

OPERATING MANUAL



NON-VIABLE PARTICLE SIZING INSTRUMENTS

Eight Stage Models BGI20800 Series



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Table of Contents

| | |
|--|----|
| 1. Preface..... | 1 |
| 2. Introduction..... | 1 |
| 3. Aerodynamic Particle Sizing..... | 2 |
| 4. Cascade Non-Viable Impactor..... | 4 |
| A. Description..... | 4 |
| B. Preparation for Use..... | 7 |
| C. Sampling..... | 8 |
| D. Analysis..... | 9 |
| E. Data Interpretation..... | 9 |
| F. Calibration..... | 14 |
| G. 60 Liter Per Minute Conversion Kit..... | 16 |
| H. 90 Liter Per Minute Conversion Kit..... | 18 |
| I. Cleaning Method for 8 Stage Non-Viable Impactors..... | 20 |

TABLE OF FIGURES AND TABLES

| | |
|--|----|
| Figure 1 BGI Sampler Simulates Human Respiratory System..... | 2 |
| Figure 2 BGI Cascade Impactor with USP Pre-Separator & Throat..... | 4 |
| Figure 3 Schematic Cross Section..... | 5 |
| Figure 4 Jet Dimensions..... | 6 |
| Figure 5 Schematic of Impactor Stage..... | 8 |
| Table 1 Data Presentation..... | 11 |
| Figure 6 Fractional Efficiency Curves..... | 12 |
| Figure 7 Particle Size Diameter Graph..... | 13 |
| Figure 8 Exploded View of 8-Stage Impactor..... | 15 |

1. PREFACE

For thirty years, industrial hygienists have been aware of the potential health effects associated with exposure to fine particles, and within the past ten years, inertial impactors have been used universally for monitoring particulate sizes in the work place. Knowledge of the aerodynamic dimension of the particles is vital to understanding their effects and to determining the best methods of control.

The purpose of this manual is to outline proper methods for the simultaneous determination of concentration and particle sizing information in the working environment using the BGI Instruments (BGI) Non-Viable Ambient Particle Sizing Samplers. This technique is based on Cascade Impaction.

2. INTRODUCTION

The BGI Non-Viable Particle Sizing Sampler is a multi-stage, multi-orifice cascade impactor, which normally is used in the environmental working areas to measure the size distribution and total concentration levels of all liquid and solid particulate matter.

The BGI Non-Viable Ambient Sampler was calibrated with unit density (1 g/cm^3) spherical particles so that all particles collected, regardless of their physical size, shape, or density, are sized aerodynamically equivalent to the reference particles. In this manner, the aerodynamic dimensions obtained in the work place can be used to determine the following:

- 1) Probable point of respiratory deposition
- 2) Particle behavior in the air
- 3) Type of control equipment needed to collect the particles
- 4) Compliance with existing Threshold Limit Values and OSHA Regulations

A brief description of the operation of the equipment follows:

- 1) Ambient gases enter the impactor inlet cone and cascade through the succeeding orifice stages with successively higher orifice velocities from Stage 0 to Stage 7. Successively smaller particles are inertially impacted onto the collection plates. The submicrometer particles, which are not collected by the last collection plate, are caught in the backup filter, which is an integral part of the impactor immediately downstream from Stage 7. Stage 0 is an orifice stage only. Stage 8 is a collection stage only.
- 2) The clean gases are carried through the vacuum tube and through the air pump and exhausted.
- 3) A constant air sample flow of 1 ACFM (28.3LPM) is provided by a continuous duty, carbon-vane vacuum pump. Flow rate through the impactor is controlled by an adjustable bleed valve on the pump, which requires periodic flow calibration to site conditions.
- 4) After sampling is completed, the sample time is recorded and the tared weighed 81mm collection media and backup filter are removed for subsequent gravimetric and/or chemical determination.
- 5) Concentration levels are determined and the size distribution is plotted.

At this point an assessment of the working environment can be made.

3. AERODYNAMIC PARTICLE SIZING

The design concept of the BGI Non-Viable Ambient Particle Sizing Sampler evolved from the following facts: The human respiratory tract is an aerodynamic classifying system for airborne particles.^{2,4} The sampling device is used as a substitute for the respiratory tract as a dust collector. As such, it should reproduce to a reasonable degree the dust collecting characteristics of the human respiratory system^{1,4} so that lung penetration by airborne particles can be predicted from sampling data. The sampling instrument should therefore classify the particles collected according to the aerodynamic dimension which, as Wells⁵ states, is the true measure of lung penetrability. The fraction of inhaled dust retained in the respiratory system and the site of deposition vary with size, shape, and density and all the physical properties of the particles that constitute the aerodynamic dimensions (Figure 1).

