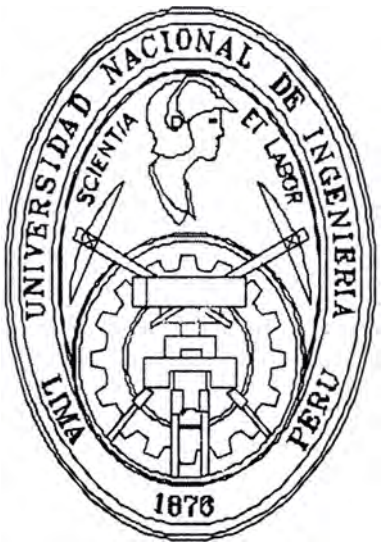
UNIVERSIDAD NACIONAL DE INGENIERIA
FACULTAD DE INGENIERIA MECANICA



VALIDACION DE LA CALIDAD DE LIMPIEZA DEL AIRE DEL LABORATORIO FARMACEUTICO DANIEL ALCIDES CARRION

INFORME DE SUFICIENCIA

PARA OPTAR EL TITULO PROFESIONAL DE:

INGENIERO MECANICO

JESUS MANUEL TORRES FELIX.

PROMOCION 2001- I

LIMA – PERU

2007

El presente trabajo lo dedico a mis Padres, sin cuyo apoyo, aliento y sacrificio permanente no me hubiese sido posible llevarlo a cabo.

TABLA DE CONTENIDOS

CAPITULO VI: COMPROBACION DEL ESTADO FINAL

PROLOGO

El presente informe se ha desarrollado en forma capitular. El en Capítulo 1 se presentan los antecedentes y los objetivos.

En el Capitulo 2 se hace la definición de lo que es una sala limpia, se mencionan los estándares internacionales para determinar la calidad del aire en laboratorios farmacéuticos, como por ejemplo la Federal Standard 209E, la ISO 14644 y la NOM-059-SSA1-2004. También se describen las principales mediciones que se realizan para poder cuantificar el grado de limpieza de una sala.

En el Capitulo 3 presentamos los diferentes equipos de medición empleados para realizar la validación de salas limpias, tales como el Generador de Aerosol, el Fotómetro de Aerosol, el Contador de Partículas–Temperatura - Humedad Relativa. Se describen sus características, sus rangos de medición y los procedimientos de empleo.

En el Capitulo 4 mostramos las mediciones preliminares tomadas de acuerdo a los procedimientos normalizados de operación, las cuales emplearemos como punto de partida para evaluar las condiciones ambientales respecto a las condiciones estandarizadas de las salas o ambientes.

En el Capitulo 5 se describen las pautas para la toma de acciones correctivas que se deben realizar al encontrar mediciones que no cumplen con las condiciones estandarizadas correspondientes a las salas para la producir medicamentos.

En el Capitulo 6 se muestra la comparación entre las mediciones iniciales y finales para tener una referencia de la variaron las condiciones luego de realizada las acciones correctivas. También se presenta una comparación entre las mediciones finales y los estándares internacionales para verificar que los ambientes se encuentran debidamente limpios y por lo tanto aptos para la producción de medicamentos.

CAPITULO I

INTRODUCCION

1.1 ANTECEDENTES

En el diseño de una planta denominada HVAC ("Heated and Ventilated Air Conditioned") para una instalación farmacéutica se debe considerar la protección de los medicamentos a fabricar, la protección del personal y la del medio ambiente. Es por dichas razones que se crearon las normas internacionales conocidas que regulan la calidad de los ambientes donde se realizan los procesos farmacéuticos.

Las normas que generalmente se emplean para validar cualquier tipo de sala limpia es la Federal Standard 209E la ISO 14644 y la NOM-059-SSA1-2004.

La Federal Standard 209 se publicó en 1963 en EE.UU. con el titulo "Clean Room and Work Station Requirements, Controlled Environments" la cual fue revisada en 1966 (209A), 1973 (209B), 1987 (C), 1988 (D) y 1992 (E).

Las salas limpias se clasifican en función del grado de limpieza del aire y uno de los métodos más aplicado es la Federal Standard 209 la cual está siendo reemplazada por la ISO 14644

1.2 OBJETIVOS

En principio debemos dar a conocer las normas internacionales que permiten cuantificar el grado de limpieza de las salas donde se realiza el proceso de manufactura de medicamentos en la industria farmacéutica, la aplicación y uso de estas normas mediante la aplicación de los protocolos de validación que nos permitirá certificar una sala limpia. El presente informe es el resultado de haber

hecho las mediciones, comprobar los resultados con las normas correspondientes, tomas las medidas correctivas y verificar finalmente el cumplimiento de las normas en el Laboratorio Farmacéutico Daniel Alcides Carrión. Es importante mencionar que la importancia del presente trabajo radica en que la factibilidad de su ejecución y buenos resultados se debe a la intervención de especialistas en ingeniería mecánica que permitieron enfocar técnicamente el uso de los instrumentos, las mediciones y colateralmente abordar el tema de la recomendación para poder corregir los errores encontrados. Normalmente esta tarea no se hace por profesionales en ingeniería mecánica, por falta de conocimiento de la aplicación de la misma por algunos sectores productivos.

Las mediciones realizadas son las de Temperatura - Humedad Relativa, Conteo de Partículas, Velocidad del aire de ingreso, Diferencial de Presiones entre salas contiguas y Prueba de Integridad de Filtro HEPA. Estas propiedades son necesarias para poder calificar el estado de limpieza de una sala de manufactura farmacéutica.

El alcance del presente informe, en principio, es presentar las normas, el usar dichas normas, dar a conocer equipos o instrumentos de medición y sus respectivos usos. Es necesario acotar que la aplicación de los conocimientos necesarios para poder verificar la calidad de limpieza se ha efectuado en las instalaciones del Laboratorio Farmacéutico Daniel Alcides Carrión, uno de los más prestigiados de la ciudad de Lima y de nuestro país.

CAPITULO 2

ESTANDARES INTERNACIONALES PARA DETERMINAR LA CALIDAD DEL AIRE EN LABORATORIOS FARMACEUTICOS.

2.1 CONSIDERACIONES GENERALES

La necesidad de un ambiente limpio para la fabricación de productos farmacéuticos industriales es un requisito indispensable en sociedad moderna. El uso de las denominadas salas limpias es diverso y también pueden emplearse en diversos campos tecnológicos, cirugía, comida, etc. En la tabla Nº 1 se detallan diversos usos de las salas limpias. Muchos productos competitivos se procesan en dichas salas limpias, y requieren instalaciones de control de contaminación y ambientes climatizados con aire de alta calidad. Hay dos aspectos a considerar, el primero es el que trata de las partículas no viables (polvo) cuya presencia, incluso en tamaño submicrónico puede reducir la vida útil de funcionamiento de un equipo. El segundo aspecto trata de las partículas microbiológicas que podría provocar infecciones si es ingerido por el ser humano. Se puede observar que muchos de los ejemplos mostrados en la tabla Nº 1 tienen una creciente demanda en nuestra sociedad por lo tanto se requiere de ambientes con aire controlado o ambientes climatizados, es por esta razón que debido a la necesidad de obtener un producto de calidad se estandarizan o normalizan los criterios de diseño para las áreas de producción.

TABLA Nº 1

PRODUCTOS QUE REQUIEREN SER FABRICADOS EN AREAS LIMPIAS

Nº	ÁREA	PRODUCTOS
1	Electrónica	Computadoras, tubos de TV, pantallas planas
2	Semiconductores	Producción de los circuitos integrados usados en memoria y control de computadora. Giroscopios de la micro mecánica, cojinetes en miniatura.
3	Óptica	Lentes, película fotográfica, equipo láser
4	Biotecnología	Producción antibiótica de la biotecnología, Ingeniería genética
5	Farmacia	Productos farmacéuticos estériles
6	Válvulas médicas	Válvulas del corazón
7	Alimenticia	Comidas y bebidas libres de contaminantes
8	Hospitales	Aislamiento de pacientes contagiosos

Fuente: Cleanroom Design by John Wiley and Sons – 1999

2.1.1 Sala limpia

Una sala limpia se define según la Federal Standard 209E como: "Un cuarto en el cual la concentración de partículas aerotransportadas es controlada y el cual contiene unas o más zonas limpias." Y según la ISO 14644-1 como: "Un cuarto en el cual la concentración de partículas aerotransportadas es controlada, y el cual es construido y utilizado de tal forma que se puede reducir al mínimo la introducción, la generación, y la retención de partículas dentro de el y otros parámetros relevantes. La temperatura, humedad, y la presión, se controlan cuanto sea necesario."

2.1.2 Clasificación de una sala limpia

Una de las formas de clasificar las salas limpias es de acuerdo a la limpieza del aire que contiene, la referencia correspondiente al respecto se encuentra en la Federal Standard 209 (hasta la edición "D").

En dicho estándar el número de partículas iguales a 0.5 µm determina el grado de limpieza y clasificación de la sala, y se mide por pie cúbico de aire. Una clasificación de salas limpias mas antigua es la Federal Standard 209D. En la Tabla Nº 2 se muestra la cantidad máxima de partículas que puede haber en una sala limpia medida por pie^3 correspondiente a cada clase.

TABLA Nº 2

CONCENTRACION MAXIMA DE PARTICULAS PARA LA CLASIFICACION DE SALAS LIMPIAS SEGÚN LA FEDERAL STANDARD 209D.

Nº	CLASE	CONCENTRACIÓN MÁXIMA DE PARTÍCULAS (Partículas/pie^3 de Aire)				
		0.1 µm	0.2 µm	0.3 µm	0.5 µm	5.0 µm
1	1	35	7.5	3	1	NA
2	10	350	75.0	30	10	NA
3	100	NA	750.0	300	100	NA
4	1000	NA	NA	NA	1000	7
5	10000	NA	NA	NA	10000	70
6	100000	NA	NA	NA	100000	700

Fuente: Federal Standard 209D - 1999

Este estándar ha sido reemplazado por una versión métrica, la Federal Standard 209E, publicado en 1992. Sin embargo, debido a su simplicidad y uso universal, pasaran muchos años antes de que se olvide la antigua clasificación FS 209D. Es también probable que la nomenclatura de la FS 209D no sea reemplazada por la Federal Standard 209E sino por la Organización internacional de estandarización, para nuestro caso sería la ISO 14644-1. En la tabla Nº 3 se muestra una comparación de las clasificaciones de las distintas normas.

TABLA Nº 3

EQUIVALENCIAS DE LAS CLASIFICACIONES DE SALAS LIMPIAS SEGÚN LA EVOLUCION DE LAS NORMAS

Nº	CLASIFICACIÓN DE SALAS LIMPIAS			CONCENTRACIÓN MÁXIMA DE PARTÍCULAS DE 0.5 µm		
	FS 209-D	FS 209-E	ISO 14644-1	ISO 14644-1 (Partículas/m^3)	FS-209D (Partículas/ft^3)	FS-209E (Partículas/m^3)
1			1			
2			2	4		4
3	1	M 1.5	3	35	1	35
4	10	M 2.5	4	352	10	353
5	100	M 3.5	5	3520	100	3530
6	1000	M 4.5	6	35200	1000	35300
7	10000	M 5.5	7	352000	10000	353000
8	100000	M 6.5	8	3520000	100000	3530000
9			9	35200000		

Fuente EN/ISO 14644-1, 1999

La nueva clasificación de salas limpias según la ISO 14644 se basa en la ecuación siguiente:

$$Cn = 10^{N} * (0.1/D)^{2.08}$$

Donde:

Cn : Concentración permitida máxima de partículas por m^3 de aire, de las partículas aerotransportadas a las cuales ser igual o más grande que el tamaño de partícula considerado, y se redondea al número entero más cercano,

N : Número de la clasificación de la ISO, que no excederá el valor de 9.

D : Tamaño de partícula considerado en µm.

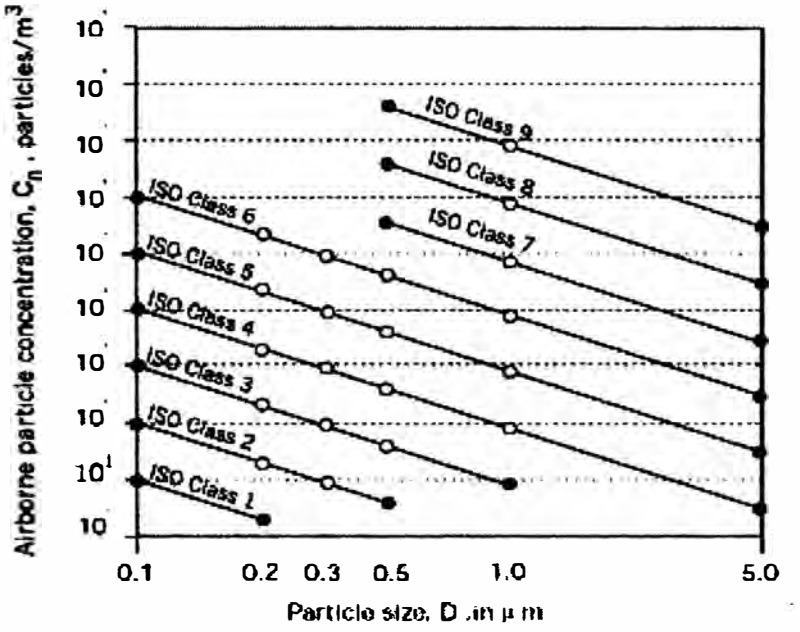
0.1 y 2.08 : Constantes.

El gráfico Nº 1, proporcionado por la ISO 14644, muestra los límites aproximados de la clase (concentraciones máximas de partículas aerotransportadas). Los límites exactos son determinados por la ecuación ya mencionada. La ISO 14644 también

proporciona información en la cual las salas limpias se pueden especificar en términos de partículas ultrafinas (más pequeño de 0.1 µm) o macro partículas (más grande de los de 5.0µm).

FIGURA Nº 1

TAMAÑO DE PARTICULAS VS CONCENTRACION DE PARTICULAS



Fuente: Cleanroom Design by John Wiley and Sons - 1999

2.1.3 Análisis estadístico de datos

Según la ISO – 14644-1, la FED STD-209D y la FED-STD-209E, los siguientes procedimientos se emplean para determinar la concentración de partículas para un conjunto de datos:

a) Determinación del promedio de la concentración de partículas por localización:

$$A_i = (X1+X_2+X_3+.....+Xn) / n$$

Donde:

A_i : Concentración promedio en la localización i

X_1 a X_n : Concentración individual de la partícula

N : Número de muestreo por localización

b) Determinación del valor medio del promedio

$$M = (A_1+A_2+A_3+.....+Am)/m$$

Donde:

A_1 a A_m : Valores promedios por localización individual

m : Número de localizaciones

c) Determinación de la desviación estándar

$$S = \sqrt{\frac{(A1-M)^2+(A2-M)^2+(A3-M)^2+.....+(An-M)^2}{m-1}}$$

Donde:

M : Valor medio de los promedios por localización

A_1 a A_m : Valores promedios por localización individual

m : Número de localizaciones

d) Distribución T-Students para el 95% de límite superior de confianza

Nº de localizaciones	2	3	4	5	6	7	8	9
95% UCL factor	6.31	2.92	2.35	2.13	2.02	1.94	1.90	1.86

e) Determinación del límite superior de confianza (UCL)

$$UCL = M + T_{0.95}\left(\frac{S}{\sqrt{m}}\right)$$

Donde:

M : Valor medio de los promedios por localización

$T_{0.95}$: Distribución T student para 95%

S : Desviación Standard

m : Número de localizaciones

d) Determinación del número mínimo de localizaciones de muestreo:

$$m = \frac{A}{2.32}$$

Donde:

m = Numero minino de localizaciones de muestreo

A = Área de la sala (m^2)

2.1.4 Clasificación de salas limpias requeridas en la industria

La clasificación de una sala limpia depende de la actividad que se realiza en dicha sala o ambiente. La tabla Nº 4 muestra las diferentes clasificaciones para salas limpias y las diferentes aplicaciones en la industria.

TABLA Nº 4

CLASIFICACION DE SALAS LIMPIAS Y SU UTILIZACION EN LA INDUSTRIA

Nº	CLASIFICACIÓN FS-209D	ACTIVIDADES REALIZADAS EN LA INDUSTRIA
1	Clase 1	Estos cuartos son utilizados solamente para la fabricación de circuitos integrados
2	Clase 10	Estos cuartos son utilizados por los fabricantes de semi-conductores y circuitos integrados con la línea de espesor debajo de 2 µm.
3	Clase 100	Son utilizados en ambientes libres de bacterias o partículas, es requerido en fabricación de medicinas inyectables. Requerido para el implante u operaciones quirúrgicas de trasplante, después de operaciones del trasplante de la médula.
4	Clase 1000	En la fabricación de equipo óptico de la alta calidad. Ensamble y prueba de giroscopios de precisión. Ensamble de cojinetes miniaturizados.
5	Clase 10000	Ensamble de equipos hidráulicos y neumáticos de precisión, válvulas servo-control
6	Clase 100000	Trabajo óptico general ensamble de componentes electrónicos, ensamble hidráulico y neumático

Fuente: Cleanroom Design by John Wiley and Sons - 1999

2.1.5 Método de cálculo de las renovaciones de aire

$$\text{Re}nv = \frac{Caudal}{Vol}$$

Donde:

Renv : Renovaciones de aire por hora

Caudal : Caudal de aire a la salida del filtro Terminal (m^3/hr)

Vol : Volumen del cuarto o ambiente (m^3)

2.2 PROCEDIMIENTOS NORMALIZADOS DE OPERACIÓN

2.2.1 Integridad de los filtros HEPA

2.2.1.1 Objetivos

Confirmar que la instalación de los filtros HEPA se realizó correctamente y verificar la no presencia de fugas puntuales en el papel filtrante y la estanqueidad del sellado de la junta elástica entre el filtro y el marco de ajuste.

2.2.1.2 Campo de aplicación

Aplicable a todas las instalaciones con filtros terminales HEPA y gabinetes de flujo laminar.

2.2.1.3 Criterios de aceptación

La penetración máxima permitida será de 0.01% de la concentración de aerosol Upstream.

Según la Federal Standard 209B, no se deben detectar fugas en el cuerpo, empaque y junta del filtro; si existen, éstas deben obturarse para cumplir con la prueba de integridad.

Según la NEBB (Nacional Enviroment Balancing Bureau), las fugas obturadas no pueden exceder el 5.0% de la superficie expuesta del filtro.

2.2.1.4 Referencias

Federal Standard 209B

Documento NEBB (Nacional Environment Balancing Bureau)

IES-RP-CC006.2 “Testing Cleanrooms” (Institute of Environment Sciences)

2.2.2 Conteo de partículas no viables

2.2.2.1 Objetivos

Permitir la clasificación de una sala limpia en cuanto a la cantidad de partículas no viables y comprobar si se mantiene dentro de los límites establecidos.

2.2.2.2 Campo de aplicación

Aplicable a todos los locales con clasificación 100, 10000, 10000 y cabinas de flujo laminar.

2.2.2.3 Criterios de aceptación

La concentración promedio de partículas en cada locación será menor que el limite para la clase

La medida de esas concentraciones promedios será menor que el límite para la clase con un 95% de límite de confianza (95% UCL)

2.2.2.4 Referencias

Federal Standard 209E

ISO 14644 – 1

IES-RP-CC006.2 "Testing cleanrooms" (Institute of Environment Sciences)

2.2.2.5 Procedimiento normalizado para determinar el número de localizaciones y el tiempo de muestreo

- La tabla Nº 3 se muestra los límites de concentración de partículas según la clasificación de la ISO 14644-1. Estos límites designan concentración de partículas por metro cúbico del tamaño igual o mayor que el que se especifica.
- Se determina la cantidad de localizaciones de muestreo según la siguiente operación.

$$m = \frac{A}{2.32}$$

Donde:

m = Numero minino de localizaciones de muestreo

A = Área de la sala (m^2)

Las localizaciones de muestreo no deberá ser inferior a 2 en cada sala, los puntos de muestreo se distribuirá uniformemente en la sala.

- Cada muestra de aire evaluada en cada punto será de un volumen suficiente para que al menos se detecten 20 partículas.
- El volumen de aire evaluado no será nunca menor de 0.0283 m^3
- La tabla Nº 5 muestra el tiempo mínimo para la medición en cada punto de muestreo.

TABLA Nº 5

TIEMPO REQUERIDO DE MEDICION POR CADA PUNTO DE MUESTREO

Nº	Clase	TIEMPO MÍNIMO (seg)
1	100	12
2	10000	6
3	100000	6

Fuente: FD STD 209 E - 1999

2.2.3 Temperatura / Humedad Relativa

2.2.3.1 Objetivos

Describir el método utilizado para la obtención de un mapeo de temperatura y humedad relativa en los locales de trabajo y comprobar si estos valores se mantienen dentro de las condiciones de diseño establecidas.

2.2.3.2 Campo de aplicación

Aplicable a todos los locales a los cuales se le suministre aire a través de un sistema de climatización que le realice un tratamiento psicrométrico al aire.

2.2.3.3 Criterios de aceptación

Los valores de temperatura y humedad relativa deben estar dentro de los límites superior e inferior fijados para demostrar una correcta distribución de las condiciones en el local.

2.2.3.4 Referencia

IES-RP-CC006.2 "Testing Cleanrooms" (Institute of Environmental Sciences)

2.2.4 Cambios de Aire por Hora / Velocidad del aire

2.2.4.1 Objetivos

Describir el método utilizado para la obtención de los cambios de aire por hora en los locales de trabajo y comprobar si estos valores se mantienen dentro de las condiciones de diseño establecidas.

2.2.4.2 Campo de aplicación

Aplicable a todos los locales a los cuales se le suministre aire a través de un sistema de climatización y en cabinas de flujo laminar.

2.2.4.3 Criterios de aceptación

Los locales con niveles de filtración iguales o superiores a 99.97% de eficiencia DOP (H13 o superior) deben tener como mínimo 20 cambios de aire por hora. Los ambientes de envasado de oftálmicos y fabricación de oftálmicos, deben tener un mínimo de 30 renovaciones de aire por hora.

2.2.4.4 Referencias

IES-RP-CC006.2 "Testing Cleanrooms" (Institute of Environmental Sciences)

FDA. 1987.

Informe 32 OMS.

En la tabla Nº 6 se muestra los cambios de aire requeridos y el nivel de filtración de aire recomendado o sugerido para las áreas productivas de los laboratorios farmacéuticos.

TABLA Nº 6

CAMBIOS DE AIRE RECOMENDADOS PARA LAS DIVERSAS AREAS PRODUCTIVAS DE LABORATORIOS FARMACEUTICOS

Nº	CLASIFICACIÓN GENERAL	CAMBIOS DE AIRE REQUERIDOS	% NIVEL DE FILTRACIÓN
1	Flujo Laminar	120 - 80	99.97 - 99.99
2	Inyectables	40 - 90	99.97
3	Preparación estéril	40	99.97
4	Preparación y llenado de líquidos y cremas	20 - 25	99.97
5	Preparación y empaque primario de sólidos	8 - 12	95
6	Empaque secundario de todas las formas farmacéuticas y salas secundarias	8 - 12	65 - 95
7	Vestieres	8 - 12	85 - 95
8	Exterior calle	N.A	N.A

Fuente: HVAC Desing. Tomado del seminario "GMP FOR PHARMACEUTICAL FINISHING FACILITIES" - 2001

2.2.5 Diferencial de presiones

2.2.5.1 Objetivos

Describir el método utilizado para la obtención de las presiones diferenciales entre los locales de trabajo y comprobar si estos valores se mantienen dentro de las condiciones de diseño establecidas.

2.2.5.2 Campo de aplicación

Aplicable a todos los locales a los cuales se le suministra aire a través de un sistema de climatización.

2.2.5.3 Criterios de aceptación

La presión diferencial entre un local estéril y otro adyacente con menor requerimiento debe estar entre 5 y 20 Pa (0.02 y 0.08 in de c H2O)

2.2.5.4 Referencias

ISO 14644 – 4

CAPITULO 3

EQUIPOS DE MEDICION

3.1 PRUEBA DE INTEGRIDAD DE LOS FILTROS TERMINALES HEPAS

3.1.1 Generador de aerosol

Descripción Técnica:

Fabricante : Air Techniques International

Modelo : TDA-4B

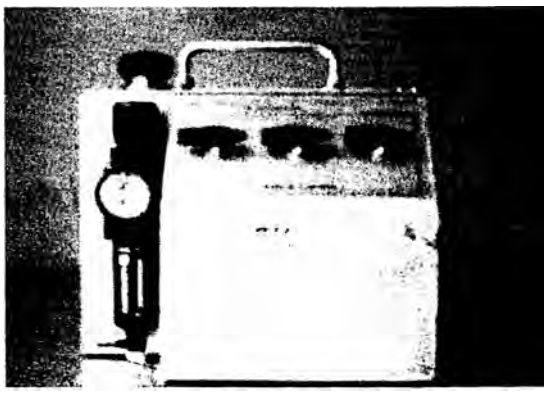
N° Serie : 16270

Descripción : Generador de aerosol polidisperso y submicrometrico en concentraciones desde 10 a 100 µg/L, utilizando PAO (Poly-alpha olefin).

Calibración : No la necesita durante su vida útil

FIGURA N° 2

GENERADOR DE AEROSOL



3.1.2 Fotómetro de aerosol

Descripción Técnica:

Fabricante : Air Techniques International

Modelo : 2H

No. Serie : 16285

Descripción : Fotómetro lineal para muestrear aire u otro gas y reportar la concentración de partículas en la muestra.

Rango : 0.00005 a 120 µg/L.

Precisión : 1% del valor total de la escala para el rango decimal en uso.

Repetibilidad : 0.5% del valor total de la escala para el rango decimal en uso.

Calibración : Se recomienda que se haga anualmente.

FIGURA Nº 3

FOTOMETRO DE AEROSOL

3.1.3 Procedimientos de uso de los instrumentos de medición

El siguiente procedimiento se ejecutará después de verificar que se establece la uniformidad del flujo de aire.

Desenroscar el tapón de llenado de liquido del generador de Aerosol TDA-4B, ubicado en la parte superior del equipo y llenarlo hasta las ¾ partes de su capacidad con el producto aerosol PAO (Poly-alpha olefin).

Conectar la salida del compresor a la entrada del filtro regulador del generador de aerosol.

Encender el compresor y ajustar a una presión de 20 psig.

Ajustar la concentración de aerosol dependiendo del sistema a probar regulando la posición de las válvulas.

Colocar la salida del generador de Aerosol en la unidad de tratamiento de aire o en el conducto de suministro de aire del filtro a una distancia no menor de 10 veces el diámetro o la dimensión mayor del conducto, contando desde el filtro, para lograr una mezcla adecuada del aerosol en la corriente de aire.

Para empezar a generar aerosol, se abrirá la válvula de suministro del compresor, esta operación se realizará cuando el fotómetro se encuentre listo para medir la concentración de aerosol sobre la superficie superior del filtro.

Conectar la sonda de escaneo al Scaning Probe Connector ubicado en el panel frontal en el puerto Downstream del fotómetro.

Encender el Fotómetro colocando el interruptor en la posición (On)

Después que el Fotómetro termina su proceso de inicialización, se selecciona los valores de referencia a ser usados, verificando que el Selector Valve se encuentre en la posición Clear. Cuando la unidad termine de calibrar el valor cero de referencia se emitirá un sonido corto.

Una vez que el equipo se encuentre listo para su uso, comience a generar aerosol en la concentración requerida

Insertar la sonda de muestreo en la toma de muestra de la cara superior del filtro. La sonda debe colocarse tan cerca de la cara superior del filtro como sea posible.

El Selector Valve deberá estar en la posición Upstream. El display % Leakage indicara la concentración que esta siendo leída comparada con el valor de referencia fijado en la inicialización del equipo. Ajustar la concentración de aerosol en el generador al valor deseado.

Presionar el botón 100 y presionar Enter. La unidad comenzará a escanear para el 100% del valor de referencia.

Después que el valor 100% de referencia ha sido tomado exitosamente, debe calibrarse el valor 0% de referencia.

Colocar el Selector Valve en posición Clear y presionar Enter. La unidad comenzara a escanear el valor 0% referencia.

Una vez que los valores 100% y 0% han sido establecidos, la unidad está lista para evaluar el filtro por la superficie interior.

Colocar el Selector Valve en la posición Downstream.

Pasar el extremo de la sonda sobre toda la superficie de la cara inferior del filtro que esta siendo escaneado a una velocidad de 1 pulg/seg y a una distancia de una pulgada de la cara del filtro.

Recorrer toda la superficie y borde del filtro para comprobar la eficiencia e integridad del filtro y el sellado en las juntas.

Si en algún momento se sobrepasa el límite establecido, recorrer lentamente en esa zona para estudiar bien la fuga detectada.

Reporte cualquier lectura superior a la establecida e identifique en un diagrama del filtro la zona observada.

3.2 CONTEO DE PARTÍCULAS NO VIABLES, TEMPERATURA Y HUMEDAD RELATIVA

3.2.1 Contador Óptico de Partículas

Descripción Técnica

Fabricante : Kanomax Japan Inc.

Modelo : 3886 GEO - *α*

Nº Serie : 595555

Rango : 0.3 a 5.0 µm

Fuente de luz : Diodo Láser

Flujo : 0.1 cfm (2.83 L/min)

Pérdida de coincidencia : Menos de 5% a 2,000000 part/pie³

Sonda Temperatura / Humedad relativa

Rango : 0 – 50 °C (32 –122 °F)

Precisión : ± 0.5°C (a velocidad de aire de 2 m/s)

Rango : 3 – 98 %HR

Precisión : ± 3.5HR (± 5% fuera del rango de 30 – 85 %HR)

Calibración : Se recomienda que sea anualmente

Sonda Velocidad del Aire

Rango : 0 – 1 m/s (0 –197FPM)

Precisión : ± 0.05 m/s (10 FPM)

Calibración : Se recomienda que sea anualmente

FIGURA Nº 4

CONTADOR OPTICO DE PARTICULAS – TEMPERATURA – HUMEDAD RELATIVA

3.2.2 Procedimientos de empleo del Contador Óptico de Partículas

Encender el contador de partículas pulsando la tecla POWER

Pulse dos veces la tecla PREV para acceder a la pantalla MODE

Seleccione la opción 4 CALC

Seleccionar el tamaño de partículas, requerimientos de almacenamiento de datos, alarma, tiempo de muestreo, frecuencias.

Cuando el contador este en modo READY, pulse la tecla STAR/STOP para comenzar las mediciones.

Este modo de medición sólo preserva los resultados. Cada medición individual no es almacenada.

3.2.3 Procedimientos de empleo del equipo para medir Temperatura y Humedad Relativa

Para la realización de este procedimiento se utiliza los mismos criterios que para realizar el conteo de partículas.

Si la prueba ocurre en un local con clasificación, y es necesario realizar la prueba de conteo de partículas, conectar al contador de partículas la sonda de temperatura- humedad relativa para obtener los valores en cada punto que esta siendo muestreado.

Si la prueba ocurre en un local sin clasificación y no es necesario realizar la prueba de conteo de partículas, conectar al contador de partículas la sonda de temperatura /humedad relativa para obtener los valores en cada punto que está siendo muestreado teniendo la precaución de colocar la protección del filtro de 0.2 micras en la succión del aire del contador de partículas.

3.3 CAMBIOS DE AIRE HORA / VELOCIDAD DEL AIRE

3.3.1 EBT Balometer

Descripción técnica

Fabricante : ALNOR TSI Incorporated

Modelo **:** EBT – 721

N° Serie **:** 9051003

Rango **:** 25 – 8000 ft/min

Precisión **:** ± 5%

Calibración **:** Si la necesita (anualmente)

FIGURA Nº 5

MEDIDOR DE CAUDAL – BALOMETER

3.3.2 Procedimiento de empleo del equipo

Para la obtención de los cambios de aire por hora en los locales, ubicar los filtros terminales o difusores a través de los cuales se le suministra aire al local.

Colocar las baterías en el micro manómetro

Encender el micro manómetro presionando I/O Key, la unidad inicializará y empezará a realizar una prueba de evaluación.

Colocar la tolva de captación de aire en cada una de las salidas de inyección de aire del sistema

Cuando el display muestre "READY" presionar el botón "READ" para inicializar la medición

Registre la lectura de la velocidad del aire de salida de la tolva el cual es registrado por el medidor digital del equipo Balometer.

Sume el resultado de los caudales en cada uno de los filtros o difusores.

Dividir el caudal total obtenido por el volumen del local que esta siendo muestreado para obtener las renovaciones de aire de la sala.

3.4 DIFERENCIAL DE PRESIONES

3.4.1 Manómetro

Descripción técnica:

Fabricante : Heise Pressure

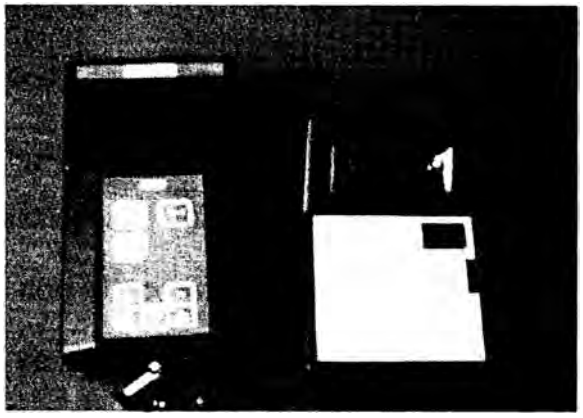
Modelo : PPM-1

Rango : 0 - 0.5 in c. H2O

Precisión : 0.07% in c. H2O

FIGURA Nº 6

MEDIDOR DE PRESIONES DIFERENCIALES



3.4.2 Procedimientos de empleo del equipo

Encender el equipo presionando el botón "ON", luego ubicar un extremo de la manguera a la toma de menor presión y colocar el otro extremo en el local de menor presión a través de la puerta.

Cerrar la puerta y tomar la lectura ubicándose en el local de mayor presión.

Verifique que las presiones no se inviertan cuando se produce la apertura de la puerta.

CAPITULO 4

COMPROBACION DEL ESTADO SITUACIONAL

4.1 RESULTADOS DE LA MEDICIÓN DE ACUERDO A LOS PROCEDIMIENTOS NORMALIZADOS DE OPERACIÓN

El presente estudio de validación de áreas limpias se realizó en el laboratorio farmacéutico D.A. CARRION S.A.C. En las áreas de microbiología, inyectables, oftálmicos y semi-sólidos, se realizaron las pruebas de integridad de filtro Terminal HEPA, realizado con el fotómetro y el generador de aerosol. El conteo de partículas para la clasificación del área, mediciones de temperatura y humedad relativa se realizaron con el contador de partículas y el diferencial de presiones entre áreas contiguas se realizó con el manómetro digital.

4.1.1 Integridad de filtro HEPA

En la tabla Nº 7, mostramos la información de las pruebas realizadas de integridad de los filtros HEPA, en las áreas mencionadas en el ítem anterior, estas pruebas se realizarón con el Fotómetro digital y el Generador de aerosol.

TABLA Nº 7

RESULTADOS DE LAS PRUEBAS DE INTEGRIDAD REALIZADA A LOS FILTROS HEPAS

Nº	ÁREA		FILTRO N°	DIMENSIONES (pulg)	PRUEBAS		CONCLUSIONES
					MEDIO	JUNTAS	
1	Microbiología	Limite Microbiano	A1	24 x 24	Ok	Ok	Cumple
		Área Estéril	A2	24 x 24	Ok	Ok	Cumple
		Preparación de Medios	A3	24 x 12	Ok	Ok	Cumple
		Esclusa	A4	24 x 24	Ok	Ok	Cumple
2	Inyectables	Llenado	B1	24 x 24	Ok	Ok	Cumple
			B2	24 x 24	Ok	Ok	Cumple
		Esclusa Vestuario	B3	24 x 12	Ok	Ok	Cumple
		Esclusa 2	B4	24 x 12	Ok	Ok	Cumple
		Fabricación	B5	24 x 24	Ok	Mal	No Cumple
			B6	24 x 24	Ok	Ok	Cumple
		Lavado	B7	24 x 24	Mal	Ok	No Cumple
		Esclusa 1	B8	24 x 24	Ok	Ok	Cumple
		Descarga y enfriamiento	B9	24 x 24	Ok	Ok	Cumple
			B10	24 x 24	Ok	Mal	No Cumple
3	Semi-Sólidos	Fabricación	C1	24 x 24	Ok	Ok	Cumple
		Envasado	C2	24 x 24	Ok	Ok	Cumple
4	Oftálmicos	Fabricación	D1	24 x 24	Mal	Ok	No Cumple
		Envasado	D2	24 x 24	Ok	Ok	Cumple
		Esclusa 1	D3	24 x 24	Ok	Ok	Cumple
		Esclusa 2	D4	24 x 24	Ok	Ok	Cumple
		Pasadizo	D5	24 x 24	Ok	Ok	Cumple
		Esclusa Envasado	D6	24 x 24	Ok	Ok	Cumple

Criterios de aceptación:

La penetración máxima permitida de aerosol ***Upstream*** será 0.01% de la concentración.

Según la **Federal Standard 209B,** no se deben detectar fugas en el cuerpo, empaque y junta del filtro. Si existen, estas deben obturarse para cumplir con la prueba de integridad.

Según la **NEBB (Nacional Environment Balancing Bureau),** las fugas obturadas no pueden exceder el 5.0% de la superficie expuesta del filtro

Nota: Ver resultados de ubicación de los filtros en los planos del anexo C

4.1.2 Conteo de partículas no viables

El conteo de partículas se realizó en las áreas donde se efectuó la prueba de integridad de filtro HEPA, el conteo de partículas se realizó utilizando el contador de partículas, con lo cual verificaremos la clasificación del diseño de la sala. En la tabla Nº 8 mostramos la clasificación del área, el número de locaciones y la cantidad de muestreo por locación y el promedio de concentración de partículas en cada sala. Se ha seleccionado el tamaño 0.5 µm/m³ y 5.0 µm/m³ ya que son las dimensiones para determinar la clasificación del área de acuerdo a la Federal Standard 209-E.

TABLA Nº 8

RESULTADOS DE LAS MEDICIONES DEL CONTEO DE PARTICULAS EN LAS AREAS MOSTRADAS

Nº	ÁREA		ISO 14644	LOCACIONES DE MUESTREO	MUESTREO POR LOCACIÓN	CONTEO TOTAL	
						Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	Microbiología	Limite Microbiano	Clase7	4	3	276121	1678
		Área Estéril	Clase7	4	3	293232	1711
		Preparación de Medios	Clase7	4	3	280898	1645
		Esclusa	Clase7	2	3	216197	1725
2	Inyectables	Llenado	Clase7	4	3	292460	1914
		Esclusa Vestuario	Clase7	2	3	301152	2314
		Esclusa 2	Clase7	2	3	265815	3876
		Fabricación	Clase7	4	3	353732	2975
		Lavado	Clase7	4	3	259648	1727
		Esclusa 1	Clase7	2	3	366428	2898
		Descarga y Enfriamiento	Clase7	4	3	355351	2987
3	Semi-Sólidos	Fabricación	Clase7	4	3	223200	1532
		Envasado	Clase7	4	3	252828	1901
4	Oftálmicos	Fabricación	Clase7	4	3	353863	2975
		Envasado	Clase7	4	3	289787	1768
		Esclusa 1	Clase7	2	3	262337	2078
		Esclusa 2	Clase7	2	3	265856	1961
		Pasadizo	Clase7	3	3	214876	1934
		Esclusa Envasado	Clase7	2	3	301152	2314

Criterios de Aceptación.

La Concentración Promedio de partículas en cada locación será menor que el límite para la clase.

La media de esas concentraciones promedios será menor que el límite para la clase con un 95% de límite de confianza (95% UCL).

Nota: Las mediciones realizadas en cada locación se muestran en el anexo A, La distribución de las mediciones se muestran en el anexo C.

4.1.3 Temperatura / Humedad Relativa

Las mediciones de temperatura y humedad relativa se realizarón en las mismas áreas y puntos de ubicación donde se realizó las mediciones del conteo de partículas, para realizar estas mediciones se utilizó el contador de partículas, conectando la sonda de temperatura y humedad relativa al contador de partículas. En las tablas 9,10,11 y 12 mostramos los datos obtenidos en las diferentes áreas.

TABLA Nº 9

PROMEDIOS DE TEMPERATURA Y HUMEDAD RELATIVA OBTENIDOS DEL AREA DE MICROBIOLOGIA

Nº	ÁREA	LOCACIÓN	TEMPERATURA (°C)	HR (%)	PROM. Temp (°C)	PROM. HR (%)
1	Limite Microbiano	1	25.6	37.3	25.10	37.18
		2	24.9	37.0		
		3	25.2	36.5		
		4	24.6	37.9		
2	Sala Estéril	1	22.0	34.2	22.60	34.93
		2	22.2	34.0		
		3	23.1	35.5		
		4	23.1	36.1		
3	Preparación de Medios	1	21.9	40.8	21.93	40.33
		2	21.9	41.4		
		3	22.1	39.4		
		4	21.8	39.7		
4	Esclusa	1	21.9	42.3	21.65	40.75
		2	21.4	39.2		

TABLA Nº 10

PROMEDIOS DE TEMPERATURA Y HUMEDAD RELATIVA OBTENIDOS DEL AREA DE INYECTABLES

Nº	ÁREA	LOCACIÓN	TEMPERATURA (°C)	HR (%)	PROM. Temp (°C)	PROM. HR (%)
1	Llenado	1	22.5	45.7	22.38	46.13
		2	22.4	46.6		
		3	22.3	46.7		
		4	22.3	46.5		
2	Esclusa Vestuario	1	22.4	36.4	21.05	39.35
		2	19.7	42.3		
3	Esclusa 2	1	22.4	36.4	21.05	39.35
		2	19.7	42.3		
4	Fabricación	1	26.5	35.7	25.80	36.38
		2	25.4	36.6		
		3	25.3	36.7		
		4	26.2	36.5		
5	Lavado	1	23.3	44.3	23.55	43.98
		2	23.6	44.3		
		3	23.7	43.7		
		4	23.6	43.6		
6	Esclusa 1	1	22.2	36.4	22.20	36.30
		2	22.2	36.2		
7	Descarga y Enfriamiento	1	22.7	45.9	22.68	45.8
		2	22.6	45.8		
		3	22.8	45.6		
		4	22.6	45.9		

TABLA Nº 11

PROMEDIOS DE TEMPERATURA Y HUMEDAD RELATIVA OBTENIDOS DEL AREA DE SEMI-SÓLIDOS

Nº	ÁREA	LOCACIÓN	TEMPERATURA (°C)	HR (%)	PROM. Temp (°C)	PROM. HR (%)
1	Fabricación	1	22.3	37.0	22.33	37.05
		2	22.4	37.1		
		3	22.3	37.0		
		4	22.3	37.1		
2	Envase	1	20.2	39.8	20.l5	39.78
		2	20.1	40.0		
		3	20.2	39.7		
		4	20.3	39.6		

TABLA Nº 12

PROMEDIOS DE TEMPERATURA Y HUMEDAD RELATIVA OBTENIDOS DEL AREA DE OFTALMICOS

Nº	ÁREA	LOCACIÓN	TEMPERATURA (°C)	HR (%)	PROM. Temp (°C)	PROM. HR (%)
1	Fabricación	1	24.2	56.3	24.50	54.40
		2	23.8	55.2		
		3	25.7	55.6		
		4	24.1	54.5		
2	Envasado	1	21.9	54.2	22.05	54.20
		2	22.0	54.8		
		3	22.1	54.2		
		4	22.2	53.6		
3	Esclusa 1	1	22.0	53.3	22.25	54.75
		2	22.8	52.2		
4	Esclusa 2	3	22.0	54.3	22.40	52.75
		4	22.5	55.2		
5	Pasadizo	1	22.2	54.1	22.40	53.60
		2	22.5	54.4		
		3	22.5	52.3		
6	Esclusa Envasado	1	22.0	54.2	22.10	54.20
		2	22.2	54.2		

Criterios de Aceptación.

Los valores de temperatura y humedad relativa deben estar dentro de los límites superior e inferior fijados para demostrar una correcta distribución de las condiciones dentro del local.

Una buena norma referencia es la mexicana PROY-NOM-059-SSA1-2004.

Nota: La distribución de las mediciones se muestran en el anexo C

4.1.4 Cambios de Aire por Hora / Velocidad del aire

Los cambios de aire por hora (renovaciones de aire por hora) se determinan realizando las mediciones de velocidad del aire a la salida de los filtros HEPA o difusores, estas mediciones se realizan con el Balometer

En la tabla Nº 13 mostramos los resultados de las mediciones tomadas en las áreas ya mencionadas.

TABLA Nº 13

RESULTADOS DE LOS CAMBIOS DE AIRE POR HORA

Nº	ÁREA		FILTRO Nº	VOLUMEN (m^3)	CAUDAL m^3/h	CAUDAL TOTAL m^3/h	RENOVACIONES DE AIRE POR HORA
1	Microbiología	Limite Microbiano	A1	34.40	339.80	339.80	9.90
		Área Estéril	A2	22.90	815.50	815.50	35.60
		Preparación de Medios	A3	26.10	577.70	577.70	22.10
		Esclusa	A4	6.80	628.60	628.60	92.40
2	Inyectables	Llenado	B1	124.60	1444.20	2845.80	22.84
			B2		1401.70		
		Esclusa Vestuario	B3	21.00	569.20	569.20	27.10
		Esclusa 2	B4	21.70	441.70	441.70	20.35
		Fabricación	B5	90.60	526.70	1070.40	11.81
			B6		543.70		
		Lavado	B7	35.40	1155.30	1155.30	32.64
		Esclusa 1	B8	21.70	662.60	662.60	30.53
		Descarga y enfriamiento	B9	89.70	985.40	2361.60	26.33
			B10		1376.20		
3	Semi-Sólidos	Fabricación	C1	58.00	1180.80	1180.80	20.36
		Envasado	C2	43.70	903.90	903.90	20.68
4	Oftálmicos	Fabricación	D1	5.10	66.30	66.30	13.00
		Envasado	D2	20.50	805.30	805.30	39.28
		Esclusa 1	D3	9.80	338.10	338.10	34.50
		Esclusa 2	D4	5.60	586.20	586.20	104.67
		Pasadizo	D5	18.10	508.00	508.00	28.07
		Esclusa Envasado	D6	2.90	433.20	433.20	149.37

Criterios de Aceptación.

Los locales deben encontrarse dentro de los parámetros de diseños especificados:

Para los locales con niveles de filtración iguales o superiores a 99.97% de eficiencia DOP (H13 o superior) deben tener como mínimo 20 cambios de aire por hora.

Para los ambientes de Envasado de Oftálmicos y Fabricación de Oftálmicos, se debe de tener un mínimo de 30 renovaciones por hora.

Nota: La distribución de las mediciones se muestran en el anexo C

4.1.5 Diferencial de presiones

En la tabla Nº 14 mostramos los diferenciales de presión entre cada sala, los siguientes datos se obtuvo empleando el manómetro digital

TABLA Nº 14

DATOS OBTENIDOS DEL DIFERENCIAL DE PRESIÓN

Nº	ÁREA		FILTRO No.	DIFERENCIAL DE PRESIÓN (Pa)
1	Microbiología	Limite Microbiano	A1	-6.27
		Área Estéril	A2	+8.77
		Preparación de Medios	A3	+5.01
		Esclusa	A4	-6.27
2	Inyectables	Llenado	B1	+7.52
			B2	
		Esclusa Vestuario	B3	+11.28
		Esclusa 2	B4	+7.52
		Fabricación	B5	+8.77
			B6	
		Lavado	B7	+6.27
		Esclusa 1	B8	-8.77
		Descarga y enfriamiento	B9	+8.77
			B10	
3	Semi-Sólidos	Fabricación	C1	+12.53
		Envasado	C2	+8.27
4	Oftálmicos	Fabricación	D1	-11.28
		Envasado	D2	+12.53
		Esclusa 1	D3	+7.52
		Esclusa 2	D4	+10.03
		Pasadizo	D5	+7.52
		Esclusa Envasado	D6	-5.01

Criterios de Aceptación.

Según la **FDA 1987,** la presión diferencial entre un local estéril y otro adyacente con menor requerimiento debe ser al menos de 12.5 Pa.

Según la **ISO 14644-4,** la presión diferencial entre un local estéril y otro adyacente con menor requerimiento debe estar entre 5 y 20 Pa.

Nota: La distribución de las mediciones se muestran en el anexo C.

4.1.6 Resumen de las observaciones encontradas en los resultados de medición

El procesamiento de los datos permite tener la información que posibilita el proceso de validación. Esta parte de la validación determina si el ambiente es aceptable para el proceso de fabricación. También indirectamente permite identificar si existen procedimientos adecuado de limpieza y mantenimiento de los equipos de aire y ductería, inclusive si hay un buen diseño de la infraestructura y equipamiento. Durante el estudio es importante utilizar los mismos puntos de muestreo para partículas viables y no viables. Esto determina si existe una correlación entre las dos pruebas. El monitoreo de partículas no viables es importante porque permite detectar fallas y fugas alrededor de los filtros HEPA, o por otras causas. Las partículas no viables detectadas durante el monitoreo pueden portar contaminantes viables. Debido a estas razones, el monitoreo de partículas no viables puede ser una buena indicación de la calidad microbiana del aire.

a) Prueba de integridad de filtro HEPA

En la tabla Nº 15 se muestra la relación de los filtros que no cumplieron con los criterios de aceptación ya expuesto en el capitulo 4.1.1. Esta información se ha extraído de la tabla Nº 7

TABLA Nº 15

FILTROS TERMINALES HEPAS QUE NO CUMPLEN LOS CRITERIOS DE ACEPTACION

Nº	ÁREA	FILTRO N°	DIMENSIONES (pulg.)	PRUEBAS		CONCLUSIONES
				Medio	Juntas	
1	Inyectable	B5	24 x 24	Ok	Mal	No Cumple
		B7	24 x 24	Mal	Ok	No Cumple
		B10	24 x 24	Ok	Mal	No Cumple
2	Fabricación Oftálmicos	D1	24 x 24	Mal	Ok	No Cumple

Observaciones:

Se detectó fugas en parte del cuerpo (Filtros B7, D1), se observó que el filtro estuvo dañado y fue en esta zona donde presentó mayor cantidad de concentración de aerosol; en los filtros B5 y B10, se presentó mayor concentración de aerosol en las juntas del filtro, estos filtros se reportaron como observados debido a que los datos obtenidos sobrepasaban la penetración máxima permitida de 0.01% de la concentración de aerosol de acuerdo a la Federal Standard 209 B

Recomendaciones:

Para los filtros que presentaron observaciones en las juntas, se recomendó desmontar el filtro HEPA y realizar un mejor sellado de las juntas del filtro. Es recomendable utilizar empaquetaduras para filtros y posteriormente sellar con silicona interna y externamente. Para los filtros que se encontraron dañados se

procedió a obturar la zona dañada teniendo en cuenta que la superficie obturada no exceda el 5% de la superficie del filtro de acuerdo al **Documento NEBB (Nacional Environment Balancing Bureau)**

b) Conteo de partículas

En la tabla Nº 16 mostramos las diferencias positivas y negativas de los datos obtenidos de las mediciones de conteo de partículas comparadas con los datos proporcionados por la ISO 14644-1 para partículas de 0.5µm y 5.0µm.

TABLA Nº 16

DIFERENCIAS DE LAS MEDICIONES DE CONTEO DE PARTICULAS RESPECTO A LA ISO 14644-1 QUE NO CUMPLIERON CON LOS CRITERIOS DE ACEPTACION

Nº	ÁREA		DATOS OBTENIDOS		ISO 14644-1 Clase 7		Δ Real % Diseño	Δ Real % Diseño
			0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm
1	Inyectables	Descarga y enfriamiento	355351	2987	352000	2930	+0.95	+1.95
		Fabricación	353732	2975	352000	2930	+0.49	+1.55
		Esclusa 1	366428	2898	352000	2930	+4.10	-1.09
2	Oftálmico	Fabricación	353863	2975	352000	2930	+0.53	+1.55

Observaciones:

En los ambientes donde se realizarón las observaciones de prueba de integridad de filtro, los niveles de concentración de partículas difieren de la concentración máxima permitida de acuerdo al criterio de aceptación del capitulo 4.1.2

Recomendaciones

Es indispensable realizar las recomendaciones presentadas en las pruebas de integridad de filtro HEPA. Al personal que labora en estos ambientes seguir los procedimientos de limpieza de acuerdo a la política de seguridad y control ambiental del laboratorio farmacéutico, debido a que el individuo puede emitir partículas de mas 0.5µm según la actividad que este realizando.

