1.0 Introduction

The anesthesia delivery system consists of the anesthesia machine and breathing circuit. The anesthesia machine provides gas and vapor delivery at constant fresh gas flow (FGF). The breathing circuit is the patient interface which converts continuous constant flow into physiologic cyclic ventilation flow. The breathing circuit also manages carbon dioxide by eliminating it from the breathing circuit. It does this by absorbing carbon dioxide in a rebreathing circuit or by throwing it away in a non-rebreathing circuit. In addition, a ventilator moves gases in and out of the breathing circuit and the patient’s lungs.

The anesthesia delivery system should also include the system for IV drug infusion, a monitoring platform, and the complete anesthesia workspace. This nomenclature does not yet apply. The monitoring platform and workspace already exist and systems for IV drug infusion have long been “just around the corner”. This presentation will cover new anesthesia delivery systems, which are major offerings from GE and Draeger.

1.1 New Company Names

GE is the term I will use for the corporate name that settled after General Electric acquired Instrumentarium in October 2003. Instrumentarium has long owned Datex. Instrumentarium acquired Ohmeda from BOC (British Oxygen Corporation) in 1998. The organization’s name evolved as Ohio Medical Products and Chemicals, Ohio Medical Products, Ohmeda Corporation, Ohmeda division of British Oxygen Corporation (BOC), Datex-Ohmeda, GE-Datex-Ohmeda, GE.

Draeger is the term I will use to describe the joint venture of Draeger Medical and Siemens Medical Instruments. This venture, formally called Draeger Medical – A Draeger and Siemens Company, was formed in April 2003. North American Draeger (makers of the Narkomed Product line for sale worldwide) had been previously acquired by Draeger Medical of Lübeck Germany in the mid 1990s. The proper spelling is Dräger.

2.0 Anesthesia Delivery Systems (ADSs)

The Anesthesia Delivery Systems (ADSs) presented will include several with SmartVent ventilators. These include the older GE Modulus SE with SmartVent 7900, Aestiva and Aisys. The GE ADU will be presented briefly to highlight its differences from conventional systems. The Draeger Fabius GS and Apollo will be presented in detail, with the Narkomed 6000 and Physioflex described briefly. The Siemens Kion system was discontinued with the Draeger-Siemens merger and will not be described.
Anesthesia delivery systems have evolved dramatically since the 1846 ether bottle which both created and delivered ether vapor. Throughout the 20th century, most anesthesia machines were mechanical gas delivery systems accompanied by mechanical vaporization and mechanical or electronic ventilation. In 1978, the Boston Anesthesia System was described and demonstrated as the first computer controlled ADS. Although never produced commercially, today’s computerized ADSs followed its design philosophy. In the late 1970s, the third major US anesthesia manufacturer, Foregger division of Puritan Bennett, left the market after several deaths resulted from massive anesthetic overdose from o-ring failure in its mechanical vapor delivery turret.

In 1989, Ohmeda (formerly Ohio Medical Products and later Datex-Ohmeda and then GE-Datex-Ohmeda and now GE) integrated anesthetic, cardiovascular, and ventilation monitoring with gas and agent delivery in the Ohmeda Modulus 2 Central Display ADS. This was the first integrated ADS and monitor. Since 1990, several other corporations have made small entries into the ADS market in the USA but have made little headway.

A major change in ADS design philosophy occurred in the late 1990s. Older systems had ventilation which was affected by fresh gas flow. The “set tidal volume” determined the volume motion of the ventilator bellows. Simultaneously, fresh gas flowing during inspiration added to the set tidal volume to increase the delivered tidal volume and exhaled tidal volume which was measured and displayed. Simultaneously, compression of gases and distension of breathing circuit tubing reduced delivered tidal volume. The end result was usually exhaled tidal volume being less than set tidal volume with low FGF and being more than set tidal volume with high FGF.

The new change in ventilation is a change to “what you set is what you get” or WYSIWYG ventilation. Around the same time, the market observed anesthetic, respiratory, and cardiovascular monitors evolve and waiver between independent and integrated configurations. The more recent evolution appears to be toward integration of all measured variables into a unified monitor capable of logically displaying time-aligned graphic trends of anesthetic, ventilation, oxygen, and cardiovascular information.

