OBA-1® & OBA-1® MRI Compact Anesthesia Unit
For use in MRI Scan Rooms

Operator’s Manual

Cardinal Medical Specialties, Inc.
4708 Pinewood Road
Louisville, KY 40218
Toll Free: 1-800-443-5997
Phone: 1-502-969-9652
Fax: 1-502-969-9777
E-mail: cardmedinc@aol.com
Visit our Website: www.OBAMED.com

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Component Location

1a. Oxygen Connector with Check Valve - male DISS 1240
1b. Air Connector with Check Valve - male DISS 1160A
2.* Oxygen Supply Filter (internal)
3a. Oxygen Supply Pressure Gauge, 0 - 100 psi
3b. Air Supply Pressure Gauge, 0 - 100 psi
4.* Low Oxygen Supply Audible Pressure Alarm (internal)
5a. Oxygen Flow Control Valve
5b. Air Flow Control Valve
6. Air Flowmeter, 0 - 10 L/pm
7. Oxygen Flowmeter, 0 - 10 L/pm
8. Vaporizer
9.* Inline Check Valve between Vaporizer and Common Gas Outlet
10. Oxygen Flush Valve, 35 L/pm
11. Common Gas Outlet, Key Index with Locking Device
12. Exhalation Valve with 22 mm Outlet Connector
13. Inhalation Valve with 22 mm Inlet Connector
14. Oxygen Sensor Port
15. Adjustable Pressure Limiter (APL) Valve with 19 mm Connector
16. Port for Pressure Monitor, Key Index, Locking
17. MRI Compatible Airway Pressure Gauge, – 40 to +80 cmH₂O
18. THERM®OSORB™ CO₂ Absorber/Humidifier Canister
19.* Foam, Absorbent Granule Barriers (Internal)
20. Breathing Bag Connector (22 mm)
21.* Breathing Bag
22. Bag/Ventilator Switch Valve
23. Fresh Gas Hose, Key Index and Locking at both Ends
24. Access Port to Breathing System Pressure Monitoring
25. Manifold, CO₂ Absorber System
26. Inhalation Valve
27. Exhalation Valve
28. Mask Elbow Occluder for Breathing Circuit Pressure Testing
29. Spare THERM®OSORB™ Canister with Seal Caps
30. Common Gas Connection to Absorber Manifold (locking)
31. Ventilator Hose Connector (22 mm)
32. Pre-use Check List (condensed)
33. Handles on each side panel (2)

* Components numbered 2, 4, 9, 19 and 21 are illustrated in several schematics elsewhere in this Operator’s Manual.

The Serial Number can be seen at the bottom of the holding bracket by removing the spare THERM®OSORB™ Canister.
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For Your Convenience

I and II are found inside Front Cover - III is found inside Back Cover

To assure continuous improvement, **Cardinal** reserves the right to implement changes without prior notice
Safety Precautions

TO ASSURE YOUR AND YOUR PATIENT’S SAFETY, PLEASE READ AND FOLLOW THESE SAFETY PRECAUTIONS:

⇒ Caution: Federal law restricts this device to sale by or on the order of a physician. The OBA-1® and OBA-1®MRI Units shall only be operated by professionals trained and qualified in the use of anesthesia equipment.

⇒ The OBA-1® and OBA-1®MRI Units are intended for the administration of general inhalation anesthesia using mixtures of oxygen, air and volatile anesthetics, and for providing breathing gas, and for either spontaneous ventilation or controlled ventilation of the patient’s lungs.

⇒ Read the entire Operator’s Manual and the Vaporizer Manual, before using the OBA-1® and OBA-1®MRI Anesthesia Units.

⇒ Use only medical grade gases which meet USP purity standards.

⇒ Never use oily or greasy substances on any anesthesia or related respiratory equipment. Oxygen under pressure and grease or oil may form an explosive mixture.

⇒ Never use a pressure reducing regulator for oxygen or air, which was used for other gases, such as carbon dioxide.

⇒ Never use a pressure reducing regulator for E or D type cylinders, which has one or both yoke pins missing. Have these regulators repaired or replaced.

⇒ When using large cylinders (G or H) or a central medical gas supply system, make sure the supply pressure to the anesthesia system never exceeds 50 psi. Check pipeline pressure gauges.

⇒ Keep open flames and combustibles (e.g. ether, acetone) away from the anesthesia system.

⇒ Connect the oxygen and air supply hoses to the OBA-1® and OBA-1®MRI Units before connecting it to the pipeline or cylinder supply. Disconnect the oxygen and air supply hoses from the pipeline or cylinder supply prior to disconnecting it from the Units.
⇒ Fill vaporizer **only** with the anesthetic agent for which it is designed. Never put water or any other fluids into the anesthetic vaporizer (see *Care of the Vaporizer*).

⇒ Before moving the OBA-1® and OBA-1®MRI Anesthesia Units, empty the anesthetic vaporizer to prevent the anesthetic agent from entering other areas of the vaporizer (e.g. by-pass) and thus causing the administration of high volume percent anesthetic concentrations. Turn the vaporizer to the “0” (zero) position. Flush the system with oxygen before moving and disconnect the oxygen and air supply hoses (see *Care of the Vaporizer*, page 23).

⇒ The vaporizer must not be tipped over or inverted. If the vaporizer has been tipped over or inverted it must be set to maximum output and flushed at 5 L/min for 2 minutes before clinical use on a patient (see *Care of the Vaporizer*).

⇒ Great care must be given not to tilt the OBA-1® and OBA-1®MRI Anesthesia Units while in use or between uses. **Always drain vaporizer completely after completing anesthesia**! Tilting the unit may cause the vaporizer to malfunction as described above.

⇒ Never move or tilt the OBA-1® or OBA-1®MRI Anesthesia Unit while not under the supervision of a practitioner to prevent damage and/or malfunction of the unit and the vaporizer.

⇒ When moving the OBA-1® or OBA-1®MRI Unit, secure all hoses, grip handles firmly with both hands and move with caution.

⇒ Do not expose the OBA-1® or OBA-1®MRI Anesthesia Units to temperatures below –5°F (–20°C) or above 122°F (50°C). If the unit was stored above or below operating temperatures, test the OBA-1® or OBA-1®MRI Anesthesia Unit and vaporizer for proper performance prior to use.

⇒ If the OBA-1® or OBA-1®MRI Anesthesia Unit was stored at extreme high or low temperature for a prolonged period of time, **do not use** before the unit has reached an operating temperature between 58°F to 95°F (15°C to 35°C).

