

QUANTITATIVE FIT TEST METHODS FOR RESPIRATORS

J. M. Clark

Chemical Defense Establishment UK

INTRODUCTION

The widespread and growing use of devices giving or claiming to give respiratory protection to the wearer against airborne material makes the testing of these devices of paramount importance. It is vital that those people who rely on respirators for their safety can have confidence that there is a very high probability of a device they are wearing meeting the standards that are claimed for it.

Of the range of functional tests that can be applied to a respirator the measurement of fit is unique. All other tests make the level of performance predictable for any unit to a high level of probability. Facial fit however is a function of the highly unpredictable geometry of the human face, its resilience and its interaction with the respirator. As no two faces are identical the quality of fit of a respirator will never be predictable, indeed repeated fittings on the same face are unlikely to give identical results.

How then can we give an assurance to the user of a respirator that the equipment with which he has been supplied will afford him the degree of protection required? Probably the only way to achieve certainty is by regular monitoring at their place of work, of every individual wearing a respirator. Such an exercise could only be justified where the risks were very high and the majority of users must continue to rely on type testing assurance of correct fit. It is therefore vital that test methods used for type approval of respirators are accurate, as closely as possible reproducible, and are applicable to a high proportion of the population.

This paper is concerned with methods which are used or have been considered for use in the UK for the testing of lung powered respirators.

CURRENT TEST METHOD

The method currently used in the UK to measure the facial fit of respirators is described in British Standard 2091.

The test agent used is a polydispersed aerosol of sodium chloride generated by a Collison spray atomiser from a 1% solution of salt. The particle size distribution is given in Fig 1 and this shows the mass median particle size to be 0.6 micrometer. The factors which governed the choice of sodium chloride as the test agent were, the availability of a relatively simple, high sensitivity instrument for the analysis of the salt and the total absence of any toxic hazard in the material so making it suitable for use with human subjects.

The method used for the quantitative analysis of the aerosol is flame photometry and the construction of a suitable high sensitivity flame photometer has been described by Webb, Poynting & Dorman (1). A hydrogen flame burns in a vertical glass tube which is connected to a horizontal tube through which the sample passes. A proportion of the sample passes up the flame tube as a result of convection induced by the hydrogen flame. Any salt particles present are vaporised by the flame and produce the characteristic sodium

emission at 589 nm. The emission is detected by a photomultiplier the output of which is amplified for measurement and recording. It is necessary, because of the limited sensitivity range of the photomultiplier, to introduce neutral density filters between the flame and the photomultiplier to attenuate the light levels at higher sample concentrations.

The light output from the flame is linearly proportional to the aerosol concentration up to approximately 0.2 mg m^{-3} . At concentrations higher than this re-absorption takes place within the flame resulting in an exponential reduction in response with increased concentration. The upper limit for measurement is in the region of 15 mg m^{-3} and the lower limit 3 ng/m^3 . A typical calibration curve is given in Fig. 2.

The tests for face seal penetration are carried out on a panel of ten subjects chosen to cover a range of facial types and sizes. The only specific requirements being that they have no facial hair which will interfere with the fit of the respirator and that significant abnormalities are excluded.

If the respirator is manufactured in more than one size, the full range must be available and the most appropriate size selected for each individual. An adaptor is fitted to the exhalation valve housing of the respirator under test and this is connected to the photometer by a light weight tube. To prevent penetration of the respirator filter interfering with the measurement of face seal penetration it is required that a high efficiency filter having a maximum penetration of 10% of the expected face seal penetration be substituted for the normal respirator canister.

The measurements are made on each subject in turn seated in a transparent enclosure to which the aerosol is fed. The measurement of sodium chloride in the exhalate is measured for a time sufficient to obtain a stable value. The subjects are required to remain as still as possible to prevent any penetrations being caused by movement.

Account must be taken of the aerosol retained in the respiratory tract of the subject. The amount retained is typically in the region of 80%. To measure this the respirator filter is removed causing the subject to breathe the undiluted aerosol. The concentration of the exhalate is then measured in the same way as before and the value obtained is used as the base level against which the penetrations are measured.

DEVELOPMENT OF THE METHOD FOR USE WITH VALVELESS MASKS

The increasing use in industry of disposable valveless masks as a supplement to a replacement for conventional oro-nasal respirators has produced a requirement to provide a quantitative measurement of their performance. This type of respirator cannot be tested by the conventional method because this relies on collecting the exhalate from the outlet valve. As these respirators are constructed from filter fabric, the wearer inhaling and exhaling through the material, no valves are required. An alternative method of assessing the penetration into the masks is to extract a sample continuously. The amount of air removed must be small with respect to the respired volume to prevent the pressure conditions inside the mask being changed significantly and hence changing the penetration.

The test agent used for valveless masks is sodium chloride generated by the same method as is used for conventional masks. The subject wearing the mask under test is placed in a transparent enclosure and surrounded by the test aerosol. A small rubber disc is stuck to the fabric of the mask and this is pierced by a large bore hypodermic needle through which the sample is removed using an ejector pump as the motive power. The sampling rate is 1 litre per minute which is adequate for analysis but is unlikely to have any significant effect on the penetration into the respirator.