El proceso del conteo de partícula deberá realizarse con cuidado evitando generar turbulencias de aire durante el proceso de trasladarse un punto a otro para realizar la medición.

c) Temperatura – Humedad Relativa

La tabla Nº 17 se muestra los ambientes que no cumplieron el criterio de aceptación mostrado en el capitulo 4.1.3, así como la diferencia de los datos obtenidos respecto a la NOM 059-SSA1-2004.

TABLA Nº 17

DIFERENCIAS DE TEMPERATURAS OBTENIDAS RESPECTO A LA NORMA NOM 059-SSA1-2004 DE LAS SALAS QUE NO CUMPLIERON CON EL CRITERIO DE ACEPTACION

Nº	LOCAL	LOCACIÓN	TEMPERATURA (°C)	PROM. Temp (°C)	NOM-059-SSA1-2004 Temp (°C)	Δ Real % Diseño
1	Limite Microbiano	1	25.6	25.1	18 – 23	+9.1
		2	24.9			
		3	25.2			
		4	24.6			
2	Fabricación Inyectables	1	26.5	25.8	18 - 23	+12.2
		2	25.4			
		3	25.3			
		4	26.2			
3	Fabricación Oftálmico	1	24.2	24.50	18 – 23	+6.5
		2	23.8			
		3	25.7			
		4	24.1			

Observaciones:

Se pudo observar un exceso en la temperatura de acuerdo a la temperatura máxima permisible dada por la norma NOM-059-SSA1-2004.

Recomendaciones

Se recomienda balancear el ingreso y la salida del aire en los ambientes mostrados, verificando que los flujos de aire se distribuyan de acuerdo a los parámetros de diseño del ambiente.

d) Cambios de Aire por Hora / Velocidad del Aire

La tabla Nº 18 muestra muestra los datos de las renovaciones de aire por hora que no cumplen el criterio de aceptación para estas áreas, para el cual mostramos la diferencia en porcentaje de los datos obtenidos respecto a los datos requeridos

TABLA Nº 18

DIFERENCIAS DE LAS RENOVACIONES DE AIRE POR HORA RESPECTO A LA FS-209E QUE NO CUMPLIERON CON LOS CRITERIOS DE ACEPTACION

LOCAL	VOLUMEN (m^3)	CAUDAL TOTAL (m^3/h)	RENOVACIONES POR HORA	RENOVACIONES POR HORA REQUERIDAS	ΔReal% / Diseño
Limite Microbiología	34.4	339.8	9.8	20	-51.0
Fabricación Inyectables	90.6	1070.4	11.8	20	-41.0
Fabricación Oftálmicos	5.1	66.3	13.0	30	-56.7

Observaciones

De acuerdo a los datos obtenidos se puede observar que existe una variación negativa respecto a la cantidad de renovaciones de aire de diseño o requeridas en el área, esto se debe al bajo caudal de aire que ingresa a la sala o ambiente

Recomendaciones

Se recomendó redistribuir los flujos de aire de los ambientes, distribuyendo los caudales de aire hacia las zonas que requieren incrementar su caudal para incrementar las renovaciones de aire teniendo presente de no restar caudal en exceso de las áreas que si cuentan con el caudal necesario.

Se recomendó revisar la capacidad de los equipos suministradores de aire y buscar posible fugas de aire a través de la ducteria

CAPITULO 5

MEDIDAS CORRECTIVAS

Un programa de Rutina de Monitoreo Ambiental, se realiza durante la vida de la instalación de los equipos de aire acondicionado, consiste en una rutina de monitoreo ambiental por lo menos cada doce meses. La recopilación de los datos obtenidos durante este tiempo es de mucha importancia e incluye datos registrados durante las paradas de planta, muestreos durante la producción así como las actividades de limpieza y mantenimiento.

Los programas de monitoreo ambiental más efectivos y eficientes son aquellos que cuentas con procedimientos claros y precisos. A continuación mostramos una serie de procesos que por lo general se emplean en los laboratorios farmacéuticos:

Programas de rutina de monitoreo ambiental para ambientes controlados.

Procedimientos de control de la contaminación en ambientes controlados

Análisis y resúmenes de los datos del monitoreo ambiental

Reportes de investigación ambiental para desviaciones ambientales

Notificación de alerta a la producción por fallas de las condiciones ambientales de diseño respecto a los criterios de aceptación.

Procedimientos de entrenamiento y concientización a los trabajadores de estas áreas de ambiente climatizado.

5.1 ESTABLECIMIENTO DEL PROGRAMA DE RUTINA DE MONITOREO AMBIENTAL

Cuando se establece un programa de rutina de monitoreo ambiental, los datos de las validaciones servirán de puntos de partida para establecer los lugares y frecuencia de monitoreo. Se utilizará un plano indicando los puntos de muestreo, este plano deberá tener símbolos representado el punto para las diferentes etapas de muestreo.

La ISO 14644-2 sobre conformidad de evaluación de salas limpias recomienda una frecuencia del control ambiental de los ambientes controlaos o climatizado, esta frecuencia se muestra en la Tabla Nº 19

TABLA Nº 19

FRECUENCIA DEL MONITOREO DE CONTROL AMBIENTAL SEGÚN LA ISO 14644-2

Nº	TIPO DE EVALUACIÓN	CLASE	TIEMPO MÁXIMO ENTRE PRUEBAS	PROCEDIMIENTOS
1	Conteo de partículas	< o igual ISO 5	6 meses	ISO 14644-1 Anexo A
		> ISO 5	12 meses	
2	Diferencial de presión	Todas las clases	12 meses	ISO 14644-1 Anexo B5
3	Velocidad del aire	Todas las clases	12 meses	ISO 14644-1 Anexo B4
4	Integridad de filtro	Todas las clases	12 meses	ISO 14644-3 Anexo B6
5	Recuperación	Todas las clases	12 meses	ISO 14644-3 Anexo B13
6	Visualización del aire	Todas las clases	12 meses	ISO 14644-3 Anexo B7

5.2 Establecimiento de los limites de alerta y acción durante el monitoreo

Los límites de alerta de las concentraciones de partículas viables y no viables en un ambiente controlado se refieren cuando se exceden de los criterios de aceptación,

originando una desviación de las condiciones normales de operación, y requiere una investigación así como las correspondientes acciones correctivas. Los límites de alerta usualmente son obtenidos de la primera validación realizada y del histórico de datos de las posteriores validaciones.

El establecimiento de los límites de alerta y acción debe ser escrito y utilizado de manera consistente. Si un límite de alerta es excedido, pueden no ser requeridas acciones correctivas, pero debe quedar registrado que fue reconocida la alerta. Pero si los niveles de alerta son constantemente excedidos, deberá tomarse una acción investigativa y correctiva.

Si se rebasan un límite de acción debe realizarse un plan de investigación, corrección y notificación al área de producción, deben ser comunicadas a las partes responsables y los otros departamentos relacionados. Las siguientes acciones pueden ser ejecutadas:

Generar un reporte de desviación ambiental

Emitir una notificación de alerta a la producción

Investigar la desviación ambiental

Ejecutar la acción correctiva

Inspeccionar el producto, colocarlo en cuarentena para su evaluación

La vía más efectiva para prevenir la salida de los límites de criterios de aceptación es implementando un programa de control ambiental. Este programa debe estar centrado en el entrenamiento del personal y los procedimientos, se debe incluir métodos que prevean o eviten la salida de los límites máximos permitidos.

5.3 REPORTE DE INVESTIGACIÓN AMBIENTAL

Una investigación ambiental se aplica a una situación que es considerada una amenaza inmediata al sistema climatizado del laboratorio farmacéutico. La

investigación será conducida si el reporte de control ambiental muestra un exceso a los límites de alerta y están continuamente fuera de control. El reporte de investigación ambiental será enviado al departamento afectado para proceder con los procedimientos establecidos.

Una investigación ambiental se inicia cuando:

Es observada una condición cuestionable en el local y áreas asociadas (contaminación ambiental)

Una muestra del monitoreo ambiental excede los criterios de aceptación para partículas viables y no viables en numerosas ocasiones en un sitio critico.

Las condiciones ambientales de temperatura o humedad relativa esta fuera del rango de diseño

La lectura de presión diferencial esta fuera del rango especificado o no mantienen la orientación del flujo en cascada

5.4 PROGRAMA DE ACCIÓN CORRECTIVA

Basados en los resultados de la investigación, las acciones correctivas pueden incluir remuestreo, sanitización, mantenimiento, revalidación, y reentrenamiento del personal.

Las acciones correctivas para ambientes controlados incluyen:

Muestreo y pruebas requeridas de acuerdo a los procedimientos de control

Revisión y/o repetición de los procedimientos de sanitización

Inspección del medio de muestreo microbiano por contaminación

Reentrenamiento de los procedimientos de limpieza al personal del área

Observar los posibles eventos inusuales durante las pruebas o muestreo

Revisar la información de las presiones diferenciales

Revisar los datos de certificación de los cuartos limpios y filtros HEPA

Revisar los reportes diarios de mantenimiento y limpieza

Revisar riesgos de contactos con el producto

Los resultados de las repruebas son registrados en el reporte de desviación ambiental para futuras referencias.

Si las evaluaciones indican que los ambientes o el sistema de climatización no cumple con los niveles de aceptación, aseguramiento de la calidad iniciara investigación ambiental y reportará a los directores de aseguramiento de la calidad y producción las desviaciones encontradas. Es responsabilidad de la dirección de Aseguramiento de calidad conducir una investigación inmediata e iniciar acciones correctivas para devolver el área a las condiciones normales de operación. Aseguramiento de la calidad es responsable de evaluar el impacto en la calidad del producto. Si existe un potencial de que el producto estuvo comprometido durante la falla, entonces debe almacenarse en cuarentena hasta que la investigación sea completada. Después de las acciones correctivas han sido tomadas, las áreas afectadas deberán ser revalidadas.

5.5 REVALIDACIÓN DE SISTEMAS CRÍTICOS

La revalidación debe realizarse cuando ocurre algún cambio significativo o alteración del sistema de climatización, o si existe algún patrón de alerta o acción en algún área. La extensión de la prueba debe determinarse caso a caso y será documentada apropiadamente. Es necesario la ejecución de una revalidación anual de los ambientes controlados y semestral para las áreas más criticas (llenado aséptico). El alcance de la revalidación no tiene que ser tan extenso como la validación inicial, pero debe incluir los mismos sitios de muestreo (un estudio estático y dinámico debe ser suficiente).

CAPITULO 6

COMPROBACION DEL ESTADO FINAL

6.1 RESULTADOS DE LA MEDICIÓN DE ACUERDO A LOS PROCEDIMIENTOS NORMALIZADOS

Las mediciones de temperatura, humedad relativa, diferencial de presión y conteo de partículas se realizarón de igual manera que al inicio, pues al realizarse las acciones correctivas se originó un desbalance de las condiciones ambientales o de diseño de las salas, es por esto que se debe revalidar las áreas nuevamente.

6.1.1 Integridad de filtro HEPA

La prueba de integridad de filtro terminal HEPA, se realizó en los ambientes que se presentaron como observados tal como se muestra en la Tabla Nº 20, no se requirió que se haga una nueva medición en los ambientes que estaban de acuerdo a los criterio de aceptación.

TABLA Nº 20

RESULTADOS DE LAS PRUEBAS DE INTEGRIDAD REALIZADA A LOS FILTROS HEPAS DESPUES DE REALIZAR LAS ACCIONES CORRECTIVAS

Nº	ÁREA	FILTRO Nº	DIMENSIONES (pulg)	PRUEBAS		CONCLUSIONES
				Medio	Juntas	
1	Inyectable	B5	24 x 24	Ok	Ok	Cumple
		B7	24 x 24	Ok	Ok	Cumple
		B10	24 x 24	Ok	Ok	Cumple
2	Fabricación Oftálmicos	D1	24 x 24	Ok	Ok	Cumple

Nota: La ubicación de los filtros se muestran en el anexo D

6.1.2 Conteo de partículas no viables

Las mediciones realizadas del conteo de partículas se muestran en la tabla Nº 21, en la cual se presentan para cada ambiente, las locaciones de muestreo, el número de muestras por locación y los promedios del conteo de partículas.

TABLA Nº 21

RESULTADOS DE LAS MEDICIONES DEL CONTEO DE PARTICULAS EN LAS AREAS MOSTRADAS DESPUES DE REALIZAR LAS MEDIDAS CORRECTIVAS

Nº	ÁREA		ISO 14644	LOCACIONES DE MUESTREO	MUESTREO POR LOCACIÓN	CONTEO TOTAL	
						Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	Microbiología	Limite Microbiano	Clase7	4	3	273235	1678
		Área Estéril	Clase7	4	3	275475	1736
		Preparación de Medios	Clase7	4	3	267790	1551
		Esclusa	Clase7	2	3	219582	2273
2	Inyectables	Llenado	Clase7	4	3	291424	1767
		Esclusa Vestuario	Clase7	2	3	246954	1843
		Esclusa 2	Clase7	2	3	282620	1490
		Fabricación	Clase7	4	3	301195	2032
		Lavado	Clase7	4	3	258351	1806
		Esclusa 1	Clase7	2	3	280642	2586
		Descarga y Enfriamiento	Clase7	4	3	305234	2073
3	Semi-Sólidos	Fabricación	Clase7	4	3	260137	1532
		Envasado	Clase7	4	3	249007	1844
4	Oftálmicos	Fabricación	Clase7	4	3	279531	1845
		Envasado	Clase7	4	3	282998	1904
		Esclusa 1	Clase7	2	3	218882	2001
		Esclusa 2	Clase7	2	3	267419	1961
		Pasadizo	Clase7	3	3	214080	1895
		Esclusa Envasado	Clase7	2	3	234216	2196

Nota: Las mediciones realizadas en cada locación se muestra en el anexo B y la distribución de las mediciones se muestran en el anexo D

6.1.3 Temperatura / Humedad Relativa

En las áreas de microbiología, inyectables, semisólidos y oftálmicos se realizó nuevamente las mediciones de temperatura y humedad relativa, debido a que al realizar las medidas correctivas se produjeron cambios en las condiciones ambientales y es importante verificar que no excedan de los criterios de aceptación. Los datos obtenidos los mostramos en las Tablas Nº 22, 23, 24,25

TABLA Nº 22

PROMEDIOS DE TEMPERATURA Y HUMEDAD RELATIVA OBTENIDOS DEL AREA DE MICROBIOLOGIA DESPUES DE REALIZAR LAS ACCIONES CORRECTIVAS

Nº	ÁREA	LOCACIÓN	TEMPERATURA (°C)	HR (%)	PROM. TEMP (°C)	PROM. HR (%)
1	Limite Microbiano	1	21.5	38.1	22.05	37.43
		2	22.3	37.2		
		3	21.9	36.5		
		4	22.5	37.9		
2	Sala Estéril	1	21.4	34.2	22.13	35.13
		2	22.2	34.7		
		3	21.8	35.5		
		4	23.1	36.1		
3	Preparación de Medios	1	20.9	39.7	21.68	39.68
		2	21.9	39.9		
		3	22.1	39.4		
		4	21.8	39.7		
4	Esclusa	1	20.8	42.3	21.10	40.75
		2	21.4	39.2		

Tabla Nº 23

PROMEDIOS DE TEMPERATURA Y HUMEDAD RELATIVA OBTENIDOS DEL AREA DE INYECTABLES DESPUES DE REALIZAR LAS ACCIONES CORRECTIVAS

Nº	Área	LOCACION	TEMPERATURA (°C)	HR (%)	PROM. TEMP (°C)	PROM. HR (%)
1	Llenado	1	20.8	44.4	21.35	45.23
		2	22.4	46.2		
		3	19.9	43.8		
		4	22.3	46.5		
2	Esclusa Vestuario	1	20.4	39.9	20.05	41.10
		2	19.7	42.3		
3	Esclusa 2	1	21.5	39.7	20.60	41.00
		2	19.7	42.3		
4	Fabricación	1	22.4	35.7	23.93	39.65
		2	21.8	42.8		
		3	25.3	36.7		
		4	26.2	43.4		
5	Lavado	1	22.4	44.3	22.85	44.10
		2	21.7	44.8		
		3	23.7	43.7		
		4	23.6	43.6		
6	Esclusa 1	1	22.2	36.4	22.20	36.30
		2	22.2	36.2		
7	Descarga y Enfriamiento	1	21.3	44.8	21.925	44.65
		2	22.6	46.3		
		3	21.2	41.6		
		4	22.6	45.9		

TABLA Nº 24

PROMEDIOS DE TEMPERATURA Y HUMEDAD RELATIVA OBTENIDOS DEL AREA DE SEMI-SÓLIDOS DESPUES DE REALIZAR LAS ACCIONES CORRECTIVAS

Nº	ÁREA	LOCACIÓN	TEMPERATURA (°C)	HR (%)	PROM. TEMP (°C)	PROM. HR (%)
1	Fabricación	1	21.9	38.9	22.00	38.68
		2	22.4	37.1		
		3	22.3	38.8		
		4	21.4	39.9		
2	Envase	1	21.5	39.8	21.15	39.83
		2	20.1	38.7		
		3	21.7	41.2		
		4	21.3	39.6		

TABLA Nº 25

PROMEDIOS DE TEMPERATURA Y HUMEDAD RELATIVA OBTENIDOS DEL AREA DE OFTALMICOS DESPUES DE REALIZAR LAS ACCIONES CORRECTIVAS

Nº	ÁREA	LOCACIÓN	TEMPERATURA (°C)	HR (%)	PROM. TEMP (°C)	PROM. HR (%)
1	Fabricación	1	24.2	56.3	24.50	54.40
		2	23.8	55.2		
		3	25.7	55.6		
		4	24.1	54.5		
2	Envasado	1	21.9	54.2	22.05	51.55
		2	22.0	49.8		
		3	22.1	48.6		
		4	22.2	53.6		
3	Esclusa 1	1	22.0	47.5	22.40	49.85
		2	22.8	52.2		
4	Esclusa 2	3	22.0	47.2	22.25	51.20
		4	22.5	55.2		
5	Pasadizo	1	22.2	46.8	22.40	47.13
		2	22.5	42.3		
		3	22.5	52.3		
6	Esclusa Envasado	1	22.0	42.1	22.10	48.15
		2	22.2	54.2		

Nota: La distribución de las mediciones se muestran en el anexo D

6.1.4 Cambios de Aire por Hora / Velocidad del aire

En la tabla Nº 26 se muestran las mediciones de caudal de aire realizado en todos los ambientes ya descritos, en el cual mostramos como datos finales las renovaciones de aire por hora en cada ambiente

TABLA Nº 26

RESULTADOS DE LOS CAMBIOS DE AIRE POR HORA DESPUES DE REALIZAR LAS ACCIONES CORRECTIVAS

Nº	ÁREA		FILTRO Nº	VOLUMEN (m^3)	CAUDAL m^3/h	CAUDAL TOTAL m^3/h	RENOVACIONES DE AIRE POR HORA
1	Microbiología	Limite Microbiano	A1	34.40	730.57	730.57	21.20
		Área Estéril	A2	22.90	543.68	543.68	23.70
		Preparación de Medios	A3	26.10	594.65	594.65	22.80
		Esclusa	A4	6.80	169.90	169.90	24.90
2	Inyectables	Llenado	B1	124.60	1359.20	2650.50	21.27
			B2		1291.20		
		Esclusa Vestuario	B3	21.00	424.80	424.80	20.19
		Esclusa 2	B4	21.70	526.70	526.70	24.22
		Fabricación	B5	90.60	1036.40	1987.80	21.94
			B6		951.40		
		Lavado	B7	35.40	866.50	866.50	24.48
		Esclusa 1	B8	21.70	543.70	543.70	25.00
		Descarga y enfriamiento	B9	89.70	764.60	2106.80	23.48
			B10		1342.20		
3	Semi-Sólidos	Fabricación	C1	58.00	1206.30	1206.30	20.80
		Envasado	C2	43.70	922.60	922.60	21.10
4	Oftálmicos	Fabricación	D1	5.10	186.90	516.30	101.30
		Envasado	D2	20.50	934.50	615.00	30.10
		Esclusa 1	D3	9.80	373.80	412.60	42.00
		Esclusa 2	D4	5.60	356.80	458.90	81.70
		Pasadizo	D5	18.10	594.70	363.40	20.10
		Esclusa Envasado	D6	2.90	290.50	375.00	130.70

Nota: La distribución de las mediciones se muestra en el anexo D

6.1.5 Diferencial de presiones

La tabla Nº 27 muestra los datos de los diferenciales de presión que se midieron en las áreas mostradas

TABLA Nº 27

DATOS OBTENIDOS DEL DIFERENCIAL DE PRESIÓN DESPUES DE REALIZAR LAS ACCIONES CORRECTIVAS

Nº	ÁREA		FILTRO Nº	DIFERENCIAL DE PRESIÓN (Pa)
1	Microbiología	Limite Microbiano	A1	+11.92
		Área Estéril	A2	+9.15
		Preparación de Medios	A3	+12.60
		Esclusa	A4	+5.22
2	Inyectables	Llenado	B1	+5.35
			B2	
		Esclusa Vestuario	B3	+9.82
		Esclusa 2	B4	+7.88
		Fabricación	B5	+10.05
			B6	
		Lavado	B7	+5.01
		Esclusa 1	B8	+5.10
		Descarga y enfriamiento	B9	+8.77
			B10	
3	Semi-Sólidos	Fabricación	C1	+13.15
		Envasado	C2	+9.15
4	Oftálmicos	Fabricación	D1	+8.90
		Envasado	D2	+12.53
		Esclusa 1	D3	+5.90
		Esclusa 2	D4	+5.25
		Pasadizo	D5	+9.80
		Esclusa Envasado	D6	+5.15

Nota: La distribución de las mediciones se muestra en el anexo D

6.2 EVALUACIÓN FINAL

6.2.1 Comparación de las mediciones después de realizar las acciones correctivas respectos al estado situacional inicial

El objetivo principal de este capitulo consiste en comparar las variaciones sufridas luego de realizar las acciones correctivas y ver en que medida afectó estas acciones las condiciones ambientales de las salas de producción

6.2.1.1 Integridad de filtro HEPA

En el punto 6.1.1 se puede observar que fueron corregidas las observaciones presentadas respecto a los filtros HEPA.

6.2.1.2 Conteo de partículas no viables

En la Tabla Nº 28 mostramos la variación en porcentaje de los estados inicial y final del conteo de partículas realizado en los ambientes de microbiología, inyectables, semisólidos y oftálmicos.

TABLA Nº 28

DIFERENCIAS DE LOS ESTADOS INICIAL Y FINAL DEL CONTEO DE PARTICULAS

Nº	ÁREAS		ESTADO INICIAL		ESTADO FINAL		Δ%	
			0.5 µm/m³	5.0 µm/m³	0.5 µm/m³	5.0 µm/m³	0.5 µm/m³	5.0 µm/m³
1	Microbiología	Limite Microbiano	276121	1678	272323	1678	-1,38	0,00
		Área estéril	293232	1711	275475	1736	-6,06	+1,46
		Preparación de Medios	280898	1645	267790	1551	-4,67	-5,71
		Esclusa	216197	1725	219582	2273	+1,57	+31,77
2	Inyectables	Llenado	292460	1914	291424	1767	-0,35	-7,68
		Esclusa Vestuario	301152	2314	246954	1843	-18,00	-20,35
		Esclusa 2	265815	3876	282620	1490	+6,32	-61,56
		Fabricación	353732	2975	301195	2032	-14,85	-31,70
		Lavado	259648	1727	258351	1806	-0,50	+4,57
		Esclusa 1	366428	2898	280642	2586	-23,41	-10,77
		Descarga y enfriamiento	355351	2987	305234	2073	-14,10	-30,60
3	Semi-Sólidos	Fabricación	222300	1532	260137	1532	+17,02	0,00
		Envasado	252828	1901	249007	1844	-1,51	-3,00
4	Oftálmicos	Fabricación	353863	2975	349531	1845	-1,22	-37,98
		Envasado	289787	1768	282998	1904	-2,34	+7,69
		Esclusa 1	262337	2078	218882	2001	-16,56	-3,71
		Esclusa 2	265856	1961	267419	1961	+0,59	0,00
		Pasadizo	214876	1934	214080	1895	-0,37	-2,02
		Esclusa Envasado	301152	2314	234216	2196	-22,23	-5,10

6.2.1.3 Temperatura – Humedad Relativa

En la Tabla Nº 29 se muestran los datos de las mediciones inicial y final de la temperatura y humedad relativa de las áreas de microbiología, inyectables, semisólido y oftálmico.

TABLA Nº 29

DIFERENCIAS DE LOS ESTADOS INICIAL Y FINAL DE LAS MEDICIONES DE TEMPERATURA Y HUMEDAD RELATIVA

Nº	ÁREAS		ESTADO INICIAL		ESTADO FINAL		Δ%	
			Temperatura ºC	Humedad Relativa %	Temperatura ºC	Humedad Relativa %	Temperatura ºC	Humedad Relativa %
1	Microbiología	Limite Microbiano	25.10	37.18	22.05	37.43	-12,15	+0,67
		Área estéril	22.60	34.93	22.13	35.13	-2,08	+0,57
		Preparación de Medios	21.93	40.33	21.68	39.68	-1,14	-1,61
		Esclusa	21.65	40.75	21.10	40.75	-2,54	0,00
2	Inyectables	Llenado	22.38	46.13	21.35	45.23	-4,60	-1,95
		Esclusa Vestuario	21.05	39.35	20.05	41.10	-4,75	+4,45
		Esclusa 2	21.05	39.35	20.60	41.00	-2,14	+4,19
		Fabricación	25.80	36.38	23.93	39.65	-7,25	+7,22
		Lavado	23.55	43.98	22.85	44.10	-2,97	+0,27
		Esclusa 1	22.50	36.30	22.20	36.30	-1,33	0,00
		Descarga y enfriamiento	22.68	45.80	21.93	44.65	-3,31	-2,51
3	Semi-Sólidos	Fabricación	22.33	37.05	22.00	38.68	-1,48	+4,40
		Envasado	20.15	39.78	21.15	39.83	+4,96	0,13
4	Oftálmicos	Fabricación	24.50	54.40	24.45	49.90	-0,20	-8,27
		Envasado	22.05	54.20	22.05	51.55	0,00	-4,89
		Esclusa 1	22.25	54.75	22.40	49.85	0,67	-8,95
		Esclusa 2	22.40	52.75	22.25	51.20	-0,67	-2,94
		Pasadizo	22.40	53.60	22.40	47.13	0,00	-12,07
		Esclusa Envasado	22.10	54.20	22.10	48.15	0,00	-11,16

6.2.1.4 Cambios de aire por Hora / Velocidad del aire

La Tabla Nº 29 muestra una comparación entre los estados situacionales inicial y final así como la variación originada por las acciones correctivas que se realizarón en las áreas ya mencionadas anteriormente.

TABLA Nº 30

DIFERENCIAS DE LOS ESTADOS INICIAL Y FINAL DE RENOVACIONES DE AIRE

Nº	ÁREAS		VOL(m^3)	ESTADO INICIAL	ESTADO FINAL	ΔRn %
				RENOVACIONES DE AIRE POR HORA	RENOVACIONES DE AIRE POR HORA	
1	Microbiología	Limite Microbiano	34.40	9.90	21.20	114,14
		Área estéril	22.90	35.60	23.70	-33,43
		Preparación de Medios	26.10	22.10	24.90	12,67
		Esclusa	6.80	92.40	22.80	-75,32
2	Inyectables	Llenado	124.60	22.84	20.19	-11,60
		Esclusa Vestuario	21.00	27.10	24.22	-10,63
		Esclusa 2	21.70	20.35	21.94	7,81
		Fabricación	90.60	11.81	25.00	111,69
		Lavado	35.40	32.64	24.48	-25,00
		Esclusa 1	21.70	30.53	23.48	-23,09
		Descarga y enfriamiento	89.70	26.33	21.27	-19,22
3	Semi-Sólidos	Fabricación	58.00	20.36	20.80	2,16
		Envasado	43.70	20.68	21.10	2,03
4	Oftálmicos	Fabricación	5.10	13.00	101.30	679,23
		Envasado	20.50	39.28	30.10	-23,37
		Esclusa 1	9.80	34.50	42.00	21,74
		Esclusa 2	5.60	104.67	81.70	-21,95
		Pasadizo	18.10	28.07	20.10	-28,39
		Esclusa Envasado	2.90	149.37	130.70	-12,50

6.2.1.5 Diferencial de presiones

La Tabla Nº 30 muestra una comparación entre los estados iniciales y finales de las mediciones de los diferenciales de presión de las áreas mostradas en la tabla.

TABLA Nº 31

COMPARACIÓN DE LOS ESTADOS INICIAL Y FINAL DE LOS DIFERENCIALES DE PRESIÓN

Nº	ÁREAS		DIFERENCIAL DE PRESIÓN INICIAL (Pa)	DIFERENCIAL DE PRESIÓN FINAL (Pa)	ΔPa %
1	Microbiología	Limite Microbiano	+11.92	+11.92	0
		Área estéril	+9.15	+9.15	0
		Preparación de Medios	+12.60	+12.60	0
		Esclusa	+5.22	+5.22	0
2	Inyectables	Llenado	+7.52	+5.35	-28.86
		Esclusa Vestuario	+11.28	+9.82	-12.94
		Esclusa 2	+7.52	+7.88	+4.79
		Fabricación	+8.77	+10.5	+19.72
		Lavado	+6.27	+5.01	-20.10
		Esclusa 1	-8.77	+5.10	-41.85
		Descarga y enfriamiento	+8.77	+8.77	0
3	Semi-Sólidos	Fabricación	+12.53	+13.15	+4.98
		Envasado	+8.27	+9.15	+10.64
4	Oftálmicos	Fabricación	-11.28	+8.90	-21.10
		Envasado	+12.53	+12.53	0
		Esclusa 1	+7.52	+5.90	-21.54
		Esclusa 2	+10.03	+5.25	-47.66
		Pasadizo	+7.52	+9.80	+30.32
		Esclusa Envasado	-5.01	+5.15	+2.79

6.2.2 Comparación de las mediciones finales respecto a los estándares internacionales

6.2.2.1 Conteo de partículas no viables

En la tabla Nº 31 se muestra la diferencia del estado final respecto a la ISO 14644-1, en el cual se puede observar que la diferencia muestra un valor negativo, indicando que las mediciones realizadas se encuentra debajo del limite permisible según la norma.

TABLA Nº 32

DIFERENCIA DEL ESTADO FINAL DEL CONTEO DE PARTICULAS RESPECTO A LA ISO 14644-1

Nº	ÁREAS		ESTADO FINAL		ISO 14644-1 ISO Clase 7		Δ Real % Diseño	
			0.5 µm/m³	5.0 µm/m³	0.5 µm/m³	5.0 µm/m³	0.5 µm/m³	5.0 µm/m³
1	Microbiología	Limite Microbiano	272323	1678	352000	2930	-22.64	-42.73
		Área estéril	275475	1736	352000	2930	-21.74	-40.75
		Preparación de Medios	267790	1551	352000	2930	-23.92	-47.06
		Esclusa	219582	2273	352000	2930	-37.62	-22.42
2	Inyectables	Llenado	291424	1767	352000	2930	-17.21	-39.69
		Esclusa Vestuario	246954	1843	352000	2930	-29.84	-37.10
		Esclusa 2	282620	1490	352000	2930	-19.71	-49.15
		Fabricación	301195	2032	352000	2930	-14.43	-30.65
		Lavado	258351	1806	352000	2930	-26.60	-38.36
		Esclusa 1	280642	2586	352000	2930	-20.27	-11.74
		Descarga y enfriamiento	305234	2073	352000	2930	-13.29	-29.25
3	Semi-Sólidos	Fabricación	260137	1532	352000	2930	-26.10	-47.71
		Envasado	249007	1844	352000	2930	-29.26	-37.06
4	Oftálmicos	Fabricación	349531	1845	352000	2930	-0.70	-37.03
		Envasado	282998	1904	352000	2930	-19.60	-35.02
		Esclusa 1	218882	2001	352000	2930	-37.82	-31.71
		Esclusa 2	267419	1961	352000	2930	-24.03	-33.07
		Pasadizo	214080	1895	352000	2930	-39.18	-35.32
		Esclusa Envasado	234216	2196	352000	2930	- 33.46	-25.05

6.2.2.2 Temperatura – Humedad Relativa

TABLA Nº 33

DIFERENCIA DEL ESTADO FINAL LAS MEDICIONES DE TEMPERATURA Y HUMEDAD RELATIVA RESPECTO A LA NOM-059-SSA1-2004

Nº	ÁREAS		ESTADO FINAL		NOM-059-SSA1-2004		Δ% Real Diseño	
			TEMPERATURA °C	HUMEDAD RELATIVA %	TEMPERATURA °C	HUMEDAD RELATIVA %	TEMPERATURA °C	HUMEDAD RELATIVA %
1	Microbiología	Limite Microbiano	22.05	37.43	18-23	30-65	-4,13	-42,42
		Área estéril	22.13	35.13	18-23	30-65	-3,78	-45,95
		Preparación de Medios	21.68	39.68	18-23	30-65	-5,74	-38,95
		Esclusa	21.10	40.75	18-23	30-65	-8,26	-37,31
2	Inyectables	Llenado	21.35	45.23	18-23	30-65	-7,17	-30,42
		Esclusa Vestuario	20.05	41.10	18-23	30-65	-12,83	-36,77
		Esclusa 2	20.60	41.00	18-23	30-65	-10,43	-36,92
		Fabricación	23.93	39.65	18-23	30-65	4,04	-39,00
		Lavado	22.85	44.10	18-23	30-65	-0,65	-32,15
		Esclusa 1	22.20	36.30	18-23	30-65	-3,48	-44,15
		Descarga y enfriamiento	21.93	44.65	18-23	30-65	-4,65	-31,31
3	Semi-Sólidos	Fabricación	22.00	38.68	18-23	30-65	-4,35	-40,49
		Envasado	21.15	39.83	18-23	30-65	-8,04	-38,72
4	Oftálmicos	Fabricación	24.45	49.90	18-23	30-65	6,30	-23,23
		Envasado	22.05	51.55	18-23	30-65	-4,13	-20,69
		Esclusa 1	22.40	49.85	18-23	30-65	-2,61	-23,31
		Esclusa 2	22.25	51.20	18-23	30-65	-3,26	-21,23
		Pasadizo	22.40	47.13	18-23	30-65	-2,61	-27,49
		Esclusa Envasado	22.10	48.15	18-23	30-65	-3,91	-25,92

6.2.2.3 Cambios de aire por Hora / Velocidad del aire

TABLA Nº 34

DIFERENCIAS DE LOS ESTADOS INICIAL Y FINAL DE RENOVACIONES DE AIRE RESPECTO A LA ISO 14644-1

Nº	ÁREAS		VOL(m^3)	ESTADO FINAL	ISO 14644-1	ΔRn %
				RENOVACIONES DE AIRE POR HORA	RENOVACIONES DE AIRE POR HORA	
1	Microbiología	Limite Microbiano	34.4	21.20	20	6,00
		Área estéril	22.9	23.70	20	18,50
		Preparación de Medios	6.8	24.90	20	24,50
		Esclusa	26.1	22.80	20	14,00
2	Inyectables	Llenado	21.0	20.19	20	0,95
		Esclusa Vestuario	21.7	24.22	20	21,10
		Esclusa 2	90.6	21.94	20	9,70
		Fabricación	21.7	25.00	20	25,00
		Lavado	35.4	24.48	20	22,40
		Esclusa 1	89.7	23.48	20	17,40
		Descarga y enfriamiento	124.6	21.27	20	6,35
3	Semi-Sólidos	Fabricación	2050	20.80	20	4,00
		Envasado	1543	21.10	20	5,50
4	Oftálmicos	Fabricación	5.1	101.30	20	406,50
		Envasado	20.5	30.10	20	50,50
		Esclusa 1	9.8	42.00	20	110,00
		Esclusa 2	5.6	81.70	20	308,50
		Pasadizo	18.1	20.10	20	0,50
		Esclusa Envasado	2.9	130.7	20	553,50

6.2.2.4 Diferencial de presiones

TABLA Nº 35

COMPARACIÓN DEL ESTADO FINAL RESPECTO A LA ISO 14644 -1 DE LOS DIFERENCIALES DE PRESIÓN

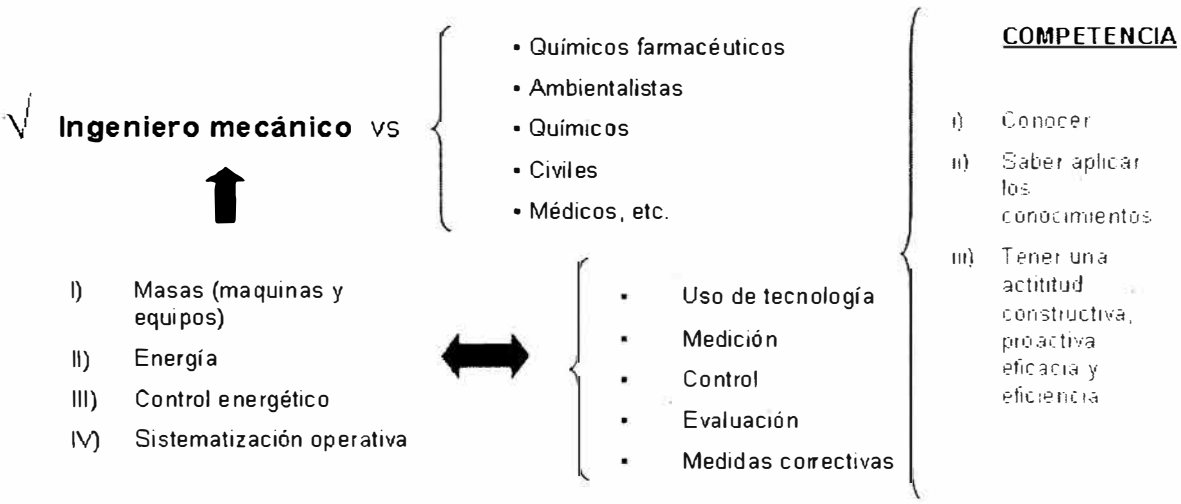
Nº	ÁREAS		DIFERENCIAL DE PRESIÓN FINAL (Pa)	ISO 14644-1 DIFERENCIAL DE PRESIÓN (Pa)	ΔPa %
1	Microbiología	Limite Microbiano	+11.92	+5.00	138,40
		Área estéril	+9.15	+5.00	83,00
		Preparación de Medios	+12.60	+5.00	152,00
		Esclusa	+5.22	+5.00	4,40
2	Inyectables	Llenado	+5.35	+5.00	7,00
		Esclusa Vestuario	+9.82	+5.00	96,40
		Esclusa 2	+7.88	+5.00	57,60
		Fabricación	+10.50	+5.00	110,00
		Lavado	+5.01	+5.00	0,20
		Esclusa 1	+5.10	+5.00	2,00
		Descarga y enfriamiento	+8.77	+5.00	75,40
3	Semi-Sólidos	Fabricación	+13.15	+5.00	163,00
		Envasado	+9.15	+5.00	83,00
4	Oftálmicos	Fabricación	+8.90	+5.00	78,00
		Envasado	+12.53	+5.00	150,60
		Esclusa 1	+5.90	+5.00	18,00
		Esclusa 2	+5.25	+5.00	5,00
		Pasadizo	+9.80	+5.00	96,00
		Esclusa Envasado	+5.15	+5.00	3,00

CONCLUSIONES

1) Se identifican las normas relacionadas a la validación de la calidad de limpieza del aire del Laboratorio Daniel Alcides Carrión.
2) Se puede implementar el equipamiento que permite realizar las mediciones relativas a la limpieza del aire.
3) Se forma un equipo de personal especializado en medir la calidad del aire.
4) Se implementa un procedimiento estándar interno de inspección de calidad.
5) Finalmente, se puede validar la calidad de la limpieza del aire a niveles de competitividad internacional y sostenerla en el tiempo.

RECOMENDACIONES

- Es necesario que el equipo técnico especializado de la alta dirección sea liderado por un profesional de la ingeniería mecánica debido a que se encuentra más capacitado para manejar sistémicamente la problemática del mantenimiento de la calidad de la limpieza del aire en los laboratorios de fabricación de fármacos.
- Debido a los temas que trata el ingeniero mecánico, tiene más ventajas competitivas para manejar el problema de la sostenibilidad de la calidad del aire de modo sistémico respecto a otros profesionales. Esto se grafica en el siguiente esquema:



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ANEXOS

Anexo A Datos de las mediciones de conteo de partículas realizadas en el Laboratorio Farmacéutico D.A. Carrión

Anexo B : Datos de las mediciones del conteo de partículas realizadas en el Laboratorio Farmacéutico D.A. Carrión después de las acciones correctivas

Anexo C : Distribución de las mediciones realizadas en el Laboratorio Farmacéutico D.A. Carrión

Anexo D : Distribución de las mediciones realizadas en el Laboratorio Farmacéutico D.A. Carrión después de realizar las acciones correctivas.

Anexo E : Relación de tablas

Anexo F : Relación de figuras.

Anexo G : Manuales de uso de los equipos de medición.

Anexo H : Certificados de calibración de los instrumentos de medición.

ANEXO A

DATOS DE LAS MEDICONES DEL CONTEO DE PARTICULAS REALIZADAS EN EL LABORATORIO FARMACEUTICO D.A. CARRIÓN

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	278280	2119	261564	1530
	239787	1413		
	266626	1059		
2	183636	1766	199528	1413
	213654	1413		
	201294	1059		
3	311829	1413	272276	1059
	264507	706		
	240493	1059		
4	318538	2119	273806	1648
	290640	1413		
	212241	1413		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
251794	1413	35267	254	17633	127	2.35	293232	1711

c) Local: Microbiología – Preparación de Medios.

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	243318	1766	231076	1530
	218598	1413		
	231311	1413		
2	218951	1766	211888	1530
	236608	1413		
	180105	1413		
3	272982	1413	259327	1413
	264507	1413		
	240493	1413		
4	317832	1059	279928	1059
	278986	1413		
	242965	706		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
245555	1383	30079	223	15040	111	2.35	280898	1645

d) Local: Microbiología - Esclusa.

- **Clasificación:** ISO Clase 7 ó 10 000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m^3	5.0 µm/m^3	Promedio 0.5 µm / m^3	Promedio 5.0 µm / m^3
1	190699	1413	187756	1413
	219657	1413		
	152913	1413		
2	173042	1059	177044	1295
	180811	1413		
	177280	1413		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
182400	1354	7575	83	5356	59	6.31	216197	1725

e) Local: Inyectables – Descarga y Enfriamiento

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m^3	5.0 µm/m^3	Promedio 0.5 µm / m^3	Promedio 5.0 µm / m^3
1	119717	3178	139846	2590
	160329	2472		
	139493	2119		
2	278633	706	294995	824
	269804	1059		
	336549	706		
3	163507	2472	146203	2707
	139140	2825		
	135961	2825		
4	337961	706	347025	706
	372570	706		
	330545	706		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
232017	1707	104965	1090	52482	545	2.35	355351	2987

f) Local: Inyectables - Llenado

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m^3	5.0 µm/m^3	Promedio 0.5 µm / m^3	Promedio 5.0 µm / m^3
1	232017	1413	248615	1648
	278633	1766		
	235196	1766		
2	282164	706	288756	1413
	321717	2119		
	262388	1413		
3	290287	2119	254383	1883
	275454	1766		
	197409	1766		
4	176220	1766	194113	1766
	193171	1766		
	212947	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
246467	1677	39143	201	19572	101	2.35	292460	1914

g) Local: Inyectables – Esclusa Vestuario

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	240140	2119	201764	2001
	202706	1766		
	162447	2119		
2	164213	2119	228957	1883
	278986	1766		
	243671	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
215361	1942	19228	83	13596	59	6.31	301152	2314

h) Local: Inyectables – Esclusa 2

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	250734	1059	224248	1295
	223189	1413		
	198822	1413		
2	175161	2119	208592	2001
	243671	2119		
	206944	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
216420	1648	11071	499	7828	353	6.31	265815	3876

i) Local: Inyectables - Fabricación

- **Clasificación:** ISO Clase 7 ó10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	169864	2472	146438	2590
	129958	3178		
	139493	2119		
2	278633	706	294995	824
	269804	1059		
	336549	706		
3	163507	2472	146203	2707
	139140	2825		
	135961	2825		
4	355266	706	345495	824
	350675	706		
	330545	1059		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
233283	1736	102510	1055	51255	527	2.35	353732	2975

j) Local: Inyectables - Lavado

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	226014	1413	232606	1413
	197409	1413		
	274395	1413		
2	259563	1059	245084	1177
	240140	1059		
	235549	1413		
3	282517	1413	261446	1413
	294171	1413		
	207650	1413		
4	254972	1766	243553	1766
	235549	1766		
	240140	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
245672	1442	11894	243	5947	121	2.35	259648	1727

k) Local: Inyectables – Esclusa 1

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	273336	1413	236726	1177
	195643	1059		
	241199	1059		
2	192112	1766	187874	1648
	187521	1766		
	183989	1413		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
212300	1413	34544	333	24426	235	6.31	366428	2898

l) Local: Semisólidos - Envasado

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	235196	1413	246261	1766
	229192	1766		
	274395	2119		
2	259563	1413	245084	1530
	240140	1766		
	235549	1413		
3	289580	1413	245202	1413
	269451	1413		
	176573	1413		
4	219657	2119	223895	1883
	211888	1766		
	240140	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
240110	1648	10823	215	5412	107	2.35	252828	1901

m) Local: Semisólidos - Fabricación

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m^3	5.0 µm/m^3	Promedio 0.5 µm / m^3	Promedio 5.0 µm / m^3
1	63566	2119	120188	1413
	173395	706		
	123601	1413		
2	294524	1059	239904	1177
	165273	1413		
	259916	1059		
3	155385	1766	122424	1177
	141259	706		
	70629	1059		
4	86874	1413	144790	1530
	76986	1413		
	270510	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
156827	1324	56488	177	28244	88	2.35	223200	1532

n) Local: Oftálmicos – Envasado de Oftálmicos

- **Clasificación:** ISO Clase 7 ó10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	166685	1413	165626	1530
	219304	1766		
	110888	1413		
2	348556	2119	284636	1648
	254619	1413		
	250734	1413		
3	180105	1766	174337	1413
	113360	1059		
	229545	1413		
4	289933	1413	256149	1766
	223895	2119		
	254619	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
220187	1589	59234	152	29617	76	2.35	289787	1768

o) Local: Oftálmico – Fabricación

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	359503	2472	345260	2590
	347849	3178		
	328426	2119		
2	278633	706	294995	824
	269804	1059		
	336549	706		
3	163507	2472	146203	2707
	139140	2825		
	135961	2825		
4	159622	706	143024	824
	129958	706		
	139493	1059		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
232371	1736	103398	1055	51699	527	2.35	353863	2975

p) Local: Oftálmicos – Esclusa 1

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m^3	5.0 µm/m^3	Promedio 0.5 µm / m^3	Promedio 5.0 µm / m^3
1	98881	2119	135844	1648
	123601	1059		
	185049	1766		
2	173395	1413	170452	1766
	186108	2119		
	151853	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
153148	1707	24472	83	17304	59	6.31	262337	2078

q) Local: Oftálmicos – Exclusa 2

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m^3	5.0 µm/m^3	Promedio 0.5 µm / m^3	Promedio 5.0 µm / m^3
1	271923	1413	209063	1530
	181871	1059		
	173395	2119		
2	343965	1766	224601	1648
	216832	2119		
	113007	1059		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
216832	1589	10987	83	7769	59	6.31	265856	1961

r) Local: Oftálmico – Pasadizo

- **Clasificación:** ISO Clase 7 ó10,000
- **Locaciones de Muestreo Tomadas:** 3
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	119717	1413	160211	1413
	160329	1059		
	200587	1766		
2	127133	706	201647	942
	269804	1059		
	208003	1059		
3	163507	1413	123366	1766
	139140	2119		
	67451	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
161741	1373	39163	413	22611	239	2.35	214876	1934

s) Local: Oftálmicos – Esclusa Envasado

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	162447	2119	201764	2001
	202706	1766		
	240140	2119		
2	164213	2119	228957	1883
	278986	1766		
	243671	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
215361	1942	19228	83	13596	59	6.31	301152	2314

ANEXO B

DATOS DE LAS MEDICIONES DEL CONTEO DE PARTICULAS REALIZADAS EN EL LABORATORIO FARMACEUTICO D.A. CARRIÓN DESPUES DE LAS ACCIONES CORRECTIVAS

a) Local: Microbiología – Limite Microbiano.

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m^3	5.0 µm/m^3	Promedio 0.5 µm / m^3	Promedio 5.0 µm / m^3
1	329133	1766	265449	1530
	200234	1413		
	266979	1413		
2	243671	2472	242376	1648
	235549	1413		
	247909	1059		
3	329133	1766	265449	1177
	200234	1059		
	266979	706		
4	329133	1766	265449	1413
	200234	1766		
	266979	706		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	0.5 µm		0.5 µm	5.0 µm
259681	1442	11536	201	5768	101	2.35	273235	1678

b) Local: Microbiología – Área Estéril.

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	311829	2119	272276	1648
	264507	1413		
	240493	1413		
2	243671	2472	242376	1648
	235549	1413		
	247909	1059		
3	329133	1766	265449	1177
	200234	1059		
	266979	706		
4	278280	1766	261564	1413
	239787	1413		
	266626	1059		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
260416	1471	12816	225	6408	113	2.35	275475	1736

c) Local: Microbiología – Preparación de Medios.

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	272982	1059	259327	1059
	264507	1413		
	240493	706		
2	218951	1766	211888	1530
	236608	1413		
	180105	1413		
3	272982	1413	259327	1413
	264507	1413		
	240493	1413		
4	218951	1059	211888	1059
	236608	1413		
	180105	706		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
235608	1265	27389	243	13695	121	2.35	267790	1551

d) Local: Microbiología - Esclusa.

