Technical Informationen

Technologie Institut Medizin GmbH (TIM)

Clean Air

Passive Waste Gas Disposal System using VAC

Prof. Ing. Thomas P. Kriesmer

Version A.00

ORS Clean-AIR_VAC_background_E_A-00

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2 Disclaimer

Important. This document will not release the user from following strictly local legal requirements or hospital's hygienic requirements.

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3 About this document

Distributing the ORS Clean Air seems quite easy. Beside users, hygienic specialists and doctors are easy to convince of the advantages of the product.

But the introduction at hospital biomed's may raise interesting questions to the theme "Disposal of patient's waste gas using the vacuum system of a hospital".

One critical issue in the argumentation is to make clear the difference between

- a traditional ANESTHETIC GAS SCAVENING SYSTEM (AGSS)

and

- a disposal of patient gas (ORS Clean AIR) using the VACUUM system

with a regulatory view to the standards ISO 8835-3 (6) , ISO 7396-2 (5) or ISO 7396-1 (4).

This document contains information derived from dialogs with customers and end users. But this document may not cover all the questions raised. Also be aware that for different questions there are similar answers.

4 Introduction

Passive Waste Gas Disposal with the Open Reservoir System „Clean AIR“.

This document describes the Open Reservoir System „Clean-Air“ with the following technical aspects:

- Nature of service
- Principal of operation
- Dilution calculation
- Regulatory & Standards
- Questions & Answers

5 Nature of Service

What is the problem with „patient gas“?

The expiratory or exhaled patient gas from application devices may contain "air" as well as other ingredients. A discharge of the expiratory gas into the room air of a patient room can lead to a contamination of

- The patient itself
- Other patients in the same room
- Medical staff
- Nursing staff
- Service & other hospital staff
- visiting relatives

with

- gases of patient’s natural metabolism (Aceton, Methan, CO_2, etc.)
- gases of patient‘s pharmaceutical metabolism (metabolites of Propofol etc.)
- therapeutic gases (Nitrogen monoxide, NO)
- reactive therapeutic gases (Nitrogen oxides, NO_x)
- gaseous anesthetic gases (Nitrous oxid - N_20, Xenon - Xe)
- volatile anesthetic gases (VA, e.g. Isoflurane, Sevoflurane, Desfluran)
- respiratory germs, air born (application without bacterial filter, active humidification etc.)
- high risk air born respiratory germs (MRSA, MRA etc.).

This could take place in

- Intensive care units (ICU)
- Post anesthesia care units (PACU)
- Intermediate care units (IMC)
- Emergency units (ER)

But also in

- Delivery rooms
- Outpatient and sectio operating rooms

The named groups of people can experience contamination that can either cause illness or lead to undesirable side effects. Increasing attention to this topic can be seen among the groups of people. Also in the legal sense of a maximum work concentration expiratory, contaminated patient gas should be derived in a controlled manner in terms of disposal. The open reservoir system "Clean-Air" uses the vacuum system of a medical facility for disposal.

