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AUTOMATED CHEMICAL WARFARE RESPIRATOR QUANTITATIVE FIT TEST INSTRUMENT

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AMD-TR-85-001

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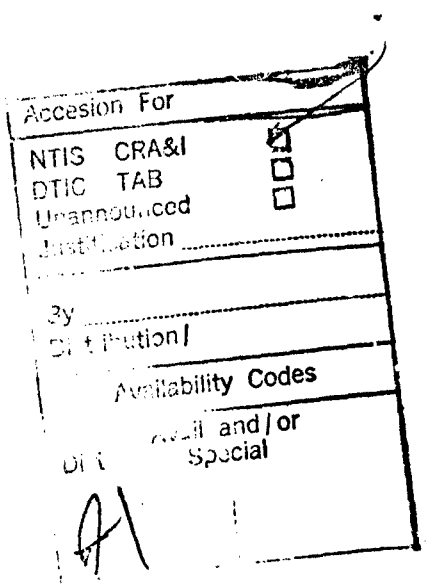

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A prototype unit of an automated chemical warfare respirator quantitative fit test instrument (Model 260 AS) was designed, assembled and tested at Dynatech Corporation. The instrument is fully automated with no operator attention required during fit tests. Fit factors as high as 10^6 can be detected with this instrument which can be continuously operated for 24 hours. Corn oil was used as an aerosol challenge agent because of its safety features that have been documented by NIOSH. Human engineering considerations were implemented in the instrument's design to assure safety of operation.

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"SUMMARY"

The presence of toxic chemical warfare agents above certain threshold concentration levels creates a respiratory hazard which must be reduced to acceptable levels. When environmental controls cannot achieve an acceptable level of exposure, respiratory protective devices must be employed to provide breathing quality air to the exposed individual. The efficacy of the respiratory protection devices, respirators, is in large part of the seal created between the device and the individual which is, in turn, a function of the ambient environment, temperature and humidity, and of muscle tone due to the degree of rest, tension, exercise, etc. These factors, coupled with the certainty that no one individual can repeatedly position a respirator at the same exact location on his face, produces a variability of fit. Determination of variability is a requisite to assessment of the level of protection provided by the respirator. Selection, proper training, and protection assessments require some quantitative measure of the efficacy of the seal between the respirator and the individual. The instrument which quantitatively defines the efficacy (fit factor) is known as a respirator quantitative fit test.

The procurement for this effort arose from a need for an automated respirator quantitative fit test instrument that could be used experimentally to develop laboratory data pertaining to respirator fit and which could serve as a prototype for an instrument to be used at or near the flight line to rapidly measure the fit factor provided by a respirator for a particular individual. The objective of this effort was to develop a rapid, automated respirator quantitative fit test instrument and standardized test procedure which would provide USAF personnel a basis for determining individual fit factors for large experimental populations and for comparison of the obtained fit factors with values thought to be clinically significant. The objective was to develop an instrument that did not require an operator to calibrate, monitor, or otherwise be involved when an individual performed a fit test. In addition, the collection, reduction and reporting of a fit factor was to be automated and the result shown on a display such that it could be viewed by the respirator wearer.

A prototype of an automated chemical warfare respirator quantitative fit test instrument was designed and assembled by Dynatech Corporation. The instrument (Dynatech Model 260AS) requires no operator attention during the fit tests. An automatic control and data acquisition system composed of Hewlett-Packard components is integrated into the instrument hardware. Fit factors as high as 10^6 can be detected with the instrument which is capable of 24 hours continuous operation. The instrument is fabricated of hardware components that do not need any replacement or maintenance for at least 14 days. Corn oil because of its documented safety is used as the challenge agent. An algorithm has been developed for reduction of the data to provide an automated interpretation of the fit factor.

Performance tests for the instrument's subsystems verified that the operational parameters of the instrument met the design objectives of the program. Aerosol mass concentration in the chamber was 25μg/litre. The mean mass aerodynamic diameter of the aerosol in the chamber was 0.35 ±0.05μ. It took the system about 2.5 minutes to build the required aerosol concentration from the cold start of the system. The chamber aerosol concentration recovery after opening and closing the door was almost instantaneous because of using the "DYNALOK" mode and because of the existence of an air lock. Systems calibrations were performed to set up the operating reference parameters of the instrument.

Quantitative fit tests using human test subjects were performed on five test subjects. Half and full mask respirators were used in these tests. The results show the instrument's capability to measure fit factors up to 10^6. Fit factors of values ranging from 1 to 10^6 were reported in the results of these tests. The instrument, as evident by this document, represents a significant advancement in the state-of-the-art of aerosol quantitative fit test instruments.

PREFACE

The United States Air Force, under Contract #F33615-83-C-0650, assigned to Dynatech Corporation the design, fabrication and test of a prototype automated respirator quantitative fit test instrument that can be used at or near the flight line for rapid measurement of fit factors afforded to an individual wearing an air-crew or ground-crew chemical warfare defense respirator.

The instrument has been needed to help the individual select the correct respirator from the available finite number of respirators of a given contour and size. The unit will also be used to train the individual to properly don, position, and adjust the respirator for comfortable and effective operation and use. Additionally, the instrument is necessary to determine the variability of fit resulting from the certainty that no one individual can repeatedly position a respirator at the same exact position on his face, and from the subtle facial feature changes experienced by an individual as a function of the ambient environment, temperature, humidity, and muscle tone due to the degree of rest, tension, exercise etc. Determination of the variability of fit for a individual is a requisite to assessment of the level of protection provided by the respirator. Quantitative measurement of the variability of fit of the face piece to the individual is performed by the instrumental procedure known as respirator quantitative fit testing.

The objective of this effort was the design and assembly of an automated instrument with no operator attention required during the fit tests. Therefore, the instrument's design implemented automatic instrument control and automated collection, reduction and reporting of the fit factors. Fit factors as high as 10^6 have been detected by the instrument which is capable of 24 hours continuous operation. The instrument was fabricated of hardware components that did not need any replacement or maintenance for at least 14 days. This has not been applied to the consumable items such as filters ....etc. Corn oil has been selected as the challenge agent for the

instrument because it is the only suitable agent that is explicitly recommended by NIOSH. System compliance to design specification was established and verified by incorporating the test plan/procedures approved by the USAF and presented in Appendix 4 (Item No. DI-T3708A, Sequence No. 9). A human test protocol approved by the USAF was implemented in man testing of respirators using this instrument.

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Chapter 1

INTRODUCTION

The fit of a respirator facepiece to an individual's face is the most important factor in providing adequate and repeatable protection for individuals wearing respiratory protective devices. Determination of the variability of fit for the same individual under different conditions is a requisite to assessment of the level of protection provided by the respirator. Quantitative measurement of the variability of fit of the facepiece to the individual is performed by the instrumental procedure known as respirator quantitative fit testing.

The objective of the present contract was to design, fabricate, and test a prototype automated respirator quantitative fit test instrument that could be used for the rapid measurement of the effectiveness of fit (fit factor) afforded to an individual wearing an aircrew or groundcrew chemical warfare defense respirator. Dynatech R/D Company has met this objective through development of an instrument which fulfills the contract's detailed design specifications.

The contract required that there be no operator attention during fit tests. We therefore designed the instrument with automatic instrument control and automated collection, reduction, and reporting of the fit factors. Fit factors as high as 10^6 can be detected by the instrument, which is capable of 24 hours continuous operation. The instrument was fabricated of hardware components that do not need any replacement or maintenance for at least 14 days, with the exception of consumable items such as filters. Corn oil was selected as the challenge agent for the instrument because it is the only suitable agent that is explicitly recommended by NIOSH. System compliance to design specification was established and verified by incorporating the test plan/procedures approved by the USAF and presented in Appendix B (Item No. DI-T3708A, Sequence No. 9). A human test protocol approved by the USAF (Appendix C) was implemented in man testing of respirators using this instrument.

We present in this text the details of the technical approach and design concepts of the instrument (Chapter 2) followed by the description of the major subsystems' design and assembly in Chapter 3. Chapter 4 describes the system performance tests, while Chapter 5 includes the results of quantitative fit testing using human subjects. A summary of the instrument design and testing is presented in Chapter 6. Appendices have been added at the end of the text to give clearer pictures of some of the procedures that have been approved by the USAF during the course of the work, and to supply some of the information required by the contract. In addition, Appendix A includes a system safety hazard analysis report.

Chapter 2

TECHNICAL APPROACH AND DESIGN CONCEPTS

2.1 State-of-the-Art in Respirator Fit Testing

The specifications for development of a prototype automated quantitative fit test instrument (QNFT) system for flight-line testing of supplied air and filtered air masks required important extensions of performance in the QNFT instrumentation and practice existing at the time of the contract award.

Prior to the design of the automated respirator fit test instrument under this contract, QNFT instruments were designed to verify Fit Factors reliably and accurately to the approximate limit FF $\cong 10^5$. All systems have required an operator to supervise the test, and to operate and monitor the instrumentation and interpret the results from strip-chart recording. Tests of 15 minutes or longer duration were standard practice. The major program objectives necessary to advance existing practice to the desired QNFT instrument performance are:

- specifications of the USAF contract which extend instrument sensitivity to a Fit Factor of 10^6;
- unattended automatic operation and data display for 24 hours without maintenance; and
- the limiting of tests to 3 minutes.

Of these specifications, the most important to achieve, and the requirement which most governs choice of systems, was the desire to achieve quantitative measurement of fit factors as high as 10^6. No measures of fit factors higher than approximately 10^5 were reliably made, and no masks or respirators whose fit performance consistently exceeds this instrument limit have been observed in fit tests (if we admit that even supplied air masks must be tested at negative pressure to recognize all operational possibilities). In present QNFT equipment the upper detectable fit factor limit depends primarily on the lowest detectable concentration limit in the

breathing zone sample which light-scattering photometers will discriminate as a mass concentration (or the flame ionization detectors in sodium chloride systems) given that challenge aerosol concentrations are limited to a small range by other considerations. To meet the extended performance requirement, then, it was clear that either the challenge agent concentration must be increased, or the detector sensitivity to the low challenge agent concentrations must be increased, or some combination of the two.

Because of the requirement to extend the dynamic range approximately three orders of magnitude beyond the existing limit of QNFT equipment, we surveyed and evaluated the feasibility of employing either gas or aerosol challenge agents, and detector means and technologies which have not previously been adopted to QNFT practice. Although of less significance in the context of the revised fit factor of 10^6, we felt that the results of our investigation were illuminating. To determine feasibility of candidates, we first set the challenge agent concentration at the upper limit we believe to be attainable, regardless of toxicity level of the agent (some agents will have lower acceptable toxic limits). For gases, we chose the criterion of oxygen-displacement, and considered a gas challenge agent concentration of 10,000 ppm (1% concentration) to be the maximum test agent concentration providing an acceptable margin of safety for a filtered-air mask test. Concentration limits for aerosol agents are more difficult to establish. Present practice is to provide a challenge atmosphere of approximately 25 µg/ℓ. At concentrations approximately equal to five times of this, a visible haze becomes apparent. Presently developed and available air-driven aerosol generators do not much exceed this supply concentration level for aerosol of small mass median diameter.* Finally, toxic concentration levels for the agent of choice provides an absolute limit. Taking these considerations into account, we set approximately 100 µg/ℓ challenge concentration as a practical limit, based on performance judged to be achievable from development experiments in our laboratory with air-driven

* Thermally generated aerosols at high concentration have been employed in filter test apparatus; however, we do not believe generation to be practical for unattended field applications with rapid start-up requirements.

aerosol generators, and allowing an acceptable toxic hazard margin for typical aerosol agents (e.g., DOP). After consideration of the final design specifications, we were able to proceed with a more conservative design at 25 ug/ℓ, and utilize a detector which represented a modest improvement over the current state-of-the-art. Refined corn oil was selected as the aerosol challenge agent based on its low toxicity, which is well documented, and the absence of any evidence of a carcinogenic potential (see Reference 1).

Gaseous challenge agents for test of in-service masks was considered when designing this instrument. However, employing gaseous challenge agents would be possible only if a straight-forward design was available which required less development than for aerosol systems, but this was not the case. We believe a test with gaseous agents for this application has the characteristics of a destructive test. Since a reactive gas that will be absorbed by the filter must be used, there would be some filter loading during the test. Perhaps of greater concern, the test agent could be desorbed and driven from the filter into the breathing zone in large concentration if the filter encountered a more active species in actual use. Because of these considerations, and the result of our calculations and survey of developed detection methods, we have concluded that there was no incentive to depart from the established practice of employing aerosol challenge agents.

Beyond the above-described considerations. the choice of system design was judged by the following criteria:

- a system requiring minimum component hardware development is desirable;
- where component hardware development is unavoidable, development modification or extension of existing developed hardware is preferred to new hardware design and development;
- system concepts and component choices must be amenable to unattended operation without components' failure or replacement for

at least 14 days period, exclusive of consumables such as filters, etc.; and

- prior operating and design experience with QNFT systems of the industrial hygiene community, respirator manufacturers, and QNFI manufacturers and laboratory researchers should be applied to these new requirements wherever they are not in conflict with intended use, practice, or conditions of operation.

We believe we have chosen the system configuration which has minimized development time and risk by complete utilization of state-of-the-art technology consistent with performance specifications and complete definitions of the development tasks and risks to achieve specified goals. This required a thorough understanding of all aspects of fit test technology and practice; the hardware, the technique, the procedures, hazard control, the integration of human engineering into the instrument system, and reliability and maintainability design for this type of equipment and service.

Presented below is a discussion of the concepts used in the design and operation of major system components as illustrated by the schematic representation of the QFTI system (Figure 1).

2.2 Design Concepts of System Components and Operation:

2.2.1 Aerosol Generator and Dilution System

An aerosol generator which can produce a log normal droplet distribution with a mean mass aerodynamic diameter (MMAD) of 0.35 μm ± 0.05 μm and a standard deviation less than or equal to 2.0 has been developed. The size distribution will be measured in the chamber rather than at the generator outlet. The generator combines the concepts on which the Laskin nozzle and Wright nebulizer are based. The Laskin type orifice system allows for control and maintenance of a steady flow of corn oil into the air stream. The impactor plate or baffle concept was taken from the Wright nebulizer design. By adjusting the distance between the nozzle and the plate, the size of the droplets which can negotiate the turn can be controlled. The droplets which impinge on the plate will return to the oil reservoir.

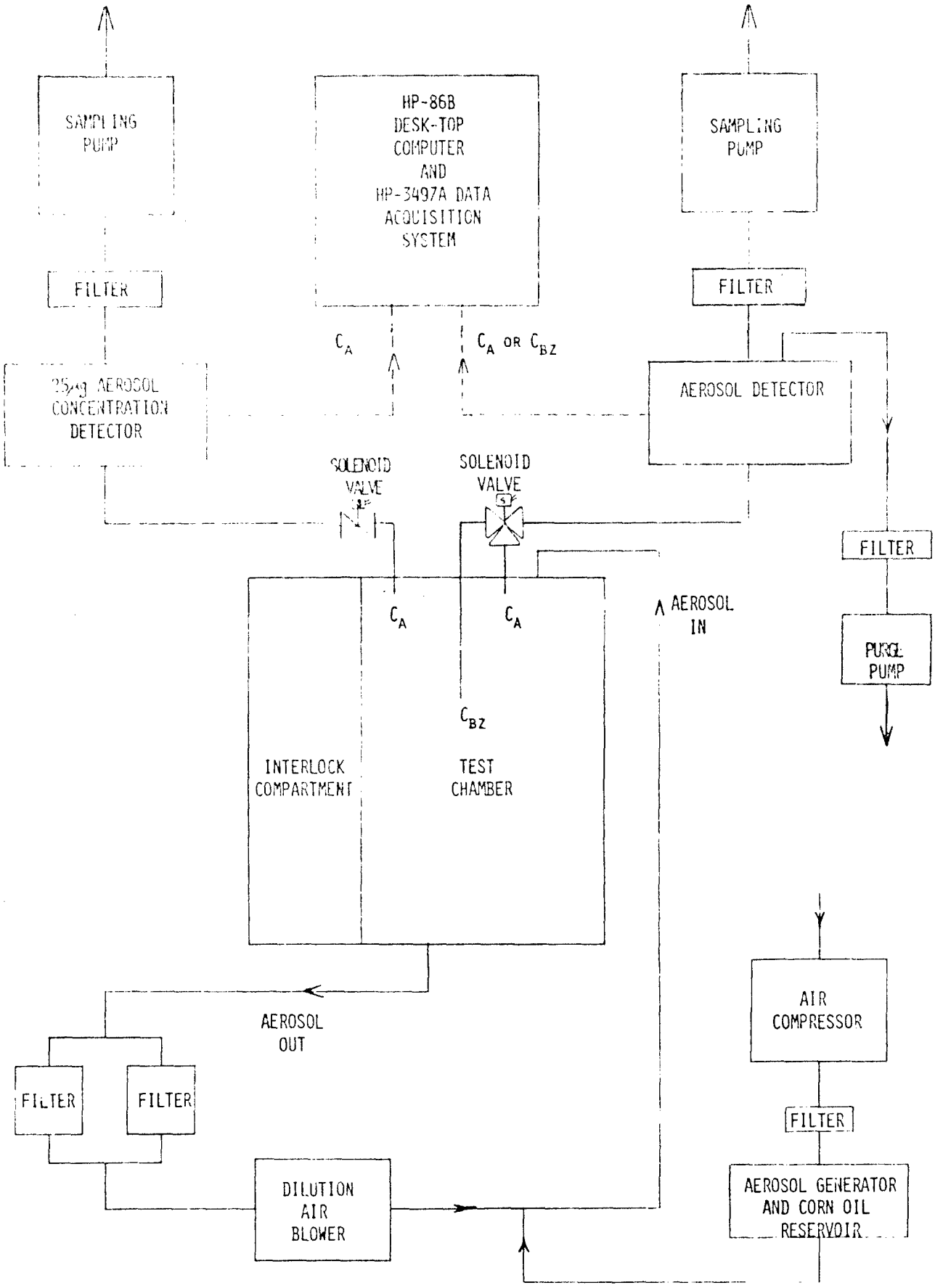

Figure 1. QFTI System Schematic

Investigation of the effects of corn oil temperature on the droplet size distribution was performed experimentally. No such effect was noticed. This enabled us to use corn oil at room temperature (approximately 20°C) for aerosol generation. The challenge agent was generated and mixed with dilution air to a concentration of 25 μg/ℓ and circulated through the test chamber at a flow rate within a range not to exceed 15 cfm, or less than 6 times the sedentary breathing rate of the average test subject based on a 30 ℓ/min (1.06 cfm) breathing rate. This helped insure that the spatial variation did not exceed the allowable 1% of the mean ambient challenge concentration ($\overline{C_a}$).

A blower was used to circulate the aerosol and dilution air mixture through a "closed" loop including the test chamber and a high efficiency particle filtering system. The aerosol mixture was regenerated continuously in order to maintain a stable concentration inside the test chamber. The entire system was operated at a pressure slightly below atmospheric with the objective of controlling leakage across the chamber boundary. Inboard-leakage also helped assure a good supply of oxygen within the system. To prevent contamination of the compressed air supplied to the generator nozzle, a particle trap and clean filtered air was used by the aerosol generator.

In order to satisfy the requirement of a cold-start equilibration time of less than 10 minutes, a rapid-start aerosol generation mode was employed. This mode of operation introduced a high concentration aerosol into the test chamber. The rapid-start mode was terminated automatically when the chamber's concentration achieved a specific level such as 90% of the desired concentration.

The requirement that the QFTI system be capable of continuous operation for a period of 24 hours without maintenance necessitated a dual dilution air filter scheme. A differential pressure transducer was installed across the main filter element to indicate when replacement was necessary. In this arrangement, when the main filter required replacement, the dilution air flow was automatically diverted to the back-up filter. A

light at the front panel of the instrument indicated that the main and back-up filters needed to be replaced during the normal maintenance cycle.

2.2.2 The Test Chamber/Interlock Booth

The QFTI system test chamber was a modification of the Dynatech Frontier Model 222-8. The chamber was 8ft x 4ft x 8ft with a 4ft x 4ft x 8ft interlock compartment. The large interlock compartment allowed for easy and thus quick entrance and exit from the test chamber. Aerosol distribution and collection plenums were included in the top and base of the test chamber, respectively. Two additional fan assemblies were added to improve the mixing characteristics within the chamber.

Control of chamber aerosol concentration perturbations was maintained by DYNALOK, an operating mode similar to rapid start, which provided rapid build-up of the test aerosol concentration and prevented excessive loss of aerosols experienced when the test chamber door was opened. It was activated when the chamber door was opened. DYNALOK, in conjunction with the interlock compartment, would reduce the magnitude of concentration perturbations and minimize stabilization time.

An annunciator control panel was installed on the wall of the test chamber. Several fittings were mounted on the test chamber wall. One would mate with the quick disconnect fitting on the free end of the breathing zone sample line. Others were for sampling the chamber's ambient concentration. Additional fittings might be provided for connection with external test equipment also.

The chamber was made of fiberglass. The windows were made of Plexiglas. The materials of the chamber were not agent tested since such testing was not required for a prototype instrument.

2.2.3 Aerosol Concentration Sampling

As shown in Figure 1, a sample of the test chamber atmosphere goes to the 25 μg aerosol concentration detector while another sample is taken from the test subject's breathing zone to the breathing zone photometer system. This photometer is also able to analyze ambient concentrations in the test chamber. Sample selection (ambient or breathing zone) was automatically controlled by a solenoid valve. The moisture level in the ambient sample did not pose a problem, because the order of magnitude of photometer response to water was several orders of magnitude less than that of aerosol; thus, that sample line was not heated.

2.2.4 The Challenge Agent Concentration Detector System

The challenge agent concentrations in the breathing zone were measured by an electro-optical system comprised of a forward light scattering photometer, dynamic logarithmic amplifier whose output was interfaced with the voltage monitoring card in the data acquisition system. A high sensitivity photomultiplier tube was used to improve the accuracy at lower concentrations. The amplifier signal was conditioned for a continuous linearized dynamic range capability of 10^7.

The ambient concentration of aerosol within the test booth was continuously monitored to ensure that it remained at the desired level. Various alternative approaches were investigated to maintain this concentration detector at minimum cost and system complexity. A 25-μg detector using forward light scattering principle coupled with a linear amplifier was selected to automatically perform this function.

2.2.5 System Packaging

The entire QFTI system was designed to operate over the specified range of environmental parameters: temperature (0°C to 40°C), humidity (5% to 95%), and barometric pressure (620 - 635 mm Hg). To ensure repeatability, the system's instruments are kept in a relatively constant

temperature environment. Vented enclosures painted with a reflective paint are used to house the system's detectors and computer control unit. The picture in Figure 2 depicts the final system housing.

2.2.6 Data Acquisition and Control System

The operation and control of the QFTI system is fully automated. A system comprised of a HP-86B personal computer and a HP-3497A data acquisition system is used. Figure 3 is a diagram indicating the various input and control signals which are monitored or controlled by the system.

The rapid start and DYNALOK operating mode controls involve the reproportioning of the dilution air and the aerosol mass from the generator. The dilution air blower output is reduced while the aerosol generator's mass output is increased. The rapid start mode is activated when the system's power is turned on. After the specified value of C_a is detected, the blower and aerosol generator are automatically reset to normal operating conditions. The DYNALOK mode is activated for a period not to exceed 20 seconds when the door to the test chamber is opened.

The control and data reduction software includes self-inspection features to detect different failure modes. Warning signals are activated if the differential pressure across the main dilution air filter reaches a predetermined maximum value or the corn oil reservoir temperature varies from the desired constant value. The selected temperature of the corn oil reservoir is maintained by a thermostatically controlled band heater and monitored by a thermistor because the proper operation of the QFTI system depends on a reasonably constant oil temperature. The switch over of the dilution air filter is automatic and replacement of all filters is performed during normal maintenance. The operating of the aerosol concentration detectors is also fully automated. At the beginning of each test, the photometer automatically establishes zero and full-scale concentration values and the 25 μg detector is calibrated using the photometer before and after each test.

