M1013A / M1019A IntelliVue G1/G5

Service Guide

IntelliVue G1/G5

M1013A/M1019A

Patient Monitoring

PHILIPS

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Introduction

This book is intended for personnel authorized to install, service or repair an IntelliVue G1 or IntelliVue G5 gas analyzer. A good understanding of the English language is a requirement.

This chapter contains the following information on the M1013A IntelliVue G1 and the M1019A IntelliVue G5:

- A description of the module, including its physical, environmental and performance specifications
- A general explanation of the measurement principles that the module uses to measure gas concentrations
- The theory of operation of the module, its components and how they work.

Who Should Use This Guide

This guide is for biomedical engineers or technicians responsible for troubleshooting, repairing, and maintaining Philips' patient monitoring systems.

How To Use This Guide

This guide is divided into seven sections. Navigate through the table of contents at the left of the screen to select the desired topic. Links to other relevant sections are also provided within the individual topics. In addition, scrolling through the topics with the page up and page down keys is also possible.

Description

The Philips M1013A IntelliVue G1 and the M1019A IntelliVue G5 work together with the IntelliVue patient monitors through an RS232 serial interface. They measure the airway gases of ventilated patients who are under general gas anesthesia, or emerging from it.

The modules produce graphical wave data, and inspired and end-tidal numeric data for the following gases:

- CO_2
- N_2O
- One volatile anesthetic agent (IntelliVue G1) / Two volatile anesthetic agents (IntelliVue G5)
- O_2 (optional with IntelliVue G1, standard with IntelliVue G5)

It also generates numerics for MAC (Minimum Alveolar Concentration) and the patient's airway respiration rate (awRR).

Responsibility of the Manufacturer

Philips only considers itself responsible for any effects on safety, EMC, reliability and performance of the equipment if:

- assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by Philips, and
- the electrical installation of the relevant room complies with national standards, and
- the instrument is used in accordance with the instructions for use.

To ensure safety and EMC, use only those Philips parts and accessories specified for use with the monitor. If non-Philips parts are used, Philips is not liable for any damage that these parts may cause to the equipment.

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Warnings and Cautions

In this guide:

- A **warning** alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.
- A **caution** alerts you where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

Physical Specifications

Size (H x W x D):	≤ 93 x ≤ 306 x 232 mm (≤ 3.66 x ≤ 12.05 x 9.13 in).
Weight:	less than 4 kg (7.94 lb)

Environmental Specifications

Operating Temperature:	10 to 40°C (50 to 104°F)
Storage Temperature:	-20 to 65°C (-4 to 149°F)
Humidity Limit (Operating):	5 to 90% RH max @ 40°C (104°F). non-condensing
Humidity Limit (Storage):	5 to 95% RH max @ 65°C (149°F). non-condensing
Altitude Range (Operating):	-305 to 2900m (-1,000 to 9,515ft)
Altitude Range (Storage):	-305 to 5000m (-1,000 to 16,404ft)
Warm-up Time:	1-2 minutes to measure CO_2, less than 6 minutes for full accuracy specifications

MDD Classification

According to the Council Directive 93/42/EEC (Medical Devices Directive) the device classification is 2A, Rule 10.

Performance Specifications

All Performance and accuracy specifications are valid based on gas sample tubing M1658A, including watertrap M1657B, and airway adapter 13902A.

Humidity Correction: For CO_2 the humidity correction can be set to “wet” or “dry”.

Wet: p [mmHg] = c [Vol%] * (p_abs - p_H_2O)/100

Dry: p [mmHg] = c [Vol%] * p_abs /100

Where p = partial pressure, c = gas concentration, p_abs = pressure in breathing circuit, p_H_2O = 21mmHg, partial pressure of water vapor of room temperature gas (23 °C, 100% rh).

For all other gases the readings are always given as dry values.

Sample Flow Rate: 200 ml/min ±20[1]

Sample Delay Time: All measurements and alarms are subject to a delay of 5 seconds.

Total System Response Time = the sum of the delay time and the parameter specific rise time.

1. After warm up or zero the flow rate may be higher than 200 ml/min for about 30 minutes.

CO_2 Measurement

Range:	0 to 76 mmHg
Accuracy:	± 0.5 vol% or 12% relative, whichever is greater
Resolution:	1 mmHg
Rise-time:	350 msec typical

AWRR derived from CO_2 Waveform

Range:	0 to 60 rpm
Accuracy:	± 1 rpm
Resolution:	1 rpm
Detection Criteria:	adaptive threshold

N_2O Measurement

Range:	0 to 100vol%
Accuracy:	± 2.0 vol% + 8% relative
Resolution:	1 vol%
Rise-time:	500 msec typical

O_2 Measurement

Range:	5 to 100vol%
Accuracy:	± 3 vol%
Resolution:	1 vol%
Rise-time:	500 msec typical

Anesthetic Agent Measurement

Agent	Range (vol%)	Accuracy	Resolution	Rise Time
Halothane	0 - 8.5	0.15 vol% + 15.0% relative	0.05	< 500
Enflurane	0 - 10.0	0.15 vol% + 15.0% relative	0.05	< 500
Isoflurane	0 - 8.0	0.15 vol% + 15.0% relative	0.05	< 500
Sevoflurane	0 - 10.0	0.15 vol% + 15.0% relative	0.05	< 500
Desflurane	0 - 20.0	0.15 vol% + 15.0% relative	0.05	< 500

Agent ID Response Time		14 s for first agent, 19 s for second agent
First Agent Detection / Identification Threshold	All agents	max. 0.3 vol%
Second Agent Detection / Identification Threshold	All agents	max. 0.4 vol% of a second agent, except if a second agent is added to Desflurane, this causes a mixture identification at the latest if the concentration of the second agent exceeds 10 vol% of the current Desflurane concentration.

Alarm Ranges

Agent	High Range	Low Range
AWRR	10 - 60 rpm (Adult/Pedi) 30 - 60 rpm (Neonatal)	0 - 55 rpm
$ETCO_2$	20 - 76 mmHg	10 - 75 mmHg
$IMCO_2$	2 - 20 mmHg	none
inN_2O	0 - 82 vol%	none
inO_2 (optional)	19-100 vol%	18 - 99 vol%
et SEV	0.1 - 9.0 vol%	0.0 - 8.9 vol%
in SEV	0.1 - 9.0 vol%	0.0 - 8.9 vol%
et DES	0.2 - 20.0 vol%	0.0 - 19.8 vol%
in DES	0.2 - 20.0 vol%	0.0 - 19.8 vol%
Halothane, Enflurane, Isoflurane		
et	0.1 - 7.5 vol%	0.0 - 7.4 vol%
in	0.1 - 7.5 vol%	0.0 - 7.4 vol%

Alarm Delay

15 seconds if no zero calibration occurs within that time.

awRR Alarm Delay

The alarm delay for the awRR low alarm is 10 sec for awRR > 20rpm and 0 sec for awRR < 20rpm. The alarm delay for the awRR high alarm is 10 sec.

Apnea Alarm

Delay Range:	10 - 40 seconds
Criterion	No detected breath within the adjusted delay time
Alarm:	Within 2 seconds after this criterion is met, if no automatic zero occurs

INOP Alarms

INOP alarms are triggered if:

- The gas analyzer is disconnected or switched off.
- The gas analyzer accuracy is in doubt.
- The equipment or any of its components malfunctions.
- Zero calibration has failed.
- The gas sample tube is occluded, or the watertrap is full.
- Any parameter is unable to measure.
- Any parameter is out of range.
- The gas analyzer is in warm-up mode.
- Gas analyzer calibration is running.
- Gas analyzer alarms are suppressed.
- No breath detected.

Theory of Operation

General Measurement Principles

The M1013A IntelliVue G1 and the M1019A IntelliVue G5 use infrared technology to measure the concentration of the gases CO_2, N_2O and the volatile anesthetic agents.

The gases which can be measured by the gas analyzer absorb infrared (IR) light. Each gas has its own absorption characteristic. The gas is transported into a sample cell, and an optical IR filter selects a specific band of IR light which has passed through the gas. For multiple gas measurement, such as in the IntelliVue G1 and G5, there are multiple IR filters. The higher the concentration of gas in a given volume the more IR light is absorbed. This means that higher concentrations of IR absorbing gas cause a lower transmission of IR light. The amount of IR light transmitted after it has been passed through the gas is measured. From the amount of IR light measured, the concentration of gas present can be calculated. This calculation provides the gas measurement value. Oxygen is measured using a paramagnetic cell.

NOTE The presence of organic cleaning solutions or gases containing freon may impact the accuracy of the infrared gas measurement.

O_2 Sensor

NOTE The O_2 Sensor is optional with IntelliVue G1 and standard with IntelliVue G5

Measurement Principle

The O_2 sensor uses a fast O_2 measurement technique that utilizes the paramagnetic properties of oxygen.

Gases with paramagnetic properties are attracted by magnetic fields. In a magnetic field the density and thus the heat conductivity of such gases is increased. The gas analyzer determines the amount of oxygen in the gas sample by measuring its heat conducting properties while switching a magnetic field on and off inside the O_2 sensor. This way the changes in the oxygen present in the magnetic field can be measured, and the amount of oxygen in the gas sample can be calculated.

Pump

The software-controlled pump generates the flow through the system and pulls the gas from the airway adapter through the measurement subsystems to the exhaust outlet. It also delivers the zero calibration gas to the sample cells of the measurement subsystems for the periodic zero procedures and it exhausts the patient's sample gas, the zero calibration and field calibration gases.

The flow-rate control logic drives the pump as hard as necessary to maintain the selected flow rate. A partial occlusion or an inefficient pump results in the pump being driven harder. A serious occlusion results in the pump being driven at or near its maximum load. If, as a result of this occlusion, the desired flow rate cannot be upheld, an occlusion INOP is triggered.

Watertrap

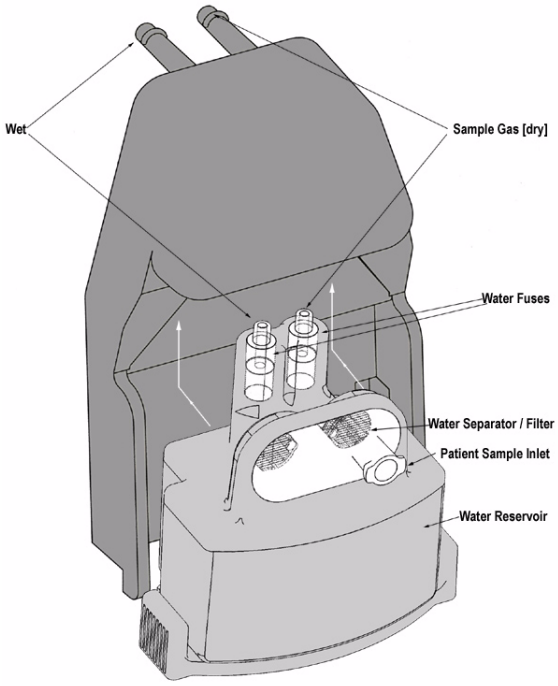


Figure 1 Watertrap

The watertrap consists of two water separation filters, two water fuses and a water reservoir. The gas sample coming from the patient may contain fluids which are separated from the gas at the first water separation filter. The gas is then split into two paths, the "measurement" path with the main part of the total gas flow (including water vapor) continuing on the "dry" side of the separation filter and the "drainage" path (containing any liquid droplets) with the smaller amount of the total flow continuing on the "wet" side of this filter through the water reservoir. At the pump both gas paths are recombined.

The watertrap itself includes “water fuses” in both the “measurement” and the “drainage” paths, consisting of a material that swells when getting wet (when the reservoir is full or when fluid penetrates the separation filter and enters the “measurement” path) and blocks the respective path at the inlet of the unit. Once the “water fuses” are blown, any passage of fluid is blocked and the gas flow resistance increases so that an occlusion is detected.

2

Installation and Patient Safety

NOTE The M1013A IntelliVue G1 and the M1019A IntelliVue G5 must be installed by qualified personnel capable of performing the post-installation checks as outlined in the Test and Inspection Matrix

This chapter describes how to install the Philips M1013A IntelliVue G1 and the M1019A IntelliVue G5. It details the operating environment required by the gas analyzers as well as instructions on how to physically connect them to the monitor and how to fit the gas exhaust return system. Next, the patient safety information is detailed. Finally, this chapter describes the software setup required and any post-installation checks that have to be performed before using the gas analyzer together with a reminder of the preventive maintenance (PM) checks and their frequencies.

CAUTION The gas analyzer must be positioned on a surface with a maximum incline of 15°. To avoid condensed water collecting in the patient sample tube, it is recommended that the gas analyzer is positioned at or above patient level, wherever possible.

Site Preparation - Introduction

This section describes the procedures you should follow to plan and prepare a site for an IntelliVue G1/ G5 installation.

Refer to the *Site Preparation* chapter in the respective IntelliVue Patient Monitor Service Guide, for details about:

- Site planning.
- Roles and responsibilities for local and Philips personnel.
- Remote installation planning.

These details are also valid for the IntelliVue G1 / G5.

IntelliVue G1/G5 Site Requirements

For space requirements and environmental requirements refer to chapter 1, *Introduction*.

Environment

WARNING Possible explosion hazard if used in the presence of flammable anesthetics.

The environment where the gas analyzer is used should be free from vibration, dust, corrosive or explosive gases, and extremes of temperature and humidity.

For a cabinet mounted installation with the monitor, allow sufficient room at the front for operation and sufficient room at the rear for servicing with the cabinet access door open.

The IntelliVue G1 and the IntelliVue G5 operate within specifications at ambient temperatures between 10°C and 40°C, 6 minutes after switching it on.

Ambient temperatures that exceed these limits could affect the accuracy of this instrument and cause damage to the components and circuits. Allow at least 2 inches (5cm) clearance around the instruments for proper air circulation.

CAUTION If the gas analyzer has been stored at temperatures below freezing, it needs a minimum of 4 hours at room temperature to warm up before any connections are made to it.

Make sure that the gas analyzer is free of condensation before operation. Condensation can form when equipment is moved from one building to another, thus being exposed to moisture and differences in temperature.

Initial Inspection

Mechanical Inspection

Open the shipping container(s) and examine each part of the INtelliVue G1 / G5 for visible damage, such as broken connectors or controls, or scratches on the equipment surfaces. If the shipping carton/ container is undamaged, check the cushioning material and note any signs of severe stress as an indication of rough handling in transit. This may be necessary to support claims for hidden damage that may only become apparent during subsequent testing.

Electrical Inspection

The IntelliVue G1 / G5 has undergone extensive testing prior to shipment. Safety testing at installation is not required (except in situations where devices are interconnected forming a system). An extensive self check may be performed. This recommendation does not supersede local requirements.

All tests are described in the *Testing and Maintenance* section of this manual.

Claims for Damage and Repackaging

Claims for Damage

When the equipment is received, if physical damage is evident or if the IntelliVue G1/ G5 does not meet the specified operational requirements of the patient safety checks or the extended self check, notify the carrier and the nearest Philips Sales/Support Office at once. Philips will arrange for immediate repair or replacement of the instrument without waiting for the claim settlement by the carrier.

Repackaging for Shipment or Storage

If the instrument is to be shipped to a Philips Sales/Support Office, securely attach a label showing the name and address of the owner, the instrument model and serial numbers, and the repair required (or symptoms of the fault). If available and reusable, the original Philips packaging should be used to provide adequate protection during transit. If the original Philips packaging is not available or reusable please contact the Philips Sales/Support Office who will provide information about adequate packaging materials and methods.

Making Connections to the IntelliVue G1/G5

All connections to the gas analyzer are made on its rear panel. Refer to Figure 2.

Figure 2 The Rear Panel

1 Local power connector; this is a 3-pin connector, used to connect the gas analyzer to AC Power. The gas analyzer can be operated from an AC power source of 100 - 240 V ± 10%, 50/60 Hz. The adjustment is made automatically by the power supply inside the module.

2 RS232 Connector (RS232 Interface); this is an RJ45 connector, used to connect the gas analyzer to the monitor.

The connection to an IntelliVue patient monitor can be made with the following cables:

- For M1013A IntelliVue G1:
  - M1013A#K11 1.5 m (M1013-61001)
  - M1013A#K12 3 m (M1013-61002)
- For M1019A IntelliVue G5

– M1019A#K11 1.5 m (M1013-61001)
– M1019A#K12 3 m (M1013-61002)

3 Equipotential Grounding Terminal; this is used to connect the gas analyzer to the hospital's equipotential grounding system.

4 Gas exhaust. If N_2O and/or other inhalation anesthetics are used during anesthesia, pollution of the operating room should be prevented. Once the gas sample has passed through the gas analyzer, it should either be **returned to** or **removed from** the anesthesia circuit.

NOTE In some countries where closed loop functionality is not available, gas must not be returned to the anesthesia circuit.

5 Fan Filter

CAUTION Combinations of medical equipment with non-medical equipment must comply with IEC 60601-1-1. Never use a multiple portable socket-outlet or extension cord when combining equipment unless the socket outlet is supplied specifically for use with that equipment.

Connecting the IntelliVue G1/G5 to AC Mains

The IntelliVue G1/G5 has a wide-range power supply that allows you to operate the monitor from an AC (alternating current) power source of 100 V to 240 V (± 10%) and 50/60 Hz (± 5%).

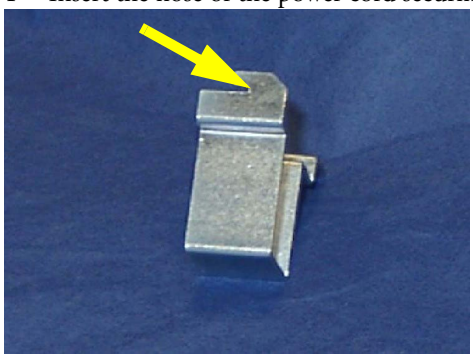
WARNING

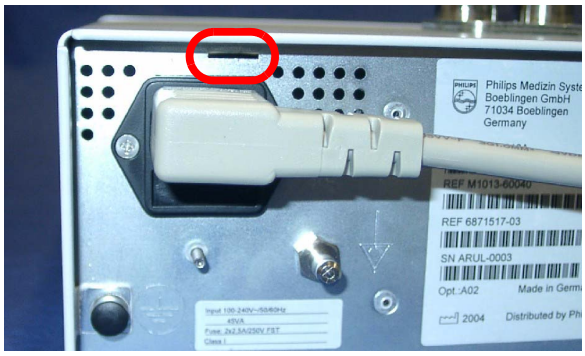
- Always use the supplied power cord with the earthed mains plug to connect the monitor to an earthed AC mains socket. Never adapt the mains plug from the power supply to fit an unearthed AC mains socket.
- Do not use AC mains extension cords or multiple portable socket-outlets. If a multiple portable socket-outlet without an approved isolation transformer is used, the interruption of its protective earthing may result in enclosure leakage currents equal to the sum of the individual earth leakage currents, so exceeding allowable limits.
- Do not connect any devices that are not supported as part of a system.
- Any non-medical device placed and operated in the patient's vicinity must be powered via an approved isolation transformer that ensures mechanical fixing of the power cords and covering of any unused power outlets.

Securing the Power Cord

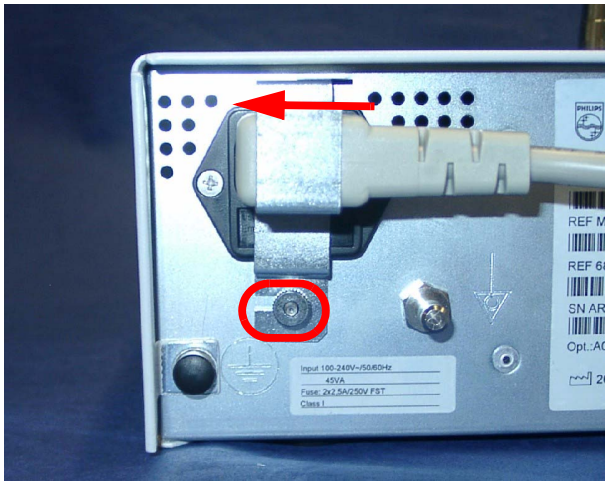
In order to prevent the power cord from accidentally being unplugged, secure it with the power cord securing bracket.

