CLEARMATE™

Operator's Manual

THORNHILL
MEDICAL

Publishers Notice

Manual Part Number: 122518

PUBLISHED BY:

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SECTION 1

Manufacturer's Contact Information

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Technical Support

For technical support, please contact your local distributor or Thornhill Research Inc. See back cover of manual for contact information.

Intended Use

The ClearMate™ System, including both a ClearMate™ Device and ClearMate™ Breathing Circuit, is a volatile agent washout system intended to enhance the elimination of volatile hydrocarbons such as carbon monoxide and anaesthetic agents from the blood through the administration of isocapnic hyperpnea.

Intended Environment

The ClearMate™ System is intended to be used in:

- Emergency departments
- Operating rooms
- Ambulances
- At the scene of an emergency

Intended Patient Population

- > 20 kg

Intended Users

The ClearMate™ System is intended to be used by:

- Physicians
- Anesthesiologists
- Emergency medical technicians (EMT)

Potential Side-Effects

The ClearMate™ induces hyperventilation and administers oxygen and carbon dioxide gas. Use of the ClearMate™ System may produce shortness of breath, sweating, nausea, and headache.

Restriction Notice

The ClearMate™ is a medical device intended for use only by or under the order of a physician.

Regulatory Compliance

CE
2797

The ClearMate™ complies with the Medical Device Directive MDD 93/42/EEC and carries the CE mark as shown.

Device Information

Device Name: Clearmate™ Volatile Agent Washout System
Device Model Number: 122549 (DISS)

PHT
DEHP

Device and circuits may contain Phthalates.

Disposal Instructions

The ClearMate™ and its components are not suitable for regular trash disposal. Follow local guidelines for proper disposal of medical devices.

Serious Incident Reporting Notice

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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SECTION 2

Product Description

The ClearMate™ volatile agent washout system requires a high-pressure O_2 source, a high-pressure CO_2 gas source, and consists of a blender to produce a six-percent (6%) CO_2-in-O_2 mixture, a demand valve, an O_2 flow meter and a breathing circuit. There are separate breathing circuits for spontaneously breathing and non-spontaneously breathing patients. Each circuit is comprised of a series of valves, an oxygen reservoir, a mask, and hoses. For non-spontaneously breathing patients, the circuit also contains a self-inflating resuscitator bag.

The O_2 flow valve is set to a predetermined clinical alveolar ventilation as the base filling flow for the patient-circuit reservoir. Any additional minute ventilation by the patient (or manually delivered) is supplied by the 6% CO_2 / 94% O_2 mixture from the demand valve. The ClearMate™ maintains a constant $PaCO_2$ while enabling increased minute ventilation (isocapnic hyperpnea) in both spontaneously breathing and manually ventilated patients. This procedure augments the washout of volatile toxic agents such as carbon monoxide, as well as anesthetics.

	**WARNING! OXYGEN VIGOROUSLY ACCELERATES COMBUSTION. TO AVOID EXPLOSION HAZARD, DO NOT USE THE CLEARMATE™ WITH ANY INSTRUMENT OR EQUIPMENT THAT MAY HAVE BEEN EXPOSED TO OIL OR GREASE CONTAMINATION.**
	**WARNING! FIRE HAZARD. DO NOT SMOKE NEAR UNIT. DO NOT OPERATE NEAR OPEN FLAME.**
	**WARNING! WHEN PROVIDING TREATMENT TO A NON-SPONTANEOUSLY BREATHING PATIENT USING THE CLEARMATE™ NON-SPONTANEOUS BREATHING PATIENT CIRCUIT, CO2 MONITORING EQUIPMENT FOR THE MEASUREMENT OF EXPIRATORY CARBON DIOXIDE CONCENTRATION IN ACCORDANCE WITH ISO 80601-2-55 MUST BE USED (ISO 80601-2-12).**

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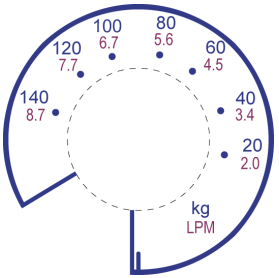
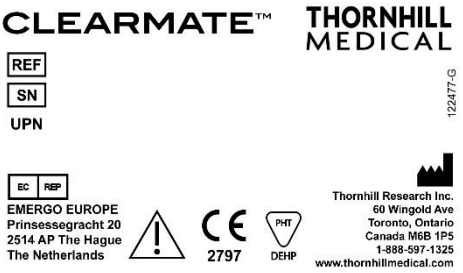
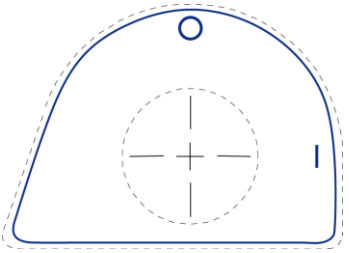
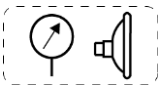
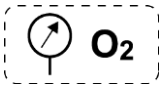
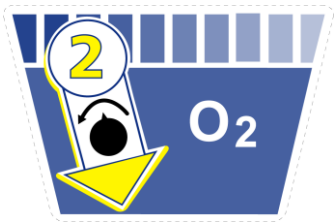
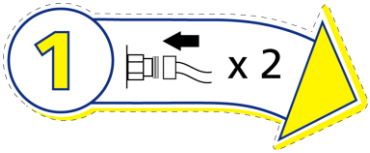
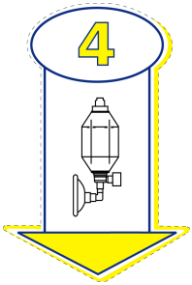
SECTION 3

Product Labeling

The following table illustrates the labels that are present on the ClearMate™. The majority of the labels are not shown in actual size.