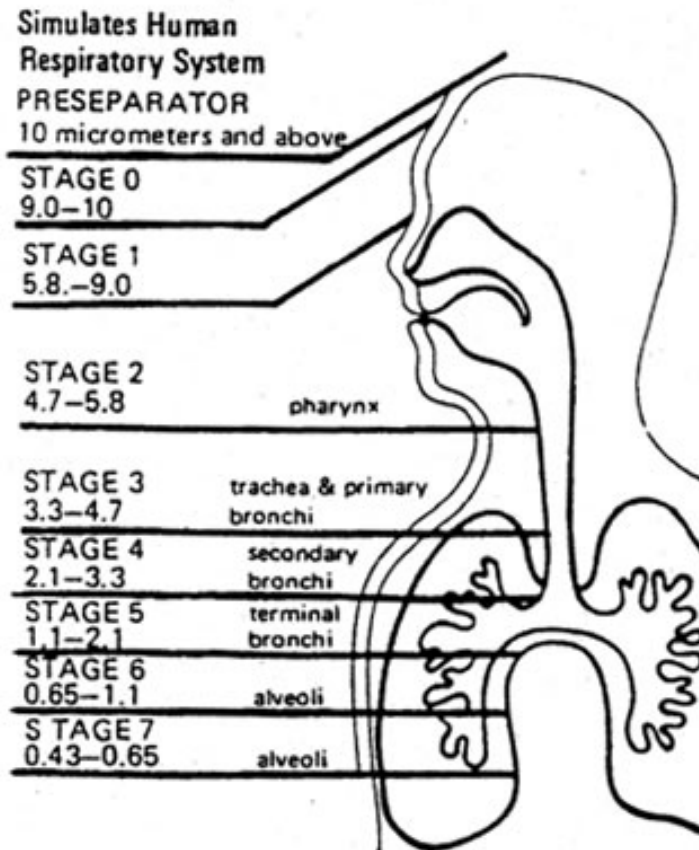


Figure 1: BGI Style Sampler Simulates Human Respiratory System

Methods that employ light scattering or filtration and microscopic sizing of particles do not reckon with density and some other properties that affect the movement of the particle in air, and therefore do not give the desired information. Because the lung penetrability of unit density spherical particles is known and since the particle sizes that are collected on each stage of the sampler have been determined, then, as long as a standard model of this sampler is used according to standard operating procedure, the stage distribution of the collected material will indicate the extent to which the sampler would have penetrated the respiratory system. With this information and with knowledge of the chemical, biological, and/or radiological properties of the material collected, the exact nature and extent of the health hazard can be assessed¹⁵.

The earliest and most fundamental work in inertial impaction theory was conducted in the early 1950's by Ranz & Wong. In this work, Ranz and Wong showed that the collection of a particle by an obstacle is a function of what is defined as the inertial impaction parameter (K):

$$K = \frac{C_p U D_p^2}{18 \mu D_c}$$

Where U is the relative velocity, p is the particle density, D_p is the particle diameter, μ is the gas viscosity, D_c is the diameter of the round jet, and C is the Cunningham slip correction factor.

Data from inertial impactors are normally presented as 50% effective cut-off diameter. For the BGI Environmental Impactors, containing round jets and flat collection surfaces, the 50% effective cut-off diameter would yield a value of 0.14 for the inertial impaction parameter K.

The Cunningham slip correction factor (C) is equal to:

$$C = 1 + (0.16 \times 10^{-4} / D_p) \text{ for normal temperatures and pressures.}$$

This factor corrects for the fact that as particle diameters approach the mean free-path length of the gas molecules, they tend to "slip" between gas molecules more easily and are therefore more easily able to cross the bulk flow streamlines. The collection efficiency is therefore slightly greater than would be predicted by inertial impaction theory for particle diameters on the order of 1 or 2 micrometers. The overlapping of particle size between stages, which is naturally inherent in all cascade impaction devices, is minimized in BGI Impactors by design. Ranz and Wong (1952) stated that as a particle passes through a jet, its nearness to the axis of the jet is one of the factors that determine whether or not the particle will reach the impaction surface. In contrast to competitive samplers which have larger rectangular jets in each stage, the BGI Impactor has 400 small, round jets. Travel of the particle is thus confined near the axis of the jets. The average distance of the particles from the axis of the jets is much less than in other Impactors. Ranz and Wong (1952) also stated that round jets have sharper cut-offs than rectangular jets. The BGI Impactor, therefore, on a theoretical basis, should have a sharper cutoff.

An inherent disadvantage of competitive samplers is that single circular orifice and multiple rectangular orifice Impactors by design must operate with high orifice velocities. This results in more turbulent flow, greater re-entrainment, and a skewing of the size distribution toward the lower end (i.e., the indicated size distribution being smaller than it really is).

4. CASCADE NON-VIABLE IMPACTOR

A. DESCRIPTION

The BGI 1ACFM (28.3 LPM) Ambient Sampler is comprised of eight aluminum stages that are held together by three spring clamps and sealed with silicone O-ring seals (Figure 2).



Figure 2: BGI Cascade Impactor with USP Pre-separator and Throat

Each impactor stage contains multiple precision drilled orifices. When air is drawn through the sampler, multiple jets of air in each stage direct any airborne particles toward the surface of the collection plate for that stage. The size of the jets is constant for each stage, but is smaller in each succeeding stage. Whether a particle is impacted on any given stage depends on its aerodynamic dimension. The range of particle sizes collected on each stage depends on the jet velocity of the stage and the cut-off of the previous stage. Any particle not collected on the first stage follows the air stream around the edge of the plate to the next stage, where it is either impacted or passed on to the succeeding stage, and so on until the jet velocity is sufficient for impaction.

There are two separate types of Ambient Samplers in use. The original design in which all eight stages contained orifices arranged in a circular pattern (Mark I) and the updated design in which the top two orifice stages contained orifices arranged in a radial pattern and the other six stages contained orifices arranged in a circular pattern (BGI-Style). All samplers purchased prior to September 1977 were Mark I and all samplers purchased after 1977 are current.

The design change from Mark I to BGI-Style was made as a result of research work showing the wall-loss and particle-bouncing errors inherent in the original design. The BGI-Style (Mark II) design has fewer holes with larger diameters on the top two stages and the orifice holes are tapered and arranged in a radial pattern to reduce turbulence.

The following is a description of the Mark I and BGI Mark II Style samplers:

Mark I:

Stages 0-6 have integral air inlet sections that contain 400 orifices arranged in a circular pattern. Stage 7 contains 201 orifices arranged in a circular pattern. The inlet sections are approximately 3.125" in diameter. The orifices are progressively smaller from top to bottom stages, ranging from 0.0625" diameter in Stage 0 to 0.0100" diameter in Stage 7. Each stage has a removable stainless steel or glass (3.25" diameter) collection plate. The exhaust section of each stage is approximately 0.75" larger in diameter than the collection plate, allowing unimpacted particles to go around the plate and into the next stage (Figure 3).

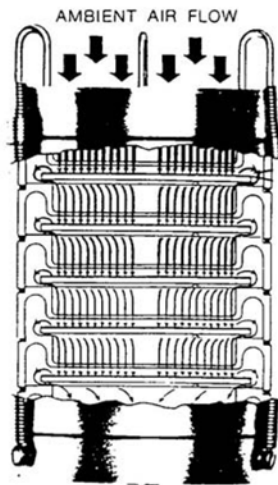


Figure 3: Schematic cross section of the non-viable impactor stages. Progressively smaller orifices increase the orifice velocity in eight successive stages causing impaction of smaller particles onto the collection discs of each succeeding stage.

