Inhalant anesthetics are developed with a number of properties including rapid onset and recovery, controllability, and, ideally, a broad safety profile. The efficacy of these agents is measured by their ability to create anesthesia within the framework of the other desirable properties. The instant invention focuses on the dosage level where analgesia occurs but amnesia or lack of consciousness does not. In addition to identifying the dosage level where pain is sharply reduced or eliminated but awareness remains, a delivery system for safe and effective delivery of the agent is described.
Scavenger for Conscious Sedation

Inhalation Agent

Active Scavenger

Oxygen

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FIG. 4
Conscious Sedation Unit with Oxygen Concentrator

- Mixer Head
- Electric Receptacles
- Anesthetic
- \( O_2 \) Concentrator
- Heater
- Optional Air Cylinder
- Cord to Power Source

**FIG. 5**
Example of RFID and/or Bar Code Label
Example of RFID Reader

FIG. 7
Example of Bar Code Reader

FIG. 8
Optical / Force Sensor

Multifunctional Bottle Holder System (holds, engages, and senses the agent Bottle)

Actuation for user (It can be mechanical, as drawn, or digital)

Agent Bottle

Leak-proof Agent Port

Fig. 9
Schematic of a pressurized reservoir

- Liquid Analgesia Agent
- Micro-Dispensing Valve
- Delivery Manifold
- Patient

Required Oxygen Source
Full Face Mask

FIG. 11A

Nasal Mask

FIG. 11B
DRUG DELIVERY SYSTEM AND METHOD FOR CONSCIOUS SEDATION/ANALGESIA

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 10/272,794, which was filed on Oct. 17, 2002. Ser. No. 10/272,794 claims the benefit of priority to U.S. provisional patent application 60/330,063. This continuation-in-part patent application claims the benefit of priority of Ser. No. 10/272,794 and Ser. No. 60/330,063.

FIELD OF THE INVENTION

[0002] This invention relates to the field of analgesia and conscious sedation. More particularly, this invention provides an apparatus and method for the delivery of halogenated ethers for producing analgesia in a patient.

BACKGROUND OF THE INVENTION

[0003] Since the mid-1800’s conscious sedation/analgesia has been used in hospital and pre-hospital settings to relieve pain. Nitrous oxide (N₂O) has been the primary inhalant agent in this regard. Sedative hypnotics such as diazepam and midazolam have been used as alternatives as have any number of barbiturates, opioids and agonist/antagonist agents.

[0004] Dentistry and oral surgery were the first applications of nitrous oxide conscious sedation and gained wide-spread acceptance following successful use on Queen Victoria. Subsequently, the use of conscious sedation spread throughout the hospital, to emergency rooms, in ambulances, and in other doctor offices.

[0005] Conscious sedation is a pain-blocking technique that allows a patient to remain partially alert during an invasive procedure. Analgesia is provided but, unlike anesthesia, the patient maintains awareness and recall. Specifically, the method is unique because patients do not perceive pain, but preserve their protective reflexes, maintain airways independently, and arouse in response to stimuli. Thus the risks of reduced or suppressed respiration associated with anesthesia are mitigated.

[0006] There are many benefits associated with conscious sedation. In particular, conscious sedation reduces anxiety in patients, particularly children. Accordingly, medical procedures are easier for the patient and the health care provider, as conscious sedation reduces patient tension and resistance to treatment. Furthermore, the technique has the potential for expansive applications. Studies have shown success with patient controlled analgesia.

[0007] The inhaled halogenated ethers offer a number of advantages in critical categories versus nitrous oxide conscious sedation or conscious sedation employing the sedative hypnotics. An example of some of the comparison with these agents is shown in Table 1.

<table>
<thead>
<tr>
<th>Features</th>
<th>Halogenated Ethers</th>
<th>Nitrous Oxide</th>
<th>IV Diazepam</th>
<th>IV Midazolam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset</td>
<td>Rapid</td>
<td>Rapid</td>
<td>Moderate</td>
<td>Moderate</td>
</tr>
<tr>
<td>Safety Profile</td>
<td>High</td>
<td>Teratogenic</td>
<td>Moderate</td>
<td>Moderate &amp; Blood Disorders</td>
</tr>
</tbody>
</table>

[0008] The combination of these features makes the halogenated ethers attractive candidates for conscious sedation. However, there is also a need for a safe, accurate and cost effective delivery system.

[0009] The use of nitrous oxide based conscious sedation has declined in recent years principally reflecting the issues with the safety profile of the gas including those items listed above, but also because of its interference with methionine synthesis in prolonged exposure. These factors are particularly relevant to female health care professionals of childbearing age who face increased risk of spontaneous abortion due to nitrous oxide’s teratogenic profile.

