AAO Guidelines for Medical, Dental, "UltraPure" Laboratory Research Ozone Generators

Abstract: Ozone is utilized for medical / dental / laboratory research procedures worldwide, and yet, international standards regarding suitable ozone technologies have not yet been set. Misunderstanding or lack of knowledge regarding ozone and ozone technologies provides the opportunity for unsuitable technology to be utilized to generate the ozone, creating an opportunity for risk for those involved. This paper is a brief summary of the components and technical details of a medical / dental / laboratory research ozone generator. These details have been organized into the categories of "Necessary, Recommendable, and Optional".

This paper assumes that in order for an Ozone Generator to qualify for Medical, Dental, "UltraPure" Laboratory Research Applications it must have the following characteristics:

1. The Ozone that is produced must be extremely pure and contaminant free ("UltraPure").
2. The Ozone is produced at a precise concentration (strength).
3. The Ozone concentration is adjustable to the level required by the operator.
4. The Ozone concentration, once adjusted to the precise concentration, remains at that concentration as long as the ozone generator is in operation (ie. the ozone level is 'stable', neither rising nor falling).
5. The Ozone Generator in question must be reliable at all times and must be proven to be high Quality and Safe to Use through an appropriate Seal of Quality Approval.

The creation and handling of ozone (O_3) is governed by the basic laws of chemistry and physics, which ultimately governs the technological and material options available. This paper therefore is a summary of the technological aspects (and materials) that are required in order for an Ozone Generator to conform to the above characteristics, and therefore for it to be considered suitable for the creation of UltraPure Contaminant Free Ozone. This information is presented in three categories: Necessary ('must have'), Recommendable ('should have'), Optional ('convenient' but not necessary).

Note: At the time of publication of this paper the FDA has yet to approve any ozone generators for medical use. It is therefore up to the consumer to be extremely careful to ensure that the ozone generator you choose is capable of providing the ozone that you require.

Necessary: Which are the <u>Necessary</u> Components of an Ozone Generator for the creation of "UltraPure Contaminant Free Ozone"?

Necessary #1: High Quality Solid State Electronics with High Voltage Protection against spikes in the power lines.

Although it is possible to manufacture an ozone generator with low grade ('cheap') electronics it is absolutely essential for an "UltraPure" Ozone Generator to be constructed of only the highest quality electronics and power handling systems. The power required to convert oxygen into ozone of sufficient concentrations for use in "UltraPure" Applications requires 8000 – 10000 volts. Constant exposure of lower quality components to these high voltages will slowly damage or destroy the components, which would result in unstable and imprecise ozone concentrations and

quite possibly complete failure of the product. Spikes in the power lines would also have similar results.

In order for an ozone generator to constantly and reliably handle these high voltages, all *components must be rated for at least 10 times their expected energy exposure*. For example, since the electrode needs to handle 10,000 volts on an ongoing basis, the 'electrode' must be constructed to handle 100,000 volts in order for it to operate reliably. In addition, circuit board components need to be rated similarly. That is, if a component is to be constantly exposed to 40W (watts) it should be rated for 400 Watts.

Unfortunately abiding by this guideline requires that the manufacturer invest in quality components that are capable of carrying higher than expected voltages, increasing the cost of construction and lowering the profit margins available to the manufacturer. It is for this reason that not all ozone generator manufacturers would abide by this recommendation. It is our opinion that the use of high quality electrical components is mandatory, not optional.

Summary: Components must be rated for 10 times the expected energy exposure, including the electrode.

Necessary #2: The use of a "Double Walled Quartz Glass Electrode" (Reason 1): To Ensure Consistency of Ozone Output Concentrations and Quality o Ozone Generator.

The "Electrode" is the component of the ozone generator where oxygen is exposed to an energy field causing some of the oxygen to be converted to ozone (the product gas). This presents a challenge to the manufacturer on several fronts.

The electrode must be constructed from a material that has the following characteristics:

a) The material and design can withstand constant exposure to high voltage electrical fields without creating any heat. Heat destroys ozone and therefore if the electrode produces heat ozone output is compromised.
b) The material must be able to withstand exposure to the energy field without succumbing to structural damage.
c) When energy is delivered to the 'electrode' it must be discharged in a smooth energy field (normally referred to as a plasma field), without the creation of any sparking or 'arcing'. Sparks are unpredictable and will not only lead to inconsistent ozone output levels but also likely cause damage to the interior circuitry of the ozone generator and have the potential to cause fires.