If you have any questions, the Customer Service Department of **CARDINAL Medical Specialties, Inc.** will be happy to assist you. **Toll Free: 1-800-443-5997**
Specifications and Features
Specifications are typical; individual units may vary.
Specifications are subject to change and improvements without notice.

Weight and Dimensions

**Height (overall):** 15 inches (38.1 cm)
**Width:** 16 inches (40.6 cm)
**Depth:** 9.5 inches (24.1 cm)
**Weight:** 34 pounds (15.4 kg) including Penlon Delta® Vaporizer, 2 full THERMH2OSORB™ CO2 absorbent canisters, 10’ oxygen and air hoses

**Operating Temperature**
**Range:** 58°F to 95°F (15°C to 35°C)

**Storage Temperature**
**Range:** -5°F to 122°F (-20 to 50°C)

**Gas Supply Source:** Oxygen and Medical Air 50 psi (345 kPa)

**Oxygen Supply Hose:** 10’ green pressure hose with 2 female DISS connectors is included with OBA-1® Units

**Air Supply Hose:** 10’ yellow pressure hose with 2 female DISS connectors is includes with the unit.

**Flow Range for Oxygen:** 0 - 10 L/min
**Flow Range for Air:** 0 - 10 L/min
**Flow Accuracy:** ±10% Full Scale

**Safety Relief Valve**
5 psi (~ 350 cm/H2O; ~34 kPa)

**NOTE:** The OBA-1® and OBA-1®MRI Units contain no Latex products.

Features

**Airway Pressure Gauge - (APG)**
Range from -40 to +80 cmH2O. The gauge is connected to a self-locking key indexed female connector. A second connector is provided to allow for the use of an optional patient pressure monitor.

**Adjustable Pressure Limiter (APL) Valve**
The APL (Adjustable Pressure Limiter) valve, also referred to as a "pop-off" valve, can be adjusted to determine ventilation pressures. It has a check valve to prevent the backflow of anesthesia waste gases. A standard 19 mm hose connector allows for connection to a scavenged suction valve.
Audible Oxygen Pressure Drop Alert
Audible signal - whistle, if pipeline oxygen pressure drops below 30 psi (207 kPa). Audible signal lasts at least for 7 seconds. This pneumatic alert system is automatically charged when oxygen pipeline pressure of 30 - 50 psi (207-345 kPa) is present. Loss of oxygen pressure does not eliminate the air supply to the air flowmeter.

Bag/Ventilator Switch Valve
The bag/ventilator switch valve allows for fast switch-over from breathing bag to (optional) ventilator and vice versa.

Common Gas Outlet (CGO)
The common gas outlet (sometimes referred to as Fresh Gas Outlet), labeled "Common Gas Outlet" is key indexed and self-locking to prevent accidental disconnection of the fresh gas hose.

Flow Control Valves
Precision needle valves, turn counter clockwise to start and increase gas flow, turn clockwise to decrease or stop gas flow.

Flowmeters
Single oxygen and air flow control knobs, glass flow tubes with etched scales and stainless steel balls (floats). Protected, etched, removable tubes. Accuracy is ± 10% full scale, calibrated with oxygen at 70°F (21°C). Flow to be read at center of stainless steel ball.

Flowmeter Control Knobs
Oxygen - green color, O₂ labeled, touch coded.
Air - yellow color, Air labeled.

Flowmeter Range
Air flow tube (left side) 0 - 10 L/min
Oxygen flow tube (right side) 0 - 10 L/min

Gas Flow through the Vaporizer
The gas flow is adjusted with the oxygen flowmeter and gas flows through the vaporizer to the common gas outlet.

Gas Supply
50 psi oxygen from pipeline or cylinder source through 10' pressure hose (green) to DISS connector (labeled - Pipeline Oxygen 50 psi).
50 psi air from pipeline or cylinder source through 10' pressure hose (yellow) to DISS connector (labeled - Pipeline Air 50 psi).
Gas Supply Pressure Gauges
Oxygen 0 - 100 psi (0 - 680 kPa) scale range (labeled - Pipeline Pressure)
Air 0 - 100 psi (0 - 680 kPa) scale range (labeled - Pipeline Pressure)

Oxygen Flush Valve
When the oxygen flush valve is fully activated, an oxygen flow rate of 35 L/min is generated. The activation is by light finger pressure on the protected green button (labeled - O₂ Flush). When finger pressure is released, a spring will return the button back to its closed position and the oxygen flush is stopped. A check valve between the vaporizer and the fresh gas outlet prevents back flows to the vaporizer due to pressure variations or flush valve activation.

Oxygen Monitoring
A port is provided in the CO₂ absorber manifold for placement of an O₂ sensor in the inhalation gas mixture going to the patient circuit. The O₂ sensor is to be connected to a free standing oxygen monitor of the practitioner's choice. The OBA-1® or OBA-1™ MRI Units must not be used without a properly functioning and calibrated oxygen monitor with alarms for high and low O₂ concentrations, complying with ISO 7767 Standard for oxygen analyzers!

THERM₂OSORB™ Absorber/Humidifier
The THERM₂OSORB™ absorber/humidifier contains approximately 650 ± 10 grams USP-NF soda lime CO₂ absorbent with ethyl violet dye indicator of CO₂ absorption. For more details see the THERM₂OSORB™ package insert.

Vaporizer
A single temperature compensated, direct reading (DRV) Penlon Delta® vaporizer is included with the OBA-1® and MRI Units.

Vaporizer Filling and Draining
Filling and draining of the vaporizer is performed with a key indexed, agent specific, color coded filler adapter. Instructions for filling and draining the vaporizer are found in the Vaporizer User Instruction Manual, which is included with each vaporizer. This manual must be read and understood before operating the vaporizer.