1 Insert the nose of the power cord securing bracket into the small slit above the power connector.





2 Slide the bracket to the left and secure it with knurled nut.



Connections to the Sample Gas Exhaust

Returning the Gas Sample

You will need the following equipment to **return** the gas sample to the anesthesia circuit:

Equipment	Part Number	Comments
Gas Exhaust Return Line	M1655B	Tubing includes two parts: Tube A = 300 cm long Tube B = 30 cm long
Gas Exhaust Return Filter	M1656B	Single patient use only
Gas Exhaust Tubing	M1015-40001	Multi-Patient use

Setting Up the Gas Return

(see diagram Figure 3)

1 Fit the shorter tube tightly to the *female* side of the filter. Shorten the tube if it is worn or does not fit tightly onto the filter.

NOTE When using the M1656B Gas Exhaust Return Filter with an old M1655A Gas Exhaust Return Line, you must cut off the luer lock connection of the shorter tube first before connecting to the filter.

2 Fit the *female* luer lock connection (*2*) of the longer tube to the *male* side of the filter.

3 Fit the open end (*5*) of the longer tube to the Anesthetic Gas Exhaust outlet.

4 Fit the open end (*4*) of the shorter tube to the ventilation circuit.

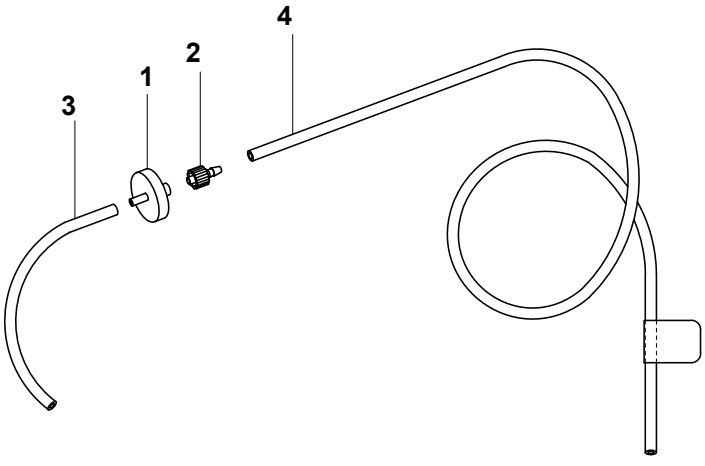


Figure 3 Setting Up the M1655B Gas Exhaust Return Line

NOTE Make sure the sample gas is routed through the CO_2 absorber before going back to the patient.

1 M1656B Gas Exhaust Return Filter

2 Female luer lock

3 Shorter tube connecting to the ventilation circuit

4 Longer tube connecting to the Anesthetic Gas Exhaust Outlet

Removing the Gas Sample

To **remove** the gas sample from the anesthesia circuit, a scavenging system needs to be connected to the gas analyzer's Anesthetic Gas Exhaust. If you intend to use a scavenging system with the gas analyzer, one of the following parts must also be connected to protect it against malfunction:

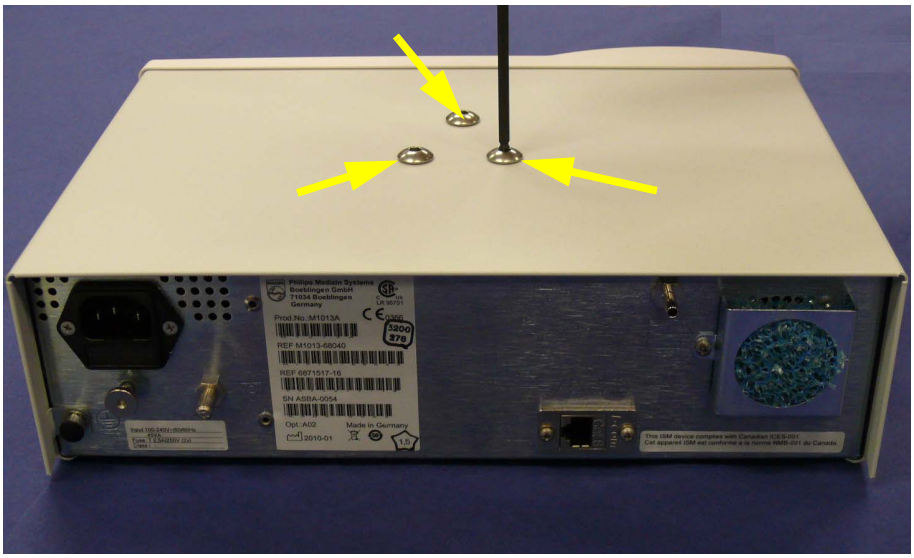
1 A ventilator reservoir where the suction pressure does not exceed 70 mbar or

2 A scavenging interface, properly set and maintained (see scavenging interface manufacturer's instructions).

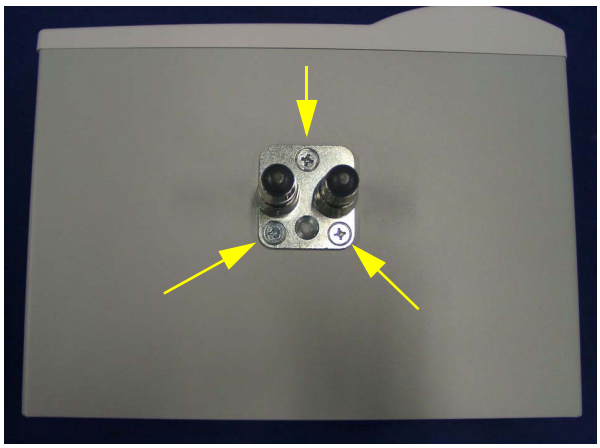
NOTE If you are not returning the gas sample into the patient's breathing circuit, install the M1655B Exhaust Return Tubing **without** the M1656B Exhaust Return Filter, shorter tube and the luer lock fitting. See the Instructions for Use provided with the tubing and filter for further details.

Installing the Top Mount

1 Remove the three rounded head screws on the top of the gas analyzer.



2 Attach the top mount to the gas analyzer using only the three short countersunk screws supplied with the mount.



NOTE Devices installed on the top mount may not weigh more than 12 kg. Make sure that any device installed on the top mount snaps in properly and is fixed securely to the mount.

Mounting Instructions

NOTE There are different mounting options available for the IntelliVue G1 / G5. This section covers the general concepts of safe mount installations and specific steps for the mounting options sold by Philips. Instructions which ship with a mounting solution should always take precedence over the instructions described in this chapter. You MUST follow the instructions that ship with the mounting solution, regardless of manufacturer.

Please mount the IntelliVie G1 / G5 using the Philips Quick Mount solution or another approved mounting solution. The mounting shall be done in a manner that no patient, operator or other person can be harmed by a IntelliVue G1 / G5 removed intentionally or released accidentally from the mount. When using the Quick Mount, be aware of the danger of accidental activation of the Quick Mount release button when lifting or moving items located under the monitor, such as pole mounts, etc.

For instructions on how to mount the monitor using the Quick Mount table mount refer to the Assembly Instructions delivered with the mounting kit M8000-64100 or 453564239731.

WARNING

- It is the customer's responsibility to have the attachment of the mounting hardware to the ceiling, wall, or mounting rail and the construction of the ceiling, wall, or mounting rail evaluated for structural integrity and compliance with all local, state and any other required codes by a registered, professional, structural and/or mechanical engineer.
- Ensure that this commitment has been met before assembling mounts.
- Incorrect mounting and use of inappropriate mounting material may lead to injury. It is the customer's responsibility to ensure that the mounting procedures have been performed correctly and the appropriate mounting devices have been used.

Setup and Configuration Procedures

This section describes final setting up and configuration procedures that must be completed after the gas analyzer is connected to the monitor and switched on before the gas analyzer is used for monitoring.

IntelliVue Serial Port Configuration

The MIB port used in the IntelliVue host monitor must be configured to “GM”.

To do this, go into service mode and then select **`Setup`** followed by **`Hardware`** and then **`MIB.`**

Altitude Configuration

The altitude setting for the monitor is important as it is used as a reference to check the gas analyzer ambient pressure measurement.

See your monitor service guide for details.

Connect Sample Input Tubing

Connect the sample input tubing to the watertrap at the luer lock connector. For details, refer to the Instructions for Use.

Post-Installation Checks

See Test and Inspection Matrix for details.

WARNING Do not use the instrument for any monitoring procedure on a patient if you identify anything which indicates impaired functioning of the instrument.

Safety Requirements Compliance and Considerations

The M1013A IntelliVue G1 and the M1019A IntelliVue G5 comply with the following international safety requirements for medical electrical equipment:

IEC 60601-1:1988 + A1:1991 + A2:1995; EN60601-1:1990 + A1:1993 + A2:1995; UL 60601-1:2003; CAN/CSA C22.2#601.1-M90; IEC 60601-1-2:2001; EN 60601-1-2:2001.

Classification (according to IEC 60601-1): Class 1, Type BF, Continuous Operation.

This ISM device complies with Canadian ICES-001. Cet appareil est conforme a la norme NMB-001 du Canada.

The possibility of hazards arising from software errors was minimized in compliance with ISO14971:2000, EN60601-1-4:1996 + A1:1999 and IEC 60601-1-4:1996 + A1:1999.

Explanation of Symbols Used

Symbols		
Caution, refer to accompanying documents	Setup*	Standby*
Power On/Off*	Equipotential grounding	2002-06 Identifies year and month of manufacture
Alternating current	Electrical signal input indicator	Electrical signal output indicator
Applied part has special protection against electric shocks (Type BF according to IEC 60601-1)and is defibrillator proof	Gas output indicator	Gas input indicator
The device complies with the requirements of the Council Directive 93/42/EEC of 14 June 1993 (Medical Device Directive). CE 0366	Indicates location of the date of manufacture and/or name and address of manufacturer	SN Indicates location of serial number
REF Indicates location of catalog number	SERVICE# Indicates location of service number	

* These symbols are replaced by English text in the U.S.A.

The IntelliVue G1 and the IntelliVue G5 are protected against the effects of defibrillation and electrosurgery.

Electrical and Safety Requirements (Customer or Philips)

Power Supply Requirements

The system and the gas analyzer can both be operated from an AC supply of 100 - 240V ±10%, 50 - 60Hz. The IntelliVue G1/G5 uses <25W typical and <45W peak.

Protective Earthing of the System

To protect the patient and hospital personnel, the cabinet of the installed equipment has to be grounded. The equipment is supplied with a detachable 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle. If a 3-wire receptacle is not available, consult the hospital electrician.

WARNING Do not use a 3-wire to 2-wire adapter.

Equipotential Grounding

Protection class 1 instruments are already included in the protective grounding (protective earth) system of the room by way of grounding contacts in the power plug. For internal examinations on the heart or the brain, Computer Module and Display Module of the System and the gas analyzer must have separate connections to the equipotential grounding system.

One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding terminal on the instrument's rear panel and the other end to one point of the equipotential grounding system. The equipotential grounding system assures that potential differences between conductive parts are limited according to requirements of applicable standards. This safety measure prevents that currents flowing through the heart of a patient caused by potential differences stimulate arrhythmias.

Examinations in or on the heart (or brain) should only be carried out in rooms designed for medical use incorporating an equipotential grounding system.

Combining Equipment

If it is not evident from the instrument specifications whether a particular instrument combination is hazardous or not, for example, due to summation of leakage currents, the user should consult the manufacturers concerned or an expert in the field, to ensure that the necessary safety of all instruments concerned will not be impaired by the proposed combination.

Connecting Non-Medical Devices

Refer to the *Site Preparation* chapter in the respective IntelliVue Patient Monitor Service Guide for details.

3

Software Uploads

For a software update of the M1013A IntelliVue G1 and M1019A IntelliVue G5 you need the most recent software as listed in the Service Bulletin (SB) or Field Change Order (FCO) and download it from the SoftServer as described there. Save it to a folder where it is easy to find, for example C:/TEMP. There will be two software files, e.g. pg01400.img for software revision 1.40 and Multi Function Module software such as mf030900.img. For M1013A with O_2 option and M1019A, both files need to be downloaded and later loaded to the device. For M1013A without O_2 option only the general software file beginning with "pg" is required; there is no MFM software for M1013A without O_2 option, so there is no need for loading the file.

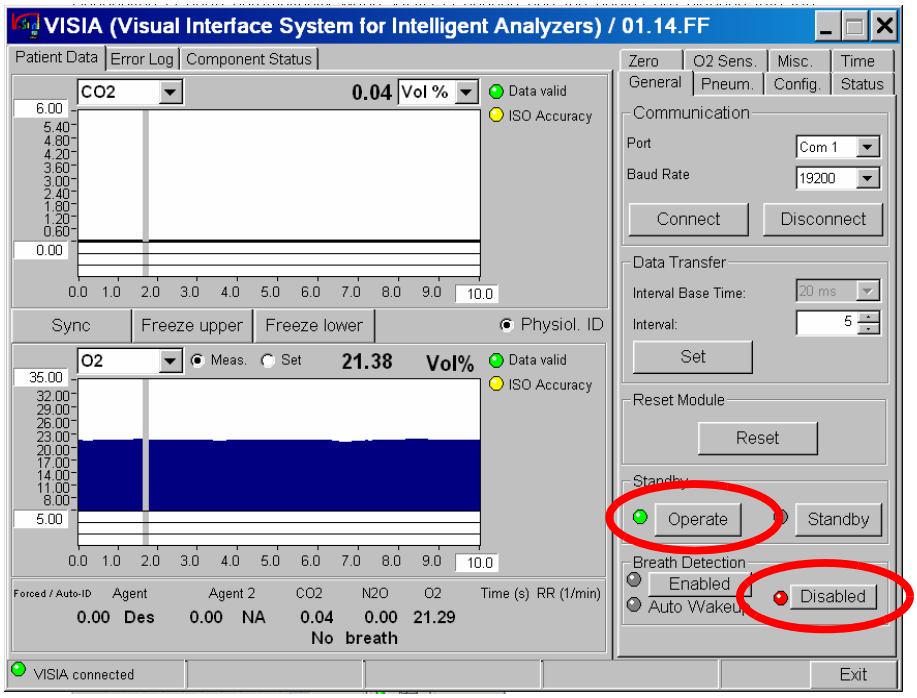
Please use the support tool VISIA 1.14.FF or higher and connect the M1013A / M1019A. The connection is made automatically when VISIA is opened and the cables are plugged into the PC/ Laptop and the M1013A / M1019A; otherwise please press the “Connect” button in the GENERAL Tab in the VISIA tool.

For automatic connection please power on the M1013A / M1019A 15 to 20 seconds before initializing the VISIA tool.

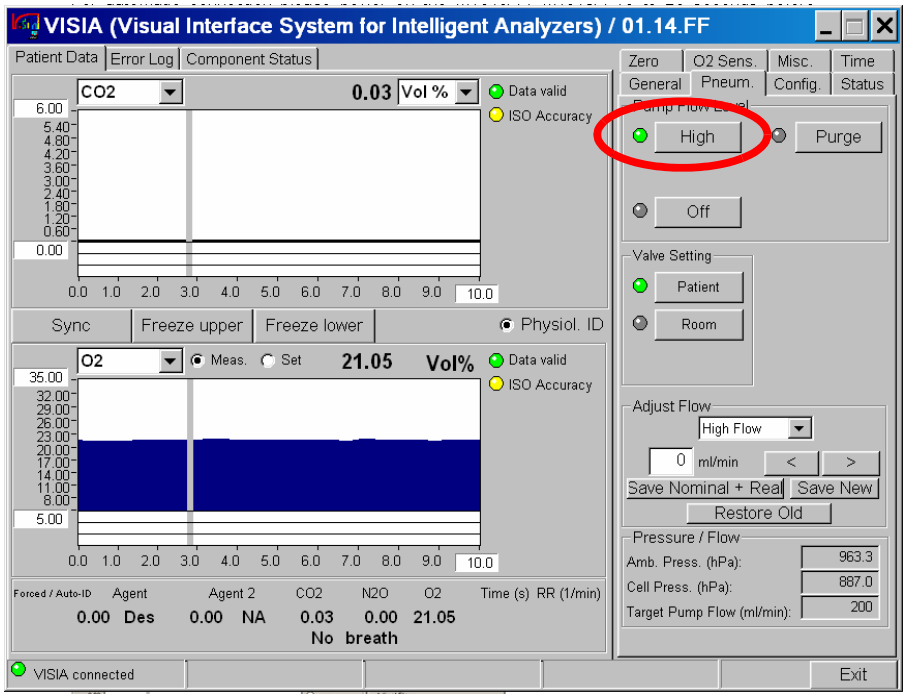
Checking the Unit for Functionality

Before performing a software update, please check the IntelliVue G1/G5 for functionality by following the steps listed below.

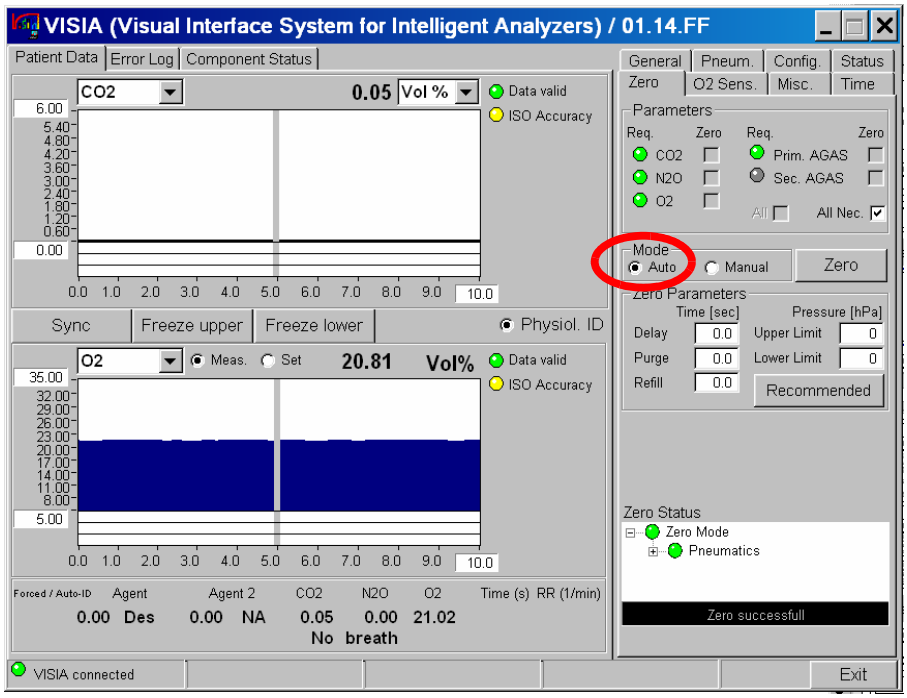
1) Set Standby to *Operate* and breath detection to *Disabled* in General Tab.



2) Then select the Pneum. Tab and set Pump Flow Level to *high*.



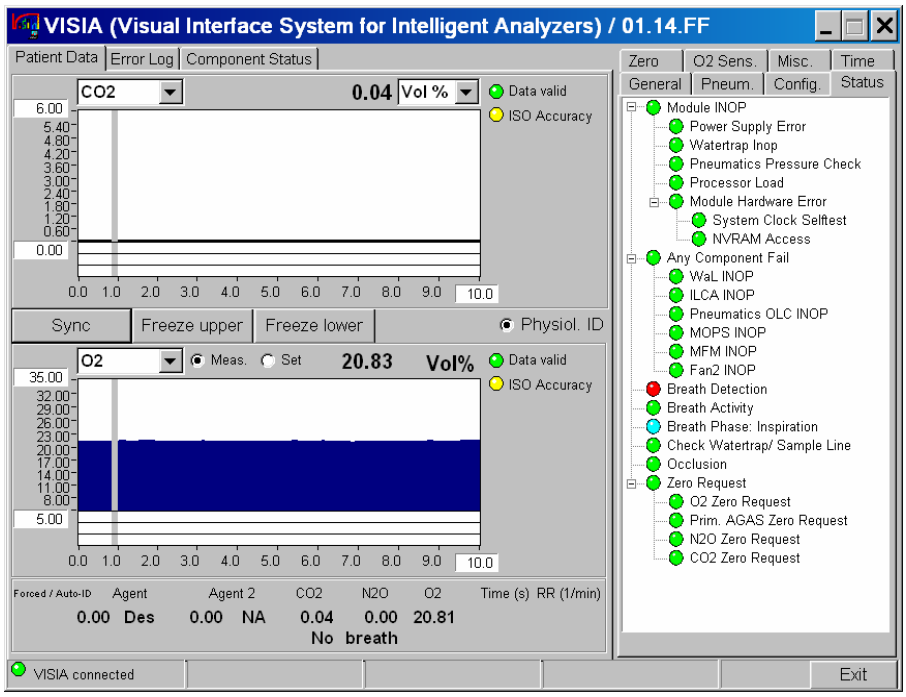
3) Select the Zero Tab and set the calibration mode to *Auto*.



