

OPERATOR'S INSTRUCTION MANUAL

NARKOMED 2B ANESTHESIA SYSTEM



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Operator's Responsibility for Patient Safety

North American Dräger anesthesia products are designed to provide the greatest degree of patient safety that is practically and technologically feasible. The design of the equipment, the accompanying literature, and the labeling on the equipment take into consideration that the purchase and use of the equipment are restricted to trained professionals, and that certain inherent characteristics of the equipment are known to the trained operator. Instructions, warnings, and caution statements are limited, therefore, to the specifics of the North American Dräger design. This publication excludes references to hazards which are obvious to a medical professional, to the consequences of product misuse, and to potentially adverse effects in patients with abnormal conditions. Product modification or misuse can be dangerous. North American Dräger disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of North American Dräger products with products supplied by other manufacturers if such a combination is not endorsed by North American Dräger.

The operator of the anesthesia system must recognize that the means of monitoring and discovering

hazardous conditions are specific to the composition of the system and the various components of the system. It is the operator, and not the various manufacturers or suppliers of components, who has control over the final composition and arrangement of the anesthesia system used in the operating room. Therefore, the responsibility for choosing the appropriate safety monitoring devices rests with the operator and user of the equipment.

Patient safety may be achieved through a wide variety of different means depending on the institutional procedures, the preference of the operators, and the application of the system. These means range from electronic surveillance of equipment performance and patient condition to simple, direct contact between operator and patient (direct observation of clinical signs). The responsibility for the selection of the best level of patient monitoring belongs solely to the equipment operator. To this extent, the manufacturer, North American Dräger, disclaims responsibility for the adequacy of the monitoring package selected for use with the anesthesia system. However, North American Dräger is available for consultation to discuss monitoring options for different applications.

Limitation of Liability

North American Dräger's liability, whether arising out of or related to manufacture and sale of the goods, their installation, demonstration, sales representation, use, performance, or otherwise, including any liability based upon North American Dräger's Product Warranty, is subject to and limited to the exclusive terms and conditions as set forth, whether based upon breach of warranty or any other cause of action whatsoever, regardless of any fault attributable to North American Dräger and regardless of the form of action (including, without limitation, breach of warranty, negligence, strict liability, or otherwise).

THE STATED EXPRESSED WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR NONINFRINGEMENT.

North American Dräger shall not be liable for, nor shall buyer be entitled to recover any special incidental, or consequential damages or for any liability incurred by buyer to any third party in any way arising out of or relating to the goods.

Warranty

All North American Dräger products are guaranteed to be free of defects for a period of one year from date of delivery. The following are exceptions to this warranty:

- 1. The defect shall be a result of workmanship or material. Defects caused by misuse, mishandling, tampering, or by modifications not authorized by North American Dräger or its representatives are not covered.
- 2. Rubber and plastic components and materials are warranted to be free of defects at time of delivery.
- 3. SPIROMED sensors, oxygen sensors, and the MINUTE VOLUMETER have a six-month limited warranty. O₂MED sensor capsules have an eight-month limited warranty from the date of delivery.
- 4. Warranty for Durasensors is limited to a period of 6 months from the date of delivery. Oxisensors are warranted to be free of defects at time of delivery.

Any product which proves to be defective in workmanship or material will be replaced, credited, or repaired with North American Dräger holding the option. North American Dräger is not responsible for deterioration, wear, or abuse. In any case, North American Dräger will not be liable beyond the original selling price.

Application of this warranty is subject to the following conditions:

- 1. North American Dräger or its authorized representative must be promptly notified, in writing, upon detection of the defective material or equipment.
- 2. Defective material or equipment must be returned, shipping prepaid, to North American Dräger or its authorized representative.
- 3. Examination by North American Dräger or its authorized representative must confirm that the defect is covered by the terms of this warranty.
- 4. Notification in writing, of defective material or equipment must be received by North American Dräger or its authorized representative no later than two (2) weeks following expiration of this warranty.

In order to assure complete protection under this warranty, the Warranty-Registration card and/or Periodic Manufacturer's Service record (if applicable) must be returned to North American Dräger within ten (10) days of receipt of the equipment.

The above is the sole warranty provided by North American Dräger. No other warranty expressed or implied is intended. Representatives of North American Dräger are not authorized to modify the terms of this warranty.

Repair & Service

In case of malfunction of this device, contact your local North American Dräger Factory Authorized Technical Service Center.

North American Dräger recommends that anesthesia machines be serviced at three month intervals. Periodic Manufacturer's Service Contracts are available for products manufactured by North American Dräger. These agreements are available from N.A.D., Inc. DrägerService or our Factory Authorized Technical Service Center.

Repair of the NARKOMED 2B shall be performed only by a North American Dräger authorized technical service representative.

Restriction

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

The NARKOMED 2B is a continuous flow anesthesia system capable of delivering up to four gases and three liquid anesthetic agents. The anesthesia machine includes an integral time-cycled, volume-preset ventilator with ascending bellows.

The anesthesia machine's monitoring system integrates the functions of the electronic monitors and organizes information from these monitors on two display screens. The monitoring package includes an oxygen analyzer, respiratory volume monitor, and breathing pressure monitor. In addition, the anesthesia machine itself monitors all key anesthesia system functions, (i.e., oxygen supply pressure, O_2/N_2O flow ratio, backup battery status).

The monitoring system organizes alarm messages into Warnings, Cautions, and Advisories, presenting them on the Centralert alarm display. Audible alarms are organized into three distinct

sound patterns and are delivered by a central audio annunciator. Additional screens present trend and real-time trace displays.

Compatible external monitors can be interfaced with the alarm system through communications ports on the rear of the monitor bank. Such interfaced monitors deliver their information in much the same manner as the integral monitors, thus taking full advantage of the system's capabilities. An optional utility shelf, designed to hold external monitoring equipment, may be mounted to the top of the NARKOMED 2B (see Figure 2).

The customer can choose an absorber system and/or a Bain circuit adapter. In addition, three different scavenger systems are available, allowing the best match with the hospital's waste gas disposal system. An adjustable PEEP valve is available on the ventilator or absorber assembly.

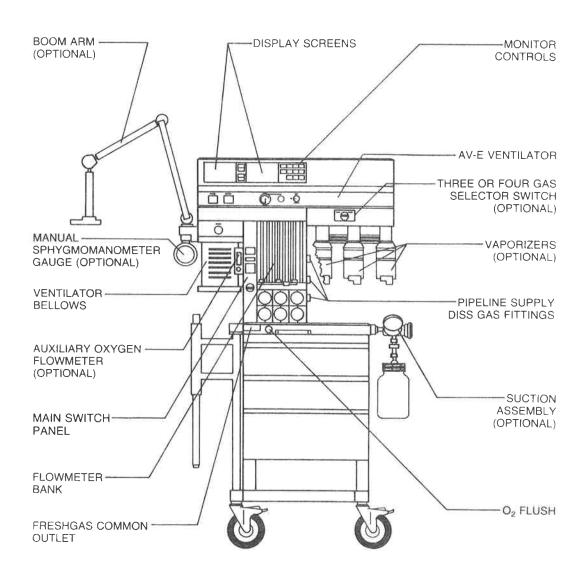


FIGURE 1: NARKOMED 2B WITH COMMON OPTIONS (FRONT VIEW)

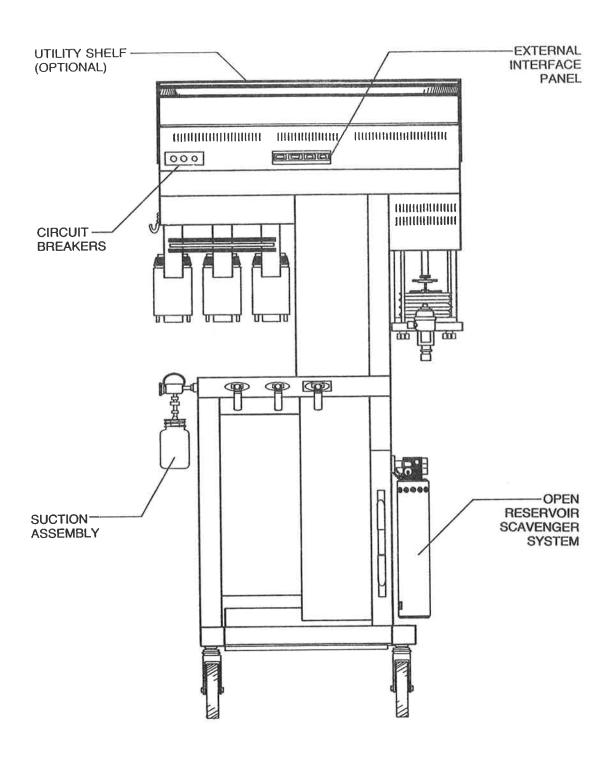


FIGURE 2: NARKOMED 2B WITH COMMON OPTIONS (REAR VIEW)

When moving the NARKOMED 2B, use only the handles shown in Figure 3. DO NOT pull the anesthesia machine by the Absorber System, Vaporizers, Ventilator Bellows, or Boom Arm.

The NARKOMED 2B is equipped with two locking casters on the front side of the machine. These casters may be unlocked by stepping on the lock mechanism on top of the caster. DO

NOT attempt to move the anesthesia machine while either of the casters are locked.

Take care when moving the anesthesia machine up or down ramps, or over thresholds.

Remove the Absorber System, along with any external monitors or equipment, before moving the anesthesia machine.

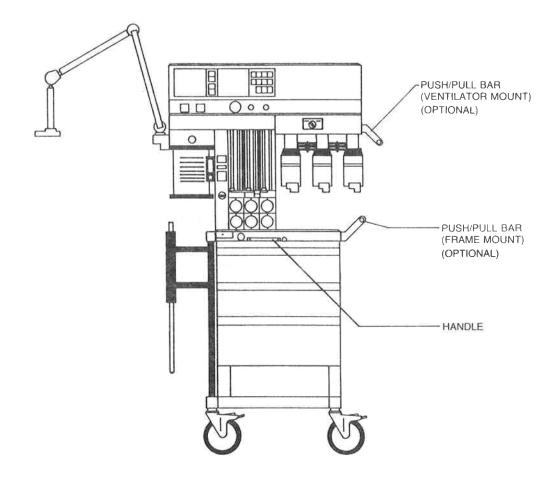


FIGURE 3: ACCEPTABLE HANDLES FOR TRANSPORT

Standard Gases

The NARKOMED 2B is equipped with pneumatic circuitry for the delivery of oxygen (O₂) and nitrous oxide (N₂O). It has at least one oxygen and one nitrous oxide yoke for attachment of reserve gas cylinders with flush-type valves. The Pin Index Safety System prevents connection of a cylinder of the incorrect type.

Optional Gases

In addition to oxygen and nitrous oxide, the NARKOMED 2B may be equipped with up to two additional gases. An additional gas may be air, oxygen-helium (O₂-He) mixture (25% O₂, 75% He) or carbon dioxide (CO₂). The additional gas may be supplied to the anesthesia system by means of pin-indexed cylinders and yokes, diameter-indexed safety system (DISS) pipeline connections (if applicable), or both (if so selected).

Color-Coding

Each connection, valve, gauge, and flowmeter is labeled and color-coded for the appropriate gas, as shown in the table below.

Pipeline Connections

The NARKOMED 2B has DISS gas fittings for oxygen, nitrous oxide, and an optional third gas. The DISS fittings, located on the right side of the flowmeter housing (Fig.1), prevent misconnection of supply hoses. The DISS inlets include check valves to prevent reverse flow leakage into the atmosphere when supply hoses are not connected, or into the attached supply hoses when reserve cylinders are in use. Each pipeline connection is equipped with a replaceable sintered bronze filter to prevent foreign material from entering the internal gas piping of the NARKOMED 2B. Pipeline gases should be supplied at 50 - 55 psi.

GAS SYSTEM COLOR-CODING				
GAS	MARKING	COLOR-CODE	CANADA	
Air	AIR	Yellow	Blk/Wht Chkrd	
Carbon Dioxide	CO2	Gray Gray		
Oxygen-Helium	O ₂ -He	Green/Brown White/Brown		
Nitrous Oxide	N20	Blue	Blue	
Oxygen	02	Green	White	

Gas Cylinder Yokes

The NARKOMED 2B can be equipped with a maximum of two oxygen and two nitrous oxide reserve cylinder hanger yokes (Figure 4). An additional yoke for a third, optional gas is available. For carbon dioxide and oxygen-helium mixture, the cylinders of these gases are the primary supply.

To prevent cylinder misconnection, the yokes are labeled, color-coded, and keyed for gas-specific cylinders using the Pin Index Safety System.

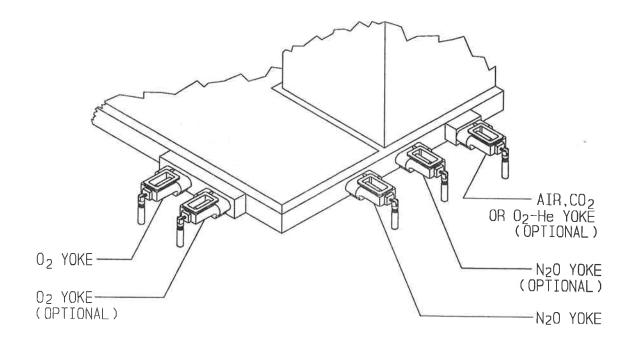


FIGURE 4: RESERVE GAS CYLINDER YOKES, THREE-GAS ARRANGEMENT (RIGHT, REAR VIEW)

A sintered bronze filter within each yoke prevents foreign material from entering the internal gas piping of the NARKOMED 2B. A check valve within each yoke prevents backflow into the reserve cylinder or leakage into the atmosphere if the reserve cylinder is not mounted on the yoke. When the machine is configured

with two yokes for the same gas, the check valve also prevents transfer of gas from one cylinder to another of the same type. When a yoke does not contain a reserve cylinder, the attached yoke plug should be placed between the yoke handle's threaded bolt and the yoke's gas inlet.

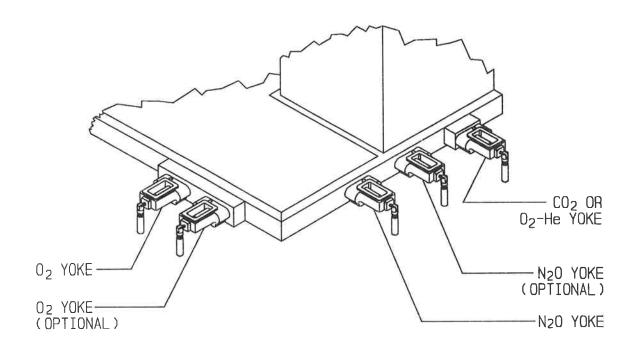


FIGURE 5: RESERVE GAS CYLINDER YOKES, FOUR-GAS ARRANGEMENT (RIGHT, REAR VIEW)

When attaching a cylinder, use only one washer between the reserve cylinder and the yoke gas inlet. The use of multiple washers may compromise the safety of the Pin Index Safety System. The integrity of both index pins should be verified whenever a new cylinder is installed. Reserve cylinders attached to the hanger yokes shall contain gas at recommended pressures outlined below:

RECOMMENDED RESERVE CYLINDER MAXIMUM PRESSURES

GAS	MAX PSI
Air	2200
Carbon Dioxide	830
Oxygen-Helium mixture	2200
Nitrous Oxide	745
Oxygen	2200

Pressure Regulators

Each reserve cylinder gas circuit incorporates a pressure regulator that controls the gas pressure from the reserve cylinders. These regulators are purposely adjusted below the commonly used hospital pipeline pressure of 50-55 psi. Such settings ensure that gas will be supplied from the pipeline and not the cylinder if both sources of supply are open. Overpressure relief valves, integral to the regulator, prevent excessive pressure in case of regulator failure or excessive pipeline pressure.

NOTE: Canadian machines are equipped with an additional pipeline overpressure relief valve that is set to open at 75 psi (520 kPa).

Reserve Cylinder Cutoff Valves (Canada)

When the pipeline supply pressure exceeds 40-43 psi, cutoff valves prevent withdrawal of gas from the reserve cylinders. This feature prohibits accidental depletion of reserve cylinders when the pipeline supply is functioning and the reserve cylinders have been left in the open position.

Cylinder Pressure Gauges

Each cylinder gas circuit on the NARKOMED 2B is provided with a cylinder pressure gauge, located at the bottom of the flowmeter panel on the front of the machine (Figs. 6, 7, & 8). Each gauge is labeled and color-coded for its respective gas.

When a cylinder valve is open, the respective cylinder pressure gauge indicates the gas pressure in the cylinder. The dial is marked with concentric scales in psi and kPa. For non-liquefied gases (O₂, air, O₂-He) the indicated pressure is proportional to the gas content of the cylinder. For liquefied gases (N₂O, CO₂) the gauge indicates the vapor pressure of the liquefied gas in the cylinder. This pressure remains constant until all of the liquid in the cylinder has vaporized. At this stage, the cylinder pressure decreases proportionally with further removal of gas from the cylinder.

When two reserve cylinders of the same gas are open at the same time, the cylinder pressure gauge will indicate the pressure in the cylinder having the higher pressure.

Pipeline Pressure Gauges

Pipeline pressure gauges for oxygen and nitrous oxide are standard (Figures 6, 7, & 8). If the anesthesia machine is equipped with a DISS inlet for air, a pipeline pressure gauge for air is also included.

These gauges are located directly below their corresponding flowmeters and flow control valves, and are labeled and color-coded for their respective gases. Concentric scales in psi and kPa indicate the delivered pipeline supply pressure. When the machine is connected to a functioning pipeline supply, each gauge should

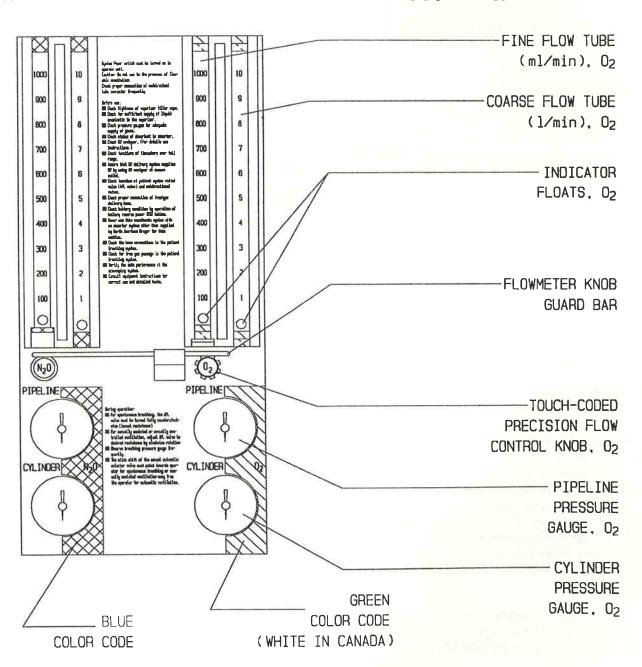


FIGURE 6: STANDARD FLOWMETER BANK

indicate 50 - 55 psi. A deviation from within this range indicates an improperly adjusted pipeline gas supply system and may adversely affect the operation of the NARKOMED 2B. A fluctuating pipeline supply pressure, for example, would cause a corresponding fluctuation of the

delivered flow of that gas. Also, an excessively low pipeline pressure may activate the corresponding reserve cylinder and deplete its contents (if the reserve cylinder valve is left in the open position).

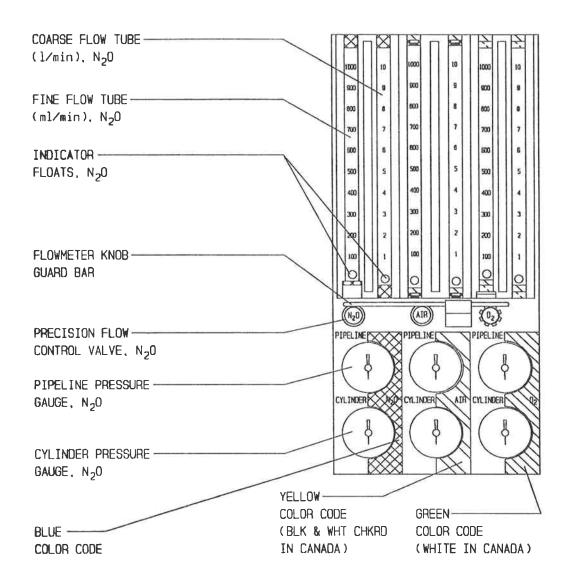


FIGURE 7: THREE-GAS FLOWMETER BANK (AIR OPTION)

Carbon dioxide and oxygen-helium mixture supplies for NARKOMED 2B machines are exclusively provided from cylinders.

Thus, these gases do not require pipeline pressure gauges.

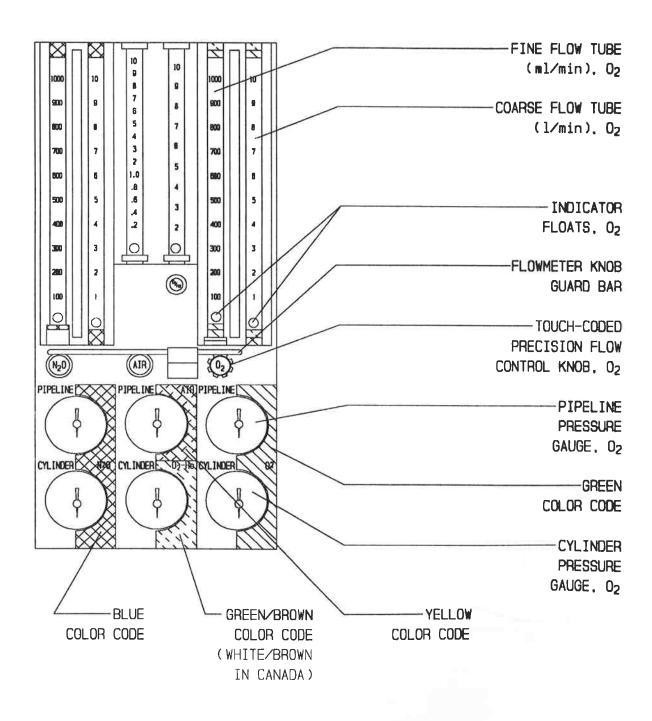


FIGURE 8: FOUR-GAS FLOWMETER BANK (AIR & OXYGEN-HELIUM OPTION)

Oxygen Supply Pressure Failure Protection Device (OFPD)

The oxygen failure protection device (OFPD) consists of a pneumatically operated valve located in the anesthesia machine's internal supply lines for all NARKOMED 2B gas circuits except oxygen. The OFPD valve is controlled by the gas pressure in the oxygen supply line. Proper oxygen pressure keeps the valve open, but a failure or reduction of pressure in the oxygen supply line will proportionally reduce and eventually shut off the supply of all other gases.

