# Oxygen On Site

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BeaconMedæs®
Continuing Education Publication

**Notes on Using this Pamphlet:**

This pamphlet is presented as a service to users of medical oxygen who may have reason to consider producing that oxygen at their site. We deal here with the production of medical oxygen for use in a central piped oxygen system and the many considerations in the development, installation and operation of such a system. The pamphlet is particularly intended for design engineers and operating personnel who are involved in the development, specification and operation of on-site medical oxygen source systems with the goal of ensuring a continuous safe supply of gas for the clinician and patient.

Although we will be discussing medical applications for oxygen, it should be understood that this is not a clinical guide and that the author in no way intends to offer a clinical opinion regarding the treatment of any particular patient with any particular concentration of oxygen.

The primary standard most referenced herein is the ISO 7396-1. This standard has now replaced the ISO 10083, and all requirements for medical concentrators are there. The user is encouraged to obtain copies of the standard (or other locally relevant standard) if they intend to implement such a system in their facility.

Any opinions expressed and/or interpretations given or implied are the sole responsibility of BeaconMedæs and the author, and users are expected and encouraged to obtain information from other sources.

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Comments on this booklet or on any aspect of medical gases are welcome and encouraged. Please send to mark.allen@beaconmedaes.com

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**Introduction**

On site oxygen systems are relatively new as central supply sources for pipeline systems in hospitals. Although some early systems date back into the 1980's these tended to be plagued with problems and many have been abandoned or decommissioned. However, in the last 10 years, their use has begun to gather momentum, helped by the issuance of pharmacopoeial monographs for Oxygen 93 by the United States Pharmacopeia and the European Pharmacopeia, as well as creation of standards like the Canadian Z305.6 and ISO 10083 standards.

The number of systems in successful operation is climbing, the technology is improving, and the options are now more diverse.

In 2016, concentrators moved from the ISO 10083 into the main ISO document for piped medical gases, the ISO 7396-1, and are proposed to appear in the next edition of the NFPA 99 (2018). With that, all the major international standards will include this source option.

The design, installation and operation of these systems has pharmaco-legal, engineering and safety aspects that should be understood by anyone interested in applying one of these systems. This pamphlet is particularly intended to assist an engineer with understanding the technology and other issues as an aid to making good design decisions when contemplating specifying one of these sources.

Our essential goal in this paper is to ensure that if you elect to design and operate such a system, that you do so safely. With these systems there are two essential aspects in a safe installation:

• The safety of the operating staff and the general public (e.g. fire prevention, prevention of explosion, etc.) and,

• The well being of the patient who is depending on the supply of oxygen for life support.

A well designed and operated system will ensure both of these.

**Cylinder, Container, Concentrator**

Air is a mixture of gases, in which ≈20.9% is oxygen. If you simply remove the other gases, you can theoretically attain any concentration of oxygen desired. All commercial production of oxygen is achieved using a concentration process (true

oxygen *generating* processes [e.g. chemical oxygen generators] are typically limited to small and restricted output applications such as emergency oxygen for aircraft).

The most common commercial process for concentrating atmospheric oxygen is to liquefy the air and then distill that liquid air into its various components. Liquefaction is a complex operation involving compression, cooling, and distillation. While in theory it could be done on a hospital level, the inherent efficiencies and economies of scale mean that in practice it is a large industrial operation. The product is a set of very pure (99.9+%) liquefied gases (liquid nitrogen, liquid oxygen, liquid argon, etc.) at very cold temperatures (< -183°C for oxygen).

Ultimately, these liquefied gases will be converted back into their gaseous state for patient use, but while in the liquid form the gas can be stored and transported efficiently. To illustrate, consider a cubic meter of oxygen. In its gaseous state (at standard atmospheric pressure) it will take up a cubic meter of space. In the standard compressed gas state (e.g. as found in typical cylinders, compressed to the very high pressure of 150 bar) it will occupy 0.0066 cubic meters. In liquid form, the same gas will occupy 0.0003 cubic meters and the pressure will not even need to be particularly high (10 to 20 bar). So liquid offers a very good way to handle a lot of gas.

The challenge is to keep the liquid cold while storing and transporting it, which requires containers with very efficient insulation. However, because no insulator is perfect, these containers are subject to heat leakage (referred to as the Normal Evaporative Rate). As heat leaks into the container the liquid will convert back into gas. This limits the shelf life of the container.

Naturally, the container is also very heavy.

With liquid, the quantity of oxygen one can transport can be scaled without much change in the labor or transport involved. But as the transport vehicle travels from the air liquefaction plant to the hospital site the container is slowly vaporizing oxygen. That gas must be vented to prevent the container exploding, so the container's contents will slowly leak away. The vehicle can only go so far before the container will arrive empty.

In practice, liquid can be moved quite a distance, especially if the transporter includes a refrigeration system. However, the economics of moving a heavy vehicle carrying a relatively low value commodity come into play, and the cost of transport rapidly dwarfs the cost of the actual gas.

In comparison, oxygen in cylinders is not subject to heat leakage, and so gas in cylinders generally has no shelf life.

To fill a cylinder it is necessary to make the oxygen (typically by liquefaction), change it into gas and compress it into the cylinders. Naturally, this additional processing adds cost. As a result, cylinder oxygen, liter for liter, is almost always more expensive than liquid, even before transportation is factored in.

While cylinder oxygen can be transported almost infinite distances, the cylinders themselves are heavy, require care in handling (because of the very high internal pressures) and are limited in storage capacity. To supply even a modest sized hospital with oxygen by cylinder is a labor and transport intensive process. To supply one at a great remove from the cylinder filling facility gets uneconomic very quickly.

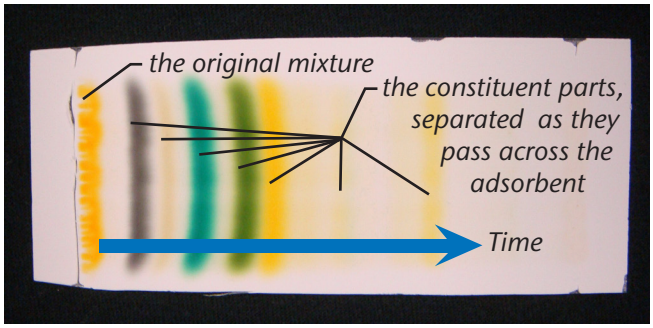
On top of these basic considerations one can add the complications inherent in water transport for facilities located on islands, interruption of transport links by snow, floods, or local unrest, transport safety rules and a host of other local considerations. Together, these factors may make liquid oxygen supply and storage problematic or unacceptably expensive.

While it is largely impractical to build a hospital-scale air liquefaction plant, it is possible to perform air separation at the single-hospital scale with membranes or adsorbent. Membranes remain a technology for someday, as they have not yet demonstrated the cost, performance and longevity of the adsorbent methods for oxygen separation. The technology of choice for these concentrator systems today is therefore adsorption.

**Theory and Practice of Concentrating Oxygen**

The fundamental building block of an adsorption oxygen concentrator is of course the adsorbent itself. These materials are selected because they have a very porous structure which naturally entraps molecules of gas. By selecting for a physical chemistry with a preference for a specific molecule, it is possible to use the material to separate the molecules as they pass through a column of the adsorbent material. The principle is the basis of the science of chromatography, and a simple thin layer chromatographic plate illustrates the effect (see Detail 6.1).

The adsorbent in a concentrator has to be chosen for it's selective retention of one gas over another, and then formed into a shape that will allow it maximum exposure to the gas mixture. This generally is a bead or hollow cylinder shape, and the material is a form of molecular sieve, usually made of carbon or aluminum oxide. A typical adsorbent bead is shown in Detail 6.2.




***Detail 6.1***
*A chromatographic plate showing the separation of constituents in a mixture over time*
*Source: www.austincc.edu/biol 1046*

A familiar example of adsorbent separation at work is the desiccant dryer, where the desiccant is selected to preferentially retain water vapor.

Exploiting the principle of the chromatograph illustrated in Detail 6.1, we can further illustrate the process of gas separation and begin to build up the elements of the actual functioning concentrator.

In Detail 7, we have illustrated a basic column or *sieve bed* filled with our adsorbent beads. We have chosen in the illustration to use an adsorbent which prefers to retain nitrogen.

As the air passes through the adsorbent, the molecules that the adsorbent can retain (e.g. nitrogen, carbon dioxide) are held back by the adsorbent, and the molecules in the feed air that the adsorbent does not retain (e.g. oxygen, argon) pass on.

When the gas reaches the outlet, it now only includes the molecules that the adsorbent does not retain. So for a time, only those molecules *elute* from the column.

Eventually, the adsorbent saturates, which means it has retained all the molecules it can, and now every molecule passes through. The relative concentrations of the molecules at the outlet returns to being the same as the feed air.

It should be obvious that the simple secret to making a concentrator is simply to draw off the concentrated oxygen molecules only during that period when the nitrogen is held back.

***Detail 6.2***
*Adsorbent (sieve) beads*

The amount of oxygen a single column system like the one described in Detail 7 could produce would of course be limited by the total amount of adsorbent the vessel contains. Obviously, such a "one shot" system would not be very practical for ongoing oxygen production.

Continuous production of oxygen requires regenerating the column by desorbing the nitrogen. That will allow the column to be recycled. There are two ways in which this is done, but we will start with the more common dual sieve bed concentrator. In this technology, two columns and some carefully designed controls are used to do this, and to repeat the cycle on a continuous basis.