The arrangement by which the sampling equipment is attached to the test subject is shown in Fig 3. An adjustable headband with a flexible arm is used to hold the sampling needle in position and very light weight rubber tubes of a sufficient length to permit unhindered movement of the head are used to connect the sampling unit to connections on the headband. Although no sampling method can avoid disturbing the fit of the mask to some extent this method has been chosen to minimize the possibility of the penetration being significantly altered.

In conditions of high humidity water vapour condenses on sodium chloride particles dissolving the salt and increasing the particle size. This increase in the particle size of the aerosol results in enhanced particle losses due to increased sedimentation velocities and inertial impaction, particularly in narrow bore sampling tubes. When sampling from inside a respirator the air sampled during the inhalation half of the cycle will be somewhat above the ambient level but will probably fall during the inhalation phase. During exhalation the humidity will be constant 100%. Hence during a full respiratory cycle it is probable that the aerosol particles will change from a dry solid with the standard size range to a liquid with an unpredictable but greatly increased size. The percentage of particles removed in sampling tubes will therefore vary during the respiratory cycle giving variable and unreliable results.

To overcome the problem of enhanced particle losses due to this effect the air drawn from the respirator is mixed with an equal volume of dry air close to the tip of the sampling probe. In order to mix the two air streams together as close as possible to the sampling tip a probe is constructed (Fig 4) from two hypodermic needles one of 12 G and the other 18 G. A hole is cut in the side of the 12 G needle and the 18 G needle is bent into a U and inserted in the hole so that the diluent is injected parallel to the sample flow. A small block of epoxy resin is cast around the joint to seal it and provide structural rigidity.

The sample flow from the mask is powered by a miniature ejector pump. This type of pump is particularly good for use with aerosols as having no moving parts the loss of particles by impaction is small. The pump is adjusted to induce a flow of 2 litres per minute, 1 litre per minute of which is the metered flow of dry air. The motive power is provided by a flow of 14 litres per minute through the ejector which when mixed with the sample and drying air gives an adequate flow for analysis in the flame photometer. This method of test measures both the penetration of the filter material and the face seal

penetration giving a value for the total inward leakage (TIL). To determine the TIL of the respirator from the analysis of the sample it is necessary to make an allowance for the aerosol retained in the respiratory tract of the subject. With valveless masks it is not possible to measure this retention factor in the way that is used for conventional respirators. Retention measurements were made on twenty-eight subjects and the mean value was found to be 81.6% with a standard deviation of 4.3%. It was therefore decided to assume a constant retention factor for all subjects of 80%. This will obviously cause some small errors in the individual values for TIL, however it will not produce a systematic error and the individual errors will be $\pm 10\%$ which is considerably smaller than the individual reproducibility, which is unlikely to be less than 25%.

A further assumption is made that the inhalation and exhalation phases of the respiratory cycle are of equal length and therefore the actual penetration, P_A will be related to the measured penetration, P_R , by:

$$P_A = 1.67 P_R$$

IMPROVEMENTS TO THE BRITISH STANDARD TEST METHOD

The existing British Standard requires the measurement of facial fit to be made on sedentary subjects and indeed it requires the subjects to remain as immobile as possible to minimize the possibility of movement of the respirator on the face. It has been recognized for some time that this method gives an unsatisfactory measurement of the facial fit likely to be achieved in realistic conditions. The development of a new standard for filtering facepiece respirators provided an opportunity to consider how the test could be altered to reflect conditions in the workplace more accurately.

As it is impossible to reproduce the range of actions likely to be undertaken by respirator users it is necessary to devise a range of exercises which represent those actions which are likely to cause an increase in the TIL. Only a small proportion of respirator users remain sedentary and therefore the primary requirement is to test the respirator on subjects during exercise. This will increase the respiration rate and probably (though not necessarily) the TIL. Movements of the head are also inevitable and have the potential, particularly in respirators with a poor fit, to cause an increase in TIL. Speech is also necessary when wearing a respirator, although it is unlikely to occur during more than a very small proportion of the wearing time, and may cause increased penetration.

The standard for filtering facepiece respirators requires testing to be carried out on a treadmill using the following exercises.

- | | | |
|----|---|-------|
| a. | Counting aloud from 1-60 | 1 min |
| b. | Walking on level surface at 6.5 km/h | 3 min |
| c. | Head movements while walking on level surface at 6.5 km/h | |
| | i. moving head from side to side 20 times | 1 min |
| | ii. moving head up and down 20 times | 1 min |
| d. | Standing | 3 min |

The TIL of the respirator is estimated by combining the final two minutes of exercises b. and d. (the first minute is excluded so that measurements are made at equilibrium) with exercises ci. and cii. on a time weighted basis. Exercise a. is excluded from the estimation of TIL as it is unlikely in practice to take place over a significant period. It is excluded in the exercises however to ensure that no permanent increase in TIL takes place following speech.

