Medical Air

A Risk Assessment

Second Edition

Air Liquide HEALTHCARE

Notes on Using this Pamphlet:

This pamphlet is presented as a service to producers and users of medical air. We deal here with medical air in its pharmaceutical form, Medical Air USP. Our purpose is to discuss quality issues surrounding the production in the healthcare facilities of this therapeutic product.

The CSA Z7396-1 medical gas pipeline standard referenced throughout this document is available in four editions. We encourage readers to familiarize themselves with the edition applicable in their province or territory.

References to the United States Pharmacopeia (USP) are for medical air purity requirements. Other countries may reference the European Pharmacopoeia (EuPharm) or a national pharmacopeia. The common theme is that all medical gas standards refer to medical air as defined by a pharmacopeia, and therefore all consider it to be a gaseous pharmaceutical. (e.g. Oxygen, Nitrous Oxide, Carbon Dioxide, etc.) Therefore, the standards treat medical air with the same respect.

Any opinions expressed and/or interpretations given or implied are the sole responsibility of Air Liquide Healthcare and the authors. Users are expected and encouraged to obtain information from other sources.

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Air Liquide Healthcare is engaged worldwide in the manufacturing and distribution of compendia medical gases. With a dedicated Healthcare World Business Line, we offer patient centric respiratory products and services in over 80 countries, including on-site production of medical air and oxygen at healthcare facilities.

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1. Introduction

According to the Canadian Institute for Health Information, respiratory disease is the second most common reason for hospital admission in Canada. **Medical Air USP** is an adjunct common to respiratory therapies such as ventilation (conventional & jet), general anaesthesia, high flow nasal cannula therapy, inhaled nitric oxide delivery, and aerosolized drug treatments.

Medical Air is a therapeutic product as defined by Health Canada. All Canadian commercial producers of Medical Air validate finished product to the United States Pharmacopeia (USP) specification and deliver cylinders marked with a Drug Identification Number (DIN).

CAN/CSA Z7396.1, as adopted within the National, BC, Alberta, and Ontario Building Codes, mandates that when produced on-site, Medical Air **shall** meet the United States Pharmacopeia (USP) specification, or such other formula as adopted within the healthcare facility's formulary[1]. The 2017 edition of this Standard requires healthcare facilities perform a **quality risk assessment** to determine the frequency of quality analysis, and where deemed in the best interests of patients, employ means to prevent off-spec product from entering the pipeline.[2]

This document provides healthcare facility professionals with a risk assessment template based on the clinical use of Medical Air. Users of this document will determine the frequency of sampling and analysis, and operating methods required to ensure the quality of Medical Air entering the pipeline meets the clinical, regulatory, and patient safety Standards.

2. Background

Canadian hospitals regularly dispense medical gases from central pipeline systems. The majority of medical gases are obtained from commercial producers, and delivered to hospitals in cylinder and bulk forms. For economic reasons, however, Medical Air is commonly manufactured on-site by the hospital's facility engineering department. This is accomplished by compressing outdoor air into a central pipeline distribution system. In some countries, given consistently high levels of outdoor air pollution, synthetic Medical Air is produced on-site by blending medical nitrogen and oxygen. Currently no healthcare facilities in Canada produce synthetic medical air.

Healthcare facilities with active ORs and ICUs may dispense 2-3 times more Medical Air than Oxygen through their pipeline systems[3]. Due to the large volume of Medical Air dispensed, on-site production is usually employed for cost efficiency. There is a downside, however, in that the equipment required to produce Medical Air suitable for patient therapy is quite complex, and must be carefully installed and maintained to limit the risk of contamination or breakdown. In this regard, CSA Z7396.1 limits the types of compressors that can be used (*eg oil flooded compressors are not permitted*), prescribes a dewpoint low enough to prevent pipeline condensation, and requires redundancy through single fault design.

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[1] CAN/CSA Z7396.1-12, s5.5.2.1.4, CAN/CSA Z7396.1-17, s5.5.2.1.3
[2] CAN/CSA Z7396.1-17, s5.5.2.1.5 & 5.5.2.1.6
[3] Based on compressor run-time analysis. Data on file.

Many clinicians are unaware the Medical Air they are treating patients with is produced on-site[4]. Considering the wall outlets are labelled "Medical", clinicians also hold a reasonable expectation that the product issued from the outlets is quality validated.

3. Medical Air USP chemical specification

The United States Pharmacopeia is a reference of uniform preparations for the most commonly used drugs—with tests to ensure their quality, potency and purity. Medical gases such as Oxygen, Nitrous Oxide, Carbon Dioxide, and Medical Air are listed by USP.

USP; these three letters convey a great deal of information to the healthcare practitioner. They let the pharmacist or doctor know that the medicine or product in the bottle meets several key quality attributes that are necessary to ensure the medicine will perform as expected. Products holding this designation and dispensed in a healthcare facility, including Medical Air, should be listed in the facility's Formulary.

