Litholyme: A Safer and more Cost Effective CO_2 Absorbent

Introduction:
In recent years there has been a struggle between cost and safety when it comes to the use of CO_2 absorbents in the operating arena. Increasingly, institutions are adopting low flow anesthesia protocols which realize significant departmental cost savings, but these procedures have been found to also significantly increase the risks associated with desiccation of soda lime based CO_2 absorbents[i]. The use of premium CO_2 absorbents which eliminate the risks associated with desiccation help to resolve this problem, but the premium price of these special absorbents reduce total cost savings that can be achieved. Another common alternative for cost reduction in the operating arena is the use of affordable conventional soda lime based absorbents in both standard and low flow systems. This approach requires more vigilant monitoring of the system and patient to minimize risks, and can be effective when followed correctly[ii], but the risk of patient injury from desiccated absorbent cannot be fully eliminated. Neither of these approaches is optimal in fully capturing the benefits of safety for the anesthesiologist and minimizing costs for the hospital system.

A proprietary new CO_2 absorbent, Litholyme, from Allied Healthcare Products, Inc., warrants a new look at this recurring dilemma by offering premium performance and ultimate safety, while maintaining a cost comparable with traditional soda lime based absorbents.

Traditional vs. Premium absorbents
All CO_2 absorbents use a catalyst, calcium hydroxide and water which react with CO_2 to form calcium carbonate, water and heat. During this cyclical process, calcium hydroxide is continually re-moistened during the exothermic reaction of CO_2 absorption until it has become fully exhausted and converted to calcium carbonate. While all CO2 absorbents undergo the same basic process to capture CO_2, there lie important safety differences between traditional and premium absorbents which stem primarily from the catalyst that is used in the formulation.

Traditional CO_2 absorbents use Sodium or Potassium catalysts to facilitate the CO_2 absorption reaction. Under desiccated conditions the reactive $Na^+ OH^-$ or $K^+ OH^-$ catalysts can preferentially bind and process inhaled anesthetic agents (Sevoflurane, Isoflurane, and Desflurane) into toxic carbon monoxide, and in the case of Sevoflurane, compound A, a known nephrotoxin[iii]. In additional to this potential for generation of harmful substances, Sodium and Potassium hydroxide catalysts used in traditional CO_2 absorbents remain in the exhausted material regenerate after use, causing the reversion of the pH based dyes that are used to indicate exhaustion. Indicator dye color reversion renders this safety mechanism unpredictable and increases the probability of inadvertent re-use of exhausted absorbent.

Premium CO_2 absorbents do not use NaOH or KOH, but instead incorporate proprietary formulations containing catalysts that do not react with common inhaled anesthetic agents, even under desiccated conditions. The absence of the Sodium and Potassium hydroxide catalysts also eliminates the potential for regeneration of the indicator dye, and provides the benefit of a permanent color change. To date, CO_2 absorbents that confer these enhanced safety characteristics have carried a premium price, limiting their adoption.

Despite the additional expense of premium CO_2 absorbents, the Anesthesia Patient Safety Foundation considers them best practice in the market due to their increased safety, especially in low-flow systems where gasses are subject to longer exposure to the CO_2 absorbent[iv].

What is Litholyme?
Litholyme is a new premium CO_2 absorbent which incorporates a Lithium catalyst to facilitate CO_2 absorption. Like other premium formulations, this lithium catalyst does not react with common inhaled anesthetic agents and therefore eliminates the potential for generation of Carbon Monoxide or Compound A. Unlike other premium absorbents however, Litholyme is cost effective to produce and therefore can be sold at prices similar to traditional CO_2 absorbents, making Litholyme the safest and most cost effective CO_2 absorbent on the market.

Litholyme's proprietary formulation provides equivalent canister life to that of traditional absorbents yet offers key features like non-reactivity with inhaled anesthetic agents, permanent color change indication, and lower exothermic reactivity, making it ideal for use in all standard and low-flow medical anesthesia applications.

Litholyme meets all of the recommendations for CO_2 absorbent selection from the 2005 APSF conference on safety considerations for CO_2 absorbent and its patented formula provides several significant advantages over other CO_2 absorbents on the market today when it comes to both safety and cost effectiveness.

