gm instruments Ltd

NV1 Rhinospirometer

User Guide
Version 8

CE 0473

NV1 Rhinospirometer Safety Information

WARNINGS/CAUTIONS

FLOWHEADS

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.

NOSEPIECES

The nosepieces are made of a material, which may cause an irritation reaction in some patients. Use of the nosepiece should be discontinued in patients who exhibit such a reaction.

Federal (USA) law restricts this device to sale by or on the order of a physician.

The use of an NV1 Rhinospirometer near to sources of electromagnetic radiation, such as mobile phones, radio transmitters, x-ray equipment etc, may prevent it from functioning correctly.

The NV1 Rhinospirometer is a medical instrument, which is classified as a Class 1 Type B device. A Class 1 Type B device categorisation is used to describe an instrument which:-

a) Does not rely on basic insulation only to provide protection against electrical shock but is constructed in such a way that accessible metal parts cannot become live in the event of failure of the basic insulation and

b) Applied parts offer protection to the subject against electrical shock and in the event of a single fault condition arising, leakage current will be limited to less than 0.5 mA.

Any incident which results in actual or potential injury or death to a subject while using NV1 should be immediately communicated to GM Instruments at the address below.

Servicing
Servicing can only be carried out by GMI approved and authorised personnel.

Storage
The NV1 Rhinospirometer and its accessories should be stored within the following temperature and humidity range:-

Temperature	-40°C to + 60°C
Humidity	20 to 80% RH non condensing

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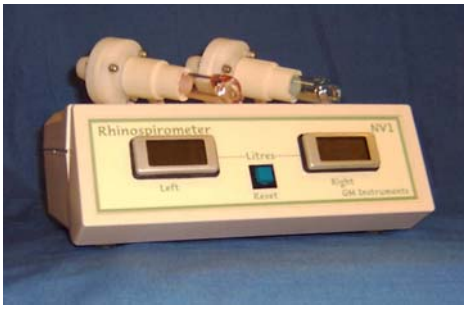


NV1 with Flowheads

USB Interface

Conical Nosepiece

Anatomical Nosepiece

INTRODUCTION

The NV1 Rhinospirometer has been developed to measure the partitioning of airflow between the two nasal passages. The patient breathes through two nasal adapters and the volume of air breathed from each side of the nose is measured over a single breath or over several breaths (several recommended). A nasal partitioning ratio (NPR) can be easily calculated from the nasal volumes obtained. (see below)
Measurement of NPR allows an objective measurement of the severity of nasal septal deviation and is also useful for studies on the nasal cycle and rhinitis.

The method is based on the following principle:

During a breathing manoeuvre a negative or positive pressure is created at the back of the nose, which is automatically applied equally to both sides of the nose. This pressure acts on the nasal passages to produce a flow rate, which will be in proportion to the pressure applied and the resistance to airflow in the passage.

By integration of these flows the volume of air passed through each of the nasal cavity can be calculated and displayed.

The nasal partitioning ratio (NPR) can be calculated from the following formula:-
NPR= Lvol-Rvol/Rvol+Lvol
where Lvol is the reading from the left side meter and Rvol is the reading from the right side meter.

A value of –1 equates to a complete obstruction of the left side , while a value of +1 equates to a complete obstruction of the right side.

Clinical work reported in Rhinology, 41, 11-15, 2003 suggests that values smaller than –0.3 to +0.3 are normal while figures greater than that indicate a degree of asymmetry, which may benefit from surgery.