Many electrodes on the market today are constructed of Stainless Steel and / or Aluminum. Unfortunately electrodes made of these materials fail in these requirements.

There are also tubes on the market today that are made from a material referred to as 'ceramic'. The ceramic material is a silica based material (far lower quality than 'glass' and with a high aluminum content) that is non-conductive. The manufacturers claim that because the 'ceramic' is a 'glass like' material that the material is high quality, and inert to the effects of ozone. Unfortunately the reality is that these 'ceramic' tubes are actually double walled tubes wherein one wall is 'ceramic' and the other wall is usually metal. The 'metal' could be stainless steel, but is most often aluminum. Keep in mind that the 'ceramic' also has a high aluminum content. The challenges are:

a) The stainless steel wall is subject to the challenges mentioned above (a) through (d), in addition to the contamination effects mentioned in "Necessary #3" below.

b) When exposed to high voltage electrical fields the *ceramic material is structurally compromised*, it simply can't withstand the high energy field. This tube is therefore prone to structural damage and ultimate failure.

c) If aluminum has been used it too is subject to the challenges mentioned above (a) through (c), with the additional concern that aluminum oxides would be added to the ozone (see "Necessary #3" below)

Quartz Glass is the ideal material from which to create the electrodes due to the fact that Quartz Glass is a unique material that makes all of the above issues inconsequential:

1) The pure structure of High Quality Quartz Glass Electrodes (no occlusions, no impurities, no imperfections) spread the energy predictably into a 'plasma field' where there is no arcing, nor sparking, of the energy field. The energy field that is produced is the beautiful 'glow' of a plasma field. Although it is possible to use "Pyrex" glass from which to create an electrode, the absence of this pure structure in Pyrex (the glass has impurities) limits the ozone output of such a tube (usually to 50-60 ug/ml or less). Quartz Glass is unique in its characteristics making it the ideal material for consistently high (and pure) concentrations of ozone.

2) Quartz Glass is impervious to the effects of the high energy field which so easily compromises other materials. A Quartz Glass electrode therefore will last a lifetime of use within the ozone generator without being structurally compromised in the least from the stress of handling thousands of volts of electricity.

3) Quartz Glass is also 100% resistant to the oxidative effects of ozone, which ensures that the ozone gas remains pure and free of contaminants. (Discussed below in Necessary #3)

4) Proper engineering techniques can ensure that a Quartz Glass tube will not produce any heat, something that is extremely difficult with a metal electrode.

Necessary #3: The use of a "Double Walled Quartz Glass Electrode"
(Reason 2): All materials in contact with the Ozone Gas while it is in the o generator must be 100% Ozone Resistant to maintain the purity and 'contaminant status of the ozone gas. Our suggestion is to insist that all ozone generators u Quartz Glass 'Electrodes' (no metal).

Very few 'ozone resistant' materials exist that qualify in this category, and at present time are considered only to be Kynar, Teflon (which should be utilized for the interior fittings and tubing), and Quartz Glass. These are considered to be infinitely resistant to oxidation even at the highest levels of ozone gas concentration. Unfortunately these materials are also expensive, so in today's economy manufacturers tend to be relying on less expensive materials in order to maximize profits. These 'less expensive' materials allow a manufacturer to lower the cost of an ozone generator, but unfortunately Quality of the Ozone Generator and Purity of the Ozone is compromised.

In recent years, North American and worldwide ozone generator manufacturers have come to rely on Ozone Tube or Electrode "Kits" that are ready to install into any ozone generator. The most popular "Electrodes" on the market today for example, are inexpensive and readily available from Chinese manufacturers who prefer to use either Stainless Steel or Aluminum as the material of choice for the tube (ie. Electrode), and prefer to connect the two tubes together (to form the 'dielectric' double wall) by utilizing cheap plastic as 'end pieces' for the tube (see photos below). Using plastic ends is far easier, less expensive, and less time consuming than welding the two tubes together at the ends.

