GM INSTRUMENTS

Naris

User Manual

V12

CE 0473

TABLE OF CONTENTS

NARIS SAFETY INFORMATION

NR6 RHINOMANOMETER SAFETY INFORMATION

Read this Operating Manual before attempting to use the Instrument.

WARNINGS

This instrument is for indoor use only and it should be used as described in this manual.

The system must not be used in the presence of flammable gases or in an environment which is susceptible to explosions (Beware of oxygen, dust, and anaesthetic gases)

To avoid risk of electric shock, the PC, if connected to a mains supply must be connected to a mains supply with a protective earth.

The unit is a PC-connected product. It is advisable not to touch the patient whilst using the equipment.

The equipment should be positioned in such a way that it can be easily disconnected from a mains-powered PC. The operation of the system can be safely terminated by switching off the PC, or removing the USB cable between the PC and the NR6

If your PC or printer does not have a power supply approved for a patient environment, then an isolation transformer, which complies with BS EN 60601-1, should be used to power the PC, Printer. You must use the transformer or run the PC by battery to ensure that the NR6 is in compliance with BS EN 60601-1.

Applied Parts. The applied parts consist of single-use foam inserts, microfoam tape, tip connectors, anterior or posterior tubing, masks (single-use /or reusable) connected to an antiviral filter, flowheads and silicon rubber tubing.

CAUTIONS

Patient connection components may cause an irritation reaction in some patients. Use of such components should be discontinued in patients who exhibit such a reaction.

Certain components are identified as single-use items. Single-use items should not be reused as they could carry infections between subjects

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

The use of an NR6 Rhinomanometer near to sources of electromagnetic radiation, such as mobile phones, radio transmitters, x-ray equipment etc, may prevent it from functioning

correctly. Appendix 1 provides guidance on the Electromagnetic environment in which to operate the instrument.

The NR6 Rhinomanometer is a medical instrument, which has an electrical classification of Class I Type B and a Medical Device Directive Classification of Class I with a measuring function.

A Class I 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 an NR6, should be immediately communicated to GM Instruments at the address on page 7.

NR6 should only be connected to other mains-powered devices such as computers and printers, which comply with EN 60950-1 and we also advise the use of a separating transformer. Unless computers and printers built to EN 60950 are used, patient safety might be compromised.

Non-medical equipment such as computers and printers should be kept out of reach of subjects being tested as such equipment does not comply with medical safety standards. Refer to clause 16 of EN 60601-1:2006 to ensure compliance.

If the PC is allowed to go into sleep mode, the USB interface is powered down. When brought out of sleep mode, the PC does not re-initialise the USB interface, and therefore it is effectively not present. A solution is to remove the USB connection at the PC or instrument side then re-connect. That may be sufficient, but if not - save any results, then close down the instrument software and restart it.

Servicing can only be carried out by GMI approved and authorised personnel. No modifications are allowed.

Storage
The A1/NR6 and its accessories should be stored within the following temperature and humidity ranges:

Temperature	-40 ^{o}C to +60 ^{o}C
Humidity	20% to 80% RH non-condensing
Pressure	50 kPa to 106 kPa

Standardisation Document:
Customers are referred to the under-noted publications which contain recommendations on the use of Rhinomanometers.

Committee report on Standardisation of Rhinomanometry. Rhinology 1984:Vol 22, 151-155.

NR6 RHINOMANOMETER TECHNICAL SPECIFICATIONS

Only factory-trained personnel or engineers familiar with the standard EN 60601 can undertake servicing of the NR6 Rhinospirometer.
Circuit diagrams will be made available to competent persons on request

Medical CE Mark	The CE mark indicates that the device meets the requirement of Annex V & VII of the Medical Device Directive 94/42/EEC	
Standards	Safety	BE EN 60601-1 :2006
	EMC	BS EN 60601-1:2007
Performance	Flow Range	+/- 800 cc/sec
	Pressure Range	+/- 800 Pa
	Accuracy	+/- 2%
Operation Environment	Temperature	+15 °C to +35 °C
	Relative Humidity	20% to 80% RH non-condensing
	Pressure	50 kPa to 106 kPa
	Duty Cycle	Continuous
	Warm Up Time	5 minutes
	Supply	USB taken from PC
Transportation and Storage	Temperature	-40 °C to +60 °C
	Relative Humidity	20% to 80% RH non-condensing
	Pressure	50 to 106 kPa
Mechanical Performance	Size	27 x 8 x 30 cm
	Weight	2 Kg

TABLE OF SYMBOLS USED

The following symbols appear on the NR6

Symbol	Meaning	Socket Type	Location	Connected Part
	Refer to Instruction Manual ISO7010-M002	USB Connector Type B	Instrument Back Panel	Computer (Via USB port)
	Type B Applied Parts IEC 60417- 5840	Tubing Connectors Flow and Pressure	Instrument Front Panel	Flow head Assembly
	Protective Earth IEC 60417 - 5019	–	Instrument Back panel - Internal	–

For connected parts marked * only connect the accessories supplied with the instrument. These parts have been tested for use with the instrument for compliance to standards IEC 60601-1 and IEC 60601-1-2.

Symbols used on labelling and packaging, as for A1, but with the following additions:

Symbol	Meaning	Location
	Do not re-use IEC7000-1051	Consumables Packaging- Filter, Nasal Inserts
	Non- sterile ISO7000-2609	Applied parts packaging- Flowhead Assembly

A1 ACOUSTIC RHINOMETER SAFETY INFORMATION

Read this Operating Manual before attempting to use the Instrument.

WARNINGS

This instrument is for indoor use only and it should be used as described in this manual.

The system must not be used in the presence of flammable gases or in an environment which is susceptible to explosions - beware of oxygen, dust, and anaesthetic gases.

To avoid risk of electric shock this equipment must be connected to a mains supply with a protective earth.

If your desktop PC or printer does not have a power supply approved for a patient environment, then an isolation transformer, which complies with BS EN 60601, should be used to power the PC, printer, and the A1 Acoustic Rhinometer. You must use the isolation transformer to ensure that the A1 Acoustic Rhinometer is in compliance with BS EN 60601.

As this is a mains-powered, PC-connected product it is advisable to not touch the patient while using the equipment.

The equipment should be positioned in such a way that it can be easily disconnected from the mains supply. The operation of the system can be safely terminated by switching off the device or removing the mains plug.

The applied part is the nosepiece, which is marked for single use. It should not be re-used, as no method of sterilisation can be guaranteed - disinfection materials may not be effective and may leave a residue, which could be harmful.

CAUTIONS

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

Nosepieces are a single-use item. Single-use items should not be reused as they could transfer infections between subjects.

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

The use of an A1 Acoustic Rhinometer near to sources of electromagnetic radiation, such as mobile phones, radio transmitters, x-ray equipment etc., may prevent it from functioning correctly.

The A1 Acoustic Rhinometer is a medical instrument, which has an electrical classification of Class l Type B and a Medical Device Directive classification of IIa.

A Class l 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 an A1 should be immediately communicated to GM Instruments at the address on page 6.

An A1 should only be connected to other mains-powered devices such as computers and printers, which comply with EN 60950-1 and we also advise the use of a separating transformer. Unless computers and printers built to EN 60950 are used, patient safety might be compromised.

Non-medical equipment such as computers and printers should be kept out of reach of subjects being tested as such equipment does not comply with medical safety standards. Refer to clause 16 of EN 60601-1:2006 to ensure compliance.

If the PC is allowed to go into sleep mode, the USB interface is powered down. When brought out of sleep mode, the PC does not re-initialise the USB interface, and therefore it is effectively not present. A solution is to remove the USB connection at the PC or instrument side then re-connect. That may be sufficient, but if not, save any results, then close down the instrument software and restart it.

Servicing can only be carried out by GMI approved and authorised personnel. No modifications are allowed.

Storage
The A1 Acoustic Rhinometer 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
Pressure	50 kPa to 106 kPa

Standardisation Document

Customers are referred to the under noted International Standardisation Committee publication which contains recommendations on the use of Acoustic Rhinometers.

Acoustic Rhinometry: Recommendations for technical specifications and standard operating procedures.
Rhinology supplement number 10, December 2000
Ole Hilberg and Ole Pedersen

A1 ACOUSTIC RHINOMETER TECHNICAL SPECIFICATIONS

Only factory-trained personnel or engineers who are familiar with the standard EN 60601 can undertake servicing of the A1 Acoustic Rhinometer.
Circuit diagrams will be made available to competent persons on request.

Medical CE Mark	The CE mark indicates that the device meets the requirement of Annex V & VII of the Medical Device Directive 94/42/EEC	
Standards	Safety	BE EN 60601-1 :2006
	EMC	BS EN 60601-1:2007
Performance (using standard nose)	Repeatability	Better than 2%
	Volume Accuracy (0cm to 5cm)	Better than 2%
	Minimum Area Accuracy (within 0cm to 5cm)	Better than 5%
	Area Range (max 20, default 10)	0.1 cm^2 to 10 cm^2
	Distance Range (using standard sound tube)	0 cm to 12 cm
	Calibration	Self - calibrating
Operation Environment	Temperature	+15 °C to +35 °C
	Relative Humidity	20% to 80% RH non-condensing
	Pressure	50 kPa to 106 kPa
	Duty Cycle	Continuous
	Warm Up Time	5 minutes
	Supply	Universal voltage – external supply
	Power	10 Watts
Transportation and Storage	Temperature	-40 °C to +60 °C
	Relative Humidity	20% to 80% RH non-condensing
	Pressure	50 kPa to 106 kPa
Mechanical Performance	Size	27 cm x 8 cm x 30 cm
	Weight	2 Kg

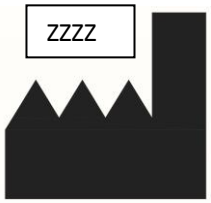
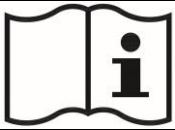
TABLE OF SYMBOLS USED

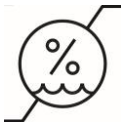
The following symbols appear on the A1 or the mains adaptor:

Symbol	Meaning	Socket Type	Location	Connected Part
	Refer to Instruction Manual ISO7010-M002	USB Connector Type B	Instrument Back Panel	Computer (Via USB port)
		5-Pin Din Socket	Instrument Back Panel	Mains AC/ DC Adaptor PCM50UT04*
	Type B Applied Parts IEC 60417- 5840	JIS C 5432-Compliant 5-Pin Socket	Instrument Front Panel	Sound Tube
	Protective Earth IEC 60417 - 5019	–	Instrument Back panel - Internal	–
	Direct Current IEC 60417 - 5931	–	Mains Adaptor AC/DC	–

For connected parts marked * only connect the accessories supplied with the instrument. These parts have been tested for use with the instrument for compliance to standards IEC 60601-1 and IEC 60601-1-2.