- **Clasificación**: ISO Clase 7 ó 10 000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m^3	5.0 µm/m^3	Promedio 0.5 µm / m^3	Promedio 5.0 µm / m^3
1	190699	1766	193642	1648
	208357	1413		
	181871	1766		
2	173042	1413	183872	1413
	180811	1766		
	197762	1059		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
188757	1530	6909	166	4885	118	6.31	219582	2273

e) Local: Inyectables – Descarga y Enfriamiento

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m^3	5.0 µm/m^3	Promedio 0.5 µm / m^3	Promedio 5.0 µm / m^3
1	286049	1766	302058	1883
	310416	1766		
	309710	2119		
2	259563	1413	284518	1648
	287815	1413		
	306178	2119		
3	321363	1766	296643	1295
	278986	1059		
	289580	1059		
4	257797	1766	269215	2001
	274395	2119		
	275454	2119		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
288109	1707	14575	311	7287	156	2.35	305234	2073

f) Local: Inyectables - Llenado

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	255325	1766	256384	1648
	278633	1413		
	235196	1766		
2	282164	1059	282046	1295
	301587	1413		
	262388	1413		
3	266979	2119	262623	1648
	275454	1059		
	245437	1766		
4	196350	1413	200823	1648
	193171	1766		
	212947	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
250469	1560	34855	177	17427	88	2.35	291424	1767

g) Local: Inyectables – Esclusa Vestuario

- **Clasificación: ISO Clase 7 ó** 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	215419	1413	235078	1530
	243318	1766		
	246496	1413		
2	190699	1059	230605	1413
	246496	1766		
	254619	1413		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
232841	1471	3163	83	2237	59	6.31	246954	1843

h) Local: Inyectables – Esclusa 2

- **Clasificación**: ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	226014	1413	216361	1177
	215419	1059		
	207650	1059		
2	255325	706	234489	1059
	219304	1059		
	228839	1413		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
225425	1118	12819	83	9064	59	6.31	282620	1490

i) Local: Inyectables - Fabricación

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	266626	1766	280869	1766
	316066	1766		
	259916	1766		
2	251440	1059	233430	1177
	240493	1059		
	208357	1413		
3	283224	1413	285343	1530
	255325	1413		
	317479	1766		
4	180105	1766	185991	2001
	193171	2472		
	184696	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
246408	1619	46627	352	23313	176	2.35	301195	2032

j) Local: Inyectables - Lavado

- **Clasificación:** 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	251440	1413	241317	1413
	212594	1413		
	259916	1413		
2	235549	1059	240375	1177
	240140	1059		
	245437	1413		
3	282517	1059	261446	1295
	294171	1413		
	207650	1413		
4	254972	1766	243553	1883
	235549	2119		
	240140	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
246673	1442	9939	310	4969	155	2.35	258351	1806

k) Local: Inyectables – Esclusa 1

- **Clasificación**: ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m^3	5.0 µm/m^3	Promedio 0.5 µm / m^3	Promedio 5.0 µm / m^3
1	223189	1413	220010	1295
	195643	1413		
	241199	1059		
2	192112	1766	197174	1648
	215419	1766		
	183989	1413		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
208592	1471	16148	250	11418	177	6.31	280642	2586

l) Local: Semisólidos - Envasado

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m^3):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m^3	5.0 µm/m^3	Promedio 0.5 µm / m^3	Promedio 5.0 µm / m^3
1	263094	1059	245437	1648
	221776	1766		
	251440	2119		
2	259563	1413	245084	1530
	240140	1766		
	235549	1413		
3	282164	1413	242729	1530
	269451	1766		
	176573	1413		
4	241552	2119	231193	1883
	211888	1766		
	240140	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
241111	1648	6720	166	3360	83	2.35	249007	1844

m) Local: Semisólidos - Fabricación

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	246496	2119	206355	1413
	198822	706		
	173748	1413		
2	251440	1059	225543	1177
	165273	1413		
	259916	1059		
3	192818	1766	134902	1177
	141259	706		
	70629	1059		
4	223189	1413	246261	1530
	245084	1413		
	270510	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
203265	1324	48401	177	24201	88	2.35	260137	1532

n) Local: Oftálmicos – Envasado de Oftálmicos

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	166685	1413	155620	1413
	189287	1413		
	110888	1413		
2	297349	2119	259916	1883
	254619	2119		
	227780	1413		
3	180105	1766	174337	1413
	113360	1059		
	229545	1413		
4	289933	1413	269098	1766
	262741	2119		
	254619	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
214743	1619	58090	243	29045	121	2.35	282998	1904

o) Local: Oftálmico – Fabricación

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 4
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	222836	2119	280987	1883
	310416	1766		
	309710	1766		
2	259563	1766	268627	1295
	240140	706		
	306178	1413		
3	191405	1413	254619	1530
	294171	1766		
	278280	1413		
4	224248	2119	258032	1530
	274395	706		
	275454	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	0.5 µm		0.5 µm	5.0 µm
265566	1560	11885	243	5943	121	2.35	279531	1845

p) Local: Oftálmicos – Esclusa 1

- **Clasificación**: ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	98881	2119	135844	2001
	123601	2119		
	185049	1766		
2	137727	2119	158563	2001
	186108	2119		
	151853	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
147203	2001	16065	0	11360	0	6.31	218882	2001

q) Local: Oftálmicos – Exclusa 2

- **Clasificación**: ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	244731	1413	208474	1530
	181871	1059		
	198822	2119		
2	343965	1766	224601	1648
	216832	2119		
	113007	1059		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
216538	1589	11404	83	8064	59	6.31	267419	1961

r) Local: Oftálmico – Pasadizo

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 3
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	180105	1413	180340	1295
	160329	1059		
	200587	1413		
2	148675	706	208827	942
	269804	1059		
	208003	1059		
3	163507	1413	168216	1766
	139140	2119		
	202000	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	5.0 µm		0.5 µm	5.0 µm
185794	1334	20848	413	12037	239	2.35	214080	1895

s) Local: Oftálmicos – Esclusa Envasado

- **Clasificación:** ISO Clase 7 ó 10,000
- **Locaciones de Muestreo Tomadas:** 2
- **Volumen de Muestreo (m³):** 0.0283
- **Tiempo de Muestreo:** 1 minuto.
- **Muestreos por locación:** 3

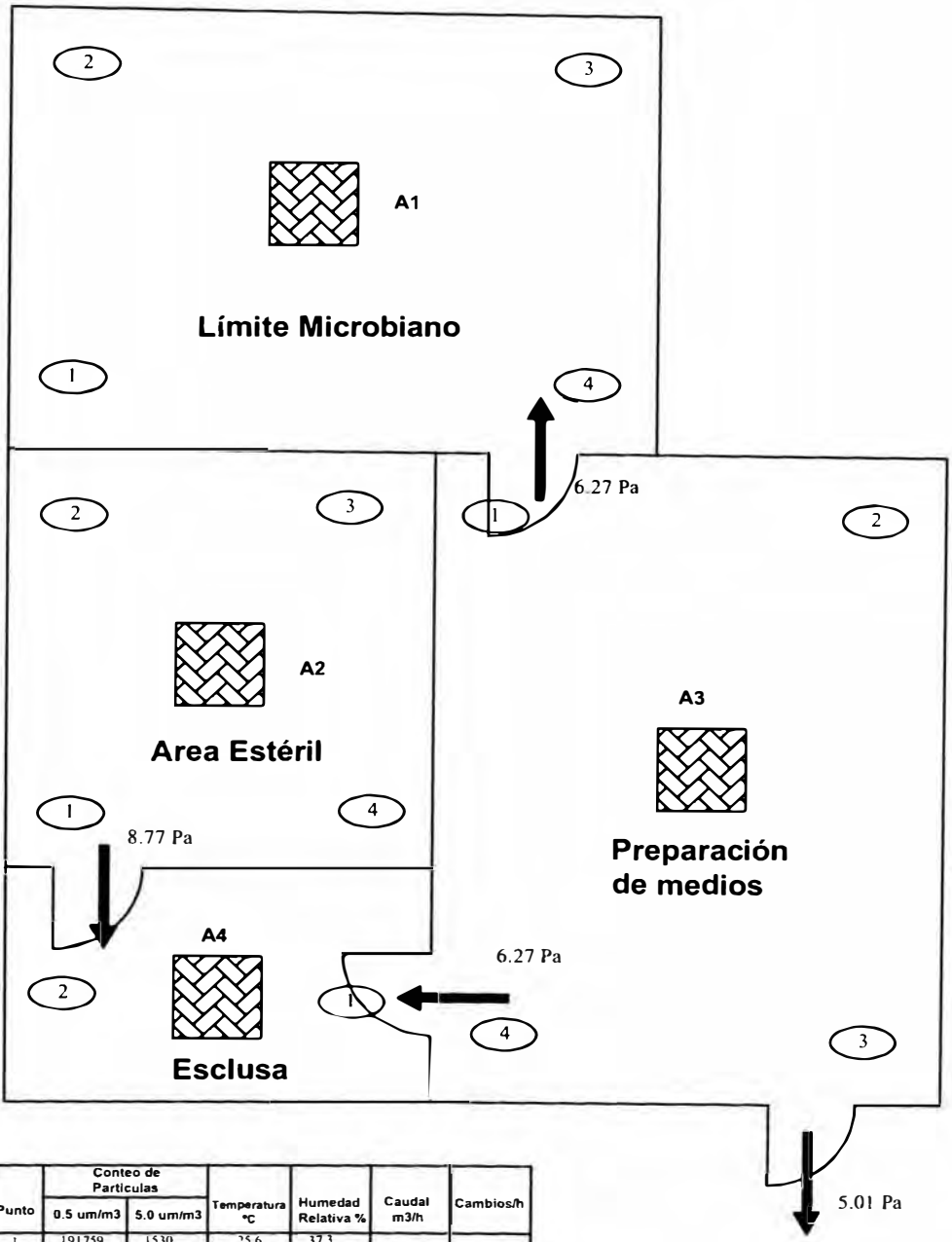
Locación	0.5 µm/m³	5.0 µm/m³	Promedio 0.5 µm / m³	Promedio 5.0 µm / m³
1	266979	2119	210122	1766
	202706	1413		
	160682	1766		
2	164213	2119	216714	1883
	278986	1766		
	206944	1766		

Media		SD		SE		UCL	Conteo Total	
0.5 µm	5.0 µm	0.5 µm	5.0 µm	0.5 µm	0.5 µm		0.5 µm	5.0 µm
213418	1825	4661	83	3296	59	6.31	234216	2196

ANEXO C

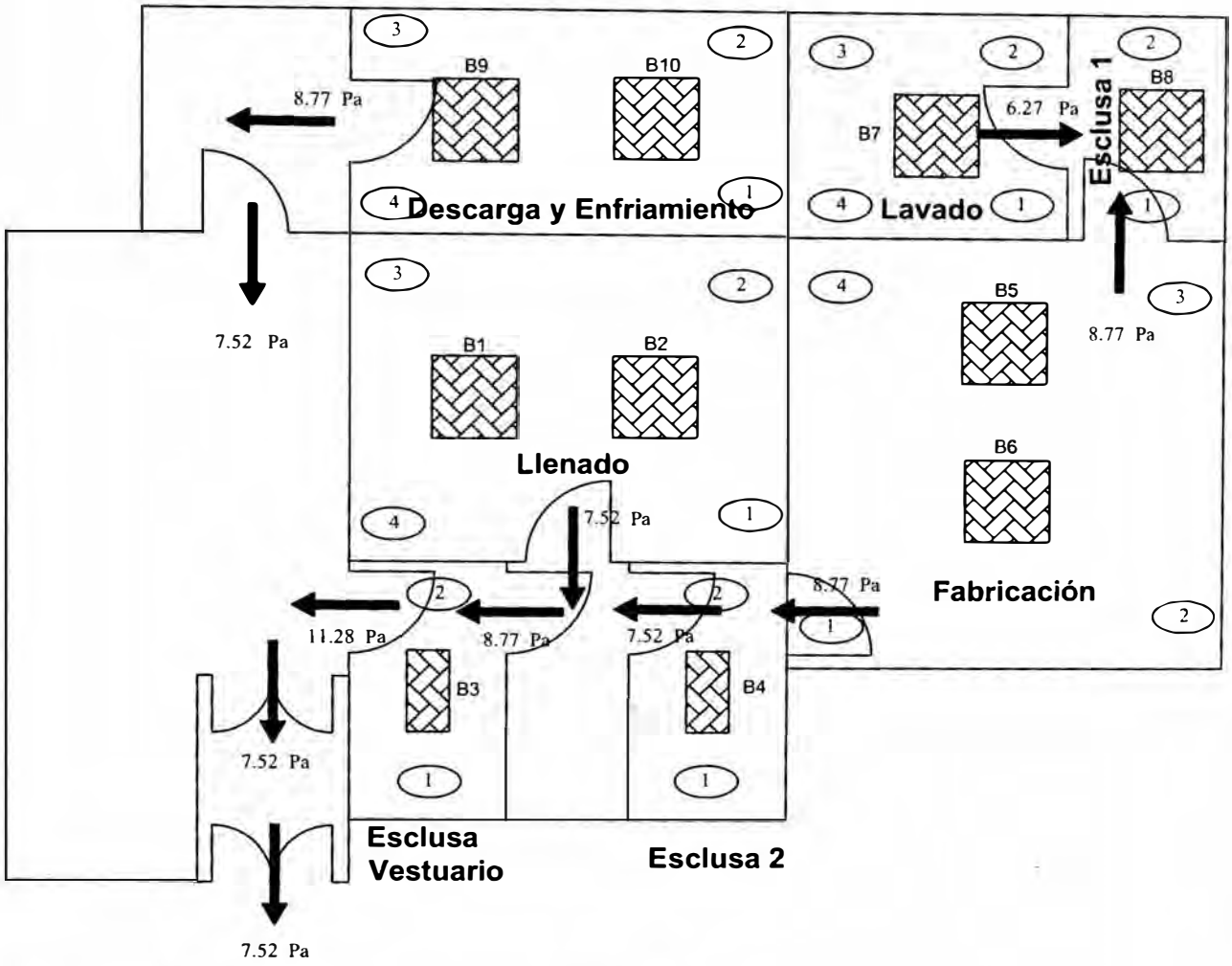
DISTRIBUCIÓN DE LAS MEDICONES REALIZADAS EN EL LABORATORIO FARMACÉUTICO D.A. CARRION

MICROBIOLOGIA



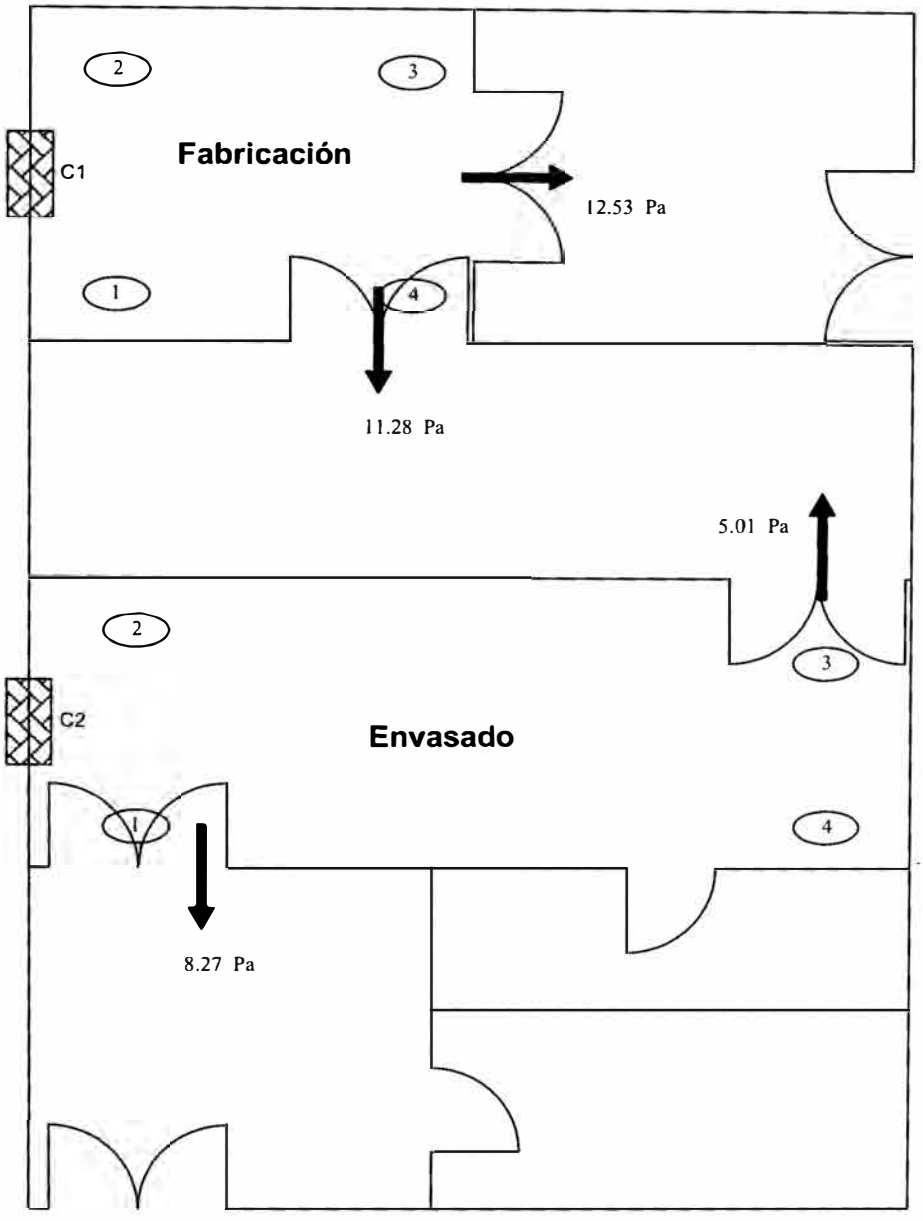
AREAS	Punto	Conteo de Particulas		Temperatura °C	Humedad Relativa %	Caudal m3/h	Cambios/h
		0.5 um/m3	5.0 um/m3				
Limite Microbiano	1	191759	1530	25 6	37 3	339 80	9 90
	2	252971	1648	24 9	37 0		
	3	265449	1177	25 2	36 5		
	4	242376	1413	24 6	37 9		
Area Esteril	1	261564	1530	22 0	34 2	815 50	35 60
	2	199528	1413	22 2	34 0		
	3	222276	1059	23 1	35 5		
	4	273806	1648	23 1	36 1		
Preparación de medios	1	231076	1530	21 9	40 8	577 70	22 10
	2	211888	1530	21 9	41 4		
	3	259327	1413	22 1	39 4		
	4	279928	1059	21 8	39 7		
Esclusa	1	187756	1413	21 9	42 3	628 60	92 40
	2	177044	1295	21 4	39 2		

INYECTABLES



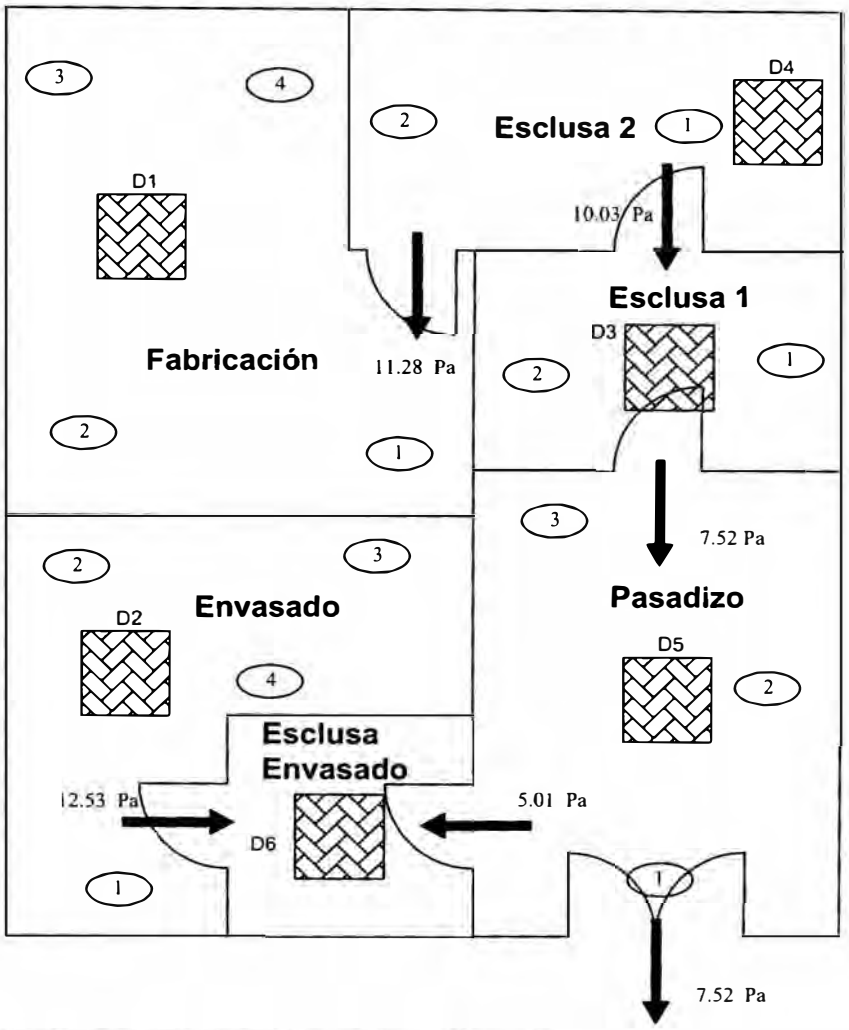
AREAS	Punto	Conteo de Particulas 0.5 um/m3	Conteo de Particulas 5.0 um/m3	Temperatura °C	Humedad Relativa %	Caudal m3/h	Cambios/h
Descarga y Enfriamiento	1	139846	2590	22 7	45 9	2361 60	26 33
	2	294995	824	22 6	45 8		
	3	146203	2707	22 8	45 6		
	4	347025	706	22 6	45 9		
Llenado	1	248615	1648	22 5	45 7	2845 80	22 84
	2	288756	1413	22 4	46 6		
	3	2543B3	1883	22 3	46 7		
	4	194113	1766	22 3	46 5		
Esclusa Vestuario	1	201764	2001	22 4	36 4	569 20	27 10
	2	228957	1883	19 7	42 3		
Esclusa 2	1	224248	1295	22 4	36 4	441 70	20 35
	2	208592	2001	19 7	42 3		
Fabricación	1	146438	2590	26 5	35 7	1070 40	11 81
	2	294995	824	25 4	36 6		
	3	146203	2707	25 3	36 7		
	4	345495	824	26 2	36 5		
Lavado	1	232606	1413	23 3	44 3	1155 30	32 64
	2	245084	1177	23 6	44 3		
	3	261446	1413	23 7	43 7		
	4	243553	1766	23 6	43 6		
Esclusa 1	1	236726	1177	22 2	36 4	662 60	30 53
	2	187874	1648	22 2	36 2		

SEMI - SOLIDOS



AREAS	Punto	Conteo de Particulas		Temperatura °C	Humedad Relativa %	Caudal m3/h	Cambios/h
		0.5 um/m3	5.0 um/m3				
Fabricación	1	120188	1413	22 3	37 0	1180 80	20 36
	2	239904	1177	22.4	37 1		
	3	122424	1177	22 3	37.0		
	4	144790	1530	22 3	37 1		
Envasado	1	246261	1766	20 2	39 8	903 90	20 68
	2	245084	1530	20 1	40 0		
	3	245202	1413	20.2	39 7		
	4	223895	1883	20 3	39 6		

OFTALMICOS

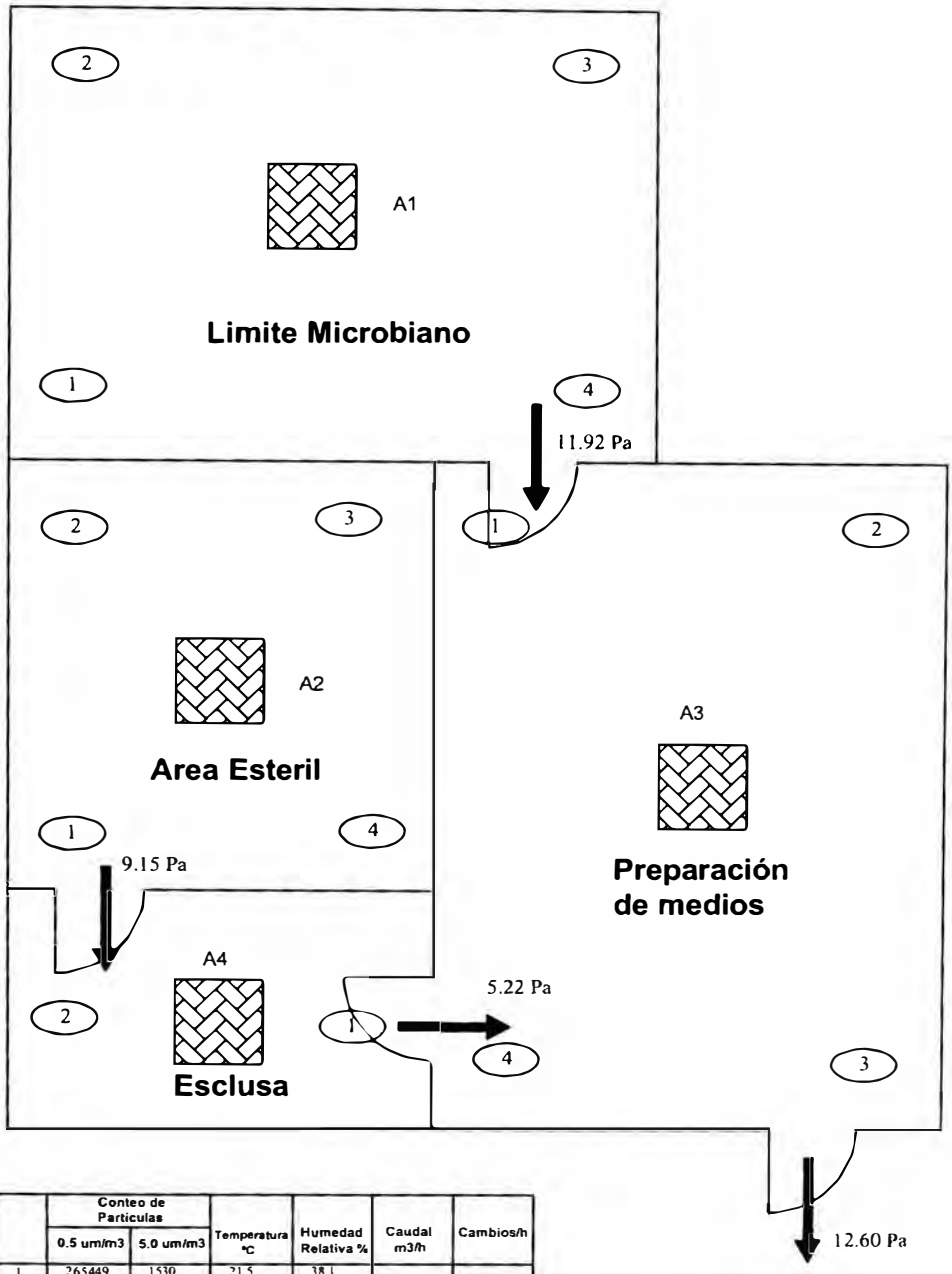


AREAS	Punto	Conteo de Particulas		Temperatura °C	Humedad Relativa %	Caudal m3/h	Cambios/h
		0.5 um/m3	5.0 um/m3				
Envasado	1	165626	1530	21.9	54.2	805.30	39.28
	2	284636	1648	22.0	54.8		
	3	174337	1413	22.1	54.2		
	4	256149	1766	22.2	53.6		
Fabricación	1	345260	2590	24.2	56.3	66.30	13.00
	2	294995	824	23.8	55.2		
	3	146203	2707	25.7	55.6		
	4	143024	824	24.1	54.5		
Esclusa 1	1	135844	1648	22.0	53.3	338.10	34.50
	2	170452	1766	22.8	52.2		
Esclusa 2	1	209063	1530	22.0	54.3	586.20	104.67
	2	224601	1648	22.5	55.2		
Pasadizo	1	160211	1413	22.2	54.1	508.00	28.07
	2	201647	942	22.5	54.4		
	3	123366	1766	22.5	52.3		
Esclusa envasado	1	201764	2001	22.0	54.2	433.20	149.37
	2	228957	1883	22.2	54.2		

ANEXO D

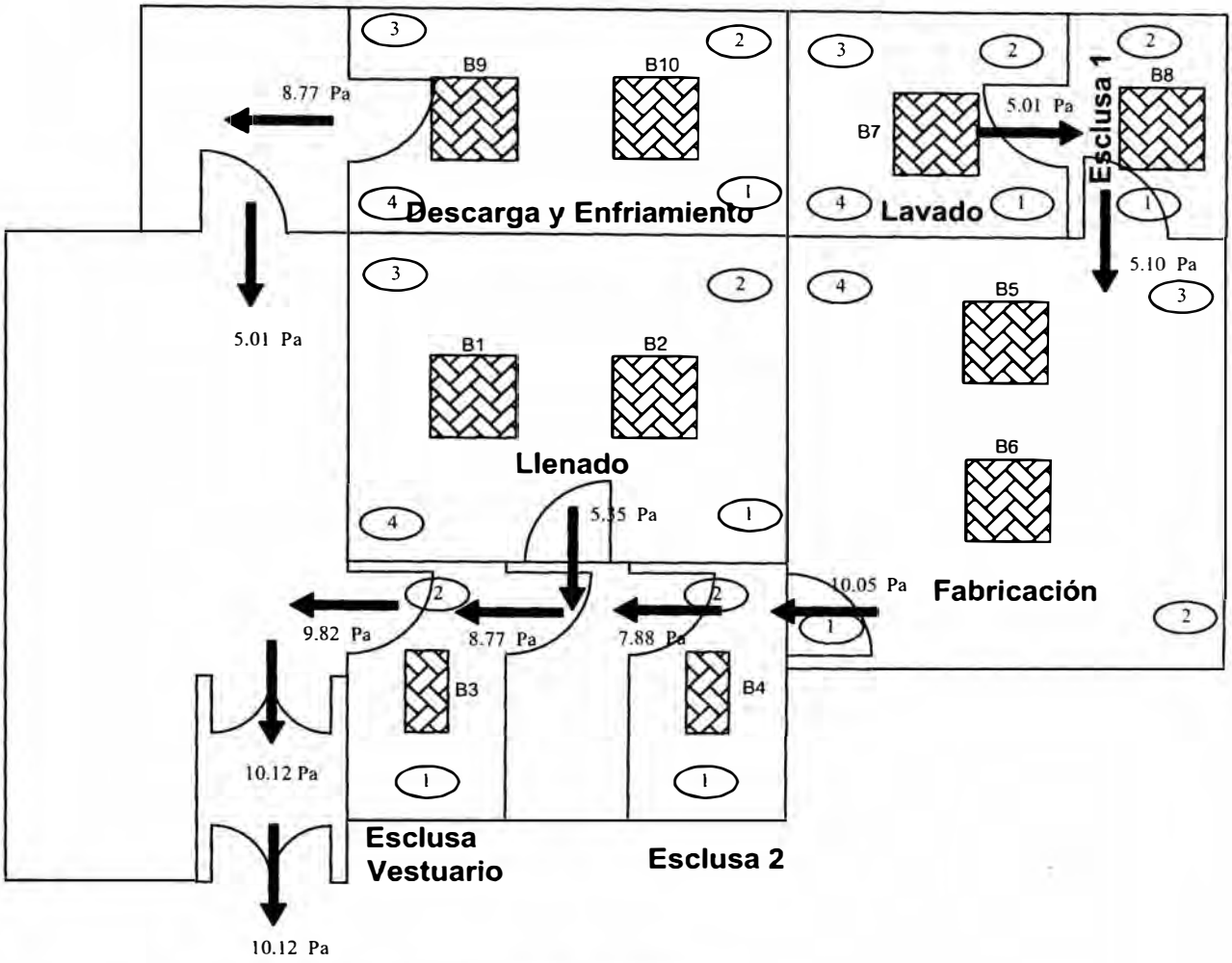
DISTRIBUCIÓN DE LAS MEDICONES REALIZADAS EN EL LABORATORIO FARMACÉUTICO D.A. CARRION DESPUES DE LAS ACCIONES CORRECTIVAS

MICROBIOLOGIA



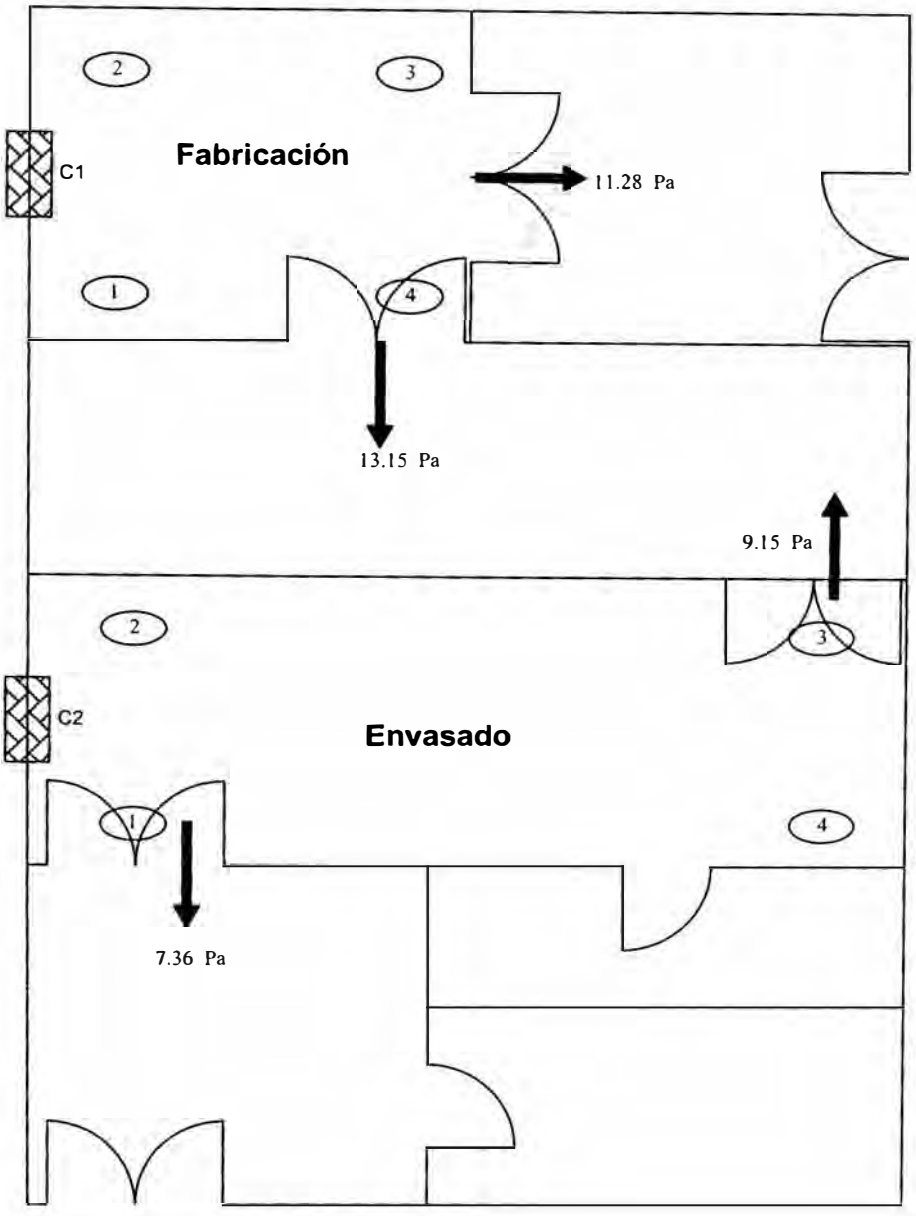
AREAS		Conteo de Particulas		Temperatura °C	Humedad Relativa %	Caudal m3/h	Cambios/h
		0.5 um/m3	5.0 um/m3				
Limite Microbiano	1	265449	1530	21.5	38.1	730.57	21.20
	2	242376	1648	22.3	37.2		
	3	265449	1177	21.9	36.5		
	4	265449	1413	22.5	37.9		
Area Esteril	1	272276	1648	21.4	34.2	543.68	23.70
	2	242376	1648	22.2	34.7		
	3	265449	1177	21.8	35.5		
	4	261564	1413	23.1	36.1		
Preparación de medios	1	259327	1059	20.9	39.7	594.65	22.80
	2	211888	1530	21.9	39.9		
	3	259327	1413	22.1	39.4		
	4	211888	1059	21.8	39.7		
Esclusa	1	193642	1648	20.8	42.3	169.90	24.90
	2	183872	1413	21.4	39.2		

INYECTABLES



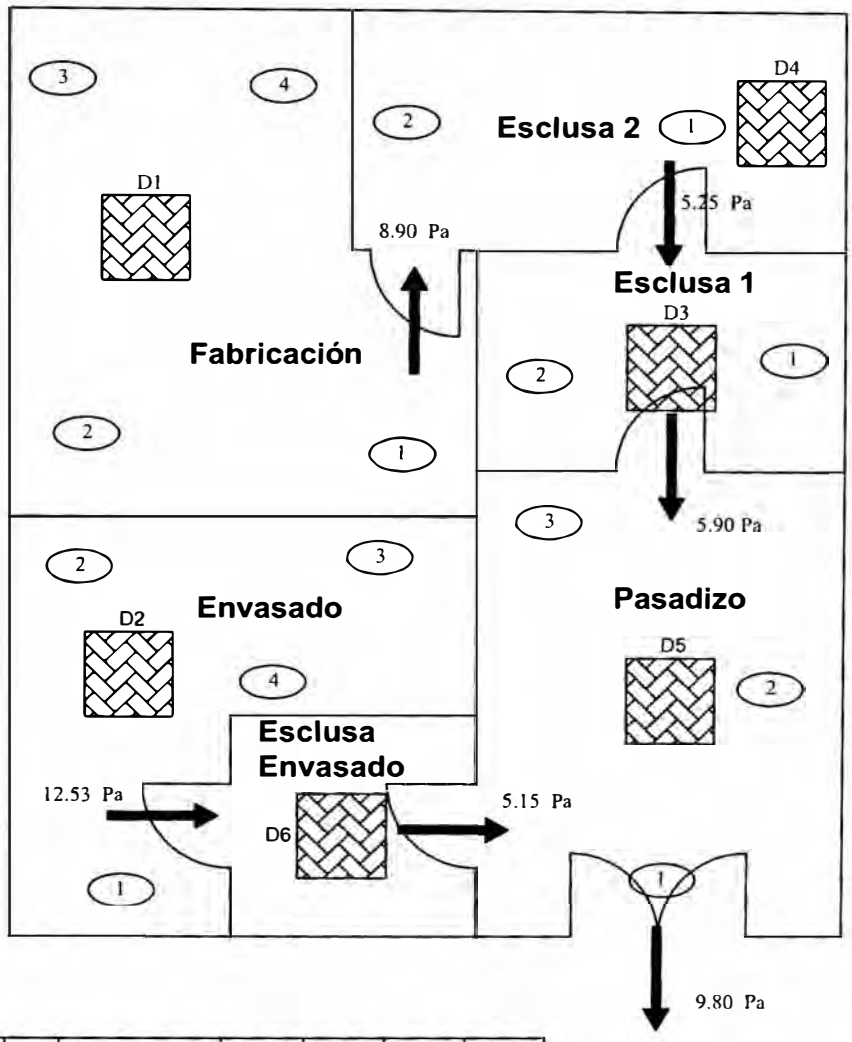
AREAS		Conteo de Particulas		Temperatura °C	Humedad Relativa %	Caudal m3/h	Cambios/h
		0.5 um/m3	5.0 um/m3				
Descarga y Enfriamiento	1	302058	1883	21 3	44.8	2106.80	23 48
	2	284518	1648	22 6	46 3		
	3	296643	1295	21 2	41 6		
	4	269215	2001	22 6	45 9		
Llenado	1	256384	1648	20 8	44 4	2650 50	21 27
	2	282046	1295	22 4	46 2		
	3	262623	1648	19 9	43 8		
	4	200823	1648	22 3	46 5		
Esclusa Vestuario	1	235078	1530	20 4	39 9	424 80	20 19
	2	230605	1413	19 7	42 3		
Esclusa 2	1	216361	1177	21 5	39 7	526 70	24 22
	2	234489	1059	19 7	42 3		
Fabricación	1	280869	1766	22 4	35 7	1987 80	21 94
	2	233430	1177	21 8	42 8		
	3	285343	1530	25 3	36 7		
	4	185991	2001	26 2	43 4		
Lavado	1	241317	1413	22 4	44 3	866 50	24 48
	2	240375	1177	21 7	44 8		
	3	261446	1295	23 7	43 7		
	4	243553	1883	23 6	43 6		
Esclusa 1	1	220010	1295	22 2	36 4	543 70	25 00
	2	197174	1648	22 2	36 2		

SEMI - SOLIDOS



AREAS		Conteo de Particulas		Temperatura °C	Humedad Relativa %	Caudal m3/h	Cambios/h
		0.5 um/m3	5.0 um/m3				
Fabricación	1	206355	1413	21 9	38 9	1206 30	20 80
	2	225543	1177	22 4	37 1		
	3	134902	1177	22 3	38 8		
	4	246261	1530	21 4	39 9		
Envasado	1	245437	1648	21 5	39 8	922 60	21 10
	2	245084	1530	20 1	38 7		
	3	242729	1530	21 7	41 2		
	4	231193	1883	21 3	39 6		

OFTALMICOS



AREAS		Conteo de Partículas		Temperatura °C	Humedad Relativa %	Caudal m3/h	Cambios/h
		0.5 um/m3	5.0 um/m3				
Envasado	1	155620	1413	21.9	54.2	615.00	30.10
	2	259916	1883	22.0	49.8		
	3	174337	1413	22.1	48.6		
	4	269098	1766	22.2	53.6		
Fabricación	1	280987	1883	24.2	56.3	516.30	101.30
	2	268627	1295	23.8	55.2		
	3	254619	1530	25.7	55.6		
	4	258032	1530	24.1	54.5		
Esclusa 1	1	135844	2001	22.0	47.5	412.60	42.00
	2	158563	2001	22.8	52.2		
Esclusa 2	1	208474	1530	22.0	47.2	458.90	81.70
	2	224601	1648	22.5	55.2		
Pasadizo	1	180340	1295	22.2	46.8	363.40	20.10
	2	208827	942	22.5	42.3		
	3	168216	1766	22.5	52.3		
Esclusa envasado	1	210122	1766	22.0	42.1	375.00	130.70
	2	216714	1883	22.2	54.2		

ANEXO E

RELACION DE TABLAS

TABLA	CAPITULO	SUBCAPITULO	NOMBRE TABLA
1	CAPITULO II	Consideraciones Generales	Productos que requieren ser fabricados en áreas limpias
2	CAPITULO II	Clasificación de una sala limpia	Concentración máxima de partículas para la clasificación de salas limpias según al Federal Standard 209 D
3	CAPITULO II	Clasificación de una sala limpia	Equivalencias de las clasificaciones de salas limpias según la evolución de las normas
4	CAPITULO II	Clasificación de salas limpias requeridas en la industria	Clasificación de salas limpias y su utilización en la industria
5	CAPITULO II	Procedimientos normalizados para determinar el numero de localizaciones y tiempo de muestreo	Tiempo requerido de medición por cada punto de muestreo
6	CAPITULO II	Cambios de aire por hora – Velocidad del aire	Cambios de aire recomendados para las diversas áreas productivas de laboratorios Farmacéuticos
7	CAPITULO IV	Integridad de Filtro HEPA	Resultados de las pruebas de integridad realizada a los Filtros HEPAS
8	CAPITULO IV	Conteo de partículas no viables	Resultados de las mediciones del conteo de partículas en las áreas mostradas
9	CAPITULO IV	Temperatura/Humedad Relativa	Promedio de temperatura y humedad relativa obtenidos del área de microbiología
10	CAPITULO IV	Temperatura/Humedad Relativa	Promedios de temperatura y humedad relativa obtenidos del área de inyectables
11	CAPITULO IV	Temperatura/Humedad Relativa	Promedios de temperatura y humedad relativa obtenidos del área de semi-sólidos
12	CAPITULO IV	Temperatura/Humedad Relativa	Promedios de temperatura y humedad relativa obtenidos del área de oftálmicos
13	CAPITULO IV	Cambios de aire por hora- Velocidad del aire	Resultados de los cambios de aire por hora
14	CAPITULO IV	Diferencial de presiones	Datos obtenidos del diferencial de presiones

TABLA	CAPITULO	SUBCAPITULO	NOMBRE TABLA
15	CAPITULO IV	Prueba de integridad de filtro HEPA	Filtros terminales HEPAS que no cumplen los criterios de aceptación
16	CAPITULO IV	Conteo de partículas	Diferencias de las mediciones de conteo de partículas respecto a la ISO 14644-1 que no cumplierón con los criterios de aceptación
17	CAPITULO IV	Temperatura-Humedad relativa	Diferencias de temperaturas obtenidas respecto a la norma NOM 059-SSA1-2004 de las salas que no cumplieron con el criterio de aceptación
18	CAPITULO IV	Cambios de aire por hora-Velocidad del aire	Diferencias de las renovaciones de aire por hora respecto a la FS 209E que no cumplieron con los criterios de aceptación
19	CAPITULO V	Establecimiento del programa de rutina de monitoreo ambiental	Frecuencia del monitoreo de control ambiental según la ISO 14644-2
20	CAPITULO VI	Integridad de filtro HEPA	Resultados de las pruebas de integridad realizada a los filtros HEPAS después de realizas las acciones correctivas
21	CAPITULO VI	Conteo de partículas no viables	Resultados de las mediciones del conteo de partículas en las áreas mostradas después de realizar las medidas correctivas
22	CAPITULO VI	Temperatura – Humedad relativa	Promedios de temperatura y humedad relativa obtenidos del área de microbiología después de realizar las acciones correctivas
23	CAPITULO VI	Temperatura – Humedad relativa	Promedios de temperatura y humedad relativa obtenidos del área de inyectables después de realizar las acciones correctivas
24	CAPITULO VI	Temperatura – Humedad relativa	promedios de temperatura y humedad relativa obtenidos del área de semisólidos después de realizar las acciones correctivas
25	CAPITULO VI	Temperatura – Humedad relativa	Promedios de temperatura y humedad relativa obtenidos del área de oftálmicos después de realizar las acciones correctivas
26	CAPITULO VI	Cambios de aire por hora-Velocidad del aire	Resultados de los cambios de aire por hora después de realizar las acciones correctivas

TABLA	CAPITULO	SUBCAPITULO	NOMBRE TABLA
27	CAPITULO VI	Diferencial de presiones	Datos obtenidos del diferencial de presión después de realizar las acciones correctivas
28	CAPITULO VI	Conteo de partículas no viables	Diferencia de los estados inicial y final del conteo de partículas
29	CAPITULO VI	Temperatura-Humedad relativa	Diferencias de los estados inicial y final de las mediciones de temperatura y humedad relativa
30	CAPITULO VI	Cambios de aire por hora-Velocidad del aire	Diferencias de los estados inicial y final de renovaciones de aire
31	CAPITULO VI	Diferencial de presiones	Comparación de los estados inicial y final de los diferenciales de presión
32	CAPITULO VI	Conteo de partículas no viables	Diferencia del estado final del conteo de partículas respecto a la ISO 14644-1
33	CAPITULO VI	Temperatura – Humedad relativa	Diferencia del estado final de las mediciones de temperatura y humedad relativa respecto a la NOM-059-SSA1-2004
34	CAPITULO VI	Cambios de aire por hora-Velocidad del aire	Diferencias de los estados inicial y final de renovaciones de aire respecto a la ISO 14644-1
35	CAPITULO VI	Diferencial de presiones	Comparación del estado final respecto a la ISO 14644-1 de los diferenciales de presión

ANEXO F

RELACIÓN DE FIGURAS

GRAFICO	CAPITULO	SUBCAPITULO	NOMBRE DEL GRAFICO
1	CAPITULO II	Clasificación de una sala limpia	Tamaño de partículas vs. concentración de partículas
2	CAPITULO III	Generador de aerosol	Generador de aerosol
3	CAPITULO III	Fotómetro de aerosol	Fotómetro de aerosol
4	CAPITULO III	Contador de partículas no viables, temperatura y humedad relativa	Contador óptico de partículas , temperatura, humedad relativa
5	CAPITULO III	EBT Balometer	Medidor de caudal - Balometer
6	CAPITULO III	Diferencial de presiones	Medidor de presiones diferenciales

ANEXO G

MANUALES DE USO DE LOS EQUIPOS DE MEDICION

Handheld Laser Particle Counter

Model 3886 GEO – α

Operation Manual

Please carefully read and understand the warnings in this manual before operation

Kanomax Japan Inc

Please store this manual in a safe place so that you can use anytime

91003
03.02

ank you for purchasing the product of Kanomax-Japan Co., Ltd.

cause this device is precision instrument, please carefully read this operation manual, and rrectly operate the instrument by keeping the instruction in this manual.

CONTENTS

mportant safety Information

anger: For prevention of accidents resulting in injury or death
ems under this heading show the conditions that is supposedly have the risk to cause injury or death, if you isregard the instruction and operate the instrument improperly.

aution: For prevention of the damage of product
ems under this heading show the conditions that may result in the physical damage to the instrument, or may make it impossible to guarantee the performance of instrument, if you disregard the instructions and operate improperly.

[Definition of Signs]

Symbol indicates there are the conditions that urge the caution (incl. danger). Subject of specific caution is drawn inside of symbol (high temperature caution in case of the figure on the left).

Symbol indicates that it is prohibited. Subject of prohibited action is given in or nearby the symbol.

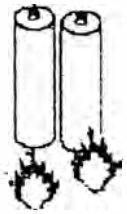
Symbol instruct or force to take a certain action. Specific action is given nearby the symbol.

⚠ Danger

Do not disassemble or heat the batteries

..... There is the danger of explosion.

Explosive



Use the supplied AC adapter for the operation by AC power.

..... It may become the cause of damage.
..... There is the danger of heat-generation or ignition, and may result in a fire or other accidents.

Forbidden

⚠ Danger

) Never disassemble or modify the main unit, sensor and the likes.

····· This instrument is using class 3B laser or the source of light. Disassembly may result in the accidents like the loss of eyesight by the exposure to laser light.

····· It may also cause the short-circuit, or complicate the maintenance of original performance.

Do not remodel/ disassemble

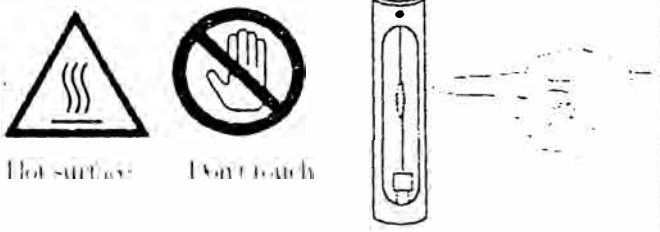
) Never put terminal into the atmosphere of flammable gas.

····· Terminal became hot so that it may cause explosion and ignition.

Do not use near Flammable gas

) Never touch the sensor

····· There is a danger of getting burnt because the sensor is heated. It may also damage the sensor itself.



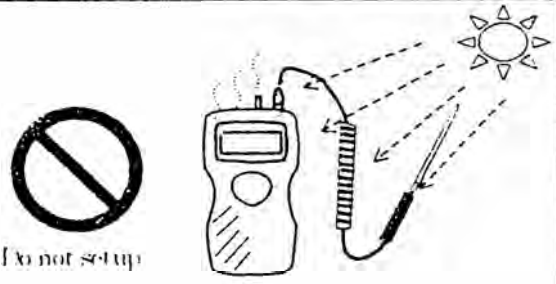
Hot surface Don't touch

⚠ Caution

) Do not carry out the measurement or leave the main unit at the places where it is hot humid or dusty.

····· This instrument may not function properly outside of the operating temperature range.

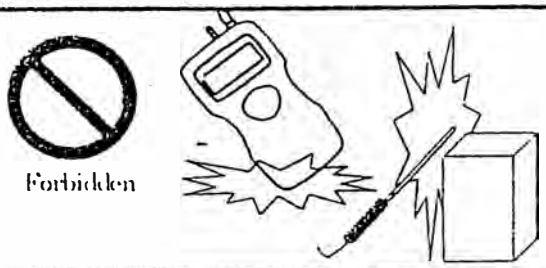
····· Exposure to the direct sunlight may result in the discoloration or disform of the body.



Do not set up

) Do not give the strong impact to the main unit and probe.

····· Falling or bumping the instrument will become the cause of damage or malfunctioning.

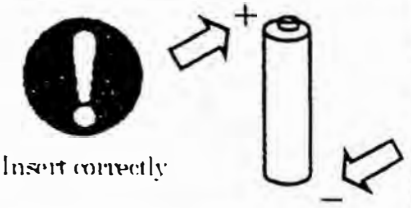


Forbidden

⚠ Caution

○ Set the batteries in the correct direction

····· It may cause the liquid leakage, and contaminate the surrounding area of the main unit.



Insert correctly

○ Do not wipe the body with solvent

····· There is the concern that the body will be disformed or deteriorated. Wipe with soft dry cloth when it gets dirty. For serious dirtiness, wipe with the cloth soaked with the neutral detergent. Never use solvents like thinner, benzine etc.


Forbidden

○ Do not use this instrument near the equipment emitting the high radiation noise because this is precision instrument.

····· This instrument may cause the malfunctioning due to noise. Air velocity sensor is especially liable to be effected by radiation noise.


Correctly

○ Use the AC power that doesn't have much noise.

····· There may be the cases those noise will cause the malfunctioning of the instrument.

○ Do not pull the probe cable strongly, nor suspend the main unit by holding the cable.

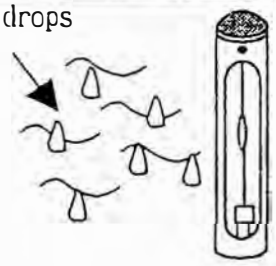
····· It may became the cause of malfunctioning and snapping of the wire.


Forbidden

○ Do not use in the atmosphere containing the droplets of water

····· The radiation of heat will change, and correct measurement will become impossible. It also becomes the cause of damage to the sensor.

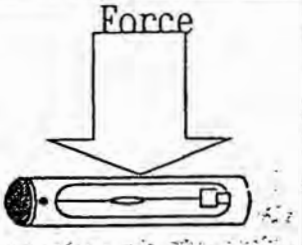

Forbidden



○ Do not apply the unreasonable force to the sensor

····· Disformation of sensor may harm the accurate measurement, or may snap the sensor in the worst case.