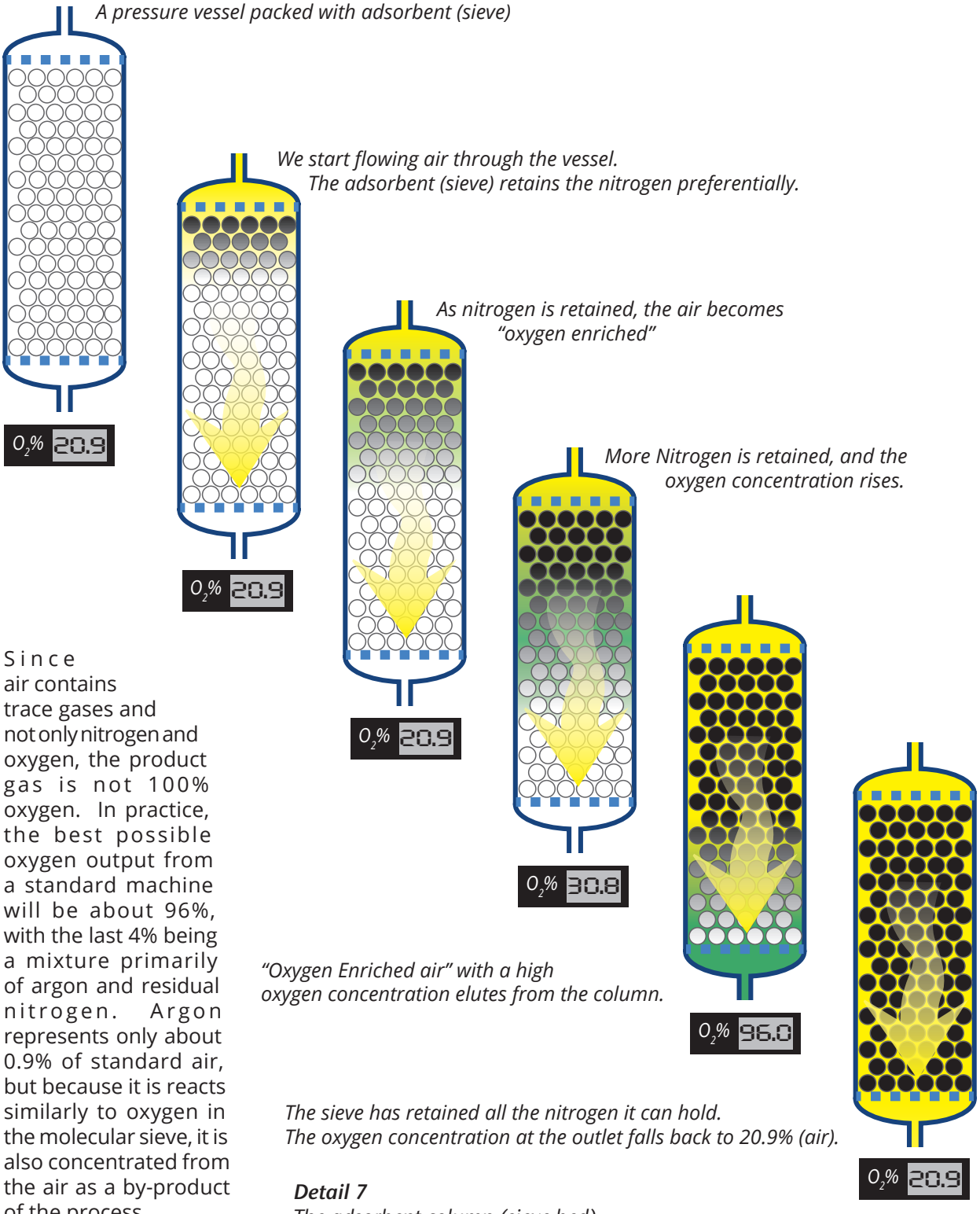
This is one of the secrets to the operation of the concentrator: the adsorbent material in the column must be equally ready to *adsorb* or *desorb* the nitrogen, based on some controllable variable. In the standard concentrator, column pressure is that variable. The adsorbent will retain nitrogen under pressure and desorb it when the pressure is reduced. *Pressure Swing* is how the column is regenerated (see Detail 8). Thus the term often applied to concentrator systems : Pressure Swing Adsorption or *PSA*.

The PSA process usually uses two columns in parallel, with the pressure in the two columns being managed using a group of valves. The first adsorbent column is pressurized, the oxygen is concentrated and passed downstream. When that column has retained all the nitrogen it can hold, the second column is switched into the gas stream and the first column is allowed to vent to atmosphere. The reduction in pressure allows the nitrogen to desorb from the column and exit the vent, assisted by a samll "sweep flow" of oxygen. When the nitrogen is all vented off, the column can be reused.

You can immediately see that the "speed" of the process (and thus the oxygen output) depends on the adsorbent's affinity for nitrogen. It must selectively retain the nitrogen but also be able to clear that nitrogen based on the pressure cycle. This can be

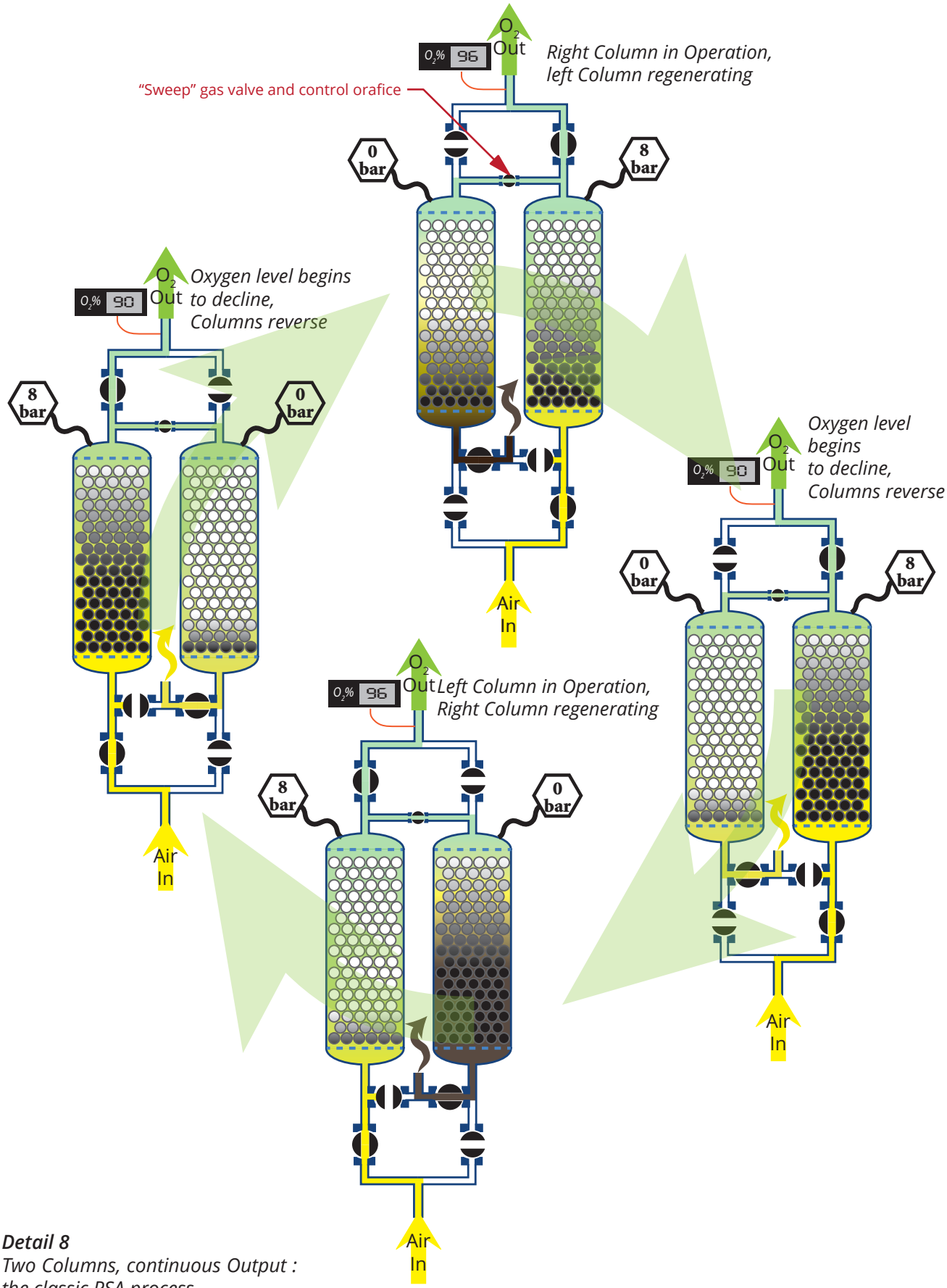
improved by either of two methods: one is to use a purge flow of oxygen to backflush the nitrogen out of the regenerating column. The second is to use a vacuum pump to evacuate the regenerating column (sometimes termed *Vacuum Swing Adsorption*)

Argon is non-toxic and has been shown to be clinically inconsequential at these levels. It's presence however prevents the concentrator from reaching higher concentrations. Concentrators do exist which can scrub the Argon and obtain 99+% oxygen, but they are significantly more costly to operate. Naturally, this limits their practical use.




Since air contains trace gases and not only nitrogen and oxygen, the product gas is not 100% oxygen. In practice, the best possible oxygen output from a standard machine will be about 96%, with the last 4% being a mixture primarily of argon and residual nitrogen. Argon represents only about 0.9% of standard air, but because it is reacts similarly to oxygen in the molecular sieve, it is also concentrated from the air as a by-product of the process.

***Detail 7***
*The adsorbent column (sieve bed)*




***Detail 8***
*Two Columns, continuous Output :*
*the classic PSA process*

The sieves available naturally determine the efficiency of the process. The best adsorbents and processes available at this writing can concentrate roughly one liter of 96% oxygen for every 9 to 10 liters of input air. However, this theoretical capability is not usual in commercially available systems, where a ratio of 12:1 can be expected.

If one draws product off the concentrator faster, the feed air to product oxygen ratio can be improved, but the trade-off is that the oxygen concentration is reduced. At a 93% concentration, the air to product oxygen ratio will be on the order of 11:1, at 90%, 9:1. This ratio is of course crucial in the evaluation of the economics of a concentrator, as we will discuss later in this pamphlet.

The VSA process is essentially the same as the PSA process, uses the same sieves and the same physical chemistry. However, instead of compressing the feed air to higher pressure, it reduces the baseline by using vacuum. For PSA, the cycle is pressure - separation - vent - pressure. For VSA, the cycle is separation - evacuation - pressure. A VSA unit can use two adsorber columns or only one, and can use substantially less energy because the air does not need to be pressurized to as high a pressure.

**Concentrators and the Pharmacopoeias**

PSA concentrators have proven reliable and invaluable for a variety of medical settings. Particularly in home health care, single patient concentrators enable a level of treatment at an unbeatable cost. Concentrators allow oxygen to be provided in many places and circumstances where classical oxygen delivery is unaffordably expensive. The clinical value of the technology is recognized by both the U.S. Pharmacopeia and the European Pharmacopeia, which both now include monographs that specifically address oxygen at concentrations between 90 and 96%. Entitled "Oxygen 93", they are written expressly to facilitate the safe medical use of concentrator produced oxygen.

There has been a ferocious debate for decades over the appropriateness of concentrator oxygen in hospital use. While this debate raged on the theory of the question, there remained the underlying reality, which was that for many facilities, they could have concentrator oxygen or no oxygen at all. These facilities, assisted by researchers from both sides of the debate, have gradually established the medical facts, which appear to be that concentrator oxygen is perfectly adequate for every ordinary medical procedure, provided that good practice is observed with regard to oximetry and other patient monitoring.

It is clear from the available research and from accumulated experience (which is piling up as concentrators become more widespread) that concentrator oxygen is therefore entirely suitable as a medical oxygen source for healthcare.

Certain standards do prohibit hyperbaric use of concentrator oxygen. This is due to lingering unease over the potential of argon toxicity. There is very little clinical evidence that such a problem exists (and as counterpoint, recently there are suggestions that

**One, Two or Three?**

*In the rarified atmosphere of the standards writing and pharmaco-legal communities, there is a debate over the legal implications of having two pharmacopeial monographs for medical oxygen (both USP and EurPharm have both). The older one, "Oxygen", defines medical oxygen as it is produced by cryogenic air separation and calls for a concentration of 99%+. The newer monograph, "Oxygen 93" defines oxygen as produced from a concentrator, and calls for oxygen with a concentration of 93% ± 3% (90 to 96%).*

*The legal question is: are these two distinct drugs or one drug at two separate concentrations? After one answers that question, then the inevitable next question is: Where does oxygen with a concentration between 96% and 99% fit in?*

*Although experience shows that this debate has little consequence to practical patient care, the answer will determine if and how concentrators can be used in some countries. The law in many places is that two drugs cannot be mixed in the facility. So if these two are separate drugs, it would be illegal to put "Oxygen 99" cylinders on an "Oxygen 93" concentrator system as reserve cylinders. That gas could flow into the system with the gas from the concentrator, and hey presto, the two drugs are mixed. On paper, that is illegal in itself and could create a "drug" that has no legal existence.*

*If on the other hand the two are simply concentrations of the same drug, then concentrator implementations become considerably more straightforward.*

*It is interesting that the problem is thorny enough that at least in europe, discussion is ongoing about creating a third monograph for "Oxygen 90+", which would permit concentrations anywhere from 90 % to 100 %.*

Argon may actually reduce the neurotoxicity of some anaesthetics [see the bibliography]).