Name / Description	Label Image
Product Name and Manufacturer Label Also includes patent information.	
O_2 Flow Control Label Weight values are shown in kilograms in blue. Flow values are shown in Liters per Minute in maroon.	
Product Identification Label Product numbering (when added) is shown in both numerical and bar-code format.	

Name / Description	Label Image
CO_2 Supply Valve Label "**O**" indicates "Off". "**I**" indicates "On".	
CO_2 Gauge Pressure Label Green area represents required pressure.	
O_2 Gauge Pressure Label Green area represents required pressure.	
CO_2 Supply Line Label Indicates that input pressure should be between 35–95 psig / 2.4–6.5 bar.	
O_2 Supply Line Label Indicates that input pressure should be between 47–95 psig / 3.2–6.5 bar.	
Airway Pressure Gauge Label	

CO_2 Pressure Gauge Label	
Name / Description	**Label**
O_2 Inlet Pressure Gauge Label	
O_2 Flow Setting Label	
CO_2 Supply On/Off Label	
Connect O_2 & CO_2	
Turn On CO_2	
Attach Patient Circuit	

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SECTION 4

Product Specifications

- Gas Supply to Device Fittings:
    - Clean and dry 100% Medical Grade CO_2 and 100% O_2
    - O_2 Pressure: 47–95 psig / 3.2–6.5 bar
    - CO_2 Pressure: 35–95 psig / 2.4–6.5 bar
- Gas Pressure Gauges – Range – 0 to 100 psig / 7 bar. Accuracy ± 2 psig / 0.4 bar.
- CO_2/O_2 Blender – Fixed at 6% CO_2, balance O_2. Accuracy ± 1% absolute.
- O_2 Flow valve – up to 8.7 LPM. Accuracy ± 12%.
- Combined demand flow available is 100 LPM at stated inlet gas pressures.
- Airway Pressure Gauge: -10 to 120 cmH_20; -1 to 12 kPa. Accuracy ± 5%.
- Physical Characteristics:
    - Dimensions: 13 x 15.25 x 4.5 in (33 x 39 x 11 cm)
    - Weight: 13.6 lb (6.2 kg)

Environmental Specifications

Variable	Storage Condition	Operating Condition
Temperature	-20°C to 60°C	+5°C to 40°C
Relative Humidity	10–90% RH	30–75% RH
Water Resistance/IP Rating	IPX4 level	IPX4 level
Vibration	10–150 Hz	10–150 Hz
Shock Resistance	15 g	15 g

Variable	Storage Condition	Operating Condition
Altitude	ClearMate™ has been validated at approximately sea level. As altitude increases, the device will provide less CO_2 to the patient and the patient may become hypocapnic. At any altitude, the device will maintain $PaCO_2$ closer to normocapnia than the administration of 100% O_2, which is the alternative standard of care.	

SECTION 5

About Warnings and Cautions

ClearMate™ is a medical device intended for use only by or under the order of a physician.

Personnel operating this equipment are responsible for reading and thoroughly understanding all product documentation provided. Service of this instrument is restricted to trained personnel only.

Statements throughout the product documentation have special significance as explained in the following table.

Icon & Type	Explanation
 **NOTE:**	*Notes are used to call attention to statements pertaining to more efficient or convenient operation or service of the equipment.*
 **CAUTION!**	**A CAUTION INDICATES THAT THERE IS A POSSIBILITY OF DAMAGE TO THE PRODUCT OR OTHER EQUIPMENT ATTACHED TO IT.**
 **WARNING!**	**A WARNING MEANS THAT THERE IS A POSSIBILITY OF PERSONAL INJURY TO THE OPERATOR OR PATIENT.**

A summary of all Cautions and Warnings used in this document follows.

Warnings

	**WARNING! DO NOT OPERATE THE CLEARMATE™ UNLESS QUALIFIED PERSONNEL ARE IN ATTENDANCE TO RESPOND TO ALARMS. PATIENTS ON LIFE-SUPPORT EQUIPMENT MUST BE MONITORED AT ALL TIMES.**
	**WARNING! LIQUIDS OR OTHER CONTAMINANTS IN EITHER GAS SUPPLY MAY CAUSE MALFUNCTION OF THIS EQUIPMENT.**
	**WARNING! THE GAS BLENDER INCORPORATED IN THIS PRODUCT IS DESIGNED TO MIX CO_2 AND O_2 ONLY. DO NOT MODIFY THE INLETS TO ACCOMMODATE OTHER SOURCE GASES.**
	**WARNING! THE GAS FAILURE ALARM WILL NOT SOUND IF BOTH SUPPLY GASES ARE BELOW 30 PSIG / 2.0 BAR.**
	**WARNING! OXYGEN VIGOROUSLY ACCELERATES COMBUSTION. TO AVOID EXPLOSION HAZARD, DO NOT USE THE CLEARMATE™ WITH ANY INSTRUMENT OR EQUIPMENT THAT MAY HAVE BEEN EXPOSED TO OIL OR GREASE CONTAMINATION.**
	**WARNING! NO PATIENT CIRCUITS OTHER THAN CLEARMATE™ BREATHING CIRCUITS SHOULD BE USED WITH THE CLEARMATE™.**
	**WARNING! DO NOT TOUCH CO_2 "SNOW" OR CO_2 TANK WITH EXPOSED SKIN.**
	**WARNING! THE CLEARMATE™ IS A MEDICAL DEVICE INTENDED FOR USE ONLY BY OR UNDER THE ORDER OF A PHYSICIAN.**
	**WARNING! FIRE HAZARD. DO NOT SMOKE NEAR UNIT. DO NOT OPERATE NEAR OPEN FLAME.**
	**WARNING! ENSURE THAT INPUT GAS PRESSURES ARE WITHIN THE LIMITS SPECIFIED IN THE DEVICE SPECIFICATIONS AND LABELLED ON THE DEVICE GAS INLETS. USE OF GASES WITH PRESSURES OUTSIDE OF THIS RANGE COULD RESULT IN INCORRECT OPERATION INCLUDING THE DELIVERY TO THE PATIENT OF A HAZARDOUS GAS MIXTURE.**