ALTERNATIVE TEST AGENTS

There has been considerable interest in the UK and Europe during recent years in alternatives to sodium chloride aerosol as the test agent for the measurement of facial fit. The reasons for seeking such an alternative are generally given as:

- a. A requirement to record the penetration continuously throughout the breathing cycle.
- b. The variable loss of aerosol particles in the respiratory tract.
- c. The assumption that a gaseous test agent will show greater penetration than an aerosol.

A considerable number of gases and vapours have been considered as candidate test agents but only a very few have proved to be worth further investigation. There are a number of requirements for suitable test agents some of which are listed below...

1. Non-toxic
2. Non-flammable
3. Not present in any significant quantities in the atmosphere
4. Sufficiently volatile to maintain a concentration of at least 1% at room temperature.
5. Suitable for quantitative analysis at concentration reductions of at least 10^{-5}
6. Inexpensive.

Even if some latitude is allowed on the less vital of these points, the requirements exclude all but a very small number of volatile compounds. The two methods described below use respectively dichlorodifluoromethane (Freon 12) and Argon. Both methods have been used by the author although only the former was developed at CDE.

METHOD USING FREON 12

The method of conducting the test is not different in principle to that in which sodium chloride aerosol is used. A concentration of 1% of Freon in air is used. The gas is mixed with the airflow to the test chamber and is set to give a velocity in the chamber of 120 mm/s. This velocity has been found by experiment to be the minimum necessary to keep the test agent concentration constant in the vicinity of the respirator. In the test enclosure used this velocity required a flow rate of 5 m³/minute which resulted in an unacceptably high consumption of Freon. To reduce this consumption a second enclosure of 15 m³ was built around the test equipment and the air from this was recirculated to the primary chamber.

The concentration both in the respirator and in the test enclosure are measured using quadrupole mass spectrometer. The particular instrument used has a theoretical sensitivity of 0.2 ppm for Freon 12 which gives practical quantifiable limit of 0.5 ppm. The maximum penetration which can be measured using this method is therefore 0.005%. The instrument was modified to accept dual sample inputs from the respirator and test enclosure. These samples are withdrawn through heated stainless steel capillary tubes at a flow rate of 20 ml/minute which gives a response time for the instrument of 100 ms. Each of the capillaries can be closed by a needle valve which permits a rapid changeover from one sampling point to the other.

When the test method was first developed an exercise to compare the results obtained by this method and the sodium chloride aerosol method was undertaken. A high efficiency respirator was adapted so that the sampling units of the mass spectrometer and the flame photometer could both be connected. Initially eleven subjects were tested by both methods. To eliminate as far as possible any changes in the face seal penetration the subjects did not remove the respirator between tests and every effort was made to ensure that alterations to fit were minimized. The results of the exercise are given in Table 1.

TABLE 1

Penetration (%)			
Subject	Test A (Freon 12)	Test B (Sodium Chloride)	B/A
1	0.012	0.076	6.3
2	0.006	0.037	6.2
3	0.027	0.017	0.6
4	0.013	0.081	6.2
5	0.009	0.041	4.6
6	0.005	0.038	7.6
7.	0.010	0.071	1.6
8.	0.037	0.059	1.8
9	0.017	0.031	1.0
10	0.087	0.090	1.0
11	0.020	0.037	1.9

The mean ratio of the penetrations obtained by the two method is 4.1 and this shows a significant difference between the methods at the 0.01 probability level.

The result not only showed a large and significant difference between the methods but also appeared to show that sodium chloride aerosol was the more penetrating test agent. If any real difference were to exist between the test agents it would be expected that the aerosol would be less penetration as there is some potential for the loss of particles by impaction. It was therefore concluded that the difference must be due. to the methods of testing and the details of both methods were carefully examined for possible errors of technique. No mechanisms for the loss of test agent in the method using Freon could be found nor were any inaccuracies in the method of analysis discovered. However two problems were found with the sodium chloride aerosol method which had been adapted to use continuous sampling at a flow rate of 1 l/minute. It was found that the pump used to withdraw the sample was giving a variable flow due to the pressure variations within the mask and also the tubes connecting the mask to the flame photometer were heavier and more restricting than the sampling capillary used for the Freon test.

The suspected causes of excessive penetrations in the aerosol test were remedied and a further comparison exercise was carried out. To eliminate as many variables possible this was made using a respirator with a variable leak which was fitted to a dummy head and connected to a breathing machine set at 20 breaths per minute of 1.5 litres capacity. The results of a series of ten trials is given in Table 2.

