BIOPAC Systems, Inc.

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TSD237 Series Pneumotach Transducers & RX237 Series Flow Heads

Instructions for Use and Maintenance

CE 0473

SPECIFICATION

BIOPAC Part #		Flowhead Type	Dead Space (ml)	Linear Range L/min	Approx. Flow for 10 mm H_2O	Tube (OD mm)	Length (mm)	Weight (gm)
Transducer	Flowhead							
TSD237B/SS46LA	RX237B	F1L	0.6	± 1	1.2 L/min	5	40	14
TSD237D/SS48LA	RX237D	F10L	2	± 10	12 L/min	8	54	22
TSD237F/SS50LA	RX237F	F100L	9	± 100	90 L/min	16	54	38
TSD237H	RX237H	F1000L	320	± 1000	485 L/min	29.5	198	260

All flowheads have linearity of 5% or better in the normal range. Flow/pressure response curves are available if requested before delivery.

FLOWHEAD INSTRUCTIONS FOR USE

CAUTION! READ BEFORE USING FLOWHEAD

- Screen flowheads will not function properly if used in humidified circuits where moisture can collect on the screens and occlude them.
- Do not use in a humidified ventilator circuit for long term continuous flow monitoring.
- Never leave in a ventilator circuit unattended unless supervised by qualified personnel who are familiar with the hazard.
- Always use an antiviral filter to prevent contamination of the flowhead, or clean/disinfect or discard after use. A contaminated flowhead could infect a subsequent user.

DESCRIPTION OF TECHNIQUE

If fine wire gauze is introduced into a stream of air, the passage of air through the gauze results in back pressure being developed, which is related to the velocity of air, and to its viscosity. If the flow is laminar, the relationship is linear.

The flowheads operate as other differential pressure (ΔP) flow meters in the equations of flow that is uses. The principal theory may be stated as a mathematical law known as Poiseuille's Law which relates the volume of air flow through a tube to the differential pressure, diameter of the tube, length of the tube and the viscosity of the flowing air. This law is based upon the assumption that the air flow in the tube is laminar. Flows with a Reynold's number less than 2000 are considered laminar. The Reynold's number is a dimensionless parameter of the air flow that is used to determine if the flow is laminar or turbulent. In laminar flow, the ΔP is linearly related to the air flow volume of the flowing air, whereas for turbulent flow the differential pressure (ΔP) is related to the square of the air flow volume of the flowing air.

In the typical respiratory flow circuit, the air flow is turbulent with Reynolds number >2000. Installing a flowhead into the flow circuit will create laminar flow because the design provides many passageways in the fine mesh screen, each of which has a uniform hydraulic diameter. The degree to which this mesh screen distributes the flow profile is a function of the Reynolds number based on screen wire diameter and mesh opening hole size.

Effect of viscosity & temperature

Poiseuille's Law states that the pressure developed in laminar air flow conditions is directly proportional to the gas viscosity. Gases show an increase in absolute viscosity with an increase in gas temperature. The differential pressure for a given volume of air flow will increase as stated by Poiseuille's Law as the viscosity of the flowing air increases. The viscosity of a gas mixture can be calculated by weighted averages of the viscosities of the gases composing the mixture. For the types of gases found in respiratory circuits over the temperature range 20-40°C the fractional change in viscosity of the mixture as a function of temperature is in the range of .0025/°C. The fractional change in the volume with temperature at constant pressure is .0034/°C. When there is a temperature difference between the flowhead and the flowing gas, the correction factor will depend on the flow rate. An estimation of this correction is very difficult to make. Temperature and gas composition would have to be monitored continuously at the flowhead with corrections made to the instantaneous flow rates. Corrections can be made by calibrating with the test gas.

Effect of gas density

Gas density is not a factor in Poiseuille's Law so it will not have an affect on the ΔP of the flowhead, but it is a factor in the Reynold's number calculation and will affect the maximum flow rate for which the PNT response is linear.

USE OF PNEUMOTACHOGRAPH

The range of pneumotachograph heads give a linear relationship between flow and pressure provided certain precautions are taken and these are listed below:

1) The gauze assembly should be free from dust or other deposits.
2) Care should be taken to ensure that condensation, if it forms on the casing, cannot run down or block the flowhead pressure ports and that the pressure tubing does not twist or bend over to produce a blockage. Condensation on the gauze must be avoided at all costs - see caution below.
3) Flows through the head should be within the range stated on the data sheet. It is unlikely that damage will result to the head with overloads up to 100% but linearity will certainly fall off.
4) The passage of flow through the head must be laminar. It is advisable to ensure that no constricting elements are placed in a gas circuit, if such elements are essential, they should be at least a length equal to six head outlet diameters from the head. It would be particularly misleading if, for example, a syringe of air was to be put through a head to check the calibration of an integrator without having a reasonable length of straight tubing on the input side of the head. The air from the syringe would simply pass through the gauze at one spot instead of covering the whole area and the flow and therefore volume indicated would be in error.

CARE OF THE PNEUMOTACHOGRAPHS

As stated above, it is essential for accuracy to ensure that the gauze assembly is kept clean from contaminants and that the head itself is kept free of infectious agents. Various methods of achieving this are discussed overleaf, but whatever method is used care should be taken to ensure that the annular rings which connect to the pressure ports are also thoroughly dry before re-using the head. Washing does not affect the pressure drop produced at a given flow and therefore does not alter the instrument calibration, provided all detergent etc is removed before the heads are thoroughly dried.