Oxygen 93 has been successfully applied as the source for hyperbaric applications, and as a result even that prohibition is likely to disappear over time. Depending on the therapy, hyperbaric applications can require very high flows of oxygen, which can also make concentrators less than ideal for the use.

Only one hurdle remains. It is known that some manufacturers of medical equipment (anaesthesia workstations, ventilators, etc.) have designed their equipment on the assumption that the oxygen from a wall outlet was 99+% and thus could be used for calibrations and as an internal machine reference. While this has always been a questionable assumption, when concentrator oxygen is used, it naturally becomes entirely invalid. Oxygen concentration from an ordinary concentrator can and will vary during normal operation between 90 and 96%. While this has been demonstrated to mean little to the patient, it can be of the first importance with the clinical apparatus.

This problem is not universal among equipment manufacturers, and it is obvious from the experiences of many users that it has not proven an insurmountable obstacle to the use of concentrators. However, until this is fully addressed by the medical device manufacturers, users of concentrator oxygen must choose their equipment with this in mind and may need to obtain calibration gases with known values to ensure certain clinical apparatus can be accurately calibrated. This subject is outside of the scope of this pamphlet, but this concern should be noted and the medical staff should always be aware when a concentrator is used as an oxygen supply.

### The Parts of a PSA Concentrator Source

Detail 10 provides a block diagram of the functional elements in a PSA concentrator supply source, as might be installed in a typical hospital.

Considering each of these modules in turn:

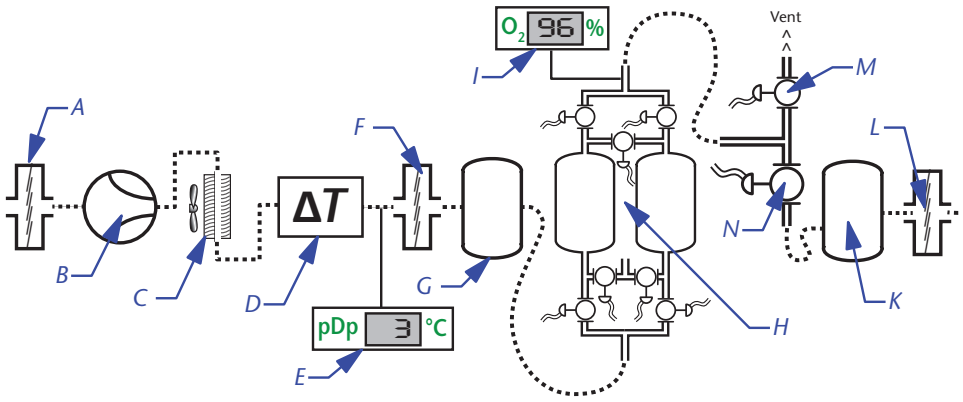
The *Air Compressor* (B) of course produces the basic feed air needed for the operation of the concentrator. As mentioned, the compressor must typically produce about 12x as much air as the concentrator can produce oxygen. So, as an example, if the concentrator is capable of 100 lpm, the compressor must be capable of 1,200 lpm. Proper sizing of the compressor is essential to obtaining the desired output.

While it may be surprising to hear, it is not typical for these concentrator sources to use oil free compressors. The primary reason for this is simply money - lubricated compressors are less expensive to buy. This is short sighted, since the adsorbents used are extremely sensitive to oil, and the presence of oil vapor in the feed air will distinctly shorten the life and reduce the capacity of the concentrator. However, providing oil lubricated compressors reduces the purchase price for the concentrator plant, and since the facility owner is probably not even conscious that so important a decision is being made, it is rarely questioned.

Because the long term effectiveness of the concentrator is very dependent on the quality of the feed air, some air treatment is vital. This will usually include some filtration, a refrigerated air dryer, and an air receiver. The filtration will remove most particulates generated by the compressor and dryer, and if an oil lubricated compressor is used is also essential to reduce the oil transmitted.

A is an inlet filter which primarily functions to protect the compressor itself.

The *dryer* (D) reduces the water vapor loading on the concentrator. PSA concentrators are particularly vulnerable to water problems in the adsorbent. The compression of the air increases the dew point of the air, and water vapor can condense inside the




***Detail 10***
*A PSA medical oxygen source*
*(note: other arrangements of components are possible)*

concentrator and cause a total failure. Water vapor will also compete with the nitrogen for space in the concentrator adsorbent and reduce efficiency of the process. Removal of the water is essential for ongoing operation so a dew point monitor (E) is a highly desirable safety device.

In trying to save money, a common design trick is to leave out the compressor aftercooler (C). This is a very poor practice which risks very hot air going into a dryer designed for inlet air of 38°C maximum. Particularly in hot climates, but possibly anywhere, this means that the dryer is less than fully effective and more water passes to the concentrator than is ideal. This is one of the problems which are invisible at start up, but can over time reduce the effectiveness of the concentrator and lead to recurrent frustration with concentrator operation.

It is unusual to see a concentrator furnished with a desiccant dryer. This is because a desiccant does not remove a great deal more water on a part per million level than does a properly functioning refrigerant dryer, but it does require purge air. Purge air increases the required size of the compressor. Since the concentrator will in any event separate water as well as nitrogen, the produced oxygen will be at a very low dew point whatever dryer is used. There is therefore little advantage to using a desiccant dryer.

F is the filter that protects the concentrator adsorbent. The filtration provided will therefore vary with the compressor type employed. It should never be coarser than 1µ and must include oil removal capabilities if oil lubricated compressors are used (activated charcoal canisters are preferred, NOT absorbent impregnated filters, which have very limited capacity). It is a vitally important maintenance item as well.

A receiver (G) is placed at the inlet to the concentrator largely to handle the surges caused when a regenerated sieve bed (at or near atmospheric pressure) is repressurized. It may also be necessary for the compressor itself, to prevent short cycling, particularly so if the compressor is not VSD controlled.

Next in line is the concentrator itself (H), which is the complex assembly described previously, comprising the two sieve beds, all the necessary control valves and the control apparatus.

There is a significant dividing line at the concentrator. On the source side, all the gas handled is air. On the patient side, all the gas handled is oxygen. This means that the various parts and pieces must be significantly different in their construction, materials, cleanliness and handling, reflecting the significantly greater hazards associated with pressurized oxygen.

On the patient side of the concentrator there is typically an oxygen receiver (K) which functions to smooth the output of the concentrator in pressure and in concentration. As you will have seen from the earlier discussion, the instantaneous concentration of oxygen from the concentrator can vary as the adsorbent runs through it's cycle. That concentration will start at the same concentration found in the purge gas when the last regeneration phase finished. It will then rise to just below 96% as the cycle reaches its' best efficiency, and then falls as the adsorbent saturates with nitrogen. This natural cyclic variation is averaged out in the oxygen receiver, with the ideal result that the outflow from the oxygen receiver would be a steady 93%. However, some manufacturers and operators intentionally run the concentration to lower concentrations in order to get more volume output. This can be done since the pharmacopeia recognizes any concentration between 90% to 96% as acceptable. The practice does allow an increase in the overall system volume output but also reduces the in built safety margin.

When choosing a concentrator, knowing the concentration at which the unit's output was measured is very important, as the volume output from a concentrator at 90% is as much as 20% more than one running at 93% or 96%.

After the oxygen receiver, the typical system will include a final filter (L), which is often misunderstood to be a sterility filter (it is not).

The diagram illustrates other important elements which are often overlooked in a source. These include the oxygen concentration monitor (I) at the concentrator itself. Often this is placed downstream of the oxygen vessel (K) to ensure that the oxygen reading is smooth (i.e. a blend of the oxygen concentration produced throughout the cycle). However, placing it there risks contaminating vessel K, but either location can achieve the desired result.

(M) is a purge valve which allows the concentrator to run when the concentration is not to standard. This is very typical of a new system just being started - the concentration must be allowed to build, and to do this the unit must operate at high flow. The purge valve allows this to happen without having to admit low concentration product gas to the main pipeline.

(N) is an automatic valve which closes when the

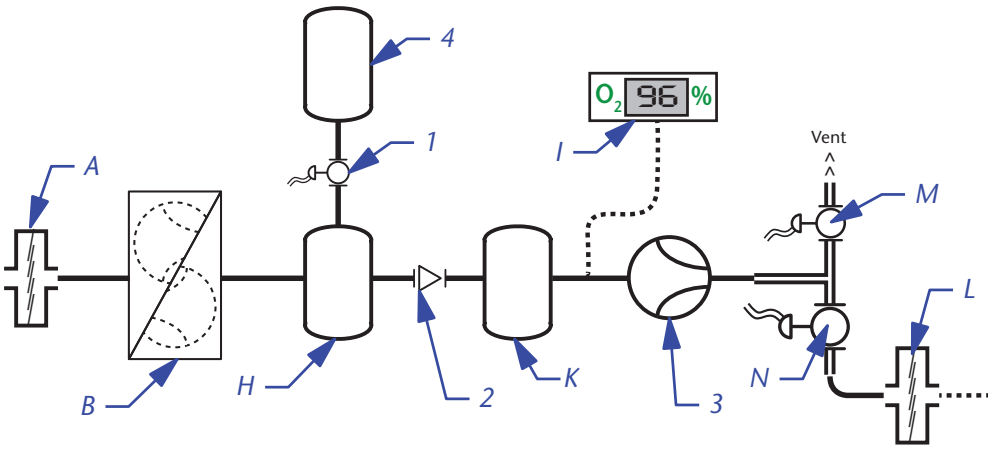
concentration of oxygen falls low at monitor (I). The function of this valve is to ensure that the oxygen in the oxygen storage vessel remains usable and is not diluted with off-specification gas. Typically M and N are coordinated.

All of these elements are visually distinct in a typical PSA source. In a VSA source, this may not be true. VSA sources may look very like a PSA source with a few extra pieces, or they may look like an integrated unit wherein the individual elements are present but not necessarily as externally obvious, distinct pieces.

We will concentrate on the unitary style unit here as it is uniquely appropriate for medical use in this form.

**The Parts of a Unitary VSA Concentrator Source**

Detail 12 shows the key elements of the unitary VSA concentrator (numbering has been preserved for comparison)




***Detail 12***
*A unitary VSA medical oxygen source*

A is an inlet filter for the compressor.

The air producer (B) however is not at all the same - in this case it is both a low pressure compressor *and a vacuum pump*. H is the single sieve bed (only one is used in this design). K is the oxygen receiver. L is the oxygen filter, M and N are the control and purge valve, just as shown for the PSA.