When the OFPD is activated, the flowmeters indicate a reduced gas flow proportional to the reduction of oxygen supply pressure. When the oxygen supply pressure (from either pipeline or reserve cylinders) drops below approximately 32 psi, a "LO O2 SUPPLY" alarm message appears on the Centralert alarm display, the "O2 SUPPLY PRESSURE" indicator on the main switch panel lights continuously red, and an intermittent audible alarm sounds.

Oxygen Supply Failure Whistle (Canada)

If the oxygen supply pressure (from either the pipeline supply or reserve cylinders) drops below approximately 32 psi, a pneumatic alarm sounds a high-pitched whistle for approximately 7 seconds.

Flow Control Valves

The flow of each gas can be adjusted with a precision needle valve. These valves are located below the low range flowmeter tube for the specific gas which it controls (Figures 6, 7, & 8). Counterclockwise rotation of the valve knob increases flow, and clockwise rotation of the valve knob decreases flow. Each flow control valve is capable of adjusting the flow within <u>full</u> range of its flowmeter(s) when supply pressures are within normal limits.

Unless the anesthesia machine has been specifically modified to eliminate the minimum oxygen flow feature (see "Minimum Oxygen Flow"), the flow of oxygen cannot be totally shut off with its flow control valve. DO NOT force the oxygen flow control knob over its end stop in an effort to shut off the flow. Forcing the knob could damage the delicate valve seat.

If only one source of oxygen supply pressure (either reserve cylinders or pipeline) fails, while the other maintains proper supply pressure within the machine's oxygen supply lines, the OFPD and "LO O2 SUPPLY" alarm will not activate.

A zero stop prevents damage to the flow control valve seats. If necessary, an authorized service representative of North American Dräger can readjust the stop. Each flow control knob is identified by its color code and chemical symbol. Also, the oxygen flow control valve is touch-coded with a deeply fluted knob.

Flowmeters

Rotameter type flowmeters, located immediately above their corresponding flow control valves (Figures 6, 7 & 8), display the flowrate of each gas delivered to the freshgas mixture. Dual (fine and coarse) flowmeter tubes are used in tandem for oxygen, nitrous oxide, and air (if provided). Single flowmeter tubes are used for any other gas.

Each flowtube has its scale etched and printed directly on the glass tubing. Oxygen, nitrous oxide, and air flowmeters are certified to be within ±3% of full scale at 20 degrees C and 760

mm Hg. Single flowtubes are certified to be within ±5% of full scale. Flowmeter ranges and accuracies are outlined in the table below.

Oxygen, nitrous oxide and air flowmeters are equipped with floats, half chrome-plated and half colored red, to indicate free movement through rotation. Single tube flowmeters are equipped with stainless steel or black glass floats. Regardless of the float type, the position of the center of the ball along the flowmeter scale should be used as an indication of the flowrate. All flowmeters are labeled and color coded with colored bands at each end of the flowtube.

FLOWTUBE RANGES & ACCURACIES			
GAS	TUBE	RANGE (1/min)	ACCURACY
Oxygen	Fine	0 - 1	±3% (Full Scale)
Oxygen	Coarse	1 - 10	±3% (Full Scale)
Nitrous Oxide	Fine	0 - 1	±3% (Full Scale)
Nitrous Oxide	Coarse	1 - 10	±3% (Full Scale)
Air	Fine	0 - 1	±3% (Full Scale)
Air	Coarse	1 - 10	±3% (Full Scale)
		0 - 1	±50 cc of rate
Air	Dual- Tapered	2 - 10	±5% (Full Scale)
Oxygen-Helium mixture	.सा कर	0 - 10	±5% (Full Scale)
Carbon Dioxide		0 - 1	±5% (Full Scale

LOW-FLOW FLOWTUBE RANGES & ACCURACIES					
GAS	TUBE	RANGE	ACCURACY		
Oxygen	Fine	0 - 500 ml/min	±2.5% (FS)		
Oxygen	Coarse	0.6 - 10 l/min	±2.5% FS (> 1 l/min) ±15% Rate (< 1 l/min)		
Nitrous Oxide	Fine	0 - 500 ml/min	±2.5% (FS)		
Nitrous Oxide	Coarse	0.6 - 10 l/min	±2.5% FS (> 1 l/min) ±15% Rate (< 1 l/min)		

Low-Flow Flowmeters (Optional)

For low-flow anesthesia, the NARKOMED 2B can be configured with low-flow, dual-tube flow-meters for oxygen and nitrous oxide. These flowmeters function in the same manner as the standard dual-tube flowmeters but are calibrated to provide greater resolution for low-flow anesthesia. They are calibrated as shown in the chart above.

Auxiliary Oxygen Flowmeter (Optional)

For the delivery of a metered flow of pure oxygen, (such as for the delivery of oxygen through a nasal cannula), an optional auxiliary oxygen flowmeter can be mounted on the left-hand side of the flowmeter bank. It is calibrated from 0 to 10 l/min. If adequate oxygen supply pressure is available (from either pipeline or reserve cylinders), oxygen is available at this flowmeter's flow control valve, regardless of the NARKOMED 2B System Power switch position.

NOTE: Since the flow control valve for the auxiliary oxygen flowmeter does not include a zero stop, take care not to overtighten the control knob.

Minimum Oxygen Flow

The oxygen dispensing system incorporates a calibrated bypass flow of 150 (±25) ml/min (at 50 psi pipeline pressure), thereby ensuring the

delivery of some oxygen even if the flow control valve is fully closed.

If required for low-flow anesthesia, the NARKOMED 2B can be optionally modified to eliminate the minimum oxygen flow feature. A label above the oxygen flowmeter tells the operator that the anesthesia machine has been modified to eliminate minimum oxygen flow. Also, this option slightly changes the performance of the Oxygen Ratio Monitor/Controller (see "Oxygen Ratio Monitor/ Controller" below).

If air is an additional gas, when the gas selector switch is set to the "ALL GASES" position, the minimum oxygen flow is automatically disabled.

Oxygen Ratio Monitor/Controller (ORMC)

The ORMC is a pneumatic O_2/N_20 interlock system designed to maintain a freshgas oxygen concentration of at least 25 (± 3)%. It permits independent control of the oxygen and nitrous oxide flows, but by proportionally limiting the nitrous oxide flow, the ORMC prevents a flow ratio that could result in a hypoxic freshgas mixture.

The ORMC works by limiting the nitrous oxide flow whenever the operator selects oxygen and nitrous oxide flow control valve settings that would result in a hypoxic freshgas mixture. For example, if the operator opens the nitrous oxide flow control valve excessively without making a

corresponding increase in the oxygen flow control valve setting, the flow of nitrous oxide will not increase, even though its flow control valve setting has been greatly increased. Similarly, if the operator decreases the oxygen flow without also decreasing the nitrous oxide flow, the nitrous oxide flow will automatically drop in proportion to the oxygen flow.

Whenever the ORMC is actively limiting the nitrous oxide flow to prevent a hypoxic freshgas mixture, an "O2/N20 LOW" alarm message appears on the Centralert alarm display, the "O2/N2O FLOW RATIO" LED indicator on the main switch panel lights continuously yellow, and a single tone audible alarm sounds. This alarm means that the nitrous oxide flow is being

automatically limited due to incorrect oxygen and nitrous oxide flow control valve settings. It does not mean that the O_2/N_2O flow ratio has caused a hypoxic mixture.

Due to rebreathing of previously exhaled gas in a circle system, lower freshgas flows require a higher oxygen concentration to maintain a sufficient inspiratory oxygen concentration. To address this problem, the ORMC has been designed to maintain higher levels of oxygen in the freshgas at lower flow rates. Figure 9 illustrates the ORMC's response curve. Note that, at lower freshgas flow rates, the ORMC maintains freshgas oxygen concentrations well above 25% of the combined oxygen and nitrous oxide flow.

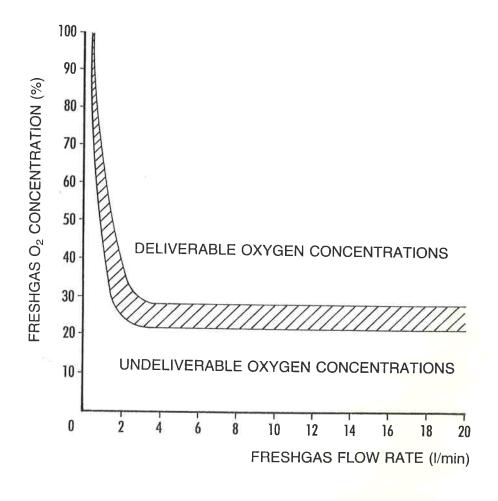


FIGURE 9: ORMC RESPONSE

It should be noted that the ORMC interlocks only the flows of oxygen and nitrous oxide. Hypoxic freshgas concentrations are possible if an additional gas other than air is used.

In the following instances, ORMC audible and visual alarms are automatically disabled (as indicated by the Advisory message "ORM ALRM OFF" on the Centralert alarm display):

- if the availability of an optional gas circuit is controlled by the gas selector switch in the "ALL GASES" position. (There is no gas selector switch for machines equipped with carbon dioxide as a third gas.)
- at nitrous oxide flows below 150 (±50) ml/min.

NOTES:

Although ORMC audible and visual alarms are automatically disabled in the above two instances, the ORMC continues to control the flow ratio of oxygen to nitrous oxide, <u>regardless of</u> the alarm status.

If the anesthesia machine has been optionally configured to eliminate the minimum oxygen flow feature, ORMC audible and visual alarms are automatically disabled at nitrous oxide flows below 750 (± 75) ml/min rather than the 150 (± 50) ml/min limit used for standard machines.

Gas Selector Switch -- Three-gas Feature (Optional)

Setting the gas selector switch to the "O2 & N2O" (left) position permits oxygen and nitrous oxide flows to the appropriate flowmeter controls. This position also enables the ORMC audible and visual alarms and enables the minimum oxygen flow.

The "ALL GASES" (right) position of the gas selector switch permits an additional gas (air or oxygen-helium mixture) to flow to its respective flowmeter control, allowing a mixture of all three gases. However, setting the switch to the "ALL GASES" position automatically disables the ORMC audible and visual alarms and also disables the minimum O₂ flow.

NOTE: Carbon dioxide, although available as an optional third gas, is not controlled by the gas selector switch. Rather, machines equipped with carbon dioxide as an optional third gas have no gas selector switch, and carbon dioxide is always available at its flow control valve.

Gas Selector Switch -- Four-gas Feature (Optional)

In NARKOMED 2B machines equipped to deliver four gases, the "O2 & N2O" (left) position of the gas selector switch permits oxygen and nitrous oxide flows to the appropriate flowmeter controls. This position also enables the ORMC audible and visual alarms and enables the minimum oxygen flow.

The "ALL GASES" (right) position of the gas selector switch in four-gas machines permits two additional gases to flow to their respective flow-meter controls, thus allowing a mixture of all four gases. The following combinations for the two additional gases are available:

- Air & Carbon Dioxide
- Air & Oxygen-Helium mixture

Setting the gas selector switch to the "ALL GASES" (right) position permits flow of all gases to the flowmeters, disables the ORMC audible and visual alarms, and disables the minimum O₂ flow features.

NOTE: Carbon Dioxide availability in four-gas machines is controlled by the gas selector switch.

Vaporizers (Optional)

The NARKOMED 2B can be equipped with up to three Vapor 19.1 vaporizers for the administration of liquid anesthetics. The vaporizers (Figs. 10 & 11) are located to the right of the flowmeter bank.

Vaporizers may be equipped with either an open-funnel filler or a pin-indexed filler. (Only pin-indexed fillers are permitted in Canada.)

A calibrated concentration of vaporized anesthetic is produced by adjusting the top-mounted handwheel of the selected vaporizer to the desired volume percent indicated on the dial. Clockwise rotation decreases the anesthetic concentration and counterclockwise rotation increases the concentration. A cam and lever interlock system, incorporated into the vaporizer bank, prevents more than one vaporizer from being activated and requires all unused vaporizers to be locked in their zero volume percent positions.

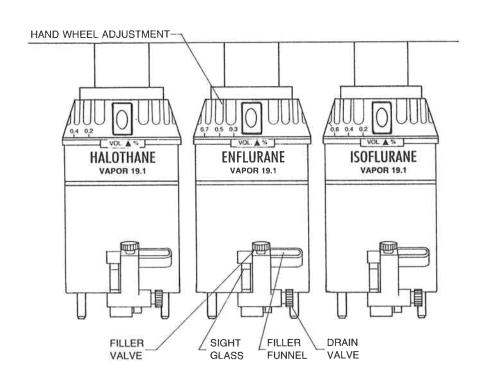


FIGURE 10: VAPORIZERS (WITH STANDARD FILLER/DRAIN MECHANISMS)

Detailed operating instructions for the vaporizers can be found in a separate manual supplied with the vaporizer.

NOTE: Only one vaporizer shall be activated at a time. If the exclusion system permits

simultaneous activation of more than one vaporizer, DO NOT use the anesthesia machine and contact an authorized NAD service representative for repairs.

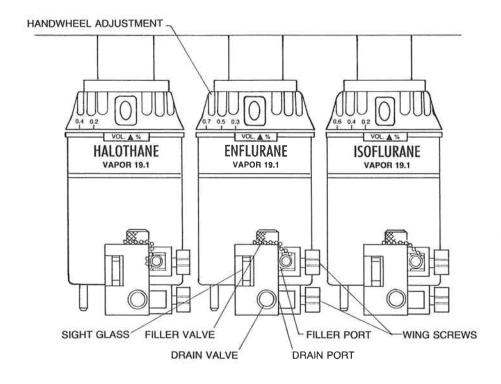


FIGURE 11:VAPORIZERS (WITH OPTIONAL PIN-INDEXED FILLER/DRAIN MECHANISMS)

Oxygen Flush

A manually operated oxygen flush valve (Figure 12) of self-closing construction is located on the left front corner of the machine's frame. A protective bezel surrounds the pushbutton to minimize accidental engagement. The valve, if actuated, delivers an unmetered oxygen flow of approximately 55 l/min directly to the freshgas common outlet of the machine. The internal connection of the freshgas line and oxygen flush line is designed to prevent the build-up of excessive pressure within certain limits of downstream resistance when flush is actuated. The oxygen flush may be operated without the System Power switch being in the "ON" position.

Freshgas Common Outlet

The freshgas common outlet (Figure 12) delivers the freshgas mixture (consisting of oxygen, nitrous oxide, optional gases, and vapors of a liquid anesthetic) to the patient breathing system. It is located to the left of the O2 flush button on the front of the anesthesia machine. The outlet's 15 mm cylindrical female fitting is designed to accept a 15 mm male fitting on the freshgas hose, which is permanently attached to the absorber inspiratory pipe. The male fitting slides into a retaining slot in the spring-loaded safety locking bar (Figure 12) to prevent inadvertent disconnection of the freshgas hose.

The 15 mm male fitting on the freshgas hose is of a specific North American Dräger design and shall not be replaced by that of any other manufacturer.

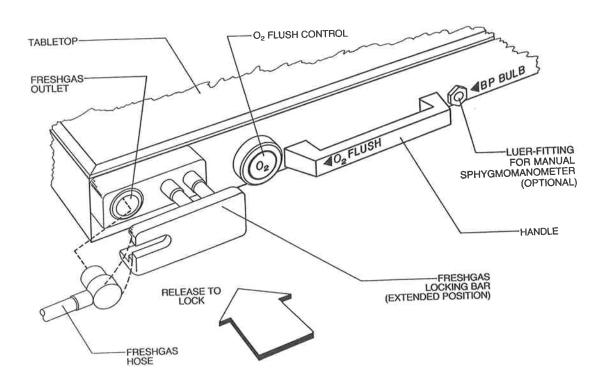


FIGURE 12: O2 FLUSH CONTROL & FRESHGAS COMMON OUTLET



Freshgas Adapter (Optional)

The optional freshgas adapter allows the NARKOMED 2B to monitor the freshgas oxygen concentration when using a non-rebreathing circuit. The freshgas adapter is designed to fit securely into the freshgas common outlet of the anesthesia machine. A detailed description and operating instructions can be found in the Freshgas Adapter Operator's Instruction Manual.

Freshgas Common Outlet (Canada)

The Freshgas Common Outlet (Figure 13) delivers the freshgas mixture (consisting of oxygen, nitrous oxide, optional gases, and vapors of a liquid anesthetic) to the patient breathing system. It is located to the left of the O2 flush button on the front of the anesthesia machine. The outlet incorporates a dual fitting that allows use of either a 15 mm male freshgas hose fitting (such as supplied with North American Dräger Absorbers and Bain Circuit Adapters) or a 22 mm female fitting with a load-bearing threaded mount (such as for Magill circuits meant to be threaded onto the freshgas common outlet).

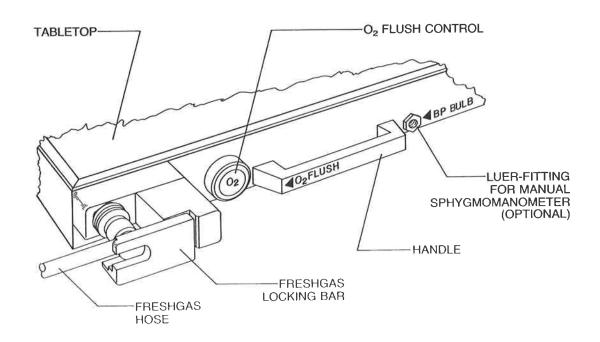


FIGURE 13: O2 FLUSH CONTROL & FRESHGAS COMMON OUTLET FOR CANADA

When using the 15 mm male and female fittings, make sure that the spring-loaded locking bar fits over the male freshgas hose fitting, thus securing it in the female fitting.

When using the Magill circuit fitting, swing the spring-loaded locking bar to the side to gain access to the threaded load bearing fitting.

Vacuum (Optional)

The NARKOMED 2B can be configured with internal vacuum piping for a suction drainage as-

sembly (Figure 1). A DISS vacuum fitting on the rear of the machine connects, via a hose, to a wall vacuum outlet. The suction drainage assembly mounts on a DISS fitting on the machine's right front corner.

The suction drainage assembly consists of a 700 cc clear glass bottle, vacuum on/off valve, vacuum control knob, and vacuum gauge. A ball float at the top of the bottle's inlet pipe automatically prevents overfill. Consult the operating instructions supplied with this device before use.

The Dräger AV-E Anesthesia Ventilator (Figure 14) is a volume-preset, time-cycled ventilator that features solid-state timing, pneumatic circuitry, and independent controls.

The pneumatic power to drive the ventilator may be supplied through the pipeline supply or, if the pipeline supply either fails or is disconnected, through reserve cylinders. The pressure of the driving gas must be between 40 and 60 PSI. The ventilator will cease to function if this pressure drops below 30 PSI.

The monitoring system's breathing pressure and expiratory flow waveform displays can be used as an aid in adjusting the AV-E ventilator. (See Trace Display in Monitoring System section.)

NOTE: The AV-E Anesthesia ventilator is designed for use with an NAD absorber system, which incorporates a manual/automatic selector valve. This valve allows the operator to bring into the breathing system either the breathing bag and pop-off valve for manual ventilation, or

the ventilator bellows for automatic ventilation. Breathing system hose connections to this valve are described in the SETUP & INSTALLATION section of this manual.

Ventilator Power Switch

The ventilator power switch controls both pneumatic and electrical power for the AV-E ventilator. In the "OFF" (9 o'clock) position the ventilator is not operable, and the Advisory message "VENT OFF" appears on the anesthesia machine's Centralert alarm display. In the "ON" (12 o'clock) position the ventilator is activated and cycles according to the settings of the other controls.

The ventilator power switch also automatically enables the respiratory volume monitor's volume-related alarms and the breathing pressure monitor's apnea pressure alarm.

For further details, see the MONITORING SYSTEM section of this manual.

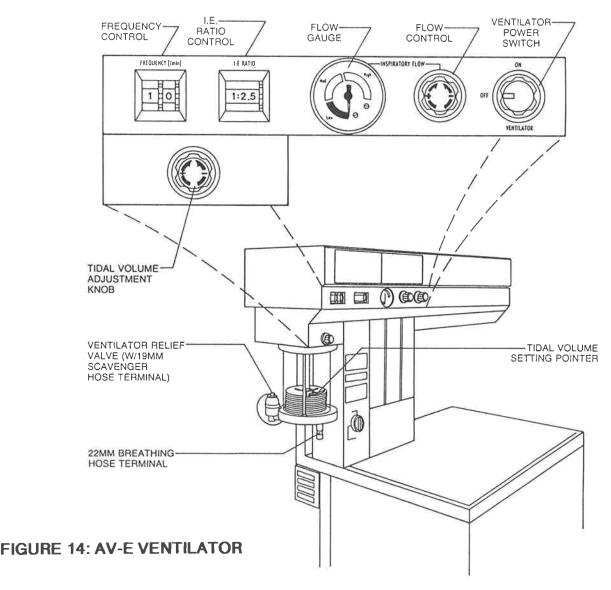
AV-E ANESTHESIA VENTILATOR (continued)

Tidal Volume Adjustment

The tidal volume may be adjusted between 50 and 1500 ml. A self-locking knob, located above the bellows assembly (Fig. 14), adjusts a bellows stop within the canister. To adjust the tidal volume, depress the self-locking knob to allow rotation. Then set the desired tidal volume, as indicated by the stop pointer on the bellows chamber scale (marked 200 to 1400 ml).

Smaller tidal volumes can be adjusted by setting the pointer below the 200 ml marking on the bellows chamber. Larger tidal volumes can be selected by choosing settings above the 1400 ml calibration. As in any volume-preset anesthesia ventilator, the actual tidal volume delivered to the patient's lungs may differ from the preset volume at the bellows. The compliance of the breathing system and freshgas flow are two possible causes for this difference. To accurately set the tidal volume, the operator should refer to the tidal volume and minute volume readings supplied by the integral respiratory volume monitor. (See Respiratory Volume Monitor section.)