Schematic overview

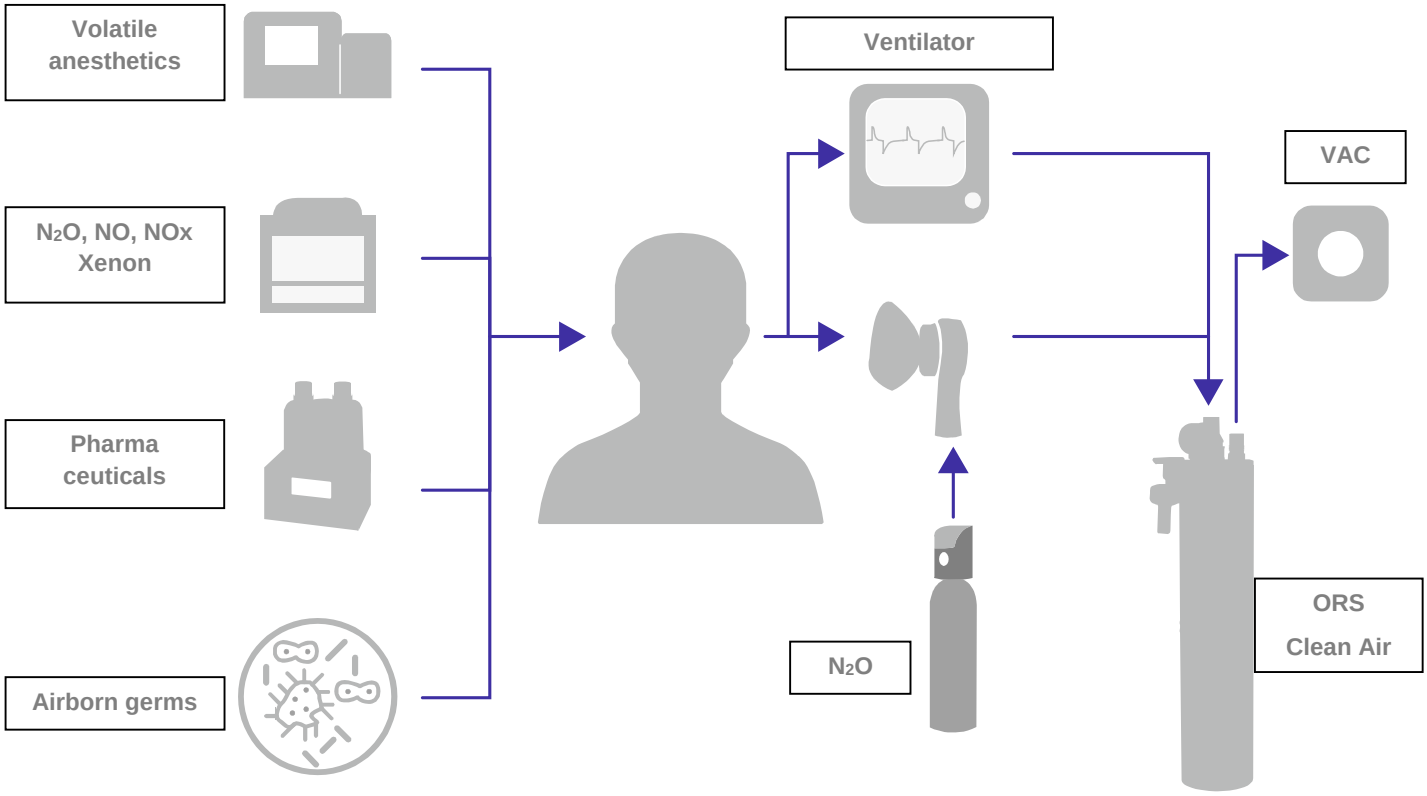


Fig. 1,schematic overview of the disposal concept

Exemplary application of an ORS Clean Air in the intensive care unit for the disposal of therapeutic gases (here anesthetic gases for inhalation sedation) at the outlet of an application device (here intensive care ventilator)

