



# Rhinomanometer NR6

User Manual  
and Installation Notes  
Issue 18



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# 1.NR6 RHINOMANOMETER SAFETY INFORMATION



**Read this Operating Manual before attempting to use the Instrument.**

## 1.1 WARNINGS/CAUTIONS

### 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.

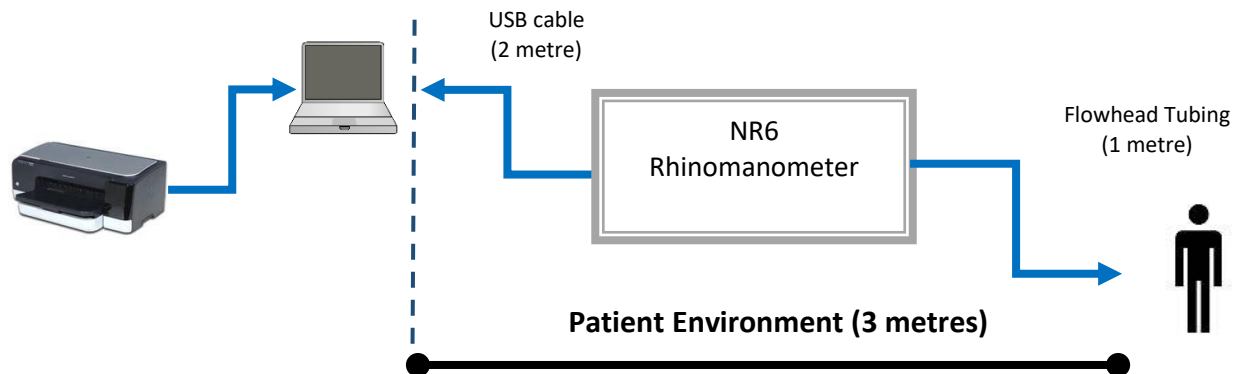
The equipment should be positioned in such a way that it can be easily disconnected from a mains powered PC. The operation of the system can be safely terminated by switching off the PC, or removing the USB cable between the PC and NR6.

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

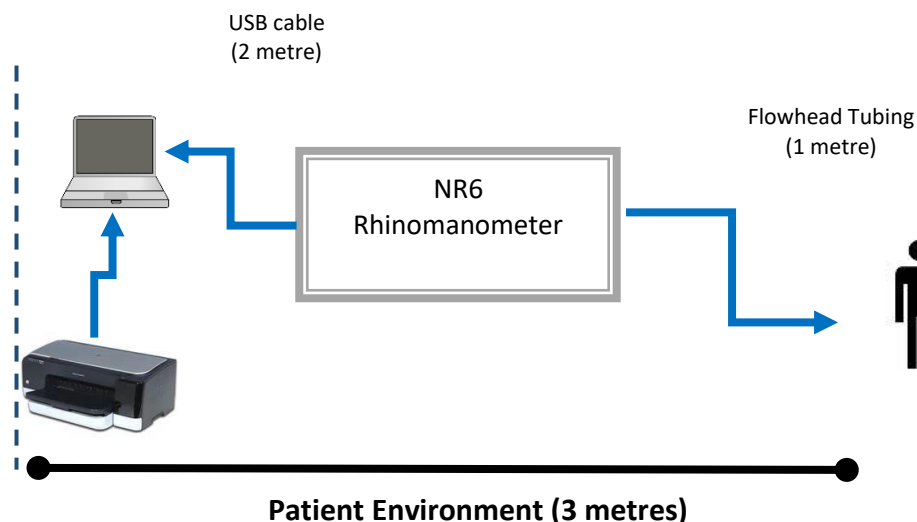
**Option 1: Patient Environment for Non – Medically approved PC & Printer**



**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.**

## 1.2 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                |

## 1.3 TECHNICAL SPECIFICATION

Only factory-trained personnel or engineers familiar with the standard EN 60601 can undertake servicing of the NR6 Rhinomanometer

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 the MDR 2017/745 |                                 |
| Standards                  | Safety                                                                          | EN 60601-1 :2006 +A1+12+A2:2021 |
|                            | EMC                                                                             | 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                       |
|                            | Power Supply                                                                    | 5V USB 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<br>ISO7010-M002 | USB Connector<br>Type B | Instrument Back<br>Panel            | Computer<br>(Via USB port)  |
|  | Type B<br>Applied Parts<br>IEC 60417- 5840  | Nozzles                 | Instrument Front<br>Panel           | Silicone Rubber<br>Tubing * |
|  | Protective Earth<br>IEC 60417 - 5019        | —                       | Instrument Back<br>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<br><br>ISO7000-3082                                       | Instrument Label                        |
|  | Date of Manufacture<br>Where ZZZZ: Date of Manufacture<br>ISO7000-2497 | Instrument Label                        |
|  | Serial Number<br>ISO7000-2498                                          | Instrument Label                        |
|  | Consult Instructions for Use<br>ISO7000-1641                           | Instrument Label                        |
|  | CE symbol, with 2797                                                   | Instrument Label                        |
|  | Do not re-use<br>IEC7000-1051                                          | Consumables<br>Packaging-<br>Nosepieces |
|  | Temperature Limit<br><br>ISO7000-0632                                  | Instrument Shipper<br>Packaging         |