Forbidden



※Air Velocity probe and Temp.& Humidity probe are options (separately sold)

1. Check of components

When unpacking, check the contents in the box using the list below

1.1 Standard accessories

Name	Model No.	Functions
Filter, ✓ Tube	Model 3886-03*1)	For the cleaning of air route in the main unit by the clean air. ✓
AC Adapter, ✓ Power cable ✓	Model 3886-01*2)	For the operation by AC power, especially continuous measurements. ✓

1.2 Options

Name	Model No.	Functions
Temp. & ✓ Humidity probe	Model 0812	For the measurements of temperature and relative humidity by connecting with the main unit
Air Velocity probe	Model 0813	For the measurements of air velocity by connecting with the main unit
Extension rod for air velocity probe	Model 0813-01	For the measurements of high places
Printer	DPU-H245	For the direct printing of measured data
Printer cable	Model 3886-07	For the connection of main unit and printer
Application soft	Model 3388-60	For the downloading of stored data in the memory to PC, or remote control of main unit by PC
RS-232C cable ✓	Model 3886-08	For the connection of main unit and PC
Carrying Case	Model 3886-02	For the safe storage of main unit and accessories
Tripod ✓		For fixing the main unit at one place for the measurement

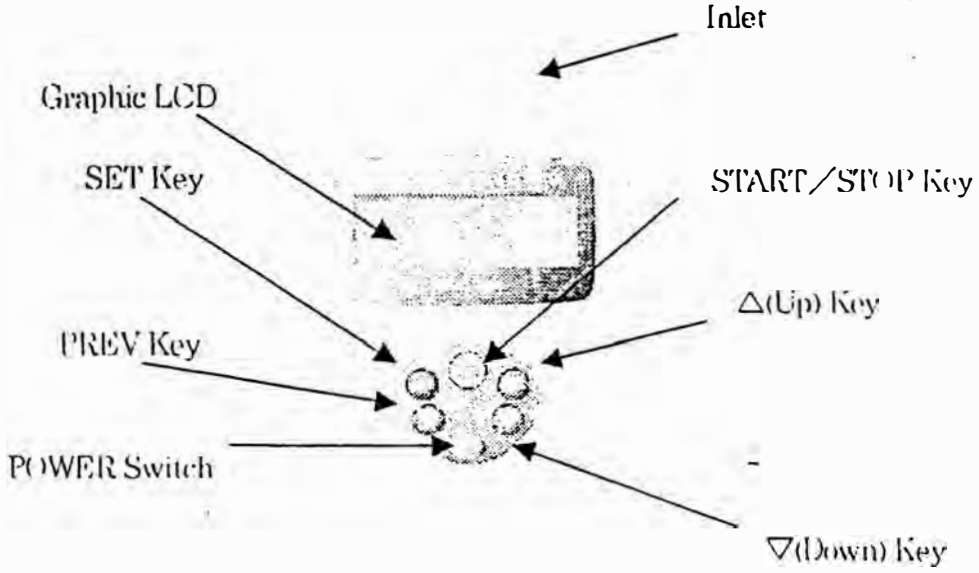
*1) The tube is not included in Model 3886-03.

*2) The tube is not included in Model 3886-01.

Description of Components

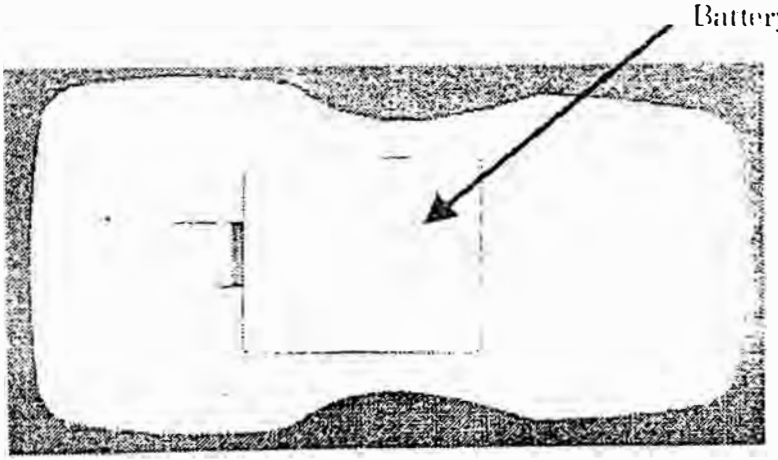
Name and functions of each component are explained in this chapter.

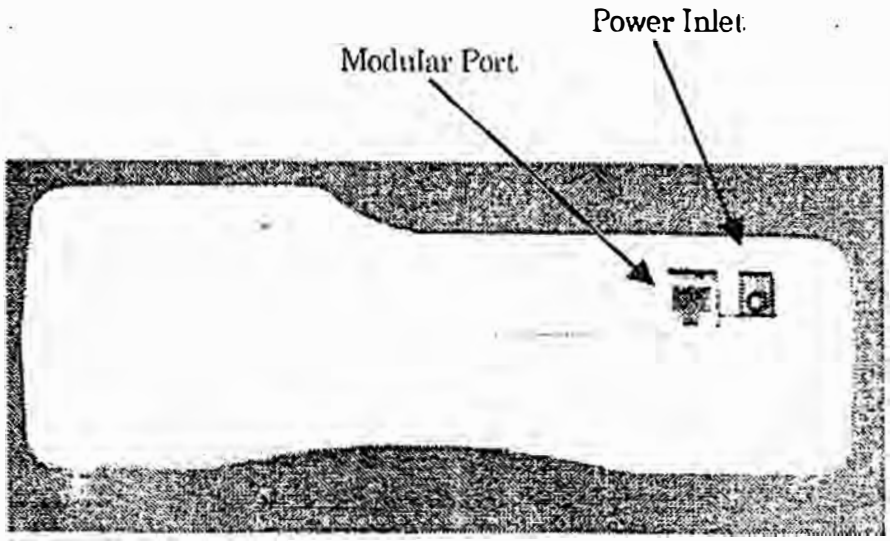
2.1 Front



Name of component	Functions
Inlet	For the collection of sampling air
Graphic LCD	For the displays of the measured data or status of operation
SET Key	For the setup of measuring parameters, movement of cursor and transition to next screen
PREV Key	To go back to the previous screen
POWER Switch	For turning on/off of the power
△(Up) Key ▽(Down) Key	For the choice of functions/parameters from menu and setting up the numbers
START/STOP Key	For the start and finish the measurement

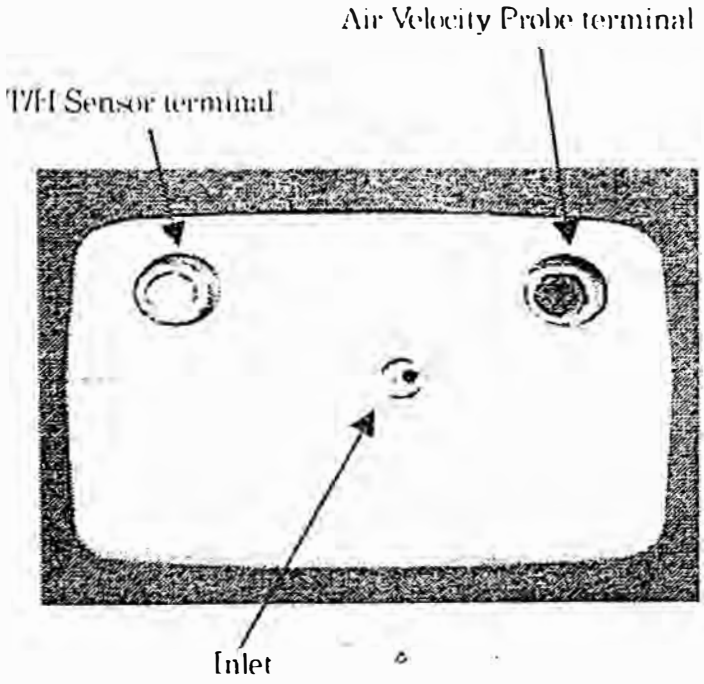
2.2 Rear





Component	Functions
Modular Port	For the transfer of the data to a printer or a PC
Power Inlet	For the power supply from AC adapter

2.4 Top



Component	Functions
Inlet	For collection of sampling air
T/H sensor terminal	For the connection with T/H Sensor
Air velocity probe terminal	For the connection with air velocity probe

3. Operation & Caution

3.1 Power supply

Please use the supplied AC adapter and refrain from the battery operation for the long consecutive measurements (more than 2 hours)

This instrument has the monitoring function of operating voltage. and battery alarm will be indicated when the voltage goes down below the specified value.

If you leave the instrument in such a conditions for a few minutes. the power automatically goes off. In some of measuring mode. the data of measurement in process will not be stored. (Please refer to Chapter 8 for details)

If the alarm sign is shown. please stop the measurement and charge the batteries. or replace with the charged batteries.

◆Use of AC adapter

Insert the plug of supplied AC adapter into the power inlet at the side of main unit.

Then. plug the another side into AC outlet.

AC power should be in the range of 86-264V 50/60Hz. Do not use the AC power outside of this range.

◆Use of batteries

Prepare 4 pieces of Ni-MH batteries (1.2V 1600mAh recommended) and fully charge them.

After the charging is completed. put the batteries into the main unit in the correct directions.

Battery life is about 3 hours. but it will vary by the type and capacity of battery. or status of charging. When oprional Temp.&Humidity probe and Air Velocity probe are used at the same time. there will be the cases that operating hours will become less than 2 hours

Figure : Direction of battery insert

※Please note that longevity in alkaline cell becomes about 1 hour and 30 minutes shorting than the nickel hydrogen battery though alkaline cell is available in this.

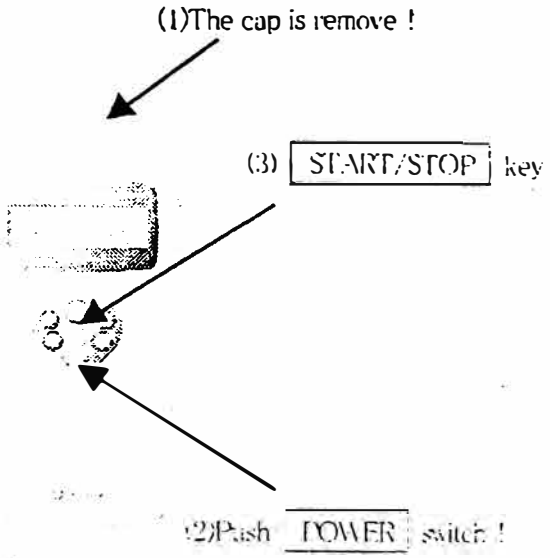
2 Turning the power on

(1) Make sure to remove the cap of air inlet at the top of the main unit.

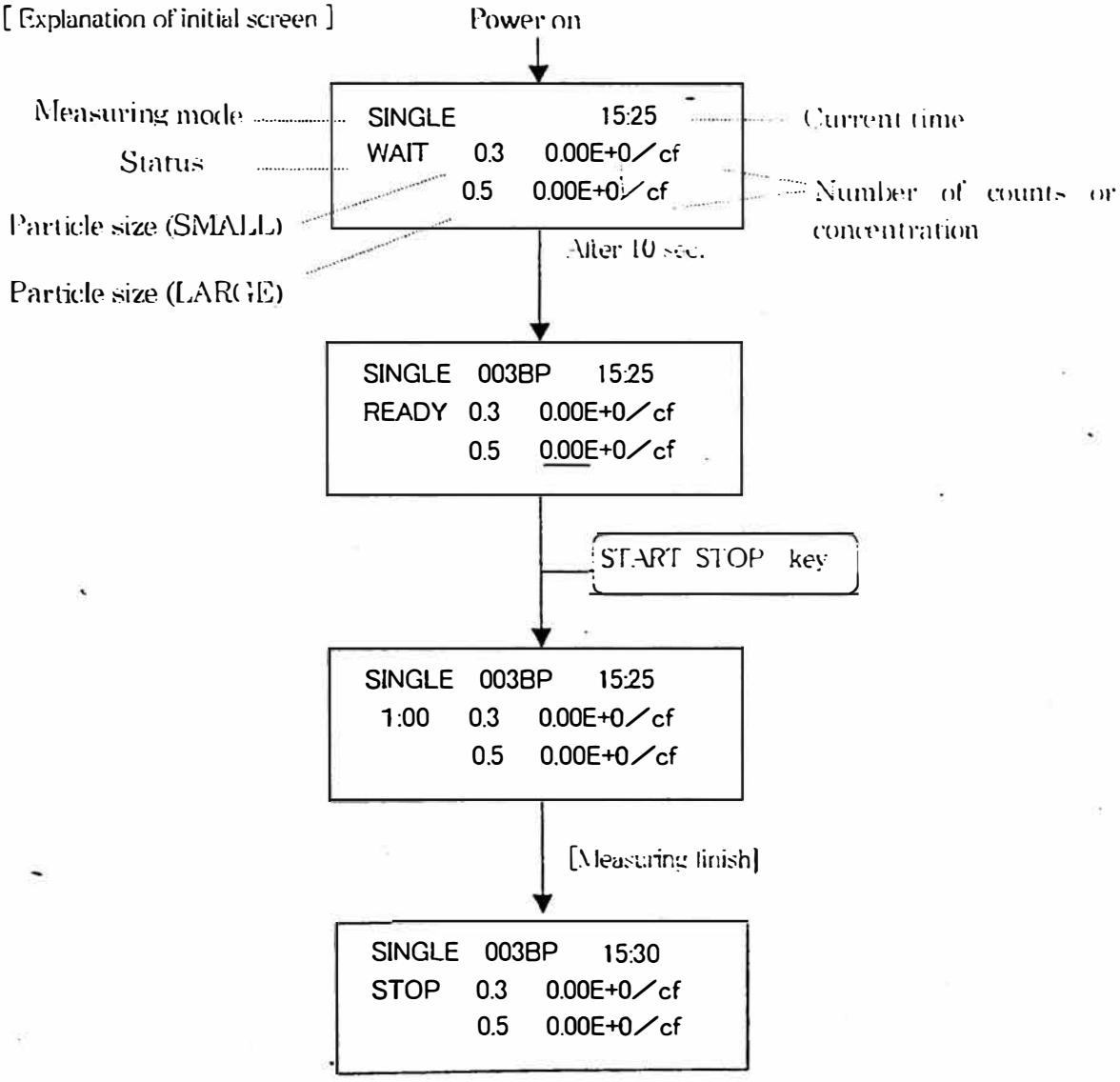
(2) Push POWER switch in the function key. Initial display shows the mode and setup data of previous measurement in WAIT status (Set at SINGLE mode at the time of delivery).
Please refer to Chapter 4 for the customizing of measuring mode or method.

(3) WAIT sign will change to READY after 10 seconds. Then, measurement can be started by pushing the START key.

At the time of delivery, sampling time is set at 1 minute, so the measurement will be automatically stopped after 1 minute.



[Explanation of initial screen]



3.3 Cautions before starting the measurements

3.3.1 Location

This product is designed and produced for the operations in clean room environment. Please refrain from using in the dressing room of clean suits, or in the ordinary environment (e.g. offices, turnery, outdoors, smoking rooms etc.)
It will contaminate the internal components and increase the maintenance frequency.

3.3.2 Connection of sampling tube

-Connect the sampling tube to air inlet for the collection of the air at distant place.

—Requirement for sampling tube —

■Material

Material of tube should be metal (stainless, copper, alloy steel), glass or synthetic resin which will not generate the plastic deposit.

■Length

Long sampling tube will liable to cause the pressure loss by bending or the obstruction by folding, which will damage the vacuum pump and increase the maintenance frequency. It also cause the deposit loss of particle and lower the accuracy of measurements. Length of sampling tube should be less than 1m.

■Pressure Loss

Large pressure loss will make it impossible to maintain 0.1cfm (+/-10%) flow rate. Pressure loss at sampling tube must be less than 1kPa (approx. 100mmH_2O).

3.4 After measurement

[Cleaning of internals]

Internals of the main unit may be contaminated after measurement.
Please carry out the following cleaning procedure after finishing the measurement.

—The method of cleaning and storage—

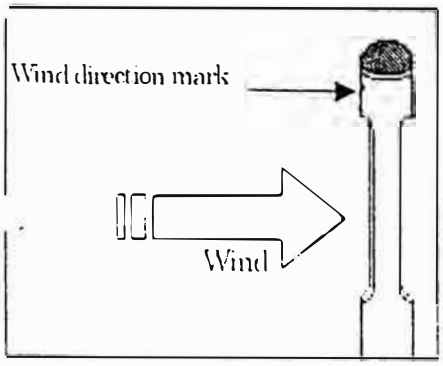
① Stop the measurement before cleaning
② Connect the filter to the air inlet at the top of the main unit, using the supplied tube.
* There is a possibility that the tube will be folded and inlet will be blocked when connecting the tube to the inlet. Operation of the instrument in such a condition will overload the vacuum pump and shorten the operating life.
③ Change UNIT to counts (CNT) and start the measurement
④ Finish the operation only after the confirmation that the count value gets stable and doesn't increase or decrease for more than 10 seconds.
⑤ Turn the power off and put the cap over the inlet

※ To prevent the contamination during storage, do not fail to cover the inlet by cap.

3.5 Measurements using optional probes (Temperature&Humidity, Air Velocity)

♦Air velocity probe

* When you measure, set wind face mark toward wind direction.
* Check the tip of probe periodically if it is not dirty.
  Dust attached to sensor influence accuracy of Measurement.



—Cleaning of the air velocity probe—

◇ Rinse tip of probe in alcohol if sensor is oily, dry it in low wind.
◇ When you get rid of dust, blow them off by blow blush for camera or rinse in water and dry them completely.

※ Turn off power when you wash sensor.
※ Do not dry probe with heat.
(Heat damages sensor and became impossible to restore.)

♦Temperature & Humidity probe

*As for measurements of air temperature, accurate value will not be given in the still air.
(Exempt from performance-guarantee range.)
You can get correct value in velocity of 0.1m/s or over. (Move probe slowly.)

*Response time in the air temperature measurement becomes quicker when the velocity is high.
For example, when air velocity is 1m/s the response time is 20 seconds. Please keep the data when indications become stabile.

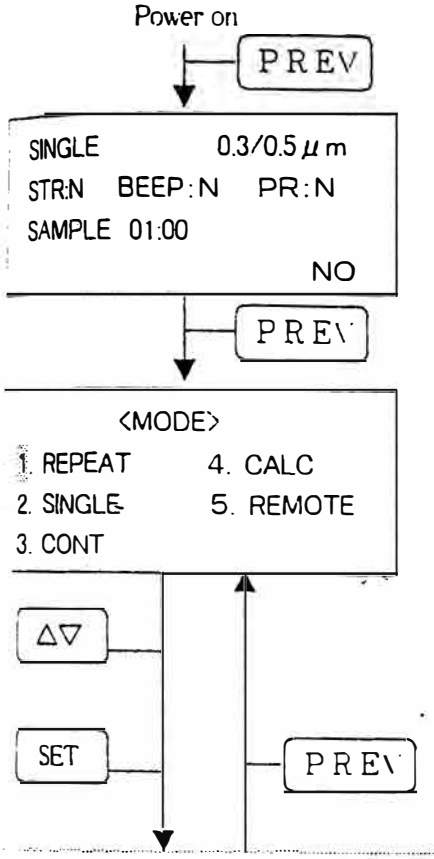
*The humidity measurement value might rise abnormally by the condensation of the humidity sensor.
In case of the measurement in rapid temperature change or long use in high humidity, keep probe for 24 hrs in 40%RH or less and dry probe when wet.

—Humidity measurement ... Comparison with ASSUMANN type psychrometer—

Because the humidity measurement function is strictly proofread using a standard humidity generation device (two temperature difference method), you will find it is handy.
And, because a steady measurement can be done as an electronic hygrometer, this unit can take the place of ASSUMANN type psychrometer.
When the comparison measurement is done between T.H.I probe and the ASSUMANN type psychrometer, the ASSUMANN type psychrometer occasionally display high humidity.
Since handling conditions like dust, dew, or how to lap gaze can influence the result of ASSUMANN.
Therefore, it is necessary to be careful when you handle the ASSUMANN type psychrometer.
Please refer to Japan Industrial Standards concerning notice in the measurement with the ASSUMANN type psychrometer etc. (JIS-Z8806 "Method of measuring humidity") etc.

4. Setting before measurement

4.1 Selection of measuring mode



(1) Push POWER key to input the power supply. Then PREV key.

(2) Push PREV key again to proceed to the setup screen

(3) Use △ ▽ key to move the cursor, and push SET key to select the mode you need.

(4) Push PREV key to go back to the MODE screen.

[1.REPEAT]

REPEAT		0.3/0.5 μm
STR:N	BEEP:N	PR:N
SAMPLE	01:00	2TIMES
INT	00:05:00	NO

[2.SINGLE]

SINGLE		0.3/0.5 μm
STR:N	BEEP:N	PR:N
SAMPLE	01:00	
		NO

[3.CONT]

CONT		0.3/0.5 μm
STR:N	BEEP:N	PR:N

[4. CALC]

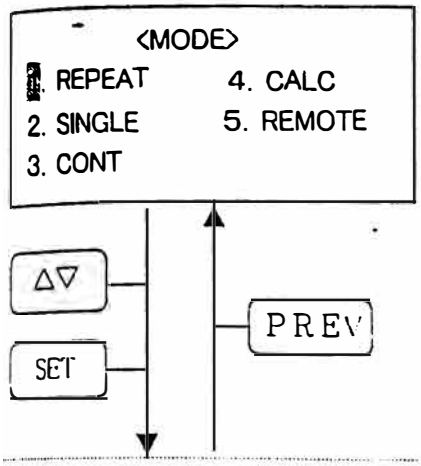
CALC		0.3/0.5 μm
STR:N	BEEP:N	PR:N
SAMPLE	01:00	2TIMES
		NO

[5. REMOTE]

REMOTE	0.3/0.5 μm
BEEP:N	
	NO

Measuring mode	Content of measurement	SAMPLE Sampling time	TIME Sampling frequency	INT Sampling interval
Repeat [5.2]	Measurement repeatedly	○	○	○
Single [5.3]	Measurement once	○	Once	○
Continuous [5.4]	Continuous measurement ; The measurement ends if STOP is pushed.	–	–	–
Calculation [5.5]	It measures repeatedly, and mean value, a standard deviation, the maximum value are calculated from data. Only result is done and the store is not done in the data store as for the store doing and each measurement result.	○	○	–
Remote [5.6]	Measurement by remote control from computer. (The application software of the option is necessary)	–	–	–

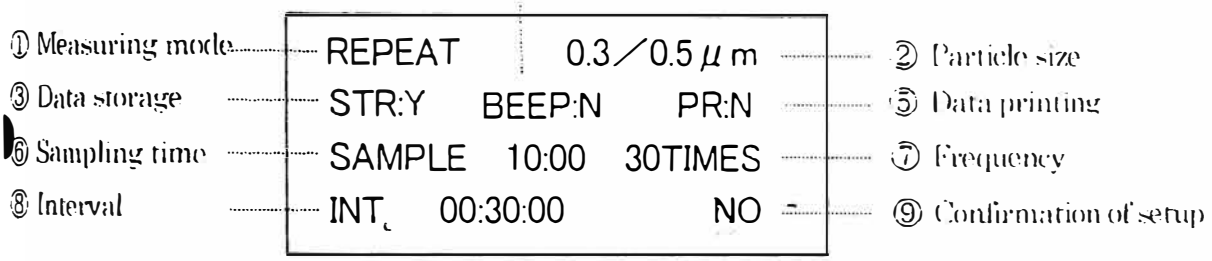
4.2 Setting the measuring condition



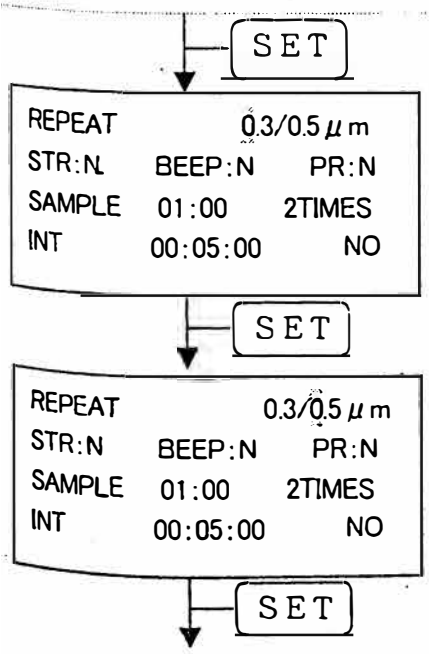
In the case of REPEAT mode (other mode even same)

Use [△] [▽] key to move the cursor, and push SET key to select the mode you need.

④Warning beep sound

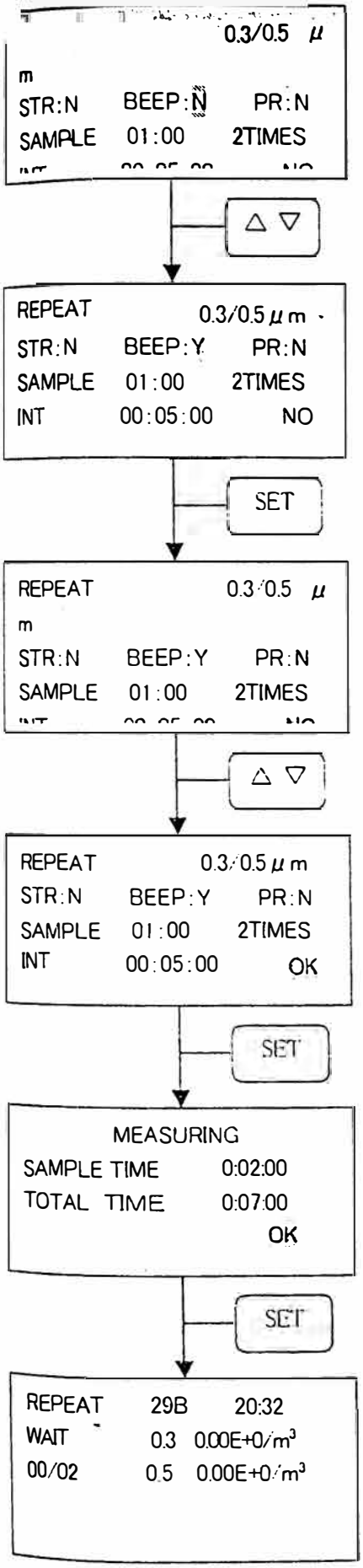


	Name	Explanation
①	Measuring mode	Five kinds of REPEAT, SINGLE, CONT, CALC, REMOTE
②	Particle size	Two kinds selection from 0.3, 0.5, 1.0, 3.0, 5.0 μm
③	Data storage	Y : data stored N : data not stored
④	Warning beep sound	Y : beep sounded N : beep not sounded
⑤	Data printing	Y : data printed after the measurement N : data not printed (refer to 6.4)
⑥	Sampling time	1 second～99 minites59 seconds
⑦	Frequency	1～99 times and continuous (CNT)
⑧	Interval	1 second～24 hours
⑨	Confirmation of setup	NO : not confirmed OK : confirmed. Press SET key to shift measurement screen.



(1) For change setting, push SET key to move the cursor.

(2) Push SET key to the item you need to change.



(3) Use △ ▽ key to change the setting condition.

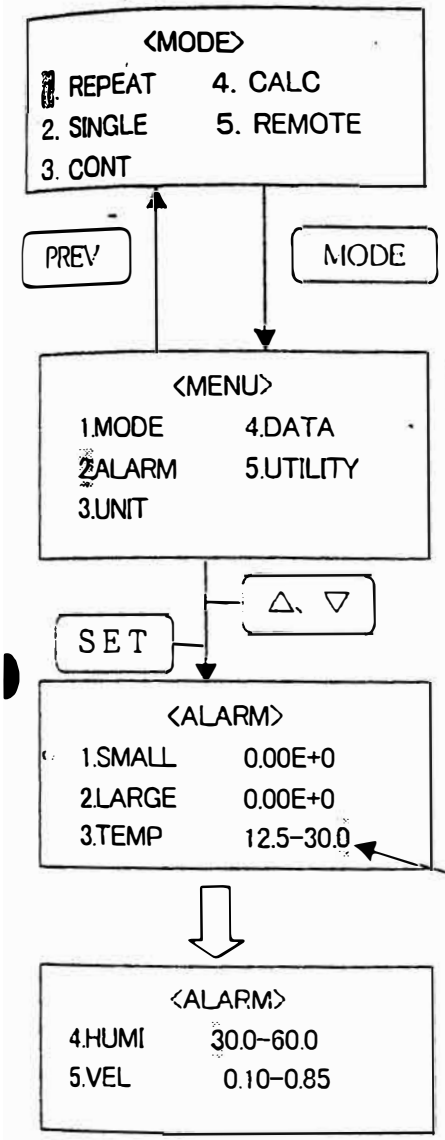
(4) If you finished your set up , push SET key to move the cursor to the position of "NO" .

(5) Change "NO" to OK using △ ▽ key.

(6) Push SET key.

(7) Push SET key to proceed to the measuring screen.

4.3 Setting of Alarm level



If PREV key is pushed at <MODE> screen, it becomes <menu> screen.

1. MODE ····· Selection of measurement mode and setup of parameter
2. ALARM ····· Setup of alarm level
3. UNIT ····· Selection of optional probe and unit
4. DATA ····· Request for stored data in built-in memory
5. UTILITY ····· Calendar and computer communication setting

In case the particle concentration exceed the acceptable level, or temperature, Relative humidity or air velocity go out of the specified range, this unit can notify the occurrence of these alarm situation.
This menu is to preset the alarm level.

If SET key is pushed when the cursor is here, it moves to the following page.

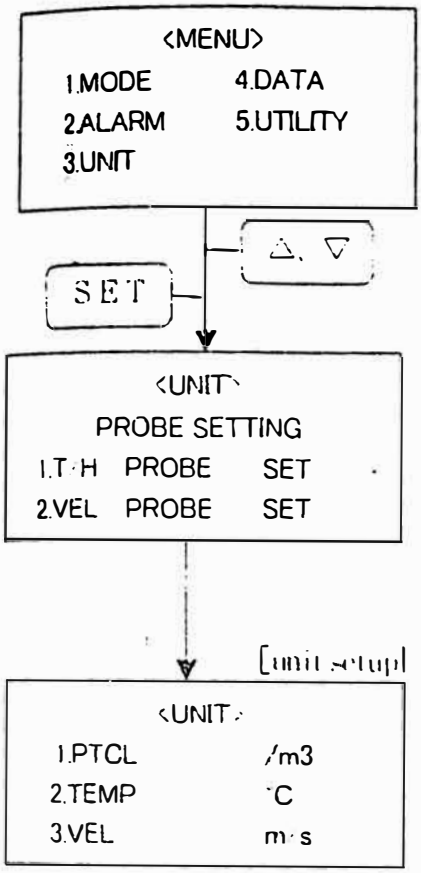
△ ▽ key	Adjust the value
SET key	Move the cursor
PREV key	Go back to MENU after the setup

			Lower bound	Upper bound	unit	Setting range
1	SMALL	Small particle	–	○	*	0~7.00E+7
2	LARGE	Large particle	–	○	*	0~7.00E+7
3	TEMP	Temperature	○	○	*	0~122.0
4	HUMI	Humidity	○	○	%RH	0~100.0
5	VEL	Air velocity	○	○	*	0~200.0

* : Selected unit (refer to 4.4)

The number flashed at the end of the sampling time if a certain parameter of measurement is not within the specified level. Once the alarm situation occurred, it will not be reset unit the data of following measurements gets within the specified level. If the unit of particle is set at "COUNT", the number flashes at the movement the count exceeded the specified level. When the buzzer is activated (BEEP:Y), it goes off when the alarm situation occurred. To operate the buzzer, make sure to set "BEEP:Y" on the setup screen of measurement mode.
To stop the buzzer, push any key other than POWER key.

4.4 Selection of option and units



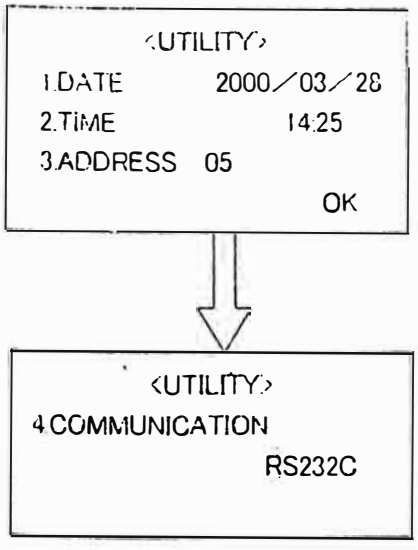
This menu is to select the optional probes and the units of particle, temperature and air velocity.

[△] [▽] key	Move the cursor
[SET] key	Shift the screen of the selected item
[PREV] key	Go back to MENU after the setup

1	T/H PROBE	T/H probe	SET : use NO : not use
2	VEL PROBE	Velocity probe	SET : use NO : not use

1.PTCL : particle ····· CNT : count /m³ : concentration in 1m³
/cf : concentration in 1cf
2.TEMP : temperature ····· °C, °F
3.VEL : air velocity ····· m/s, FPM

4.5 Calendar and computer communication setting

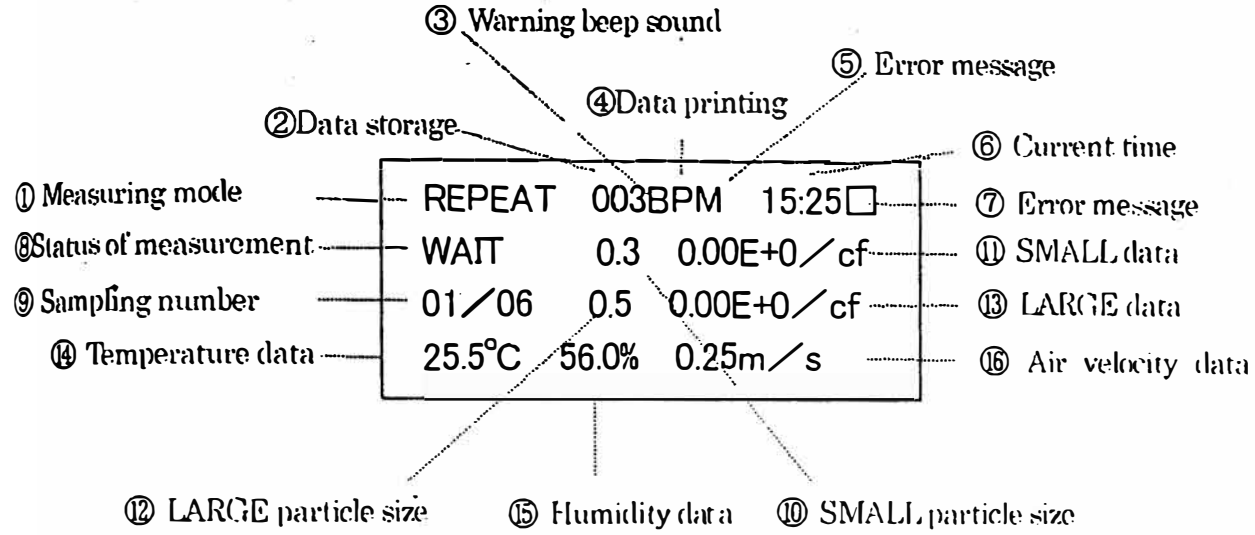


1	DATE	Year, Month, Date
2	TIME	Hour, Minute Next item set up
3	ADDRESS	When RS232C address is setup by the master PC, measurement software of Kanomax is set as 00.
4	COMMUNICATION	Communication with PC

[△] [▽] key	Adjust the value
[SET] key	Move the cursor
[PREV] key	Go back to MENU after the setup

5. Measurement method

5.1 Explanation of measurement screen



	Name	Explanation
1	Measuring mode	Five kinds of REPEAT, SINGLE, CONT, CALC, REMOTE
2	Data storage	003: Store No. Display no : data not store
3	Warning beep sound	B : Beep sounded Display no : beep not sounded
4	Data printing	P : data printed Display no : data not printed (refer to 6.1)
5	Error message	M : the buffer memory is over loaded when printing the data (refer to 8)
6	Current time	Refer to 4.5
7	Error message	F : Flow rate L : Light source O : Over the maximum concentration (refer to 8)
8	Status of measurement	WAIT : Starting up READY : Ready for measurement STOP : Measurement finished (refer to 5.2~5.6)
9	Sampling time	Tag number of the current measurement/ the specified sampling frequency.
10	SMALL particle size	Smaller of 2 particle sizes chose at setup screen.
11	SMALL data	The number of counts or concentration of the particle size on 10. (refer to 4.4)
12	LARGE particle size	Lager of 2 particle sizes chose at setup screen.
13	LARGE data	The number of counts or concentration of the particle size on 10. (refer to 4.4)
14	Temperature data	Show the data by selected the T/H probe uses (refer to 4.4)
15	Humidity data	Show the data by selected the T/H probe uses (refer to 4.4)
16	Air velocity data	Show the data by selected the Air velocity probe uses (refer to 4.4)

...tting the sampling time, frequency and interval of each measurement, this unit automatically measures as specified and stops after measurements. Interval is the time between the beginning of first measurement and the next. The setting of the particle size (um), data storage (STR), alarm (BEEP) and printout (PR) are possible.

Display screen	Operation key	Operation explanation
<MODE> 1.REPEAT 4.CALC 2.SINGLE 5.REMOTE 3.CONT	POWER	Push POWER key to input the power supply.
	PREV	Push PREV key twice to proceed MODE screen
	△ ▽ SET	Select 1.REPEAT
REPEAT 0.3／0.5 μm STR:Y BEEP:N PR:N SAMPLE 10:00 30TIMES INT 00:30:00 OK	△ ▽ SET	■ Setup the particle size, requirement of data storage , alarm , printout, sampling time, frequency and interval of measurement. Use △ ▽ key to change the setting condition, then push SET key. After the input is done, change NO to OK and push SET key.
MEASURING SAMPLE TIME 5:00:00 ← ① TOTAL TIME 14:40:00 ← ② OK	△ ▽ SET	① : sum total of sampling time ② : total length of time from the beginning to the end of measurement After confirming these TIMEs, change NO to OK and push SET key.
REPEAT 003BPM 15:25 WAIT 0.3 0.00E+0／cf 01／30 0.5 0.00E+0／cf	WAIT Mode	WAIT sign is shown for the stabilization of internal pump.
REPEAT 003BPM 15:25 READY 0.3 0.00E+0／cf 01／30 0.5 0.00E+0／cf	READY Mode	WAIT sign turns to READY in 10 seconds and measurement can be started.
REPEAT 004BPM 15:25 ③ →09:59 0.3 0.00E+0／cf ④ →01／30 0.5 0.00E+0／cf	START／STOP	Push START/STOP key to start the measurement. The display shows the real-time data. ③ : remaining time of each measurements ④ : measurement number
NEXT 004BPM 15:35 ⑤ →15:55 0.3 0.00E+0／cf 02／30 0.5 0.00E+0／cf	Interval menu	Screen changes to interval mode after the sampling time is over. ⑤ : starting time of next measurement
REPEAT 004BPM 15:55 09:59 0.3 0.00E+0／cf 02／30 0.5 0.00E+0／cf	Measuring	Measurement is automatically started from the indicated starting time. ★ The data is printed after the sampling time is over if you chose printout. (refer to 6.4) ★ To stop the measurement halfway Push START/STOP key. Only the data of finished previous measurement before pushing the STOP key will be stored if you chose data storage

6.3 SINGLE mode

By setting the sampling time, this unit automatically stops after the specified time.
The setting of the particle size (um), data storage (STR), alarm (BEEP) and printout (PR) are possible.

Display screen	Operation key	Operation explanation
<MODE> 1.REPEAT 4.CALC 2.SINGLE 5.REMOTE 3.CONT	POWER	Push POWER key to input the power supply.
	PREV	Push PREV key twice to proceed MODE screen
	△ ▽ SET	Select 2. SINGLE
SINGLE 0.3／0.5 μm STR:Y BEEP:N PR:N SAMPLE 10:00 - OK	△ ▽ SET	■Setup the particle size, requirement of data storage , alarm , printout, sampling time. Use △ ▽ key to change the setting condition, then push SET key. After the input is done, change NO to OK and push SET key.
SINGLE 003BPM 15:25 WAIT 0.3 0.00E+0／cf 0.5 0.00E+0／cf.	WAIT Mode	WAIT sign is shown for the stabilization of internal pump.
SINGLE 003BPM 15:25 READY 0.3 0.00E+0／cf 0.5 0.00E+0／cf	READY Mode	WAIT sign turns to READY in 10 seconds and measurement can be started. Push START/STOP key to start the measurement
SINGLE 004BPM 15:25 ⑥ →09:59 0.3 0.00E+0／cf 0.5 0.00E+0／cf	START／STOP	The display shows the real-time data. Remaining time of each measurements ⑥ : measurement number
SINGLE 004BPM 15:35 STOP 0.3 0.00E+0／cf 0.5 0.00E+0／cf	INTERVAL menu	Screen changes to interval menu after the sampling time is over. ★ The data is printed after the sampling time is over if you chose printout. (refer to 6.4) ★ To stop the measurement halfway Push START/STOP key. Only the data of finished previous measurement before pushing the STOP key will be stored if you chose data storage

The particle size can be switched with the △ ▽ key on the measurement screen.
UNIT:[CNT] [/m³] [/ft³]

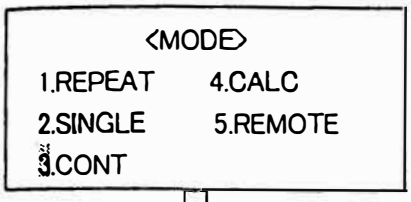
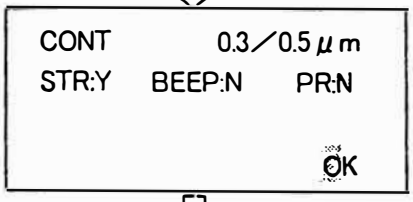
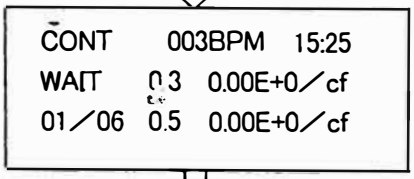
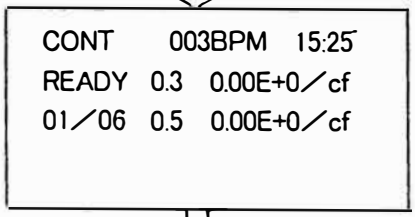
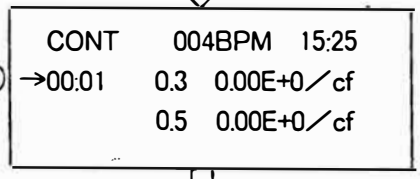
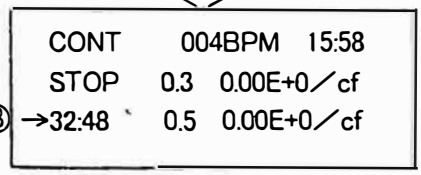
5.5 CALCULATION mode

It is a mode by which measures repeatedly, and mean value from the measurement data, a standard deviation, the maximum value, and minimum value are calculated . Only result is preserved, and each measurement result is not preserved in the data store . The measurement frequency can be set at the grain size, the data store, warning, the printer, and the sample time.

Display screen	Operation key	Operation explanation
<MODE> 1.REPEAT 4.CALC 2.SINGLE 5.REMOTE 3.CONT	POWER	Push POWER key to input the power supply.
	PREV	Push PREV key twice to proceed MODE screen
	△ ▽ SET	Select 4. CALC
CALC 0.3／0.5 μm STR:Y BEEP:N PR:N SAMPLE 10:00 06TIMES OK	△ ▽ SET	■ Setup the particle size, requirement of data storage , alarm , printout, sampling time, frequency. Use △ ▽ key to change the setting Condition, then push SET key. After the input is done, change NO to OK and push SET key.
CALC 003BPM 15:25 WAIT 0.3 0.00E+0／cf 01／06 0.5 0.00E+0／cf	WAIT Mode	WAIT sign is shown for the stabilization of internal pump
CALC 003BPM 15:25 READY 0.3 0.00E+0／cf 01／06 0.5 0.00E+0／cf	READY Mode	WAIT sign turns to READY in 10 seconds and measurement can be started. Push START/STOP key to start the measurement
⑧ →CALC 004BPM 15:25 ⑨ →09:59 0.3 0.00E+0／cf 01／06 0.5 0.00E+0／cf	START／STOP	The display shows the real-time data. Remaining time of each measurements ⑧ : The sample time of the remainder is displayed. ⑨ : Present measurement frequency The last measurement data is maintained on the screen for five seconds though the following measurement begins at the same time as ending measuring time.
CALC AVE 0.00E+／cf 0.3 μm S.D 0.00E+0／cf 06T MAX 0.00E+0／cf MIN 0.00E+0／cf	Display of result. SET	After the last data is displayed for five seconds, result is displayed when the set measurement frequency ends. The data of the small<SMALL> particle is displayed first . It is possible to switch with the data of the large<LARGE> particle in the SET key. ★ Data changes in order saying the temperature, humidity, Air velocity , the small particle, and the large particle whenever the SET key is pushed when the temperature humidity and Air velocity probe are used.
CALC AVE 0.00E+／cf 0.5 μm S.D 0.00E+／cf 0.6T MAX 0.00E+0／cf MIX 0.00E+0／cf	PREV	It returns to measuring the set screen with the PREV key. ★ When the measurement ends when setting the printer is Y, the result is printed at once .(refer to 6.4) ★ When the START STOP key is pushed while measuring, the measurement is stopped, and the measurement data of times ahead of that is used and operated.
CALC 0.3／0.5 μm STR:Y BEEP:N PR:N SAMPLE 10:00 06TIMES OK		

5.4 CONTINUOS mode

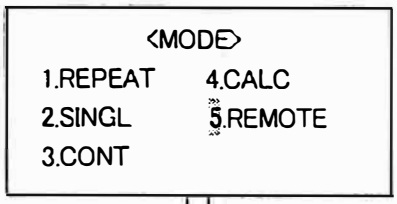
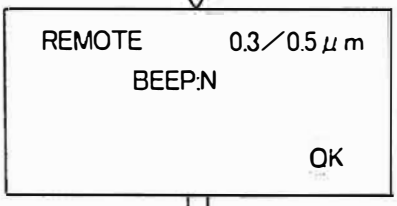
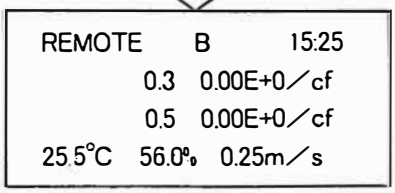
It is a mode not to set the sample time, and nor to begin, and to end the measurement with the START/STOP key.
Particle size(μm)、 data store(STR)、 Warning(BEEP)、 Printer(PR) can be set.

Display screen	Operation key	Operation explanation
	POWER	Push POWER key to input the power supply.
	PREV	Push PREV key twice to proceed MODE screen
	△ ▽ set	Select 3. CONT
	△ ▽ set	■ Setup the particle size. requirement of data storage . alarm . printout. Use △ ▽ key to change the setting Condition. then push SET key. After the input is done. change NO to OK and push SET key.
	WAIT Mode	WAIT sign is shown for the stabilization of internal pump The particle size can be switched with the △ ▽ key on the measurement screen. UNIT:[CNT] [m³] [cf]
	READY Mode	WAIT sign turns to READY in 10 seconds and measurement can be started. Push START/STOP key to start the measurement
	START／STOP	The display shows the real-time data. Remaining time of each measurements ⑦ : Measurement time (Count up) ★ "01:00m" and the display change into the following of 59:59 (It is 59second of 59 minutes.)
	START／STOP	START/STOP key is pushed, and the measurement is ended. ⑧ : Measurement time ★ The data is printed after the sampling time is Over if you chose printout. (refer to 6.4)

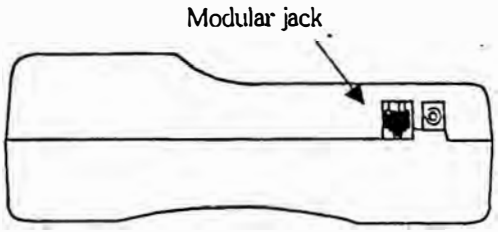
5.6 REMOTE mode

From computer to measurement mode by remote control
(The application software of the option is necessary.)

The connection method with the computer is the same method as forwarding the record data. (Refer to 6.3)

Display screen	Operation key	Operation explanation
	POWER	Push POWER key to input the power supply.
	PREV	Push PREV key twice to proceed MODE screen
	△ ▽ SET	Select 5. REMOTE
	△ ▽ SET	■ Setup the particle size, alarm .. Use △ ▽ key to change the setting Condition, then push SET key. After the input is done, change NO to OK and push SET key.
		The measurement begins automatically when the application software is operated.

6.3 Dump of stored data··· <4.DATA>→<2.DUMP>



Put the optional RS-232C cable into the modular jack of GEO-α, and connect other side of the cable with the PC to transmit the stored data.
Do the communication setting of the PC and make the condition that the PC can readout the data.

<DUMP>
STORE 139
1.START 001
2.END 139

⇩

Start transmitting

1	START	The first tag number of the stored data to be transmitted
2	END	The last tag number of the stored data to be transmitted

△ ▽ key	Adjust the value
SET key	Move the cursor
START/STOP key	Start transmitting of the stored data
PREV key	Go back to DATA

Preparations

Computer, Application soft (Option), RS-232C cable (Model 3886-08 : Option).
Signal cable connect GEO-α with PC

Setting up the computer

Function	GEO-α
Word length	8 bit
Parity bit	None
Set parity	Odd number
Baud rate	9600

Signal cable

GEO-α		Connection	Computer (D-sub 9 pin)	
Pin number	Signal name		Pin number	Signal name
1	TXD		2	RXD
3	RXD		3	TXD
5	CTS		7	RTS
6	GND		5	GND
			4	DTR
			6	DSR

◆Forwarding data format

(1) Repeat, Single, Continuous mode

Format	Byte	Explanation
999 crlf	5	Store No
9 crlf	3	Measurement mode (1 : Repeat, 2 : Single, 3 : Continuous)
99.99.99 crlf	10	Measurement start date
99.99.99 crlf	10	Measurement start time
99.99.99 crlf	10	Sampling time (hours, minutes, seconds)
xxx crlf	5	Particle unit (CNT, /cf, /m^3)
x crlf	4	Temperature unit (C, F)
xxx crlf	5	Air velocity unit (m/s, FPM)
x.x.x crlf	7	Error message (L : Light source, F : Flow rate, O : Over the maximum concentration)
999999999 crlf	11	Count data of 0.3μm, 90999E+99crlf using /cf or /m^3 as unit
999999999 crlf	11	Count data of 0.5μm, 90999E+99crlf using /cf or /m^3 as unit
999999999 crlf	11	Count data of 1μm, 90999E+99crlf using /cf or /m^3 as unit
999999999 crlf	11	Count data of 3μm, 90999E+99crlf using /cf or /m^3 as unit
999999999 crlf	11	Count data of 5μm, 90999E+99crlf using /cf or /m^3 as unit
*999.9 crlf	7	Temperature data
*999.9 crlf	7	Humidity data
*9.999 crlf	7	Air velocity data, 999.9 crlf using FPT as unit
Total	135	

*) · T/H or Air velocity probe is not sereeted it becomes " ***** crlf"

· It becomes"###.#" when the value of T/H probe exceeds measurement range.

· It becomes"###.#" using m/s as unit (when the value of Air velocity probe exceeds measurement range.)

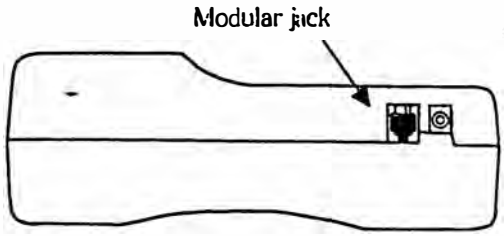
Using FRM as unit, it becomes "###.#".

