GM INSTRUMENTS

NV2 Rhinospirometer

User Guide

Version 3

CE 2797

CONTENTS

1. NV 2 Rhinospirometer Important Safety Information

Read this Operating Manual before attempting to use the Instrument.

Warnings

The NV2 is suitable for use in a professional healthcare facility, except near HF surgical equipment or outside the RF shielded room of a medical system for magnetic resonance imaging where the intensity of EM disturbances is high.

For the purposes of EN60601-1-2: 2015; the NV2 has essential performance which is to measure the volume of air breathed from each nasal passage in order to calculate the nasal partitioning ratio, any unintentional increases in these values must NOT be interpreted by the clinician/user as a valid measurement.

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

"WARNING: 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. The maximum length for the USB cable is 2 metres"

"WARNING: 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 NV2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

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

"WARNING 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)"

"WARNING This unit is a PC connected product. It is advisable not to touch the patient while using the equipment."

"WARNING 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 NV2."

"WARNING 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
If the PC and/or printer are not medically approved then NV2 should be positioned as shown below, outwith the patient environment. The PC and/or printer must be compliant to EN60950-1.

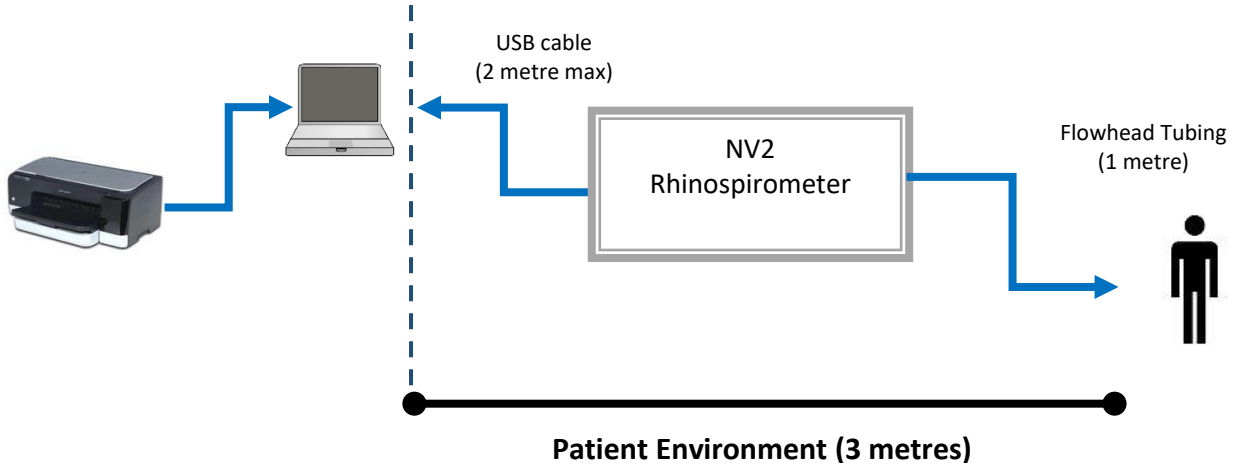


Figure 1: Patient Environment for Non-Medically approved PC & Printer

Option 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 below.

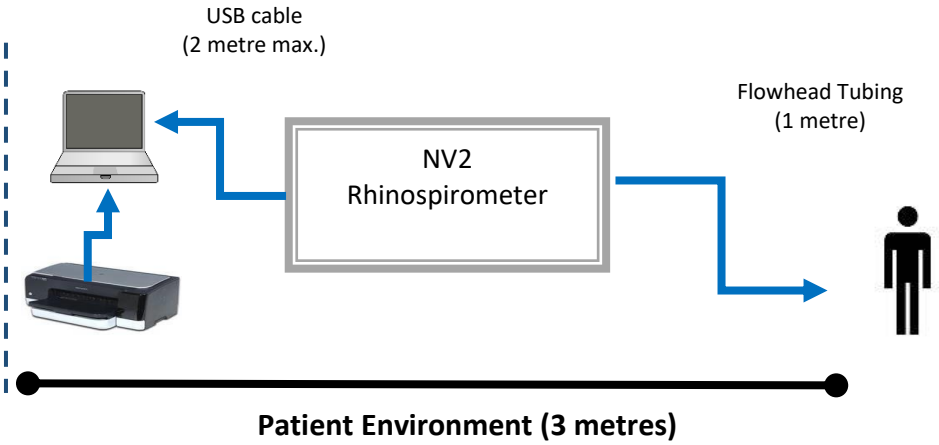


Figure 2: Patient Environment for Medically approved PC & Printer

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 on battery power without mains connection.