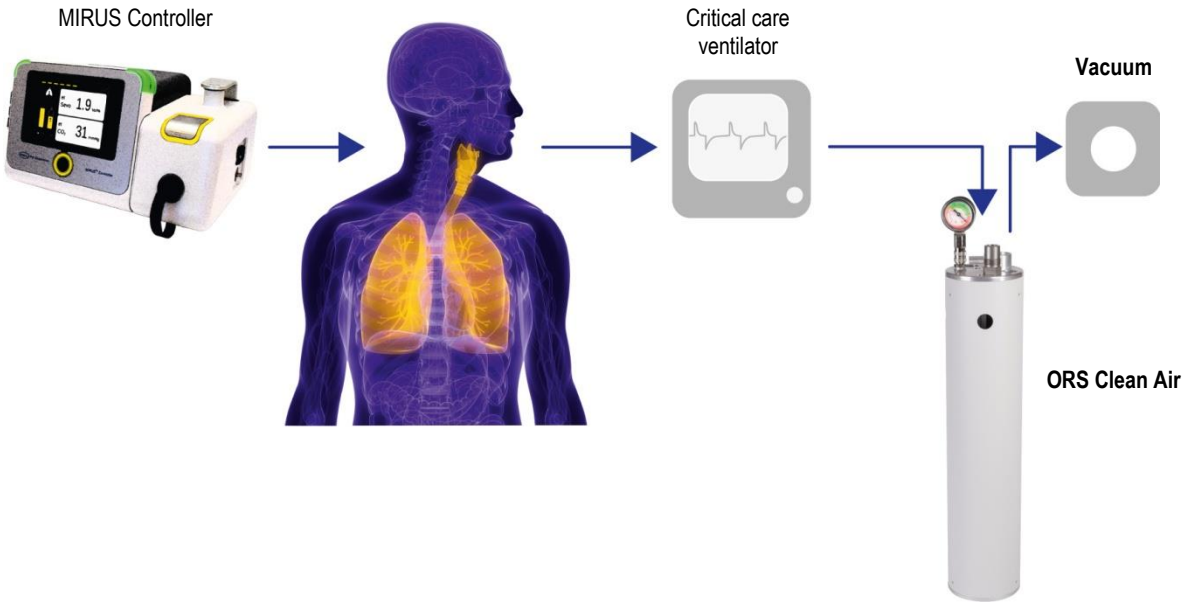


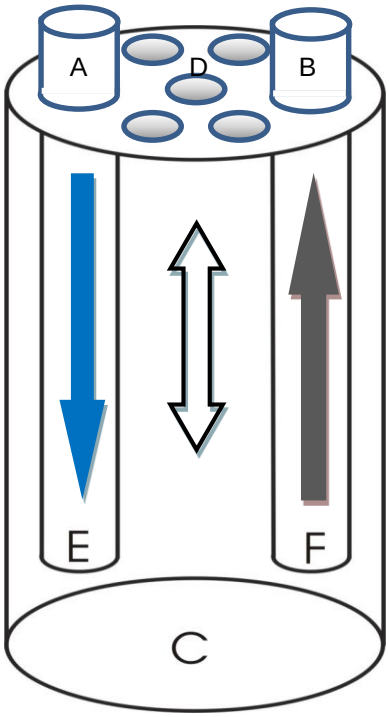
Fig. 2, exemplary application of an ORS Clean Air

6 Principal of operation

The ORS Clean Air is a passive patient gas disposal system for operation at the vacuum system of a medical facility.

The purpose of an ORS Clean Air is to collect and dispose of patient gases from the expiratory outlet of an application device (e.g. an intensive care ventilator) in order to minimize the exposure of the environment and personnel to these patient gases.

At the same time, the ORS Clean Air prevents the expiratory side of the application device (e.g. anesthesia device, ventilator, etc.) from being impaired by the vacuum suction and thus serves to protect the patient.



Schematically, an "Open Reservoir Scavenger" (ORS), like the "Clean AIR", consists of a reservoir that is open at the top and two tubes that enter the reservoir and serve as inlet and outlet.

A: Connection to the expiratory side of the Application device (AG)

B: Connection to the vacuum system VAC

C: Reservoir

D: Openness to atmosphere

E: Inlet into the reservoir

F: Outlet into the vacuum system

= contaminated patient gas

= clean ambient air

= exhausted gas mixture

Fig. 3, Operating principle of the Open Reservoir Scavengers

There are two tubes in the reservoir:

- A supply that feeds the patient gas to be disposed of from the expiratory side of the applicator into the reservoir (E).
- An exhaust air at which the patient gas to be disposed of is sucked into the vacuum line (F).

At the inlet connection (A), the applicator introduces patient gas into the reservoir discontinuously (pulsed), e.g. due to the set respiratory frequency and tidal volume. At the same time, the vacuum system generates a constant volume flow out of the reservoir at the outlet (F). The suction volume flow through the outlet is set so that its minute volume is greater than the patient's minute volume. This ensures that in principle more is aspirated than the patient gas introduced by the application device.

Although on average the volume flow of the suction is greater than that of the inlet, the pulsed input of the patient gas causes higher gas flows for a short time. For this reason, the reservoir is open to the atmosphere through openings (D) in the lid and ensures continuous equalization of the pressure with the environment.

During the expiration phase clean room air can escape and during the inspiration phase clean room air from the environment is drawn back into the reservoir.

The container into which the tubes project forms the reservoir. The volume of this is designed in such a way that the patient gas introduced displaces the clean gas volume above the level of the inlet and outlet upwards, but does not escape through the openings in the lid itself. There is always a defined buffer of uncontaminated air below the openings (D) against atmosphere. During the inspiration phase, when no patient gas is introduced into the reservoir, the vacuum line draws clean room air through the openings and thus again forms the necessary buffer for the next expiration.