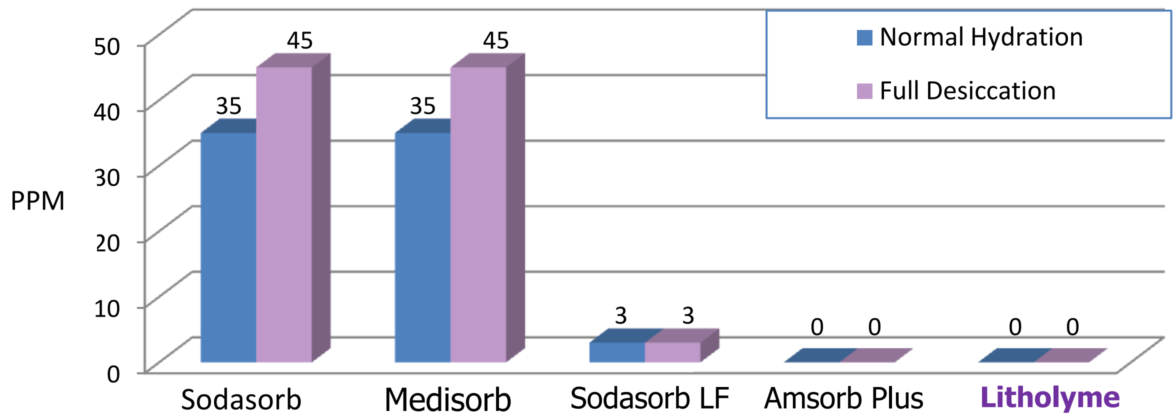
Litholyme is safe, even when subjected to total desiccation:
Desiccation of CO_2 absorbent is a common concern for anesthesiologists as it facilitates degradation of anesthetic agents in traditional soda lime and reduces the capacity of the CO_2 absorbent. In 2005, recurring safety issues related to desiccation of CO_2 absorbent culminated in the formation of a task force by the Anesthesia Patient Safety Foundation to address the issue Carbon dioxide Absorbent desiccation. From this meeting guidelines were established reduce the potential for use of desiccated CO_2 absorbent. The first of these recommendations is to use a CO_2 absorbent whose composition is such that exposure to volatile anesthetics does not result in significant degradation of the volatile anesthetic [ii].

Litholyme's patented formulation effectively eliminates the risks associated with CO_2 absorbent dehydration by eliminating the potential for anesthetic reagent interaction or excessive heat through the use of a lithium catalyst.

Litholyme eliminates the potential for generation of Carbon Monoxide or Compound A:
Traditional CO_2 absorbents incorporate strong bases like NAOH or KOH to catalyze the absorption reaction. Under dehydration, these strong bases begin to bind and degrade commonly used anesthetic agents like Sevoflurane, Isoflurane, Desflurane, and Nitrous Oxide[v] forming hazardous byproducts like Carbon Monoxide and Compound A.

A side by side study was performed by Dr. Thomas Dahms[vi] to compare degradation products of Litholyme to that of other commercially available premium and traditional CO_2 absorbents under normal conditions and under conditions that simulate a situation in which the fresh gas flow was left on over the weekend. This study introduced Sevoflurane and Desflurane respectively into a simulated patient environment using hydrated and desiccated CO_2 absorbents. Several CO_2 absorbents were exposed to these anesthetic agents under both hydrated (12%-18% moisture as supplied by manufacturer) conditions and following 36 hours of desiccation from constant fresh gas flow at 4 liters per minute without the introduction of CO_2 (resulting in 81%-86% moisture loss). The data below indicates the byproduct concentration of each CO_2 absorbent during one hour of exposure to anesthetic agents following these CO2 absorbent treatments. While traditional soda lime based absorbents showed significant accumulation of byproducts under desiccated conditions, Litholyme did not produce any Compound A or Carbon Monoxide.

Comparison of Accumulated Compound A Production under Hydrated and Desiccated Conditions



Comparison of Accumulated Carbon Monoxide Production Under Hydrated and Desiccated Conditions

Brand Name	Sodasorb	Medisorb	Sodasorb LF	Amsorb Plus	Litholyme
Normal Hydration (12%-18% moisture)	1 ppm	1 ppm	0 ppm	0 ppm	0 ppm
Full Desiccation (81-86% moisture loss)	>1000 ppm	>1000 ppm	0 ppm	0 ppm	0 ppm