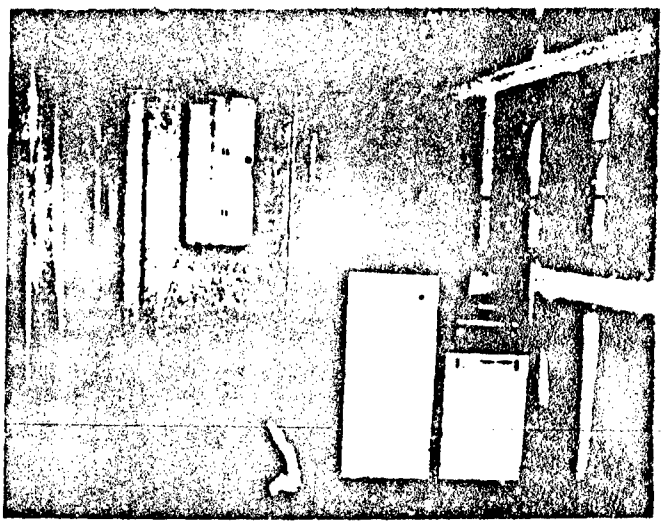

Figure 2. A Picture for the Instrument and the Chamber

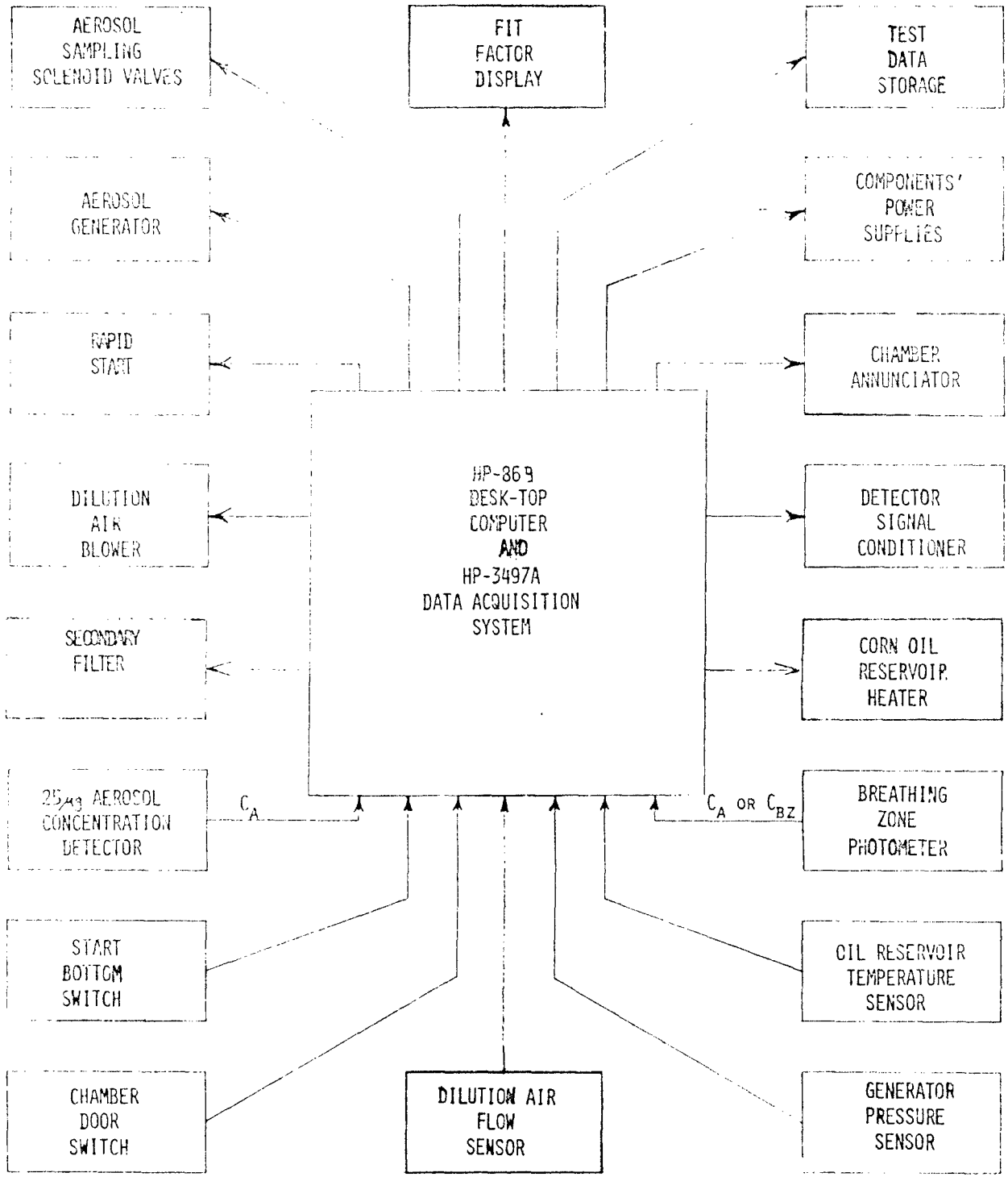

Figure 3. QFTI Data Acquisition and Control System

2.2.7 Calculation of Protection Factor

Using the automated data acquisition system, we would be able to scan both the photometer (C_{bz}) and the 25 µg detector (C_a) outputs as frequently as 100 m sec. We scanned these outputs at 1 sec intervals only. Digital integration of these signals was performed during each exercise and a value for the fit factor for each exercise was calculated. If equal time is assumed for each exercise, the final fit factor can be calculated by taking the average of the fit factors of all exercises. If the duration of each exercise differs, digital integration is performed for the whole range to calculate the final fit factor, in addition to performing it for each individual exercise.

The basic concepts for the calculation of the average fit factor during each exercise and for the whole test were provided by the equations:

$$FF = \frac{\overline{C_a}}{\overline{C_{bz}}}$$

FF: average fit factor during an exercise or a group of exercises;

$\overline{C_a}$: average chamber concentration defined as the average of initial and final chamber concentrations for all the test exercises;

$$\overline{C_a} = \frac{C_{ai} + C_{af}}{2}$$

$\overline{C_{bz}}$: average breathing zone concentration during an exercise or a group of exercises defined as;

$$\overline{C_{bz}} = \frac{1}{n} \sum_{i=1}^{n} C_{bz_i}$$

C_{bz_i} = the instantaneous breathing zone concentration measured every 1 sec during the test.

2.2.8 Conceptual Sequence of Operation:

Ten minutes prior to the first fit test, the system power will be turned on. The operator loads the program into the computer memory and inputs the test operation parameters (e.g., duration, and number of tests). The automatic operation of the instrument starts by activiting the oil reservoir heater switch. When the corn oil reservoir temperature attains a specified minimum, the following will be activated:

- power supplies of photometers and transducers;
- ventilation blowers;
- aerosol generator; and
- dilution air blower.

When the program verifies that the aerosol generator and the dilution air blower operate at the right conditions, the rapid start operating mode is activated. It will be deactivated when the test chamber aerosol concentration reaches 90% of its specified value. The aerosol generator and dilution air flow will be automatically reset to their normal operating conditions. A message on the computer screen will indicate that the system is ready for test, and will instruct the test subject to enter his name and serial number before entering the chamber.

The test subject dons his respirator, with the sampling line properly attached, and enters the test chamber through the interlock compartment. Upon opening the door to the test chamber, the DYNALOK operating mode is activated. This mode is deactivated in the same manner as the rapid start. Once the DYNALOK feature is deactivated, the 25 µg detector is calibrated using the breathing zone photometer, and the photometer establishes its full-scale reference value corresponding to the test chamber's aerosol concentration. The photometer sampling pump shuts down, the purge system starts, and the photometer's zero is set. Test procedures instructions will be conveyed to the test subject by automatic lighting of signs fixed to the wall of the test chamber.

At the completion of the exercise routine, the 25 µg detector will measure another value of chamber aerosol concentration (C_a). The test subject will be instructed to disconnect the sampling line and leave the test chamber. The DYNALOK feature will be activated for 20 seconds or less to compensate for the loss in the chamber aerosol concentration resulting from opening the chamber door. Fit factors for individual exercises and the whole test are displayed on the CRT so that the test subject may assess his respirator fit. A hard copy of them will be printed for book keeping purposes. In addition, all test parameters and output data will be stored on a disc for future analysis.

For shut down of the system, the system power should be turned off. Chamber doors may be opened to accelerate the aerosol removal from the test chamber.

Chapter 3

INSTRUMENT MAJOR SUB-SYSTEMS DESIGN/DESCRIPTION

Through integrating the various technologies of aerosol generation, aerosol detection and computer automation, the instrument (Dynatech Model 260 AS) provides the most advanced capability of quantitative man fit testing of respirators or evaluation of respirator components, fittings, and related hardware.

Test aerosols are mechanically generated by a specially designed Dynatech aerosol generator with integrated atomizing technology, jets and impactors to produce a mean mass aerodynamic particle diameter and mean particle diameter by count of 0.35 ± 0.05 μ. The generator output is mixed with clean filtered air which can be proportioned by the user to obtain aerosol concentrations of 25 ± 5 μg/liter. Control of chamber aerosol concentrations is greatly enhanced by the addition of a feature called DYNALOK. This was incorporated to provide a rapid build-up of the test aerosol concentration and prevent excessive loss of aerosols normally experienced when the test chamber doors are opened or closed. The eletro-optical detection system is comprised of 2 forward light scattering photometers, a dynamic linear/log amplifier and an integrated computer which have all been engineered to provide the user with stable and accurate measurements of aerosol concentrations over a linearized dynamic range of 10^7. The control and data acquisition system is comprised of Hewlett-Packard components engineered to provide complete automation of the test sequence and data acquisition and reduction. This technology gives a combination of features providing a test capability consistent with established test protocols and contract requirements.

The physical concept of Dynatech Model 260 AS is presented in Figure 4. The instrument is semi-portable and housed in a steel enclosure approximately 52 x 46 x 23 inches. The initial set up of the instrument integrated with Dynatech test chamber model 222-8B is shown in Figure 5.

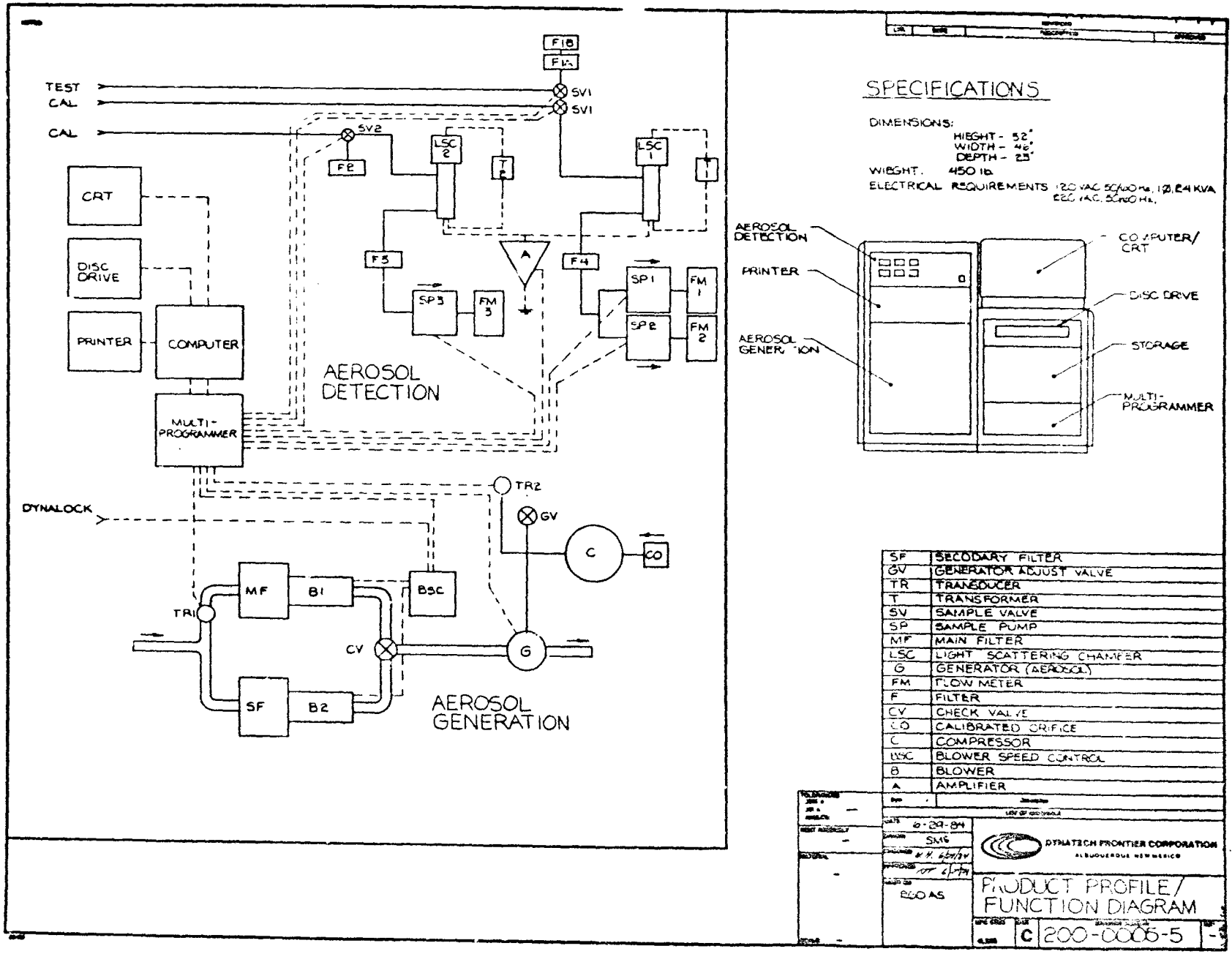

Figure 4. Product Profile/Function Diagram

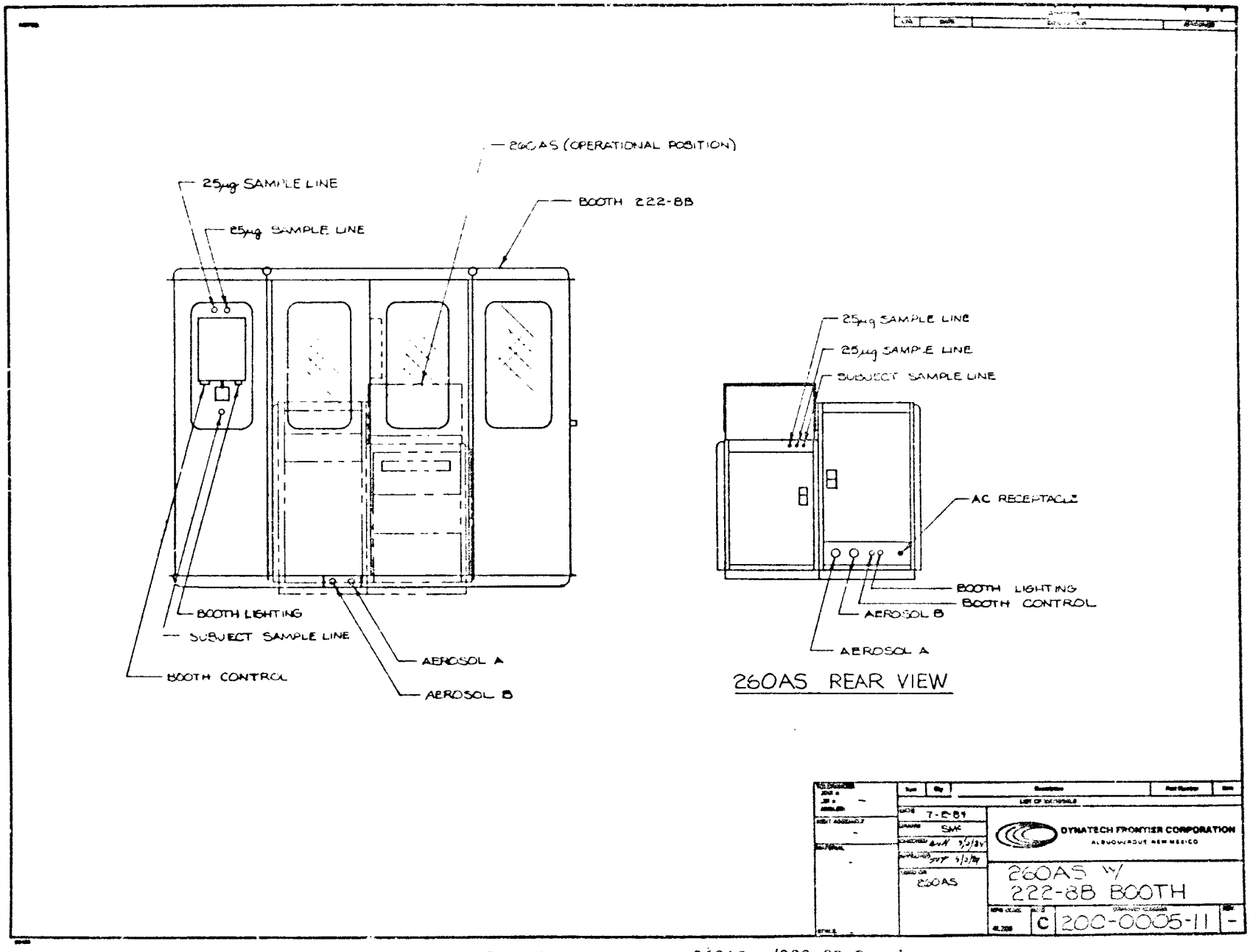

Figure 5. The Instrument 260AS w/222-8B Booth

We present below a detailed description of the system and its main components: the aerosol generation and concentration control system, the electro-optical detection system, and the control and data acquisition system.

3.1 The Aerosol Generation and Concentration Control System

The aerosol generation system (Figure 6) consists of:

- an air compressor
- pressure control valves
- generator pressure indicator and transducer
- the aerosol generator and impactor
- dilution air blower with transducer
- high efficiency air cleaning filter

These components, described below, are integrated to provide a complete pneumatic control and delivery capability.

3.1.1 The Air Compressor

The air compressor is an oiless carbon vein rotary pump which supplies low pressure air to the generator jets over a pressure range of 3 to 15 PSIG. Manual and automatic pressure adjustments are provided for the purpose of adjusting the generator pressure and obtaining aerosol concentrations in the dilution air flow of 25 ± 5 micrograms per liter. This pneumatic device is operated under a reasonably constant load to maintain cool operating temperatures and prolong its service life.

3.1.2 The Aerosol Generator

The oil mist aerosol generator consists of air jets, oil induction system, nozzle, thermal control elements and integrated impactor assembly which are contained inside the temperature controlled oil reservoir bottle, an integral part of the generator housing. Low pressure air from

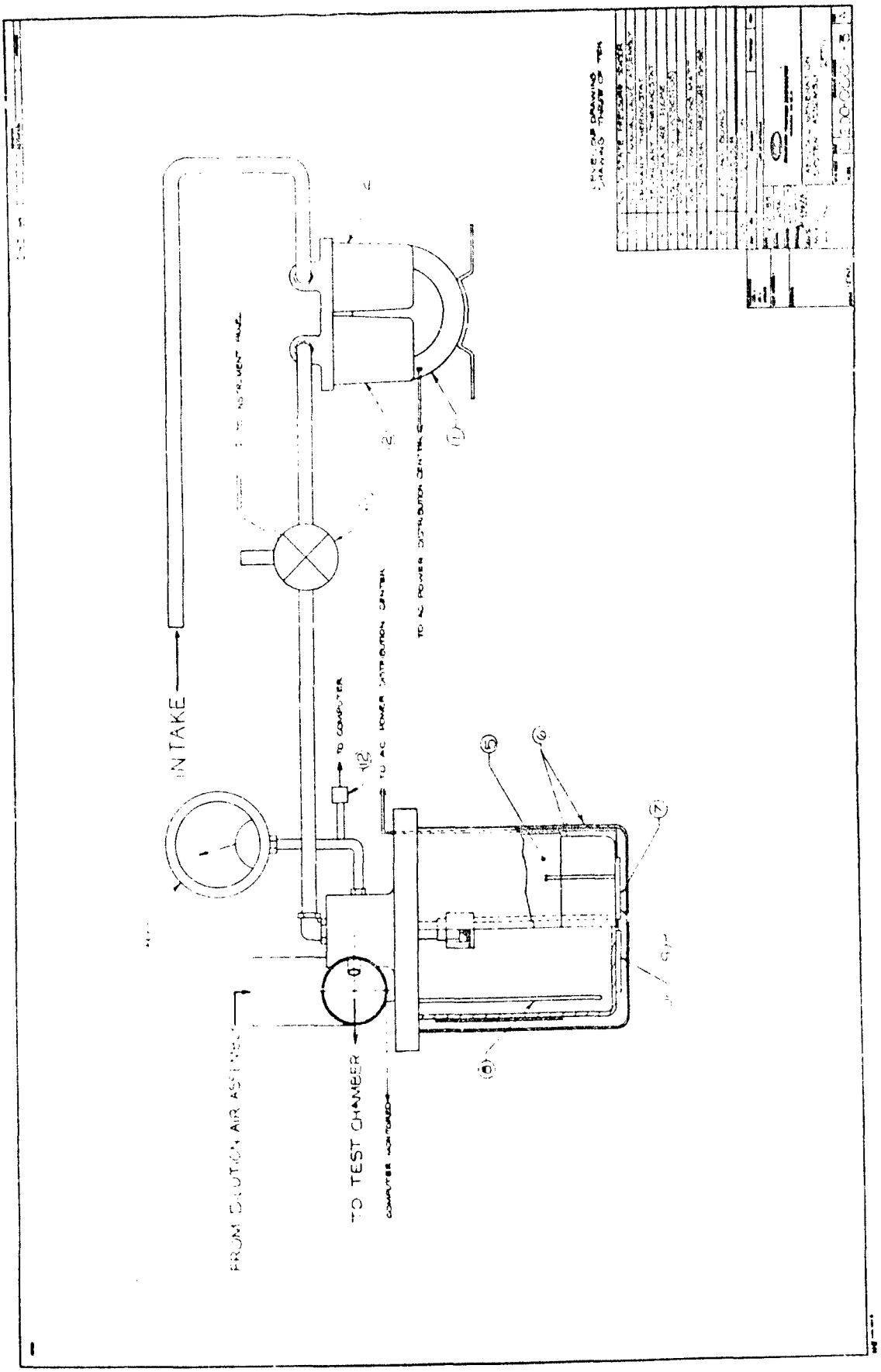

Figure 6. Aerosol Generation System Assembly

the compressor flows into the generator where the oil, which is temperature controlled at temperature not less than 20°C, is inducted and sheared off into droplets of desired size. This shearing action results from the high velocity air passing through the nozzle. These droplets of oil are carried by the airstream into the impactor assembly. Once in the impactor assembly, the streamlines of the air flow attempt to make a 90° turn to avoid the impactor plate. Particles above a certain size and mass are forced to impact upon the plate while the smaller particles remain in the airstream. This results from the inertial forces acting on the suspended oil droplets as they attempt to navigate the 90° turn. The size distribution of the particles remaining in the airstream is controlled by the nozzle to impactor plate distance and the velocity of the aerosol stream passing through the nozzle orifice. Once the aerosol leaves the impactor plate region it is carried up through the generator housing and is delivered into the dilution air conduit at a 45° angle to the dilution air streamlines. The oil droplets impact on the impactor plate, and in other areas of the generator recombine into liquid and return to the oil reservoir.

3.1.3 The Dilution Air Blowers

The dilution air blowers (Figure 7) are variable speed two-stage vacuum turbine devices with an 8 x 8 x 3 inches high efficiency filter mounted on their intake. The operating characteristics of this blower plus the improved efficiency of the new filter design results in the generation of a slight negative pressure at the blower intake which is reflected in the test chamber. A regulated power supply controls the blower speed and provides precise regulation of the dilution air flow rate. The blower output passes through an elbow flowmeter which generates a differential pressure proportional to the volume flow of dilution air. Aerosol is introduced downstream from the elbow flowmeter, at a 45° angle, just prior to the aerosol line connections on the rear quarter panel of the instrument. However, due to the angle of aerosol introduction and the temperature difference between the generator air and dilution air, impaction and coalescence may occur. Thus, a small oil trap was installed just inside the aerosol line connection on the rear panel. This trap reduces the amount of liquid

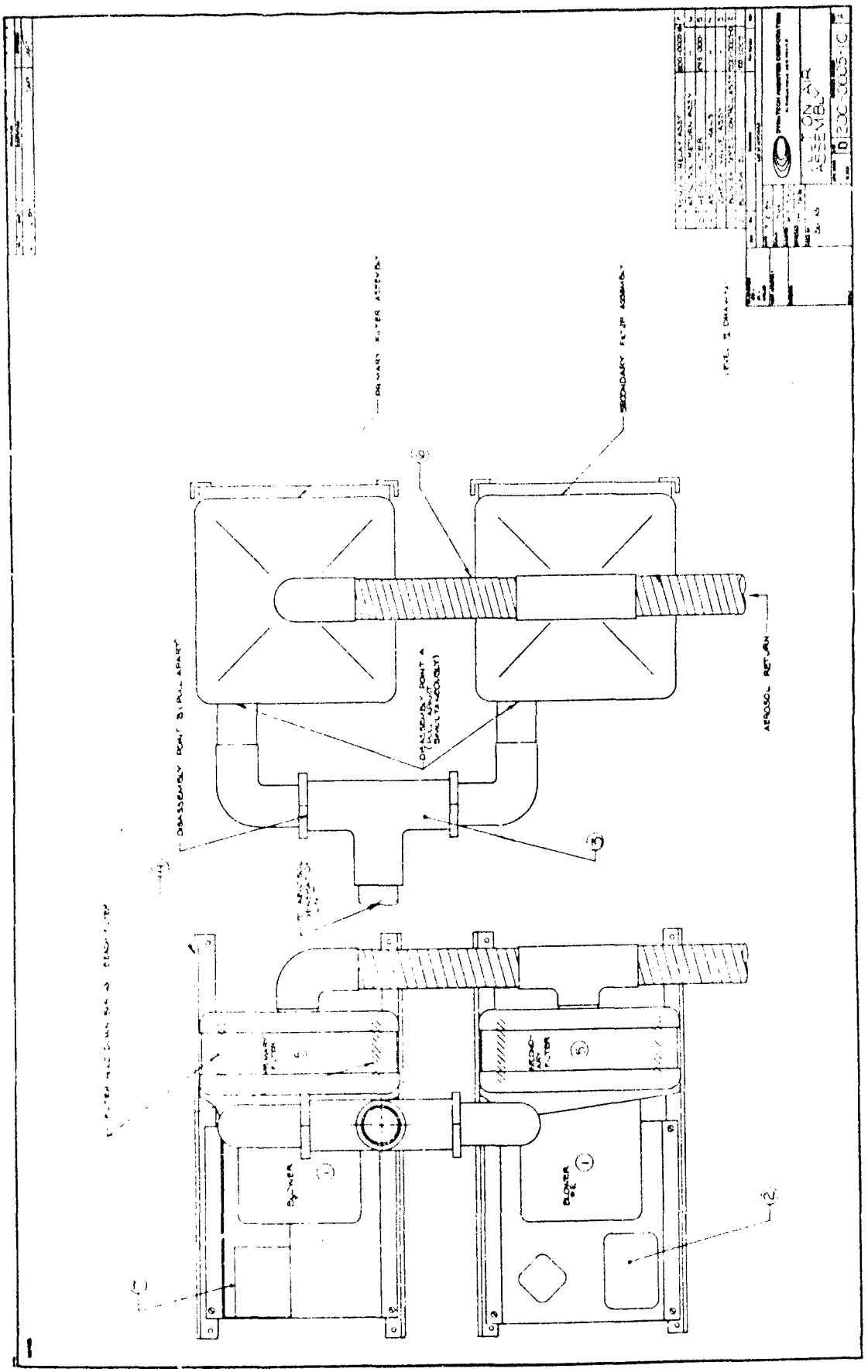

Figure 7. Dilution Air Assembly

entering the hoses which connect the instrument to its test chamber. This mixture of oil droplets and air is used to develop a test aerosol in the chamber. Once this mixture passes through the test chamber, it is returned to the instrument and cleaned by the high efficiency HEPA filter.