TABLE 2

Penetration %

Subject	Test A (Freon 12)	Test B	
		Sodium Chloride aerosol	B/A
1	0.008	0.010	1.25
2	0.011	0.014	1.27
3	0.09	0.08	0.89
4	0.11	0.13	1.18
5	0.19	0.17	0.90
6	0.25	0.22	0.88
7	0.48	0.45	0.94
8	0.60	0.67	1.12
9	0.90	0.90	1.00
10	1.15	1.05	0.91

The results showed a mean ratio of 1.03 (SD 0.15) for the methods which was not a significant difference. It was therefore provisionally concluded that the difficulties with the modified aerosol method had been overcome. This was confirmed over a period of time by testing a number of respirators on several subjects. Examination of thirty-six results shows a ratio between the two test methods of 0.95 (SD 0.19) which confirms that there is no significant difference in results obtained by the two methods.

The test method using Freon 12 as a tracer has proved useful as a research tool enabling a detailed examination to be made of the pattern of penetration during the breathing cycle. Also specific activities which may tend to cause transient leaks can be examined and methods of eliminating them tested. However as a routine test method it has no significant advantages over the sodium chloride aerosol method and several disadvantages including lower sensitivity, higher cost and a higher level of operator skill.

METHOD USING ARGON

This method of measuring facial fit was first described by Griffin and Longson (2).

The basis of the method is that a subject wearing the respirator under test is surrounded by an atmosphere of 100% Argon in a transparent enclosure. Oxygen is supplied for respiration and a sample is continuously withdrawn from the exhaled flow and analysed for Argon content.

It is claimed that the method will give accurate determinations of face seal leakage in the range 0.001% to 80% with oxygen containing up to 0.005% Argon.

The requirement to supply oxygen to the mask and to collect the exhalate for analysis calls for great care to prevent the face seal being distorted by the weight of tubes. A lung governed demand valve is required to regulate the flow of oxygen to the mask and if the test is to be realistic a restriction must be included to simulate the resistance of the filter.

In order to sample the exhaled gases the mask is connected to a bladder of 5 litres capacity the exit of which is restricted to maintain a slight positive pressure. A continuous sample is removed from the bladder for analysis by mass spectrometry.

During the test the subject is surrounded by an inert atmosphere and therefore there is a danger that a gross leak in the respirator under test could reduce the partial pressure of oxygen to a dangerous level if air was used for respiration. The use of oxygen removes this risk as a leak in excess of 80% would be necessary to reduce the oxygen to below the level present in air. A second reason for using oxygen is that the Argon content is less than that of air and so the base level against which leakage must be measured is lower.

There are no medical hazards inherent in the use of oxygen for these tests but their safety must be carefully considered. Constant supervision by a responsible person of all tests is required as a mistake made in connecting the gas supplies or the loss of the oxygen supply during a test could result in the wearer breathing pure Argon.

The reasons often given for selecting Argon as a test agent are; its complete lack of toxicity, its cheapness and ready availability. In order to reduce the problem of its presence in the atmosphere the test subject is supplied with medical oxygen in place of air - the oxygen containing a lower concentration of Argon than air. The concentration of Argon in medical oxygen is claimed to be approximately 50 ppm (2). Enquiries with British Oxygen Company however reveal that Medical Oxygen contains less than 3000 ppm Argon but the concentration is variable and no exact figure is available. Research grade oxygen containing 50 ppm Argon is available but the cost is 700 Pounds for 2000 litres which would make the cost of routine testing prohibitive. The reason for concern with the level of Argon in the oxygen supply is that any leakage must be measured against this background. If the background concentration is of the same order of magnitude as the minimum leakage it is required to measure, then no problem arises? if, however, the background is greater than the leakage by an order of magnitude or more measurement becomes difficult if not impossible. The method claims to give accurate determinations of leakage between 80% and 0.001%. To illustrate the difficulties of measuring above a background the following example may be considered.

Example: The concentration of Argon in the medical oxygen supplied to the test subject is 0.3%. The Argon in the exhalate is measured using a quadrupole mass spectrometer, the output of which is roughly proportional to the gas pressure in the vacuum system. The normal working pressure of the machine is approximately 3×10^{-6} torr, but this may vary slightly with the temperature of inlet system or due to slight occlusion of the inlet. If the pressure were to increase to 3.1×10^{-6} this would not be detectable from the ion gauge meter but would produce a 3.3% increase in the signal due to Argon, thus appearing to give a concentration of 0.31%. This could result in giving a false leak of 0.01% or disguising a real leak of the same magnitude.

Errors can also arise due to small instabilities in the quadrupole field, the ion source and the electron multiplier, increasing the probability of inaccurate leakage measurements.

The retention of tracer in the lungs has the potential to be a source of error in the measurement of face seal leakage. Two forms of retention occur; reversible and irreversible. Irreversible retention occurs when the tracer is an aerosol (such as NaCl aerosol) and a proportion of the particles is retained by the lung or dissolves in the body fluids. Reversible retention occurs when the tracer is a gas or vapour which is soluble in the body fluids and absorption or desorption occurs according to the direction of the concentration gradient across the lung.