Symbols used on labelling and packaging:

SYMBOL	MEANING	LOCATION
	Date and Manufacturer Where ZZZZ: Date of Manufacture ISO7000-3082	Instrument Label
	Serial Number ISO7000-2498	Instrument Label
	Consult Instructions for Use ISO7000-1641	Instrument Label
	Council Decision 93/465/EC. Annex B(d)	Instrument Label

	Do not re-use IEC7000-1051	Consumables Packaging- Nosepieces
	Non- sterile ISO7000-2609	Applied parts packaging- Nosepieces
	Temperature Limit ISO7000-0632	Instrument Shipper Packaging
	Humidity Limitation ISO7000-2620	Instrument Shipper Packaging
	Mandatory Action Sign ISO 7010- M001	Operating Manual

ADDRESS AND CONTACT DETAILS:

MANUFACTURED BY:

G M INSTRUMENTS LTD,
UNIT 6 ASHGROVE
ASHGROVE ROAD,
KILWINNING,
KA13 6PU,
UK

TEL: +44 (0)1294 554664
FAX: +44 (0)1294 551154
EMAIL: enquiries@gm-instruments.com
WEBSITE: www.gm-instruments.com

INSTALLATION

SOFTWARE

Installation of the NR6 Software is described fully in the accompanying manual titled "**NARIS Software Manual"**

INSTALLING THE NARIS HARDWARE

NR6 HARDWARE CONNECTIONS

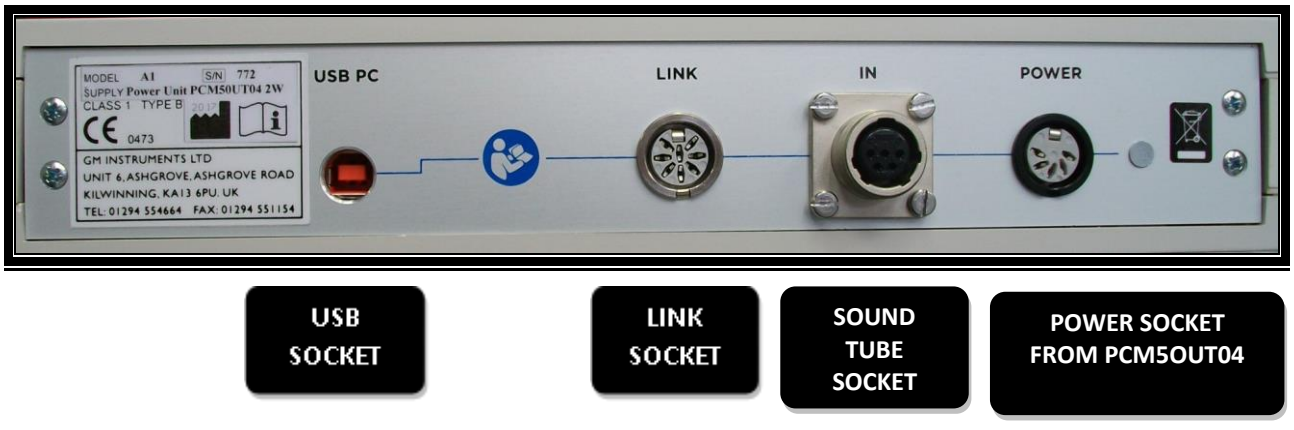
Please see the pictures below for the NR6 hardware connections:

NR6 front view - flowhead and pressure connections

Back panel view showing a link cable socket to A1 and USB socket

The NR6 box has four nozzles on it, which are colour coded: Black is the pressure input, Blue is the pressure reference, Red is the positive flow input, Green is the negative flow input.
Connect each tube onto the input nozzle with the corresponding coloured marker, i.e. black -> black, red -> red etc.
Connect the free ends of the tubes to their corresponding coloured markers – green and red tubes onto the green and red nozzles on the flowhead, and the tube marked blue onto the mask port marked blue. If you are going to be making posterior tests, the tube marked black will also go onto the mask nozzle marked black, but if you are going to make anterior measurements, it will go onto an anterior tube connector. In this case the mask nozzle marked black should be closed, using the plug provided

A1 HARDWARE CONNECTIONS



USB SOCKET

LINK SOCKET

SOUND TUBE SOCKET

POWER SOCKET FROM PCM5OUT04

A1 back panel view showing USB socket, which connects to the PC, a link socket, which connects to an NR6 link socket, the sound tube socket, the power socket, and the relevant manufacturing labels.

INTRODUCTION TO MEASUREMENT TECHNIQUES

Hardware and software has been provided to allow for:

1) the determination of Nasal Area-Distance plots by **acoustic reflection**
2) the determination of Nasal Airway Resistance by the measurement of flow and pressure signals

The **Acoustic method** is based on the following principle:

A sound pulse propagates in a tube and enters the nasal cavity through a nosepiece, where it is reflected by local changes in cross-sectional area. The incident and reflected signals are then measured by a microphone in the sound tube.

From these measurements, it is possible to calculate the cross-sectional area as a function of the distance into the cavity by use of algorithms developed by Ware and Aki (1969).

By integration of this curve the volume of the nasal cavity is calculated.

The method has been developed for use in the tracheo-bronchial system by Jackson et al. (1977), and for use in the nose by Hilberg et al.(1989).

For further information, the reader should consult these publications:

1. A.C. JACKSON, J.P. BUTLER, E.J. MILLET, F.G. HOPPIN JR., AND S.V. DAWSON. Airway geometry by analysis of acoustic pulse response measurements. J. Appl. Physiol. 43(3):523-536,1977.

2. J.A. WARE, AND K. AKI. Continuous and discrete inverse scattering problems in a stratified elastic medium. I. Plane waves at normal incidence.
J. Acoust. Soc. Am. 45:911- 921,1969.

3. O. HILBERG, A.C. JACKSON, D.L. SWIFT, AND O.F. PEDERSEN. Acoustic Rhinometry, evaluation of nasal cavity geometry by acoustic reflection. J. Appl. Physiol. 66:295303,1989.

The principals of **Rhinomanometry** are very well known and have been described in many papers, but at its simplest a rhinomanometer measures nasal flow and the pressure required to produce that flow.

The calculation techniques, which are used to present relevant numerical information from the flow and pressure signals, are described in the rhinomanometry standardisation paper.

HOW TO MAKE AND RECORD MEASUREMENTS

Two methods of acquiring data are provided within the Naris software: rhinomanometric acquisition, and acoustic acquisition.

These are described separately in the sections below.

RHINOMANOMETER OVERVIEW

The measure of rhinomanometry or nasal airway resistance (R) depends on measuring nasal air flow (F) and the pressure (P) producing that airflow:

$$R = P/F$$

Resistance = R. Pressure = P. Flow = F

Nasal airflow is collected by a mask, which must form an airtight seal around the face, and is then passed out through a pneumotachograph head in which the flow is converted to a pressure differential. This differential is transmitted to the NR6 by means of the tubes marked with red and green bands.

Nasal pressure is the more difficult parameter to measure and this is done using one of two standard techniques:

ANTERIOR TEST (detailed on P12)

In the anterior test the black pressure tube is connected to one side of the nose while airflow is measured through the other side, allowing for resistance to be calculated on that side. The pressure tube is then moved to the second side, flow is recorded, and resistance is calculated again. The two resistance values are then put into the formula below to calculate total resistance:

$$\frac{1}{R\ TOTAL} = \frac{1}{R\ LEFT} + \frac{1}{R\ RIGHT}$$

The pressure connection to the nose is made by either:

- a tip connector pushed through a small hole punched in microfoam tape, or a foam insert
- linked to the black pressure tube using anterior tubing and an anterior connector.

The reference pressure tube (blue) is connected to the mask.

It is essential that the pressure connection is airtight, and this should be checked by:

1) Connecting the anterior tubing to the side of the nose which is not being measured

2) Holding or taping the free end of the anterior tubing against the soft part of the subject's cheek
3) Asking the patient to obstruct the free side of their nose with a finger while you block the free end of the anterior tube. If the patient tries to gently breathe in and out through their nose they will be able to tell you if they feel any air leakage at the tape or foam connection to their nose.
4) Having achieved no leakage, and without moving the anterior tube, carefully place the mask on the face, starting just above the bridge of the nose, and ask the subject to hold the mask in place.

Connect the free end of the anterior tube to the black ringed pressure tube from the NR6, using the anterior connector.

POSTERIOR TEST (detailed on P 15)

In the posterior test, a length of posterior tubing is connected onto the black nozzle inside the mask– cut just long enough to sit on the tongue - and the lips closed round the tube. Provided the soft palate is relaxed, the pressure measured by this mouth tube will be the same as the pressure driving airflow through the nose. This pressure signal is taken to the NR6 by means of the tube with the black ring marker on it, which is connected to the black nozzle on the outside of the mask. The reference pressure tube (blue) is also connected to the outside of the mask. Patient co-operation is required to use this technique, in which a measure of total nasal resistance is obtained from one test.