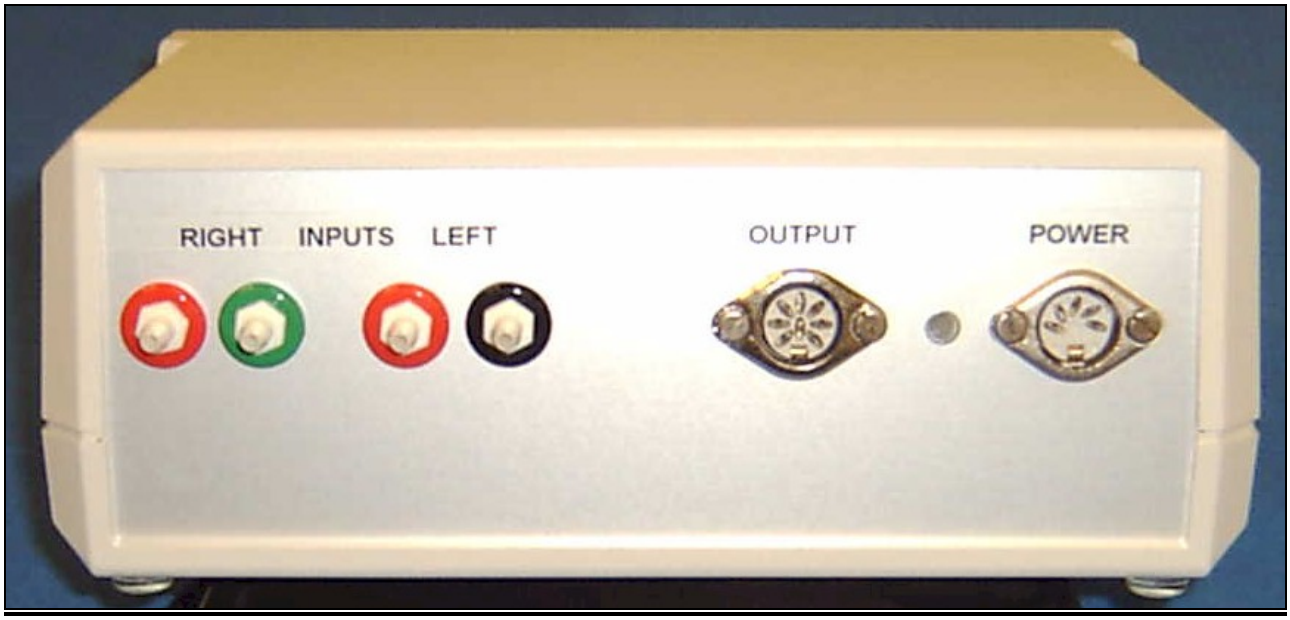
The method has been developed in association with Prof. Ron Eccles at the Cold Research Centre, University of Cardiff, and readers are referred to the list of publications contained on page 18.

INSTALLATION

Installing the NV1

(For PC connected units, see the accompanying Software Guide)
The NV1 Rhinospirometer will work when its Power Unit is connected to any standard mains voltage and frequency (eg 110/220/240 Volts 50/60 Hz) and the output of the Power Unit is connected to the socket on the back of NV1.

WARNING An electrical shock hazard exists. Care should be taken when handling any of the power components



Connecting the flowheads
Connection between the NV1 box, and the flowheads is by means of two pairs of twin tubing. This tubing has colour coded ends to ensure correct polarisation.