|                                                                                     |                                                     |                                                  |
|-------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------------------------------------|
|    | Humidity Limitation<br>ISO7000-2620                 | Instrument Shipper<br>Packaging                  |
|    | Atmospheric Pressure limitation<br>ISO7000-2621     | Instrument Shipper<br>Packaging                  |
|    | Mandatory Action Sign<br>ISO 7010- M001             | Operating Manual                                 |
| Error! Objects cannot be created from editing field codes.                          | Authorized Representative in the European Community | Instrument Shipper<br>Packaging & User<br>Manual |
|    | Medical device<br>15223-1 ref.5.7.7                 | Instrument Label                                 |
|   | Unique device identifier<br>15223-1 ref.5.7.10      | Instrument Label                                 |
|  | Catalogue Number<br>ISO 7000-2493                   | Instrument Label                                 |
|  | Fragile, handle with care<br>ISO 7000-0621          | Instrument Shipper<br>Packaging                  |
|  | Keep dry<br>ISO 7000-0626                           | Instrument Shipper<br>Packaging                  |
|  | This way up<br>ISO 7000-0623                        | Instrument Shipper<br>Packaging                  |

**ADDRESS AND CONTACT DETAILS:****MANUFACTURED BY:**

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## 1.4 INTENDED USE

The NR6 Rhinomanometer is intended to be used by a Health Care Professional to quantify nasal obstruction. This is achieved by a non-invasive examination of the nasal cavity, plotting post nasal pressure against the resultant flow.

## 2. 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**

### 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

### 3. RHINOMANOMETRY OVERVIEW

The NR6 Rhinomanometer calculates nasal airway resistance by measuring nasal air flow and the pressure producing

that flow.

The device comprises a computer, running the Rhinomanometer software, and a patient sensor device. The patient sensor device measures nasal pressure and airflow by means of pressure sensors in a hardware unit which transfers the data to the computer via a USB connection.

Software running on the computer provides the user interface of the device, and receives data from the hardware unit.

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:

#### 3.1 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.

### 3.2 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

## 4. 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.

## 5. 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.

### 5.1 ANTERIOR METHOD (a)

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.

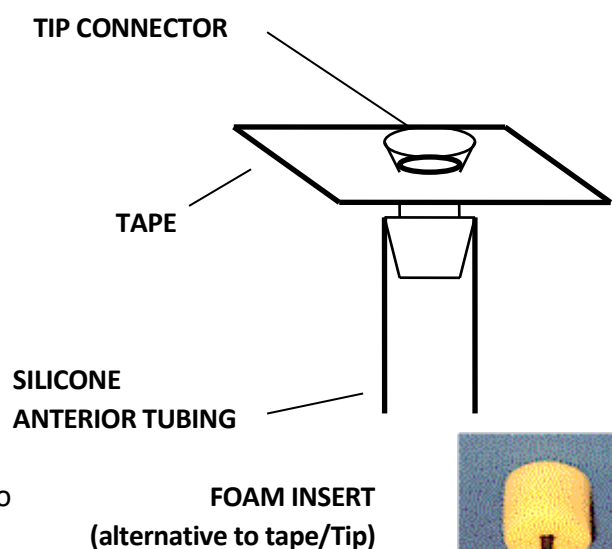
In this method flow is measured on the open nostril. The mouth should be closed during the test and once the resistance figure for one side has been obtained, the role of the nostrils is reversed by moving the tape assembly or foam insert to the other nostril.

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.

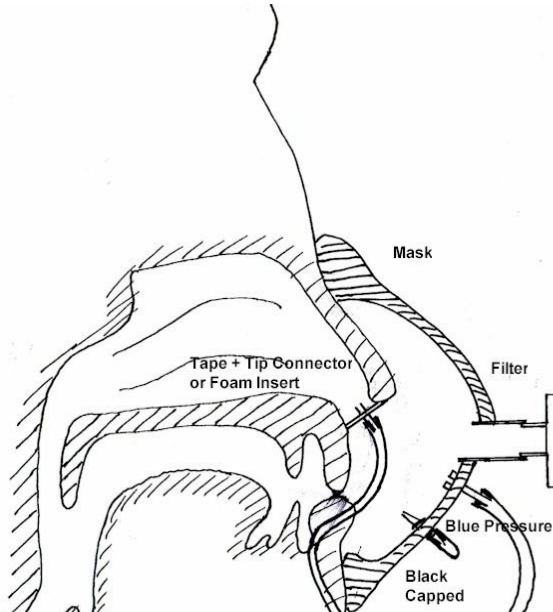
**If foam inserts are to be used, substitute the foam insert for the tip connector and tape as shown below.**