The USP monograph for Medical Air stipulates that wall outlets be labelled "Medical Air" and the product dispensed meet the quality formula identified in the following table. To give the USP formula contaminants context we look to NIOSH guidelines for the recommended exposure limit for a healthy adult.

Medical Air USP chemical specification		**NIOSH REL**
Constituent	**Parameter/threshold limit**	
Oxygen (v/v)	19.5% - 23.5%	n/a
Humidity (pressure dew point)	< -5 °C (CSA Z7396.1)	n/a
Carbon monoxide	< 10 ppm	TWA 35 ppm
Carbon dioxide	< 500 ppm	TWA 5000 ppm
NOx (nitrogen dioxide + nitric oxide)	< 2.5 ppm	ST NO_2 1 ppm TWA NO 25 ppm
Sulphur dioxide	< 5 ppm	TWA 2 ppm, ST 5 ppm
Oil	No discernable (*chilled mirror test*)	n/a

REL = recommended exposure level, TWA = time weighted average over 8 hours.

ST = short term, usually 15 minutes or less

[4] Air Liquide Healthcare market survey, 2011.

4. **Other Formulas**

Although the USP formula represents the north american Standard for commercial production, healthcare facilities may produce to a different formula. The European Pharmacopeia monograph lists the same contaminants as USP, with stricter limits for CO, NOx, humidity, and SO_2.[5]

When selecting a formula, consideration should be given to industrial respiratory irritants common to the location, and when other contaminants are pervasive (*eg ozone*) they too should be monitored and when deemed necessary, engineered controls should be implemented to protect respiratory patients.

5. **Manufacturing medical gases on site — Responsibility for medical gas quality**

When produced on-site for dispensing on-site (ie *no packaging and transport*) at a healthcare facility, the responsibility for product quality should be assigned to a qualified person.

Pursuant to the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law), the healthcare facility shall be responsible for reporting any suspected or measured adverse events or any product quality complaints.

Users of this Risk Assessment are encouraged to familiarize themselves with CAN/CSA 7396.1-17 Annex S.

6. **Quality Risk Management**

Risk management principles are effectively utilized in many areas of industry, including finance, insurance, occupational safety, public health, and by agencies regulating these industries. In addition, the importance of *quality systems* has been recognized in the pharmaceutical industry, and it is becoming evident through progressive CSA Standards that quality risk management is necessary to protect patients served in public healthcare facilities.

Risk is often defined as the combination of the probability of occurrence of *harm* and the *severity* of that harm. Achieving a shared understanding of the application of risk management amongst a diverse set of *stakeholders* is paramount to the protection of patients.

[5] Comparison of European, US & Japanese Pharmacopeia Monographs for Medicinal Gases, EIGA Doc 152-11.

Medical Air Quality Risk Assessments[6]

Canada's latest medical gas piping standard requires a risk assessment be performed before producing medical air on-site. A risk assessment consists of the identification of hazards and the analysis and evaluation associated with exposure to those hazards. Quality risk assessments begin with a well-defined problem description or risk question. When the risk in question is well defined, an appropriate risk management tool will be more readily identifiable. As an aid to clearly defining the risk(s) for a Medical Air quality risk assessment, there are three fundamental questions:

1. What might go wrong?
2. What is the likelihood (*probability*) it will go wrong?
3. What are the consequences (*severity*)?

Answering the first question can be as simple as looking outdoors. On-site Medical Air quality is linked to outdoor air quality. Forest fire smoke, vehicle exhaust, power generator fumes and industry near and far may influence the air drawn in by medical air compressors. And while standard medical air filtration does a reasonable job blocking fine particles, it does little to filter chemical impurities. Studies confirm outdoor levels of nitric oxide[7] [8] and other contaminants associated with air pollution pass through typical medical air systems and find their way to patients through the pipeline. In Figure 1 we see carbon monoxide measured at a random wall outlet mirrors the levels measured on the roof of a Canadian hospital[9].

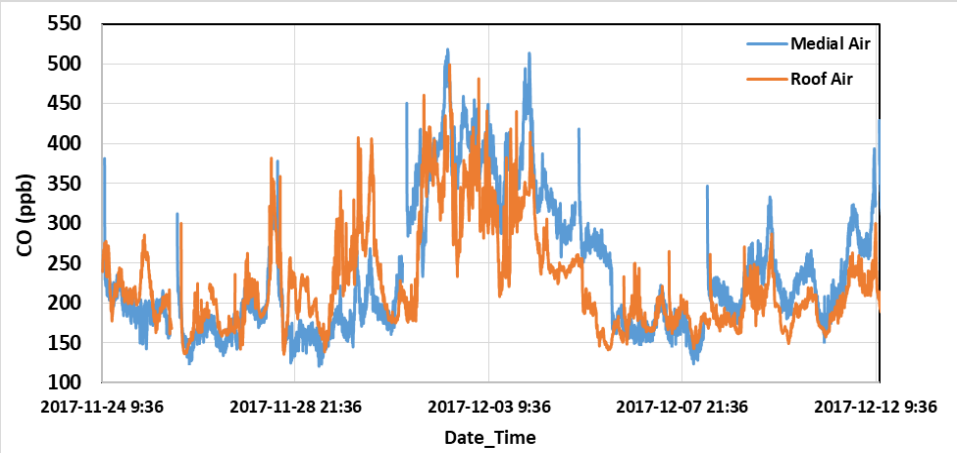


Figure 1

The answer to question one is, therefore: outdoor air contaminants such as carbon monoxide, carbon dioxide, nitric oxide, nitrogen dioxide, and sulphur dioxide are outside the facility