WARNING: Always drain vaporizer completely before moving the unit and after ending anesthesia for the day!
Circuit Diagram
OBA-1® and OBA-1®MRI
Anesthesia System

50 psi Air
50 psi O₂

1a 2a 3a 3b 2b 5a 5b 8 9 11 12 13 14 15 16 17 18 19 20 21 22

Patient Oxygen Monitor WGES Pressure Monitor

Manifold Outline

*
Glossary - Circuit Diagram

1a. Air Connector with Check Valve - male DISS (Diameter Index Safety System)
1b. Oxygen Connector with Check Valve—male DISS Diameter Index Safety System)
2a. Air Inlet Filter
2b. Oxygen Inlet Filter
3a. Air Supply Pressure Gauge - calibrated from 0 - 100 psi
3b. Oxygen Supply Pressure Gauge calibrated from 0 - 100 psi
4. Oxygen Supply Failure Alarm
5a. Air Flow Control Needle Valve
5b. Oxygen Flow Control Needle Valve
6. Air Flowmeter calibrated from 0 - 10 L/min
7. Oxygen Flowmeter calibrated from 0 - 10 L/min
8. Temperature Compensated Vaporizer
9*. Back Pressure Check Valve only used with Non-Backpressure Compensated Vaporizers
10. Oxygen Flush Valve (35 to 50 L/min)
11. Key Index Common Gas Outlet
12. Expiratory Valve with 22 mm Elbow Connector
13. Inspiratory Valve with 22 mm Elbow Connector
14. Oxygen Sensor
15. APL (Adjustable Pressure Limiter) Valve with 19 mm Connector for WGES (Waste Gas Elimination System)
   The APL Valve is incorporated in the Bag/Ventilator Switch Valve (not shown).
16. Key Index Connector with Safety Lock for cmH2O Pressure Gauge for Patient System Pressure Monitor
17. 0 - 80 cmH2O Patient System Pressure Gauge
18. THERM2OSORB™ CO2 Absorber/Humidifier
19. Foam Granule Barrier
20. Breathing Bag Connector as part of the Bag/Ventilator Switch Valve (not shown).
21. Breathing Bag
22. Manifold includes parts of the Patient Breathing System
23. Pressure Relief Valve - 5 psi

**NOTE:** When oxygen supply pressure is reduced, the oxygen concentration will not decrease below 21% at the common gas outlet, if air is in use.
Operation of the OBA-1® and OBA-1®MRI Anesthesia Units

Use diagrams of the OBA-1® & OBA-1®MRI Unit with Patient Breathing Circuit as reference and read the following procedures carefully.

Preparation for the Anesthesia Procedure

Required Materials and Supplies:

1) Oxygen pressure supply source of 50 psi.  
   Medical air pressure supply source of 50 psi.
2) Patient breathing circuit with corrugated hoses and 15/22 mm 
   Y-connector, elbow with gas sampling port, mask, or endotracheal tube with 15 mm connector.
3) Breathing Bag (21) of size appropriate for patient.
4) Fresh THERMH2OSORB™ canister.
5) Full vaporizer. Check that filler and drain plugs are closed.
6) 19 mm hose connected to an active suction interface valve or 
   similar scavenging device.
7) Oxygen monitor (mandatory), calibrated and functional.
8) Pressure monitor for breathing system.
9) CO₂ monitor and/or exhaled volume monitor.

Settings of Controls and Valves on the OBA® & OBA-1®MRI Units:

1) Open APL valve (15) by turning counter clockwise.
2) Close flow control valves (5a and 5b) by turning completely 
   clockwise - do not over-tighten.
3) Turn hand wheel of anesthetic vaporizer (8) to "0" (zero).

Preparation of the OBA® & OBA-1®MRI Units:

NOTE:
Test low pressure system for leaks once a day or if the anesthesia practitioner changes. Use the Low Pressure System Leak Tester (provided).

1) Connect 50 psi oxygen supply hose to the male oxygen DISS 
   connector (1a) and 50 psi air supply hose to the male air DISS 
   connector (1b) of the OBA-1® & OBA-1®MRI Units.
2) Make sure fresh gas hose is connected and locked to manifold and common gas outlet (11).
3) If necessary, replace THERMHOSORB™ (18) with fresh unit.
4) Fill anesthetic vaporizer (8) with the correct anesthetic agent. Observe the sight glass. Stop filling once the fluid has reached the top line of the sight glass.
5) Replace filler plug and close completely by turning clockwise.
6) Attach the two corrugated hoses of the breathing circuit to the inspiratory valve (13) and expiratory valve (12).
7) Attach breathing bag (21) to breathing bag elbow (20).
8) Attach one end of a 19 mm corrugated hose to the outlet port of the APL valve (15) and the other end to an active suction.
9) If applicable, connect vacuum system to the scavenger interface.
10) Calibrate oxygen monitor and set alarm limits.
11) If applicable, check defaults and/or set alarms of pressure monitor.
12) Connect CO₂ monitor to gas sampling port of breathing circuit.
13) If applicable, attach exhaled gas spirometer at exhalation valve.
14) Pressure test breathing circuit for any leaks.

**Clinical Application of the Anesthesia Unit**

The OBA-1® and OBA-1® MRI Anesthesia Units are devices that allows for the administration of anesthetic agent to patients. The vaporizer converts a liquid anesthetic agent into a measured amount of vapor, which is carried to the patient by the oxygen flow.

The THERMHOSORB™ absorber (18) must still be able to absorb CO₂. **Evaluate condition of soda lime absorbent at the end of a case by observing the extend of the color change in the canister.** **Discard canister, if extensive color change has occurred. Replace with fresh THERMHOSORB™ canister.** Breathing bag (21), patient breathing circuit and all accessory tubing and bags must be connected. After the oxygen and/or air supply is turned on and the waste gas elimination system is connected, the anesthesia apparatus is ready to use.

Oxygen and/or air flow is selected by turning the oxygen flow control valve (5b) for the oxygen flow meter (7) and/or the air flow control valve (5a) for the air flow meter (6) counter clockwise, which will gradually fill the breathing bag (21). The "Y" connector of the patient
breathing circuit is then usually attached to a mask or endotracheal tube connector. When the breathing bag (21) is squeezed, the gas mixture flows through the THERMH₂OSORB™ (18) and the inspiratory valve (13) into the patient’s lungs. As soon as the pressure on the breathing bag (21) is released, the patient exhales through the expiratory valve (12) into the breathing bag (21).

In the breathing bag (21) the exhaled gas mixes with the fresh gas which is flowing constantly. When the bag is squeezed again, the mixed gases are forced through the THERMH₂OSORB™ (18), where the exhaled carbon dioxide is removed and the ventilatory cycle is repeated.

During the above process, the operator may elect to add an anesthetic agent. The operator will turn the concentration knob of the vaporizer to the desired volume percent concentration. Oxygen and/or air will pass through the vaporizer and carry the anesthetic vapor to the common gas outlet (11).

The operator may also determine the inspiratory pressure when ventilating the patient by adjusting the APL valve (15), while observing the cmH₂O pressure gauge (17). The more the APL valve (15) is opened, the lower the pressure. The more the APL valve (15) is closed, the higher the pressure. The operator should monitor pressures during the ventilatory process on the pressure gauge (17) frequently. A tubing with a key indexed quick connector can be attached to the airway pressure port (16), which transfers the pressure to an optional pressure monitor.

