GM INSTRUMENTS

Acoustic Rhinometer A1

Instructions for Use / User Manual

Issue 5

CE 2797

Table of Contents

A1 ACOUSTIC RHINOMETER SAFETY INFORMATION

Read this Operating Manual before attempting to use the Instrument.

WARNINGS

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

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

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

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

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

The computer may not be connected to the internet.

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

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

CAUTIONS

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

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

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

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

The A1 Acoustic Rhinometer is a medical instrument, which has an electrical classification of Class I

Type B and a Medical Device Directive classification of IIa. A Class l Type B device categorisation is used to describe an instrument which:

a) Does not rely on basic insulation only to provide protection against electrical shock but is constructed in such a way that accessible metal parts cannot become live in the event of failure of the basic insulation, and
b) Applied parts offer protection to the subject against electrical shock and in the event of a single fault condition arising, leakage current will be limited to less than 0.5 mA.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. Contact GM Instruments at the address on page 10.

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

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

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

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

Standardisation Document.

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

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

INTENDED USE

The A1 Acoustic Rhinometer is used to quantify nasal obstruction. The device is intended to be used by a Health Care Professional for non-invasive examinations of the nasal cavity using a sound pulse technology.

INDICATIONS FOR USE

The A1 is indicated for use where nasal obstructions are suspected, or when quantification of the nasal cavity before and after a procedure or challenge is required.

INTENDED USERS

The A1 Acoustic Rhinometer provides information to assist ENT Surgeons, Allergists, researchers into nasal function and those involved in sleep studies with information to guide their treatments and research. Typically, any medically trained technician, nurse, or doctor will be considered competent to use the device.

INTENDED POPULATION

The A1 Acoustic Rhinometer is intended to be used in paediatric and adult populations (including pregnant and breast-feeding women), regardless of gender.

BENEFITS

The A1 Acoustic Rhinometer has the following Benefits

1. Able to quantify the level of nasal obstruction
2. Provides a rapid non-invasive examination
3. Can be used for pre/post comparisons to assess outcome of intervention or therapy

DESCRIPTION of the A1 Acoustic Rhinometer

The A1 Acoustic Rhinometer allows a very rapid non-invasive examination of the nasal cavity using a sound pulse technique.

The device comprises a hardware unit, with the sound tube attached by a cable, and software running on a computer. The sound tube contains a microphone, and is coupled to the test subject's nose with a nosepiece. The hardware unit is powered by a separate power supply, and connected to a computer via a USB cable.

Software running on the computer provides the user interface of the device, and sends and receives acoustic signals via the hardware unit.

Figure 1. The A1 Acoustic Rhinometer

STORAGE

The A1 Acoustic Rhinometer and its accessories should be stored within the following temperature and humidity ranges:

Temperature	-40°C to +60°C
Humidity	30% to 90% RH non-condensing

TECHNICAL SPECIFICATIONS

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

Performance (using standard nose)	Repeatability	Better than 2%
	Volume Accuracy (0cm to 5cm)	Better than 2%
	Minimum Area Accuracy (within 0cm to 5cm)	Better than 5%
	Area Range (max 20, default 10)	0.1 cm^2 to 10 cm^2
	Distance Range (using standard sound tube)	0 cm to 12 cm
	Calibration	User Calibrated
Operation Environment	Temperature	+15 °C to +35 °C
	Relative Humidity	20% to 90% RH non-condensing
	Duty Cycle	Continuous
	Warm Up Time	5 minutes
	Supply	Universal voltage – external supply
	Power	10 Watts
Transportation and Storage	Temperature	-40 °C to +60 °C
	Relative Humidity	30% to 90% RH non-condensing
Mechanical Performance	Size	27 x 8 x 30 cm
	Weight	2 Kg

TABLE OF SYMBOLS USED

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

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

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

Symbols used on labelling and packaging:

SYMBOL	Indication
	Manufacturer
	EU Authorised Representative
	Date of Manufacture
	Catalogue Number
	Serial Number
	Medical Device
	Consult Instructions for Use
	CE Mark
	Do not re-use
	Non- sterile
	Temperature Limit
	Humidity Limitation
	Unique Device Identifier

ADDRESS AND CONTACT DETAILS:

MANUFACTURED BY:
GM Instruments Ltd, Block 1 Annickbank Innovation Campus, Annick Road, Irvine, KA11 4LF, UK.