### 2.1 GE ADU and Aisys

The GE ADU (GE-Datex-Ohmeda Anesthesia Delivery Unit) was approved by the US FDA in 1999. It is an integrated anesthesia workstation for gases, vapors and ventilation as well as monitoring of anesthesia, cardiovascular function, ventilation, and information management. For many of the advanced anesthesia machine functions available with this system, the Datex AS3/AS5 physiologic monitor is required.

The ADU was the first US machines to allow oxygen flow of 0 ml/min. This functionality was approved by the US FDA apparently because other internal safeguards maintain safe inspired oxygen concentration in the presence of high or low oxygen flow. Fresh gas oxygen concentration cannot be set below 25%, but this does not provide sufficient protection. The
ADU is capable of totally closed circuit operation if sampled gas is returned to the breathing circuit. GE does not have approval for this use.

The breathing circuit of the ADU is unique in that fresh gas is delivered downstream of the inspiratory valve. All previous machines delivered fresh gas upstream from the inspiratory valve into the CO2 absorber. Because of this delivery location, the advantages and disadvantages of fresh gas storage in the CO2 absorber are not found in the ADU. The ADU is likely not to be troubled by CO2 absorbent drying. Also because of the fresh gas entry site, ADU will be prone to inspiratory gas concentration change within a single inspiratory cycle in a breath. Thus, a measure of mean (rather than the traditional peak) inspired concentration is needed to allow the clinician to know the real inspired concentration. This functionality is now available from GE in the AS 3/5 Monitor.

The successor to ADU in the USA is Aisys. Its overall functionality is similar to ADU except that FGF enters the absorber just upstream from the inspiratory valve. Because of this location, with high FGF inspired agent and gas concentration can be changed rapidly and this can result in very quick and effective changes in anesthetic depth when desired. The ADU vaporizer is called the Aladin. The Aladin delivers constant partial pressure of all agents, including desflurane, at all altitudes. That makes it different from the Tec 6 desflurane vaporizer which delivers constant concentration and therefore decreased partial pressure at altitude. Aladin provides the same clinically-appropriate constant-partial-pressure performance as conventional vaporizers for the agents of lower vapor pressure such as halothane, isoflurane, sevoflurane, and enfurane.

There are other features that make ADU and Aisys advantageous over their predecessors. ADU and Aisys have disposable pre-filled CO2 absorber which can be removed during anesthesia administration for replacement or to provide rebreathing of CO2. Its small size has been considered a disadvantage by some users. The ADU and Aisys hardware and software compute Total Gas and Vapor Delivered and displays this to the user with the touch of a few buttons. There is no display of usage rate and no graph of usage. For ventilation monitoring and feedback, but not for ventilator function, the ADU used a mandatory and Aisys an optional external flow sensor mounted at the patient “Y” is named the D-Lite Sensor. This sensor has some water sensitivity. The ADU and Aisys are primarily electronic and electronic failure renders them almost inoperative. Electronic failures have been reported. The ADU became very popular in Canada round 2000.

### 2.2 DRAEGER ADSs – not described in full

The Draeger Julian anesthesia system was marketed for a short period in the USA. The Draeger Narkomed 6000 was the last of the Narkomed series of ADSs. In it, Draeger integrated many electronic functions into a primarily mechanical machine. This ADS continued the North American Draeger anesthesia machine developments of the 1980s and 1990s. The Draeger Physioflex ADS system began sales in Europe around 1990. It was never sold or approved for sale in the US. It was replaced by the Zeus ADS in Europe. Its functionality and appearance are reminiscent of the Boston Anesthesia System of 1976. It provides closed circuit anesthesia as its major functional advantage. The user specifies inspired oxygen and expired agent concentrations. Functions are varied.
concentration desired in the breathing circuit and Zeus delivers flows and concentrations to achieve this setting. A circulating flow of 30 LPM keeps the inspiratory and expiratory circuit limbs fully mixed. The Zeus dramatically reduces Compound A production from sevoflurane, even when metabolic closed circuit (200 mL/min) flows.