The APL valve (15) also serves as an exhaust for waste gases. These waste gases are routed to a scavenger interface valve which is connected to an active or passive suction system.
Gas Flow
through the Patient Breathing Section
of the OBA-1® OBA-1®MRI Anesthesia Units

Eight different phases of the gas flow through the breathing section of the OBA-1® or OBA-1®MRI Anesthesia System are shown on the following pages.

Please Note:
Although no oxygen monitor is provided as part of the OBA-1® and OBA-1®MRI Anesthesia Units, it is mandatory that it is always operated with an oxygen monitor which is in proper operating condition and incorporates audible and visual alarms.

Note: When oxygen supply pressure is reduced, the oxygen concentration will not decrease below 21% at the common gas outlet, if air is in use.

It is further recommended to monitor end-tidal CO₂. This requires a patient breathing circuit with a port on the y-piece for the connection of a CO₂ monitor.

For details about oxygen, pressure, CO₂ monitors and patient breathing circuits, please contact your Dealer or the Service Department of Cardinal Medical Specialties.
Phase 1 - Oxygen Flush

Activation of the oxygen flush valve (not shown) charges the patient breathing system with 100% oxygen. The gas is forced at 50 L/min through the common gas outlet (11) into the breathing bag (21), and then through the THERMH₂OSORB™ absorber/humidifier (18). The oxygen continues to flow through the open inspiratory valve (13) to the patient. The oxygen sensor (14) will signal 100% oxygen concentration to the oxygen monitor (optional).

Should gases from a previous exhalation be present in the breathing circuit, they will be flushed out by the 100% oxygen gas flow and all carbon dioxide will be removed in the THERMH₂OSORB™ absorber/humidifier (18).
**Phase 2 - Spontaneous Inhalation**

When the patient initiates an inhalation, he creates a sub-atmospheric pressure in the breathing system. This sub-atmospheric pressure opens the inspiratory valve (13), while at the same time the sub-atmospheric pressure keeps the expiratory valve (12) closed. Since the fresh gas—during the flush it consists of 100% oxygen—will continue to flow from the fresh gas outlet, the excess gas will be evacuated from the breathing system through the APL (Adjustable Pressure Limiter) valve (15). The gas will be removed through a scavenger system.
**Phase 3 - Exhalation**

As the patient begins to exhale, positive pressure develops which opens the expiratory valve (12), but keeps the inspiratory valve (13) closed. The patient exhales into the breathing bag (21), where the exhaled gas is mixed with fresh gas. The exhaled gas contains CO\(_2\). At this point an anesthetic agent may be added from the vaporizer (not shown) to the fresh gas flow.
Phase 4 - Exhalation

As the exhalation continues, the breathing bag (21) expands with a dry fresh gas mixture and with the exhaled patient gas containing CO₂. The bag expansion depends on the adjustment of the APL valve (15).
Phase 5 - Exhalation

The expansion of the breathing bag (21) during the exhalation depends on the adjustment of the APL valve (15). The excess fresh gas mixture from the fresh gas outlet is directed through the THERMH₂OSORB™ absorber/humidifier (18) to the APL valve (15). From there the gas will be removed through a scavenger system.
Phase 6 - Assisted Manual Ventilation

Assisted ventilation is initiated by squeezing the breathing bag (21). This creates a pressure which is registered on the patient system pressure gauge (17). The exhaled gas which contains CO$_2$ and the completely dry fresh gas mixture which may contain an anesthetic agent, are transferred from the breathing bag (21) to the THERMH$_2$OSORB™ absorber/humidifier (18). The absorbent removes CO$_2$ from the exhaled gas and the exothermic reaction generates heat and water vapor which is added to the inhaled gas. The warm and humidified gas flows through the inspiratory valve (13) to the patient. The inspiratory oxygen concentration is exposed to the oxygen sensor (14) which is connected to an oxygen monitor.
Phase 7 - Assisted Manual Ventilation

The breathing pressure as registered on the breathing system pressure gauge (17) will depend on the adjustment of the APL valve (15), the patient’s lung compliance and the pressure applied to the breathing bag (21). All excess gas will exhaust through the APL valve (15) and will be removed through a scavenger system.
Phase 8 - Exhalation

When the pressure on the breathing bag (21) is released, exhalation can begin. The patient exhales through the expiratory valve (12) into the breathing bag (21), where the exhaled gas is mixed with fresh gas and the ventilatory cycle is repeated.
**THERMH₂OSORB™ Absorber/Humidifier -
Breathing System Overview**

CO₂ absorption and humidification in a closed or semi-closed circle rebreathing system is accomplished in the OBA-1® and OBA-1® MRI Unit by the THERMH₂OSORB™ absorber manifold system which utilizes a prefilled, disposable canister (THERMH₂OSORB™) containing CO₂ absorbent. This unit is mated to the OBA-1® MRI absorber manifold which is comprised of the following components:

1. THERMH₂OSORB™ CO₂ absorber canister (transparent, disposable)
2. Unidirectional Valves - inhalation and exhalation, transparent, non-interchangeable, (disinfectable), 360° swivel with 22 mm connectors.
4. Fresh gas supply hose to common fresh gas outlet (size specific connector and locking).
5. O₂ sensor port with adapters to accommodate sensors from various O₂ monitors.
6. Breathing circuit pressure monitoring hose connection to pressure gauge (size specific connector with safety lock) and locking connecting port for breathing system monitor.
7. APL (Adjustable Pressure Limiter) valve "pop-off" with 19 mm tube connector to scavenger system.

Provision is made for storage of a second THERMH₂OSORB™ canister in the OBA-1® Unit. During use, the active canister is easily viewed for color change of the absorbent granules indicating absorbent exhaustion. No tools are necessary to connect or disconnect the THERMH₂OSORB™ canister and the OBA-1® Unit. Installation of the backup canister can be accomplished in 15 - 20 seconds without concern for leaks developing. There is no water accumulation in the bottom of the THERMH₂OSORB™ absorbent canister during operation, as water vapor from the exothermic reaction of CO₂ absorption is added directly into the patient's inhalation gas, before con-
Densation can occur in the canister. Humidification of the patient is enhanced compared to conventional metallic CO₂ absorbers.

Both, the OBA-1⁰, OBA-1⁰MRI and THERMH₂OSORB™ system can function in closed, open or semi-closed breathing modes at appropriate gas flows.

The OBA-1™ MRI and THERMH₂OSORB™ CO₂ absorber system will accommodate many types of anesthesia breathing system including

1) Jackson-Rees, Mapleson, Magill, etc.
2) Coaxial circuits
3) Conventional circuits
4) Nasal cannulas

All components of the absorber system can be disinfected except for the THERMH₂OSORB™ canister, which is disposable.