Many elements from the PSA are not here - and there are some elements that do not appear on the PSA design. However, the overall impression is of a simpler concept with fewer parts, which is one of the advantages of the design.

The compressor will fill the sieve bed, which in turn will separate the oxygen, just as in the PSA. The first gas off the sieve is stored in the purge recovery tank (4) for later use. Then, the oxygen passes into the oxygen storage receiver (K). The pressure achieved by the compressor here is not high. While in a PSA the compressor pressure is as high as 10 bar, in this system it is only ≈1.5 bar. Therefore, the oxygen must be boosted to the pipeline pressure of 4 bar using a separate booster compressor (3). While the pipeline system is being fed from the storage receiver, the sieve (H) is regenerated using the original air producer reversed and running as a vacuum pump, *pulling* the nitrogen off the sieve (assisted by the gas previously stored in the purge recovery tank, which passes back over the sieve and helps sweep away the nitrogen).

Because the pressures involved are low, the problem of wringing out water vapor is not so severe. Water vapor put on the sieve bed during each cycle is removed by the vacuum at the end of the cycle, eliminating the need for a dryer in most cases. The air producer used is oil-free, so no elaborate activated carbon canister is needed either.

As in the PSA, the unit needs to have a vent and isolation valve to allow the system to purge (N and M), and an oxygen filter (L).

The oxygen concentration monitor (I) is essential here as well, and might read from either side of the oxygen compressor, or either side of the storage vessel, but is probably best located as illustrated.

**The First Rule of Medical Gas**

Irrespective of which medical gas system standard you choose to read or enforce, they all aim to satisfy the first rule of medical gas, which is simply : "Always supply the patient".

When one sets out to design an oxygen source system employing concentrator units, this paramount rule applies with them as well. Since there is no gas supplier to share the responsibility, all of this burden falls on the engineer and operator. (The same of course is true for a medical air source system - a fact

often overlooked.)

Beyond this essential guiding principle, remember that we are producing a drug governed under a pharmacopoeial monograph. Therefore, it is essential to ensure that the gas being produced is within the correct concentration range and meets all other purity requirements.

We must further take into consideration that this is after all oxygen at very high concentrations. Safety with oxygen is more complex than any other medical gas because the gas is highly reactive - which in practice means it will promote fires. Even a small fire will shut down a source of supply as surely as the most spectacular mechanical or control failure. An internal fire within the pipeline can cause disaster by producing toxic gases as well.

Producing and piping oxygen therefore requires close attention to elements of the system which in other medical gases are often ignored. With oxygen the gas itself can react with items in the gas stream that are improperly cleaned (e.g. pipe, fittings and accessory items), materials that are not correctly chosen (e.g. polymers, lubricants, seats and seals), bad installation methods (e.g. use of pipe dope) and the rooms and enclosures in which we locate the equipment. The reaction can be dramatic (as in fire or explosion) or subtle (as in accelerated corrosion), but is potentially deadly either way. We will discuss this problem more under the heading of Operation.

Making sure the source system meets the First Rule and all it's corollaries is the first essential goal of good system design.

**The Design of the Cascade**

Anything mechanical can fail. This old engineering saw is the starting premise for all medical gas source design. Under this rule, the first principle of design for continuity of supply is redundancy - providing at least two equally capable main sources.

We will be reliant on external utilities (electrical power in particular), which is not true to the same degree for a typical liquid or cylinder based oxygen system. Therefore extra consideration must be given to ensuring utility supplies (e.g. emergency power supplies). Whenever practical the oxygen system should include a mode of supply which is independent of utilities (e.g. a cylinder reserve).

The conclusion one will reach is that a complete source of supply consists of three (or more) supply subsystems. Each should be as independent from the others as possible so no one failure can affect them all. The independent control in each subsystem should provide for operating the air source and the oxygen generator for that subsystem, and any central logic provides only for desirable extras like power management, equalized wear, and maintenance management. The cascade from primary to secondary to reserve should also be independent of the central control if possible, so if the central control should fail, supply to the patient is not effected.

In Detail 14, the major elements of this complete concentrator source of supply are more completely detailed, to show the essential operating elements.

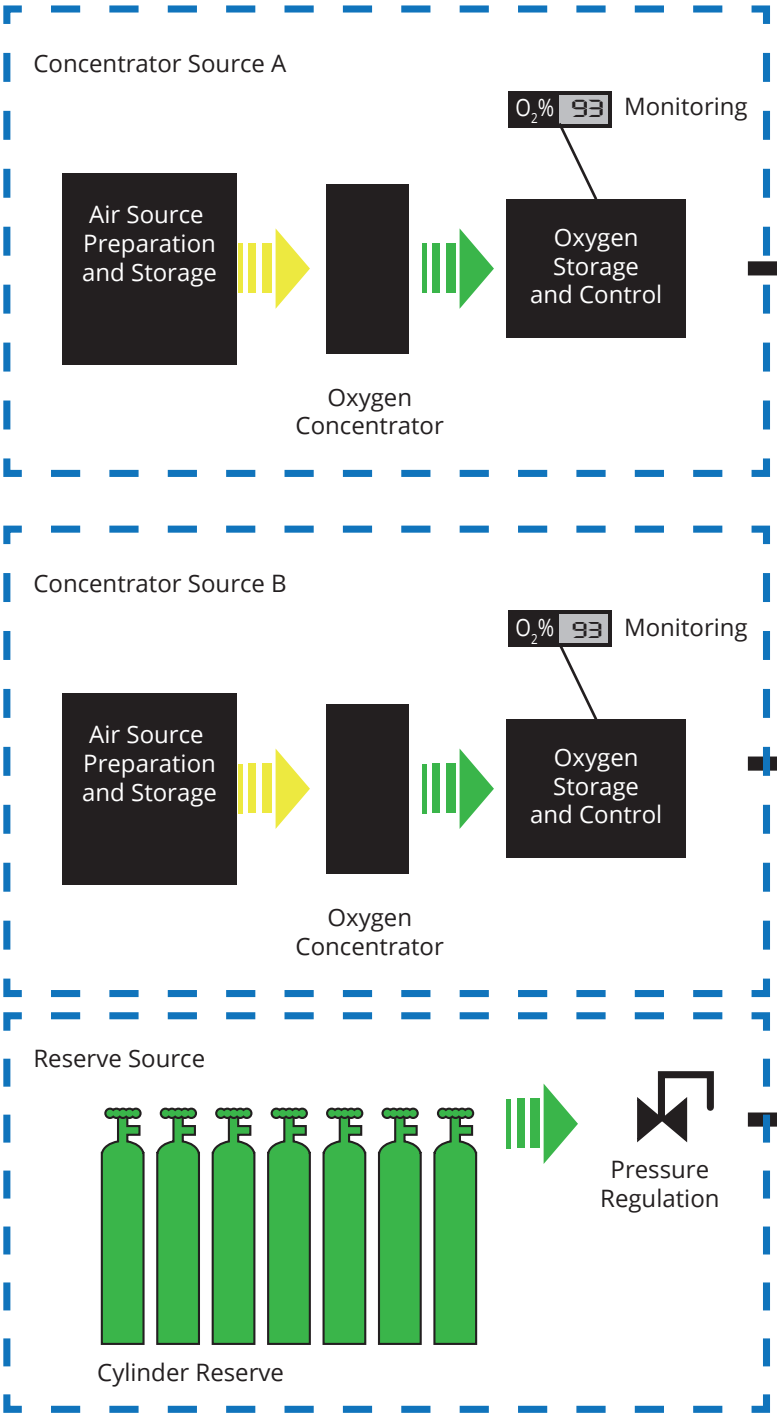
Three sources are illustrated. Concentrator Source A and Concentrator Source B are usually identical in components and in capacity. If sized correctly, they are each 100% of the worst-case demand calculated for the facility. Therefore either concentrator source may therefore be placed in operation as the *primary* source.

The "Monitoring" section will typically include at least a pressure switch and an oxygen monitor. The valving in the concentrator is so arranged that low oxygen concentration will prevent flow from the concentrator (valve N in Detail 10 and 12) and the pressure in the common line will fall. That fall in pressure is the primary way that the second concentrator is brought online. In this simple manner, the cascade is monitored and made reliable whether or not there is a central control.

If neither of the concentrator sources can supply adequate pressure (for any reason), then the system will fall onto the cylinders, which are regulated at a lower output pressure than either of the concentrator sources, but still higher than pipeline pressure. As long as either concentrator is operating, their higher output pressure will hold the reserve off line.

In the typical PSA system, it is very important to thoroughly understand this indirect, pressure moderated control method, as it is typical of most concentrator sources. The oxygen concentration of each PSA module is monitored, but the immediate control of which of the three sources is feeding the pipeline is achieved by pressure differential between the three sources.

There is one additional element often seen on PSA sources related to the above when they are not provided with the purge and isolation valves (N and M). A control orifice is placed at the outlet




***Detail 14***
*A complete medical oxygen source (3 supplies)*
*(note: other arrangements of components are possible)*

of the source. This is an essential element of the self-regulating cascade and performs two related functions: first, it limits the amount of oxygen product gas which can be drawn from the oxygen receiver. This ensures the concentrator is not overdrawn and thus that the oxygen concentration can be maintained at the desired 90-96%. Second, when more oxygen is required than can pass the orifice, the pressure will drop and the *secondary* source can begin to feed the system (this might be either the second concentrator source(s) or the cylinder reserve). This is accomplished entirely though the pressure differential.

As you can see, if multiple concentrator sources are provided and in operation, this design permits more than one source to feed the system, up to the sum of the output from their respective orifices. In effect this creates a surge capacity in the event of a user requirement greater than one concentrator can manage.

VSA systems cannot be operated using this simple pressure cascade philosophy. The trade-off is that they are capable of much more sophisticated operation and pressure control using variable speed drive with the oxygen booster compressors.

Concentrators sieves need to run. One cannot stop the process because the molecules will equalize through out the bed very quickly. So they react badly to being turned on and off. This is a very serious issue with a multiple-source supply system as we have described. If one source is in primary, the other is off, and may not in fact be able to start very quickly if called to supply oxygen.

However, hospitals have highly variable demand and can sorely tax classic PSA units and compressors by forcing them to start and stop to match the demand. Even coupled with VSD compressors, the concentrators themselves will suffer when run this way. The VSA operating principle is better suited to variable demand, since the concentrator sieve always operates as if at full flow, and when it is not operating it can be held under vacuum, ready for the next cycle and preventing contamination of the adsorbent by water vapor. The booster compressor is always able to supply oxygen off the storage tank, allowing the systems to react smoothly and in fact to "load balance", running all the concentrators continuously

but at low levels so they are all continuously ready.

ISO rules require at least two of the concentrator driven sources as described, with the third source ideally being a supply which does not depend on power, hence the cylinder source illustrated. Naturally, there are facilities where cylinders can only provide a supply for a brief time, far too short for practical supply under anything near normal use. These facilities may need to consider supply safeguards additional to cylinder reserves.

NFPA rules would allow for a two source supply system, which would have one concentrator source and a cylinder reserve. Naturally, this is less secure and has less resilience in emergencies. A limited system of this type should be avoided where high dependency patient care is anticipated.