	**WARNING! DO NOT BLOCK CIRCUIT EXHALATION PORT OR OVERFILL RELIEF.**
	**WARNING! ENSURE THE O_2 RESERVOIR IS FREE TO INFLATE AND MONITOR THE O_2 RESERVOIR FOR INFLATION AND DEFLATION. IF INFLATION AND DEFLATION IS NOT OBSERVED, CHECK O_2 SETTINGS.**
	**WARNING! DO NOT USE THE CLEARMATE™ IF DAMAGED.**
	**WARNING! CLEARMATE™ AND ITS ACCESSORIES MAY CONTAIN PHTHALATES. PHTHALATES ARE CLASSIFIED AS CARCINOGENIC, MUTAGENIC OR TOXIC TO REPRODUCTION. IN ORDER TO REDUCE THE POTENTIAL RISK FROM PHTHALATES, LONG TERM EXPOSURE SHOULD BE AVOIDED IN THE TREATMENT OF CHILDREN AND PREGNANT OR NURSING WOMEN.**
	**WARNING! WHEN PROVIDING TREATMENT TO A NON-SPONTANEOUSLY BREATHING PATIENT USING THE CLEARMATE™ NON-SPONTANEOUS BREATHING PATIENT CIRCUIT, CO2 MONITORING EQUIPMENT FOR THE MEASUREMENT OF EXPIRATORY CARBON DIOXIDE CONCENTRATION IN ACCORDANCE WITH ISO 80601-2-55 MUST BE USED (ISO 80601-2-12).**

Cautions

	**CAUTION! DO NOT IMMERSE ANY PART OF THE CLEARMATE™ IN LIQUID. DO NOT AUTOCLAVE. DAMAGE WILL RESULT.**

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SECTION 6

ClearMate™ Components

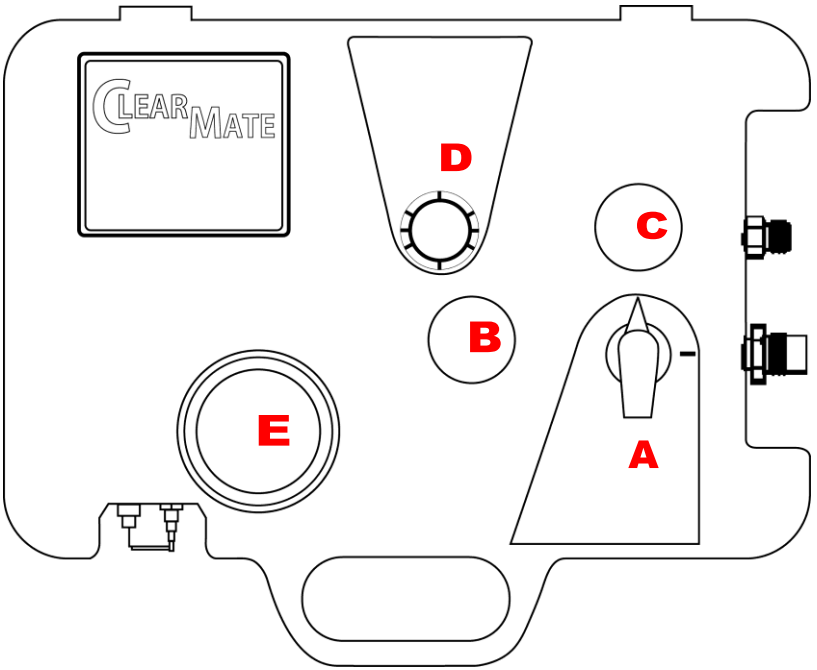

Figure 1: Front Panel Controls

Front Panel Controls	
Label	**Control / Gauge**
A	Carbon Dioxide (CO_2) Gas On/Off Switch
B	Carbon Dioxide (CO_2) Gas Pressure Gauge
C	Oxygen (O_2) Gas Pressure Gauge
D	O_2 Flow Control (kg / LPM) Knob
E	Airway Pressure Gauge

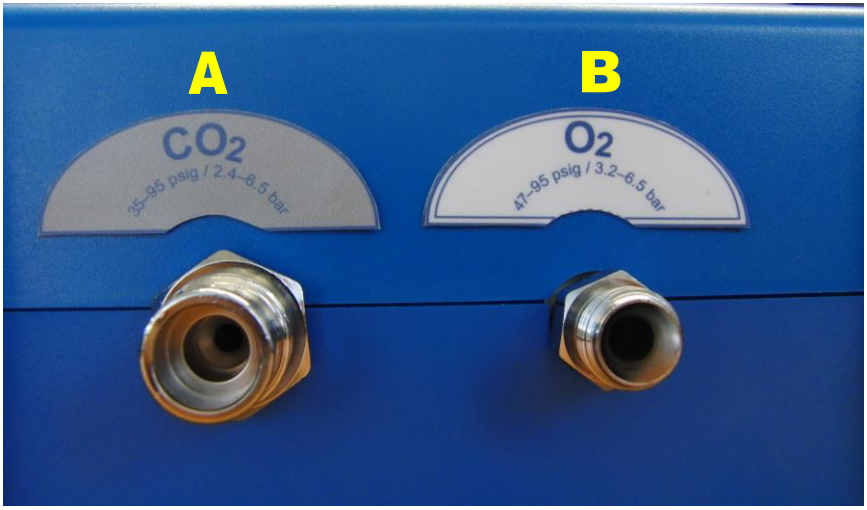

Figure 2: Right-Side Panel Connections

	NOTE: *In photo above, DISS fittings are shown. Right-side panel connections will vary depending on fitting type used.*