For more details see the THERMH₂OSORB™ package insert.
Care of the Vaporizer
(Read the Vaporizer Manual included with the OBA-1® Units before using the Vaporizer)

Vaporizers are calibrated for a specific anesthetic agent. **Never** use a different agent than the one for which the vaporizer is specified. The use of the wrong agent may be detrimental to the patient. Prevent foreign matter from entering the vaporizer. Observe all instructions in the Vaporizer Manual.

**Before using the Vaporizer:**
(Excerpt from Vaporizer Manual - pages 7 and 8 - paragraphs 11 to 13)

1. **If a vaporizer is transported when filled with liquid drug, the control must be in the “0” (zero) position during transport and a period of at least two minutes in a secured upright position must elapse before connection to an anesthetic breathing system.** Movement during transport can result in an over-dosage unless time is allowed for drainage of liquid to the normal position. **If a vaporizer has been transported with the control in the open position it must be flushed at 5 L/min for 2 minutes before clinical use on a patient.**

2. **The vaporizer must not be tipped over or inverted.** If the vaporizer has been tipped over or inverted it must be set to maximum output and flushed at 5 L/min for 2 minutes before clinical use on a patient.

3. **The vaporizer must be securely fixed and in an upright position before connecting to a patient.** There is a danger of over-dosage if sudden inadvertent movement occurs during use.

**WARNING:** Always drain vaporizer completely before moving the unit and after ending anesthesia for the day!

Have vaporizer checked for accuracy in accordance with Vaporizer Manual instructions or immediately, if a malfunction is suspected.

There are no user serviceable parts in the vaporizer. Should the vaporizer require service, call the Customer Service Department of CARDINAL Medical Specialties, Inc. for information:

**Toll Free:** 1-800-443-5997
Disinfection of the OBA-1® and OBA-1®MRI Units and Accessories covering all internal parts of the Patient Breathing Circuit

Wear gloves, mask and eye protection for all disinfection procedures!

Disinfection of the OBA-1® and OBA-1®MRI CO₂ absorber system can be accomplished quickly and economically by using the methods shown in the chart below. The CO₂ absorber system can be separated into (5) five major components for ease and thoroughness of cleaning, disinfection and sterilization.

1. Absorber manifold (1) with APL valve assembly (reusable)
2. Inspiratory (1) and expiratory (1) directional valves (reusable)
3. THERMOH₂OSORB (1) CO₂ absorbent canister (disposable)
4. Patient breathing circuit (reusable or disposable)
5. Oxygen sensor (1)

* follow manufacturer's recommendation

<table>
<thead>
<tr>
<th>OBA-1® and OBA-1®MRI Components</th>
<th>Autoclaving</th>
<th>Liquid Disinfection</th>
<th>Bacteriostatic Wipes</th>
<th>Discard Safely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manifold with APL Valve</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inspiratory Valve/Expiratory Valve</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bag/Ventilator Switch Valve</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>THERM H₂OSORB™ CO₂ Canister</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Patient Breathing Circuit (reusable)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Breathing Circuit (disposable)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxygen Sensor*</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>External Surfaces of OBA-1® Units</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* follow manufacturer's recommendation
Hospital grade disinfectant solutions should be ready for use and have a broad spectrum of effectiveness. They must be bactericidal, virucidal, fungicidal and tuberculocidal.

A widely used hospital liquid disinfectant is CaviCide®.

Products containing glutaraldehyde are not recommended.

Liquid disinfectant agents should be safe for use on non-organic materials including plastics, stainless steel, brass, chrome, rubber, silicone, painted or anodized surfaces. Instruction for use of the liquid disinfectant must be followed closely.

Internal passageways of the absorber manifold are easily reached by the liquid disinfectant during the soak and rinse cycles of the disinfection process.

**Processing Procedure**

1) Remove the oxygen sensor (14), disconnect the fresh gas quick connector and pressure connector from the manifold.
2) Remove the 19 mm blue scavenger hose from APL valve (15) and scavenger system and discard safely.
3) Separate the OBA-1™ MRI manifold from the THERMH₂O-SORB™ CO₂ absorbent canister (18).
4) Remove the oxygen sensor (14) from manifold and disinfect surface with bacteriostatic wipe.
4) Remove the inspiratory (13) and expiratory (12) valves by pulling upwards while twisting.
5) Rinse and submerge valves and manifold in a germicidal solution, such as CaviCide®. Do not autoclave inspiratory and expiratory valves.
6) Wipe surface of the entire anesthesia apparatus with a germicidal solution or bacteriostatic wipes.
7) Reassemble all components and test OBA-1® or OBA-1®MRI Anesthesia Unit according to the checkout procedure on page III on the inside of the back cover.
OBA-1® and OBA-1®MRI
Parts and Accessories

Replacement Parts
- User replaceable -
(Numbers in parentheses indicate numbers of units included with purchase of OBA-1® and OBA-1®MRI)

(1) 10' Oxygen Pressure Hose with 2 female DISS Connectors
(1) 10' Air Pressure Hose with 2 female DISS Connectors
(1) Oxygen manifold for 2 E-cylinders with yoke/regulator and pipeline connection.
(1) Absorber System Manifold - complete
(1) Breathing System Pressure Gauge with Key Index Connector for OBA-1® and OBA-1®MRI
(1) Breathing Pressure Monitor Tubing with Key Index Connector
(1) 19 mm Hose Assembly, 36" long
(1) Rubber Plug for Oxygen Sensor Port
(1) Silicone Rubber O-Ring for Inspiratory Valve Port
(4) Silicone Rubber O-Rings for Expiratory Valve Port, Oxygen Sensor Port and THERMH2OSORB™ Connection Ports
(1) Low Pressure System Leak Test Bulb with Connector
(2†) THERMH2OSORB™ CO₂ Absorber Canisters
(1†) 12", 19 mm Corrugated Waste Gas Hose
(1‡) Inspiratory Valve Assembly
(1‡) Expiratory Valve Assembly
(† these items are disposable)
(‡ these items are reusable after disinfection and pressure testing)