[6] CAN/CSA Z1002-12, Occupational health and safety — Hazard identification and elimination and risk assessment and control.
[7] Pinsky MR, Gene F, Lee KH, Delgado E: Contamination of hospital compressed air with nitric oxide. Chest; 111:1759-63.
[8] Benzing A, Loop T, Mols G, Geiger K: Unintended inhalation of Nitric Oxide by Contamination of Compressed Air: Anesthesiology 1999, 91:945-50.
[9] Medical Air Quality study in progress, University of Toronto: data on file.

operator's control, and without effective management patients may inadvertently be exposed to them through centrally piped medical air.

So what is the likelihood that product quality will drift out of bounds? In 2014, Air Liquide Healthcare introduced North America's first quality control service for medical air produced at hospitals. This quality control system continuously samples and analyzes the compressed and filtered air using sensor technologies that meet or exceed USP prescribed analytical accuracy[10] and records 11,520 associated data points per day.

Through this quality control service Air Liquide Healthcare has amassed over 100,000,000 data points that tell us:

- Quality breaches occur without warning, day and night
- Most breaches last less than 10 minutes, while some persist for days
- The most common breach is CO_2 > 500 ppm
- Root causes range from production methodology to variable outdoor air quality
- Quality breaches have occurred at <u>every</u> site we monitor, rural and urban.

With strong evidence telling us to expect a quality breach, we are left to assess consequences. While there are numerous studies confirming the health effects of common air pollutants, very few evaluate the impact on fragile respiratory patients. So we must start in a general sense by looking at the chemical elements in the U.S.P. formula and postulate impacts of a breach condition:

U.S.P. Element (breach condition)	**Impact Considerations**
Oxygen content high (>23.5% v/v)	Measured incidents of high oxygen content are thus far limited to <30% v/v and duration is typically less than 5 minutes. It is generally assumed that short term high oxygen releases will homogenize through pipeline travel.
Oxygen content low (<19.5% v/v)	Short term oxygen deprivation can have serious health effects in ventilated patients, especially neonates. Most anoxia monitors are set to alarm at 18% v/v, and there are cases on record of site produced Medical Air with O_2 levels below this threshold.
Carbon monoxide (>10 ppm)	Carbon monoxide is a well studied respiratory asphyxiant. Sustained exposure to CO levels as low as 8.7 ppm can have long term health effect.[11] Exposure to high levels of CO (ie >100 ppm) can be fatal. Exposure to carbon monoxide has been shown to heighten levels of carboxyhemoglobin, which exacerbates myocardial ischemia during graded exercise in subjects with coronary artery disease.[12] Hemoglobin is ~240 times more attracted to CO than oxygen, so ensuring CO levels below the U.S.P. limit of 10 ppm is of paramount importance. Common sources of CO include vehicle exhaust, wood burning fires, and diesel exhaust emitted from transport vehicles and hospital emergency power generators.

[10] Scott Freedom 5000 chemiluminescence sensors for CO, NO, NO_2, $O_2$and SO_2. Vaisala Carbocap GMT220 infrared monitor for CO_2. Vaisala DRYCAP dewpoint monitor for humidity.
[11] Townsend CL, Maynard RL, Effects on health of prolonged exposure to low concentrations of carbon monoxide, Occup Environ Med 2002;59:708–711.
[12] Short-Term Effects of Carbon Monoxide Exposure on the Exercise Performance of Subjects with Coronary Artery Disease