Blower selection is based on the differential pressure across its intake filter. Filter flow versus pressure characteristics allows for a maximum pressure point to be established which indicates an end-of-life point. When this point is reached, computer monitoring automatically shuts down the primary dilution air blower/filter assembly and activates the back-up or secondary system. This switch over is recognized by the computer and indicated on the status lamps on the front panel of the unit.

To maintain balanced dilution air flows a simple plastic switch check valve is provided on the discharge of the blower assembly thus reducing the necessity for redundant active control systems.

3.2 The Electro-Optical Detection System

The aerosol detectors, whose assembly is shown in Figure 8, are comprised of two forward light scattering chambers and a linear/logarithmic amplifier which has been specifically developed to accurately detect and measure aerosols and/or airborne particulates.

3.2.1 The Photometer

This photometer measures the relative aerosol concentrations by detecting the intensity of light scattered forward by the particles as they are drawn through the scattering chamber. The optical arrangement of the light scattering chamber is such that no light will strike the photo-multiplier dynodes unless the particulates enter the sensitive region of the chamber. An aerosol or particulate, when drawn through the chamber, must, by design, pass through the sensitive region; therefore, the light energy will be scattered forward to the detector. The intensity of the scattered light is proportional to the mass concentration of the suspended particulates. The

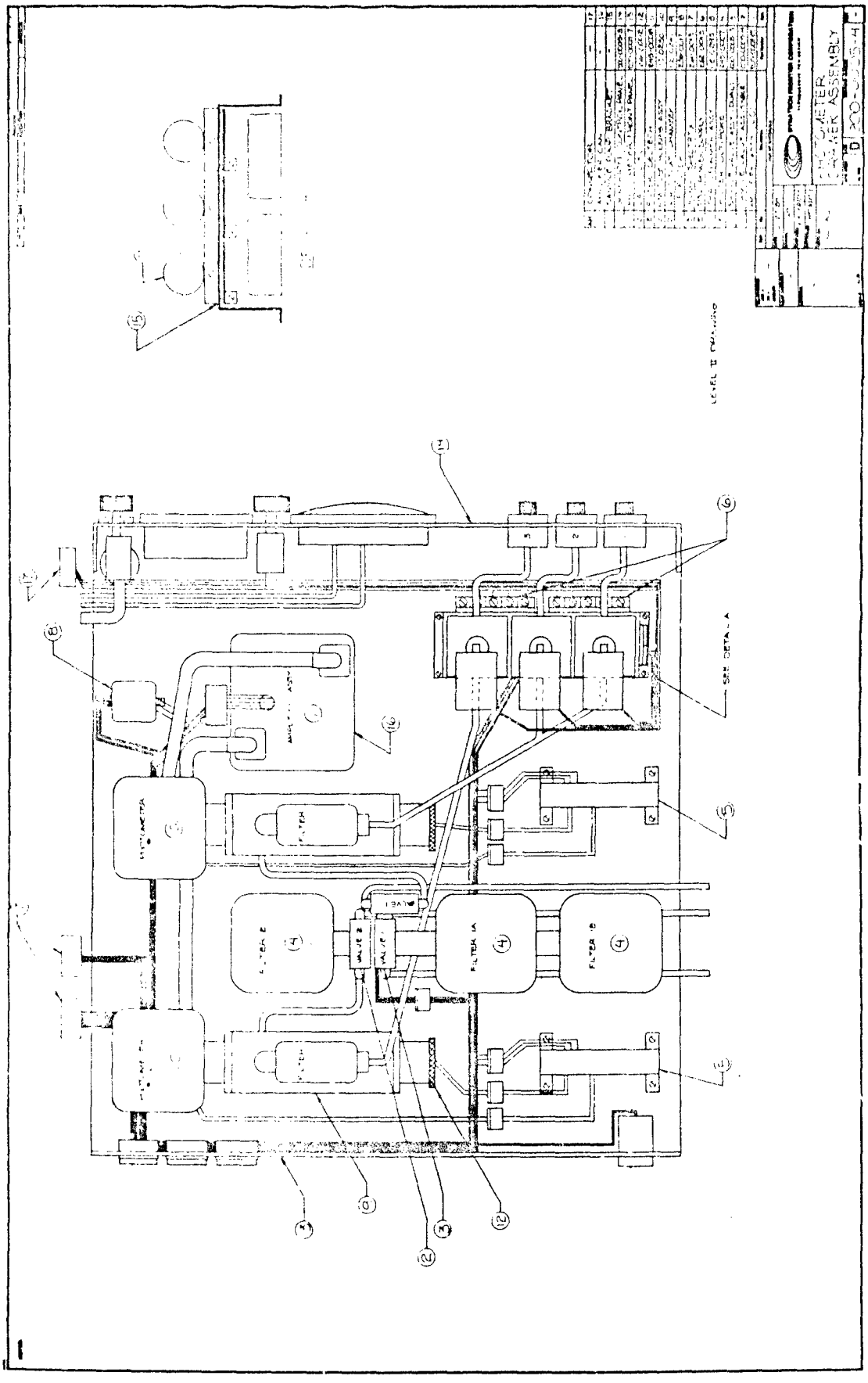

Figure 8. Photometer Drawer Assembly

photomultiplier tube signal is amplified and conditioned to provide an input signal to the computer and/or recorder indication, which is the analog of the aerosol concentration.

Based on the requirement to provide on line monitoring of the chamber aerosol concentration as well as that penetrating the breathing zone, two separate detectors were required. The first required the ability to monitor gross concentrations of 20-30 µg/liter, therefore, a simple current to voltage converter was incorporated as a signal conditioner to interface with this computer and designed to be an integral part of the amplifier section. The requirement for the second detector was somewhat more complex in that the dynamic capability was extended to 10^7. Rather than elect to enter the realm of automatic range switching which can produce errors in continuous range monitoring, a log amplifier was incorporated to establish the required dynamic range.

To increase the dynamic range of the log amplifier the signal was compressed electronically to establish the full dynamic range then re-expanded mathematically to obtain output data compatible with the ratiometric concept of QNFT. To further compensate for deviations in chamber aerosol concentrations, the linear output was used to constantly adjust ratios of challenge to breathing zone concentrations based on a fixed point of reference established with each computer calibration cycle.

3.2.2 Sampling Valves

Low impaction solenoid valves (Figures 9 and 10) are used to control the sample air through the scattering chambers of the 25µg detector (the chamber concentration detector), and the photometer (the breathing zone concentration detector). The 25µg detector has two modes of sampling; the first is sampling of the chamber concentration for test or calibration purposes, and the second is establishing a zero reference by pulling console air through two high efficiency filters at a factory set flow rate of approximately 3 litres/min to purge the light scattering chamber of the 25µg detector.

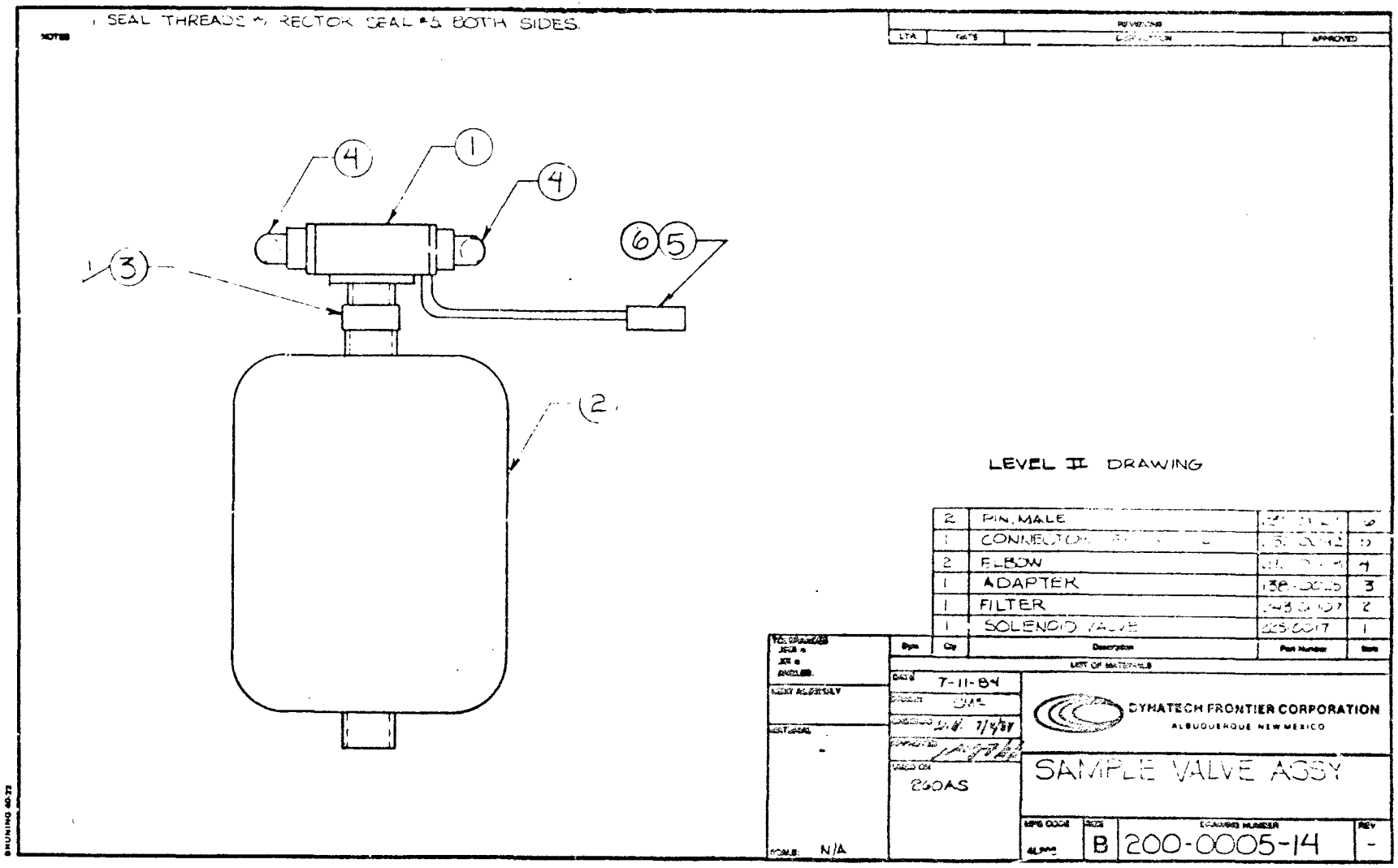

Figure 9. Sample Valve Assembly - 25ug Detector

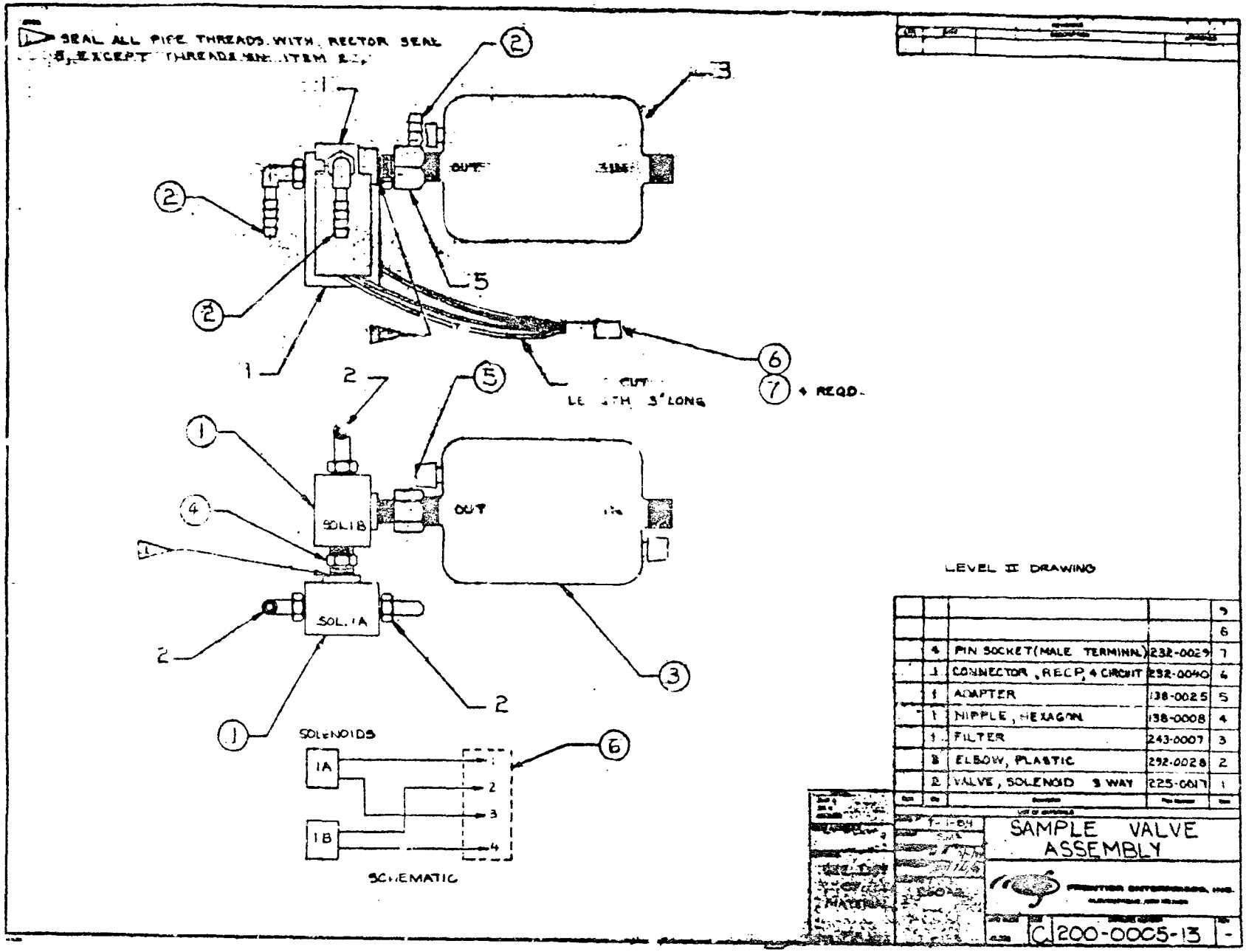

Figure 10. Sample Valve Assembly - BZ Photometer

The photometer (the breathing zone concentration detector) has three modes of sampling:

- Calibrate — samples the concentration of the test aerosol in the chamber
- Test — samples the aerosol concentration inside the respirator breathing zone
- Zero — establishes a test reference by pulling console air through two high efficiency filters to purge the light scattering chamber. This purging flow rate is factory set at approximately 6 litres/min.

3.2.3 The Linear/Logarithmic Amplifier

The linear/log amplifier, designed as an integral component of the electro-optical system, is a solid state device constructed from discrete components. The linear segment of the amplifier is connected to the 25µg detector while the logarithmic segment is connected to the breathing zone photometer. The device provides active selective signal filtration to eliminate undesirable electronic noise without removing any test related information. Other important features of this device include rapid response time, current to voltage conversion, integration of all amplifier controls and a metal enclosure to reduce the effects of stray electromagnetic interference. Combining all those features in the device design results in a dynamic range of 10^7 in signal conditioning which is necessary for measurement of fit factors up to 10^6 as required by the contract.

3.3 The Control and Data Acquisition System

The control and data acquisition system is comprised of a Hewlett-Packard personal computer, disc drive, printer, and video monitor connected to a Hewlett-Packard 3497A data acquisition system and its accessories. Presented below is a description of the components of the control and data acquisition system included in the device.

3.3.1 Hewlett-Packard 86B

The HP-86B personal computer has 128 K bytes built-in user memory that is expandable to 640K, built-in electronic disc ROM, built-in HP-IB interface, and optional local keyboards. The HP-86B BASIC, residing in an internal ROM, has all the standard BASIC commands, plus a few additional ones for such operations as printing the CRT display, counting time intervals, and reading and writing program and data files. There is also a set of graphics commands useful in graph plotting. This BASIC is relatively user-friendly and free of unexpected errors, compared to other BASICs; any combination or nesting of numerical or string operations seems to work, as long as the statement is correct syntactically. The operating system contains a standard set of commands for editing programs, loading and storing program files on discs, etc. There are special keys on the keyboard that automatically type in many of these commands. There is also a set of keys useful in editing: keys to move the cursor, delete a character, insert characters, and delete to end of line. These are convenient when making minor changes in a statement without retyping the entire statement.

3.3.2 HP-82905B

This dot matrix impact printer offers both permanent copy and fan-fold forms capability. The printer's speed (characters per second) is 80 cps peak. Column width (at 10 characters per inch) is 80 characters.

3.3.3 HP-9121 D Dual Disc Drive

This flexible disc system (540 K bytes) combines the speed of random access with low cost, removable media. This system features 3.5 inch media with a unique media protection system residing both in the disc itself and in the disc drive. The disc has a hard center for precise head placement, and consists of a protective hard polymer housing with an autoshutter contamination shield over the read/write window. The disc drive houses an auto shutter mechanism and media monitor.

3.3.4 HP 3497A Control and Data Acquisition Unit

The "mainframe" is a box with five slots for plug-in modules, plus a special slot for the DVM. It contains logic for partial instruction decoding and slot number decoding, as well as a real time clock and calendar, and some memory for data storage. It has an internal analog bus to allow the passing of an analog voltage from one plug-in module to another.

3.3.5 5 1/2 Digit DVM (Option 001)

The DVM has four ranges, the lowest being 0.1 volt, 6 digit resolution max, triggering either internally, through software, or by a pulse into a rear jack; input voltage is either via the mainframe analog bus or into the rear binding posts. The cage is left ungrounded to allow it to be connected to the thermocouple "guard" lead (through the relay multiplexer).

3.3.6 20 Channel Relay Multiplexer (44422A) With Thermocouple Compensation

Each channel consists of a high, low, and guard. The multiplexer is also used as a voltage measurement instrument. When a channel is switched or closed, it is connected directly to the analog bus of the 3497A. On the board the channels are labeled A0-A9 and B0-B9. When the module is in slot 4, these correspond to channel numbers 20 to 39. Voltage measured on channel B9(39) is used as a reference voltage for thermocouple temperature cold junction compensation, (already programmed) in the software.

3.3.7 Actuator/Digital Output Assembly (Option 110 44428A)

This module consists of 16 wetted form C (single pole-double throw) relays. Each relay can be individually closed and can safely switch one amp at 100 volts, making this assembly ideal for switching power to (actuating) multiple external devices. The 44428A relays were specially selected for "bounceless" switching, allowing the assembly to be used as a 16 bit wide digital output.

3.3.8 Analog Output Module (D/A Converters) (44429A)

Each module is a dual unit. Output range is -10 V. to 10v. at 15 mA. Resolution is 2.5 mv., i.e., the output changes in steps of 2.5 mv. The unit has separate voltage sense terminals for situations in which there is voltage drop in the output lines.

3.3.9 Interface

HP-IB is basically an IEEE-488 parallel bus. The extender cable may be used to interface a second device, such as the printer or the dual disc drive to the HP-86B through the same interface board. The 3497A scanner unit is factory wired with a device address of 09; if two scanners are used, the address of one of them would have to be modified.

3.4 The Test Chamber

The test chamber provides the interface of Dynatech Model 260 AS and the respirator system under evaluation. The connections between the instrument and the chamber which include aerosol hoses and electrical interfacing, result in a system capable of preventing excessive loss of test aerosols and a rapid establishment of the test environment. The chamber is provided with interface connections for sampling aerosols in both the test chamber and the breathing zone. A computer controlled annunciator system (Figure 11) was built into the booth to continuously communicate visually with the test subject while performing the test. The annunciator panel consists of different prepared messages that may be lighted sequentially to convey different instructions to the test subject. Another annunciator panel (Figure 12) was built in the air lock adjacent to the inside chamber door including permanently lighted instructions to the test subject to prepare him to enter the test chamber. The chamber mainframe was constructed of durable fiberglass with a gel coat intersurface which lends itself to easy cleaning and maintenance. The integration of an air lock compartment into the chamber enhanced the necessary integrity of the chamber to contain the test aerosols at stable concentration during respirator evaluation.

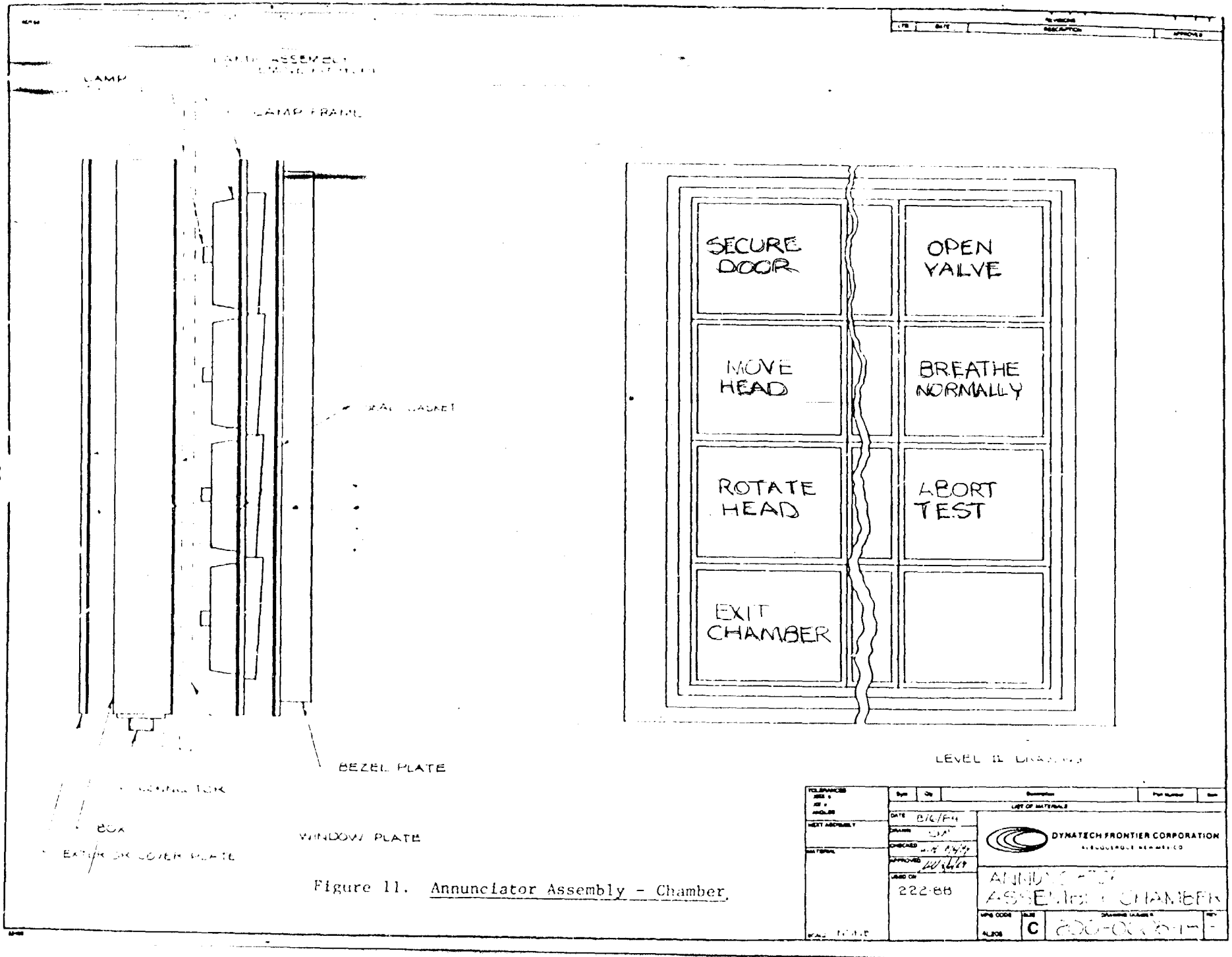

Figure 11. Annunciator Assembly - Chamber

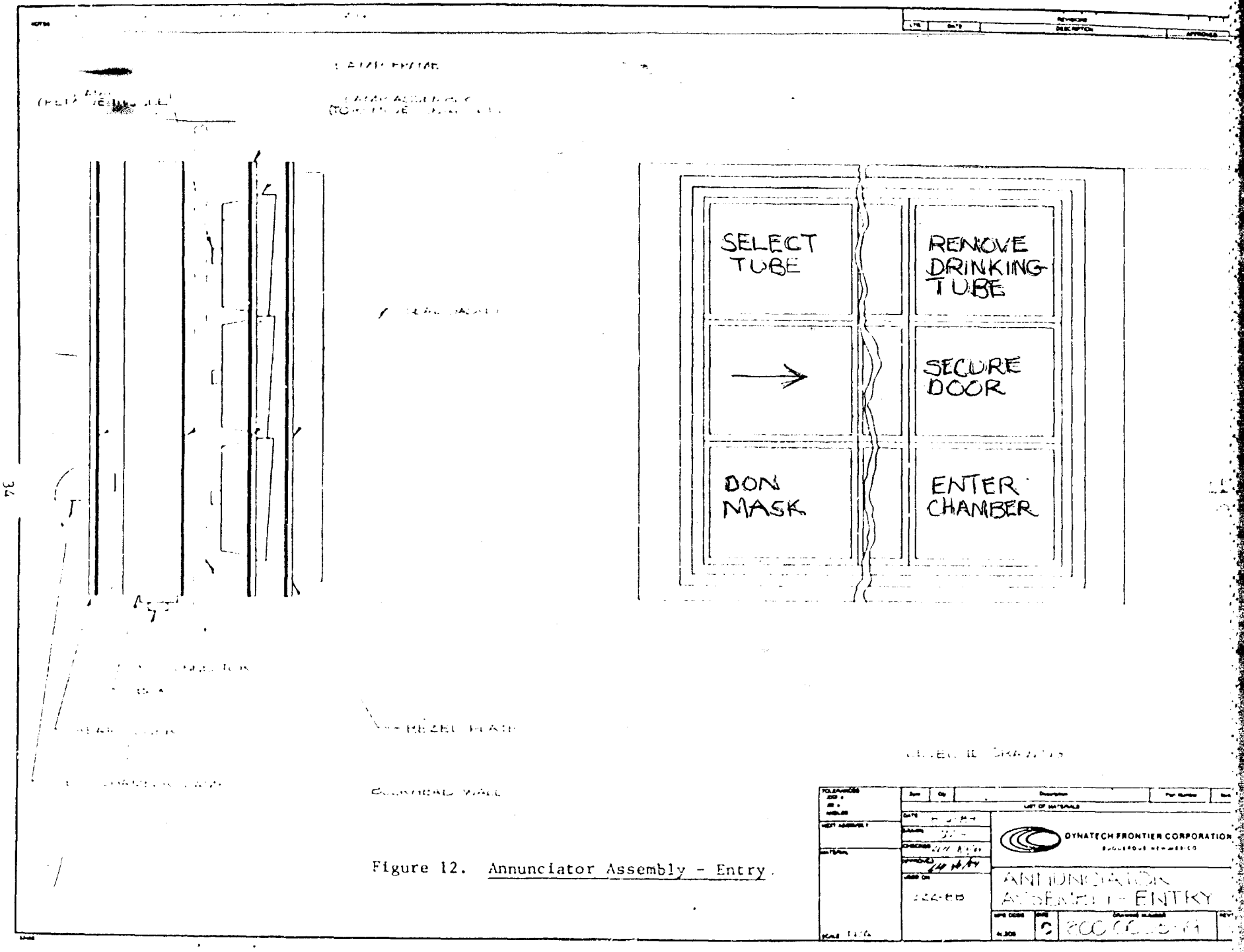

Figure 12. Annunciator Assembly - Entry.