[0010] N₂O is relatively impotent. As discussed in the description of the invention below, this impotence requires that limits are placed on the inspired percentage of N₂O to insure patients receive sufficient oxygen. The concentration of oxygen in the atmosphere approximates 21%. As a result, most international regulatory agencies, including the United States Food and Drug Administration (“FDA”) established oxygen delivery guidelines to avoid hypoxia. The most common ratio is 70% N₂O/30% oxygen, although some delivery systems maintain 50% oxygen. At a 70% mixture of N₂O, conscious sedation occurs in most patients. The 70% N₂O/30% oxygen mixture, on a sustained basis at the delivery level has a Minimum Alveolar Content (“MAC”) of 0.636 MAC.

[0011] Six inhaled ethers are in use today: halothane, methoxyflurane, enfurane, isoflurane, sevoflurane and desflurane. (Terrell, then of Airco, Inc., synthesized enfurane, isoflurane and desflurane.) These compounds were developed focusing on being non-flammable, non-addictive, potent, having rapid induction properties and cardiovascular stability. Traditionally these products have been packaged in 100 ml and 250 ml brown glass bottles and vaporized using an agent specific, temperature compensated system.

[0012] These drugs were developed for anesthesia. None of the inhaled ethers was developed as an inhalant analgesic. This reflected industry perceptions that either there was no need for an inhalant analgesic or there was the absence of cost-effective specialized equipment to administer these agents as analgesics. The equipment developed for anesthesia use in hospital settings was both sophisticated and expensive, frequently costing over $100,000. The combination of these factors virtually eliminated the ability to use these drugs as conscious sedation agents, particularly in the pre-hospital setting.
SUMMARY OF THE INVENTION

[0013] The invention may be embodied as a method or system, such as:

1. A method for delivery of a mixture to a patient effective to produce analgesia without loss of consciousness in a patient wherein the method comprises:

[0014] a) forming a gaseous mixture of oxygen and a halogenated material selected from the group consisting of halogenated ethers and halothane by mixing oxygen with the halogenated material in a delivery manifold, the manifold having a controller configured to provide a gas having a concentration of the halogenated material that is limited to not more than about 0.636 MAC; and

[0015] b) controlling the proportions of oxygen and halogenated material in the gaseous mixture by metering a liquid flow of the halogenated material into a gas containing the oxygen such that the gaseous mixture comprises a ratio of oxygen to halogenated material effective for producing analgesia without loss of consciousness in the patient;

[0016] c) delivering said gaseous mixture to the patient to produce analgesia without loss of consciousness in the patient; and

[0017] d) performing a medical or dental intervention or procedure during analgesia while the patient is conscious.

2. The method of item 1, including one or more of the following:

[0018] a. active analgesic agent recovery;
[0019] b. monitoring the patient with an EKG, NIBP, SaO2, and/or capnography, or other respiration monitoring; and/or
[0020] c. measuring oxygen concentration.

3. The method of item 1 wherein the halogenated material is enflurane.

4. The method of item 1 wherein the halogenated material is isoflurane.

5. The method of item 1 wherein the halogenated material is sevoflurane.

6. The method of item 1 wherein the halogenated material is desflurane.

7. A system for delivering gas to a patient to produce analgesia without loss of consciousness in the patient comprising:

[0021] a) an oxygen source;
[0022] b) a reservoir suitable for storing a liquid phase of an analgesia producing agent, the agent being a halogenated material selected from the group consisting of halogenated ethers and halothane;
[0023] c) a delivery manifold having a pair of inputs connected to the oxygen source and to the reservoir, respectively, and having an output, the manifold providing a gaseous mixture of oxygen and the analgesia producing agent by metering a flow of the liquid halogenated material into the oxygen, the manifold having a controller configured to provide the gaseous mixture such that the halogenated material is limited to not more than about 0.636 MAC for producing analgesia without loss of consciousness; and

[0024] d) means for conveying the gaseous mixture from the output of the delivery manifold to a patient for producing analgesia without loss of consciousness in the patient while a medical or dental intervention or procedure is carried out.

8. The gas delivery system of item 7, wherein the delivery manifold comprises a pressure regulator and a flow meter connected in fluid communication, the flow meter being in fluid communication with the output of the delivery manifold.

9. The gas delivery system of item 8, wherein the pressure regulator is in fluid communication with the input of the delivery manifold connected to the oxygen source and the flow meter is in fluid communication with the input of the delivery manifold connected to the reservoir.

10. The gas delivery system of item 7, further including heating means operatively associated with the reservoir containing analgesia producing agent and ambient temperature sensing means in controlling relation to a heating means to provide compensation for changes in environmental temperature conditions.

11. The gas delivery system of item 7, further including an oxygen flush arrangement operatively coupled between the oxygen source and a patient.