Carbon Dioxide (>500 ppm)	Carbon dioxide is odourless, invisible, and tasteless. With average outdoor levels at 405 ppm, and industry standard medical air drying methods having a catch and release[13] effect, this contaminant has a high probability of surpassing the U.S.P. limit if not monitored and managed. While 500 ppm of CO_2 may not be of concern to some clinicians, it should be noted that a sudden and larger volume of CO_2 released from a medical air dryer can travel in the pipeline as a bolus for more than 1,000 meters and cause short term oxygen deprivation when exiting through a wall outlet (see Appendix B). Additional causes of increased CO_2 levels in Medical Air are patient transport helicopter landings and nearby forest fires (eg Fort McMurray wildfire in 2016 blanketed Edmonton in smoke, some 450 kilometers away)[14]. Exposures to concentrations of 8% or more may cause death, unconsciousness, or convulsions.[15]
Humidity (> -5° C pressure dewpoint*)	Humidity is controlled in order to prevent bacterial growth in the pipeline as well as protect sensitive medical devices from moisture damage. In 2014 the Windsor Regional Hospital cancelled surgeries and suffered a $1,000,000 in equipment repair and replacement costs when condensation in their centrally piped medical air impacted 12 anesthesia machines[16]. While moisture in medical air pipelines and related device damage is well documented, more study on pipeline bio-burden is necessary.
NOx (NO + NO_2 > 2.5 ppm)	Nitric oxide is a very effective vasodilator and in the drug form is indicated for persistent pulmonary hypertension in the neonate[17]. Inhaled nitric oxide is delivered through ventilation circuits and generally involves dosing levels from 0.5 - 20 ppm. Where facilities treat patients with inhaled nitric oxide, inadvertent administration of nitric oxide from piped medical air should be avoided.[18] Nitrogen dioxide is a common air pollutant emitted from industry and vehicle exhaust. As a gas it has a reddish brownish colour and sharp, biting odour. Per World Health Organization guidance, NO_2 is a toxic gas with significant health effects[19]. Around the world NO_2 is credited with exacerbating respiratory ailments causing people to seek emergency medical care[20]. Studies investigating the relationship between personal NO_2 exposures and respiratory health outcomes also support an association between chronic NO_2 exposure and adverse effects. This contaminant was identified in the Health Canada 1987 Exposure Guidelines for Residential Indoor Air Quality as the NOx species that could have adverse health effects at concentrations potentially encountered in indoor air.[21]
Sulphur dioxide (> 5 ppm)	Sulphur dioxide is the subject of many ambient air pollution health effects

[13] Edwards P, Medical Air Checkup, Canadian Healthcare Facilities, Vol 37:30-31.
[14] AHS reinstates air quality advisory as smoke drifts into Capital Region, www.globalnews.ca/news/2712551/smoke-drifts-into-capital-region-as-ahs-lifts-air-quality-advisory/
[15] Rice S., *HUMAN HEALTH RISK ASSESSMENT OF CO2: SURVIVORS OF ACUTE HIGH-LEVEL EXPOSURE AND POPULATIONS SENSITIVE TO PROLONGED LOW-LEVEL EXPOSURE*, May 2004.
[16] Operating room docs scramble after anesthesia machines fail, Windsor Star, July 24, 2014.
[17] Kinox™, www.vitalaire.com/medical-gases-products/medical-gases/kinox/
[18] Benzing et al, *Unintended Inhalation of Nitric Oxide by Contamination of Compressed Air*, Anesthesiology 1999, 91:945-50
[19] WHO Air quality guidelines for particulate matter, ozone, nitrogen dioxide and sulfur dioxide. Global update 2005.
[20] Rasche, M et al, Rapid increases in nitrogen oxides are associated with acute myocardial infarction: A case-crossover study, European Journal of Preventive Cardiology, February 15, 2018
[21] Residential Indoor Air Quality Guideline: Nitrogen Dioxide - Health Canada 1987

	studies. It is a toxic gas widely considered as a primary factor in air pollution mortality[22]. It is known to contribute to premature birth and can be especially problematic for asthmatics. Although NIOSH lists a TWA of 5 ppm, in 2008 the American Conference of Governmental Industrial Hygienists published a short term exposure limit of 0.25 ppm.
Oil (none detectable)	Not considered given CSA restrictions on use of oil flooded compressor technologies.

* CSA Z7396.1 prescribed dewpoint, which exceeds U.S.P. requirements.

Since Medical Air is a common adjunct to respiratory therapies, we recommend expanding the question set with a few **site specific** queries:

1. Are the therapies involving Medical Air at this site typically of long (> 2 hours) or short (< 2 hours) duration?
2. Do the typical medical devices involved monitor the U.S.P. chemical elements within the Medical Air prior to patient inhalation, and alarm in the event of an off-spec condition?
3. Will the patient typically be able to voice concern if they sense a problem during treatment *(eg strange smell)*?

Answers can be used to formulate site specific ***Potential for Harmful Exposure***. The following table assesses the most common therapies involving Medical Air.

Therapy	**Typical Duration**	**Device Alarms***	**Patient Alert**	**Potential for Harmful Exposure**
Aerosol Drug Delivery	Short	No	Possible	Low
High Flow Therapy	Long	No	Possible	Low - High**
Mechanical Ventilation	Long	No	Unlikely to No	High
Neonatal Isolette Environment Control	Long	No	No	High
Infant Resuscitation	Short	No	No	Low
General Anaesthesia	Long	No	No	High
Hyperbaric Therapy**	Short	No	No	High

** While some devices monitor oxygen content, none monitor all U.S.P. chemical elements.*
***Some high flow therapy devices use room air whilst others use piped Medical Air.*
**** Hyperbaric therapy is often thought to involve oxygen alone, however most therapies involve breathable air and in many cases Medical Air is employed. If a stand-alone compressor system is used for hyperbaric chambers, consideration should be given to quality control and means for off-spec prevention pursuant to the quality formula referenced in CSA Z2751.5-05 Hyperbaric Chambers.*

Note: *typically occupational health literature references long term exposures to be of 8 hours or more, and these references apply to*

[22] Short term effects of ambient sulphur dioxide and particulate matter on mortality in 12 European cities: results from time series data from the APHEA project, BMJ 1997;314:1658

healthy people. For the purposes of this Risk Assessment, we define 2 hours or more to be long term since Medical Air is used to treat people suffering a respiratory ailment.