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

AUTHORIZED REPRESENTATIVE:
Advena Ltd, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, Malta

INSTALLATION

INSTALLING THE A1 SOFTWARE

Installation of the A1 software is described fully in the accompanying manual titled:

A1 Acoustic Rhinometer Software Manual

INSTALLING THE A1 UNIT

The A1 Acoustic Rhinometer can operate on any PC which runs a Windows based operating system which has a free USB socket.

Connections between the A1 box, its sound tube, its power module and the PC are by means of polarised connectors which can only be inserted in the correct socket and with the correct orientation.

Connect the sound tube and the power module prior to powering up the A1, **but do not connect the USB cable until the A1 software and A/D board driver software are installed.**

N.B. Units which comply with EN60950 should be used.

HARDWARE IDENTIFICATION

Calibration plug ----- supplied with the A1 Clinical and A1 Clinical/Research
Artificial nose and Straight Tube----- supplied with the A1 Clinical/Research

A1 rear view and connections

NOTE: LINK SOCKET ONLY USED WHEN CONNECTED WITH NR6 IN NARIS CONFIGURATION

INTRODUCTION

Hardware and software have been provided with the A1 Acoustic Rhinometer to allow for the determination of **Nasal Obstruction** by plotting Nasal Area against Distance using Acoustic Reflections.

The method is based on the following principle:

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

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

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

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

For further information, the reader should consult these publications:

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

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

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

HOW TO MAKE MEASUREMENTS

The A1 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.

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

CALIBRATION

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

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

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

The system is now ready for use.

PATIENT PREPARATION

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

The nosepieces supplied with the system include 15 conical and 5 pairs of each size of anatomical probes (medium & large). These are handed and colour-coded, i.e. one is for use on the right side (red) and one for the left side (blue).
N.B. The caution statement on page 3 at the front of this manual.

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

MAKING MEASUREMENTS

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

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

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

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

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

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

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

SWITCHING OFF

The software can be closed by clicking on **File** and then selecting **Exit** from the drop-down menu.
The hardware can be powered down by unplugging, or by switching off the mains plug.
N.B. If you allow the PC to go to sleep or hibernate, the USB is disabled and will not re-initialise unless you either:

a) Restart the PC or
b) Close the A1 acquisition screen (if open), unplug the USB cable and then re-insert it.

We recommend that you disable the sleep/hibernate function, under Windows.

FACTORS WHICH AFFECT ACCURACY

Measurement accuracy and repeatability will depend on the following:

Calibration:	Perform a calibration at least twice a day
Temperature:	Use equipment in controlled conditions between +15°C & +35°C
External noise:	Use equipment in conditions where the background noise is below 65 dB
Angle of probe (relative to the head):	Aim for floor of nose
Rigidity of probe:	Doesn't move
Effect of probe on the nose:	Avoid distortion
Patient co-operation:	Hold breath during measurements
Nosepiece/nose seal:	Use gel and careful positioning to ensure a good seal.
Check for leaks/Distortion:	Repeat test at least twice if not 3 times and check for variation, i.e. apply/remove probe 2 or 3 times, testing each time and compare results.
Electromagnetic disturbances:	Exposure to excessive fields from nearby RF transmitters may the equipment not to function or measure correctly. If the measurement trace is not parallel to the horizontal axis in the first range of -4.5 to 0 centimetres, then the results should be discarded as invalid.

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

ENVIRONMENTAL FACTORS

Temperature Effects

An increase in the temperature of the gas through which the sound pulse travels lowers its density and therefore the rate at which it travels through the gas. The overall effect is in the range of 3% / 20°C. Distance is therefore slightly overestimated if there is an increase in temperature.

Altitude Effects

The effect of altitude is significant on the density of a gas and, therefore, on the speed of sound at an altitude of 1000m. As such distance will be overestimated by 7%.

Electromagnetic Disturbances

Exposure to excessive fields from nearby RF transmitters may the equipment not to function or measure correctly. If the measurement trace is not parallel to the horizontal axis in the first range of -4.5 to 0 centimetres, then the results should be discarded as invalid.

A1 TROUBLESHOOTING

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

START UP

An instance of the application is already active

- The software is already open in another window

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

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

License key is missing or invalid!