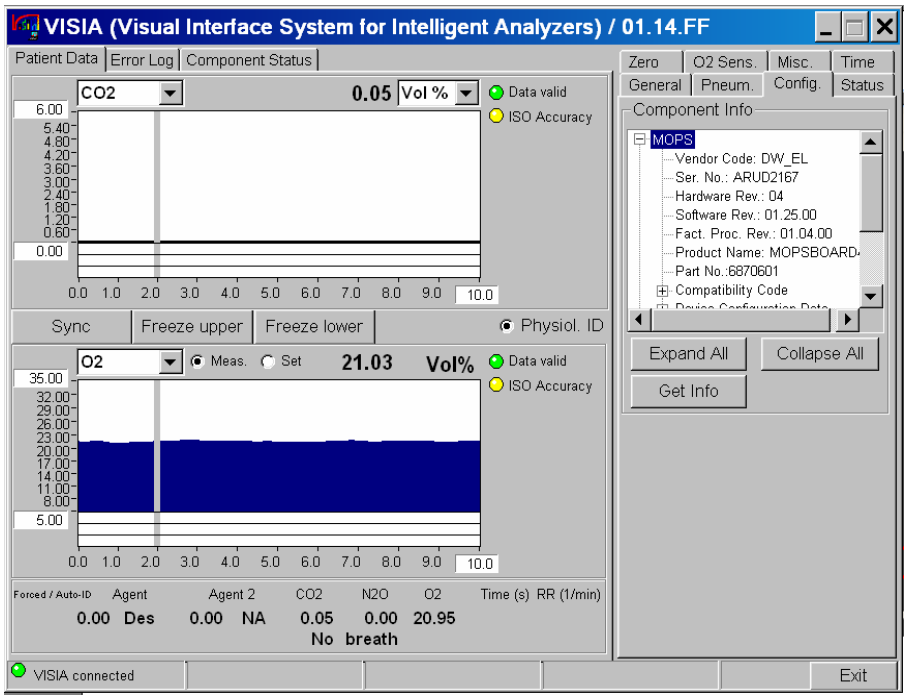
4) Wait for the automatic Zero calibration to start or choose *Manual* and press the “Zero” button. Please make sure to switch the calibration mode back to *Auto* after a successful Zero calibration.

CO_2 should be approximately 0.03 Vol. %, O_2 should be approximately 20.8 Vol. %, N_2O and Agent 1 and 2 should be 0 Vol. %. Data valid will have a green LED; ISO accuracy will have a yellow LED for a successful calibration.

5) In the Status Tab you will see green LEDs for the whole unit except for Breath detection and Breath Phase: Inspiration.

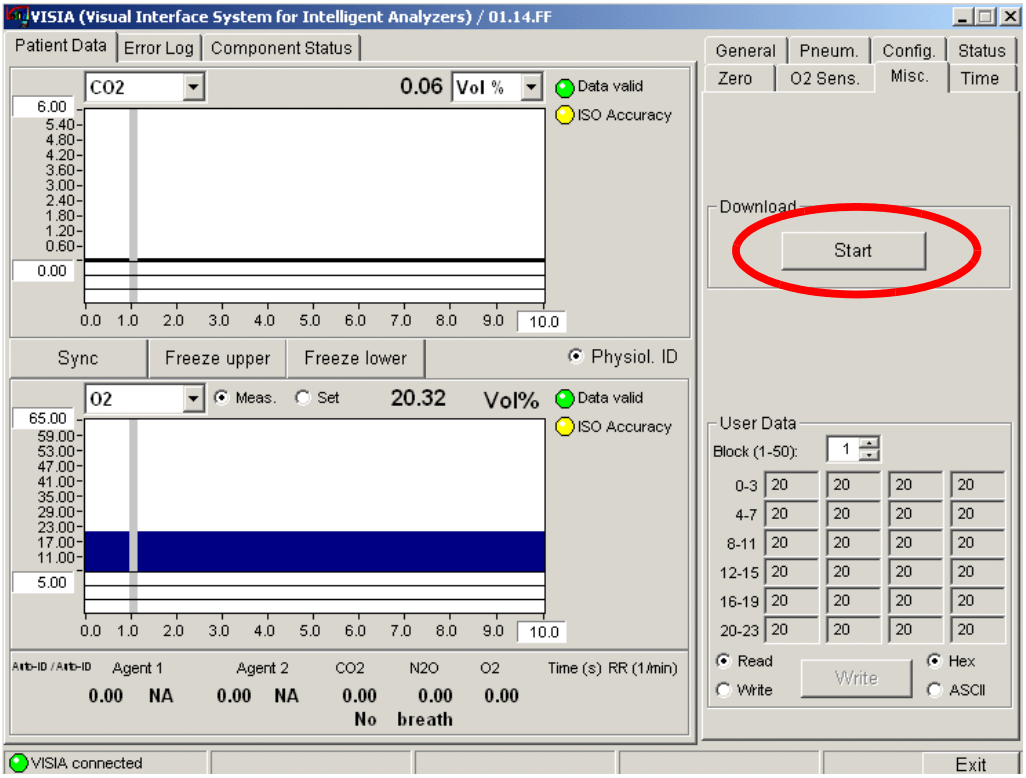


6) Check the software configuration in the Config. Tab: Expand the MOPS item in the Component Info window to check the Software rev. (e.g. 1.25.00 before upload) and then go to the MFM item (except for M1013A IntelliVue G1 without O_2 option) below and expand that as well. Check the Multi Function Module software (e.g. 2.10.00 before upload)

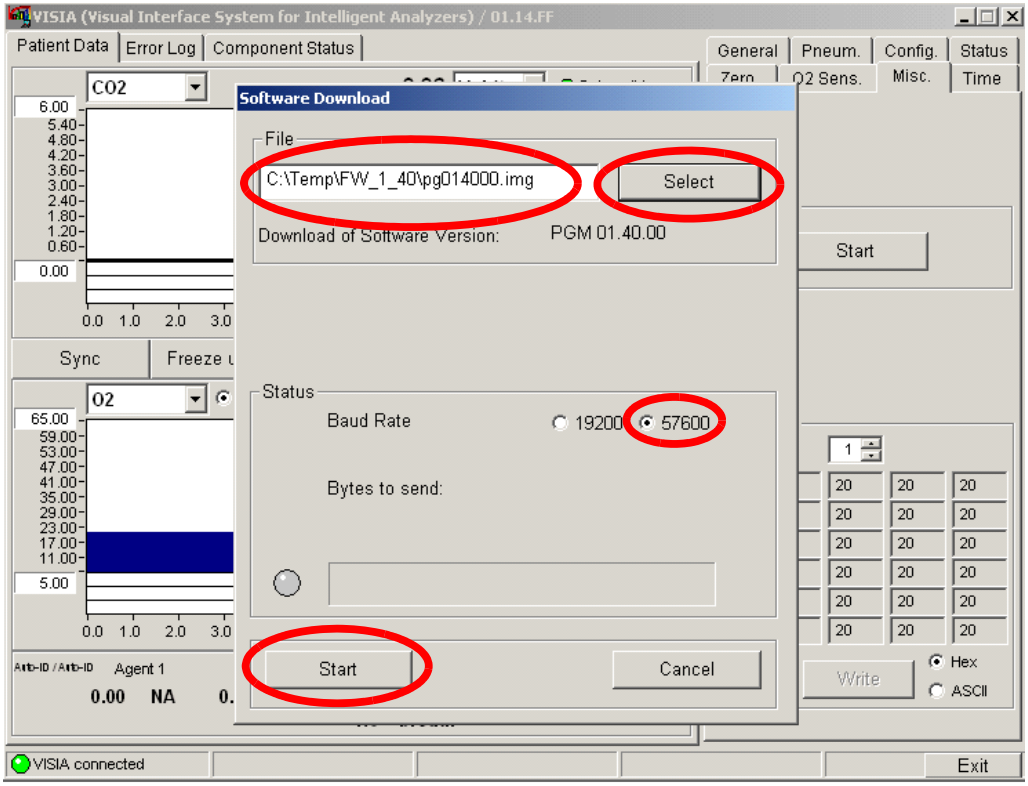


Uploading the Software

1) After checking the unit, please select the MISC Tab in the VISIA tool. In the DOWNLOAD section, click on the START button.

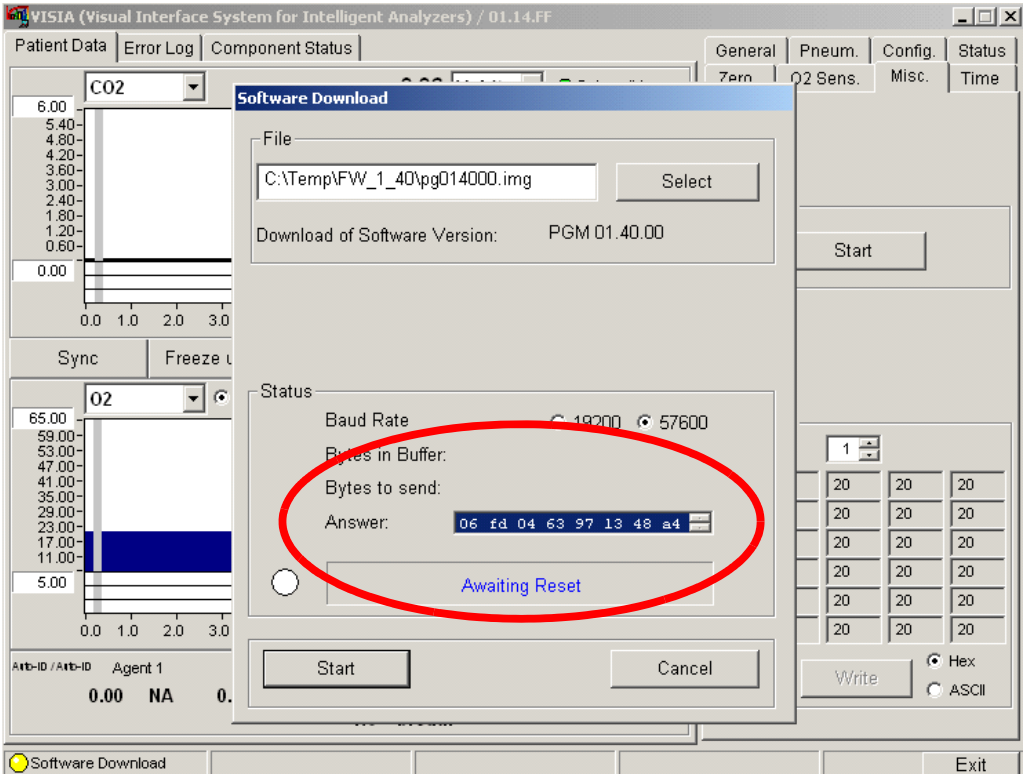


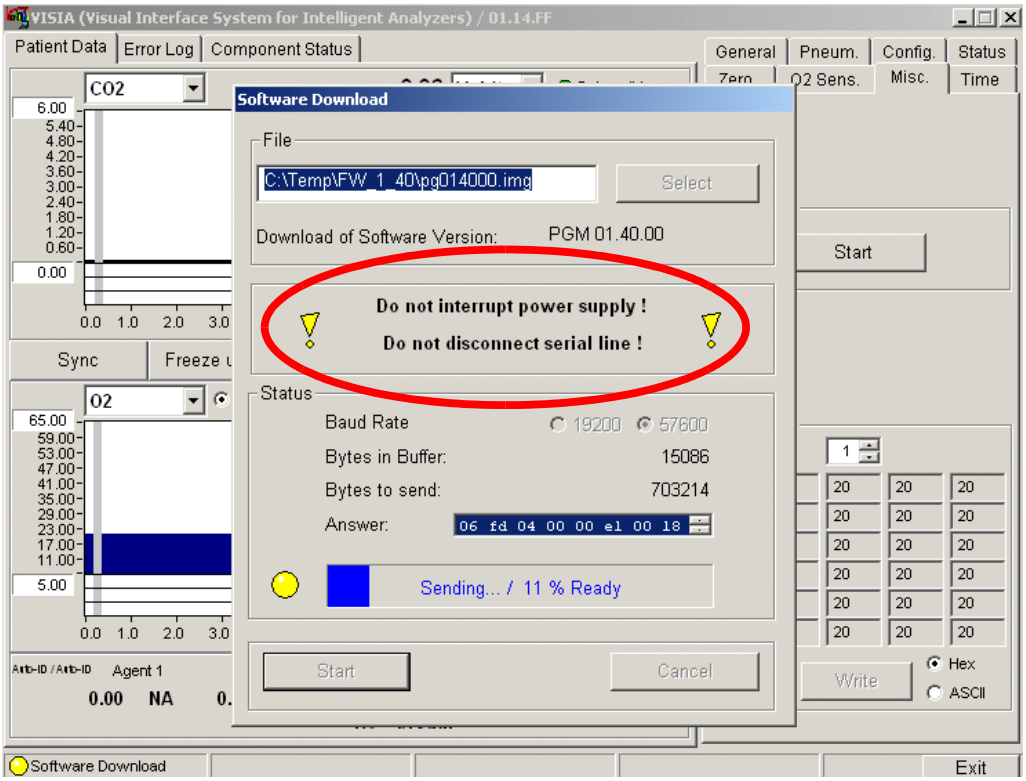
2) Next a pop-up window will open. Click on the *Select* button and choose the first software file from the folder to which it was downloaded. Both software files must be loaded to the device (except for M1013A without O_2 option). The order in which the files are loaded is irrelevant. The Baud rate is automatically set to 57600. Do not change this setting.



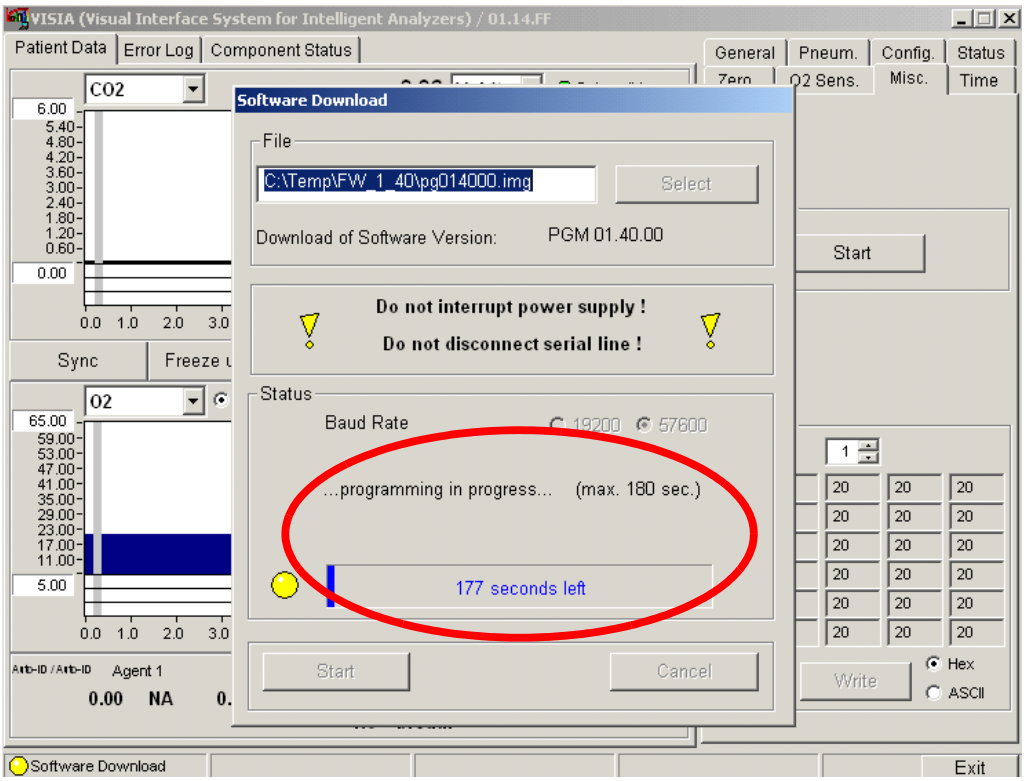
3) Click on the *Start* button and wait for the automatic software load procedure to begin. This may take a few seconds (up to 15 sec to start) and can be observed in the status bar in the lower half of the pop-up window. Do not interrupt this procedure.

The whole procedure can take up to 5 minutes for each file, but will normally require less than that.


VISIA (Visual Interface System for Intelligent Analyzers) / 01.14.FF
Patient Data
Error Log
Component Status
General
Pneum.
Config.
Status
O2 Sens.
Misc.
Time
CO2
O2
Sync
Software Download
File
C:\Temp\FW_1_40\pg014000.img
Select
Download of Software Version:
PGM 01.40.00
Status
Baud Rate
19200
57600
Bytes in Buffer:
Bytes to send:
Answer:
06 fd 04 63 97 13 48 a4
Awaiting Reset
Start
Cancel
Write
Hex
ASCII
Agent 1
Software Download
Exit

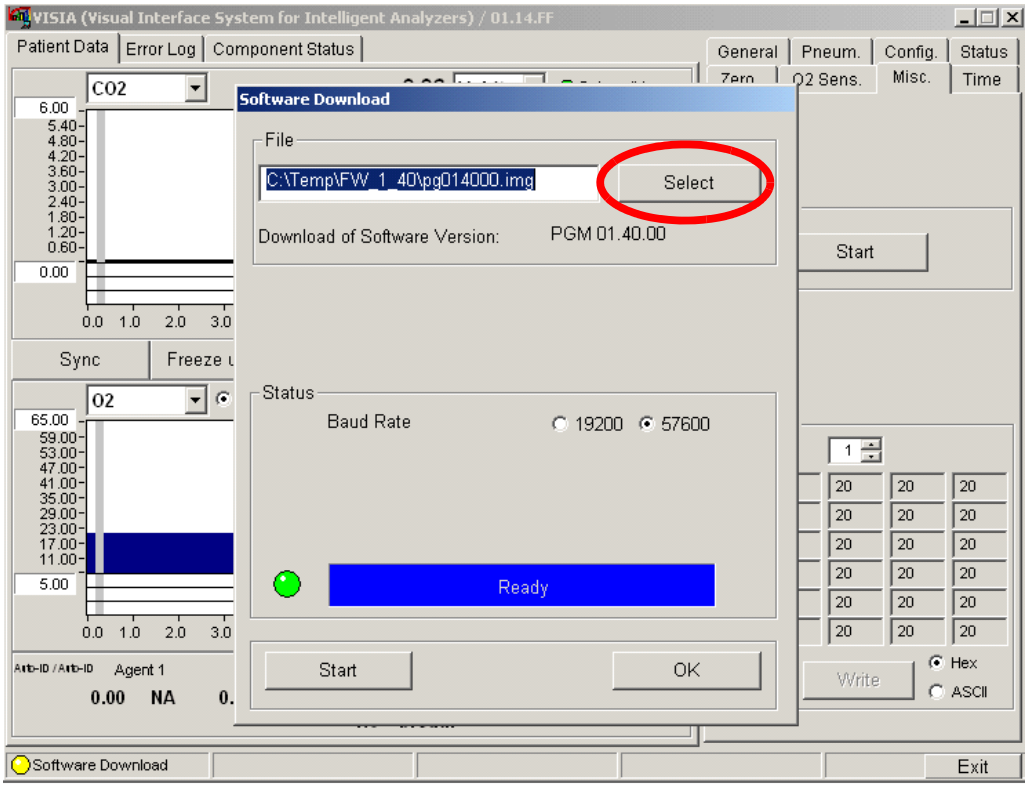

VISIA (Visual Interface System for Intelligent Analyzers) / 01.14.FF
Patient Data
Error Log
Component Status
General
Pneum.
Config.
Status
O2 Sens.
Misc.
Time
CO2
O2
Sync
Software Download
File
C:\Temp\FW_1_40\pg014000.img
Select
Download of Software Version:
PGM 01.40.00
Do not interrupt power supply !
Do not disconnect serial line !
Status
Baud Rate
19200
57600
Bytes in Buffer:
15086
Bytes to send:
703214
Answer:
06 fd 04 00 00 e1 00 18
Sending... / 11 % Ready
Start
Cancel
Write
Hex
ASCII
Agent 1
Software Download
Exit

CAUTION While loading, please do not interrupt the Power Supply. Do not disconnect the serial line. This may destroy the memory in the module and the module will need to be exchanged and repaired.