Unfortunately these materials contribute toxic impurities to the ozone as described below.

Example 1: An "Ozone Electrode" Available at Low Cost from Chinese Manufacturers

Two photos of the same Chinese "Ozone Electrode" are displayed. The photo on the left is of the complete tube as it would arrive from the Chinese supplier. In addition to the tube, a low quality 'power pack' is provided, enabling quick and easy connectivity to either 220 / 240 volt power supply, or 110 / 120 volt power supply. Note the metal tube and plastic ends.

In the photo on the right, the end of the Electrode has been removed, and a glass cylinder within the tube is partially removed showing the use of a rubber "O" ring at the end that has been used to seal the tube to prevent leaking of the ozone. Rubber is easily oxidized by the ozone and toxic byproducts will be added to the ozone gas stream.

The "Ozone Tube" or "Electrode" displayed above is a very common design. This tube was removed from an American built Ozone Generator that is marketed as a "Medical Ozone Generator". Clearly this tube is not qualified for this use due to the following:

1) The main portion of the tube is made from Stainless Steel. Stainless steel will oxidize upon contact with ozone and release chromium and iron into the ozone gas stream (contaminating the ozone).
2) Rather than 'weld' the stainless steel ends together to create a seal at the end, the Chinese builders of this tube chose to use an easier and less expensive method, plastic caps glued to the end. Unfortunately the plastic ends of this tube are not ozone resistant, and will oxidize upon exposure to the ozone, releasing toxic byproducts into the ozone gas stream (plasticizers and oxidized plastic breakdown byproducts).
3) The use of the rubber "O" ring is extremely troublesome (see the ring in the right hand photo). Rubber is easily oxidized by the product ozone gas, and will readily oxidize to produce toxic byproducts that will be added to the ozone gas stream.
4) Aluminum – although the tube in the photo above is constructed of stainless steel it is important to point out that many tubes of a similar nature and source (China) are made from aluminum. Aluminum is easily oxidized by the ozone within the tube, releasing aluminum oxides into the ozone gas stream. Aluminum oxides are toxic.

The challenge the international community faces, is that due to the low cost and ease of use of these poor quality ozone tubes, these tubes and others like them are becoming the most popular tubes for manufacturers to use in their ozone generators today. Clearly, due to fact that the components of these tubes are easily oxidized, and the fact that the resulting byproducts added to the ozone are toxic, these tubes are not suitable for use in Ozone Generators that are to be used for UltraPure Applications, nor Medical, Dental, or Laboratory research applications.

***Summary**: Establishing a standard that Quartz Glass Tubes (electrodes) must be utilized will prevent metal tubes from being used, thereby preventing metal contamination of the ozone.*

Necessary #4: All Materials in Contact with the Ozone Gas must 100% Ozone Resistant

The necessity of ensuring the 'electrode' is 100% resistant to the oxidative effects of the ozone has been discussed in the section above. However other possible sources of contamination of the ozone are the internal tubing, which directs the ozone out of the ozone generator, and also any connectors or fittings that the ozone may contact in its journey through the tubing. The only materials that are suitable in this case are: Teflon tubing, and Kynar or Teflon connectors. Teflon and Kynar are both 100% resistant to oxidation; they will neither add contaminants to the ozone nor fail (crack) due to oxidation. Since both are expensive, many companies prefer to use plastic tubing and plastic connectors inside the generator which as described above will be oxidized by the ozone and therefore contribute toxic byproducts to the ozone gas. In the middle ground is Silicone Tubing, used outside most ozone generators because it is soft, bendable, and easy to work with. While Silicone Tubing will not be oxidized by the ozone it will be 'dried' by the ozone, causing it to eventually crack and leak. This is easily rectified if the ozone is outside the ozone generator (the tubing is easily replaced by the owner) however companies that use Silicone Tubing 'inside' the ozone generator simply guarantee that within a relatively short time the tubing will crack, leak, and the ozone generator will have to be returned to the manufacturer for service (to replace the silicone tubing).

Summary: Only Kynar connectors and Teflon tubing should be used inside an ozone generator. The ozone resistance of these materials prevents them from being oxidized, thereby preventing the contamination of the ozone gas and also preventing future leaks.