The solubility of Argon in the body fluids is approximately 2.2 ml Ar/100 ml fluid at atmospheric pressure and if the volume of extracellular body fluid is taken as 14 litres (3) the total Argon content of the body would be 300 ml of free gas. Inert gases have a half-life during washout of about 5 minutes for the most accessible fluids (3,4) and therefore if we assume a breathing rate of 30 litres/min the concentration of Argon exhaled during this period would be 0.05% if we further assume that the most accessible fluids comprise 50% of the extracellular fluid. It would therefore appear that when conducting leakage tests using Argon as the tracer adequate time should be allowed for washout before beginning the test.

Having achieved equilibrium with the reduced partial pressure of Argon in the oxygen the body fluids have the capacity to absorb Argon should the concentration increase. Thus should transient leaks in the respirator seal occur they may be absorbed by the body fluids and so remain undetected. No reference on the absorption dynamics of Argon has been found so this problem is difficult to quantify without experimental work.

From the above considerations it is clear that there are many serious difficulties associated with the use of Argon as a test agent with few compensating advantages.

INDIVIDUAL FITTING OF RESPIRATORS

It is widely recognized that some individuals have much greater difficulties than the majority of the population in obtaining the required level of protection from a respirator. Such individuals comprise a sizeable minority of the population and appear not to be readily identifiable by their facial characteristics. Where respirators are used in conditions that pose an immediate threat to life or are required to provide a very high level of protection it is important to identify such individuals to ensure that they are provided with the degree of protection necessary.

The only practical method of ensuring a universal level of protection is to measure the facial fit on every individual using their personal respirator.

A method by which these measurements can be made has been developed. A portable flame photometer, originally designed for the on-site testing of filter installations has been adapted to the requirements of respirator testing. This is used together with a sodium chloride aerosol generator (Collison atomizer) and a portable transparent enclosure in a test based on British Standard 2091.

The equipment is now being used in a research project which aims to measure the facial fit of 5000 industrial respirator wearers and will attempt to correlate this with anthropometric data.

CONCLUSIONS

1. The measurement of the facial fit of respirators should be carried out in a manner which at least attempts to simulate realistic conditions of wear.
2. For routine testing the sodium chloride aerosol method appears to have the greater ratio of advantages to disadvantages when compared with other known methods.
3. No basic difference has been found between results obtained using an aerosol and a gas as the test agents.
4. Certain gaseous test agents such as Freon 12 may have advantage over the aerosol method for particular applications.

REFERENCES

1. WEBB I J, POYNTING R and DORMAN R G
An improved sodium chloride particulate test for air conditioning filters. Filtration and Separation. November/December 1976. PP609-612
2. GRIFFIN O G, and LONGSON D T
The hazard due to inward leakage of gas into a full face mask. Anal. Occ. Hyg. Vol 13. 1970. ppl47-51
3. MOUNTCASTLE V
Medical Physiology (Part II). Morley.
4. COTES J E
Lung function. Blackwell