Right-Side Panel Connections	
Label	**Connection**
A	100% CO_2 Gas Inlet (35–95 psig / 2.4–6.5 bar)
B	100% O_2 Gas Inlet (47–95 psig / 3.2–6.5 bar)

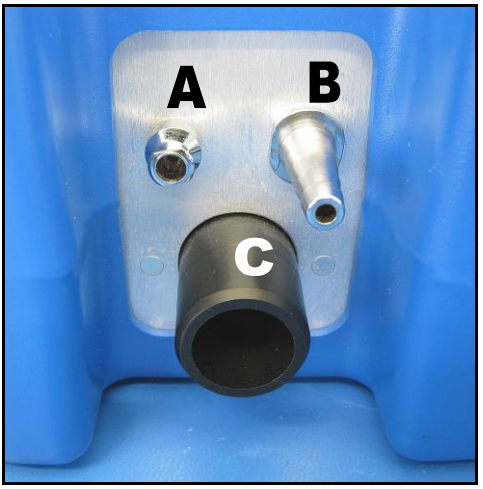

Figure 3: System Circuit Connections

System Circuit Connections	
Label	**Connection**
A	Airway Pressure Sensor Line Inlet
B	Oxygen Flow Outlet Port
C	Demand Valve Outlet Port

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SECTION 7

Operating Instructions Overview

The ClearMate™ maintains an approximately constant arterial CO2 partial pressure (PaCO2) irrespective of patient ventilation by the setting of a baseline O2 flow which, in this system, is equal to resting alveolar ventilation. Any additional gas flow required to meet the patient ventilation is made up with a 6% CO2 / 94% O2 mixture. This enables the increased ventilation for the purpose of increasing the washout of volatile toxic agents without undue reduction in PaCO2.

	**WARNING! THE GAS BLENDER INCORPORATED IN THIS PRODUCT IS DESIGNED TO MIX CO_2 AND O_2 ONLY. DO NOT MODIFY THE INLETS TO ACCOMMODATE OTHER SOURCE GASES.**
	**WARNING! DO NOT TOUCH CO_2 "SNOW" OR CO_2 TANK WITH EXPOSED SKIN.**

	**NOTE***:* The breathing circuits for use with ClearMate™ are single use.

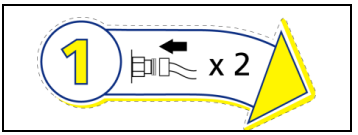
Instructions for Use of Isocapnic Hyperpnea (IH) to Accelerate the Elimination of Volatile Hydrocarbons

	**WARNING! DO NOT USE THE CLEARMATE™ IF DAMAGED.**

Firmly mount the ClearMate™ onto the ClearMate™ stand, or place it securely on a flat, hard surface.

1) Connect one end of the O_2 hose to the O_2 inlet fitting on the ClearMate™ (*labelled B in Figure 2*). Connect the other end to a clean, dry medical-grade O_2 supply. Ensure supply is delivering O_2 at a pressure between 47-95psi.

Connect one end of the CO_2 hose to the CO_2 inlet fitting on the ClearMate™ (*labelled A in Figure 2*). Connect the other end to a clean, dry medical-grade CO_2 supply – do not turn on CO_2 supply yet.



2) Set the oxygen flow to match the patient's estimated resting minute ventilation (minute ventilation estimations based on lean body weight are provided as a guidance in Table 1 and on the device label).

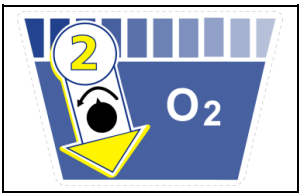


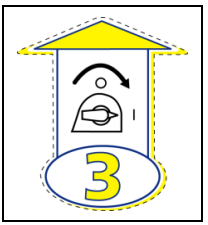
Table 1, which follows, illustrates the general relationship between alveolar ventilation, as determined by the O_2 flow setting, and patient lean body weight. The O_2 gas flow when adjusted to the appropriate table value should achieve a target $PetCO_2$ of 45-50 mmHg.

Table 1: O_2 Flow Settings

O_2 Flow Settings	
Weight (kg)	**Litres Per Minute (LPM)**
20	2.1
40	3.4
60	4.5
80	5.6
100	6.7
120	7.7
140	8.7

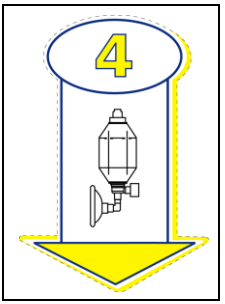
	WARNING! ENSURE THE O_2 RESERVOIR IS FREE TO INFLATE AND MONITOR THE O_2 RESERVOIR FOR INFLATION AND DEFLATION. IF INFLATION AND DEFLATION IS NOT OBSERVED, CHECK O_2 SETTINGS.