7. Risk Based Sampling Frequency Decision

Considering the information provided, we now return to the purpose of the Quality Risk Assessment; ***to determine the frequency of sampling and analysis, and operating methods required to ensure the quality of medical air entering the pipeline meets the clinical, regulatory, and patient safety Standards*.**

With a high likelihood that a quality breach will occur wherever Medical Air is made on-site, and knowing there are health effects if exposed to the chemical contaminants listed in the USP formula, we believe the determining risk factor is **potential for harmful exposure**. Where the potential is high, we recommend **continuous** chemical analysis and automatic means for off-spec prevention. Generally, these would be sites with a labour and delivery department, active operating rooms, or intensive care units employing mechanical ventilation protocols involving centrally piped Medical Air.

Where potential for harmful exposure is low, the frequency of monitoring and method of off-spec prevention should be **site determined**. Such sites are also likely to be low volume dispensers, in which case it may be financially prudent to transfer the burden of quality control to a commercial producer and feed your pipeline with high pressure Medical Air U.S.P. cylinders.

8. Site Based Risk Assessment and Review

This document is intended to be used as a generic guide for site specific evaluations. The quality data referenced is an aggregate from multiple healthcare facilities located in both urban and rural settings.

It is recommended that users of this document consider site specific factors that may influence the quality of outdoor air used in the medical air manufacturing process, such as proximity to industry, major roadways, and the use of medivac helicopters..

It is also recommended that a new risk assessment be performed every three to five years or whenever major renovations take place.

9. Best practices for on-site manufacturing of Medical Air

Through development of this risk assessment the authors interviewed clinicians, facility managers, and audited a number of medical air systems. The following best practices were discussed:

- Facility managers are generally responsible for on-site production, and should know the product specification required by clinicians.
- Employ Good Manufacturing Practices (GMP) when producing a therapeutic product. The hallmarks of GMP are quality assurance and quality control. CSA Z7396.1 provides guidance and rules to ensure a quality assured system design. This risk assessment is intended to confirm the level of quality control required by clinicians, and it is the facility manager's responsibility to implement such.
- Repeat the Quality Risk Assessment after major renovations or every five (5) years in order to document changes to the facility or its surroundings that may impact product quality.
- Carefully select quality sensors, with special attention to measurement range and accuracy vis-a-vis alarm thresholds. Most sensing devices are most accurate in the middle third of their range.
- Carefully select the grade of gases used to calibrate chemical sensors. The accuracy of your measurements is based on the accuracy of your sensors and the gases used to calibrate them.
- Calibrate and maintain quality sensors per manufacturer's instructions. Most hygrometers and all chemical sensors fail at the zero (0) end of their range. Don't be fooled by an uncalibrated sensor or exhausted chemical cell.
- Locate quality sensors so they monitor the on-site production and not the commercial produced high pressure reserve cylinders. Certain mechanical actions may be dependent on the quality sensor output *(eg Air Liquide's prevent & purge system*) and should not be influenced by the product contained in the high pressure reserve cylinders.
- Design the high pressure reserve cylinders in a way that segregates back-up for quality breaches from mechanical shut-downs *(See Appendix C)*. This approach makes cylinder management much easier.
- Employ means to automatically prevent off-spec gas from entering the pipeline *(See Appendix C)*.
- In the event of a quality breach, purge the air system prior to shutting it down. Most quality breaches are the result of a transient outdoor condition, and the contaminant(s) may be flushed and the system automatically brought back online based upon a return to acceptable quality output.
- Review your facility's Code Grey *shelter in place* protocol to ensure it includes management of the Medical Air system. If the outdoor air quality drives the hospital to put HVAC systems to 95-100% recirculation, the same air should not be drawn into the Medical Air system.
- Exercise your reserve to reconfirm peak demand, ensure operability and integrity of high pressure connections.

ADDITIONAL REFERENCES

Allen M, Edwards P: Medical Air White Paper, September 15, 2014

Edwards P, Medical Air: Quality and reliability is vital, IFHE Digest, 2016: 36-38.

Edwards P, Assessing the quality of on-site medical air, IFHE Digest, 2018: 84-86.

Edwards P, Medical Air Matters, Canadian Healthcare Facilities, Vol 34: 38.