12. The gas delivery system of item 7 wherein the oxygen source comprises a cylinder.

13. The gas delivery system of item 7 wherein the reservoir comprises a cylinder.

14. The gas delivery system of item 7 wherein the reservoir has a muted index.

15. The gas delivery system of item 7 wherein the pressure regulator is digital.

16. The gas delivery system of item 7 wherein the pressure regulator is analog.

17. The gas delivery system of item 7 wherein a gas scavenging system is provided.

18. A drug delivery system having a reservoir to provide halogenated material, the halogenated material being selected from the group consisting of halogenated ethers and halothane, wherein the reservoir is suitable for storing the halogenated material in a liquid phase, and a delivery manifold for providing a gaseous mixture of oxygen and the halogenated material by metering a flow of the liquid halogenated material into the oxygen, the manifold including a controller configured to provide a concentration of the halogenated material in a gas phase that is limited to not more than about 0.636 MAC for producing analgesia without loss of consciousness in a patient that is undergoing a medical or dental intervention or procedure.

19. The drug delivery system of item 18, wherein the halogenated material is halothane.

20. The drug delivery system of item 18, wherein the halogenated material is enflurane.

21. The drug delivery system of item 18, wherein the halogenated material is isoflurane.

22. The drug delivery system of item 18, wherein the halogenated material is sevoflurane.

23. The drug delivery system of item 18, wherein the halogenated material is desflurane.

24. The drug delivery system of item 7, including one or more of the following:

[0025] a. a system for active analgesic agent recovery;
[0026] b. a system for monitoring the patient with an EKG, NIBP, SaO2, and/or capnography, or other respiration monitoring;
[0027] c. a system for measuring oxygen concentration;
[0028] d. a system for confirming the type of analgesic agent, which may include an RFID (Radio Frequency Identification Device), or bar code;
[0029] e. a system for collecting, storing and providing data about the operations of the conscious sedation system and/or the patient;
[0030] f. a system for holding the bottle that maintains pressure between the bottle and a conduit carrying analgesic agent from the bottle;
[0031] g. a system for pressurizing a reservoir that holds liquid analgesic agent;
[0032] h. one or more masks for delivering vaporized analgesic agent to a patient;
[0033] i. connectors facilitating connection of the drug delivery system to a centralized oxygen and/or scavenging system.

BRIEF DESCRIPTION OF THE DRAWINGS

[0034] For a fuller understanding of the nature and objects of the invention, reference should be made to the accompanying drawings and the subsequent description. Briefly, the drawings are:

[0035] FIG. 1 is a block diagram showing an embodiment of the invention.

[0036] FIG. 2 is a diagrammatic perspective view of another embodiment of the invention.

[0037] FIG. 3 is a diagrammatic perspective view similar to FIG. 2 but rotated about 180 degrees.

[0038] FIG. 4 depicts part of a system according to the invention;

[0039] FIG. 5 is depiction of a system according to the invention;

[0040] FIG. 6 depicts an identification tag;

[0041] FIG. 7 depicts an RFID reader;

[0042] FIG. 8 depicts a bar code scanner;

[0043] FIG. 9 depicts a bottle holder;

[0044] FIG. 10 is a schematic of a system according to the invention that has a pressurized reservoir;

[0045] FIGS. 11A, 11B, 11C, and 11D depict devices for delivering analgesic agent to a patient; and

[0046] FIG. 12 depicts part of a system according to the invention.

FURTHER DESCRIPTION OF THE INVENTION

[0047] Modern inhalation agents are halogenated ethers. They are generally characterized by a specific gravity between 1.0 and 2.0, low molecular weights (165.0-200.0), a low boiling point (22 degrees C to 104 degrees C), and significant potency—0.16%-7.8% of an agent on oxygen will put 99% of adults into anesthesia. These variables are important in the characterization of this invention as the drugs are converted from liquid to gas and delivered with a carrier gas—usually oxygen but sometimes a combination of oxygen and another gas or gases including oxygen, nitrous oxide and/or air.

[0048] However, the agents vary in many important respects. Some agents including methoxyflurane, halothane and sevoflurane are known to react to metals. To some extent these same agents decompose in the presence of "soda lime" (calcium hydroxide) and/or UV light. To a greater or lesser extent, all halogenated agents are solvents. A delivery system for conscious sedation must be compatible with the agent in use.

Example I

[0049] The potency of anesthetic agents is measured by the minimum alveolar concentration of an anesthetic producing immobility in 50% of patients, defined as 39 year old males, undergoing surgical incision ("MAC"). The MAC of potent inhaled agents varies significantly. The MAC of nitrous oxide, the leading inhalant conscious sedation drug, can only be determined under unusual conditions of temperature and pressure, such as a hyperbaric chamber, when additional dosages can be provided without creating hypoxia. Research suggests the MAC of nitrous oxide to be 110%. Thus, to create anesthesia, most patients would suffocate. Conversely, the MAC of methoxyflurane, an early-halogenated ether is only 0.16%. In present inhalant conscious sedation systems, nitrous oxide is delivered in conjunction with a minimum of 30% oxygen to insure the patient maintains a sufficient level of oxygen. In the United States, the Food and Drug Administration ("FDA") has set 70% nitrous oxide as the limit for delivery in a conscious sedation unit. For this description a MAC equivalent of 70% nitrous oxide will be used for comparison with other inhalants, as shown in Table 2.