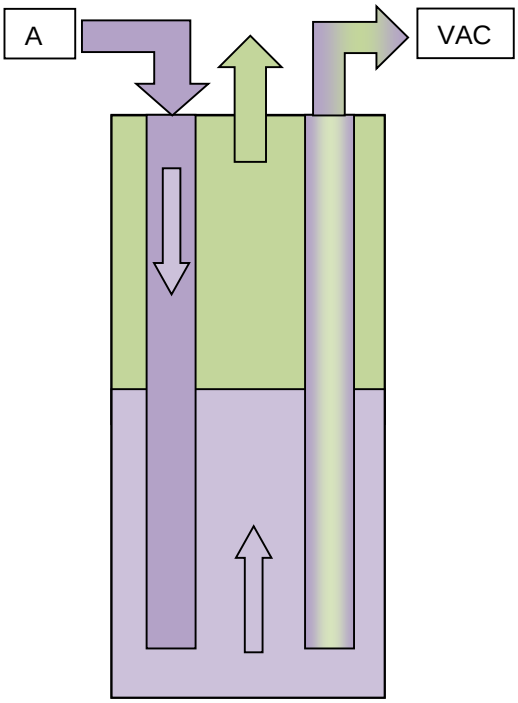


Fig. 4, Expiration phase of the AG

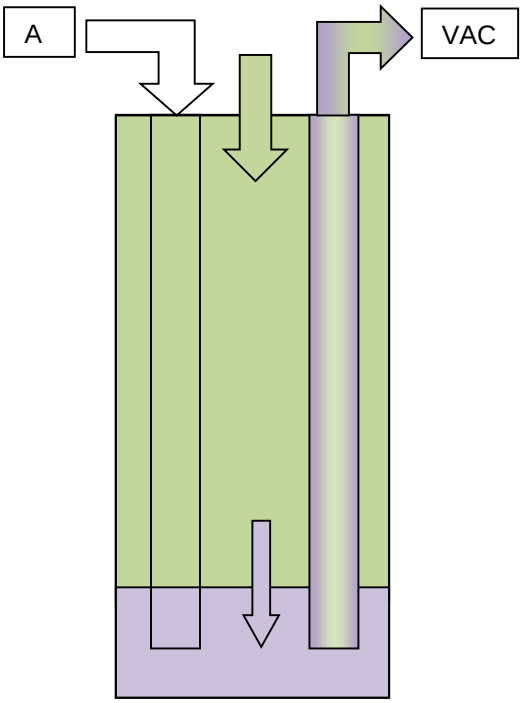


Fig. 5, Inspiration phase of the AG

= Exp. Gas = Ambient air = Gas in VAC

Important to know:

- an "Open Reservoir Scavenger" is maintenance-free, i.e. it does not need to be emptied or disposed of after a certain period of operation, like an anaesthetic gas filter.
- an "Open Reservoir Scavenger" does not contain any filter materials to be cleaned or changed.

7 Dilution calculations

7.1 Approach

In the following dilution calculation, we consider three aspects in total:

- the typical and maximum concentration of a gas to be handled at the outlet of an applicator.

- the system-related dilution in ORS Clean AIR.

- the system-related dilution in the vacuum distribution network.

This is calculated in the following chapters for typical patient gas disposals as an example.

7.2 Gas concentrations at the outlet of the application device

The typical and maximum concentrations of the therapeutic and metabolic gases to be handled at the outlet of the application device are listed below:

Gas type	Typical concentration	Maximum concentration	Comment
Therapy gases			
Isoflurane	0.6 Vol% (MAC 0.5)	1.8 Vol% (MAC 1.5)	ICU, MAC 1.5 temporarily
Sevoflurane	1.1 Vol% (MAC 0.5)	2.0 Vol% (MAC 1.5)	ICU, MAC 1.5 kurzzeitig
Desflurane	3.0 Vol% (MAC 0.5)	6.0 Vol% (MAC 1.5)	ICU, MAC 1.5 temporarily
N_2O	50 Vol%	50 Vol%	Livopan premix 50%N_2O/50%O_2
NO	10 ppm = 0.001 Vol%	60 ppm = 0.006 Vol%	ICU, 60ppm temporarily
Xenon	35 Vol% (MAC 0.5)	70 Vol% (MAC 1.0)	ICU, MAC 1.0 temporarily
O_2	25 Vol% (FeO_2)	95 Vol% (FeO_2)	ICU, FiO_2= 30 or 100 Vol% temporarily
N2	66 Vol%	79 Vol%	Uncritical
Metabolic gases			
CO_2	5.0 Vol%	10.0 Vol%	Uncritical
CH_4	10 ppm = 0.001 Vol%	50 ppm = 0.005 Vol%	Methane
C_3H_6O	10 ppm = 0.001 Vol%	50 ppm = 0.005 Vol%	Acetone

Tab.1, Gas concentrations at the outlet of the application device

7.3 Gas concentrations at the ORS Clean Air outlet

Since the ORS Clean Air has a fixed vacuum suction volume flow of 25 l/min and the patient volume flows to be disposed of at the outlet of the applicator vary between 3 and 15 l/min for adults, the suction volume flow is always higher than the input volume flow. The ORS Clean Air therefore sucks the difference between the suction volume flow and the input volume flow from the ambient air into the reservoir through the reservoir openings in the upper part of the ORS Clean Air and thus dilutes the input volume flow before it is passed on to the vacuum extraction point.