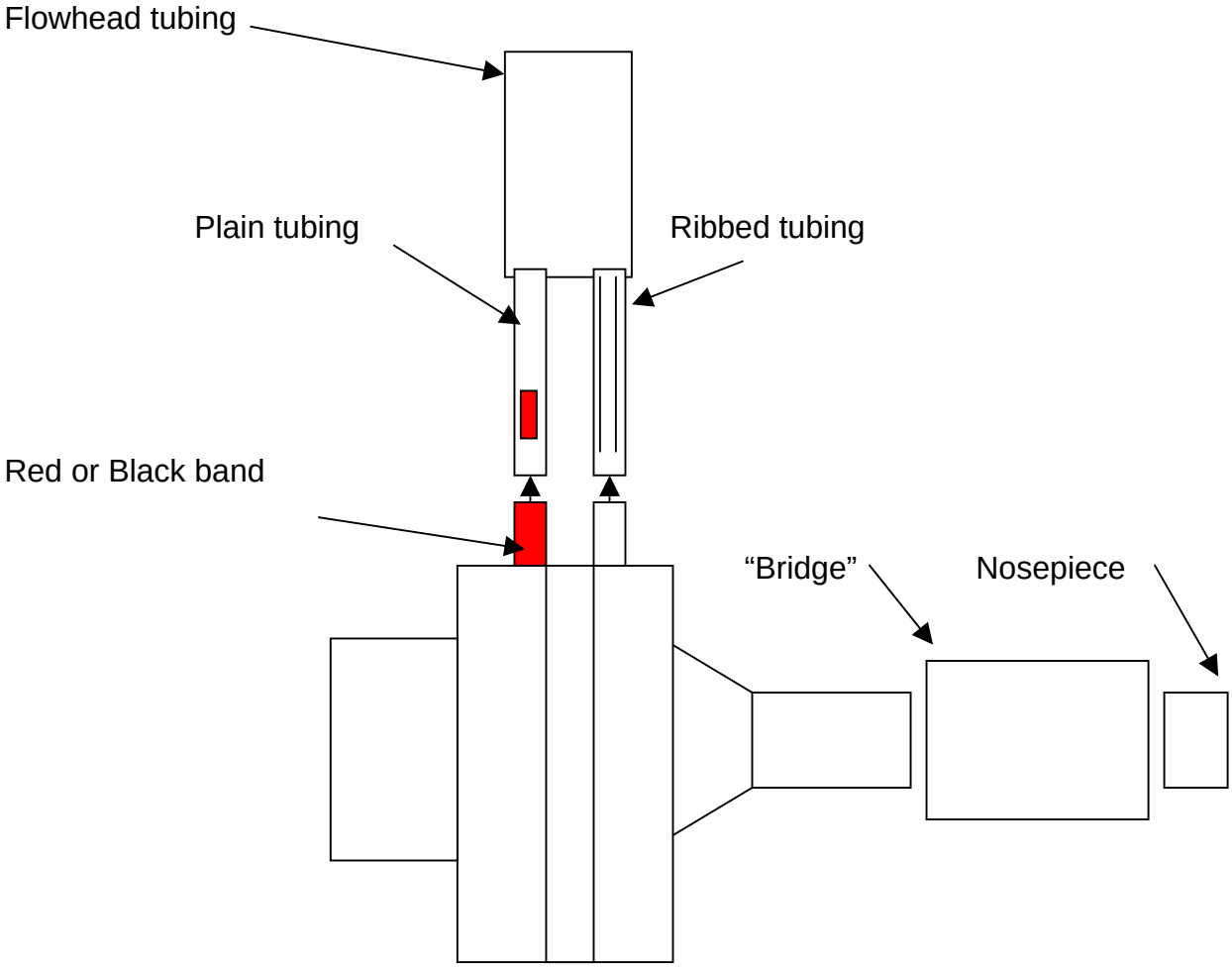
If incorrectly connected an NV1 meter could show left side results as right and right side results as left. It could also read inspiratory values instead of expiratory or vice versa.

The flowheads are marked not only for correct twin flow tube polarisation but also for side. The flowhead marked LEFT should be connected to the ports at the back of NV1 marked LEFT. The flowhead marked RIGHT should be connected to the ports at the back of NV1 marked RIGHT.

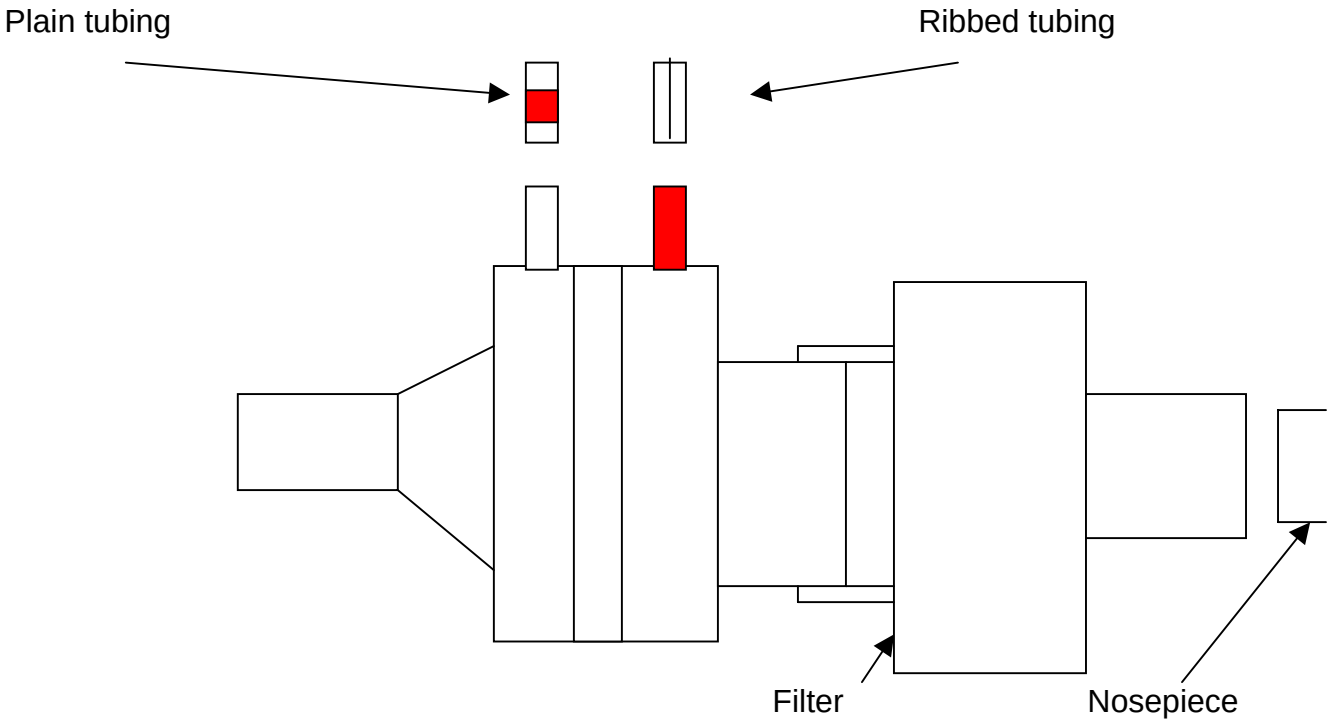
One side of each flowhead should be connected to a nosepiece, using the “bridge” adaptor supplied or through standard anti viral filters. (which may require an alteration to the “polorisation” of the flowhead and the marking on one of its associated tubes.
The nosepieces are coded as follows:-
RIGHT (colour coded red and stamped D) or
LEFT (colour coded blue and stamped S)