Managing carbon monoxide in long-term care facilities and hospitals: National Collaborating Centre For Environmental Health *(www.ncceh.ca/sites/default/files/CO_Meeting_2013_Report_0.pdf)*

Short-Term Effects of Carbon Monoxide Exposure on the Exercise Performance of Subjects with Coronary Artery Disease. *(www.nejm.org/doi/full/10.1056/nejm198911233212102)*

Residential Indoor Air Quality Guideline: Nitrogen Dioxide; Health Canada *(www.canada.ca/en/health-canada/services/publications/healthy-living/residential-indoor-air-quality-guideline-nitrogen-dioxide.html)*

APPENDIX A - Site Based Risk Assessment Template

Date:
Facility Name:
Address:
Assessor(s):

The following therapies involving Medical Air are delivered at this site *(check all that apply)*.

	Therapy	Potential For Harmful Exposure
☐	Aerosol Drug Delivery	Low
☐	High Flow Nasal Cannula Therapy	Low - High
☐	Mechanical Ventilation	High
☐	Neonatal Isolette Environment Control	High
☐	Infant Resuscitation	Low
☐	General Anaesthesia	High
☐	Hyperbaric Therapy	High
☐		
☐		
☐		

We the undersigned recommend the following sampling and analysis frequency and method of off-spec prevention for the Medical Air being made at the above referenced site:

- ❑ Full time sampling and analysis for the chosen specification and means for automatic prevention of off-spec gas entering the pipeline distribution system.

- ❑ _____ *(daily, monthly, quarterly)* sampling and analysis for the chosen specification and means for automatic prevention of off-spec gas entering the pipeline distribution system.

- ❑ Bi-annual sampling from a random terminal unit and lab analysis for compliance with the USP chemical specification.

At this facility Medical Air shall be produced to the following specification:

- ❑ U. S. Pharmacopeia
- ❑ European Pharmacopeia
- ❑ Other, with the following elements monitored and threshold limits as noted

  - ❑ Oxygen *Threshold limits* _____
  - ❑ Carbon Dioxide *Threshold limits* _____
  - ❑ Carbon Monoxide *Threshold limits* _____
  - ❑ Humidity *Threshold limits* _____
  - ❑ Nitric Oxide *Threshold limits* _____
  - ❑ Nitrogen Dioxide *Threshold limits* _____
  - ❑ Sulphur Dioxide *Threshold limits* _____
  - ❑ Other_____ *Threshold limits* _____
  - ❑ Other_____ *Threshold limits* _____

Chief Medical Officer _____

Anaesthesia Director _____

Respiratory Therapy Director _____

Facilities Engineering Director _____

Pharmacy Director _____

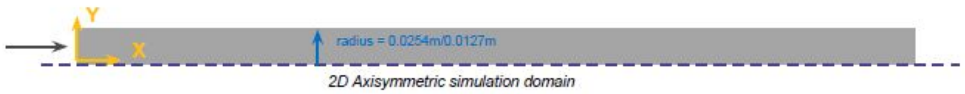
APPENDIX B - CO_2 Bolus Travel in a Pipeline

Given its unique gas properties, can a CO_2 bolus traverse a medical gas pipeline intact and cause short term oxygen deprivation whilst exiting via a terminal unit? This question was studied by Benjamin Straubhaar and Jiefu Ma at Air Liquide's Delaware Research & Technology Centre. The following slides are an extract from their modelling synopsis, including Case 3 results where it was determined a CO_2 bolus can travel as far as 1,320 meters before homogenizing in the air for safe terminal unit exit.

Operating conditions

- Operating pressure is 50 psi (3.44738 bars or 344738 Pa)
- Operating temperature is at room temperature 20°C
- Humidity is neglected
- Pipes are of 2 dimensions (ID): 2" and/or 1/2"
- Flow rate is assumed to be 50L/min@ambient conditions
- The CO_2 bolus is assumed to be 1L@ambient conditions

	Case 1	Case 2	Case 3
Pipe length (m)	20	100	100
Pipe diameter (m)	d_{h1} = 2" = 0.0508	d_{h2} = 1/2" = 0.0127	d_{h2} = 1/2" = 0.0127
Section (m^2)	$A_1 = \pi d_{h1}^2 / 4 = 2.03 \times 10^{-3}$	$A_2 = 1.27 \times 10^{-4}$	$A_2 = 1.27 \times 10^{-4}$
Flow Rate @ 50psi, 20°C	q_1 = 50 L/min	q_1 = 50 L/min	q_1 = 14.7 L/min (converted from 50L/min @ambient conditions)
Average inlet velocity (m/s)	$u_1 = q_1/A_1 = 0.12$	$u_2 = q_1/A_2 = 6.56$	$u_3 = q_2/A_2 = 1.93$ q_2 = 50 L/min@1atm
Reynolds number	$Re_1 = \rho_{air} u_1 d_{h1} / \mu_{air} \sim 5690$	$Re_2 = \rho_{air} u_2 d_{h2} / \mu_{air} \sim 22763$	$Re_3 = \rho_{air} u_2 d_{h2} / \mu_{air} \sim 6692$



2D Axisymmetric simulation domain

ρ_{CO_2} @50psi and 20°C ~ 6.34 kg/m³
μ_{CO_2} @50psi and 20°C ~ 1.47 x 10⁻⁵ Pa.s