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

License key does not match product!

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

FILE MANAGEMENT

The requested file cannot be loaded in this application

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

File saving attempt failed!

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

Target file already exists!

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

Directory "%s" does not exist

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

No filename given

- You have clicked on save without specifying a file name

Export to "%s" has failed!

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

ACOUSTIC ACQUISITION

The hardware board with number %d is not recognized

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

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

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

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

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

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

- As 10 above

Error Code 1001..1008 - Arithmetic error during computation

- May be a PC memory issue

Error Code 1009 - Signal below trigger level

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

Error Code 1050 - Error saving calibration data!

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

Error Code 2000 - Acquisition aborted

- Software/hardware issue has prevented the program from running

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

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

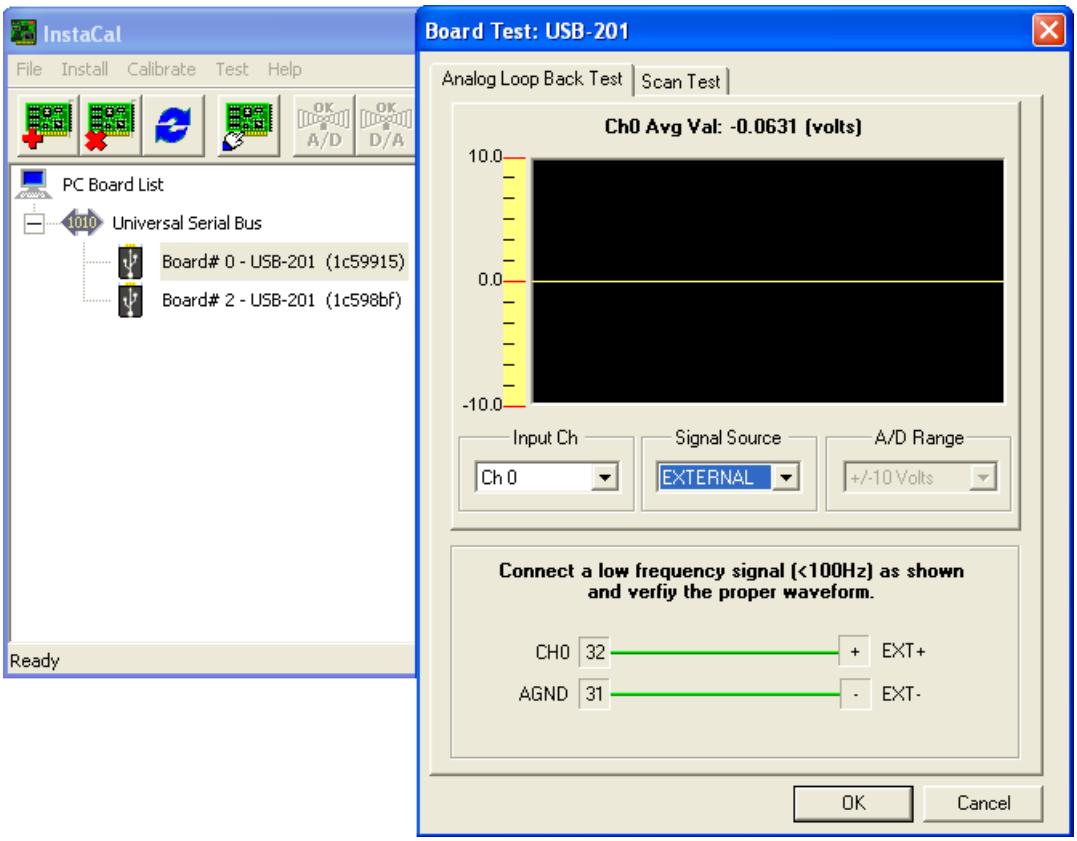
InstaCal

Navigate to the MCC (Measurement Computing Company) folder using **My Computer** and double-click on the program **Inscal32.exe** - C:/Program Files(x86)/Measurement Computing/DAQ.
N.B. In a 32-bit system this will be C:/Program Files/Measurement Computing/DAQ as a 32-bit system won't have an x86 folder.

The opening dialog will show which boards are installed.

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

  The line you see should lie on 0 Volts and should respond to talking into the open end of the sound tube – if this is ok then the microphone and connections between A1, the A/D card and the PC are ok.