Optional Items

A. Fresh Gas Hose Adapter for Nasal Cannulas
B. Fresh Gas Hose for Non-Rebreathing Circuits
C. Fresh Gas Hose for Oxygen Administration
D. Airway Pressure Sensing Tube with Luer Lock
E. Airway Pressure Transfer Tube
F. Airway Pressure Sensing Tube with Connector for plain Nipple
G. Dust Cover
H. Complete Set of Items A-G
a) Utility Shelf  7”x 14” (folds against back panel of OBA-1® Units)
b) Mobile Cart with fold-down handle and 4” casters (fits in car trunk)
c) Shipping, Storage, Security Case (standard)
d) Shipping, Storage, Security Case (lockable)
e) Waste Gas Suction Scavenging Manifold
f) Wall Mounting Shelf
g) Oxygen manifold for 2 E-cylinders with 2 yoke/regulators and pipeline connection
h) Medical air manifold for 1 E-cylinder with yoke/regulator and pipeline connection.
i) Medical air manifold for 2 E-cylinders with 2 yoke/regulators and pipeline connection
j) Oxygen manifold for 2 oxygen E-cylinders with yoke/regulator but no pipeline connection
k) Medical air manifold for 2 air E-cylinders with yoke/regulator but no pipeline connection
l) E-cylinder Yoke/Regulator Assembly for oxygen with male DISS connector
m) E-cylinder Yoke/Regulator Assembly for medical air with male DISS connector
n) H-cylinder Regulator for oxygen with male DISS connector
o) H-cylinder Regulator for medical air with male DISS connector
p) Gas Pressure Supply Hoses for oxygen with female DISS connectors on both ends (specify length)
q) Gas Pressure Supply Hoses for medical air with female DISS connectors on both ends (specify length)
r)* Ohmeda Key Index Oxygen Quick Connector for Wall Outlet
s)* Chemetron Key Index Oxygen Quick Connector for Wall Outlet
t) Oxygen Monitor with HI-LOW Alarms
u) Breathing System Pressure Monitor with HI-LOW Alarms

* Other Quick Connectors for Oxygen Wall Outlets are available - specify type

Note: Parts and Accessories may be ordered from CARDINAL Medical Specialties, Inc. or with a credit card from the “Catalog” page of the www.OBAMED.com Website.
<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>No gas flow to machine</td>
<td>Gas supply hose not connected</td>
<td>Connect gas supply hose to cylinder or central gas piping system and DISS connector of the anesthesia apparatus</td>
</tr>
<tr>
<td></td>
<td>Gas cylinder turned off</td>
<td>Turn on gas cylinder supply</td>
</tr>
<tr>
<td></td>
<td>Oxygen and/or air flow control valve (5a/5b) turned off</td>
<td>Turn on oxygen and/or air flowmeter control valve (5a/5b) and adjust flow rate</td>
</tr>
<tr>
<td>Gas flows, but breathing bag (21) will not inflate</td>
<td>Breathing bag (21) is leaking</td>
<td>Replace breathing bag (21), check bag mount (20) for leaks</td>
</tr>
<tr>
<td></td>
<td>APL valve (15) is opened completely</td>
<td>Turn APL valve (15) clockwise until breathing bag (21) begins to inflate</td>
</tr>
<tr>
<td>Gas flow not sufficient</td>
<td>Oxygen and/or air flow set too low</td>
<td>Increase oxygen and/or air flow rate (5a/5b)</td>
</tr>
<tr>
<td></td>
<td>Leak in patient breathing circuit</td>
<td>Check all hose connections, and fit around mask or endotracheal tube cuff</td>
</tr>
<tr>
<td>Oxygen or air flow control valve (5a or 5b) is hard to turn</td>
<td>Dirty or damaged needle valve</td>
<td>Flow valve needs cleaning or replacement</td>
</tr>
<tr>
<td>Oxygen or air pressure gauge(s) shows 50 psi, but there is no gas flow</td>
<td>Fresh gas hose(s) not properly connected</td>
<td>Check both ends of fresh gas hose(s) for proper connection. Open flowmeter valve</td>
</tr>
<tr>
<td><strong>Problem</strong></td>
<td><strong>Possible Cause</strong></td>
<td><strong>Solution</strong></td>
</tr>
<tr>
<td>------------</td>
<td>-------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Oxygen flush button (10) inoperative</td>
<td>Damaged flush valve (10)</td>
<td>Flush valve (10) needs cleaning or replacement</td>
</tr>
<tr>
<td>Very low or no anesthetic vapor output</td>
<td>Vaporizer (8) empty</td>
<td>Fill vaporizer (8)</td>
</tr>
<tr>
<td></td>
<td>Vaporizer (8) turned off</td>
<td>Turn anesthetic vaporizer (8) on</td>
</tr>
<tr>
<td></td>
<td>Vaporizer (8) malfunctions</td>
<td>Vaporizer (8) requires servicing - see manual</td>
</tr>
<tr>
<td></td>
<td>Vaporizer (8) too cold</td>
<td>Wait until vaporizer (8) has warmed up to operating temperature</td>
</tr>
<tr>
<td>APL valve (15) is hard to turn</td>
<td>APL valve (15) is dirty or damaged</td>
<td>APL (15) valve must be cleaned or repaired</td>
</tr>
<tr>
<td>Needle on cmH₂O (APG) pressure gauge (17) is not at &quot;0&quot; when all gases are turned off</td>
<td>cmH₂O (APG) gauge (17) needs to be adjusted</td>
<td>Carefully remove lens cover from cmH₂O airway pressure gauge (17). Adjust set screw with small screw driver to &quot;0&quot; position</td>
</tr>
<tr>
<td></td>
<td>Gauge has been overpressurized</td>
<td>Adjust or replace gauge as needed</td>
</tr>
<tr>
<td>Needle on cmH₂O (APG) pressure gauge (17) does not move</td>
<td>Mechanical damage to gauge</td>
<td>Replace cmH₂O pressure gauge (17)</td>
</tr>
<tr>
<td></td>
<td>Gauge not connected</td>
<td>Connect gauge</td>
</tr>
<tr>
<td></td>
<td>No pressure in patient system</td>
<td>Check for leaks in the patient breathing system</td>
</tr>
<tr>
<td>Problem</td>
<td>Possible Cause</td>
<td>Solution</td>
</tr>
<tr>
<td>---------</td>
<td>---------------</td>
<td>----------</td>
</tr>
<tr>
<td>Needle on (APG) cmH₂O pressure gauge (17) indicates several centimeters of positive pressure after expiration has ended</td>
<td>Constriction or obstruction downstream from APL valve (15)</td>
<td>Check scavenger hose for possible obstruction. Remove scavenger hose and drain moisture. Replace scavenger hose. Check charcoal canister for obstruction - replace, if necessary.</td>
</tr>
<tr>
<td></td>
<td>PEEP source active</td>
<td>Adjust or remove PEEP source</td>
</tr>
<tr>
<td></td>
<td>High O₂ flow</td>
<td>Adjust O₂ flow as necessary and/or check positive pressure relief valve and scavenger interface valve</td>
</tr>
<tr>
<td>Needle on (APG) cmH₂O pressure gauge (17) indicates a negative pressure after exhalation has ended</td>
<td>Too much vacuum on scavenger interface</td>
<td>If using active suction, decrease vacuum to scavenger interface. Check scavenger system bag. Bag should not totally deflate between breaths</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Check negative pressure relief valve in scavenger interface valve for malfunction or occlusion by foreign object, lint, etc.</td>
</tr>
</tbody>
</table>
Limited Five Year Warranty