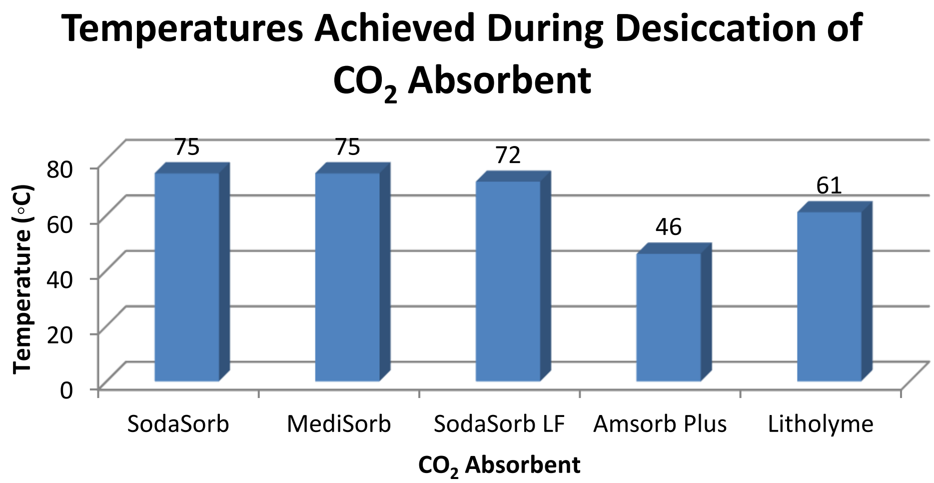
Litholyme is minimally exothermic:

It is widely recognized that the absorption of CO_2 is exothermic and that this exothermic reaction becomes more prominent with dehydration of the CO_2 absorbent. With some traditional CO_2 absorbents this exothermic reaction can generate temperatures high enough to cause potential combustion of the anesthetic gases[vii]. Even under normal conditions with both conventional and premium CO_2 absorbents the higher temperatures that are seen with low flow anesthesia have been thought to increase the rate of degradation of anesthetic gasses, and in the case of Sevoflurane, suspected to increase production of Compound A[viii].

Regulation of heat in the breathing system is an important factor to consider when choosing a CO_2 absorbent. It has been indicated that moderate levels of heat in a closed circuit, low flow system can be beneficial to the regulation of the anesthetic agent and can increase patient comfort during the procedure[ix]. Excessive heat, on the other hand, has been shown to increase absorption of inhaled anesthetic agents and, with traditional soda lime based absorbents, increase the rate of anesthetic degradation into harmful byproducts.

The CO_2 absorption reaction that takes place with Litholyme is less exothermic than traditional CO_2 absorbents and therefore generates only low levels of heat, making it safer for use in both standard and low-flow applications.

A controlled study was performed which compared the maximum temperature achieved in competitive CO_2 absorbent canisters under conditions that have been known to generate high levels of heat using traditional CO_2 absorbents. The study measured the absorbent bed temperature of several CO_2 absorbents through the process of consumption as they were subjected to 500ml/min gas flow with CO_2 levels of 35-40 mmHg (250-300 ml/min). The table below shows a side by side comparison of the maximum temperature achieved for commonly used traditional CO2 absorbents Sodasorb and Medisorb, as well as the premium CO_2 absorbents Sodasorb LF, Amsorb Plus and Litholyme. This data shows that none of the current CO_2 absorbents on the market generate dangerous levels of heat under these conditions. All of the premium CO_2 absorbents produced lower levels of heat than the traditional soda lime based absorbents. Under these conditions Litholyme produced a maximal bed temperature of 61 $^{\circ}$C



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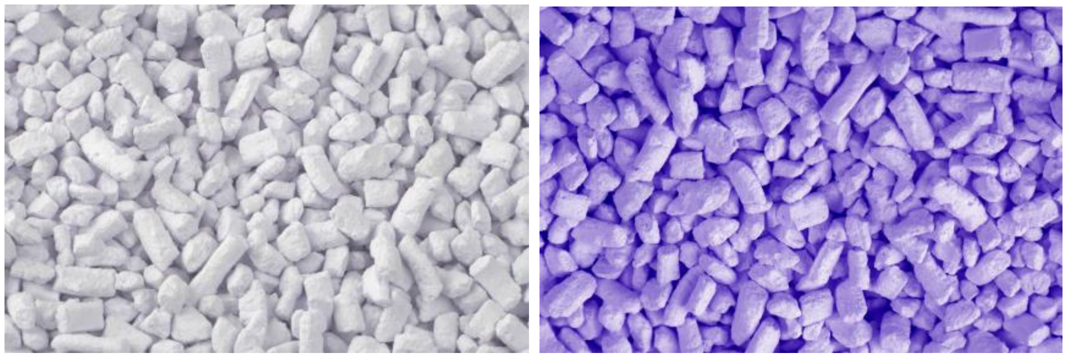
Litholyme incorporates a permanent and profound color change indicator:
Litholyme's patented formulation incorporates ethyl violet, a common indicator dye, in a way that provides all the benefits of a pH based indicator dye, but does not allow the color of the indicator to revert over time.