ρ_{air} @50psi and 20°C ~ 5 kg/m³
μ_{air} @50psi and 20°C ~ 1.83 x 10⁻⁵ Pa.s

CO2 bolus

Volume of the bolus at 50psi – independent of the case:

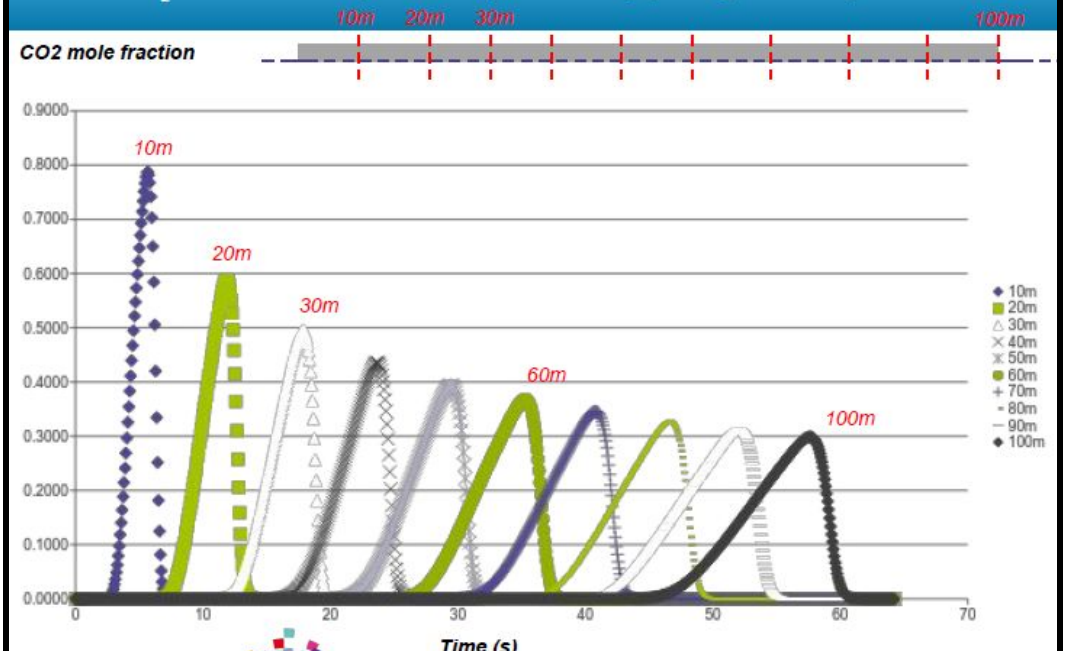
V_1 =1L of CO_2 at ambient conditions. **V_2 at 50psi?**
Ideal gas law → $p_1.V_1 = p_2.V_2 \rightarrow \underline{V_2} = p_1.V_1 / p_2 = 101325 \times 1.10^{-3} / 344738 \underline{= 2.9.10^{-4}\ m^3}$

Length of the bolus – dependant of the case :

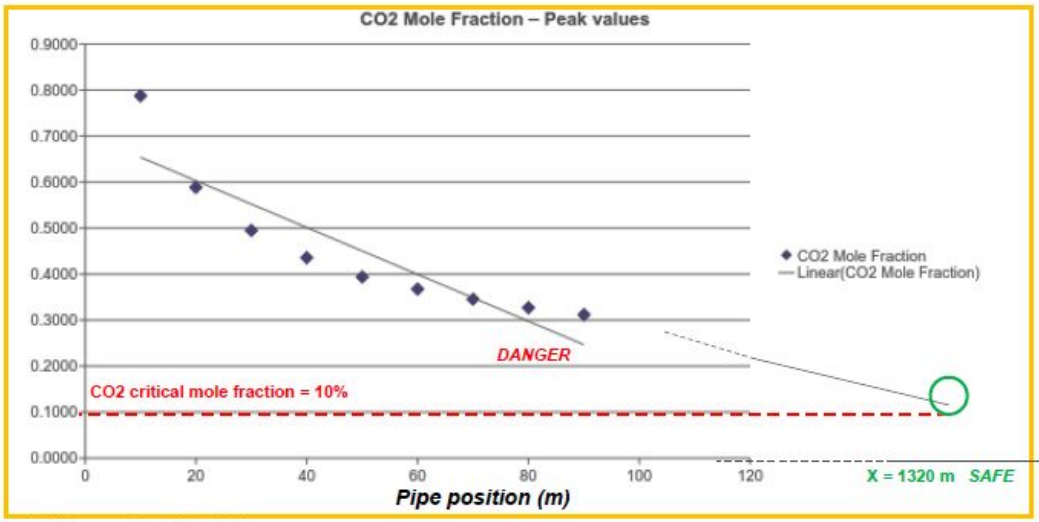
→ $\underline{L_{2^{nd}}} = V_1/A_1 = 2.9.10^{-4} / 2.03 \times 10^{-3} \underline{= 0.14\ m}$ and $\underline{L_{1/2^{nd}}} = V_2/A_2 = 2.9.10^{-4} / 1.27 \times 10^{-4} \underline{= 2.28\ m}$

Initially, the bolus is located between $X = L_{start}$ and $X = L_{start} + L$.