(2) Calculation mode

Format	Byte	Explanation
999 crlf	5	Store No
9 crlf	3	Measurement mode (4 : Calculation)
99,99,99 crlf	10	Measurement start date
99,99,99 crlf	10	Measurement start time
99999 crlf	7	Measurement number
99,99,99 crlf	10	Sampling time (hours, minutes, seconds)
xxx crlf	5	Particle unit (CNT , /cf , /m³)
x crlf	4	Temperature unit (C , F)
xxx crlf	5	Air velocity unit (m/s , FPM)
x,x,x crlf	7	Error message (L : Light source, F : Flow rate, O : Over the maximum concentration)
9.999E-99,	10	Average of 0.3㎛
9.999E-99,	10	Standard deviation of 0.3㎛
999999999,	10	Maximum data of 0.3㎛, 9.999E+99 crlf using /cf or /m³ as unit
999999999 crlf	11	Minimum data of 0.3㎛, 9.999E+99 crlf using /cf or /m³ as unit
9.999E-99,	10	Average of 0.5㎛
9.999E-99,	10	Standard deviation of 0.5㎛
999999999,	10	Maximum data of 0.5㎛, 9.999E+99 crlf using /cf or /m³ as unit
999999999 crlf	11	Minimum data of 0.5㎛, 9.999E+99 crlf using /cf or /m³ as unit
9.999E-99,	10	Average of 1㎛
9.999E-99,	10	Standard deviation of 1㎛
999999999,	10	Maximum data of 1㎛, 9.999E+99 crlf using /cf or /m³ as unit
999999999 crlf	11	Minimum data of 1㎛, 9.999E+99 crlf using /cf or /m³ as unit
9.999E-99,	10	Average of 3㎛
9.999E-99,	10	Standard deviation of 3㎛
999999999,	10	Maximum data of 3㎛, 9.999E+99 crlf using /cf or /m³ as unit
999999999 crlf	11	Minimum data of 3㎛, 9.999E+99 crlf using /cf or /m³ as unit
9.999E-99,	10	Average of 5㎛
9.999E-99,	10	Standard deviation of 5㎛
999999999,	10	Maximum data of 5㎛, 9.999E+99 crlf using /cf or /m³ as unit
999999999 crlf	11	Minimum data of 5㎛, 9.999E+99 crlf using /cf or /m³ as unit
999.9,	6	Average of Temperature
999.9,	6	Temperature data standard deviation
999.9,	6	Maximum data of Temperature
999.9 crlf	7	Minimum data of Temperature
999.9,	6	Average of Humidity
999.9,	6	Standard deviation of Humidity
999.9,	6	Maximum data of Humidity
999.9 crlf	7	Minimum data of Humidity data
9.999,	6	Average of Air velocity 999.9 using FRM as unit
9.999,	6	Standard deviation of Air velocity 999.9 using FRM as unit
9.999,	6	Maximum data of Air velocity 999.9 using FRM as unit
9.999 crlf	7	Minimum data of Air velocity 999.9 using FRM as unit
Total	346	

*) · T/H or Air velocity probe is not selected it becomes " ***** crlf".
· It becomes "###.#" when the value of T/H probe exceeds measurement range.
· It becomes "###.#" using m/s as unit
(when the value of Air velocity probe exceeds measurement range.)

6.4 Printout of stored data··· <4.DATA>→<3.PRINT>



Put the optional Printer cable into the modular jack of GEO- , and connect other side of the cable with the Printer to print the stored data.

<PRINT>
STORE 139
1.START 001
2.END 139

Start printing

1	START	The first tag number of the stored data to be printed
2	END	The last tag number of the stored data to be printed

△ ▽ key	Adjust the value
SET key	Move the cursor
START/STOP key	Start printing of the stored data
PREV key	Go back to DATA

Preparations

Printer (Option) ····· Recommendatory Printer Model. DPU-201GS (SEIKO CO., LTD).
Signal cable (Model 3886-07 : Option), Signal cable connect GEO-α with Printer

DIP Switch Setting (DPU-201GS)

Switch Number	Function	GEO-α	Printer
SW1	Word length	8 bit	ON
SW2	Parity bit	None	ON
SW3	Set parity	Odd number	ON
SW4~6	Baud rat	9600	following table

Baud rate	SW4	SW5	SW6
9600	OFF	OFF	ON

*If you use DPU-H245, Please leave it to a default setting.

Signal cable

GEO-α		Printer	
Pin number	Signal name	Pin number	Signal name
1	TXD	3	DATA
6	GND	4	GND
5	CTS	8	BUSY
6	GND	5	GND

《Al 》
When interval is set lower than 15 seconds at REPEAT mode, it may not print the data causing of buffer memory over.

◆ Example of printout

(1) Repeat, Single, Continuous mode

```
2000/03/21  16:40:00   E=
REPEAT          STORE  10  05:30
 0.3um  564700 CNT
 0.5um   10457 CNT
 1.0um     323 CNT
 3.0um      36 CNT
 5.0um       8 CNT
  23.2℃  45.7%RH  0.64m/S
```

(2) Calculation mode

```
 2000/03/21  16:40:00   E=LFO
CALCULATION STORE  13  05:30
                          10TIMES
0.3um AVE   6.66E+04  CNT
      STD   3.94E+03  CNT
      MAX      71334  CNT
      MIN      60875  CNT
0.5um AVE   2.78E+03  CNT
      STD   2.76E+02  CNT
      MAX       3096  CNT
      MIN       2422  CNT
1.0um AVE   9.83E+01  CNT
      STD   3.90E+01  CNT
      MAX        156  CNT
      MIN         67  CNT
3.0um AVE   3.76E+00  CNT
      STD   3.46E+00  CNT
      MAX          9  CNT
      MIN          0  CNT
5.0um AVE   3.00E-01  CNT
      STD   4.56E-01  CNT
      MAX          1  CNT
      MIN          0  CNT
TEMP  AVE   23.5 °C
      STD    0.3 °C
      MAX   24.0 °C
      MIN   23.2 °C
HUM   AVE   52.9 %RH
      STD    1.2 %RH
      MAX   54.4 %RH
      MIN   51.5 %RH
VEL   AVE   0.20 m/S
      STD   0.03 m/S
      MAX   0.25 m/S
      MIN   0.18 m/S
```

(3) During measurement

(Repeat, Single, Continuous mode)

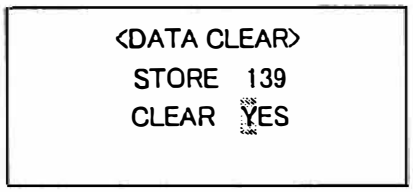
```
2000/03/21  16:40:00   E=LFO
REPEAT          1      05:30
0.3um  564700 CNT
0.5um   10457 CNT
23.2℃  45.7%RH  0.64m/S
```

Only two particle sizes are printed.

(4) During measurement (Calculation mode)

```
 2000/03/21  16:40:00   E=
CALCULATION            05:30
                          10TIMES
0.3um AVE   6.66E+04  CNT
      STD   3.94E+03  CNT
      MAX      71334  CNT
      MIN      60875  CNT
0.5um AVE   2.78E+03  CNT
      STD   2.76E+02  CNT
      MAX       3096  CNT
      MIN       2422  CNT
TEMP  AVE   23.5 °C
      STD    0.3 °C
      MAX   24.0 °C
      MIN   23.2 °C
HUM   AVE   52.9 %RH
      STD    1.2 %RH
      MAX   54.4 %RH
      MIN   51.5 %RH
VEL   AVE   0.20 m/S
      STD   0.03 m/S
      MAX   0.25 m/S
      MIN   0.18 m/S
```

6.5 Delete of stored data··· <4.DATA>→<4. CLEAR >



ALL the stored data will be deleted by executing this function.

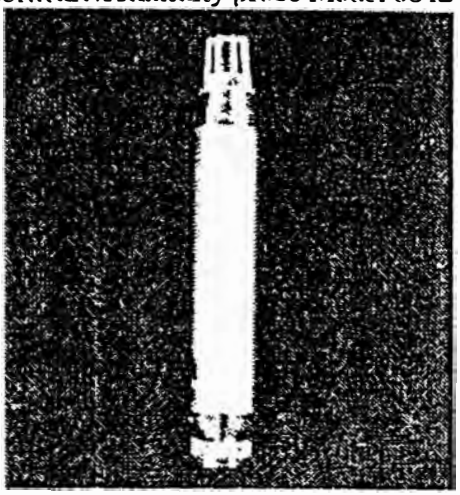
CLEAR	YES : data deletion NO : delete not

△ ▽ key	Adjust the value
START STOP key	Shift the data display screen
PREV key	Go back to DATA

7. How to use option probes

7.1 Option probes

Temperature/Humidity probe Model 0842



Air velocity probe Model 0843

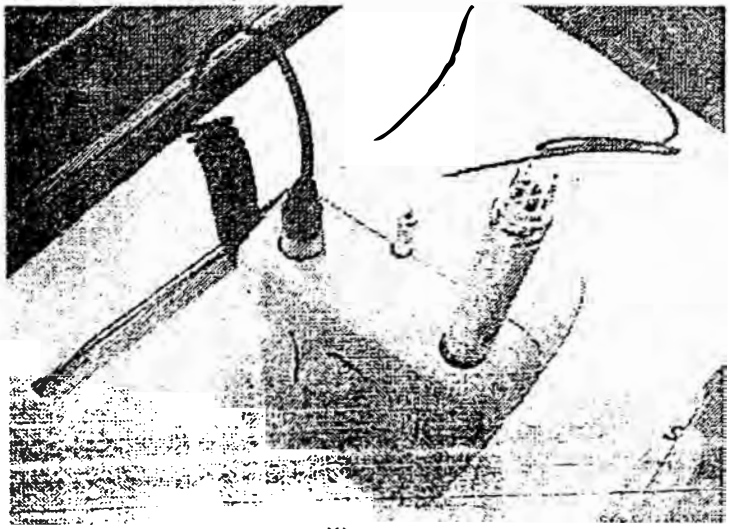
7.2 Installation of probes

<<Attention>>

Please install probes after the power supply of GEO-α is turned off.

Put T/H probe into "T/H" of GEO-α (refer to 2.4) and put Air velocity probe into "VEL", then close each lock screw cap. Please remove the cover when probes are installed.

GEO-α with T/H probe and Air velocity probe installed



7.3 Setting of display

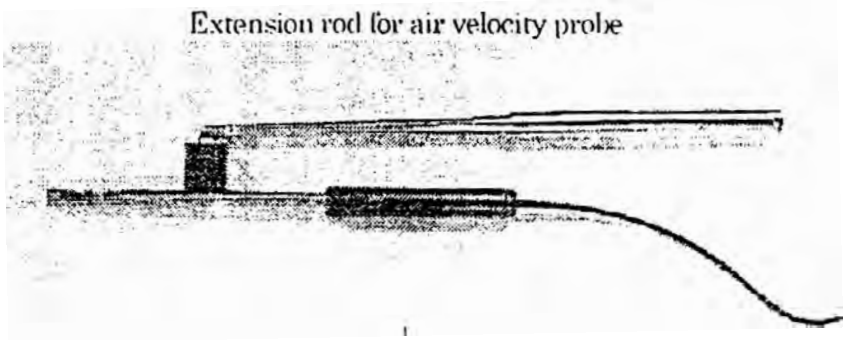
To display the data, please refer to 4.4.

To set the alarm, please refer to 4.3.

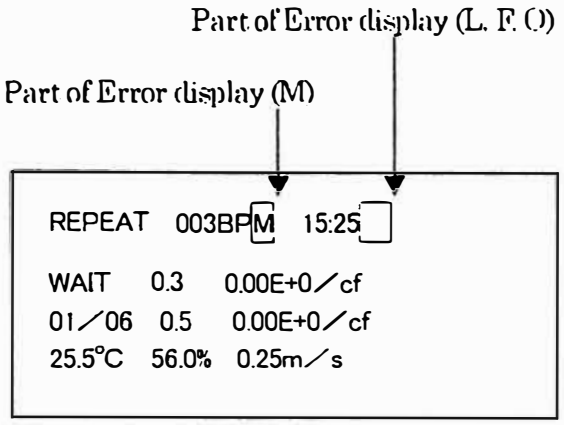
7.4 Extension rod for air velocity probe

To measure air velocity of right under the filter, please use Extension rod Model 0843-01 as occasion demands. Put the probe into the rod from the side of sensor. At this time, please pay attention so as not touch the element of the sensor.

Extension rod for air velocity probe



8. Error message

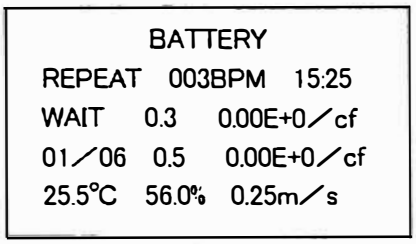


The error display under the measurement display as shown in left figure.
As for the display error, one character of the initial is displayed based on the display priority level of each error.

Error message	Content of error	Action
L	Abnormality of laser power	It's a breakdown of the laser luminescence part. Please contact the nearest office for information.
F	Error of flow rate	It is displayed that flow rate exceeds regulated value. (2.83L/min ±10%) When "GEO-α" is applied the filter or tube to inlet, please remove it. When "F" doesn't disappear even if it's removed, it is a breakdown of the passage system which contains the pump. Please contact the nearest office for information.
O	Over the maximum concentration	It is displayed to exceed the concentration which can be measured by GEO-α. Please move to cleaner place, measure or install and measure with filter. When "O" doesn't disappear , please contact the nearest office for information.
M	Over the printer buffer	It is displayed that the printer buffer exceeded that when printing data during measurement. Please note that the data after that is not printed.

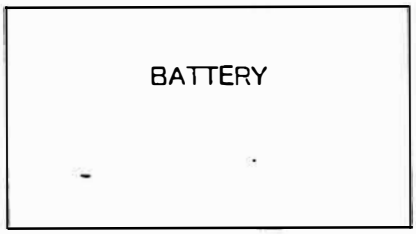
《Attention》
There is a possibility of an exaggerated buffer when 15 seconds or less are set, and measurement interval (INT) of REPEAT mode is printed during measurement. Please go after setting the measurement interval at 15 seconds or more when printing during measurement.

9. Battery check



(1) First alarm

If the battery voltage become below 4.5 V the first alarm massage "BATTERY" indicate in the top of the display. In this case,it is need to replace the batteries or using AC adapter. If there is no action for about 5 min. at this situation. the second alarm massage "BATTERY" only indicate in the center of the display. Then GEO-α stop the measurement and turn off..



(2)Second alarm

■ In the case of the first alarm massage. it can store the collecting data. Refer the under the table. Basically it can be stored the data while indicating the first alarm massage.

Measurement mode	Data store
REPEAT	All data can be stored
SINGLE	If the measurement is finished between the first alarm. the data can be stored.
CONTINUOUS	If you push the "stop" key between at the first alarm, the data can be stored.
CALCULATION	The data can be stored by using the data until collecting until the first alarm massage.

10. Specification

Measuring particle size	0.3、0.5、1.0、3.0、5.0μm
Light Source	Laser Diode
Counting Efficiency	Meets JIS B9921
Zero Count	Meets JIS B9921
Coincidence Loss	Less than 5% at 2,000,000 particles cf
Flow Rate	0.1 cfm (2.83 L/min)
Sampling Time	1 second–99 minutes 59second (adjustable in second)
Sampling Frequency	1–99 times, or Continuous
Mode of measurement	Single/Repeat Continuous/Calculation
Display	20 letters, 4lines LCD
Error sign	Counts beyond max concentration, Drop of laser power. Out of regulated flow rate (+/–10%), Low battery
Interface	RS–232C or RS–485 (Selectable on menu page), RJ–11 Connector ×1. RS–485 is for cascade connection
Communication protocol	Baud Rate 9600bps
Buffer Memory	500 data (In Calculation mode, 1 measurement is counted as 4 data)
Power supply	4 pieces of AA–size Ni–MH battery (1.8V–1.6Ah) or AC adapter (Input 100–240V) Battery are not included and cannot be chaged by AC adapter.
Operating hours	Max. 3 hours (By Ni–MH batteries)
Dimensions	115(W)×70(H)×211(D) mm
Weight	Approx. 980 g (with batteries)
Environment operation condition	Ambient temperature range:10–35°C
Standard Accessories	AC adapter, Filter, Tube, Handle, Operation manual
Options	Printer, Printer cable, Temperature Humidity probe, Air velocity probe, Extension rod for Air velocity probe, Carrying case, Tripod, Application software, RS–232C cable

Temperature/Humidity Probe	Model 0842
Temperature range	0～50°C(32～122° F)
Accuracy	+/–0.5°C (at over 0.2 m/s air velocity)
Humidity range	3–98%RH
Accuracy	+/–3%RH (+/–5% at the outside of 30–85%RH)
Dimensions	φ20×150mm

Air velocity Probe	Model 0843
Air velocity range	0～1m/s(0～197FPM)
Accuracy	±0.05m/s(10FPM)
Dimension	φ20×150 mm Curl cord 0.2m(Max. extended length 1.5m)

Carrying case	Model 3886-02

Extension rod for air velocity probe	Model 0843-01

11. Troubleshooting

Symptom	Possible Cause/Corrective Action	Reference
No Display	Not corrective plug in AC adapter → Confirm plugging AC adapter Low or dead batteries → Replace Batteries → or charging batteries	3.1
Display "BATTERY" alarm	Need charging batteries → Charge batteries	3.1
Flashing the reading	Exceed the alarm level → Confirm the alarm level	4.3
Not display the reading of the option Prove	Not set the optional prove → Set the optional prove	4.4
Not begin measurement	If display is "WAIT" → Wait until display "READY" After the changing the display, Re – push the "START" key If display is "READY" → Push the "START" key If display is "STOP" → Push the "STRAT READY Wait until display "READY" After the changing the display, Re – push the "START" key	4
The particle count or particle concentration is high	The environmental particle concentration may be high → Attach the filter to inlet of the counter	
The particle count or particle concentration is low	It may be occur "L" abnormality of laser power or "I" error.	
Display "==.="	It means over range.	
The reading of velocity is low	Confirm the direction of wind velocity to probe.	
The reading of temperature is High	If the wind velocity is actually zero, the reading is not correct. Measure at the place of upper 0.1m/s wind velocity.	
No printing	· The setting of the BAUD rate is not correct. → Confirm the setting of the printer. · Confirm the cable.	6.4
At the "DUMP" mode, not take the data	· The setting of the BAUD rate is not correct. → Confirm the setting of the HOST PC. · Confirm the cable. · Confirm the condition of the HOST PC.	6.3
At the "DUMP" mode, data is not correct	Output format is not correct → Re – set the format	6.3, 6.4

OPERATOR'S MANUAL
for
Air Operated Aerosol Generators

Models TDA-4B, TDA-4Blite & TDA-6C

Revision D

Air Techniques International
Division of Hamilton Associates, Inc
11403 Cronridge Drive
Owings Mills, MD 21117 USA
TEL 410-363-9696
FAX 410-363-9695
www.atitest.com

Generator Description

ATI manufactures portable Laskin nozzle aerosol generators which produce a sub micron poly-dispersed oil mist aerosol in concentrations from 10 to 100 micrograms per liter (ug/l) at air flows from 50 to 8,100 cfm @ 20 psig.

Aerosol generators and photometers are used to integrity test or locate leaks in high efficiency air filtration systems. Filter manufacturers use this equipment to scan ULPA and HEPA filters to verify they are free from manufacturing defects. Filter certifiers use this equipment to insure that filters were not damaged in shipping and have been installed properly, eliminating any leakage.

With the proper generator and photometer combination, filter deficiencies such as pinholes, thin spots, gasket leaks, frame leaks or seal problems can be quickly and quantifiably pinpointed and corrected thus protecting product and personnel.

The TDA-4B, TDA-4Blite & TDA-6C feature several improvements over preceding units including rugged stainless steel construction, larger fill ports, individual nozzle control, and a 3" standard sanitary flange outlet. An optional hose adapter, part number 9300100, is available for introducing the aerosol into positive pressure systems.

CAUTION

DO NOT EXCEED 100 psig INPUT PRESSURE

WARNING!

UNDER NO CIRCUMSTANCES SHOULD THE AEROSOL OUTLET BE COMPLETELY BLOCKED DURING OPERATION. BLOCKAGE OF THE OUTLET WILL CAUSE SEVERE DAMAGE TO THE UNIT AND POSSIBLE INJURY TO PERSONNEL!

TDA-4B Features

The TDA-4B is the latest design in rugged, lightweight Laskin nozzle generators from ATI. The TDA-4B is a small, compact aerosol generator that requires only a supply of clean, compressed air to create poly-dispersed sub micron oil aerosol.

The TDA-4B has 6 Laskin nozzles. When its total output at 20 psig is diluted by 810 cfm of air, the aerosol concentration is approximately 100 ug/liter. Three valves permit the unit to be operated with 1 to 6 nozzles, providing a wide range of aerosol concentrations.

The TDA-4B is recommended for testing systems with airflows of 8,100 cfm and lower. It is ideal for workstations, Negative Pressure Filtration Units, biosafety cabinets, ceiling modules, small or portable cleanrooms, or HEPA filter units in installations where an adequate supply of clean, compressed air is readily available.

OPERATING INSTRUCTIONS
TDA-4B AEROSOL GENERATOR (6 Laskin nozzle)

1. Unscrew LIQUID FILL cap located on top of cabinet and fill sight gauge to 3/4 full with desired liquid aerosol agent. Do not overfill. Refill when the level falls to the halfway point on the sight gauge.

2. Attach a source of clean, dry, compressed air to the filter/regulator air inlet. A shut-off valve (ball-type) is recommended to turn the air to the unit on and off.

3. Turn air on and adjust the filter/regulator control knob for a pressure of 20 psig. To lock this adjustment in, simply push down on control knob.

4. Varying aerosol output concentration.

1 Nozzle	Valve #1 ON Valve #2 OFF Valve #3 OFF
2 Nozzle	Valve #1 OFF Valve #2 ON Valve #3 OFF
3 Nozzle	Valve #1 OFF Valve #2 OFF Valve #3 ON
4 Nozzle	Valve #1 ON Valve #2 OFF Valve #3 ON
5 Nozzle	Valve #1 OFF Valve #2 ON Valve #3 ON
6 Nozzle	Valve #1 ON Valve #2 ON Valve #3 ON

NOTE: If more than 20 psig is used, the output concentration will increase and, conversely, if less than 20 psig is used, the output concentration will decrease.

TDA-4Blite Features

The TDA-4Blite is a smaller, lower capacity version of the TDA-4B that still retains all the improved features. The TDA-4Blite was specifically designed for use in biosafety cabinets. Its small size and low cost make it the ideal generator for biosafety cabinet testing and HEPA filter vacuums.

The TDA-4Blite has 3 Laskin nozzles. When its total output at 20 psig is diluted by 405 cfm of air, the aerosol concentration is approximately 100 ug/l. Two valves permit the unit to operate with 1 to 3 nozzles to provide a wide range of aerosol concentrations.

OPERATING INSTRUCTIONS
TDA-4Blite AEROSOL GENERATOR (3 Laskin nozzle)

1. Unscrew LIQUID FILL cap located on top of cabinet and fill sight gauge to 3/4 full with desired liquid aerosol agent. Do not overfill. Refill when the level falls to the halfway point on the sight gauge.

2. Attach a source of clean, dry, compressed air to the filter/regulator air inlet. A shut-off valve (ball-type) is recommended to turn the air to the unit on and off.

3. Turn air on and adjust the filter/regulator control knob for a pressure of 20 psig. To lock this adjustment in, simply push down on control knob.

4. Varying aerosol output concentration.

1 Nozzle	**Valve #1 ON** **Valve #2 OFF**
2 Nozzle	**Valve #1 OFF** **Valve #2 ON**
3 Nozzle	**Valve #1 ON** **Valve # 2 ON**

NOTE: **If more than 20 psig is used, the output concentration will increase and, conversely, if less than 20 psig is used, the output concentration will decrease.**

TDA-4B Specifications

Aerosol Output Range: 50-8,100 cfm
Aerosol Concentration 100 ug/1@ 810 cfm
Aerosol Concentration 10 ug/1@ 8,100 cfm
Generator Type: 1 to 6 Laskin nozzles
Compressed Air: 3 to 18 cfm @ 20 psig

Aerosol Type: Polydispersed (Cold)
Size: 10" L × 11" W × 9" H
(25cm L × 28cm W × 23cm H)
Weight-Pounds (lbs): 16 lbs.
Weight-Kilograms (kg): 7.3 kg
Electrical: (Not Required)

TDA-4Blite Specifications

Aerosol Output Range: 50-4,050 cfm
Aerosol Concentration 100 ug/1@ 405 cfm
Aerosol Concentration 10 ug/1@ 4,050 cfm
Generator Type: 1 to 3 Laskin nozzles
Compressed Air: 3 to 9 cfm @ 20 psig

Aerosol Type: Poly-dispersed (Cold)
Size: 10" L × 8" W × 9" H
(25cm L × 20cm W × 23cm H)
Weight-Pounds (lbs): 12 lbs.
Weight-Kilograms (kg): 5.5 kg
Electrical: (Not Required)

TDA-4B & TDA-4Blite Aerosol Output Calculation

These units include a total of either 3 or 6 Laskin nozzles incorporated into the cabinet. The aerosol concentration depends on the compressed air pressure and flow available for consumption by the nozzle. With 20 psig applied, each jet emits 18.75 slpm of air containing 1,275 ug/l of aerosol. When this aerosol is diluted with 135 cfm of air, the aerosol concentration becomes approximately 100 micrograms per liter. The equation below is for purposes of calculating the aerosol output in micrograms per liter (ug/l) when 20 psig is applied to the nozzle jets.

$$\frac{13{,}500 \times (\#\text{ of nozzles being used})}{\text{Total airflow (CFM)}}$$

TDA-6C Features

The TDA-6C is the latest design in rugged, lightweight Laskin nozzle generators from ATI. The TDA-6C is a self-contained aerosol generator that requires only a suitable voltage source to create poly-dispersed sub micron oil aerosol.

The TDA-6C has 6 Laskin nozzle jets. When its total output at 20 psig is diluted by 200 cfm of air, the aerosol concentration is approximately 100-ug/l. A valve permits the unit to be operated with either 2 or 6 nozzle jets, providing a wide range of aerosol concentrations.

The TDA-6C is recommended for testing systems with airflows of 2,000 cfm and lower. It is ideal for workstations, Negative Pressure Filtration Units, Bio-safety cabinets, ceiling modules, small or portable cleanrooms, or HEPA filter units in installations where an adequate supply of clean, compressed air is not readily available.

OPERATING INSTRUCTIONS
TDA-6C AEROSOL GENERATOR (1 ½ Laskin nozzle)

1. Unscrew LIQUID FILL cap located on top of cabinet and fill sight gauge to 3/4 full with desired liquid aerosol agent. Do not overfill. Refill when the level falls to the halfway point on the sight gauge.

2. Connect the unit to an appropriate, grounded, power outlet.

3. Position the generator near the aerosol introduction point of the system under test. A sealed connection to a duct system may be established by using a 3" sanitary flange adapter.

4. Depress the power switch and adjust for desired output concentration.

5. Varying aerosol output concentration.

2 Jet (1/2 nozzle)	Valve #1 OFF
6 Jet (1 ½ nozzle)	Valve #1 ON

NOTE: If more than 20 psig is used, the output concentration will increase and, conversely, if less than 20 psig is used, the output concentration will decrease.

TDA-6C Specifications

Aerosol Output Range: 50-2,025 cfm
Aerosol Concentration 100 ug/1@ 202 cfm
Aerosol Concentration 10 ug/1@ 2,025 cfm
Generator Type: 2 to 6 Laskin nozzle Jets
Aerosol Type: Poly-dispersed (Cold)

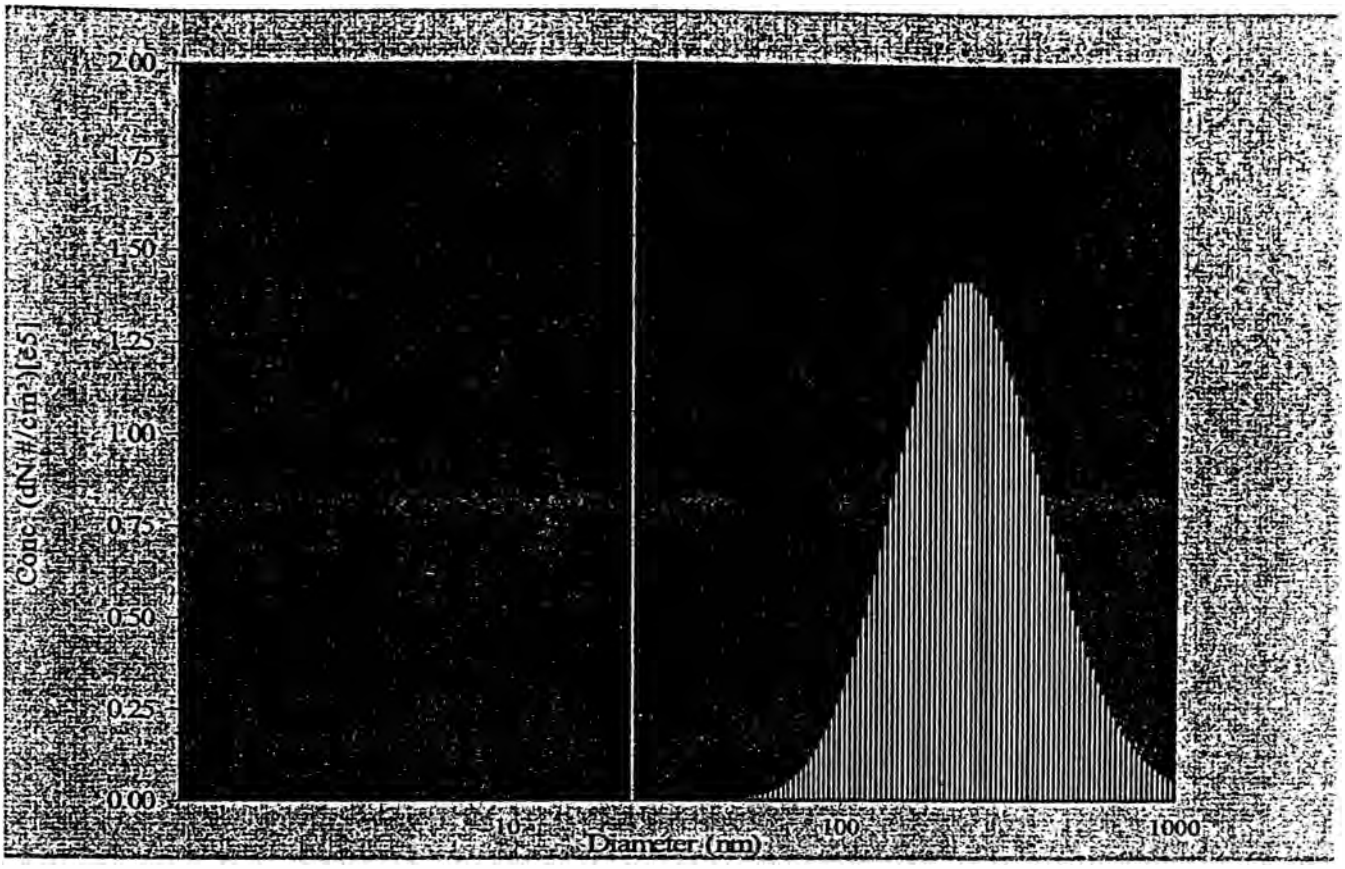
Size: 21" L × 8" W × 11" H
(54cm L × 20cm W × 28cm H)
Weight-Pounds (lbs): 55 lbs.
Weight-Kilograms (kg): 25 kg
Electrical: 110 Vac / 60 HZ or 220 Vac / 50 HZ

TDA-6C Aerosol output calculation

This unit includes a total of 1 1/2 Laskin nozzles incorporated into the cabinet. Each nozzle consists of four jets located at the nozzle tip, for a total of six jets. The aerosol concentration depends on the compressed air pressure and flow available for consumption by the nozzle. With 20 psig applied, each jet emits 18.75 slpm of air containing 1,275 ug/l of aerosol. When this aerosol is diluted with 135 cfm of air, the aerosol concentration becomes approximately 25 micrograms per liter. The equation below is for purposes of calculating the aerosol output in micrograms per liter (ug/l) when 20 psig is applied to the nozzle jets.

$$\frac{3375 \times (\#\text{ of jets being used})}{\text{Total airflow (CFM)}}$$

Type III-A Laskin Nozzle Aerosol Distribution @ 20 PSI Using PAO Oil



	Number	Surface	Mass	Volume
	Particle Size	Particle Size	Particle Size	Particle Size
median (nm)	242	414	529	529
mean (nm)	278	453	549	549
geo. mean (nm)	245	405	502	502
mode (nm)	241	429	615	615
geo. st. dev.	1.65	1.62	1.55	1.55
total conc.	4.98e+006 (#/cm³)	1.56e+012 (nm²/cm³)	1.41e+005 (µg/m³)	1.18e+014 (nm³/cm³)

The following liquids may be used in ATI air operated generators to produce aerosol:

DOP / DEHP (Di 2 ethylhexyl-phthalate)

PAO (Poly-alpha olefin) / Emery 3004

DOS / DEHS (Di-2-ethylhexyl-sebacate)

Mineral Oil

Ondina EL

Kaydol

Polyethylene Glycol (PEG 400)

Paraffin Oil

MAINTENANCE

1. If clean, dry, compressed air is used with this unit, little maintenance should be required. (TDA-4B & TDA-4Blite only)

2. Drain the compressed air filter/regulator daily, or more often, if required. (TDA-4B & TDA-4Blite only)

3. Yearly, under daily operation, drain all liquid and flush with a solvent to remove any residue from the unit. (TDA-4Blite, TDA-4B & TDA-6C)

Note

BEFORE SHIPPING UNIT

1. Drain all liquid from unit.

2. Verify that the LIQUID FILL cap is tight.

3. Stuff aerosol outlet flange with liquid-absorbing cloth or paper to prevent residue from damaging shipping container. (All units)

4. Tape or plug the compressed air inlet on air filter/regulator to prevent internal damage by foreign material. (TDA-4B & TDA-4Blite only)

5. Package the unit in a triple wall carton with a minimum of 3 inches of loose packing fill on all sides.

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Sales/Customer Service – Ruth Lanahan rlanahan@atitest.com

ACCESSORIES

ADAPTER KIT

Converts the 3"-sanitary outlet flange of all generators to ¾"-FNPT thread. No hose terminations are supplied due to the high level of variability in requirements. ATI's technical support personnel are always willing and capable of sourcing or configuring hose termination connections to suit a specific application.

The **9300100**-adapter kit consists of the following:

1 piece	3" to ¾ "-FNPT adapter plate
1 piece	sanitary adapter clamp
1 piece	sanitary adapter gasket
1 piece	compression fitting, ¾" liquid tight conduit to ¾" MNPT

Liquid tight conduit is also available for purchase by the foot using part # **5200106**.

AEROSOL REAGENTS

T100-0625	**(5 gallon container)**	DOP / DEHP (Di-2-ethylhexyl-phthalate)
T000-0795	**(5 gallon container)**	Emery 3004 / PAO (Poly-alpha olefin)

Please contact ATI's customer service department for current pricing and delivery.

OPERATOR'S MANUAL

for the

2H and 2H-N Aerosol Photometers

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Division of Hamilton Associates, Inc

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1800110 **Revision C**

Table of Contents

Model 2H

Guidelines to the use of this manual

SYMBOLS

The following symbols are used throughout the manual to draw attention to items or procedures that require special notice or care.

Operator required action.

Note: Contains important information that, if ignored, can cause inaccurate readings.

Caution: Contains information that, if ignored, can cause equipment damage.

Warning: Contains information that, if ignored, can cause injury or death to those handling the equipment.

Conventions

[Window] Indicates the information displayed in a window on the Control Panel.

<Function> indicates a button on the Control Panel.

1 INSTALLATION

1.1 REQUIREMENTS

NOTE: High ambient temperatures may create instability in the readings.

The 2H requires the following for proper operation:

- Stable electrical power at 90/240 VAC, single phase, 50/60 Hz, 5 amps.
- Environment Operating Range: 35° to105° Fahrenheit (1.6° to 40.6° Celsius) with less than 75% relative humidity.

1.2 UNPACKING

NOTE: Save all packaging material for future use.

Carefully unpack and remove the 2H Aerosol Photometer and all accessories from its shipping container. If the instrument has been damaged in transit, notify the shipper immediately.

Make sure the following items are included with both the 2H (9300133) and the 2HHP (9300134):

1) 1 power cord, 6700001
2) 12 feet of clear PVC tubing, 5200116
3) Operating Manual, 1800110
4) Calibration certificate

The following items are optional. Check the order packing slip.

1) Shipping case, 9300145
2) 2H-SP Scanning Probe, complete, 9300144
   a) 1 round isokinetic nozzle (red), T2E0-0572
   b) 1 rectangular isokinetic nozzle (blue), T2E0-0798
   c) 1 NSF 1" round nozzle (black), T2E0-0005
   d) 1 Scanning probe, T2SP-0881

If any of these items are on the order packing slip but missing from the shipment, contact ATI immediately at:

Air Techniques International
Division of Hamilton Associates
11403 Cronridge Drive
Owings Mills, Maryland 21117-2247 U.S.A.
Tel: 410 363-9696 Fax: 410 363-9695
www.atitest.com

2 GENERAL INFORMATION

2.1 DESCRIPTION

The 2H is a forward light-scattering, linear photometer. It operates on 100 to 240 VAC, 50 or 60 Hz, adjusting automatically. The basic functions of the 2H are to sample air or other gas and report the concentration of particulates in the sample.

This unit is also available in a nuclear version, the 2H-N. The nuclear version is the same size and has the same features as the 2H, plus a sealed sampling chamber and an additional ULPA filter to contain all contamination within the unit.

The 2H is compact and lightweight, measuring 13.5 x 9.5 x 5.0 inches (34.3 x 24.0 x 12.7 cm) and weighing only 15.5 lbs (7.0 kg). The instrument case is constructed of die cast aluminum and has a swing arm carrying handle that folds up under the case to tilt the unit up for easy viewing. The pressure-sensitive keypad and large, bright LED displays and indicators provide ease of operation and readability. The auto-ranging and one-step zeroing features assure the accuracy of all readings.

WARNING: If the unit is used in a manner not specified within the user's manual, the protection offered by the equipment may be impaired.

2.2 SAMPLING SYSTEM

A vacuum pump provides a sample flow rate of 1 cfm (28.3 liters per minute) for the instrument. It is an oil-free, dual head, rotary vane pump with a direct-coupled DC motor.

A selector valve on the front panel directs the airflow through the sampling system to the scattering chamber from three possible sources. The **CLEAR** position directs clean air from an internal ULPA filter to the scattering chamber for zeroing the instrument. The **UPSTREAM** position permits sampling of the air above the filter being challenged, and the **DOWNSTREAM** position permits sampling of the air that penetrates the filter.

2.2.1 Light Scattering Chamber (LSC)

The scattering chamber is not only an integral part of the sampling system; it is a major component in itself. The scattering chamber is a complex electro-optical unit that consists of a pair of hollow cones connected at the apexes. A pair of collimating lenses first straightens the light emerging from the light source, and then focuses it at the center of the sampling cone. An aperture forms a dark cone around the photomultiplier, preventing light from arriving directly on the photomultiplier. A condensing lens opposite the LED source focuses light scattered into this dark cone onto the photomultiplier tube.

2.2.2 Electronics

The signal from the photomultiplier is amplified and delivered to a signal-conditioning, analog-to-digital converter that is then sent to the microprocessor.

2.2.3 Theory of Operation

When air or gas is drawn through the scattering chamber, particulate matter in the sample passes through the focal point of the scattering chamber. Particulate matter scatters light into the dark cone and onto the photomultiplier tube, which converts the light into an electrical signal. The signal is amplified and digitized, then analyzed by a microprocessor to determine the intensity of the light scattered by the signal. This signal is then compared to a reference signal to provide an output that is normalized by the reference signal.

A photometer is ideally suited to detect particulate matter in air or gas, reporting the mass concentrations encountered on a digital display. Particles from less than 0.1 micron to approximately 600 microns can be detected by the 2H. Since the photometer reports concentration of particulate matter (relatively independent of size, shape, or color), many applications are possible. By using a baseline of 100 micrograms per liter of aerosol, it is possible to directly read the concentrations of aerosol.

2.2.4 Filter Leak Testing: The Most Common Application

The most common application of the 2H is to detect leaks in high efficiency filter systems (HEPA & ULPA). To establish the integrity of a filtration system, a challenge agent consisting of an airborne test aerosol is generated and introduced upstream of the filter. The challenge agent is used to provide enough particulate matter above the filter to allow statistically valid measurements below the filter.

The test aerosol should be introduced into the system on the upstream side of the filter or filters as far from the filters as is practical to insure adequate mixing with the airflow in the duct. A commonly used guideline that assures adequate mixing is ten duct diameters upstream of the filter. A sample of the aerosol/air mixture should be taken from the upstream side, close to the filters under test to verify the necessary upstream challenge. This sample is also used to set the 100% baseline. The 0% baseline is then adjusted using particle-free air supplied by the internal ULPA filter. The instrument is now ready to detect and quantify leakage on the downstream side of the filter as a percentage of the available upstream aerosol/air mixture.

A scanning test is performed using the optional 2H-SP hand-held scanning probe. The entire area of the filter is sampled by passing the probe in overlapping strokes across the face and perimeter of the filter. The end of the probe should be held within one inch of the filter face and scanned at a traverse rate of no more than 10 feet per minute (2 inches per second). Overlapping passes should be made over the entire filter face, around the periphery of the filter, along the bond between the filter pack and the frame, and around the seal of the filter. The display indicates the percent of leakage through or around the filter. The scanning probe is supplied with 3 types of nozzles that can be screwed onto the end of the flexible probe. The round, black nozzle is 1 inch (25 mm) in diameter, which complies with NSF (National Sanitation Foundation) Standard 49-

1992. The rectangular, blue isokinetic nozzle is used for faster scanning and is accepted by many standards, including NSF 49-2002. The round, red nozzle is also an isokinetic nozzle. The isokinetic nozzles are designed for face velocities of 90 ± 20 feet per minute (fpm).

2.2.5 Capabilities

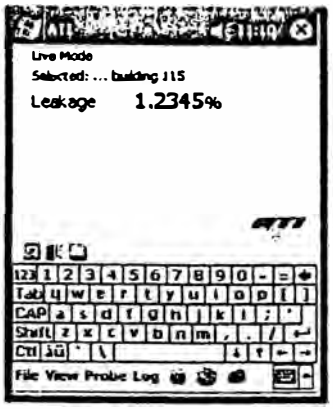
NOTE: Before attempting to operate this unit, become familiar with the features and functions.

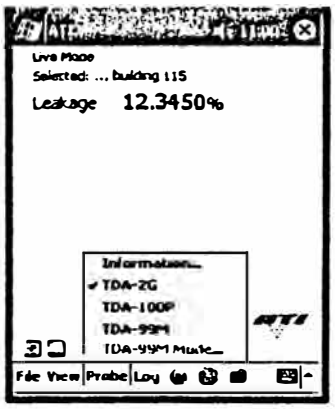
Measurements

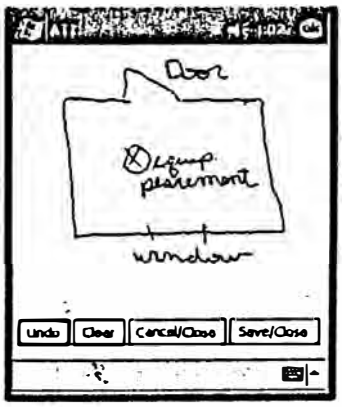
- % Leakage
- Absolute aerosol concentration

2.2.6 Input / Output features

- Alarm (audible and visual). When a reading exceeds the user selected alarm point, a tone will sound and the display will flash on and off.
- Serial Data Output. % Leakage data is sent out the unit's serial port. This data can be logged on ATI's DAS1 or DAS2 data acquisition systems. The following are screenshots of the DAS1 interface. Contact ATI or your local representative for more information about the data acquisition systems available from ATI.







3 SETUP

3.1 LOCATIONS & FUNCTIONS

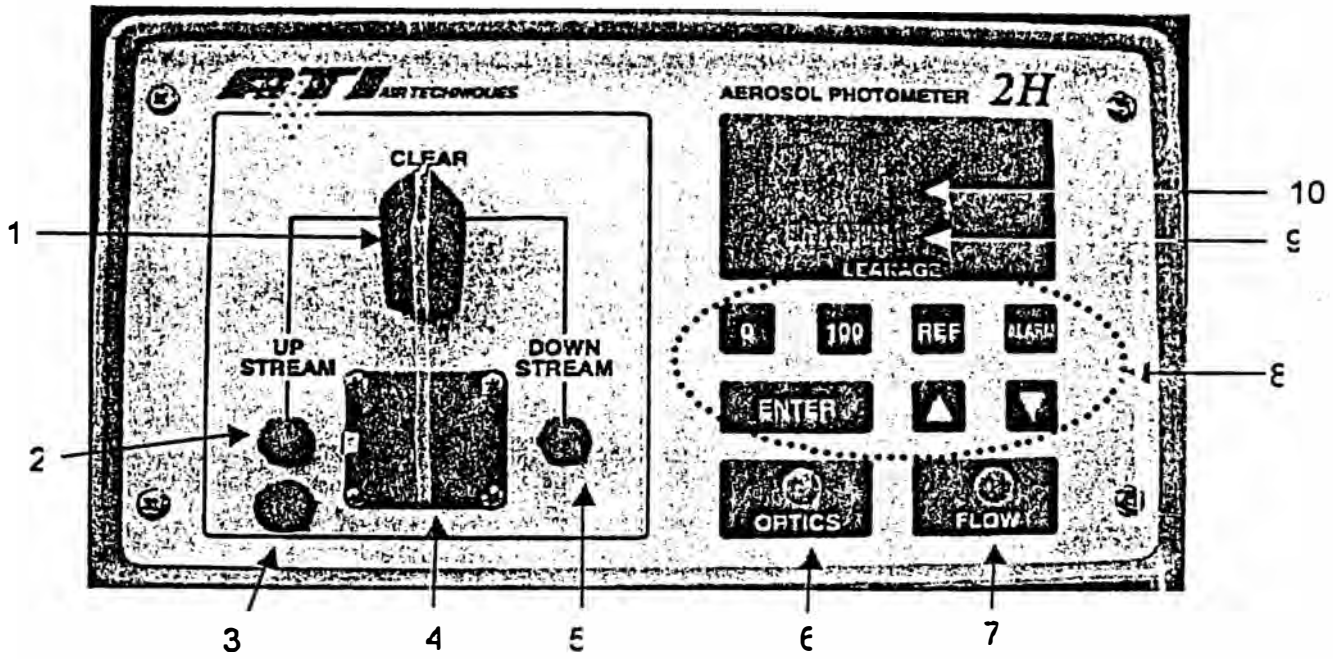


Figure 1. Front View

1. **Selector Valve.** Selects the sample source.
2. **Upstream Sample Port.** Connects to the sample tubing that is used to measure the ups ream aerosol concentration.
3. **Scanning Probe Ground Jack.** Electrical ground connection for scanning probe shieldi ıg. (Required for CE compliance)
4. **Scanning Probe Connector.** Electrical connection for the optional Scanning Probe.

> **NOTE:** Connect the Scanning Probe before applying power to the 2H. Failure to do so will result in the lack of operation of Scanning Probe's display. If this occurs, simply turn off the power to the unit and restart the system.

5. **Downstream Sample Port.** Connects to the sample tubing or optional Scanning Probe that is used to measure the downstream sample.
6. **Optics indicator light. .** Corresponds to the cleanliness of the optics. Displays green when the zero reference is within 5% of original setting, yellow from 5% to 10% of original factory setting, and red when the zero reference has shifted by more than 10%.
   Do NOT rely on the Internal Reference feature if the optics indicator light is red.

7. **Flow indicator light.** Displays green when flow is within 5% of 1 CFM, yellow when flow is from 5% to 10% of 1 CFM, and red when flow is more than 10% above or below 1 CFM.
8. **Function Keys.** Used for setting operating parameters and initiating program routines
9. **Bar Graph Display.** Displays an analog representation of the % leakage to aid in isolating leaks.
10. **Front Panel Display.** Indicates % leakage readings and error messages.

3.2 FRONT PANEL CONTROLS AND INDICATORS

The front panel contains seven pressure-activated function keys. The **<0>, <100>, <REF>**, and **<ALARM>** keys each contain a red LED to indicate the state of the switch or to prompt the operator. The **<Δ>** and **<∇>** keys are used to scroll among selections as they are shown on the **% LEAKAGE** display. The **<ENTER>** key serves as the command key for sending information to the processor and for initiating or stopping system routines. The **<Δ>, <∇>,** and **<ENTER>** keys contain no indicator LED.

The **% LEAKAGE** display is an array of high-visibility LED's that forms a display screen. The Front Panel Display shows alphanumeric messages. Below it is a Bar Graph Display that gives a visual indication of internal photometer cycling or an analog representation of quantity or percentage.

The Scanning Probe contains an unlabeled display on the pistol grip that is a half-scale duplicate of the **% LEAKAGE** Indicator. The two displays are driven by the same electronics and will always read exactly the same.

The Selector Valve, the Scanning Probe connector, and the two barbed fittings are discussed later.

3.3 SCANNING PROBE CONNECTIONS

If using the 2H with the Scanning Probe, connect the probe's electrical connector to the 12-pin connector on the front panel of the 2H before applying power to the photometer. Otherwise, the display on the Scanning Probe will not function. Connect the probe's sampling hose to the barbed **DOWNSTREAM** fitting to the right of the 12-pin connector. The cable and sampling hose are bound as a single, flexible umbilical. Select the appropriate probe nozzle and screw it onto the threaded end of the flexible portion of the Scanning Probe.

Note: When using the TDA-2SP Scanning Probe with the 2H, the probe must be connected to the photometer before the power is turned on. Otherwise the 2H will not detect the probe and no display will be observed on the pistol grip. If this occurs, switch the power off, verify that the probe is connected properly, and then switch the power back on.

3.4 REAR PANEL CONNECTIONS

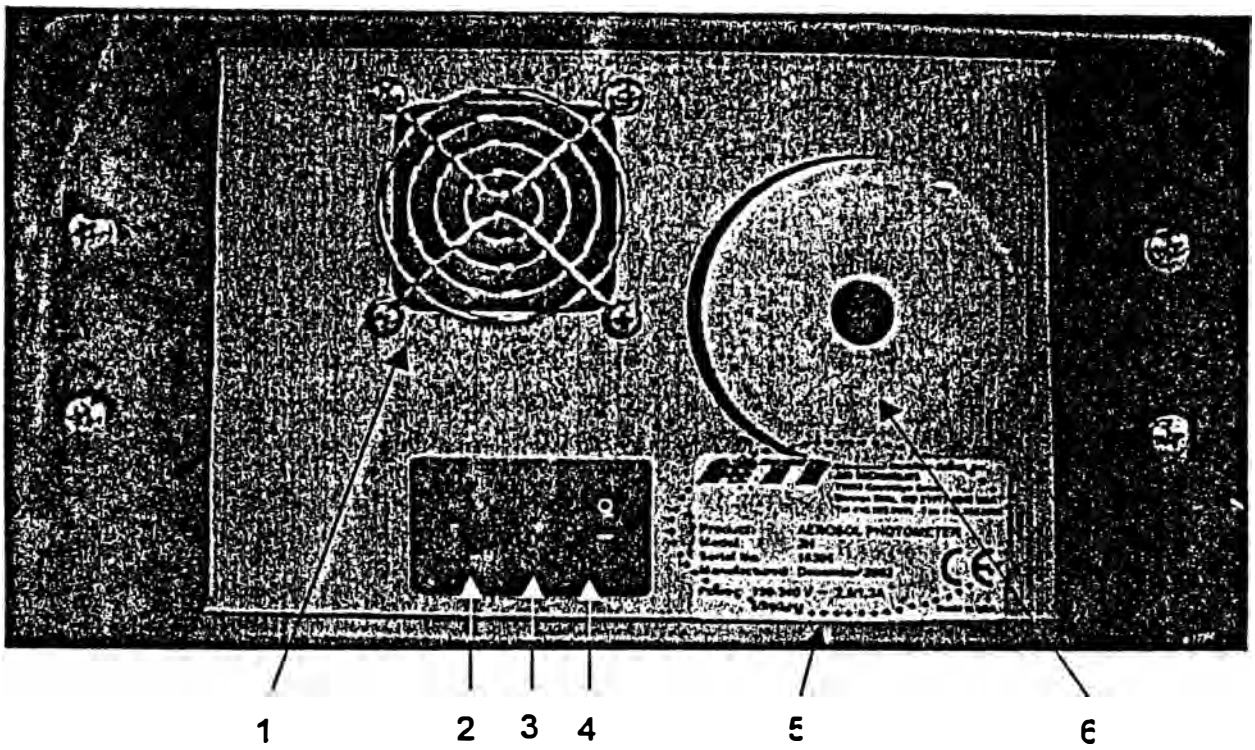


Figure 2. Rear Panel

1. **Cooling Fan** – Maintains airflow through the unit's enclosure to stabilize electronics.
2. **Power Connector with** –Connects to the Power Cord.
3. **Fuse Block** – Contains 2-amp fuse and spare fuse.
4. **Power Switch** – Rocker Switch. Turns system power on and off.
5. **Serial Number Label** – Lists the model and serial number.
6. **Vacuum Pump Exhaust** – Allows a filter to be installed to eliminate particulate emissions.