The position of the tidal volume indicator can be adjusted by an NAD authorized service representative to give correct indications for a specific combination of freshgas flow and equipment compliance.



AV-E ANESTHESIA VENTILATOR (continued)

Frequency Control

The respiratory frequency can be set between 1 and 99 BPM (in 1 BPM increments) with a two-digit thumbwheel switch labeled "FREQUENCY" (Fig. 14).

Inspiratory/Expiratory (I:E) Phase Time Ratio Control

The operator can vary the inspiratory/expiratory phase time ratio in calibrated steps from 1:1 through 1:4.5. Calibrations are marked on the I:E controller-indicator thumbwheel at 0.5 increments. The thumbwheel is located to the right of the frequency thumbwheel and is labeled "I:E RATIO" (Fig. 14).

Inspiratory Flow Control

The rotary knob marked "INSPIRATORY FLOW" controls the flow rate of gas into the bellows chamber, and thus the inspiratory flow rate of gas into the patient's lungs. However, due to such variables as total lung compliance, equipment compliance, and airway resistance, the inspiratory flow control cannot be calibrated with numerical values. Instead, the gauge to the left of the control knob is labeled with three zones, "LOW," "MEDIUM," and "HIGH" (Fig. 14).

The flow setting should be adjusted so that the bellows is fully compressed at the end of the inspiratory phase. However, too high a flow setting will collapse the already compressed bellows at the end of the inspiratory phase. Such bellows deformation can increase the delivered tidal volume by as much as 100 ml. In order to deliver the desired, preset tidal volume, adjust the inspiratory flow control so that the bellows corrugations make contact with each other and do not deform at the end of the inspiratory phase.

The "INSPIRATORY FLOW" control setting also affects the peak inspiratory pressure that can be developed within the patient breathing system. Always check the pressure indicated by

the breathing system pressure gauge when adjusting the inspiratory flow control.

Ventilator Relief Valve

During automatic ventilation, the manual/automatic selector valve isolates the absorber's APL (automatic pressure limiting) valve from the breathing system. Thus, to compensate for the continuous introduction of freshgas into the breathing system, the ventilator incorporates a relief valve behind the bellows chamber.

The ventilator relief valve remains closed until the very end of expiration so that the ascending bellows can expand upward and refill. As in any ascending bellows, the force needed to overcome gravity acting on the bellows causes a PEEP within the breathing system, in this case approximately 2 cm H₂O. The ventilator relief valve maintains a PEEP of approximately 2 cm H₂O.

Bellows PEEP Valve (Optional)

An optional ventilator PEEP valve mounts beneath the bellows. (An optional absorber-mounted PEEP valve is also available.) The operator can set a PEEP of approximately 2 to 18 cm H₂O with the PEEP valve control knob. Clockwise rotation of the knob increases PEEP and counterclockwise rotation decreases PEEP. The breathing system pressure gauge and the BAROMED breathing pressure monitor indicate the amount of PEEP at the end of exhalation. For details, see the Bellows PEEP Valve Instruction Manual.

Before use, perform Step 29-B of this manual's Pre-Use Checkout Procedure.

Power Supply

The NARKOMED 2B is equipped with a central power supply for the ventilator, alarm system, and integrated monitors. The NARKOMED 2B shall always be plugged into an active AC outlet when in use.

Power Cable

A fifteen foot cable with a standard 3-prong hospital grade plug supplies the AC power required by the NARKOMED 2B. The allowable input voltage range is from 90 to 130 VAC at 50 to 60 Hz. Excess cable length may be stored on the cord wrap at the rear of the NARKOMED 2B. When unplugging the power cable, pull the plug, never the cord.

Hospital Grade Convenience Receptacles

The NARKOMED 2B includes four convenience receptacles supplied with unswitched power. These hospital grade receptacles are mounted on the underside of the rear of the monitor bank assembly. The total current draw for devices plugged into the receptacles shall not exceed 5 amps. A 5-amp circuit breaker protects the convenience receptacle circuit. This circuit also incorporates an EMI filter, which minimizes interference with the anesthesia machine from devices devices plugged into the convenience receptacles.

NOTE: Devices plugged into the convenience receptacles contribute to the anesthesia system's total leakage current. This total leakage current shall not exceed 100 microamps.

240 Volt Power Supply (Optional)

The NARKOMED 2B can be equipped with an optional 240 VAC power supply. A 4.5 meter cable supplies the AC power. The allowable input voltage range is from 200 to 260 VAC at 50

to 60 Hz. The 240 VAC power supply does not include convenience receptacles. A pilot light replaces the circuit breaker for the convenience receptacles; it illuminates when AC power is supplied to the NARKOMED 2B.

Battery Backup System

The battery backup system consists of a rechargeable 12 volt battery (6.5 amp-hour, sealed lead-acid) and a built-in battery charging system. The battery and charging system are not user-serviceable and are mounted within the monitoring bank.

Although most hospitals have emergency generators to provide AC power when line power fails, delays are frequently encountered before generator power comes on line. The battery backup system automatically provides power during the interim between line power failure and the activation of the hospital's emergency generator. The backup battery also provides power when the anesthesia machine's power cable is accidentally unplugged during a case

When the hospital's emergency generator comes on line (or when a disconnected power cable is reconnected), the NARKOMED 2B automatically switches back to AC power and recharges its battery. The battery charging system will charge the battery any time that the power cable is connected to an active AC power source. The charger will take approximately 16 hours to recharge a fully discharged battery.

Backup Battery Operating Instructions

To prevent premature battery failure, backup battery power shall be used only during interruption of primary electric service. No anesthetic procedure shall be started using a NARKOMED 2B anesthesia machine if the yellow "AC POWER FAIL" indicator or the yellow "BATTERY LOW" indicator is illuminated.

POWER SUPPLY SYSTEM (continued)

The operator must test the backup battery system daily by pressing the "BATTERY TEST" button on the main switch panel (Figure 15). Before pressing the test button, make sure that the System Power switch is in the "ON" position. A green light indicates that power is available to operate the electrical components of the anesthesia machine, but it does not indicate how long this power will be provided. This depends on the duration of previous battery use and recharging.

Machine Functions While on Backup Battery Power

If the hospital's primary AC power fails, the backup battery system works in two stages:

1. When fully charged, the backup battery will power all machine functions, except the AC convenience receptacles, for a minimum of 30 minutes. As an indication of AC power disruption, the yellow "AC POWER FAIL" indicator on the main switch panel illuminates, the advisory message "AC PWR FAIL" appears on the Centralert alarm display, and a single-tone audible alarm sounds.

As use of the backup battery proceeds, the battery capacity will gradually decline. When the battery voltage drops below the normal operating threshold, the yellow "BATTERY LOW" indicator on the main switch panel illuminates, and the caution message "AC/BATT FAIL" appears on the Centralert alarm display.

2. In the second stage (when the battery voltage drops to 10 volts), all electrical power to the anesthesia machine is automatically cut off to prevent deep discharge of the battery. (Deep discharge damages lead-acid batteries.) At this point, all gas supply systems remain operative. However, since battery power has been cut off, the AV-E ventilator is inoperative, and manual ventilation by bag squeezing must be performed. In this final stage, the anesthesia machine cannot provide monitoring or alarm functions until it is reconnected to an active AC power source.

Circuit Breakers

The NARKOMED 2B electrical system includes three magnetic circuit breakers to protect the various machine functions (primary AC power input, convenience receptacles, reserve battery power). The circuit breakers are located on the rear of the monitoring bank. When the white plunger of a circuit breaker is flush with the surface of its black base, the circuit breaker is in its normal, closed position. A circuit breaker is open (tripped) when its white plunger extends beyond its black base. The cause of an open breaker must be investigated. Equipment that has caused the breaker to open shall be repaired or replaced before the anesthesia system is returned to service.

EMI Filtering

All power for the NARKOMED 2B is filtered for conducted electromagnetic interference by a low pass filter in the primary AC line. This filter also prevents noise generated within the NARKOMED 2B from leaving the device through the AC line.

The main switch panel, located between the ventilator bellows and flowmeter bank, incorporates alarms to communicate the status of the system as a whole. These alarms are annunciated and simultaneously displayed on the Centralert alarm display (see the MONITORING SYSTEM section of this manual).

Figure 15 illustrates the indicators and controls on the main switch panel.

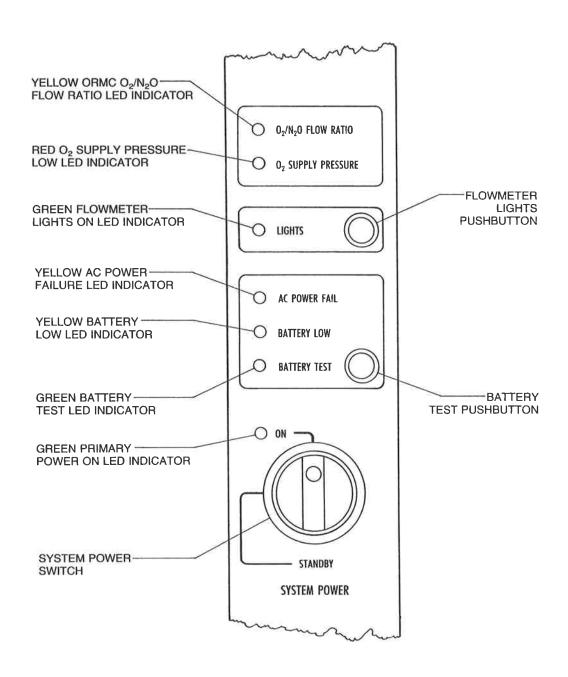


FIGURE 15: MAIN SWITCH PANEL

MAIN SWITCH PANEL (continued)

O2/N2O Flow Ratio (ORMC)

The oxygen flow ratio alarm indicator (marked "O2/N2O FLOW RATIO") activates whenever the ORMC limits the nitrous oxide flow in order to maintain a freshgas oxygen concentration of at least 25 (±3) % of the combined oxygen and nitrous oxide flow. Therefore, this alarm means that the oxygen and/or nitrous flow control valves have been incorrectly set and the ORMC has responded by limiting nitrous oxide flow. This alarm does not mean that the freshgas mixture itself has become hypoxic.

Whenever the ORMC is actively limiting the nitrous oxide flow to prevent a hypoxic freshgas mixture, an "O2/N20 LOW" alarm message appears on the Centralert alarm display, the "O2/N2O FLOW RATIO" LED indicator on the main switch panel lights continuously yellow, and a single-tone audible alarm sounds.

Due to the rebreathing of previously exhaled gas in a circle system, lower freshgas flows require a correspondingly higher oxygen concentration to maintain a sufficient inspiratory oxygen concentration. To address this problem, the ORMC has been designed to maintain higher levels of oxygen in the freshgas at lower flow rates (see Figure 9). Thus, especially at low freshgas flow rates, the O2/N2O FLOW RATIO alarm may activate at freshgas oxygen concentrations well above 25% of the combined oxygen and nitrous oxide flow.

It should be noted that the ORMC interlocks only the flows of oxygen and nitrous oxide. Hypoxic freshgas concentrations are possible if an additional gas other than air is used.

In the following instances, ORMC audible and visual alarms are automatically disabled (as indicated by the Advisory message "ORM ALRM OFF" on the Centralert alarm display):

If the availability of an optional additional gas circuit is controlled by the gas selector switch, and the switch is placed in the "ALL GASES" position. (There is no gas selector switch for machines equipped with carbon dioxide as a third gas.)

- At nitrous oxide flows below 150 (±50) ml/min.

NOTES:

Although ORMC audible and visual alarms are automatically disabled in the above two instances, the ORMC continues to control the flow ratio of oxygen to nitrous oxide <u>regardless of the alarm status</u>.

If the anesthesia machine has been optionally configured to eliminate the minimum oxygen flow feature, ORMC audible and visual alarms are automatically disabled at nitrous oxide flows below 750 (± 75) ml/min instead of the 150 (± 50) ml/min limit used for standard machines.

Oxygen Supply Pressure Alarm

The oxygen supply pressure alarm activates if the oxygen supply pressure (from either the pipeline supply or reserve cylinders) in the system decreases below approximately 32 psi. The LED indicator marked "O2 SUPPLY PRESSURE" lights continuously red, the alarm message "LO O2 SUPPLY" appears on the Centralert alarm display, and an intermittent audible alarm sounds.

NOTE: If only one of the sources of oxygen supply pressure (either reserve cylinders or pipeline) fails while the other maintains proper supply pressure within the machine's oxygen supply lines, the oxygen supply pressure alarm will not activate.

In addition, Canadian machines are equipped with a pneumatically-operated whistle alarm to warn the operator of oxygen supply pressure failure by sounding for approximately 7 seconds.

Battery Test

The operator must test the backup battery system daily by pressing the black "BATTERY TEST" pushbutton. Before pressing the pushbutton, make sure that the System Power switch is in the "ON" position. If the battery has been charged to normal operating potential, the green indicator lights when the pushbutton to its right is pressed. Any time that the battery



MAIN SWITCH PANEL (continued)

potential drops below the normal operating threshold, the yellow "BATTERY LOW" LED lights, whether the "BATTERY TEST" button has been pressed or not.

NOTE: Do not rely <u>only</u> on the "BATTERY LOW" indicator for an assessment of battery capacity. If the backup battery became completely depleted and the machine did not have AC power, the "BATTERY LOW" indicator would have no source of power. Therefore, always remember to perform the daily battery test.

AC Power Failure Indicator

The yellow "AC POWER FAIL" LED signals AC power disruption. The LED illuminates whenever the battery supplies power to the monitoring system and the electronic ventilator. A single-tone audible alarm also sounds when AC power is first disrupted. If the anesthesia machine's backup battery is completely discharged, the AC power failure indicator will not be supplied with the power.

System Power Switch

The System Power switch of the NARKOMED 2B has two functional positions: "STANDBY" (9 o'clock position) and "ON" (12 o'clock position). Set to the "ON" position, the System Power switch actuates all gas and electric power. Set in the "STANDBY" position, the switch shuts down the alarm system and the gas supplies.

The System Power switch must be depressed when turning it to a new position to prevent inadvertent disengagement. A green LED indicator adjacent to the switch remains lit any time that the switch is "ON" and supplying power to the machine. Also, a single brief tone sounds when the switch is turned to the "ON" position.

Regardless of the switch setting, the battery charging circuit and convenience receptacles are activated whenever the power cable is attached to an active wall receptacle. To prevent drainage of the backup battery and waste or depletion of the oxygen supply through the minimum oxygen flow, the System Power switch must be turned to the "STANDBY" position whenever the machine is not in use.

Flowmeter Lights

A pushbutton on the main switch panel controls lights for the flowmeter panel.

GENERAL DESCRIPTION

The NARKOMED 2B incorporates three standard, integral monitors: an oxygen analyzer, a breathing pressure monitor, and a respiratory volume monitor.

These monitors present all of their information on a CRT display (see Figure 16a). All visual alarm signals (alphanumeric alarm messages) are centralized on the CRT display and organized into a three-tiered alarm structure. A central audio annunciator produces all audible alarms, using three different sound patterns to indicate three different levels of alarm urgency.

The monitoring system also interlocks the audible alarms so that only the highest priority, currently active alarm signal is annunciated while others are suppressed. This design eliminates the confusion caused by multiple, simultaneous alarm sounds.

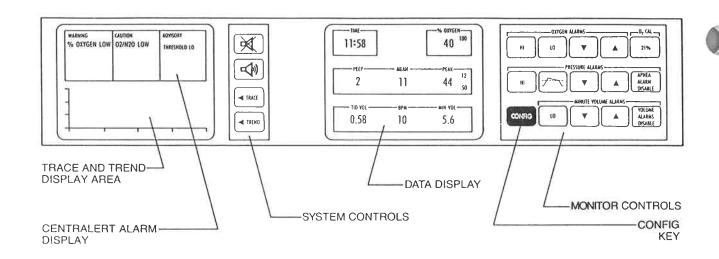


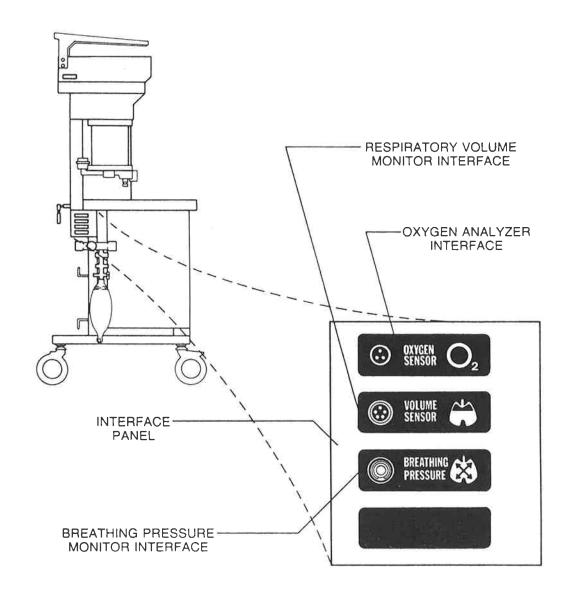
FIGURE 16a: NARKOMED 2B MONITORING SYSTEM FRONT PANEL

MONITORING SYSTEM (continued)

The oxygen analyzer and respiratory volume monitor require sensors to be mounted within the patient breathing system. The breathing pressure monitor requires a pressure sensing pilot line. Figure 16b illustrates these sensor connections. For complete installation details, refer to the individual monitor headings within

this section and the comprehensive SETUP & INSTALLATION section of this manual.

For details on externally interfaced monitors, refer to the operator's manual supplied with the device. Interfacing instructions can be found in the SETUP & INSTALLATION section of this manual.





MONITORING SYSTEM (continued)

NARKOMED 2B SELF-DIAGNOSTICS

When the System Power switch is turned to the "ON" position, the NARKOMED 2B performs extensive self-tests on its internal hardware. As these tests are performed, messages appear on the CRT, indicating the status of various components of the NARKOMED 2B monitoring system. There are three possible conclusions to the self-tests:

<u>FUNCTIONAL</u>: Normal operation of the machine continues.

CONDITIONALLY FUNCTIONAL: A keystroke is required to continue operation, but it should be noted that some of the non-critical functions of the machine (such as the two serial port interfaces) may be non-functional. A North American Dräger service representative should be notified.

NON-FUNCTIONAL: Operation of the machine is halted, and the monitoring package will not operate under this condition. The NARKOMED 2B should not be used, and a North American Dräger service representative should be notified immediately.

The conclusion to the self-test is posted on the left display after its completion.

After successful completion of NARKOMED 2B Self-Diagnostics, the following events occur:

- The left-hand screen shows the Centralert alarm display and the breathing pressure waveform.
- The right-hand screen shows a digital data display.
- All continuous audible alarms are silenced for a period of 120 seconds to allow machine setup without nuisance alarms. During this period, any occurrence of a new alarm will produce a non-repeating tone pattern appropriate for its priority.
- The breathing pressure apnea alarm is automatically disabled on power-up to avoid a spurious alarm with a spontaneously

breathing patient. The alarm can be manually enabled with the "APNEA ALARM DISABLE" key; it is automatically enabled when the ventilator is turned on.

 The respiratory volume monitor's low minute volume and apnea volume alarms are automatically disabled on power-up to prevent nuisance alarms during patient setup. These alarms can be immediately enabled with the "VOLUME ALARMS DISABLE" key or the ventilator power switch.

CENTRALERT ALARM DISPLAY

The Centralert alarm display occupies the upper half of the left-hand display screen (see Figure 17). As alarm conditions occur, alarm messages (such as "% OXYGEN LO") are indicated on the Centralert alarm display and organized into one of three categories: Warning, Caution, and Advisory.

Each type of alarm message produces a different sound pattern:

Warning: A continuously repeating tone pattern.

Caution: An intermittently repeating tone pattern.

Advisory: A single tone or nothing.

Alarm messages are listed in order of the time of occurrence, with the most recent alarm messages appearing at the bottom of the list. To alert the operator of the time at which a Warning or Caution occurs, an arrow appears to the left of the most recent alarm message on the screen (Figure 17). If the alarm condition creating this message is then resolved, the arrow disappears and does not reappear until the occurrence of a new alarm condition.

NOTE: If the number of alarm messages in any of the three categories exceeds the space provided on the display screen for that category, additional alarm messages will be held in the machine's memory until space is available (i.e., through the resolution of some of the displayed alarm conditions).



AUDIO SILENCE CONTROL

Two keys to the right of the Centralert alarm display (Figure 17) can be used to temporarily silence and enable continuous audible alarms. Pressing the Audible Alarm Silence key (labeled with a crossed-out speaker) once silences existing alarms for a period of 60 seconds. Pressing the Audible Alarm Silence key twice silences existing alarms for a period of 120 seconds. The occurrence of a new alarm during a silence

period results in a non-repeating tone pattern corresponding to the alarm. The audio silence condition and the silent time remaining are displayed at the bottom of the ADVISORY section of the Centralert alarm display. Audible alarms can be immediately enabled at any time by pressing the Audible Alarm Enable key (labeled with a speaker producing sound) located beneath the silence key.

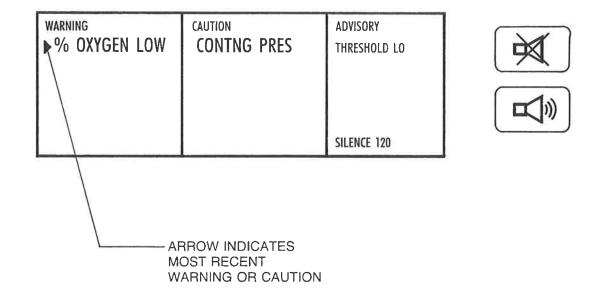


FIGURE 17: CENTRALERT ALARM DISPLAY AND AUDIO SILENCE KEYS

TRACE/TREND DISPLAY

The lower half of the left-hand display screen can show either trends or the breathing pressure waveform.

Trace Display

Pressing the "TRACE" key selects the breathing pressure waveform (see Figure 18). The breathing pressure waveform provides the operator with a visual assessment of lung mechanics and ventilation. The patient's positive end expiratory pressure (PEEP) corresponds to the amount of pressure that the baseline is raised from zero.