The Siemens Kion entered and left the US market. Distinguishing features of this machine were its electronic gas control, several modes of ventilation, rebreathing and non-rebreathing circuit functionality, and a rotating turret allowing selection among three vaporizers. The Kion showed its electronic gas delivery on the front panel. It displays and labels “preset oxygen concentration” and fresh gas flow. Because inspired oxygen differs from fresh gas oxygen concentration, this display was confusing to many users and predisposed to incorrect use and the perceived inability to control inspired oxygen. Siemens Medical is now part of the Siemens-Draeger venture and this ADS was discontinued.

3.0 Achieving New Functionality – Generalities

An important function of the Anesthesia Machine is controlling Fresh Gas Flow (FGF). With conventional machines, gas delivery is controlled mechanically. The user rotates a mechanical knob attached to the needle valve which mechanically adjusts the narrow channel between the valve pin and seat. A rotameter measures the flow with a floating ball or cylinder which rises to a height which depicts the flow according to the scale etched or printed on the tube. At the low end of the flow range, the space between float and tube acts as an orifice and the height of the float is determined by gas density. At the high end of the flow range, the float and walls of the tube form a long narrow annular channel which acts as a laminar flow resistor and the height of the float is determined by gas viscosity.

With electronic gas delivery, a knob or slider is set and valves or sonic flow nozzles (mass flow controllers) are switched on or off in varying numbers or for varying times to create the desired flow for each single gas. Next, resistive, restrictive, or mass flow meters measure the flow, verifying that actual equals set flow. Finally, numbers, bar graphs, or pie slices display the flow.

Draeger’s ADSs use mechanical-electric flow controllers, the needle value is mechanical and the flow measurement is electronic. The flow indicator changes in response to the measured, not the set flow so the display appears slightly sluggish or delayed.

Vaporization is traditionally accomplished and regulated mechanically. The user adjusts a large calibrated control dial which controls the vaporizer setting. This dial moves the valve which controls the internal bypass flow, the flow which does not interact with saturated anesthetic vapor. With most modern vaporizers, the valve leading into the chamber changes with temperature while dial setting controls the valve carrying saturated vapor from the vaporizing chamber into the main flow path. Vaporizers so designed (Draeger Vapor 19, 2000, GE Tec 5,6,7) produce constant partial pressure output at any barometric pressure, independent of weather or altitude. Because partial pressure of anesthetic is the determinant of anesthetic depth, these vaporizers anesthetize the same at any altitude. Agent is not measured or displayed by the
vaporizer. The dial indicator is all the information which is provided. Inspired and expired partial pressure or concentration is measured by a anesthetic agent monitor, either separate or integrated in the ADS.

With the Tec 6 vaporizer for desflurane, agent liquid is heated to approximately 40C to reach a vapor pressure of 1500 mmHg. This pressurized vapor is quantitatively mixed with equal-pressure rotameter gas. In this way, constant concentration is produced by the vaporizer. With the Desflurane Tec 6 vaporizer, anesthetic effect is proportional to atmospheric pressure which decreases with altitude. Thus, vaporizer setting must be increased when anesthesia is administered at altitudes above sea level. Depending on how the anesthetic agent analyzer is calibrated and read, it can either elucidate or confuse barometric pressure effects.

With electronic vaporization in ADU and Aisys, a knob or slider is set and a computer or electronic circuitry determines the remainder of vaporizer activity. In the GE Aladin vaporizer, a single vaporizer accepts a different reservoir for each agent. In the Aladin, vaporized agent is added to the rotameter flow. A number and a triangular display show the partial pressure (% atmos) for all anesthetic agents.

### 4.0 Major Changes in Breathing Circuits and Ventilation

One of the major advances in ADS design is WYSIWYG (What you set is what you get). For gas delivery, systems have always functioned this way. The needle valve controls, the rotameter displays, and the set partial pressure is delivered to the breathing circuit. For vapor delivery, this has been true since design moved from Copper Kettle™ (Foregger) and Vernitrol™ (Ohio Medical Products, now GE) to direct reading vaporizers (DRVs). However, the mixing of exhaled gas with fresh gas to produce inspired gas confuses many clinicians. What you set is what you get (WYSIWYG) at the Fresh Gas Connection from machine to breathing circuit. What you deliver to the patient might be quite different.. The patient receives the flow-weighted average of expired gas flow and fresh gas flow, mitigated by the breathing circuit design..