**Selecting An Oxygen Source**

To this point, we have discussed the theory and operation of the basic concentrator system. When we turn to the engineering of the oxygen for a pipeline system, the source of supply can be considered simply as a "black box", for the purpose of sizing.

The essential central question in engineering a concentrator source is of course how much oxygen will be needed. The question has two dimensions: the *average requirement* and the *peak requirement*.

Average requirement is the oxygen which would be used when averaged over a long period of time ("we use 20 cylinders a week, which is 138,000 liters of gas. Therefore we use an average of 13.7 lpm"). This can be taken as the baseline load for the oxygen source.

The peak capacity is the flow rate under worst case. ("when all our 10 ventilators are in operation, each of our ventilators can draw at a instantaneous flow rate of 250 lpm. So worst case is probably 10 patients all being ventilated at one time, each ventilator needing 250 lpm, so 250 x 10 = 2,500 liters per minute.").

As is immediately obvious, the difference in these two is immense. This variability is what makes determining sizing quite tricky, as medical facilities vary enormously in their usage of medical gas. Patient census rises and falls, equipment in use varies, the types of therapies in use changes. There are no absolutes in the process.

With traditional oxygen sources, it is very possible to have equipment capable of an instantaneous flow rate this high but untroubled if flow rates go down to near zero. Their only limit is in the regulating and control equipment and rarely the gas supply itself. The main challenge with these is to ensure enough storage capacity (liquid tank size, cylinder count).

In a concentrator source, the limit is in the capacity of the concentrator(s) to make oxygen. Concentrators operate best when designed and operated at a steady draw rate. They do not have large inherent surge capability and react poorly to being under or over drawn. To design a concentrator for either 13.7 lpm or 2,500 lpm is quite feasible, but to design one capable of both is challenging. Other strategies must be employed.

With an existing facility, one has the luxury of being able to take a site survey. This is the surest way of assessing the sizing, far better than any standardized table. One can use this information to determine average usage over as long a period as the facility is able to provide data (oxygen purchase records for instance).

After the average use, an assessment must be made of the maximum rate of usage, which will require some idea of the maximum number of ventilators possibly in use, the number of operating theatres, nurseries and intensive care beds and other high use areas included in the facility. The actual consumption through the clinical equipment used there will allow an estimate of the worst case (peak) draw rate.

In the absence of better information as described above, there is no "standard" sizing. There are however, a variety of methods in use. One technique uses a simple table (Detail 15).

***Detail 15***
***Sample Sizing Method for Oxygen Sources***

| Occupancy | lpm | Units of count |
|---|---|---|
| Critical care | 10 | per bed |
| Operating Theatres | 10 | per room |
| Other outlets | 1 | per room |

The better method is based on detailed assessment of the site, which in turn requires some field work and discussion with the clinical staff.

A very good starting point is a baseline consumption estimate based on historic experience with average usage in medical facilities. This tells us that over a very broad range of facilities, long term consumption per patient is in the range of 0.4 - 0.8 lpm. (Note this is NOT per terminal but per patient). Naturally,

this will vary from place to place. Use in the U.S. for instance, where oxygen availability at every bedside can be taken for granted, will be far more lavish than might be expected in a place where oxygen availability is limited to special care areas and the operating theatres.

So based on this, a facility of 150 beds with an average patient mix might have a base load that could be served with a concentrator having an output of 60 to 120 lpm. This is a very broad range, and reflects the great diversity of medical facilities which use oxygen. One must assess a given facility in terms of what is being done there. Clearly, a facility with a high proportion of operating rooms, pediatrics, nurseries, and intensive care should be calculated at the top of this range. A clinic or other facility performing only minor procedures on an outpatient basis might be assessed at the lower end of the range.

***Detail 16***
***Oxygen Consumption for Representative Clinical Equipment[1]***

*Note: the maximum volume that an adult can breathe is roughly 30 lpm. Thus, even if one administered only oxygen to fulfill the entire respiratory needs of an adult patient, they could take no more. Use beyond this amount is consumption by the device and whenever possible, should be provided using medical air - see the sidebar "Oxygen Discipline" on page 13.*

| Equipment type | lpm |
|---|---|
| Ventilators [2] | |
| ICU | 25-75 |
| Oscillating or "jet" | 75 |
| Anesthesia machine | |
| Ventilator [2] | 25 |
| Flush (note that this is for brief periods only) | 100 |
| Croup or Mist Tents, Hoods, Incubators [2] | 10-15 |
| Standard adult patient with flowmeter and: | |
| Nasal cannula | 1-6 |
| Mask | 5-15 |
| Resuscitation | up to 30 |
| Hyperbaric, Single chamber[2] | up to 500 |

*Notes:*
*[1] these numbers are rough estimates for guidance only, and actual information should be substituted whenever possible.*
*[2] these devices may also use medical air for all or part of this volume (e.g. through a blender), or may use medical air in addition to this volume.*

This number is of course only a base line, and a concentrator selected using only this value may be unsatisfactory because daily use involves peaks and troughs in demand that this system could not handle.

The peak rate is much harder is to assess. The need here is not to assess the "worst case" which the system will hopefully never see, but rather the ordinary peak flows which the system will see often.

Some questions that must be asked:

The maximum number of ventilators the facility intends to deploy. What is their make, peak flow rate, and are they equipped to use air or other power source (e.g. electric) or will they require oxygen as the power gas?

The number of operating theatres, and other high use areas included in the facility. What clinical needs do these areas have? Is there specific equipment that will be used in these areas which must be accounted for (croup tents, blenders, anesthesia ventilators, perfusion machines, etc.) The more detail one can collect on the actual consumption through the clinical equipment will allow a more accurate estimate of the worst case peak flow (see detail 15).

It is essential to not over estimate this consumption as much as to not under estimate it. To simply add together all the consumption is not valid, because some simultaneous use is inevitable and needs to be factored. Naturally, this is also where the most difficult decision needs to be made, and the answer is very individual to each facility. Only the medical staff and the owner can offer insight into this, based on the expected patient populations and the type and mode of care to be performed.

One seeks to determine, as examples:

• How many patients are expected to be using oxygen on a typical day?

• What mode of delivery would be used (ventilator, blender, supportive oxygen via nasal cannula, etc.)

• What extraordinary oxygen uses are anticipated which imply higher than usual flow rates (e.g. resuscitative procedures, oxygen flush following anesthesia, oxygen enrichment inside infant incubators and croup tents, etc.)

With all those patients and therapies in action, what

kind of demand will that place on the source?

Altogether this will allow an estimate of an ordinary "peak rate".

If the facility is critical access, then some estimate of the absolute worst case conditions should also be made. This requires considerable thought. The expense to "prepare for the worst" can be truly exorbitant and can also have negative consequences on the reliability of the equipment, which cannot sit idle indefinitely. Operating procedures can be devised to ensure that the equipment is ready to run, but the capital cost may be out of reach. The facility must consider that in a true crisis, the only realistic answer may be triage.

The last concern is the one no hospital likes to hear, but it is important to know - how is their attention to details? Do they shut off every unused flowmeter? Do they disconnect the anesthesia machines at night? Is their maintenance attentive to leaky outlets? Obviously, in an existing facility this can be observed, first hand, but in a new facility it can't be easily assessed. Waste is one of the biggest consumers of oxygen in many facilities, and must be considered in the sizing exercise. 5-10% waste would not be unusual unless outlet maintenance is especially good.

With these two or three data points estimated, it needs to be understood that the actual demand will vary as patient populations change. An ideal system must be selected to operate effectively across the entire range.

An example of the sizing process is given in Annex A.

**Monitoring, Alarms and Labelling**

In general, the oxygen source will be alarmed in line with any other source of supply. This will include an alert as the system steps down each element of the cascade, an alert when the reserve is below a minimum volume, and a line pressure signal for low and high pipeline pressures (see Detail 24 for how these might operate).

Additionally, a concentrator supply system should provide alerts whenever the oxygen quality or concentration is not as expected. This is so critical that it is appropriate to have two oxygen concentration monitors essentially in series: one monitors each concentrator source and one monitors the common line passing into the pipeline. These will not only drive alarms, but will also directly control the concentrator sources and drive the cascade under some circumstances.

A variety of other signals can be considered:

**Oxygen Discipline**

*One precursor to successfully employing concentrator oxygen is to control the use of oxygen and to limit that use to true patient care requirements. It may seem counter intuitive, but any facility considering concentrator oxygen should first install a good medical air system. Air can perform many of the functions of oxygen as long as it is available, accessible and reliable. Some things to consider are:*

*1. One should never use the oxygen as a power gas for ventilators (including anaesthesia ventilators), to drive vacuum venturis, or for any other applications where the gas is not breathed directly by the patients. Most of these applications can be performed as well or better using medical air. Some applications might be accomplished using either gas. An example would be croup tents. They are huge consumers of gas because they need to drive the nebulizers that maintain the humidity in the tent, but that gas does not always have to be oxygen.*

*2. This may in some cases mean a modification in clinical practice. The patient and the process may need to be separated, so the process can be powered by air, and the actual patient gas can be oxygen or blended gas. In our croup tent example, the infant may still need supplemental oxygen. So, a nasal cannula may need to be provided to administer the necessary oxygen but the humidity can still be controlled with air.*

*3. Certain equipment may need specific modification. For instance it is not uncommon to see anesthesia ventilators powered with oxygen. It is not widely known they can be ordered or modified with the necessary plumbing to power the ventilator with air. This has no effect on the patient, since the patient does not breathe the power gas. It does however greatly reduce the amount of oxygen needed to perform surgery.*

*4. Oxygen conserver devices should be employed whenever possible. These are widely available and serve to administer oxygen only when the patient is inhaling. Obviously, that means that oxygen is not flowing to a patient who is breathing out, and greatly reduces waste. This reduces the base load and the peak load both, and therefore represent good economics in all respects.*

• Some systems will monitor the Carbon Monoxide (CO) level coming from the compressor to the concentrator. This is not especially relevant to the final product, since the adsorbent in the concentrator tends to remove these gases as a by-product of the concentration process. However, it is useful to know that there is a problem with the incoming air quality as this can help prevent other problems longer term. CO is a useful indicator gas to help identify such developing problems.

• Dew point between the dryer and the concentrator may be monitored to ensure the dryer is working and water does not enter the concentrator. This is particularly relevant when using a refrigerated dryer.

• Some systems provide alarms for specific maintenance issues. These are usually specific to the machine employed and might be triggered from the compressor, the concentrator, the dryers, filters and/or controls. A typical example is a filter change indicator, compressor over-temperature indicator or low oil pressure signal.

If the facility is provided with a BMS system, it is usual to take these alarms out to the BMS system as well as showing them on the local alarm and the master alarms.

Generally speaking, labelling in a facility served by a concentrator is simply "Oxygen". Such labels are white with green lettering under the ISO color scheme, and Green or White with white or green lettering respectively under the NFPA color scheme.

Although this is common practice, notionally the labelling should be in keeping with the pharmacopeia, which would have the labelling say "Oxygen 93", and the coloration would be that of a mixed gas - in this case Green and Brown (mixture of oxygen and argon) (see Detail 18). However, such a label could confuse the users and patients, and opens up the


***Detail 18***
*A possible but rarely used label for Oxygen 93 following mixed gas protocols.*

whole problem of the gap between oxygen 93 and oxygen 99 (see sidebar on page 9). As a result it is not often used.