"WARNING" Applied Parts. The Applied Parts comprise, single use nosepieces, connected to an antiviral filter, flowheads and two twin silicone rubber tubes.

CAUTIONS

The nosepieces are made of a material (Conical nosepieces made from polycarbonate and Anatomical nosepiece made from polystyrene), which may cause an irritation reaction in some patients. Use of the nosepiece 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 carry infections between subjects.

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

The use of an NV2 Rhinospirometer 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 NV2 Rhinospirometer 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 NV2 should be immediately communicated to GM Instruments at the address below.

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 Rhinospirometer and computer and /or printer form a Medical System, refer to clause 16 of EN 60601-1:2006 to ensure compliance.

If the PC is 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. 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

Screen flowheads will not function properly if humidified air is passed through them. This can be avoided and the flowhead protected from contamination by adding an antiviral filter to the nosepiece side of the flowhead.

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

2. Storage

The NV2 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

3. Technical Specification

Only factory-trained personnel or engineers familiar with the standard EN 60601 can undertake servicing of the NV2 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 93/42/EEC	
Standards	Safety	BS EN 60601-1:2006 +A12:2014
	EMC	BS EN 60601-1-2: 2015
PC based unit	PC USB link	5 volts DC
Operation Environment	Temperature	+15 °C to +23 °C
	Relative Humidity	20 % to 80 % Non- condensing
	Warm up time	5 minutes
Performance	Repeatability	Better than 2% FSD
	Volume Accuracy (0 to 5 litres)	Better than 3% FSD
	Duty Cycle	Continuous
Storage and Transportation conditions	Temperature	-40 °C to +60 °C
	Relative Humidity	20 % to 80 % Non- condensing
Mechanical	Size	21 x 8 x 15 cm
	Weight	2Kg

Additional Technical Information (relative to EN 60601-1:2006) is also provided in Appendix 2

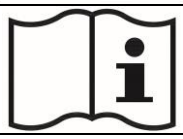
4. **Table of symbols used**

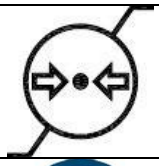
The following symbols appear on the NV2

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	Flowhead 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
	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
	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:

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5. INTRODUCTION

The NV2 Rhinospirometer has been developed for use by clinicians/ surgeons working within the field of rhinology as a screening tool. Its principle use is to give quantifiable guidance as to whether someone with a Septal Deviation shall benefit from surgery.

It 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.

The NV2 measures the partitioning of airflow between the two nasal passages, allowing the calculation of the Nasal Partitioning ratio (NPR). This value then allows an objective measurement of the severity of nasal septal deviation and is also useful for studies on the nasal cycle and rhinitis.

The patient inspires through two nasal adapters and the volume of air breathed from each side of the nose is measured. The nasal partitioning ratio (NPR) calculation is automatically done in the PC. Additional information derived from a measurement includes, mean and peak flow rates.

The method is based on the following principle:

During inspiration a negative pressure is created at the back of the nose, which is automatically applied equally to both sides of the nose. This pressure acts on the nasal passages to produce a flow rate, which will be in proportion to the pressure applied and the resistance to airflow in the passage.
By integration of these flows the volume of air passed through each of the nasal cavities can be calculated and displayed.
The nasal partitioning ratio (NPR) can be calculated from the following formula:-

$$NPR = Lvol - Rvol / Rvol + Lvol$$

Where:
Lvol: is the reading from the left side meter
Rvol: is the reading from the right side meter.

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

Clinical work reported in Rhinology, 41, 11-15, 2003 suggests that values smaller than –0.3 to +0.3 are normal while figures greater than that indicate a degree of asymmetry, which may benefit from surgery. The method has been developed in association with Prof. Ron Eccles at the Cold Research Centre, University of Cardiff. It should be noted that the test measurements are effort dependant, so absolute accuracy is not critical as it is the ratio of one side to the other, therefore the room for ratio error is low. Quantifiable guidance is given by the NV2 and readers are referred to the list of publications contained in Appendix 3.

6. Installation

NV2 Software
Please see the accompanying User Software Guide

NV2 Hardware

Connecting the flowheads
Connection between the NV2 box, and the flowheads is by means of two pairs of twin tubing. This tubing has colour coded bands to ensure correct polarisation.

If incorrectly connected an NV2 meter could show left side results as right and right side results as left. It could also read expiratory values instead of inspiratory or vice versa.

If the coloured bands on the twin tubing and on the flowheads are correctly matched, the blue flowhead will be connected to the ports on the NV2 marked left and the flowhead coloured Red will be connected to the ports on the NV2 marked right.