BGI-Style (Model Mark II):

Orifice Stages 0 and 1 have integral air inlet sections that contain 96 orifices arranged in a radial pattern. Stages 2 through 6 have integral air inlet sections that contain 400 orifices arranged in a circular pattern. Stage 7 contains 201 orifices arranged in a circular pattern. The orifices are progressively smaller from top to bottom stages, ranging from 0.1004" diameter on stage 0 to 0.0100" diameter on stage 7. Each stage has a removable stainless steel collection plate. The exhaust section of each stage is approximately 0.75" larger in diameter than the collection plate, allowing unimpacted particles to go around the plate and into the next stage (Figure 3). The top two stainless steel collection plates have 7/8" holes in the center to allow air flow through the center also.

Impactor Pre-separator

If sampling in environments containing particles larger than 10 micrometers, a pre- separator must be used to prevent particle bouncing and re-entrainment errors. Researchers have shown that significant errors will occur with large particles if no pre-separator is used. The BGI Non-Viable Impactor pre-separator is an impaction chamber with one 0.53" diameter inlet orifice and three outlet vent tubes. The outlet tubes are 1.0" above the impaction surface. This design results in very low turbulence and allows collection of several grams of particulate without overloading the pre-separator. The device acts as a plenum to remove large >10micron particles.

When using the pre-separator, simply replace the standard inlet cone on the sampler with the pre-separator. The pre-separator base contains three spring hold-down slots, and fits the BGI Impactor with no further adjustment required.

The BGI Non-Viable Ambient Sampler and vacuum pump include their own carrying case for ease of portability.

A constant air sample flow of 1 ACFM (28.3LPM) is provided by a continuous duty vacuum pump. Flow rate is controlled by an adjustable valve on the pump and periodic calibration is recommended. Requirements for flow rate adjustments can be found in Section F. The sampler is supplied with a built-in backup filter which will accommodate an 81 mm filter disc. Normally, binder less glass fiber 81mm filter media is used because of its high collection efficiency for sub micrometer particles.

Following are the jet dimensions for each stage (Figure 4):

| Stage | BGI Mark II | | Mark I | |
|-------|---------------------------|-----------------|---------------------------|-----------------|
| | Orifice Diameter (inches) | Number of Orifi | Orifice Diameter (inches) | Number of Orifi |
| 0 | 0.1004 | 96 | 0.0625 | 400 |
| 1 | 0.0743 | 96 | 0.0465 | 400 |
| 2 | 0.0360 | 400 | 0.0360 | 400 |
| 3 | 0.0280 | 400 | 0.0280 | 400 |
| 4 | 0.0210 | 400 | 0.0210 | 400 |
| 5 | 0.0135 | 400 | 0.0135 | 400 |
| 6 | 0.0100 | 400 | 0.0100 | 400 |
| 7 | 0.0100 | 201 | 0.0100 | 201 |
| F | .110 | Filter Holder | 0.1100 | Filter Holder |

Figure 4: Jet Dimensions for Each Stage

B. PREPARATION FOR USE

The orifice stages, pre-separator and collection plates must be clean before assembly of the Sampler. A mild detergent and warm water are sufficient for cleaning. The soap can be removed by holding the stages and plates under hot running water. Complete soap removal for the stages is more quickly done by immersing them in an ultrasonic cleaner containing clean water. After the soap is removed, the stages and plates may be rinsed with acetone which removes the water and which itself quickly evaporates, or they can be spread out on paper towels and blotted dry. Either operation may leave slight traces of film which are easily removed with a lint-free wiping paper. The stages and plates should be handled by the edge to prevent getting skin oil on the orifice and collection surfaces. Each stage should be examined for any material in the holes. If holes are plugged, or partially plugged, a jet blast of dry air, or a portable Freon gun, is effective in cleaning the holes.

The complete impactor assembly consists of an inlet cone, nine stages, eight collection plates and a backup filter. An impactor pre-separator is optional. The stages are numbered 0, 1, 2, 3, 4, 5, 6, 7 and F. Stage 0 is an orifice stage only. Stage F contains the collection plate for Stage 7 and the backup filter. Each stage contains an O-ring (Silicone Standard, Teflon optional) for sealing. In addition, there is a large-diameter O-ring inside Stage F which holds the backup filter in place. The optional pre-separator simply replaces the inlet cone and requires no modification.

The impactor assembly begins by placing Stage F on the base plate stage. A pre-weighed 81mm glass fiber backup filter is inserted into Stage F and the large-diameter O-ring placed into position around the periphery of the filter. Next, place pre-weighed collection plate No. 7 onto Stage F so that the plate rests on the three raised, notched metal seats to prevent plate movement. There is no differentiation between top and bottom for the glass plates. The stainless steel plates should be placed with the curved lip down so that a raised, smooth surface is exposed for particle impingement. This is followed by Stage 7, collection plate 6, Stage 6, and so on until the inlet cone or pre-separator is positioned last. Note that if you have a BGI Style sampler, the stainless steel collection plates that fit onto the raised notched seats on top of stages 2 and 1 should have a 7/8" hole in the center of the plates.

It should be noted that there are three metal pins extending from the base of each orifice stage. These pins hold the collection plates in place so that the sampler can be used in any sampling orientation.

In addition, most people use special collection substrates other than the glass and stainless steel plates because of lighter tare weight and/or specific analytical requirements. These collection materials consist of glass fiber, cellulose, aluminum foil, vinyl metrical and other materials which must be placed into the inverted stainless steel collection plate. The collection substrate for plates 1 and 2 have open centers (7/8" hole) while the remaining 6 collection discs and backup filter are solid.

The substrate surface must be level with the top of the curved stainless steel lip to maintain jet-to-collection-surface spacing. When using collection substrates, the Sampler should be used in an upright position at all times.

After the Sampler has been assembled, connect the outlet nipple on the base stage to the pump intake port with the rubber tubing supplied with the sampler. If a longer piece of tubing is required in order to position the Sampler remotely from the vacuum source, refer to Section F for re-calibration procedures.