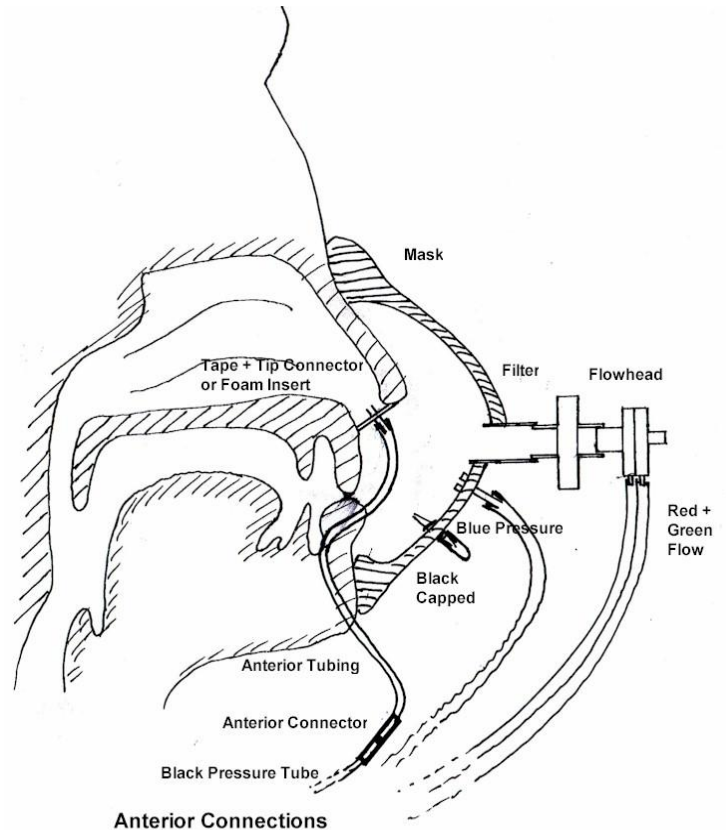
#### ANTERIOR TEST PREPARATION

- 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  
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
- 
- The diagram illustrates a patient's head and neck in profile, wearing a mask. A tube labeled 'Mask' is connected to the mask. This tube leads to a 'Filter' and then to a 'Blue Pressure' tube. A 'Black Capped' tube is also shown, connected to the 'Blue Pressure' tube. A 'Tape + Tip Connector or Foam Insert' is shown securing the mask to the patient's face. Arrows indicate the flow of air from the mask through the tubes to the flowhead.



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

## 5.2 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

### 5.3 POSTERIOR METHOD (B)

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:

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

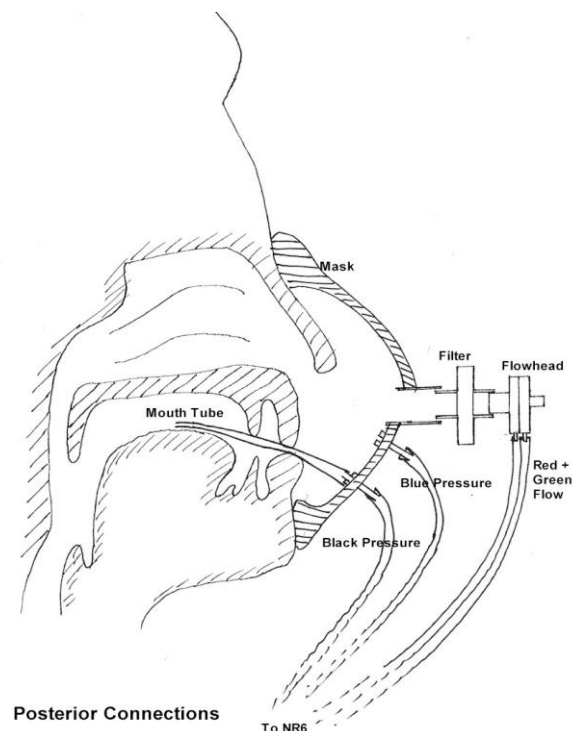
This technique does not interfere in any way with the nasal passages, but it does have the disadvantage that it depends on the mouth area having an uninterrupted connection to the respiratory tract. It is therefore essential that:

- 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

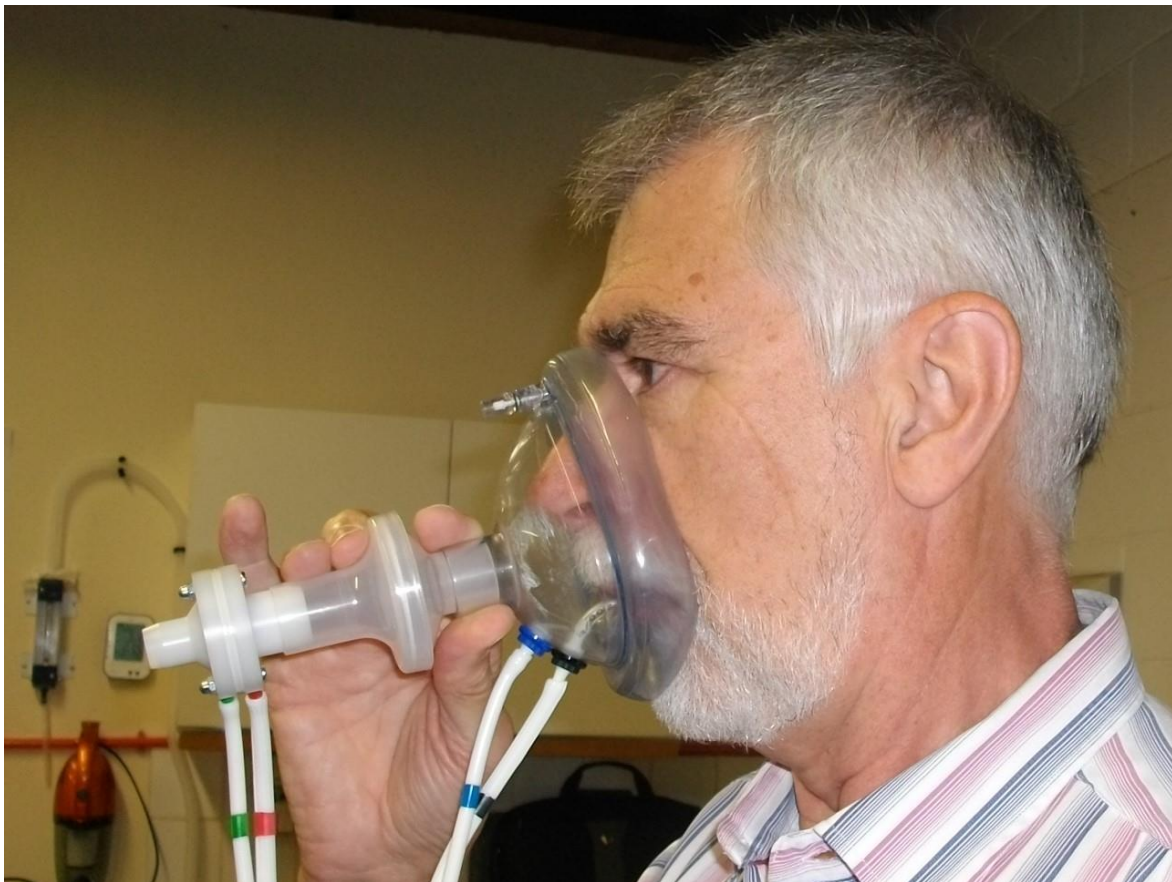
position that allows their cheeks to puff out with each expiration. Try it first without the mask and then with the mask in position. If the cheeks can move in and out, the soft palate, tongue etc. must be correctly positioned and posterior measurements can be made.

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.

#### 5.4 POSTERIOR MEASUREMENT



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



A posterior test being made

## 6.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.

## 7.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)

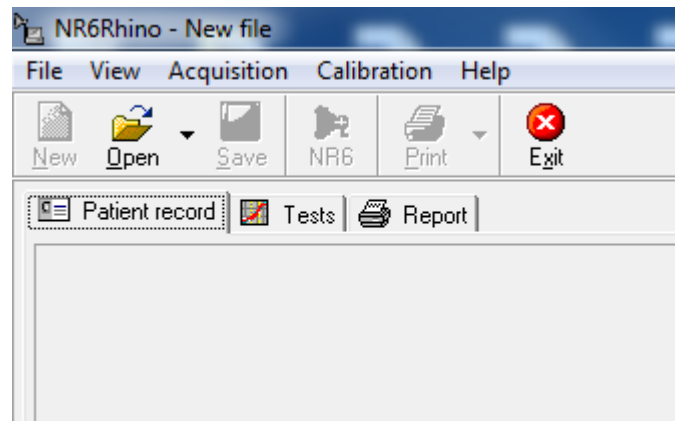
**1001..1008 - Arithmetic error during computation**

- 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.

## 8.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

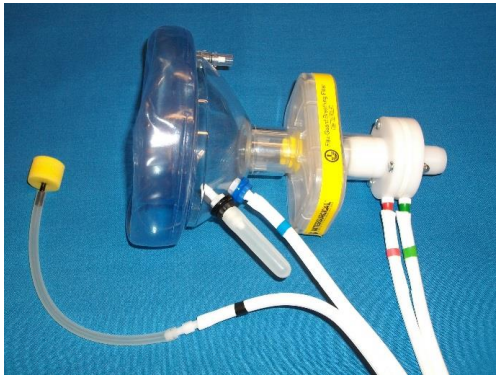
**REUSABLE ITEMS:**

- Re-usable mask

These can be reused if decontamination process is followed as per the instructions of APPENDIX 4.