That does not mean that oxygen and oxygen 93 can be considered identical. However much it can be proven that the two can achieve the same clinical results, they will necessitate different setting for equipment and dosages for patients. It is essential that the clinical staff know that the pipeline is being fed with oxygen from a concentrator, so they are aware that the actual concentration of oxygen will vary. If the system is furnished with a cylinder reserve, that variation could be as great as 90-99%. With a cylinder filling reserve, or without any cylinder reserve at all, the variation can still be 90-96%

An informed medical staff can then make appropriate accommodation for calibrations and settings so the clinical equipment performs as expected. They also need to be attentive to their techniques for assessing patient $O_2$ saturation (e.g. oximetry), and not make assumptions based on past experience with piped oxygen.

**Operating an On Site Oxygen Facility**

There are concentrators all over the world which have been removed from service because they were not found to operate to the satisfaction of the users. In fact, these events are not ordinarily a failing in the concentrator. Most often, they result from a lack of understanding and attention to the quirks in the operation and maintenance of the machine.

In most facilities, medical gas systems are basically very reliable with little attention or maintenance required. Maintenance on medical gas equipment is therefore often spotty and infrequent. The tendency is to assume that a concentrator system can be installed and largely ignored like medical air or vacuum, and this is a fatal mistake.

Producing oxygen on site implies that the facility is taking on all the roles that the gas supplier handles when oxygen is purchased. This includes ensuring the gas delivered to the pipeline is at the cleanliness, purity and concentration specified in the pharmacopeia. In truth, the facility already has this responsibility for medical air - but most facilities cheerfully ignore that. They can get away with being so casual because the challenge with air is less, there are fewer ways in which failure will punish you, and the consequences to patients are less severe.

Oxygen is a ***much*** more critical utility.

As mechanical and electrical/electronic devices go, a concentrator system is easily within the skill of the average hospital engineer or biomedical technician. Any reputable manufacturer will of course provide

a detailed preventative maintenance schedule for the facility to observe. The operations found there should be generally familiar. There is no particular reason that an average facility staff cannot effectively operate a concentrator system.

However, many facilities that undertake to operate a concentrator system do so without the necessary trained staff, and in doing so they are immediately headed toward trouble. The systems are not maintenance free and they are not very tolerant of abuse or neglect. It is essential that prescribed operations be performed correctly and on schedule, that problems with the machine be promptly repaired, and that warning symptoms be carefully noted and corrected. A concentrator source is not a good place to try and save money - maintenance and repairs need to done promptly and correctly, and it should be assumed that the ongoing operation of the system will have a cost.

One of the most basic of functions is housekeeping. It is not unusual to see medical vacuum pumps and air compressor installations which are essentially ignored and therefore are filthy with dust, debris, and surrounded with all kinds of trash. This is very bad, but concentrators will not tolerate this kind of abuse. They need to be kept clean and in top condition, particularly when any work is done which exposes any part which will be in contact with oxygen gas.

The one aspect of a concentrator the average maintenance staff is not necessarily used to handling are the oxygen concentration monitors. They will be second nature to the biomedical staff, since they are not unlike other periodically calibrated devices that are common in clinical equipment. However, many facilities with concentrators do not have trained biomed techs on staff, and this role must be assigned to someone else.

The concentration monitors and their associated alarms are the most important single element in successful operation of the machine, as they determine the operating conditions, quality of the oxygen output and many of the fail-safe aspects of system operation. The care, testing and especially calibration of these requires close attention. The system cannot be safely operated with any of the monitors being out of service for any reason.

The valves on a PSA concentrator are pivotal in the operation of the system, and are beset by the same problems that afflict desiccant dryers. Adsorbent fines, worn seals, and actuator problems will all, at some time in the life of the system, prevent proper operation of the valves. Even small leaks past the valves can influence quality, concentration and available quantity of the product oxygen.

Understanding the operation of the various valves is essential to being able to troubleshoot incipient failure. Replacing or servicing them promptly is essential to ensuring ongoing operation. They are handling near pure oxygen, so they must be handled carefully and with extraordinary attention to cleanliness in procedures, tools and parts.

Some of the least expensive components are also vital. The filter that removes the oil from the air after the compressor is essential to prevent the passage of oil to the concentrator when an oil lubricated compressor is being used. Since oil vapor is one of the things that will poison the adsorbent, this is an element that rewards careful attention.

Simply preventing dirt from getting to the concentrators is surprisingly important, and filter maintenance also performs this role.

The dryer protects the adsorbent against damage from liquid water (a feed air dew point monitor should be included for this reason). An ineffective dryer forces the concentrator to act as the dryer, and reduces its' overall efficiency. At worst, liquid water will form in the sieve bed, poisoning the adsorbent.

Concentrator systems are complex and in some ways delicate. Unlike most medical gas equipment, they do not tolerate being ignored. They aren't hard to operate, but good maintenance, properly trained staff and attention to detail are the keys to operating one successfully and winning the benefits the system was purchased to provide.

**Concentrator Economics**

Concentrators don't usually pay for themselves. It is a common fantasy for a facility owner to look at their oxygen bill and dream of getting free oxygen from their own on-site oxygen production. After all, the air is free, right?

These dreams ignore the realities. A concentrator uses a fair amount of electricity to drive the compressors. At an average 12:1 air to product oxygen ratio, the amount of air compressed is huge compared with the oxygen made. Each volume of air compressed costs energy and hastens maintenance of the system. Unless power is very cheap, the power bill can be heavy, but the cost per liter of oxygen is still good.

Based on power consumed, if a facility pays only $0.12 per kWh for their electricity (a very low rate for most of the world), and they use a compressor that can produce 150 liters / kW (a reasonably middle of the road value), that implies about 13 liters of oxygen per kW, or $0.002 per liter. To fill a cylinder containing 6,900 liters with this oxygen will cost something like $1.38. At a peak efficiency of 9:1 air to product oxygen ratio from the concentrator, a cylinder would be about $0.69. Some VSA units are even more energy efficient, and their power cost can be half that of a PSA, so these numbers will look even better.

This is attractive compared to oxygen from liquid or cylinders, because the cost of transportation is the largest expense involved with those supplies.

This is only the cost of power. To analyze the real payback of an investment in a concentrator, the costs of capital, maintenance, risk and in some places regulatory compliance need to be factored in as well. When all costs are considered, most concentrator installations cannot be said to "pay" at all.

There are four primary reasons concentrators become especially attractive:

1. The facility is in a place where air separation plants are few or unavailable (e.g. less developed geographies, military and disaster relief support facilities).

2. The facility is far away from an air separation facility (e.g. rural areas, remote facilities, ships, etc.)

3. Transportation of oxygen is impractical. This list would include islands, countries with poor distribution networks, mountainous areas, etc.) It will also include facilities where extended separation from normal supply can be expected, such as facilities in snow country, where hurricanes and typhoons are common, places where seismic activity is a concern, civil unrest or conflicts are active, or where other foreseeable events may prevent supplies from arriving.

4. The facility's location does not allow oxygen to be stored or deliveries are problematic. These are often urban facilities where land is unavailable and traditional oxygen tanks cannot be placed safely or accessed for filling.

In these cases, on-site oxygen production may be the only way to obtain oxygen reliably and economics must take a back seat to practical concerns.

The dream of a financial payback is not always impossible. The fifth reason to use concentrators is where the oxygen suppliers have simply priced the gas too high. Their reason may be related to one of the above problems, meaning their costs are very high, or they may simply be charging a lot because they feel they can. In these cases, on-site production has been found to offer some financial return. It is a relatively simple and worthwhile calculation to make.

There are also a number of different ways to handle the financial side of a concentrator which will look more or less like the methods facilities use to pay for their oxygen today. These include:

***Outright purchase.*** The facility buys the machine, and deals with the installation and maintenance as separate contracts or does it themselves. This is the most common financing model, but usually has the disadvantage that the installation is problematic and the maintenance is neglected.

***Lease.*** Also an outright purchase, but using a financial intermediary and defraying the purchase price over time.

***Rent.*** This option is an interesting one if the facility chooses the right partner. It closely resembles the way hospitals traditionally pay for oxygen supplies in cylinders or in liquid form, where the equipment is rented from the supplier and the facility pays a monthly fee, plus they pay for the gas used. In a concentrator rental, the facility pays a monthly fee for the equipment (so there is no separate cost for the gas). If the partner is the right one, the monthly fee can include the installation, all required maintenance and repair services as well. In such a contract, the partner is essentially responsible for the equipment's operation and the facility need not worry about anything. At the end of the contract, the equipment reverts to the partner.

***Rent to own.*** With the right partner, this is the same as the rental above, but at the end of the contract the facility owns the equipment. This is generally better than simple rental, since it avoids the disruption involved at the end of a contract when equipment must be removed.

In any lease or rental model, the selection of a partner who has the capability to manage the installation, commissioning and maintenance is the key to satisfaction. Very few facilities have the resources or trained personnel to manage these systems.

**The Life of a Concentrator**

It is surprising to travel around the world and see abandoned concentrator installations where the facility tried a concentrator, found it frustrating and unreliable, and returned to traditional supplies.

The reason why this happens are complicated, but there seem to be some common threads:

1. Concentrators MUST be maintained. It is a certainty that a facility without a competent maintenance staff and a good program for maintaining the concentrator will in fact be abandoning the machine in time.

2. Feed air is everything. If the feed air to the concentrator is not kept free of water, clean and free of oil the facility will find their concentrator unreliable and expensive to operate. Bad quality feed air will poison the molecular sieve, and replacing the sieve is expensive, can be quite tricky and of course is doomed to failure if the feed air continues to be of bad quality. Molecular sieve which is run with good quality feed air can last indefinitely, so if you are changing your sieve often you need to pay attention to the feed air. If you are saving money up front with an oil lubricated compressor, you can assume it will cost you later in changing the sieve.

3. Concentrators are not "happy" run against constant variation in demand as is normal to a hospital setting. They want to run constantly and at full demand. Careful sizing and selection is important. VSA systems are more tolerant than PSA systems in this regard.

4. Concentrators want to be cool. Particularly in tropical locations, concentrators are often run in locations which are much too hot, which reduces their output and the oxygen percentage they can achieve.

It is important to derate concentrators where the ambient temperature is high (note that this complicates the problems caused by #3 above). In some cases it may be necessary to air condition the concentrator room. Attention to aftercoolers, drains and dryers is also essential in hot and humid locations.

5. Concentrators are often under specified. In their eagerness to make the sale, many concentrator suppliers cut corners and install systems which are far too minimal to work well under medical conditions. Common findings: oil lubricated air compressors with no activated carbon, no dew point monitor, (sometimes no dryer at all), no aftercooling, poor quality drains or none at all, poor ventilation in the room so the compressor heats the concentrator, no oxygen monitoring, no flow limiter between the concentrator and the system, a single concentrator source without any backup, rooms that are too hot.

Attention to these points is the magic that allows one installation to run well and another to frustrate the user and ultimately to sit abandoned and rusting, money wasted.