The rear panel contains a recessed, 3-pronged male Power Connector, with an integral fuse block and power switch, and a Vacuum Pump Exhaust HEPA Filter.

⚠ **CAUTION:** The 2H should always be positioned so that the Power Switch, located on the rear panel, is readily accessible in the event the unit needs to be powered off quickly.

The Power Connector accepts the female end of the Power Cord that comes with the unit. The internal power supply is a universal supply that can operate at either 50 or 60 Hz and with any voltage from 90 to 240 volts, for use in virtually all countries. Therefore, any plug with the correct female end (IEC-320 standard) may be attached to the unit and the universal power supply will automatically switch to use the supplied input power.

The Vacuum Pump Exhaust HEPA Filter is provided so that the sensitive environments of cleanrooms can be maintained. The air expelled by the unit is continually filtered of all particulate matter generated by testing aerosols and the unit using this HEPA exhaust system.

3.5 SIDE CONNECTION

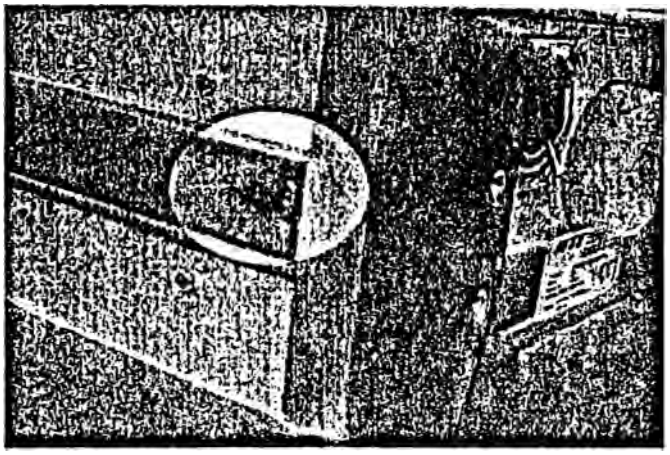


Figure 3. RS-232 Port

RS-232 Port. % Leakage data is continuously sent via the RS-232 port as it is updated on the Front Panel Display, approximately once per second.

It is recommended that this data be logged to either one of ATI's data acquisition systems, the DAS1 or the DAS2. Contact ATI or your local representative to learn more about data logging options.

If using a terminal program to receive this data, a straight cable must be used (as opposed to a null modem cable). If using a Pocket PC (PPC) to receive data, the type of cable will depend upon the brand of PPC. Contact ATI customer service for complete details.

4 OPERATION

4.1 INITIALIZATION

If the Scanning Probe is being used, connect it to the Scanning Probe Connector and the Downstream Port. Verify that the Selector Valve is in the **CLEAR** position. Apply power to the 2H by setting the Power Switch to the **1** (On) position. The following events will occur:

1. The display will show "8.8.8.8.8."
2. All of the LED's in the bar graph will be illuminated.
3. The LED's in the 0, 100, REF, and ALARM buttons will be illuminated.
4. A short beep will sound.

These events indicate that the unit has started and also give the user the opportunity to check the integrity of all the LED's with the exception of the flow and optics LED's. The flow LED will be green, yellow, or red. The optics LED will be off at this time. After a few moments, the firmware revision (main PCB) will be displayed.

Next the screen will go blank and, after a few more moments, another short beep will sound. The LED's in the bar graph will more in a "back and forth" pattern, indicating that the initialization process has begun. During this process, the very important task of checking the cleanliness of the optics is being performed. Be patient, as this may take up to a minute. Upon completion of this task, the optics light will be green, yellow, or red.

After the optics check is complete, the reference light will blink, indicating that it is time to select a reference. Follow these steps to complete the setup:

1. Press **<ENTER>**.
2. Use the **<Δ>** (Up) and **<∇>** (Down) function keys to select the reference of choice.
3. Press **<ENTER>**.
4. Use the **<Δ>** (Up) and **<∇>** (Down) function keys to select the internal reference factor.

The zero LED will begin to blink indicating that it is time to set the zero reference. Double check the selector valve is set to clear.

5. Press **<ENTER>**.

The bar graph display will indicate that the unit is sampling the zero reference value. Upon completion, a short tone will sound and the unit will begin sampling and sending data via the serial port.

4.2 SETUP PARAMETERS

The 2H has thirteen (13) operating parameters (not counting L0), nine (9) of which are programmable by the operator to facilitate setting up the instrument for operation. Some of these parameters have been factory set, but can be optionally reset by the operator. If required, these parameters can be returned to the factory default setting at any time. Other parameters are

accessible for programming only at the factory. The thirteen parameters are listed in the table below. Valid ranges and default settings for each parameter are also listed, where applicable.

Parameter	Description	Valid Range	Default Value
L0	Run	-	-
L1	Audible Alarm	ON / OFF	OFF
L2	0% Sample Time	5 - 120 seconds	10 seconds
L3	100% Sample Time	5 - 120 seconds	10 seconds
L4	Decimal Places	3 - 4	4
L5	Internal Reference	-	DOP
L6	Hour Meter	-	-
L7	Load Factory Defaults	-	-
L8	Software Revision	-	-
L9	Bar Graph Display	ON / OFF	ON
L10	Display Intensity	1 - 8	6
L11	Optics Check	ON / OFF	ON
L12	0% Purge Time	0 - 120	0
L13	100% Purge Time	0 - 120	0

To enter the parameters setting menu proceed as follows:

1. Press **<Δ>** function key (Up arrow).The display will read "- - - - -"
2. Press **<ENTER>**. L0 will be displayed.

NOTE: If the **<ENTER>** key is not pressed within about 3 seconds, the unit will assume this was an accidental key press and return to sampling mode.

3. The **<Δ>** (Up) and **<∇>** (Down) function keys are used to scroll through the parameters from L0 to L13.
4. To access a parameter once it is displayed, press the **<ENTER>** function key.
5. Select the desired setting for the parameter by using the **<Δ>** (Up) and **<∇>** (Down) function keys.
6. When the desired setting is displayed, press the **<ENTER>** function key to store the setting.
7. When the setting of the parameters is complete, scroll to L0 and press **<ENTER>**. The unit will return to sampling mode.

4.3 CHANGING SETUP PARAMETERS

L0 – Exit Parameter Menu

This is a non-programmable parameter. This parameter is used to both enter and exit the parameter setting menu. When L0 is selected, the programmable parameter settings are included in the operating routine. Scroll to L0 and press **<ENTER>** to return to running mode.

L1 – Audible Alarm ON / OFF

Options: Off
On

Default: Off

Enables or disables the audible portion of the 2H alarms. The unit parameter is factory set to off.

When L1 is displayed in the parameter menu, press the **<ENTER>** function key to access the stored setting. Press the **<Δ>** (Up) and **<∇>** (Down) function keys to change the displayed setting between ON and OFF.

Press **<ENTER>** to set the selection and return to the parameter select menu. **[L1]** will be displayed.

L2 – 0% Sample Time

Options: 5 - 120

Default: 10

Establishes the period over which the 0% aerosol sample is average.

When **[L2]** is displayed in the parameter menu, press the **<ENTER>** function key to access the stored setting.

Press the **<Δ>** (Up) and **<∇>** (Down) function keys to change the displayed setting between 5 and 120. Press **<ENTER>** when done. **L2** will be displayed.

L3 – 100% Sample Time

Options: 5-120

Default: 10

Establishes the period over which the 100% aerosol sample is averaged.

When **[L3]** is displayed in the parameter menu, press the **<ENTER>** function key to access the stored setting.

Press the **<Δ>** (Up) and **<∇>** (Down) function keys to change the displayed setting between 5 and 120. Press **<ENTER>** when done. **[L3]** will be displayed.

L4 – Decimal Places to be displayed

Options: 3 or 4

Default: 4

This parameter is used to select either 3 or 4 decimal places on the % Leakage Display.

When **[L4]** is displayed in the parameter menu, press the **<ENTER>** function key to access the stored setting.

Press the **<Δ>** (Up) and **<∇>** (Down) function keys to move the displayed setting between 3 and 4 on the display (3=0.001%, 4=0.0001%).

Press **<ENTER>** to set the selection and return to the parameter select menu. **[L4]** will be displayed.

L5 – Aerosol Reference Selection

Options: DOP, PAO, USER, HIGH

Default: DOP

When **[L5]** is displayed in the parameter menu, press the **<ENTER>** function key to access the stored setting.

Note: Refer to section 4.5, page 20 "changing the reference" to change the selection or reestablish internal reference.

See A-7 for correction factors to be used in conjunction with other challenge aerosols.

Press **<ENTER>** to set the selection and return to the parameter select menu. **[L5]** will be displayed.

L6 – Hour Meter

Options: N/A

Default: N/A

Displays the total running time for the unit.

L10 – % Leakage Display Intensity

Options: 1-8

Default: 6

[L10] is used to adjust the intensity of the green LED display in the % Leakage display.

When **[L10]** is displayed in the parameter menu, press the **<ENTER>** function key to access the stored setting.

Press the **<Δ>** (Up) and **<∇>** (Down) function keys to move the displayed setting between 1 and 8 on the display.

Press **<ENTER>** to set the selection and return to the parameter select menu. **[L10]** will be displayed.

L11 – Optics Check Option

Options: OFF - Disabled
ON - Enabled

Default: ON - Enabled

[L11] is used to select between checking the optics after every zero calibration and checking the optics only at the initial zero calibration at startup.

When **[L11]** is displayed in the parameter menu, press the **<ENTER>** function key to access the stored setting.

Press the **<Δ>** (Up) and **<∇>** (Down) function keys to move the displayed setting between ON and OFF on the display.

Press **<ENTER>** to set the selection and return to the parameter select menu. **[L11]** will be displayed.

L12 – 0% Purge Time

Options: 0 - 120

Default: 0

Set the length of time for the system to run before taking reading when calculating the zero value.

2. The **REF** LED will flash and the display will go blank.
3. Press the **<ENTER>** function key. If the **<ENTER>** key is not pressed within about three (3) seconds, the unit will return to sampling mode.
4. Use the **<Δ>** (Up) and **<∇>** (Down) function keys to select the desired reference.
5. Press the **<ENTER>** function key.
6. Use the **<Δ>** (Up) and **<∇>** (Down) function keys to select the desired internal reference factor.
7. Press the **<ENTER>** function key.

The zero LED will begin to blink indicating that it is time to set the zero reference. Double check the selector valve is set to clear.

8. Press **<ENTER>**.

The bar graph display will indicate that the unit is sampling the zero reference value. Upon completion, the unit will return to the sampling mode.

4.6 UPSTREAM AEROSOL MEASUREMENTS (DOP OR PAO)

Note: Do not perform the steps in this section until completing section 4.1, Initialization.

Note: If there is a concern that the zero baselines may have drifted, the operator may re-zero the instrument at any time by positioning the selector valve to the clear position, pressing the **<0>** button, and pressing **<ENTER>**.

WARNING: The unit should be placed on a flat, stable surface with the area to be monitored within reach of the sample lines.

1. Insert the **UPSTREAM** sample line into the upstream aerosol / air mixture.

Note: The sample line should be as close to the upstream side of the filter as possible.

2. Turn the Selector Valve to the **UPSTREAM** position. This switches the sample airflow to the **UPSTREAM** sampling port on the front panel. The **% LEAKAGE** display indicates the upstream concentration as compared to the reference that was set in the initialization section.

Note: Adjust aerosol for desired challenge aerosol concentration.

4.7 MEASURING % LEAKAGE - USER DEFINED REFERENCE (USER)

1. Insert the **UPSTREAM** sample line into the upstream aerosol/air mixture.

Note: The sample line should be as close to the upstream side of the filter as possible.

The photometer is comparing the real-time concentration of the upstream challenge to the concentration of this same source when it was initially used to establish the 100% baseline. In other words, it is comparing the current concentration level to the starting level.

If the reading seems reasonable, normal testing may be resumed by turning the Selector Valve back to the DOWNSTREAM position.

If the concentration of the challenge aerosol has changed significantly, the upstream source should be examined for the cause. Once the situation has been corrected, the upstream challenge aerosol should be restarted, stabilized, and then used to re-establish the 100% baseline as described previously.

5.5 CLEANING THE TDA-2SP SCANNING PROBE SCREENS

The TDA-2SP Scanning Probe is a rugged, low maintenance device. The probe contains a course wire screen near the base of the flexible neck to prevent fibers and large particles from being drawn into the photometer. In addition, there are screens in each of the two round nozzles that thread onto the flexible neck. The blue rectangular nozzle contains no screen.

If the screens accumulate a significant amount of debris and become partially clogged, it can interfere with the airflow and affect the accuracy of the photometer and may put an unnecessary strain on the vacuum pump.
It is recommended that all screens be wiped clean with a lint-free cloth before use each day.

If the screens are punctured, replace them immediately. Spare nozzles and replacement scanning probe components can be ordered from ATI (see Section A-4).

To access the screen in the flexible neck, unscrew the flexible extension from the probe body. A small tool may be necessary to reach into the neck to remove and wipe the surface of the screen.

5.6 REPLACING THE MAIN POWER FUSES

Position the 2H with the rear panel readily accessible. Locate the fuse block at the center of the power entry connector. Press the top and bottom tabs toward the center and pull the fuse block straight out from the power entry connector. The two (2) fuses will be exposed for inspection and/or replacement. Replace the fuse block by gently inserting it back into the power entry connector until the tabs snap back into their original location.

5.7 REPLACING THE HEPA EXHAUST FILTER

Position the 2H with the rear panel readily accessible. Rotate the HEPA exhaust filter in a counter-clockwise direction until the threads are free of the rear panel bushing. Install the new replacement filter in the same orientation as the filter that was replaced. Care should be taken to avoid cross-threading the filter housing. When installed correctly a cylindrical well should be visible through the filter port. This design directs exhausted airflow to the outside of the filter media core, providing greater surface area and prolonging service life.

A-2. TROUBLESHOOTING

CONTROLLER Error Messages

ERROR CODES – SYSTEM PROBLEMS

Problems	Cause	Corrective Action
E1 – Calibration flags not set	The unit has not been calibrated or the unit has lost memory.	Return the unit to ATI or Authorized service center for repair and service as soon as possible.
E2 – LSC voltage not stable	Concentration readings are not stable enough to perform a reliable 100%, 0%, or optics check.	1. Ensure that the selector valve is in the correct position and try again. 2. Check the aerosol source.
E3 – Optics Dirty	Sufficient aerosol condensation and/or particulates have built up on the internal optics such that a reliable reading using the internal references is not possible.	1. Return the unit to ATI for repair and service as soon as possible. 2. Do not use the internal references. Instead use the USER reference.
E4 – 100% calibration failed	There is insufficient aerosol for the unit to capture a reliable 100% value for the USER reference.	1. Check the aerosol source. 2. Use a higher concentration as the 100% reference.

***USER** is a stored sampled concentration saved by the user, to be displayed as 100%.
This value is stored in memory until a new value is sampled and saved by the user.
To set: After completing the setting **100%** procedure below, Press the **REF** button and **"USER"** will be displayed. Press **<ENTER>, 0** will blink; turn the Selector Valve to **CLEAR**, and press **<ENTER>**.

***HIGH** allows sampling of concentrations above 130µg/L, exceeding 200µg/L. This setting should only be used for sampling quickly and sparingly, as such concentrations will adversely affect the cleanliness of the optics.

SETTING 100%

Connect Upstream Sample Line & set Selector Valve set to **UPSTREAM**

<100>	**<100>** key LED flashes
<ENTER>	Bar graph scans .The unit averages 100% for a time defined by the L13 setting. When the **<0>** LED flashes turn the **Selector Valve** to **Clear.**
<ENTER>	Checks optics (if L11=1) and sets 0%.

*Note: This setting can be saved by pressing **REF, <ENTER>**, and resetting **0**).
(See ***USER** above)

Ready for Testing

OPTICS and FLOW LED'S

OPTICS LED: GREEN- Optics clean, Internal Reference within 5% of original value.
Orange- Optics affected, Internal Reference shifted to 5% to 10% of original value.
RED- Optics compromised, Internal Reference shifted by more than 10%.
Do NOT rely on Internal Reference.
***Note:** The unit can continue to be operated by using the **SETTING 100%** procedure above.

FLOW LED: Green- Flow within 5% of 1 CFM.
Orange- Flow within 5% to 10% of 1 CFM
Red- Flow is more than 10% above or below 1 CFM

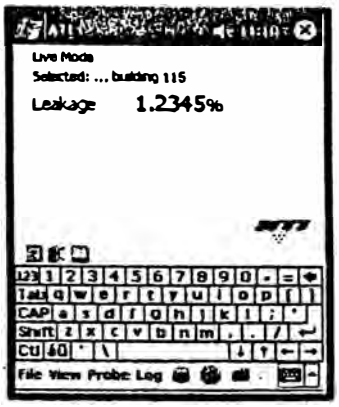
2H-N Spare part kit, 9300143	
ULPA Filter, 5500001	(2)
Selector valve, T2G0-0931	(2)
*Sealed cone w/ fittings, T2H-N-0949	(2)
Brass fittings, T2G0-0907	(4)
Brass fittings, 5100006	(8)
Poly-flo tubing, 5200102	(25 ft)
PVC tubing, clear, 5200116	(5 ft)

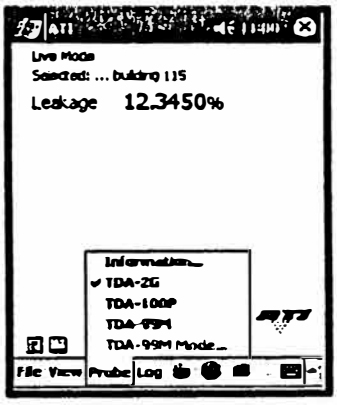
For use with 2H-N only

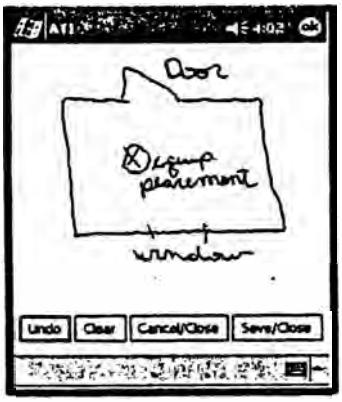
Scanning Probe flex-probe segments	
Segment, 5100001	(3)
Female threaded end segment, 5100004	(1)
Male threaded end segment, 5100002	(1)
Male close nipple, 5100101	(1)

A-6. RS-232 COMMUNICATION

The 2H serial output is formatted as a continuous string of ASCII numeric characters. The recommended method for capturing this data is to use the DAS1 or DAS2 data acquisition system from ATI. Shown below are screenshots from the DAS1 on a pocket PC. Contact ATI customer service for details and other information.







Alternatively, this data can be captured with a generic terminal. The required port protocol is: 2400, N, 8, 1.

A-8. DECLARATION OF CE CONFORMITY

We: **AIR TECHNIQUES INTERNATIONAL**
11403 Cronridge Drive
Owings Mills
Maryland 21117-2247
USA
Tel: (410) 363-9696
Fax: (410) 363-9695
Website: http://www.atitest.com

declare under our sole responsibility that the product,

2H Digital Aerosol Photometer,

is in conformity with the following directives:

Application of Council Directive(s):	Standard(s) to which Conformity is Declared:
Electromagnetic Compatibility Directive (89/336/EEC)	EN 61326-1:1998
Low Voltage Directive (73/23/EEC)	EN 61010-1:2001

Design documentation is maintained at:

Air Techniques International
11403 Cronridge Drive
Owings Mills, Maryland 21117-2247
USA

Eric A. Hanson

Eric Hanson
President
Air Techniques International

Date of Issue: 02 September 2003
Place of Issue: Owings Mills,
Maryland 21117-2247
USA

OPERATOR'S MANUAL

for

Air Operated Aerosol Generators

Models TDA-4B, TDA-4Blite & TDA-6C

Revision D

Air Techniques International
Division of Hamilton Associates, Inc
11403 Cronridge Drive
Owings Mills, MD 21117 USA
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Generator Description

ATI manufactures portable Laskin nozzle aerosol generators which produce a sub micron poly-dispersed oil mist aerosol in concentrations from 10 to 100 micrograms per liter (ug/l) at air flows from 50 to 8,100 cfm @ 20 psig.

Aerosol generators and photometers are used to integrity test or locate leaks in high efficiency air filtration systems. Filter manufacturers use this equipment to scan ULPA and HEPA filters to verify they are free from manufacturing defects. Filter certifiers use this equipment to insure that filters were not damaged in shipping and have been installed properly, eliminating any leakage.

With the proper generator and photometer combination, filter deficiencies such as pinholes, thin spots, gasket leaks, frame leaks or seal problems can be quickly and quantifiably pinpointed and corrected thus protecting product and personnel.

The TDA-4B, TDA-4Blite & TDA-6C feature several improvements over preceding units including rugged stainless steel construction, larger fill ports, individual nozzle control, and a 3" standard sanitary flange outlet. An optional hose adapter, part number 9300100, is available for introducing the aerosol into positive pressure systems.

CAUTION

DO NOT EXCEED 100 psig INPUT PRESSURE

WARNING!

UNDER NO CIRCUMSTANCES SHOULD THE AEROSOL OUTLET BE COMPLETELY BLOCKED DURING OPERATION. BLOCKAGE OF THE OUTLET WILL CAUSE SEVERE DAMAGE TO THE UNIT AND POSSIBLE INJURY TO PERSONNEL!

TDA-4B Features

The TDA-4B is the latest design in rugged, lightweight Laskin nozzle generators from ATI. The TDA-4B is a small, compact aerosol generator that requires only a supply of clean, compressed air to create poly-dispersed sub micron oil aerosol.

The TDA-4B has 6 Laskin nozzles. When its total output at 20 psig is diluted by 810 cfm of air, the aerosol concentration is approximately 100 ug/liter. Three valves permit the unit to be operated with 1 to 6 nozzles, providing a wide range of aerosol concentrations.

The TDA-4B is recommended for testing systems with airflows of 8,100 cfm and lower. It is ideal for workstations, Negative Pressure Filtration Units, biosafety cabinets, ceiling modules, small or portable cleanrooms, or HEPA filter units in installations where an adequate supply of clean, compressed air is readily available.

OPERATING INSTRUCTIONS
TDA-4B AEROSOL GENERATOR (6 Laskin nozzle)

1. Unscrew LIQUID FILL cap located on top of cabinet and fill sight gauge to 3/4 full with desired liquid aerosol agent. Do not overfill. Refill when the level falls to the halfway point on the sight gauge.

2. Attach a source of clean, dry, compressed air to the filter/regulator air inlet. A shut-off valve (ball-type) is recommended to turn the air to the unit on and off.

3. Turn air on and adjust the filter/regulator control knob for a pressure of 20 psig. To lock this adjustment in, simply push down on control knob.

4. Varying aerosol output concentration.

1 Nozzle	Valve #1 ON Valve #2 OFF Valve #3 OFF
2 Nozzle	Valve #1 OFF Valve #2 ON Valve #3 OFF
3 Nozzle	Valve #1 OFF Valve #2 OFF Valve #3 ON
4 Nozzle	Valve #1 ON Valve #2 OFF Valve #3 ON
5 Nozzle	Valve #1 OFF Valve #2 ON Valve #3 ON
6 Nozzle	Valve #1 ON Valve #2 ON Valve #3 ON

NOTE: If more than 20 psig is used, the output concentration will increase and, conversely, if less than 20 psig is used, the output concentration will decrease.

TDA-4Blite Features

The TDA-4Blite is a smaller, lower capacity version of the TDA-4B that still retains all the improved features. The TDA-4Blite was specifically designed for use in biosafety cabinets. Its small size and low cost make it the ideal generator for biosafety cabinet testing and HEPA filter vacuums.

The TDA-4Blite has 3 Laskin nozzles. When its total output at 20 psig is diluted by 405 cfm of air, the aerosol concentration is approximately 100 ug/l. Two valves permit the unit to operate with 1 to 3 nozzles to provide a wide range of aerosol concentrations.

OPERATING INSTRUCTIONS
TDA-4Blite AEROSOL GENERATOR (3 Laskin nozzle)

1. Unscrew LIQUID FILL cap located on top of cabinet and fill sight gauge to 3/4 full with desired liquid aerosol agent. Do not overfill. Refill when the level falls to the halfway point on the sight gauge.

2. Attach a source of clean, dry, compressed air to the filter/regulator air inlet. A shut-off valve (ball-type) is recommended to turn the air to the unit on and off.

3. Turn air on and adjust the filter/regulator control knob for a pressure of 20 psig. To lock this adjustment in, simply push down on control knob.

4. Varying aerosol output concentration.

1 Nozzle	**Valve #1 ON** **Valve #2 OFF**
2 Nozzle	**Valve #1 OFF** **Valve #2 ON**
3 Nozzle	**Valve #1 ON** **Valve # 2 ON**

NOTE: If more than 20 psig is used, the output concentration will increase and, conversely, if less than 20 psig is used, the output concentration will decrease.

TDA-4B Specifications

Aerosol Output Range: 50-8,100 cfm
Aerosol Concentration 100 ug/1@ 810 cfm
Aerosol Concentration 10 ug/1@ 8,100 cfm
Generator Type: 1 to 6 Laskin nozzles
Compressed Air: 3 to 18 cfm @ 20 psig

Aerosol Type: Polydispersed (Cold)
Size: 10" L × 11" W × 9" H
(25cm L × 28cm W × 23cm H)
Weight-Pounds (lbs): 16 lbs.
Weight-Kilograms (kg): 7.3 kg
Electrical: (Not Required)

TDA-4Blite Specifications

Aerosol Output Range: 50-4,050 cfm
Aerosol Concentration 100 ug/1@ 405 cfm
Aerosol Concentration 10 ug/1@ 4,050 cfm
Generator Type: 1 to 3 Laskin nozzles
Compressed Air: 3 to 9 cfm @ 20 psig

Aerosol Type: Poly-dispersed (Cold)
Size: 10" L × 8" W × 9" H
(25cm L × 20cm W × 23cm H)
Weight-Pounds (lbs): 12 lbs.
Weight-Kilograms (kg): 5.5 kg
Electrical: (Not Required)

TDA-4B & TDA-4Blite Aerosol Output Calculation

These units include a total of either 3 or 6 Laskin nozzles incorporated into the cabinet. The aerosol concentration depends on the compressed air pressure and flow available for consumption by the nozzle. With 20 psig applied, each jet emits 18.75 slpm of air containing 1,275 ug/l of aerosol. When this aerosol is diluted with 135 cfm of air, the aerosol concentration becomes approximately 100 micrograms per liter. The equation below is for purposes of calculating the aerosol output in micrograms per liter (ug/l) when 20 psig is applied to the nozzle jets.

$$ug/L = \frac{13{,}500 \times (\#\text{ of nozzles being used})}{\text{Total airflow (CFM)}}$$

TDA-6C Features

The TDA-6C is the latest design in rugged, lightweight Laskin nozzle generators from ATI. The TDA-6C is a self-contained aerosol generator that requires only a suitable voltage source to create poly-dispersed sub micron oil aerosol.

The TDA-6C has 6 Laskin nozzle jets. When its total output at 20 psig is diluted by 200 cfm of air, the aerosol concentration is approximately 100-ug/l. A valve permits the unit to be operated with either 2 or 6 nozzle jets, providing a wide range of aerosol concentrations.

The TDA-6C is recommended for testing systems with airflows of 2,000 cfm and lower. It is ideal for workstations, Negative Pressure Filtration Units, Bio-safety cabinets, ceiling modules, small or portable cleanrooms, or HEPA filter units in installations where an adequate supply of clean, compressed air is not readily available.

OPERATING INSTRUCTIONS
TDA-6C AEROSOL GENERATOR (1 ½ Laskin nozzle)

1. Unscrew LIQUID FILL cap located on top of cabinet and fill sight gauge to 3/4 full with desired liquid aerosol agent. Do not overfill. Refill when the level falls to the halfway point on the sight gauge.
2. Connect the unit to an appropriate, grounded, power outlet.
3. Position the generator near the aerosol introduction point of the system under test. A sealed connection to a duct system may be established by using a 3" sanitary flange adapter.
4. Depress the power switch and adjust for desired output concentration.
5. Varying aerosol output concentration.

2 Jet (1/2 nozzle)	Valve #1 OFF
6 Jet (1 ½ nozzle)	Valve #1 ON

NOTE: If more than 20 psig is used, the output concentration will increase and, conversely, if less than 20 psig is used, the output concentration will decrease.

TDA-6C Specifications

Aerosol Output Range: 50-2,025 cfm
Aerosol Concentration 100 ug/1@ 202 cfm
Aerosol Concentration 10 ug/1@ 2,025 cfm
Generator Type: 2 to 6 Laskin nozzle Jets
Aerosol Type: Poly-dispersed (Cold)

Size: 21" L × 8" W × 11" H
(54cm L × 20cm W × 28cm H)
Weight-Pounds (lbs): 55 lbs.
Weight-Kilograms (kg): 25 kg
Electrical: 110 Vac / 60 HZ or 220 Vac / 50 HZ

TDA-6C Features

The TDA-6C is the latest design in rugged, lightweight Laskin nozzle generators from ATI. The TDA-6C is a self-contained aerosol generator that requires only a suitable voltage source to create poly-dispersed sub micron oil aerosol.

The TDA-6C has 6 Laskin nozzle jets. When its total output at 20 psig is diluted by 200 cfm of air, the aerosol concentration is approximately 100 ug/l. A valve permits the unit to be operated with either 2 or 6 nozzle jets, providing a wide range of aerosol concentrations.

The TDA-6C is recommended for testing systems with airflows of 2,000 cfm and lower. It is ideal for workstations, Negative Pressure Filtration Units, Bio-safety cabinets, ceiling modules, small or portable cleanrooms, or HEPA filter units in installations where an adequate supply of clean, compressed air is not readily available.

OPERATING INSTRUCTIONS
TDA-6C AEROSOL GENERATOR (1 ½ Laskin nozzle)

1. Unscrew LIQUID FILL cap located on top of cabinet and fill sight gauge to 3/4 full with desired liquid aerosol agent. Do not overfill. Refill when the level falls to the halfway point on the sight gauge.

2. Connect the unit to an appropriate, grounded, power outlet.

3. Position the generator near the aerosol introduction point of the system under test. A sealed connection to a duct system may be established by using a 3" sanitary flange adapter.

4. Depress the power switch and adjust for desired output concentration.

5. Varying aerosol output concentration.

2 Jet (1/2 nozzle)	Valve #1 OFF
6 Jet (1 ½ nozzle)	Valve #1 ON

NOTE: If more than 20 psig is used, the output concentration will increase and, conversely, if less than 20 psig is used, the output concentration will decrease.

TDA-6C Specifications

Aerosol Output Range: 50-2,025 cfm
Aerosol Concentration 100 ug/1@ 202 cfm
Aerosol Concentration 10 ug/1@ 2,025 cfm
Generator Type: 2 to 6 Laskin nozzle Jets
Aerosol Type: Poly-dispersed (Cold)

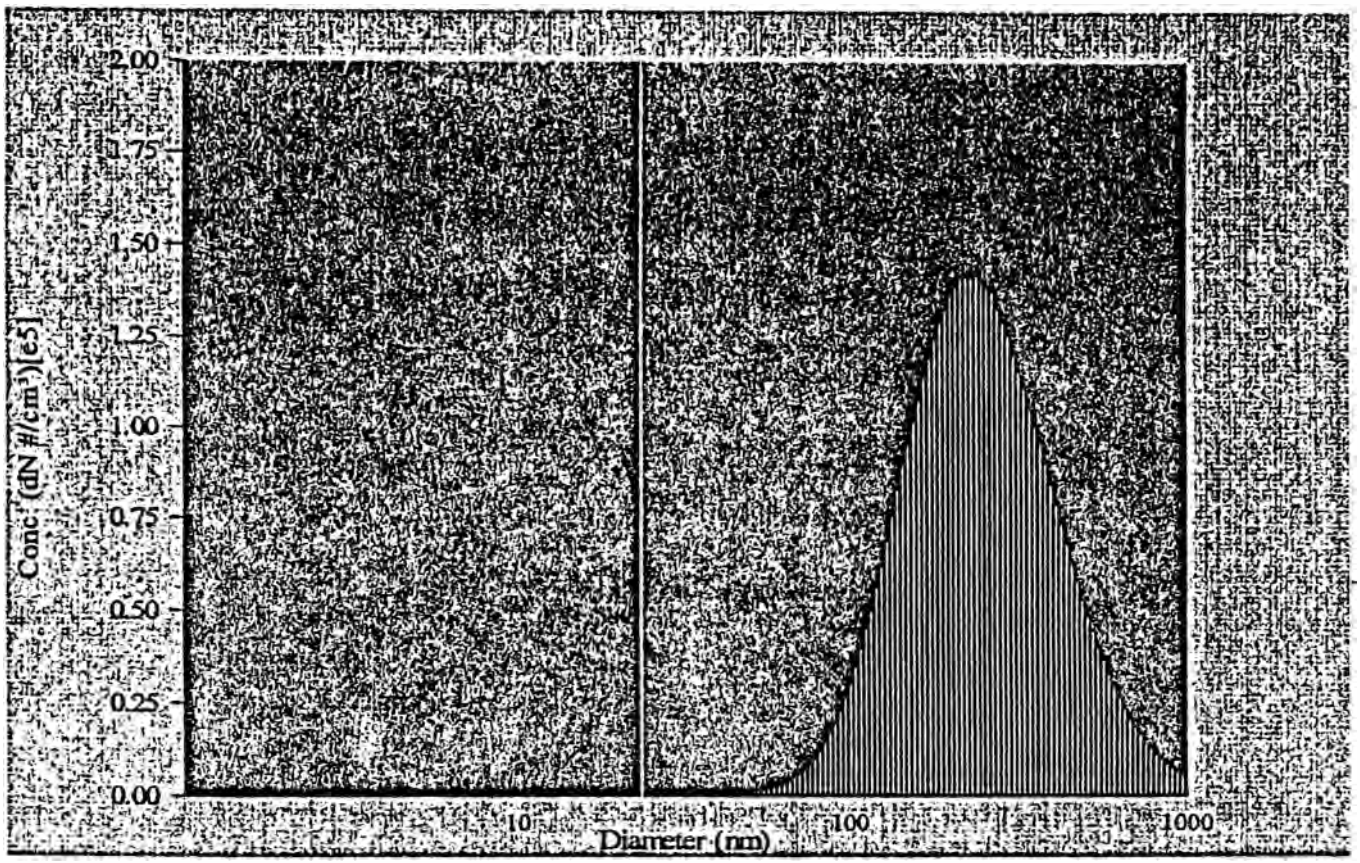
Size: 21" L × 8" W × 11" H
(54cm L × 20cm W × 28cm H)
Weight-Pounds (lbs): 55 lbs.
Weight-Kilograms (kg): 25 kg
Electrical: 110 Vac / 60 HZ or 220 Vac / 50 HZ

TDA-6C Aerosol output calculation

This unit includes a total of 1 1/2 Laskin nozzles incorporated into the cabinet. Each nozzle consists of four jets located at the nozzle tip, for a total of six jets. The aerosol concentration depends on the compressed air pressure and flow available for consumption by the nozzle. With 20 psig applied, each jet emits 18.75 slpm of air containing 1,275 ug/l of aerosol. When this aerosol is diluted with 135 cfm of air, the aerosol concentration becomes approximately 25 micrograms per liter. The equation below is for purposes of calculating the aerosol output in micrograms per liter (ug/l) when 20 psig is applied to the nozzle jets.

$$\frac{3375 \times (\text{\# of jets being used})}{\text{Total airflow (CFM)}}$$

Type III-A Laskin Nozzle Aerosol Distribution @ 20 PSI Using PAO Oil



	Number	Surface	Mass	Volume
	Particle Size	Particle Size	Particle Size	Particle Size
median (nm)	242	414	529	529
mean (nm)	278	453	549	549
geo. mean (nm)	245	405	502	502
mode (nm)	241	429	615	615
geo. st. dev.	1.65	1.62	1.55	1.55
total conc.	4.98e+006 (#/cm³)	1.56e+012 (nm²/cm³)	1.41e+005 (µg/m³)	1.18e+014 (nm³/cm³)

The following liquids may be used in ATI air operated generators to produce aerosol:

DOP / DEHP (Di 2 ethylhexyl-phthalate)

PAO (Poly-alpha olefin) / Emery 3004

DOS / DEHS (Di-2-ethylhexyl-sebacate)

Mineral Oil

Ondina EL

Kaydol

Polyethylene Glycol (PEG 400)

Paraffin Oil

MAINTENANCE

1. If clean, dry, compressed air is used with this unit, little maintenance should be required. (TDA-4B & TDA-4Blite only)

2. Drain the compressed air filter/regulator daily, or more often, if required. (TDA-4B & TDA-4Blite only)

3. Yearly, under daily operation, drain all liquid and flush with a solvent to remove any residue from the unit. (TDA-4Blite, TDA-4B & TDA-6C)

Note

BEFORE SHIPPING UNIT

1. Drain all liquid from unit.

2. Verify that the LIQUID FILL cap is tight.

3. Stuff aerosol outlet flange with liquid-absorbing cloth or paper to prevent residue from damaging shipping container. (All units)

4. Tape or plug the compressed air inlet on air filter/regulator to prevent internal damage by foreign material. (TDA-4B & TDA-4Blite only)

5. Package the unit in a triple wall carton with a minimum of 3 inches of loose packing fill on all sides.

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Technical Assistance/Support – Tony Hawkins ahawkins@atitest.com

Sales/Customer Service –Laura Bergstrom lbergstrom@atitest.com

Sales/Customer Service – Ruth Lanahan rlanahan@atitest.com

ACCESSORIES

ADAPTER KIT

Converts the 3"-sanitary outlet flange of all generators to ¾"-FNPT thread. No hose terminations are supplied due to the high level of variability in requirements. ATI's technical support personnel are always willing and capable of sourcing or configuring hose termination connections to suit a specific application.

The **9300100**-adapter kit consists of the following:

1 piece	3" to ¾ "-FNPT adapter plate
1 piece	sanitary adapter clamp
1 piece	sanitary adapter gasket
1 piece	compression fitting, ¾" liquid tight conduit to ¾" MNPT

Liquid tight conduit is also available for purchase by the foot using part # **5200106**.

AEROSOL REAGENTS

T100-0625	**(5 gallon container)**	DOP / DEHP (Di-2-ethylhexyl-phthalate)
T000-0795	**(5 gallon container)**	Emery 3004 / PAO (Poly-alpha olefin)

Please contact ATI's customer service department for current pricing and delivery.

CONTENTS

About This Manual

This manual explains how to set up, operate and maintain the Alnor® Electronic Balancing Tools (EBT) Models EBT720 and EBT721. Read it thoroughly before using the instrument.

Formatting and Typography

- Step-by-step instructions are numbered in boldface type: **1**, **2**, **3**, etc., set flush-left against the margin.
- References to keys on the micromanometer and the instrument's displayed readout are represented by a typeface called Arial. In addition to the different typeface, displayed messages appear in quotes.
- When reference is made to other sections of the manual, the section title is italicized.

Technical Assistance—Help!

For technical assistance or questions about the instrument of this manual, or if the Electronic Balancing Tool needs repair or recalibration, call Technical Support at (651) 490-2707 or (800) 861-7897. Product application notes are available to provide more information on the product. These application notes, as well as other related material, can be obtained by calling Customer Service or by visiting the Alnor web site at http://www.alnor.com.

Chapter 1. Introduction

The Electronic Balancing Tools (EBT) Models EBT720 and EBT721 are lightweight and easy-to-use instruments packaged with a variety of accessories for measuring pressure, temperature, humidity, air velocity, and air volume. Features of the micromanometer include:

- Single-function keys for ease of use
- Auto-zero for pressure measurements, auto-density correction, and back-pressure compensation when used with a capture hood
- User-selectable English and metric units
- Conversions between actual and standard flow
- Discrete or continuous display and data logging capabilities
- Output port for downloading to a printer or a PC
- Powered by AC adapter or batteries (rechargeable NiMH or alkaline)
- Full field calibration

The Electronic Balancing Tool is designed for:

- Test and balance professionals
- Mechanical contractors
- Industrial hygienists
- Plant engineers and facilities maintenance personnel

Applications include:

- Test, balance, or commission HVAC systems
- Test clean rooms and biological safety cabinets
- Measure fume hood or filter face velocity
- Measure pressure, temperature, relative humidity, air velocity, or air flow

Instrument Description

The basic EBT720 includes a micromanometer, carrying case, 18 in. (46 cm) pitot tube, (2) static pressure probes, (2) 8 ft (2.4 m) Norprene® tubing, user manual, CompuDat™ for Windows® data downloading software and RS232 interface cable, neck strap, internal NiMH battery charger, (4) AA NiMH batteries, AC adapter, and NIST traceable certificate.

The basic EBT721 contains all of the EBT720 components plus 2 ft × 2 ft (610 mm × 610 mm) air capture hood, frame, and base. A variety of optional tools *(see below)* are also available to meet your measurement needs.

The following paragraphs provide brief descriptions of the micromanometer and the various standard and optional tools for use with the EBT. Refer to Chapters 3 and 4 for more detailed information on using the micromanometer and taking measurements with various sensors and probes.

®Norprene is a registered trademark of Norton Performance Plastics, Akron, Ohio, USA.

Micromanometer

Figures 1 and 2 show the features of the micromanometer used in the Models EBT720 and EBT721.

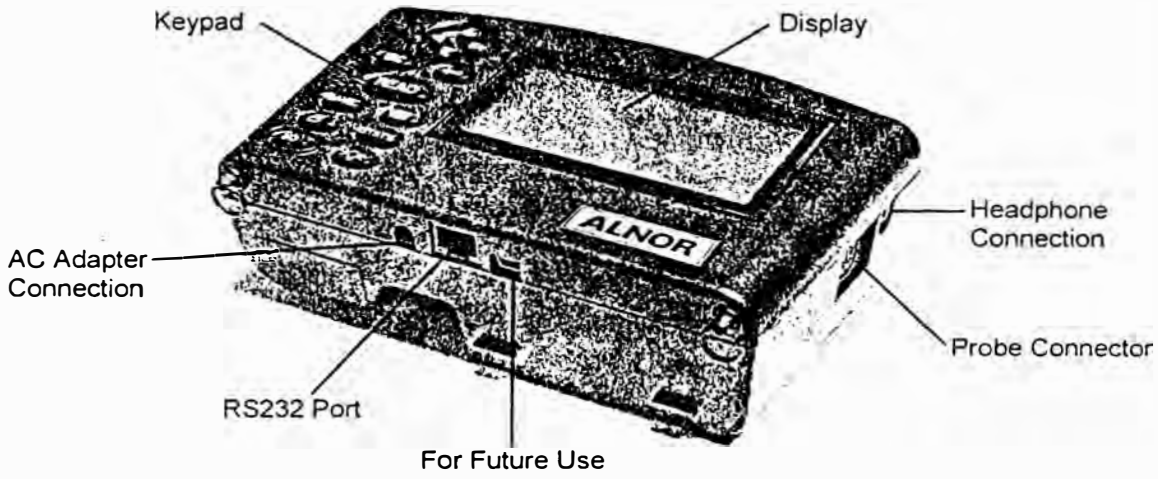


Figure 1: Features of the Alnor Models EBT720 and EBT721 Micromanometer, Front View

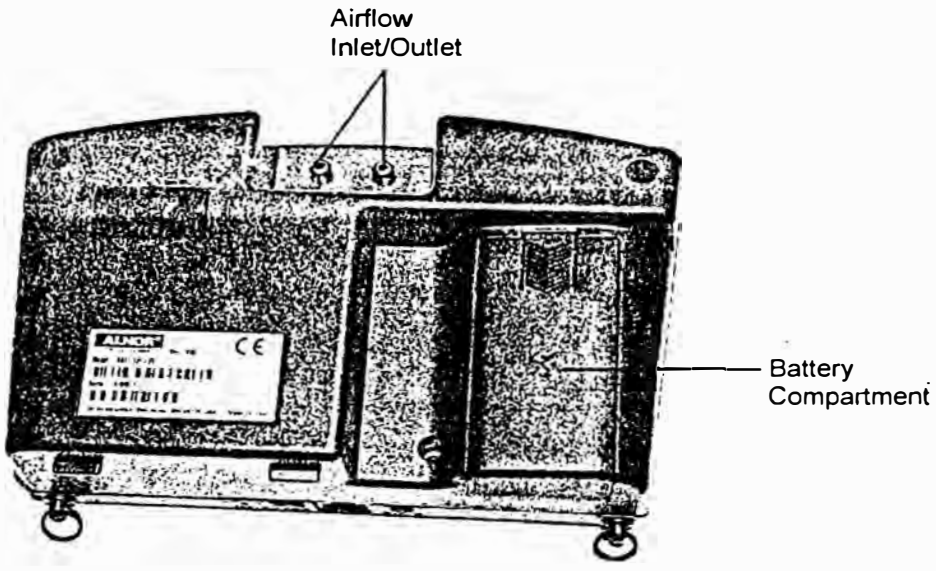


Figure 2: Features of the Alnor Models EBT720 and EBT721 Micromanometer, Back View

Micromanometer

The micromanometer is a multifunction instrument useful in obtaining air velocity, air flow, absolute and differential pressure, temperature, and humidity measurements when used with the tools listed below. The lightweight micromanometer incorporates auto-zeroing for high-accuracy, low-end pressure measurements.

Standard Tools

This section gives a brief description of standard tools for the micromanometer.

Pitot Tube

The pitot tube is primarily used to obtain air velocity, air volume, and velocity pressure measurements within ductwork.

Static Pressure Probe

The static pressure probe is primarily used to obtain static pressure measurements within ductwork.

Optional Tools

This section gives a brief description of optional tools for the micromanometer.

Capture Hoods

Capture hoods are primarily used to obtain volumetric air flow measurements through diffusers, registers and grilles. Capture hoods are available in a kit with one 2 ft × 2 ft (610 mm × 610 mm) fabric hood, frame, and base assembly. Alternate hood sizes are available and descriptions and part numbers can be found in Table 2 of Chapter 2 in this manual.

Velocity Matrix

The velocity matrix is primarily used to obtain area-averaged multi-point air velocity measurements useful in laboratory hood face velocity testing, filter face velocity testing, and other applications.

Air Flow Probe

The air flow probe is primarily used to obtain single point air velocity or air volume measurements in ductwork.

Temperature Probe

The temperature probe is used to obtain temperature measurements over the range of -40 to 250°F (-40 to 121°C).

Temperature/Humidity Probe

The temperature/humidity probe is used to obtain temperature measurements over the range of 14 to 140°F (-10 to 60°C), humidity measurements over the range of 0 to 95% RH, along with calculated wet bulb temperature of 40 to 140°F (4 to 60°C) and dewpoint temperature of 5 to 120°F (-15 to 49°C).

Chapter 2. Unpacking and Setting Up

This chapter describes unpacking and setting up (preparing) the Electronic Balancing Tool (EBT) for use. Figure 3 shows a picture of the Model EBT720 with a velocity matrix measuring the face velocity on a laboratory hood.

Figure 3: Model EBT720 with Velocity Matrix

Unpacking

As you unpack the instrument and accessories, check the components against your packing list. If any parts are missing or damaged, notify us immediately. Tables 1 and 2 list available standard and optional components.

Table 1: List of Standard and Optional Components

Item	Part No.
Alnor Models EBT720 and EBT721 Electronic Balancing Tools	EBT720-XXX EBT721-XXX
Carrying case, EBT720	1319378
Carrying case, wheeled hood kit, EBT721	1319379
AA-size NiMH battery, four required	1208048
Operation and Service Manual	1980497
Velocity Matrix Add On Kit	801090
Air Flow Probe	800187
Printer, Serial (U.S.A. and Canada)	8928
12 in. (30 cm) Pitot Probe	634634000
18 in. (46 cm) Pitot Probe	634634001
24 in. (61 cm) Pitot Probe	634634002
36 in. (91 cm) Pitot Probe	634634003
60 in. (152 cm) Pitot Probe	634634005
Temperature Probe	800188
Temperature and Humidity Probe	800189
Battery Charger, includes 4 NiMH batteries	801093

Item	Part No.
AC Adapter (USA)	8710-USA
AC Adapter (EU)	8710-EUA
AC Adapter (UK)	8710-UKA
AC Adapter (AU)	8710-AUA

Table 2: List of Optional Hood Components

Item	Part No.
1 ft × 4 ft (305 mm × 1220 mm) and 2 ft × 4 ft (610 mm × 1220 mm) fabric hood and frame kit	801094
1 ft × 5 ft (305 mm × 1525 mm) and 3 ft × 3 ft (915 mm × 915 mm) fabric hood and frame kit	801095
1 ft × 4 ft (305 mm × 1220 mm) fabric hood and frame kit	800878
2 ft × 4 ft (610 mm × 1220 mm) fabric hood and frame kit	800879
1 ft × 5 ft (305 mm × 1525 mm) fabric hood and frame kit	800934
3 ft × 3 ft (915 mm × 915 mm) fabric hood and frame kit	800935
8 in. × 21 in. (203 mm × 533 mm) BSC fabric hood, frame, poles, and stand kit	801050
10 in. × 21 in. (254 mm × 533 mm) BSC fabric hood, frame, poles, and stand kit	801051

Please complete the registration card included with this product and mail it promptly. The card allows us to inform you of product updates. If you prefer, register through the Alnor web site.

Preparing the Instrument for Use

Before you can use the Electronic Balancing Tool, you must decide on a power source.

Power the Micromanometer with the AC Adapter

When the AC adapter is plugged into the micromanometer, the unit automatically turns on, runs a brief diagnostic check, and briefly lights all segments of the display. It then displays the type of batteries the unit is set to use (alkaline or rechargeable NiMH) and turns itself OFF.

Whenever the AC adapter is plugged into the micromanometer, the rechargeable batteries are recharged. (Assuming you are using rechargeable batteries and the switch inside the battery compartment is set to NiMH. See below.)

Power the Micromanometer with Batteries

When not using the AC adapter, the Electronic Balancing Tool requires four AA-size batteries to operate. These can be either alkaline batteries or rechargeable NiMH batteries. For your convenience, four NiMH batteries are included with the EBT.

To select the type of batteries you are using:

1. Turn the unit off and locate the battery cover on the back of the micromanometer (see Figure 4).

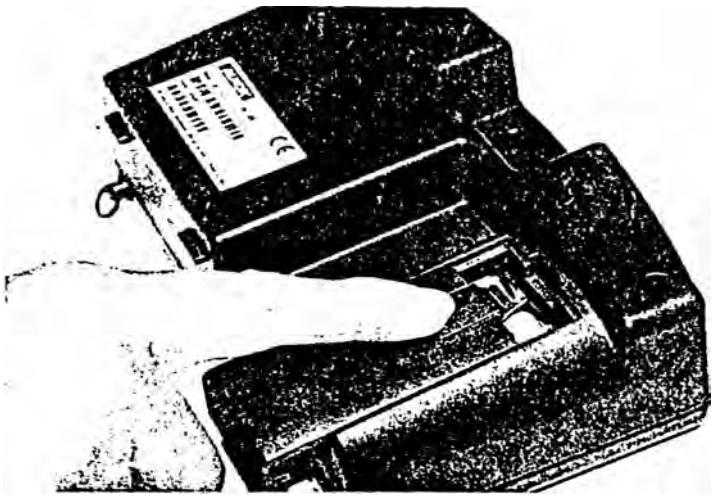


Figure 4: Battery Cover Removal

2. Press down on the compartment cover and slide it down. (The cover slides off.)
3. Remove the battery holder by pulling up on the bottom (to loosen it) and then pulling the battery holder free.
4. Refer to Figure 5 and set the battery selection switch to indicate the type of batteries you are using.