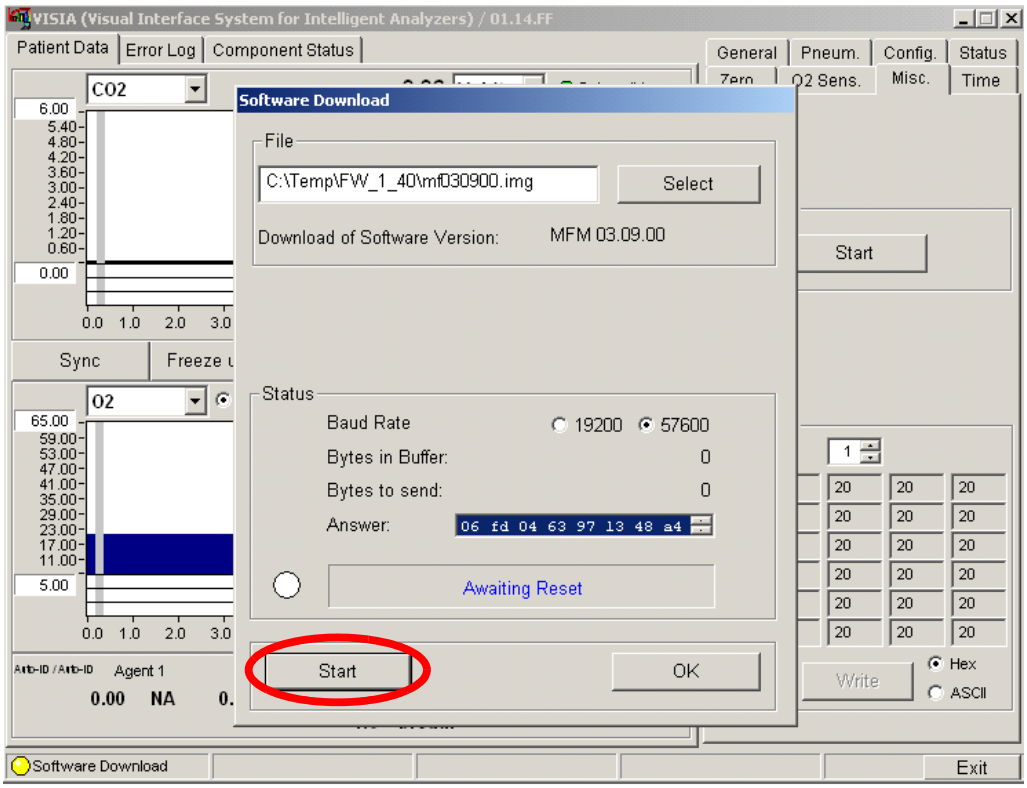


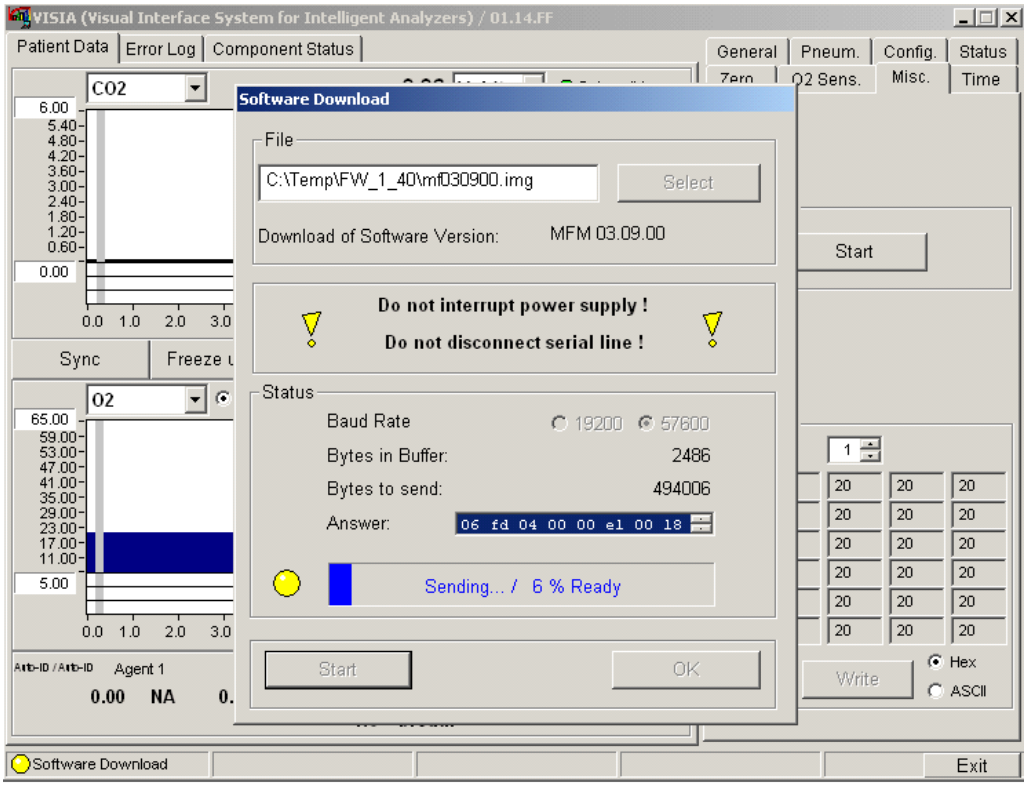
4) When the download is finished, the programming process will automatically start, as indicated in the Status section ("…programming in progress… (max. 180 sec.)") and in the status bar. The programming process can run at maximum 180 sec, but will normally be faster.

5) When the first file upload is complete(see picture below), please **do not** click on the OK button (except for M1013A without O2 option). For M1013A with O2 option and M1019A the second software file must be loaded and programmed

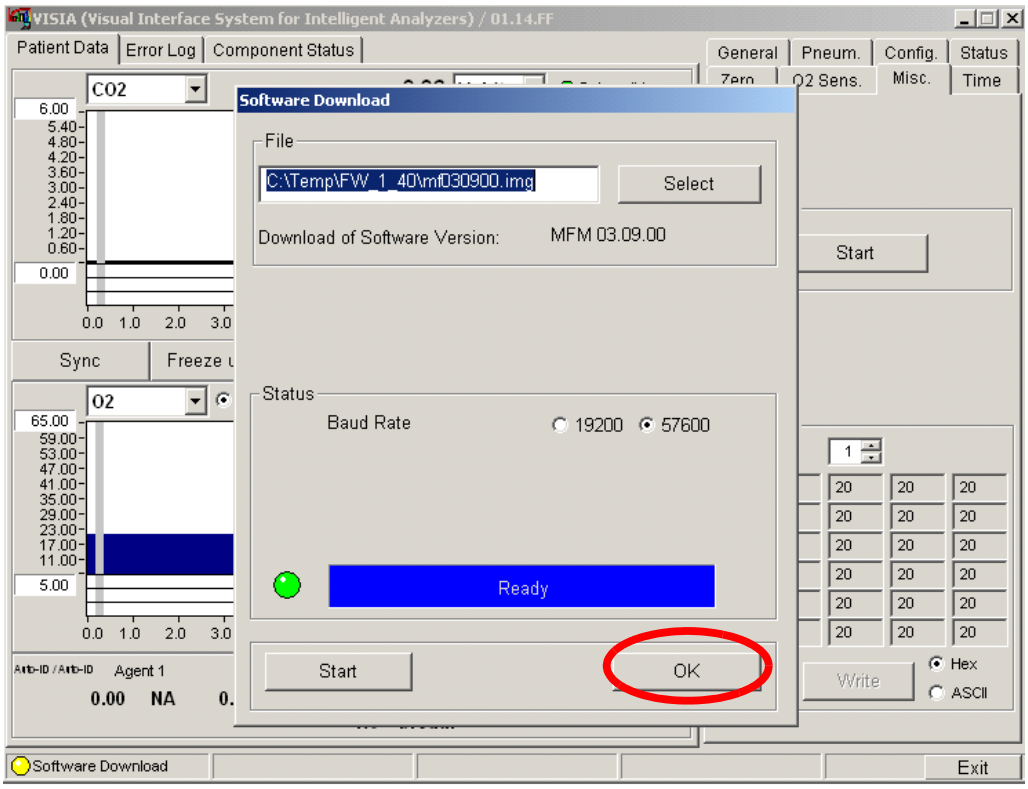


6) Click on *Select* again, and choose the second software file. Then click on the *Start* button.





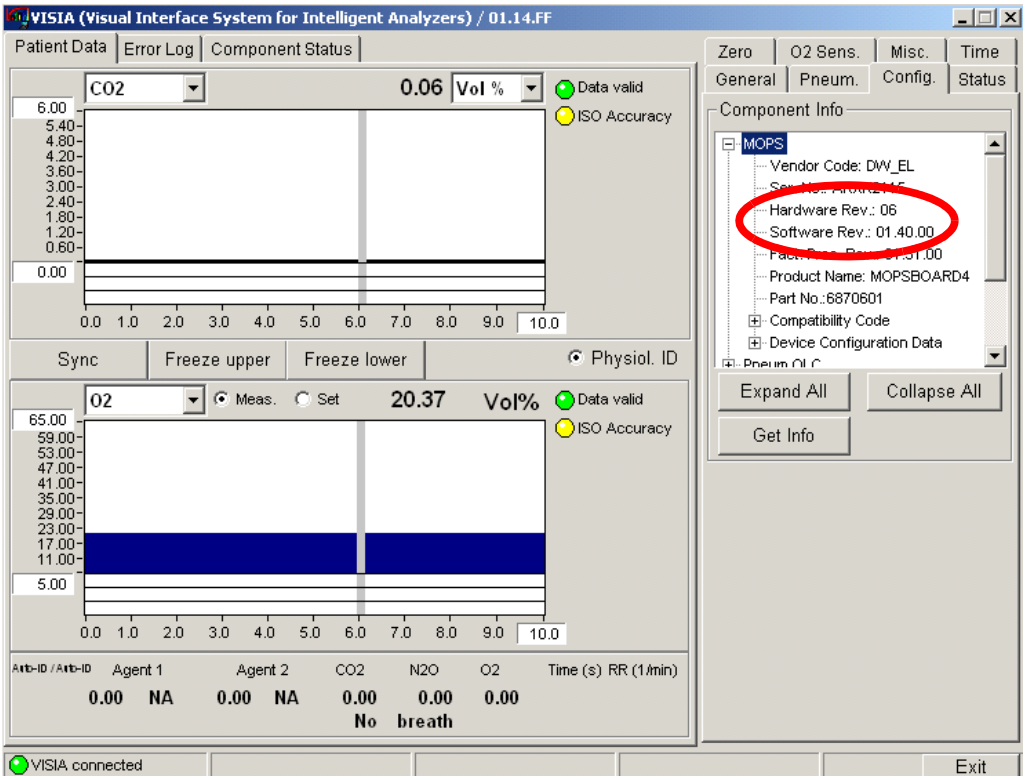
7) Follow the same steps as with the first file. When the programming process is finished click on the *OK* button.



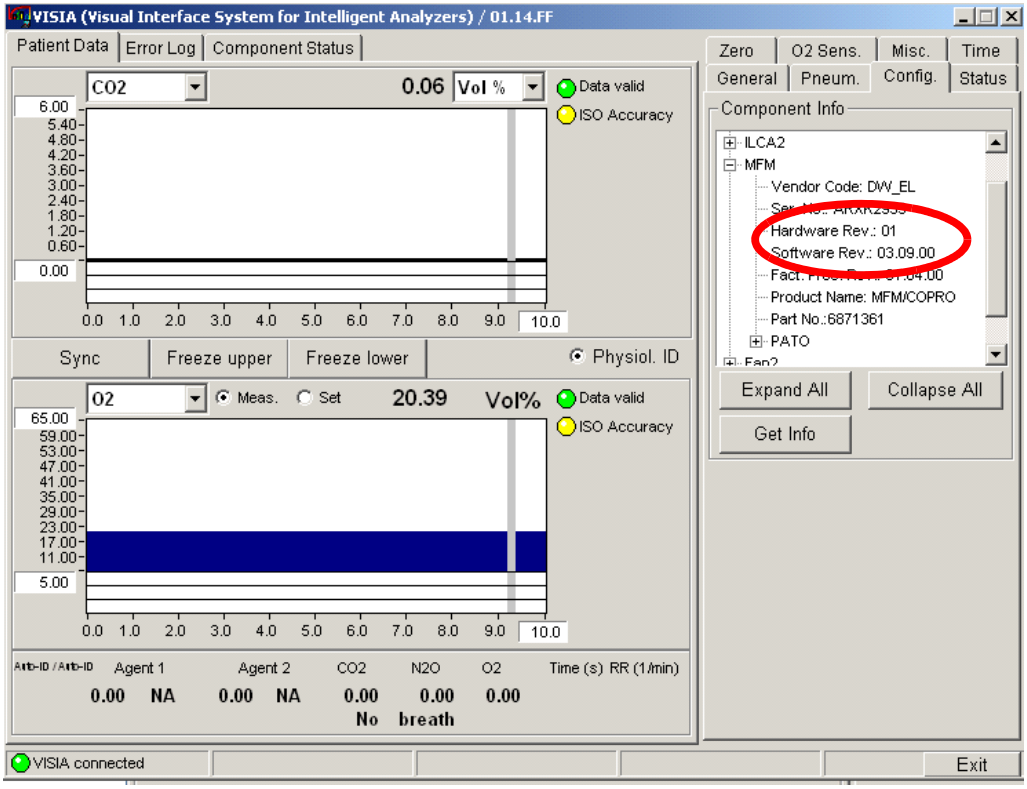
NOTE After download and programming is complete, the connection will be lost. You will need to reconnect in the General Tab in order to check whether the software upload was successful.

8) Please wait a few seconds (approximately 10 sec, maybe select a few Tabs to re-establish the screen) after reconnection to set the unit to *Operate* and *Disabled for Breath detection* in the General Tab. Then select the Pneum. Tab again and set the Pump Flow Level to *High*, then select the Zero Tab and select *Auto* again.

9) For checking the software, select the Config. Tab and expand MOPS and MFM again.



In MOPS you should see the new software, e.g. Software Rev.: 1.32.00 and in MFM the new software for the Multi Function Module, e.g. Software Rev.: 2.15.00 (except for M1013A without O2 option, there you will only need to check the MOPS section).



10) The software file(s) are now successfully loaded and programmed.

4

Testing and Maintenance

Introduction

This chapter provides a checklist of the testing and maintenance procedures to ensure the performance and safety of the IntelliVue G1/G5.

These tests must be performed only by qualified personnel certified by the responsible organization. Qualifications required are: training on the subject, knowledge, experience and acquaintance with the relevant technologies, standards and local regulations. The personnel assessing safety must be able to recognize possible consequences and risks arising from non-conforming equipment.

All recurring safety and performance assurance tests must be performed under equal environmental conditions to be comparable.

Preventive Maintenance refers specifically to the series of tests required to make sure the measurement results are accurate. The accuracy and performance procedures are designed to be completed as specified in the following sections or when readings are in question.

For detailed instructions on the maintenance and cleaning of the G1/G5 and its accessories, see Care and Cleaning and Maintenance and Troubleshooting in the G1/G5 Instructions for Use.

Terminology and Definitions

The following terms and definitions are used throughout this chapter and taken from the international standards IEC 60601-1, IEC 60601-1-1 and IEC 62353.

- **Medical System:** a medical electrical system is a combination of at least one medical electrical device and other electrical equipment, interconnected by functional connection or use of a multiple portable socket-outlet.
- **Patient Environment:** any area in which intentional or unintentional contact can occur between the patient and parts of the medical system or between the patient and other persons who have had contact with parts of the medical system. The patient environment is defined anywhere within 1.5m (5 feet) of the perimeter of the patient's bed and 2.5m (8.2 feet) from the floor.
- **Separation Device/Transformer:** a component or arrangement of components with input parts and output parts that, for safety reasons, prevent a transfer of unwanted voltage or current between parts of a medical system.
- **Multiple Portable Socket-Outlet:** a combination of two or more socket-outlets intended to be connected to or integrated with flexible cables or cords, which can easily be moved from one place to another while connected to the power mains.

- **Functional Connection:** an electrical connection for transfer of signals and/or power.
- **Tests:** Safety or Performance Assurance test procedures which may consist of several steps.

Recommended Frequency

Tests			Frequency
Preventive Maintenance		Fan Filter Check	Once every six months
		Fan Check	
		Replace PM parts	Once a year
Other Regular Tests		Visual Inspection	Before each use
		Power On Test	
Performance Assurance Tests		Leak Check	Once a year, or if you suspect the measurement is incorrect.
		Flow Rate Check	
		Pressure Sensor Test	
		Gas Calibration Test	
		Mounting Integrity Test	
Safety Tests	**Visual**	Visual Inspection	After each service event
	Electrical	Protective Earth	Once every two years and after repairs where the power supply has been removed or replaced or the monitor has been damaged by impact
		Equipment Leakage Current	

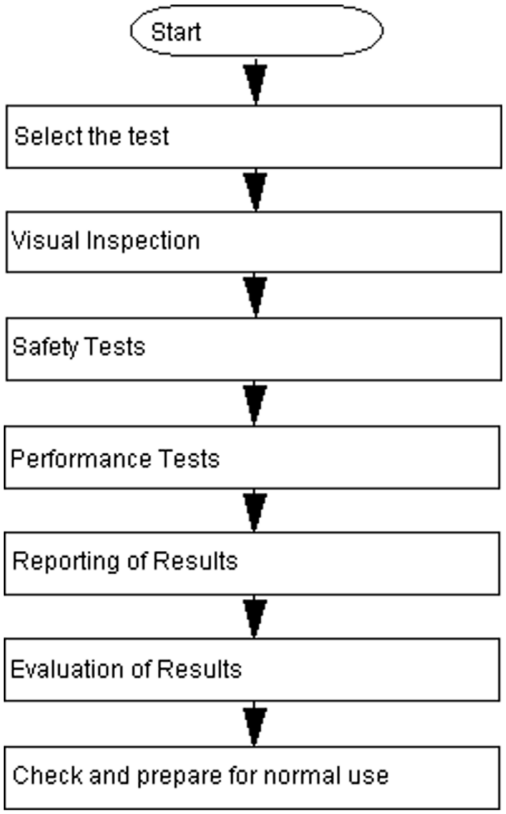
When to perform Tests

This table tells you when to perform specific tests.The corresponding test procedures are described in the following sections.

Service Event **(When performing.....**	**Test Block(s) Required** **..... Complete these tests)**
Installation	Visual Check, Power On Check, Leak Check, Component Status Check, Fan Check, Zero Calibration Check, Gas Calibration Test and Normal Operation Check
Preventive Maintenance	Fan Check, Leak Check, Component Status Check, Zero Calibration Check, Gas Calibration Test and Normal Operation Check, Electrical Safety

NOTE It is the responsibility of the facility operator or their designee to obtain reference values for recurring safety and system tests. These reference values are the results of the first test cycles after an installation. You may also purchase this service from Philips.

Testing Sequence



Visual Inspection

Before Each Use

Check all exterior housings for cracks and damage. Check the condition of all external cables, especially for splits or cracks and signs of twisting. If serious damage is evident, the cable should be replaced immediately. Check that all mountings are correctly installed and secure. Refer to the instructions that accompany the relevant mounting solution. Check the water trap, the sample line tubing and output tubing. Make sure they are in place, that they are not kinked or broken and that there is no (or very little) water inside which can prevent these accessories from functioning as specified.