If expiratory air is to be allowed through the flowheads, anti-viral anaesthetic filters should be used to protect the flowheads. These should be placed between the colour coded nosepiece and the flowhead, with the blue nosepiece connected to the left side and the red nosepiece to the right.

Anatomical nosepieces sit outside of the nose and have a profile which match elongated nostrils provided the pointed part is directed towards the middle of the nose. They are supplied in pairs, as the profile of each is different, and are supplied in 2 sizes.

RIGHT sided ones are colour coded red, and when in use are placed with the pointed section towards the middle of the nose. They are connected to the flowhead coloured Red and the subject's right nostril.

LEFT sided ones are colour coded blue, and when in use are placed with the pointed section towards the middle of the nose. They are connected to the flowhead coloured Blue and the subject's left nostril.

A illustrations follow on the next page, which show how to connect the tubing, the right flowhead, the "bridge" and the nosepiece for inspiratory and expiratory measurements.

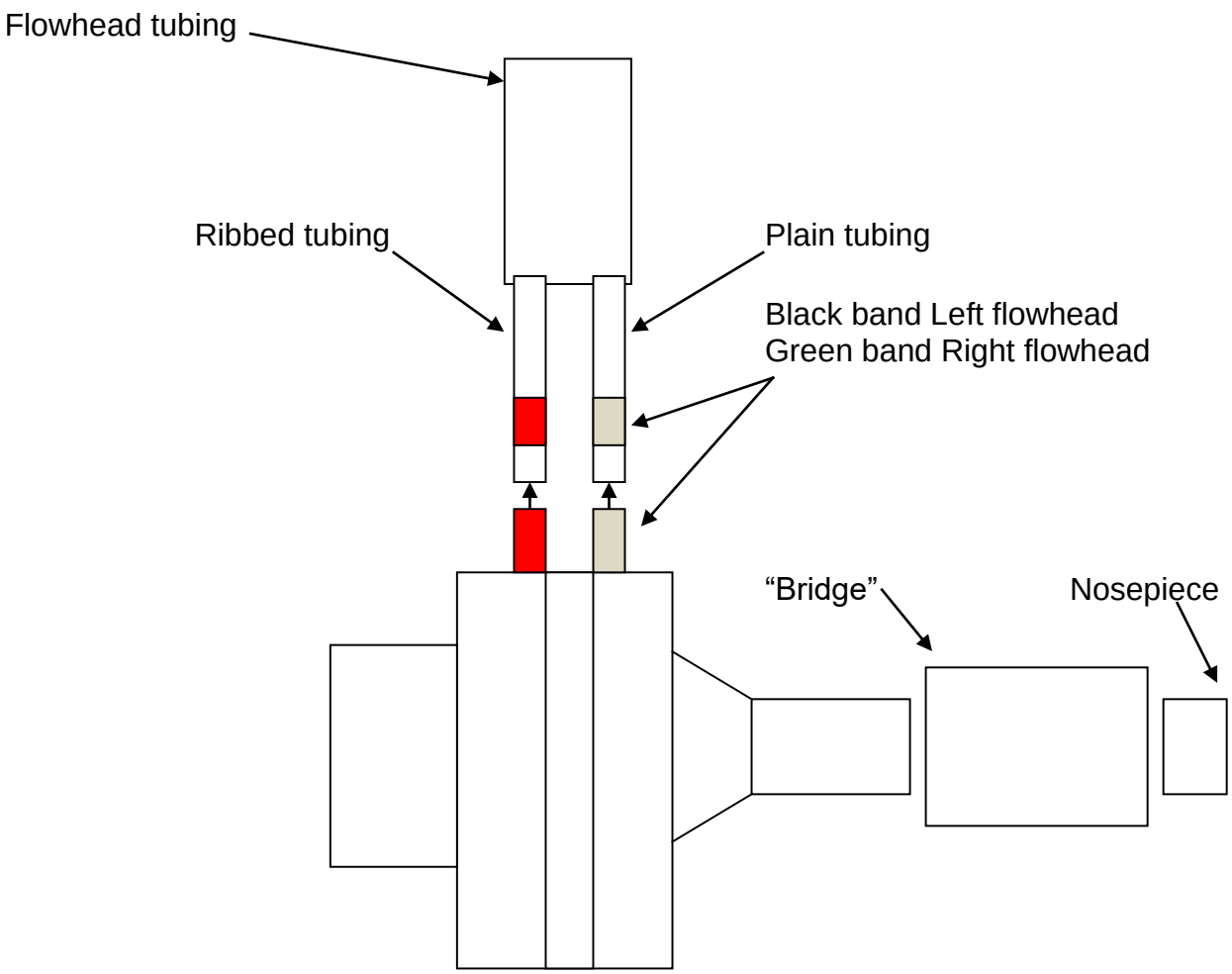


Figure 1: Connections where the measurement of a single breath of inspired air is required.