<table>
<thead>
<tr>
<th>Drug</th>
<th>MAC*</th>
<th>Implied CS Level</th>
<th>MAC Equivalent</th>
<th>Inhaled Oxygen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrous Oxide</td>
<td>110%</td>
<td>70.00%</td>
<td>0.636</td>
<td>30.00%</td>
</tr>
<tr>
<td>Existing Inhalation Drugs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methoxyflurane</td>
<td>0.16%</td>
<td>0.10%</td>
<td>0.636</td>
<td>99.90%</td>
</tr>
<tr>
<td>Halothane</td>
<td>0.75%</td>
<td>0.48%</td>
<td>0.636</td>
<td>99.52%</td>
</tr>
<tr>
<td>Isoflurane</td>
<td>1.55%</td>
<td>0.73%</td>
<td>0.636</td>
<td>99.27%</td>
</tr>
<tr>
<td>Enflurane</td>
<td>1.08%</td>
<td>1.07%</td>
<td>0.636</td>
<td>98.93%</td>
</tr>
<tr>
<td>Sevoflurane</td>
<td>2.00%</td>
<td>1.27%</td>
<td>0.636</td>
<td>98.73%</td>
</tr>
<tr>
<td>Desflurane</td>
<td>6.00%</td>
<td>3.82%</td>
<td>0.636</td>
<td>96.18%</td>
</tr>
</tbody>
</table>

*MAC is shown in 100% oxygen for middle-aged men. MAC varies with age and personal habits including alcohol and drug ingestion.

[0050] For patients who would benefit from higher levels of oxygen delivery including, but not limited to those with Cardiac Artery Disease (CAD), replacement of nitrous oxide with an inhalant analgesia could provide improvement in myocardial oxygenation.

Example II

[0051] To deliver a concentration of the relevant agent that creates analgesia but not loss of awareness (either amnesia or loss of consciousness) requires a finely calibrated instrument through which the agent can flow with very minimal risk of overdose or delivery of hypoxic mixture (FIG. 1.) To be practical in the outpatient setting the device must be cost-effective, preferably costing less than anesthesia machines which presently cost $100,000 or more. Compared to the sedative hypnotics, barbiturates, opioids and agonist/antagonists that can also be used for sedation, the invention offers more rapid onset and recovery and less risk of abuse potential. The invention therefore comprises an oxygen delivery mechanism, either an O2 cylinder(s) and/or manifold system to oxygen storage ("O2 source") 16 and a reservoir for the analgesia agent 12, for example but not limited to an agent compatible cylinder; a heating element 14 attached to the analgesia reservoir 12, for example but not limited to a heating plate, linked to an ambient temperature sensor to allow compensation for environmental temperature and pressure. Heating of the analgesia reservoir 12 by the heating element
allows control of the pressure of the agent in the reservoir such that the flow of the agent can be properly regulated despite changing ambient temperatures. The reservoir system comprises a mated index system to ensure that only the agent specified can be filled into the reservoir and, once filled, can only be mated to a delivery system specific to that agent. Oxygen from the O\textsubscript{2} source flows through a delivery manifold system including a sensitive pressure regulator to a flow meter, either analog or electronic, where it is mixed in strict proportions with the agent from the reservoir and will accurately meter the dosage of the agent to +/-0.1% of gas flow or less. While the agent could be routed to the flow meter directly, it may be also be arranged to flow through the delivery manifold to regulate flow and ensure that safety devices including but not limited to an automatic agent shutoff system if oxygen flow is shutoff or determined to be insufficient. An oxygen flush system allows the practitioner to rapidly fill a patient’s lungs and force exhalation of the residual agent. The system is arranged so that when the O\textsubscript{2} flush is triggered the flow of analgesic is automatically ceased because the O\textsubscript{2} flush is linked to the analgesia reservoir by a three-way valve such that when the O\textsubscript{2} flush is on the analgesia is off, and vice versa. The mixing head and/or flow meter system allows the user to regulate gas flow and agent concentration up to the conscious sedation limits established by the appropriate regulatory authority, and is sufficiently accurate in calibration to allow agent flow to approach the desired CS levels. In addition, the controlled heating element and the flow meter can be operated in a co-operative relationship to regulate the flow of the analgesic agent.

As shown in FIGS. 2 and 3, an embodiment of the invention is a stand alone doctor’s office unit. FIG. 2 shows a heater; a mixer head; an oxygen pressure control; a vapor pressure control; an oxygen flush control; a nasal cannula outlet port; an inhaler outlet port; an oxygen pressure gauge; a vapor pressure gauge; an optional monitor; a flow rate control; an anesthetic concentration control; a select nasal/102 inhaler switch; and an on/off control.