Case 3: CO_2 Mole Fraction captured every 10 meters (pipe length is 100m)



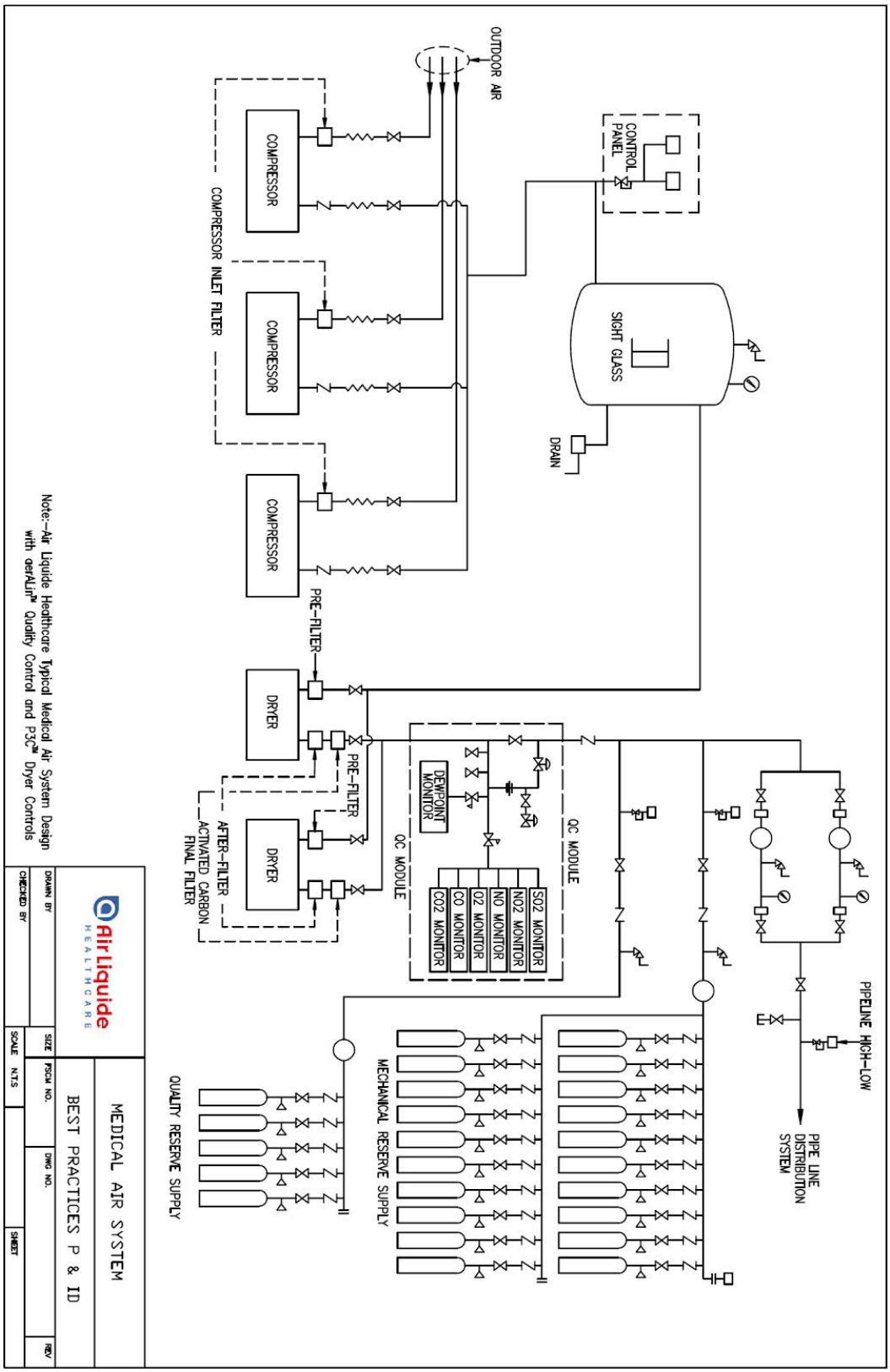
Case 3



Solving $y_{int} = 0.1 \rightarrow$ **X = 1320m**

Two main differences with the previous case (Case 2) are observed:
- Due to the lower velocity, the turbulence induced is lower (smaller Reynolds number) , the CO_2 bolus does not mix as quickly → the peak value decreases slowly and it takes longer to reach the safe level (1320m vs 270m).
- The maximum reached at the 1st peak is lower than Case 2 (0.78 vs 0.93): the bolus reaches the first 10m after 8s (vs 3s) so it has more time to diffuse. Similarly, the last peak is reached after 55s (vs 17s).

APPENDIX C - Medical Air System Best Practices P & ID



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