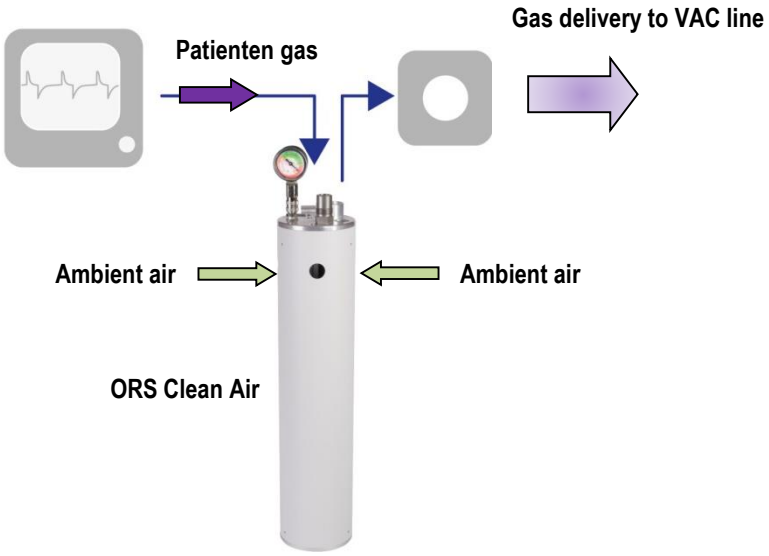


Fig. 6, Dilution in ORS Clean Air before entering the vacuum extraction point

Note: The O_2 concentration of the ambient air was assumed to be 20.8 Vol%.

In the following, the concentrations are calculated based on the following assumptions:

- A: typical gas concentration and typical patient volume flow of an adult with 7.5 l/min minute volume This is the situation majority of all use cases will be encountered

- B: maximum gas concentration and maximum patient flow rate of an adult with 15 L/min (worst case) minute volume (MV) (at FiO_2 = 100% for ARDS patients only 10 L/min). In case B it is to be assumed that this case will only be temporary.

Gas type	A: Typical situation	B: Maximum situation	Comment
Therapy gases			
Isoflurane	0.18 Vol% (MAC 0.5)	1.08 Vol% (MAC 1.5)	ICU, MAC 1.5 temporarily
Sevoflurane	0.33 Vol% (MAC 0.5)	1.20 Vol% (MAC 1.5)	ICU, MAC 1.5 temporarily
Desflurane	0.90 Vol% (MAC 0.5)	5.40 Vol% (MAC 1.5)	ICU, MAC 1.5 temporarily
N_2O	15 Vol%	30 Vol%	Livopan Premix 50%N_2O/50%O_2
NO	3 ppm = 0.0003 Vol%	36 ppm = 0.0036 Vol%	ICU, 60ppm temporarily
Xenon	10.50 Vol% (MAC 0.5)	42.00 Vol% (MAC 1.0)	ICU, MAC 1.0 temporarily
O_2	22.48 Vol%	48.88 Vol%	ICU, FiO_2= 30 or 100 Vol% temporarily
N2	76.30 Vol%	42.00 Vol%	Uncritical
Metabolic gases			
CO_2	1.50 Vol%	5.40 Vol%	Uncritical
CH_4	3 ppm = 0.0003 Vol%	30 ppm = 0.003 Vol%	Methane
C_3H_6O	3 ppm = 0.0003 Vol%	30 ppm = 0.003 Vol%	Actone

Tab.2, Gas concentrations at the outlet of the ORS Clean Air

7.4 Gas concentrations at the outlet of the VAC system

In the following the typical construction of a vacuum system in hospitals according to the standard DIN EN ISO 7396-1 is shown:

1: VAC tapping point
2: Flexible connecting piece
3: Shut-off valve for maintenance
4: Riser shut-off valve
5: Branch shut-off valve
6: Switch for pressure alarm
7: Range shut-off valve
W: Pipeline for vacuum

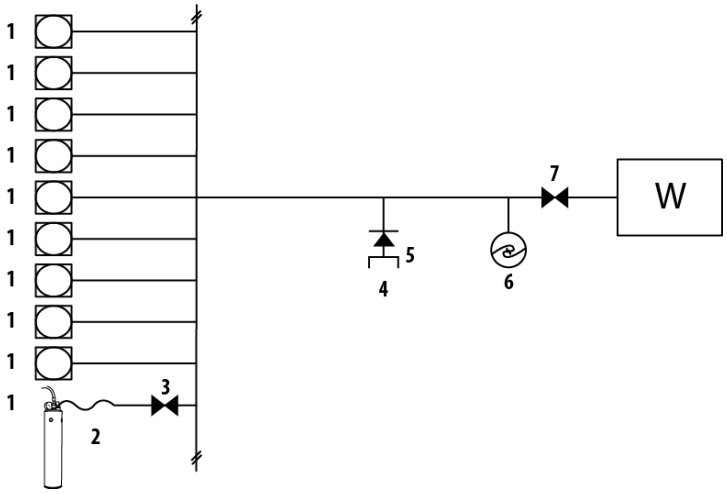


Fig. 7, Vacuum distribution system

W: Pipeline for vacuum
8: Branch shut-off valve
9: Switch for pressure alarm
10: Shut-off valve riser pipe
11: Main shut-off valve
12: Source shut-off valve
13: Outlet
S: Water trap
T: Bacteria filter
U: Storage tank
V: Supply source vacuum

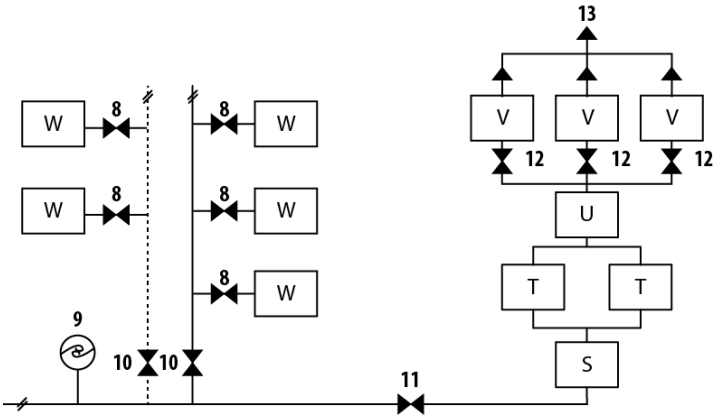


Fig. 8, Vacuum pumping system

In the following calculation we assume, as an example, that the vacuum system corresponds to the following typical hospital constellation (7):

- VAC tapping point volume flow = 35 l/min
- Structure of the VAC network
  - Intensive Care Unit
    - 20 VAC tapping points
    - Simultaneity factor 75% with Ø 10 l/min
    - System volume flow = 150 l/min
  - Operating Wing
    - 20 VAC tapping points
    - Simultaneity factor 100% with Ø 10 l/min
    - System volume flow = 200 l/min
  - Delivery room
    - 10 VAC tapping points
    - Simultaneity factor 50% with Ø 10 l/min
    - System volume flow = 50 l/min
  - General care
    - 200 VAC tapping points
    - Simultaneity factor 15% with Ø 5 l/min
    - System volume flow = 150 l/min
  - Real System volume flow = 550 l/min
- 1 active ORS Clean Air with tapping point volume flow = 25 l/min

The following table shows the dilutions of the gases introduced via the ORS Clean Air in the dilution by the VAC system for the scenarios:

- A: typical gas concentration and typical patient volume flow of an adult with 7.5 l/min. That's the situation will encounter use cases.

- B: maximum gas concentration and maximum patient flow rate of an adult with 15 L/min (worst case) minute volume (MV) (with FiO_2 = 100% for ARDS patients only 10 L/min). In case B it is to be assumed that this case will only be temporary.