PRINCIPAL POINTS TO NOTE

1) Prepare the patient by having them wait in relaxed quiet conditions for 15 to 20 minutes prior to measurements being taken, and decongest them

2) Check for leakage of the pressure tube and for good mask fit

3) Ask the patient to breathe in a quiet relaxed way - avoid excited, rapid manoeuvres

Posterior and Anterior tests can be performed using a fixed reference level (selectable from 75 Pa to 300 Pa) or, alternatively, under the Broms technique with a radius of 200 units. In either case, resistance is calculated when the trace crosses the fix line or arc of the circle.

The recommended reference points are as follows:

Standard posterior	75 Pa
Standard anterior	150 Pa
Broms	200 units

It is recommended that resistance values be averaged over at least 4 breaths, and as such is offered by default.

In addition to resistance values, Rohrer coefficients are also calculated for K1 and K2:
K0 should be zero as the curve goes through the origin
K1 represents the laminar flow part of the curve

K2 represents the turbulent part of the curve

PERFORMING A MEASUREMENT

The program has adopted many standard windows conventions and can be controlled by using the mouse, function keys, or "hot keys". Most are self-explanatory but some features may not be immediately obvious e.g. how to compare one test against another to get % change figures, or how to mark a group of files for printout. A software guide has been supplied separately to aid quick referral.

Most errors in Rhinomanometry can be attributed to:

a) **POOR PATIENT PREPARATION**
Patients should be in a stable environment for 15 - 20 minutes and should be asked to blow their nose or be decongested prior to testing. They should also be advised to breathe at a normal level and rate.

b) **POOR PATIENT CONNECTION**
The pressure tube and mask must not leak and must be placed on the face correctly to avoid distorting the nose.

Errors arising from a) can be avoided by careful processing of patients prior to testing, and those arising from b) can be checked by using the batch test facility (Clinical/Research version only). Essentially, the batch test facility allows rapid retesting of a patient with automatic comparison of one of the measured parameters and production of mean, standard deviation and coefficient of variation figures for the test runs repeated for that patient.

The process to be followed is therefore:

- connect and test patient
- disconnect patient
- reconnect and retest patient.

Continue this process until the CV figure drops to an acceptable level.

PERFORMING A TEST

The patient should be connected to the instrument **only when the screen shows the flow and pressure axes**, and after checking that the dot lies on the origin of the graph. If the system is not correctly zeroed, while no subject is connected, press **Z** on the keyboard, or click on the **Zero** button.

a) **ANTERIOR METHOD**

The anterior test requires no patient co-operation and can therefore be performed on any subject. The technique requires that one side of the nose be used as an extension to the pressure tube (to monitor the pressure component relative to the mask pressure) and this connection is achieved using either:

1) Microfoam tape, a tip connector, anterior tubing, and an anterior connector, or
2) A foam insert, anterior tubing, and an anterior connector

The black mask-mounted connector should be sealed during the anterior method, as it is not required.

In this method flow is measured on the open nostril. The mouth should be closed during the test and once the resistance figure for one side has been obtained, the role of the nostrils is reversed by moving the tape assembly or foam insert to the other nostril.

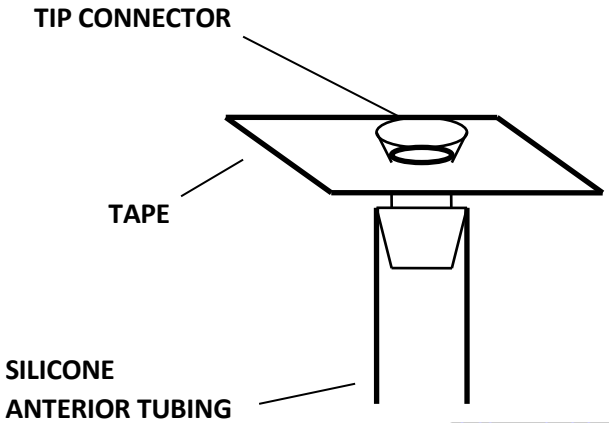
It is a fundamental requirement of this technique that an airtight connection of the instrument pressure tube onto one side of the nose be made with as little distortion as possible. Satisfying this criterion results in the best possible accuracy.

N.B If foam inserts are to be used, substitute the foam insert for the tip connector and tape as shown below.

ANTERIOR TEST PREPARATION

a) make a hole in the tape using the smallest die on the punch supplied

b) fit a tip connector and 15 cm of anterior tubing to the tape as shown (or 15 cm of anterior tubing onto a foam insert). De-grease the nose with an appropriate agent such as surgical spirit



c) fix the tape onto the nose (or foam into the nose), position the tube against the cheek where it will be during the test,

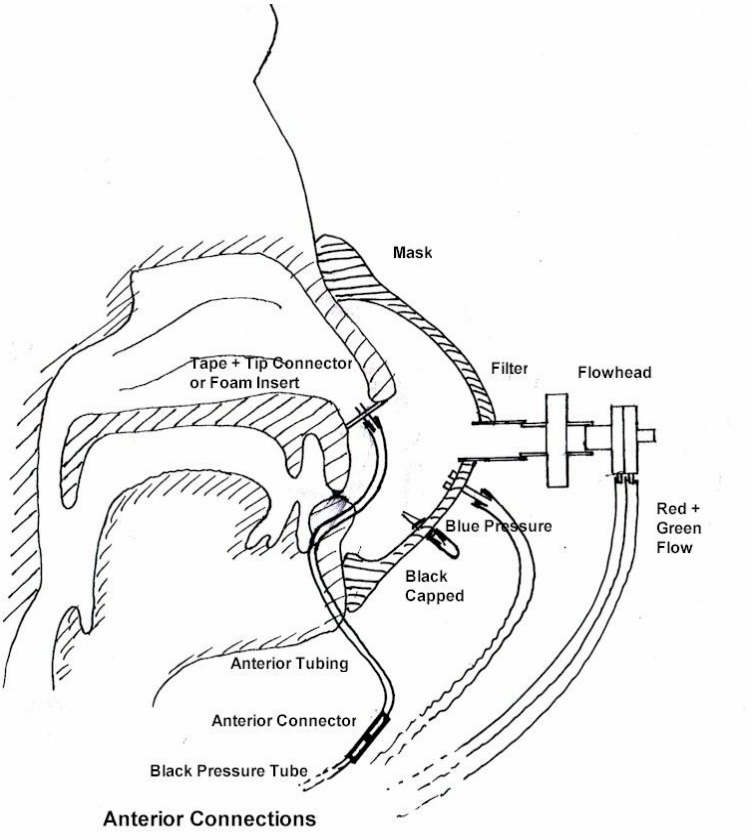
FOAM INSERT
(alternative to tape/Tip)

and check for leakage by blocking the free end of the tube with your finger, ask the subject to block their open nostril with their thumb and gently breathe in and out through their nose – they will feel any leakage

d) if airtight, secure the tube in this position by bringing the mask up to the face, taking care to position it on the bridge of the nose and ask the patient to hold the mask assembly there (see page 22 for pictures)

e) connect the anterior tubing's free end to the pressure tube (marked black) using the anterior tube connector

f) ask the patient to maintain pressure on the mask to achieve an airtight seal while closing their lips and breathing through their nose. Ensure that the patient's fingers do not obstruct the output from the flowhead

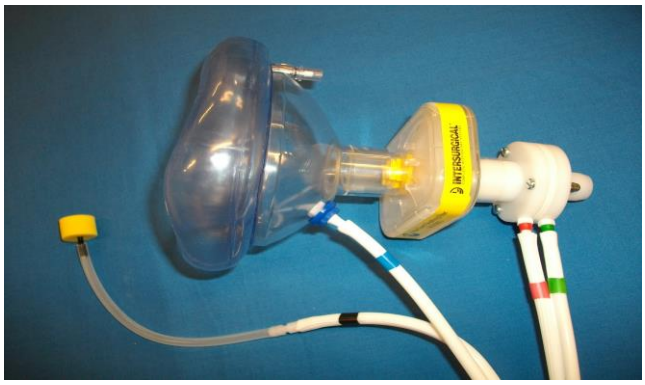


Anterior Connections

There are two principal hazards associated with this technique:

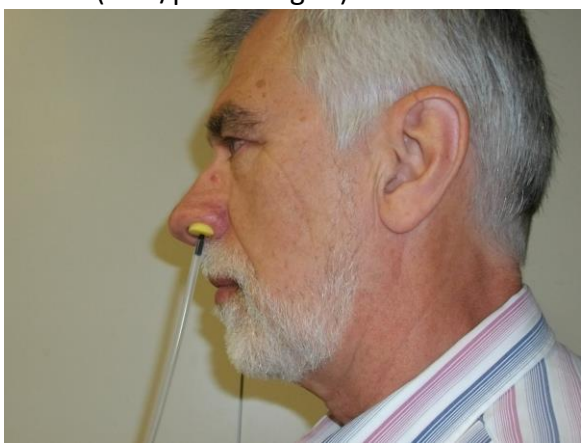
a) The patient could press so hard that the anterior tube collapses and is obstructed completely - this will result in the display showing an almost vertical line and can be corrected by asking the patient to apply a little less pressure

b) If the respiratory rate is too high there will be a tendency to create an open loop on the display. In the event of this occurring, the patient should be given time to become familiar with the mask and then asked to breathe more slowly