**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.

## 9. SUPPLIED PARTS

| INSTRUMENT AND ASSOCIATED PARTS                         | GMI CODE         | QUANITIY |
|---------------------------------------------------------|------------------|----------|
| NR6 Rhinomanometer<br>(Clincial / Clincial Research)    | NR6-C/ NR6-CR    | 1        |
| USB Cable (maximum length 2m)                           | GM-USB           | 1        |
| Flowhead                                                | NR-FL            | 1        |
| Four Tube Set                                           | NR-4T            | 1        |
| Software Manual                                         | DOC-NR6-IFU-002  | 1        |
| User Manual                                             | DOC-NR6-IFU-001  | 1        |
| NR6 Software USB                                        | NR-C-SW/NR-CR-SW | 1        |
| Measurement Computing CD                                | MCC              | 1        |
| Rhinocal <small>CLINICAL/RESEARCH VERSIONS ONLY</small> | RHINOCAL         | 1        |

## CONSUMABLES STARTER PACK

### COMMON PARTS

|                         |       |   |
|-------------------------|-------|---|
| Adult Mask (Re-useable) | NR-RA | 1 |
| Child Mask (Re-useable) | NR-RC | 1 |
| *Filter (single use)    | NR-FR | 1 |

### ANTERIOR PARTS

|                          |         |                    |
|--------------------------|---------|--------------------|
| *Anterior Tube Connector | NR-AT   | 1                  |
| *Anterior Tubing         | NR-AT.1 | 1 x 1 metre length |
| *Tip Connectors          | NR-TC   | 1 x Pkt/5          |
| *Tape for Tip Connectors | NR-TAPE | 1                  |
| *Foam Inserts Large      | NR-LI   | 1 x Pkt/4          |
| *Foam Inserts Standard   | NR-STNI | 1 x Pkt/4          |
| *Foam Inserts Small      | NR-SMSI | 1 x Pkt/4          |
| Hole Punch for tape      | NR-HP   | 1                  |

### POSTERIOR PARTS

|                        |       |                    |
|------------------------|-------|--------------------|
| *Posterior Mouth Tubes | NR-PT | 1 x 1 metre length |
|------------------------|-------|--------------------|

## 10. 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.

# 11. MAINTENANCE MANUAL

## 11.1 CALIBRATION

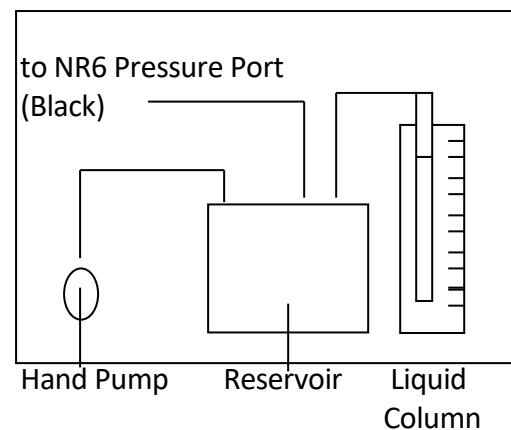
A calibration check should be made, and if required the instrument adjusted, in the following circumstances:

- if the pressure or flow transducers are changed
- if the flowhead is contaminated with dust or other particles or has been washed or disinfected
- if some time has elapsed since the last calibration (ideally a check should be made before each testing session)
- if there is any uncertainty about the results achieved

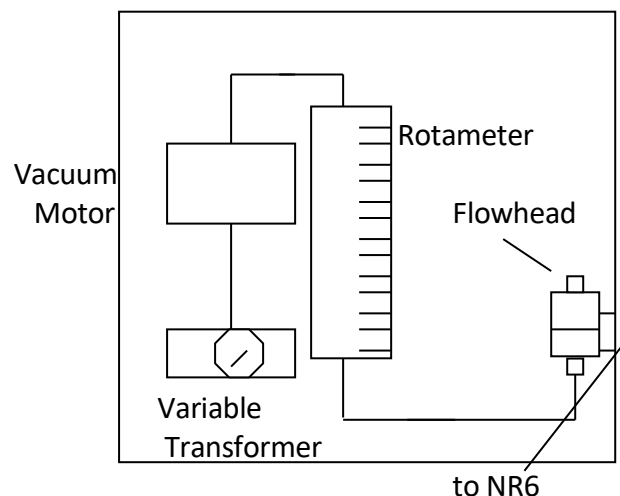
Two transducers are used in each NR6 - one for measuring the flow and one for measuring the pressure. They can be set using static individual calibration units, such as a liquid column for pressure and a rotameter for flow.