On the basis of the exemplary vacuum system described above calculated with the parameters:

- real VAC system volume flow = 550 l/min

- Number of active ORS Clean Air = 1 with VAC Flow = 25 l/min

Gas type	A: Typical situation	B: Maximum situation	Comment
Therapy gases			
Isoflurane	0.0078 Vol%	0.0470 Vol%	ICU, MAC 1.5 temporarily
Sevoflurane	0.0143 Vol%	0.0861 Vol%	ICU, MAC 1.5 temporarily
Desflurane	0.0391 Vol%	0.2348 Vol%	ICU, MAC 1.5 temporarily
N_2O	0.6522 Vol%	1.3043 Vol%	Livopan Premix 50%N_2O/50%O_2
NO	0.0000 Vol%	0.0002 Vol%	ICU, 60ppm temporarily
Xenon	0.4565 Vol%	1.8261 Vol%	ICU, MAC 1.0 temporarily
O_2	20.8730 Vol%	22.0210 Vol%	ICU, FiO_2= 30 or 100 Vol% temporarily
N2	79.0618 Vol%	77.7442 Vol%	Uncritical
Metabolic gases			
CO_2	0.0652 Vol%	0.2348 Vol%	Uncritical
CH_4	0.0000 Vol%	0.0001 Vol%	Methane
C_3H_6O	0.0000 Vol%	0.0001 Vol%	Actone

Tab.3, Gas concentrations at the outlet of the vacuum system

You can see that all concentration is uncritical.

Special view on O_2.
With the same constellation, but a number of active ORS Clean Air = 10
with VAC Flow = 25 L/min, the result for O_2:

Gas type	A: Typical situation	B: Maximum situation	Comment
Therapy gases			
O_2	21.3250 Vol%	29.5750 Vol%	ICU, FiO_2= 30 or 100 Vol% temporarily

Note: The O_2 concentration of the ambient air was assumed to be 20.8 Vol%.

8 Questions & Answers (Q&A)

8.1 General questions & answers about ORS

What does "ORS" stand for?

ORS stands for **O**pen **R**eservoir **S**cavenger. This refers to an open reservoir system through which no contained patient gas can flow into the surrounding air but always surrounding air can flow into the reservoir.

Which ORS Clean Air versions are available?

Currently there are 3 versions of the ORS Clean Air.

ORS CA-01 Suitable for many ventilators (e.g. DRÄGER; PB, GE)

ORS CA-02 Suitable for MAQUET Servo-i, Servo-U etc.

ORS CA-04 Suitable for Hamilton S1 etc.

ORS Clean Air and AGSS or NGA

The ORS Clean Air must not be connected to an NGA.

Obligation to instruct ORS Clean Air

The ORS Clean Air is a class 1 medical device, and there is no obligation for instruction in the areas where the Medical Devices Act (MPG) applies - Germany and Austria. In other countries, the respective country-specific regulations may differ and must be checked accordingly by the distributor.

Cleaning and disinfection

The ORS Clean Air can be wiped clean and wipe disinfected with alcohol-based detergents and disinfectants. A soft, damp cloth can also be used for easy cleaning without disinfection.

How big and how heavy is the Clean Air

The ORS Clean Air has a size of approximately 100 X 490 mm (diameter x height). The weight is approx. 2.2 kg.

How big and how heavy is the packaging of the Clean Air

The ORS Clean Air comes in a transport carton with the dimensions (WxDxH) (cm): approx. 58.5 x 22 x 20.5 cm. The total weight is approx. 3 kg.

How is the ORS Clean Air attached to the unit?

The ORS Clean Air has a standard rail claw. This allows the ORS Clean Air to be mounted near the unit, on the unit's carriage or on the unit itself.

What advantages does the ORS Clean Air offer?

For the ORS Clean Air applies:

- Easy mounting with standard rail adapters
- Space-saving, vertically oriented design
- Quiet
- Available for almost all current intensive care ventilators
- Suitable ventilator connections available
- Can be connected to various applications that supply expiratory patient gas
- Country specific vacuum connection hoses available
- High quality metal components. No plastic
- There are no filters to change
- There are no disposable parts
- No consumable material is required
- No power connection is required
- Driven by existing vacuum system

8.2 Technical Questions & Answers

In the following, we discuss technical questions that may arise when feeding contaminated patient gases (anaesthetic and therapeutic gases) into the vacuum system.

Can the gas to be disposed of damage the vacuum pumps?