C. SAMPLING

When ready to sample, the vacuum pump is turned on and a sample stream of 1 ACFM will flow through the sampler. Figure 5 shows how impaction occurs at the orifice collector interfaces.

Normally, there is no variation in flow rate throughout the sampling period since a constant pressure drop is maintained (no filtration occurs except at the backup filter, resulting in minimal pressure changes). The particle size range collected at each of the eight stages depends on the orifice velocity of the specific stage, the distance between the orifices and the collection surface, and the collection characteristics of the proceeding stage. The combination of a constant flow rate and successively smaller diameter orifices increases the velocity of sample air as it cascades through the Sampler, resulting in the impaction of progressively smaller particles in succeeding stages. At 1 ACFM (28.3LPM) the particle fractionation ranges from 10.0 to 0.4 micrometers diameter (Figure 1).

Particles too small to be impacted on the last collection plate are collected in the backup filter which is an optional, integral part of the sampler. Normal sampling periods vary from a few minutes to several hours, depending upon the workroom contamination levels and the sensitivity of the analytical procedure. Ten milligrams of particulate matter on any one stage represents an approximate upper limit because of re-entrainment problems. Overloading the Sampler can be detected easily by visual inspection and is rarely encountered in industrial hygiene applications. Whenever over-sampling occurs, rather than having well-defined, discrete piles of particulates, trails of particles can be seen leading from the sample deposits toward the periphery of the plate. This type of sample should be discarded.

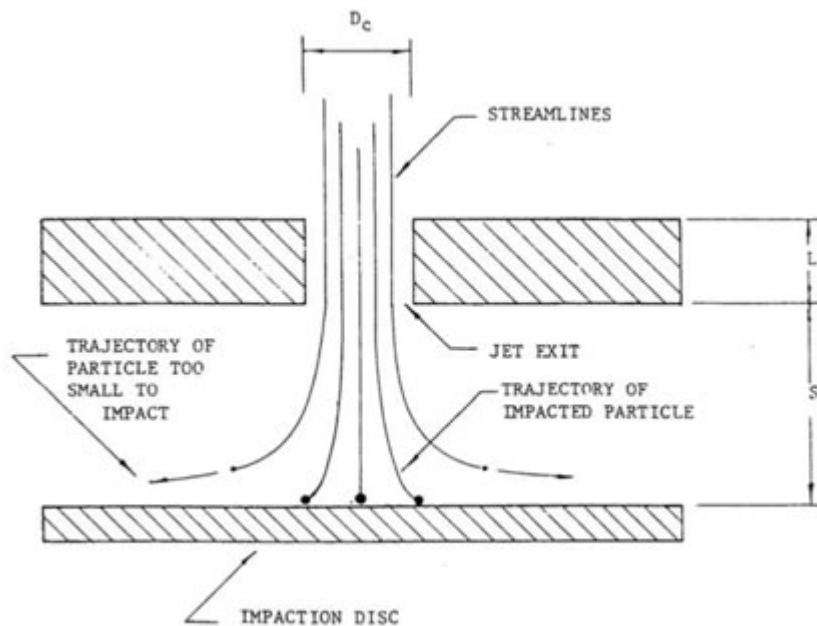


Figure 5: Schematic of Impactor Dstage

After the sampling has been completed, the Sampler is disassembled. The collection plates and backup filter are removed and replaced with fresh, preconditioned, preweighed collection media. After conditioning, the collection media can be weighed for net particulate accumulations, or the particulate matter can be analyzed chemically for the various components of interest.

Since airborne particulates have hygroscopic characteristics, all collection media used in the impactor should be preconditioned prior to weighing – both before and after a sampling cycle – in a desiccator. Filter weighing should be made to an accuracy of ± 0.02 mg and a precision of ± 0.01 mg.

It should be kept in mind that whenever a sample has been collected, the particle sizing has already been completed. To determine the nature of the size distribution, simply perform the required gravimetric and/or chemical analyses.

D. ANALYSIS

The analytical requirements determine the type of collection surface used. Normally, the stainless steel and glass plates are not used as the collection surfaces for gravimetric determinations because of the high tare-weight-to-sample-weight ratio. Glass fiber discs are normally used for these analyses because of their light weight and non-hygroscopic properties. However, other types of collection media are required for most chemical determinations because of the high and variable trace metal background levels in glass fiber. Stainless steel plates are used in many applications where the collected sample is washed off for subsequent chemical analyses. Glass plates are used rarely and only when there is need to look at the collected particles optically. It is impossible to correlate aerodynamic dimensions with physical size because of the unknown particle density and shape characteristics. In addition, the particles might have shattered in impaction, which will not affect the aerodynamic sizing but would affect any optical sizing significantly.

E. DATA INTERPRETATION

- a) Determine the change in weight for each stage in the impactor including the backup filter.
- b) Add up the weight changes to obtain the total particulate weight collected.
- c) Divide the amount collected on each stage by the total amount collected to determine the percentage of the total collected in each fraction (Table 1).*

*Note that the preseparator fraction is added to Stage 0 and the sum of both fractions is larger than the D_{p50} for Stage 0. In summary, the pre-separator does not give an additional size cut, but prevents particle bouncing and re-entrainment so that the impactor stages perform properly.

- d) The particle density should be considered as 1.0 g/cm^3 so that the particle sizes can be reported as equivalent aerodynamic diameters.
- e) Using Figure 1, select the lower size (smallest number) for each size range. This number represents the effective cut-off diameter (ECD) for each stage. This ECD can also be obtained from Figure 6.

- f) Graph the results on log-probability paper with the ECD as the ordinate and the cumulative percent less than the size range by weight as the abscissa (Figure 7).
- g) Assuming a log-normal particle size distribution, the particle size geometric standard deviation σ_g is given by:

$$\sigma_g = \frac{84.13\% \text{ Diameter}}{50\% \text{ Diameter}} = \frac{50\% \text{ Diameter}}{15.87\% \text{ Diameter}}$$

Whenever these two standard deviations are not equal (such as represented in a bimodal distribution), then the size distribution is not represented by a straight line (not really log-normal). A better method of presenting the standard deviation is:

$$\sigma_g = (84.13\% \text{ Diameter} / 15.87\% \text{ Diameter})^{1/2}$$

Generally, the particle size information should be presented in graphical form rather than merely reporting the mass mean diameter and the standard geometric deviation. By plotting the ECD and cumulative percent on log-probability paper, the particle concentration for any size range can be determined.