For ventilation, the WYSIWYG concept has been violated for generations of clinicians. The interaction among fresh gas flow, bellows movement, lung compliance, circuit distention and gas compression have confused anesthesia care providers for decades. No matter what the situation, it appeared that the measured exhaled tidal volume differed from the set tidal volume. More recently, ventilator function has become independent of fresh gas flow and compliance. This is achieved in one of several ways described later with regard to each design and each vendor.

Inspired gas composition has always been confusing to most clinicians. Inspired gas is created effectively or ineffectively, economically or uneconomically, by adjusting the flow of oxygen, air, nitrous oxide and the vaporizer setting. In each case, inspired gas is composed of a mixture of fresh gas and exhaled patient gas and is often not what is desired by the clinician. Thus, low fresh gas flow is difficult for some clinicians to utilize
5.0 Ventilation Control

The new ADSs achieve inhaled tidal volumes and minute ventilation equal to what is set. What you set is what you get (WYSIWYG). They each have many specific modes of ventilation with slightly different names and functionalities. Overall, the modes are quite similar. The two major manufactures use very different technologies to reach this goal as I will describe below. GE uses SmartVent with feedback control on inspired flow and volume while Draeger uses Fresh Gas Flow decoupling during inspiration.

5.1 GE SmartVent™ (Aestiva, Avance, Aspire, ADU, Aisys)

All modern GE ADSs use the same SmartVent™ technology. It provides two classes of ventilation - volume control and pressure control. These classes of control are then classified in various control and assist modes. SmartVent compensates for but does not disclose circuit compliance to the user. It compensates for leaks but doesn't disclose leak rate. Its mode of controlling tidal volume is the following. SmartVent measures inspired flow and tidal volume and terminates and controls bellows displacement to force this value to be close to that which was set. Ventilation control uses measured inspired tidal volume and controls it to the set value.

The key element of the GE SmartVent is the flow sensor. It is a variable-orifice sensor (VOS) for flow. The VOS is a resposable (limited-reuse disposable) which uses electro mechanical technology. There are two flow sensors, one in each of the circuit limbs. The flow sensor is placed between the circuit limb and the CO2 absorber. The technology is a variable-orifice differential-pressure flow sensor. The variable orifice gives the sensor a nonlinear pressure-flow relationship which allows it to maintain reasonable sensitivity and accuracy over a wide range of flow rates, much better than could be achieved with a linear or with a quadratic (orifice) flow analyzer. Successive increments in flow cause smaller increments in pressure across the orifice whose size increases with flow through it. The orifice size increases by opening a flap over a hole, both of which are part of a single piece of Mylar®. The differential pressure transducer measures pressure across this variable orifice and there is a one-to-one relationship between pressure and flow. The pressure-flow relationship of each VOS is measured and recorded at the factory and each resposable sensor contains a circuit chip which stores the response curve for that particular sensor.

The SmartVent functions as follows. Initial tidal volume is created by flow and time control. As the bellows is caused to push gas into the breathing circuit and the patient’s lungs, flow is measured every 40 milliseconds. Instantaneous flow and cumulative flow within a breath are recorded. When the set tidal volume is reached, the bellows stops. As the patient exhales, expired flow is measured continuously by another VOS. When exhalation is complete, software computes the volume exhaled. If it differs from set inspired tidal volume, the user is alerted and the bellows movement on the next breath changes to compensate.

With the GE SmartVent, inspiratory and expiratory flow sensors are the key elements to create and monitor safe and effective ventilation. For this reason, it is imperative that they functional
properly. The Model 7900 SmartVent exposes two separate VOSs on the inspiratory and expiratory limbs between breathing circuit and CO2 absorber while later GE ventilators uses sensors similarly located but hidden under a removable plastic manifold. When the tubes are exposed they can become caught or kinked and thereby occlude.