The subject is asked to breathe fully out, apply the nosepieces to their nose, and then breathe in fully through their nose.

If desired the process above can be repeated and the volumes achieved summed by having the subject remove the nosepieces, breathe out through their nose, re connect the nosepieces and breathe in again.

This process avoids contamination of the flowheads and bridge tubing.

If it is deemed necessary to add an anti viral filter to the system, either for added protection when making inspiratory measurements or because you want to allow inspiratory and expiratory air to pass through the flowhead, an anti-viral filter, which has standard anaesthetic size couplings, can be used in place of the "Bridge". To add such a unit, it will be necessary to reverse the flowhead and as a consequence also reverse its tubing as shown below:-

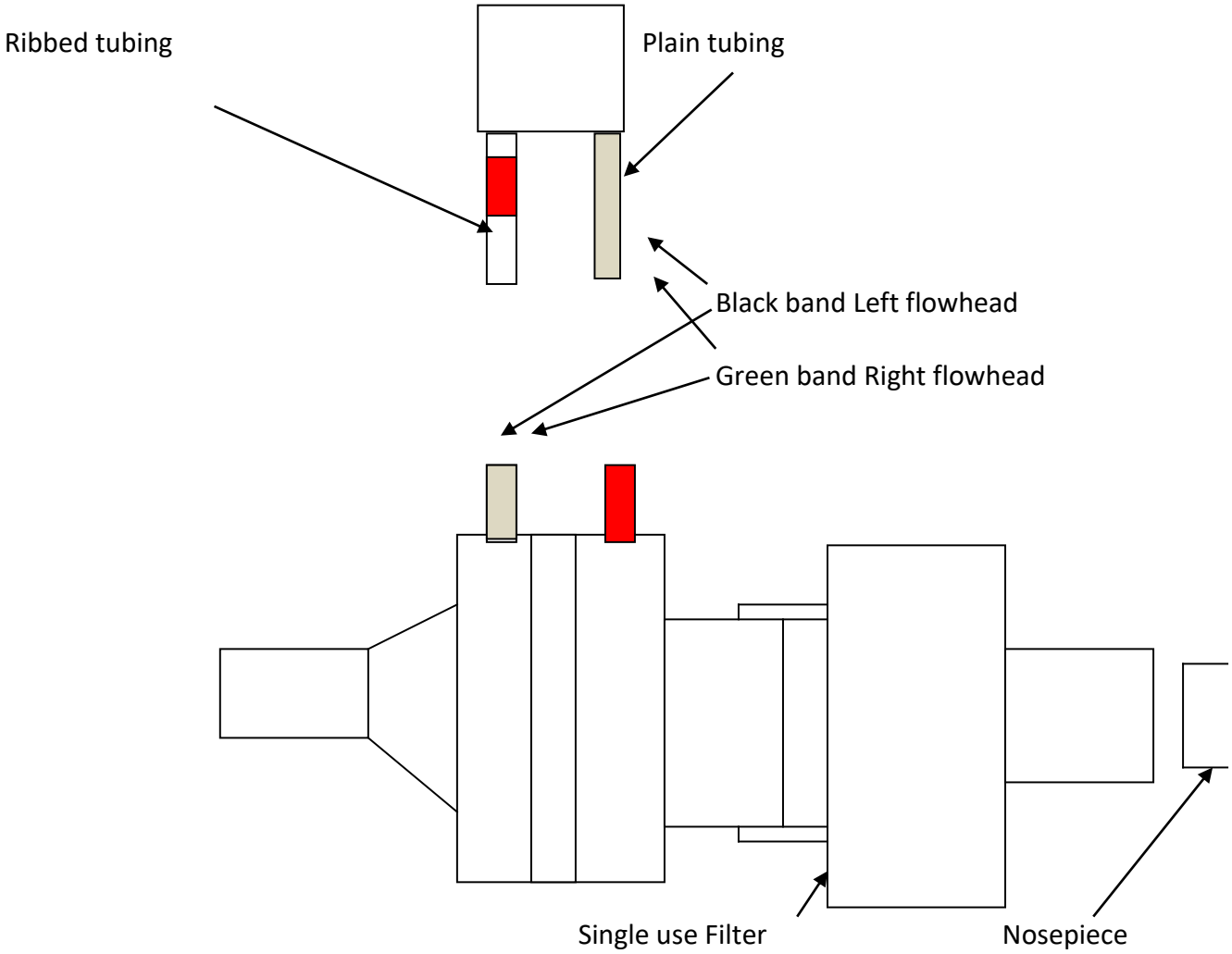


Figure 2: Connections where the measurement of inspired air is required and when expiration is allowed through the flowhead

The configuration above can be used to protect the flowheads from contamination if two or three inhalation and expiration breathing manoeuvres are to be performed, without asking the subject to remove and reconnect the nose pieces between each breath.

