GM INSTRUMENTS

Rhinomanometer NR6

User Manual

and Installation Notes

V16

CE 2797

TABLE OF CONTENTS

NR6 RHINOMANOMETER SAFETY INFORMATION

Read this Operating Manual before attempting to use the Instrument.

WARNINGS

This Instrument is for indoor use, in a professional healthcare facility only and used as described in this manual.

It should not be used near active High Frequency Surgical Equipment nor in the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of Electro Magnetic disturbances are high.

Use of this equipment adjacent to, or stacked with, other equipment should be avoided because it could result in improper operation. If necessary, this equipment and the other equipment should be observed to verify they are operating normally.

Should the NR6 be affected by external influences such as those described above, it may not perform correctly. Determination of correct operation can be easily assessed as described in page 12 of this manual.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME SYSTEM, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

This unit is a PC connected product. It is advisable not to touch the patient while 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 NR6.

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

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)

The use of PC and Printer in the Patient Environment is defined below and must be followed to ensure safety compliance of the instrument

Option 1: Patient Environment for Non – Medically approved PC & Printer

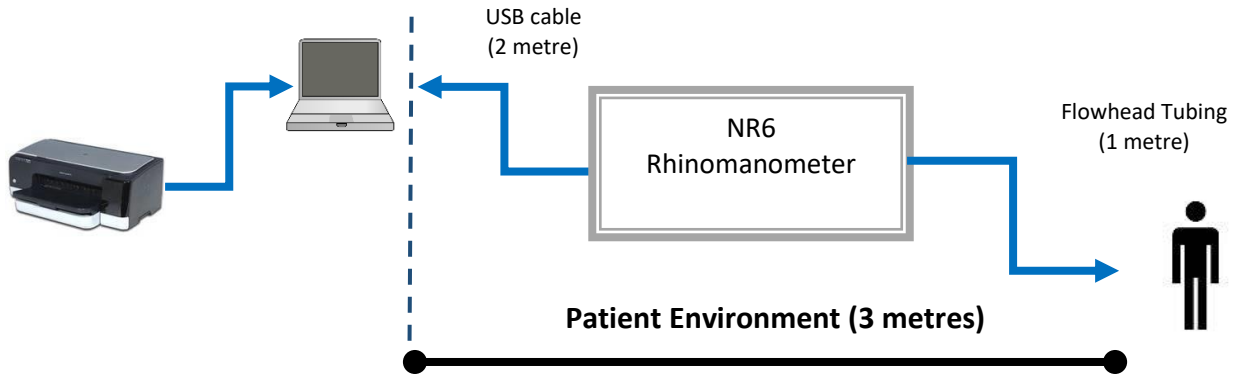


Figure 1: Patient Environment for Non-Medically approved PC & Printer

If the PC and/or printer are non-medically approved then it should be positioned as shown in Figure 1, out with the patient environment. The PC and/or printer must be compliant to EN60950-1.

Option 2: Patient Environment for Medically approved PC & Printer

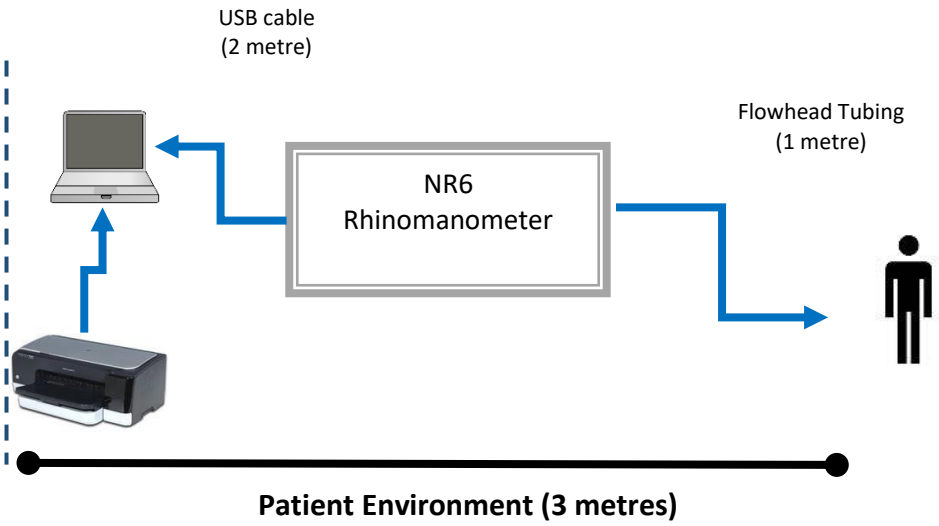


Figure 2: Patient Environment for Medically approved PC & Printer

If the PC and/or printer is compliant to BS EN 60601-1 and medically approved then the Printer and PC can be positioned within the patient environment as shown in Figure 2.