EXPLANATION OF HOW InstaCal WORKS

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

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

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

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

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

A1TEST

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

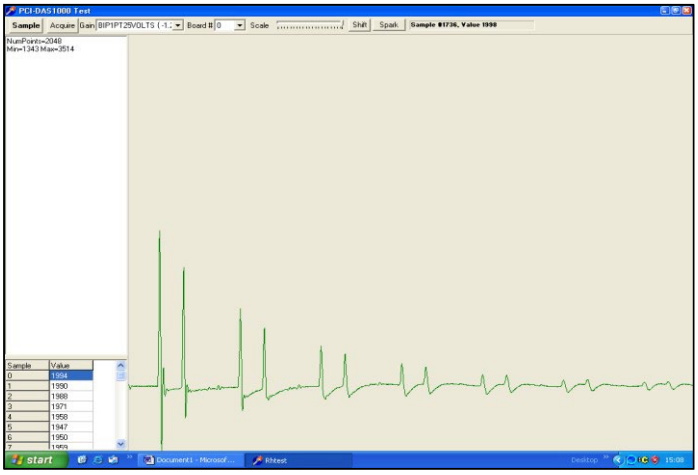
Double-clicking on the name will start the application.

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

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

The baseline should be between 1950 and 2050 units.

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



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

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

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

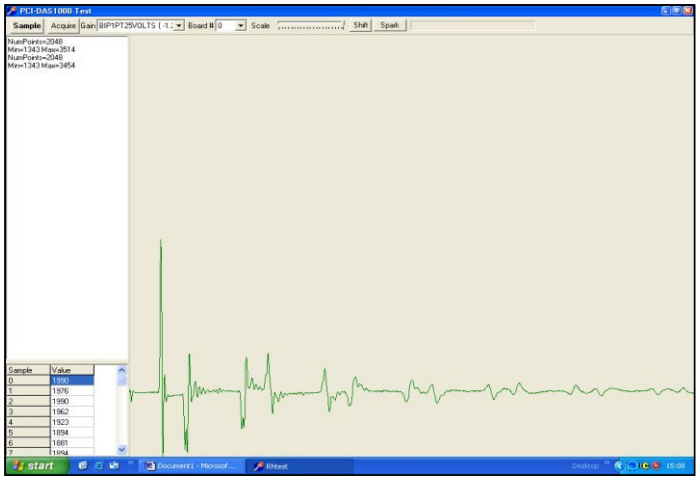
The trace above shows the microphone signal output plotted against sample numbers.

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

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

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

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



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

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

SUPPLIED PARTS

INSTRUMENT AND ASSOCIATED PARTS	GMI CODE	QUANTITY
A1 Acoustic Rhinometer	A1-C	ONE
USB Cable	GM-USB	ONE
Sound Tube	A1-STM	ONE
Calibration Plug	A1-CP	ONE
External Power Supply	A1/PR	ONE
User and Software Manual	DOC-A1-UM-001	ONE
A1/MCC Software	A1-C-SW	ONE
*Large Anatomical Nosepieces	A1/NV1-PRL	5 Pairs
*Medium Anatomical Nosepieces	A1/NV1-PRM	5 pairs
*8 mm Conical Nosepieces	A1/NV1-PR8S	15 pcs

CLINICAL/RESEARCH VERSION

Artificial Nose and Straight Tube	A1-AN.1	ONE

SPARE PARTS AND ACCESSORIES

NOSEPIECES:

*A1/NV1-PRM	Medium anatomically conformed nosepiece
*A1/NV1-PRL	Large anatomically conformed nosepiece
*A1/NV1-PR8S	Conical nosepiece

MISCELLANEOUS:

A1-CP	Replacement calibration plug
A1 Mic Sub	Replacement microphone and inner sound tube
GM-USB	USB Cable

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

Note: Parts listed above with (*) are supplied as non- sterile and due to their inertness have no expiry date.

MAINTENANCE MANUAL

OVERVIEW

The Acoustic Rhinometer should be calibrated each day using the built-in facility. In addition to this, the cables should be inspected regularly for signs of damage, in particular the region of the sound tube and its link to the PC. Do not use the equipment if damaged.