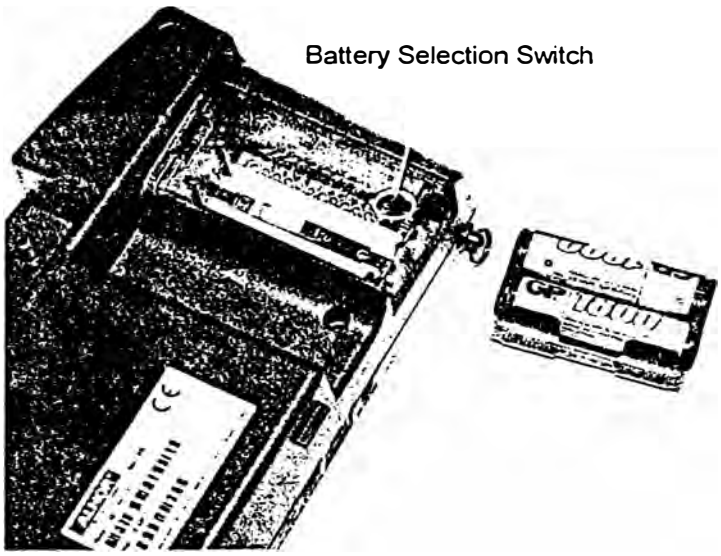


Figure 5: Location of Battery Type Selector Switch

5. Reinstall the battery holder and replace the battery compartment cover.

To install replacement batteries:

1. Turn the unit off and locate the battery cover on the back of the micromanometer (see Figure 4).
2. Press down on the compartment cover and slide it down. (The cover slides off.)
3. Remove the battery holder by pulling up on the bottom (to loosen it) and then remove the battery holder.

4. Remove the old batteries and replace with fresh batteries (alkaline or rechargeable NiMH). Make certain batteries are correctly oriented.
5. Verify the battery selection switch is correctly set (see Figure 5).
6. Reinstall the battery holder and replace the compartment cover.

Note: *Make sure the battery holder is oriented so that its terminals make contact with the spring contacts in the battery compartment.*

If fresh, new alkaline batteries are used, the battery indicator will show 4 bars when first turned on. With NiMH batteries, the indicator *may* show a lower value even when they are fully charged.

Notes: *The percent power remaining will not be accurate for NiMH batteries because their voltage does not decrease linearly with power use.*

Due to the danger of battery leakage, remove batteries from the battery compartment before storage. Never mix battery types.

The NiMH batteries should only be charged at room temperature. Starting with batteries that are too cold or too warm can cause the charge cycle to stop early.

Connecting the Pitot Tube to the Micromanometer

The static pressure port (-) on the pitot tube will be connected to the negative pressure (-) port on the micromanometer, and the total pressure port (+) on the pitot tube will be connected to the positive (+) port on the micromanometer (see Figure 6).

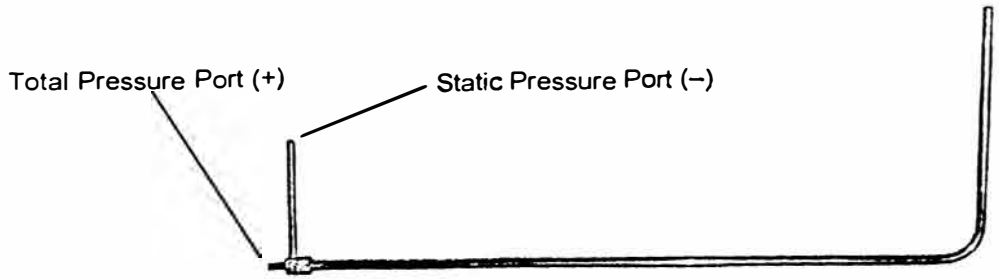


Figure 6: Pitot Tube

Connecting the Static Pressure Port to the Micromanometer

The static pressure port on the static pressure probe will be connected to the (+) port on the micromanometer. The (-) port on the micromanometer will be open to atmosphere (see Figure 7).

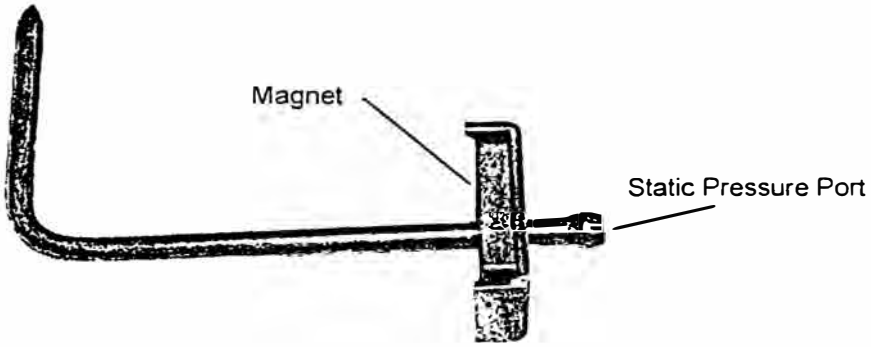


Figure 7: Static Pressure Probe

Attaching the Micromanometer to the Capture Hood Base

1. Tilt the meter forward and align the tabs in the base of the meter with the two matching slots in the bottom of the recessed area at the front of the base (see Figure 8).
2. When the tabs are engaged in the slots, press firmly on the face of the meter above the display until the tab in the top center of the meter "clicks" into the bent metal retaining clip in the base.
3. Attach the temperature cable and the back pressure flap switch cable to the right side of the meter.
4. To remove the meter from the base, first disconnect the temperature cable and the back pressure flap switch cable, then press upward on the metal retaining clip to release the meter from the base.

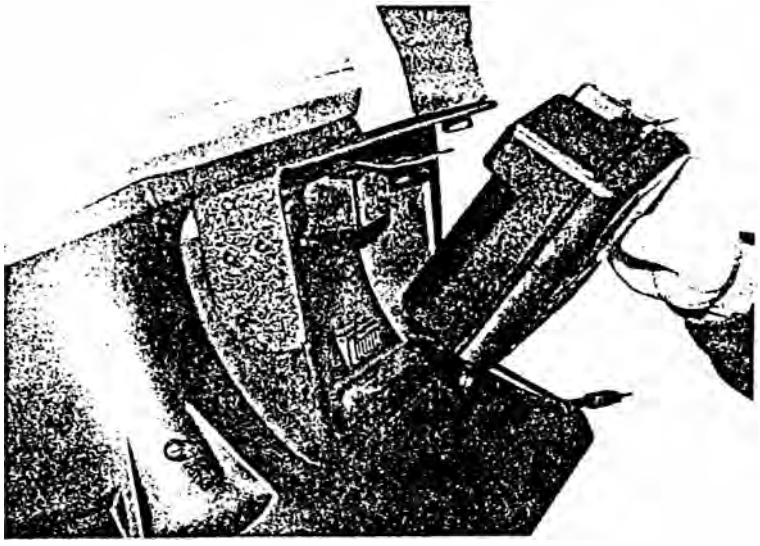


Figure 8: Attaching the Meter to the Capture Hood Base

Connecting the Velocity Matrix to the Micromanometer

The positive port (+) is located on the side of the Velocity Matrix that is opposite the handle assembly. The positive port (+) on the Velocity Matrix will be connected to the (+) port on the micromanometer, and the negative port (-) on the Velocity Matrix is connected to the (-) port on the micromanometer.

Standoffs can be screwed together to make different lengths and are used to maintain a fixed and level orientation away from a filter. The standoffs are attached to the positive (+) side of the velocity matrix.

The handle assembly is attached to the downstream or negative (-) side in the center of the velocity matrix (see Figure 9).

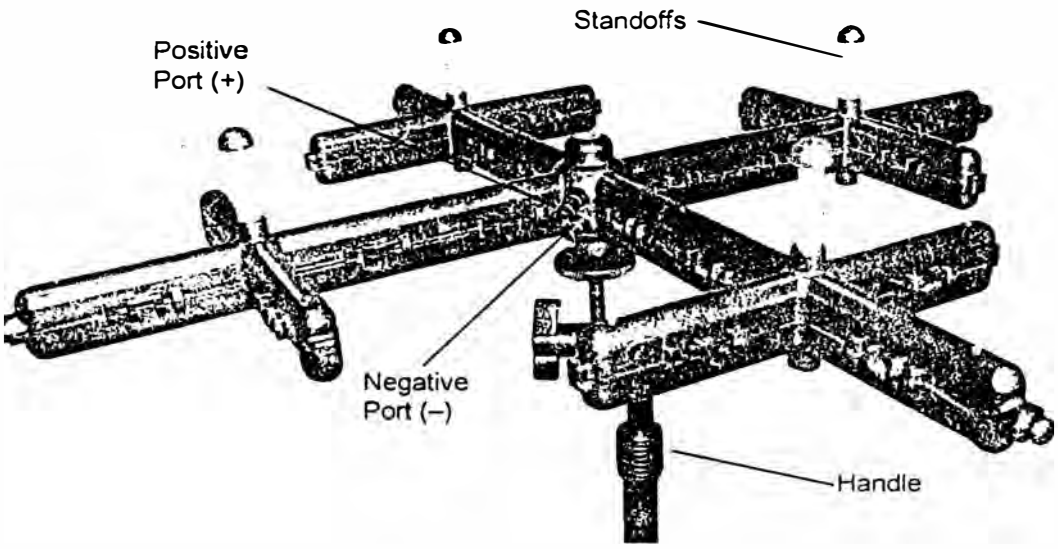


Figure 9: Velocity Matrix

Connecting the Air Flow Probe to the Micromanometer

The static pressure port (-) on the Air Flow Probe will be connected to the negative pressure (-) port on the micromanometer, and the total pressure port (+) on the Air Flow Probe will be connected to the positive (+) port on the micromanometer (see Figure 10).

Note: *Observe the arrow indicator on the Air Flow Probe when taking air velocity or air volume measurements.*

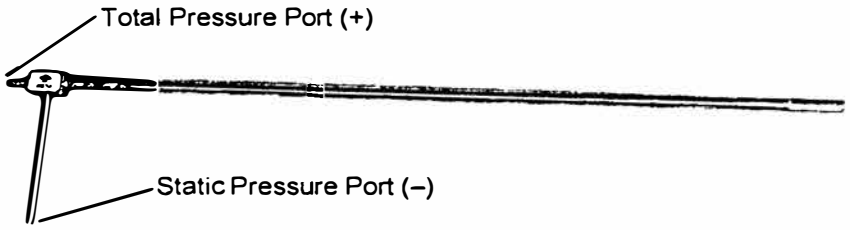


Figure 10: Air Flow Probe

Connecting the Temperature Probe or Temperature and Humidity Probe to the Micromanometer

The Temperature probe and Temperature/Humidity probe attach to the 8-pin connector located on the right hand side of the micromanometer. When connecting the probe to the meter, the dimple on the connector must be aligned to fit the receptacle indentation on the meter (see Figure 11).

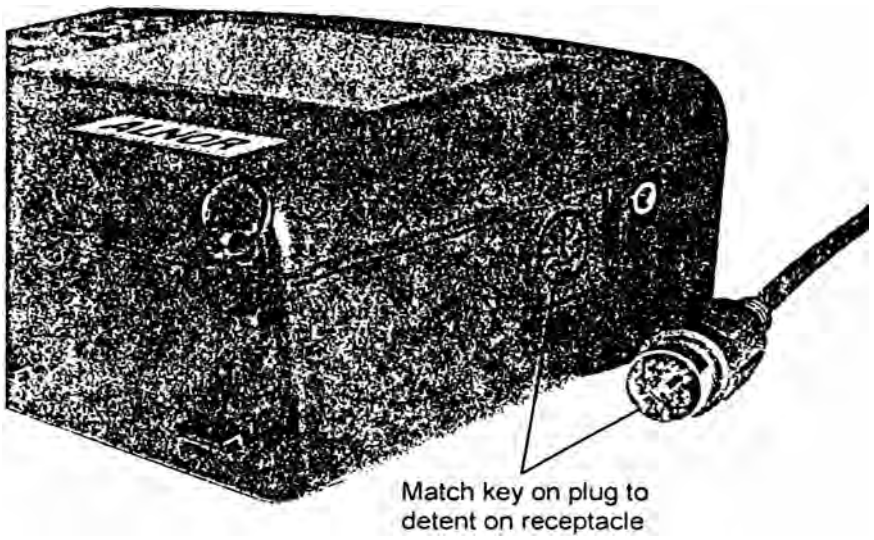


Figure 11: Connector for the Temperature Probe or Temperature/Humidity Probe

Chapter 3. Getting Started

This section provides information to help you quickly become familiar with the Models EBT720 and EBT721 Micromanometer functions. It also includes step-by-step instructions for taking Sample readings.

Keypad Operation

The keypad lets you enter information, initiate functions, and change values stored in the micromanometer. It will be helpful before operating the micromanometer to understand more fully what each of the keys do.

◄ ► ▼ and▲

The arrow keys let you navigate through menus or select options. Generally only one set of arrow keys (▲,▼ or ◄,► are operational for any given operation. Use ◄ and ► to move through menus; use ▲ and ▼ to increase or decrease a value.

ESC

The ESCAPE key is used to cancel or end an operation or back up to the last screen of displayed information. The ESC key is useful if you press ↵ and realize you meant to use one of the other keys.

↵

The ENTER key is used to accept the present value or move to the next level of a menu.

READ

If the display mode is set to SINGLE, pressing the READ key begins a reading, which stops automatically when the reading is done.

If the display mode is set to RUNAVG, the micromanometer will measure continuously, and pressing READ will alternately pause or resume the measurement. (See Chapter 4 on how to set the display mode to SINGLE or RUNAVG.)

There is a red button on the capture hood base that has the same function as the READ key.

Note: *Pressing the READ key will not store any measurement to memory.*

SAVE

The SAVE key is used to save the currently displayed measurement to the data logging memory.

NEXT TEST

The NEXT TEST key is used to select a new unused Test Id for saving Samples when logging data.

🖷

The PRINT key downloads data to an optional printer or to a computer. Refer to Chapter 4 for information on downloading data.

STATS

The STATISTICS key lets you display COUNT, MINimum, MAXimum and AVeraGe for the Test ID currently selected for logging data.

I/O
The ON/OFF key is used to turn the micromanometer on or off.

The BACKLIGHT key turns the display's backlighting on and off. Use backlighting only when working in areas where you cannot read the display with existing light. Backlighting has a significant impact on battery life.

Common Terms

In this manual there are several terms that are used in different places. The following is a brief explanation of the meanings of terms.

Sample

A Sample consists of all of the measurement parameters stored each time the SAVE key is pressed, or after each logging interval has passed. The maximum number of Samples is 1000.

Logging Interval

The Logging Interval is the frequency period that the micromanometer will log readings, when logging is set to CONTIN (continuous). For example, if logging is set to CONTIN and the logging interval is set to 60 seconds, a Sample can be taken and saved automatically every 60 seconds. Refer to chapter 4 for more information on continuous data logging.

Test ID

A Test ID consists of a group of Samples. A Test ID can contain up to 1000 Samples. The maximum number of Test IDs is 255.

Any new Sample will be saved to the current Test ID. You can change the current Test ID at any time to keep your data organized, refer to instructions in Chapter 4.

The unit does not allow you to store Samples of different character in the same Test ID. If the READ key is pressed after changes have been made to the Tool or display units or some other parameter, TEST ID flashes on the display and a new unused TEST ID is selected.

In addition to the data for each Sample, the statistics that are available to view by TEST ID are:

SUM - The sum of all stored values in that TEST ID. (SUM is only available for hood flow or Diffuser Flow [flow from pressure and K-Factor])

MINIMUM - The lowest value stored in that TEST ID

MAXIMUM - The highest value stored in that TEST ID

AVERAGE - The SUM divided by the number of Samples

COUNT - The number of Samples in that TEST ID

Once you have collected data in a Test ID, you can send it to a printer or a computer. See instructions for downloading data in Chapter 4.

Step-By-Step Example Operation

The quickest way to become acquainted with the operation of the Electronic Balancing Tool is to take a few Samples while in the pressure mode.

To take Samples proceed as follows:

1. Connect the AC adapter to the micromanometer or install batteries in the micromanometer (see Chapter 2).
2. Turn on the micromanometer by pressing the I/O key. The unit displays INIT (initializing) and runs a brief diagnostic test.
3. If the display mode is set to SINGLE, the unit will stop and show READY on the display. Pressing READ will begin a reading, which stops automatically when the reading is done. If the display mode is set to RUNAVG, the micromanometer will start measuring continuously, and pressing READ will pause and resume the measurement. (See Chapter 4 on how to set the display mode to SINGLE or RUNAVG.)
4. While the unit reads the measurements, it makes a "clicking" sound.
5. When data collection is finished, the display shows the pressure reading. Press the SAVE key to save the displayed reading to the currently selected Test ID. (If the SAVE key is pressed before the micromanometer has collected enough data to save, NO.DATA is displayed.)
6. Repeat steps 4-5 to save additional Samples.

Refer to Chapter 4 for detailed "How To" information on recalling the saved Samples and many other specific operations.

Chapter 4. How To

This chapter explains how to perform a variety of operations:

- Select a Tool/Probe
- Set the Date and Time
- Change the current Test ID
- Recall Sample Data
- Delete Sample Data
- Delete All Sample Data
- Select/Set a K-factor
- View/Set Standard Pressure and Temperature
- Set Units of Measure for Temperature, Pressure, Flow and Humidity
- Select the RS232C Output Device (Computer or Printer)
- Set the Baud Rate
- Set the Date and Decimal Format
- Set Display Mode for Running Average or Single
- Select Discrete or Continuous Logging
- Turn Back Pressure Compensation On and Off
- Take Back Pressure Compensated Hood Readings
- Set Deadband On and Off
- Calibrate the Micromanometer
- Select User vs. Factory Calibration
- Connect and Download to a Printer
- Connect and Download to a Computer
- Data Acquisition (Polling)

Note: *The operations described below assume you are starting from the READY display. As you use the instrument, you will find it unnecessary to return to the READY display each time. Press the ESC key (one or more times) to return to the READY display.*

Select a Tool

The instrument accepts a number of different measurement devices, referred to as Tools. The Tools are:

- Capture hoods for measuring flow from grilles and diffusers.
- A velocity matrix for area-averaged multi-point velocity measurements.
- Pitot tubes for flow and velocity measurements.
- Air Flow probes for flow and velocity measurements.
- A Diffuser Flow tool which can calculate flow for diffusers equipped with differential pressure taps. (The Diffuser Flow tool is a flow calculation method, not a physical device.) For the Diffuser Flow tool, flow is calculated from the square root of pressure times a user entered K-factor.

Table 3 identifies each Tool and the units of measure available for that tool.

Table 3: Tool Selection Display

Display Shows	Tool	Units Available
Pressure units only	Pressure	in H_2O, mm H_2O, cm H_2O, Pa, hPa, kPa, mm Hg, cm Hg, in Hg,
 with flow units	Capture Hood	l/s, m^3/hr, m^3/min, CFM
Pressure units with K-factor and flow units	Diffuser Flow	l/s, m^3/hr, m^3/min, CFM
 with flow units	Air Flow Probe Flow	l/s, m^3/hr, m^3/min, CFM
 with velocity units	Air Flow Probe Velocity	ft/min, m/s
 with flow units	Pitot Tube Flow	l/s, m^3/hr, m^3/min, CFM
 with velocity units	Pitot Tube Velocity	ft/min, m/s
	Velocity Matrix	ft/min, m/s

To select a Tool, proceed as follows:

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until TOOL appears.
3. Press ↵. The display shows an icon and units (see Table 3 above) to indicate the currently selected TOOL and the units selected for it.
4. Press ▲ or ▼ to scroll through the available TOOLs. See Table 3 above.
5. When the TOOL you want to use is displayed, press ↵.
6. If you select "flow" using either a pitot tube or an Air Flow probe, the display will flash a ○ and □. This indicates that you need to enter the duct shape and duct size. Proceed with steps 7-10. If you selected another TOOL, you will return to the TOOL menu.

   Note: The only way to change the duct shape or size later is to re-enter the Tool select menu and re-select the Tool.
7. Use ▲ or ▼ to select the duct shape and stop the flashing.
8. Press ↵. The display shows the currently selected duct size (flashing).
9. Use ▲ or ▼ to change the size. (If you selected a rectangular size, you need to enter/change the size for both height and width, even if the duct is square. Change the x dimension first, then press ↵ and change the y dimension).
10. Press ↵ to exit to the TOOL menu.

Set the Time and Date

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until SETUP appears.
3. Press ↵.
4. Press ▶ until TIME is displayed.
5. Press ↵. The display shows the current time and date. The hours value is flashing.
6. Use ◀ and ▶ to move between values and ▲ and ▼ to adjust values.
7. Press ↵ when you have set the time and date as desired.

Note: You can change the date format (see "Set Format" below). Allowable formats are mm.dd and dd.mm.

Change the Currently Selected Test ID

To change the Test ID in which Samples will be stored, proceed as follows:

1. Press ↵ to display CHANGE Test ID.
2. Press ↵ to display the current Test ID.
3. Use ▲ and ▼ to select the Test ID you want to use.

Note: If you press ▲ again after the highest numbered Test ID is displayed, you will add a new Test ID. (The Test ID is empty until you send Samples to it.) Also, if you press SAVE (or try to automatically log data to a Test ID) and the Tool or display units or measurement parameters are different from the information already stored in the currently selected Test ID, the instrument will automatically change the currently selected Test ID to a new unused Test ID. See the description of "TEST IDs" in Chapter 3.

Recall Sample Data

To recall Sample data so that you can review it or send it to a printer or computer, proceed as follows:

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until RECALL appears.
3. Press ↵ to display the current Test ID.
4. Use ▲ and ▼ to select the Test ID you want to recall a Sample from.
5. Press ↵. The COUNT for the selected Test ID is displayed. (Count is the number of Samples in the Test ID.)

   Press ▲ or ▼ to display an entry in the selected Test ID. In addition to displaying individual Sample values, you can also view the MAX, MIN, AVG, and SUM of the data in the Test ID. (SUM is only available for hood flow or Diffuser Flow [flow from pressure and K-Factor].) Hold down ▲ or ▼ to scroll quickly through the data.

Delete Sample Data

You can delete data in three ways: 1) delete all Sample data in all Test IDs, 2) delete all Sample data for a single Test ID, and 3) delete only the last Sample currently stored in a Test ID.

Delete all Sample Data

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until DELETE appears.
3. Press ↵. The display shows DELETE ALL.
4. Press ↵. The instrument counts down from 3 to 0 and then deletes all Sample data.

Note: This countdown gives you time to change your mind. If you decide not to delete all samples after pressing ↵, press ESC before the count reaches 0. Samples will ***not*** *be deleted.*

Delete the Samples Stored in a Single Test ID

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until DELETE appears.
3. Press ↵. The display shows DELETE ALL.
4. Press ▶. The display shows DELETE Test ID.
5. Press ↵. The display shows the currently selected Test ID.
6. Use ▲ and ▼ to display the Test ID whose Samples you want to delete.
7. Press ↵. "DELETE" flashes while all Samples for the selected Test ID are deleted.
8. Repeat steps 6 and 7 to delete other Test IDs.

Delete a Single Sample

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until DELETE appears.
3. Press ↵. The display shows DELETE ALL.
4. Press ▶. The display shows DELETE Test ID.
5. Press ▶. The display shows DELETE #.
6. Press ↵. The display shows the currently selected Test ID.
7. Use ▲ and ▼ to display the Test ID containing the Sample you want to delete.
8. Press ↵. The display shows the last Sample in the Test ID.
9. Press ↵. "DELETE" flashes while the last Sample of the selected Test ID is deleted.
10. Repeat step 9 to delete other Samples in the selected Test ID.

Select/Set a K-factor for a Tool

It is possible to enter K-Factors to adjust the calculations of the velocity and flow measurements.

For Hood Flow, Pitot Velocity, Pitot Flow, Air Flow Probe Flow, Air Flow Probe Velocity and Velocity Matrix, the K-Factor is simply multiplied by the calculated velocity or flow in order to get the displayed value. For these Tools, use of a K-Factor is optional and setting the K-Factor to 1.0 will turn it off. The K-factor range for these Tools is 0.500 to 1.500.

For the Diffuser Flow Tool (Flow from Pressure and K-factor), the use of a K-Factor is mandatory. The displayed flow for this tool is the square root of pressure times the entered K-Factor. The K-factor range for this Tool is 0.001 to 9.999.

You can only enter a K-factor if you have selected a Tool that can use a K-factor. The Pressure Tool does not use K-factors.

To select or set a K-factor, proceed as follows:

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until K-FACT appears.
3. Press ↵. The K-factor currently being used flashes on the display.
4. Press ▶ to scroll through the available K-factors or turn the K-factor Off. The instrument lets you set four K-factors for each tool that uses a K-factor.
5. If you want to change the value of a K-factor, use ▲ and ▼ to change the K-factor to the value desired.
6. Press ↵ to accept the desired K-factor. K-FACT is displayed.
7. You can repeat steps 3–6 to select and/or adjust other K-factors for the Tool. Once you set a K-factor it remains set until you change it.

View/Set Standard Pressure and Temperature

Temperature and barometric pressure are used for calculating some of the flow and velocity measurements shown by this instrument, as follows:

For the Pitot Flow, Pitot Velocity, Air Flow "Flow", Air Flow Velocity, Velocity Matrix, and Hood tools, the instrument uses barometric pressure measured by an internal barometric pressure sensor.

For these tools, the instrument will also use temperature measured by a temperature sensor plugged into the side of the meter.

The hood base temperature sensor, the accessory temperature sensor, or the accessory temperature/humidity probe can be used for supplying this temperature measurement. If none of these temperature sensors are plugged in, you will need to enter the flow temperature using the STP.SET menu.

For the Diffuser Flow tool (Flow from Pressure and K-factor), temperature and barometric pressure are not used for calculating flow. Therefore the user is not required to enter a temperature for this tool.

To display the Barometric Pressure:

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until STP.SET appears.
3. Press ↵. ACT.STD is displayed.
4. Press ▶ until B.PRESS appears. The measured barometric pressure is displayed. Barometric pressure is not changeable by the user.
5. Press ESC to return to the STP.SET menu.

To view the Measured Temperature and set the Entered Temperature:

Note: *Since the entered temperature is not used for the Diffuser Flow tool (Flow from Pressure and K-factor), this ENT.MES menu screen is not available if that tool is selected.*

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until STP.SET appears.
3. Press ↵. ACT.STD is displayed.
4. Press ▶ until ENT.MES appears.
5. Press ↵. The display shows the user ENTered temperature on the left and the currently MEaSured temperature on the right (If a temperature sensor is plugged in).
6. Adjust the user entered temperature using ▲ and ▼, then press ↵ to save it and return to the STP.SET menu.

   Note: *To save time, if a temperature probe is installed, you can copy the measured temperature to the entered temperature, by pressing READ.*

   ENTered temperature is used for density correction of velocity or flow values only if no temperature probe is connected. If a temperature probe is connected during velocity or flow measurement, MEaSured temperature will be used for density correction. For most accurate density correction, be sure the connected temperature probe is exposed to the temperature of the flow or velocity being measured.

To Select Actual Flow/Velocity or Standard Flow/Velocity:
(The Actual/Standard selection is used for all tools displaying flow and velocity except the Diffuser Flow [Flow from Pressure and K-factor] tool.)

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until STP.SET appears.
3. Press ↵. ACT.STD is displayed.
4. Press ↵. The display shows the currently selected option (flashing). Options are ACTUAL and STD.
5. Use ▲ or ▼ to select the option you want to use.
6. Press ↵. ENT.MES is displayed.
7. Press ESC to return to the STP.SET menu.

Set Units of Measure for Temperature, Pressure, Velocity/Flow and Humidity

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until SETUP appears.
3. Press ↵.
4. Press ▶ until UNITS appears.
5. Press ↵. The display shows TEMP.
6. Press ↵. The display shows the current temperature units. Options are °F or °C.
7. Use ▲ and ▼ to select between options.
8. Press ↵ when you have selected the desired units.
9. Press ▶ until PRESS is displayed.
10. Press ↵. The display shows the current pressure units. Options are: in. H_2O, cm. H_2O, mm H_2O, in. Hg, cm. Hg, mm Hg, kPa, hPa, and Pa.
11. Use ▲ and ▼ to select between options.
12. Press ↵ when you have selected the desired units.
13. Press ▶ until VELFLO is displayed.
14. Press ↵. The display shows the current velocity/flow units. Options are ft/min for velocity with CFM for flow, and m/s for velocity with either l/s, m^3/h, or m^3/min for flow.
15. Use ▲ and ▼ to select between options. (If m^3/h, or m^3/min is selected for flow, m/s will be used for velocity even though "m/s" is not shown on the display.)
16. Press ↵ when you have selected the desired units.
17. Press ▶ until HUMID is displayed.
18. Press ↵. The display shows the current humidity units. Options are DEWPT, WETBULB, and %RH.
19. Use ▲ and ▼ to select between options.
20. Press ↵ when you have selected the desired units.
21. Press ESC twice to return to SETUP.

Select the RS232 Output Device (Computer or Printer)

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until SETUP appears.
3. Press ↵.
4. Press ▶ until COM.DEV appears.
5. Press ↵. The display shows the current selection: PRINTR or COMPU.

6. Press ▲ or ▼ to change device.
7. Press ↵. COM.DEV is displayed.
8. Press ESC to return to SETUP.

Set the Baud Rate

Before transferring data to a computer or printer, you must set the baud rate to the speed at which your printer or computer will accept information.

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until SETUP appears.
3. Press ↵.
4. Press ▶ until BAUD appears.
5. Press ↵. The display shows the currently selected baud rate.
6. Press ▲ or ▼ to change the baud rate. Options are: 19200, 9600, 4800, 2400, and 1200.
7. Press ↵. BAUD is displayed.
8. Press ESC to return to SETUP.

Set the Format for Date and Decimal

The Format option lets you set the format for the date (mm/dd or dd/mm) and also for the delimiter (. or ,) the instrument uses.

1. Press ↵ to display CHANGE.
2. Press ▶ until SETUP appears.
3. Press ↵.
4. Press ▶ until FORMAT appears.
5. Press ↵. The currently selected format appears.
6. Press ▲ or ▼ to change the format. Options are:
   - Peri nndd (use a period for the delimiter and show date as month/day)
   - Peri ddnn (use a period for the delimiter and show date as day/month)
   - Conn nndd (use a comma for the delimiter and show date as month/day)
   - Conn ddnn. (use a comma for the delimiter and show date as day/month)
7. Press ↵ to select the new format. FORMAT is displayed.
8. Press ESC to return to SETUP.

Set Display Mode for Running Average or Single

If Single is selected, the instrument will show READY on its display, and will not start taking readings until READ is pressed.

If Running Average is selected, the instrument will constantly measure and display a running average. The READ button can then be used to stop and start the running average.

1. Press ↵ to display CHANGE Test Id.
2. Press ▶ until SETUP appears.
3. Press ↵.
4. Press ▶ until DS.MODE appears.
5. Press ↵. The display shows the currently selected display mode. Options are: RUNAVG and SINGLE.
6. Press ▲ or ▼ to change the display mode.
7. Press ↵. DS.MODE is displayed.
8. Press ESC to return to SETUP.

Select Discrete or Continuous Logging

Discrete logging means you have to press SAVE each time you want to save a displayed reading. Continuous logging means reading and saving is done automatically at the user-selectable Sample Logging Interval. Then the continuous logging is started and stopped by pressing SAVE.

1. Press ↵ to display CHANGE.
2. Press ▶ until SETUP appears.
3. Press ↵.
4. Press ▶ until LOG appears.
5. Press ↵. The display shows the currently selected option. Options are: DISCRT and CONTIN.
6. Press ▲ or ▼ to change the logging option.
7. Press ↵. If you selected DISCRT, LOG is displayed. Continue with step 9. If you selected CONTIN, the display shows LOG.INT to indicate you must enter a logging interval.

   Note: *Continuous logging is not available if backpressure compensation is turned on. In this case the message TURN BP OFF is displayed and the change to continuous logging is not allowed. Refer to the following section for instructions on how to turn backpressure compensation off.*

8. Press ▲ and ▼ to select the logging interval. Options are (in sec.): 10, 15, 20, 30, 60, 120, 180, 240, 300, 360, 420, 480, 540, and 600.
9. Press ↵. LOG is displayed.
10. Press ESC to return to SETUP.

Turn Back Pressure Compensation On and Off

Back pressure caused by flow through the capture hood can lower the flow being measured, causing measurement error. If it is desired to minimize this error, turn the back pressure compensation on.

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until SETUP appears.
3. Press ↵.
4. Press ▶ until BP.COMP appears.
5. Press ↵. The display shows whether back pressure compensation is on or off.
6. Press ▲ or ▼ to change the option. Options are: ON and OFF.
7. Press ↵. BP.COMP is displayed.
8. Press ESC to return to the main display.

Take Back Pressure Compensated Hood Readings

When back pressure compensation is turned on, the sequence of taking flow readings with the capture hood is somewhat different.

1. Open the flap in the capture hood base.
2. Hold the capture hood to the diffuser being measured to capture its air flow.
3. Press READ on the meter face or the red "Read Switch" on the left side of the hood base. READ OPEn flashes on the display.
4. When the open-flap reading is done, CLOSE tHE FLAP is displayed.
5. Close the flap and press READ (or the Read Switch). READ CLOSEd flashes on the display.
6. When the closed-flap reading is done, the backpressure compensated flow is displayed.
7. If you want to save the flow reading to log memory, press SAVE now. STORE is shown on the display, then the saved reading is shown.
8. Before pressing any more buttons, open the flap.
9. If the display mode is set to SINGLE, pressing READ now will start a new backpressure compensated reading.

   If the display mode is set to RUNAVG, pressing READ now will measure and display a running average of ***non-backpressure-compensated*** readings. Press READ once more to start a new backpressure compensated reading.

Set Deadband On and Off

The deadband determines the velocity or volume measurement threshold for displaying 0. If the deadband is ON, readings below 18 fpm (0.0914 m/s) or 18 cfm (30.58 m^3/h, 8.49 l/s) will be displayed as 0. If the deadband is OFF, readings down to 0 will be displayed. The default is set to ON.

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until SETUP appears.
3. Press ↵.
4. Press ▶ until DEADbAnd appears.
5. Press ↵. The display shows whether DEADbAnd is on or off.
6. Press ▲ or ▼ to change the option. Options are: ON and OFF.
7. Press ↵. DEADbAnd is displayed.
8. Press ESC to return to the main display.

Calibrate the Micromanometer (User Calibration)

A full instrument checkout and calibration with a calibration certificate is available from the factory. However, some users prefer to calibrate their own instruments. Pressure, temperature and humidity can be calibrated in the field.

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until CALIB appears.
3. Press ↵. The display shows CALIB plus which measurement is selected for calibration.
4. Press ▶ until the desired measurement to calibrate is shown.
5. Press ↵. The display shows SPAN and the requested calibration condition is shown on the bottom left. If the current measurement is available for display, it will be shown on the bottom right.
6. Try to expose the sensor being calibrated to a condition close to the requested calibration condition on the lower left. Press ▲ or ▼ to change the value shown on the lower left to the actual value you want the display to read under that condition.
7. Press ↵. The display will show the next desired span condition. Repeat steps 6–7 until the display shows DONE. If any errors are shown on the display it is because the user calibration data taken is too much different from the factory calibration data. Error codes are explained at the end of Chapter 7.

   Note: *The calibration for the accessory temperature/humidity probe is saved on an EEPROM in the probe. If that probe is unplugged and used in a different micromanometer, the calibration will follow the probe. The calibration for the temperature probe and the hood base temperature sensor is saved in the micromanometer. If those probes are unplugged and used in a different manometer, the calibration will* ***not*** *follow the probe.*

Select User Calibration or Factory Calibration

Performing a user calibration does not erase the factory calibration because the user calibration is saved in a different place than the factory calibration. It is possible to re-select whether the micromanometer uses the user or factory calibration at any time.

1. Press ↵ to display CHANGE Test ID.
2. Press ▶ until CALIB appears.
3. Press ↵. The display shows CALIB plus which measurement is selected for calibration.
4. Press ▶ until the display shows SOURCE U-F for the desired measurement.
5. Press ↵. The display shows SOURCE and whether USEr or FACt is selected for that measurement.
6. Press ▲ or ▼ to select USEr or FACt.
7. Press ↵ to save the selection.

Note: For the accessory temperature/humidity probe it is not possible to mix user and factory calibrations for the different measurements. For example, USEr cannot be selected for temperature with FACt selected for humidity.

Connect and Download Data to an Optional Printer

To connect a printer, use the RS232 printer cable supplied with the optional printer. Note that the printer interface cable is different from the computer interface cable.

The printer must be set to the same baud rate as the instrument. To change the baud rate of the printer, refer to the printer's operations manual. Always turn the instrument on ***before*** the printer. If the printer prints question marks (??????), asterisks (******), or random characters, reset it by turning it off and then on again. Figure 12 illustrates the printout information for a single sample.

```
--------------------------
MODEL: EBT721

SERIAL: 0404004
--------------------------
TEST ID:     2
Sample:      1
02/16/04
15:14:31        1.00 CFM
Shape=Round
Dia =    4.0   in. ø
Entered Temp=      74.4 °F
Baro. Press=   29.16 in.Hg
15:14:31        28.5 %rh
```

Figure 12: Sample Print Out

The Models EBT720 and EBT721 allow printing of the entire memory, all Samples stored within a particular Test ID, or an individual Sample.

To print the entire memory, press and hold the key. This starts a countdown from 3 to 0 on the display. When the display shows "0", release the button. If you release the key at any time other than 0 during the countdown, nothing will print. The display will flash "Send dAtA" while printing.

To print all samples stored within a particular Test ID, first enter the RECALL menu. Select the desired Test ID to print using the up/down arrow keys. Then press and release the key. The display will flash "Send dAtA" while sending.

To print an individual sample, first enter the RECALL menu. Select the Test ID containing the desired sample using the up/down arrow keys and press ↵. Use the up/down arrow keys to scroll thru MIN, MAX, etc until the desired Sample is displayed. Then press and release the (print icon) key. The display will flash "Send dAtA" while sending.

Connect and Download Data to a Computer

Use the RS232 computer interface cable (provided) to connect the instrument to a COM port on the computer. A 9-pin to 25-pin adapter will be required if your computer has a 25-pin serial port connector.

The program "HyperTerminal®" which comes with Microsoft Windows® can be used for capturing data sent by the micromanometer. To send data from the micromanometer, use the printing function of the micromanometer, as shown above.

The program "CompuDat™" which comes with your micromanometer can be used to assist in downloading data to a Windows®-based computer and formatting that data. To install CompuDat software, run the SETUP.EXE file on the CompuDat distribution disc. Once you open the program, it is self-directing and provides all the necessary instructions for downloading data.

Data Acquisition (Polling)

The micromanometer is designed to allow the user to perform polling through the use of a computer. The computer must send an upper case 'V' to the micromanometer while the micromanometer is taking measurements. The 'V' must be sent alone, without a carriage return or linefeed. The micromanometer will then output the values of the last measurements read. Note that the 'V' polling command will not start the micromanometer taking new measurements, therefore, it works much better if the micromanometer display mode is set to RUNAVG.

You must write your own program to use the 'V' polling command. Therefore this command is only designed for medium-to-advanced programmers who need real-time data acquisition. The 'V' polling command cannot be used to request logged data.

®HyperTerminal is a registered trademark of Hilgraeve, Inc.

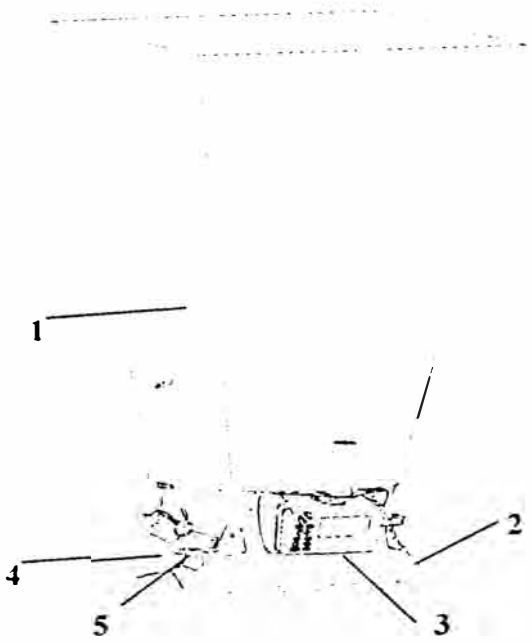
®Windows is a registered trademark of Microsoft Corporation.

Chapter 5. Changing Flow Hoods

This chapter identifies the flow hood parts and gives instructions for assembling the flow hood.

Flow Hood Parts Identification

Figure 13 identifies the major parts of the capture hood, which are described in the following paragraphs. Before using the hood, please familiarize yourself with the various parts. You may also refer to Tables 1 through 3.



1 Fabric hood - Basic hood assembly
2 Base allows micromanometer to be attached
3 Micromanometer with display
4 Flap Actuator
5 Read Switch

Figure 13: Flow Hood Components

Hood Assembly

The Flow Hood is shipped from the factory partially assembled with the 2 ft × 2 ft (610 mm × 610 mm) nylon hood attached to the base. If you wish to use another hood size, see "Changing Hoods," below.

To complete the assembly of the 2 ft × 2 ft (610 mm × 610 mm) hood, follow these six steps:

1. Place the base of the capture hood on the floor.
2. Lift the top of the fabric. Insert one end of a support pole into its pole mount in the base. There is a cup in each corner of the frame to accept the other end of each support pole.
3. Grasp the support pole. Bend the pole slightly to insert the top end of the pole into the support pole cup located in the opposite corner of the fabric frame. The poles are connected to the frame corners in a crisscross fashion as shown in Figure 14.

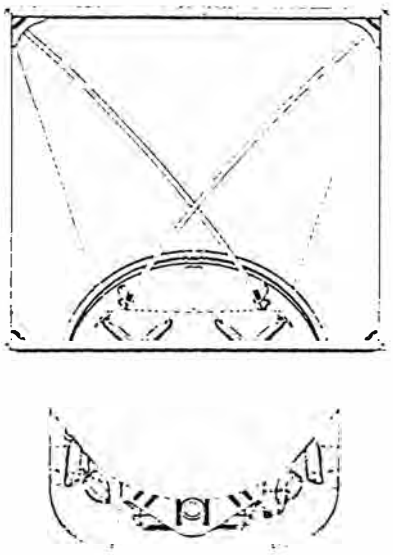


Figure 14: Installing a Support Pole

4. Insert the second support pole into the pole mount on the opposite side of the base.
5. Repeat step 3 for the second support pole.
6. Repeat steps 4 and 5 for the remaining two support poles.

Four other hood sizes are available from TSI and can be purchased separately. Available hood sizes are identified by the dimensions of the frame structure at the top of the hood and include 2 ft × 4 ft (610 mm × 1220 mm), 1 ft × 4 ft (305 mm × 1220 mm), 1 ft × 5 ft (305 mm × 1525 mm) and 3 ft × 3 ft (915 mm × 915 mm).

To change hood sizes, first remove the hood currently attached to the base. To remove the attached hood, first unlatch the cinch belt where the fabric is attached to the base. Then remove the fabric from its frame structure by pulling the shock cord out of the aluminum frame. Finally, fold up the fabric you just removed so that it can fit into one of the accessory pockets inside the carrying case. It is a good idea to fold the fabric so that the tag identifying its size remains visible for future reference.

Alternate Hood Installation

Refer to Figures 15 through 18 to determine the frame channels needed to assemble any of the standard sized frames. Select the pieces required for the frame size desired and assemble with the aid of the appropriate figure. Each channel is labeled with its number for easy identification. Several sections (numbers 1, 3, and 4) consist of a straight channel portion (each a different length) and a corner piece. This corner piece has an eyelet and slot arrangement which mates with a similar eyelet and slot at the end of the straight portion of the channel pieces (see Figure 19). These pieces can be slid together and are self locking by means of a retention spring. The arrangement forms a rugged frame which is additionally strengthened when the hood is attached.

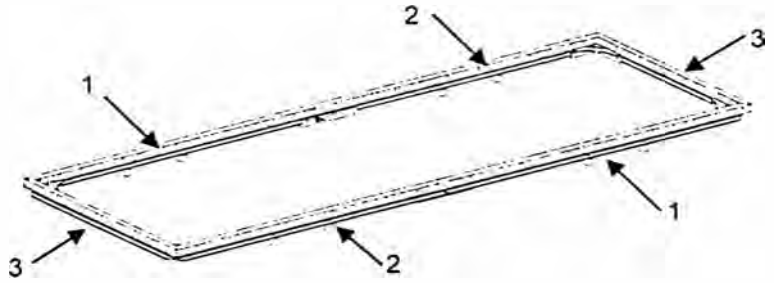


Figure 15: 1 ft × 4 ft (305 mm x 1220 mm) Frame

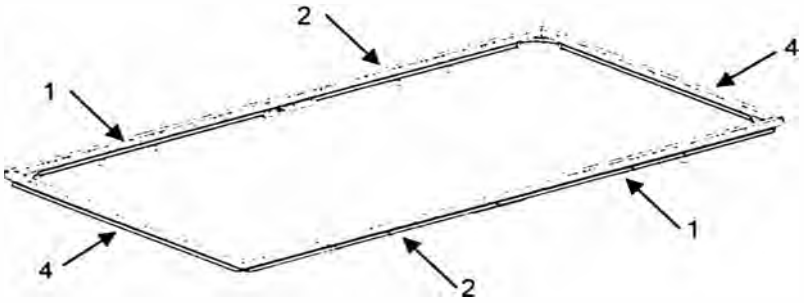


Figure 16: 2 ft × 4 ft (610 mm x 1220 mm) Frame

The number 1 and 5 channels also have a wing nut at the straight end which will mate with an angle and studs on the ends of numbers 2, 5 and 6 to form the longer frame sides (see Figure 20).

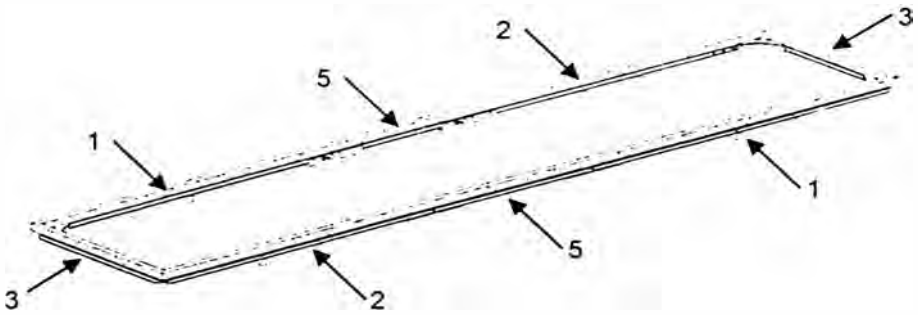


Figure 17: 1 ft × 5 ft (305 mm × 1525 mm) Frame

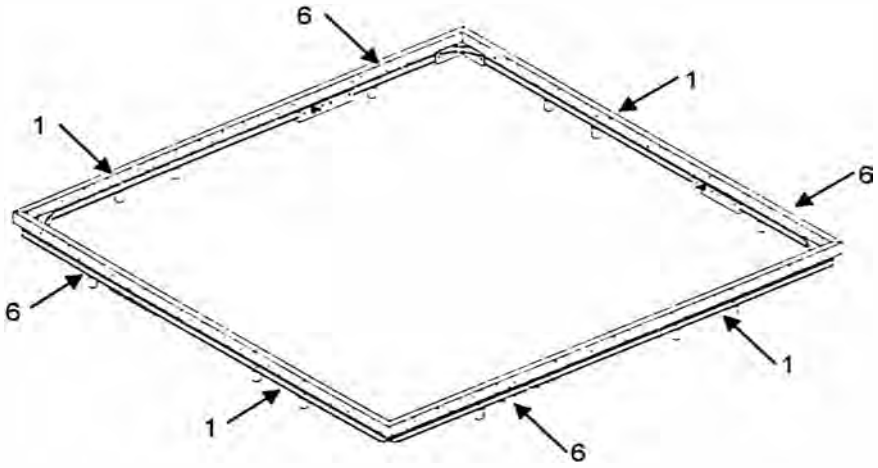


Figure 18: 3 ft × 3 ft (915 mm × 915 mm) Frame

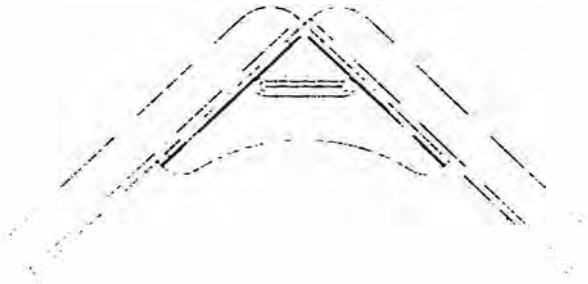


Figure 19: Frame Corner Assembly

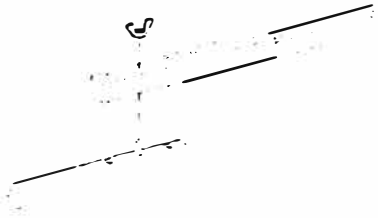


Figure 20: Frame Side Coupler Assembly

Each hood is constructed in a trapezoidal shape, sewn together so that one open end forms a round attachment to the base, and the other forms a square or rectangle large enough to fit its matching frame assembly. Around the frame end of the hood, an elastic shock cord has been sewn into the hood. This cord is of a size such that it can be pushed into the open side of the U-shaped channels of the frame.

In general, attach a hood to the frame first, and then to the base unit. By stretching around the frame corners the cord is slightly reduced in diameter and is easier to press into the frame channel.

Note: *The hood corners should always be aligned with the corners of the base, near the hood support brackets. The base has rivets located in the corners which can be used as a guide for aligning the hood corners.*

Direct Inflow Measurement Hood for Biological Safety Cabinets

The BSC hood kits for the model EBT721 Balometer are designed to measure the inflow or exhaust flow through a biological safety cabinet (see Figure 21). Part numbers and description of each kit can be found in Table 2 of this manual.

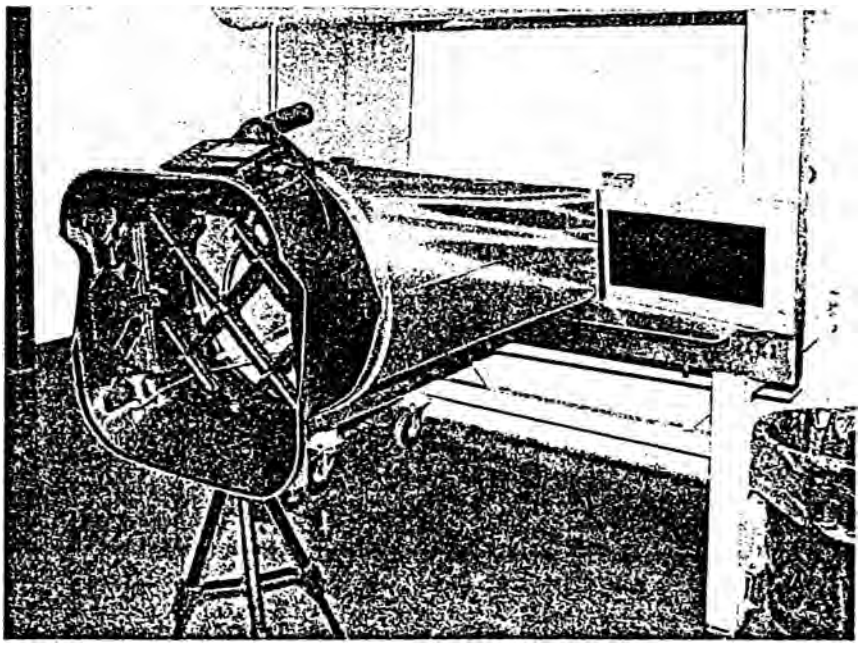


Figure 21: Direct Inflow Measurement Hood

The direct inflow BSC hood includes (see Figure 22):

- ❑ Fixed frame assembly with four removable flaps
- ❑ Fabric hood
- ❑ Hood support poles
- ❑ Base mounting hardware (threaded insert, washer, and screw)
- ❑ Telescopic pole stand with case to freely hold the EBT Balometer in a vertical position when mounted to a biological safety cabinet or lab hood

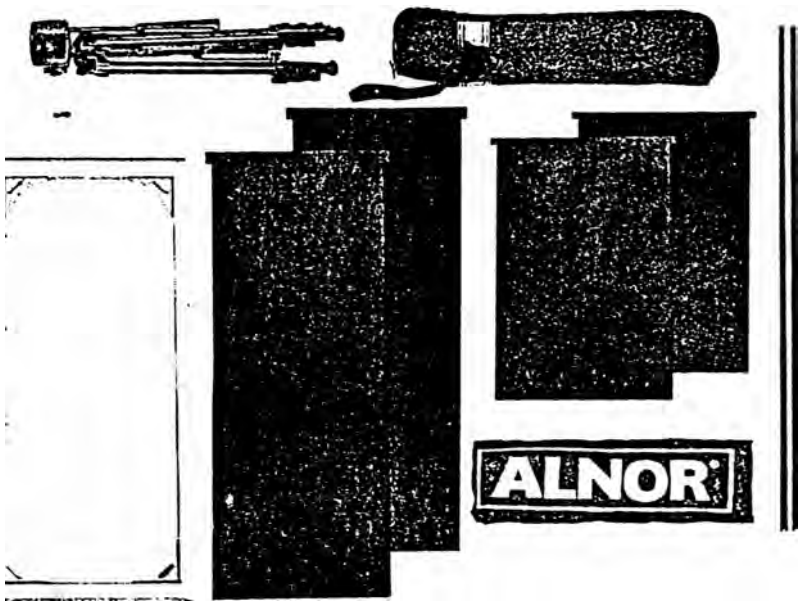


Figure 22: Direct Inflow Measurement Hood Components

To complete the assembly of the BSC hood, follow these seven steps:

1. Remove the plug located at the back of the base assembly and insert the Philips screw with washer into the hole from the inside of the base (see Figure 23). Place the threaded insert on the outside of the base opposite the screw and tighten with a Philips screwdriver.