In circumstances where the PC and /or printer are not medically approved but are to be used within the patient environment then an isolation transformer, which is in compliance to BS EN 60601-1 MUST be used to ensure safety compliance, or run the PC by only battery without mains connection.

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 a Medical Device Directive Classification of Class I with a measuring function.

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 8.

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, please see the earlier definitions shown in Figure 1. The combination of the Rhinomanometer and computer and/or printer make up a medical system, refer to the current version of EN 60601-1 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 NR6 Rhinomanometer and its accessories should be stored within the following temperature and humidity ranges:

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

TECHNICAL SPECIFICATION

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 +A1:2013
	EMC	BS EN 60601-1-2:2015
Performance	Flow Range	+/- 800cc/sec
	Pressure Range	+/- 800Pa
	Accuracy	+/- 2%
Operation Environment	Temperature	+15 °C to +35 °C
	Relative Humidity	20% to 80% RH non-condensing
	Pressure	50 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

Additional Technical Information (relative to EN 60601-1) is also provided in Appendix 2.

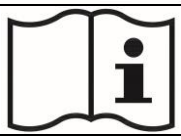
TABLE OF SYMBOLS USED

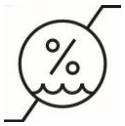
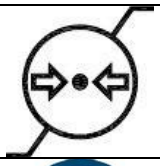
The following symbols appear on the NR6

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	Nozzles	Instrument Front Panel	Silicone Rubber Tubing *
	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:

SYMBOL	MEANING	LOCATION
	Manufacturer ISO7000-3082	Instrument Label
 ZZZZ	Date of Manufacture Where ZZZZ: Date of Manufacture ISO7000-2497	Instrument Label
	Serial Number ISO7000-2498	Instrument Label
	Consult Instructions for Use ISO7000-1641	Instrument Label

CE 0000	Council Decision 93/465/EC. Annex B(d) + 93/42/EC	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
	Atmospheric Pressure limitation ISO7000-2621	Instrument Shipper Packaging
	Mandatory Action Sign ISO 7010- M001	Operating Manual

ADDRESS AND CONTACT DETAILS:

MANUFACTURED BY:

GM Instruments Ltd
Greig House
Annickbank Innovation Campus
Annick Road
Irvine
KA11 4LF
UK

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

INSTALLATION

Hardware and software have been provided with the NR6 Rhinomanometer to allow for the determination of a well-defined assessment of the function of the nose and of recording changes within it due to surgical intervention, allergic response, or other factors.

INSTALLING THE NR6 SOFTWARE
Installation of the NR6 Software is described fully in the accompanying manual titled "**NR6 Software Manual"**

INSTALLING THE NR6 HARDWARE
The NR6 Rhinomanometer can operate on any PC which runs a Windows based operating system which has a free USB socket. Operate with PC and Printer as shown in the warnings section

Once the software installation is complete then connect the USB cable from the PC into the NR6

NR6 REAR VIEW AND CONNECTIONS

USB SOCKET

LINK SOCKET

NOTE: LINK SOCKET ONLY USED WHEN CONNECTRED WITH A1 IN NARIS CONFIGURATION

NR6 FRONT VIEW AND CONNECTIONS

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 anterior, it will go onto an anterior tube connector. In this case the mask nozzle marked black should be closed, using the plug provided

RHINOMANOMETRY OVERVIEW

The measure of Rhinomanometer or nasal airway resistance depends on measuring nasal air flow and the pressure 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 round the face, and is then passed 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 P13)

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 the nose with a finger while you block the free end of the anterior tube. If the patient then 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 P16)

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 to 300 Pa or cc/sec) 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

Resistance values averaged over at least 4 breaths is recommended and 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 letter" 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**
They should be in a stable environment for 15 - 20 minutes and be asked to blow their nose or be decongested prior to testing. They should also be advised to breathe at a normal rate and level.

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.