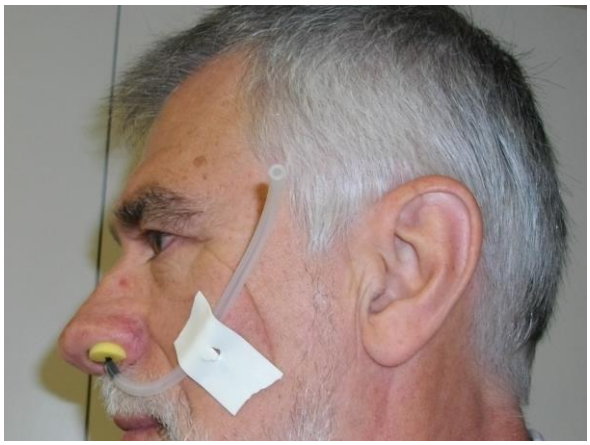

Mask assembly for anterior testing

ANTERIOR TEST PROCESS

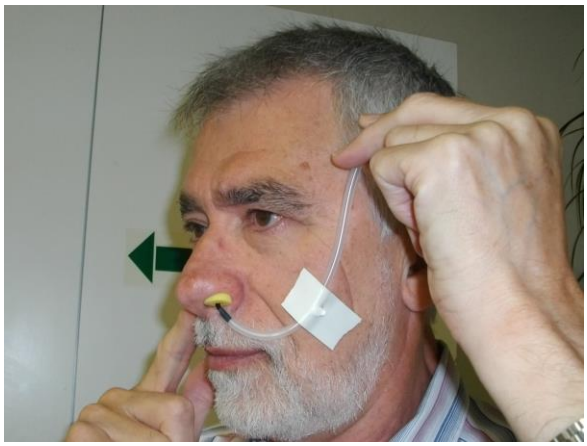
Start the NR6 software, and set up a new record for a new patient, or click on **Open** if the subject already has a record file. Click on the NR6 Acquire button to access the recording screen (flow/pressure grid) then:



Insert the foam to the reference nostril



Position the tube on the soft part of the cheek



Test for leakage

Place the mask on the face to secure the tube

Ask the subject to quietly breath through their nose with their mouth closed. If the traces reach the default sample point, click on the red button to record data. If not ask them to increase the depth of their breathing. After four cycles have been recorded (default), move the foam (or tape) to the other nostril and repeat the process.

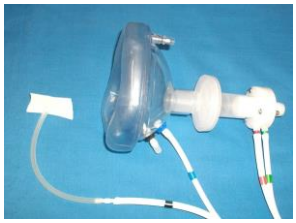
ANTERIOR COMPONENTS

Hole Punch

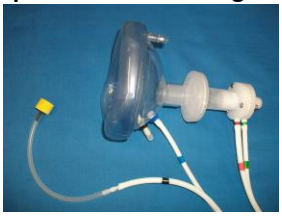
Anterior Tape

Anterior tip connector

Single Use Mask



Anterior mask with Tape/Tip connections



Anterior mask with Foam connections

b) **POSTERIOR METHOD**

The posterior method allows direct measurement of total nasal resistance from a single manoeuvre without any direct contact with the nose, and as such is perhaps the preferred technique.

The mask assembly comprises an anti-viral filter, a pneumotachograph (to measure flow), and a black nozzle onto which can be added disposable posterior tubes (to measure pressure). The subject should be asked to put the disposable tube in their mouth and close their lips around it while breathing through their nose. Under ideal conditions the pressure developed in the mouth will equal that behind the nasal passages and by dividing this pressure by the passing flow, a measure of resistance can be obtained:

$$\textbf{Resistance} = \frac{\textbf{Pressure}}{\textbf{Flow}}$$

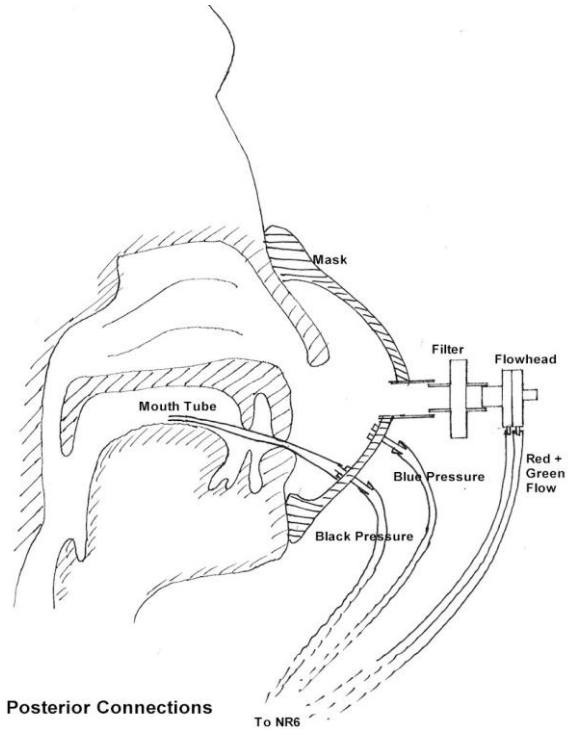
This technique does not interfere in any way with the nasal passages, but it does have the disadvantage that it depends on the mouth area having an uninterrupted connection to the respiratory tract. It is therefore essential that:

a) the subject does not bite the mouth tube
b) the end of the tube is not blocked by the tongue, cheek, or saliva
c) the soft palate is relaxed and the back of the tongue is held down in the mouth

Difficulty may be experienced in training some subjects to perform satisfactorily - success figures of around 80% for adults and 50-70% for children may be typical.

Two techniques have been found useful in training subjects.

1. Allow the subject to obtain visual feedback by watching the screen. By looking at the trace the clinician can tell the patient when a valid test has been obtained (it will pass through the origin) and within a short time the patient will associate a successful test with a certain posture, meaning tests can now be made

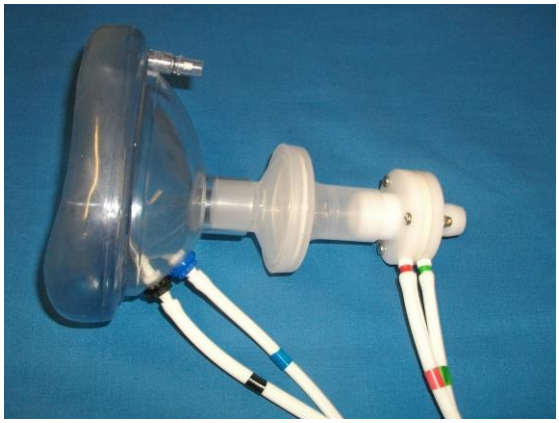


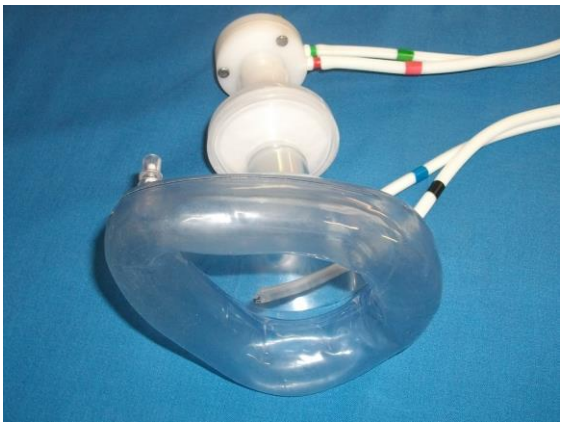
2. Ask the subject to breathe through their nose deeply with their mouth shut and adopt a

position that allows their cheeks to puff out with each expiration. Try it first without the mask and then with the mask in position. If the cheeks can move in and out, the soft palate, tongue etc. must be correctly positioned, and posterior measurements can be made.

3. Keeping the head erect and the jaw forward during measurements can also help keep the back of the mouth in direct contact with the nasal driving pressure signal.

POSTERIOR MEASUREMENT





Mask showing Posterior tube connections and above, with a posterior mouth tube included

A posterior test being made

COMMON PROBLEMS AND TROUBLESHOOTING

The principal problems are as follows:

a) There is leakage in the pressure tube circuit. The trace is almost vertical and it's only when using the Broms technique that you can calculate results because the trace will not reach the 75 Pa or 150 Pa sample point threshold line used in the standard technique. Check the pressure tube connections to the patient and to the NR6 box (black-ringed tube).

b) There is leakage in the flow circuit. The trace is almost horizontal indicating a very high resistance or little to no flow component.

c) Check the mask fit and that the tube runs between the flowhead and the NR6 box (red and green). Check that the black mask port is capped when doing an anterior test.

d) The spot does not move when a pressure or flow is applied, or moves in a very erratic way. This suggests that the A/D card has not been installed properly (has it been set to Board 0?), or there is no connection between the NR6 and the PC (Is the green light on the front of NR6 illuminated)?

e) There is no response on the screen to flow or pressure input, but the connections are intact and the light on the front of the instrument is lit.