The peak pressure corresponds to the peak of the waveform. The inspiratory flow rate can be correlated with the slope of the trace as it rises toward the peak pressure; the steeper the slope, the higher the flow rate. The length of the inspiratory pause (if present) can be visually determined by noting the length of the plateau that extends from the peak pressure to the decrease in pressure that corresponds to expiration.

The trace can be scaled for either 0 to 40 or 0 to 125 cm H_2O . If the pressure high limit is set above 60 cm H_2O the display uses the 0 to 125 cm H_2O scale and the threshold is not displayed on the waveform.

The horizontal dotted line on the waveform represents the threshold pressure (apnea) alarm limit. See the BREATHING PRESSURE MONITOR section for more details.

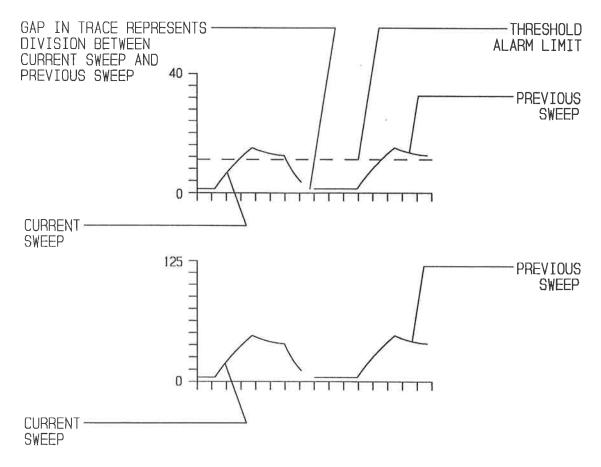


FIGURE 18: TRACE DISPLAY (BREATHING PRESSURE SHOWN)



Trend Display

By pressing the "TREND" key, the operator can select a trend display for either percent oxygen, breathing rate, or minute volume. If compatible external monitors (i.e., pulse oximeter, NIBP, or CO₂) have been interfaced with the system, trend displays for oxygen saturation, pulse, temperature, blood pressure, and CO₂ parameters can also appear. The selected trend variable appears at the top of the trend graph's vertical axis, and the horizontal axis is calibrated in time (see Figure 19). A line graph, representing the historical variations of the trended measurement, travels from left to right across the graph as new trend data accumulates.

Each trend display has a fixed vertical axis scale. The horizontal axis is calibrated in military time for a period of one hour. Since the Narkomed 2B starts trending available data on power-up, it rounds off the time scale labeling to the previous ten minute increment for ease of reading.

For example, if the Narkomed 2B is powered-up at 12:23 and begins monitoring at that point, when the "TREND" key is pressed, a trend graph will appear with the left-most time mark representing 12:20. The operator should note that if the trend display did not receive data between 12:20 and 12:23, there will be a gap on the left hand portion of the trend graph display (see Fig. 19). This gap does not represent a loss of data but rather shows that data for the gap has not been trended.

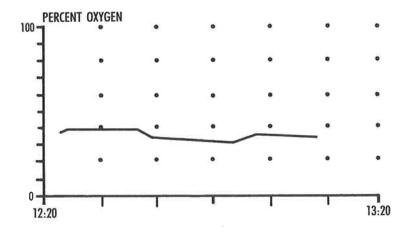


FIGURE 19: TREND DISPLAY (% O₂ SHOWN)

As trending proceeds past one hour, the trend display adjusts the time scale as follows: When the graph fills up with trend data, the trend display creates a new time scale that carries over only the most recent 50 minutes of data from the previous graph. The other 10 minutes of trend data is erased from memory.

NOTE: The Noninvasive Blood Pressure trend appears as a vertical bar on the display screen. The top and bottom of the bar represent systolic and diastolic pressure respectively, and the unshaded gap in the bar represents the mean blood pressure.

The CO₂ trend appears as a shaded area on the screen showing the CO₂ envelope, with the top of the area representing end-tidal CO₂ and the bottom representing inspiratory CO₂.

DATA DISPLAY

The right-hand screen is reserved for a data display that provides numerical information from all monitors (see Figure 16a). Alarm limits appear to the right of measured variables and are smaller in size on the screen. If a monitor is not supplying information, the space reserved for that monitor's data will remain blank on the data display.

Keys grouped to the right of the data display control various monitor functions. The individual monitor sections below explain these controls and their interaction with the data display.

ALARM DISABLE FUNCTIONS

To avoid nuisance alarms during setup of the anesthesia machine, breathing pressure apnea alarms and volume related alarms can be disabled through the Respiratory Volume Monitor and Breathing Pressure Monitor controls. For complete details, refer to the monitor Operating Instructions sections of this manual.



CONFIGURATION

Certain aspects of the NARKOMED 2B can be configured by the user. This is done by invoking the Configure screen (Figure 20) using the "CONFIG" key at the bottom left of the monitor control key panel (see Figure 16a).

During configuration, the column of keys to the right of the configure screen temporarily function according to their corresponding on-screen labels. The "SELECT" labeled key allows the operator to configure the following:

- audio annunciator volume
- current date

- current time
- serial Port A configuration.

The variable selected for adjustment is highlighted by a box, and the "INC" and "DEC" labeled keys are used to increase or decrease the value of that selected variable.

Pressing the "EXIT" labeled key will terminate configuration and return the screen to the Centralert alarm display. Otherwise, configuration is automatically terminated after one minute with no keystroke.

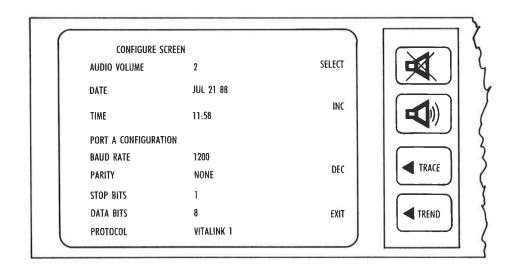


FIGURE 20: CONFIGURE SCREEN



^{*}Only Port A can be configured by the user. Port B is permanently configured for use with the Co-Writer anesthesia recorder. Port A is designed to communicate using the Vitalink Communications Protocol. Refer to the Vitalink Technical Reference Manual for Vitalink programming details.



The oxygen analyzer uses a dual redundant galvanic cell sensor to monitor and digitally display the oxygen concentration in the patient breathing system. The operator can set low and high oxygen concentration alarm limits, calibrate the monitor to 21% oxygen with a single keystroke, and view oxygen concentration data on a trend graph display.

Oxygen Analyzer Sensor Installation (Figure 21)

- 1. Remove the new sensor capsule from its sealed package and discard the circular piece of foam packing and the circular piece of aluminum foil. Unscrew the sensor housing cover from the sensor housing. Insert the sensor capsule into the sensor housing, making sure electrical contacts in the sensor housing mate with the copper rings on the sensor capsule.
- 2. Screw the sensor housing cover back into place on the sensor housing.
- Pull the inspiratory valve dome plug from the inspiratory valve dome and remove the sensor cap from the sensor housing cover.
- 4. Check the inspiratory valve dome and valve disc for cracks. If any cracks are present, replace the cracked valve dome or valve disc.
- 5. Insert the sensor assembly into the inspiratory valve dome by pressing it into place.
- 6. Insert the sensor cord connector into the "OXYGEN SENSOR" input receptacle on the left of the oxygen analyzer sensor interface.
- 7. Check for leaks from the oxygen analyzer sensor assembly by performing a breathing and freshgas delivery system test as described in the PRE-USE CHECKOUT PROCEDURE of this manual.

Care of Sensor Assembly

The sensor capsule works by taking in oxygen, which then initiates an electrochemical reaction within the capsule. The oxygen analyzer reads the voltage produced by this reaction and translates it into an oxygen concentration measurement.

When removing a new sensor capsule from its sealed package and installing it into the sensor assembly, the operator must wait 15 minutes (with the sensor capsule correctly installed into the sensor housing) before calibration. This waiting period allows the capsule's electrochemical reaction to achieve a state of equilibrium acceptable for monitoring. During this waiting period, the monitor may not accept a calibration.

Conversely, if a sensor capsule is removed from the sensor assembly for a prolonged period of time, it can absorb too much oxygen. In this instance, the capsule needs a waiting period equal to the time spent outside the sensor assembly before normal operation can resume. Therefore, the sensor <u>capsule</u> should not be removed from its housing except for replacement when it is exhausted or defective.

NOTE: During the waiting period, the sensor capsule must be correctly installed into the sensor housing, but the oxygen analyzer does not have to be powered up.

Exposure to oxygen (even the 21% oxygen concentration of room air) causes gradual decay of the sensor capsule. Thus, to prolong capsule life, the sensor assembly should be removed from the patient breathing circuit and capped when not in use.



OXYGEN ANALYZER (continued)

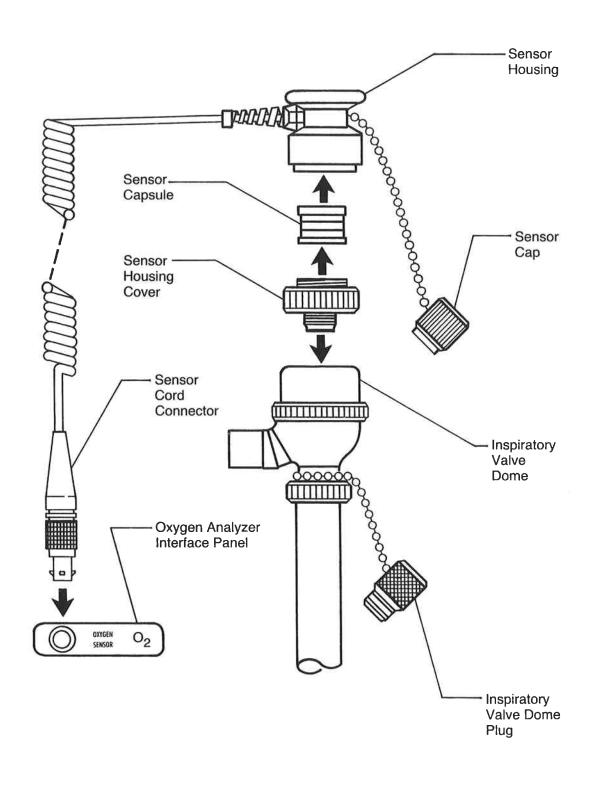


FIGURE 21: OXYGEN ANALYZER SENSOR INSTALLATION



After Power-Up

When the anesthesia machine's System Power switch is turned to the "ON" position, and following self diagnostics, the digital O₂ display area should immediately show the currently sensed oxygen concentration. The smaller numbers to the right of the oxygen concentration measurement represent the high and low alarm limits.

If the oxygen analyzer does not have a calibration value in its memory, the digital display areas will remain blank, and the Advisory messages "O2 NOT CAL" and "O2 ALRM OFF" will appear on the Centralert alarm display. In this instance, a calibration procedure as described below must be performed.

If the oxygen analyzer has not been calibrated in the last 18 hours, but the monitor does have a calibration value in its memory, the display area will show an oxygen concentration, and the Advisory message "O2 CAL DUE" will appear on the Centralert alarm display. In this instance, the monitor can be used, but the calibration procedure below should be performed as soon as possible.

Oxygen Analyzer Calibration Procedure

Calibration should be performed as part of the daily, pre-operative setup of the anesthesia equipment. Follow these step-by-step instructions:

Step 1: Prior to calibration, remove the sensor assembly from the inspiratory valve dome and close off the dome with the inspiratory valve dome plug. (Do not disassemble the sensor assembly further.)

Step 2: With the sensor cap off the sensor assembly, hold the sensor assembly away from any open part of the patient breathing system and away from any gas fittings. This step ensures that the sensor will be exposed to the 21% oxygen concentration normally found in ambient air, and it avoids the influence of breathing system gases.

Step 3: When the sensor is exposed <u>only</u> to room air, press the "O2 CAL" key. The display area will show the message "CALIBRATING" during calibration, and the Advisory messages "O2 NOT CAL" and "O2 ALRM OFF" will appear on the Centralert alarm d play.

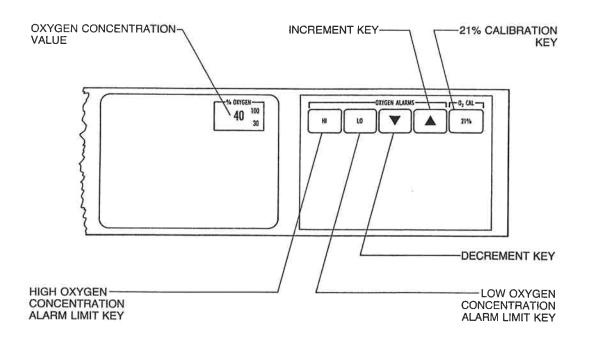


FIGURE 22: OXYGEN ANALYZER CONTROLS AND DISPLAY



Oxygen Analyzer Operating Instructions (continued)

The length of time that the monitor takes to calibrate depends on the gas mixture to which the sensor had been exposed prior to calibration. If the sensor had been exposed to 21% O₂ for greater than one minute, calibration can take as little as 10 seconds. If the sensor had been exposed to higher concentrations of oxygen, calibration may last up to 50 seconds. Typically, calibration will last less than 30 seconds.

Step 4: When the monitor has completed calibration, the Advisory messages "O2 NOT CAL" and "O2 ALRM OFF" are removed from the Centralert alarm display, and the currently sensed oxygen concentration appears in the display area. Now, pull the inspiratory valve dome plug and re-insert the sensor assembly.

If, at the end of the calibration period, the display area remains blank, the calibration attempt has not succeeded. (This condition is also indicated by the Advisory messages "O2 SENS ERR", "O2 NOT CAL", and "O2 ALRM OFF".)

An unsuccessful calibration can be caused by:

- A sensor exposed to an excessively lean or excessively rich oxygen calibration mixture. Make sure that the sensor is exposed only to room air for the entire calibration period.
- A sensor exposed to a constantly changing calibration mixture. As above, make sure that the sensor is exposed only to room air for the entire calibration period.

NOTE: In this instance, the "O2 SENS ERR" message is replaced by "O2 CAL ERR".

- A sensor that has not received the proper waiting period. If the sensor capsule has been removed from the sensor assembly, a waiting period equal to the time that the capsule spent outside the sensor assembly (up to one week) is necessary. New sensors require a 15 minute waiting period.

- An exhausted sensor. If the sensor capsule has decayed beyond its useful service life (see specifications in APPENDIX 1), replace the decayed sensor with a new sensor and allow for the proper waiting period.
- A defective sensor. If the sensor contains too great a difference between the outputs of the two sensor halves, replace a defective sensor with a new sensor and allow for the proper waiting period.
- A disconnected sensor. With the sensor disconnected, the display area will be blank, and the messages "O2 SENS DISC", "O2 NOT CAL", and "O2 ALRM OFF" will appear on the Centralert alarm display. In this instance, reconnect the sensor cord to the interface panel on the anesthesia machine and press the "O2 CAL" key again.

During operation, the oxygen analyzer may also determine that a calibration procedure is required and advise the operator to calibrate the O₂ monitor at the next convenient moment.

Correct Calibration

If the oxygen analyzer is improperly calibrated, it can result in an inaccurate measurement. When a calibration gas mixture is excessively rich or lean in oxygen, the monitor will not complete an attempted calibration. However, if the calibration gas is rich or lean yet still within certain limits, the monitor will complete the calibration. As a result, the oxygen monitor will display an oxygen percentage either greater or less than the actual oxygen percentage. Therefore, make sure that the sensor is exposed only to room air during the entire calibration period.

Figure 23 describes the relationship between the calibration mixture and the accuracy of O_2 measurement.



Oxygen Analyzer Operating Instructions (continued)

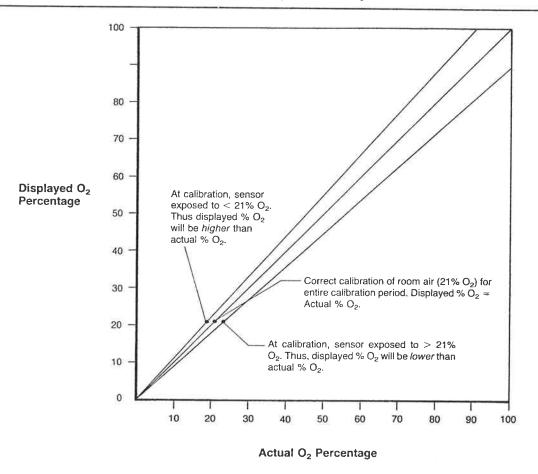


FIGURE 23: MEASUREMENT ERROR DUE TO INCORRECT CALIBRATION

Adjusting Alarm Limits

The "HI" and "LO" keys can be used to adjust alarm limits. Pressing either key places a box around the appropriate alarm limit on the data display. While the alarm limit remains highlighted, the increment and decrement keys (marked with arrows) can be used to adjust the alarm limit. The box disappears after five seconds if these keys are not pressed.

The high limit can be adjusted within a range of 22 to 100% and the low alarm limit can be adjusted within 21 to 99%.

The oxygen analyzer does not allow the high and low alarm limit settings to overlap. The highest low limit setting is equal to the high limit setting minus 1 volume %. The lowest high limit setting is equal to the low limit setting plus 1 volume %. For example, a low limit setting of 30% provides

a high limit adjustment <u>range</u> of 31% to 100% and a high limit <u>setting</u> of 40% provides a low limit adjustment <u>range</u> of 21% to 39%.

Holding either the increment or decrement key in a depressed position will hasten the the alarm limit's rate of change. For fine adjustment, the increment or decrement key can be intermittently pressed.

Power-On Default Alarm Limits

Oxygen analyzer factory-set default alarm limits are 30% for the low alarm limit setting and 100% for the high alarm limit setting. The monitor automatically sets these limits on power-up.



Summary of Oxygen Analyzer Alarm Signals

Low Oxygen Warning

The oxygen analyzer continuously compares the current oxygen percentage with the preset low oxygen alarm limit. If the measured oxygen concentration falls below the low alarm limit, the Warning message "% OXYGEN LOW" appears on the Centralert alarm display, and a continuous audible alarm sounds.

As soon as the measured oxygen concentration exceeds the low oxygen alarm limit, alarm annunciation ceases.

High Oxygen Advisory

If the measured oxygen concentration exceeds the preset high alarm limit, the Advisory message "% OXYGEN HI" appears on the Centralert alarm display, and a single-tone audible alarm sounds.

As soon as the measured oxygen concentration falls below the high oxygen alarm limit, alarm annunciation ceases.

Monitor Not Calibrated Advisory

Any time the oxygen analyzer enters an uncalibrated state, the Advisory messages "O2 NOT CAL" and "O2 ALRM OFF" appear on the Centralert alarm display, and the display area is blanked.

Calibration Required Advisory

Any time that the monitor has a valid calibration value in the battery backed-up memory, but it has been over 18 hours since the last valid calibration, the Advisory message "O2 CAL DUE" appears on the Centralert alarm display. In this instance, the monitor can be used, but a calibration should be performed as soon as possible.



Summary of Oxygen Analyzer Alarm Signals (continued)

Sensor Disconnect Advisory

If the sensor cord becomes disconnected (or is damaged enough to cause an open circuit) the Advisory messages "O2 SENS DISC", "O2 NOT CAL", and "O2 ALARM OFF" appear on the Centralert alarm display, and a single-tone audible alarm sounds. Also, since cord disconnection invalidates the calibration, the oxygen concentration display areas are blanked.

If the operator then plugs the sensor cord back into the interface panel, the "O2 SENS DISC" Advisory message is removed from the Centralert alarm display, and the display area remains blank until a new calibration is performed.

Sensor Error Advisory

During calibration and monitoring, the oxygen analyzer checks for a difference between the outputs of the two sensor halves. If the difference exceeds a predetermined percentage, the Advisory message "O2 SENS ERR" appears on the Centralert alarm display.

During calibration, the oxygen analyzer also checks the sensor's output against a range of acceptable output voltages. There are three possible causes for deviation from within this range:

<u>Exhausted Sensor</u>: If the sensor's capacity is exhausted, its output voltage will not meet the required minimum.

<u>Incorrect Calibration Environment</u>: If the operator exposes the sensor to an excessively rich or lean oxygen mixture during calibration, the sensor's output will either exceed or fall below the acceptable output range.

Improper Waiting Period: If the operator doesn't allow for a proper waiting period for a new sensor or for a sensor removed from the sensor housing, the sensor's output can either exceed or fall below the acceptable output range.

If a sensor error condition is detected <u>during monitoring</u>, an "O2 SENS ERR" Advisory message appears on the Centralert alarm display, but operation can continue. If the monitor detects this condition during calibration, the calibration will be invalidated, as shown by a blank display area at the end of the calibration period, and the Advisory messages "O2 NOT CAL", "O2 ALRM OFF", and "O2 SENS ERR".

Improper Calibration Advisory

During monitoring, if the calculated oxygen concentration exceeds 103%, the Advisory message "O2 CAL ERR" appears on the Centralert alarm display and remains there until a new calibration is performed. (A calculated oxygen concentration of 100% is displayed for all values ≥ 100%.)

During monitoring, if the calculated oxygen percentage exceeds 105%, the oxygen analyzer invalidates the present calibration. The display area is blanked, and the Advisory messages "O2 CAL ERR", "O2 NOT CAL", and "O2 ALRM OFF" appear on the Centralert alarm display. The display area remains blank until a new calibration is performed.

During calibration, if the sensor is exposed to a constantly changing gas mixture, the calibration will be invalidated; the "O2 CAL ERR" Advisory message will also replace the "O2 SENS ERR" message normally used for an invalidated calibration.





General Description

The breathing pressure monitor uses a solidstate pressure transducer to measure and digitally display mean, peak, and positive end expiratory pressure (PEEP) in cm H₂O. The display range is from -50 to 125 cm H₂O, with a 1 cm H₂O resolution. The monitor can sense pressure at either the absorber or patient Y-piece, depending on which supplied pilot line is used.

The operator can set an apnea (threshold pressure) alarm limit and a high pressure alarm limit. Alarms are provided for high pressure, subatmospheric pressure, pressure below the

threshold for 15 and 30 seconds, and continuing pressure above the set threshold for 15 seconds. The unit can also alert the operator of an improperly set threshold pressure.