**Advanced Topics**

**Peak Loading Strategies**

The most difficult part of concentrator sizing is trying to deal with the peak load. There are different strategies, the bluntest being simply sizing the system for the peak. Since these systems are costly, and ideally one is looking to reduce the cost of the oxygen, that strategy is deeply unattractive.

It is possible sometimes to reduce the first cost of the system by making it smaller without taking undue risk, and below are two of the ways that is done. The first is legitimate, the second is at best questionable. They include;

1) multiplexing the concentrator sources. In this strategy, one takes advantage of the fact that the standard requires a minimum of two sources but will allow for more. Thus, instead of trying to serve the demand with one large concentrator supply source, one divides the demand by two or even more. So in our earlier example, instead of two concentrator supply sources each for 2,500 lpm, one can place three concentrator supply sources, each for 1,250 lpm. Together, two manage the worst case, and one alone can better handle the ordinary requirement. The requirement for redundancy is still met by the third supply source and the cylinder reserve. This can of course be carried much further, for instance with four supply sources each of 835 lpm, so three handle the maximum requirement, and the increments in capacity are more finite.

Although on paper one can continue this indefinitely, in practice this strategy can also increase the initial cost of the system. On the other hand, it will usually reduce the operating cost.

2) drawing into the secondary and reserve. This is not allowed under any standard, and it must be considered a high risk strategy. It is sometimes employed (not always with the owner's knowledge) as a tool to reduce the initial cost of the concentrator or to compensate for a concentrator which is sized too small. As such it should be understood by anyone interested in installing a concentrator system or who

may be surprised to see a great variation in prices from different vendors.

The strategy is most plausible in a facility which rarely experiences the maximum draw rate, but operates reliably in a low use range and only experiences peak demand occasionally. A clinic for instance might be in this situation.

In this case, the source is sized at some value closer to the average rate and the cylinder reserve is ideally sized larger than absolutely necessary. In the event of a very high demand, the source would cascade so that the primary concentrator, then the secondary, and finally the cylinder reserve would come on line in sequence and would simultaneously all be operating to accommodate the surge.

In our extreme example, with a base line of 14 lpm, but a peak of 2,500 lpm, the two concentrator sources might be sized for 100 lpm each. A peak demand to 7 times (100 lpm) the base load can then be accommodated through one concentrator source and 14 times (196 lpm) can be accommodated through both. However, should the facility experience an actual 2,500 lpm peak demand, 2,100 lpm will have to come from the cylinders, as the concentrators could furnish only 200 lpm. One can readily see that a system built this way would be vastly less expensive than a system sized to the 2,500 lpm peak.

Obviously, the peak period must be relatively short for this strategy to work, since the reserve cylinders are quite limited in their capacity. Again to look at our example, a peak demand for 2,500 liters/minute can be met for only about 20 minutes if the reserve begins with 10 full cylinders.

It is important to emphasize that all systems are designed to cascade this way under the standards, but they do so to handle the unexpected. This is definitely not how the standards envision these systems operating everyday. The standards expect that the primary source alone (which could in practice be multiple individual units as described previously) should be able to handle the demand.

Just the obvious problems with this include:

• The secondary source may not be ready to operate, and may require some “spin up” time.

• The cylinders are a very finite resource, and each time they are drawn down, the capacity available to handle the next surge is less.

• The alarms would be triggered but no problem will be evident. That means the operator will be confused and annoyed and when a real problem is signalled, they will naturally not react. The absence of a Secondary in Use alarm or a long “delay” in the alarm activation is thus an indication that this strategy may be intentionally designed into a system to reduce the cost.

Because the cylinders are an essential part of this strategy, it is most common to see this tactic employed when the system is equipped with a cylinder refilling facility, which helps to keep the cylinders in a full and available state (see *Cylinder Filling* on page 22).

3) local manifolds or cylinder supplies can be furnished for critical areas of the facility such as ICU. This is more a compensation or risk mitigation strategy than a way to manage the source, but it can ease the stress of making the source sizing decision and can also provide a cushion should the source ever give trouble.

**Multi-purposing the Compressor**

Can a compressor intended for a medical oxygen source be used for other purposes, for instance for medical or surgical air?

Since these compressors are already very large in many cases, it is tempting to make them just a little bigger and draw off from the same machine the medical air, and maybe the surgical or instrument air. This has in fact been done, and certainly can work. The argument against it is simply “too many eggs in one basket.” If the one compressor fails, you will have lost medical air, oxygen and instrument air all at once.

The counterargument is of course that you still have the #2 compressor and the in-built redundancy in the system serves you here as much as it does in a standard installation.

All the standards frown on doing this and it would not be permitted under any of them. We would argue that it is an unacceptable increase in risk and should not be attempted.

There is however another view that turns this on it’s head - should I interconnect the air compressors for oxygen, instrument air and medical air (closed off with a valve for instance) so if one compressor fails I can use the other(s) to keep the other system(s) operational in an emergency? An example would be if the oxygen concentrator compressor failed, I might be able to take the medical air compressor and use

it to feed the concentrator in a crisis.

In this case the interconnection is not increasing the ordinary risk (the units are not interconnected normally, but only when the valve is opened in case of need) but is providing a way to deal with a serious problem should it occur.

The idea is seductive, but has one serious flaw: each of the systems is sized independently and controlled independently. If you attempted to use one for a purpose for which it was not intended or sized, could it continue to perform it's original function? Is it's output pressure, cleanliness and flow usable as the input for the alternative purpose? Can it be controlled without creating an unsafe condition in either source? The answer to these questions in any randomly chosen facility would almost certainly be No.

Unless it were specifically engineered with this in mind, one would lose all or part of the ability to provide the original service, and the now interconnected compressor is not going to reliably respond to the usual controls. The trade-off might be worthwhile, but it is for the facility's risk manager to decide.

This falls out of the usual medical gas standards and into the area of risk management and emergency preparedness, where a facility is at liberty to do what it wishes to ensure patient safety. If done, it needs to be approached with caution and engineered with the greatest care. This too should be considered a high risk strategy.

**Cylinder Filling**

Cylinder filling involves taking the oxygen off a concentrator and compressing it into cylinders. There are two aspects of the question:

The first motivation is the wish to take oxygen 93 from the system and use it to keep the cylinder reserve full. Many concentrator systems are designed with this capability included because it saves trouble monitoring and changing cylinders. And after all the reason for using a concentrator may be because they have difficulties getting cylinders supplied in the first place.

The mechanics are deceptively simple. One connects the intake of a special booster compressor off the main system header. That booster compressor will compress the oxygen to 150 bar or thereabouts and push it back into the cylinders. When the cylinders are run down, the booster compressor simply refills them during off-peak periods and the reserve supply never needs changing.

The deceptive part of "simple" comes from:
• The controls. They must detect when the cylinders are low, ***and*** they must detect when the pipeline is drawing less than one concentrator can produce. When both conditions are true, the cylinder filling can go on without reducing the supply available to the patient, otherwise it must stop.

• Cylinder filling is inherently dangerous. The pressures are very high and the cylinders at these pressures are little less than bombs. The booster compressor must trickle the gas into the cylinders to allow the heat of compression to dissipate safely.

Cylinders are pressure vessels and must be periodically tested and recertified in most countries, and even where it is not a legal requirement it is certainly wise. The cylinders can fatigue when continually pressurized and depressurized and the risk of an explosion will increase with time and with every pressure cycle. Retesting is an administrative burden, and in some places may be difficult to manage at all. But it must not be ignored - the time bomb is always ticking. Commercial cylinder filling plants operate under the assumption that it is not a question of ***if*** a cylinder will explode, it is a question of ***when***, and their safety and containment practices are set up accordingly.

• We are compressing oxygen, the most reactive of all the medical gases. The system and all it's component parts must be designed and carefully maintained to be suitable for oxygen at 150 bar or more. This is a tall ask - particularly for the booster compressor itself, which has moving parts that must be lubricated and of course will wear out. There are not many manufacturers of these highly specialized machines and they are expensive to buy. Maintenance is equally specialized. "Cleaned for oxygen service" has real meaning at these pressures, and must be considered every time the high pressure elements of the system are touched.

These risks are manageable in a fixed installation such as a reserve cylinder header that includes a trickle fill compressor. The fact that the cylinders are essentially stationary and only need to be removed for pressure testing every few years keeps the risks minimal. Thus, these filling systems are a very common accessory on medical concentrator installations. The risks become much harder to manage if the cylinders are changed.

The second motivation for cylinder filling arises with the realization that you have a supply of oxygen, a

supply of cylinders, a way to fill them, and patients around who need gas. Why not fill the cylinders and become a miniature gas company, selling the gas to local dentists, for home care, ambulances, etc?

The problem with this is that one actually *does* become a gas company - subject to all the rules and regulations any pharmaceutical producer must meet. That means documentation of the purity and pharmacopoeial compliance of every cylinder filled and sold; maintaining traceability of all the gas sold; testing all the cylinders; following strict transportation regulations; submitting to regular inspections, etc, etc.

In short, for following all the GMP (Good Manufacturing Practice) rules established by FDA or the equivalent local authority.

Plus of course you as the gas producer now carry ***all*** the liability.

The task is so daunting and the resources needed to comply so expensive that they would ordinarily consume what profit there might be in the idea. Regulatory people take a very dim view of the whole idea and in places the practice is outright illegal. It is prohibited under the ISO standard as well as others.

All this is not always a deterrent. There are facilities, particularly in remote areas and in countries with lax drug manufacturing rules, who have undertaken to distribute cylinder oxygen from a concentrator. In their defense, sometimes imperfect is better than none at all, but the case must be well out of the ordinary.