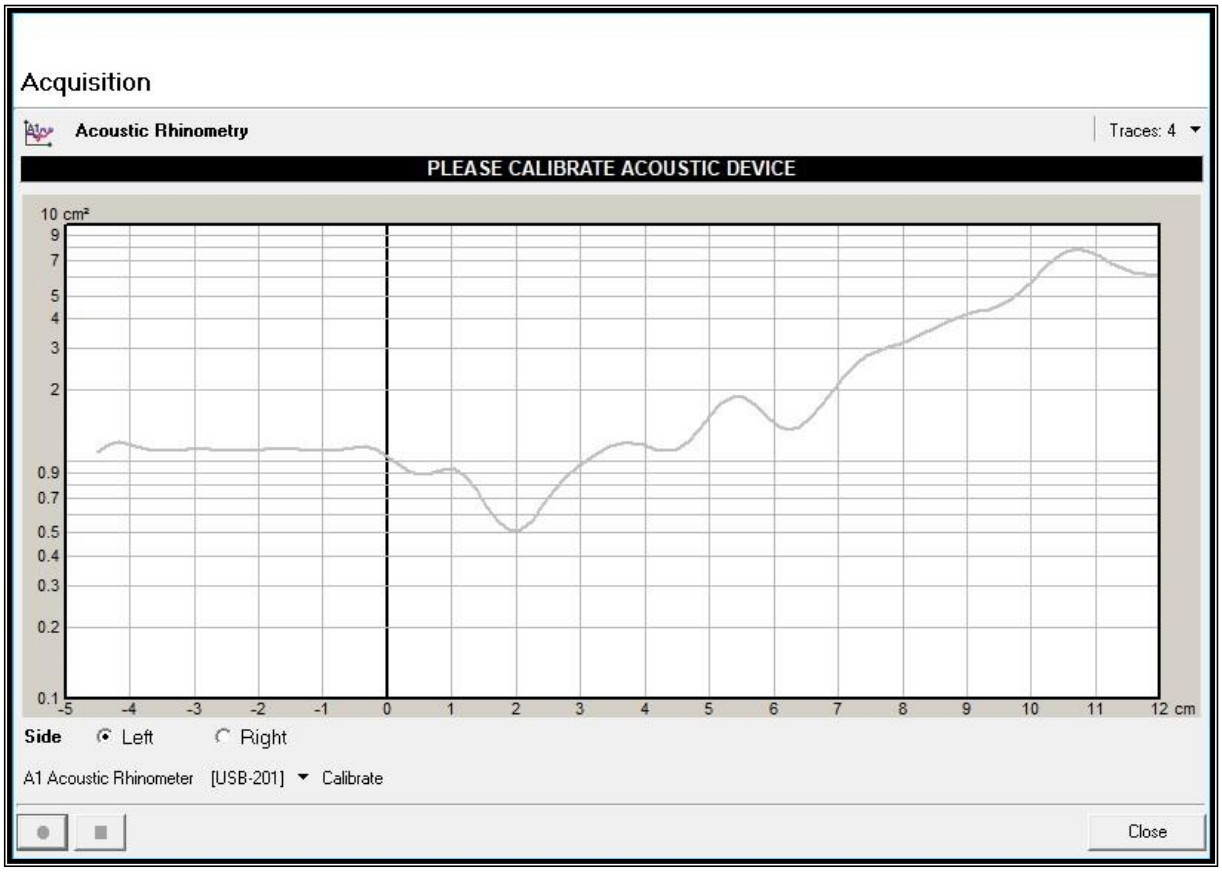
1) Check that the USB cable is in place, linking the NR6 and PC.
2) Run the program Instacal to ensure that the NR6 USB module has been recognised by the PC (see software manual)
3) Check that the PC has not been allowed to go into sleep or power down mode.

   If the PC has been allowed to go in to sleep mode, the USB interface is powered down. When brought out of sleep mode, the PC does not re initialise the USB interface, and therefore it is effectively not present. One solution is to remove the USB connection at the PC or instrument side then re-connect. That may be sufficient, but if not, save any results, and close down the instrument software and restart it.

ACOUSTIC MEASUREMENTS

ACOUSTIC RHINOMETRY CALIBRATION

Prior to use, the A1 device **MUST** be calibrated for correct operation.
To perform a calibration: switch on the A1, put the calibration plug in the sound tube, click on the Acoustic icon on the main toolbar, and then on the **Calibrate** button as show below.



A1 Acoustic Rhinometer [USB-201] calibrated will show when completed

A1 sound tube with calibration plug fitted, ready for calibration.

The system is now ready for use.

WHICH ACOUSTIC NOSEPIECE?

There are two types of nosepiece supplied with the acoustic system. Two sizes of anatomical (medium and large), and one size of conical (8mm). The anatomical nosepieces are handed, i.e. one is for use on the right side (marked D and coloured red) and one for the left side (marked S and coloured blue). The conical nosepiece can be used on either side.

ANATOMICAL AND CONICAL ACOUSTIC NOSEPIECES

The choice of nosepiece depends on which will give the best seal between the nosepiece and the nose, with the least distortion.

The choice of nosepiece depends on which will give the best seal with the least distortion.
The conical nosepieces are suitable for use with a nose which has a small round opening, while the anatomical nosepieces are designed to sit on the outside of a nose with a long narrow opening, and are shaped to make it easy, in most circumstances, to get a good seal. In addition, they have a flange which a soluble gel can be put onto to reduce any remaining gap .

CHILD NOSEPIECES

The nosepieces supplied with the **child sound tube** are 4.5 cm long and are manufactured from silicone rubber. As the wall thickness is 1.5 mm it is possible to run a bead of gel around the end of the tube, which will help obtain an airtight connection to the nose. Alternatively, an additional washer can be added to the end of the child nose piece to increase the width where gel can be added.

N.B. the caution statement on page 4 at the front of this manual

MAKING MEASUREMENTS

1) Have the patient sit back in a chair (some workers advocate use of an adjustable forehead and chin rest), select and fit a nosepiece, and apply the sound tube (perhaps suitably prepared with gel) to the selected side. The sound tube can be held by the patient, or by the clinician but we believe this is best left to the patient, with one hand holding the sound tube near the bottom and one near the top.

2) When suitably positioned, ask the patient to close their mouth and **gently** breathe in and out through their nose to check for leakage between their nose and the nosepiece.

3) If OK, ask them to open their mouth and return to mouth-breathing. When ready to make the measurement, ask the patient to take a breath in through their mouth and hold their breath. Click on the red **Acquire** button, or middle-click on the mouse with the cursor inside the capture window to sample the data. This process can be repeated until at least 3 consecutive results show little variation. If the patient can co-operate, the measurements may be made in rapid succession (with 600mS or so between samples) during a single breath-hold manoeuvre.
   N.B. a footswitch (optional extra) is available as an alternative to clicking on the red **Acquire** button.

4) If the results are satisfactory, select the other side (L or R), and repeat the process, remembering to change the nosepiece, if anatomical.

5) The test results are automatically added to the patient's results file.

6) Click on **Print** to print out the currently highlighted curves, or alternatively click on **Report** to select the curves from the displayed list for printout. If you want a full page print out of a particular test, you can highlight it and click on the arrow on the right of the printer symbol and select **Print on full page.**

7) The results can be saved by clicking on **Save**, confirming the file name to save to, and then clicking on **OK**.

FACTORS WHICH AFFECT ACCURACY

Measurement accuracy and repeatability will depend on the following:

Calibration:	Perform a calibration at least twice a day
Temperature:	Use equipment in controlled conditions between 20°C & 23°C
External noise:	Use equipment in conditions where the background noise is below 65 dB
Angle of probe (relative to the head):	Aim for floor of nose
Rigidity of probe:	Doesn't move
Effect of probe on the nose:	Avoid distortion
Patient co-operation:	Hold breath during measurements
Nosepiece/nose seal:	Use gel and careful positioning to ensure a good 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 results.

The Acoustic Standardisation Committee have now reported on the measurement and this is referred to on page 4 of this manual.

ENVIRONMENTAL FACTORS

TEMPERATURE EFFECT

An increase in the temperature of the gas through which the sound pulse travels will lower its density and therefore the rate at which the pulse travels through the gas. The overall effect is in the range of 3% / 20 ^{o}C. Distance is therefore slightly overestimated if there is an increase in temperature.

ALTITUDE EFFECT

The effect of altitude is significant on the density of a gas and therefore on the speed of sound, for example, at an altitude of 1km, distance is overestimated by 7%.

MAINTENANCE

MICROPHONE AND TRANSDUCER DIAGNOSTICS

The InstaCal program C:\\(**Program Files(x86)/Measurement Computing/DAQ/inscal32.exe**) provides facilities, which can be used to check the integrity of the microphone in A1 and the transducers in NR6.

A1

Run InstaCal (inscal32.exe) and select your A/D board by highlighting **USB-201**.

Click on **Test** -> **Analog** -> **Scan Test** -> **Scan Options**.
Set the following options:

Scan channels	= CH0 through CH0
A/D range	= ± 10 Volts
Scan rate	= 1000
Mode	= Continuous
Data format	= Volts

Click on **OK**/**Start**

If you now create a click or gently tap on the sound tube or speak close to the open sound tube end, you will see the response on the trace in the window.

NR6 (Flow)

Run InstaCal as described above and select your A/D board by highlighting **USB-201**.

Click on **Test** -> **Analog** -> **Scan Test** -> **Scan Options**.

Set the following options:

Scan channels	= CH1 through CH1
A/D range	= ± 10 Volts
Scan rate	= 1000
Mode	= Continuous
Data format	= Volts

Click on **OK**/**Start**

If you now create a flow through the flowhead, or gently press on one of the flow nozzles the trace will show this. The trace should lie close to zero units and travel up and down from there. If it lies significantly lower or higher than zero units the **Flow Offset** potentiometer on the NR6 circuit board (VR1) can be adjusted in real time to correct this.

NR6 (Pressure)

Run InstaCal as described above and select your A/D board by highlighting **USB-201**.

Click on **Test** -> **Analog** -> **Scan Test** -> **Scan Options**.

Set the following options:

Scan channels	= CH2 through CH2
A/D range	= ± 10 Volts
Scan rate	= 1000
Mode	= Continuous
Data format	= Volts

Click on OK/Start.

If you now create a pressure on the NR6 pressure tube, or gently press on the pressure nozzle the trace will show this. The trace should lie at close to zero units and travel up and down from there. If it lies significantly lower or higher than zero units the **Pressure Offset** potentiometer on the NR6 circuit board (VR4) can be adjusted in real time to correct this.

A1 TROUBLESHOOTING

If the PC is allowed to go into sleep mode, the USB interface is powered down. When brought out of sleep mode, the PC does not re-initialise the USB interface, and therefore it is effectively not present. A solution is to remove the USB connection at the PC or instrument side then re-connect. That may be sufficient, but if not, save any results, close down the instrument software, and restart it.

START UP

An instance of the application is already active

- The software is already open in another window

Error adding font GM.TTF or the file GM.TTF could not be loaded

- The font has not been added to your Windows font folder

License key is missing or invalid!