3) Press in the CO_2 ON/OFF switch and turn it clockwise to the ON position. Ensure CO_2 supply is delivering CO_2 at a pressure between 35-95psi. Monitor the CO_2 pressure gauge periodically throughout the administration of treatment.



	NOTE*: The gas failure alarm will activate if the CO2 gas is connected first, and the CO2 control is ON. The alarm will reset upon connection of the O2 supply gas.*

4) Attach circuit.



a) Non-Spontaneous Breathing Patient Circuit (see illustration on page 32)

i) Attach O_2 tubing to O_2 Flow Outlet port on the system unit (*labelled B on Figure 6*).

ii) Attach 22 mm corrugated tubing to Demand Valve Outlet Port on box (*labelled C on Figure 6*).

iii) Attach airway pressure sensor line to Airway Pressure Sensor Line Inlet (*labelled A on Figure 6*).

iv) Connect CO_2 monitoring equipment to the circuit for the measurement of expiratory carbon dioxide concentration (in accordance with ISO 80601-2-55):

(1) Using a side-stream CO_2 monitor: Connect side-stream CO_2 monitor respiratory gas sampling line to the sample port located on the proximal side of the manual resuscitator component of the circuit as shown in Figure 4: (on page 26).

(2) Using an in-line CO_2 monitor: Disconnect the patient mask from the elbow fitting and connect CO_2 respiratory gas monitor in-line between these two components as shown in Figure 5: (on page 27).

v) Manually ventilate the patient. Note that if patient's ventilation rate can be safely increased, doing so will increase the rate of elimination of the volatile hydrocarbon.

For CO elimination, manually ventilate the patient at their resting tidal volume with an increased frequency of approximately 20 breaths per minute[1].

	**NOTE***: The patient pCO_2 must be continuously monitored using a respiratory gas monitor to ensure that it remains at a clinically safe level as determined by the attendant healthcare practitioner; if not, discontinue treatment with ClearMate™.*

b) Spontaneous Breathing Patient Breathing Circuit (see illustration on page 30)

i) Attach O_2 tubing to O_2 Flow Outlet on the system unit (*labelled B on Figure 6*).

[1] Becker HF, Polo O, McNamara SG, Berthon-Jones M, Sullivan CE. Effect of different levels of hyperoxia on breathing in healthy subjects. J.Appl.Physiol. 1996;81:1683-1690.

ii) Attach 22 mm corrugated tubing to Demand Valve Outlet Port on box (*labelled C on Figure 6*).

iii) Use occlusive mask to prevent leaks on inspiration.

iv) If the patient is awake and cooperative, the patient should spontaneously hyperventilate as pure oxygen causes some hyperventilation. If patient pCO_2 is prevented from falling (via the ClearMate™), patient ventilation will spontaneously increase by 200-300% without any further actions[1, 2].

If required, the attendant can coach the patient to increase their minute ventilation by breathing "harder" (taking deeper breaths) and by breathing at a higher frequency. If the ventilation of the patient is depressed, or a greater rate of elimination is desired, use the Non-Spontaneous Breathing Patient Circuit to manually assist ventilation.

	**NOTE***: When treating spontaneously breathing patients with the Spontaneous Breathing Patient Breathing Circuit, the monitoring of the patient's pCO_2 using a respiratory gas monitor is not required but is recommended.*

5) Patient blood gas measurements (CO or carboxyhemoglobin) will indicate the duration of treatment. In the absence of such data, the half-time of elimination of CO with isocapnic hyperpnea is approximately 30 minutes[3,4], with males being somewhat longer than females[5]. The first 30 minutes of treatment is the most effective in CO elimination. However, the duration of treatment may be prolonged to get additional elimination.

[2] Becker H, Polo O, McNamara SG, Berthon-Jones M, Sullivan CE. Ventilatory response to isocapnic hyperoxia. J.Appl.Physiol. 1995;78:696-701.

[3] Takeuchi A, Vesely A, Rucker J, Sommer LZ, Tesler J, Lavine E, et al. A simple "new" method to accelerate clearance of carbon monoxide. Am.J.Respir.Crit Care Med. 2000;161:1816-1819.

[4] Anand JK, Crabbe GG, Dunbar EM, Farrell MH, Pooley J, Roles N. Hyperbaric oxygen for carbon monoxide poisoning in England. British Medical Journal. 1988;296.

[5] Zavorsky GS, Tesler J, Rucker J, Fedorko L, Duffin J, Fisher JA. Rates of carbon monoxide elimination in males and females. Physiological reports. 2014;2.

	NOTE: *For those with severe clinical symptoms, the recovery of consciousness or mental abilities can be used as a milestone for the duration of treatment. High blood levels of CO may occur in the absence of neurological symptoms. There is no adverse effect of administering the ClearMate™ in the absence of CO poisoning. There is also no harm in sustaining mild hyperventilation with the ClearMate™.*

Figure 4: Sidestream Gas Analyzer Attachment Point

Figure 5: In-line Gas Analyzer Attachment Point

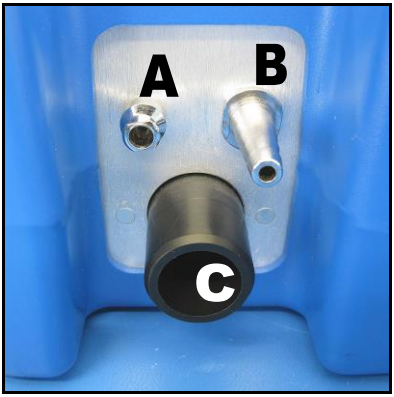


Figure 6: System Circuit Connections

	**WARNING! THE GAS FAILURE ALARM WILL NOT SOUND IF BOTH SUPPLY GASES ARE BELOW 30 PSIG / 2.0 BAR.**
	**WARNING! DO NOT OPERATE THE CLEARMATE™ UNLESS QUALIFIED PERSONNEL ARE IN ATTENDANCE TO RESPOND TO ALARMS. PATIENTS ON LIFE-SUPPORT EQUIPMENT MUST BE MONITORED AT ALL TIMES.**