Necessary #5: Ozone Generators be certified by an independent testing body for Electrical, Quality, Fire Safety and Proof of Professional Manufacturing. International Quality Approvals include CE, ETL, CSA, UL, QAI, TUV etc.

"Home Made" Ozone Generators are proliferating throughout the world, especially in North America and South Africa. Unfortunately they are all marketed as High Quality Medical Grade Ozone Generators. One way for professionals to ensure that they are not going to be tricked into purchasing a low quality 'home made' product masquerading as a professional quality product, is to insist on ensuring that their product of choice has at least one of the above mentioned "Safety and Quality" Approvals.

Insisting upon a seal of Quality Approval will guarantee that the product is professionally made due to the fact that in order to obtain these approvals:

1. The product has to pass rigorous Third Party laboratory testing whereby the product is tested in accordance with accepted local Quality and Safety Standards. Should the product pass these Quality and Safety Standard tests…..
2. The Factory in which the product is manufactured is inspected to ensure Quality Controls are in place and every ozone generator which is manufactured is the same high quality as the ozone generator that was tested in the laboratory. Not only is the factory inspected once, but in order to maintain the Quality Approval…..
3. The Factory is inspected 2 to 4 times per year (depending upon the Quality Approval of the product) to ensure that Quality Control measures are still in place and components being used in the construction of the product are the same components that were used in the original sample that was tested in the factory. These ongoing Factory inspections ensures that the company does not get lazy and stop Quality Controls, nor will they be able to cut corners by substituting replacement components into the product to save on costs of construction.

If a seal of Quality Approval (such as those listed above) is missing from the product it would mean that neither the product nor the factory have been inspected. This in turn would indicate that either the product is too poor in quality to pass the rigorous Quality Testing Procedures, the product is 'home made' and there is no factory, or both. If the Ozone Generator cannot pass these Safety and Quality tests, or if it is 'home made', we would likely all agree that it should not be used in a professional setting.

In Summary, the lack of any Seal of Quality should be a clear indicator that the product is not to be trusted, nor used for UltraPure Applications.

Necessary #6: The Ozone Generator must use Purified Oxygen as the Feed Gas (and was originally designed to do so; post production alterations should not be acceptable).

In many countries around the world the basic parameters of a "Medical / Dental Research Ozone Generator" or "UltraPure Output Ozone Generator" are unknown. Therefore it may come to some surprise to those setting international standards that it is necessary to dictate in the standards that the Ozone Generator of choice must be one that *was originally designed to be used with Purified Oxygen as the feed gas (not 'air')*.

For example in South Africa and also America, medical / dental / laboratory research professionals are routinely using ozone generators that use 'air' as a feed gas for "UltraPure Applications", that is, those applications where the operator is assuming that the ozone being produced is extremely pure, contaminant free, and available in precision concentrations. In these countries it is not common knowledge that using 'air' as the feed gas is *inappropriate* for the following reasons:

a) Oxygen is the raw material from which an ozone generator creates ozone. "Air" contains only 21% O2 (approximately). Unfortunately an ozone generator is not capable of creating ozone concentrations high enough for "UltraPure Applications" if the feed gas is 'air', due to the insufficient concentrations of oxygen.

b) "Air" contains 78% Nitrogen (approximately). When the air enters the energy field of the ozone generator, the oxygen will combine with the nitrogen to create "nitric oxides" such as NO, NO_2, NO_3. These 'nitric oxides' are considered to be toxic.

c) If humid (moisture laden) air used as the feed gas for an ozone generator an additional byproduct can be created by the ozone generator which is nitric acid* (HNO_3). Nitric Acid is a strong acid which will accumulate within the ozone generator and could destroy internal components of the ozone generator. It is also known to accumulate inside the tubing of an ozone generator as yellow bubbles of liquid, painful to the touch. (*Interesting notation: HNO_3 is only formed if the Electrode is made of metal. If the electrode is made of glass, Nitric Acid is not formed.)