- Either no license key is present or it does not match the program

License key does not match product!

- The key file in the program folder does not match the program

FILE MANAGEMENT

The requested file cannot be loaded in this application

- The record file you tried to load is not matched to this program

File saving attempt failed!

- The record file has not been saved --- is the folder valid and do you hold the correct permissions to save to it?

Target file already exists!

- You are attempting to overwrite an existing file with this name

Directory "%s" does not exist

- The directory (folder) you are trying to save to or load from does not exist.

No filename given

- You have clicked on save without specifying a file name

Export to "%s" has failed!

- The data export you have set up has failed. Perhaps the folder name is wrong?

ACOUSTIC ACQUISITION

The hardware board with number %d is not recognized

- The USB A/D board you have specified is not installed (open InstaCal to register the board)

Error Code 10 - Invalid sampling rate (MCC UL Error 24 - Invalid sampling rate specified)

- The sampling rate specified in the program setup is too high for the USB or PC hardware to cope with - alter the basic sampling rate in the Devices tab (File/Settings/Devices)

Error Code 11 - The selected gain is not supported (MCC UL Error 30 - Invalid range specified)

- This applies to the setting up of A1Test.exe, where the gain parameter has been incorrectly entered

Error Code 12 - Sampling rate too high (MCC UL Error 29 - Overrun)

- As 10 above

Error Code 1001..1008 - Arithmetic error during computation

- May be a PC memory issue

Error Code 1009 - Signal below trigger level

- Either there is no click, it is weak, or the microphone or cable is faulty.
- (Use A1Test.exe to measure signal strength) If appropriate, VR2 may be increased if the signal is only a little below the trigger level or the trigger level setting can be reduced to below the measured signal level in the Acquisition (adv) tab. Details on how to use A1test.exe can be found below

Error Code 1050 - Error saving calibration data!

- The new calibration file generated has not been saved. Either the folder name specified during setup is not present, or you don't have permission to write to it

Error Code 2000 - Acquisition aborted

- Software/hardware issue has prevented the program from running

It is important that the software is loaded in the sequence suggested in the installation section of the **A1 Acoustic User Software Guide**.

If issues arise when trying to use the system, the following can be used to check that the system has been correctly set up, and to diagnose any problems:

InstaCal

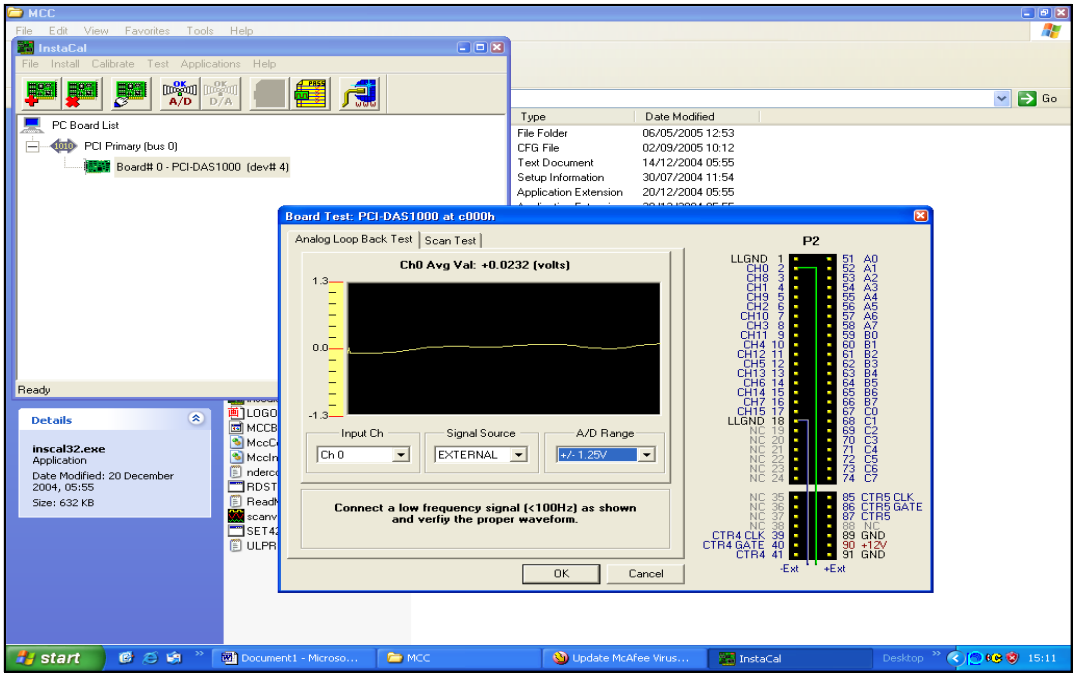
Navigate to the MCC (Measurement Computing Company) folder, using **My Computer** and double-click on the program **Inscal32.exe** - C:/Program Files(x86)/Measurement Computing/DAQ.

N.B. In a 32-bit system this will be C:/Program Files/Measurement Computing/DAQ as a 32-bit system won't have an x86 folder.

The opening dialog will show which boards are installed.

- The board you installed should be numbered 0 (or the corresponding number in the A1 software, if for some reason you have multiple devices installed)
- Select **Test** from the top bar and **Analog** from the drop-down menu then **CH0**, signal source **External** and A/D range **± 10V (for 201 USB interface)**

  The line you see should lie on zero Volts and should move when talking into the open end of the sound tube – if this is ok then the microphone and connections between A1, the A/D card and the PC are ok.



EXPLANATION OF HOW InstaCal WORKS

Each time InstaCal is opened, it looks to see what Measurement Computing Company interfaces it can find. The first one it finds it allocates to **board 0** and the next to **board 1**, and so on. It records the board type and serial number and automatically edits a .ini file to include this information.

If you change one acoustic system for another, it will have the same board type, but it will have a different serial number, which means that the USB will not be recognised and the driver will not be loaded.

If you run InstaCal again, it will look for Measurement Computing Company interfaces. It will realise that the one already recorded is no longer present (by comparing serial numbers) and offer to remove it. When you answer yes, InstaCal will offer to record the new USB interface and when you click **OK** it will edit the .ini file to include the new board type and serial number. If board 0 is free, it will automatically allocate it to board 0, otherwise it will allocate it to the lowest available board number.

It is for these reasons that you can't only unplug one A1 instrument and replace it with another. You must run InstaCal to let it recognise that the first one is no longer present, delete it, and replace it with the new one.

If you have two USB devices connected, both can be registered by InstaCal ---- one as board 0 and one as board 1. Provided you go into the software of one of them (**File** -> **Settings** -> **Device**) and change it to board 1 then you can easily switch between each system without having to run InstaCal.

A1TEST

In the A1 folder, you will find a program called **A1TEST.EXE** – this folder will be wherever you declared as the location during the installation process.

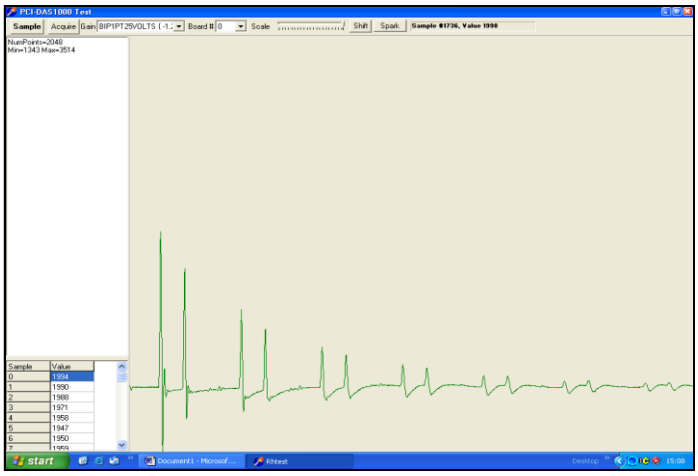
Double-clicking on the name will start the application.

For board type **USB-201** select Gain = ±10 volts, Digital Port = AUX, Sample Rate **=** 100000.

Click on **Sample**. You should see the microphone response on the screen. If you point the mouse cursor under the trace, it will tell you the amplitude of the trace at each point.

The baseline should be between 1950 and 2050 units.

The value is only updated when you click on **Sample**. The picture below shows a typical display when the calibration plug is fitted to the sound tube and sample is selected.



The peak pulse size is also documented in the table on the left-hand side as **Maximum**.

It should peak at a level greater than that set within the A1 program for **Trigger**, and, using VR2, is normally set to **between 3200 and 3500**.

If the peak height is smaller than this the level can be increased by using the **gain control** resistor, VR2, on the A1 circuit board.

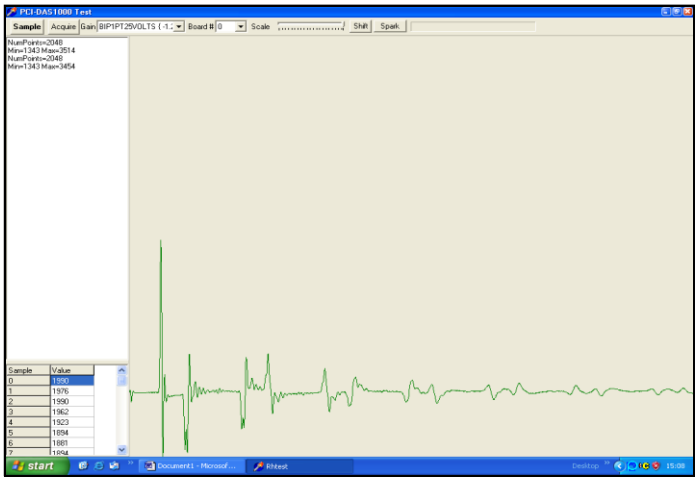
The trace above shows the microphone signal output plotted against sample numbers.