	**WARNING! WHEN PROVIDING TREATMENT TO A NON-SPONTANEOUSLY BREATHING PATIENT USING THE CLEARMATE™ NON-SPONTANEOUS BREATHING PATIENT CIRCUIT, CO2 MONITORING EQUIPMENT FOR THE MEASUREMENT OF EXPIRATORY CARBON DIOXIDE CONCENTRATION IN ACCORDANCE WITH ISO 80601-2-55 MUST BE USED (ISO 80601-2-12).**

	**NOTE***: When ClearMate™ is not in use, ensure that the CO_2 ON/OFF switch is turned OFF, the O_2 flow control is turned below 2 LPM, and that the gas sources are turned off or disconnected.*

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SECTION 8

Patient Circuit Diagrams

Spontaneous Breathing Patient Circuit

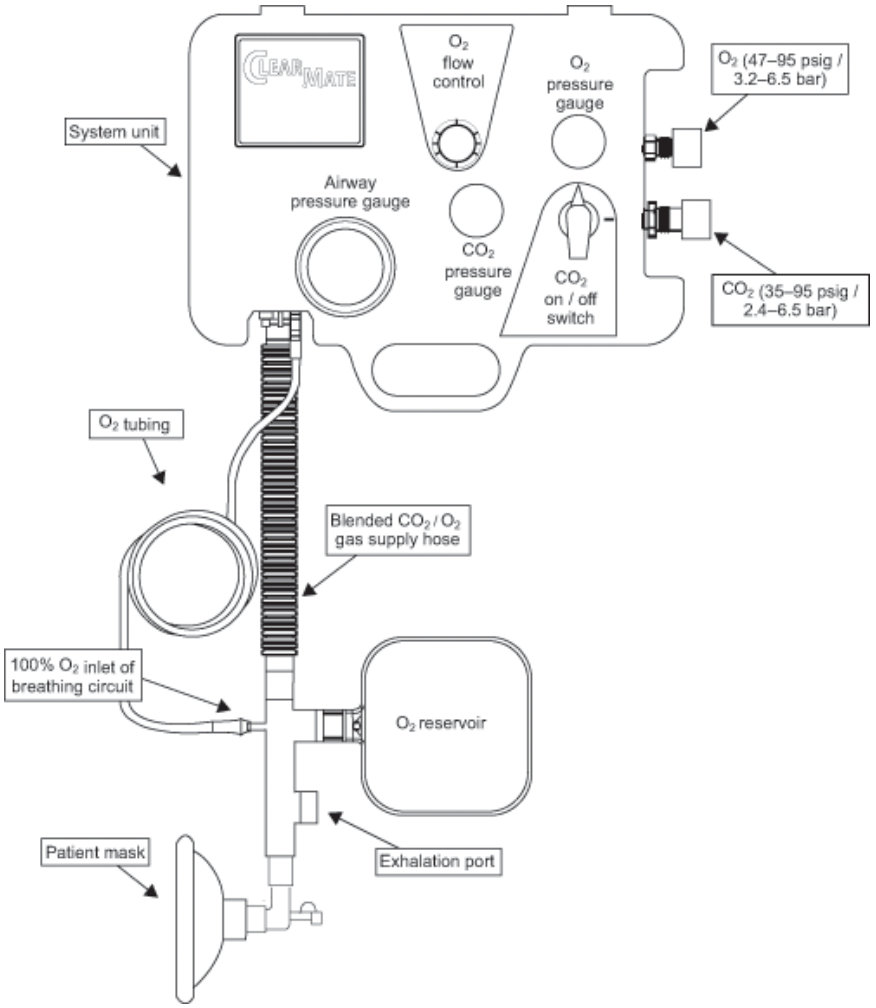

Figure 7: Spontaneous Breathing Patient Circuit

	**WARNING! ENSURE THAT INPUT GAS PRESSURES ARE WITHIN THE LIMITS SPECIFIED IN THE DEVICE SPECIFICATIONS AND LABELLED ON THE DEVICE GAS INLETS. USE OF GASES WITH PRESSURES OUTSIDE OF THIS RANGE COULD RESULT IN INCORRECT OPERATION INCLUDING THE DELIVERY TO THE PATIENT OF A HAZARDOUS GAS MIXTURE.**
	**WARNING! DO NOT BLOCK CIRCUIT EXHALATION PORT.**