All CARDINAL Medical Specialties, Inc. (hereafter called CARDINAL) products are guaranteed to be free of defects for a period of five (5) years from the date of delivery and shall include workmanship and material. The following are exceptions to this warranty:

1) Defects caused by misuse, mishandling or by modifications not authorized by CARDINAL.
2) Rubber and plastic components and materials are warranted to be free of defects at time of delivery.
3) Warranty for the anesthetic vaporizer depends on the type of vaporizer purchased and coincides with the warranty stated by the manufacturer of said vaporizer in the Vaporizer Manual accompanying the OBA-1® or OBA-1® MRI Anesthesia Unit.

Any product which proves to be defective in workmanship or material will be replaced, credited or repaired at the discretion of CARDINAL. CARDINAL is not responsible for normal deterioration, wear and tear or abuse. In any case, CARDINAL will not be liable beyond the original selling price.

Application of this warranty is subject to the following conditions:

1. CARDINAL must be promptly notified upon detection of the defective product or material.
2. If the defective product or material cannot be repaired at the customer's site, it must be returned to CARDINAL, shipping prepaid. Return shipping will be charged to the customer.
3. Examination of the product or material by CARDINAL must confirm that the defect is covered by the terms of this warranty.
4. Notification of the defective product or material must be received by CARDINAL no later than two (2) weeks following the expiration of this warranty.

In order to assure complete protection under this warranty, the Warranty Registration Card (if applicable) must be returned to CARDINAL within ten (10) business days of receipt of the product.

The above is the sole warranty provided by CARDINAL. No other warranty expressed or implied is intended. Representatives of CARDINAL or its agents are not authorized to modify the terms of this warranty.
Limitation of Liability

CARDINAL’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 CARDINAL’S Product Warranty, is subject to and limited to the exclusive terms and conditions as set forth above, whether based upon breach of warranty or any other cause of action whatsoever, regardless of any fault attributable to CARDINAL, and regardless of the form of action (including, without limitation, breach of warranty, negligence, strict liability or otherwise).

THE STATED EXPRESS WARRANTIES ARE IN LIEU OF ALL WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS OR ANY PARTICULAR PURPOSE OR NON-INFRINGEMENT. CARDINAL 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.

In the unlikely event of a disagreement, the place of venue is Louisville, Kentucky, U.S.A.
Gas Flow Concentrations and Conversions

Per Cent Oxygen Concentrations at various Oxygen/Air Flow Ratios

\[
\text{% Oxygen Concentration} = \frac{\text{Oxygen (L/min)} \times 100 + \text{Air (L/min)} \times 21}{\text{Total Liter Flow}}
\]

<table>
<thead>
<tr>
<th>Oxygen (L/min)</th>
<th>Air (L/min)</th>
<th>% Oxygen Concentr.</th>
<th>Oxygen (L/min)</th>
<th>Air (L/min)</th>
<th>% Oxygen Concentr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>.3</td>
<td>10.0</td>
<td>23.3%</td>
<td>.3</td>
<td>1.0</td>
<td>39.2%</td>
</tr>
<tr>
<td>.5</td>
<td>10.0</td>
<td>24.8%</td>
<td>.5</td>
<td>1.0</td>
<td>47.3%</td>
</tr>
<tr>
<td>.8</td>
<td>10.0</td>
<td>26.9%</td>
<td>.8</td>
<td>1.0</td>
<td>56.1%</td>
</tr>
<tr>
<td>1.0</td>
<td>10.0</td>
<td>28.2%</td>
<td>1.0</td>
<td>1.0</td>
<td>60.5%</td>
</tr>
<tr>
<td>2.0</td>
<td>10.0</td>
<td>34.2%</td>
<td>1.0</td>
<td>2.0</td>
<td>47.3%</td>
</tr>
<tr>
<td>3.0</td>
<td>10.0</td>
<td>39.2%</td>
<td></td>
<td>3.0</td>
<td>40.8%</td>
</tr>
<tr>
<td>4.0</td>
<td>10.0</td>
<td>43.6%</td>
<td>1.0</td>
<td>4.0</td>
<td>36.8%</td>
</tr>
<tr>
<td>5.0</td>
<td>10.0</td>
<td>47.3%</td>
<td>2.0</td>
<td>1.0</td>
<td>73.7%</td>
</tr>
<tr>
<td>6.0</td>
<td>10.0</td>
<td>50.6%</td>
<td>2.0</td>
<td>2.0</td>
<td>60.5%</td>
</tr>
<tr>
<td>7.0</td>
<td>10.0</td>
<td>53.5%</td>
<td>2.0</td>
<td>3.0</td>
<td>52.6%</td>
</tr>
<tr>
<td>8.0</td>
<td>10.0</td>
<td>56.1%</td>
<td></td>
<td>1.0</td>
<td>80.3%</td>
</tr>
<tr>
<td>9.0</td>
<td>10.0</td>
<td>58.4%</td>
<td>3.0</td>
<td>2.0</td>
<td>68.4%</td>
</tr>
<tr>
<td>10.0</td>
<td>10.0</td>
<td>60.5%</td>
<td>3.0</td>
<td>3.0</td>
<td>60.5%</td>
</tr>
</tbody>
</table>

Factors:

- 1 atm = 1,033 cmH₂O = 760 mmHg = 760 Torr = 1.013 mb = 14.7 psi
- 1 psi = 70.3 cmH₂O = 51.7 mmHg = 68.9 mb = 6.9 kPa
- 1 mmHg = 1.36 cmH₂O = 1.02 mb
- 1 cmH₂O = 0.736 Hg = 0.981 mb
Use of the OBA-1® MRI Unit in a Scan Room

The OBA-1® MRI Unit can be safely used in a MRI scan room with shielded or unshielded magnets up to 1.5 tesla. The OBA-1® MRI Unit may be placed within the 5 Gauss line immediately next to the patient, without interfering with the surgical or the scanning procedure. The OBA-1® MRI Unit was successfully tested at Norton Hospital in Louisville, Kentucky and at the University of Kentucky Medical Center in various MRI scanner Models (Picker Open System, GE Signa, SP, GE Signa Lx, GE Signa CV and Siemens Symphony Magnetom) at 0.2, 0.5, 1.0 and 1.5 tesla.