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

INSTRUMENT CLEANING AND DECONTAMINATION

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

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

Should the sound tube enclosure require cleaning for any reason, unplug it from the A1 device and wipe it with a damp cloth or cleaning wipes. Do not allow liquid to run into the sound tube.

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The A1 is intended for use in the electromagnetic environment specified below. The customer or the user of the A1 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Class B	The A1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The A1 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC61000-3-3	Complies	

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The A1 is intended for use in the electromagnetic environment specified below. The customer or the user of the A1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -**
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material,
Electrical fast transient / burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital
Surge IEC61000-4- 5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>95 % dip in U_T) For 0.5 cycle 40% U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) For 5 s	<5% U_T (>95 % dip in U_T) For 0.5 cycle 40% U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) For 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the A1 requires continued operation during power mains interruptions, it is recommended that the A1 be powered from an uninterruptable power supply or a battery.
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The A1 is intended for use in the electromagnetic environment specified below. The customer or the user of the A1 should assure that it is used in such anenvironment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the A1, including any cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td></tr>
<tr><td>Conducted RF IEC61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3Vrms</td><td>Recommended separation distance (d)</td></tr>
<tr><td></td><td>6Vrms in ISM bands between 0.15-80MHz</td><td>6Vrms</td><td>$d = 1.2\sqrt{P}$</td></tr>
<tr><td></td><td></td><td></td><td>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz</td></tr>
<tr><td>Radiated RF IEC61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3V/m</td><td>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
</table>

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	Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NR6 is used exceeds the applicable RF compliance level above, the A1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the A1

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

Warning: No modification to this equipment is allowed.
6.2 The A1 Acoustic Rhinometer is powered by an external universal mains power module. Power can be removed by unplugging the mains plug, or by switching power off at the mains socket.

It complies with the specification for Class 1 ME equipment, and is used along with a PC and printer, normally supplied by the customer.
N.B. The warning on page 3 about the PC and printer being compliant with EN 60950 and placing these items out of the reach of a subject

The applied parts are the nosepieces which are classified as a 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 which are required to be sterile.

6.5 The A1 Acoustic Rhinometer is **NOT** suitable for use in an oxygen rich environment.

6.6 The A1 Acoustic Rhinometer is rated for continuous use.

7.2.2 The A1 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** -> **About…** found on the top toolbar of the A1 software.

7.2.3 Information is given in the **Warnings and Cautions** section (page 3) 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 The A1 power supply module is marked PCM50UT04. No other external supply can be used, unless supplied by GM Instruments as a replacement.

7.2.6 The A1 power supply module provides DC voltages of ±12 volts and + 5 volts from an input which can range from 100 Volts to 240 Volts AC at 50 Hz to 60 Hz. The power supply module is rated at 42W.

7.2.7 The A1 consumes 10W.

7.2.11 The A1 Acoustic Rhinometer is rated for continuous use.

7.2.17 Environmental conditions for transport and storage.
Temperature: -40 °C to +60 °C
Humidity: 30 to 90% RH
7.9.1 The A1 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.

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

7.9.2.3 The power module provided with the A1 (PCM50UT04) is considered to be part of the ME equipment.

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

7.9.2.7 The equipment should be positioned so that it can be disconnected from the mains supply quickly and easily.

7.9.2.10 Error Messages --- see **A1 Troubleshooting** on page 19.

7.9.2.11 The A1 software can be closed by clicking on File -> Exit from the main toolbar. The A1 hardware can be switched off by removing the mains plug or by switching off the mains plug at the socket.

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. Operational tasks such as calibration, and performance adjustments using the straight tube and artificial nose, are described elsewhere in this manual and in the sheets which accompany the tube and nose.

7.9.2.15 The applied parts (nosepieces) should be disposed of after use in line with your hospital or clinic's policy on disposal of potentially contaminated plastic parts.
The A1 Acoustic Rhinometer 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 are interchangeable by service personnel are the power module and the mains cable. If these are changed, a PAT test to the current standard should be made prior to allowing release for use.

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 A1 Acoustic Rhinometer is not allowed.

7.9.3.4 If access to the A1 circuit board is required:

Disconnect the A1 from the mains supply by unplugging or switching off at socket

- Turn the unit over and remove the four feet on the base using a screwdriver
- Carefully turn the unit back over and remove the top panel
- The circuit board can now be accessed and, if voltage measurements are required, the mains power can be reconnected