- h) From Table 1 and Figure 7 it can be seen that approximately 97% of this hypothetical sample is respirable (below 7 micron), that the mass mean diameter is 2.0 μm and that the standard geometric deviation is 1.9 μm

Table 1: Data Presentation

| Stage | Tare (g)* | Final (g) | Net (mg) | % in size range | Cumulative % \geq less than size range | Size Range Micrometers | ECD Micrometers |
|---------------|------------------|------------------|-----------------|------------------------|--|-------------------------------|------------------------|
| Pre-seperator | 0 | 0.00009 | 0.09 | 0.7) | | 10.0 & Above | 10.0 |
| | | | |) 1.3 | | | |
| 0 | 1.000 | 1.00009 | 0.09 | 0.6) | 98.7 | 9.0 – 10.0 | 9.0 |
| 1 | 1.000 | 1.00017 | 0.17 | 1.2 | 97.5 | 5.8 – 9.0 | 5.8 |
| 2 | 1.000 | 1.00082 | 0.82 | 5.7 | 91.8 | 4.7 – 5.8 | 4.7 |
| 3 | 1.000 | 1.00194 | 1.94 | 13.6 | 78.2 | 3.3 – 4.7 | 3.3 |
| 4 | 1.000 | 1.00472 | 4.72 | 33.1 | 45.1 | 2.1 – 3.3 | 2.1 |
| 5 | 1.000 | 1.00431 | 4.31 | 30.2 | 14.9 | 1.1 – 2.1 | 1.1 |
| 6 | 1.000 | 1.00100 | 1.00 | 7.0 | 7.9 | 0.7 – 1.1 | 0.7 |
| 7 | 1.000 | 1.00082 | 0.82 | 5.7 | 2.2 | 0.4 – 0.7 | 0.4 |
| Filter | 1.000 | 1.00031 | 0.31 | 2.2 | 0 | 0 – 0.4 | 0 |

*Note: Collection substrates will seldom weigh exactly the same.

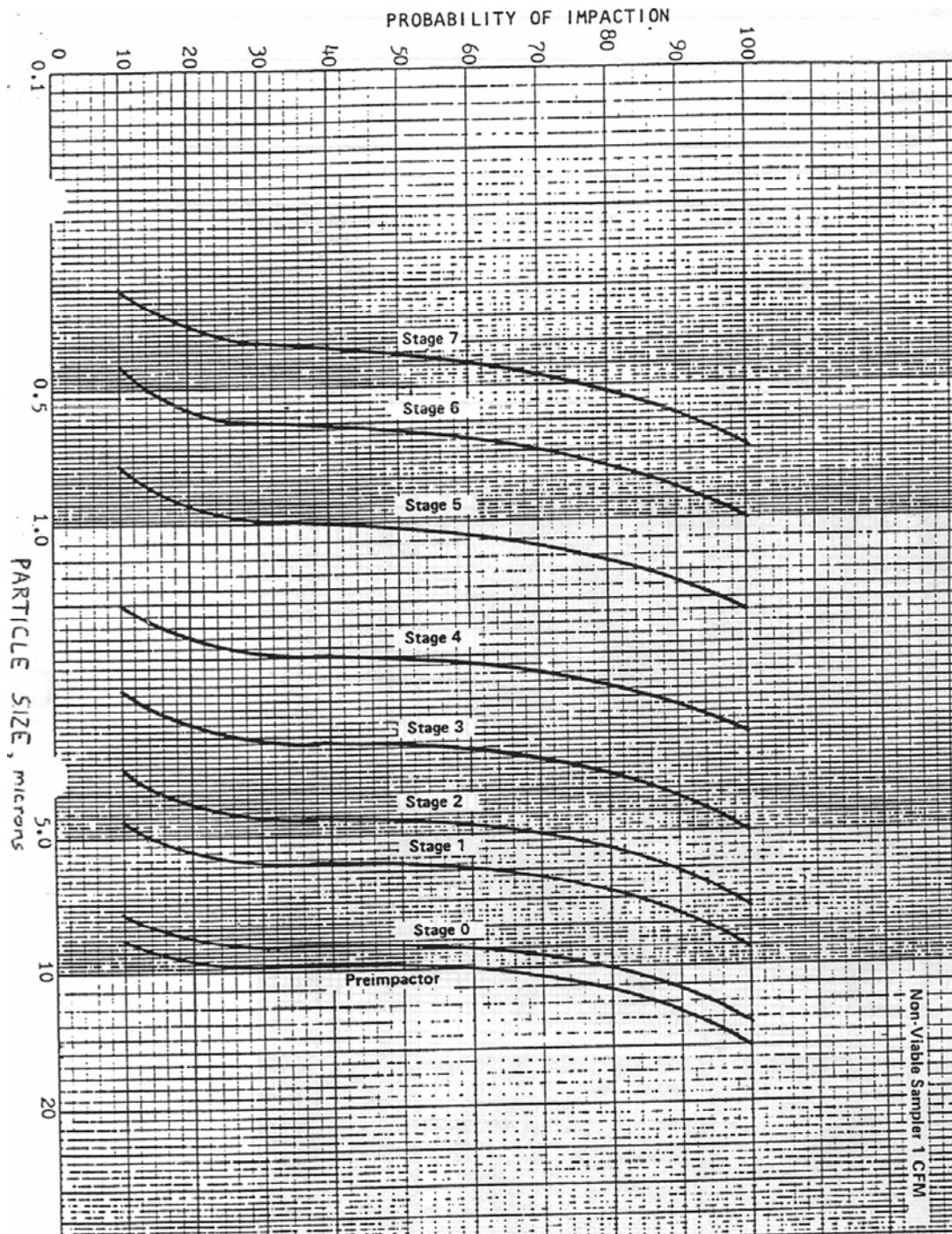


Figure 6: Fractional Efficiency Curves

Company: _____

Application: _____

Particle Size Distribution Data:

1. Source: _____

2. Method of Determination: _____

3. Data: _____

| Particle Diameter (Microns) | Percent In Size Range | Cumulative Percent Less Than |
|-----------------------------|-----------------------|------------------------------|
| ≥ 9.0 | 1.3 | 98.7 |
| 5.8 - 9.0 | 1.2 | 97.5 |
| 4.7 - 5.8 | 5.7 | 91.8 |
| 3.3 - 4.7 | 13.6 | 78.2 |
| 2.1 - 3.3 | 33.1 | 45.1 |
| 1.1 - 2.1 | 30.2 | 14.9 |
| 0.7 - 1.1 | 7.0 | 7.9 |
| 0.4 - 0.7 | 5.7 | 2.2 |
| 0 - 0.4 | 2.2 | 0 |

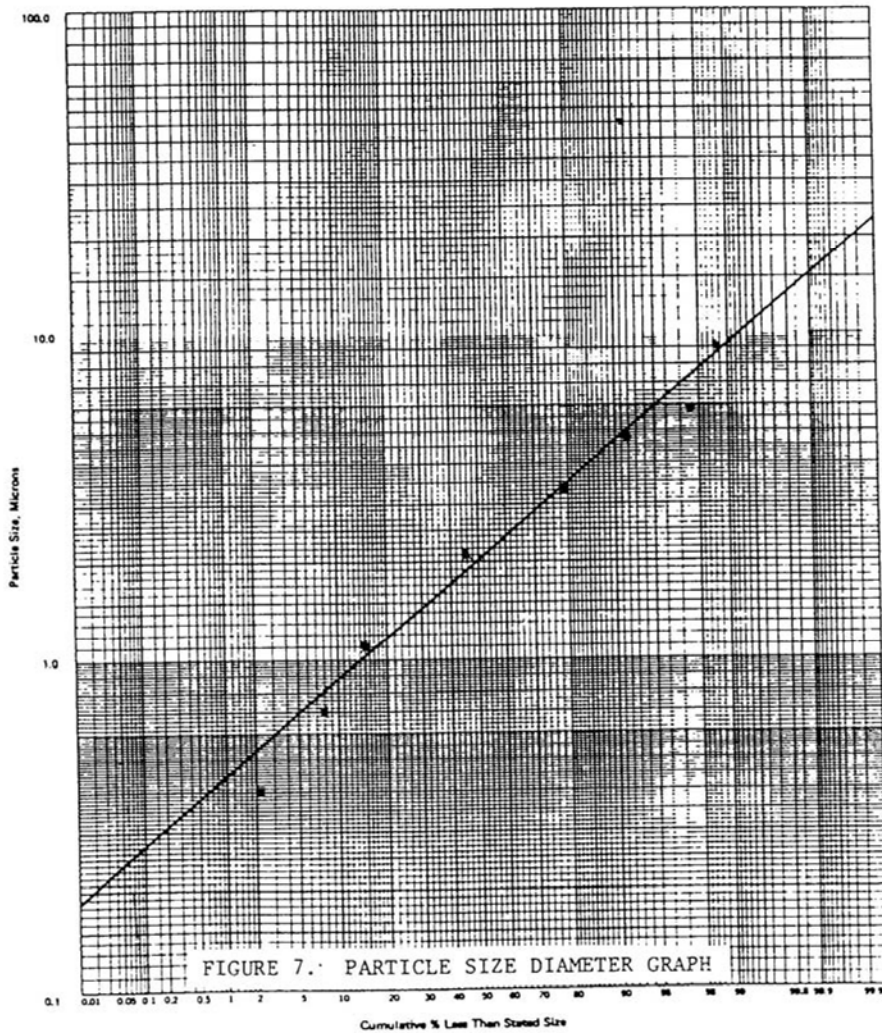


Figure 7: Particle Size Diameter Graph

F. CALIBRATION

Since the size fraction for each stage is determined by the orifice velocities, it is important that the sampler be operated at 1 ACFM. For this reason, the unit should be periodically re-calibrated and whenever non-standard temperatures and pressures are encountered, calibration should be performed at the sampling conditions. Do not use rubber tubing of smaller diameter or length different than that supplied with the impactor unless the flow rate is readjusted.

Each pump is equipped with an adjustable valve. Typically, the valve knob is removed after calibration to prevent unauthorized adjustment.

Each pump-impactor assembly should be calibrated at the local environment upon receipt. In order to recalibrate at the local sampling environment, the following procedure is recommended:

Place a calibrated dry gas meter upstream from the impactor. Attach a short 1" I.D. hose with approximately 1/4" wall to the inlet cone of the impactor and the other end to the outlet of the dry gas meter. Adjust the pump valve until 1 ACFM is being drawn through the impactor over a three minute test period as determined with an accurate stop watch. After maintaining 1 ACFM for three minutes, tighten the lock nut on the adjustment valve.

Because of the 1.4 ACFM free flow rating of the motor/pump, up to 50-feet of tubing can be used between the impactor and the pump while still maintaining 1 ACFM through the actual impactor.

Please find the following additional instructions if a 12 Volt pump will be used:

12 Volt Pump Operation: Battery required – 12 Volt automotive-type, minimum 69 amp hour capacity.

To operate properly:

- 1) Connect the clip of the red shielded pump wire to positive (+ or red) battery terminal.
- 2) Connect the slip of the black shielded wire to negative (-) terminal. The pump should start immediately.
- 3) If the pump does not start, check the battery voltage. It should be not less than 12 volts under a light load and 13 volts under no load.
- 4) If the pump does not operate with a fully charged battery, check the battery clip connections and wires for poor connections.
- 5) Should the pump fail to operate after Steps 1 through 4 are completed, please refer to the original manufacturer's instructions.
- 6) The pumping rate of the 12 Volt D.C. pump will vary with voltage. Normal pump operation requires a current draw of approximately 11 amps. Continuous running in excess of 3-hours may result in reduced battery voltage and lower CFM through the impactor.
- 7) Fully recharge the battery between uses.