WARNING

The oxygen supply regulator-yokes and aluminum cylinders shall always be placed outside the 5 Gauss line, up to 25 feet from the OBA-1® MRI. The OBA-1® MRI oxygen manifold may be connected to the pipeline supply, with the 25' pressure hose connected to the regulator-yoke. If the walls of the MRI scan room represent the 5 Gauss line, the regulator-yokes and aluminum cylinders should be located on the outside of these walls. This may require feeding the gas supply pressure hoses through an existing opening in the wall or the doorway to the outside of the MRI scan room before connecting them to the gas source (see figure below).

Location of emergency oxygen back-up yoke regulators and aluminum cylinders located outside the 5 Gauss line up to 25' from the OBA-1® MRI unit when piped medical gases are not available or fail in the MRI scan room.
OBA-1<sup>®</sup> MRI Test Results
GE Signa CV Shielded Scanner; 1.5 tesla - 8 KW

<table>
<thead>
<tr>
<th>Parameter</th>
<th>High SAR scan; TG=190</th>
<th>High Gradient scan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Avg. SAR=0.9948</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Peak SAR=1.9896</td>
<td></td>
</tr>
<tr>
<td>TE</td>
<td>minfull</td>
<td>min</td>
</tr>
<tr>
<td>TR(ms)</td>
<td>234</td>
<td>261</td>
</tr>
<tr>
<td>ETL</td>
<td>24</td>
<td>N/A</td>
</tr>
<tr>
<td>Flip Angle</td>
<td>90</td>
<td>30</td>
</tr>
<tr>
<td>RBW</td>
<td>31.25</td>
<td>2</td>
</tr>
<tr>
<td>FOV(cm)</td>
<td>48</td>
<td>1</td>
</tr>
<tr>
<td>Slice thickness</td>
<td>5.5</td>
<td>1.0</td>
</tr>
<tr>
<td>Matrix</td>
<td>256 x 256</td>
<td>512 x 512</td>
</tr>
<tr>
<td>NEX</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Phase FOV</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>O₂ - L/min:</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>5.0</td>
<td>5.0</td>
</tr>
<tr>
<td></td>
<td>10.0</td>
<td>9.9</td>
</tr>
<tr>
<td>Air - L/min:</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>5.0</td>
<td>4.9</td>
</tr>
<tr>
<td></td>
<td>10.0</td>
<td>10.0</td>
</tr>
<tr>
<td>Vol% concentr.</td>
<td>1.0</td>
<td>1.09 (+0.9%)</td>
</tr>
<tr>
<td></td>
<td>3.5</td>
<td>3.81 (+8.9%)</td>
</tr>
<tr>
<td></td>
<td>6.0</td>
<td>7.63 (+27.2%)</td>
</tr>
</tbody>
</table>

Degradation: None  Artifacts: None

The air and oxygen flowmeters, the flush valve and the pneumatic oxygen alarm performed correctly as specified after the exposure to the shielded magnet of the 8KW, 1.5 tesla GE Signa CV Scanner.

The vol% output of the Sigma Elite® vaporizer corresponded again with the vaporizer settings after the exposure to the magnet, while the output of the vaporizer increased from 0.9 vol% at the 1.0% setting to 27.2% at the 6.0% setting during exposure to the magnetic field. This coincides with the findings of the manufacturer of the vaporizer.
Pre-use Checkout Procedure for OBA-1® & OBA-1® MRI Units

Format recommended by the U.S. Food and Drug Administration

1. *Verify that backup ventilation equipment is available and functional.
2. *Disconnect fresh gas hose quick connector on top of OBA-1® & OBA-1® MRI Unit. Squeeze suction bulb completely flat. Attach suction bulb to common gas outlet. Release pressure on the bulb which should remain in its flattened state for at least 10 seconds. Remove suction bulb and reconnect fresh gas hose.
3. *Close oxygen/air flow control valves and turn vaporizer off. Fill vaporizer, check fill level and tighten filler and drain plugs.
4. *Connect high pressure oxygen and air hoses to DISS inlets. Oxygen and air pipeline pressure gauges should read between 45 and 55 psi.
5. *Open cylinder and verify at least half full for E-cylinder (about 1,100 psi, ~ 315 liters) or at least 500 psi for H-cylinder (about 1,550 liters).
6. *Turn oxygen and air supply on, adjust flow through the full range of both flowmeters, checking for smooth operation of floats and undamaged flow tubes, then turn flowmeters off.
7. *Ensure proper connection between APL valve and active suction system valve.
8. *Check oxygen monitor batteries. Remove oxygen sensor from manifold block and ensure that the monitor reads 21% oxygen concentration in room air. Verify that low O₂ alarm is enabled and functioning. Reinstall O₂ sensor in manifold block and flush breathing system with oxygen. Verify that monitor reads greater than 90% O₂.
9. Check that breathing circuit is complete and unobstructed. Verify that CO₂ absorbent in THERMH₂OSORB™ is adequate, if canister has been previously used.
10. Set gas flow to zero, close APL valve and attach Y-piece to test port. Pressurize breathing system to about 30 cmH₂O with oxygen flush. Ensure that pressure remains steady for at least 10 seconds. Open APL valve and ensure that pressure decreases.
11. Remove Y-piece from test port and attach a second breathing bag to Y-piece and set oxygen flow to 5 L/min. Ventilate manually and assure proper inflation and deflation of artificial lungs (second breathing bag). Check for proper action of unidirectional valves. Test by squeezing the breathing bag for appropriate feel of system for resistance and compliance. Remove second breathing bag from Y-piece.
12. Check, calibrate and set alarm limits for all monitors.
13. Turn vaporizer off, open APL valve, turn flowmeters to zero and activate oxygen flush for 3 seconds.

* (If an anesthesia provider uses the same anesthesia unit in successive cases, these steps need not to be repeated after the initial checkout.)
WARNING
Tilting the vaporizer while moving the anesthesia machine can result in patient injury or death.

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

The OBA-1® MRI is intended for administration of general inhalation anesthesia using mixtures of oxygen, air, and volatile anesthetics, and for providing breathing gas, and for either spontaneous ventilation or controlled ventilation of patients lungs.

Visit our Website
www.OBAMED.com

Composition, Design and Layout
Klaus O. Becker, RRT
Bardstown, KY 40004
502-349-9390

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