FIG. 3 shows an oxygen source: a heater; a mixer head; electric receptacles; an optional air cylinder; and a power cord. These features may be coupled with others including but not limited to the ability to modify the unit to be portable for emergency or military use; the ability to modify the unit for patient controlled analgesia ("PCA"); attaching a scavenging system for recovered exhaled agent and removing it to the environment; incorporating or allowing the unit to be compatible with physiologic monitoring including but not limited to oximetry. EKG, blood pressure, carbon dioxide, monitoring and depth of consciousness monitors; the ability in one or more configurations to make the device compatible with diagnostic imaging devices including but not limited to nuclear magnetic resonance devices (MRIs) to allow analgesic delivery to patients requiring sedation or pain relief during MRI imaging.

Clinical utilization of conscious sedation is possible in a wide ranging number of procedures including but not limited to dental and oral surgery procedures, burn debridement, pain relief in emergency and trauma situations, administration in the intensive care, cardiac care or critical care units, in examination or work on the extremities including pediatric procedures, labor and delivery, to reduce anxiety in individuals with fear of needle insertion, and where prolonged immobilization would be difficult without the delivery of a sedation agent.

Additionally, the invention has the following attributes. The invention increases oxygenation of blood, an important feature for individuals with poor myocardial or cerebral oxygenation. The invention increases occupational safety when analgesics described herein are substituted for nitrous oxide, an important feature for women of child-bearing age. The invention can reduce claustrophobia-associated anxiety and relieve pain in patients facing prolonged periods of inactivity, such as during nuclear magnetic resonance imaging (MRI) when used with an MR-safe (1.5 tesla) version of the delivery system. Similarly, the invention may be used for sedation in Intensive Care Units (ICU), Critical Care Units (CCU), or during cardiac catheterization, implantable defibrillator or pacemaker adjustments, and in general pain relief. The device may be provided in alternative configurations, such as with a stand or method for holding patient monitors, including integration of the monitors with the system. Additionally, the device may be provided with a regulator system that senses the depth of a patient’s inhalation to allow safe patient controlled analgesia administration.

Having provided an overview of systems that are in keeping with the invention, descriptions will now be given of features that may be found in a system according to the invention.

Active Scavenging:

Inhalation analgesics are fluorocarbons and greenhouse gases. See Table 3. Regulatory and environmental legislation have been enacted in a number of markets, particularly Canada and Western Europe, to protect operating room staff from repeated exposure to these agents. Further, some groups have counseled their members to include potential greenhouse gas impact of the agents if the choice does not impact therapeutic outcome.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Lifetime (y)</th>
<th>GW\textsubscript{20}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon dioxide\textsuperscript{15}</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Sevoflurane</td>
<td>1.2</td>
<td>349</td>
</tr>
<tr>
<td>Isoflurane</td>
<td>3.6</td>
<td>1401</td>
</tr>
<tr>
<td>Desflurane</td>
<td>10</td>
<td>3714</td>
</tr>
<tr>
<td>Nitrous oxide\textsuperscript{15}</td>
<td>114</td>
<td>289</td>
</tr>
</tbody>
</table>

GW\textsubscript{20} = 20-year global warming potential.

In an embodiment of the invention, active scavenging devices are used to recover the inhalation analgesics exhaled by the patient.

Inhalation agents offer real therapeutic benefits when used as sedatives or analgesics including profound pain relief, very rapid recovery, lower incidence of drug interaction reflecting their primary pathway of respiratory excretion and minimized risk of post procedure delirium, particularly in the elderly. A challenge in using these drugs in non-traditional settings (examples include but are not limited to: ICU/CCU and diagnostic rooms in the hospital; doctor and dental offices, and field emergency locations) is that these settings frequently do not have waste gas scavenging systems.
Thus the patient, theatre staff and environment are exposed to the low levels of agent the conscious sedation system patient scavenging system captures. In an embodiment of the invention, an active scavenger is included. The active scavenger captures waste agent, separates the waste agent from the exhaled gases, principally carbon dioxide, and accumulates the waste agent for either appropriate incineration or recycle back to an anesthetic when appropriate recovery technology is developed and approved by informed regulatory agencies, such as the United States Food & Drug Administration ("FDA"). FIG. 4 depicts a system according to the invention that includes a device for actively scavenging anesthetic gas from exhaled by the patient's.

Monitored Care:

In 2011, the American Society of Anesthesiologists ("ASA") approved guidelines for the administration of mild and moderate sedation to include different types of patient monitoring. These monitors included non-invasive blood pressure ("NIBP"), pulse oximetry ("SpO2"), EKG, and respiration monitoring. An example of respiration monitoring would be capnography. A system according to the invention may include systems for monitoring these aspects of the patient.