A diagram follows on the next page, which shows how to connect the tubing, the “bridge” and the nosepiece for expiratory measurements and the changes required to measure inspiration and to fit an antiviral filter to the system.

NV1 can then be switched on and allowed to warm up for 5 minutes prior to use.



NB An antiviral filter can be used in place of the "Bridge". To connect such a unit, which has standard anaesthetic size couplings, it may be necessary to reverse the flowhead as shown:=



TO MAKE AND RECORD MEASUREMENTS

Having become familiar with the hardware you are now ready to record measurements.

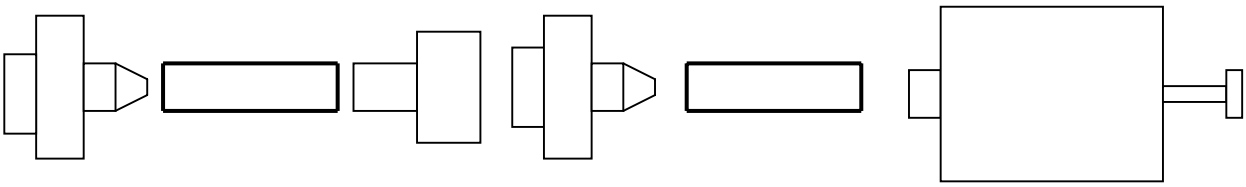
Calibration
Operation of the unit can be easily checked without any additional equipment, or calibrated by using a known volume syringe.

Quick performance check:-
If the flowheads are connected in series and room air is drawn through them simultaneously at a rate lower than 800 cc/second, both meters should read the same number. If they do read the same or within a couple of digits of each other, then the system is ready for use.
It is possible that both are out of calibration by the same amount, but the likelihood of that happening is very remote. If however a full calibration is required then the process is as follows:-

Full Calibration check and adjustment:-
If the flowheads are connected in series and room air is drawn through them simultaneously, using a syringe of known volume, and at a rate lower than 800 cc/second, (a very slow draw) both meters should read the volume drawn by the syringe. If they do read the same volume as the syringe used to produce the reading, or within a couple of digits of that volume, then the system is ready for use.
If they don't read the level they should, according to the syringe, adjustment to the calibration can be made using presets inside NV1 marked VR5 - RIGHT and VR2 - LEFT. Having made a change to the calibration it is good practice to repeat the calibration check again to confirm the correction.

The system is now ready for use.

Flowheads in series ready for calibration or calibration check



Flowhead - Bridge - Connector-Flowhead - Bridge - Syringe

Patient preparation

The patient should be prepared, prior to testing, by having them in a quiet stable environment for 15 to 20 minutes. If your interest is surgical and you want to look at structure, they should be decongested and asked to blow their nose prior to measurement.
If your interest is in monitoring response to a decongestant or to an allergen then again the patient should be asked to blow their nose prior to measurement.