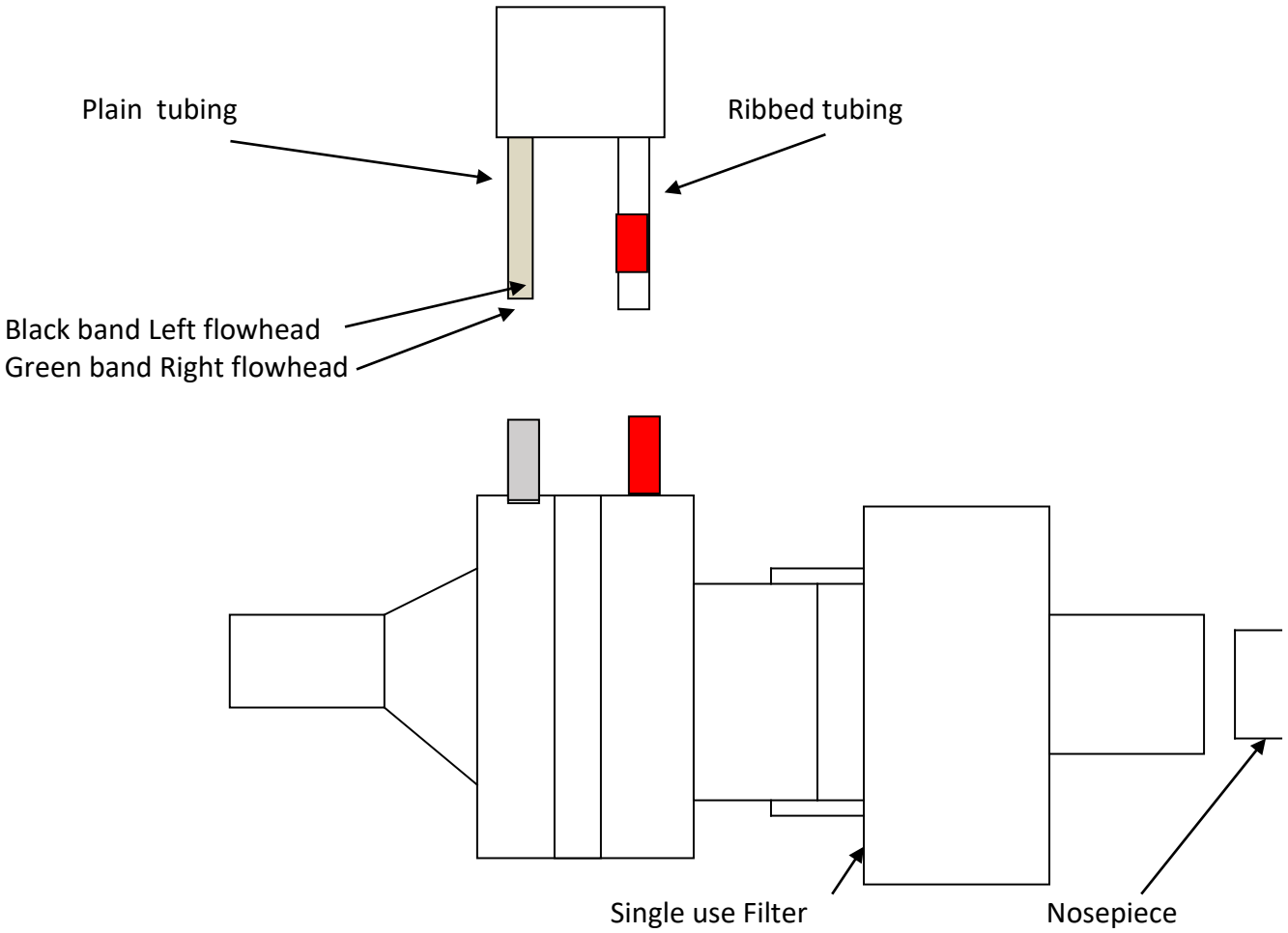


Figure 3: Connections required to measure expired air, instead of inspired, while protecting the flowhead from possible contamination.