Oxygen Concentrator:

The need for sedation and pain relief is not limited to hospitals, free standing surgical, or doctor office settings. The use of an oxygen and/or an air cylinder provide only limited periods of portability in a conscious sedation system. Smaller cylinders allow greatly portability but have limited useful life. It is a further challenge to replace these cylinders in rural, field or emergency settings. As such, there is a demand for a self-generating oxygen system that can be incorporated in the device to allow its on-going use in these field and trauma situations. An embodiment of the invention may include an oxygen concentration device into the system. FIG. 5 depicts one such embodiment. The oxygen concentrator separates the desired level of oxygen from the environment, and that oxygen is used in the system along with the anaglesia producing agent to achieve the desired effect on the patient. One such oxygen separation technology is pressure swing absorption ("PSA"), although other modalities could be used.

Drug Identification:

A system according to the invention may include systems for ensuring that the correct drug is used. Because the physical properties (density, viscosity, vapor pressure, heat content, etc) and the medical properties (potency, minimum alveolar concentration, ease of induction, side effects, etc.) of the individual inhalation agents differ, the device must correspond to the agent that is being delivered. Engineering standards (i.e., ISO, ASTM standards) dictate that precautions be taken to ensure that the correct drug is used with the correct device.

One way to identify drugs is by RFID (radio frequency identification) labeling. See FIG. 6. A label with an RFID tag is physically placed on the container of the drug. This RFID tag is programmed with information such as the identity of the drug, lot number, expiration date, bottle size, manufacturer, etc. An RFID reader (See FIG. 7) that is installed into the conscious sedation device reads the information on the RFID label of the drug after the drug bottle has been placed into the bottle holder of the conscious sedation device. The reader confirms that the correct drug is placed into the bottle holder prior to the machine operating and the inlet valve opening, allowing the drug to enter the conscious sedation device.

Another way to identify drugs is by bar scan labeling. A label (See FIG. 6) with bar code is physically placed on the container of the drug. This bar code has information such as the identity of the drug, lot number, expiration date, bottle size, manufacturer, etc. A bar code reader (See FIG. 8) that is installed into the conscious sedation device reads the information on the bar code label of the drug after the drug bottle has been placed into the bottle holder of the conscious sedation device. The reader confirms that the correct drug is placed into the bottle holder prior to the machine operating and the inlet valve opening, allowing the drug to enter the conscious sedation device.

For example, a conscious sedation device that is designed and built to deliver sevoflurane to patients must only allow sevoflurane to enter. The sevoflurane conscious sedation device may have an RFID or bar code reader installed on it. The sevoflurane bottles may have labels that include RFID or bar codes on them that uniquely identify them as containing sevoflurane. The software on the sevoflurane conscious sedation device may be programmed to read the drug bottle RFID tag or bar code. If the RFID tag or bar code identifies the drug as sevoflurane, then the sevoflurane conscious sedation device would operate normally, and allow liquid sevoflurane from the bottle to enter the sevoflurane conscious sedation device, flow into a reservoir, be metered into a flow of oxygen where it vaporizes, and then conveyed to the patient to effect conscious sedation.

Note that conscious sedation devices can potentially be used with a single agent (sevoflurane, enfurane, desflurane, isoflurane, halothane) or potentially with a multiple of these agents. The drug labeling and device programming would fit the specific case. For example, for a conscious sedation device that operates with sevoflurane, halothane, and isoflurane, the reader would identify that these three drugs could be suitable for use with the device, whereas other drugs (or other liquids in bottles) are not suitable for use.

If the RFID tag or bar code identified the drug or liquid as different than a drug permitted for that system, then the conscious sedation device would indicate an error code, notify the user that the wrong drug or liquid is attempting to be used, and would not allow the drug to enter the system.

Data Gathering:

Documentation of patient monitoring, drug usage data, and procedure duration during medical or dental procedures is important for patient safety and billing purposes. Patient monitoring, such as ECG, blood pressure, oxygen saturation levels, pulse, breathing, and/or exhaled carbon dioxide provide medical practitioners with the ability to monitor the health of the patient when sedated. Actions can be taken to ensure that the patient remains healthy during a procedure. The duration of the procedure and the amount of drug used for a patient also can be used to bill patients.

Documentation of this data may be facilitated by downloading data to a patient chart, a hospital information system, personal digital assistant, or similar device. An embodiment of the invention may include one or more devices for receiving, storing and subsequently providing such data, for example by hardcopy, communication ports, or wirelessly.

A system according to the invention may incorporate a printer and/or electronics to enable these capabilities.
The device may periodically record data from each of the patient monitors (ECG, blood pressure, oxygen saturation levels, pulse, breathing, and/or exhaled carbon dioxide) and/or variables from the micro-flow titration system (oxygen flow rate, agent concentration). Such a system may calculate or measure the amount of agent and oxygen that is used and record that data periodically.

[0076] The data may be retained in memory and/or printed periodically or at the end of each procedure, or day, or week. The data can be downloaded from memory through cables attached to a communication port, such as USB, RS-232, firewire, serial ports, parallel ports, specialized ports, etc. The data can be downloaded from memory wirelessly using Bluetooth, wireless modem, infrared, and/or Wi-Fi, or equivalent technology. Preferably such data can be formatted expeditiously to fit into patient electronic records, paper records, and/or hospital information systems.