The development of a complete homogeneous aerosol concentration was realized by optimized inlet diffusers design, and by the use of two mixing fans which were installed near the point of aerosol entry.

Chapter 4

SYSTEM PERFORMANCE TESTS RESULTS AND DISCUSSIONS

System compliance to design specifications outlined in the Air Force Contract #F33615-83-C-0650 and approved at the critical design review meetings was established by incorporating a series of performance tests in accordance with the system test plan/procedures. These tests were designed to analyze the performance of the subsystems for functional variations and stability under different ambient conditions of temperature, humidity, ambient aerosol concentrations, and atmospheric pressure. Each of these tests served to investigate a few items of the system's test plan and procedures.

Below is a description and discussion of the subsystems' performance tests and results, grouped in two major groups: the first group contains the performance tests for the aerosol generation systems; the second group contains the performance tests for the chamber and the electro-optical detection systems. All tests were performed using the instrument's control and data acquisition system. Thus, the results represent the performance tests of all the major subsystems of the instrument.

4.1 Aerosol Generation/Dilution Air System Tests:

Aerosol size distributions in the chamber were measured at different operating conditions to verify that the aerosol generation system is in compliance with the approved design criteria. Two independent measurement techniques were utilized to perform these measurements. The first technique utilized photometry and inertial impactors to obtain the mass distribution and the mean mass aerodynamic diameter in the chamber. Inertial impactors sized at 0.2, 0.5, 1.5, and 3μ were used to obtain the mass distribution which was assumed to be a log normal one. The second technique utilized laser spectrometry (PMS Model LAS-X) to measure both

particle size distribution, and mean particle size by count. This gives us a verification for the inertial impactors data and establishes our compliance with the requirement that the particles are less than 2μm in diameter, and the geometric standard deviation of ≤ 2.0.

An important design parameter that was investigated prior to the generator design is the influence of heating the corn oil on the aerosol size distribution by count at two different aerosol temperatures (20°C and 40°C) using two different aerosol generators. The results of tests on the two generators are presented as cumulative log normal distribution in Figures 13 and 14. Both figures clearly show that heating the corn oil from 20°C to 40°C has no effect on the aerosol size distribution. Thus, we elected to use corn oil at 20°C temperature for aerosol generation when we proceeded with the design of the instrument's aerosol generator. The results of the performance tests on our aerosol generator are presented below.

Figures 15 depicts the particle mass size distribution in the chamber using the inertial impactors and photometry techniques. Two different experiments are presented in the figure: the first one is performed at ambient conditions of 20°C and 30% RH, the second one is performed at 22°C and 49% RH. The mean mass aerodynamic diameters for the two experiments were 0.34 and 0.38 respectively, which is well within our specified size of 0.35 ± 0.05μ at the normal operating conditions. The results in Figure 15 show an increase in the mean mass aerodynamic diameter with an increase in ambient relative humidity.

Figure 16 gives the aerosol size distribution by count at normal operating conditions in the chamber (6 psig generator pressure and 5 cfm dilution air flow). The experiment was performed at ambient conditions of 22°C temperature and 49% RH, and yielded a mean particle size by count of 0.33μ, compared to 0.38μ yielded by the initial impactor at the same ambient conditions. This gives a standard deviation of 1.23 between the mean mass aerodynamic diameter (inertial impactor data), and the mean count particle

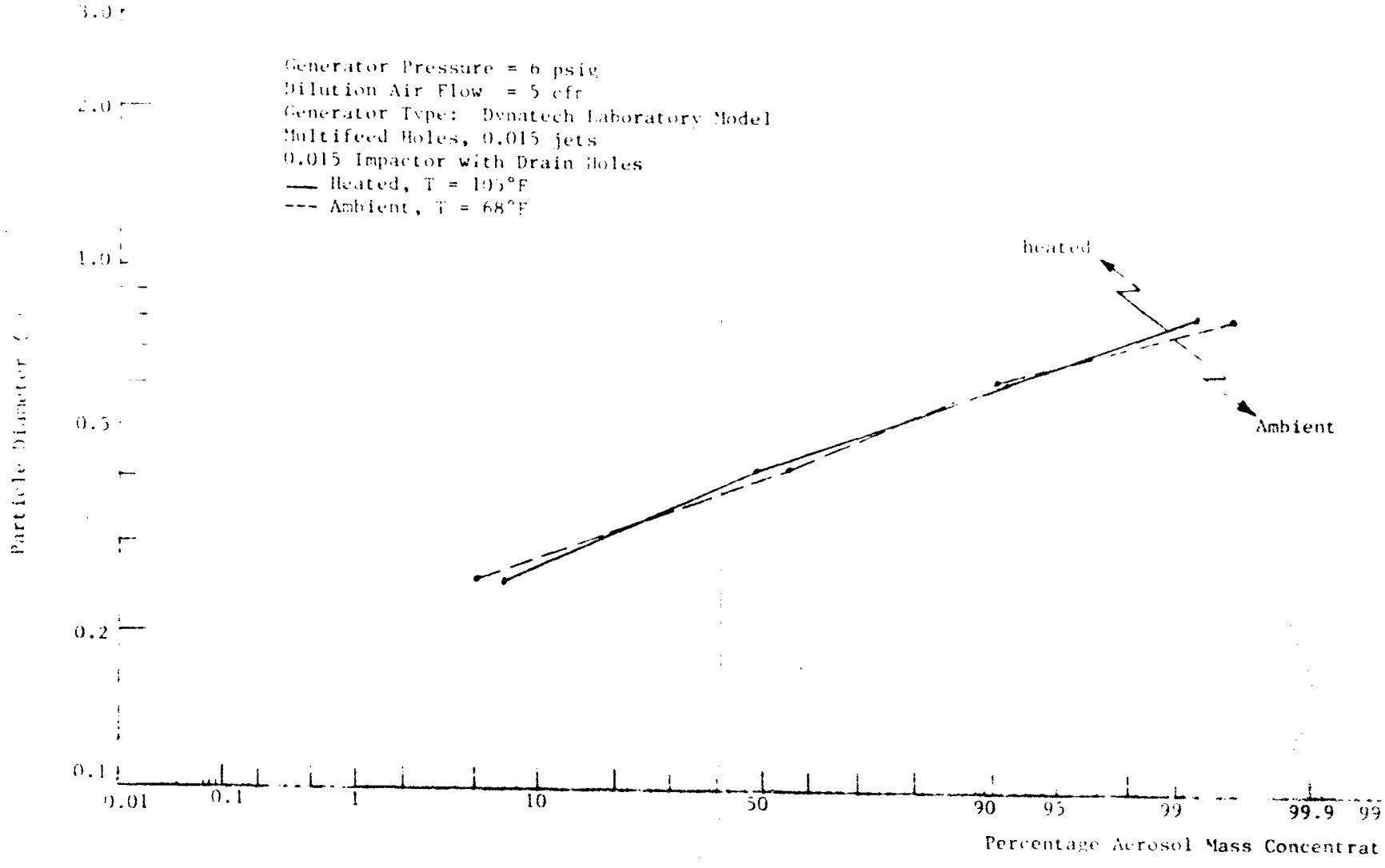

Figure 13. Effect of Heating the Corn Oil on Aerosol Mass Size Distribution

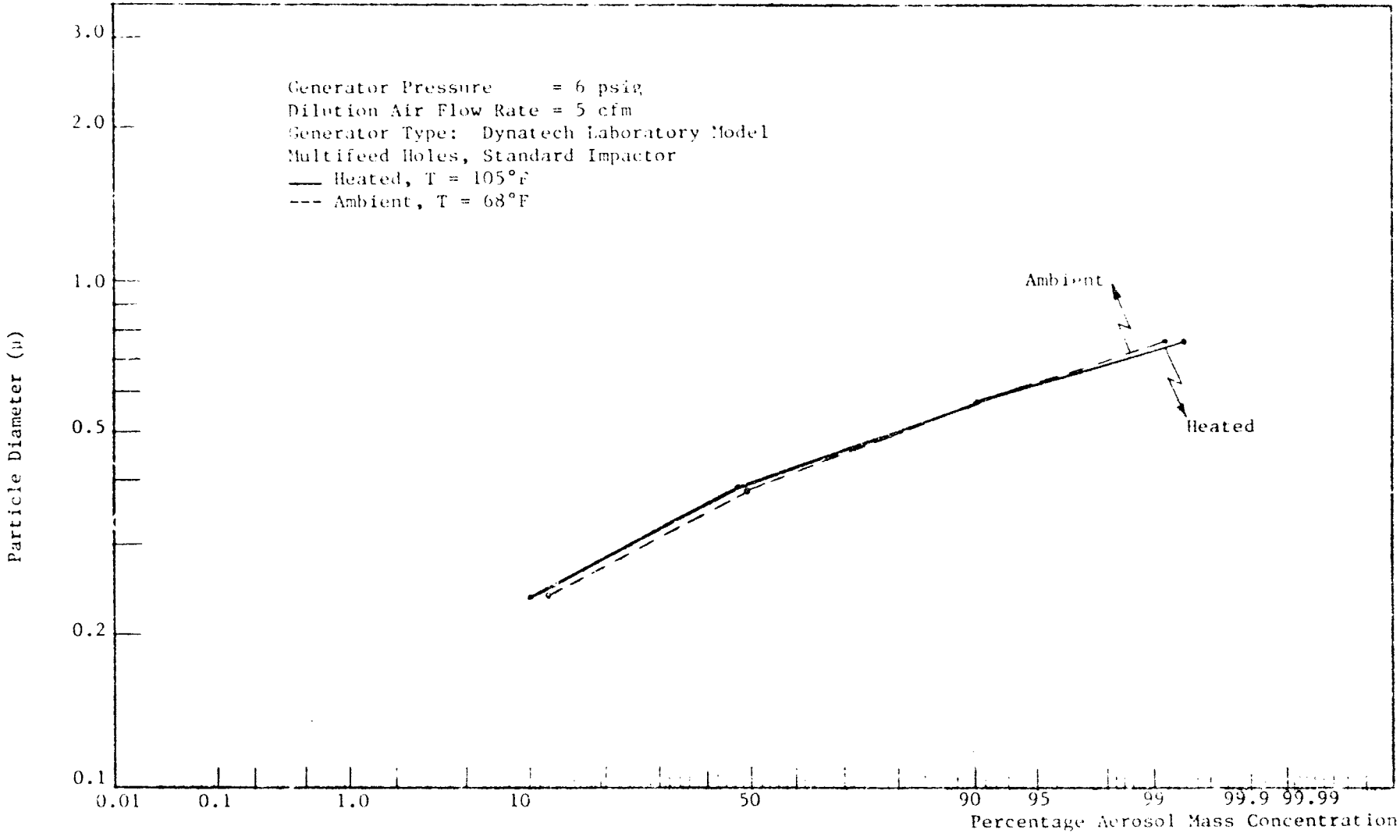

Figure 14. Effect of Heating the Corn Oil on Aerosol Mass Size Distribution

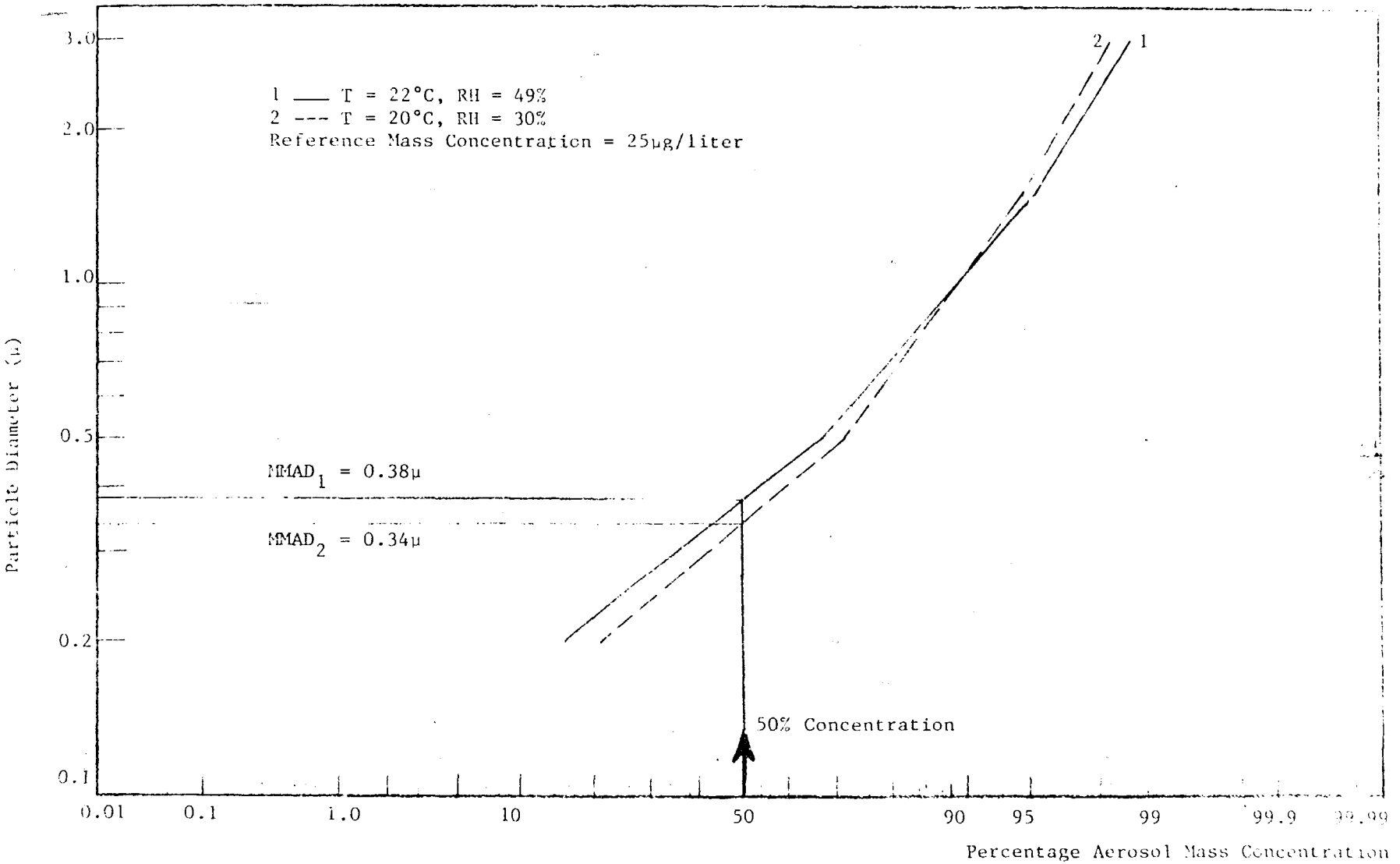

Figure 15. Aerosol Mass Size Distribution Using Inertial Impactors

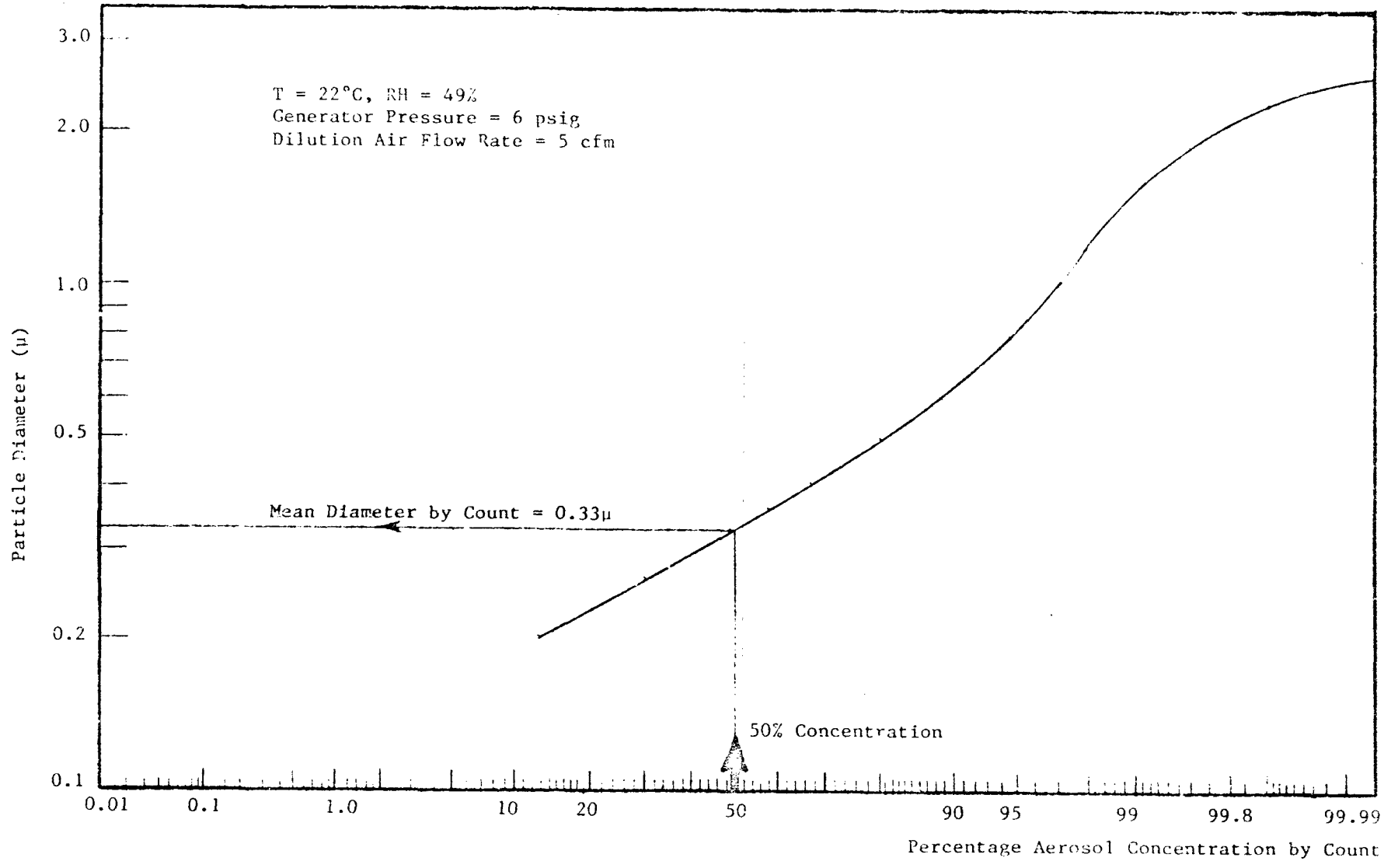

Figure 16. Aerosol Size Distribution Using Particle Counter (PMS Model LAS-X)

diameter (laser spectrometer data). The results in Figures 15 and 16 clearly show the instrument's compliance to the requirement of mean aerosol particle size of 0.35 ± 0.05μ at normal operating conditions. Figure 14 also shows that 99.85% of the particles by count is less than 2μ in diameter which is another contract requirement. This also is illustrated in Figure 17 which shows the number of particles at each size range for the same experiment whose results plotted in Figure 16.

The effect of increasing the generator pressure on the aerosol size distribution can be best illustrated by Figure 18 which shows the cumulative size distributions for generator pressures of 5, 6, and 15 psig for the same dilution air flow of 5 cfm and the same ambient conditions of 22°C temperature and 49% relative humidity. The figure shows that increasing generator pressure increased the mean particle diameter by count from 0.31μ at generator pressure of 5 psig to 0.57μ at generator pressure of 15 psig. The Figure also shows that the number of small aerosol particles decreased as generator pressure increased; though over 99% of the particles were less than 2μ in diameter in all cases. These results justify our selection for the generator operating pressure of 6 psig which gives us the required mean aerosol size with the required distribution and standard deviation.

4.2 Chamber/Optical Detection System Tests:

We describe in this section a group of tests that have been performed on the chamber to investigate aerosol uniformity, concentration, stability, and spatial distribution in the chamber at different operating conditions. These tests were used as a means to set up the instrument operation parameters and to verify the instrument's compliance to design specifications. The measurements were performed using the instrument's electro-optical detection system, and the control and data acquisition system. Thus, they also served as a check for these systems.

Uniformity of aerosol mass concentration in the chamber has been verified by remote single point sampling utilizing a 3X3X6 matrix under steady state conditions. Mass concentrations were detected photometrically

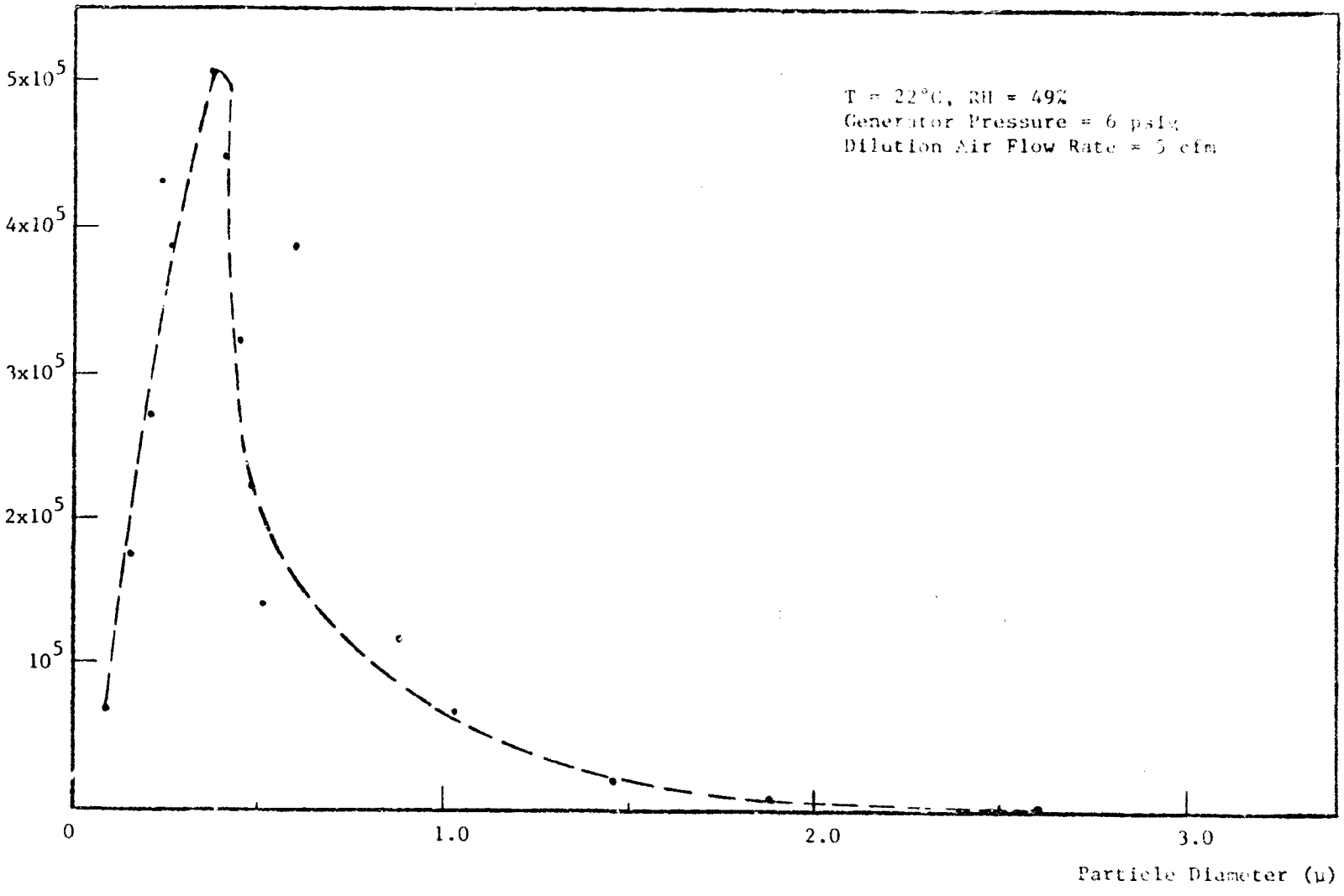

Figure 17. Particle Size Distribution Using Particle Counter (PMS Model LAS-X)

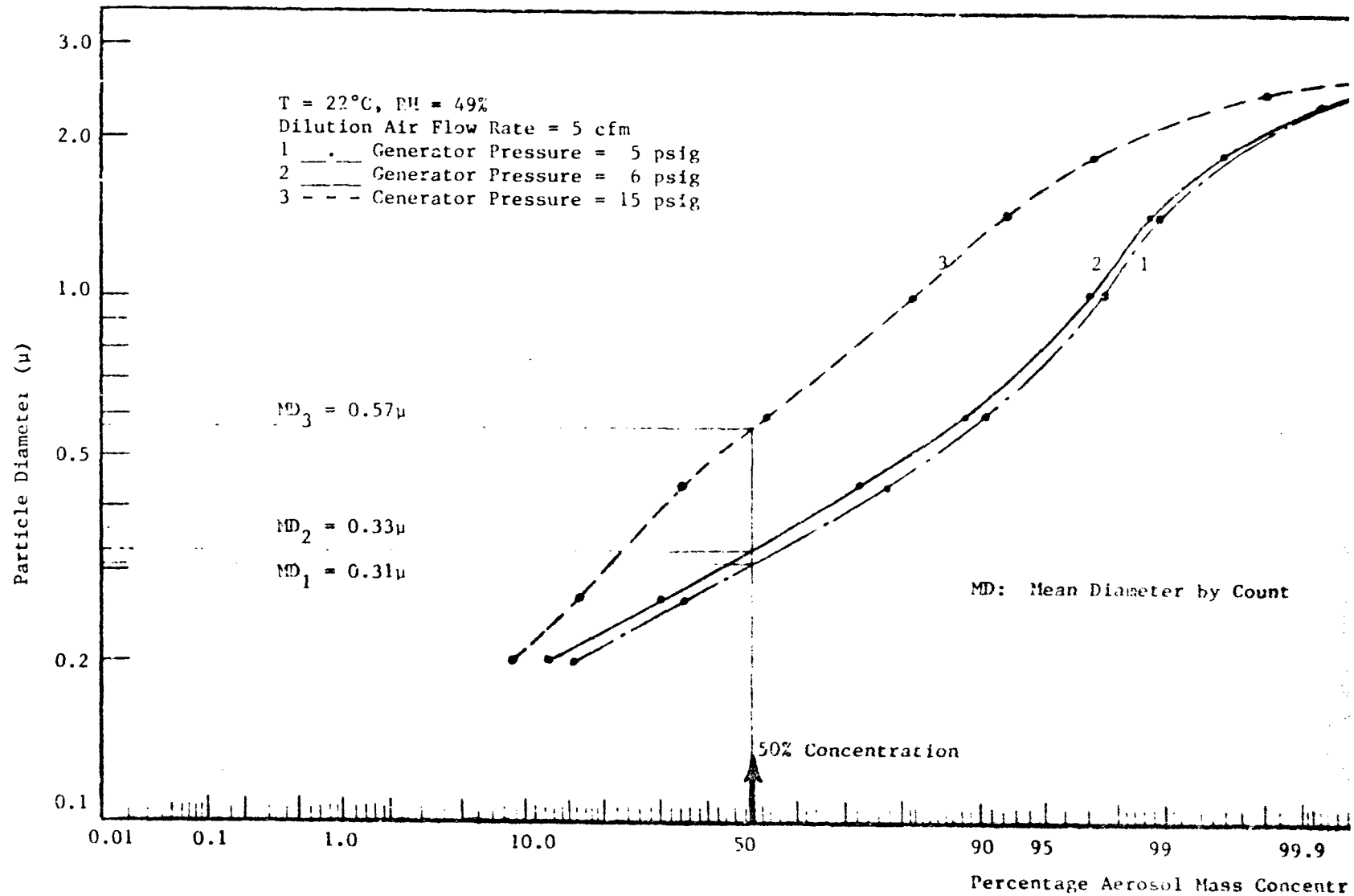

Figure 18. Aerosol Size Distribution Using Particle Counter (PMS Model LAS-X)

using the 25µg detector. A 6 inch boundary layer at the chamber wall was excluded from the matrix, but all volume envelope normally occupied by the test subject was included. Figure 19 shows a schematic of the test area with the locations and numbers of all test points in the matrix. The chamber mapping utilizing the 3X3X6 matrix has been performed three times at different ambient conditions. Table 1 gives the direct measurements at each mapping point for the three tests. The table shows the average chamber concentration reading for each test C_a, the maximum positive and maximum negative; and the average percentage deviation from the average reading for every test. The table also shows that the average percentage deviation in the aerosol mass concentration is within the 1% limit required in the contract.