The configuration shown above, which includes a single use anti viral filter, is necessary to protect the flowheads from contamination if expiratory breathing manoeuvres are to be performed.

Connecting the Power

The 2 metre USB cable supplied can be plugged into the back of NV2 and to the PC. Do not use a USB cable longer than 2 metres.

Having connected everything as described above the NV2 software can be started and the instrument allowed to warm up for 5 minutes prior to use.

7. TO MAKE AND RECORD MEASUREMENTS

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

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

Quick performance check:-
Start the software, click on the acquire button, connect the flowheads in series and draw room air through both simultaneously **at a rate lower than 800 cc/second**.

The volume shown for both right and left should be the same. This is detailed in "To make a new Record" section of the Software Manual.

If they do read the same or within a couple of digits of each other, then the system is ready for use.

It is possible that both are out of calibration by the same amount, but the likelihood of that happening is very remote.

If however a full calibration is required then the process is described in the maintenance section of this manual.

Patient Preparation
The patient should be prepared, prior to testing, by having them in a quiet stable environment for 15 to 20 minutes. As the NV2 is intended to be used to record the structural difference between right and left sides of the nose often the application of a decongestant will be required and the nose blown prior to making a measurement.

Which nose piece?
The choice of nosepiece depends on which will give the best seal between the nosepiece and the nose, with the minimum distortion.

Anatomical
The anatomical nosepieces supplied with NV2 are in 2 sizes (medium & large).
These are handed i.e. one is for use on the right side (colour coded red) and one for the left side (colour coded blue).
The anatomical probes are designed to sit on the outside of the nose and are shaped to make it easy, in most circumstances, to get a good seal. In addition they have a flange onto which can be put a non allergenic soluble gel, to take up any remaining gap.
Anatomical nosepieces are placed with the pointed section directed towards the middle of the nose.

Conical
An alternative conical shaped nosepiece is also supplied, which has the advantage that it is not "handed" and can be used on either left or right sides.

NB the caution statement on page 3 at the front of this manual. Nosepieces are marked for single use only, to prevent the transfer of infections between subjects.

Making Measurements

1) Switch on the PC and allow 5 to 10 minutes warm up
2) Before you make measurements, place the flowheads and tubing on the bench and click on the acquire button.
3) Indicate to the subject that they should, exhale fully, apply the nosepieces (perhaps suitably prepared with gel) to the nose, with the pointed ends of each flange pointing towards each other, at which time the operator should click on the red record button and ask the subject to inhale fully through their nose.

Nosepieces ----Anatomical ---------- Conical

The volumes achieved can be saved and the calculation will have been performed for you and displayed on the screen, along with some flow parameters.

If the outcome is YES the subject is likely to benefit from septal surgery, and if NO the subject is unlikely to benefit from septal surgery. The above process can be repeated if desired, from 2) above.

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

The formula for calculating NPR can be found on page 8 of this manual.

8. Error Messages

NV2 PC LINKED VERSION TROUBLESHOOTING

The Power ON LED on the front of NV2 does not light up.

- **Check that the USB cable is in place, linking the NV2 and PC.**
- **Run Instacal to ensure that the NV2 USB module has been recognised by the PC**
- **Check that the PC has not been allowed to go into sleep or power down mode.**

If the PC is 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. 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 NV2 software and restart it

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

9. Factors which affect absolute accuracy

Measurement accuracy and repeatability will depend on the following:-

Calibration:	Relative levels at least, should be regularly checked (see quick check note on Page 13
Temperature:	Use equipment in controlled conditions between 15 °C & 23°C.
Rigidity of nosepiece:	Try not to move.
Effect of nosepiece on the nose:	Minimise distortion.
Patient cooperation:	Only breathe in when asked to do so.
Nosepiece/nose seal:	Consider using gel and careful positioning to ensure seal.
Check for leaks/Distortion:	Repeat test at least twice if not 3 times and check for variation in the NPR figure. I.e. apply/remove probe 2 or 3 times, testing each time and compare the NPR ratio. (Not absolute values)

10. Maintenance / Technical Information

NV2 Overview

The NV2 Rhinospirometer should be calibrated regularly if absolute values are important. If not then a relative calibration check can be made as described earlier to ensure that if the same flow is passed through both heads simultaneously, the same values are achieved. In addition to this the cables, tubes and flowheads should be regularly inspected for signs of damage or contamination.

The nosepieces supplied are for single use only. Anti viral filters are intended for single patient use with a maximum time limit on usage with one subject. Check the instructions which are supplied with the filter.