NaCl TEST AEROSOL BS 4400 BS 209!
PRODUCED BY ATOMISING 1% NaCl SOL AT 50 psi

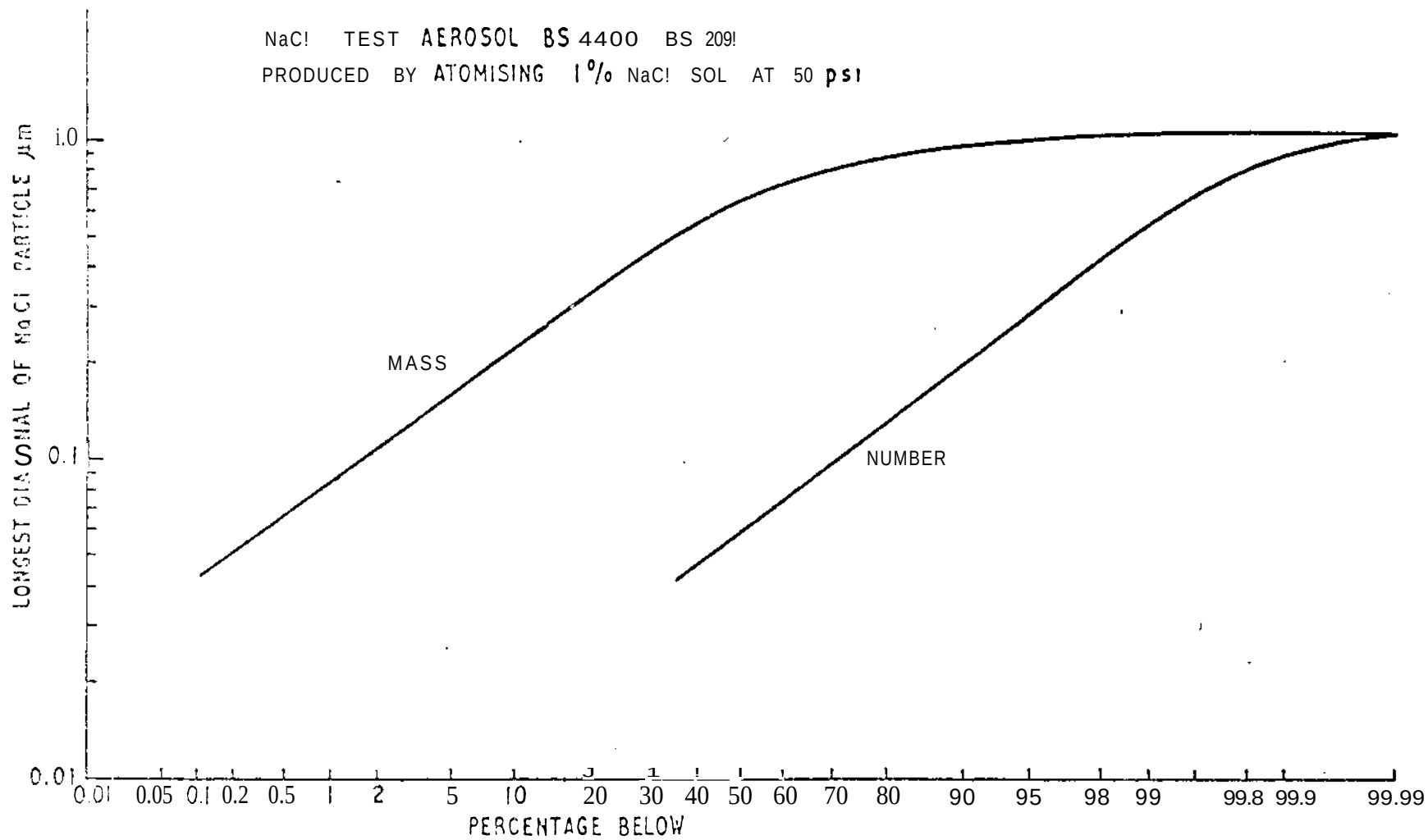


FIG.1.