Which nose piece?

The nosepieces supplied with NV1 are in 2 sizes (medium & large).
These are handed i.e. one is for use on the
right side (marked D or colour coded red) and one for the
left side (marked S or colour coded blue).
NB the caution statement on page 2 at the front of this manual.
The choice of nosepiece depends on which will give the best seal between the nosepiece and the nose, with the minimum distortion.

The anatomical probes are designed to sit on the outside of the nose and are shaped to make it easy, in most circumstances, to get a good seal. In addition they have a flange onto which can be put a soluble gel, to take up any remaining gap.

An alternative conical shaped nosepiece is also available, which has the advantage that it is not “handed” and can be used on either left or right sides.
It may be easier to achieve a seal with this kind of nosepiece, but they do tend to cause distortion of the nasal valve area and should not be used if your investigations involve assessments of nasal valve function.

Making measurements

1) Have the patient sit erect in a chair (some workers advocate use of an adjustable forehead and chin rest) and ask them to mouth breathe.
2) Apply the nosepieces (perhaps suitably prepared with gel) to the nose, with the pointed ends of each flange pointing towards each other, if you are using anatomical nosepieces. The nosepieces can be held by the patient, or by the clinician but we believe this is best left to the patient.
3) When suitably positioned, press the reset button on the front of NV1 and ask the patient to close their mouth and gently take a breath in through their nose, or a series of breaths in and out through their nose until a volume of 3 litres has been "collected" on one side.
4) If values have been recorded ok, ask the subject to remove the nosepieces and return to mouth breathing.
5) The operator then has to write down the figures displayed, which should remain stable. If they start to decrease, then there is negative integrator drift. If they start to increase, then there is either positive integrator drift, transducer drift, droplets of liquid in the tubing or kinked tubing. If the values are stable, note the meter readings and press the reset button. The above process can be repeated if desired, from 2) above.

The absolute values of the volumes achieved are not normally considered to be very significant, rather the ratio of LEFT to RIGHT is what is of interest as that directly relates to the degree of obstruction on one side relative to the other.

The formula for calculating NPR can be found on page 4 of this manual.

Factors which affect absolute accuracy

Measurement accuracy and repeatability will depend on the following:-

Calibration:-	Relative levels at least, should be regularly checked (see quick check note on Page 8)
Temperature:-	Use equipment in controlled conditions between 18 & 22°C.
Rigidity of nosepiece	Try not to move.
Effect of nosepiece on the nose:-	Avoid distortion.
Patient cooperation:-	Mouth breath before and after measures.
Nosepiece/nose seal:-	Use gel and careful positioning to ensure seal.
Check for leaks/Distortion:-	Repeat test at least twice if not 3 times and check for variation i.e. apply/remove probe 2 or 3 times, testing each time and compare ratio. (not absolute values)

MAINTENANCE

NV1 Overview

The NV1 Rhinospirometer should be calibrated regularly if absolute values are important. If not then a relative calibration check can be made as described earlier to ensure that if the same flow is passed through both heads simultaneously, then the same values are achieved. In addition to this the cables, tubes and flowheads should be regularly inspected for signs of damage or contamination.

The nosepieces supplied are for single use only. Care should be taken in use to prevent the passage of nasal secretions down the nosepieces and into the flowhead. Should this occur, the flowhead should be cleaned by one of the methods described below and then thoroughly dried prior to calibrating and using.

Flowheads

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 GMI 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 airflow 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 airflow that is used to determine if the flow is laminar or turbulent. In laminar flow, the ΔP is linearly related to the airflow volume of the flowing air, whereas for turbulent flow the differential pressure (ΔP) is related to the square of the airflow volume of the flowing air.

Installing a GMI 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 airflow 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 airflow 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. The use of room air at about 20 °C drawn through the flowhead during the inspiratory manoeuvre removes the need to make the corrections discussed above.

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 GMI 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 kept below 800 cc/second (48 Litres/minute.)
4) The passage of flow through the head must be laminar. It would be particularly misleading if for example, a syringe with a small outlet diameter was used to put a known volume of air through a flowhead to check the calibration of NV1. 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. NV1 can be used to record a single large inspiratory manoever, which helps to avoid contamination, but much of the published work shows it being used to record a series of inspirations or expirations with air passing through the head in both directions. Should cleaning become necessary, 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 within the flowhead, 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/ STERILISING FLOWHEADS/NOSEPIECES

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 - **sterilisation** 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, eg stethoscopes, washing bowls - **cleaning** and drying usually adequate.