Routine Maintenance

The following inspections should be made on a regular basis:-

1) Examine the connections between the NV2 enclosure and the PC
2) Examine the cable between PC and the wall socket.
3) Examine the tube connections between the front of the NV2 and the flowheads to ensure that the colour bands match, the tubes are fully pushed on to the NV2 nozzles and to the flowhead nozzles.
4) Examine the tubes for any damage. If split, they should be replaced.

External cleaning

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 with cleaning wipes. Do not allow liquid to run into the enclosure.

Flowheads

The flowheads can be wiped externally with a damp cloth or a cloth soaked in an alcohol based solution.

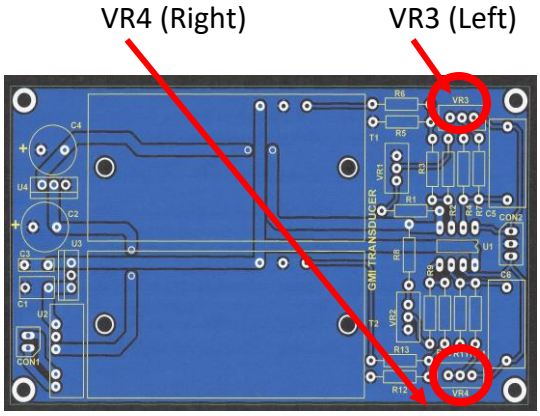
Twin Tubing

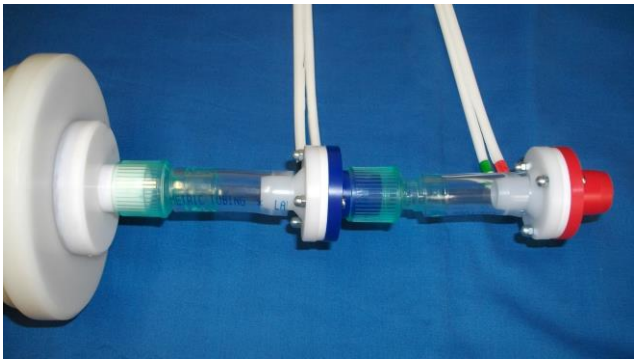
The white tubing can be wiped externally with a damp cloth or a cloth soaked in an alcohol based solution.

11. Full Calibration check and adjustment:

If the flowheads are connected in series and room air is drawn through them simultaneously, using a syringe of known volume, and **at a rate lower than 800 cc/second**, (a very slow draw) both meters should read the volume drawn by the syringe. If they do read the same volume as the syringe used to produce the reading, or within a couple of digits of that volume, then the system is ready for use.
If they don't read the level they should, according to the syringe, adjustment to the calibration can be made using presets inside NV2 marked VR4 - RIGHT and VR3 - LEFT.

Turn NV2 onto its top panel, exposing the 4 feet. Remove the 4 feet. Turn the NV2 back onto its base and remove the top panel. Remove the 4 screws from the lid of the diecast box and ease it gently over the 4 tubes. This will give access to the calibration presets. Run the NV2 software, select the acquisition icon
Adjust V4 for the right channel and V3 for the left (highlighted below) If the volume read is low, turn the appropriate preset one eighth of a turn clockwise, or if high, turn it one eighth of a turn anticlockwise, exit the acquisition screen, select it again (to automatically zero the transducers), then apply a known volume again. Repeat as required to achieve the correct results. Verify by doing another test.





Flowheads in series ready for calibration or calibration check

Flowhead Description

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

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

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

Effect of viscosity & temperature

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

Effect of gas density

Gas density is not a factor in Poiseuille's Law so it will not have an affect on the ΔP of the flowhead, but it is a factor in the Reynold's number calculation and will affect the maximum flow rate for which the PNT response is linear. The flowheads used with NV2 provide a linear flow/pressure relationship up to 800 cc/sec.

12. 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.

Care of Flowheads

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. NV2 can be used to record a single large inspiratory manoeuvre, or the sum of a number of inspiratory manoeuvres, which helps to avoid contamination, but much of the published work shows it being used to record a series of inspirations or expirations with air passing through the head in both directions**.**

We recommend the use of the anti-viral filter which allows measurements involving expiratory air to take place without compromising the flowhead.

Anti-Viral Filter

We recommend use of the Intersurgical Filta-guard filter (code 1944) unless one has been approved and supplied by your hospital. The Intersurgical unit is specified as being 99.999% efficient for bacterial/viral filtration. This filter is intended for use by one patient only and over a period not exceeding 24 hours. Its use must be restricted to situations approved by Intersurgical. No filter is 100% efficient so you may consider it prudent, if dealing with a patient who has a known or probable infection problem to follow the manual cleaning/disinfection process described in section 13.