	**NOTE***:* The breathing circuits for use with ClearMate™ are single use.

Non-Spontaneous Breathing Patient Circuit

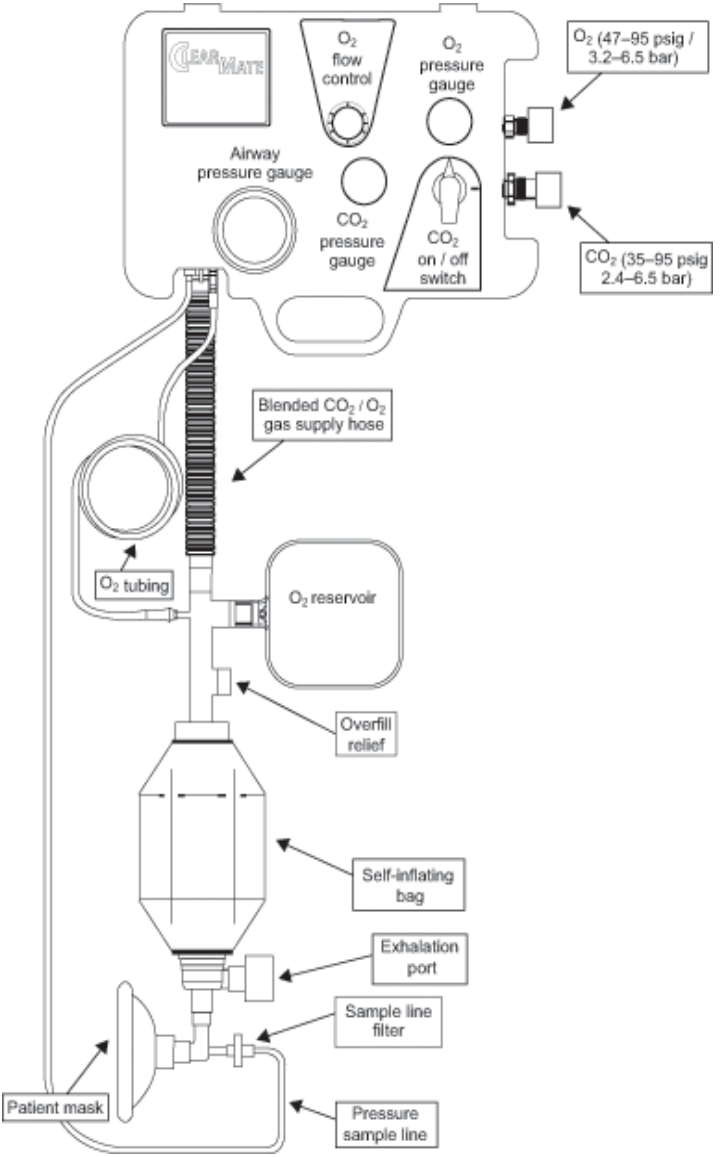

Figure 8: Non-Spontaneous Breathing Patient Circuit

	**WARNING! ENSURE THAT INPUT GAS PRESSURES ARE WITHIN THE LIMITS SPECIFIED IN THE DEVICE SPECIFICATIONS AND LABELLED ON THE DEVICE GAS INLETS. USE OF GASES WITH PRESSURES OUTSIDE OF THIS RANGE COULD RESULT IN INCORRECT OPERATION INCLUDING THE DELIVERY TO THE PATIENT OF A HAZARDOUS GAS MIXTURE.**
	**WARNING! DO NOT BLOCK CIRCUIT EXHALATION PORT OR OVERFILL RELIEF.**
	**WARNING! WHEN PROVIDING TREATMENT TO A NON-SPONTANEOUSLY BREATHING PATIENT USING THE CLEARMATE™ NON-SPONTANEOUS BREATHING PATIENT CIRCUIT, CO2 MONITORING EQUIPMENT FOR THE MEASUREMENT OF EXPIRATORY CARBON DIOXIDE CONCENTRATION IN ACCORDANCE WITH ISO 80601-2-55 MUST BE USED (ISO 80601-2-12).**

	**NOTE***:* The breathing circuits for use with ClearMate™ are single use.

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SECTION 9

Alarms

The ClearMate™ has built-in safety features that protect the patient against loss of the O_2 supply while CO_2 is pressurizing the system. The ClearMate™ will function normally as an O_2 delivery system if CO_2 is not used, or if CO_2 pressure is lost. Loss of CO_2 pressure is indicated on the system pressure gauge but not signalled with an alarm.

If the O_2 gas supply drops below 40 psig / 2.75 bar, an alarm will sound. If the CO_2 gas fails, or is exhausted, only O_2 will continue to be delivered to the patient. If the O_2 supply fails with the CO_2 source attached, the system will shut off all gas to the demand valve and a pneumatically driven alarm will sound.

If the O_2 supply fails without the CO_2 source attached, the alarm will sound when the pressure drops below 40 psig / 2.75 bar, and it will sound for only the duration of the supply of O_2 to drive the alarm. If the O_2 supply fails with the CO_2 source attached, the alarm will sound when the O_2 pressure drops below 40 psig / 2.75 bar, and it will continue sounding for the duration of the CO_2 supply to drive the alarm.

Note the following:

1. The alarm volume cannot be adjusted.
2. The audible alarm cannot be silenced or reset manually.
3. Once an alarm condition no longer exists, the audible alarm resets.
4. Loss of CO_2 is indicated by the pressure gauge only. No audible alarm will sound.

WARNING! THE GAS FAILURE ALARM WILL NOT SOUND IF BOTH SUPPLY GASES ARE BELOW 30 PSIG / 2.0 BAR.