If water droplets form in any of the four pressure sensing tubes, pressure is not properly conducted, the VOS is unable to measure flow and the ventilator alarms and announces its inability to compensate or its inability to ventilate the patient. It does this audibly and visibly. Water occlusion happens frequently when fresh gas flow is less than 1 LPM unless a heat and moisture exchanger (HME) is used between patient and flow sensors. This is usually accomplished with an HME at the circuit bifurcation near the patient, termed the wye or Y. Newer versions of the SmartVent seem less sensitive to water condensation. Nonetheless, with all ADSs equipped with the GE SmartVent, a heat and moisture exchanger (HME), effective in blocking water vapor, must be used. This is especially needed if low fresh gas flow is used or has been used recently on the same ADS.

Because the SmartVent ventilator uses a traditional upright bellows in a clear plastic chamber, bellows height can be observed and quantitative closed circuit anesthesia can be administered easily. With low flow or closed circuit sampled gas must be returned to the breathing circuit. This could be done using the Expiratory Pressure Sensing Port on the Modulus SE with SmartVent. The newer GE ADSs require an additional adapter. GE does not supply “Sample Gas Return Connectors” because this functionality has not been approved by the US FDA. This is probably because air is returned with the sampled gas when GE multi-gas monitors are used.

When SmartVent is set to volume-controlled ventilation (VCV), there is no inspiratory pause between the end of inspiration and the beginning of expiration. Thus it is difficult to differentiate problems of resistance from problems of compliance. Inspiratory pause can be set by careful menu navigation through the ventilator control settings.

5.2 Draeger Fabius and Apollo Fresh Gas Decoupling

The Draeger Fabius GS (Fabius Gas System) has a piston ventilator with user-set tidal volume. Ventilation is maintained unchanged with changing fresh gas flow. This is accomplished by Fresh Gas Decoupling. This decoupling is achieved by storing fresh gas in the reservoir bag during the time when the piston is pushing inspiration. As fresh gas is stored during inspiration the reservoir bag expands. Many users find the expanding reservoir bag confusing at first. Fabius ventilator modifies ventilation volume by adjusting piston movement according to circuit compliance and gas compression measured during automated machine pre-use check. Further compensation is not possible.

Exhaled tidal volume is measured using a hot wire anemometer as the flow sensor. This is located in the CO2 absorber, just downstream of the expiratory valve. This sensor is comprised of two small heated wires in the center of the expiratory flow pathway. Cooling of one of the self-heated wires is proportional to flow which computes tidal volume. The specific heat of desflurane is higher than that of the other agents. Because the anemometer senses heat removal
which is proportional to specific heat, “Desflurane Compensation” must be switched correctly on or off to avoid measurement error.

The Draeger flow sensor is not impervious to moisture but it appears to be much less sensitive than SmartVent. In addition, errors in flow measurement do not result in inaccurate tidal volume or inability to ventilate. Errors only result in incorrect reported tidal volume, with correct tidal volume generally delivered despite any error in flow measurement.

The ventilator piston always returns to its resting location after each breath. Thus, monitoring its position does not add to clinical monitoring. Draeger therefore places the piston out of direct view. It is located left of the flowmeters under a cover with a small plastic window. Absence of a visible bellows makes closed circuit anesthesia difficult and quantitative closed circuit anesthesia impossible. It also makes anesthesia for thoracic surgery difficult since lung leaks cannot be quantified. When the reservoir bag is totally empty and the refilling piston is drawing in room air, Fabius GS alarms to indicate this.

Adjustments to the Fabius GS ventilator are made by pressing the button corresponding to the parameter to be changed, rotating the control knob, and pressing the control knob to confirm the change. Many new users find this control paradigm difficult to adapt to and find desired changes in ventilation often not achieved. If the change is not confirmed Fabius sounds a repeated alert.

5.3 FABIUS GS Breathing Circuit - Three Versions of COSY

The Draeger Fabius GS Compact System for CO2 absorption (termed COSY) is different from earlier breathing circuits in other machines. This breathing circuit has only one CO2 canister and the canister either can or cannot be changed during use depending on whether the disposable or reusable option is purchased, respectively. The relief valve (previously called APL = adjustable pressure limiting or pop off valve) has a wide open position just beyond the lowest pressure setting. In this position, the knob lifts approximately 0.8 mm and provides very low opening pressure to the patient’s airway and breathing circuit. For this reason, it is easier to maintain a tight mask fit before induction with this design. This allows alveolar oxygenation (denitrogenation or pre-oxygenation) without patient complaint, even in the presence of moderately high fresh gas flow.