CLEANING/ DISINFECTING/ STERILIZING FLOWHEADS

The accepted ground rules for the risks that medical equipment poses to patients are:

High Risk Items in close contact with a break in the skin or mucous membrane or introduced into a normally sterile body area, e.g. surgical instruments, syringes & needles, intrauterine devices and associated equipment, dressings, urinary and other catheters - **sterilization** is required.

Medium Risk Items in contact with intact mucous membranes, e.g. respiratory equipment, gastroscopes, or other items contaminated with particularly virulent or readily transmissible organisms, or if the item is to be used on highly susceptible patients - **disinfection** required.

Low Risk Items in contact with normal and intact skin, e.g., stethoscopes, washing bowls - **cleaning** and drying usually adequate.

To define the terms within the definitions above:

Sterilization is a process used to reduce an object free from all living organisms.

Disinfection is a process used to reduce the number of microorganisms but not usually of bacterial spores: the process does not necessarily kill or remove all microorganisms but reduces them to a level which is not harmful to health.

Cleaning is a process which removes contaminants including dust, soil, large numbers of microorganisms and the organic matter (e.g. feces, blood) which protects them. Cleaning is an always useful, sometimes essential, prerequisite to disinfection and sterilisation.

Decontamination is a general term for the destruction or removal of microbial contamination to render an item safe. This will include methods of cleaning, disinfection and sterilisation.

In the case of a flowhead direct patient contact is normally made using a mouthpiece, tubing or mask. There is no need to decontaminate these components as they are all single use items.

There is however concern about the possibility of contamination being deposited onto the flowhead beyond the single use items and then being available to subsequent users.

There are 3 ways of dealing with this:

1) A washer/disinfector could be used to achieve thermal disinfection. This process should be restricted a maximum temperature of 85° C and all solutions routinely used to reprocess anaesthetic equipment tubing, should be suitable. This processing should be considered between each patient and the calibration of the flowhead checked after such processing.
2) Alternatively, an antiviral filter could be placed between the patient and flowhead obviating the need to disinfect the flowhead.

   We recommend use of the Intersurgical Filta-guard filter (code 1944). This is specified by Intersurgical to be 99.999% efficient for bacterial/viral filtration. This filter is intended for use by one patient only and over a period not exceeding 24 hours. Its use must be restricted to situations approved by Intersurgical. No filter is 100% efficient so you may consider it prudent, if dealing with a patient who has a known or probable infection problem, to decontaminate the flowhead after use even when a filter has been used.
3) The flowhead could be cleaned/disinfected or sterilized as required between subjects, and a table of methods considered suitable for this is noted below for each flowhead type. Please note that your hospital's policy in this regard should take precedent over the suggestions below. If other materials are used and are found to damage a flowhead—send us the details and we will replace the head.

Flowhead Part #	Material	Autoclaving	High Energy Irradiation	Ethylene Oxide	Boiling Water
RX237B, RX237D, RX237F	ACETAL	✓	×	✓	✓
RX237H, F300L, F1000L	ABS	×	✓	×	×

MATERIALS USED AND RANGE INDICATED

All flowheads in this range use a stainless steel mesh as the resistive element.

DEMOUNTABLE FLOWHEADS TYPE RX237H AND F300L

These flowheads, although large, are light in weight as their casings are formed in plastic. The construction is such that they can be dismantled with ease to give good access to the interchangeable gauze assembly. The F1000L is formed from acrylic while the RX237H is formed from ABS and is suitable for adults during exercise and for certain types of lung function test.

Spare parts: twin tubing, gauze assembly F1000LSG.

SEMIDISPOSABLE FLOWHEAD TYPE F300L

This head is injection moulded in ABS and comes as a complete single unit. Although it will stand frequent washing, if the head does become excessively fouled (or infected) it can be discarded altogether and replaced for little cost. It is intended to cater for most adult applications, with the exception of hard exercise and certain lung function tests.

Spare parts: twin tubing.

DEMOUNTABLE FLOWHEADS TYPE RX237B, RX237D, RX237F

These heads are machined from acetal to give good stability with low weight and have found application in pediatrics and in the respiration measurement of animals such a dogs, cats, rats, and mice. As with head types F1000L and RX237H, interchangeable gauze assemblies are available.

Spare parts: twin tubing, gauze assemblies F1LSG, F10LSG of F100LSG.

All instruments' current range have linearity of 5% or better in the normal range. Flow/pressure response curves are available if requested before delivery.

CAUTIONS

One of the problems that has been encountered with pneumotachographs is condensation from expired air. This can be prevented by fitting a non-return valve and measuring only inspiration or alternatively by heating the flowhead, but viscosity errors may arise which, in the first few breaths especially, preheat the inspired air most uncomfortably. In this range of heads the problem is approached from a fresh angle. By mounting a fine stainless steel gauze in plastic rings the thermal inertia is greatly reduced. The gauze therefore rapidly equilibrates in temperature with passing air and condensation is minimal.

Should condensation start to form on the gauze assembly, calibration will be affected and in extreme cases complete blockage of the flow path may result. If condensation does start to form, use of the head must be discontinued until it is replaced with another head or the existing head is thoroughly dried out.