### CALIBRATION EQUIPMENT

**A. Pressure Gauge** - a liquid column covering the range 0-500 Pa (51mm H<sub>2</sub>O). 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 0-500cm<sup>3</sup>/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:

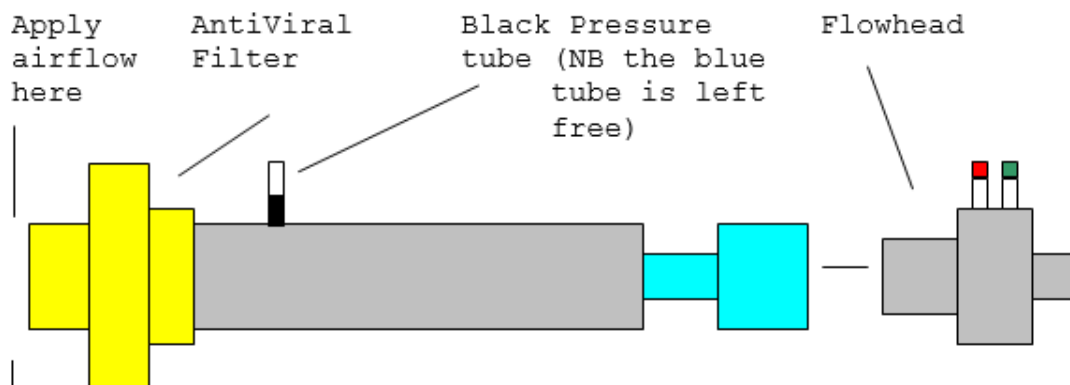
- a) Switch on the instrument and allow 5 minutes warm-up time
- b) Select calibration from the setup menu bar item and zero the output
- c) Apply a flow of 300cm<sup>3</sup>/s (18 litres/minute) to the flowhead and if the value shown on the screen is not correct, adjust the flow calibration potentiometer, 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<sub>2</sub>O) 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

## 11.2 NOTES ON USE OF RHINOCAL (Clinical/Research only)

The RHINOCAL unit is intended to provide a quick and easy way of checking the calibration status of a rhinomanometer. It does not provide information, which will allow the unit to be adjusted.

To use Rhinocal follow the undernoted procedure.

- 1) Switch on NR6 and start the program in the normal way.
- 3) Connect the flowhead and pressure tube to RHINOCAL as shown.



*Note an antiviral filter can be fitted to the end of the Rhinocal unit to avoid contamination of Rhinocal or flowhead. If fitted as shown it will not affect the values achieved.*

- 3) Select **acquire data (with no batch facility switched on)**  
**anterior test**  
**threshold + 300 Pa**
- 4) Use either:-
  - a) a syringe to provide a flowrate in and out through Rhinocal or
  - b) your mouth to provide inhalation and expiration through Rhinocal.
- 5) Click on record. After 4 cycles you will be asked if you want to record the other side - click on YES.
- 6) A 3rd test showing the combined L/R Expiration and Inspiration values will be added, the values for which should lie within the range:-

$$\text{INSP} = x.xx \quad \text{EXP} = x.xx \quad + 0.04 \text{ Pa/cc/s.}$$

If they lie significantly outwith the range shown above, repeat the measurement to confirm and if still outwith, consideration should be given to having the NR6 recalibrated.

- 7) It may be useful to save the files obtained under, for instance, the filename calcheck and to open this file prior to subsequent checking as this will allow a continuing record to be built.