Example: At the present time in America, a Chinese made ozone generator suitable only for simple air purification, is currently being offered as a "Dental Ozone Generator". The ozone generator was originally designed to be used with 'air' as a feed gas (it has a built in air pump to draw in the air). The person selling these ozone generators disables the air pump, and adds a fitting for an oxygen tank to be attached. Unfortunately the high energy field within the ozone generator was not intended to be used in proximity to pure oxygen. As a result, several of these ozone generators have caught fire. Therefore, in addition to accepting the standard that only 'purified O_2' is used as a feed gas *it must be clarified that the ozone generator should also have been originally designed to be used with oxygen*, and should not be a modified 'air fed' ozone generator.

Necessary #7: Full Range of Ozone Output Concentrations Must be Available

A vast array of Ozone Applications are available to the research professional wishing to adopt the use of ozone. In order to accommodate these Ozone Applications, a vast array of ozone output concentrations are required. The ideal range of ozone concentrations to have available would be 1 ug/ml to 100 ug/ml (the upper levels are for water and ozonated saline). Therefore, the ozone generator of choice must provide the professional with a full selection of ozone concentration levels to ensure the professional is capable of performing all ozone application methods.

Necessary #8: A Safe Method of Destroying Offgassing Ozone Must be Provided

It is essential that high concentrations of ozone are prevented from entering the air. This is only possible if an internal or external Catalytic Ozone Destruct is provided with the ozone equipment. Customers should be cautioned to avoid Ozone Destructs that use Carbon as the active agent to destroy the ozone, as the reaction between high concentrations of ozone and carbon can create enough heat to cause an explosion.

Summary: Catalytic or Thermal Ozone Destructs must be provided to prevent 'offgassing'. They must not be made of carbon due to the risk of explosion and/or fire.

Recommendable: Which are the <u>Recommendable</u> Components of an Ozone Generator for the creation of "Ultra Pure Contaminant Free Ozone"?

Recommendable #1: Built in 10 Position Switch (manual or digital) to adjust the Ozone Concentration.

Without a control switch to change the energy exposure of the oxygen to the energy field the customer must rely on the basic standard oxygen flow rates as the only method of controlling the ozone output level. While it is possible to use only the standard 5 (to 7) flow rates to control the ozone output, it severely limits the number of concentrations available to the operator.

A built in control dial enabling the operator to change the level of energy imparted to the oxygen ensures that several ozone concentrations are available at each oxygen flow rate. This dramatically increases the ozone concentration options available to the operator, increasing the accuracy and efficacy of the ozone applications.

Recommendable #2: Built in Syringe Port for handy filling of Syringes.

The most common methods of apply ozone require the transportation of the ozone to the site of use. This is most often handled by the filling of a syringe. In order for a Syringe port to be useful and safe, the Syringe Port must have the following capabilities:

1) The ability to attach a syringe to the port easily and quickly.
2) The ability of the operator to easily open and close the Syringe Port.
3) The assurance that the Syringe Port will not leak when the filling of the syringe is taking place.
4) The assurance that the Syringe Port is constructed of 'ozone resistant' materials
5) The assurance that any ozone produced before and after the syringe is filled, is prevented from escaping into the surrounding atmosphere in the room.

Recommendable #3: Access to the Ozone for Ozone Applications other than just filling Syringes.

An extensive array of ozone applications is available to the professional. However some of these ozone applications require a relatively long duration of access to the ozone gas, requiring that the gas flow freely (into a contained space) for 20 – 30 minutes.

Therefore, is would be recommended that any professional ensure that the ozone can be accessed a variety of ways, and for a flexible period of time. If one is restricted to simply filling a syringe with ozone, the applications methods available are restricted to low volume, low duration application methods.

Recommendable #4: Duration of Warranty should exceed 2 Years (the ideal valid period is 5 Years)

With reference to the section Necessary #1 and Necessary #2 where it was discussed that the components of an ozone generator are under constant stressful exposure to high voltage energy fields, the reader may wish to consider that a short warranty and/or severely limited warranty should bring into question the quality of the ozone generator and the nature of the electrical components. If the manufacturer has compromised component quality in preference to higher profits, this will usually be displayed in a relatively short warranty period. Low quality components will not be able to handle the stress of the high voltage electrical fields and reliability issues are certain to arise. It is therefore our suggestion that a 1 Year Warranty should be avoided in preference for the 5 Year Warranty.