Another group of ten tests were performed at different environmental conditions to establish the steadiness of the aerosol mass concentration in the chamber. Aerosol mass concentrations were monitored by single point photometric sampling using the 25µg detector. The sampling point was at the center of the chamber and 12" from the top. Test duration was more than two hours with readings indicating the chamber concentrations being recorded every ten minutes. A summary of results is shown in Table 2. The table shows that the aerosol mass concentrations in the chamber were uniform and steady for all the tests at different environmental conditions. For each test, the maximum positive and maximum negative percentage deviations from the average chamber mass concentrations were in the order of 1%. These deviations are much lower than the 10% variation in concentration allowed in the contract specifications.

We also performed several tests to check the steadiness of the aerosol mass concentration on the chamber within a one minute period and within a three minute period. We utilized the same technique mentioned in the previous paragraph with a recording freqdency of five seconds instead of ten minutes. We used both the 25µg detector and the breathing zone photometer to measure the chamber concentration in these tests. All the tests showed the aerosol chamber concentration to be steady with deviations in the order of 2% for all of the tests.

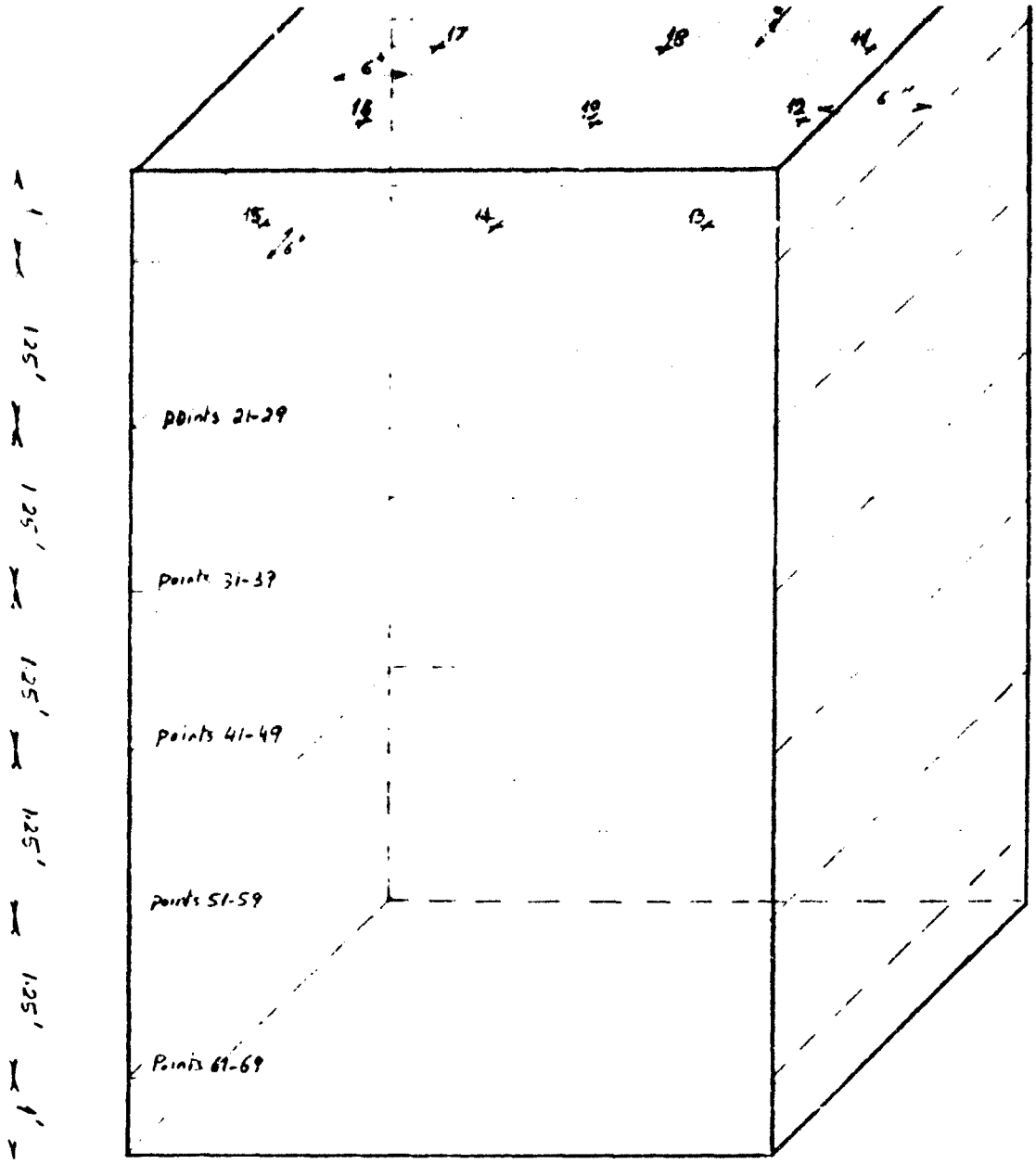

Figure 19. Mapping Locations in the Chamber

Table 1.3X3X6 CHAMBER MAPPING AT DIFFERENT ENVIRONMENTAL CONDITIONS

TEST POINT	CHAMBER CONCENTRATION READING USING 25µg DETECTOR (VOLTS)		
	Test #1 T = 22°C & RH = 7% & BP = 622 mm Hg	Test #2 T = 22°C & RH = 42% & BP = 622 mm Hg	Test #3 T = 23°C & RH = 94% & BP = 622 mm Hg
11	6.124	6.194	6.140
12	6.068	6.118	6.140
13	6.081	6.133	6.124
14	6.081	6.142	6.129
15	6.088	6.129	6.141
16	6.088	6.105	6.137
17	6.068	6.124	6.139
18	6.087	6.118	6.151
19	6.087	6.120	6.152
21	6.146	6.194	6.201
22	6.068	6.107	6.136
23	6.070	6.125	6.142
24	6.082	6.121	6.123
25	6.078	6.120	6.139
26	6.093	6.117	6.118
27	6.096	6.122	6.112
28	6.102	6.143	6.122
29	6.097	6.107	6.123
31	6.182	6.200	6.195
32	6.136	6.120	6.130
33	6.138	6.145	6.154
34	6.142	6.126	6.135
35	6.149	6.143	6.157
36	6.136	6.127	6.140
37	6.125	6.128	6.132
38	6.157	6.132	6.160
39	6.131	6.146	6.137
41	6.190	6.184	6.221
42	6.117	6.132	6.144
43	6.126	6.155	6.130
44	6.133	6.150	6.124
45	6.126	6.129	6.114
46	6.137	6.139	6.131
47	6.126	6.126	6.142
48	6.144	6.117	6.127
49	6.145	6.114	6.128

Table 1. (Continued)

TEST POINT	CHAMBER CONCENTRATION READING USING 25µg DETECTOR (VOLTS)		
	Test #1 T = 22°C & RH = 7% & BP = 622 mm Hg	Test #2 T = 22°C & RH = 42% & BP = 622 mm Hg	Test #3 T = 23°C & RH = 94% & BP = 622 mm Hg
51	6.193	6.192	6.172
52	6.141	6.136	6.105
53	6.149	6.128	6.101
54	6.146	6.124	6.106
55	6.142	6.126	6.106
56	6.145	6.111	6.123
57	6.147	6.121	6.129
58	6.153	6.117	6.130
59	6.162	6.122	6.134
61	6.186	6.194	6.222
62	6.119	6.109	6.137
63	6.137	6.121	6.150
64	6.143	6.106	6.147
65	6.117	6.107	6.167
66	6.132	6.120	6.150
67	6.132	6.115	6.153
68	6.125	6.112	6.131
69	6.132	6.116	6.112
Average Chamber Concentration Reading (Volts)	6.125	6.132	6.140
Percentage Deviation from the Average Reading	+0.6% -1.39%	+1.11% -0.44%	+1.3% -0.57%
Average Percentage Deviation	0.99%	0.78%	0.94%

Table 2. "STABILITY OF CHAMBER CONCENTRATION AT DIFFERENT AMBIENT CONDITIONS"

TEST [illegible]	TEMPERATURE °C	RELATIVE HUMIDITY (%)	BAROMETRIC PRESSURE (mm Hg)	DURATION OF TEST (min)	NUMBER OF READINGS	TIME PERIOD BETWEEN READINGS (min)	25 ppm DETECTOR AVERAGE READING FOR CHAMBER CONCENT (VOLTS)	MAX [illegible] % DEVIATION	MAX NEGATIVE % DEVIATION
1	4.5	3	622	150	16	10	6.392	0.59%	-0.47%
2	7.1	7	622	170	18	10	6.442	0.66%	-1.12%
3	6.1	42	622	160	17	10	6.174	0.50%	-0.37%
4	7.8	92	622	180	19	10	6.175	0.81%	-0.53%
5	20.4	7	622	120	13	10	6.467	0.99%	-1.23%
6	19	42	622	130	14	10	6.448	0.86%	-1.35%
7	22	97	622	120	13	10	6.395	0.78%	-0.47%
8	42.5	6	622	160	17	10	6.365	0.83%	-0.52%
9	40.1	46	622	140	15	10	6.399	0.58%	-0.47%
10	39	97	622	170	18	10	6.281	1.4%	-1.27%

This served to verify our compliance to the requirement that the percentage variation in aerosol concentration should not exceed 10% of the mean value of chamber concentration during the quantitative fit testing of each subject.

The influence of the "RAPID START" mode on the build up of chamber concentrations has been documented in Figure 20 which shows the chamber concentration versus time for two cases; the first was following 2 minutes, 45 seconds of "RAPID START" operation and the second was when no "RAPID START" was used. The figure clearly suggests that employing the "RAPID START" in our experimental procedure was necessary for the chamber concentration to reach its steady state value in a time period less than the required 10 minutes from the cold start of the system.

The "RAPID START" mode under the name of "DYNALOK" was also employed during the test to compensate for any perturbation in chamber concentration due to opening or closing the chamber door during tests. Figure 21 shows that using "DYNALOK" mode for a time period of 20 sec when opening and closing the door helps to keep the chamber aerosol concentration at a steady value. However, the figure also shows that the perturbations in aerosol concentrations when not employing "DYNALOK" was far below the 10% limit in concentration variation required for the instrument's design. This is obviously due to the use of an air lock in the chamber.

We performed two different experiments (Figure 22) to estimate the time required to purge the chamber of the aerosol under different operating conditions. In the first experiment, the generator was turned off while the dilution air flow was kept on. We monitored aerosol concentration decay in the chamber using the 25µg detector. Complete purge of the chamber was accomplished in less than two hours. The second experiment started with both aerosol generator and dilution air flow turned off for 3 hours. Chamber concentration decayed only to about 35% of its original value during this period. Then dilution air flow was turned on, and the chamber purge was completed in the next two hours. Thus, it was our conclusion that turning

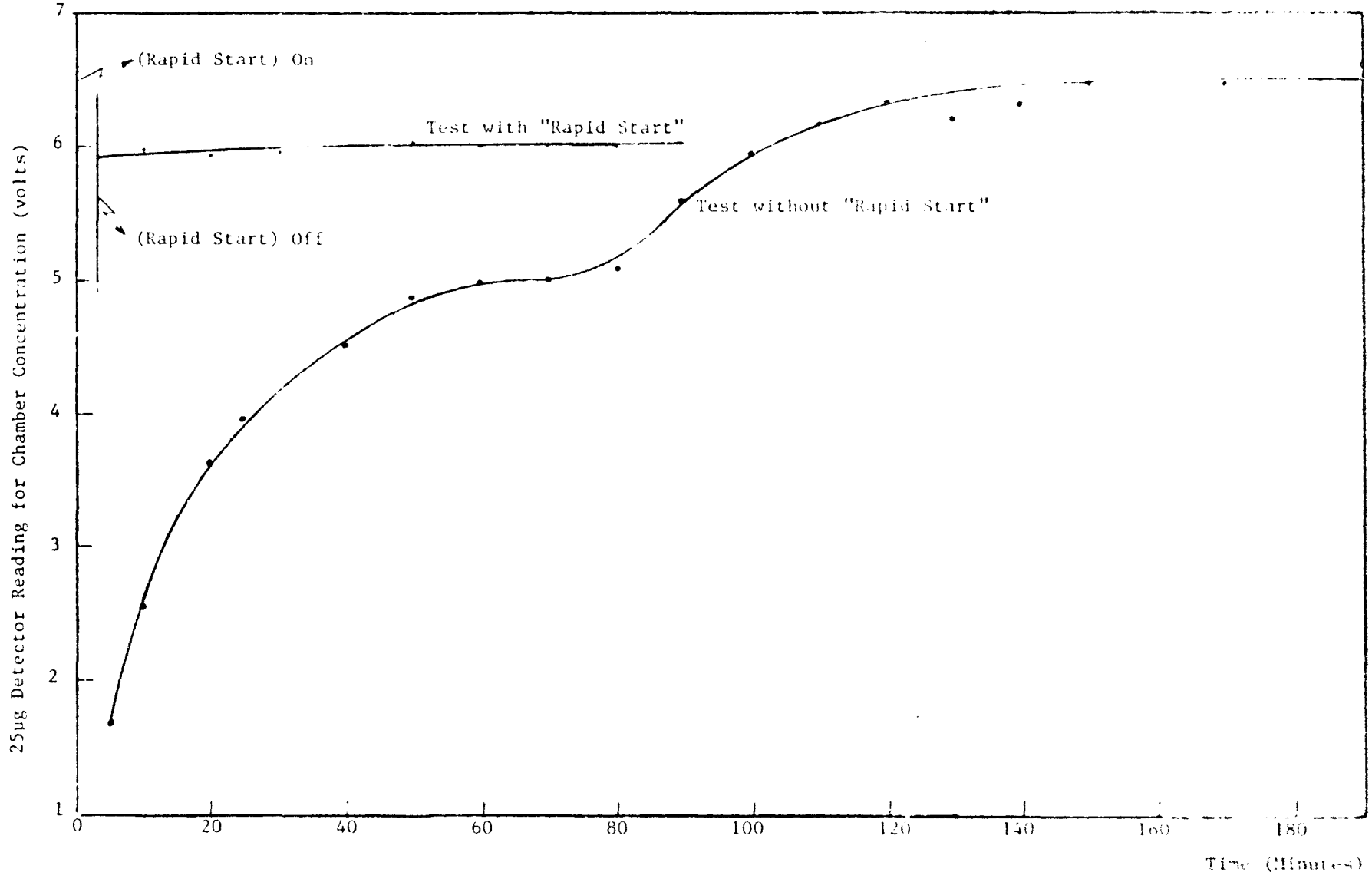

Figure 20. Influence of "Rapid Start" on Build-Up of Chamber Concentration

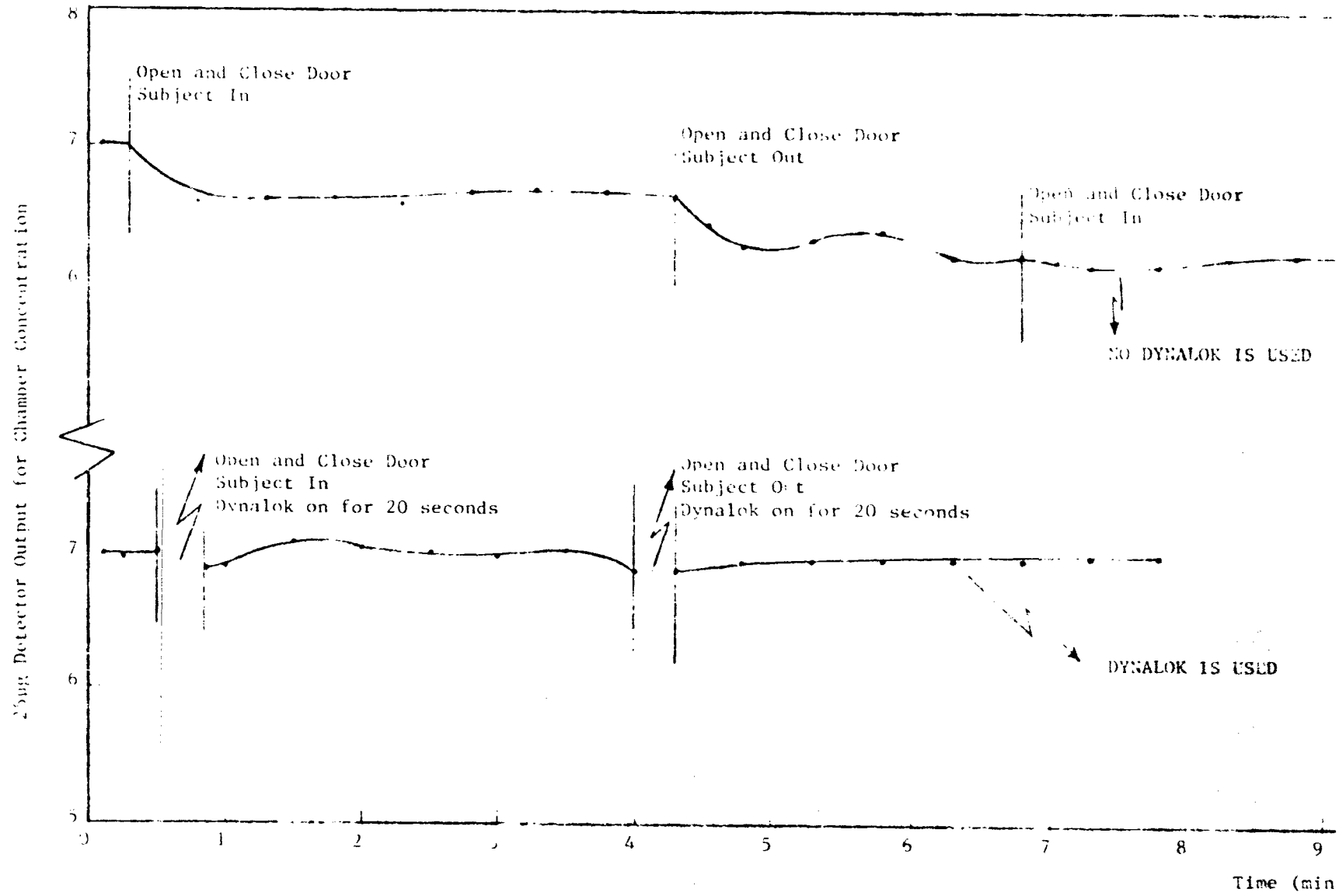

Figure 21. Recovery of Perturbation in Chamber Concentration With and Without "DYNALOK"

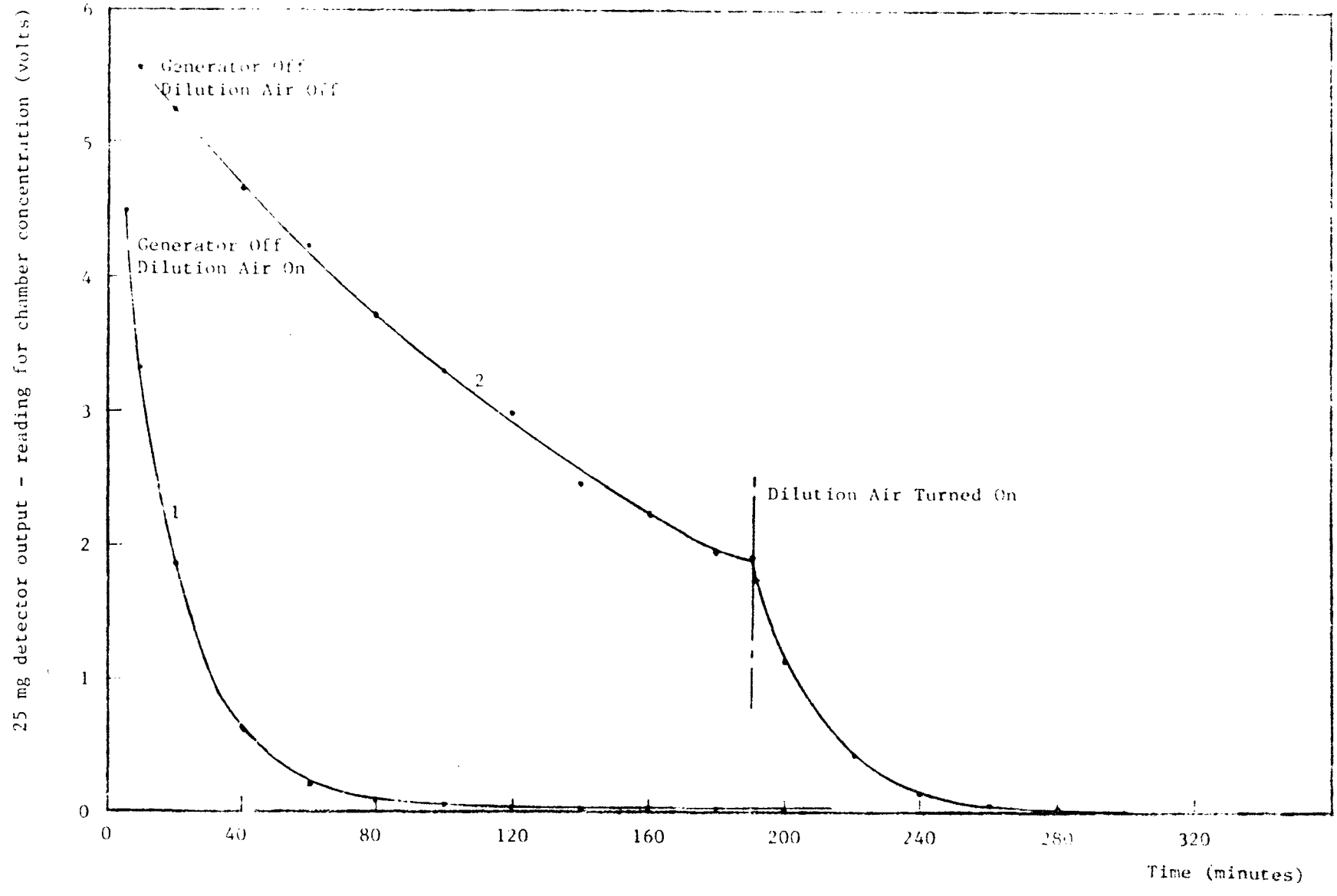

Figure 22. Chamber Concentration Decay Using Two Different Mechanisms (Estimation of Chamber Purge Time)