After Each Service, Maintenance or Repair Event

Ensure all fuses accessible from the outside comply with the manufacturer's specification.

Check:

- the integrity of mechanical parts, internally and externally.
- any damage or contamination, internally and externally
- that no loose parts or foreign bodies remain in the device after servicing or repair.

- the integrity of all relevant accessories.

Power On Test

1 Switch on gas analyzer and patient monitor and check for any INOP messages after the warmup phase. Make sure that the gas analyzer is not in Standby.

2 Wait for 12 minutes and make sure that no gas analyzer related INOP messages appear (except "GM No Breath", "GM Alarm Suppress", "GM CAL RUNNING" or "GM ZERO RUNNING).

Ensure that the displayed values correspond to the ambient air (21% O_2 ±3%, 0% all other gases).

The expected test result is pass: No unexpected INOP messages and correct ambient air values.

Safety Tests

Safety tests are comprised of the following tests performed on the monitoring system:

- protective earth resistance
- equipment leakage current

Safety test requirements are set according to international standards, their national deviations and specific local requirements. The safety tests detailed in this Service Guide are derived from international standards but may not be sufficient to meet local requirements. We recommend that you file the results of safety tests. This may help to identify a problem early particularly if the test results deteriorate over a period of time.

Each individual piece of equipment which has its own connection to mains or which can be connected or disconnected from mains without the use of a tool must be tested individually.

Accessories which can affect the safety of the equipment under test or the results of the safety test must be included in the tests and documented.

Warnings, Cautions, and Safety Precautions

- These tests are well established procedures of detecting abnormalities that, if undetected, could result in danger to either the patient or the operator.
- Disconnect the device under test from the patient before performing safety tests.
- Disconnect the device under test from mains before performing safety tests. If this is not possible, ensure that the performance of these tests does not result in danger to the safety analyzer operator, patients or other individuals.
- Test equipment (for example, a *Safety Analyzer*) is required to perform the safety tests. Please refer to Annex C of IEC/EN 62353 for exact requirements for the measurement equipment and for measurement circuits for protective earth resistance and leakage currents. Refer to the documentation that accompanies the test equipment. Only certified technicians should perform safety testing.
- The consistent use of a *Safety Analyzer* as a routine step in closing a repair or upgrade is emphasized as a mandatory step to maintain user and patient safety. You can also use the *Safety Analyzer* as a troubleshooting tool to detect abnormalities of line voltage and grounding plus total current loads.
- During safety testing, mains voltage and electrical currents are applied to the device under test. Ensure that there are no open electrical conductive parts during the performance of these tests. Avoid that users, patients or other individuals come into contact with touch voltage.

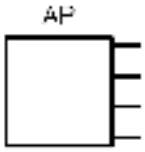
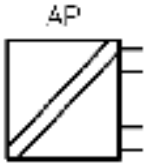
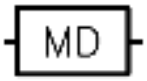
- For Europe and Asia/Pacific, the monitor complies with:
  IEC 60601-1:1988 + A1:1991 + A2:1995; EN60601-1:1990 + A1:1993 + A2:1995; IEC 60601-1-1:2001; EN 60601-1-1:2001; IEC 60601-1-2:2001; EN 60601-1-2:2001.
  For USA, the monitor complies with:
  UL60601-1
  For Canada, CAN/CSA C22.2#601.1-M90
- Local regulations supersede the testing requirements listed in this chapter.
- If a non-medical electrical device is connected to a medical electrical device, the resulting medical electrical system must comply with IEC/EN 60601-1-1.
- Perform safety tests as described on the following pages.

Safety Test Procedures

Use the test procedures outlined here **only** for verifying and recording the initial values prior to or at installation, safe installation or service of the product, and for periodic recurrent testing. The setups used for these tests and the acceptable ranges of values are derived from local and international standards but may not be equivalent. These tests are not a substitute for local safety testing where it is required for an installation or a service event. If using an approved safety tester, perform the tests in accordance with the information provided by the manufacturer of the tester and in accordance with your local regulations, for example IEC/EN 60601-1, UL60601-1 (US), IEC/EN 62353, and IEC/EN 60601-1-1. The safety tester should print results as detailed in this chapter, together with other data.

Please refer to Annex C of IEC/EN 62353 for requirements for the measurement equipment and for measurement circuits for protective earth resistance and leakage currents.

The following symbols are used in the diagrams illustrating the safety tests:

	Supply mains		Protective earth
L, N	Supply mains terminals	PE	Protective earth terminal
	Mains part		Applied part
	F-type applied part		Measuring device
	Resistance measuring device		Connection to accessible conductive parts
.....	Optional connection		

The IntelliVue G1 and the IntelliVue G5 are protected against the effects of defibrillation and electrosurgery.

CAUTION **After each service, maintenance or repair event:**

Ensure all fuses accessible from the outside comply with the manufacturer's specification.

Check:

- the integrity of mechanical parts, internally and externally.
- any damage or contamination, internally and externally.
- that no loose parts or foreign bodies remain in the device after servicing or repair.
- the integrity of all relevant accessories.

Hints for Correct Performance of Safety Tests

- Perform a visual inspection on all detachable power cords used with the monitoring system and include these in all safety test procedures.
- Connection lines such as data lines or functional earth conductors may appear to act like protective earth connections. These may lead to incorrect measurements and need to be considered during testing. If necessary, unplug these connections.
- During measurements, the device under test shall be isolated from earth (e.g. test on an insulated work bench), except the protective earth conductor in the power supply cord.
- Position all cables and cords in such a manner that they do not influence the safety tests.
- Measurement of insulation resistance is not required.
- When testing a medical electrical system, where possible, test it such that potential ground voltage variations are present as they may be during actual use.

Guideline for Performance of Safety Tests

This section introduces the general principle of performing recurrent safety tests. Product specific test descriptions are described in the following sections.

Connect the detachable power cord of the device under test to the safety analyzer's test mains port. Connect the enclosure test lead of the safety analyzer to the enclosure of the device under test, e.g. to the equipotential connector. Refer to the documentation that accompanies the safety analyzer for further details on how to set up and perform the test.

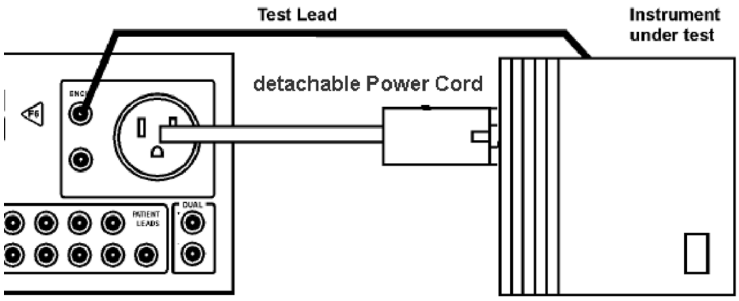


Figure 4 Protective Earth Resistance Test - Setup Example

NOTE The test lead needs to go to parts that require protective earthing. This may be a single connection or several tested after each other.

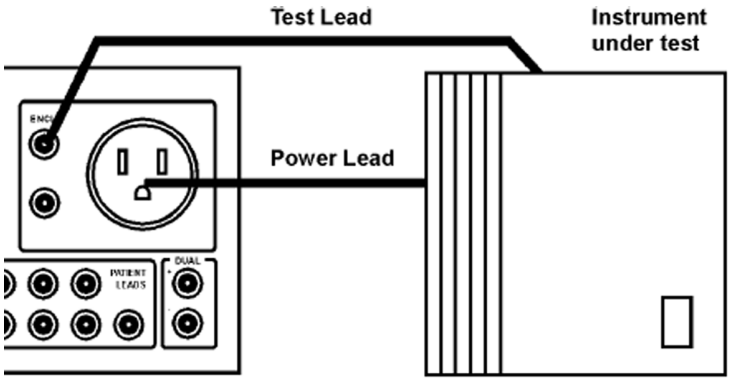


Figure 5 Equipment Leakage Current Test - Setup Example

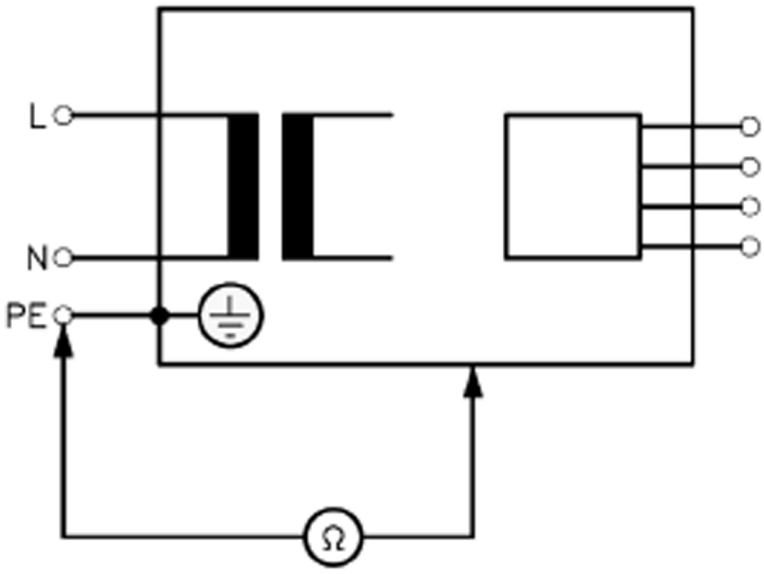
NOTE The test lead needs to go to the grounded enclosure parts, the ungrounded enclosure parts and all of the applied parts connected together.

NOTE The above graphics resemble the Metron QA-90 setup and are protected by copyright. Copyright owned by Fluke (Metron).

Electrical Safety Testing

S(1): Protective Earth Resistance Test

Test to perform:



Measuring circuit for the measurement of Protective Earth Resistance in medical electrical equipment that is disconnected from the supply mains.

This measures the impedance of the Protective Earth (PE) terminal to all exposed metal parts of the Device under Test (DUT), which are for safety reasons connected to the Protective Earth (PE).

You can find metal parts of the device at the equipotential connector.

Measurements shall be performed using a measuring device capable to deliver a current of at least 200 mA into 500 mOhms with maximum open circuit voltage of 24V

This safety test is based on IEC/EN 62353.

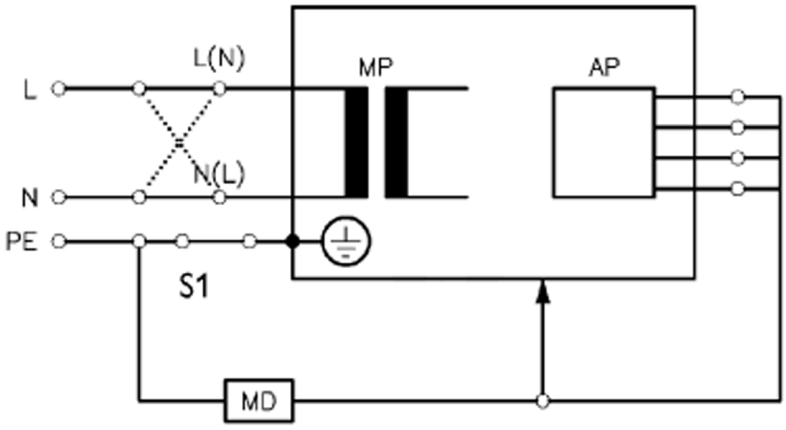
Report the highest value (X1).

Test	Expected test results
Protective Earth Resistance Test (with mains cable)	X1 <= 300mOhms

NOTE
- If the protective earth resistance test fails, testing must be discontinued immediately and the device under test must be repaired or labeled as defective.
- All values for current and voltage are the root mean square (r.m.s.) values, unless otherwise stated.
- Flex the power cord during the protective earth resistance test to evaluate its integrity. If it does not pass the test, exchange the power cord. Then repeat the test. If it still does not pass, follow the instructions in the first bullet point of this note above.

S(2) Equipment Leakage Current Test - Normal Condition

Test to perform:



Measuring circuit for the measurement of Equipment Leakage Current - *Direct method* **according to IEC/EN 62353.**

This test measures leakage current of accessible conductive and non-conductive metal parts of the monitor and the functional earth leakage current. It tests normal and reversed polarity. Perform the test with S1 closed (Normal Condition).

There are no parts of the equipment that are not protectively earthed. Disconnect any data cables and any connections that may provide an extraneous earth path. Test the device under test (DUT) on an insulated surface. Do not touch the DUT during testing.

This safety test is based on IEC/EN 62353.

For measurement limits, refer to Safety (2) test, Test and Inspection Matrix.

Report the highest value (X1).

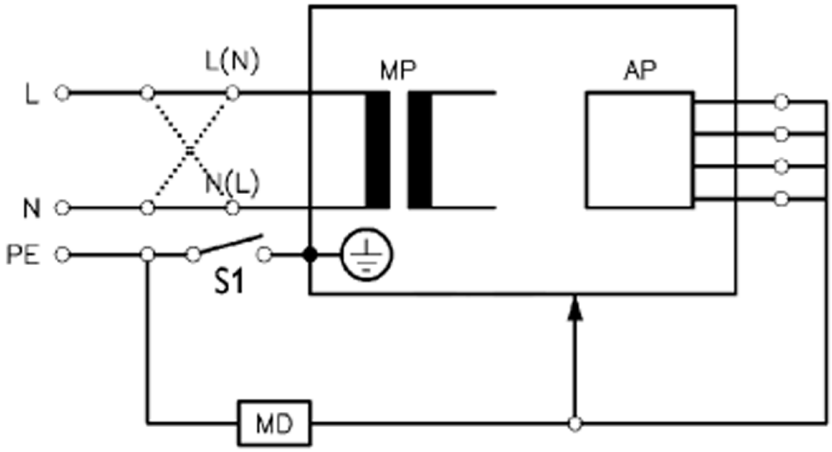
Test	Expected Test Results
Equipment Leakage Current Test (Normal Condition - with mains cable)	X1 <= 100µA

NOTE All values for current and voltage are the root mean square (r.m.s.) values, unless otherwise stated.

In case of an IT-power system, this safety test measurement requires a special measuring circuit, for example with its own integrated TN-system or use of an external isolation transformer attached to the safety test device.

S(3) Equipment Leakage Current Test - Single Fault Condition

Test to perform:



Measuring circuit for the measurement of Equipment Leakage Current - *Direct method* **according to IEC/EN 62353.**

This test measures leakage current of accessible conductive and non-conductive metal parts of the monitor and the functional earth leakage current. It tests normal and reversed polarity. Perform the test with S1 open (Single Fault Condition).

There are no parts of the equipment that are not protectively earthed. Disconnect any data cables and any connections that may provide an extraneous earth path. Test the device under test (DUT) on an insulated surface. Do not touch the DUT during testing.

This safety test is based on IEC/EN 62353.

For measurement limits, refer to Safety (3) test, Test and Inspection Matrix.

Report the highest value (X2).

Test	Expected Test Results
Equipment Leakage Current Test (Single Fault Condition - with mains cable)	X2 <= 300µA

NOTE All values for current and voltage are the root mean square (r.m.s.) values, unless otherwise stated.

In case of an IT-power system, this safety test measurement requires a special measuring circuit, for example with its own integrated TN-system or use of an external isolation transformer attached to the safety test device.

Reference: Allowable Values for IEC 60601-1:1998 and UL 60601-1 Measurements

Protective Earth resistance (between the PROTECTIVE EARTH TERMINAL and any ACCESSIBLE METAL PART which is PROTECTIVELY EARTHED, w/o power cord): 100mOhms

Protective Earth resistance of power cord: 100mOhms

Enclosure leakage current (IEC 60601-1 and UL60601-1): 100 µA (N.C.)

Enclosure leakage current:(IEC 60601-1): 500 µA (S.F.C)

Enclosure leakage current (UL 60601-1): 300 µA (S.F.C)

All values for current and voltage are the root mean square (r.m.s.) values, unless otherwise stated.

Insulation Resistance

It is not recommended to perform measurements of the insulation resistance. Refer to IEC 62353 for details about methods of the insulation resistance measurement.

System Test

After mounting and setting up a system, perform system safety tests according to IEC/EN 60601-1-1. Please refer to the patient monitor's service guide for details on when and how to perform system tests.

What is a Medical Electrical System

A medical electrical system is a combination of at least one medical electrical piece of equipment and other electrical equipment, interconnected by functional connection or use of a multiple portable socket-outlet.

- Devices forming a medical electrical system must comply either with IEC/EN 60601-1-1 or IEC 60601-1 edition 3 clause 16.
- Any electrical device such as IT equipment that is connected to the medical electrical equipment must comply either with IEC/EN 60601-1-1 or IEC 60601-1 edition 3 clause 16 and be tested accordingly.
- Non-medical electrical equipment may require connection through a separating device (e.g. an isolation transformer).

General Requirements for a System

After installation or subsequent modification, a system must comply with the requirements of the system standard IEC/EN 60601-1-1 or IEC 60601-1 edition 3 clause 16. Compliance is checked by inspection, testing or analysis, as specified in the IEC/EN 60601-1-1 or in this book.

Medical electrical equipment must comply with the requirements of the general standard IEC/EN 60601-1, its relevant particular standards and specific national deviations. Non-medical electrical equipment shall comply with IEC safety standards that are relevant to that equipment.

Relevant standards for some non-medical electrical equipment may have limits for equipment leakage currents higher than required by the standard IEC/EN 60601-1-1 or IEC 60601-1 edition 3 clause 16. These higher limits are acceptable only outside the patient environment. It is essential to reduce equipment leakage currents to values specified in IEC/EN 60601-1 when non-medical electrical equipment is to be used within the patient environment.

Preventive Maintenance Procedures

WARNING Failure to implement a satisfactory maintenance schedule by the individual, hospital or institution responsible for the operation of this equipment may cause equipment failure and possible health hazards.

The following sections describe the **Preventive Maintenance** tasks (PMs) required to keep the gas analyzer in good working order. PMs are performed to a timetable before problems arise as a means to reduce failures.

CAUTION Take precautions when dealing with potentially contaminated parts, such as tubing and other components of the patient circuit. Wear gloves, mask and gown while handling components that come into contact with the patient's exhalant gas or fluids.

Here is a list of the PM tasks required to ensure satisfactory operation of the gas analyzer within its specified limits and how often they must be performed.

- Check the fan filter for occlusions every **6 months**.
- Check the fan in the gas analyzer for proper operation every **6 months**.
- Check the gas analyzer's accuracy at least once every **12 months**, or whenever the validity of the readings is in doubt.
- Replace the PM parts every **12 months**.

Check electrical safety (ground impedance and enclosure leakage current test) at least every **12 months** or every time the device is removed and reinstalled.

Cleaning

The user should be encouraged to periodically clean the exterior casing of the gas analyzer. The outside of the gas sample tubing should be cleaned before connecting to the next patient.

CAUTION Never leave the gas analyzer running without the watertrap attached, as sucked in dust or cleaning agents may irreparably damage the instrument. Ideally, switch off the gas analyzer or go into Standby mode when cleaning the instrument.

Replace PM Parts

Every **12months** the following PM parts should be replaced:

- fan filter
- watertrap manifold seals

Replacing the Fan Filter

1 Pull out the fan filter towards you from the fan and replace it with a new one.

Replacing the Watertrap Manifold Seals

1 Pull out the two seals from the tubing connectors of the manifold using pointed tweezers; slide one side of the tweezers between the seal and the connector, then grasp and pull.

2 Take a new seal in the tweezers and press it onto the fitting in the tubing connector. Push down on the seal using the handle of the tweezers (or another blunt instrument), taking care not to damage the seal, until it sits properly. Repeat with the second seal.

Performance Assurance Tests - Checking and Calibrating the Gas Analyzer

The following sections explain how to check the gas analyzer to ensure that it is operating within its specified limits. A list of the equipment required to carry out the checks is included, as well as step-by step instructions for the calibrations.

If you receive fail indications while testing, refer to the troubleshooting section of this document for guidance.

Access Service Functions of the Gas Analyzer

Service functions of the IntelliVue G1 and IntelliVue G5 are accessed with the M1013A/M1019A Service Software (VISIA tool) which is available on the Service CD shipped with the product.