13. Cleaning of Patient Contact Parts

Nosepieces

In the case of NV2 direct patient contact is made with a nosepiece, which is **a single use** component. There is no need to decontaminate these, as they are single use items.

As there is a possibility of contamination being deposited onto the flowhead beyond the single use items and thus being available to subsequent users, then we strongly recommend the use of anti-viral filters

Flowheads

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.

<u>Manual Cleaning/ Disinfection</u>

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

14. Supplied Parts

The following parts are supplied with the Instrument

NV2 transducer box	1
NV2TUB left	1
NV2TUB right	1
NV2/USB cable	1
Anti-Viral Filters	2
"Bridge" Tubing	2
PRM* Medium nosepieces (pairs)	5
PRL* Large nosepiece Pairs	5
PR8S* Conical nosepieces	16
Intersurgical Adaptor Code 1961	1
Operating and Software Manuals	1
Software Discs/Thumb drive (GMI + MCC)	1

15. Spare Parts and Consumables

Additional consumables or spare parts can be ordered against the codes below

Consumables

Medium anatomically conformed nosepiece	PRM*
Large anatomically conformed nosepiece	PRL*
Conical nosepieces	PR8S*

Spare Parts

MF100L	Respiratory Flowhead*
Flowhead tubing	Supplied by the metre length (Right or Left)*
"Bridge" Tubing	Supplied in pairs*
Intersurgical Connector	1962 000
NV2/USB	USB link to PC
MF100LSG	Replacement Gauze Assembly
Anti viral filter	Westmed 6216 or Intersurgical Filta Guard 1944 000

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 and manufacturer's declaration – electromagnetic Emissions		
Required Test	**Compliance**	**Comments**
RF emissions CISPR 11	Group 1 Class B	The equipment is suitable 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	
Guidance and manufacturer's declaration – electromagnetic Immunity		
Required Test	**60601 test level for equipment used in a professional healthcare facility environment 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 80MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz
Proximity fields from RF wireless communications IEC61000-4-3	Frequency - Test Level 385MHz - 27 V/m 450MHz - 28 V/m 710MHz – 9V/m 745MHz – 9V/m 780MHz – 9V/m 810MHz - 28 V/m 870MHz - 28 V/m 930MHz - 28 V/m 1.72GHz - 28 V/m 1.845GHz - 28 V/m 1.97GHz - 28 V/m 2.45 GHz - 28 V/m 5.24GHz – 9V/m 5.50GHz – 9V/m 5.875GHz – 9V/m	Frequency - Test Level 385MHz - 27 V/m 450MHz - 28 V/m 710MHz – 9V/m 745MHz – 9V/m 780MHz – 9V/m 810MHz - 28 V/m 870MHz - 28 V/m 930MHz - 28 V/m 1.72GHz - 28 V/m 1.845GHz - 28 V/m 1.97GHz - 28 V/m 2.45 GHz - 28 V/m 5.24GHz – 9V/m 5.50GHz – 9V/m 5.875GHz – 9V/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	N / A

	± 2 kV line(s) to earth for input / output lines	
Conducted RF IEC61000-4-6	3 V - 150 kHz to 80 MHz 6V - ISM radio 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 Magnetic field IEC61000-4-8	30 A/m	30 A/m

Appendix 2: Technical Information (relative to EN 60601-1:2006)

No modification to this equipment is allowed.

6.2 When the NV2 Rhinospirometer 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, single use nosepieces, ideally connected to an anti viral filter or tube connector, flowheads and two twin 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 NV2 Rhinospirometer is **NOT** suitable for use in an oxygen rich environment.

6.6 The NV2 Rhinospirometer rated for continuous use.

7.2.2 The NV2 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 NV2 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 Nosepiece packaging labels identify these as for single use only.

7.2.5 NV2 cannot be powered directly from the mains supply

7.2.6 The NV2 USB connection provides DC voltages of 5 volts dc.

7.2.11 The NV2 Rhinospirometer 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

7.9.1 The NV2 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.

7.9.2.3 The combination of the NV2 Rhinospirometer and the computer form an ME system

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 section in section 8 (P16)

7.9.2.11 The NV2 software can be closed by clicking on FILE and EXIT. The NV2 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 (nosepieces) should be disposed of after use in line with your hospital or clinics policy on disposal of potentially contaminated plastic parts.
The NV2 Rhinospirometer 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 (NV2TUBleft and NV2tubright)

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 NV2 Rhinospirometer is not allowed.

7.9.3.4 If access to the NV2 circuit board is required:-
Disconnect the NV2 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: References

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

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

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

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

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

Appendix 4: Definitions for Cleaning/Disinfecting/Sterilising

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.