The apnea (threshold pressure) alarm is automatically enabled when the main power switch of the ventilator is in the "ON" position.

To determine its zero point, the breathing pressure monitor automatically exposes the pressure transducer to ambient pressure. This procedure lasts less than one second and does not affect monitoring.

BREATHING PRESSURE MONITOR (continued)

Pilot Line Installation

North American Dräger anesthesia machines are supplied with two different breathing pressure pilot lines.

Install the shorter pilot line (approx. 38", with quick-connect fittings on both ends) as follows (refer to Figure 25):

Insert one of the male quick-connect fittings on the pilot line into the female quick-connect fitting mounted on the rear of the gas pipe that extends from the absorber top assembly. Insert the other male quick-connect fitting into the female quick-connect fitting on the breathing pressure monitor interface panel.

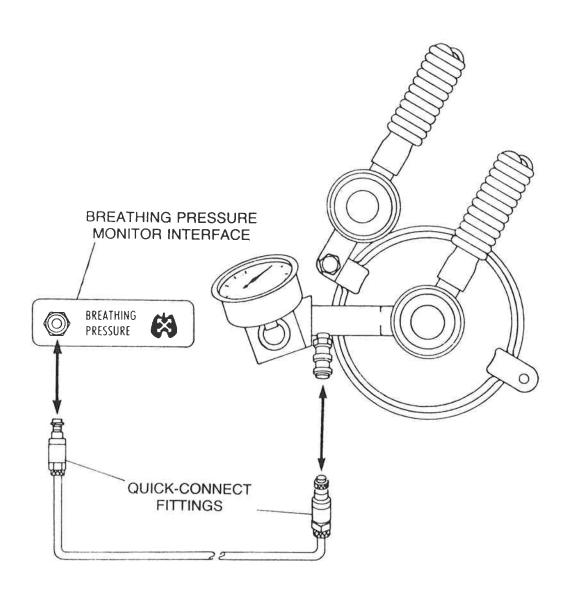


FIGURE 25: INSTALLATION OF BREATHING PRESSURE PILOT LINE AT ABSORBER



BREATHING PRESSURE MONITOR (continued)

The absorber gas pipe female quick-connect fitting has a self-closing construction and may be left unused when employing the longer pilot line.

Install the longer pilot line (approx. 67", with a quick-connect fitting on one end and a Luer type fitting on the other end) as follows (Refer to Figure 26):

Insert the male quick-connect fitting on the pilot line into the female quick-connect fitting on the breathing pressure monitor interface panel. Mate the male Luer fitting on the pilot line with an appropriate female Luer fitting on either the patient Y-piece or a 15 mm adapter on the patient side of the Y-piece. Use the four plastic hose clips attached to the pilot line to mount it on either of the breathing hoses leading to the Y-piece.

For either type of pilot line, check the line for obstructions and moisture accumulation before and during use.

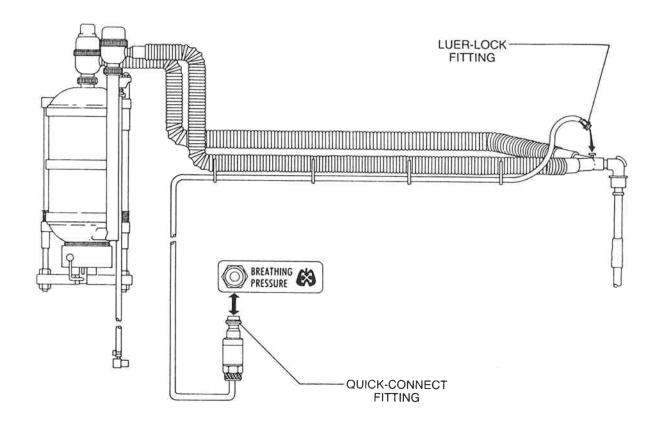




FIGURE 26: INSTALLATION OF BREATHING PRESSURE PILOT LINE AT PATIENT Y-PIECE

BREATHING PRESSURE MONITOR (continued)

Choice of Monitoring Location

North American Dräger has no control over the type of breathing hoses and Y-piece that will ultimately be used with NAD absorber system and pressure monitors, specifically whether such user-supplied components include a terminal for pressure monitoring at or near the Y-piece. Thus, in order to ensure that some form of pressure monitoring is always used, we have made provisions for pressure monitoring at the absorber (the quick-connect fitting on the absorber gas pipe). However, this provision for pressure monitoring at the absorber shall not be construed as a recommendation from North American Dräger for this monitoring location.

In fact, arguments can be made for pressure monitoring at either the Y-piece or at the absorber. Advocates of Y-piece pressure monitoring first claim that it more accurately reflects the pressure developed in the patient's lungs. They also claim that an occluded breathing system can be more easily detected with this method when compared with pressure monitoring at the absorber. For example, if the inspiratory breathing hose became kinked or occluded during automatic ventilation, the ventilator bellows would continue to cycle against the blocked hose. A pressure monitor connected at the Y-piece (downstream of the occlusion) could sense either an absence of pressure fluctuation and alarm, or could sense a reduced pressure fluctuation (below the threshold pressure alarm limit) and alarm. In contrast, a pressure monitor connected at the absorber (upstream of the occlusion) could sense a pressure fluctuation above the threshold pressure alarm limit, and thus would not alarm. (Both of these scenarios assume that the occlusion does not cause a peak pressure high enough to activate the peak pressure alarm, which is meant to detect pressures likely to cause barotrauma.)

However, North American Dräger disagrees with the idea of relying on pressure monitoring to detect an occluded/blocked breathing circuit. CO₂ and respiratory flow monitoring provide superior detection of occluded/blocked breathing paths when compared to pressure monitoring, which will detect such conditions only in some instances. North American Dräger pressure monitors are therefore not promoted for the detection of occluded/blocked breathing paths.

Further, Y-piece pressure monitoring has several disadvantages that could collectively cause the operator to neglect connecting the pressure monitoring pilot line. Examples include: increased contamination of the pilot line due to its proximity to secretions, buildup of condensation within the pilot line, and the introduction of additional disconnection points (if the pilot line connects to a 15 mm adapter).

In conclusion, the responsibility for the selection of pressure monitoring at either the absorber or the Y-piece rests with the operator. The operator's clinical considerations, over which North American Dräger has no control, must be considered to make this decision. North American Dräger is available to discuss in detail the positive and negative aspects of each pressure monitoring approach.

Breathing Pressure Monitor Operating Instructions

After Power Up (Refer to Figure 27)

When the anesthesia machine's System Power switch is turned to the "ON" position, the breathing pressure monitor is ready to display data. The apnea (threshold pressure) alarm is automatically disabled after power up (see below for details).

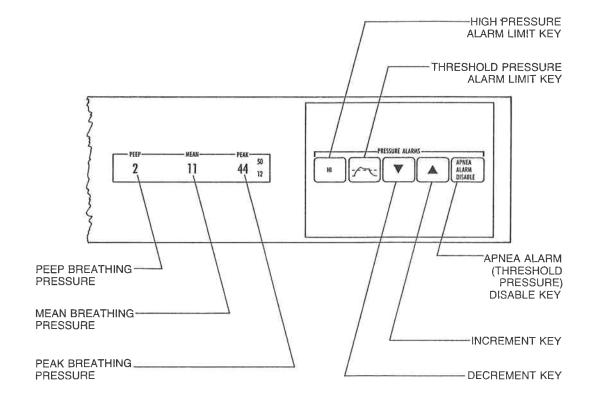
Automatic Apnea Alarm Disable

On power-up, the breathing pressure monitor automatically disables the apnea (threshold pressure) alarm, as indicated by the Advisory message "APNEA-P OFF" on the Centralert alarm display. This automatic disable period allows patient setup without nuisance alarms and

is in effect <u>only</u> when the ventilator power switch is in the "OFF" position. The operator can cancel the automatic disable period by pressing the "APNEA ALARM DISABLE" key, or by turning the ventilator power switch to the "ON" position.

Apnea Alarm Disable Key & Ventilator Interface

During spontaneous ventilation, the patient's expiration produces a pressure fluctuation of only a few cm H₂O, as opposed to the larger pressure fluctuation seen during positive pressure ventilation. Thus, to prevent spurious apnea alarms, the breathing pressure monitor's apnea (threshold pressure) alarm can be disabled with the "APNEA ALARM DISABLE" key.





Breathing Pressure Monitor Operating Instructions (continued)

This key can be used to disable and enable the audible and visual alarm signals for the apnea alarm. During the disabled period, the alarm message "APNEA-P OFF" appears on the Centralert alarm display. Pressing the key again enables the audible and visual alarm signals for the apnea alarm, indicated by the removal of the "APNEA-P OFF" message. Successive keystrokes will toggle the apnea alarm on and off.

To ensure that apnea pressure monitoring is used during automatic ventilation, the apnea disable key is tied into the ventilator power switch. If the operator turns the ventilator power switch to the "ON" position, the apnea alarm is automatically enabled, even if the apnea alarm had been disabled with the "APNEA ALARM DISABLE" key. If the operator turns the ventilator power switch to the "OFF" position, the apnea alarm remains enabled and must be disabled manually, if desired, by pressing the "APNEA ALARM DISABLE" key.

NOTES:

- -- The threshold pressure delay period of 15 and 30 seconds begins from the time that the apnea alarm is re-enabled, with either the "APNEA ALARM DISABLE" key or the ventilator power switch.
- -- The apnea alarm cannot be disabled while the ventilator power switch is in the "ON" position.

Displays

The breathing pressure monitor provides three simultaneous displays (see Figure 27). In the digital display area, the right most number is the peak pressure, the middle is the mean pressure, and the left most is the PEEP.

The peak pressure is the highest instantaneous pressure value for each breath. The mean pressure represents the average of all of the instantaneous pressure values recorded during each breath. The PEEP pressure is the pressure at the end of exhalation. The possible display range

for all three display modes is -50 to at least 125 cm H_2O .

The threshold pressure and high pressure alarm limits appear on the data display as smaller numbers to the right of the "PEAK PRES" variable. The high pressure alarm limit corresponds to the upper number, and the threshold pressure alarm limit corresponds to the lower number.

Adjusting Alarm Limits

The high pressure alarm limit key (labeled "HI") and the threshold alarm limit key (labeled with a drawing of a pressure waveform) can be used to adjust alarm limits.

Pressing either the "HI" or threshold key places a box around the appropriate alarm limit. While the alarm limit remains highlighted, the increment and decrement keys (labeled with arrows) can be used to adjust the alarm limit. The box disappears in five seconds if these keys are not pressed.

The high pressure alarm limit can be adjusted within a range of 30 to 125 cm H_2O , and the threshold pressure alarm limit can be adjusted within a range of 5 to 30 cm H_2O .

Holding either the increment or decrement key in a depressed position will hasten the alarm limit's rate of change. For fine adjustment, the increment or decrement key can be intermittently pressed.

Power-On Default Alarm Limits

The breathing pressure monitor's factory-set default alarm limits are 50 cm H₂O for the high pressure alarm limit and 12 cm H₂O for the threshold pressure alarm limit. The monitor automatically sets these limits on power-up.



Breathing Pressure Monitor Operating Instructions (continued)

Setting the Threshold Pressure Alarm Limit

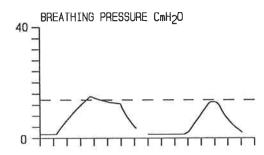
(Refer to Figure 28)

If a breathing system leak or partial disconnection occurs while the threshold pressure alarm limit is set significantly lower than the peak pressure, continued positive pressure ventilation can produce a pressure fluctuation large enough to exceed the threshold (and thus satisfy the monitor's alarm), yet too small to provide adequate ventilation.

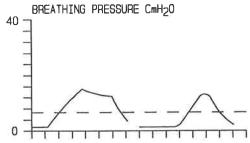
To address this problem, the breathing pressure monitor displays a "THRESHOLD LO" Advisory on the Centralert alarm display under the following circumstances:

- If the sensed peak pressure exceeds the set threshold by more than 6 cm H₂O at threshold pressure alarm limit settings of 5 through 20 cm H₂O.
- If the sensed peak pressure exceeds the set threshold by more than 8 cm H₂O at threshold pressure alarm limit settings of 21 through 29 cm H₂O.

Since the maximum threshold pressure alarm limit setting is 30 cm H₂O, setting the threshold pressure alarm limit at 30 cm H₂O disables the "THRESHOLD LO" Advisory.



- 1. Threshold pressure alarm limit correctly 2. Thus after partial breathing system set to within 6cm H2O of peak pressure (for elarm limit settings of 5 through 20cm H₂O). (Threshold pressure not shown on waveform when scale is 0-125).
 - disconnection or leak, small pressure fluctuation does not cross threshold pressure elerm limit. Operator is warned of apnes condition.



- 1. Threshold pressure alarm limit incorrectly set more than 6cm H₂O below peak pressure.
- 2. Thus after partial breathing system disconnection or leak. small pressure fluctuation in system satisfies incorrectly set threshold pressure alarm limit. Operator is not elerted of apnea condition.



FIGURE 28: THRESHOLD PRESSURE ALARM LIMIT

Breathing Pressure Monitor Operating Instructions (continued)

* Apnea (Threshold Pressure) Alarm Limit

If the measured breathing pressure remains below the threshold pressure alarm limit for more than 15 seconds, the Caution message "APNEA PRES" appears on the Centralert alarm display, and an intermittent audible alarm sounds.

If the measured breathing pressure continues to remain below the threshold pressure alarm limit for an additional 15 seconds (30 seconds total), the breathing pressure display area is blanked, the Caution message "APNEA - PRES" is upgraded to a Warning on the Centralert alarm display, and a continuously repeating audible alarm sounds.

As soon as the measured breathing pressure exceeds the threshold pressure alarm limit, alarm annunciation ceases.

Since the threshold pressure alarm limit should be adjusted as close as possible to the patient's peak inspiratory pressure without exceeding it, the breathing pressure monitor advises the operator of an improperly set threshold pressure alarm limit. A "THRESHOLD LO" Advisory message appears on the Centralert alarm display if the sensed peak pressure exceeds the threshold pressure alarm limit by more than 6 cm H₂O at threshold pressure alarm limit settings of 5 through 20 cm H₂O, and by more than 8 cm H₂O at threshold pressure alarm limit settings of 21 through 29 cm H₂O. Since the maximum threshold pressure alarm limit is 30 cm H₂O, setting the threshold pressure alarm limit at 30 cm H₂O disables the "THRESHOLD LO" Advisory.

Continuing Pressure (Threshold Pressure Limit)

If the measured breathing pressure remains above the threshold pressure alarm limit for more than 15 seconds, the breathing pressure display area is blanked, the Caution message "CONTNG PRES" appears on the Centralert alarm display, and an intermittent audible alarm sounds. As soon as the measured breathing pressure drops below the threshold pressure alarm limit, alarm annunciation ceases.

High Pressure

If the measured breathing pressure exceeds the high pressure limit, the Warning message "VENT PRES HI" appears on the Centralert alarm display, and a continuously repeating audible alarm sounds. This alarm condition is cleared as soon as the measured breathing pressure drops below the high pressure alarm limit. However, the alarm signal is extended for 5 seconds to allow the operator to note a high pressure condition that comes and goes rapidly.

Sub-Atmospheric Pressure

If the measured breathing pressure falls below $-10 \text{ cm H}_2\text{O}$, the Warning message "SUB ATM PRES" appears on the Centralert alarm display, and a continuously repeating audible alarm sounds. This alarm condition is cleared when the sensed pressure rises above $-10 \text{ cm H}_2\text{O}$. However, the alarm signal is extended for 5 seconds to allow the operator to note a sub-atmospheric pressure condition that comes and goes rapidly.

^{*} Apnea pressure alarm signals can be disabled with the "APNEA ALARM DISABLE" key when the ventilator power switch is in the "OFF" position.

Summary of Breathing Monitor Alarm Signals (continued)

Excessive PEEP Caution

Any time that the monitor measures a PEEP of 26 cm H_2O or greater, the Caution message "PEEP > 25" appears on the Centralert alarm display and an intermittent audible alarm sounds. Alarm annunciation ceases as soon as the measured PEEP drops below 26 cm H_2O . Also, an Apnea or Continuing Pressure alarm condition will clear this alarm condition.

PEEP Active Advisory

Any time that the monitor measures a PEEP of 5 cm H₂O or greater, the Advisory message "PEEP > 4" appears on the Centralert alarm display.

As soon as the measured PEEP drops below 5 cm H_2O , the Advisory message is cleared from the display.

Apnea Alarm Off

Any time that the apnea pressure alarm (threshold pressure alarm limit) has been disabled with the "APNEA ALARM DISABLE" key, the Advisory message "APNEA-P OFF" appears on the Centralert alarm display. This Advisory is also generated automatically after power-up if the ventilator power switch is in the OFF position.

WARNING	CAUTION	ADVISORY
APNEA-PRES	APNEA-PRES	THRESHOLD LO
VENT PRES HI	CONTNG PRES	APNEA-P OFF
SUB ATM PRES	PEEP > 25	PEEP > 4



General Description

The respiratory volume monitor employs a positive displacement rotating-lobe impeller that generates electronic pulses in response to the patient's expiratory flow. The monitor converts these pulse patterns into meaningful readings for Minute Volume, Tidal Volume, and Respiratory Rate displays.

The operator can set a low alarm limit for minute volume. Fixed alarms are provided for low tidal volume, high respiratory rate, and reverse flow through the sensor. An apnea alarm is generated if the monitor does not sense a valid breath for 15 and 30 seconds. A sensor failure alarm warns of a disconnected or damaged sensor.

The monitor's volume alarms are automatically enabled when the ventilator power switch is turned to the "ON" position.

The respiratory volume monitor's readings can appear on the data and trend displays.

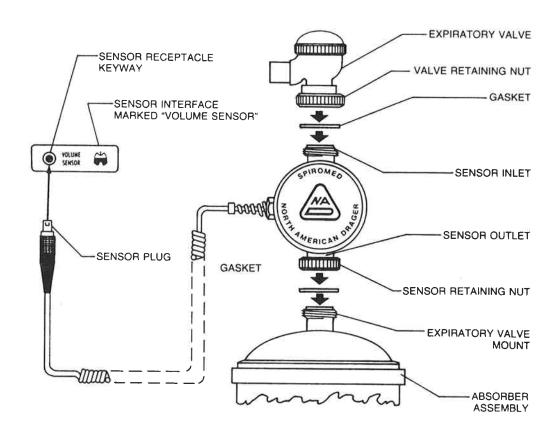


FIGURE 30: RESPIRATORY VOLUME MONITOR SENSOR INSTALLATION

Respiratory Volume Monitor Sensor Installation

Sensor Installation (Refer to Figure 30)

- 1. Remove the expiratory valve from the NAD absorber assembly by unscrewing the valve retaining nut.
- 2. Make sure that the gasket above the threads of the absorber expiratory valve mount is properly seated and in good condition.
- 3. Attach the respiratory volume monitor sensor to the NAD absorber assembly by positioning the sensor at the location previously occupied by the expiratory valve, and then by hand tightening the sensor retaining nut. The sensor retaining nut is specific to the expiratory valve mount and will not fit the inspiratory valve mount.
- 4. Verify that a red silicone gasket in good condition is properly seated above the

- threads of the respiratory volume monitor sensor inlet.
- 5. Attach the expiratory valve to the top of the sensor inlet by threading the valve retaining nut onto the sensor inlet. Hand tighten the valve retaining nut.
- 6. With the sensor and expiratory valve securely in place, align the sensor plug key axially with the sensor receptacle keyway on the anesthesia machine. Push the sensor plug into place, taking care not to twist the plug to avoid damage to the connecting pins. An audible click indicates complete contact engagement and latching.

NOTE: When removing the sensor from the absorber assembly, DO NOT twist the sensor to loosen the sensor retaining nut. Instead, hold the sensor to keep it from twisting and then loosen the sensor retaining nut.

Respiratory Volume Monitor Operating Instructions

After Power-Up

When the anesthesia machine's System Power switch is turned to the "ON" position, the monitor is ready to display tidal volume. However, a full minute of respiration must be registered before Minute Volume and Breathing Rate readings can appear in the display area.

If the ventilator is turned off after power-up, all volume alarms are disabled to allow patient setup without nuisance alarms. The volume alarms are automatically enabled when the ventilator is turned on.

Volume Alarms Disable Key & Ventilator Interface

The "VOLUME ALARMS DISABLE" key can be used to disable and enable audible and visual alarm signals for the Tidal Volume, Minute Volume, and Apnea-Volume alarms. During the

disabled period, the Advisory message "VOL ALRM OFF" appears on the Centralert alarm display. Pressing the key again enables the audible and visual volume alarms, as indicated by the removal of the "VOL ALRM OFF" message from the Centralert alarm display. Successive keystrokes will toggle the alarms on and off.

To ensure that the volume alarms are used during automatic ventilation, the "VOLUME ALARMS DISABLE" key is tied into the ventilator power switch. If the operator turns the ventilator power switch to the "ON" position, the volume alarms are automatically enabled, even if they had been disabled with the "VOLUME ALARMS DISABLE" key. However, since some users may want to use automatic ventilation with a non-rebreathing circuit (in which the respiratory volume monitor cannot be used), the volume alarms can be manually disabled while the ventilator power switch is in the "ON" position.

Respiratory Volume Monitor Operating Instructions (continued)

Displays

The respiratory volume monitor displays three measurements: minute volume, tidal volume, and respiratory rate (See Fig. 31).

Minute Volume Display

The minute volume display continuously indicates the total volume of exhaled gas accumulated during the previous minute of respiration. It, therefore, represents a true measurement of the minute volume and not the result of a calculation. If a full one-minute history of exhaled volume is not available, the "MIN VOL" display area will remain blank.

The minute volume display also shows the low minute volume alarm limit to the right of the minute volume reading.

Tidal Volume Display

The tidal volume display indicates the tidal volume for each breath. If a breath has not been registered for 30 seconds, the "TID VOL" display area will remain blank.

Respiratory Rate Display

The respiratory rate ("BPM") display indicates the total number of breaths (exhalation cycles) registered by the monitor during the previous minute of respiratory activity. As with the minute volume display, if a full minute of respiration has not occurred, the "BPM" display area will remain blank.