Determination of satisfactory setup and performance environment.

Having selected the acquisition icon to display the measurement grid, the cursor should sit on the origin of the xy display and in the absence pressure or flow inputs, should remain there. If it does not, the environment is not suitable, or a fault exists and testing should be abandoned, while the reasons for this movement from the origin are investigated.
If the cursor remains stable on the origin, the subject can be connected to the instrument and tests performed. The resulting measurements achieved are acceptable as long as the resulting traces are broadly sigmoid in shape and go through the origin of the graph. If the traces do not go through the origin or random excursions of the flow or pressure signals are shown, the test should be abandoned and any values produced ignored. Such effects may be brought about by radio interference.
All other degradations are an acceptable loss of performance.

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 is 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.

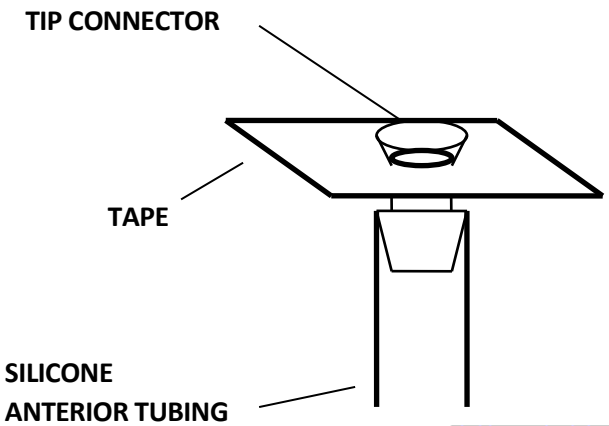
It is a fundamental requirement of this technique that an airtight connection of the instrument pressure tube onto one side of the nose be made with as little distortion as possible. Satisfying this criterion results in the best possible accuracy.

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 15cm 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, and check for leakage by blocking the

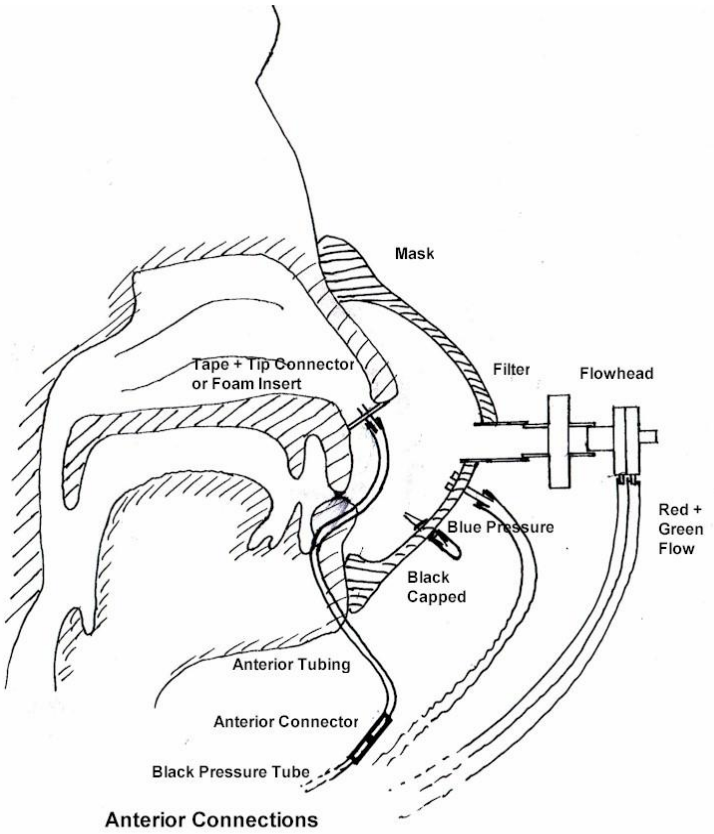
FOAM INSERT
(alternative to tape/Tip)

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 14 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

