

K953269

Non-confidential Summary of Safety and Effectiveness

DEC 20 1996

July 12, 1995

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Official Contact: Randy Hickle, M.D., President

Proprietary or Trade name: SafeCircuit Manifold / Pulmonary Unit

Common / Usual name: Gas scavenging apparatus

Classification name: Gas scavenging apparatus

Intended device: SafeCircuit Manifold / Pulmonary Unit

Predicate devices: Ohmeda and North American Drager Waste Gas Scavenging Interfaces; Dryden SONRA, Gibeck-Dryden CO₂ absorber, Ohmeda CO₂ absorber

Device description:

The SafeCircuit Manifold/Pulmonary Unit is comprised of a single manifold unit which has been divided into two (2) halves or functional chambers which function to:

- 1) Deliver supplemental oxygen during inhalation and,
- 2) Scavenge the patient's exhaled breath.

The SafeCircuit Manifold / Pulmonary Unit incorporates directional valves similar to the directional valves of the standard CO₂ absorber system of anesthesia gas machines and the Dryden disposable CO₂ absorber to establish the inhalation / exhalation flow of gases.

In addition, as required in the Standard Specification for Anesthetic Equipment - Scavenging Systems for Anesthetic Gases, ASTM 1343-91, there must be a means to relieve excess positive and negative pressures. The SafeCircuit Manifold utilizes relief valves, similar to the Ohmeda Waste Gas unit and the Dryden SONRA, which will -

1. "Pop-off" or release any excess positive pressure on the exhalation side into the room should there be excess positive pressures. (Labeled EPPRV)
2. Entrain room air, should there be excess negative pressure from the vacuum so that this excess negative pressure is not directed toward the patient circuit. (Labeled ENPRV)

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Device description (continued):

In order to provide safe and effective oxygen delivery / inhalation unit, the use of excess positive and negative pressure relief valves are also incorporated in the inhalation side of the patient circuit. In this case they function to perform when -

1. Insufficient or no flow of oxygen occurs then, the patient can entrain room air, 21% oxygen through the excess negative pressure valve. (Labeled INPRV)
2. If there is excess oxygen flow, then the excess positive pressure valve will "pop-off" and the excess flow and / or pressure relieved to the outside. (Labeled IPPRV)

The method of connecting the SafeCircuit Manifold to the patient is via a standard breathing circuit which is comprised of two (2) tubes, wye piece to connect to a mask and a reservoir bag to collect excess gases and allow for manual ventilation if required. This circuit would connect to the SafeCircuit Adhesive Mask, approved K950771, to provide an effective seal between the patient's face / airway and the SafeCircuit Manifold. As on the Waste Gas Interface Systems of Ohmeda a scavenging reservoir bag, with 19 / 30 mm fitting, is utilized, the SafeCircuit Manifold/ Pulmonary Unit will also have this overflow (expiratory) reservoir bag. It is intended to utilize a 30 mm fitting for this scavenge reservoir bag as the proposed international, ISO, standard is 30 mm.

The unit has also incorporated filters at the back of the unit at each excess relief condition port opening to filter the air released to the environment or entrained when excess positive or negative pressure conditions occur. These filters are to reduce any airborne contaminants, dust, dirt from the air entrained or released during exhalation.

The SafeCircuit Manifold/Pulmonary Unit is designed to be mounted on the wall or on a pole so that the device can be conveniently located next to the patient and various wall outlets - oxygen and vacuum.

Intended use:

The SafeCircuit Manifold/Pulmonary Unit, is intended to be used to scavenging of waste anesthetic gases from patients recovery for general anesthesia and provide supplemental oxygen. When used with the SafeCircuit Adhesive mask and a standard breathing circuit, the unit helps to reduce the amount of anesthetic agents and airborne contaminants released to the work environment of the healthcare worker.

Indicated population and environment:

The SafeCircuit Manifold/Pulmonary Unit, is indicated for use with adult and pediatric patients recovering from general anesthesia. The environment is in the post anesthesia recovery room which may be located in a hospital, outpatient surgery center or equivalent facility where patients are observed and monitored following anesthesia.

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Attribute	SafeCircuit Manifold	North American Drager Waste Gas Interface	Ohmeda Waste Gas Interface	Dryden SONRA	Gibeck-Dryden CO ₂ absorber
Use					
Scavenging waste anesthetic gases	Yes	Yes	Yes	Yes	N/A
Delivers gases like oxygen to patients	Yes	N/A	N/A	Yes	Yes
Indicated for adult / pediatric patients	Yes	Yes	Yes	Yes	Yes
Indicated for extended use	Yes	Yes	Yes	Yes	No
Design					
Directional flow valves inhalation / exhalation	Yes	No	No	Yes	Yes
Excess positive pressure reliefs	Yes	Yes	Yes	Yes	N/A
Excess negative pressure reliefs	Yes	Yes	Yes	Yes	N/A
Can entrain room air during inhalation	Yes	N/A	N/A	Yes	N/A

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Attribute	SafeCircuit Manifold	North American Drager Waste Gas Interface	Ohmeda Waste Gas Interface	Dryden SONRA	Gibeck-Dryden CO₂ absorber
Can entrain room air to satisfy excess negative pressure from vacuum	Yes	Yes	Yes	Yes	N/A
Has patient inhalation reservoir bag	Yes	N/A	N/A	Yes	Yes
Has overflow gas scavenging (exhalation) reservoir bag	Yes	Yes	Yes	Yes	N/A
Connects to vacuum for scavenging	Yes	Yes	Yes	Yes	No
Patient circuit fittings 22 mm	Yes	N/A	N/A	Yes	Yes
Scavenging fittings 19 /30 mm	Yes	Yes	Yes	Yes	Yes
Requires periodic maintenance	Yes	Yes	Yes	Yes	N/A
Provided non-sterile	Yes	Yes	Yes	Yes	Yes
Has filters at excess pressure relief port openings	Yes	No	No	No	N/A
Materials					
Directional valves	SR, PE, PP	N/A	PE, PP	SR	SR

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Attribute	SafeCircuit Manifold	North American Drager Waste Gas Interface	Ohmeda Waste Gas Interface	Dryden SONRA	Gibeck-Dryden CO₂ absorber
Housing / body	ABS, PC, PP PS, metal	ABS, metal	metal	PC,PS	PS,PC,ABS
Performance Standards					
22 mm / 15 mm ASTM 1054-87	Yes	Yes	Yes	Yes	Yes
ASTM Scavenging 1343-91	Yes	Yes	Yes	Yes	N/A
5.3.1 Normal negative pressure < 0.5 cm	Yes	Yes	Yes	Yes	N/A
5.3.2 Positive pressure ambient	Yes	Yes	Yes	Yes	N/A
5.3.3 Positive w/ flush	Not applicable - no flush capabilities in intended environment				
5.3.4 Positive pressure occluded < 10 cm	Yes	Yes	Yes	Yes	N/A
5.3.5 Positive, occluded, flush	Not applicable - no flush capabilities in intended environment				
5.4 Leakage < 100ml/min	Yes	Yes	Yes	Yes	N/A
ISO 8835.3.2 draft 30 mm	Yes	No	No	No	No