## 11.3 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.

## 11.4 SERVICING

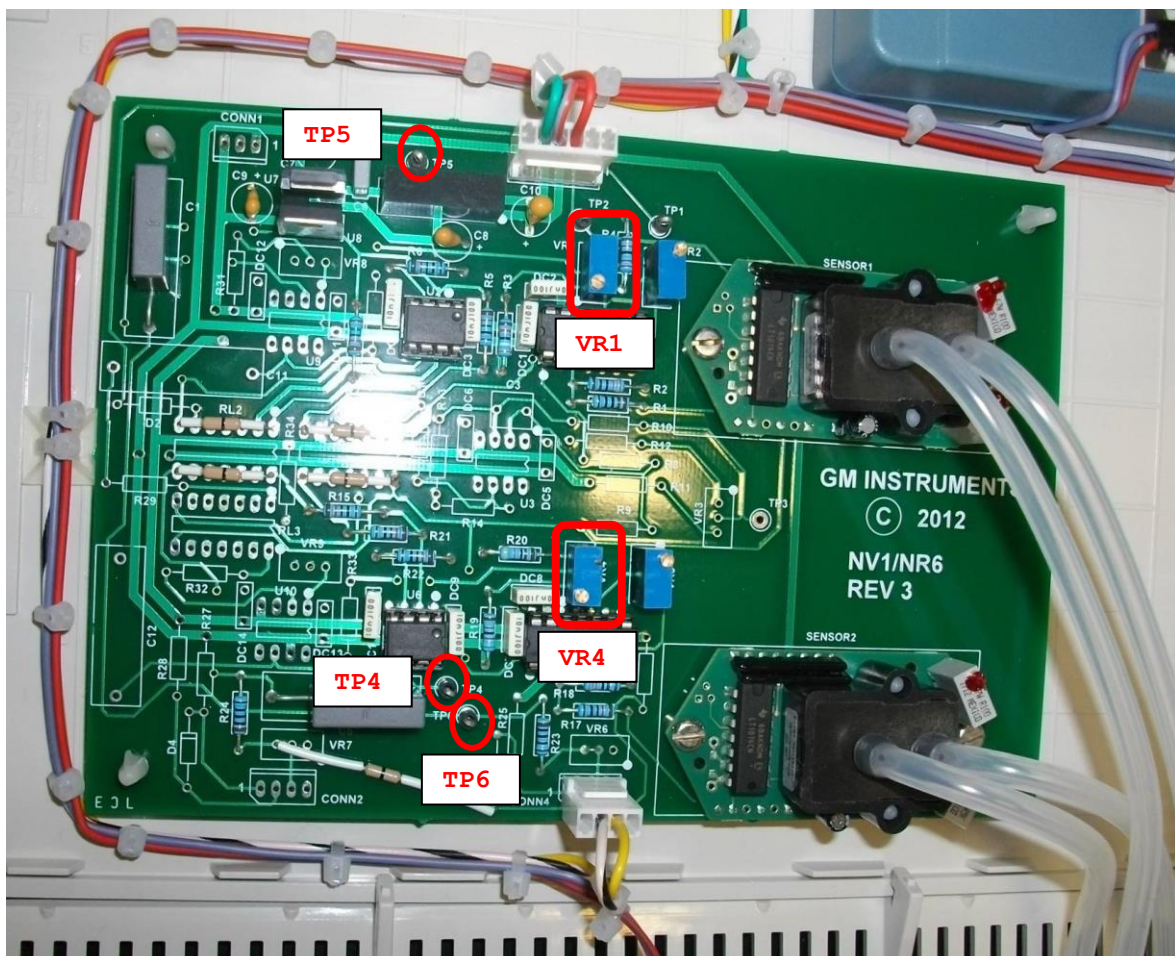


**Servicing can only be carried out by GMI approved and authorised personnel. No modifications are allowed.**

The NR6 contains two transducers with associated instrumentation amplifiers, balance and gain controls, and an isolated +5 Volts to  $\pm 8V$  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.

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Copyright Protection.

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## Appendix 1: Electromagnetic Compatibility

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

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

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

**No modification to this equipment is allowed.**

**6.2** 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 the Regulation 2017/745 (EU MDR) 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 is 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 manoeuvres 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**

| <b>FLOWHEAD TYPE</b> | <b>LINEAR RANGE cc/sec</b> | <b>APPROX. FLOW for 10mm WG</b> | <b>TUBE OUTSIDE DIAMETER</b> | <b>LENGTH mm</b> | <b>WEIGHT gm</b> |
|----------------------|----------------------------|---------------------------------|------------------------------|------------------|------------------|
| 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 5

## **APPENDIX 4: CLEANING/DISINFECTION/STERILISATION OF REUSABLE MASK**

### **1. GENERAL INFORMATION**

- The reusable devices are supplied non-sterile and must be unpacked, cleaned, disinfected and sterilized prior to use.
- Devices must be reprocessed prior to each use.
- The manufacturer is not responsible for damage resulting from improper reprocessing.
- It is recommended to use an automated procedure because automated cleaning and disinfection are significantly more effective.
- To achieve effective reprocessing, heavy soiling must not be allowed to dry on the device and must be removed immediately after use.
- Silicone devices must not come in contact with oil and grease.

### **2. CLEANING / DISINFECTION**

#### **2.1. Automatic Cleaning/Disinfection**

##### **Notes Regarding the use of Washer disinfectors.**

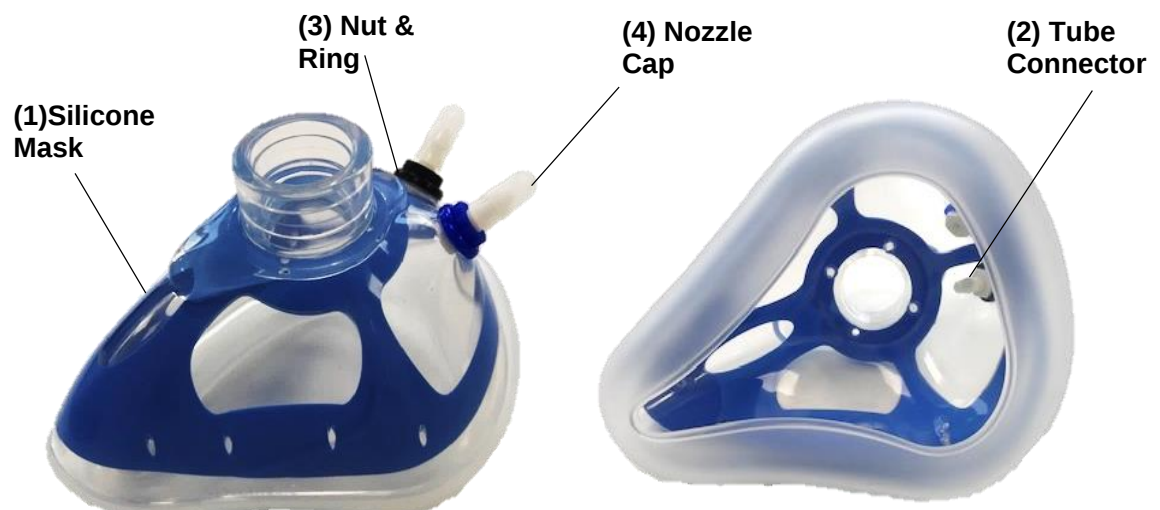
- Use deionised water.