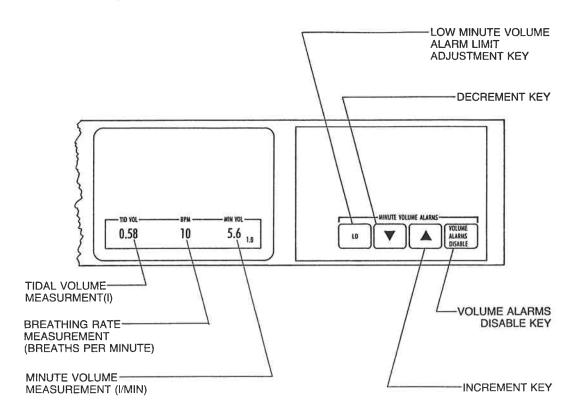


FIGURE 31: RESPIRATORY VOLUME MONITOR CONTROLS AND DISPLAY

Summary of Respiratory Volume Monitor Alarm Signals

Adjusting the Low Minute Volume Alarm Limit

The "LO" key can be used to adjust the low minute volume alarm limit. Pressing the "LO" key places a box around the low minute volume alarm limit (to the right of the "MIN VOL" reading). While the low minute volume alarm limit remains highlighted, it can be adjusted with the the increment and decrement keys (labeled with arrows). The box disappears in five seconds if the keys are not pressed.

The low minute volume alarm limit can be adjusted from 0.5 to 10.0 liters.

Holding either the increment or decrement key in a depressed position will hasten the alarm limit's rate of change. For fine adjustment, the increment or decrement key can be intermittently pressed.

Power-On Default Alarm Limit

The respiratory volume monitor's factory-set default alarm limit for low minute volume is 3.0 liters. The monitor automatically sets this limit on power-up.

Apnea-Volume

The respiratory volume monitor continuously monitors the expiratory flow in the patient breathing system. By processing the expiratory flow patterns, the monitor can determine if a "valid" breath has occurred. A valid breath must have a tidal volume greater than 80 ml.

If a valid breath is not detected for a period of at least 15 seconds, a red "APNEA" LED indicator lights continuously, the Caution message "APNEA-VOL" appears on the Centralert alarm display, and an intermittent audible alarm sounds.

If a valid breath is not detected for an additional 15 seconds (30 seconds total), the red "APNEA" LED indicator begins to flash on and off, the Caution message "APNEA-VOL" is upgraded to a Warning on the Centralert alarm display, and a continuously repeating audible alarm sounds. Also, the display area pertaining to the Respiratory Volume Monitor will be blanked.

As soon as a valid breath is detected, alarm annunciation ceases, and a Tidal Volume reading can appear in the display window. However, a full minute of respiratory activity must be regis-

WARNING APNEA-VOL	CAUTION APNEA-VOL MIN VOL LOW	ADVISORY REVERSE FLOW VOL SEN DISC
	MIN VOL LOW	VOL ALRM OFF

FIGURE 32: CENTRALERT ALARM DISPLAY WITH ALL POSSIBLE RESPIRATORY VOLUME MONITOR ALARM MESSAGES

Summary of Respiratory Volume Monitor Alarm Signals

remain on the screen for about ten seconds after the resumption of forward flow. Extending the alarm message in this manner allows the

NOTE: Volume-related alarms can be disabled with the "VOLUME ALARMS DISABLE" key.

tered before the Minute Volume and

Respiratory Rate can be displayed.

the resumption of forward flow. Extending the alarm message in this manner allows the operator to note an intermittent reverse flow condition.

Low Minute Volume

Low Minute Volume

If at any time the monitor measures a Minute Volume less than the low Minute Volume alarm limit, the Caution message "MIN VOL LOW" appears on the Centralert alarm display, and an intermittent audible alarm sounds. As soon as the monitor measures a Minute Volume equal to or greater than the low alarm limit, alarm annunciation ceases.

Reverse Flow

If the respiratory volume monitor measures a reverse flow through the sensor greater than 20 ml, a single-tone audible alarm sounds, and the Advisory message "REVERSE FLOW" appears on the Centralert alarm display. A forward flow greater than 20 ml will clear the alarm condition, but the "REVERSE FLOW" alarm message will

Sensor Disconnect

If the respiratory volume monitor sensor cord is not properly connected to its input receptacle on the anesthesia machine (or if the cord is damaged enough to cause an open circuit), the Advisory messages "VOL SEN DISC" and "VOL ALRM OFF" appear on the Centralert alarm display, and the digital and bargraph display areas are blanked. Reconnecting the sensor cord will clear the alarm condition.

Volume Alarms Off

Any time that the volume alarms have been disabled with the alarms disable/enable key, the Advisory message "VOL ALRM OFF" appears on the Centralert alarm display. (This alarm condition is also generated by sensor cord disconnection.)



An aneroid manual sphygmomanometer can be mounted on the NARKOMED 2B (see Fig. 33).

The sphygmomanometer gauge mounts on the left-hand side of the anesthesia machine, above the ventilator bellows, either on a mount on the machine itself or on the underside of the optional boom arm. To install the gauge, tighten the gauge's threaded mounting ring in a clockwise direction over the gauge mount. Then, attach the fitting on the free end of the gauge hose to the fitting labeled "BP GAUGE" on the upper left side of the anesthesia machine.

To install the blood pressure cuff, first attach the short hose on the cuff to the longer extension hose. The two hoses join with Luer lock fittings. Then, attach the free end of the extension hose to the fitting labeled "BP CUFF" on the patient interface panel.

To install the cuff inflation bulb, insert the male Lucr fitting (slip-fit type) on the bulb hose into the female Lucr fitting (labeled "BP BULB") to the right of the O2 flush button on the front the anesthesia machine.

After installation, check the gauge's pressure indication. With zero pressure applied to the gauge and cuff, the gauge pointer should remain within the band marked on the face plate. The gauge accuracy is ± 1 % within a range of 75-225 mm Hg and ± 3 % outside of this range.

To check the manual sphygmomanometer for leaks, place the blood pressure cuff around a rigid cylindrical object of approximately the

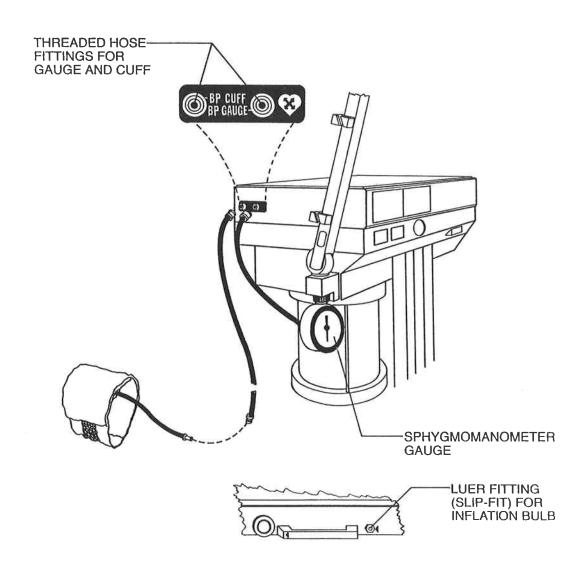


MANUAL SPHYGMOMANOMETER (optional) (continued)

same diameter as a human arm. Inflate the cuff to a pressure of 200 mm Hg, as indicated on the sphygmomanometer gauge. Then, watch the gauge reading for 30 seconds; the gauge indication shall not decrease more than 10 mm Hg within this time period.

To isolate a specific source of leaks, eliminate components from the system and perform the

test described above. For example, to exclude the cuff inflation bulb, pinch the cuff inflation hose after inflating the cuff to 200 mm Hg. To exclude the cuff itself, remove the extension hose from the interface panel, occlude the "BP CUFF" fitting, and then pressurize the gauge to a reading of 200 mm Hg.







Initial setup of a NARKOMED 2B Anesthesia Machine shall be by or under the direct supervision of an authorized North American Dräger representative.

Vaporizers

Vaporizers shall be installed during the initial setup performed by an authorized North American Dräger service representative. After initial setup, if a vaporizer bypass block must be replaced with a vaporizer, this procedure must be performed by an authorized North American Dräger service representative. In addition, any such replacement must be followed by a breathing and freshgas delivery system pressure test as described in Step 26 of this manual's Pre-Use Checkout Procedure.

Auxiliary and Optional Equipment

Instructions for the setup and installation of auxiliary and optional equipment are included within the operator's manuals supplied with each device.

Pipeline Connections

Pipeline connections for oxygen, nitrous oxide, and an optional third gas are located on the side of the flowmeter housing (Fig. 34). Standard Diameter Indexed Safety System (DISS) gas fittings are used for each gas.

Attach pipeline supply hoses as follows:

- 1. Turn the NARKOMED 2B System Power switch to "STANDBY" and close the reserve gas cylinders with the cylinder wrench tethered to the rear of the anesthesia machine.
- 2. Connect the gas fitting on the supply hose to the corresponding gas fitting on the side of the flowmeter housing (Fig. 34). Use a wrench to tighten the attached hex nut.
- 3. Attach the other end of the supply hose to the appropriate, functioning hospital pipeline supplies.
- 4. Check for sufficient pipeline pressure (50-55 psi) using the pressure gauge on the front of the NARKOMED 2B.
- 5. Turn the NARKOMED 2B System Power switch to "ON".
- 6. Turn on the oxygen flow to 10 L/min and turn off all other gases.
- 7. Verify the delivery of pure oxygen to the patient breathing system by using the oxygen analyzer. First, flush the patient breathing system repeatedly by pressing the O₂ flush button. Then, open the O₂ flow control valve to a flow of 8 L/min. With the oxygen sensor mounted in the inspiratory valve dome, the Oxygen Analyzer display area should read 100 (±3) % oxygen.
- 8. Close the O₂ flow control valve and turn the NARKOMED System Power switch to "STANDBY".



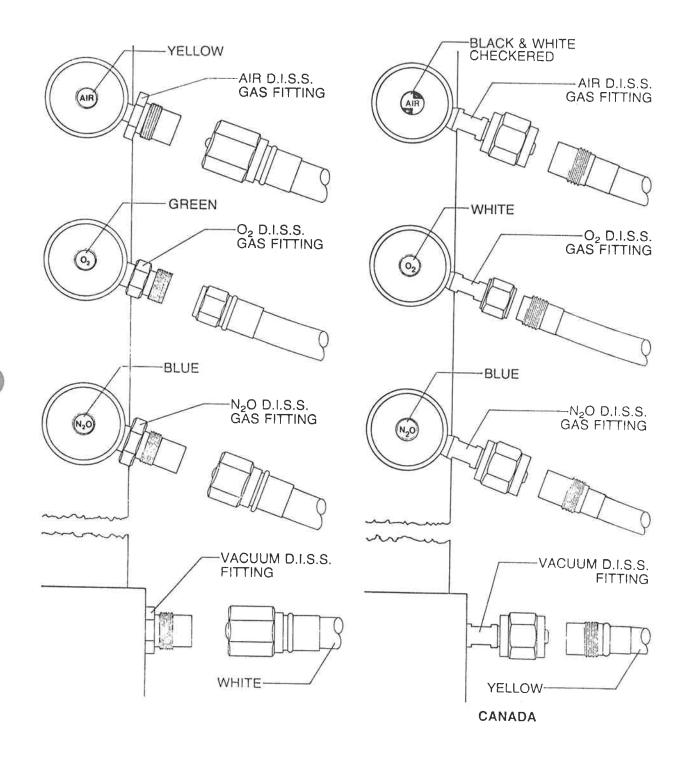


FIGURE 34: SUPPLY LINE DISS GAS FITTINGS AND SUPPLY HOSE CONNECTIONS (AIR OPTION)

Cylinder Connections

The NARKOMED 2B is equipped with ANSI standard pin-indexed hanger yokes for E-size reserve gas cylinders. Reserve cylinders are attached as follows (see Fig. 35):

- 1. Turn the System Power switch to "STANDBY" and disconnect the hospital pipeline supply hose.
- 2. Remove the old sealing washers from the seat of the gas inlet in the yoke.
- 3. Insert a new washer onto the seat of the yoke gas inlet connection.

- 4. Verify the presence and integrity of the two index pins below the gas inlet.
- 5. Insert the head of a gas cylinder with matching gas color code into the yoke from below, such that the gas outlet and indexing holes on the cylinder head are facing the gas inlet and indexing pins on the yoke assembly.
- 6. Engage the indexing holes with the index pins and screw the yoke handle clockwise against the cylinder head, such that the point of the yoke handle bolt is aligned with the countersunk recess on the back of the cylinder head.
- 7. Verify that the sealing washer is in place, that the index pins are engaged, and that the cylinder hangs vertically. Tighten securely.

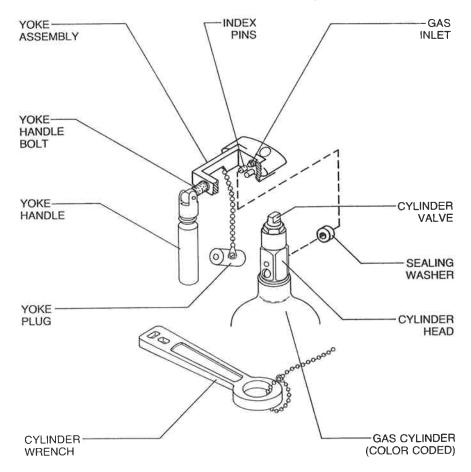


FIGURE 35: RESERVE GAS CYLINDER INSTALLATION

- 8. Open the cylinder valve by turning the cylinder valve stem in a counterclockwise direction, using the cylinder wrench tethered to the rear of the NARKOMED 2B.
- 9. Check for adequate cylinder pressure on the pressure gauge on the anesthesia machine.
- 10. Turn the System Power switch to "ON" and verify the gas flow from the exchanged cylinder by opening the corresponding flow control valve and observing its flowmeter.
- 11. If the oxygen cylinder was exchanged, verify the delivery of pure oxygen to the patient breathing system by using the oxygen analyzer.
- 12. Close the flow control valve(s) and turn the System Power switch to the "STANDBY" position.

Electrical Power Connection

The NARKOMED 2B is equipped with a 15A power cable and a hospital grade plug for 117 VAC primary electrical power. Attach the NARKOMED 2B to electrical power as follows:

- 1. Turn the NARKOMED 2B System Power switch to "STANDBY."
- 2. Unwrap sufficient length of power cord.
- 3. Plug the power cable into a 117 VAC hospital grade outlet.
- 4. Turn the System Power switch of the NARKOMED 2B to "ON." The central monitoring display should now be active.
- 5. Verify that the battery-in-use ("AC POWER FAIL") indicator on the main switch panel remains extinguished.
- 6. Verify that all circuit breakers, located on the lower right side of the frame, remain reset (i.e., pushed in).

 Turn the System Power switch of the NARKOMED to "STANDBY."

External Monitors--DATA IN & DATA OUT PORTS

All NAD Data Network-compatible monitoring equipment can be interfaced to the monitoring system of the NARKOMED 2B via data communications ports on the rear of the monitor bank.

External monitors are connected as follows:

- Turn the System Power switch of the NARKOMED 2B to "STANDBY."
- 2. Attach the Network cable between the "DATA OUT" terminal on the NARKOMED 2B and the "DATA IN" terminal of the external monitor, and secure the cable with the captive 4-40 screws on the cable plug.
- 3. Similarly, attach the cable between the "DATA OUT" terminal of the external monitor and the "DATA IN" terminal of the NARKOMED 2B.
- 4. Plug the external monitor power cable into the 117 VAC convenience receptacle on the rear of the monitor bank. The total amount of current drawn by devices plugged into the four convenience receptacles shall not exceed 5 amps.
- Turn on the System Power switch of the NARKOMED 2B. Turn on the external monitor.
- 6. Simulate an alarm condition that will trigger an alarm on the external monitor. The alarm should be annunciated by the system central audio annunciator, and should be displayed on the Centralert alarm display.
- 7. Turn off the NARKOMED 2B (i.e., System Power switch to "STANDBY") and the external monitor.

Serial Ports

The NARKOMED 2B incorporates two RS-232 serial ports for interfacing the NARKOMED 2B to other monitoring or data processing equipment.

Port B is permanently configured for communication with a Co-Writer anesthesia recorder. Port A is configured for communications using the Vitalink (version 1.00) protocol. Vitalink is an asynchronous, full duplex, RS-232 protocol which can be used for data exchange between the NARKOMED 2B and an external device.

The section entitled "CONFIGURATION" explains how to configure Port A baud rate, parity, data bits, and stop bits. (See Appendix 1 for pinout and configurable parameters.) Refer to the Vitalink Technical Reference Manual for programming details on how to interface using Vitalink.

The following procedure should be used when connecting an external device to the NARKOMED 2B:

- Turn the system power switch of the NARKOMED 2B to "STANDBY". Turn off the external device.
- Attach the appropriate serial cable between the NARKOMED 2B serial port ("PORT A" or "PORT B") and the serial port on the external monitor. Secure the cable with the captive screws provided.
- Plug the external monitor power cable into the 117 VAC convenience receptacle on the rear of the anesthesia machine. The total amount of current drawn by devices plugged into the four convenience receptacles shall not exceed 5 amps.
- Turn on the System Power switch of the NARKOMED 2B. Turn on the external monitor.

Absorber System and Monitor Sensors

Install the absorber system and monitor sensors as described below (Figs. 36 & 37). This installation presumes the use of an appropriate scavenger system with the absorber system. If using a Bain circuit adapter, consult the manual supplied with the adapter.

- 1. Slip the absorber mounting stud into the absorber pole on the swivel arm.
- 2. Tighten the set screw on the absorber pole to lock the absorber in place.
- 3. Pull the freshgas locking bar, located on the front of the NARKOMED 2B, out to its extended position (Figs. 12 & 36). Insert the 15 mm male fitting on the freshgas hose axially into the 15 mm female terminal. Release the spring-loaded locking bar over the fitting, allowing it to "lock" the fitting into place.
- 4. Attach a 22 mm breathing hose (Fig. 37) between the ventilator bellows 22 mm terminal marked "VENTILATOR HOSE" and the 22 mm terminal on the rear of the manual/automatic selector valve, which is also marked "VENTILATOR HOSE."
- 5. Attach a 22 mm breathing hose (Fig. 36) between the 22 mm hose terminal on the inspiratory valve marked "INSPIRATION" and one side of the Y-piece.
- 6. Similarly, attach another 22 mm breathing hose (Fig. 36) between the other side of the Y-piece and the 22 mm hose terminal on the expiratory valve marked "EXPIRATION."
- 7. Attach the breathing bag to the swivel bag mount 22 mm terminal marked "BREATHING BAG" (Fig. 36).
- 8. Connect the 19 mm scavenger hose between the 19 mm terminal (marked "SCAVENGER HOSE") on the bottom of the absorber pole (Fig. 36) and the 19 mm terminal (marked "SCAVENGER HOSE") on the scavenger (Fig. 37).

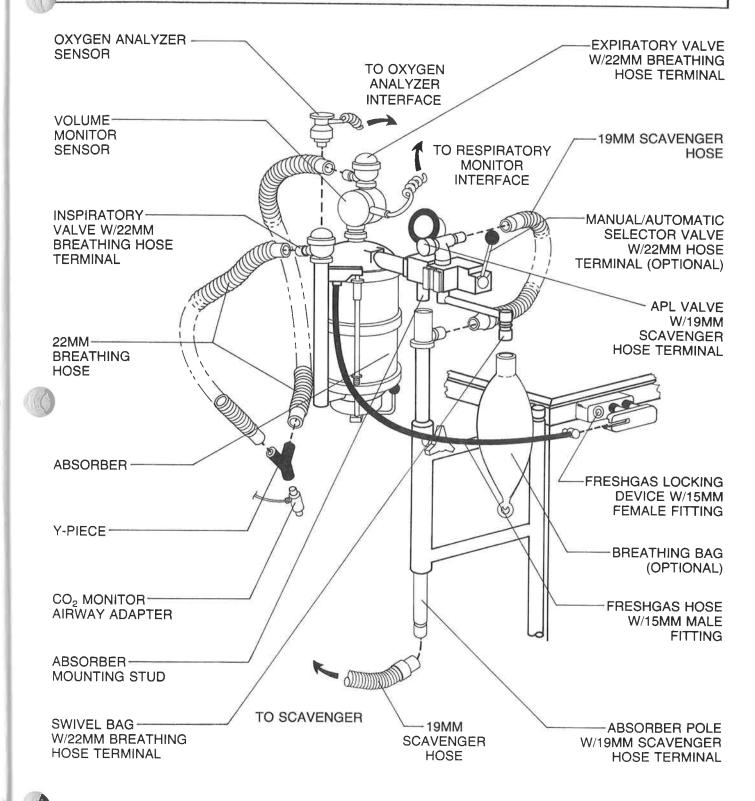


FIGURE 36: ABSORBER INSTALLATION (FRONT VIEW)

- 9. Attach the breathing pressure pilot line to the connector on the system interface panel marked "BREATHING PRESSURE" (Fig. 37). If the shorter pilot line is used, it reads the pressure at the absorber top dome gas pipe by means of a quick-connect fitting. If the longer pilot line is used, it reads the pressure at or near the patient Y-piece, at either a 15 mm adapter with the appropriate Luer fitting or a Y-piece with the appropriate Luer fitting.
- 10. Connect the Oxygen Analyzer sensor cord to the connector on the interface panel marked "OXYGEN SENSOR" (Fig. 37). Make sure that the oxygen sensor assembly is properly mounted in the inspiratory valve dome.
- 11. Connect the 19 mm scavenger hose between the 19 mm terminal (marked "SCAVENGER HOSE") on the rear of the APL valve and the 19 mm terminal (marked "SCAVENGER HOSE") on the rear of the absorber pole (Fig. 37).
- 12. Install the Respiratory Volume Monitor sensor between the expiratory valve and the absorber. Plug the sensor cord into the connector on the interface panel marked "VOLUME SENSOR" (Fig. 37).
- 13. If using a carbon dioxide monitor, connect its sample tubing (or airway sensor) to the patient breathing system.
- 14. Verify the functional integrity of the breathing system by obstructing the patient side of the Y-piece and ventilating the breathing circuit. There should be a cyclic increase and decrease in the breathing pressure.
- 15. Verify the delivery of oxygen by providing oxygen to the breathing circuit. The measured oxygen concentration should rise towards 100%.
- 16. Perform a complete Pre-Use Checkout Procedure as described in this manual.

