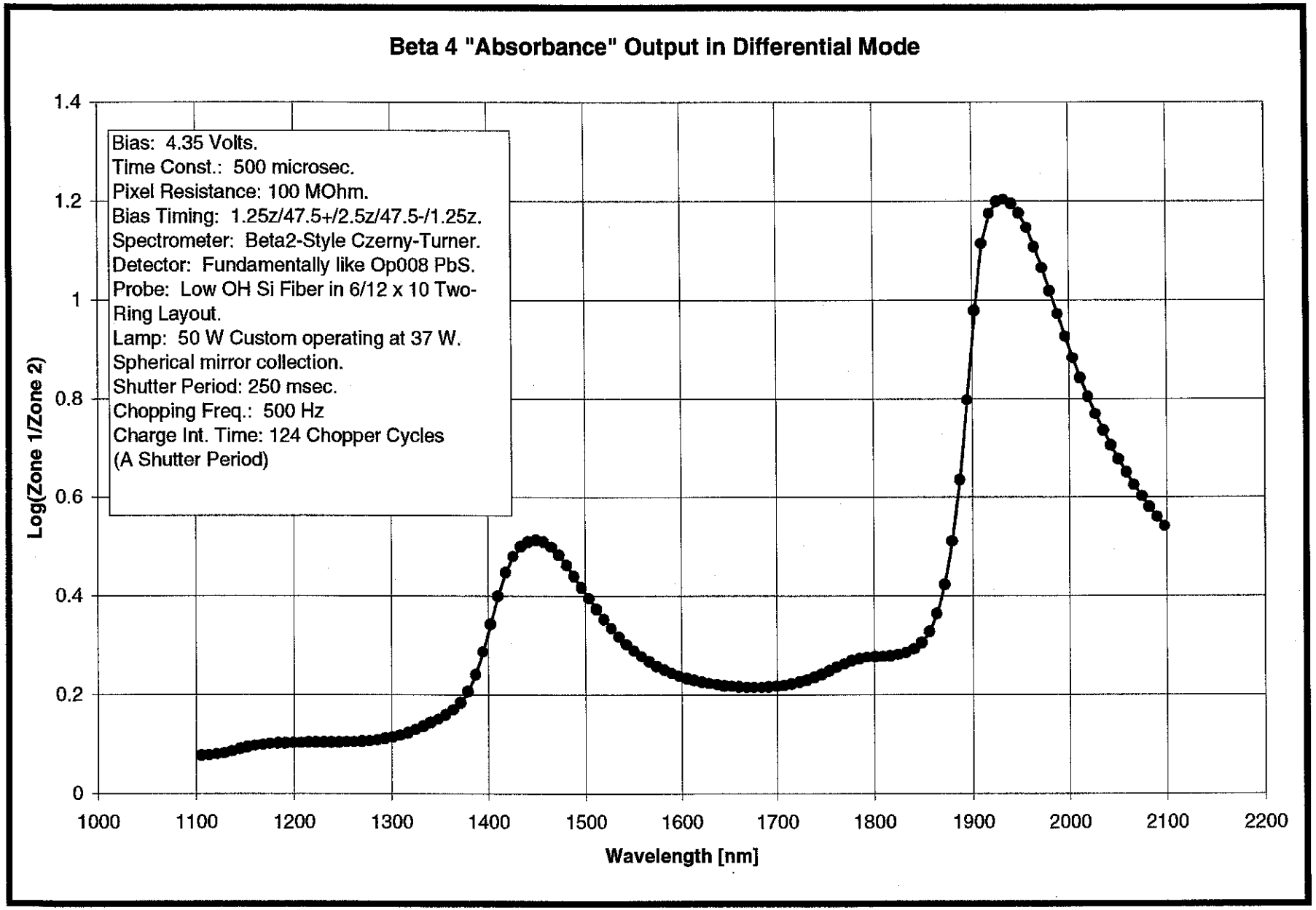
B4SYS3.XLS BETA 4 A to D OUT

by: Mark DiFrancesco



B4SYS3.XLS LOG[ZONE1| ZONE2]

by: Mark DiFrancesco



Research Report

Biocontrol Technology, Inc.

From: Mark DiFrancesco
Date: 15 January 1996

Subject: Beta 4 Status at Deadline

At the beginning of the Beta 4 project, a deadline was set by which a working system was to have been completed. As this deadline, January 15, 1996 has passed, the following summary of the state of the project is presented.

The Present Status

The Illuminator: Sufficient parts have been procured or fabricated for a build. Assembly of mechanical and optical parts has been completed. Some testing with a custom 50W bulb has been done with success.
Presently, we are using a gold-plated collector mirror. Dielectric-coated mirrors, serving as filters as well as reflectors, are not expected at the dock until late January.
Custom 50W bulbs are under test. I-V curves and burn-in data have been taken. Data to determine efficiency (radiant power out Vs. electrical power in) has been taken and shall be analyzed before 1/19/96.
Remaining: Fine alignment and testing including measurement of power delivered to the probe.

The Probe: A differential probe has been assembled. Two of the ten pickup fibers of this probe broke in the assembly process. Though it may not be entirely suitable for a final Beta 4 build, it will serve well as a test device. Allowing a week for mechanical parts to be made, it is estimated to take less than one additional man-week to assemble another probe.
Remaining: Efficiency of power delivery from the illuminator to the skin end needs to be measured.

The Spectrometer: Sufficient parts for the holographic spectrometer have been fabricated or procured for a build. The spectrometer has been assembled.
Gold-plated folding mirrors are delayed until the end of January. As a temporary substitute, aluminum mirrors have been acquired and installed.