When and how to check the Gas Analyzer

To ensure that the gas analyzer operates within the specified limits, it must be checked every 12 months. If you find values outside the tolerance limits while checking, please refer to the troubleshooting section in order to determine whether the instrument can be calibrated again or needs to be repaired.

Whenever the readings are in doubt, a gas calibration check should be performed.

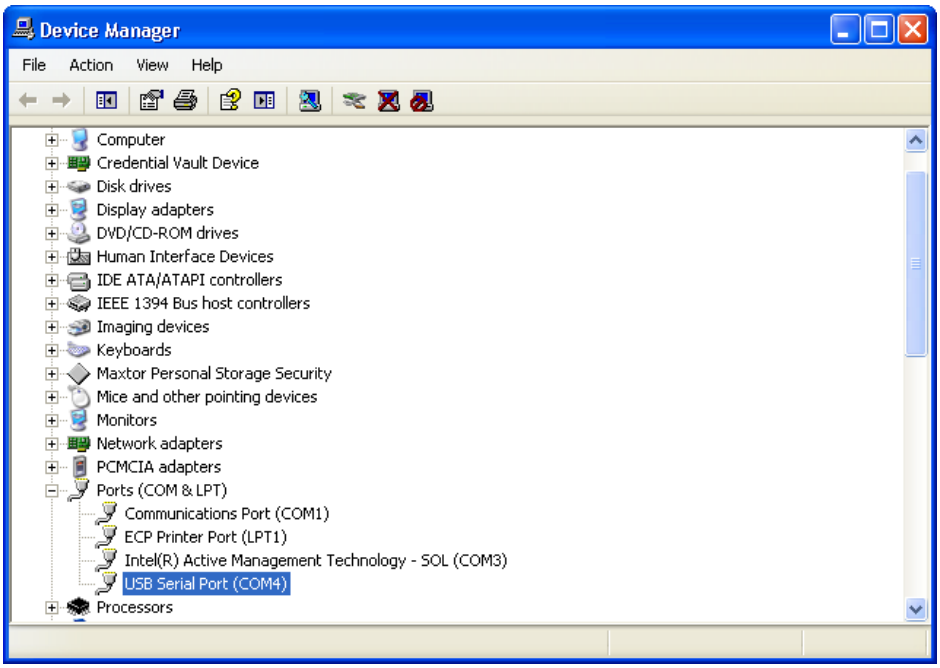
Equipment required for checking

The following equipment is required for checking the gas analyzer. If applicable, part numbers are given in the parts list section of this manual.

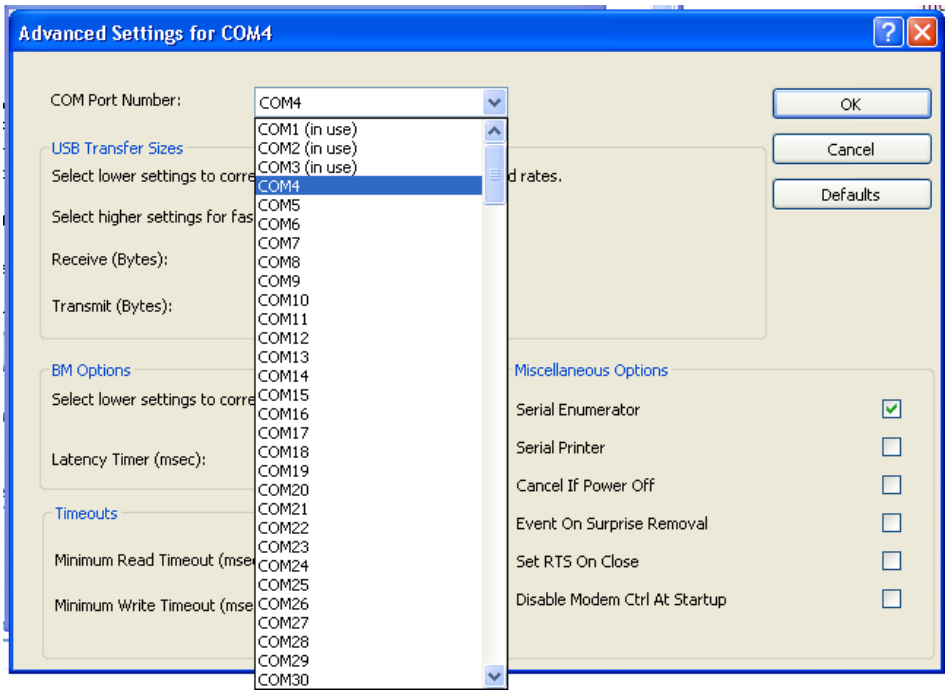
Equipment	Philips part # or other recommendation	Accuracy
IntelliVue G1/G5 PC cable	M1013-61005 / 451261005001 (RS232 - if necessary, a USB-to-RS232 serial adapter can be used. See note below)	n/a
TSI Flowmeter	453564178121	±3 ml/min or better
Digital Barometer/ Pressure Indicator	Barometer/Digital Pressure Indicator with an accuracy of ±2mbar or better. Recommended: DRUCK DPI 705, 2bar, absolute	±2 mbar or better
Watertrap	M1657B / 989803110871	n/a
Sample Tubing	M1658A / 989803104671	n/a
Calibration Gas Reservoir Bag	M1659A / 989803104681	n/a
Calibration Gas	M1662A / 451261001391	n/a
Gas Exhaust Return Line or Exhaust Tubing	M1655B / 989803145671 or M1015-40001 / 453563227921	n/a
Leakage Test Kit	M1013-64002 / 451261014851	n/A

NOTE If your PC/Laptop does not have an RS232 serial connector, you can use a USB-to-RS232 Serial adapter. For the COM port settings, you need to change the USB Serial port to COM1. To do this:

1 Go to **`Control Panel -> System -> Hardware - Device Manager`** and select the USB Serial Port.



2 Right click on the USB Serial Port, click **`Properties`** and select **`Advanced`**.



3 Select COM1 from the drop down menu and click OK.

Annual Checks

Perform the following procedure once a year

1 Connect a PC/Laptop running the Service Software (VISIA tool) to the instrument and wait for the first zero calibration after the start up period. (Make sure that zero mode is switched to **Auto** - see “Zero Calibration” on page 59)

2 Check that there are no reported errors.

3 Perform the pneumatic tests:

   a. Leak check

   b. Flow rate check

   c. Pressure sensor test.

4 Gas calibration tests

Connecting the Gas Analyzer to a PC/Laptop

To set up a computer as a service host for the gas analyzer, a serial connection must be established with the IntelliVue G1/G5 PC cable (for part number see "Equipment Required for Checking"). Connect the RJ45 connector of the cable to the appropriate receptacle on the back of the gas analyzer (see Figure 6), and then connect the D-SUB9 connector of the cable to the serial port of your computer.

Switch on the gas analyzer and then start the VISIA software on your computer.

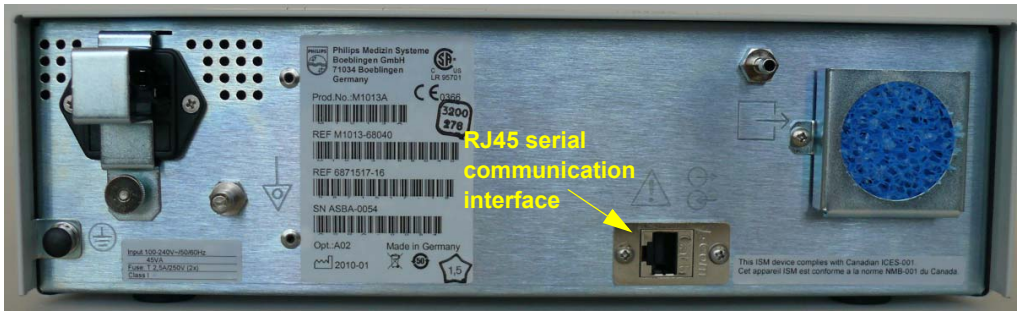


Figure 6 RJ45 connection on the back of the gas analyzer

Getting started with the VISIA software

NOTE After each use of the VISIA tool, the G1/G5 must be switched off and back on again before being used for patient monitoring.

When the VISIA tool starts up, it is switched to *Standby,* Breath Detection is *Enabled*, and the Pump Flow Level is *Off*. Check the COM port for correct settings (Baud Rate: 19200) and push the “Connect” button if the connection was not established automatically after starting the VISIA tool.

In order to keep the gas analyzer running, always do the following first:

1 Switch the tool to *Operate*,

2 Switch Breath Detection to *Disabled* (as shown in Figure 7) and

3 switch Pump Flow Level to *High* (as shown in Figure 8).

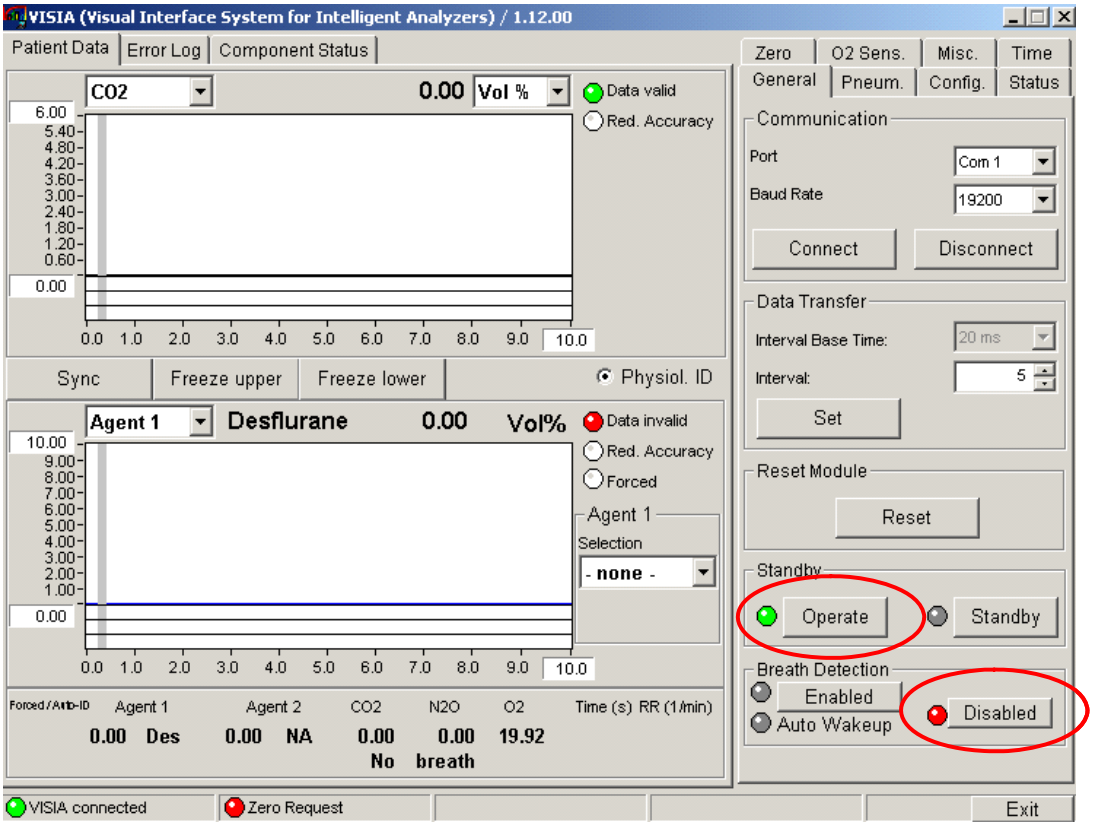


Figure 7 General Tab in VISIA tool

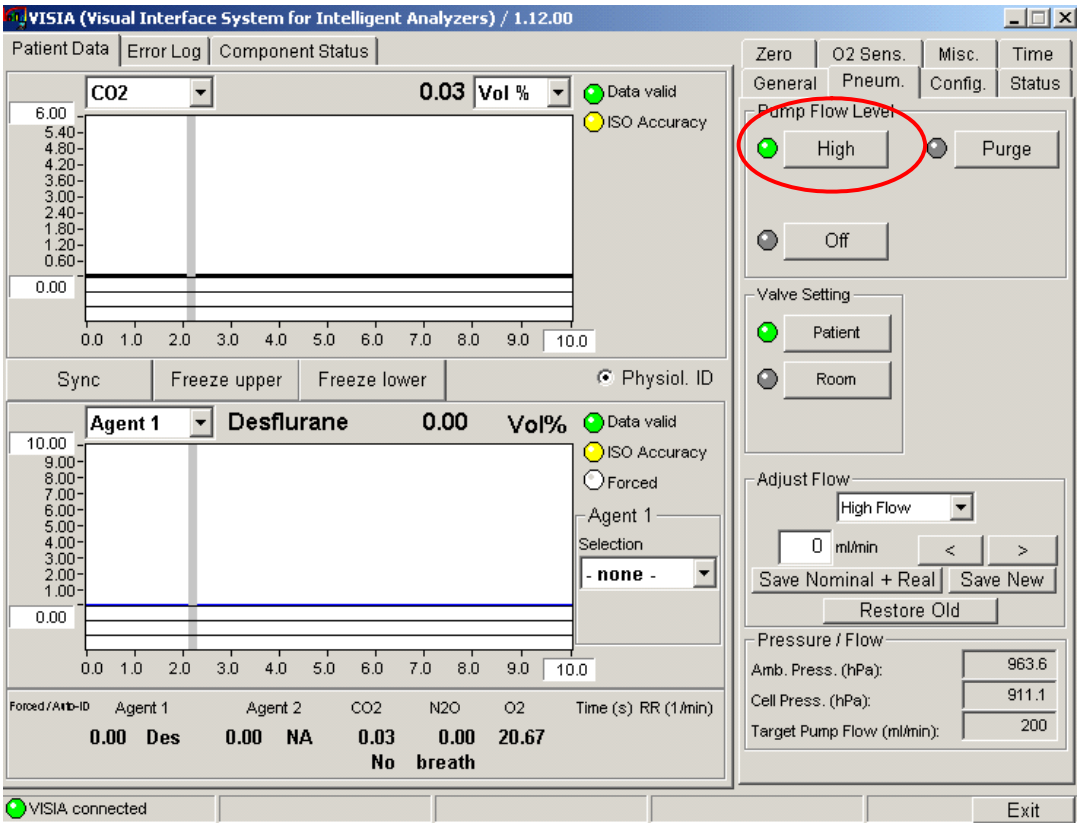


Figure 8 Pneumatic Tab in VISIA tool

Zero Calibration

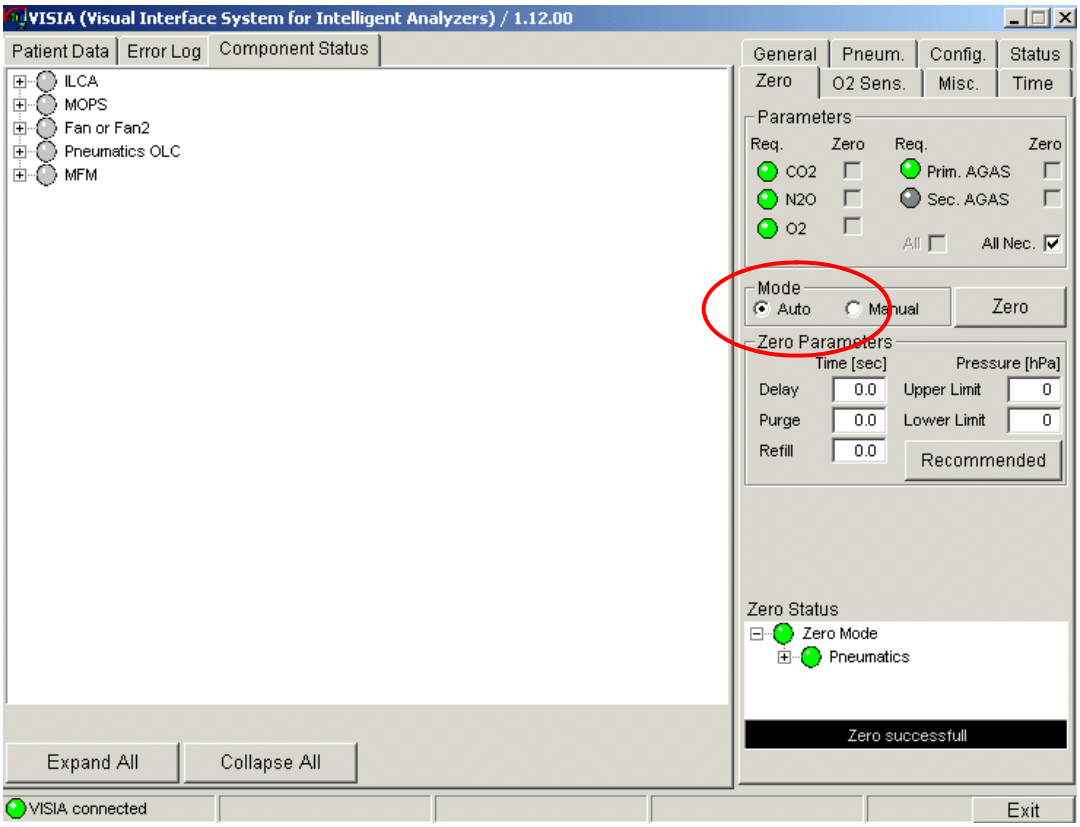


Figure 9 Zero Calibration

The IntelliVue G1 and G5 require a periodic zero calibration. Whenever this is due, the instrument sends a zero request command to the host monitor. The Philips patient monitor automatically initiates a zero calibration whenever it receives such a request from the gas analyzer - if you want the VISIA tool to do the same, you have to switch the zero mode from Manual to Auto (see Figure 9).

Zero requests occur 5 and 10 minutes after power on and then every two hours.

You can also initiate a zero calibration manually by pressing the Zero button.

A zero calibration can either be run on selected gas channels only or on all necessary channels. The latter is recommended and therefore the *All Nec.* check box should always be checked in the Zero tab.

Zero Calibration Test

Test Procedure:

- Make sure that the *All Nec.* check box is checked in the Zero tab
- Press the *Zero* button. Note that the Mode in the Zero tab must be switched to *Manual* for this test. Do not forget to switch it back to *Auto* upon completion of the test.

Expected Result: a “Zero successful” message in the lower right hand side of the Zero tab and only green soft-LEDs in the Zero Status area.

If this test fails, perform a Leak Check and a Flowrate Check and rerun the Zero Calibration Test. If it fails again, the gas analyzer needs to be replaced.

Test	Expected Test Results
Zero Calibration Test	Zero succesful and green soft-LEDs in the Zero Status area

Component Status Check

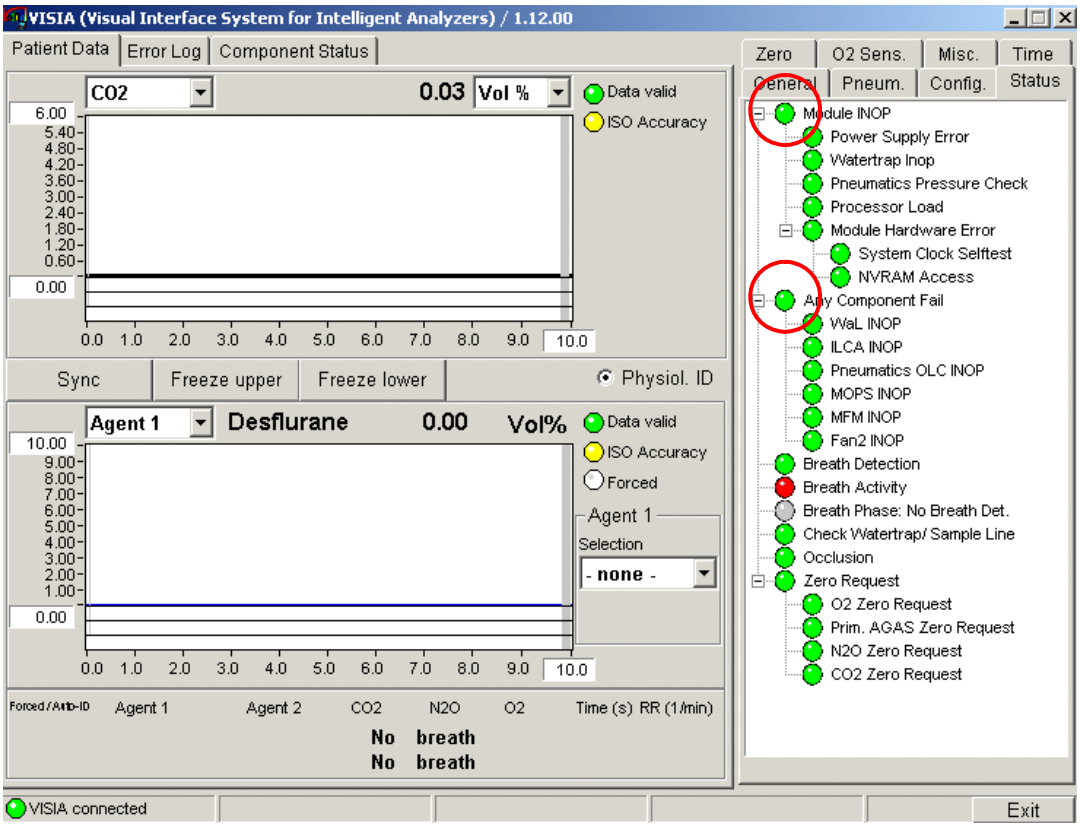


Figure 10 Component Status Check with the Status Tab in VISIA Tool

Wait for the first automatic zero calibration to complete (for details on automatic zero calibrations refer to “Zero Calibration” on page 59)

To check the status of the gas analyzer's components, open the Status tab on the right hand side of the VISIA tool as shown in Figure 10.