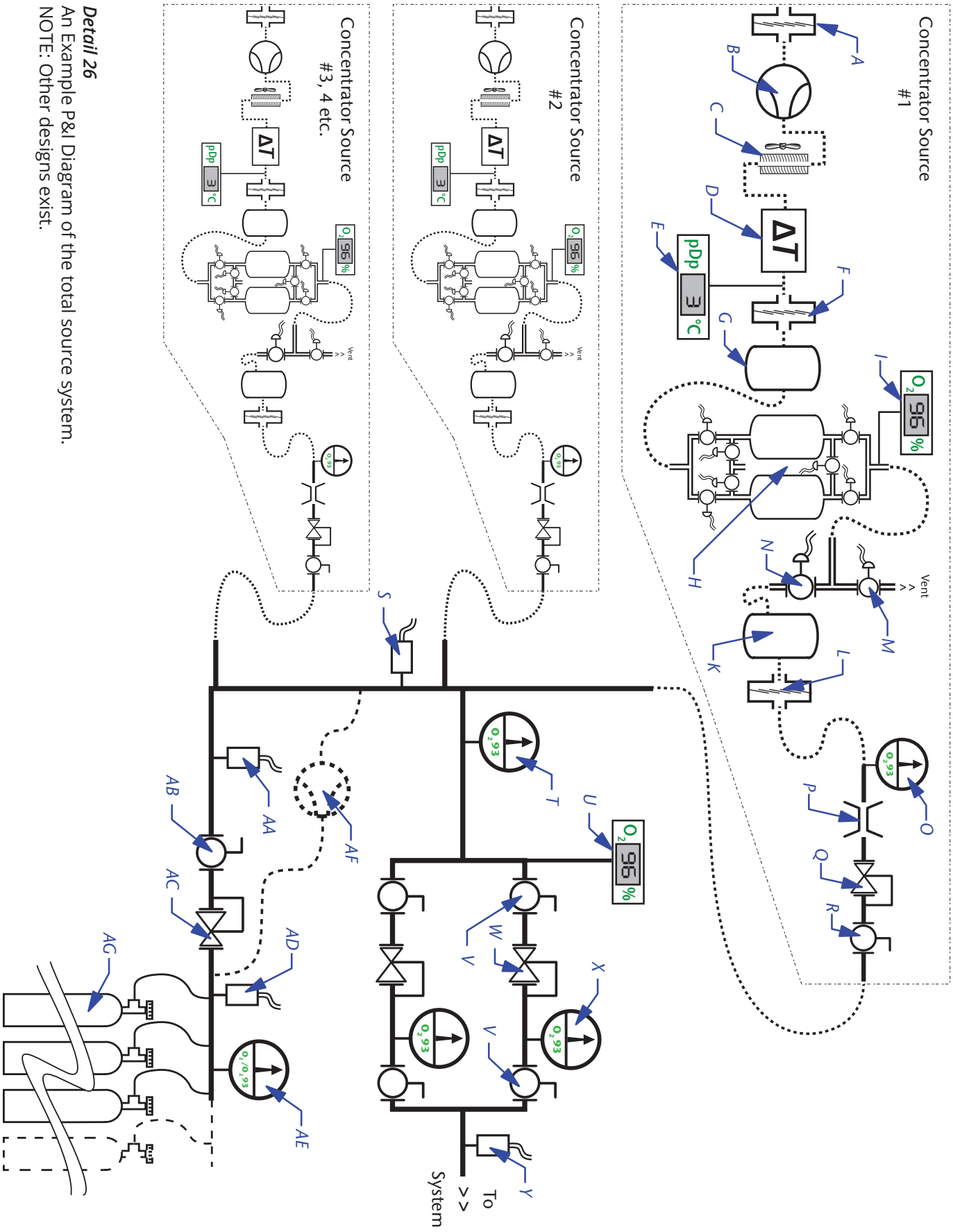
One note: if cylinder filling is part of your design, ***purchase*** the cylinders from a quality cylinder manufacturer as part of the manifold. Consider such cylinders a permanent part of the filling manifold.

Never put oxygen cylinders from your gas supplier onto a filling system. The system will of course fill them with concentrator-produced Oxygen 93, and you will have contaminated the contents, which were probably originally Oxygen 99% and labelled as such.

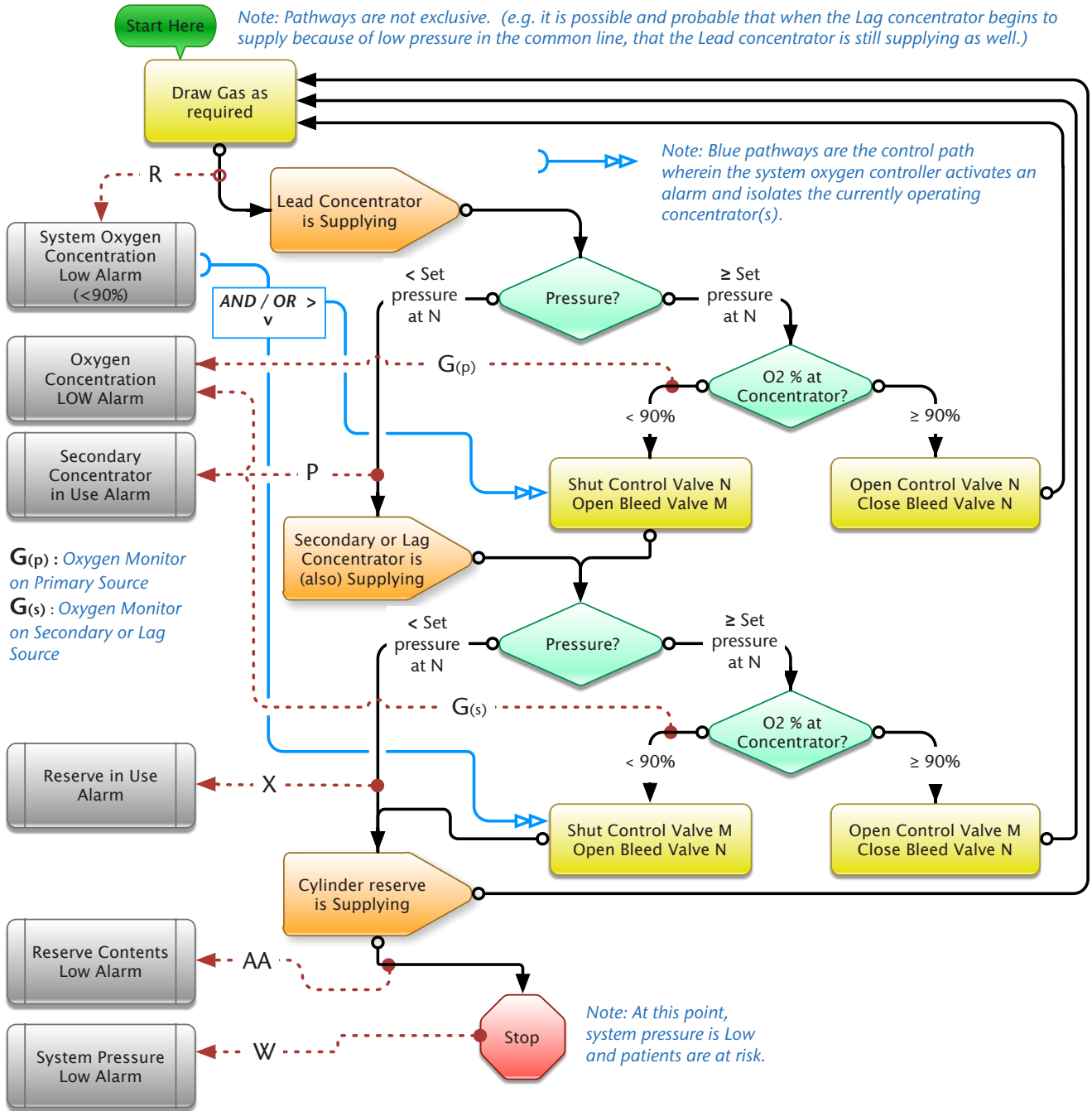
Cylinders from gas companies are also usually rented, and the monthly rental charge for cylinders used as a permanent part of the filling system can add up to an immense cost over the life of the system.

***Components Index for Detail 26***

| | |
|---|---|
| A | Inlet filter |
| B | Compressor |
| C | Aftercooler |
| D | Air dryer |
| E | Dew point monitor |
| F | Filter |
| G | Air receiver |
| H | Oxygen Concentrator |
| I | Oxygen Monitor |
| N | Concentrator outlet control valve |
| M | Purge or Bleed control valve |
| K | Oxygen receiver |
| L | Filter (oxygen) |
| O | Pressure gauge (Concentrator output) |
| P | Flow limiting orifice or regulator |
| Q | Concentrator pressure regulator |
| R | Concentrator isolation valve |
| S | Secondary concentrator in use pressure sensor |
| T | Common header pressure gauge |
| U | System oxygen monitor |
| V | Final line regulator isolating valve |
| W | Final line regulator |
| X | Final line pressure gauge |
| Y | System pressure sensor |
| AA | Reserve in use sensor |
| AB | Reserve isolation valve |
| AC | Reserve pressure regulator |
| AD | Reserve contents sensor |
| AE | Reserve contents gauge |
| AF | Reserve filling booster compressor |
| AG | Reserve cylinders |




***Detail 26***
An Example P&I Diagram of the total source system.
NOTE: Other designs exist.




***Detail 27***
*The Operating Logic of a Concentrator System*
*NOTE: Other designs exist.*

**An Example of the Sizing Process**

Our sample facility:

150 bed general hospital in a rural setting.

The facility features 5 general purpose operating rooms, 20 adult intensive care beds, and 20 nurseries for normal births.

The facility is not specifically equipped to handle premature births or critical infants, but of course will do their best should that kind of care be required. The rest of the facility's beds will be used for any patient who presents themselves. Only the rooms on the first and second floors will be piped with oxygen (about half).

They do have a 10 bay emergency room, which they expect to be very busy, since most of the patients will probably present themselves there, as primary healthcare in the area is very limited. These will have oxygen.

They do have have access to cylinder oxygen so they do not wish to include cylinder filling as part of their process.

The situation then is:
5 O.R.
20 ICU
20 Nurseries
10 Emergency
95 General patient rooms, but only 47 with oxygen.

102 beds with oxygen

102 x 0.7 lpm/bed = 71.4 lpm base load (see page 14).
*(My internal dialog: I've used 0.7 since the patients are likely to be sicker than average, and the beds equipped with oxygen will probably see a higher percentage of patients needing oxygen than might be average in another facility)*

The facility cannot afford a lot of expensive equipment, so the equipment will not be anything out of the ordinary. Each piped bed will have a flowmeter, there will be five anesthesia machines, each with a ventilator, there will be 10 ICU ventilators, but these are equipped to use medical air (see page 13) and a medical air system is to be installed. Use of the oxygen therefore will not be exceptionally high in the ICU.

The nurseries will have 10 incubators, and these are equipped to provide elevated oxygen. They don't use croup tents, but they do have some masks that can humidify the air for the patients under a hood. Everyone here is aware that oxygen is limited and they must restrict use to patients who actually need it. Standard practice for the doctors is to do an oxygen flush through the anaesthesia machine at the end of each surgery.

*(My internal dialog: I am going to assume that every piped standard bed has a patient using oxygen in some way. But, I'll split the difference for these and instead of 5 lpm, I'll use 2.5 lpm per bed that's piped. So 47 x 2.5 = 117.5 [see page 13])*

The nursery is a big user, and there is a possibility that there could be some high use periods if they had multiple hoods or incubators using large quantities of oxygen. A worst case would assume all 10 incubators running oxygen, which I'll assume to average at 12 lpm (12 x 10 = 120) [see page 13]. They have only standard anesthesia machines, which probably use oxygen for the ventilators, and these will run 25 lpm. I'll assume they could all be in operation at one time. (25*5 = 125). I doubt more than one will be flushing at any given time, and this will be only occasionally and briefly, so I am not going to add any demand for that.

I hear that they think they are pretty careful with the oxygen and are likely to keep waste to a minimum. However, that can't be relied upon, so I want to factor in some capacity for handling any poor technique.
I'll add 10% for waste, based on the base load number (71.4 x 10% = 7.1)

So 117.5 + 120 + 125 + 7.1 = 369.6 lpm. If I compare that to the Detail 16 sizing table, which shows 297, and the base load number of 71, I'm comfortable with my result, and I will look for a system making 370 LPM or more.

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Note : The following articles are included as an interesting counterpoise to the often expressed view that Argon is toxic.

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M. Coburn, R. Rossaint
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Coburn M, Sanders RD, Ma D, et al.
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