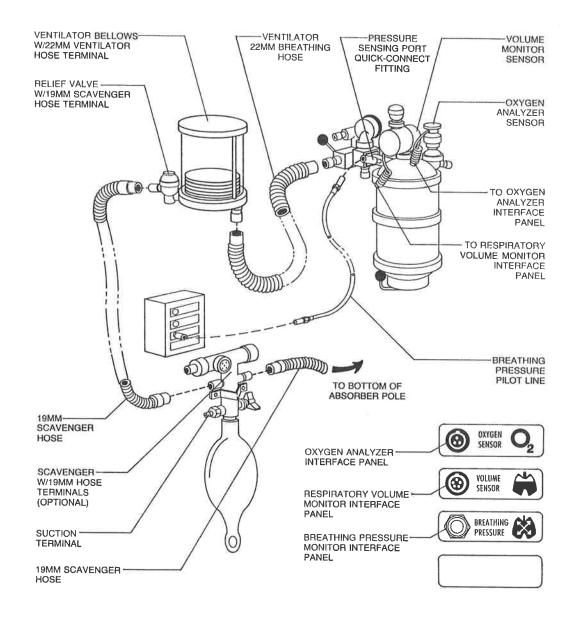
Scavenger System

Installation of a suction scavenger system (Fig. 37) on the NARKOMED 2B is as follows:

NOTE: North American Dräger sells three different types of scavenger systems. The following installation procedure applies only to the suction scavenger system. For details on the other systems, consult their instruction manuals.

- 1. Using the mounting bracket, install the scavenger on the side of the anesthesia unit as shown in Figure 37.
- Attach a wall suction hose between the wall suction outlet and the suction terminal (DISS or hose barb w/adapter) on the scavenger.
- 3. Attach the scavenger reservoir bag to the scavenger at the terminal marked "RESERVOIR BAG."
- 4. Attach the 19 mm scavenger hose between the 19 mm terminal (marked "SCAVENGER HOSE") on the ventilator relief valve (Fig. 37) and the 19 mm terminal (marked "SCAVENGER HOSE") on the left-hand side of the scavenger.
- 5. Attach the 19 mm scavenger hose between the 19 mm terminal (marked "SCAVENGER HOSE") on the rear of the APL valve (Fig. 36) and the 19 mm terminal (marked "SCAVENGER HOSE") on the rear of the absorber pole.
- 6. Attach the 19 mm scavenger hose between the 19 mm terminal (marked "SCAVENGER HOSE") on the bottom of the absorber pole (Fig. 36) and the 19 mm terminal (marked "SCAVENGER HOSE") on the right-hand side of the scavenger (Fig. 37).

- 7. Adjust the vacuum valve wing nut on the scavenger to prevent overfilling or over-draining of the reservoir bag during ventilation.
- 8. Verify the proper functioning of the scavenger system. Check for excessive PEEP or NEEP during ventilation.





Prior to operating the NARKOMED 2B, the following checkout procedures shall be performed to ensure the machine is ready for use. If the anesthesia machine fails any of these procedures identified by an asterisk (*), do not use the machine, and contact an authorized North American Dräger Service Representative.

NOTE: Do not insert any additional components into the anesthesia system after the checkout procedure has been started.

- 1. Enter the anesthesia machine serial number, located on the right rear leg, into the anesthesia record.
- 2. Verify the presence of a valid inspection sticker on the rear of the NARKOMED 2B, indicating that the anesthesia machine has been serviced and inspected by an authorized North American Dräger service representative.
- 3. Verify the presence of a reserve cylinder wrench, tethered to the rear of the anesthesia machine, adjacent to one of the reserve cylinders.
- 4. Connect the electrical power cable to a live 117 VAC receptacle that will accept and properly ground the anesthesia unit's line power cable (for the 240 V option, use a 220/240 V power outlet). DO NOT use "cheater" plugs.
- 5. Connect the hospital pipeline supply hoses from the anesthesia machine's DISS fittings to the appropriate wall outlet DISS fittings.
- *6. Calibrate the oxygen sensor: Expose the oxygen sensor to ambient air and perform a calibration. (See the "Oxygen Analyzer" section of this manual for details.)
- *7. Verify that the correct gases are supplied to the anesthesia machine inlets.
- *8. Inspect the supply hoses for cracks or wear.

- *9. Check for sufficient pipeline pressure: The pressure for each gas, indicated on the pipeline pressure gauge below the flow control valves, should be 50 55 psi. Open the flow control valve for each gas to a moderate value; the pressure indicated at the pipeline pressure gauge shall not decrease more than 5 psi.
- *10. Check the oxygen cylinder supplies:
 - A. Disconnect the pipeline supply (if connected). With the reserve oxygen cylinder(s) closed, actuate the oxygen flush button on the front of the anesthesia machine. Hold the button in until the pipeline and cylinder pressure gauges indicate zero pressure.
 - B. Verify the existence of 2 index pins in the yoke.
 - C. Open the oxygen cylinder (or one of the cylinders if equipped with dual yokes) and check the cylinder pressure gauge. A full oxygen cylinder should indicate a pressure of about 2200 psi. Replace any cylinder with a pressure less than 600 psi. At least one cylinder should be nearly full.

Then, to check for a high pressure leak, close the cylinder and observe the cylinder pressure gauge for a decrease of the pressure indication.

- D. If equipped with dual oxygen reserve cylinder yokes, press the flush button again to empty the piping. Then, repeat the above two steps for the second reserve cylinder.
- *11. Check the nitrous oxide cylinder supplies:
 - A. Disconnect the pipeline supply (if connected). With the reserve cylinder(s) closed, open the nitrous oxide flow control valve until the nitrous oxide pipeline and cylinder pressure gauges indicate zero pressure.



- B. Verify the existence of 2 index pins in the yoke.
- C. Open the cylinder (or one of the cylinders if equipped with dual N_2O yokes) and check the cylinder pressure gauge. A full nitrous oxide cylinder should show a pressure gauge indication of about 745 psi. Replace any cylinder with a pressure less than 600 psi. At least one cylinder should be nearly full.

Then, to check for a high pressure leak, close the cylinder and observe the cylinder pressure gauge for a decrease of the pressure indication.

- D. If equipped with dual nitrous oxide reserve cylinder yokes, flush the nitrous oxide piping again with the nitrous oxide flow control valve. Then repeat the above two steps.
- Check additional gas cylinder supplies (optional):
 - A. Disconnect the pipeline supply (applicable to air only). With the reserve cylinder closed, open the flow control valve until the cylinder and pipeline pressure gauges (air only) indicate zero pressure.
 - B. Verify the existence of two index pins in the yoke.
 - C. Open the cylinder and check the cylinder pressure gauge. Replace the cylinder if its contents are insufficient for the intended procedure. After checking the cylinder's pressure, close the cylinder and observe the cylinder pressure gauge for evidence of a high pressure leak.
- *13. Check for sufficient supply of liquid anesthetic in the vaporizer(s): The liquid level, as indicated by the vaporizer sight glass, must be between the minimum and maximum markings.

- *14. Check for tightness of the vaporizer fill and drain valves: The vaporizer fill and drain valves must be completely closed to prevent leakage of liquid anesthetic and freshgas.
- *15. Check the vaporizer exclusion device, which prevents more than one vaporizer from being activated simultaneously. Make sure that when each vaporizer handwheel is turned to a setting greater than 0, the others remain locked in their 0 positions. Then, turn all vaporizers to the 0 position.
- *16. Check the function of the flowmeters:
 Adjust the flow control knob for each gas and verify the proper operation of the corresponding flowmeters. The float shall move freely over the full range of each flowmeter.
- *17. Check the oxygen failure protection device: With all gases available on the machine set to a flow of about 1 l/min, discontinue the oxygen flow by disconnecting the oxygen pipeline supply hose and closing the oxygen reserve cylinder(s). The flow of all other gases, as indicated by their flowmeters, shall decrease in proportion to the decrease in oxygen flow and eventually shut off.
- *17a. Check the oxygen supply failure whistle (Canada): With all gases available on the machine set to a flow of about 1 l/min, discontinue the oxygen flow by disconnecting the oxygen pipeline supply hose and closing the oxygen reserve cylinder(s). The flow of all other gases, as indicated by their flowmeters, shall decrease in proportion to the decrease in oxygen flow and eventually shut off. The audible O₂ supply failure alarm shall sound for approximately 7 seconds when O₂ supply drops below approximately 32 psi.

*18. Check the function of the ORMC: If the anesthesia machine includes an additional gas selector switch, set the switch to the "O2 + N2O" position. With the nitrous oxide flow control valve open to a flow of 10 l/min, vary the oxygen flow with the oxygen flow control valve. The nitrous oxide flow, as indicated on the nitrous oxide flowmeter, shall automatically vary in response to the adjustment of the oxygen flow control valve.

The ORMC shall maintain a freshgas oxygen/nitrous oxide flow ratio of at least 25 (± 3) %. At low flows the ORMC will maintain a freshgas oxygen concentration higher than 25%. The O_2/N_2O flow ratio alarm shall be activated while the ORMC is limiting the nitrous oxide flow.

- *19. Test the oxygen flush: Pressing the oxygen flush button must result in an audible gas flow sound, accompanied by a marked increase in oxygen concentration in the breathing system.
- *20. Verify the delivered oxygen concentration: Repeatedly flush the patient breathing system by pressing the O₂ flush button. Open the oxygen flow control valve to a flow of 8 l/min and close the other flow control valves. With the oxygen analyzer sensor mounted in the inspiratory valve dome, the oxygen analyzer display area should read 100 (±3) % oxygen concentration.
- *21. Open the oxygen flow control valve to an 8 l/min flow and close all other flow control valves. Sniff the gas coming from the freshgas common outlet. There should be no noticeable odor.
- *22. Check the reserve battery power: Pressing the "BATTERY TEST" button on the anesthesia machine's main switch panel shall result in the illumination of the green LED indicator directly to the left of the test button. The yellow "BATTERY"

- LOW" LED indicator shall remain extinguished.
- *23. Check the hose connections in the breathing system (refer to Figures 36 & 37 in the SETUP & INSTALLATION section of this manual):
 - A. The freshgas hose of the breathing system <u>intended for use</u> must be connected to the freshgas common outlet of the the anesthesia machine.
 - B. A 22 mm breathing hose shall be connected between the inspiratory valve on the absorber and the Y-piece.
 - C. A 22 mm breathing hose shall be connected between the expiratory valve on the absorber and the Y-piece.
 - D. A 22 mm breathing hose shall be connected between the ventilator breathing hose terminal and the manual/automatic selector valve breathing hose terminal.
 - E. A breathing bag of sufficient capacity and appropriate construction shall be connected to the breathing bag terminal of the breathing system.
 - F. If CO₂ monitoring is provided, the sample line shall be connected to the 15 mm patient side of the Y-piece.
 - G. The breathing pressure pilot line shall be properly connected between the system sensor interface panel and either the absorber quick-connect fitting or the appropriate fitting at or near the patient Y-piece.
 - H. A 19 mm scavenger hose shall be connected between the ventilator relief valve and the scavenger interface.
 - I. A 19 mm scavenger hose shall be connected between the APL valve on the absorber and the 19 mm hose terminal on the rear of the absorber pole.



- J. A 19 mm scavenger hose shall be connected between the bottom of the absorber pole and the scavenger interface.
- K. Adjust the vacuum (for suction system scavengers) for the scavenging system as required.
- L. Check for water accumulation in the breathing and scavenger hoses, and in the absorber dust cup. Remove any water found.
- *24. Check the status of the absorbent in the absorber system: Ensure an adequate supply of CO₂ absorbent in the absorber system. Consult the absorbent manufacturer's literature and replace the absorbent when signs of exhausted absorbent are evident. Make sure that the color change represents the absorbent's true state of depletion and is not due to regeneration after a rest period.

Remove accumulated absorbent dust and water from the absorber dust cup. Absorbent is caustic and is a strong irritant to the eyes, skin, and respiratory tract. When emptying the absorber dust cup, take care not to spill its caustic contents.

- *25. Check for free gas passage in the patient breathing system: With a surgical mask over your mouth, inhale and exhale through the breathing system (each limb individually if possible). Verify the unidirectional flow in each limb and then reconnect the tubing.
- *26. Perform a breathing and freshgas delivery system pressure test: This test detects leaks from the patient breathing system and freshgas delivery system.

To perform the test:

A. First close all flow control valves on the anesthesia machine.

- B. Turn the System Power switch of the NARKOMED to the "STANDBY" position.
- C. Turn the vaporizers to 0 concentration. Interconnect the 22 mm ports of the inspiratory and expiratory valves with a 22 mm breathing hose.
- D. Set manual/automatic selector valve to "BAG."
- E. Close the APL valve by turning the knob fully clockwise to its stop position.
- F. Attach the supplied test terminal to the breathing bag mount.
- G. Connect a sphygmomanometer squeeze bulb (available from North American Dräger) to the hose barb on the test terminal.
- H. Pump the squeeze bulb by hand until the breathing system pressure gauge indicates pressure of at least 50 cm H₂0 (not to exceed 80 cm H₂O).
- I. Observe the pressure drop at the breathing system pressure gauge. 30 seconds or longer shall be required for a pressure drop from 50 to 30 cm H_2O .
- *27. Check the function of the patient system relief valve (adjustable pressure limiting or "APL" valve): The APL valve must be capable of relieving excess gas from the breathing system into the scavenger system

To check the APL valve's flow resistance:

- A. First set the manual/automatic selector valve to the "BAG" position.
- B. Remove the bag from the swivel arm bag mount.
- C. Interconnect the 22 mm ports of the inspiratory and expiratory valves with a 22 mm hose.

D. Open the oxygen flow control valve to a flow of 10 l/min and occlude the absorber breathing bag terminal. Push the O2 flush

button to inflate the scavenger reservoir

E. The flow of oxygen shall now exit through the scavenger's positive pressure relief valve. At this point, the absorber system's breathing pressure gauge shall indicate a pressure less than 10.0 cm H₂O.

NOTE: To test the Scavenger Interface for Air Conditioning Systems and the Open Reservoir Scavenger, refer to each

- device's instruction manual.
- *29. Test the ventilator:

bag.

A. Check for proper pressure and flow at the Y-piece during the inspiratory and expiratory phases. Turn the anesthesia unit System Power switch and ventilator power switch to their "ON" positions. Place the manual/automatic selector valve in the "AUTO" position. Adjust the oxygen flow control valve to a 3 1/min flow. Set the ventilator frequency to 3 BPM, the I:E ratio to 1:2, and the tidal volume to approximately one liter. (If testing the Pediatric Bellows or Adult/Pediatric Bellows, adjust the tidal volume to 200 ml.)

Adjust the ventilator flow control to the maximum of the "low" zone on the flow gauge. Occlude the patient side of the Y-piece. Fill the ventilator bellows by pressing the O₂ flush button. Observe the breathing system pressure gauge as the ventilator cycles. The pressure gauge shall indicate a pressure in excess of 30 cm H₂O when the bellows has completed its downward travel. At the end of the expiratory phase, when the bellows has completed its upward travel, the pressure should be about 2 cm H₂O.

B. If the ventilator or absorber is equipped with a PEEP valve, verify the PEEP valve's performance. Attach a breathing bag to the patient Y-piece with

- D.Completely open the APL valve by turning the control knob fully counterclockwise to its stop position.
- E. Open the oxygen flow control valve to a flow of 81/min.
- F. Occlude the bag mount opening, and watch for a pressure increase on the breathing system pressure gauge. This pressure increase, a reflection of the valve's flow resistance, shall not exceed 2 cm H₂O.
- *28. Verify the safe performance of the suction scavenging system. With the scavenging system properly set up and operating, test for positive and negative pressure relief.

To test for negative pressure relief:

- Short circuit the absorber's spiratory and expiratory valves with a 22 mm breathing hose. Set the manual/automatic selector valve to the "BAG" position. Turn the APL valve fully counterclockwise.
- B. With the scavenger needle valve open enough to allow flow through the scavenger and all flow control valves on the anesthesia machine closed, occlude the absorber breathing bag mount. At this point, the absorber breathing pressure gauge shall indicate only a negligible negative pressure (no lower than -1.0 cm H_2O).

To test for positive pressure relief:

- A. Perform step A above.
- B. If the absorber system or ventilator bellows is equipped with a PEEP valve, turn the PEEP valve control knob fully counterclockwise to its lowest setting.
- C. Adjust the scavenger needle valve to a completely closed position by turning it fully clock-wise.



an appropriate adapter such as an NAD combination mask elbow with a 22 mm male fitting for the breathing bag and 15 mm male fitting for the Y-piece. With the manual/automatic selector valve in the "AUTO" position, set the ventilator to the desired frequency.

Then adjust the PEEP valve to different values and observe the breathing system pressure gauge to verify performance. Turn the PEEP valve control knob fully counterclockwise to its lowest setting after the test has been completed.

30. Check the alarm limit settings: The NARKOMED 2B automatically sets monitor alarm limits to a default configuration when the System Power switch is turned on. Check these settings and adjust if necessary. Alarm limits may be adjusted at the beginning of or during a procedure. Also, make sure that external monitors (if present) are connected properly and annunciate alarms through the anesthesia machine's central audio annunciator.

- *31. Test the alarm functions of all monitors: simulate alarm conditions and check for appropriate alarm signals.
- 32. After the above checkout procedure has been performed, verify that the pipeline gas supply hoses are connected. Check the final positions of all controls, specifically the flow control valves, vaporizer controls, manual/automatic selector valve, PEEP valve control knob, APL valve control knob, ventilator power switch, and the System Power switch of the NARKOMED 2B.
- 33. Flush the system with 100% oxygen by pressing the O₂ flush button.

NOTE: If a breathing system other than an absorber system is used, consult the checkout procedure for that system in the appropriate manual.

Perform cleaning and sterilization according to hospital-established policies and procedures as well as the following additional specifications:

Accessory Equipment

For specific details on cleaning monitor sensors and the absorber system, refer to each device's operator's instruction manual.

Surfaces

Clean painted, plated, and plastic surfaces of the NARKOMED 2B with a soft cloth moistened with an aqueous germicidal cleanser.

Mix the germicidal cleanser in accordance with instructions provided by the manufacturer. Use a moist wiping cloth only. Do not allow liquid to enter the interior of the NARKOMED 2B.

DO NOT use solvent cleaners or abrasive cleaning agents on any surfaces of the NARKOMED 2B.

DO NOT use anesthetic agents for cleaning purposes.

Ventilator Bellows Assembly

The bellows assembly and the ventilator relief valve are the only ventilator components in contact with the patient's breath. Follow these step-by-step cleaning and sterilization procedures:

1. Remove the ventilator bellows assembly by loosening the two wing nuts at the bottom of the bellows canister.

CLEANING & STERILIZATION (continued)

2. Unscrew the knurled ring nut around the ventilator relief valve and pull the relief valve dome and pilot line away from the relief valve body. Remove the ventilator bellows from the assembly by unscrewing it in a counterclockwise direction. Then, clean the bellows assembly and all its parts with a mild detergent solution followed by a distilled water rinse.

NOTE: Special care must be taken not to change the position of the adjustment lock ring on the ventilator relief valve dome. DO NOT attempt to loosen the knurled relief valve ring nut by twisting the pilot line hose barb.

- 3. Drip dry the assembly and all parts. If necessary sterilize them in ethylene oxide gas (cold cycle), followed by shelf aeration for 24 hours or 8 hours aeration in an appropriate aeration cabinet.
- 4. After aeration, fit the relief valve dome onto the relief valve body, and tighten the knurled ring nut. Replace the ventilator bellows followed by the entire bellows assembly into the bellows canister. Ensure that the ventilator relief valve pilot line is completely dry. If necessary, dry the line with compressed air or oxygen.
- 5. After reassembly, test automatic ventilation cycling as described in step 29 of the Pre-Use Checkout Procedure.

Rubber Goods

Follow hospital procedures and sterilizer manufacturer's instructions for the sterilization of hoses, breathing bags, and other components of the breathing system.

After sterilization with ethylene oxide (cold cycle), properly aerate rubber goods.

Inspiratory and Expiratory Valves

Refer to the detailed instructions in the <u>Absorber System Operator's Instruction Manual</u>.

Respiratory Volume Monitor Sensor

Clean the sensor after each working day by running distilled water through the housing. (Do not immerse the sensor in water). After this procedure, dry the sensor with a hose-drying unit or allow it to dry overnight.

Do not autoclave the sensor. Instead, sterilize it with ethylene oxide gas at a temperature not exceeding 50 degrees C. After ethylene oxide sterilization, aerate the sensor for at least 3 hours in an appropriate aeration cabinet.

Lubricate the sensor bearings after 2 months of use or after 30 ethylene oxide sterilizations (whichever comes first). Follow the instructions in the supplied Sensor Lubrication Kit. Do not use any lubricant other than the one provided in the Sensor Lubrication Kit.

Dirt and insufficient lubrication can impair free movement of the respiratory volume monitor sensor parts, thereby causing false, low volume measurements, and possibly false alarms. To prevent such problems, follow the above cleaning and lubrication recommendations.

Breathing Pressure Pilot Line

Both types of pilot lines can be gas sterilized with ethylene oxide. First, clean the pilot line with a mild detergent solution and rinse it with water. Then, dry the pilot line thoroughly, for example with a tube drying device. At this point, gas sterilize the pilot line with a cold cycle and then allow it to properly aerate (at least 8 hours in an appropriate aeration cabinet).

CLEANING & STERILIZATION (continued)

Oxygen Sensor Capsule and Sensor Housing

Do not autoclave the sensor assembly. Sterilize the sensor housing and capsule with ethylene oxide gas at a temperature not exceeding 50 degrees C. After sterilization with ethylene oxide, aerate the sensor assembly for at least three hours at a temperature not exceeding 45 degrees C.

Manual Sphygmomanometer

In typical usage, the Manual Sphygmomanometer will not require any further cleaning than wipe down with a liquid disinfection agent. However, if further disinfection is required, remove the sphygmomanometer gauge assembly, hoses, and blood pressure cuff from the anesthesia machine and sterilize them with ethylene oxide gas (cold cycle), followed by appropriate aeration as per the sterilizer manufacturer's instructions.

NOTE: The gauge assembly cannot withstand the heat of autoclaving, and therefore must NOT be autoclaved.