In addition to Fresh Gas Flow Decoupling, COSY configuration in Fabius GS needs to be understood by the user. There are currently three COSY varieties in the installed base of Fabius GS. All use fresh gas decoupling to store fresh gas during ventilator inspiration. In the original COSY (COSY 2.5), the reservoir bag was located just before the inspiratory valve, a different design than in other ADSs. In this location, fresh gas was diverted directly into the reservoir bag where it was stored while the ventilator piston delivered inspiration to the patient. The hope was that this would retain fresh gas in preference to exhaled gas and provide faster gas composition change when desired.

Unfortunately, this design led to occasional large transient leaks. These occurred when stiff lungs exhaled through a large diameter (low resistance) tracheal tube and through a moderate-
resistance CO2 absorber on the way to the compliant reservoir bag. In this situation, the resistance of the CO2 absorbent combined with the brief high puff of flow led to a transient rise in pressure in the expiratory limb of the circuit. This pressure was above the scavenger relief valve opening pressure and the valve opened. This produced a “puff leak” which was as high as 3.5 Liters per minute average.

Discovering and understanding this problem led Draeger to modify the COSY design to COSY-2.6. By making minor modifications in the absorber channels, Draeger engineers functionally moved the reservoir bag from the inspiratory to the expiratory side of the CO2 absorber. This returned COSY-2.6 to a standard configuration, bag-before-CO2-absorber. By sending the exhaled gas directly to the reservoir bag, the infinite compliance of the unfilled bag absorbed the entire expiratory flow puff without raising the pressure seen by the scavenging valve. Gas loss was thereby totally eliminated. COSY-2.6 systems allow totally closed circuit anesthesia. This requires sample gas return to the circuit, of course.

COSY-2.6 can be distinguished from COSY-2.5 by carefully observing the location of the reservoir bag connection to the COSY. The bag connects near the valve to which it is connected. Thus, the bag is near the inspiratory valve in COSY-2.5, the system which can leak. The bag is near the expiratory valve in COSY-2.6, the system which does not leak. Adding to the confusion, the inspiratory and expiratory valves are located on the right and left, respectively. This is the opposite of other ADSs.

The new COSY-3 reverses the location of all components on the top of the COSY, placing the APL valve and expiratory limb near the clinician. The control hoses are no longer visible and susceptible to disconnection.

5.4 Draeger Apollo

The Draeger Apollo is similar in functionality to the Fabius and Tiro. The breathing circuit is simply called the Breathing System. It functions like that in the other Draeger products. The ADS includes an integrated gas monitoring bench. It thereby knows when it is and is not delivering desflurane and the user need not set desflurane compensation of ventilation volume. The display occupies a large area and displays numeric and graphic trends of all variables controlled, measured, and derived from respiratory variables.

5.5 Control of inspired gas and agent concentration

Inspired concentration control with Draeger Breathing Systems is not as fast as with GE Breathing Systems. Recent published studies showed that in preparation for patients susceptible to malignant hyperthermia, anesthetic agent cannot be cleared down to 5 parts per million from the Draeger circuits in less than one hour. Very high fresh gas flow of oxygen and air and removal of the reservoir bag speeds the removal of anesthetic agent. Adding a charcoal agent absorber to the inspiratory limb in preparation for a susceptible patient solves the problem quickly.
This rebreathing problem becomes important at the termination of anesthesia. Even with maximum FGF of 12 LPM, inspired agent concentration cannot be reduced to zero for five (5) minutes unless extraordinary maneuvers are used. These include very high fresh gas flow (Oxygen and Air at full flow, totaling 50 LPM) or continuously pressing the Oxygen Flush Button. These high flow techniques are safe because the fresh gas flow is decoupled from the inspired tidal volume, as described above. Future breathing circuit design changes will likely correct this difficulty.

6.0 Summary

In summary, there are several new ADSs on the market in the USA. Each has its strengths and weakness. It is important for the clinical care provider to understand the subtleties of the Anesthesia Delivery System he or she uses