Expected result: The two top-level entries in this view, *Module INOP* and *Any Component Fail* , show green soft-LEDs.

If this test fails, perform a leak check and a flowrate calibration. Then rerun the test. If the test fails again, the gas analyzer needs to be replaced.

Test	Expected Test Results
Component Status Check	*Module INOP* and *Any Component Fail* show green soft-LEDs

Pneumatic Tests

These tests ensure the integrity of the pneumatics system, which has a big impact on the quality of the measured values. Make sure that all the pneumatics tests are passed before checking the measurement accuracy.

Equipment needed:

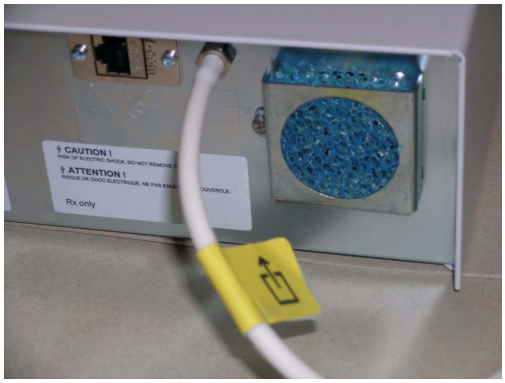
- M1655B Gas Exhaust Return Line
- 453564178121 TSI Flowmeter
- M1657B Watertrap
- M1658A Sample Tubing
- M1013-64002 Leakage Test Kit
- Digital Pressure Indicator

Leak Check

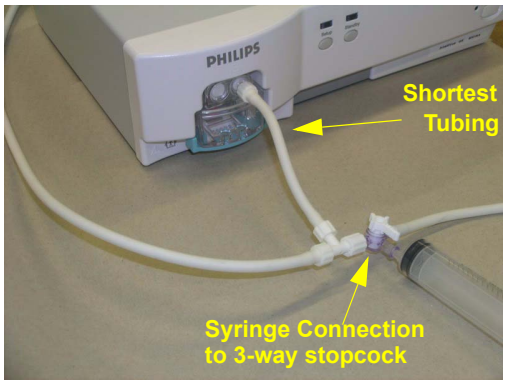
Checking for leaks between inlet and pump

1 Trigger a zero procedure (all necessary parameters) via the service host, watch it progress and wait until it is finished (zero successful).

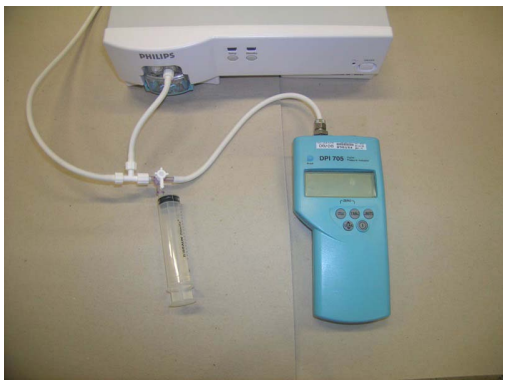
2 Attach the long tubing with the yellow outlet flag to the outlet of the gas analyzer.



3 Connect the shortest piece of tubing to the watertrap and then connect the syringe (20 ml) to the 3-way stopcock as shown below. Make sure that this connection is tight..



4 Connect the tubing directly to the digital pressure indicator.



NOTE Do not connect the tubing to any additional tubing you may have connected to the digital pressure indicator.

5 Check that the pump flow level is set to *off* in the VISIA tool, or switch off the gas analyzer.

6 Draw at the syringe until the digital pressure indicator shows a difference of 220 mbar between the ambient pressure and the sample cell pressure.

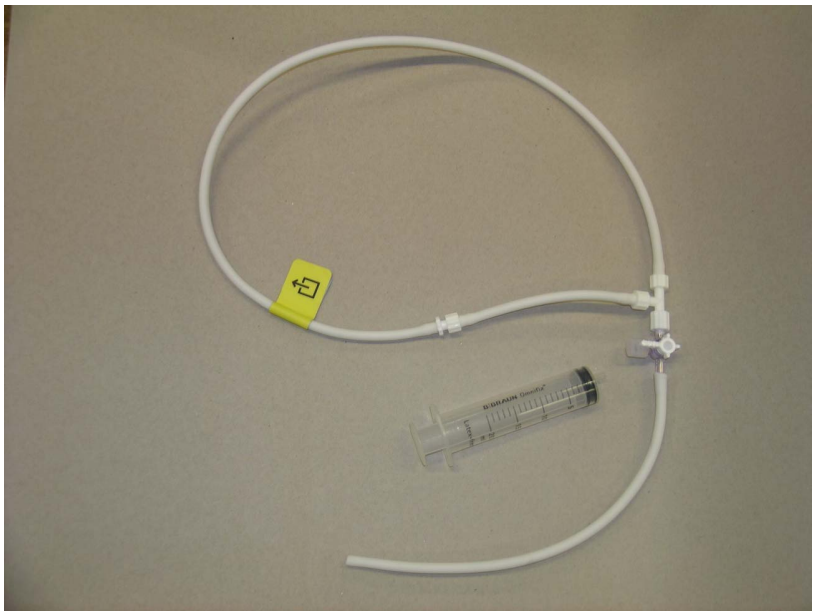
7 Close the 3-way stopcock to the syringe and wait 5-10 seconds. In this time, the overall pressure should stabilize at approximately 200 mbar below ambient pressure.

8 After 1 minute, check the pressure. The pressure should not increase more than 80 mbar in 1 minute for the test to pass.

9 If this test fails, perform Kit Leak Test as described below to verify that there is no leakage impact from the test kit used for the leak check between inlet and pump.

Kit Leak Test Procedure:

1 Form a loop with the leakage test kit as shown in the picture below. Use the female luer thread/luer slip to attach the long tubing to the watertrap tubing.



2 Connect a syringe to the 3-way stopcock and a digital pressure indicator to the open tubing.

3 Draw at the syringe until the digital pressure indicator shows 210 mbar below ambient pressure.

4 Close the 3-way stopcock to syringe and wait 5-10 seconds. In this time, the overall pressure should stabilize at approximately 200 mbar below ambient pressure.

5 After 1 minute, check the pressure. The pressure should not increase more than 5 mbar in 1 minute for the test to pass.

6 If this test fails, exchange the leakage test kit. If this test passes, exchange the gas analyzer.

Expected result for the Leak Check (not for the Kit leak test):

After 1 minute, check the pressure. The pressure should not increase more than 80 mbar in 1 minute for the test to pass.

If this test fails, make sure that there are no leaks in the setup and rerun the test. If it still fails, the gas analyzer has an internal leakage and needs to be replaced.

Test	Expected Test Results
Leak Check	Pressure Increase ≤ 80mbar within 1 min.

Flow Rate Check

CAUTION For this check, always measure the gas analyzer flow rate at the sample gas inlet. Measuring at the outlet may lead to incorrect flow readings due to ripple on the gas flow.

Test Procedure:

- Connect sample line to the watertrap
- Connect a flowmeter to Luer-Lock connector of the sample line

Expected Result: Sampling rate is 200±20 ml/min

NOTE After warm up or zero the flow rate may be higher than 200 ml/min for about 30 minutes. Please wait until the flow stabilizes.

In case the pump flow is out of the specified limits, it needs to be adjusted following the procedure described in the section "Flow Rate Adjustment".

Test	Expected Test Results
Flow Rate Check	Sampling rate is 200±20 ml/min

Pressure Sensor Test

Zero Pressure Test Procedure:

- Trigger a zero procedure (all necessary parameters) via the service host, watch it progress and wait until it is finished (zero successful).
- Measure ambient pressure with independent digital barometer.
- Compare the ambient pressure measured with the digital barometer with the ambient pressure measured by IntelliVue G1/G5 as shown by the VISIA tool.

Expected result: The deviation between the two measured values is < 10 mbar.

Amplification Pressure Test Procedure:

- Switch to the *Pneum.* tab on the VISIA tool.
- Set pump flow to *off*
- Switch valve setting to *patient* (default setting after startup of IntelliVue G1/G5)
- Connect digital pressure indicator and the leakage test kit. See Instructions for Use supplied with the leakage test kit for details (M1013-9302B).
- Follow the leakage test kit IfU to apply negative pressure and wait until you have a pressure of 200 mbar below ambient.
- Wait until the negative pressure has stabilized.
- Compare the pressure measured with the digital pressure indicator with the sample cell pressure measured by the IntelliVue G1/G5 as shown by the VISIA tool

Expected result: The deviation between the two measured values is < 10 mbar.

If any of the two pressure sensor tests fails, the unit needs to be exchanged.

Test	Expected Test Results
Pressure Sensor Test	Deviation between the two measured values is <10mbar

Flow Rate Adjustment

CAUTION For this adjustment, always measure the gas analyzer flow rate at the gas sample inlet. Measuring at the outlet may lead to incorrect flow readings due to ripple on the gas flow.

In case the gas analyzer flow rate is outside the tolerance limits, it can be adjusted according to the following procedure:

1 Make sure you measure the flow at the gas analyzer's inlet.

2 Select High Flow in the Adjust Flow pull down menu (See Figure 11).

3 Connect the sample line to the watertrap and check the difference between the sample cell pressure and the ambient pressure. It should read between 80 and 100 mbar in the VISIA tool.

4 Connect the flowmeter to the sample line. The pressure difference may now be slightly higher than before. A decrease of up to 150 mbar is acceptable.

5 Now use the < and > buttons to decrease or increase the flow until it is inside the tolerance limits.

6 Press the Save New button to store the new flow rate setting.

7 Switch the pump to *off* and then *high* again and check the flow in the flowmeter and in the Target Pump Flow field in the VISIA tool.

If the flow rate cannot be brought inside the tolerance limits, the gas analyzer needs to be replaced.

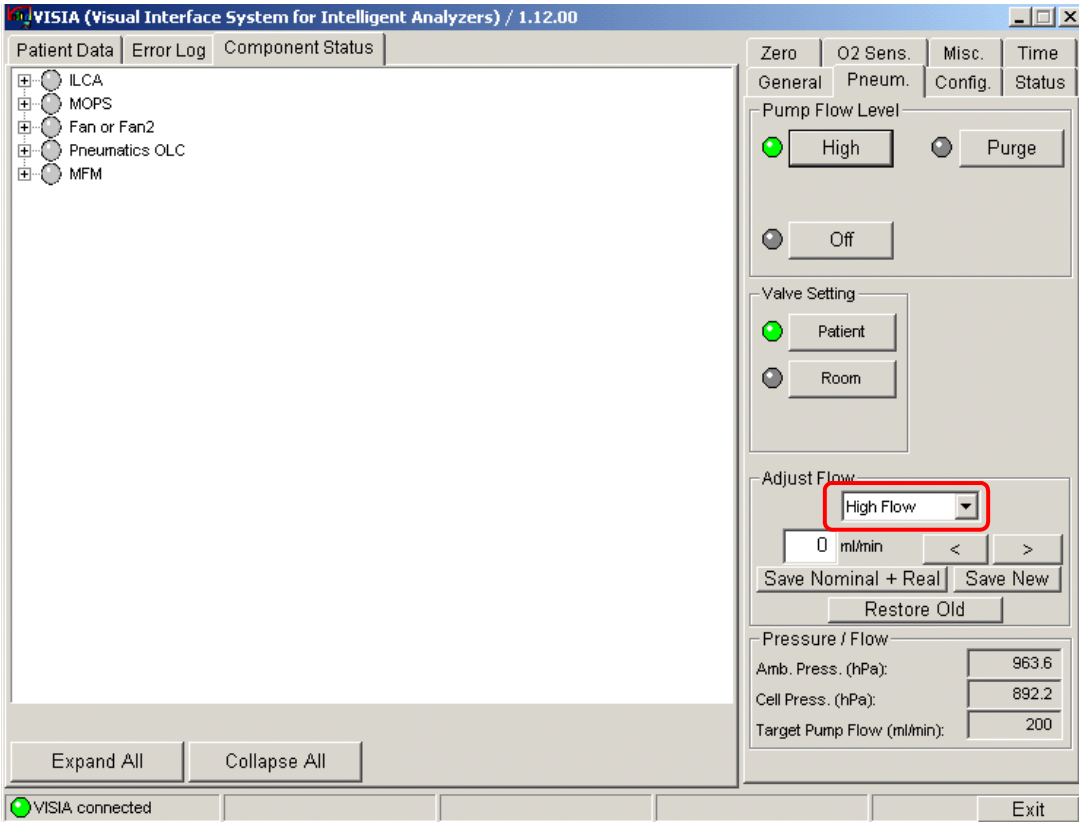


Figure 11 Flow Rate Adjustment

The Restore Old button brings back the last saved flow rate. Once a new flow rate has been saved, only this flow rate can be recalled when attempting to restore an old one.

Gas Calibration Test

The gas analyzer should run for at least 6 minutes until the Data soft-LED in the Patient Data reads *Data Valid* before continuing with the following calibration procedures. This is to allow the module to reach ISO accuracy (see Figure 13). Use the M2211A Flow Regulator when performing the gas calibration test. Refer to the instruction sheet provided with the flow regulator for detailed instructions for use.

Before performing Gas Calibration Test, you must first:

- pass all Pneumatic Tests (Leak Test, Flowrate Test, Pressure Sensor Test),
- pass a Zero Calibration,
- ensure that there is enough gas in the check gas bottle,
- check tubing assembly and reservoir bags for leaks or damage.

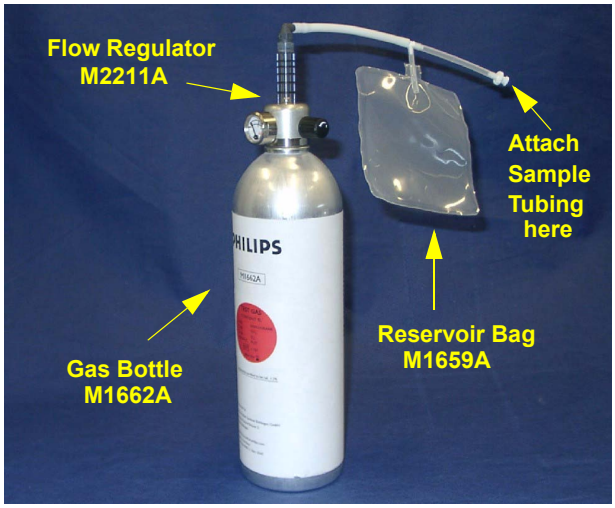


Figure 12 Span Checking Equipment including Gas Canister and Spray Valve

The procedure to check the gas accuracy is as follows:

1 Set *Breath Detection* to *Disabled* in the General Tab.

2 Select the Patient Data Tab in the VISIA tool so that you can see the waveforms (see Figure 13).

3 Set the upper Gas section to CO_2 (make sure the unit is set to Vol%) and the lower Gas section to *Agent 1* (see Figure 13).

4 On the M1013A, set *Agent 1* to *DES* for measuring Desflurane. On the M1019A, set *Agent 1* to *Auto ID* and make sure Desflurane is detected.

5 Set the pump flow level to *high*.

6 Make sure the pump is on, then connect the calibration gas bottle, the reservoir bag and the sample line as shown in Figure 12.

7 Wait until the reservoir bag is empty. Wait for another 10 seconds to let the IntelliVue G1/G5 completely evacuate the reservoir bag.

8 Now fill the reservoir bag with gas.

CAUTION Do not pressurize the reservoir bag.

Do not attempt the span check process if there are any visible leaks in the bag or tubing.

Prevent the bag from emptying before the gas calibration test is complete.

9 Wait until the two gas concentration curves are completely flat as shown in Figure 13.

NOTE With the M1019A, the “Agent 1 Selection” field shown below, should read “Auto ID”

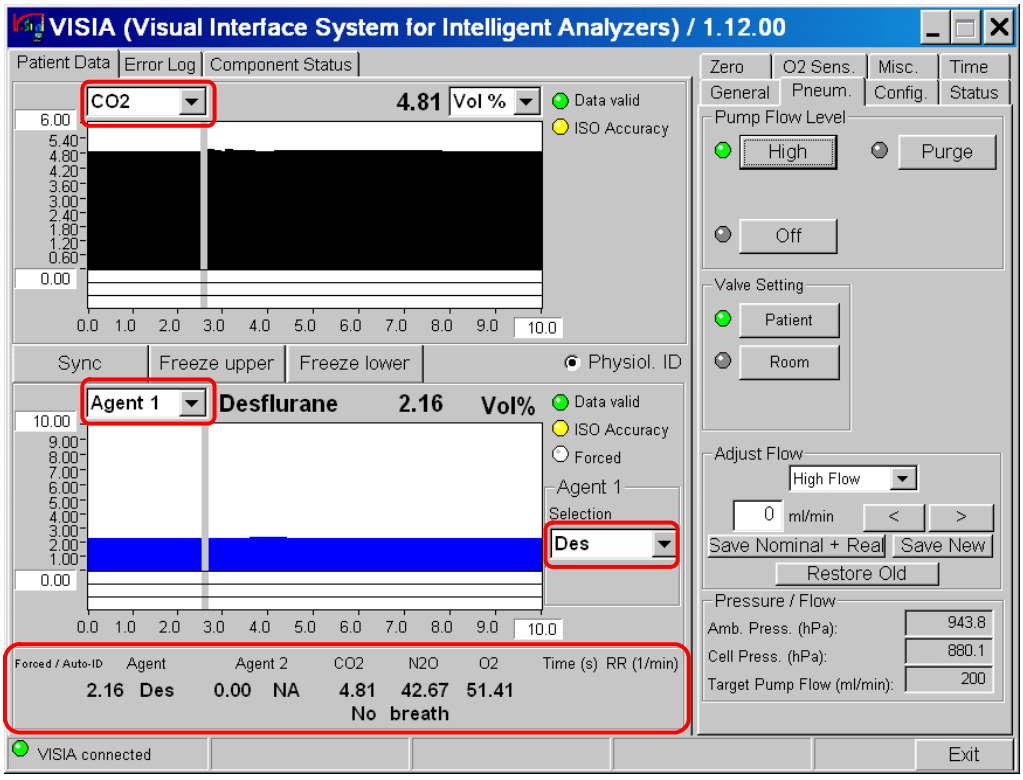


Figure 13 Patient Data Window during Gas Calibration Test

10 Now compare the numeric values shown in the lower section of the Patient Data Window with the concentrations as printed on the calibration gas canister. (You can press the *Freeze Upper* button to make the values stay in the view for comparison.)