The first large peak shows the response when the click sound reaches the microphone on its way up the tube.

The second peak shows the reflected signal from the calibration plug returning back down the tube and reaching the microphone again.

Each pair of pulses that follow show the event repeating, as the sound travels up and down the closed tube.

If the calibration plug is removed, the trace will change as shown below and you will be able to hear the click when **Sample** is selected.



Selection of what constitutes incident and reflected waves is controlled by settings within the A1 program for:
incident wave window,
reflected wave start point and
reflected wavelength.

These are set for a particular length of sound tube and should not be altered.

SUPPLIED PARTS

INSTRUMENT AND ASSOCIATED PARTS	GMI CODE	QUANTITY
A1 Acoustic Rhinometer	A1	ONE
USB Cable	A1/Cable	ONE
Sound Tube	A1M	ONE
Calibration Plug	A1PLUG	ONE
External Power Supply	PCM50UT04	ONE
Software Manual	NR-SM	ONE
User Manual	NR-UM	ONE
A1 Software CD	NR-Disk	ONE
Measurement Computing CD	MCC	ONE
*Large Anatomical Nosepieces	A1/PRL	5 Pairs
*Medium Anatomical Nosepieces	A1/PRM	5 pairs
*8 mm Conical Nosepieces	A1/PR8	15 pcs

CLINICAL/RESEARCH VERSION

Artificial Nose and Straight Tube	A1 test	ONE

SPARE PARTS AND ACCESSORIES

NOSEPIECES:

*A1/PRM	Medium anatomically conformed nosepiece
*A1/PRL	Large anatomically conformed nosepiece
*A1/PR8	Conical nosepiece

MISCELLANEOUS:

A1/PLUG	Replacement calibration plug
A1/MIC	Replacement microphone and inner sound tube
A1/CABLE	USB Cable

If you have any questions about your Acoustic Rhinomanometer or require spare parts or consumables (part numbers listed above) then please contact your supplier or GM Instruments directly.
We will be able to advise you and give you help with any problem you may encounter.

Note: Parts listed above with (*) are supplied as non- sterile and due to their inertness have no lot number, expiry date or year of manufacturing

CLEANING AND DECONTAMINATION

ENCLOSURE

Should either 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.

A1 SOUND TUBE

Under normal use, employing the disposable nosepieces supplied, no routine cleaning is believed necessary.

If, in the course of use, material should run past the nosepiece and into the sound tube this can be cleaned as follows:

a) Switch off power to the instrument, and unplug the sound tube from the A1 device.

b) Loosen the 3 round-headed screws, which secure the outer tube. Loosen the white insert screw near the nosepiece socket. Carefully slide the outer tube towards the nosepiece end of the sound tube, to uncover the microphone connector, then prise the microphone cable connectors apart (we recommend using a flat-head screwdriver).

c) Loosen the inner sound tube-securing white insert screw from the sound generator box and withdraw the tube.

The tube can now be cleaned with a non-alcoholic antiseptic wipe (push the wipe down the sound tube with a suitably long thin object) and if desired, gas sterilised.
Do not allow liquids to run into the tube as the microphone could be damaged.

d) Assembly is the opposite of the process above. Particular attention should be paid to ensuring:

1) The inner sound tube is properly secured in the holder at the bottom of the sound generator box, having been properly inserted, and is held in this position while the insert screw is carefully tightened.

2) The microphone is carefully reconnected to the system by connecting the plug and socket again, but without pulling at the cable while doing so.

3) The outer tube is replaced after the microphone has been reconnected, and that the screws securing the outer tube are not over tightened

   N.B. the white insert screw should mate up with an indentation found on the side wall of the nosepiece holder, via a small grey plastic disc.

A1 ACOUSTIC RHINOMETER

CALIBRATION

The Acoustic Rhinometer should be calibrated each day using the built-in facility. In addition to this, the cables should be inspected regularly for signs of damage, in particular the region of the sound tube and its link to the PC.

The nosepieces supplied are for single-use only. Care should be taken in use to prevent the passage of nasal secretions down the nosepiece and into the sound tube. Should this occur, the sound tube should be removed from the sound box, cleaned by one of the methods described below and then thoroughly dried prior to reconnecting it to the sound box.
N.B. Take care not to over tighten the fixing screws when re-fitting the tube as this could damage the tube.

ROUTINE MAINTENANCE

Nosepieces are supplied for single use only.

Care should be taken in use to prevent the passage of nasal secretions down the nosepieces and into the sound tube. Should this occur, the sound tube should be removed from the sound box, cleaned by one of the methods described below and then thoroughly dried prior to fitting back onto the sound box.

N.B. take care to not over tighten the fixing plastic screws when re-fitting the tube as this may cause damage to it

NR6 RHINOMANOMETER

CALIBRATION

A calibration check should be made, and if required the instrument adjusted, in the following circumstances:

a) if the pressure or flow transducers are changed

b) if the flowhead is contaminated with dust or other particles or has been washed or disinfected

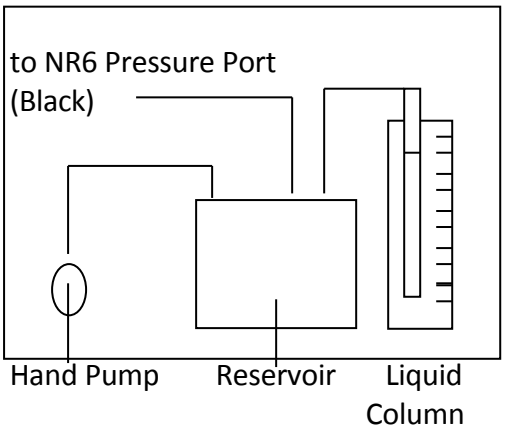
c) if some time has elapsed since the last calibration (ideally a check should be made before each testing session)

d) if there is any uncertainty about the results achieved

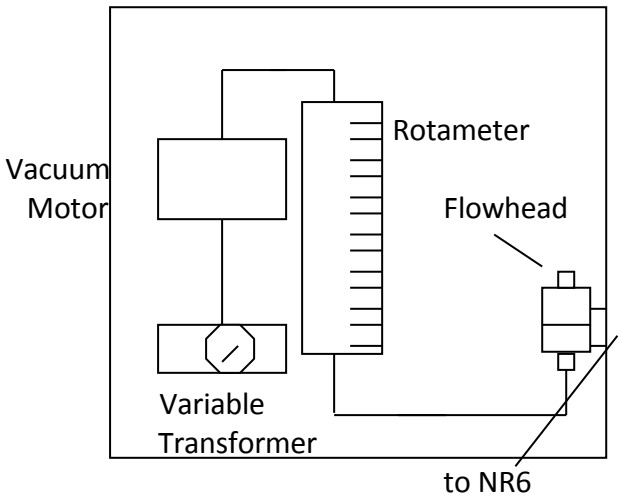
Two transducers are used in each NR6 - one for measuring the flow and one for measuring the pressure. They can be set using static individual calibration units, such as a liquid column for pressure and a rotameter for flow.

CALIBRATION EQUIPMENT

A. **Pressure Gauge** - a liquid column covering the range 0-500 Pa (51mm H_20). It is an added convenience if this is connected in the manner shown because adjustment to the desired pressure level is more easily achieved



B. **Flow Gauge** - such as a rotameter covering the range 0-500cm3/sec. (0-30 l/min) and an adjustable source of flow with a variable voltage supply. Such a motor is available from manufacturers of vacuum cleaners and the speed at which it runs, and therefore the flow it produces, can be controlled by powering it from a variable trans-former



The procedure to be employed is as follows:

a) Switch on the instrument and allow 5 minutes warm-up time

b) Select calibration from the setup menu bar item. Zero the output

c) Apply a flow of 300cm3/S (18 litres/minute) to the flowhead and if the value shown on the screen is not correct, adjust the flow calibration potentiometer, marked VR2 inside the NR6 until the reading is correct

d) Remove the flow and check that the value returns to zero. If it does not, reset the zero position, apply the flow and, if necessary, re-adjust the flow calibration potentiometer, VR_2

e) Apply a pressure of 300 Pa (31mm H_20) to the black input nozzle and, if the value on the screen does not read 300, adjust the potentiometer VR_5 inside the NR6 until it does read correctly

f) Remove the pressure and check that the value returns to zero. If it does not, reset the zero position, re-apply the pressure and, if necessary, make a further adjustment of the pressure calibration potentiometer

MAINTENANCE

The routine maintenance which is required is as follows:

a) Regularly check the condition of the **pneumotachograph** which is mounted on the mask and the condition of the plastic tubes which connect the mask to the instrument. The pneumotachograph should be kept clean, as dust build-up on the gauze will result in incorrect results. The gauze, mask, tip connectors and tubes can be washed, subjected to sterilising solution and can be gas sterilised, but must be thoroughly dried out prior to making measurements - **they cannot be autoclaved**. The tubing should not be used if it kinks or if it becomes slack on the pneumotachograph or instrument connector tubes. It should be replaced by a new length.

b) Conditions of various instrument-to-PC interconnecting cables should be checked regularly to look for damage to insulation.

c) 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.

SERVICING

Servicing can only be carried out by GMI approved and authorised personnel. No modifications are allowed.

The NR6 contains two transducers with associated instrumentation amplifiers, balance and gain controls, and an isolated +5 Volts to ±8V DC converter. Full circuit diagrams are available on request and service adjustments are noted below.

TRANSDUCER SETUP ADJUSTMENTS

1. Switch on the NR6 and allow 5 minutes to warm up.

2. Measure the voltage between test point 5 and test point 4 using a sensitive DC voltmeter. Adjust pressure offset potentiometer VR_4 to give a reading of 0 volts.

3. Measure the voltage between test point 5 and test point 6 using a sensitive DC voltmeter. Adjust flow offset potentiometer VR_1 to give a reading of 0 volts.