##### **Notes Regarding the use of Cleaning agents and disinfectants.**

- When alkaline cleaning agents are used, the agent must be subsequently neutralised.
- Do not use drying agents.

##### **Procedure:**

- 1) Disassemble the product.



- 2) Place the products into the injector carriage :

| Product/Items                                                     | Positioning in the injector carriage  |
|-------------------------------------------------------------------|---------------------------------------|
| Tube Connector (2), blue/black Nut & ring (3) and Nozzle caps (4) | Mesh Tray (securing with a cover net) |
| Silicone Mask (1),                                                | Injector jets                         |

- 3) Start the program with the following parameters:
  - a) Pre-rinse with deionised water at 20°C (68°F) with an exposure time of 1 min.
  - b) Clean at 55°C (131°F) with an exposure time of 5 min. using deionised water and Sekumatic® ProClean cleaning agent (dose:0.5%(5ml/l)).
  - c) Neutralise with Sekumatic® FNZ at 20°C (68°F) with an exposure time of 2 min. (dose: 0.1% (1 ml/l)).
  - d) Rinse with deionised water at 20°C (68°F) with an exposure time of 2 min.
  - e) Thermal disinfection at 93°C (199°F) for 5 min. with deionised water.
  - f) Dry at 100°C (212°F).
- 4) Check for visible contamination. If necessary repeat the processing.
- 5) All parts must be dry and free from damage (cracks, ruptures etc.) Assemble the product as shown in the diagram.
- 6) Check the devices according to the section “Checks” and prepare them for sterilization (see section “packaging”).

## 2.2. Manual Cleaning/Disinfection

### **Notes Regarding the use of Cleaning agents and disinfectants.**

- Prepare the cleaning and disinfection solutions prior to each manual cycle.
- Use deionised water

### **Procedure:.**

- 1) Disassemble the product.
- 2) Prepare a 2% (30 ml/l) cleaning and disinfection solution of Sekusept® Aktiv with deionised water at 20°C (68°F). After 15 min. the cleaning and disinfection solution can be used
- 3) Clean the devices with soft sponges in the cleaning and disinfection solution. Areas difficult to access must be cleaned with soft brushes. Hard brushes and other materials which may damage the silicone cuff or the silicone surface of the devices must not be used.
- 4) Place the devices into the cleaning and disinfection solution and leave for 15 mins. Ensure all internal cavities are covered with solution.
- 5) Remove cleaning and disinfection solution by rinsing thoroughly with deionised water. Remaining Residues can shorten the device life span or can lead to material damage.
- 6) Dry the devices. Avoid any accumulation of water.
- 7) Check for visible contamination. If necessary repeat the processing.

- 8) All parts must be dry and free from damage (cracks, ruptures etc.). Assemble the product as shown in the diagram.
- 9) Check the devices according to the section “Checks” and prepare them for sterilization (see section “packaging”).

### 3. CHECKS

After disinfection and before every use, the devices must be visually inspected for damage (cracks, breakages, etc.). Damaged or leaky devices must not be used.

### 4. PACKAGING

- Sterilise only the assembled product.
- After the cleaning and disinfection procedure, the devices must be packed into a package that is suitable for steam sterilisation (according to the currently valid versions of DIN EN 868 and DIN EN ISO 11607).

### 5. STERILISATION

#### **Notes regarding Sterilisation:**

- Devices or sterilisation packages must be protected from mechanical damage.

#### **Sterilisation:**

- The devices must be steam sterilised using a fractional vacuum process.
- Exposure time is 5 min. with a sterilisation temperature of 134°C (273°F).

### 6. REUSABILITY

The end of the lifespan for reusable devices is basically determined by wear and damage caused by its use. Considering the maximum lifespan of 5 years, reusable devices can be reprocessed up to 100 times if used properly and if the cleaning, disinfection and sterilisation instructions are complied with. Every further reuse is the responsibility of the user (see section “checks”).

### 7. WARNING

By using the devices on patients with suspected prion disease there may be a risk of high transmission. In such case the doctor must decide whether the device is either disposed of (see section “disposal”) or reprocessed according to national directives.

**8. STORAGE CONDITIONS**

Considering the maximum lifespan of 5 years, the device can be stored in its original packaging under the following conditions:

- Protect from heat and store in a dry place.
- Protect from sunlight and sources of heat.
- Do not store silicone devices together with devices made of PVC or rubber.

**9. SERVICE**

Prior to the return of medical devices for complaints/repairs, the devices must have run through the complete reprocessing process to exclude any risk for the staff of the manufacturer. For safety reasons the manufacturer preserves the right to refuse soiled or contaminated devices.

**10. DISPOSAL**

Used or damaged devices must be disposed of in accordance with the relevant national or international legal regulations.

## **APPENDIX 5: 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.

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