11 Verify that the values measured by the gas analyzer are within the specified limits

Gas Type	Allowed Tolerance
Anesthetic Agent	±0.5 vol%
CO_2	± 0.7 vol%
N_2O	±6.2 vol%
O_2	± 3vol%

Disposal of Empty Gas Cylinder

1 Empty cylinder completely by pushing in the pin of the valve.

2 Once the cylinder is empty, drill a hole in the cylinder

CAUTION Be careful to assure that the cylinder is completely empty before you try to drill the cylinder.

3 Write "Empty" on the cylinder and place it with your scrap metal or, if you do not collect scrap metal for recycling, dispose of the cylinder.

Mounting Integrity Test

If at any time:

- one or more of the four of the quick mount screws are loose
- there is a clearance between the quick mount and the monitor bottom housing
- the G1/G5 mounting is unstable

remove the G1/G5 from the mount and disassemble the quick mount. Ensure that the threading of the G1/G5 is not damaged.

If the quick mount is damaged, exchange the quick mount.

Ensure that all quick mount screws are tight (3.5 Nm). Test the quick mount by pressing the quick release button. If it comes back out gradually and regularly, the quick mount is inserted correctly. If it gets stuck, the quick mount is not centered and must be reinserted correctly.

If you notice any damage to the threading of the G1/G5 chassis, send the G1/G5 in for bench repair.

Test	Expected test results
Mounting Integrity Test	All quick mount screws are tight. No damage to quick or fix mount. No damage to threading of G1/G5.

Reporting of Test Results

Philips recommends all test results are documented in accordance with local laws. Authorized Philips personnel report the test result back to Philips. While hospital personnel (biomedical engineers or technicians) do not need to report results to Philips, Philips recommends that they record and store the test results in accordance with local laws.

The following table lists what to record after completing the tests in this chapter. Record the results in the empty column in the Test and Inspection Matrix.

The following is a guide as to what your documentation should include:

- Identification of the testing body (for example, which company or department carried out the tests).
- Name of the person(s) who performed the tests and the concluding evaluation.
- Identification of the device(s) and accessories being tested (serial number, etc.).

- The actual tests (incl. visual inspections, performance tests, safety and system tests) and measurements required
- Date of testing and of the concluding evaluation.
- A record of the actual values of the test results, and whether these values passed or failed the tests.
- Date and confirmation of the person who performed the tests and evaluation.

The device under test should be marked according to the test result: passed or failed.

Carrying Out and Reporting Tests

Test Report

Testing Organization: Name of testing person: Date:	(Check one of the following three options) Test before putting into service (reference value) Recurrent Test Test after Repair
Responsible Organization:	
Device Under Test:	ID-Number:
Product Number:	Serial No.:
Accessories:	
Measurement Equipment (Manufacturer, Type, Serial No., Calibration Date):	
Safety Test Method used	
Functional Test (parameters tested):	
Mains voltage and frequency used during safety testing:	

Test and Inspection Matrix - Checks with Patient Monitor

Test Block Name	Test or Inspection to be performed	Expected Test Result	What to Record on Service Record
Visual Check	Check for any mechanical damage and all external leads and accessories. Is the device free of damage and are all accessories properly set up?	Expected answer is "yes". If so, visual test is passed.	V: P or V: F where P=Pass and F=Fail
Power On Check	1. Switch on gas analyzer and patient monitor and check for any INOP messages after the warmup phase. Make sure that the gas analyzer is not in Standby. 2. Wait for 12 minutes and make sure that no INOP messages appear (except “GM No Breath”, “GM Alarm Suppress”, “GM Cal running” and “GM Zero running”). 3. Ensure that the displayed values correspond to the ambient air (21% O_2 ±3%, 0% all other gases).	Expected result: No INOP messages and correct ambient air values. If so, Power On test is passed.	PO: P or PO: F where P=Pass and F=Fail
Normal Operation Check	Enter Monitoring mode on the patient monitor and check that all gas analyzer related waves and numerics are present and correspond to the user’s configuration.	Expected answer is "yes". If so, performance normal operation check is passed.	NO: P or NO: F where P=Pass and F=Fail
Fan Check	Check that the fan runs smoothly.	Expected answer is "yes".	FA: P or FA: F where P=Pass and F=Fail
Mounting Integrity Test	Perform the Mounting Integrity Test	All quick mount screws are tight. No damage to quick or fix mount. No damage to threading of G1/G5.	MI: P or MI: F where P=Pass and F=Fail
Safety (1)	Perform Safety Test (1): Protective Earth resistance	With mains cable: Maximum impedance (X1): <= 300 mOhms)	S(1):P/X1 or S(1):F/X1 where P=Pass and F=Fail
Safety (2)	Perform Safety Test (2): Equipment Leakage Current -Normal Condition.	With mains cable: Maximum leakage current (X1): <= 100µA	S(2):P/X1 or S(2):F/X1 where P=Pass and F=Fail

Test Block Name	Test or Inspection to be performed	Expected Test Result	What to Record on Service Record
Safety (3)	Perform Safety Test (3): Equipment Leakage Current - Single Fault Condition (Open Earth)	With mains cable: Maximum impedance (X2): <= 300 µA)	S(3):P/X2 or S(3):F/X2 where P=Pass and F=Fail
Alarming Functionality	Set the apnea alarm delay to 10 seconds and then breathe twice into the gas inlet. (Make sure to set the apnea alarm delay back to its original setting after completing the test).	Apnea alarm is issued 10 seconds after breathing into the inlet has stoppped.	A: P or A: F where P=Pass and F=Fail

Checks with VISIA Tool

Test Block Name	Test or Inspection to be performed	Expected Test Result	What to Record on Service Record
Zero Calibration Test	Is the status of the zero calibration "Zero successful" in the Service Software after a zero calibration has been performed?	Expected answer is "yes". Zero succesful and green soft-LEDs in the Zero Status area	ZC:P or ZC:F where P=Pass and F=Fail
Component Status Check	Perform Component Status Check as described in “Checking and Calibrating the Gas Analyzer”.	*Module INOP* and *Any Component Fail* show green soft-LEDs	CS:P or CS:F where P=Pass and F=Fail
Leak Check	Perform Leak Check as described in “Checking and Calibrating the Gas Analyzer”.	Pressure Increase ≤ 80mbar within 1 min.	LC: P or LC: F where P=Pass and F=Fail
Flowrate Check	Perform Flowrate Check as described in “Checking and Calibrating the Gas Analyzer”.	Sampling Rate is 200±20 ml/min	FC: P or FC: F where P=Pass and F= Fail
Pressure Sensor Test	Perform Pressure Sensor Test as described in “Checking and Calibrating the Gas Analyzer”.	Deviation between the two measured values is <10mbar	PS:P or PS:F where P = Pass and F = Fail
Gas Calibration Test	Perform the Gas Calibration Test as described in “Checking and Calibrating the Gas Analyzer”.	**Allowed Tolerance:** Anesthetic Agent: ±0.5 vol% CO2: ±0.7 vol% N2O: ±6.2 vol% O2: ± 3vol%	GCT:P or GCT:F where P=Pass and F=Fail

Evaluation

	Yes	No
Safety and Functional Test passed		
Repair required at a later date, safety and functional test passed		
Device must be taken out of operation until repair and passed tests		
Device failed and must be taken out of operation.		

Notes

Next Recurrent Test:

Name:_____

Date/Signature:_____

Evaluation of Test Results

The evaluation of the test results must be performed by appropriately trained personnel with sufficient product, safety testing and application knowledge.

If any test results are between 90% and 100% of the respective expected result, the previously measured reference values must be taken into consideration for the assessment of the electrical safety of the device under test. If no reference values are available, you should consider shorter intervals between upcoming recurrent tests.

NOTE If any single test fails, testing must be discontinued immediately and the device under test must be repaired or labeled as defective. Be sure to inform the user about the test failure in writing.

Other Regular Tests

The care and cleaning requirements that apply to the monitor and its accessories are described in the Instructions for Use. This section details periodic maintenance procedures recommended for the monitor and its accessories.

After Installation, Testing or Repair

Before handing the patient monitor over to the end-user, make sure it is configured appropriately and that it is in monitoring mode. Ensure that the user receives the current revision of the monitor documentation.

5

Troubleshooting the Gas Analyzer

This chapter provides a recommended procedure for locating and identifying faults on the gas analyzer.

It details how to identify hardware problems and how to proceed when measurement related INOPs occur.

It details how to proceed when errors are flagged for:

- Failed calibration checks and procedures
- Failed diagnostic checks.

Equipment needed for troubleshooting:

Equipment	Philips part # or other recommendation	Accuracy
IntelliVue G1/G5 PC cable	M1013-61005 / 451261005001	n/a
TSI Flowmeter	453564178121	±3 ml/min or better
Digital Barometer	Recommended: DRUCK DPI 705, 2bar, absolute	±2 mbar or better
Watertrap	M1657B / 989803110871	n/a
Sample Tubing	M1658A / 989803104671	n/a
Calibration Gas Reservoir Bag	M1659A / 989803104681	n/a
Calibration Gas	M1662A / 451261001391	n/a
Gas Exhaust Return Line	M1655B / 989803145671	n/a

Technical Alarm Messages (INOPs)

INOP Message, Indication	What to do
GM ACCURACY? Numerics shown with -?-	If zero is suspended, gas analyzer measurement accuracy may be reduced. Check that the gas inlet, watertrap, and gas outlet tubing are not occluded. If this INOP persists, follow the troubleshooting procedure described in this chapter.
GM ALARM SUPPRESS	Gas Analyzer alarms will be suppressed until breathing activity is first detected.
GM CAL RUNNING	An internal calibration of the gas analyzer is running. Wait for the calibration to finish.
GM INCOMPATIBLE INOP tone	This version of the Gas Analyzer is not supported. Follow the troubleshooting procedure described in this chapter.
GM MALFUNCTION Numerics replaced by -?-, INOP tone, gas analyzer's Setup LED may be blinking	There is a problem with the Gas Analyzer hardware. Check the connection to the monitor. Switch the Gas Analyzer off and then on again. If this INOP persists, follow the troubleshooting procedure described in this chapter.
GM NO BREATH et and in numerics show the same value	No breath detected. Check the patient connections.
GM NOT AVAILABLE INOP tone.	The Gas Analyzer is either disconnected or switched off.
GM OCCLUSION Numerics replaced by -?-, INOP tone	Make sure that the sample line and exhaust line tubing is not kinked. Check the airway adapter for a build up of water. Empty the fluid and reposition the adapter if necessary. Ensure that the airway adapter port is facing upwards. Try replacing the sample line, watertrap, or exhaust line. If this INOP persists, follow the troubleshooting procedure described in this chapter.
GM STANDBY	To resume gas monitoring, select Exit Standby in the **Setup GA** menu. This INOP may also appear during the warmup phase of the gas analyzer.
GM ZERO FAILED Numerics shown with -?-	A Gas Analyzer zero calibration failed. Check the exhaust tube for an occlusion or kinking and replace if necessary. Manually start another zero. If the zero has failed more than once, follow the troubleshooting procedure described in this chapter.
GM ZERO RUNNING First zero: numerics shown with ? or replaced by -?-, Second zero: numerics replaced by -?-, INOP tone	Autozero in progress. If first zero fails then system will retry; if the retry fails then the **GM ZERO FAILED** INOP is activated. **Note:** The gas analyzer tries 3 zeros before the INOP appears.
GM SWITCHED OFF INOP tone	The gas analyzer has switched off all possible internal components due to overheating. Switch off the gas analyzer and allow it to cool down before resuming monitoring. If INOP persists follow the troubleshooting procedure described in this chapter.
GM WARMUP Numerics shown with -?-	The Gas Analyzer has not yet reached operating temperature and the measurement accuracy may be reduced.
GM CHECK WATERTRAP	The watertrap is full. Check that the sample line and/or watertrap is not disconnected.

INOP Message, Indication	What to do
GM COMPONENT MALF Numerics shown with -?-	A gas analyzer component is in malfunction. Some parameters may be unavailable or measured with reduced accuracy. Switch the gas analyzer off and then on again. If the INOP persists follow the troubleshooting procedure described in this chapter.
AGENT CALCULATING	The gas analyzer is calculating the agent concentration. Wait until calculation is finished.
<AGT> CHANGE SCALE	The wave of the agent shown is clipped (DES/ENF/HAL/SEV/ISO). Select a more appropriate wave scale to display the whole wave.
AGT MEAS MALFUNCTION Numerics replaced by -?-, INOP tone	There is a problem with the agent measurement. Switch the gas analyzer off and then on again. If this INOP persists, follow the troubleshooting procedure described in this chapter.
AGENT MIXTURE Numerics shown with ? or replaced by -?-, M1019A IntelliVue G5 may also show two valid numerics	The Gas Analyzer has detected more than one agent in the gas sample. Agent measurement accuracy may be reduced when using the M1019A IntelliVue G5.
<AGT> UNABLE TO MEAS Numerics replaced by -?-, INOP tone	The Gas Analyzer currently cannot measure the agent shown (DES/ENF/HAL/SEV/ISO). If this INOP persists, follow the troubleshooting procedure described in this chapter.
<AGT> OVERRANGE Numerics replaced by -?-, INOP tone	The <AGT> value is higher than the measurement range. If you suspect a false high value, follow the troubleshooting procedure described in this chapter.
AWRR OVERRANGE Numerics shown with -?-, INOP tone	The measured respiration rate is higher than the maximum measurable range.
CO_2 CHANGE SCALE	The CO_2 wave is clipped. Select a more appropriate wave scale to display the whole wave.
CO_2 OVERRANGE Numerics replaced by -?-, INOP tone	The CO_2 value is higher than the measurement range. If you suspect a false high value, follow the troubleshooting procedure described in this chapter.
CO_2 UNABLE TO MEAS Numeric is replaced by -?-, INOP tone	The Gas Analyzer currently cannot measure CO_2. If this INOP persists, follow the troubleshooting procedure described in this chapter.
MAC CHECK SOURCES INOP tone may appear	Either not all measurements or values required to perform the calculation are available or some of the required values are questionable. Check the measurement sources and make sure they are all switched on and that none of them are invalid or questionable.
MAC CORRECTION?	Enhanced MAC correction is on, but values for patient age and/or temperature are not available. Please enter these values.
N_2O CHANGE SCALE	The N_2O wave is clipped. Select a more appropriate wave scale to display the whole wave.
N_2O OVERRANGE Numerics replaced by -?-, INOP tone	The N_2O value is higher than the measurement range. If you suspect a false high value, follow the troubleshooting procedure described in this chapter.
N_2O UNABLE TO MEAS. Numerics replaced by -?-, INOP tone	The Gas Analyzer currently cannot measure N_2O. If this INOP persists, follow the troubleshooting procedure described in this chapter.

INOP Message, Indication	What to do
O_2 **CHANGE SCALE**	The O_2 wave is clipped. Select a more appropriate wave scale to display the whole wave.
O_2 **OVERRANGE** Numerics replaced by -?-, INOP tone	The O_2 value is higher than the measurement range. If you suspect a false high value, follow the troubleshooting procedure described in this chapter.
O_2 **UNABLE TO MEAS** Numerics replaced by -?-, INOP tone	The Gas Analyzer currently cannot measure O_2. If this INOP persists, follow the troubleshooting procedure described in this chapter.
O_2 **ZERO FAILED** Numerics replaced by -?-, INOP tone	An O_2 zero calibration failed. Follow the troubleshooting procedure described in this chapter.

Troubleshooting

If the measurement accuracy is in doubt or if an INOP indicates a technical problem, please perform the tests listed below. They are described in detail in the chapter Checking and Calibrating the Gas Analyzer.

Please perform the tests in the following order:

1 Zero Calibration

2 Leak Check

3 Pump Test

4 Flow Rate Check

5 Pressure Sensor Test

6 Component Status Check

7 Gas Calibration Test

If the flow rate cannot be adjusted or if any of the other tests fails, the gas analyzer needs to be exchanged. Please order the appropriate exchange unit.

NOTE An exchange instrument always comes without the top mounting. Please remove and keep the mounting from the top of the instrument including the screws for use with the exchange instrument.

6

Repairing the Gas Analyzer

Introduction

This section contains detailed removal and replacement procedures for all field-replaceable units in the gas analyzer.

Who Should Perform Repairs

Only qualified service personnel should open the IntellIVue G1 / G5 housing, remove and replace components, or make adjustments. If your medical facility does not have qualified service personnel, contact Philips' Response Center or your local Philips representative.

WARNING

- Switch off the instrument and disconnect it from the mains power supply. Take standard electrostatic precautions. For example, a wrist strap connected to electrical ground.
- Voltages dangerous to life are present in the instrument. Do not perform any disassembly or reassembly procedures with power applied to the instrument. Failure to adhere to this warning could cause serious injury or death.

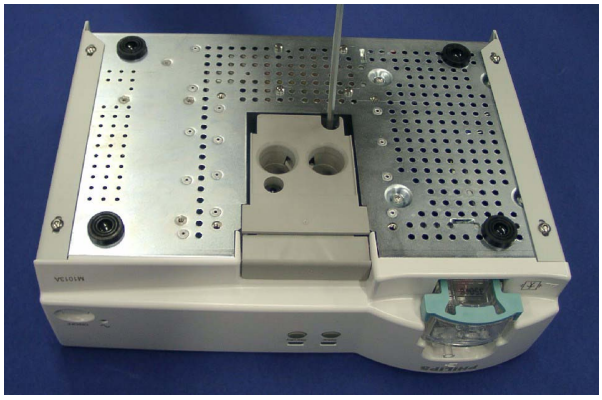
Tools required

- 1 hexagon socket screw key (4.0)
- 1 hexagon socket screw key (2.5)
- ESD mat and wrist strap

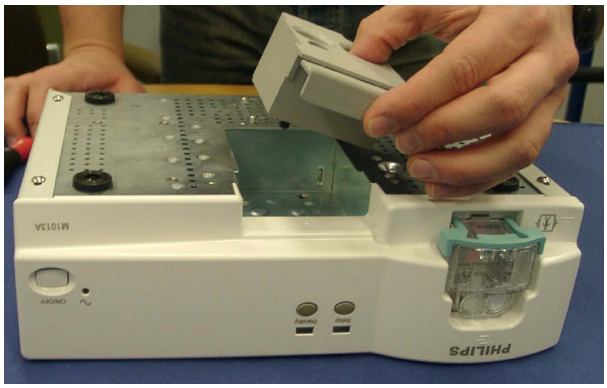
NOTE Your IntelliVue G1 / G5 may look slightly different than on the pictures in this chapter, depending on the options ordered

Removing the Bottom Quick Release Mount

1 Remove the two screws securing the bottom quick release mount.



2 Lift out the mount.



7

Parts List

This chapter provides the replacement and exchange part numbers (if available) for the Philips M1013A IntelliVue G1 and the M1019A IntelliVue G5 and calibration equipment. Refer to the following table to identify the part and part number.

Exchange Parts

Exchange Part Number		New Assembly Part Number		Description
CMS Number	12NC Number	CMS Number	12NC Number	
M1013-68010	451261003781	M1013-60010	451261003721	IntelliVue G1 basic (US version)
M1013-68020	451261003791	M1013-60020	451261003731	IntelliVue G1 basic (international version)
M1013-68030	451261003801	M1013-60030	451261003741	IntelliVue G1 incl. fast O_2 (US version)
M1013-68040	451261003811	M1013-60040	451261003751	IntelliVue G1 incl. fast O_2 (international version)
M1019-68050	451261012171	M1019-60050	451261012151	IntelliVue G5 (US Version)
M1019-68060	451261012181	M1019-60060	451261012161	IntelliVue G5 (international Version)

Replacement Parts

CMS Part Number	12NC Part Number	Description
M1013-64001	451261004971	Fan Filter Kit
M1026-60146	453563467211	Watertrap Manifold Seals
M1013-61005	451261005001	IntelliVue G1/G5 PC Cable (RS232; if necessary, a USB-to-RS232 serial adapter can be used)
M1013-61001	451261006221	IntelliVue cable 1,5 m
M1013-61002	451261004991	IntelliVue cable 3 m

CMS Part Number	12NC Part Number	Description
M1013-61003	451261006231	IntelliVue cable 10 m
M8000-64100	451261001381	Table Mount (for top of gas analyzer)
-	453564227351	Mounting Assembly (for bottom of gas analyzer)
M1013-01201	451261006261	Power Cord Securing Bracket

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