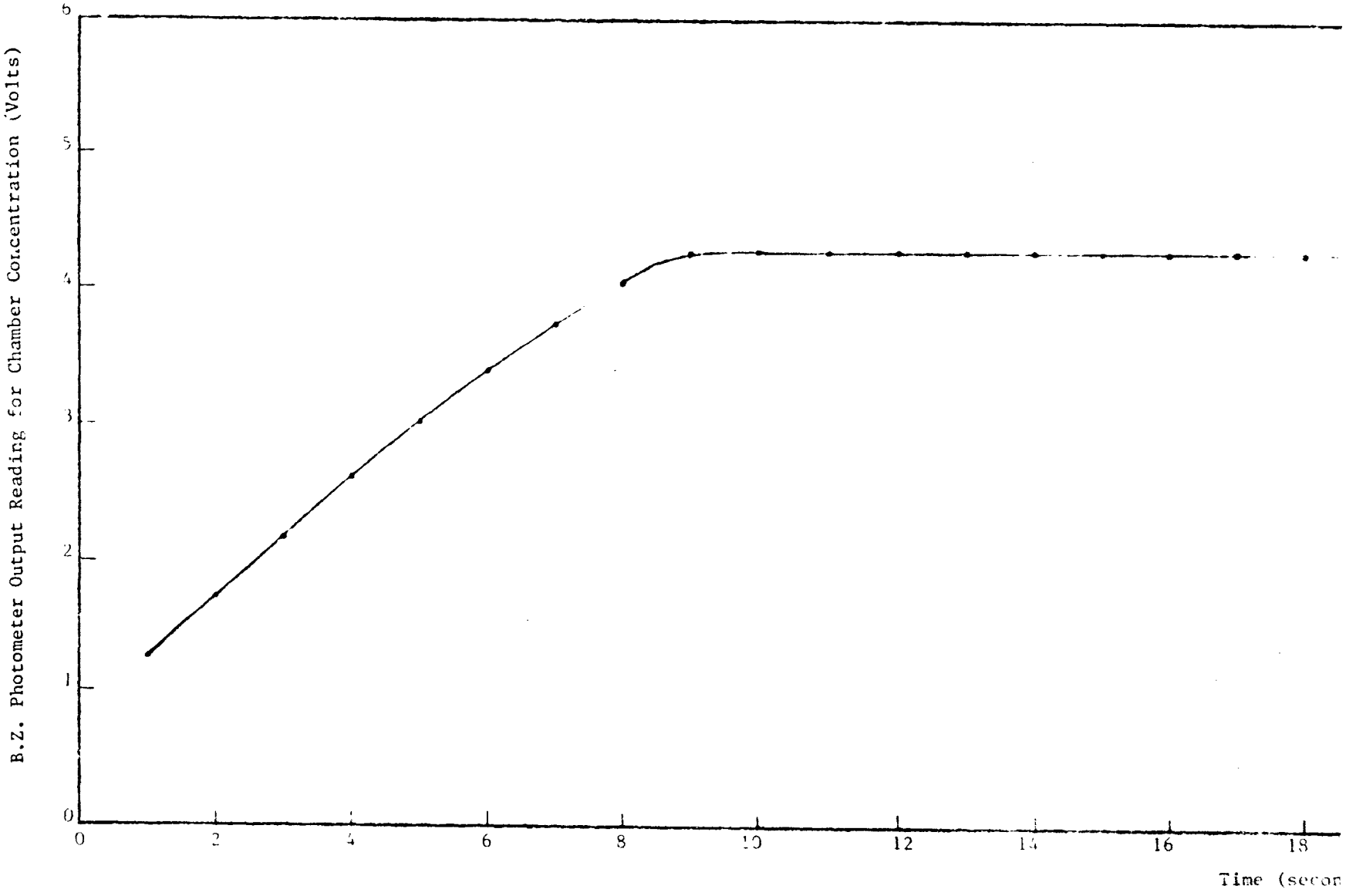

Figure 24. Breaching Zone (B.Z.) Photometer Response during Fast Chamber Concentration Build-Up

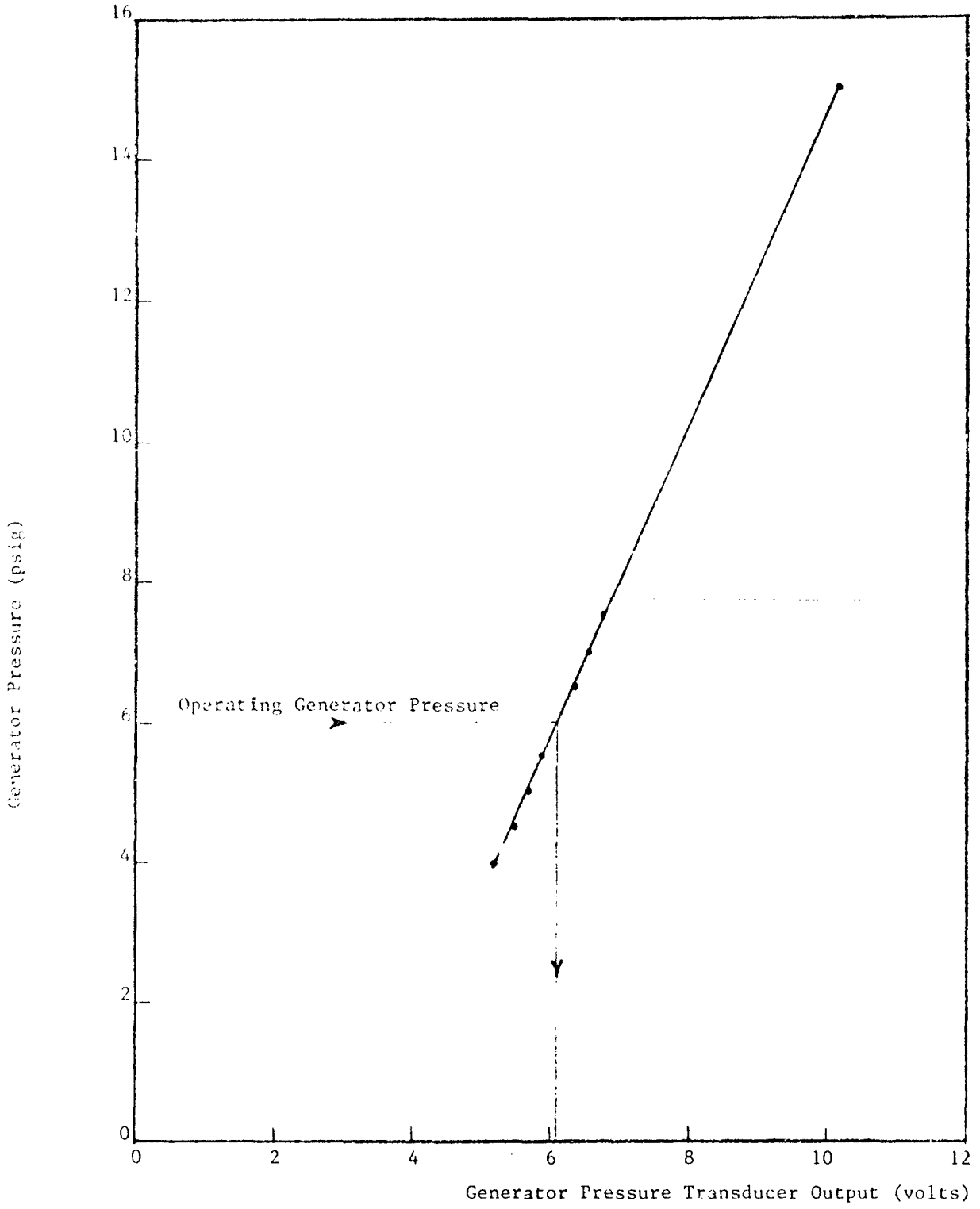

Figure 25. Aerosol Generator Calibration

volts which is used in the control program as a reference value to check the correctness of the generator pressure.

A similar calibration curve was plotted in Figure 26 for the dilution air system. An elbow flow meter was used in the system to generate a differential pressure proportional to the volume flow rate of the dilution air. The analog value of this differential pressure (inch water) was measured using the dilution air differential pressure gauge mounted on the rear panel of the top drawer. A differential pressure transducer was also used to measure this differential in volts. The relation between both quantities is presented in Figure 26. Figure 26 should be coupled with Figure 27 which gives differential pressure (inch water) versus dilution air flow (cfm) to determine the right dilution air flow setting at different altitudes. For example, we used Figure 27 to determine differential pressure gauge setting (inch water) for a certain flow rate (5 cfm for this instrument), then, we used Figure 26 to determine the corresponding transducer output in volts to be used as reference data in the control program.

The breathing zone (B.Z.) photometer output has been linearized by calibrating the chamber concentration versus the photometer output over a wide range of chamber concentrations. The linearization of the photometer output was needed because of the use of a logarithmic amplifier in the B.Z. photometer system to help us achieve an instrument dynamic capability of 10^7 that was required to measure fit factors up to 10^6. The calibration was performed using a decaying concentration experiment. We used a Dynatech Model 264 to measure the concentration percentage in the chamber while the B.Z. photometer output readings corresponding to these concentrations were measured using the computer system in our instrument (Model 260AS). We started the experiment by establishing the 100% concentration level on Model 264 and recording the corresponding B.Z. photometer output. The 100% concentration in this experiment corresponded to the aerosol reference mass concentration of 25µg/litres. Then, the aerosol generator was turned off while dilution air flow was kept on, causing continuous decay in chamber concentrations. Readings of different chamber concentrations were recorded versus the corresponding photometer output readings. The data of this experiment is plotted in Figure 28, and has been fitted by a least square fit of the form:

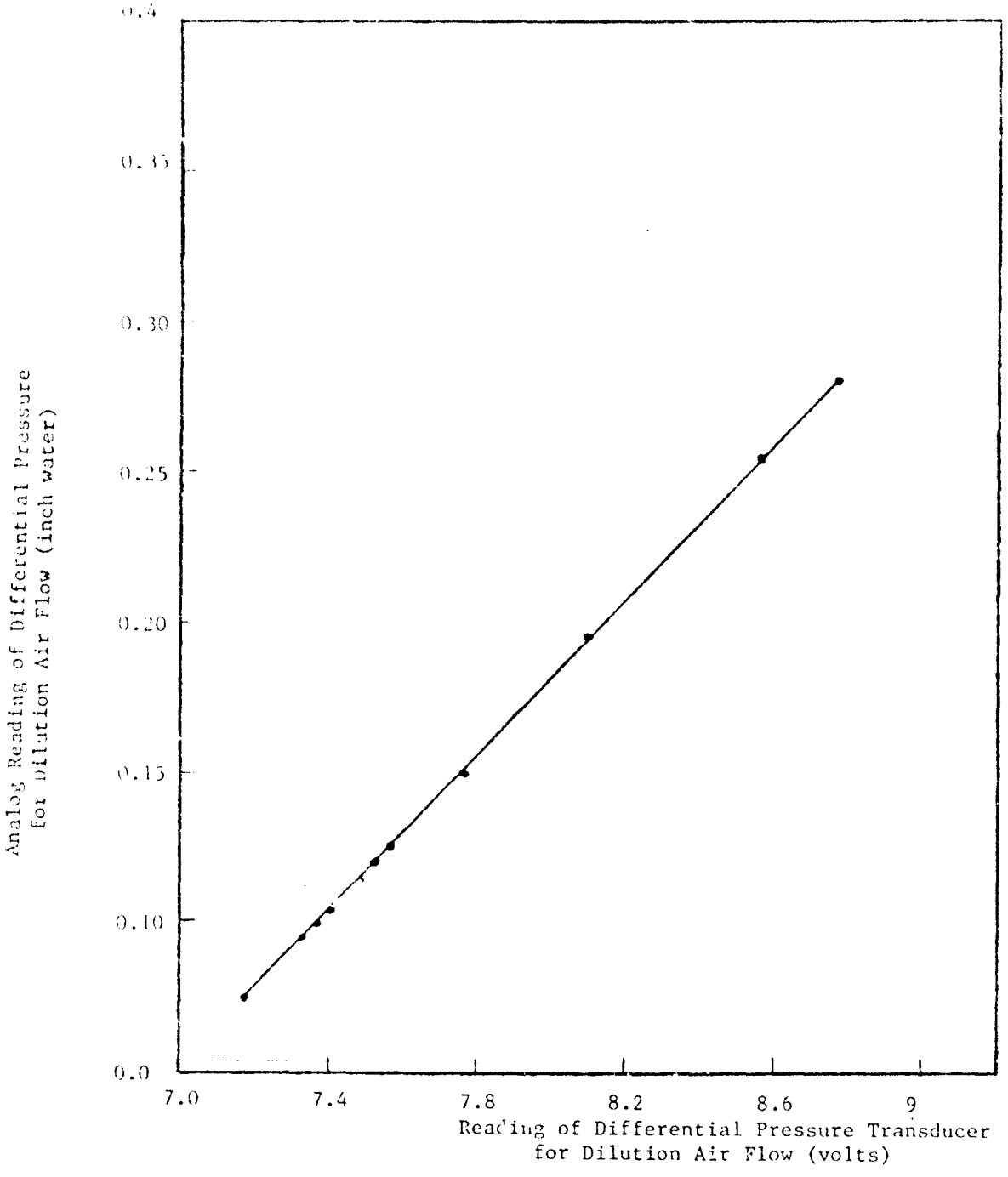

Figure 26. Dilution Air Flow System Calibration

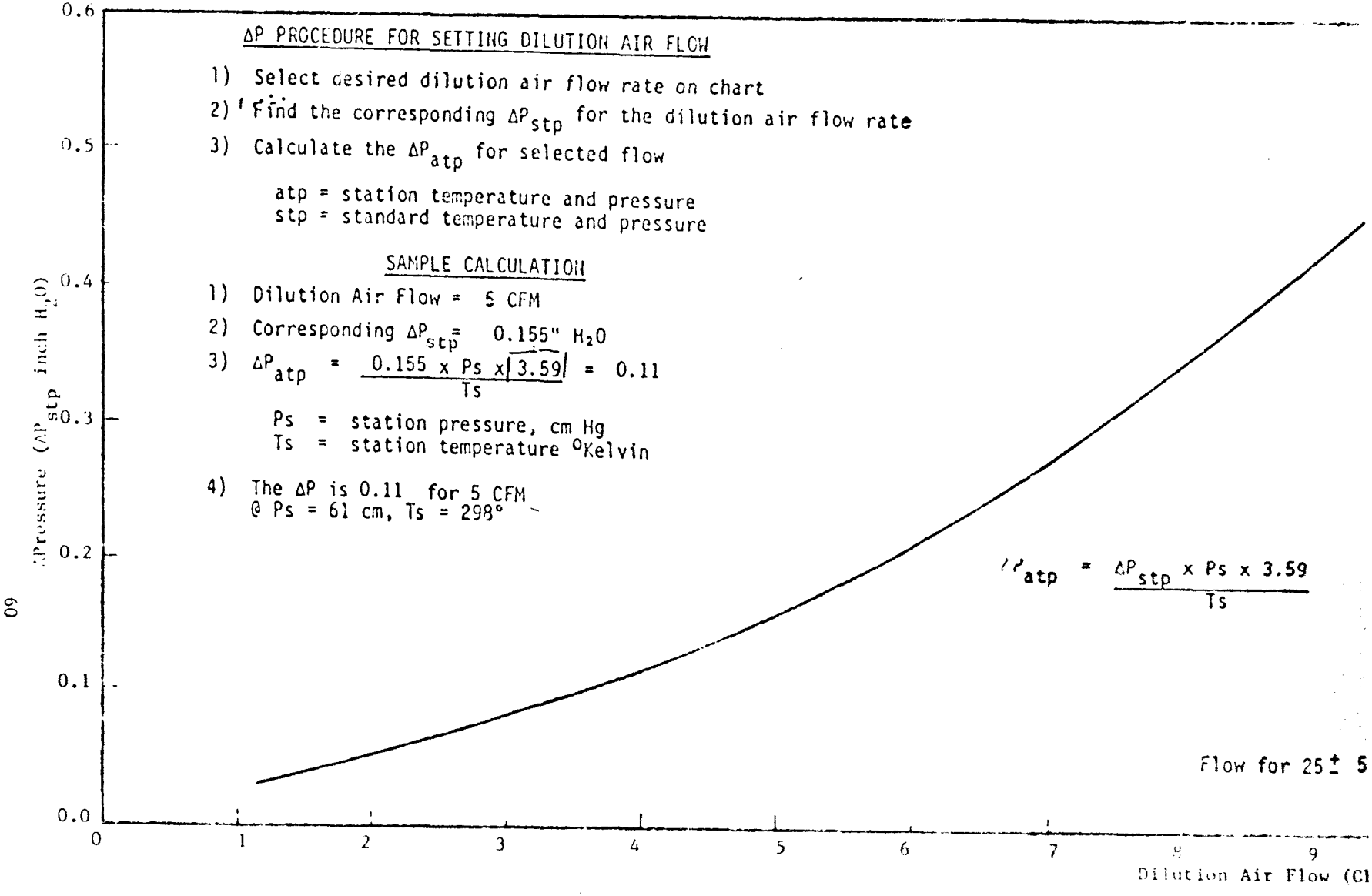

Figure 27. Pressure versus Dilution Air Flow Data

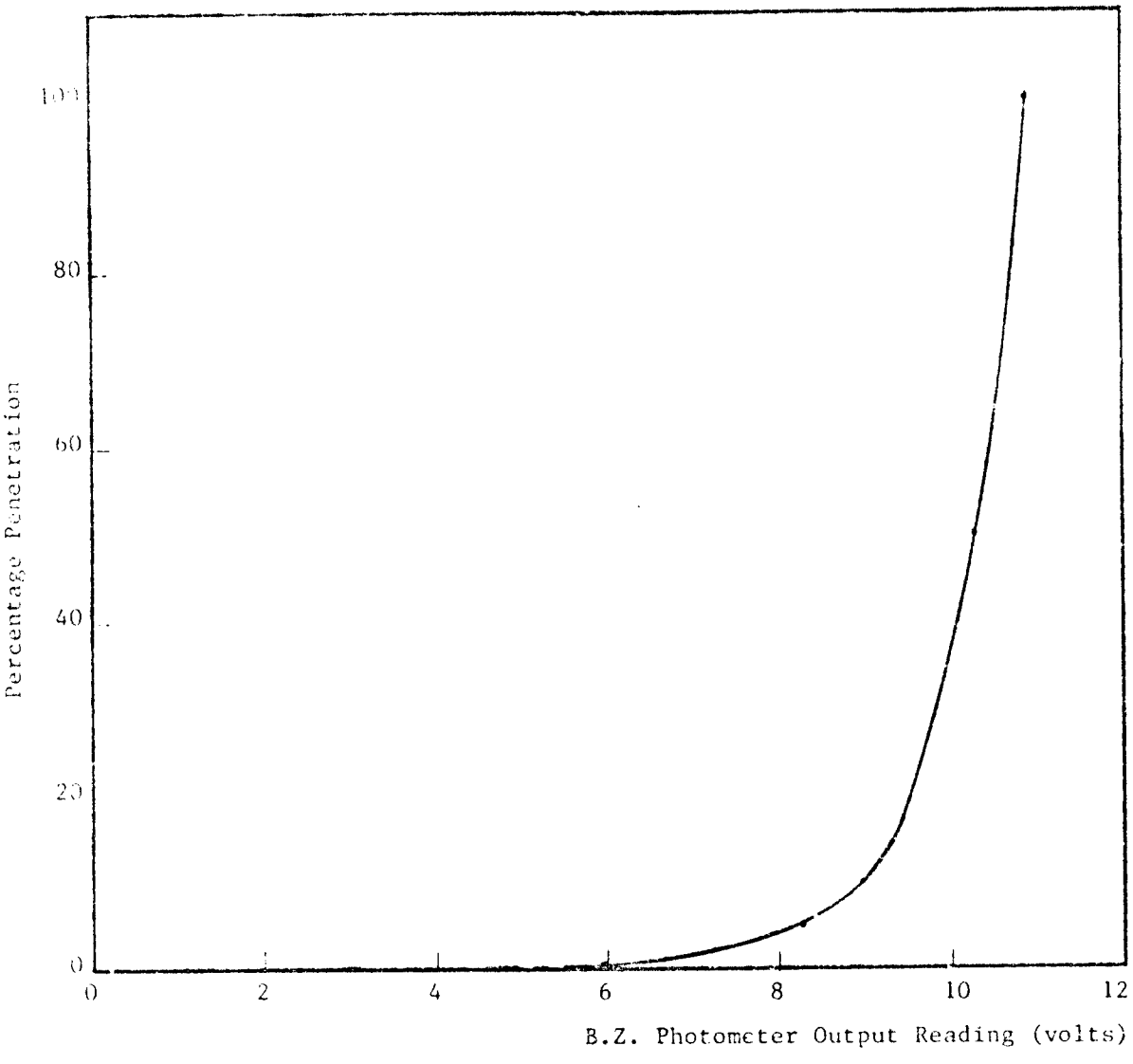

Figure 28. Breathing Zone Photometer Calibration

$$\log_{10}(C_{bz}) = -3.651957 + 3.783315 \log_{10}(V + 1) \qquad (1)$$

For V > 1.34v:

$$\log_{10}(C_{bz}) = -2.8543198 + 0.438104\ V$$

where C_{bz}: percentage concentration or penetration measured using the B.Z. photometer relative to a reference aerosol mass concentration of 25µg/litre; and

V: direct B.Z. photometer output reading (volts) corresponding to the above mentioned quantity.

The above equations were used in the control and data acquisition program to directly obtain the percentage concentration measured using the B.Z. photometer from its voltage output monitored by the instrument's computer system. The linearized response of the instrument using the above equation has provided meaningful interpretation of the data in the form of aerosol penetration in percentage. A detailed description of reducing fit factors from actual photometer readings is given in Chapter 5.

The last major calibration is the determination of the 25µg detector output corresponding to a chamber concentration of 25µg/litre. The output of the 25µg detector is linearly proportional to the chamber concentration because of the use of linear amplification in this system. Thus, knowing C_{25} helps to establish the chamber concentration at any other voltage output. Aerosol mass concentrations in the chamber were monitored using gravimetric sampling. Output of the 25µg detector was recorded during sampling. We found by averaging three experiments that 25µg detector output of 6 volts corresponded to a chamber mass concentration of 25µg/litre. The aerosol generator pressure was 6 psig and the dilution air flow rate was 5 cfm at this value of chamber concentration.

Chapter 5

QUANTITATIVE MAN FIT TESTING PROCEDURES AND RESULTS

A series of quantitative fit tests were conducted on 5 individuals to verify the instrument's performance during actual fit testing and to check the effect of replicated testing using the instrument on the mean value of fit and variability of fit. Each of the five individuals was tested six different times using two different respirators; one was a half face respirator (MSA COMFOII), and the other was a full face respirator provided by the Air Force (MSA-11-97). Human test protocol (Appendix C) was explained to test subjects before the tests, and each subject signed the investigator agreement affidavit enclosed with the test protocol before participation.

We present below a description of the test series, detailed data reduction of the fit factors from the photometers' output data, and test results and discussion.

5.1 Test Series Description

5.1.1 Test Respirator

Respirators selected for use in the tests were thoroughly checked to meet the following requirements:

a. It should be recognized as a good fitting respirator, available in multiple face sizes, providing a high likelihood of adequate fit over the spectrum of fit factors.

b. It should be equipped with high efficiency ($E \geq 99.97\%$) particulate filters to remove the test aerosol.

c. It should be in good condition and free from defects.

d. It should be equipped with a standardized sample probe and fitting for quantitative fit testing.

All respirators were thoroughly inspected, cleaned, and equipped with a sample fitting. Each individual was assigned a suitable half face and full face respirator, reserved for their use throughout the test series, to minimize variability of defects, elastomer, filters, sampling hardware, etc.

Respirator size was selected for comfort and visual conformance of faceseal. Imposition of this constraint should provide fit data which would be a "middle-of-the-road" variability. In other words, the only way to further minimize variability would be to select the best fitting respirator for each individual. This step, however, would not provide fit factors which were low enough to test all hypotheses. Mixing brands and styles, on the other hand, would be likely to introduce more variability in the fit.

5.1.2 Test Subjects

Five test subjects, both male and female, were selected on the basis of availability for the test series and provided with the best fitting of three sizes of mask. The subjects were not selected to conform to any of the anthropometric test panel criteria presently available. Test subjects were not respirator users and were not allowed to select respirators quantitatively. Qualitative tests were not employed to screen worst fit cases. Positive and negative pressure tests were conducted during donning practice and before each fit test. All were instructed to obtain the most comfortable and best fit prior to the test, but were not allowed to adjust the mask for best quantitative fit.

5.1.3 Test Equipment

The test set up consisted of the automated respirator fit test instrument (Dynatech Model 260AS) in conjunction with the test chamber (Model 222-8B). Details of the instrument hardware were presented in Chapter 2.

The aerosol test agent used was USP Grade Corn oil at a concentration of 25µg/litre and a mean mass aerodynamic diameter of 0.35±0.05µ

with a geometric standard deviation less than 2.0. The aerosol test chamber was operated at a dilution air flow rate of 5 cfm.

The use of the 25µg detector and the breathing zone photometer required losses and minor sensitivity differences to be matched. It also required matching the voltage output of the 25µg detector with the corresponding percentage penetration values resulting from the linearized photometer output. This was performed by calibrating both photometers against a standard sampling zone within the test chamber at an aerosol mass concentration of 25µg/litre. The photometer's calibration was performed every 8 hours during the instrument's operation. The computer system of the instrument was used for data acquisition and reduction of these calibrations which were performed at selected time intervals during the system's operation. The results were stored in the computer memory and were used during quantitative fit testing of human subjects.

5.1.4 Test Protocol

The Quantitative Fit Test was carried out on each of the five persons, replicated three times for each subject with both the half and full face respirators. Samples were taken simultaneously from the standard sample port. Subjects were alternated so that each test required a complete re-donning of the respirator. Each subject was assigned the selected respirator which was disinfected and bagged between each use. Six exercises were selected to be performed by each individual for 30 seconds each during each three minute test. These exercises were normal breathing, deep breathing, side to side head motion, up and down head motion, counting, and normal breathing. During normal breathing, mask penetrations have peaks and valleys corresponding to inhalation and exhalation respectively. Deep breathing increases the peak penetrations during inhalation because a greater pressure differential is created across the mask, thus causing leaks to increase. When performing side-to-side head motion exercise, peaks of penetration in excess of previously measured values indicate improper strap tension, thus allowing the mask to unseat in a head turning motion. The head up-and-down exercise primarily tests the chin cup seal, nose bridge

fit, and head strap tension. Counting aloud pattern is similar to deep breathing with penetrations indicating poor mouth/cheek fit superimposed upon the breathing profile. Finally, the test subject is instructed to breathe normally because the measured penetrations allows the operator to verify if the mask has moved during exercises. The final normal breathing exercise pattern is usually slightly less than or equal to the initial value. A greater value indicates a mask that does not fit well and is thereby subject to movement during exercises. The reduction in penetration, if observed, is due to sweat in the seal region and is a beneficial sealing effect. The penetration in percent is calculated for each exercise and corrected according to the photometers' calibrations. The data collected during the test are reduced, printed and displayed using the instrument's computer system.