Soda Lime based products on the market also use Ethyl Violet, a pH based indicator which turns violet when the CO_2 absorbent is exhausted. Ethyl Violet has a critical pH of 10.3 at which the compound changes from colorless to violet due to the elimination of a hydroxyl ion and a resultant shift in the light absorption frequency of the molecule into the visible range. As conventional soda lime based products absorb CO_2, they drop in pH from around 13.5 in fresh absorbent to below 10 when expended. This pH shift causes the bonded indicator dye to turn violet[x].

Unfortunately, with conventional CO_2 absorbents, if they are left to sit once expended, they can revert to their fresh white color, even though they are fully consumed. This is due to the regeneration of Sodium Hydroxide or Potassium Hydroxide in the spent absorbent. While these strong bases are consumed during the CO_2 absorption reaction, their properties are such that they are capable of slowly regenerating until the pH of the absorbent rises above 10, at which point the absorbent once again loses its violet color.

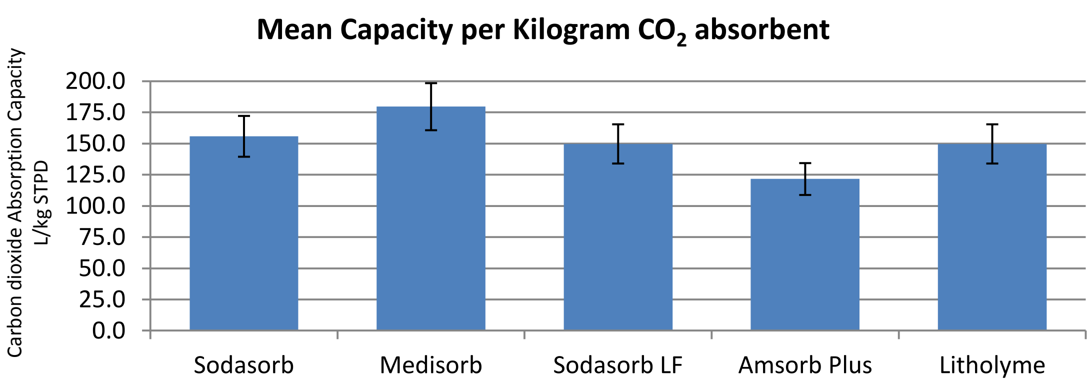
The absence of Sodium Hydroxide or Potassium Hydroxide in Litholyme ensures that once Litholyme turns to violet, it will remain violet permanently. It also produces a more vibrant violet color than other absorbents that use ethyl violet. The result is that once Litholyme is exhausted it stays violet, and the unmistakable color change provides certain indication of the status of the absorbent.



Fresh Litholyme has a grayish white color which changes to a deep violet color as the granules are exhausted. This Gradual color change is permanent and will not revert if left to sit.

Litholyme provides efficient canister life:
With other premium CO_2 absorbents, the formulation that allows them to offer increased safety also provides absorption capacity as much as 30% lower than that of traditional CO_2 absorbents, resulting in more frequent canister changes. This lower efficiency translates into substantial additional departmental costs over time and occasionally requires a change in departmental protocol to accommodate the shorter canister life.

Litholyme's patented formulation has a high CO_2 absorption capacity similar to that of traditional soda lime based absorbents. To demonstrate the comparative canister life of CO_2 absorbents, an independent side-by-side study was performed which measured the absorbent capacity of various brands of CO_2 absorbents under standard flow conditions. This study demonstrates that under controlled conditions the absorption capacity of Litholyme is statistically equivalent to that of traditional CO_2 absorbents, and statistically larger than that of Amsorb Plus. In this experiment Litholyme produced an average absorption capacity of 150 Liters CO_2/Kg, before 0.5 % $FiCO_2$ breakthrough occurred, where Amsorb Plus produced an average absorption capacity of only 120 Liters CO_2/Kg. In fact, Litholyme's marketing literature claims a high absorption capacity of 169 L/kg, more than that of even some traditional CO2 absorbents.



The similar CO_2 absorption capacity of Litholyme as compared to traditional CO_2 absorbents makes Litholyme an ideal candidate for substitution in modern anesthesia protocols.

Litholyme's combination of enhanced safety and reliable performance offered at traditional CO_2 absorbent prices make it possible to achieve the highest level of safety at lower costs than ever before. Regardless of whether your institution is currently using traditional soda lime or a premium CO_2 absorbent, Litholyme should be given strong consideration for its ability to enhance safety while maintaining or significantly reducing the cost of departmental operations under standard or low flow applications.

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[v] Morio M, Fujii K, Satoh N, et al. Reaction of sevoflurane and its degradation products with soda lime: Toxicity of the byproducts. Anesthesiology 1992;77:1159–64

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