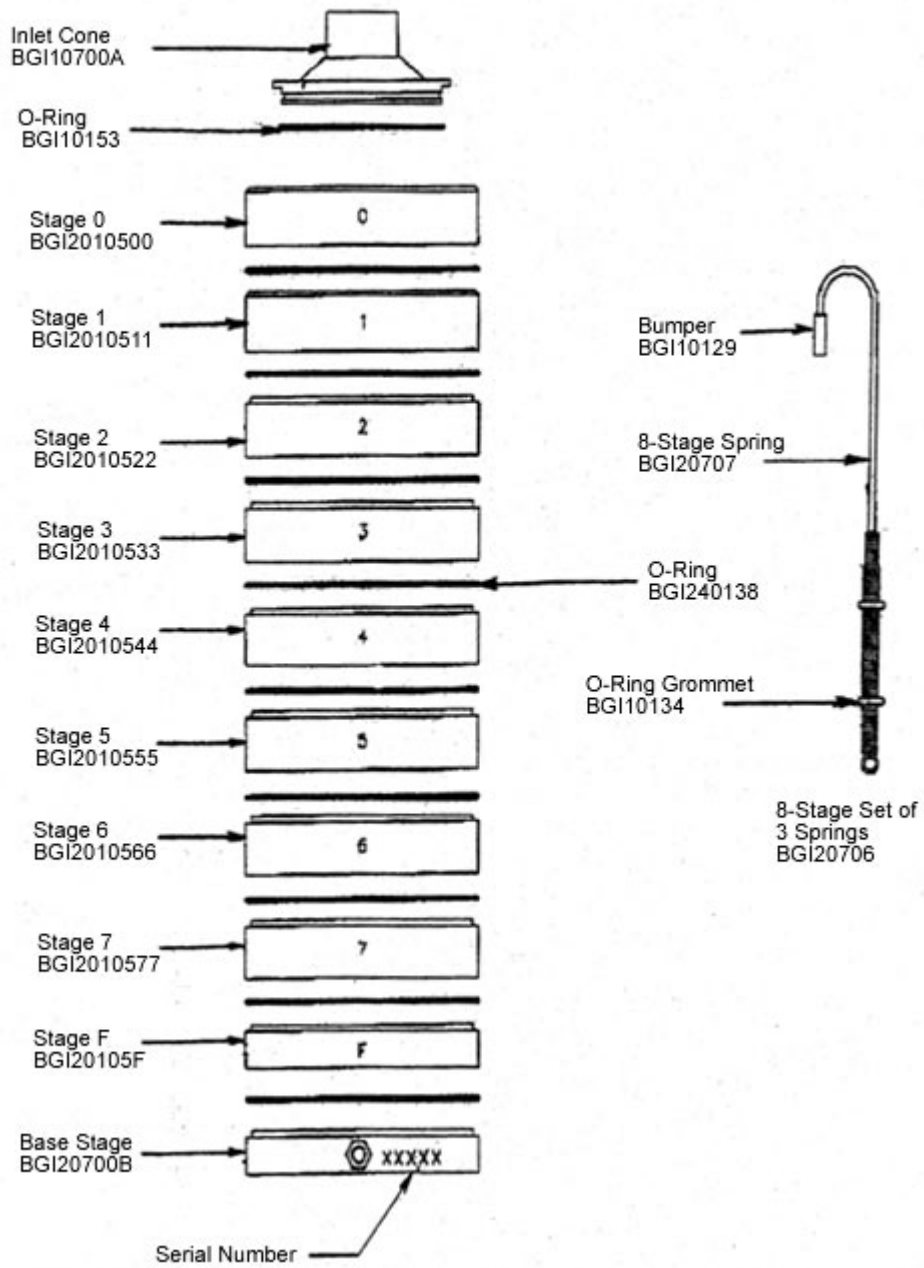


Figure 8: Exploded View of 8-Stage Impactor

G. 60 LITER PER MINUTE CONVERSION KIT

The BGI Non-Viable Cascade Impactor was designed to operate at a flow rate of 1 CFM or 28.3 liters/minute. This yields cut-points in the range 0.4 to 9.0 μm . However present pharmacopoeia requirements dictate that in the case of Dry Powder Inhalers (DPIs), a flow rate should be used which creates a 4kPa pressure drop over the inhaler under test. The result is that in most cases a flow-rate higher than 28.3 liters/minute is required due to the high resistance that DPIs impose.

When using the BGI Cascade Impactor at flow rates greater than 28.3 liters/minute, the cut-points become lower and the inter-stage discrimination is also reduced.

For user convenience the 60 liter/minute conversion kit has been designed as a modification to the standard BGI Non-Viable Cascade Impactor, such that it can be operated at 60 liters/min while retaining, as near as possible, the same cut-points as with the unmodified impactor at 28.3 liters/minute. The empirical formula can still be used to determine cut-points close to 60 liters/min.

WARNING:

Some solvents form flammable vapor-air mixtures that could be ignited on passage through a vacuum pump. Appropriate precautions should be taken to ensure operator safety during test (e.g., alternative solvents, use of vapor traps, minimal pump operating times, etc.).

COMPONENTS

| | |
|---|--------------------------------------|
| 1 | Stage “-0” |
| 1 | Stage “-1” |
| 1 | Inter-Stage ‘O’ ring |
| 1 | Collection Plate (with center hole) |
| 1 | Stage Visible Inspection Certificate |

ASSEMBLY

To assemble the 60 liter/minute conversion kit and retrofit to existing assembled impactor:

Place the O- ring for Stage “-0” in the groove provided.

Unclamp the impactor and remove Stage 7 (including collection plate) and Stage 0.

Seat Stage “-0” onto Stage 1 (in place of Stage 0).

Place the conversion kit collection plate (with center hole) on Stage “-0”.

Seat Stage “-1” on top of Stage “-0”.

Re-clamp the impactor.

The impactor should now consist of 8 stages, Stages “-1” to 6.

The collection plates should consist of three with holes for the top three stages and five without holes for the bottom five stages.