WARNINGS

Anesthesia Machine:

Any person involved with the setup, operation, or maintenance of the NARKOMED anesthesia machine must be thoroughly familiar with this instruction manual.

This anesthesia system will not respond automatically to certain changes in patient condition, operator error, or failure of components. The system is designed to be operated under the constant surveillance and control of a qualified operator.

The "PRE-USE CHECKOUT PROCEDURE" of this manual must be performed prior to each case and must be performed in the room in which the anesthesia machine is to be used.

No third-party components shall be attached to the NARKOMED anesthesia machine, ventilator, or breathing system (except for certain approved exceptions).

Service of this machine shall be by an authorized representative of North American Dräger.

The NARKOMED is designed for use with non-flammable anesthetic agents. Flammable anesthetic agents shall not be used with this equipment.

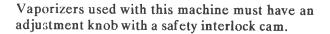
Oil and grease may combine explosively with oxygen or nitrous oxide. For this reason, oil and grease shall never be allowed to come in contact with reserve cylinders, cylinder valves, gauges, fittings, etc., which conduct oxygen or nitrous oxide within the machine. For further information regarding safety precautions in the use of medical gases, consult Compressed Gas Association Pamphlets P-2, and the appropriate sections of NFPA Standard 99.

Check reserve cylinder yokes for the presence of two index pins each time a cylinder is attached to the machine.

Use only **one** reserve cylinder gasket per yoke. The use of more than one gasket could cause leakage of the cylinder gas and could compromise the pin indexing system.

Yoke check valves may not always provide a leak-free seal. Always place a yoke plug in each unused yoke to prevent leakage.

PRECAUTIONS (MAINTENANCE & USE) (continued)



The ORMC maintains a nominal O_2/N_2O freshgas flow ratio of at least 25 (±3) %. Hypoxic freshgas mixtures may be delivered if an additional gas other than air is used.

Delivery hoses used between wall outlets and anesthesia machines have been the cause of accidents when, during assembly, an oxygen fitting has been placed on one end of the hose and a nitrous oxide fitting on the other end. Hoses must be carefully checked each time a machine is connected to a wall or ceiling outlet to ensure that both ends of the hose are indexed for the same gas.

Ensure that the locking device of the freshgas outlet is in its fully retracted position, thus properly securing the freshgas hose fitting.

The oxygen flow control valve is set to deliver a minimum O_2 flow of 150 (\pm 25) ml/min (unless the machine is optionally configured to eliminate the minimum O_2 flow, or an additional air gas circuit is selected). Thus, to prevent waste or depletion of the oxygen supply, ensure that the System Power switch is in the "STANDBY" position when the machine is not in use.

The NARKOMED 2B shall only be used in conjunction with the integral oxygen analyzer, breathing pressure monitor, and respiratory volume monitor.

Patient Breathing System:

The NARKOMED patient breathing system shall not be used in conjunction with any additional components that establish a flow direction.

DO NOT pinch or kink the freshgas hose leading from the freshgas common outlet to the absorber.

CAUTIONS

Anesthesia Machine:

Due to the weight of the NARKOMED 2B, the anesthesia machine should only be moved by people who are physically capable of the task. It is recommended that two people move the anesthesia machine to aid in maneuverability on inclines, around corners, and over raised thresholds (i.e., elevators).

When moving the NARKOMED 2B, remove all monitors and equipment from the top shelf, remove the absorber system, and use only the handles provided. Take care when crossing thresholds and moving up or down ramps.

Devices plugged into the anesthesia machine's convenience receptacles contribute to the anesthesia system's total leakage current. This total leakage current shall not exceed 100 microamps.

Refer any servicing to qualified service personnel.



Unless the unit is specifically modified to eliminate the minimum oxygen flow, the flow of oxygen cannot be totally shut off using the oxygen flow control valve. Do not force the oxygen flow control knob over the end stop of the valve. Forcing the knob could damage the delicate valve seat.

To ensure that gas supplies are at adequate pressure, pipeline pressure gauges should indicate steady pressures of at least 50 - 55 psi.

To ensure that the backup battery is in a continuously ready state, a successful Battery Test (i.e., "Battery Test" green indicator illuminates) should be performed prior to each anesthesia procedure.

To test for erroneous flow indications due to a lodged flowmeter float, the individual flow control valves should be opened and closed in a manner sufficient to demonstrate the free movement of each float up and down the full range of its respective flowmeter tube.



PRECAUTIONS (MAINTENANCE & USE) (continued)

To avoid leakage of anesthetic vapors into the operating room atmosphere, the vaporizer filler valves (Figs. 10 & 11) should be tightened (turned fully clockwise). Vaporizer drain valves should also be tightened fully clockwise.

Although designed to minimize the effects of ambient radio-frequency interference, the functioning of the NARKOMED 2B may be adversely affected by the operation of electrosurgical equipment or short wave or microwave diathermy equipment in the vicinity.

Communications may be temporarily affected by electromagnetic interference due to the use of certain electrosurgical equipment.

Regardless of the indications of any alarm or monitoring device, patient chest movement shall be the primary indication of a securely connected, properly ventilated patient.

Patient Breathing System:

To prevent leaks and misdirection of gas pathways, all hoses should be correctly and tightly fitted, as shown in Figures 36 & 37. Special care must be taken to assure that all 19 mm hoses are attached to the proper 19 mm connectors. Possible machine malfunction and harm to the patient could occur if the scavenger hoses were attached to any 22 mm connection.

To ensure proper absorption of carbon dioxide, the CO₂ absorbent should be checked prior to use. To aid in this assessment, an absorbent should be used which contains an indicator that changes color as the absorbent becomes saturated with carbon dioxide. Absorbent showing a significant color change should not be used to begin a procedure. Make sure that the color change represents the absorbent's true state of depletion, and is not due to regeneration after a rest period.

To prevent excessive pressure from developing within the breathing circuit during spontaneous or manually assisted ventilation, the resistance of the fully-opened adjustable pressure limiting (APL) valve must not exceed 2 cm H₂O at an 8 1/min flow.

To ensure proper direction of gas flow during inspiratory and expiratory phases, the following must occur: (1) the inspiratory valve must provide free gas passage from the breathing system to the patient and not allow backflow from the patient into the breathing system, (2) the expiratory valve must provide free gas passage exclusively from the patient to the breathing system, and (3) the disks in both valves should move freely without sticking.

To ensure that either the ventilator or breathing bag is properly engaged in the breathing circuit, the stick shift lever of the manual/automatic selector valve must be positioned properly. This lever must be positioned toward the operator for spontaneous breathing or manually assisted bag ventilation. The word "BAG" will be visible in the selector valve window. For automatic (ventilator-controlled) ventilation, the stick shift lever of the manual/automatic selector valve must be positioned away from the operator. The word "AUTO" will be visible in the selector valve window. The manual/automatic selector valve shall not be used in an intermediate position, indicated by the color red visible in the valve window.

To minimize mechanical resistance to the patient's exhalation during spontaneous breathing, the control knob of the APL valve must be turned fully counterclockwise. For manually assisted or manually controlled ventilation, APL valve resistance must be increased, as desired, by clockwise rotation of the APL valve control knob.

Respiratory Volume Monitor:

Although designed to minimize the effects of ambient radio-frequency interference, the functioning of the Respiratory Volume Monitor may be adversely affected by the operation of electrosurgical equipment or short wave or microwave diathermy equipment in the vicinity.

Sudden, irregular expiratory flow may cause erratic Minute Volume and Respiratory Rate displays. To avoid such erroneous measurements, the operator should defer reading the display

PRECAUTIONS (MAINTENANCE & USE) (continued)

until a full minute has elapsed after the irregular flow has stopped.

Do not autoclave the volume monitor sensor. Ethylene oxide sterilization of the sensor must not expose it to a temperature greater than 50 degrees C. Following ethylene oxide sterilization, the sensor must be aerated for at least three hours in an appropriate aeration cabinet.

Breathing Pressure Monitor:

The threshold pressure alarm limit should be set as close as possible to the sensed peak pressure without exceeding it.

Oxygen Analyzer:

Under no circumstances will an oxygen analyzer capsule be removed from its housing except for replacement when it is exhausted or defective.

If an oxygen analyzer sensor capsule is removed from its housing, the capsule must be reinstalled into the housing and then given a waiting period equal to the period of its removal (up to one week) before normal operation of the oxygen analyzer can resume.

When not in use, the sensor assembly should be removed from the patient breathing system (inspiratory valve dome), and its port should be covered with the sensor cap.

Do not remove the new sensor capsule from its package until it is to be used.

Do not use a cracked inspiratory valve dome. Inspect the valve dome before use and, if necessary, replace it with the supplied spare inspiratory valve dome.

Do not autoclave the sensor assembly.

Description		Part Numbe	er
Breathing Hose (22 mm x 23" LG)		. 9995123 . 9995132 . 9995140	A A A
Scavenging Hose (19 mm x 10" LG)		. 9995220	Α
Breathing Bags (1.0 1)	* *	9995320999533099953409995350	A A A A
Suction scavenger reservoir bag (5.0 l, blue)		. 9991885	P
Adult Bellows (Replacement bellows)		. 4106930	A
Volume Monitor Sensor Assembly	• •	. 4106362	A
Volume Sensor Lubrication Kit (supplied w/Sensor Assembly)		. 2218180	P
Gasket (exp. valve mount & sensor inlet)		. 1101690	P
Breathing Pressure Pilot Line (to absorber) Breathing Pressure Pilot Line (w/Luer to Y-piece) .		. 4109368 . 4108528	A A
Oxygen Analyzer Sensor Capsule		. 6803290	P
Oxygen Sensor Housing & Cable Assembly		.4106363	A
Inspiratory Valve Dome		.4108329	A
Inspiratory Valve Dome Plug		. 4106387	A
Data cable (DB9/DB25/2.5 ft) for 9 to 25 pin adapter Data cable (DB9/DB25/10 ft) for use with Co-Writer . Data cable (DB9/DB9/2.5 ft) for use with Vitalink Data cable (DB9/DB25/10 ft) for Epson compatible pri		.4109804 .4110328	P A
Data network cable (DB15/DB15/2 ft) use with data lo	op.	.4110510	A
Narkomed 2B Operator's Instruction Manual	• •	. 4109733	Р
Vitalink Technical Reference Manual	• • •	. 4110117	P

GENERAL
Maximum Dimensions (L x H x W) 40 x 68 x 25 inches
Weight (approximate)
ELECTRICAL
Primary input voltage (Allowable) 90 to 130 VAC @ 50 to 60 Hz
Primary input current ≤6 amps (RMS total) ≤1 amp (machine) ≤5 amps (receptacles)
Primary input power (includes receptacles) ≤ 780 Watts
Leakage current ≤ 100 microamps
Ground impedance ≤ 0.1 ohm (60 Hz source)
Dielectric withstand ≥ 1250 VAC (per UL 544)
Chassis resistance
ELECTRICAL (240 Volt Option)
Primary input voltage (Allowable)
Primary input current ≤ 0.4 amps @ 240 VAC, 50 Hz
Primary input power ≤ 100 Watts
Leakage current
Ground impedance ≤ 0.1 ohm (60 Hz source)
Dielectric withstand ≥ 1500 VAC (per IEC-601-1)
Chassis resistance
Conductive caster resistance ≤ 250 Mohms

ELECTRICAL (continued)	
Circuit breakers:	
Primary AC power input (machine)	C
Convenience receptacles 5.0 amps AC	C
Reserve battery power	2
Back-up battery:	
Type Sealed lead-acid, maintenance-free	9
Charging time ≤ 16 hours	3
Reserve power time ≤ 30 min	ח
GAS DELIVERY SYSTEM	
Pipeline inlet connections DISS, male (ANSI B57.1-1977) Nut with nipple (Canada))
Pipeline inlet pressure 50-55 psi (345-380 kPa)(O2, N2O, Air))
Cylinder connectionsPin indexed hanger yokes (ANSI B57.1-1977))
Overpressure relief valve	
Regulator safety relief valve	
Cylinder pressures recommended maximum pressures	
O ₂ , AIR, O ₂ -He)
Freshgas common outlet	3
Freshgas common outlet (Canada) 15 mm female, 22 mm male	3
O_2 flush flowrate)

```
GAS DELIVERY SYSTEM (continued)
<u>Flowmeters</u> (Standard)
(ambient conditions of 20° C and 760 mm Hg)
O_2, N_2O, AIR (Fine) . . . . . . . . . 0 - 1000 ml/min ±3% FS
O_2, N_2O, AIR (Coarse). . . . . . . . . . . . . . . . . 1 - 10 l/min ±3% FS
AIR (dual-tapered) . . . . . . . . . . . 0 - 10 l/min ±5% FS
O<sub>2</sub>-He
                     . . . . . . . . . . . 0 - 10 1/min ±5% FS
Flowmeters (Optional, Low-Flow)
± 15% Rate @ (<1 1/min)
Flowmeters (Optional, Auxiliary Oxygen)
                                ....0 - 10 1/min \pm 5\% FS
Vaporizers (Vapor 19.1)
Halothane:
 Adjustment range . . . . . . . . . . . . . . . 0.2 - 5 vol%
 Accuracy . . (\pm 0.15 \text{ vol}\% \text{ or } \pm 15\% \text{ of setting, whichever is greater})
Enflurane:
 Adjustment range . . . . . . . . . . . . . . . 0.3 - 7 vol%
 Accuracy . . (\pm 0.2 vol% or \pm 20\% of setting, whichever is greater;
             for flow settings > 6.0 and < 15 l/min and handwheel
             settings > 5.0 vol%, accuracy is between -30% and
             +20% of setting.)
Isoflurane:
                             . . . . . . . . . 0.2 - 5 vol%
 Adjustment range . . . . . . .
 Accuracy . . .±0.15 vol% or ±15% of setting, whichever is greater
```

VENTILATOR
Frequency
ENVIRONMENTAL
Storage:
Temperature
Operating:
Temperature
MANUAL SPHYGMOMANOMETER
Type
Type
OXYGEN ANALYZER
Range
BREATHING PRESSURE MONITOR
Range

SPIROMETER			
Resolution			0.1 to 99.9 l 0.1 l whichever is greater
Resolution Accuracy		% or 0.01 l,	0.03 to 9.99 l 0.01 l whichever is greater 0.03 l
Resolution			2 to 50 BPM 2 BPM whichever is greater
SERIAL INTERFACE			
Serial Port A Type			RS-232C, DTE
	PIN #	PORT A	
	1 2 3 4 5 6 7 8 9 SHIELD	NC RXD TXD NC GND NC RTS CTS NC 0.005 uF to chassis	
Doug Doto			300, 1200
Baud Rate			•
Parity		• • • • •	. Odd, Even, or None
Data Bits			7 or 8
Stop Bits			1 or 2
Protocol			Vitalink

CLASS	ALARM MESSAGE	CONDITION	AUDIO
	% OXYGEN LOW	%02 < low limit setting	
W A	APNEA - PRES	Apnea for 30 seconds	C O N
R N I N G	APNEA - VOL	Apnea for 30 seconds	T I N U
G	VENT PRES HI	Pressure > high limit	o U S
	SUB ATM PRES	Pressure < -10 cm H₂O	
	LO O2 SUPPLY	O ₂ supply pressure < 32 psi	
	APNEA - PRES	Apnea for 15 seconds	_
C	APNEA - VOL	Apnea for 15 seconds	I N T E
U T I	CONTNG PRES	Pressure > threshold limit for 15 seconds	R M I T
N	PEEP > 25	Peep ≥ 26 cm H ₂ O	T E N T
	MIN VOL LOW	Minimum Volume < low limit	
	AC/BATT FAIL	Narkomed 2B not receiving line power and battery < 11 VDC	

APPENDIX 2: NARKOMED 2B ALARM MESSAGES (continued)



CLASS	ALARM MESSAGE	CONDITION	AUDIO
	O2 SENS DISC	Sensor cord disconnected	c
	02/N20 LOW	ORMC limiting N2O	S I N G
	% OXYGEN HI	%O₂ > high limit	L E
	AC PWR FAIL	NM2B not receiving line power	O N E
	REVERSE FLOW	Reverse flow > 20 ml	
A D V I	VOL SEN DISC	Sensor cord disconnected	
S O R Y	O2 CAL DUE	> 18 hrs since last O ₂ analyzer calibration	,
ı	O2 NOT CAL	O ₂ analyzer not calibrated	
	O2 SENS ERR	O ₂ analyzer sensor error	N O
	O2 CAL ERR	Bad calibration data	N E
	THRESHOLD LO	Threshold pressure alarm limit set > 5 cm H ₂ O from peak	
	PEEP > 4	PEEP ≥ 5 cm H ₂ O	

APPENDIX 2: NARKOMED 2B ALARM MESSAGES (continued)

CLASS	ALARM MESSAGE	CONDITION	AUDIO
	BATTERY LOW	NM2B battery < 11 VDC	
1 -	SPEAKER FAIL	NM2B primary speaker failure	
A	SILENCE XXX	Temporary alarm silence in effect	
D V I S	VENT OFF	AV-E ventilator power switch in OFF position	N O N
O R Y	ORM ALRM OFF	ORMC alarm disabled	Ē
	APNEA-P OFF	Apnea pressure threshold alarm disabled	
	O2 ALRM OFF	O ₂ analyzer patient alarms disabled	
	VOL ALRM OFF	Volume alarms disabled	

PROBLEM	POSSIBLE CAUSE	REMEDY
Excessive PEEP	Improperly adjusted vent relief valve	Contact NAD service
	Insufficient suction scavenger flow	Increase suction scavenger flow valve setting
	PEEP valve active	Decrease PEEP valve setting
Excessive NEEP	Excessive suction scavenger flow	Reduce suction scavenger flowrate
Bellows won't reach stop during expiration		Decrease frequency
	Frequency too high for selected tidal volume	Increase expiratory phase time
	Improperly adjusted vent relief valve	Contact NAD service
Ventilator	Frequency set to 00	Select correct frequency
won't cycle	Low 02 supply pressure	Provide sufficient oxygen supply pressure
Bellows won't compress during inspiration	Absorber manual/automatic selector valve in "BAG" position	Place manual/automatic selector valve in "AUTO" position
	Inspiratory flow control setting on ventilator too low	Increase inspiratory flow control setting
	Frequency too high	Decrease frequency

APPENDIX 3: NARKOMED 2B TROUBLESHOOTING GUIDE (continued)

PROBLEM	POSSIBLE CAUSE	REMEDY
Blank display area	One full minute has not elapsed (for Minute Volume and Respiratory Rate) since respiration began	Wait 1 full minute to read display
1	Apnea condition	Correct apnea condition
Blank display area, "VOL SEN DISC" & "VOL ALRM OFF" alarm messages on	Sensor cord disconnected	Reconnect sensor cord plug to interface panel on anesthesia machine
Centralert alarm display	Sensor cord damaged	Repair sensor cord
	Leak between sensor and expiratory valve	Check for presence of gasket. Make sure that gasket is in good condition and is seated properly
"REVERSE FLOW" alarm message on Centralert alarm display	Expiratory valve not closing completely during inspiration	Check expiratory valve disc and pins. Clean, repair, or replace expiratory valve
	Defective sensor	Repair or replace sensor
Tidal volume readings obtained are consistently low and sensor is noisy during operation	Excessive friction in sensor	Lubricate, repair, or replace sensor

APPENDIX 3: NARKOMED 2B TROUBLESHOOTING GUIDE (continued)

OXYGEN ANALYZER		
PROBLEM	POSSIBLE CAUSE	REMEDY
Display area blank when a reading is ex- pected. "O2 NOT CAL" & "O2 ALRM OFF" messages on Centralert alarm display.	Calibration is necessary	Perform proper calib- ration. Remove sensor from breathing circuit and press "O2 CAL" key. Make sure sensor is exposed only to room air.
O ₂ analyzer fails to remem- ber calibration	Back-up memory power not available	Allow anesthesia ma- chine backup battery to recharge
alarm display but monitor continues to function	Hardware malfunction	Contact NAD service
Pressing "02 CAL" key does not initiate calibration.	Sensor cord is dis- connected	Reconnect sensor cord to input receptacle or anesthesia machine
	Sensor cord is damaged	Replace housing/cord assembly
	Sensor is exposed to in- correct oxygen concen- tration	Expose sensor to room air for 21% calibration
Pressing "O2	Sensor exposed to con- stantly changing calib- ration mixture	
CAL" key initi- ates calibra- tion, but dis- play window remains blank at end of calibra- tion period	Sensor capsule had been removed from housing for a prolonged period	Allow for waiting period equal to dura- tion of capsule removal
	New capsule not given proper waiting period	Allow for 15 minute waiting period
	Exhausted or defective sensor capsule	Replace sensor capsule. Allow for 15 minute waiting period

APPENDIX 3: NARKOMED 2B TROUBLESHOOTING GUIDE (continued)

OXYGEN ANALYZER (continued) PROBLEM POSSIBLE CAUSE REMEDY During monitor-Defective sensor housing Replace housing/cable ing: "O2 SENS and cable assembly DISC", "O2 ALRM OFF", & "O2 NOT CAL" messages Sensor cord is discon-Reconnect sensor cord nected to input receptacle on on Centralert anesthesia machine alarm display. No pressure Pilot line not connected Ensure that pilot line readout in disis properly connected play area during ventilation Pilot line occluded or Ensure that lumen of kinked pilot line is free of obstructions Erratic readings Condensate accumulation Drain and reconnect in pilot line pilot line

Visual symbols are used on N.A.D. products to provide quick and easy recognition of the product's function. A list of symbols and their descriptions is given below.

O_2	Oxygen Concentration
CO ₂	Carbon Dioxide Concentration
	Gas Concentration
	Breathing Pressure
	Breathing Volume
	Blood Pressure
@	Arterial Oxygen Saturation
×	Audible Alarm Disable
	Audible Alarm Enable
→	Threshold Pressure Alarm Limit
SET	Automatic Threshold Set
DISPLAY	Display Select

INDEA ::::::::::::::::::::::::::::::::::::	
)	
A	Connections for system interface, 29
Absorbent, handling, 70	Convenience receptacles, 24
Absorber system	Co-writer, setup, 63
installation, 63-65	Cylinders
AC power, 24	connection, 61-62
AC power failure indicator, 28	maximum pressures, 8
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