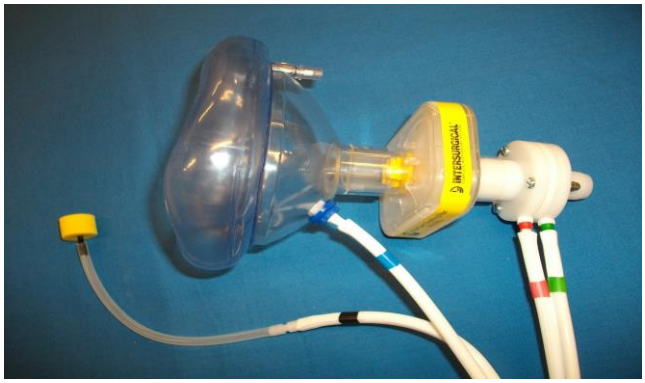


Anterior Connections

There are two principal hazards associated with this technique:

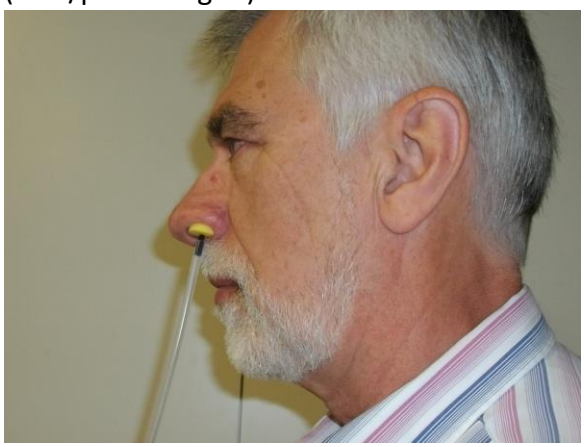
a) The patient could press so hard that the anterior tube collapses and is obstructed completely - this will result in the display showing an almost vertical line and can be corrected by asking the patient to apply a little less pressure

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

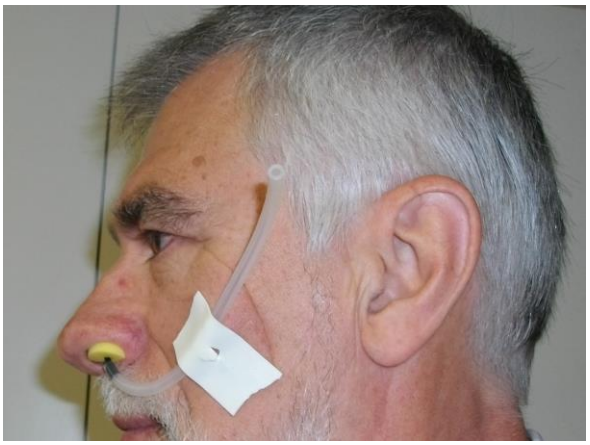

Mask assembly for anterior testing

ANTERIOR TEST PROCESS

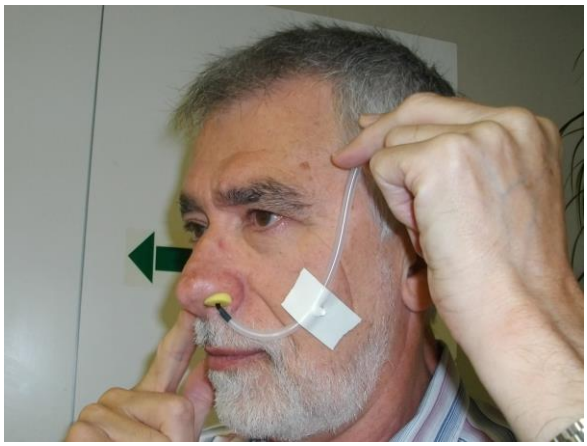
Start the NR6 software, and set up a new record for a new patient, or click on **Open** if the subject already has a record file. Click on the NR6 Acquire button to access the recording screen (flow/pressure grid) then:



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 4 (default) cycles have been recorded, move the foam (or tape) to the other nostril and repeat the process.

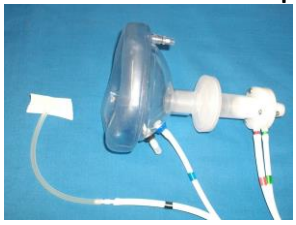
ANTERIOR COMPONENTS

Hole Punch

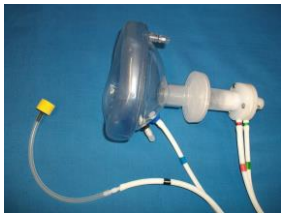
Anterior Tape

Single Use Mask

Anterior tip con



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. By dividing this pressure by the passing flow, a measure of resistance can be obtained:

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

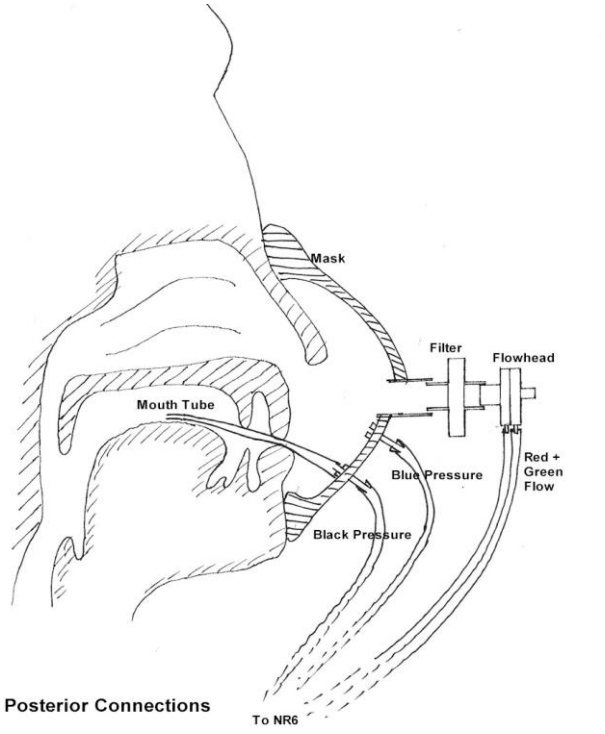
This technique does not interfere in any way with the nasal passages, but it does have the disadvantage that it depends on the mouth area having an uninterrupted connection to the respiratory tract. It is therefore essential that:

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. The clinician, by looking at the trace, 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

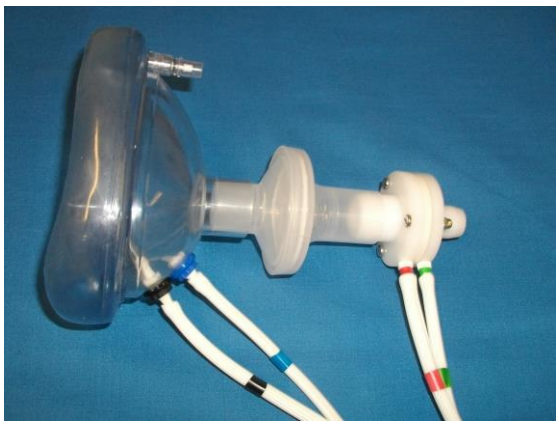


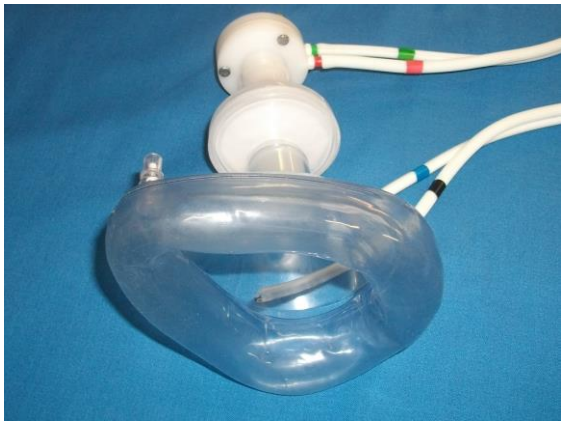
2. Ask the subject to breathe through their nose deeply with their mouth shut and adopt a

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 that 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.

f) If the cursor does not remain on the origin of the graph or erratically jumps in the flow or pressure axis directions, there could be a water droplet in a tube, an internal fault or the NR6 is being exposed to RF interference. If such conditions pertain, any measurement results must be ignored as they could be invalid.

ERROR MESSAGES

START UP

An instance of the application is already active

- You are starting the program for a second time.

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. This is normally achieved automatically on installation.

License key is missing or invalid!

- Either no license key is present or it doesn't 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 is set with permissions to save to?

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?