[0077] Bottle Holder:

[0078] The bottle containing the inhalant analgesic may be held in position by a multifunctional bottle holder system. An example of such a system is depicted in FIG. 9. Such a system securely holds the bottle in the orientation and position needed to fill the reservoir (function 1). The interface between the bottle and the reservoir is a leak-proof proprietary port. This leak-proof capability contributes to the objective of reducing operating room pollution, and the emission of greenhouse gases. The mechanism of bottle-port engagement can be achieved either by twisting or pushing the bottle. The multifunctional bottle holder system will also ensure this engagement (function 2) while securely holding the bottle in place. Another function that the bottle holder system may fulfill is sensing the presence of the bottle and/or its liquid level (function 3). This may be accomplished with a force/pressure sensor and/or with a light/optical sensor. All sensors used in the multifunctional bottle holder may be concealed from the user of the invention in order to guarantee its integrity and aesthetic appearance. These three functions may be achieved via a single action of the user, which may be mechanical (such as engaging a handle) or digital/electronic (as with a push of a button), in order to minimize the effort and the time required to operate a system according to the invention, while also improving safety, and efficiency.

[0079] Pressurized Tank:

[0080] For accurate and reproducible micro liter dispensed volumes of liquid analgesic into a flow stream, several system constraints along with pressure characterize system performance may be implemented. A reliable means of controlling flow can be obtained by combining, a micro-flow titration system with a reservoir pressurized by a regulated oxygen source. The amount of pressure needed will depend on the fluid properties of the liquid being dispensed (viscosity, density, etc.), gas flow rates (1-10 LPM) as well as, the dispenser mechanism being used. It may be that the amount of pressure for a particular system may need to be determined experimentally. Too little or too much pressure may result in inaccurate liquid metering. In the first instance the liquid may collect in the micro-dispensing valve and accumulate. In the second instance the liquid may splatter. We determined that a pressurized reservoir at between 0.5 and 20 psig is advantageous to accurately dispense the inhalant agent into the oxygen flow stream. Figure depicts a system having a pressurized reservoir.

[0081] Masks:

[0082] A conscious sedation system according to the invention may be used to deliver an inhalant analgesic agent, such as sevoflurane, along with oxygen in order to produce analgesia and/or conscious sedation so that acute care procedures may be carried out. The choice of delivery devices for oxygen and the inhalation agent depends on many factors, such as the application for which the delivery device is being used, efficacy of the delivery device, and patient acceptance.

[0083] FIGS. 11A through 11D depict four delivery devices. The full face mask (FIG. 11A) fully covers the patient's mouth and nose. Some patients may find a full face mask to be claustrophobic and for procedures where access to the mouth is necessary, such as those in oral surgery, or procedures where a patient may need to communicate, a full face mask may not be the best option. The nasal mask (FIG. 11B), which is designed to fit over the nose, may be a better choice, or the nasal cannula (FIG. 11C), which includes a tube, that fits behind the ears with a pair of prongs, which are placed in the nostrils. During mask ventilation if unable to produce an accurate airway, a nasal trumpet (FIG. 11D), which is a tube designed to be inserted into the nasal passageway may also be another inhalant/oxygen delivery device option for the conscious sedation system.

[0084] Centralized Systems:

[0085] The invention may have redundant handling of the inhalant drug, oxygen, and/or of waste gases for the safety of both the patient and the user. The device may be equipped with a sub-sized oxygen tank and with a portable scavenging system. This improves portability of the invention, while maintaining usability in non-traditional settings (examples include but are not limited to: ICU/CCU and diagnostic rooms in the hospital; doctor and dental offices, and field emergency locations), where a centralized waste gas scavenging system and/or an oxygen line are unavailable. However, the invention may be able to interface to the centralized/wall-mounted oxygen/scavenging lines, if they are available. In this case, the on-board oxygen tank will serve as a backup in case of failure of the main line.

[0086] To further improve safety and redundancy it is possible to add a small reservoir of inhalant drug within the manifold itself. FIG. 12 depicts such a system. This reservoir can hold from 1/50th of the volume of the bottle all the way to the volume of the bottle itself, and may be refilled continuously from the bottle that is engaged via the multifunctional bottle holder system. The presence of this reservoir may enable the user ample time to replace an empty bottle of inhalant drug, without negatively impacting the flow of inhalant drug being delivered to the patient.

[0087] Although the present invention has been described with respect to one or more particular embodiments, it will be understood that other embodiments of the present invention may be made without departing from the spirit and scope of the present invention. Hence, the present invention is deemed limited only by the appended claims and the reasonable interpretation thereof.