The holographic grating has been partially tested and appears to have sufficient efficiency.
Remaining: Fine alignment and testing of efficiency and spot quality at the detector plane.

The Detector Array: To date, two arrays have been received from NEP and one has been received from Optoelectronics.
The NEP arrays were originally sent without lids for testing. These have been returned for lid sealing. Three more arrays will complete the order. Of the two received, one did not appear to be functional (but, possibly repairable) while the other appeared to be working as expected. Delivery of three complete arrays is expected by 19 January. Two others have an undetermined expected date of delivery.
The single Optoelectronics array received so far has not been tested. The remaining four arrays of the original order will be requested once the first one is assessed.
Remaining: Measurement of pertinent characteristics of the PbS in these arrays as well as the functionality of the MUX chips.

The Electronics and Software: All three custom boards have been acquired.
Population of the analog board is underway.
Population of the DSP board is complete and testing, so far, has shown no problems.
Completion of all board population is expected by late January.
Testing will probably take until late February.
Software for the digital signal processing has not yet been written. However, it can be completed with less than a week's notice. It is a modification of code already written for the D1000.
HC-11-based data processing, an alternative to the DSP approach, requires programming. Though some progress has been made to complete this, much remains to be done. A programmer dedicated to this task is needed. As the DSP approach appears to be successful, this task is reduced to minimal importance.
Remaining: It is evident that the electronics define the completion date for the Beta 4. By the end of electronics testing in February, the optical/mechanical components can be completed.

The Case: Plans have been drawn for a case of suitable dimensions to house all of the components above. Final dimensions should be on the order of 8.5" x 10" x 3.5". Metal for the case will not be cut until a decision as been made regarding the future dispensation of the Beta 4 in the R&D group.

Theory and Modeling: A spreadsheet following the flow of power through the Beta 4 system, including skin, has been completed. A similar spreadsheet attempting to detail noise and drift can be completed by mid to late January.

Monte-Carlo photon propagation modeling is also being performed to assess the efficacy of probe designs. Analysis of model data can expect to be completed by late January.

A Critique of the Project

It is, of course, easier to critique a project using hindsight. When in the midst of the effort, most actions appear essential and most problems unavoidable. The following comments are made as the history of the Beta 4 project is reviewed.

Specifications before designs: One of the most important "innovations" of the Beta 4 project was to be an approach to development which utilized documented specifications and criteria for each subcomponent. These criteria, based on measurements at BICO or on reliable literature, were to be determined before design.
This approach was followed for some components, i.e. the illuminator. For many of the components, however, the specifications were developed, at best, in parallel with the design process. Some issues, such as the source/pickup fiber separation for the probe, were never resolved fully before design (due, in this case, to a faulty Monte-Carlo program).
In hindsight, it is realized that we knew less about design criteria than we thought before project initiation. We needed a few months just to get the specifications documented.

Slow start?: Some components and some modeling for the Beta 4 began even before its official announcement. Others, ironically those whose development time was feared to be long, took considerable time to launch. It was on the order of a month since the project's inception, for instance, before the array detector development began in earnest.

Organization: As with most projects, there was room for improvement in organization. Though it was well attempted in the beginning, conveyance of project status and technical issues to all participants faltered as the project proceeded. Schedules needed to be updated more regularly with better estimates of deadlines. A "Pert" chart style of scheduling would have been useful for connecting the many project paths. The impact of the holidays was not well anticipated.

Performance of participants generally excellent, however...: It must be noted that the perseverance and application of technical abilities of the R&D group as well as members of the Electronics Engineering Group were of the highest quality. In about six months, a new sensor, incorporating a number of major innovations, has been developed from scratch to nearly the point of testing all major components before final assembly.
There is, however, some criticism in order:

It was difficult to cultivate a "just get it done as well as possible" attitude as opposed to belabored research.

Deadlines were, at times, simply not taken seriously.

More initiative was in order, particularly with regard to suggesting possibly better ways of completing tasks than those proposed by management via schedules, etc. We are all experts of one form or another. Effective networking of that expertise can avoid lengthy bouts with confusing situations and contingencies.

Most of the issues just mentioned relate, perhaps, to the stereotypical nature of R&D personnel. We tend to come from backgrounds in which deadlines, if existing at all, are nebular. Projects like this one required, unfortunately, rather limited time horizons.

The Future of the Beta 4

As mentioned in the electronics section of the status report above, the earliest date, in my opinion, by which we might put together a complete, functioning Beta 4 is the end of February. By "functioning" I mean that it will be able to collect spectra. As this effort would require involvement of members of the Electronics Engineering Group, delays are likely since the D1000 takes precedence. The EE Group would be required to complete the DSP software as well as aid in the testing of all boards. In the R&D Group Abramson could continue with electronics testing while Elder performs alignment and testing of the optical components. We would also need to enlist the help of a mechanical designer to complete the plans for the case. Again, fewer personnel are available in R&D for continuing the Beta 4 as new projects, particularly the Delta 1 and skin studies proceed.

Having said this, it appears that ending the Beta 4 project completely at this time will result in little, if any, utilization of the components and concepts resulting from its development so far. It is my recommendation that the project be taken at least to the assembly of a functioning integrated system.

Finally, the Beta 4 may represent the point of diminishing returns when it comes to diffuse reflectance near-infrared spectroscopy (DRNIRS). If the device works as specified, it is difficult to imagine a further reduction in size or performance by a factor greater than about two. In other words, if glucose is to be detected via DRNIRS, it better be done with the Beta 4.