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SECTION 10

Troubleshooting

Table 2: Troubleshooting

Potential Problem / Hazard	Potential Cause	Corrective Action
Alarm sounding	1. O_2 is less than 40 psig / 2.75 bar 2. CO_2 connected, switch on, but O_2 not connected	1. Check O_2 inlet pressures
No alarm sounds when: **1. O_2 is less than 40 psig / 2.75 bar** **2. CO_2 connected, switch on, but O_2 not connected**	1. Inlet gas contamination, alarm module malfunction	1. Call Technical Support
Resuscitator bag fills slowly or not at all	1. Demand valve failure 2. O_2 inlet pressure low	1. Call Technical Support 2. Check O_2 inlet pressure
Inspiratory CO_2 / O_2 blend incorrect	1. CO_2 turned off 2. CO_2 tank depleted 3. CO_2 regulator failure	1. Turn CO_2 control clockwise 90° 2. Replace CO_2 tank 3. Call Technical Support

Potential Problem / Hazard	Potential Cause	Corrective Action
	4. Blender failure 5. Blender out of calibration	4. Call Technical Support 5. Call Technical Support
Continuous CO_2 / O_2 flow	1. Demand valve failure	1. Call Technical Support
End Tidal partial pressure of CO_2 rising	1. O_2 flow too low	1. Check O_2 flow setting to see if it is improperly set (*see Table 1*) 2. Increase O_2 flow 3. Call Technical Support
End Tidal partial pressure of CO_2 falling	1. O_2 flow too high	1. Check O_2 flow setting to see if it is improperly set (*see Table 1*) 2. Call Technical Support

SECTION 11

Routine Maintenance

Routine maintenance of the ClearMate™ is limited to the following:

- Required preventative maintenance every two years
- Cleaning of the exterior surfaces

Cleaning

The exterior surfaces of the ClearMate™ can be cleaned with a mild soap or liquid disinfectant solution. Do not use cleaning agents that contain abrasives.

	**CAUTION! DO NOT IMMERSE ANY PART OF THE CLEARMATE™ DEVICE IN LIQUID. DO NOT AUTOCLAVE. DAMAGE WILL RESULT.**

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SECTION 12

ClearMate™ Accessories

Table 3: Accessories List

Part #	Part Name
128445	ClearMate™ Hoses Kit DISS to DISS for O_2 and CO_2
127468	ClearMate™ Hoses Kit NIST for O_2 and CO_2
127469	ClearMate™ Hoses Kit AFNOR for O_2 and CO_2
127471	ClearMate™ Hoses Kit SIS for O_2 and CO_2
128286	ClearMate™ Hoses Kit DISS to AGA O_2 and CO_2
128328	ClearMate™ Hoses Kit DIN for O_2 and CO_2
129198	ClearMate™ Hoses Kit BS for O_2 and DISS for CO_2
122658	ClearMate™ Stand
128230	CO_2 Regulator with CGA 940 Pin Index Yoke and DISS Hose
122659	ClearMate™ Box of 6 Non-Spontaneous Breathing Patient Circuits
124153	ClearMate™ Box of 6 Spontaneous Breathing Patient Circuits

WARNING! NO PATIENT CIRCUITS OTHER THAN CLEARMATE™ BREATHING CIRCUITS SHOULD BE USED WITH THE CLEARMATE™.

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SECTION 13

Limited Warranty

Thornhill Research Inc. ("TRI") warrants that its products will be free from defects in material and workmanship for a period of two (2) years from the date of shipment. TRI does not warrant that the operation of any product will be uninterrupted or error free.

For warranty service or repair, the purchaser must first contact the TRI service department. The service department will first attempt to resolve the issue by phone. If TRI determines, at TRI's sole discretion, that the product is in need of repair, TRI will provide a returned merchandise authorization (RMA) to return the unit, together with instructions for shipping. The product must be returned to Thornhill Research Inc. or a service facility designated by Thornhill Research Inc., shipping prepaid by the purchaser.

Products must be shipped back in their original shipping containers unless otherwise authorized by TRI. Once the returned item is inspected by TRI, TRI will determine, in its sole discretion, whether this LIMITED WARRANTY applies. If TRI determines that the LIMITED WARRANTY applies, TRI will repair or replace the defective product at TRI's option, and ship the system back to the customer, with a method of TRI's choosing, at TRI's cost.

If TRI determines, in its sole discretion, that this LIMITED WARRANTY does not apply, the customer will be requested to authorize the repairs, and upon authorization, will be billed for the repair together with the cost for return shipping in accordance with the customer's shipping instructions.

LIMITATION OF WARRANTY

To qualify for the warranty, the purchaser must use and maintain the system according to the procedures set out in the Operator's Manual. Ordinary maintenance, as specified in the Operator's Manual is not covered under this LIMITED WARRANTY.

The foregoing warranty does not apply to defects or damage to the unit resulting from:

- Improper use or misuse
- Neglect, fire, flood, loss, theft

- Normal wear and tear
- Improper or inadequate maintenance
- Unauthorized modifications or repairs
- Use of the system with unauthorized accessories or consumables
- Use or storage outside the product specifications as determined solely at the discretion of TRI.

This warranty is VOID if:

- Any part of a TRI product or system is repaired or opened by an unauthorized repair person
- Any part of a TRI product or system is used with an incompatible accessory or part
- TRI recommends return of a product for service or repair and the customer elects not to return the product for service
- The customer fails to maintain the product as set out in the Operator's Manual or Service Manual
- The product is used in a manner or for a use not set out in the intended use section of the Operator's Manual.

The remedies provided in this LIMITED WARRANTY are your sole and exclusive remedies. To the extent allowed by law, there are no other warranties expressed or implied, including without limitation any expressed or implied warranties or conditions of merchantability, satisfactory quality, and fitness for a particular purpose.

LIMITATION OF LIABILITY

IN NO EVENT SHALL TRI BE LIABLE FOR DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS, EXEMPLARY DAMAGES, COMMERCIAL LOSS FROM ANY CAUSE, PERSONAL INJURY, BUSINESS INTERRUPTION, LOSS OF USE, OR OTHER DAMAGES, WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY AND WHETHER ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

TRI's liability for damages of any kind shall, in any event, be limited to the purchase price of the defective unit.

NOT TRANSFERRABLE

This warranty is valid for the original purchaser only and may not be transferred.

Index

Part #: 122518-R

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