5.2 Data Reduction and Analysis

The procedure to calculate the fit factors was outlined in general terms in Chapter 2 of this document. We present below the step-by-step calculation of a fit factor from the direct output voltages of the breathing zone photometer and the 25µg detector.

From the calibration values aerosol concentration in the chamber is set at 25µg/litre which corresponds to a value C_{25} (volts) on the 25µg detector. The breathing zone photometer is used to get a measurement for chamber concentration V_{ref}, which is linearized using Equation 1 in Section 4.3 to obtain the penetration in percent corresponding to the C_{25} voltage value. This penetration in percent C_{aref} is calculated from:

i.) For $V_{ref} \leq 1.34v$:

$$\log_{10}(C_{aref}) = -3.651957 + 3.783315 \log_{10}(V_{ref} + 1) = A_{ref} \quad (2)$$

ii.) For $V_{ref} > 1.34v$:

$$\log_{10}(C_{aref}) = -2.8543198 + 0.438104 V_{ref} = A_{ref}$$

$$C_{aref} = (10)^{A_{ref}}$$

The values C_{aref} and C_{25} are the percent penetration on the B.Z.photometer and voltage output of the 25µg detector for a chamber concentration of 25µg/litre. To get the corresponding percent penetration referred to the B.Z. photometer for any value of chamber concentration measured by the 25µg detector, we multiply the measured value by the ratio (C_{aref}/C_{25}) as will be shown below.

During each exercise, the voltage output V of the B.Z. photometer is being scanned and recorded every one second for the duration of the exercise (30 seconds in our test program). The corresponding breathing zone percentage penetration is calculated from the linearization equation (Equation 1 Section 4.3).

For $V \leq 1.34$ v:

$$\log_{10}(C_{bzi}) = -3.651957 + 3.783315 \log_{10}(V + 1) = A \qquad (3)$$

For $V > 1.34$v:

$$\log_{10}(C_{bzi}) = -2.8543198 + 0.438104\ V = A$$

$$C_{bzi} = (10)^{A}$$

The values of C_{bz} during each exercise or group of exercises is averaged using the relation.

$$\overline{C}_{bz} = \frac{1}{n-1} \sum_{i=2}^{n} C_{bz_i} \qquad (4)$$

The chamber concentration using the 25µg detector $\overline{C_{a(v)}}$ in volts has been determined by averaging the chamber concentrations before and after each test.

$$\overline{C}_{a(v)} = \frac{C_{ai} + C_{af}}{2} \qquad (5)$$

To change the units of $\overline{C_a}$ from volts to percent penetration same as units of $\overline{C_{bz}}$, we multiply $\overline{C_{a(v)}}$ by the calibration ratio (C_{aref}/C_{25}) calculated before. Thus, percent penetration ($\overline{C_a}$) representing actual chamber concentration during the test is

$$\overline{C_a} = \overline{C_{a(v)}} \cdot \frac{C_{aref}}{C_{25}} \tag{5}$$

From Equation 3 and 5, the fit factor is

$$FF = \frac{\overline{C_a}}{\overline{C_{bz}}} \tag{6}$$

$$FF = \frac{\overline{C_{a(v)}}}{\overline{C_{bz}}} \cdot \frac{C_{aref}}{C_{25}} \tag{7}$$

where FF is the average fit factor during an exercise or a group of exercises.

For each test, the printed or displayed output data includes the test subject personal information, number of exercises, duration of each exercise, and the fit factors for individual exercises and the whole test. A sample of the output data sheet is shown in Figure 29.

The results of quantitative fit testing for all test subjects follows below.

OUTPUT DATA
==========

NAME :
SERIAL NUMBER :MSA COMFO 11 MED
DATE & TIME :27:06:11:45:24 (DAY:MO:HR:M:S)

NUMBER OF EXERCISES =6

DURATION OF EACH EXERCISE =30 SEC

FIT FACTOR RESULTS
==========

FIT FACTOR FOR EXERCISE# 1 = 7.762E+004

FIT FACTOR FOR EXERCISE# 2 = 4.671E+005

FIT FACTOR FOR EXERCISE# 3 = 4.933E+005

FIT FACTOR FOR EXERCISE# 4 = 2.038E+003

FIT FACTOR FOR EXERCISE# 5 = 3.409E+002

FIT FACTOR FOR EXERCISE# 6 = 1.200E+003

AVERAGE FIT FACTOR FOR THE WHOLE TEST = 2.725E+003

Figure 29. Output data sample

5.3 Results and Discussions:

Tables 3 to 7 provide tabulations of the fit factors calculated during each quantitative fit test and printed on the instrument's output data sheet. Each table includes the output data of all tests for an individual test subject, including the results for both half face and full face respirators. Notwithstanding the fact that there is quite a bit of data to look at, it is all there in relatively convenient form.

The above tables show that the test subjects C and E have had more consistent fits in all their tests than the other three subjects. This is due to their prior experience, though limited, with donning and wearing a respirator. The inexperience of other test subjects, in addition to the requirement that they can't do two tests in a row without undonning and donning the respirator, is considered a prime reason for the variation in fit shown in the tables. Test subjects were allowed to see their test results after each test, and helpful hints were given to them when they had a bad fitting. In some cases, this helped to improve their fitting in subsequent tests.

The variation of the data over the whole range of the instrument's capability served as a verification of the instruments ability to yield fit factors over the required spectrum of 1 to 10^6.

5.4 Concluding Remarks:

A respirator wearer receives a degree of protection which is called the fit factor. The overall fit provided derives from two sources, the integrity of the mask and its air purifying or supplying circuit, and the facepiece to face seal. This is a crucial consideration to remember. The user can select a mask and purifying element which meets the criteria required by the ambient conditions and the applicable threshold limit values after a complete analysis of conditions and consultation with the

Table 3. CALCULATED FIT FACTORS FOR QUANTITATIVE MAN FIT TESTING
[TEST SUBJECT: A]

TEST #	RESPIRATOR TYPE	RESPIRATOR BRAND	RESPIRATOR SIZE	FIT FACTORS						
				NORMAL BREATHING FF1	DEEP BREATHING FF2	HEAD SIDE/SIDE FF3	HEAD UP/DOWN FF4	COUNTING FF5	NORMAL BREATHING FF6	TEST AVERAGE FFavg
1	Half	MSA COMFO II	M	6.431×10^2	4.489×10^5	1.305×10^3	4.277×10^5	4.411×10^5	4.068×10^5	6.370×10^3
2	Half	MSA COMFO II	M	2.043×10^4	3.741×10^5	4.314×10^3	3.886×10^5	5.225×10^5	5.026×10^5	4.405×10^4
3	Half	MSA COMFO II	M	4.625×10^2	4.492×10^4	2.236×10^1	1.055×10^3	3.471×10^5	2.423×10^2	2.666×10^2
3A	Half	MSA COMFO II	M	3.604×10^3	3.925×10^5	4.049×10^5	3.959×10^5	4.448×10^5	4.835×10^5	5.427×10^4
4	Full	MSA-11-97	M	3.855×10^5	3.836×10^5	4.313×10^5	3.695×10^5	4.461×10^5	4.174×10^5	4.042×10^5
5	Full	MSA-11-97	M	1.877	1.357	1.348	1.349	1.403	1.361	1.433
5A	Full	MSA-11-97	M (With Glasses)	5.421×10^5	5.745×10^5	3.79×10^5	4.532×10^5	4.079×10^5	5.389×10^5	4.742×10^5
6	Full	MSA-11-97	M	4.195×10^5	5.838×10^5	4.929×10^5	4.196×10^5	4.090×10^5	3.743×10^5	4.417×10^5

* Number of exercises = 6 & Duration of each exercise = 30 seconds.

Table 4. CALCULATED FIT FACTORS FOR QUANTITATIVE MAN FIT TESTING
[TEST SUBJECT: B]

TEST	RESPIRATOR TYPE	RESPIRATOR BRAND	RESPIRATOR SIZE	FIT FACTORS						
				NORMAL BREATHING	DEEP BREATHING	HEAD SIDE/SIDE	HEAD UP/DOWN	COUNTING	NORMAL BREATHING	TEST AVERAGE
				FF1	FF2	FF3	FF4	FF5	FF6	FFavg
1	Half	MSA COMFO II	M	1.001×10^3	4.255×10^5	4.014×10^5	2.092×10^5	4.674×10^5	5.293×10^5	1.999×10^4
2	Half	MSA COMFO II	M	3.311×10^4	8.856×10^3	8.983×10^1	4.103×10^2	8.280×10^2	4.386×10^5	7.681×10^2
3	Half	MSA COMFO II	M	3.655×10^2	3.873×10^2	3.099×10^2	2.406×10^2	1.456×10^2	3.892×10^2	2.804×10^2
4	Full	MSA-11-97	M	3.379×10^5	4.758×10^5	4.329×10^5	3.757×10^5	5.842×10^5	4.176×10^5	7.746×10^4
5	Full	MSA-11-97	M	4.277×10^3	5.624×10^5	4.489×10^5	4.261×10^5	4.145×10^5	4.111×10^5	6.490×10^4
6	Full	MSA-11-97	M	5.588×10^2	9.733×10^1	1.327×10^2	3.154×10^2	4.919×10^5	2.579×10^3	3.685×10^2

* Number of exercises = 6 & Duration of each exercise = 30 seconds.

Table 5. CALCULATED FIT FACTORS FOR QUANTITATIVE MAN FIT TESTING
[TEST SUBJECT: C]

TEST #	RESPIRATOR TYPE	RESPIRATOR BRAND	RESPIRATOR SIZE	FIT FACTORS						
				NORMAL BREATHING FF1	DEEP BREATHING FF2	HEAD SIDE/SIDE FF3	HEAD UP/DOWN FF4	COUNTING FF5	NORMAL BREATHING FF6	TEST AVERAGE FFavg
1	Half	MSA COMFO II	L	1.076×10^5	4.565×10^5	5.906×10^5	4.348×10^5	3.809×10^5	3.572×10^5	3.133×10^5
2	Half	MSA COMFO II	L	2.419×10^5	5.432×10^5	5.026×10^5	4.542×10^5	4.770×10^5	4.200×10^5	4.180×10^5
3	Half	MSA COMFO II	L	6.630×10^5	3.328×10^5	4.249×10^5	4.258×10^5	3.442×10^5	3.347×10^5	4.026×10^5
4	Full	MSA-11-97	M	4.214×10^4	3.897×10^5	4.372×10^5	3.728×10^5	4.721×10^5	4.855×10^5	2.264×10^5
5	Full	MSA-11-97	M	1.942×10^3	4.793×10^5	3.631×10^5	3.995×10^5	3.747×10^5	4.966×10^5	3.404×10^4
6	Full	MSA-11-97	M	8.082×10^4	4.550×10^5	4.349×10^5	4.151×10^5	3.825×10^5	5.028×10^5	2.902×10^5

* Number of exercises = 6 & Duration of each exercise = 30 seconds.

Table 6. CALCULATED FIT FACTORS FOR QUANTITATIVE MAN FIT TESTING
[TEST SUBJECT: D]

TEST #	RESPIRATOR TYPE	RESPIRATOR BRAND	RESPIRATOR SIZE	FIT FACTORS						
				NORMAL BREATHING FF1	DEEP BREATHING FF2	HEAD SIDE/SIDE FF3	HEAD UP/DOWN FF4	COUNTING FF5	NORMAL BREATHING FF6	TEST AVERA FF$_{av}$
1	Half	MSA COMFO I'	M	1.849×10^2	8.179×10^3	1.567×10^1	8.392×10^1	1.117×10^3	1.161×10^4	1.488 X
2	Half	MSA COMFO II	M	4.337×10^3	6.927×10^1	1.123×10^1	7.693	9.532	8.395	1.652 X
3	Half	MSA COMFO II	M	3.513×10^5	3.838×10^5	1.587×10^4	4.130×10^5	4.372×10^5	1.986×10^5	1.290 X
4	Full	MSA-11-97	M	6.552×10^5	3.786×10^5	4.409×10^5	5.452×10^5	4.894×10^5	3.005×10^5	4.466 X
5	Full	MSA-11-97	M	6.948×10^3	1.768×10^3	8.038×10^3	5.074×10^5	2.046×10^5	9.192×10^5	1.188 X
6	Full	MSA-11-97	M	4.084×10^5	3.751×10^5	4.266×10^5	3.464×10^5	5.478×10^5	3.881×10^5	4.087 X

* Number of exercises = 6 & Duration of each exercise = 30 seconds.

Table 7. CALCULATED FIT FACTORS FOR QUANTITATIVE MAN FIT TESTING
[TEST SUBJECT: E]

TEST #	RESPIRATOR TYPE	RESPIRATOR BRAND	RESPIRATOR SIZE	FIT FACTORS						
				NORMAL BREATHING FF1	DEEP BREATHING FF2	HEAD SIDE/SIDE FF3	HEAD UP/DOWN FF4	COUNTING FF5	NORMAL BREATHING FF6	TEST AVERAGE FF_{avg}
1	Half	MSA COMFO II	M	5.404×10^5	3.952×10^5	4.241×10^4	4.069×10^4	4.695×10^3	1.544×10^3	7.750×10^2
2	Half	MSA COMFO II	M	7.222×10^5	4.430×10^5	6.074×10^5	4.784×10^5	4.393×10^5	3.890×10^5	4.956×10^5
3	Half	MSA COMFO II	M	7.762×10^4	4.671×10^5	4.933×10^5	2.038×10^3	3.409×10^2	1.200×10^3	2.725×10^3
4	Full	MSA-11-97	M	4.539×10^5	5.011×10^5	4.032×10^5	4.182×10^5	4.992×10^5	4.554×10^5	4.528×10^5
5	Full	MSA-11-97	M	1.031×10^4	1.427×10^3	3.955×10^5	3.767×10^5	5.956×10^5	4.288×10^5	1.809×10^4
6	Full	MSA-11-97	M	3.065×10^5	4.191×10^5	4.526×10^5	3.668×10^5	4.579×10^5	4.320×10^5	4.001×10^5

* Number of exercises = 6 & Duration of each exercise = 30 seconds.

respirator manufacturer. The manufacturer has tested his device and determined the limits of use after serious consideration of design and test data. The manufacturer has also submitted his device to the National Institute for Occupational Safety and Health, Test and Certification Board, (NIOSH - TCB) for independent test and evaluation with respect to his specifications and general overall government regulations and guidelines. All of this tends to assure the user that he is purchasing and using a product which meets certain minimum levels of acceptance and performance. What is does not do is supply any knowledge of the remaining source of protection, the facepiece to face seal.

The tremendous variability in facial features, when considering the millions of people using respirators, cannot be controlled by the manufacturer. As a result, he may offer several sizes and styles of facepiece in an attempt to fit ever larger numbers of wearers with at least one mask. Different manufacturers use different form criteria and, fortunately, for the respirator user, there exists somewhere a mask form which will fit an individual better than any other form. It must be recognized at the outset that there exists a fraction of people which cannot be adequately fitted with any of the available, approved, respirator masks. Finding the mask which the user, training the user to wear it, and assuring that adequate protection levels are maintained is what Quantitative Man Fit testing is all about.

Placing these considerations in proper perspective, it is vitally important to understand some of the characteristics of improper fit. For a mask which does not fit properly, it is difficult to predict the characteristics of the facepiece to face seal fit factor. Successive fitting trials may result in the variation of fit factors over two to three orders of magnitude. The mask moves around on the face, causes facial irritation, and becomes an object of use distrust and dislike. A properly fitting respirator will minimize these factors and will provide for reasonably consistent measurement of protection factors, that is, the variability can be maintained within an order of magnitude, many times to less than a factor of two. It is essential to provide a sufficiently satisfactory fit to allow

estimation of the minimum fit factor. This is virtually impossible to achieve with a poor fitting respirator unless you take credit for ridiculously low fit factors, many times approaching something less than 5.

As we now focus upon quantitative fit testing, we realize with greater clarity the three distinct features of quantitative testing:

1) Selection of the proper respirator - the brand and model which provides the highest individual fit factor is clearly the item to be selected for further use and training;

2) Training with the proper respirator - repetitive testing which demonstrates the user's ability to properly don the mask and achieve consistent fit factors is what training is all about; and

3) Documentation of results - maintenance of the proper records must include actual test data which indicates proper selection and adequate training.

Section 6

SUMMARY

A prototype of an automated chemical warfare respirator quantitative fit test instrument was designed and assembled at Dynatech Corporation. The instrument (Dynatech Model 260AS) requires no operator attention during the fit tests. An automatic control and data acquisition system composed of Hewlett-Packard components was integrated into the instrument hardware. Fit factors as high as 10^6 can be detected with the instrument which is capable of 24 hours continuous operation. The instrument was fabricated of hardware components that do not need any replacement or maintenance for at least 14 days. Corn oil because of its documented safety was used as the challenge agent.

Performance tests for the instrument's subsystems verified that the operation parameters of the instrument met contract requirements. Aerosol mass concentration in the chamber was 25ug/litre. The mean mass aerodynamic diameter of the aerosol in the chamber was 0.35 ± 0.05μ. It took the system about 2.5 minutes to build the required aerosol concentration from the cold start of the system. The chamber aerosol concentration recovery after opening and closing the door was almost instantaneous because of using the "DYNALOK" mode and because of the existence of an air lock. System's calibrations were performed to set up the operating reference parameters of the instrument.

Quantitative fit tests using human test subjects were performed on five test subjects. Half and full mask respirators were used in these tests. The results show the instrument's capability to measure fit factors up to 10^6. Fit factors of values ranging from 1 to 10^6 were reported in the results of these tests.

A system safety hazard analysis was presented documenting the safety of the system in both design and operation. The instrument, as evident by this document, represents a significant advancement in the state-of-the-art of aerosol quantitative fit test instruments.

APPENDIX A

SYSTEM SAFETY HAZARD ANALYSIS REPORT

Item # DI-H-7048 Sequence # 7

APPENDIX A

SYSTEM SAFETY HAZARD ANALYSIS REPORT

Item #DI-H-7048 Sequence #7

System safety hazard analysis for the quantitative fit test instrument requires safety analysis for both the test agent and the engineering design of the system. Presented below is an analysis of both items.

A.1 Aerosol Safety:

Corn oil is a clear, light yellow, oily liquid with a faint characteristic odor and taste. Refined corn oil is composed almost entirely (99%) of triglycerides, which are the primary forms of body fat. These triglycerides contain a mixture of saturated and unsaturated fatty acids which include lineoleic acid, a polyunsaturated fatty acid comprising 34 - 62% of corn oil, one of the essential fatty acids. The physical and chemical data of corn oil are presented in the human test protocol (Appendix E). Based on the available data, it is suggested that corn oil has a low order of toxicity. The data also suggests that inhalation of corn oil aerosol appears to offer little risk of human injury. Since the particle size is in the respirable range and the actual amount of aerosol allowed to enter the breathing zone is so minute, the detection by human bioassay fluid is not probable and lung depositions are unlikely.

A.2 Engineering Design Safety:

The following safety considerations were implemented in the design and fabrication of the system to minimize risks when using the instrument.

1. All instrument controls are located such as to prevent the test subject from interfacing with any power connection.

2. Access to main line power and other sources of power deemed as potential shock hazards are restricted to access by qualified service personnel only.

3. Power cable systems are isolated for environmental and human protection.

4. All power circuits are fused.

5. System chassis are at reference power ground.

6. All prime movers are protected and isolated for normal operations.

7. Environmentally sensitive subsystems/systems are protected.

8. System ventilation system provides clean, filtered, pressurized air to avoid contaminants from ambient conditions.

9. Test chamber includes doors and pop out windows.

10. Test chamber materials are inflammable in normal environments.

11. Enclosure system was designed with security locks on all access doors.

12. External and internal lighting are provided to eliminate all potential walkway hazards.

13. Annunciators' communication systems are isolated from ambient and test environment.

14. Night vision lighting is provided in the test chamber.

15. Control program failure criteria provide automatic shut down during operational or functional malfunctions.

APPENDIX B

ENVIRONMENTAL AND SYSTEM TEST PLAN/PROCEDURES

Item # DI-T3708A Sequence # 9

Appendix B

ENVIRONMENTAL AND SYSTEM TEST PLAN/PROCEDURES

Item No. DI-T3708A, Sequence No. 9

Objective

To determine the compliance of the system hardware and performance to the specifications and objectives outlined.

Program

System compliance to design specifications will be established and verified by incorporating a three-phase procedure:

Phase 1: Components and sub-systems manufactured by Dynatech will be subjected to normal manufacturing controls and quality assurance procedures.

Phase 2: Standard vendor components, system and/or sub-systems purchased will be required to meet engineering performance criteria or as specified under Certificates of Compliance.

Phase 3: Component, sub-system or system integration into end-item equipment will be evaluated for compliance to overall specifications and objectives established using environmental and performance criteria.

Environmental Test Matrix

Performance of sub-systems manufactured by Dynatech will be analyzed for functional variations and stability under the conditions of temperature, humidity, ambient aerosol concentrations, and atmospheric pressure, as outlined in Table 1.

Pre-test conditioning of manufactured components and sub-systems will provide stabilization prior to initiating engineering tests. The environmental base shall be air temperature and require a four-hour pre-test soak, as the conclusion of which a 20-hour test sequence will be initiated. Humidity stabilization to require a one-hour soak prior to functional testing. These procedures to apply to all environmental conditions not classified as nominal. Based on this general protocol, each test series at a specified temperature will be 63 hours minimum.

Failure criteria for termination of a given environmental test series will be based on the following:

A. Elapse Time
B. Mode of Failure
C. Level of Failure
D. Significance of Failure

Table 1

ENVIRONMENTAL TEST MATRIX

TEMPERATURE (°C) ±5	HUMIDITY (%) RH ±5	ATMOSPHERIC PRESSURE (mm Hg) ±10
0	5	625
0	45	625
0	95	625
20	5	625
*20	*45	*625
20	95	625
40	5	625
40	45	625
40	95	625

* To be considered nominal environmental conditions.

Individual and combinational failure mode parameters will be established based on the function being evaluated.

Systems and/or sub-systems which are commercially available and standard equipment will be subjected to nominal environmental conditions where vendors' Certificates of Compliance to temperature, humidity and atmospheric temperature are received. Pending lack of non-availability of Certificates of Compliance, each system and/or sub-system test parameter will be evaluated based on vendor recommendations, service history and functional mode to be incorporated into the end item.

Environmental testing of the integrated equipment package will be conducted at nominal test conditions of 20°C, 45% RH and 625mm of mercury barometric pressure, then the conditions stated in Table 1.

Sub-System Performance Tests

The basic system will be divided into four major sub-systems for environmental and performance verification prior to package integration. Performance of the component sub-systems to be evaluated with respect to end-item conformance to environmental and operational criteria. These sub-systems are listed as:

1. Test Chamber, to include all hardware and active elements.

2. Aerosol Generator and Dilution Air, to include chamber ventilation, sampling circuits, control elements, filtration elements, generator and associated interconnecting hardware.

3. Aerosol Detectors, to include signal conditioning, air transducers, sampling circuits, control and filtration elements, as well as interconnecting hardware.

4. Computer System, to include data reduction modes, signal conditioners, interface control elements, monitoring transducers, active components, and associated hardware.

A fifth element, not considered a sub-system, will be those elements considered as the integrated package, which will include all of the above four items. Performance and environmental testing of this integrated package will be conducted at the nominal test conditions of 20°C, 45% R.H. and 625mm of mercury barometric pressure within the conditions stated in Table 2.1.

1.0 Test Chamber Enclosure

The sub-system designed to contain the secondary mass distribution of the challenge aerosol concentration (C_a).

1.1 The environmental test matrix to apply to all sub-systems of this section.

1.2 Aerosol Uniformity

1.2.1 Steady state mean reference aerosol mass concentrations to be determined by single-point photometric monitoring.

1.2.1.1 Sample rate to be $\leq$ 3 LPM but $\geq$ 1 LPM

1.2.1.2 Sample duration to be sufficient to draw a 3-liter sample, minimum.

1.2.1.3 Reference mass concentrations to be $\geq$ 20 mg/m^3 but $\leq$ 30 mg/m^3.

2.1.3.1 Mass concentrations to be determined by gravimetric analysis.

2.1.3.2 Mass sampling to be sufficient to draw 250 liters per 25 mg/m^3 concentration.

1.2.1.4 Reference mass concentrations to be monitored from the initiation of generator startup at T+10 minutes and each 60 minutes thereafter until the test cycle is terminated. Aerosol mass to be maintained within ±5 percent of concentration established in Paragraph 2.1.3. as monitored photometrically.

1.2.2 Transit aerosol perturbations (test subject entry/egress or analog simulations) will be monitored photometrically.

1.2.2.1 Sample rate to be $\leq$ 3 LPM but $\geq$ 1 LPM.

1.2.2.2 Sample duration to be sufficient to draw a 3-liter sample, minimum.

1.2.2.3 Reference mass concentrations to be monitored during perturbations to determine restoration of the concentration established in Paragraph 1.2.1.3 to within ±10 percent at one minute.

1.2.2.4 Interlock aerosol leakage duration to be monitored during perturbations to determine entry-egress leakage profiles.

1.2.2.5 Entry/egress perturbations to be executed not less than ten repetitions and spaced to simulated QNFT procedures.

1.2.3 Uniformity of mass concentrations will be determined by remote single-point sampling, utilizing a 3 x 3 x 6 matrix under steady state conditions, photometrically.

1.2.3.1 Sample rate to be $\leq$ to 3 LPM but $\geq$ 1 LPM.

1.2.3.2 Sample duration to be sufficient to draw a 1-liter sample, minimum.

1.2.3.3 Determinations of matrix uniformity will be monitored not less than three repetitions.

1.2.3.4 Matrix to exclude 6-inch boundary layer at the chamber wall but to include volume envelope normally occupied by test subject.