Recommendable #5:
Educated and Dependable Customer Support Team for "After Purchase" Follow Up Support

Hand in hand with a long term warranty from a dependable company would be the availability of a Customer Support Team for follow up customer support after the purchase has been made. Many ozone generator companies around the world are 'one man operations' with no formal Customer Support Staff. Others have staff members they label as Customer Support, however they have neither formal education nor proper training that would enable them to effectively support the customer. It is therefore recommendable that the purchase of an ozone generator be made from a company capable of providing high quality, dependable and educated follow up Customer Support for the setup, trouble shooting, and application questions that will inevitably arise after a purchase.

Recommendable #6:
Properly Ventilated Cabinet

In an attempt to prove that the "Ozone Technology" employed inside the ozone generator does not produce any heat, and therefore must be high quality, many ozone generator manufacturers will utilize cabinets that offer no ventilation at all for the internal circuitry. Assuming that they have actually designed and built an electrode that does not produce heat, these companies have forgotten that all of the other electronics inside the appliance do produce heat, especially circuit boards and power transformers.

Where there is electricity (especially the 10,000 volts required to create ozone), there is always a certain amount of heat generated. This is an inarguable fact based upon the physics of electronics. In the attempt to prove that their technology does not produce any heat, a company that utilizes a cabinet with no ventilation ironically ensures that the temperature

will rise inside their ozone generator, which unfortunately will destroy some of the ozone, making the ozone output levels lower than expected. The ozone levels will also be 'unstable' due to the fact that the level of degradation of the ozone from O_3 to O_2 will be dependent upon the temperature inside the cabinet, which is variable due to the fact that it is dependent upon the length of time the ozone generator has been running (and therefore building up the heat).

Proper ventilation in the form of vents, and in some cases, air movement fans, ensures that the minor amount of natural heat produced by the electronics is easily dissipated. If this is properly addressed, and assuming that the 'ozone electrode' employed in the design truly does not produce heat, then the concentrations of ozone produced by the ozone generator should be stable and trustworthy.

Summary: All cabinets, regardless of the technology utilized to create the ozone, must be properly ventilated.

Optional:

Which are the purely Optional Components of an Ozone Generator for the creation of "Ultra Pure Contaminant Free Ozone"?

Optional #1: Built in Ozone Concentration meter with full time digital display.

This component would be recommendable or necessary for products unable to display consistency in ozone concentration levels, or have been have been found to have questionable manufacturing practices.

Optional #2: Built in Ozone Flowmeter.

This is an interesting and sometimes useful 'secondary confirmation' of the rate of flow of the input oxygen and therefore the rate of flow of the output ozone gas, but is not absolutely necessary.

Optional #3: Built in Ozone Destruct Unit

A built in Ozone Destruct unit enables the ozone generator to be creating ozone, and yet at the same time this ozone is being destroyed. The value of the internal Ozone Destruct Unit is as follows:

1) Some ozone generators could require several minutes to 'warm up' to the point where the ozone concentrations are consistent (this may be apparent if the ozone generator has a built in Ozone Monitor). Running the ozone generator but not utilizing the ozone would require that the ozone be destroyed by an internal Ozone Destruct Unit (or an external Ozone Destruct Unit).

2) Sometimes it can be convenient to set the ozone generator to produce the proper ozone concentration, turn on the ozone generator so that it is producing the proper ozone concentration, and then complete the set-up of the research or final communication with the subject before the ozone flow is 'turned on' or before the syringe is filled.

The built in Ozone Destruct Unit ensures ozone produced in these situations is not allowed to enter the environment (air) in which the ozone generator is operating. (Please note: in absence of the Internal Ozone Destruct Unit, an "External" Ozone Destruct Unit with External Syringe port MUST be provided with the ozone generator to ensure ozone does not enter the room while filling a syringe.)

Optional #3: Built in Timer for Start / Stop of the Ozone Production.

Highly valuable for longer term ozone application methods that require more than a few minutes to complete, the use of a built in timer to turn off the ozone production after a preset time has elapsed is both a useful component, and could also be considered a safety component to prevent overexposure to ozone.