ACQUISITION

The hardware board with number %d is not recognized

- The USB A/D board you have specified is not installed (correct using Instacal)

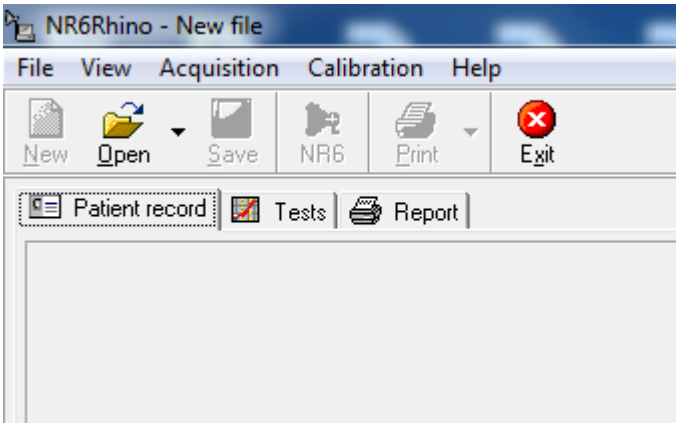
1001..1008 - Arithmetic error during computation

- May be a PC memory issue

2000 - Acquisition aborted

- Software/hardware issue has prevented the program from running

Another possible error that may arise is one where the software loads, but the buttons on the toolbar for capturing a measurement appear greyed out, as shown below.



This issue will most likely have arisen from the .ini file not being present in the directory containing the software, or that the folder has not got the correct security permissions set (every user will need Read/Write permission for this folder).

To fix this problem, open a Windows File Explorer window, navigate to the C:\ drive, and where it says “Search” in the top right corner of the screen, type Acoustic.ini. Next, right-click on the file, select ‘Cut’ or ‘Copy’, and then right-click in the folder containing the software and select ‘Paste’.

Explanation of how the InstaCal program works

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

If you change one rhinomanometer 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, 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 say yes it will edit the **.ini** file to include the new board type and serial number. If board 0 is free, it will automatically designate it as board 0.

It is for these reasons that you can't just unplug one NR6 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 NR6 devices connected, both can be registered by InstaCal ---- one as board 0 and the other as board 1. By changing the active board within the software (**File** -> **Settings** -> **Rhinomanometry** -> **Devices**) and switching between board 0 and board 1 you can easily move between each system without having to run InstaCal.

CLEANING OF PATIENT CONTACT PARTS

In the case of the Rhinomanometer direct patient contact can be made by:

SINGLE USE ITEMS: These should be disposed of after use

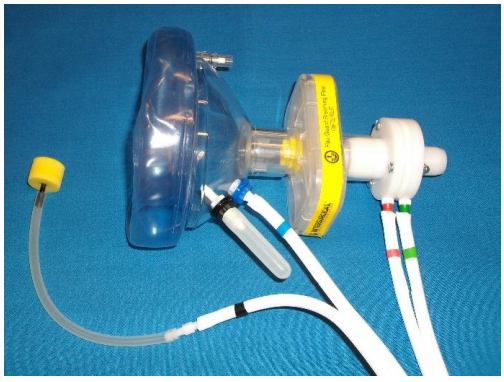
- Single-use mask
- Anti-viral filter
- Posterior tubing
- Anterior tubing
- Tip connector
- Microfoam tape
- Foam inserts

REUSABLE ITEMS: These can be reused if decontamination process is followed as per the instructions of the mask manufacturer (supplied with the masks).

- Re-usable mask

Flowheads:

We **strongly recommend** the use of the **anti-viral filter** which allows measurements to take place without contaminating either the flowhead or the tubing. The position of the anti-viral is shown below



Adult mask setup for **Anterior** test with Filter. Note the blanking plug on the black mask

Adult mask setup for **Posterior** test with Filter

We recommend use of the Intersurgical Filter-guard filter (code 1944) or Westmed bacterial filter (WM6216). These are specified to be 99.999% efficient for bacterial/viral filtration and has ports which fit our NR6 mask on one side and our flowhead on the other. 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 / Westmed. 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. Further details for this can be found in Appendix 3

If required the tubing between the NR6 Rhinomanometer and patient components can be wiped with 70% isopropyl soaked cloths/wipes.

SUPPLIED PARTS

INSTRUMENT AND ASSOCIATED PARTS	GMI CODE	QUANITIY
NR6 Rhinomanometer	NR6	ONE
USB Cable (maximum length 2m)	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 InsertPkt/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.