CUT-POINTS

The cut-points for the modified impactor were determined by experimental techniques; details of which are available on request.

| Cut-Points for Modified Impactor Shown Against Unmodified Impactor | | | |
|---|-----------------------|---|-----------------------|
| Unmodified Impactor (@ 28.3 liters/min) | | Modified Impactor (@60 liters/min) | |
| Stage | Cut-Point (µm) | Stage | Cut-point (µm) |
| 0 | 9.0 | -1 | 8.6 |
| 1 | 5.8 | -0 | 6.5 |
| 2 | 4.7 | 1 | 4.4 |
| 3 | 3.3 | 2 | 3.3 |
| 4 | 2.1 | 3 | 2.0 |
| 5 | 1.1 | 4 | 1.1 |
| 6 | 0.7 | 5 | 0.54 |
| 7 | 0.4 | 6 | 0.25 |

Notes:

- 1. The modified BGI Cascade Impactor should be validated before use.**
- 2. If a pre-separator is required, then a "high-top" version of the Pre-separator should be purchased for use with the 60 liter/min Conversion Kit. It is not recommend that the "standard" pre-separator be used with the 60 liter/min Conversion Kit, as this will give a cut-off point lower than that of Stage “-1”.**

H. 90 LITER PER MINUTE CONVERSION KIT

The BGI Cascade Impactor was designed to operate at a flow rate of 28.3 liters/minute (1CFM). This yields cut-points in the range 0.4 to 9.0 μm . However present pharmacopoeia requirements dictate that in the case of Dry Powder Inhalers (DPIs), a flow rate should be used which creates a 4kPa pressure drop over the inhaler under test. The result is that in most cases a flow-rate higher than 28.3 liters/minute is required due to the high resistance that DPIs impose.

When using the BGI Non-Viable Impactor at flow rates greater than 28.3 liters/minute, the cut-points become lower and the inter-stage discrimination is also reduced.

For user convenience the 90 liter/minute conversion kit has been designed as a modification to the standard BGI Cascade Impactor, such that it can be operated at 90 liters/min while retaining, as near as possible, the same cut-points as with the unmodified impactor at 28.3 liters/minute. The empirical formula can still be used to determine cut-points close to 90 liters/min.

WARNING:

Some solvents form flammable vapor-air mixtures that could be ignited on passage through a vacuum pump. Appropriate precautions should be taken to ensure operator safety during test (e.g., alternative solvents, use of vapor traps, minimal pump operating times, etc.).

COMPONENTS

| | |
|---|-------------------------------------|
| 1 | Stage “-0” |
| 1 | Stage “-1” |
| 1 | Stage “-2” |
| 2 | Inter-Stage ‘O’ ring |
| 2 | Collection Plate (with center hole) |
| 1 | Stage Visual Inspection Certificate |

ASSEMBLY

To assemble the 90 liter/minute conversion kit and retrofit to existing assembled impactor:

Place an 'O' ring for Stage “-0” in the groove provided.

Place an 'O' ring for Stage “-1” in the groove provided.

Unclamp the impactor and remove Stage 6, Stage 7 and Stage 0 (including collection plates).

Seat Stage “-0” onto Stage 1 (in place of Stage 0).

Place a conversion kit collection plate (with center hole) on Stage “-0”.

Seat Stage “-1” on top of Stage “-0”.

Place a conversion kit collection plate (with center hole) on Stage “-1”.

Seat Stage “-2” on top of Stage “-1”.

Re-clamp the impactor.

The impactor should now consist of 8 stages, Stages “-2” to 5.

The collection plates should consist of four with holes for the top four stages and four without holes for the bottom four stages.

CUT-POINTS

The cut-points for the modified impactor were determined by experimental techniques; details of which are available on request.

| Cut-Points for Modified Impactor Shown Against Unmodified Impactor | | | |
|---|-----------------------|---|-----------------------|
| Unmodified Impactor (@ 28.3 liters/min) | | Modified Impactor (@90 liters/min) | |
| Stage | Cut-Point (µm) | Stage | Cut-point (µm) |
| 0 | 9.0 | -2 | 8.0 |
| 1 | 5.8 | -1 | 6.5 |
| 2 | 4.7 | -0 | 5.2 |
| 3 | 3.3 | 1 | 3.5 |
| 4 | 2.1 | 2 | 2.6 |
| 5 | 1.1 | 3 | 1.7 |
| 6 | 0.7 | 4 | 1.0 |
| 7 | 0.4 | 5 | 0.43 |

Notes:

- 1. The modified BGI Non-Viable Cascade Impactor should be validated before use.**
- 2. It is not recommend that the "standard" pre-separator be used with the 90 liter/min Conversion Kit, as this will give a cut-off point lower than that of Stage “-1”.**

I. CLEANING METHOD FOR 8 STAGE NON-VIABLE IMPACTORS (USING AN ULTRASONIC CLEANING SYSTEM)

1. Fill the tank of the Ultrasonic Cleaning System with clean water. Note: Never allow the liquid level to drop below 25mm from the top of the tank.
2. Add a cap full of cleaning agent (typically Ambersil Aquasafe, Nutracon etc providing that the cleaning detergent has neutral pH) to the tank. The manufacturer's dilution instructions must be followed.
3. Heat the tank to approximately 50°C to 60°C.
4. (Rinse with an organic solvent if required). Place the dismantled impactor stages into a suitable rack/basket to separate them during the cleaning process and also to allow the maximum surface area of the plate to be exposed to the liquid in the tank.
5. Lower the rack/basket holding the impactor stages into the tank.
6. Switch on the Ultrasonic facility for 5 minutes for stages 0-4; -2, -1 and -0; and for a maximum of 2 minutes for stages 5-7.
7. Switch off the Ultrasonic facility and remove the impactor stages from the tank.
8. Wash all the stages in clean cold water.
9. Remove surplus water from the stages with clean compressed air.
10. Place the stages into a Heater Cabinet set to approximately 35°C to 40°C and leave for at least 30 minutes.
11. If any holes still appear not to be clean or clear, then use a clean, soft-haired brush with warm water with detergent to remove any further contaminant. Repeat steps 4 through 10 inclusive for these stages.
- 12. DO NOT** at any time “soak” the impactor stages for long periods in any solvent or aqueous media.

Revision History

V.1.0.0

Text Created

November, 2009