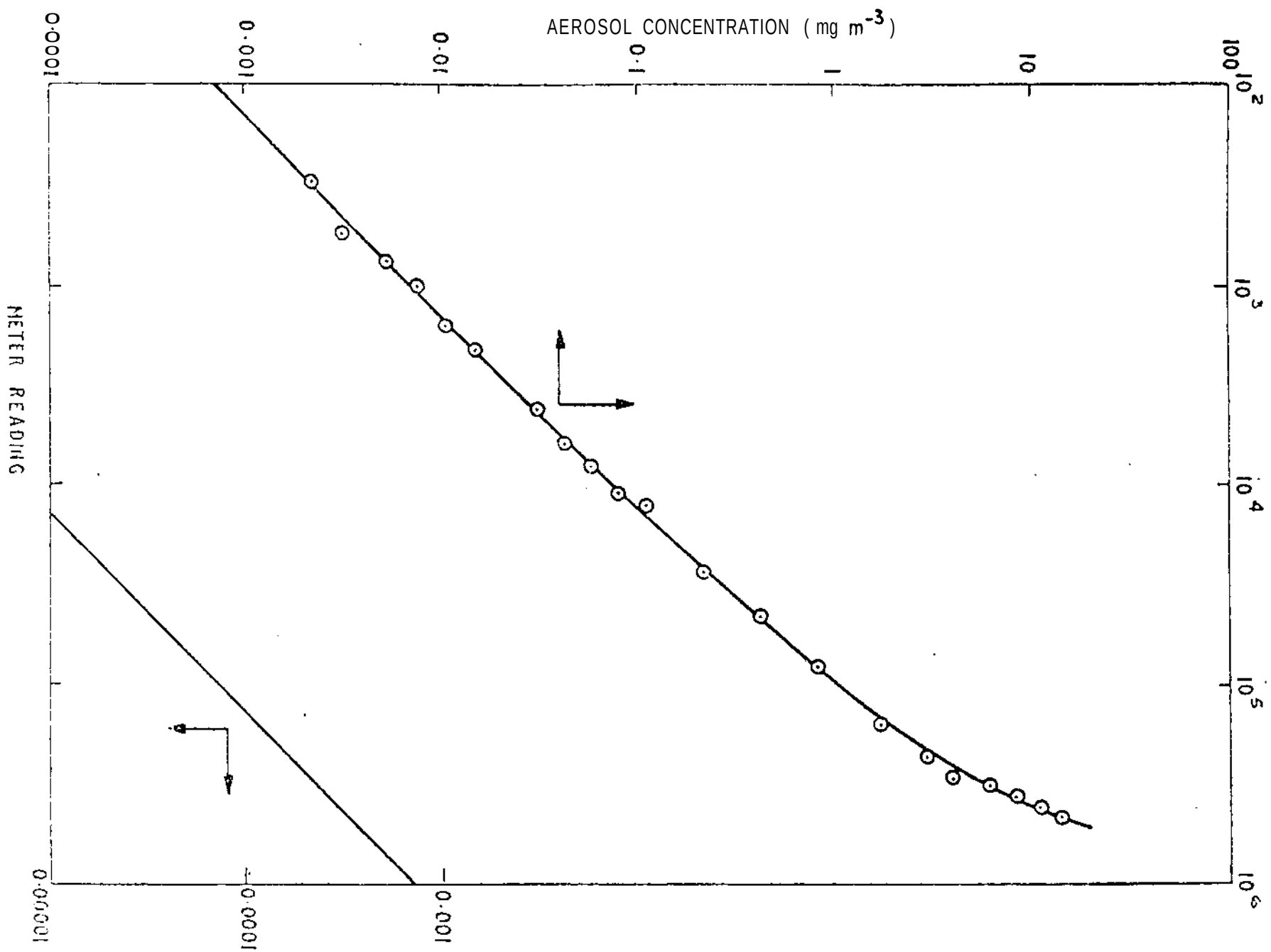


FIG. 2

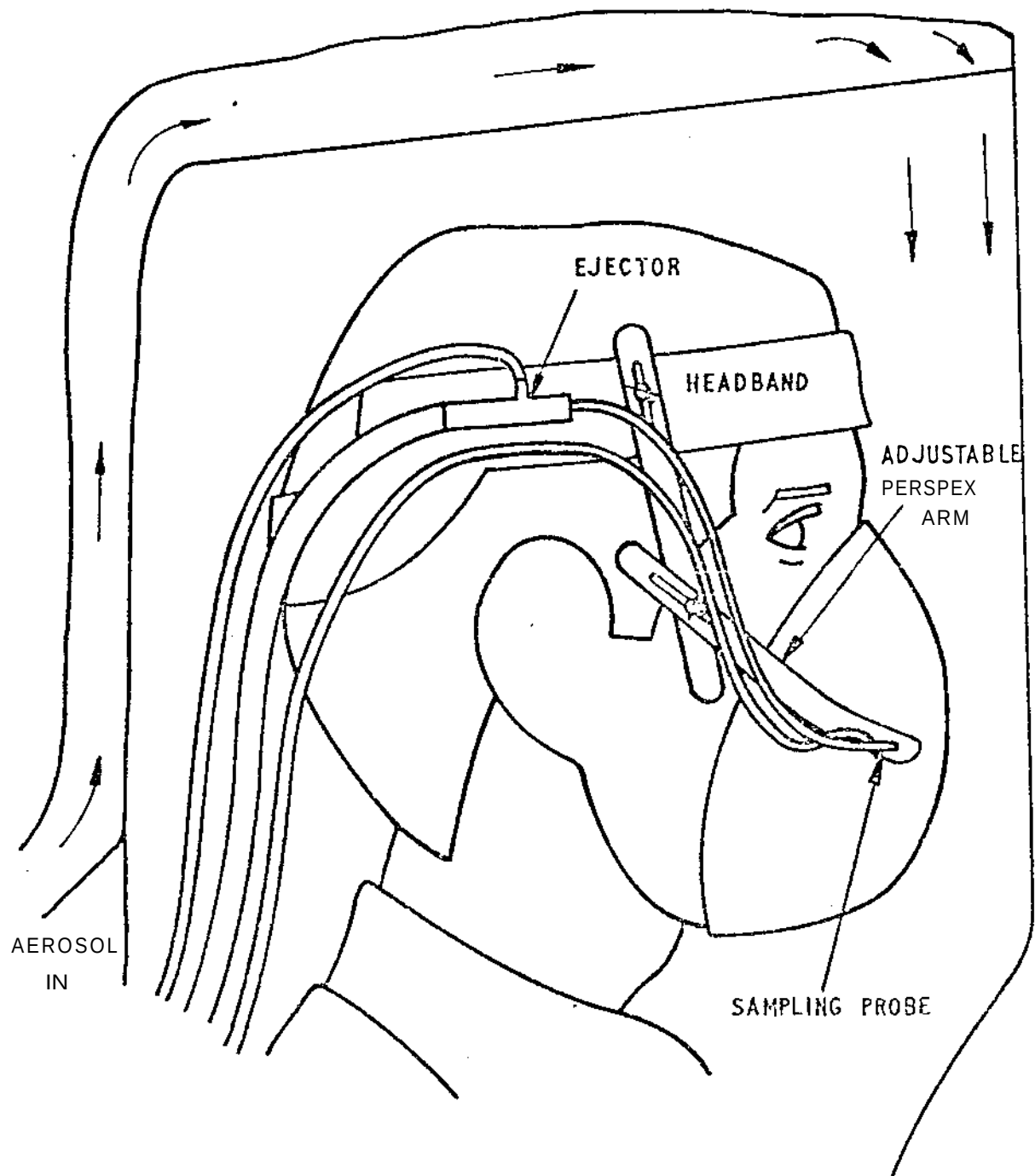


FIG. 3.