1.2.3.5 Reference mass concentrations to be monitored during matrix observations, Paragraph 2.1, based on random sampling.

1.2.3.6 Single-point random matrix samples to be monitored at the conclusion of individual perturbation events.

1.2.4 Steady state aerosol parameters of mean mass aerodynamic diameter (MMAD) and particle size distribution to be monitored by utilizing photometry, inertial impactors and particle counters.

1.2.4.1 Sample rate to be 3 LPM, utilizing photometry and inertial impactors.

2.4.1.1 Sample duration to be sufficient to draw a 1-liter sample, minimum.

2.4.1.2 Impactors to be sized at 0.2, 0.5, 1.5 and 3.0 μm.

2.4.1.3 Mass distributions to be observed not less than three repetitions and will assume a log-normal distribution.

2.4.1.4 MMAD to be within 0.35 ±0.05 um.

1.2.4.2 Particle size distribution by count to verify mean particle size and maximum particle size to be monitored (Reference 1.2.4.1.3) to establish compliance with 99 percent particle sizing $\leq$ 2.5 um.

1.2.4.3 Log-normal analysis to establish MMAD, mean particle size and confirm standard geometric deviations of $\leq$ 2.0 will be used to present data.

1.2.5 Transit aerosol parameters of MMAD to monitored with photometry and inertial impactors (Reference 1.2.2.3) (2.4.1.2) to determine restoration stability (Reference 1.2.2).

1.3 Aerosol Leakage

1.3.1 Steady state aerosol concentration containment to be evaluated, using photometric survey.

1.3.2 All modular seals to be scanned to determine ambient increases in particulates due to leakage.

1.3.3 Chamber wall penetrations to be monitored for ambient increases in particulates due to leakage.

1.3.4 Chamber door seals and windows shall be surveyed for static leakage to ambient.

1.3.5 Tests to be performed during temperature matrix operations and shall not exceed 1 percent of the reference mass concentration.

1.4 Main Frame

1.4.1 Active components to be evaluated for deterioration in performance, using visual inspection and cause/effect data as observed in Sections 2.0 and 3.0.

1.4.2 Aerosol plating on internal structures in direct contact with reference aerosol mass to be visually inspected.

1.4.3 Ambient lighting and visual communication components to be surveyed to deterioration which could affect system performance, using in-service histories for man-related chambers.

1.4.4 Internal hardware, i.e., sample quick disconnects, door closures and associated sampling tubing to be inspected visually and photometrically, as applicable.

4.4.1 Quick disconnect hardware to be surveyed photometrically for leakage based on in-service history supported by 250 individual operations.

4.4.2 Electrical components, fans, and switches germain to system operation to be visually inspected to determine plate-out conditions detrimental to perform.

1.4.5 Door entry/egress to simulate 250 minimum operations to assure positive sealing of hardware to support in-service history.

2.0 Aerosol Generator/Dilution Air System

The sub-system is designed to generate, filtrate, and control aerosols prior to mass distribution in the test chamber enclosure.

2.1 The environmental test matrix to apply to all sub tests of this section unless otherwise modified.

2.2 Aerosol Generation

2.2.1 Steady state reference aerosol mass to be determined through gravimetric analysis.

2.2.1.1 Generator output to be monitored gravimetrically based on pressure over the expected range of 4 to 15 PSIG.

2.2.1.2 Generator oil reservoir to be maintained at 20±2°C.

2.2.1.3 Generator output to be monitored for secondary performance at oil reservoir $\geq 0°C \leq 18°C$.

2.2.1.4 Mass and particle size distribution to be surveyed by aging/dilution, utilizing photometry, impactors and particle counting (Reference 1.2.4).

2.2.1.5 Oil mass requirements for continuous 24-hour operation to be determined by analysis and based on a minimum of 4-hour generation.

2.2.2 The generator main frame and associated hardware to be analyzed for environmental deterioration.

2.2.2.1 Seals and insulating materials to be tested for 100-hour aging at T = 65°C ± 5°C in environmental chamber to verify vendor material specifications and in-service history.

2.2.2.2 Seal and insulating materials to be analyzed visually for deterioration.

2.2.2.3 Associated non-metallic fluid conductors to be performance tested for deterioration and analyzed based on in-service history.

2.2.3 Generator Prime Mover (compressor) to be tested in compliance with system environmental specification, service histories and vendor specifications.

2.2.3.1 Compressor pressure and flow variations analyzed with respect to cause and effect on generator aerosol mass and particle size output (Reference 1.2.0).

2.2.3.2 Compressor components in contact with compressed gases to be analyzed for mechanical wear before and after environmental testing.

2.2.3.3 Compressor clean filters to be inspected before and after environmental testing.

2.2.3.4 Compressor thermal stability with respect to all functional parameters to be evaluated based on in-service use and the manufacturer's specifications.

2.3 Dilution Air System

2.3.1 Chamber ventilation filtration components shall be evaluated to determine the parameter of steady state performance.

2.3.1.1 Filter pressure versus flow of aerosol contaminated air (25 ±5mg/liter) will be monitored over a range of 3 to 15 SCFM to establish end of life criteria.

2.3.1.2 Prime mover (dilution air blower) to be tested to determine the affects of variations in volume flow on reference mass aerosol concentrations (Reference Paragraph 1.2.1).

2.3.1.3 End of life filter detection transducers to be evaluated with respect to pressure/flow characteristics over a flow range consistent with nomical operation of approximately 12 SCFM.

2.3.1.4 Fluid conductors and filter holder to be surveyed photometrically to confirm zero aerosol leakage to filter end of life over the full range of normal volumetric flows.

2.3.2 Ventilation control sub-systems shall be evaluated to confirm compliance with system performance criteria.

2.3.2.1 Solid-state power controls for regulation of the ventilation blower to be evaluated to establish design/performance criteria over the full range of volumetric flows (Reference 3.1.2).

2.3.2.2 Filter selection valve positioning control system to be evaluated with respect to full range operation.

2.3.2.2.1. Full valve seating to be functionally tested to determine the affects of impaction oil films on seating characteristics (Reference 3.1.1).

2.3.2.2.2 Valve geometry to be surveyed photometrically to confirm zero leakage over full range of volumetric flows (Reference 3.1.4).

2.3.2.3 Computer interface control systems to be tested for conformance to interface requirements and control sequence, utilizing simulated conditions of normal operation.

3.0 Aerosol Detection

The sub-systems designed to monitor and control test chamber aerosol concentrations.

3.1 The environment test matrix to apply to all sub tests of this section.

3.2 Solid state reference aerosol monitoring sub-system to be tested to determine the response to variations in concentrations between 15 and 35 mg/m^3.

3.2.1 Transducer response and stability to be evaluated over the range stipulated, using gravimetric analysis (Reference 1.2.1.3).

3.2.2 Transducer signal conditioning amplifier to be evaluated over the range stipulated for repeatability, stability and response (Reference 1.2.1.3), based on in-service histories.

3.2.3 Aerosol sampling system shall be evaluated to determine compliance with continuous monitoring requirements of 24-hour maintenance-free operation.

3.2.3.1 Sampling pump to be analyzed for pressure/flow variations with respect to aerosol delivery and transducer response (Reference 3.2.1) over a flow range of 1 to 3 LPM.

3.2.3.2 Sampling pump protection filters to be evaluated for aerosol loading, utilizing contaminated air (25 ± 5 mg/m^3) over a flow range of 1 to 3 LPM to determine performance affects on transducer response.

3.2.3.3 Sampling and interconnecting hardware shall be evaluated for aerosol impaction and oil film development, utilizing contaminated air (25 ± 5 mg/m^3) to determine the affects on transducer response (Reference 3.2.1, 3.2.3.2).

3.2.4 System and sub-system components to be surveyed photometrically to verify zero leakage during normal operation (3.2.3).

3.3 Dynamic Aerosol Detector (photometer) shall be tested to determine the response, stability and sensitivity over the full performance range of 25 ± 5 mg/m^3 to 25 ± 5 x 10^6 mg/m^3.

3.3.1 Aerosol sampling system shall be evaluated to determine compliance with sampling duty cycle of 24-hour maintenance-free operation.

3.3.1.1 Sampling pump to be analyzed for pressure/flow variations with respect to aerosol delivery and monitoring over a flow range of 1 to 3 LPM.

3.3.1.2 Sampling pump protection filters shall be evaluated for aerosol loading, utilizing contaminated air (25 ± 5 x 10^{-3} mg/m^3) over a flow range of 1 to 3 LPM to determine stability of photometric response.

3.3.1.3 Sampling and interconnecting hardware shall be evaluated for aerosol impaction and oil film development, utilizing contaminated air (25 ± 5 x 10^{-3} mg/m^3) to determine stability of photometric response.

3.3.1.4 Sampling control valves to be evaluated for functional control of sampling modes, impaction losses and oil film development by visual and photometrically, utilizing $25 \pm 5 \times 10^{-2}$ mg/m^3 aerosol contaminated air.

3.3.1.5 System and sub-system components to be surveyed photometrically to verify zero leakage during normal operation.

3.3.2 Dynamic aerosol transducer shall be evaluated to determine response times sensitivity, stability, signal to noise ratios and linearity over a dynamic range of 10^6.

3.3.2.1 Transducer response time shall be monitored during transit aerosol concentrations over a sample range of 1 to 3 LPM, utilizing aerosol concentrations of 0-0.25-0 mg/m^3, 0-2.5-0 mg/m^3, 0-25-0 mg/m^3.

3.3.2.2 Transducer sensitivity shall be established, using 25 ± 5 mg/m^3 to $25 \pm 5 \times 10^{-6}$ mg/m^3, over a sample flow range of 1 to 3 LPM.

3.3.2.2.1 Aerosol concentrations of 25 ± 5 mg/m^3 to $25 \pm 5 \times 10^{-3}$ to be established through dilution and generator mass output control, utilizing standard aging chambers.

3.3.2.2.2 Aerosol concentrations of $25 \pm 5 \times 10^{-3}$ mg/m^3 to $25 \pm 5 \times 10^{-6}$ mg/m^3 to be established through dilution and generator mass output control, utilizing standard aging chambers, mass impactors and micro-selective filtration.

3.3.2.2.3 Aerosol concentrations to be monitored by gravimeter analysis and particle counting for mass variations.

3.3.2.3 Transducer stability shall be monitored, utilizing steady state aerosol concentrations (Reference 1.2.1).

3.3.2.4 Transducer signal to noise ratios to be established under zero aerosol concentration monitoring on dynamic ranges of 10^{-5} and 10^{-6} verified by particle count.

3.3.2.5 Transducer linearity to be established under the conditions of Paragraph 3.3.2.2.

3.3.3 Transducer signal conditioning and computer-controlled interfacing to be evaluated over the full transducer

response for repeatability, stability and response based on in-service histories (Reference Paragraph 3.3.2).

4.0 Computer System

The sub-system designed to monitor, control and provide data reduction for the integrated aerosol generation and detection instrument.

The environmental test matrix to apply to all sub-system components manu factured by Dynatech to interface purchased computer hardware to control and detection modules. Computer components will be evaluated based on the ven dors' Certificate of Compliance to system specifications.

4.1 The environmental test matrix to apply to all sub-system components manufactured by Dynatech for the purpose of interfacing computer hardware. Computer components will be evaluated based on vendors' Certificates of Compliance to system specifications.

4.2 Computer/Test Chamber interface to be evaluated in accordance with Paragraphs 1.2.1, 1.2.2, 1.2.4, 2.2, 2.2.3, and 2.3.2.

4.3 Computer Aerosol Generation interface to be evaluated in accordance with Paragraphs 1.2.1, 1.2.2, 1.2.3, 1.2.4, 2.2, 2.2.3, and 2.3.

4.4 Computer/Aerosol Detection interface to be evaluated in accordance with Paragraphs 3.2 and 3.3.

5.0 Performance Test

The integrated system performance to be evaluated under similar conditions specified for sub-system groups. Compliance to specifications and objectives will be established and verified by incorporating a three-phase procedure.

5.1 The nominal environmental test matrix will apply to all sub tests of this section unless otherwise specified.

5.2 Aerosol Generation

- 5.2.1 Steady state mean reference aerosol concentrations to be determined by single-point photometric monitoring (Reference Paragraph 1.2.1).
- 5.2.2 Transit aerosol perturbations (test subject entry/egress or analog simulations) will be monitored photometrically (Reference Paragraph 1.2.2).
- 5.2.3 Uniformity of mass concentrations will be determined by remote single-point sampling, utilizing a 3 x 3 x 6 matrix under steady state conditions, photometrically (Reference Paragraph 1.2.3).

5.2.4 Steady state aerosol parameters of mean mass aerodynamic diameter (MMAD) and particle size distribution to be monitored by utilizing photometry, inertial impactors and particle counters (Reference Paragraph 1.2.4).

5.2.5 Transit aerosol parameters of MMAD to be monitored with photometry and inertial impactors to determine restoration stability (Reference Paragraph 1.2.5).

5.3 Aerosol Leakage

5.3.1 Steady state chamber aerosol concentration containment to be surveyed photometrically (Reference 1.3).

5.3.2 System internal modular construction and aerosol hardware to be scanned to determine zero increases in ambient particulate matter (Reference 1.3, 2.2, 2.3, and 3.2).

5.3.3 Enclosure ventilation blower and filter assembly to be evaluated for internal ambient control.

5.3.3.1 Filter intake to be challenged with a 25 ± 5 mg/m^3 aerosol to establish assembly efficiency.

5.3.3.2 All enclosure seals to be surveyed to establish efficiency of enclosure ventilation system when challenged with a 25 ± 5 mg/m^3 aerosol.

5.3.3.3 Enclosure design to prevent internal components and dust protected sub-systems from being exposed to more than 1 percent of the ambient particulate matter.

5.4 Aerosol Detection

5.4.1 Solid state reference aerosol monitoring to be evaluated to determine response characteristics with respect to variations in concentrations between 20 and 30 mg/m^3 (Reference Paragraph 3.2).

5.4.2 Dynamic aerosol detector shall be tested to determine the response, stability and sensitivity over the full performance range of 25 ± 5 mg/m^3 to 25 ± 5 x 10^{-6} mg/m^3 (Reference Paragraph 3.3).

5.4.2.1 Transducer sensitivity/linearity shall be verified, using specified aerosol concentrations ranging from 25 ± 5 mg/m^3 to 25 ± 5 x 10^{-6} mg/m^3 (Reference Paragraph 3.3.2.2).

5.4.2.2 Secondary transducer sensitivity/linearity tests (QNFT simulation) shall be conducted to verify breathing zone concentrations photometrically.

5.4.2.2.1 Simulation of QNFT to be conducted, utilizing Man Simulator where mask-to-face sealing results in zero

leakage at breathing rates of 10 liters minimum..

5.4.2.2.2 Simulation of QNFT to be conducted, utilizing DFC Man Simulator (5.4.2.2.1) where aerosol penetrations will result from calibrated filter assemblies over the dynamic range at breathing rates of 10 liters minimum.

5.4.3 All aerosol detection transducers, sampling pumps, plumbing and interconnecting hardware to be surveyed for zero leakage while the instrument is operating under nominal conditions.

System Test Procedures

System and major equipment groups will be tested to verify conformance to design specifications under simulated operating conditions utilizing standard Dynatech Frontier Corporation Quality Control and engineering procedures.

- Temperature: all temperatures to monitored using Model 400, thermistors, Yellow Springs Instrument Company.
- Humidity: relative humidities to be measured using an asperated wet/dry bulb detector, Dynatech Frontier Corporation.
- Barometric Pressure: atmospheric pressure to be monitored with a Model AW250 barometer, Dynatech Frontier Corporation.
- Aerosol Mass: Primary standard, Laser Aerosol Spectrometer System, Model LAS-200, Particle Measuring Systems, Inc. Secordary standard, mass gravimetric system, Dynatech Frontier Corporation.
- Aerosol Particle Size: Primary standard, Laser Aerosol Spectrometer System, Model LAS-200, Particle Measuring System, Inc. Secondary Standard Inertial Impactors, Model 300, Photometer Model 260, Dynatech Frontier Corporation.
- Aerosol Mass Concentrations: Survey mode only, Photometer Model 260, Dynatech Frontier Corporation.
- Filter Penetrations: Primary standard, Laser Aerosol Spectrometer System, Model LAS-200, Particle Measuring Systems, Inc. Secondary standard Photometer Model 260, Dynatech Frontier Corporation.
- Filter Test: Model 362 Filter Test Stand and Photometer Model 260, Dynatech Frontier Corporation.

- Gas Volume Flow: Model 10-111, Brooks Flowmeter and Model DTM-115, Singer Dry Gas Meter.

- Man Simulator: Model 6267, Dynatech Frontier Corporation.

- Voltage, Current and Resistance: Model 177, Keithley DMM, Keithley Instrument, Inc. Model 1120 Analab Scope, Analytical Laboratory Instruments.

- Environmental Chamber: Model FE 222-4X Systems Testing Unit, Dynatech Frontier Corporation.

Data Reduction

Reduction of raw test data will be consistent with the objective to obtain a suitable statistical analysis for performance computation and instrument control. To simplify the data transformation, raw data will be summarized in digital form and represented in tabular form. Discrete data which is normally distributed will be further represented graphically utilizing linear regression techniques. Aerosol data related to particle size and mass distributions will be represented graphically using log-normal techniques. Error analysis and standard deviations will be determined using the appropriate analysis technique.

APPENDIX C

HUMAN TEST PROTOCOL

Appendix C

HUMAN TEST PROTOCOL

Introduction

State-of-the-art Quantitative Fit Text (QNFT) Instruments are designed to verify fit factors reliably and accurately to a limit of approximately 10^5. These systems normally require an operator to supervise the test, monitor the equipment and interpret the results. As a matter of practice, establishing a fair estimate of the relative efficiency of fit may require observations of 15 minutes or longer, in addition to data reduction time. Increasing instrument performance by an order of magnitude, implementing unattended automation and reducing the test sequence by 80 percent, in compliance with flight-line test criteria, clearly defines the major development effort.

The primary source of leakage into a respiratory protection device is through the seal between the respirator and the face or man-mask interface. Respirator leakage must be measured while worn by a test subject performing a set of predetermined exercises in a simulant atmosphere. Therefore, the breathing zone or other specified internal cavity is normally fitted with a probe for monitoring the level of outside atmosphere which enters the respirator. The fit factor is then defined as the ratio of the challenge agent concentration outside the respirator to the concentration detected in the internal cavities. This leakage evacuation technique, although not directly correlated to live chemical tests, provides the best technical assessment currently available to simulate respirator performance under field conditions.

Development of a prototype automated QNFT system in compliance with the specifications outlined in Contract F33615-83-C-0650 requires several important extensions in current technology. Verification of performance criteria will be established by implementing a three-phase evaluation program.

Phase 1 - Evaluation of the instrument system or sub-system performance utilizing engineering controls to verify hardware and operational conformance to design specifications.

Phase 2 - Analysis of instrument performance with respect to conformance to flight-line QNFT parameters, established using analog simulations.

Phase 3 - Verification of performance during on-line, real time QNFT testing with human subjects to establish compliance with analog simulations and that all instrument functions are consistent with design goals.

Standard Dynatech laboratory procedures, outlined in the environmental and performance test plan, will be employed to verify compliance to the objectives of Phases 1 and 2. Phase 3 is to be initiated only after successful completion of the engineering evaluations.

Phase 3 Test - Evaluations during this phase will consist of two (2) test sequences both using corn oil as the test aerosol. A brief description follows.

Test Sequence 1. Test subjects will be fitted with a quality commercial full-face respirator equipped with high-efficiency particulate filters. The respirator shall be in good condition and free from defects. Standard QNFT tests will be conducted on each test subject and replicated ten (10) times.

Test Sequence 2. Test subjects will be fitted with a control group of GFE furnished masks which are known to be free of defects. Prior to quantitative fit testing, their mask seals will be checked qualitatively with isomyl acetate. QNFT test will be conducted on each test subject and replicated ten (10) times.

Test Method - A challenge concentration of 25 ± 5 mg/m^3 of corn oil in the form of a polydispersed aerosol having a mean mass aerodynamic diameter (MMAD) of 0.35 ± .05 is generated and delivered to a 4 ft. x 4 ft. x 7.5 ft test chamber. The test aerosol is atomized at room temperature utilizing clean filtered air, diluted with clean air and circulated through the test chamber. The test chamber atmosphere is maintained within the above-stated limits.

The concentration of corn oil that has leaked into the respirator/mask is measured by continuously sampling the air in the internal cavities. The sampling rate will be $\geq$ 1 but $\leq$ 3 liters per minute and monitored by a multi-decade forward light scattering photometer. Quantifying the average penetration, fit factor determinations will be analyzed from strip chart recordings and compared to computer analysis.

Test exercises will be performed at random in compliance with flight-line objectives. Total test time to be limited to a maximum of three (3) minutes. Tests are as follows:

Test 1. Normal breathing
Test 2. Deep breathing
Test 3. Head movement, orbital, deep breathing
Test 4. Manual mask adjustment, normal breathing

Test Protocol - Sequence 1. Subject respirators will be tested using corn oil on a Dynatech Model 362 respirator tester. After quality assurance testing, the respirator will

be probed in the oral-nasal region and retested to insure proper probe installation. The subject will enter the test chamber and perform the exercises as instructed by the computer. When failures are detected, leakage rates greater than one percent (1%), the subject will be instructed to exit the test chamber and the test sequence terminated. The subject will exit the chamber and remove his/her mask between each test series. Masks will be inspected and the face seal area cleaned prior to retesting.

Test Protocol - Sequence 2. Subjects to be fitted with GFE mask assemblies containing drinking tubes. The mask assembly to be tested using corn oil on a Dynatech Model 362 respirator tester. Leakage under quality assurance testing to be 0.005% of the challenge agent. Once fitted with mask assembly, subject will enter test chamber and perform the exercises as instructed by the computer. When failures are detected, leakage rates greater than one percent (1%), the subject will be instructed to exit the test chamber and the test sequence terminated.

During this sequence, the subject will interface with the computer-controlled QNFT instrument system and receive all test instructions by computer visual display. The subject will exit the chamber and remove his/her mask between each test series and all replications will be monitored by computer sequencing.

Test Agent - Corn oil is a clear, light yellow, oily liquid with a faint characteristic odor and taste. Refined corn oil is composed almost entirely (99%) of triglycerides, which are the primary forms of body fat. These triglycerides contain a mixture of saturated and unsaturated fatty acids which include lineoleic acid, a polyunsaturated fatty acid comprising 34-62% of corn oil, one of the essential fatty acids.

Use Rate

Concentration = 25 ± 5 mg/m^3
Rate of regeneration ≈ 35 mg per minute
24-hour consumption ≈ 10 gms

Exposure Potential

(a) Skin adsorption - negligible
(b) Ingestion - Low probability
(c) Inhalation - Low probability. Aerosol concentrations in the mask one percent (1%) require subject to be removed from test chamber prior to three (3) minute test completion.

Physical Data

1. Synonyms
   Chem Abstract Registry No: 8001-307
   Chem Abstract Type/Name: Corn oil

   Maise Oil
   Maydol
   Mazola Oil

2. Physical Properties
   Molecular Formula: Unknown
   Constituents: Glycerides of the following fatty acids:

   Myristic 0.1-1%, Palmitic 8-12% stearic 2.5-4.5%, Hexadecentic 0.2-1.6%, Oleic 19-49%, Linoleic 34-62%. Unsaponifiable fraction, 1-3%. The crude oil may contain up to 2% phospholipids.

   Physical Form: Light clear, oily liquid, yellow oil, Faint characteristic odor and taste.

   Density: 0.916-0.921 (25°C/25°C)
   Melting Point: -18 to -10°C
   Flash Point[2]: 562-618°F
   Autoignition Temperature [3,4]: 74°F
   Index of Refraction: 1.470-1.474 (25°C)
   Solubility[3]: Slightly sol. in alcohol. Miscible with chloroform, ether, benzeme, petroleum ether

3. No environmental or occupational data are available.

Subject Selection - Only interested investigators assigned to the project will be used in the Phase 3 testing. Investigators are between the ages of 22 and 50 years. Testing will only require the use of three investigators each totally familiar with the program and considered experts in QNFT instruments and procedures.

All records, including a copy of the signed consent form, will be maintained in the Dynatech project file. Reference Appendix A.

Safety - Corn oil concentrations will be monitored and controlled by automation to within 25 ± 5 mg/m^3.

Concentrations inside the mask exceeding one percent (1%) of the challenge concentration will require termination of the test and removal of subject from the test chamber.

Test subjects will wear standard laboratory smocks over street clothes and GFE mask/full-face respirator.

Heat stress will be minimal since the tests will be conducted at ambient temperatures between 70-80 degrees Fahrenheit.

Subjects will be advised to wash face and hands at the conclusion of a fit test. Eye wash stations will be provided in the test area in the event eye wash is required.

Dynatech's Safety Officer will provide immediate transportation to a physician if required.

The Test Director will insure that all procedures in this protocol are followed and will terminate the test if there is cause to believe continuation may result in injury to subjects or test personnel.

Risk - Based on available data, inhalation of corn oil aerosol appears to offer little risk of human injury and the actual amount of material allowed to enter the breathing zone is so minute that detection by human bioassay fluid is not probable since MMAD's are well within the respirable range.

INVESTIGATOR AGREEMENT AFFIDAVIT

I, _____, as an interested investigator, and having the full capacity to consent, do hereby agree to participate in the developmental test program entitled "Critical Performance Evaluation of an Automated Fit Test Instrument System," Phase 3, under the direction of Mostafa A. Sharaf and Samuel J. Troutman. The implications of my voluntary participation; the nature and purpose; and the methods and test protocols are fully understood by me and do not deviate from standard Dynatech procedures.

Furthermore, I understand that I may, at any time during the course of this program, revoke my consent and withdraw from the study without prejudice.

_____ _____
Signature Date

I will attest to the fact that the individual referred to above is completely informed on the procedures and risks as outlined and hereby witness the investigator's signature.

_____ _____
Witness's Signature Date
Wayne Hixenbaugh
Test Coordinator