MAINTENANCE MANUAL

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

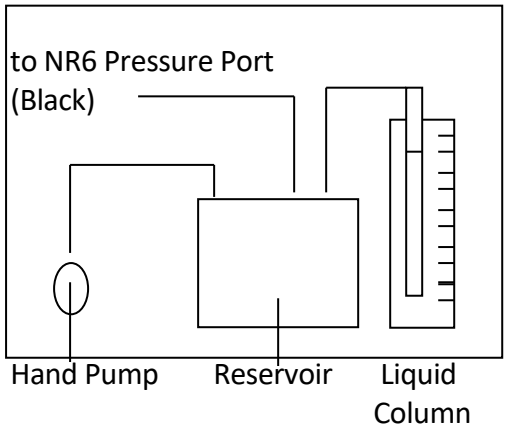
c) if some time has elapsed since the last calibration (ideally a check should be made before each testing session)

d) if there is any uncertainty about the results achieved

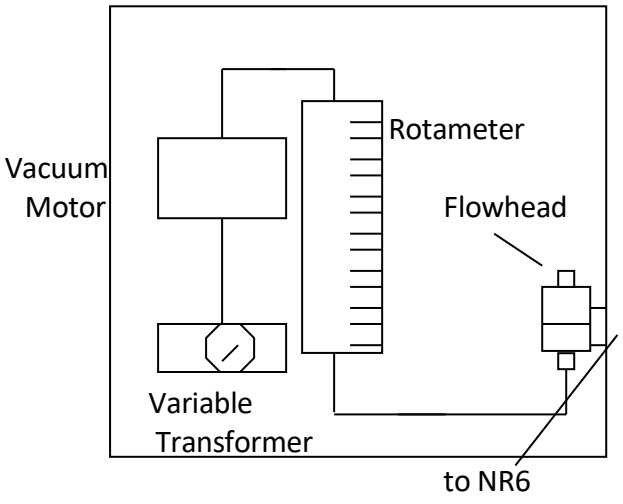
Two transducers are used in each NR6 - one for measuring the flow and one for measuring the pressure. They can be set using static individual calibration units, such as a liquid column for pressure and a rotameter for flow.

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 transformer



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 and zero the output

c) Apply a flow of 300cm_3/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, VR2.

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 VR5 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 the 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.

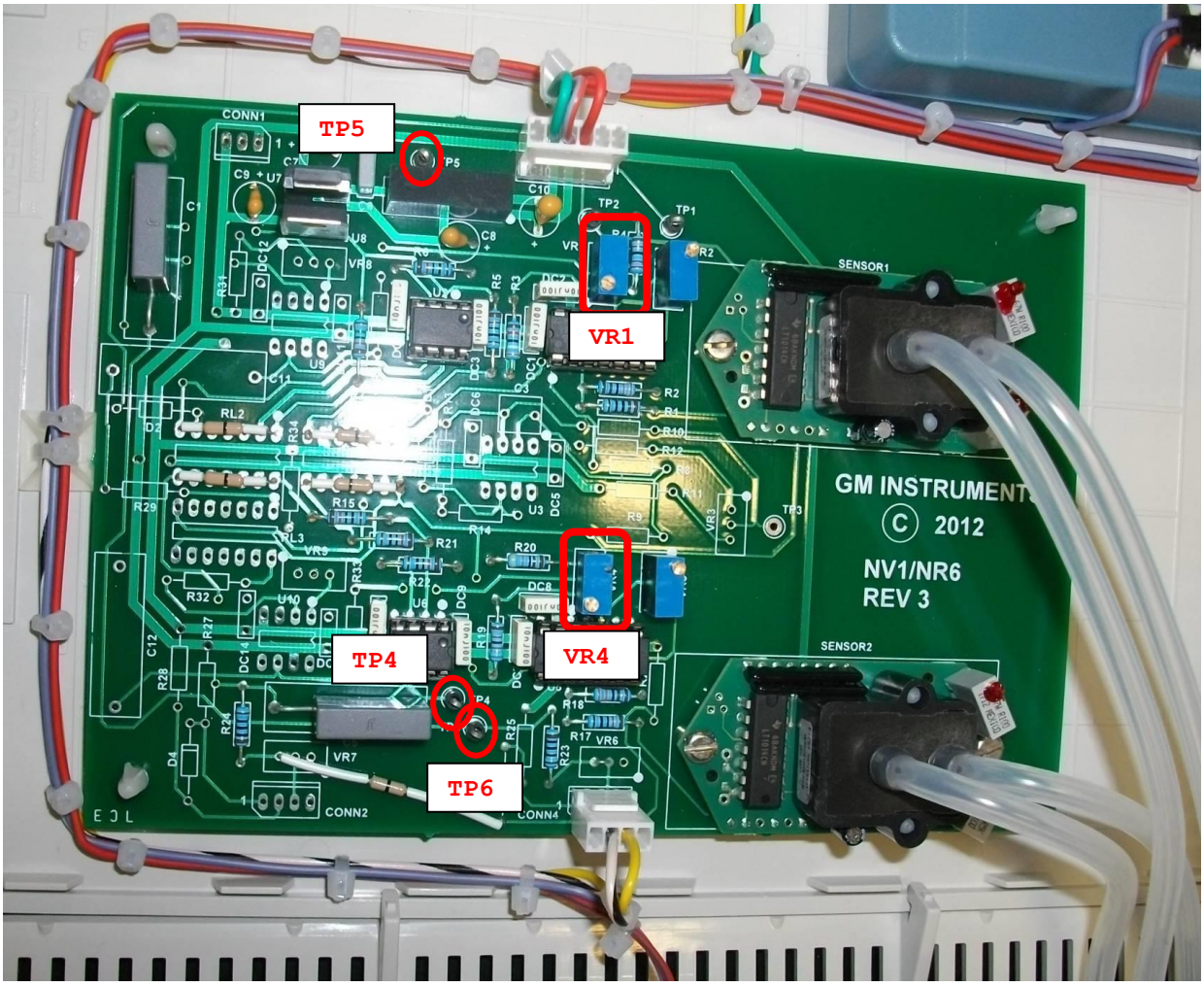
The NR6 contains two transducers with associated instrumentation amplifiers, balance and gain controls, and an isolated +5 Volts to ±8V DC converter. Full circuit diagrams are available on request and service adjustments are noted below.