TRANSDUCER CALIBRATION ADJUSTMENTS

1. Pressure Channel - the gain of the pressure transducer is adjusted by means of calibration potentiometer, VR_5.

2. Flow Channel - the gain of the flow transducers is adjusted by means of calibration potentiometer, VR_2.

SUPPLIED PARTS

INSTRUMENT AND ASSOCIATED PARTS	GMI CODE	QUANITIY
NR6 Rhinomanometer	NR6	ONE
USB Cable	NR-USB	ONE
Flowhead	NR-FL	ONE
Four Tube Set	NR-4T	ONE
Software Manual	NR-SM	ONE
User Manual	NR-UM	ONE
NR6 Software CD	NR-Disk	ONE
Measurement Computing CD	MCC	ONE
Rhinocal **CLINICAL/RESEARCH VERSIONS ONLY**	NR-CAL	ONE

CONSUMABLES STARTER PACK

COMMON PARTS		
Adult Mask (Re-useable)	NR-RA	ONE
Child Mask (Re-useable)	NR-RC	ONE
*Filter (single use)	NR-Filter	ONE
ANTERIOR PARTS		
*Anterior Tube Connector	NR/AT/CON	ONE
*Anterior Tubing	NR/ANTUB	1 metre length
*Tip Connectors	NR/TIP/CON	Pkt/5
*Tape for Tip Connectors	NR/TAPE	ONE
*Foam Inserts Large	NR Large Inserts	Pkt/4
*Foam Inserts Standard	NR Std Insert	Pkt/4
*Foam Inserts Small	NR Small Insert	Pkt/4
Hole Punch for tape	NR/HP	ONE
POSTERIOR PARTS		
*Posterior Mouth Tubes	NR/POSTUB	1 metre length

Spare Parts and Consumables

If you have any questions about your Rhinomanometer or require spare parts or consumables (part numbers listed above) then please contact your supplier or GM Instruments directly. We will be able to advise you and give you help with any problem you may encounter.

Note: Parts listed above with (*) are supplied as non- sterile and due to their inertness have no lot number, expiry date or year of manufacturing.

Appendix 1: Guidance on the Electromagnetic environment in which to operate the instrument

Guidance and manufacturer's declaration – electromagnetic emissions		
The NR6 is intended for use in the electromagnetic environment specified below. The customer or the user of the NR6 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11		The NR6 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11		The NR6 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2		
Voltage fluctuations / flicker emissions IEC61000-3-3		

Appendix 1: Guidance on the Electromagnetic environment in which to operate the instrument (cont.)

Guidance and manufacturer's declaration – electromagnetic immunity			
The NR6 is intended for use in the electromagnetic environment specified below. The customer or the user of the NR6 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -**
Electrostatic discharge (ESD) IEC61000-4-2	± 6 kV contact ± 8 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material,
Electrical fast transient / burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines		Mains power quality should be that of a typical commercial or hospital
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth		Mains power quality should be that of a typical commercial or hospital
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>95 % dip in U_T) For 0.5 cycle 40% U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) For 5 s		Mains power quality should be that of a typical commercial or hospital environment. If the user of the NR6 requires continued operation during power mains interruptions, it is recommended that the NR6 be powered from an uninterruptable power supply or a battery.
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristics of a typical location in a
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Appendix 1: Guidance on the Electromagnetic environment in which to operate the instrument (cont.)

Guidance and manufacturer's declaration – electromagnetic immunity			
The NR6 is intended for use in the electromagnetic environment specified below. The customer or the user of the NR6 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	[V1]V	Portable and mobile RF communications equipment should be used no closer to any part of the NR6, including any cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance (*d*)** $d = [3,5/V1]\sqrt{P}$
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E1]V/m	$d = [3,5/E1]\sqrt{P}$ 80 MHz to 800 MHz $d = [7/E1]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NR6 is used exceeds the applicable RF compliance level above, the NR6 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the NR6

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Appendix 1: Guidance on the Electromagnetic environment in which to operate the instrument (cont.)

Recommended separation distances between portable and mobile RF communications equipment and the NR6			
The NR6 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NR6 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NR6 as recommended below, according to the maximum output power of the			
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter m**		
	150 KHz to 80 MHz ***d* = [3,5/V1]√P**	**80 MHz to 800 MHz** ***d* = [3,5/E1]√P**	**800 MHz to 2.5 GHz** ***d* = [7/E1]√P**
0.01			
0.1			
1			
10			
100			

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.

APPENDIX 2: TECHNCIAL INFORMATION (relative to EN 60601-1:2006)

No modification to this equipment is allowed.

6.2 When the NR6 Rhinomanometer is powered by a PC, power can be removed by unplugging the PC mains plug, by switching power off at the mains plug, or by removing the USB cable from either socket.

It complies with the specification for Class I ME equipment, and can only be used along with a PC and printer, normally supplied by the customer. NB the warning made earlier about the PC and printer being compliant with EN 60950 and placing these items out of the reach of a subject.

The Applied Parts comprise, mask, anti-viral filter or posterior or anterior tubing, tip connector, microfoam tape, foam inserts, flowhead and silicone rubber tubes which are classified as type B applied part.

6.3 The enclosure does not provide protection against the ingress of liquids and is therefore classified as IPX0.

6.4 There are no parts which are supplied sterile or are required to be sterile.

6.5 The NR6 Rhinomanometer is **NOT** suitable for use in an oxygen rich environment.

6.6 The NR6 Rhinomanometer rated for continuous use.

7.2.2 The NR6 serial number can be found on the label on the back panel, and the software version number can be viewed on the start-up screen and by clicking on Help, found on the top bar of the NR6 software

7.2.3 Information is given in the Warning and Caution section of this manual, which the user must read prior to operating this instrument. Appropriate labels are fixed to the back panel

7.2.4 Single use parts are identified by packaging labels detailing single use only

7.2.5 NR6 cannot be powered directly from the mains supply

7.2.6 The NR6 USB connection provides DC voltages of 5 volts dc.

7.2.11 The NR6 Rhinomanometer is rated for continuous use.

7.2.17 Environmental conditions for transport and storage with no additional special measures

Temperature:	-40 °C to +60 °C
Humidity:	20 to 80% RH
Pressure:	50 to 106 kPa

7.9.1 The NR6 can be used by any medically trained technician, nurse or doctor, who has either read this manual or who has been trained by a competent authority in its use.

7.9.2.5 The nose pieces are considered to be the applied part.

7.9.2.7 The equipment should be positioned to enable it to be disconnected from the supply quickly and easily.

7.9.2.10 Error Messages --- see Troubleshooting page 18

7.9.2.11 The NR6 software can be closed by clicking on FILE and EXIT. The NR6 hardware can be switched off by either of the following:
Removing the PC MAINS PLUG
By switching off the PC MAINS PLUG at the socket
By disconnecting it from the PC USB socket
Powering down the PC

7.9.2.13 There are no parts which need routine maintenance or servicing other than general “housekeeping”, such as keeping the equipment clean and cables free of twisting

7.9.2.15 The applied parts should be disposed of after use in line with your hospital or clinics policy on disposal of potentially contaminated plastic parts.
The NR6 Rhinomanometer can be returned to GM Instruments for dismantling and disposal, while your PC/Printer should be returned to your supplier for dismantling and disposal. These parts are subject to the WEEE directive, and should not be disposed of in landfill.

7.9.3.2 The only parts which is interchangeable by service personnel are the USB cable and flowhead tubing

7.9.3.3 Circuit diagrams, component lists and parts lists are available on request, along with email/telephone advice to service personnel trained on EN 60601-1:2006 and qualified to work on ME devices. Modification of the NR6 Rhinomanometer is not allowed.

7.9.3.4 If access to the NR6 circuit board is required:-
Disconnect the NR6 from the supply by disconnecting the USB cable linking it to the computer
Turn the unit over and remove the 4 feet on the base.
Turn the unit back over and remove the top panel.
The circuit board can now be accessed and if voltage measurements are required, the USB link can be reconnected.

APPENDIX 3: CARE OF FLOWHEADS

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

1) The gauze assembly, through which the air passes, should be free from dust or other contaminants.

2) Care should be taken to ensure that condensation, if it forms on the flowhead 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. This will not be a problem for inspiratory manoeuvres or for expiratory manoeuvers if anti-viral filters are used.

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 NV2. 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.

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.

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.

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.

CLEANING OF FLOWHEAD

Due to the nature of the flowheads then Autoclaving, High Energy Irradiation and Boiling Water are NOT allowable.

Should cleaning become necessary then we suggest the following cleaning/disinfection process.

Manual Cleaning/ Disinfection

1. Prepare a 2% (30ml/l) cleaning and disinfection of Sekusept® AKTIV with deionised water at 20 °C (68°C)
2. After 15 minutes the cleaning and disinfection solution can be used
3. Clean the flowhead with soft sponges in the cleaning and disinfection solution. Any areas difficult to access should be reached with soft brushes.
4. Leave the flowhead in the solution for 15 minutes ensuring that it is fully submerged
5. Remove from the cleaning/disinfection solution and rinse thoroughly with deionised water
6. Dry the device thoroughly
7. Check for visible contamination and repeat steps above if required
8. Check the flowhead for damage

Special 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

The flowheads can be repeatedly sterilised without limitation as long as there is no physical damage observed to any of the parts. If damage is observed and/or measurements become unusual then please contact to GMI to arrange a replacement.

Note: Due to the nature of the flowhead then it is possible to use Ethylene Oxide Processing, if you have this facility available to you and you wish to use it. We recommend that you follow the protocol that is established at your facility and should there be any issues identified then please contact to GMI for a replacement.

Note definitions of Definitions for Cleaning/Disinfecting/Sterilising are show in Appendix 4

APPEDNIX 4: DEFINITIONS FOR CLEANING/DISINFECTING/STERILIZING

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.