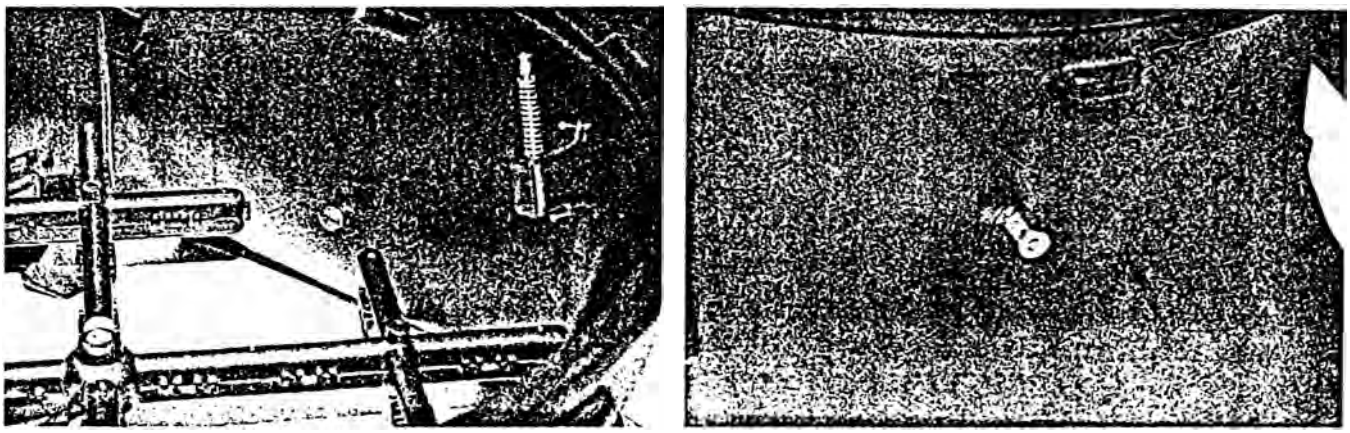


Figure 23: Remove Plug Located at Back of Base Assembly

2. Attach the fabric hood and hood support poles to the frame and base assembly in the same manner as previously described for the other hood sizes.
3. Insert the flaps into the slots from the side of the frame where the fabric hood is attached to the U-channel of the frame (see Figure 24). Use the different flap lengths to fit various cabinet widths.

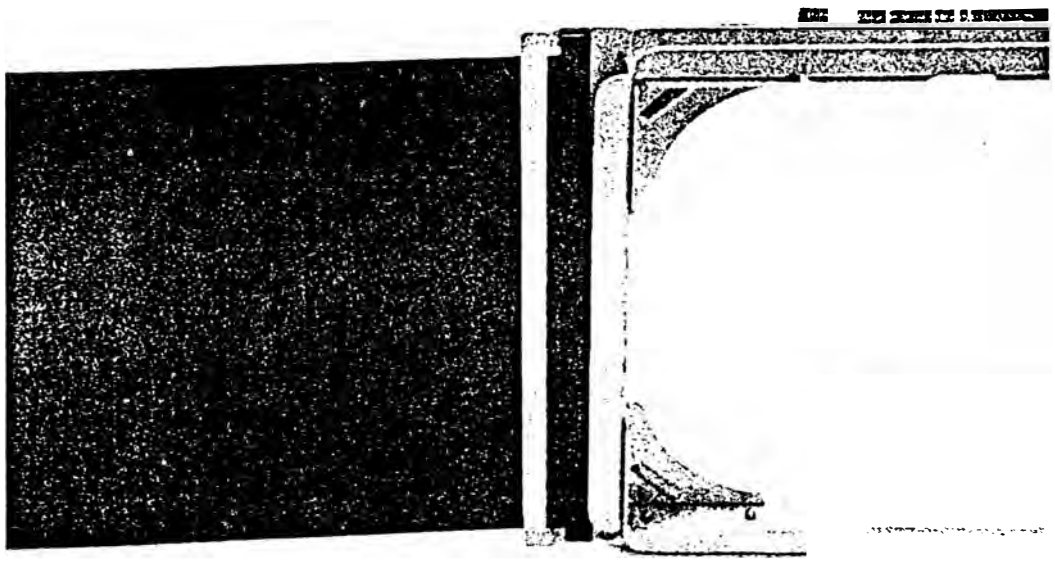


Figure 24: Attach Fabric Hood and Hood Support Poles to Frame and Base Assembly

4. Mount the EBT Balometer base to the telescopic stand by fastening the screw on the telescopic stand to the threaded insert mounted on the base opposite the display/manometer (see Figure 25).

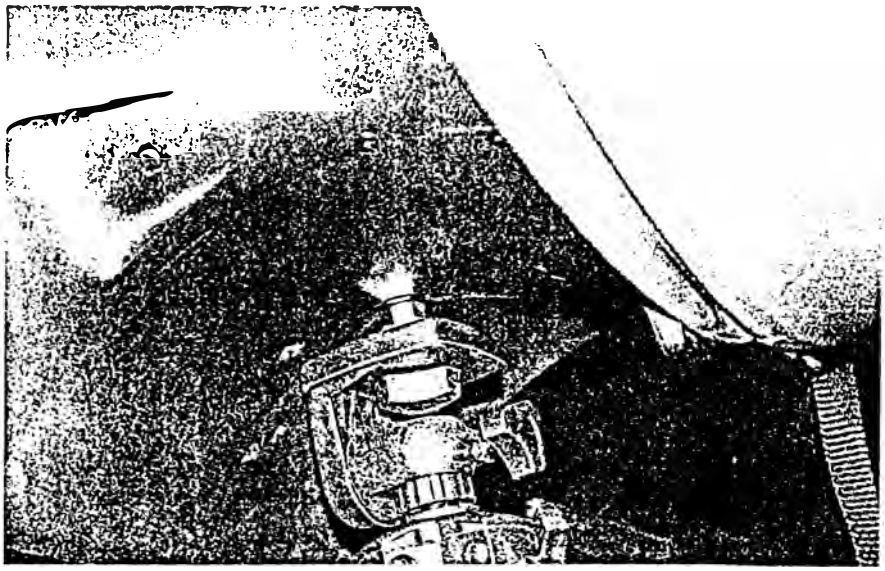


Figure 25: Mount EBT Balometer Base to Telescopic Stand

5. Adjust the height and position of the telescopic stand so that the bottom part of the hood frame rests against the cabinet opening, and the EBT Balometer is horizontal to the cabinet (see Figure 26).

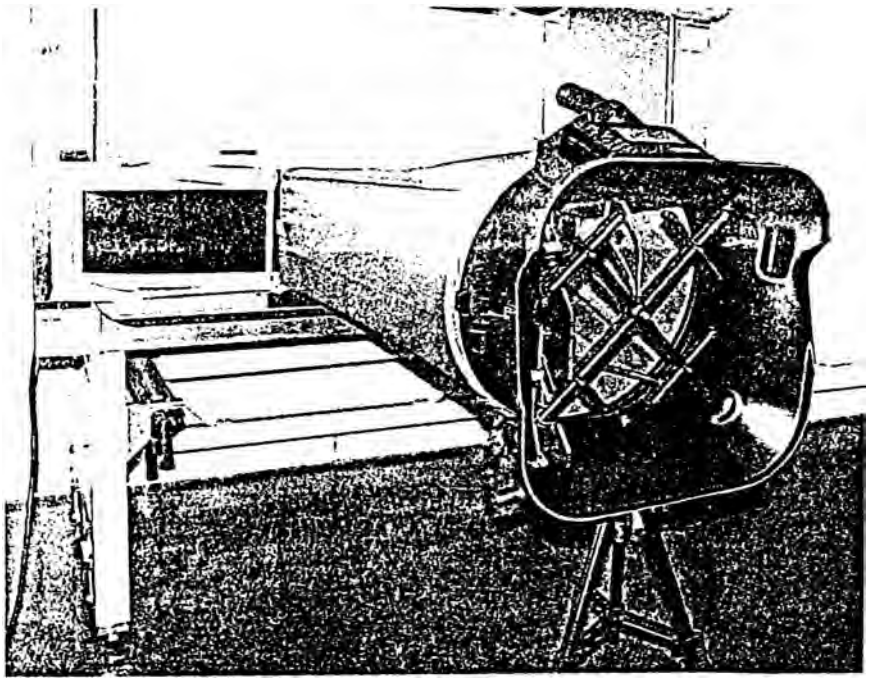


Figure 26: Adjust Height and Position of Telescopic Stand

6. Lower the sash of the cabinet until it rests on the foam lip of the hood frame (see Figure 27).

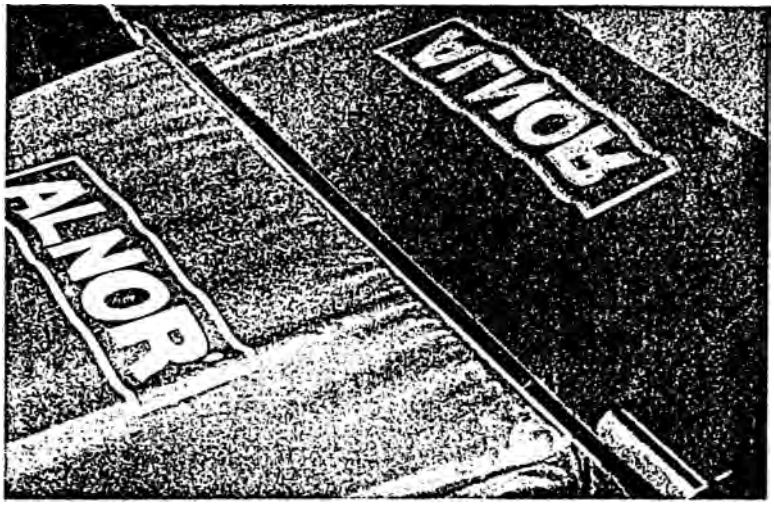


Figure 27: Lower Sash of Cabinet Until it Rests on Foam Lip of Hood Frame

7. Adjust the flaps to cover the opening of the cabinet. Tape the edges of the flaps to the sash and frame of the cabinet to create a tight fit. The unit is now ready to make measurements (see Figure 28).

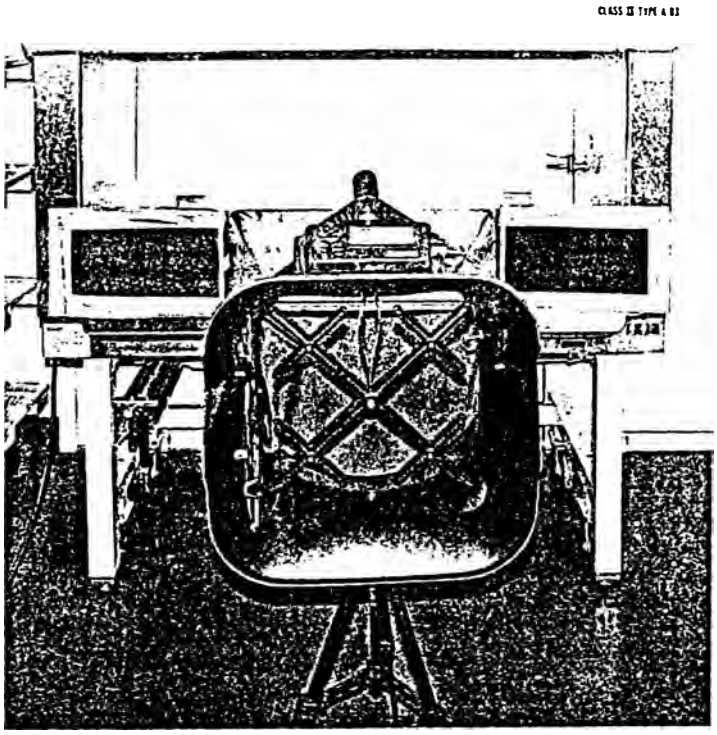


Figure 28: Unit Ready to Make Measurements

Chapter 6. Flow Measurements Using the Capture Hood

There are two methods of making flow measurements using the capture hood: Non-Backpressure Compensated and Backpressure Compensated methods (see "Appendix A. Back Pressure," for an explanation of the implications of capture hood-induced back pressure on the measured flow). Flows in both "Supply" and "Return" flow direction can be taken with either non-backpressure compensated or backpressure compensated mode.

Note: *"Return" flows will be indicated by a negative flow number, as long as the tubes leading to the Matrix manifold in the base are connected properly. The proper tube orientation is from the upper portion of the Matrix manifold leading to the positive "+" port on the back of the meter.*

Non-Backpressure Compensated Measurements

To take non-backpressure compensated measurements, be sure the Back Pressure Compensation function is turned "OFF" (see "Turn Back Pressure Compensation On and Off" in Chapter 4).

Non-backpressure compensated measurements can only be made with the back pressure flap in the "OPEN" position. If you attempt to make a non-backpressure compensated measurement with the flap closed or partially closed, the meter will display the message "CLOSE the FLAP".

In the non-backpressure compensated mode, it is possible to take either single measurements or running average measurements (see "Set Display Mode for Running Average or Single" in Chapter 4).

Single Measurements

"Single" measurements are individual flow measurements initiated by pressing either the "READ" button on the meter, or the red trigger button on the left side of the base. Depending on the flow being measured, a single reading will take from one to eight seconds to complete (lower flows take longer).

Note: Keep the hood in place during the entire measurement, otherwise the reading will be in error.

Running Average Measurements

In the "Running Average" measurement mode, the meter will constantly measure and display a running average of flow. This mode is useful when making adjustments to the flow.

If you wish to "hold" a particular value on the display, momentarily press either the "READ" key on the meter or the red trigger button on the base. To restart the running average measurements from a "held" value, simply press the "READ" key or the red trigger button again.

Note: *The running average utilizes a variable time constant determined by the meter (not user selectable) depending on the flow. At very low flows, under 100 ft^3/min, for example, the time constant is approximately 8 seconds. When using the "Running Average" mode for adjusting flows (setting or changing duct damper positions, for instance), keep in mind that there will be a lag time after flow adjustments are made for the meter to settle at any new flow reading.*

Backpressure Compensated Measurements

In most cases, backpressure compensated measurements will provide the most satisfactory flow measurement results.

In order to prepare for backpressure compensated measurements, be sure the Back Pressure Compensation function is turned "ON" (see "Turn Back Pressure Compensation On and Off" in Chapter 4).

Backpressure compensated measurements require two sequential measurements: first with the back pressure flap "OPEN" and then with the flap "CLOSED".

Here is the sequence of operation:

1. Place the capture hood over the diffuser, grille or other opening through which you wish to make a measurement.
2. Open the back pressure flap. This can easily be accomplished by pressing up on the flap handle with your left hand as you hold the hood in place. Press until the flap clicks into full open position.
3. Press the red trigger button. Again, this is easily accomplished with your left hand as you hold the hood in place. The message "READ OPEN" will flash as the meter takes its reading. (In very low flows, this step and step 5 may take as many as 8 seconds each. Higher flows will require less time.)
4. Wait for the message "CLOSE the FLAP", and then close the flap by pulling down on the flap handle until it clicks into the fully closed position.
5. Press the red trigger button. The message "READ Closed" will flash as the meter takes its reading.
6. The backpressure compensated measurement value will appear and remain on the display until another reading is initiated, or some other meter function is initiated.

Note: *It is important that the capture hood see the same flow for both parts of the backpressure compensated flow measurement. It is best to keep the hood in place for both measurements, but it is alright to remove and replace the hood between the two readings. However, if the flow is changed or changing during or between the two measurements, the measurement results will be inaccurate.*

Error Display

If the limits of allowed flow parameters are exceeded during a backpressure compensated measurement, an error message will be displayed. This can happen if there are flow reversals during the measurement or other changes in the flow during the measurement (such as changing a damper position), or as a result of other operator errors.

Chapter 7. Maintenance and Troubleshooting

The Electronic Balancing Tool (EBT) Models EBT720 and EBT721 are designed for long-term field use. If used with reasonable care, it should be able to make precise measurements over a long time period. Some of the components can be cleaned periodically. When cleaning the components, please follow the instructions given below.

Fabric Hood

The hoods can be washed with mild detergent and cold water. When washing the hood, keep the hood away from objects with sharp corners or sharp edges. Careless cleaning may cause damage.

If the fabric gets ripped it should be replaced or repaired. Duct tape can be placed over the rip on both sides of the fabric for temporary repair.

To replace a damaged fabric or to order a different fabric size, contact your local TSI/Alnor products distributor. To determine who your local TSI/Alnor products distributor is, you may call toll-free at (800) 861-7897.

If you wish to order a new hood fabric, use the following part numbers shown in Table 4.

Table 4: Hood Fabric Only Part Numbers

Fabric Hood Size	Part Number
2 ft × 2 ft (610 mm × 610 mm)	1801183
2 ft × 4 ft (610 mm × 1220 mm)	1801185
1 ft × 4 ft (305 mm × 1220 mm)	1801184
3 ft × 3 ft (915 mm × 915 mm)	1801187
1 ft × 5 ft (305 mm × 1525 mm)	1801186

Micromanometer

The micromanometer case, display screen and keys can be cleaned using a damp cloth with mild detergent solution. Do **not** immerse it in water. Wipe the unit dry before use.

Manifold

If you observe the flow sensing taps of the manifold becoming clogged with dust or other material, clean them with a damp cloth. The manifold should be kept in place during cleaning. Do **not** apply excessive forces on the grid of the manifold. If any part of the grid is damaged, please contact Customer Service for repair information.

Cases

If the instrument case or storage case needs cleaning, wipe it off with a soft cloth and isopropyl alcohol or a mild detergent.

Calibration

TSI recommends an annual calibration for the instrument. For a nominal fee, we will calibrate the unit and return it to you with a certificate of calibration and NIST traceability. This "annual checkup" assures you of consistently accurate readings. To calibrate the instrument, please ship the complete package that includes the meter, the base, the manifold and any fabrics used. Everything should be packed carefully within the carrying case and then inside a shipping box. The original shipping box is preferred. Prior to shipment, please contact Customer Service for an RMA (Return Materials Authorization) number at (651) 490-2707, (800) 861-7897 or visit the Service page our website at www.alnor.com to complete an RMA# form online.

Ship directly to:

TSI Incorporated
Alnor Products
ATTN: Customer Service
500 Cardigan Road
Shoreview, MN 55126-3996

Tables 5 and 6 list the symptoms, possible causes, and recommended solutions for common problems encountered with the instrument. If your symptom is not listed, or if none of the solutions solves your problem, please contact the factory.

Table 5: Troubleshooting the Instrument

Symptom	Possible Causes	Corrective Action
No display	Unit not turned on.	Press I/O key.
	Low or dead batteries.	Replace the batteries.
	Dirty battery contacts.	Clean the battery contacts.
	AC adapter not connected.	Plug in AC adapter.
"  " flashing on display	Low battery charge.	Replace or recharge the batteries. Clean the battery contacts.
	Dirty battery contacts.	
"888888" flashing on display	The pressure is too high to measure. This same display is shown if measuring velocity or flow and the pressure at that velocity is too high.	The maximum pressure is shown on the specifications page.
"8888" flashing on display	The temperature is too high to measure.	The maximum temperature is shown on the specifications page.

Table 6 lists the possible error codes and their meanings. All error codes are preceded by 'ERR.'

Table 6: Error Codes

Error Code	Possible Causes	Corrective Action
10	The AC adapter voltage is too low. The NiMH batteries will not recharge fully with low AC adapter voltage.	Use correct AC adapter.
11	The AC adapter voltage is too high. The NiMH batteries will not fast-charge with high AC adapter voltage.	Use correct AC adapter.
12	Model number checksum error.	Return to factory.
13	Serial number checksum error.	Return to factory.
14	Accessory temperature/humidity probe checksum error for humidity.	Perform user calibration or return to factory.
15	Accessory temperature/humidity probe checksum error for temperature.	Perform user calibration or return to factory.
16	Accessory temperature probe calibration checksum error.	Perform user calibration or return to factory.
17	Hood temperature probe calibration checksum error.	Perform user calibration or return to factory.
18	Pressure sensor calibration checksum error.	Perform user calibration or return to factory.
19	A to D converter calibration checksum error.	Return to factory.
20	Barometric pressure sensor calibration checksum error.	Return to factory.
30	Pressure calibration voltage at 1 in. H_2O must be less than pressure calibration voltage at 5 in. H_2O.	Make sure calibration pressures are correct.
31	Pressure calibration voltage at 5 in. H_2O must be less than pressure calibration voltage at 15 in. H_2O.	Make sure calibration pressures are correct.
32	While performing user calibration of accessory temperature/humidity probe, the correct probe was not found.	The accessory temperature/humidity probe was either not plugged in or is faulty.
33	While performing user calibration of hood temperature sensor or accessory temperature sensor, the accessory temperature/humidity probe was found instead.	Plug in the selected probe.
34	Barometric pressure measured was <15.00 in. Hg.	The barometric pressure is too low to take a reading.
35	Barometric pressure measured was >40.00 in. Hg.	The barometric pressure is too high to take a reading

Error Code	Possible Causes	Corrective Action
36	Flap closed pressure was < flap open pressure, or flap open versus flap closed pressure ratio exceeds allowed limits.	Take data again.
37	There was an error reading the AD7708 A to D converter.	Return to factory if error re-occurs.
38	There was an error reading the AD7718 A to D converter.	Return to factory if error re-occurs.
39,40, 41,42	Error in logged data.	If using accessory temp/humidity probe, make sure probe securely connected. Erase logged data.
43	Could not send RS232 data because the receiving device was busy >10 seconds.	Make sure printer or computer is ready to receive. Check RS232 interface cable.
50	Pressure sensor zero voltage is too high.	Return to factory if error re-occurs.
51	Pressure sensor gain out of range.	Perform user calibration or return to factory.
52	Lithium battery voltage is too low.	Replace lithium battery or return to factory.
53	AD7708 A to D converter calibration factor out of range.	Return to factory.
54	AD7718 A to D converter calibration factor out of range.	Return to factory.
55	User entered flow temperature out of range.	The micromanometer has reset the temperature to 70.0°F (21.1°C) to correct it.
56	Barometric pressure zero factor out of range.	Return to factory.
57	Barometric pressure span factor out of range.	Return to factory.
58	Offset factor for user temperature sensor calibration out of range.	Re-do user calibration, set temperature sensor calibration to FACT, or return to factory.
59	Slope factor for user temperature sensor calibration out of range.	Re-do user calibration, set temperature sensor calibration to FACT, or return to factory.
60	Humidity sensor voltage at 20% RH out of range.	Perform user calibration or return to factory.
61	Humidity sensor voltage at 80% RH out of range.	Perform user calibration or return to factory.
62	Pressure sensor gain factor A out of range.	Perform user calibration or return to factory.
63	Pressure sensor gain factor B out of range.	Perform user calibration or return to factory.

Error Code	Possible Causes	Corrective Action
64	Pressure sensor gain factor C out of range.	Perform user calibration or return to factory.
68	Pressure sensor divider calibration out of range.	Return to factory.
69	A to D reference voltage out of range.	Return to factory.
70	5V reference voltage out of range.	Return to factory.
71, 72	An invalid K-Factor was corrected.	The micromanometer has set the K-factor to 1.0 to correct it.
74	Pressure voltage for user pressure calibration out of range.	Re-do user calibration.
75	User temperature calibration >5°F (3°C) different from factory calibration.	Re-do user calibration. Replace temperature probe.
>100	Internal program error.	Please contact the factory.

Appendix A. Back Pressure

The quantity of air flowing through a supply diffuser or a return grille is reduced to some extent whenever a capture hood is placed over the flow opening. The amount of flow reduction will vary depending on the combined effects of the diffuser/grille resistance, the capture hood resistance, and the flow rate.

The Electronic Balancing Tool features a built-in capability to make flow measurements which are compensated for the effects of the capture hood-induced back pressure. This is accomplished by taking two sequential flow measurements at a diffuser or grille, the first with the back pressure flap "OPEN" and the second with the flap "CLOSED". The resulting Backpressure Compensated Flow displayed by the meter represents the air flow through the diffuser/grille in its original state, that is, without the presence of the capture hood.

Verifying Flow Measurements

It is always the recommended practice to verify the flow measurements obtained with a capture hood by performing appropriate* multi-point, in-duct velocity traverses using a Pitot-static tube or a thermal anemometer.

We recommend the use of the Log-linear method when traversing a round duct, and the Log-Tchebycheff method when traversing a rectangular duct.

*We recommend that you refer to the most up-to-date copy of the duct traverse specification you require from an approved regulatory or professional organization.

Appendix B. Actual vs. Standard Air Velocity and Flow Measurements

Actual Air Velocity is also known as the "local" air velocity. It can be thought of as the speed of a microscopic dust particle being carried along in the air stream.

Actual Air Velocity is measured with a Pitot tube using the basic formula:

$$V_{ACT} = 1096.7 \times \frac{\sqrt{VP}}{\rho_{air}} \qquad \text{Eq. (1)}$$

where: V_{ACT} is Actual Air Velocity, in units of (Actual Feet per Minute)
VP is Velocity Pressure, measured in units of (in. H_2O)
ρ_{air} is the air density, in units of (lb_m/ft^3)

Air density, ρ_{air}, can be calculated from the equation:

$$\rho_{air} = 1.325 \times \frac{P_{ACT}}{T_{ACT} + 460} \qquad \text{Eq. (2)}$$

where: P_{ACT} is the atmospheric pressure, in units of (in. Hg)
T_{ACT} is the local air temperature, in units of (°F)

Standard Air Velocity is also known as the mass velocity of air. It can be thought of as the local air velocity corrected to standard conditions of air. Standard Conditions are defined as air at 70°F and P_{STD} = 29.92 in. Hg.

Substituting Standard Conditions into Eq. (2) above we can see that:

$$\rho_{air_{STD}} = 1.325 \times \frac{29.92}{70 + 460} = 0.0748 \frac{lb_m}{ft^3} \qquad \text{Eq. (3)}$$

Standard Air Velocity and Standard Air Flow are often the preferred units of measure when evaluating Heating, Ventilating and Air-Conditioning (HVAC) system performance because the heat-carrying capacity (and cooling capacity) of air is directly related to Standard, not Actual, units of measure.

Converting between Standard and Actual units of measure simply involves an inverse air density ratio, as follows.

From the continuity of mass equation, we can state the following:

$$\rho_{air_{ACT}} \times V_{ACT} = \rho_{air_{STD}} \times V_{STD} \qquad \text{Eq. (4)}$$

Thus, to convert from Actual Velocity to Standard Velocity, use the following equation:

$$\frac{\rho_{air_{ACT}}}{\rho_{air_{STD}}} \times V_{ACT} = V_{STD} \qquad \text{Eq. (5)}$$

Substituting known values into Eq. (5), we get:

$$\frac{P_{ACT}}{T_{ACT}+460} \times \frac{70+460}{29.92} \times V_{ACT} = V_{STD}$$

or,

$$V_{ACT} \times \frac{P_{ACT}}{T_{ACT}+460} \times 17.714 = V_{STD} \qquad \text{Eq (6)}$$

where: P_{ACT} is the local atmospheric pressure, as measured by the EBT, for example, in units of (in. Hg)
T_{ACT} is the local temperature of the air flow being measured, in units of (°F)
V_{ACT} is Actual Air Velocity, in units of (AFPM)
V_{STD} is Standard Air Velocity, in units of (SFPM)

Similarly, to convert from Standard to Actual Air Velocity, use the following equation:

$$V_{STD} \times \frac{T_{ACT}+460}{P_{ACT}} \times 0.05645 = V_{ACT} \qquad \text{Eq. (7)}$$

For Volumetric Flow measurements, the analysis is exactly the same.

Thus:

$$Flow_{ACT} \times \frac{P_{ACT}}{T_{ACT}+460} \times 17.714 = Flow_{STD} \qquad \text{Eq (8)}$$

$$Flow_{STD} \times \frac{T_{ACT}+460}{P_{ACT}} \times 0.05645 = Flow_{ACT} \qquad \text{Eq (9)}$$

where: $Flow_{ACT}$ is Actual Air Flow, in units of (ACFM)
$Flow_{STD}$ is Standard Air Flow, in units of (SCFM)

Note: *The Models EBT720 and EBT721 perform these calculations automatically. You can choose to view velocity or flow measurements in either "Actual" or "Standard" units of measure.*

ANEXO G

CERTIFICADOS DE CALIBRACION DE LOS INSTRUMENTOS DE MEDICIÓN

Certificate of Calibration
Handheld Laser Particle Counter

Cert.No. KCA540509

MODEL GEO－α
Serial No. 595555
Calib. Date 12－June－2004

National Standard: National Metrology Institute of Japan, National Institute of Advanced Industrial Science and Technology

Calibrator: JQA

Calibration Standard: Electrostatic Mobility Classifier; Aerosol Electrometer; Precision Film Flow Calibration System; Standard Particle Generator; LPC Reference for Comparison Test

Kanomax Japan Inc.

KANOMAX MODEL GEO－α

Kanomax Japan Inc.(KJI) does hereby certify that all materials, components, and workmanship used in the manufacture of this equipment are in strict accordance with the applicable specifications agreed upon by KJI and the customer and with all published specifications.

The accuracy and stability of standards maintained by KJI are traceable to the National Research Laboratory of Metrology Japan, or have been derived from acceptable values of natural physical constants, or by the ratio type of self-calibration.

This calibration has been performed in accordance with the following appropriate procedures.

JIS B-9921.

Standards	Model	S/N	Calibrator
Electrostatic Mobility Classifier	TSI 3071	82	K J I
Aerosol Electrometer	TSI 3068	65	K J I
Precision Film Flow Calibration System	Gilibrator-2	705-0072	J Q A

K J I : KANOMAX JAPAN INC.
JQA : JAPAN QUALITY ASSURANCE ORGANIZATION

KANOMAX JAPAN INC.
The Quality Assurance Dept.

KANOMAX

Test Sheet

Model Handy LPC
GEO−α

Serial No. 595555

Date June 12, 2004.

Item	Procedure/Standard	Result	Judge
Sampling air flowrate	The flowrate should be within 2.83 l/min ±5%.	2.86L/min	OK
Panel operation	The sheet key should be operated and LCD is correctly displayed.		OK
Computer communication	The LPC should communicate when the LPC is connected to a Computer.		OK
Printer communication	The Printer should be printed the data out when the LPC is connected to the Printer.		OK
False count level	The count value should be below 1 count per 10 minutes when the zero-filter is put on the LPC inlet.	0 COUNTS	OK
Threshold voltage	The threshold voltage for each particle size of standard PSL particles should be less than 5V respectively.	$V_{0.3}$= 0.56V $V_{0.5}$= 1.67V $V_{1.0}$= 2.46V $V_{3.0}$= 3.48V $V_{5.0}$= 4.35V	OK
Comparison test	The ratio of the particle counts of the calibrated LPC to the standard one should be 100±10% for the 0.3 and 0.5 um standard PSL particles.	98.8%(0.3) 103.0%(0.5)	OK

* The above procedure and the standard for this LPC are suit the JIS B 9921.

Check	Signed
	miyauchi

KANOMAX JAPAN INC.
2-1 Shimizu, Suita, Osaka, 565-0805 Japan
Phone 06-6877-0443

AIR TECHNIQUES INTERNATIONAL
A Division of Hamilton Associates, Inc.
11403 Cronridge Drive • Owings Mills, MD 21117-2247 USA • Tel 410.363.9696 •
Fax 410.363.9695
http://www.attest.com

NIST TRACEABLE CERTIFICATION & CALIBRATION REPORT

(National Institute of Standards & Technology) DIGITAL AEROSOL PHOTOMETER

Customer HI-TECH REFRIGERACION S.A. ID # _____
P.O. # CIA Order # 67119
Model # 2H Serial # 16285

	CALIBRATION EQUIPMENT USED	SERIAL #	NIST CAL DATE	CAL DUE DATE
X	Keithly Picoamp Source	274317	6/3/04	6/3/05
X	Fluke DMM	7989013	1/21/04	1/21/05
X	Flowmeter	8116	4/24/04	4/24/05

LOCATION		AS FOUND	AS LEFT	MFG. TOL.	PERFORMANCE		AS FOUND	AS LEFT	MFG. TOL.
J6-WHT	(C)		440	>220mV/Def	0.001%	(C)		81	.80±.04X10^{-10}*
J9-1	(C)		5.08	+5V ±1V	0.01%	(C)		81	.80±.04X10^{-9}*
J9-5	(C)		15.00	+15V ±45V	0.10%	(C)		81	.80±.04X10^{-8}*
J9-8	(C)		-14.90	-15V ±45V	1.0%	(C)		81	.80±.04X10^{-7}*
U4-3	(C)		-12.05	-12V ±5V	10%	(C)		81	.80±.04X10^{-6}*
U8-1	(C)		11.9	+12V ±5V	100%	(C)		81	.80±.04X10^{-5}*
U12-6	(C)		5.00	+5V ±20mV	Smpflow	(C)		28.3	28.3±2.8 slpm
U13-1	(C)		10.0	+10V+.1/-.4V	Straylight			0012	N/A
A/D V @ 10 LPM			1.90	N/A					
A/D V @ 28.35 LPM			2.86	N/A					* AMPERES

UNIT FOUND: ☐ In Tolerance ☐ Out of Tolerance ☐ Inoperable

• Internal Ref refers to a known concentration level and has no effect upon instrument operation.
(A) In tolerance when received (B) Out of tolerance when received (C) New Instrument, NA

MAINTENANCE PERFORMED

☐ Rework Scattering Chamber	☐ Align Optics	☐ Test Absolute Filter	☒ Final Test
☐ Replace Smoke Chamber	☐ Test Scanning Probe	☐ Replace Gaskets	☐
Clean Sampling System	☐ Test Electrical Connections	☐ Tighten Loose Hardware	☐
☐ Replace Cell Lamp	☐ Perform Voltage Measurements	☐ Leak Check	☐

CALIBRATION PROCEDURES USED TEMP: 24 ^{0}C R.H.: 50 %

☐ PCL-030-WI ☒ PCL 104 WI

CALIBRATION PER ISO 10012:2003 and ANSI/NCSL Z540-1-1994

All results contained within this certificate relate only to the item(s) calibrated. This certificate shall not be reproduced except in full and with the written consent of ATI

CALIBRATED BY:	Shelley Beer	CAL DATE:	08/26/2004	CAL DUE:	08/26/2005
FINAL INSPECTION:	MS	NQA REVIEW (For NUCLEAR ACCOUNTS ONLY):			N/A

CALIBRATION CERTIFICATE

Company Name: COLE-PARMER INSTRUMENTS
625 EAST BUNKER COURT
VERNON HILLS IL 60061

Instrument Under Test: Model#: **MA204E15007**
Serial#: **0305021**

Calibration Date: **MARCH 24,2005**

This instrument has been calibrated with measurement standards whose accuracy is traceable to the National Institute of Standards and Technology test numbers:

Test Number: **1120011324**

Instrument A is used for pressure ranges to 0.5 Inches of water (125 Pascals)
Instrument B is used for pressure ranges to 5.0 Inches of water (1250 Pascals)

Calibration Instrument: Heise Pressure Indicator Model PPM-1
Calibration Standard ID# : QAID 1324

	Instrument A	Instrument B
Certification ID#:	44649-36317	44650-47425
Pressure Range:	0 - .50000" H_2O	0 – 5.0000" H_2O
Serial #:	44649	44650
Accuracy:	0.07%	0.10%
Last Calibrated:	03/08/05	03/08/05
Calibration Due Date:	03/08/06	03/08/06

All standards used in this calibration are maintained in accordance with the latest revisions of ANSI/NCSL Z540-1 and ISO-10012.

By: _____

Title: QA Associate
Date: MARCH 24,2005

CERTIFICATE OF CALIBRATION AND TESTING

Alnor Model 540 Alnor Serial No. 54127034

Description Differential Pressure Meter

Calibration Standard TSI Pressure Calibration Bench #121

CALIBRATION VERIFICATION RESULTS

Calibration Standard	Instrument Output	Difference	Error Compared to Tolerance: Tolerance Limit-	0	Tolerance Limit+
-998.099Pa	-997.850Pa	-0.0 %		*	
0.000Pa	0.000Pa	0.00Pa		*	
498.676Pa	498.178Pa	-0.1 %		*	
1982.499Pa	1988.975Pa	0.3 %			*
3485.003Pa	3480.768Pa	-0.1 %		*	

Environmental Conditions:

Temperature: 23.7 °C Pressure: 732.8 mmHg

Humidity: 33.30 %RH Dewpoint: 6.7 °C

Tolerance Limits:

± 1% of reading ± 1 Pa

Alnor does hereby certify that all materials, components, and workmanship used in the manufacture of this equipment are in strict accordance with the applicable specifications agreed upon by Alnor and the customer and with all published specifications. All performance and acceptance tests required under this contract were successfully conducted according to required specifications. Furthermore, all test and calibration data supplied by Alnor has been obtained using standards whose accuracies are traceable to the National Institute of Standards and Technology (NIST) or has been verified with respect to instrumentation whose accuracy is traceable to NIST, or is derived from accepted values of physical constants. Our Quality Management System complies with ISO 9001 requirements and calibration procedures for this instrument adhere to ISO 10012. The accuracy of the pressure calibration facilities is at least a ratio of 5.8:1 with respect to the accuracy specifications of the instrument being calibrated.

Applicable Test Report	Report Number	Date Last Verified	Date Due
DC Voltage	E000048	07-22-04	07-22-05
Pressure 15 in	E000808	08-25-04	08-25-05

Mary S Yoy
Calibrated by

☑ Final Function Check

Dec 10, 2004
Calibration Date

Alnor

Shipping Address: 500 Cardigan Road Shoreview, MN 55126 USA
Phone: (800) 777-8356 **or** (651) 490-2711 **Fax:** (651) 490-2874

CERTIFICATE OF CALIBRATION AND TESTING

Alnor Model 540 Alnor Serial No. 54127034

Description Differential Pressure Meter

Calibration Standard TSI Pressure Calibration Bench #121

CALIBRATION VERIFICATION RESULTS

Calibration Standard	Instrument Output	Difference	Error Compared to Tolerance: Tolerance Limit-	0	Tolerance Limit+
-4.007inH2O	-4.006inH2O	-0.0 %		*	
0.000inH2O	0.000inH2O	0.00inH2O		*	
2.002inH2O	2.000inH2O	-0.1 %		*	
7.959inH2O	7.985inH2O	0.3 %			*
13.991inH2O	13.974inH2O	-0.1 %		*	

Environmental Conditions:

Temperature: 74.66 °F Pressure: 28.85 in. Hg

Humidity: 33.30 %RH Dewpoint: 44.06 °F

Tolerance Limits:

± 1% of reading ± 0.005" H2O

Alnor does hereby certify that all materials, components, and workmanship used in the manufacture of this equipment are in strict accordance with the applicable specifications agreed upon by Alnor and the customer and with all published specifications. All performance and acceptance tests required under this contract were successfully conducted according to required specifications. Furthermore, all test and calibration data supplied by Alnor has been obtained using standards whose accuracies are traceable to the National Institute of Standards and Technology (NIST) or has been verified with respect to instrumentation whose accuracy is traceable to NIST, or is derived from accepted values of physical constants. Our Quality Management System complies with ISO 9001 requirements and calibration procedures for this instrument adhere to ISO 10012. The accuracy of the pressure calibration facilities is at least a ratio of 5.8:1 with respect to the accuracy specifications of the instrument being calibrated.

Applicable Test Report	Report Number	Date Last Verified	Date Due
DC Voltage	E000048	07-22-04	07-22-05
Pressure 15 in	E000808	08-25-04	08-25-05

Calibrated by

☑ Final Function Check

Dec 10, 2004
Calibration Date

Alnor

Shipping Address: 500 Cardigan Road Shoreview, MN 55126 USA
Phone: (800) 777-8356 or (651) 490-2711 **Fax:** (651) 490-2874

ALNOR
TSI Incorporated

CERTIFICATE OF CALIBRATION

TSI Incorporated, Alnor Products, 500 Cardigan Road, Shoreview, MN 55126 USA
TEL:1-800-424-7427 1-651-490-2811 FAX: 1-651-490-3824 www.alnor.com

ENVIRONMENT CONDITION		
TEMPERATURE	73.3	° F
RELATIVE HUMIDITY	27.7	% RH
BAROMETRIC PRESSURE	28.99	inHg

MODEL	EBT™ Micromanometer EBT-721
SERIAL NO.	90510003

CALIBRATION STANDARDS USED
Manometer Calibration Bench 1

☒ AS LEFT ☒ IN TOLERANCE
☐ AS FOUND ☐ OUT OF TOLERANCE

CALIBRATION DATA

TESTING POINTS	BAROMETRIC PRESSURE MEASURED IN in.Hg			DIFFERENTIAL PRESSURE MEASURED IN in.H2O		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	19.75	19.73	19.36 ~ 20.14	0.102	0.103	0.099 ~ 0.105
2	28.99	28.99	28.42 ~ 29.56	0.476	0.477	0.466 ~ 0.486
3	34.69	34.68	34.00 ~ 35.38	2.82	2.83	2.77 ~ 2.87
4	-	-	-	12.2	12.1	12.0 ~ 12.4
5	-	-	-	14.9	14.9	14.7 ~ 15.1

TESTING POINTS	TEMPERATURE MEASURED IN °F			HUMIDITY MEASURED IN %RH		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	-38.0	-38.0	-37.0 ~ -39.0	71.4	71.4	71.3 ~ 71.5
2	5.0	5.0	4.7 ~ 5.3	5.9	6.0	5.8 ~ 6.0
3	77.0	77.0	76.8 ~ 77.2	-	-	-
4	158.0	158.0	157.8 ~ 158.2	-	-	-
5	230.0	230.0	229.8 ~ 230.2	-	-	-

** Indicates out of tolerance condition*

Recommended Next Calibration Date:

TSI Incorporated does hereby certify that the above described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self calibration techniques. The calibration ratio for this instrument is at least 6.7:1 for barometric pressure and 3:1 for differential pressure. TSI's calibration system meets ISO-9001:2000 and complies with ISO 10012:2003, Quality Assurance Requirements for Measuring Equipment. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E002798	04-06-04	04-06-05
DC Voltage	E002797	04-06-04	04-06-05
Pressure	E002400	11-19-04	05-19-05
Pressure	E002447	07-30-04	07-30-05

Calibration procedure used: 9011158A

M. C. Pittman
Calibrated By

Mar. 8, 2005
Calibration Date

1083501A

ALNOR
TSI Incorporated

CERTIFICATE OF CALIBRATION

TSI Incorporated, Alnor Products, 500 Cardigan Road, Shoreview, MN 55126 USA
TEL:1-800-424-7427 1-651-490-2811 FAX: 1-651-490-3824 www.alnor.com

ENVIRONMENT CONDITION		
TEMPERATURE	23.7	° C
RELATIVE HUMIDITY	28.2	% RH
BAROMETRIC PRESSURE	744	mmHg

MODEL	EBT™ Balometer® EBT-721
SERIAL NO.	90510003

CALIBRATION STANDARDS USED
Capture Hood Calibration System 3

☒ AS LEFT	☒ IN TOLERANCE
☐ AS FOUND	☐ OUT OF TOLERANCE

CALIBRATION DATA

Tolerance: ± (3% of reading + 3.3 l/s)

TESTING POINTS	SUPPLY DATA MEASURED IN l/s			RETURN DATA MEASURED IN l/s		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	898	905	868 ~ 928	894	883	864 ~ 924
2	707	715	683 ~ 731	709	704	685 ~ 733
3	564	569	544 ~ 584	565	562	545 ~ 585
4	424	428	408 ~ 440	424	425	408 ~ 440
5	283	288	272 ~ 294	283	283	272 ~ 294
6	141	141	134 ~ 148	142	141	135 ~ 149
7	48	48	44 ~ 52	47	48	43 ~ 51

** Indicates out of tolerance condition*

Recommended Next Calibration Date:

TSI Incorporated does hereby certify that the above described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self calibration techniques. The calibration ratio for this instrument is at least 2.4:1. TSI's calibration system meets ISO-9001:2000 and complies with ISO 10012:2003, Quality Assurance Requirements for Measuring Equipment. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E002072	E000808	E002082
Thermometer	E002080	07-07-04	08-25-04
Pressure	03-16-05	03-16-05	07-07-05
Pressure	08-25-05	09-16-05	09-16-05

Calibration procedure used: 128000124

Calibrated By

Mar. 21, 2005
Calibration Date

1083503A

ALNOR
TSI Incorporated

CERTIFICATE OF CALIBRATION

TSI Incorporated, Alnor Products, 500 Cardigan Road, Shoreview, MN 55126 USA
TEL:1-800-424-7427 1-651-490-2811 FAX: 1-651-490-3824 www.alnor.com

ENVIRONMENT CONDITION		
TEMPERATURE	23.7	° C
RELATIVE HUMIDITY	28.2	% RH
BAROMETRIC PRESSURE	744	mmHg

MODEL	EBT™ Balometer® EBT-721
SERIAL NO.	90510003

CALIBRATION STANDARDS USED
Capture Hood Calibration System 3

☒ AS LEFT ☒ IN TOLERANCE
☐ AS FOUND ☐ OUT OF TOLERANCE

CALIBRATION DATA

Tolerance: ± (3% of reading + 11.9 m^3/h)

TESTING POINTS	SUPPLY DATA MEASURED IN m^3/h			RETURN DATA MEASURED IN m^3/h		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	3232	3259	3124 ~ 3340	3220	3181	3112 ~ 3328
2	2547	2574	2459 ~ 2635	2554	2533	2466 ~ 2642
3	2030	2049	1958 ~ 2102	2034	2022	1962 ~ 2106
4	1527	1539	1470 ~ 1584	1527	1529	1470 ~ 1584
5	1018	1038	976 ~ 1060	1018	1019	976 ~ 1060
6	508	508	481 ~ 535	511	508	484 ~ 538
7	172	172	155 ~ 189	168	172	152 ~ 184

** Indicates out of tolerance condition*

Recommended Next Calibration Date:

TSI Incorporated does hereby certify that the above described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self calibration techniques. The calibration ratio for this instrument is at least 2.4:1. TSI's calibration system meets ISO-9001:2000 and complies with ISO 10012:2003, Quality Assurance Requirements for Measuring Equipment. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E002072	E000808	E002082
Thermometer	E002080	07-07-04	08-25-04
Pressure	03-16-05	03-16-05	07-07-05
Pressure	08-25-05	09-16-05	09-16-05

Calibration procedure used: 128000124

Calibrated By

Mar. 21, 2005
Calibration Date

ALNOR
TSI Incorporated

CERTIFICATE OF CALIBRATION

TSI Incorporated, Alnor Products, 500 Cardigan Road, Shoreview, MN 55126 USA
TEL:1-800-424-7427 1-651-490-2811 FAX: 1-651-490-3824 www.alnor.com

ENVIRONMENT CONDITION		
TEMPERATURE	22.9	°C
RELATIVE HUMIDITY	27.7	% RH
BAROMETRIC PRESSURE	736	mmHg

MODEL	EBT™ Micromanometer EBT-721
SERIAL NO.	90510003

CALIBRATION STANDARDS USED
Manometer Calibration Bench 1

☒ AS LEFT ☒ IN TOLERANCE
☐ AS FOUND ☐ OUT OF TOLERANCE

CALIBRATION DATA

TESTING POINTS	BAROMETRIC PRESSURE MEASURED IN mmHg			DIFFERENTIAL PRESSURE MEASURED IN Pa		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	502	501	492 - 512	25.0	26.0	24.3 - 25.7
2	736	736	721 - 751	119	119	116 - 122
3	881	881	863 - 899	702	705	688 - 716
4	-	-	-	3039	3014	2978 - 3100
5	-	-	-	3711	3711	3637 - 3785

TESTING POINTS	TEMPERATURE MEASURED IN °C			HUMIDITY MEASURED IN %RH		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	-38.9	-38.9	-38.3 - -39.4	71.4	71.4	71.3 - 71.5
2	-15.0	-15.0	-14.8 - -15.2	5.9	6.0	5.8 - 6.0
3	25.0	25.0	24.9 - 25.1	-	-	-
4	70.0	70.0	69.9 - 70.1	-	-	-
5	110.0	110.0	109.9 - 110.1	-	-	-

** Indicates out of tolerance condition*

Recommended Next Calibration Date:

TSI Incorporated does hereby certify that the above described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self calibration techniques. The calibration ratio for this instrument is at least 6.7:1 for barometric pressure and 3:1 for differential pressure. TSI's calibration system meets ISO-9001:2000 and complies with ISO 10012:2003, Quality Assurance Requirements for Measuring Equipment. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E002798	04-06-04	04-06-05
DC Voltage	E002797	04-06-04	04-06-05
Pressure	E002400	11-19-04	05-19-05
Pressure	E002447	07-30-04	07-30-05

Calibration procedure used: 9011158A

N.C. Peterson
Calibrated By

Mar. 8, 2005
Calibration Date

1083601A

ALNOR
TSI Incorporated

CERTIFICATE OF CALIBRATION

TSI Incorporated, Alnor Products, 500 Cardigan Road, Shoreview, MN 55126 USA
TEL:1-800-424-7427 1-651-490-2811 FAX: 1-651-490-3824 www.alnor.com

ENVIRONMENT CONDITION		
TEMPERATURE	74.7	° F
RELATIVE HUMIDITY	28.2	% RH
BAROMETRIC PRESSURE	29.3	inHg

MODEL	EBT™ Micromanometer EBT-721
SERIAL NO.	90510003

CALIBRATION STANDARDS USED
Capture Hood Calibration System 3

☒ AS LEFT	☒ IN TOLERANCE
☐ AS FOUND	☐ OUT OF TOLERANCE

CALIBRATION DATA

Tolerance: ± (3% of reading + 7.0 cfm)

TESTING POINTS	SUPPLY DATA MEASURED IN ft^3/min			RETURN DATA MEASURED IN ft^3/min		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	1902	1918	1838 ~ 1966	1895	1872	1832 ~ 1958
2	1499	1515	1448 ~ 1550	1503	1491	1451 ~ 1555
3	1195	1206	1153 ~ 1237	1197	1190	1155 ~ 1239
4	899	906	866 ~ 932	899	900	866 ~ 932
5	599	611	575 ~ 623	599	600	575 ~ 623
6	299	299	284 ~ 314	301	299	285 ~ 317
7	101	101	91 ~ 111	99	101	90 ~ 108

** Indicates out of tolerance condition*

Recommended Next Calibration Date:

TSI Incorporated does hereby certify that the above described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self calibration techniques. The calibration ratio for this instrument is at least 2.4:1. TSI's calibration system meets ISO-9001:2000 and complies with ISO 10012:2003, Quality Assurance Requirements for Measuring Equipment. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E002072	E000808	E002082
Thermometer	E002080	07-07-04	08-25-04
Pressure	03-16-05	03-16-05	07-07-05
Pressure	08-25-05	09-16-05	09-16-05

Calibration procedure used: 128000124

Calibrated By

Mar. 21, 2005
Calibration Date