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 VR4 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 VR1 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, VR5.

2. Flow Channel - the gain of the flow transducers is adjusted by means of calibration potentiometer, VR2.

Appendix 1: Electromagnetic Compatibility

Electromagnetic Compatibility Requirements - Emissions		
Required Test	**Compliance**	**Comments**
RF emissions CISPR 11	Group 1 Class B	For use in a professional healthcare facility environment only
Harmonic emissions IEC61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC61000-3-3	N/A	
Electromagnetic Compatibility Requirements - Immunity		
Required Test	**60601 test level for equipment used in a professional healthcare facility only**	**Compliance level**
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air
Radiated RF EM Fields IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz
Proximity fields from RF wireless communications IEC61000-4-3	385MHz - 27 V/m 450MHz - 28 V/m 710, 745, 780MHz - 9 V/m 810, 870, 930MHz - 28V/m 1.72, 1.845, 1.97GHz - 28 V/m 2.45 GHz - 28 V/m 5.24, 5.5, 5.875GHz - 9 V/m	385MHz - 27 V/m 450MHz - 28 V/m 710, 745, 780MHz - 9 V/m 810, 870, 930MHz - 28V/m 1.72, 1.845, 1.97GHz - 28 V/m 2.45 GHz - 28 V/m 5.24, 5.5, 5.875GHz - 9 V/m
Electrical fast transient / burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	N/A
Surge IEC61000-4-5	± 0.5, 1, 2 kV line(s) to earth, ± 0.5, 1 kV line(s) to line(s) for power supply lines ± 2 kV line(s) to earth for input / output lines	N/A

Conducted RF IEC61000-4-6	3 V - 150 kHz to 80 MHz 6V - ISM bands between 150 kHz to 80 MHz	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0% U_T (100 % dip in U_T) For 0.5 cycle 0% U_T (100 % dip in U_T) For 1 cycle 70 % U_T (30 % dip in U_T) for 25/30 cycles 0% U_T (100 % dip in U_T) For 250/300 cycles	N/A
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	30 A/m	30 A/m

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

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 in accordance with MDD 93/42/EEC and can only be used along with a PC and printer, normally supplied by the customer. The patient environment and conditions for usage are defined earlier.

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 mask, anti-viral filter or posterior or anterior tubing, tip connector, Microfoam tape, foam inserts, flowhead and silicone rubber tubes 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 the latest version of EN 60601-1 and qualified to work on ME devices. Modification of the NR6 Rhinomanometer is not allowed. If the USB cable requires replacement, it must be replaced by one of the same length/specification.

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.