What is claimed is:

1. A method for delivery of a mixture to a patient effective to produce analgesia without loss of consciousness in a patient wherein the method comprises:

   a) forming a gaseous mixture of oxygen and a halogenated material selected from the group consisting of halogenated ethers and halothane by mixing oxygen with the halogenated material in a delivery manifold, the manifold having a controller configured to provide a gas having a concentration of the halogenated material that is limited to not more than about 0.666 MAC; and
b) controlling the proportions of oxygen and halogenated material in the gaseous mixture by metering a liquid flow of the halogenated material into a gas containing the oxygen such that the gaseous mixture comprises a ratio of oxygen to halogenated material effective for producing analgesia without loss of consciousness in the patient;

e) delivering said gaseous mixture to the patient to produce analgesia without loss of consciousness in the patient; and

d) performing a medical or dental intervention or procedure during analgesia while the patient is conscious.

2. The method of claim 1, including one or more of the following:

a) active analgesic agent recovery;
b) monitoring the patient with an EKG, NIBP, SaO₂, and/or capnography, or other respiration monitoring; and/or

c) measuring oxygen concentration.

3. The method of claim 1 wherein the halogenated material is enflurane.

4. The method of claim 1 wherein the halogenated material is isoflurane.

5. The method of claim 1 wherein the halogenated material is sevoflurane.

6. The method of claim 1 wherein the halogenated material is desflurane.

7. A system for delivering gas to a patient to produce analgesia without loss of consciousness in the patient comprising:

a) an oxygen source;
b) a reservoir suitable for storing a liquid phase of an analgesia producing agent, the agent being a halogenated material selected from the group consisting of halogenated ethers and halothane;
c) a delivery manifold having a pair of inputs connected to the oxygen source and to the reservoir, respectively, and having an output, the manifold providing a gaseous mixture of oxygen and the analgesia producing agent by metering a flow of the liquid halogenated material into the oxygen, the manifold having a controller configured to provide the gaseous mixture such that the halogenated material is limited to not more than about 0.636 MAC for producing analgesia without loss of consciousness; and

d) means for conveying the gaseous mixture from the output of the delivery manifold to a patient for producing analgesia without loss of consciousness in the patient while a medical or dental intervention or procedure is carried out.

8. The gas delivery system of claim 7, wherein the delivery manifold comprises a pressure regulator and a flow meter connected in fluid communication, the flow meter being in fluid communication with the output of the delivery manifold.

9. The gas delivery system of claim 8, wherein the pressure regulator is in fluid communication with the input of the delivery manifold connected to the oxygen source and the flow meter is in fluid communication with the input of the delivery manifold connected to the reservoir.

10. The gas delivery system of claim 7, further including heating means operatively associated with the reservoir containing analgesia producing agent and ambient temperature sensing means in controlling relation to a heating means to provide compensation for changes in environmental temperature conditions.

11. The gas delivery system of claim 7, further including an oxygen flush arrangement operatively coupled between the oxygen source and a patient.

12. The gas delivery system of claim 7 wherein the oxygen source comprises a cylinder.

13. The gas delivery system of claim 7 wherein the reservoir comprises a cylinder.

14. The gas delivery system of claim 7 wherein the reservoir has a mated index.

15. The gas delivery system of claim 7 wherein the pressure regulator is digital.

16. The gas delivery system of claim 7 wherein the pressure regulator is analog.

17. The gas delivery system of claim 7 wherein a gas scavenging system is provided.

18. A drug delivery system having a reservoir to provide halogenated material, the halogenated material being selected from the group consisting of halogenated ethers and halothane, wherein the reservoir is suitable for storing the halogenated material in a liquid phase, and a delivery manifold for providing a gaseous mixture of oxygen and the halogenated material by metering a flow of the liquid halogenated material into the oxygen, the manifold including a controller configured to provide a concentration of the halogenated material in a gas phase that is limited to not more than about 0.636 MAC for producing analgesia without loss of consciousness in a patient that is undergoing a medical or dental intervention or procedure.

19. The drug delivery system of claim 18, wherein the halogenated material is halothane.

20. The drug delivery system of claim 18, wherein the halogenated material is enflurane.

21. The drug delivery system of claim 18, wherein the halogenated material is isoflurane.

22. The drug delivery system of claim 18, wherein the halogenated material is sevoflurane.

23. The drug delivery system of claim 18, wherein the halogenated material is desflurane.

24. The drug delivery system of claim 7, including one or more of the following:

a) a system for active analgesic agent recovery;
b) a system for monitoring the patient with an EKG, NIBP, SaO₂, and/or capnography, or other respiration monitoring;

c) a system for measuring oxygen concentration;
d) a system for confirming the type of analgesic agent, which may include an RFID (Radio Frequency Identification Device), or bar code;
e) a system for collecting, storing and providing data about the operations of the conscious sedation system and/or the patient;
f) a system for holding the bottle that maintains pressure between the bottle and a conduit carrying analgesic agent from the bottle;
g) a system for pressurizing a reservoir that holds liquid analgesic agent;
h) one or more masks for delivering vaporized analgesic agent to a patient;
i) connectors facilitating connection of the drug delivery system to a centralized oxygen and/or scavenging system.