To define the terms within the definitions above:

Sterilisation 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 (eg faeces, 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 NV1 direct patient contact is made with a nosepiece, which is a single use component. There is no need to decontaminate these, as they are 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 2 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 sterilised as required between subjects and a table of methods considered suitable for this is noted below for each flowhead type. Please note that your hospitals 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.

Material	Flowhead Type	Autoclaving	High Energy Irradiation	Ethylene Oxide	Boiling Water
ACETAL	**MF100L**	**N**	**N**	**Y**	**N**

MATERIALS USED AND RANGE INDICATED

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

DEMOUNTABLE FLOWHEADS TYPE MF100L

These heads are machined from acetal to give good stability with low weight. Interchangeable gauze assemblies are available.

Spare parts:- twin tubing, gauze assemblies F100LSG.

SPECIFICATION

FLOWHED TYPE	LINEAR RANGE cc/sec	APPROX. FLOW for 10mm WG	TUBE OUTSIDE DIAMETER	LENGTH mm	WEIGHT gm
MF100L	± 800	700 cc/sec	16 mm	54	38

The MF100L has linearity of 3% or better in the normal range.

CAUTIONS

One of the problems that has been encountered with pneumotachographs is condensation from expired air. This can be prevented by measuring only inspiration as in NV1 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 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.

Spare Parts and Accessories.

NV1/PRM	Medium anatomically conformed nosepiece
NV1/PRL	Large anatomically conformed nosepiece
NV1/PR8	Small size conical nosepiece
NV1/PR10	Medium size conical nosepiece
NV1/PR12	Large size conical nosepiece
NV1/Power Unit	Universal PCM50ut04
MF100L	Respiratory Flowhead
Flowhead tubing	Supplied by the metre length (Right or Left)
“Bridge” Tubing	Supplied in pairs

Instrument cleaning / decontamination procedure

Enclosure

Should the enclosure require cleaning for any reason, unplug it from the PC and wipe it with a damp cloth, or a cloth soaked in a mild alcohol based solution or cleaning wipes. Do not allow liquid to run into the enclosure.

Flowheads/tubing

If used for a single large inspiratory measurement, with the disposable nosepieces supplied, no routine cleaning is believed necessary.

If used with antiviral filters, disposable nose pieces and bi directional flow, no routine cleaning is believed necessary.

If in the course of use the flowhead does become contaminated, it can be cleaned as discussed earlier in this manual.

Electrical Information.
Factory-trained personnel or engineers familiar with the standard EN 60601 can only undertake servicing of the NV1 Rhinospirometer. Circuit diagrams will be made available to competent persons on request.

Specification:-

Size 21x08x15 cm		Weight 2Kgm
Supply Voltage		universal.
Supply Power consumption....		3 Watts
Repeatability		better than 2% FSD
Volume accuracy (0 to 5 litres)		better than 3% FSD
Standards	Electrical	BS EN 60601:1996
	EMC	BS EN 60601-1-2;2002
Warm up time		5 minutes
Operating temperature		+ 15 to + 35°C
Operating humidity		20 to 80% RH NC
Duty cycle		Continuous

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References:-
Cuddihy PJ, Eccles R. The use of nasal spirometry as an objective measure of nasal septal deviation and the effectiveness of septal surgery. Clin Otolaryngol 2003;28(4):325-30.

Cuddihy PJ, Eccles R. The use of nasal spirometry for the assessment of unilateral nasal obstruction associated with changes in posture in healthy subjects and subjects with upper respiratory tract infection. Clin Otolaryngol 2003;28(2):108-11.

Hanif J, Eccles R, Jawad S. The use of a portable spirometer for studies on the nasal cycle. American Journal of Rhinology 2001;15:303-306.

Hanif J, Jawad SS, Eccles R. A study to assess the usefulness of a portable spirometer to quantify the severity of nasal septal deviation. Rhinology 2003;41(1):11-5.

Roblin DG, Eccles R. Normal range for nasal partitioning of airflow determined by nasal spirometry in 100 healthy subjects. Am J Rhinol 2003;17(4):179-83.