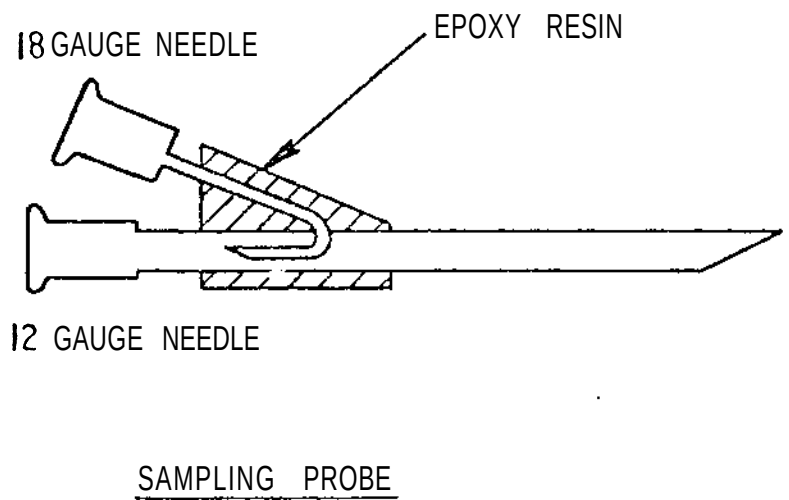


FIG. 4.

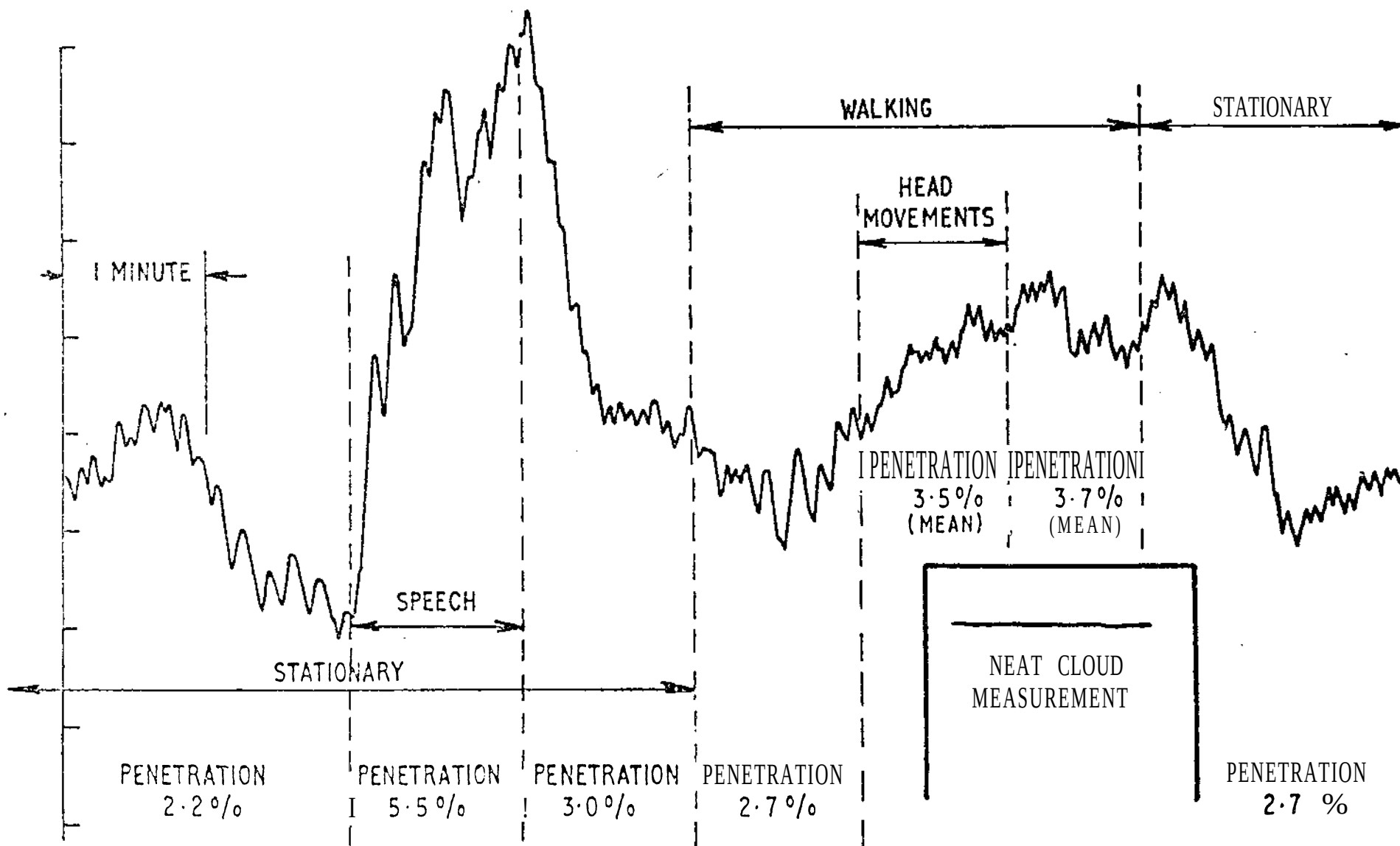


FIG 5