We must first distinguish between two basic types of vacuum pumps:

- dry compressing vacuum pumps, i.e. pumps where no lubricant comes into contact with the medium to be pumped and
- oil-sealed vacuum pumps, i.e. pumps in which lubricant is used to seal and lubricate the pump and comes into contact with the medium to be pumped.

and into the different groups of media to be pumped:

- volatile anaesthetics, halogenated hydrocarbons which have lipophilic solvent properties
- potentially harmful gases, such as O_2, N_2O, NO, acetone, methane (I will deal with the question of potentially oxidizing gases below)
- harmless gases such as N_2, CO_2, xenon, argon

Since the vacuum system according to DIN EN ISO 7396-1 must also be able to dispose of medical gas used in the supply system (Def. § 3.28) as well as metabolic gases typical for the patient, this actually answers the question already, namely no.

Nevertheless, here is a brief technical consideration of halogenated hydrocarbons (anaesthetic gases):

Dry-compressing vacuum pumps are hardly affected by lipophilic solvents such as anaesthetic gases even in high concentrations.

Oil-sealed vacuum pumps require separate consideration due to the lipophilic solvent properties of halogenated hydrocarbons (anaesthetic gases). In oil-sealed or oil-lubricated vacuum pumps, halogenated hydrocarbons can dissolve and accumulate in the pump operating medium oil. This could theoretically lead to a reduction in the lubricity of the operating medium over time. On the one hand, these very small quantities of volatile anaesthetics (see dilution calculation) do not pose a risk to the vacuum system. On the other hand, the risk of long-term accumulation is greatly reduced because the boiling points of the anaesthetic gases (Desflurane = 22°C, Isoflurane = 48°C, Sevoflurane = 58°C) are significantly lower than the normal oil operating temperature (> 70°C). This means that the anaesthetic gases cannot accumulate significantly in the operating medium oil, but instead evaporate again and are evacuated via the pump ventilation.

Regular maintenance with oil change according to the pump manufacturer's specifications should nevertheless be observed. Furthermore, separation filters in the infrastructure should be checked or replaced regularly in accordance with the manufacturer's specifications.

For other therapeutic gases, dilution calculations show that the concentrations entering the vacuum system are already so strongly diluted that, when e.g. NO is introduced and oxidized to NO_2, nitrous acid (HNO_2) could theoretically be formed, but the dilution (see dilution calculation) cannot produce concentrations that could cause serious damage to the infrastructure and the vacuum pumps themselves.

What about the output of the vacuum system?

According to standard EN ISO 7396-1 (Piping systems for medical gases, Part 1: Piping systems for compressed medical gases and vacuum), the outlets of the vacuum pumps must be led outside.

If this dedicated gas routing of the pump outlets to the outside is not the case in an installation, active ventilation of the pump room is mandatory. In both cases, there can therefore be no accumulation of harmful gases (anaesthetic or therapy gases) in the "outlet" area of the vacuum pumps.

Can introduced patient gas escape from another withdrawal point?

According to standard EN ISO 7396-1 (Piping systems for medical gases, Part 1: Piping systems for compressed medical gases and vacuum), the vacuum sources (pumps) must be designed as triple redundancy to prevent a drop in vacuum - vacuum. Due to the resulting permanent vacuum on the vacuum line, there is only one direction of flow for gases, namely from the open tapping point to the vacuum source.

Gas flow from one tapping point to another is therefore impossible.

This risk can only occur if an ACTIVE system that feeds in larger quantities of gas, such as an ACTIVE anaesthetic gas transport system, is connected to an extraction point of the vacuum system. This combination is therefore rightly prohibited. However, as shown above, **the "Open Reservoir Scavenger" is a PASSIVE system and therefore cannot cause this risk.**

The vacuum unit is a medical device of class II b. Is the disposal of patient, anaesthetic or therapy gases permitted at all?

The purpose of the vacuum system is the disposal of liquids, gases and secretions. The typical application of the vacuum system in a hospital includes, according to the system manufacturer information, patient gas disposal such as "bronchial suction in anesthesia and intensive care" (3). It is therefore permissible to dispose of patient gases from other sources, such as expired breathing air, through the same system.

Why may vacuum systems according to No. 5.7.12 DIN EN ISO 7396-1 not be used as drive units for anaesthetic gas transfer systems?

The term "Anesthesia Gas Scavenging System" (AGSS) is clearly defined in DIN EN ISO 8835-3 (6) as an ACTIVE system (Introduction: "This part of ISO 8835 is intended to ensure that an active AGSS for.... ". Active systems generally must not be coupled with a vacuum system in accordance with DIN EN ISO 7396-1, since as an active system they would compromise the basic function of the vacuum system. For this reason, EN ISO 7396-1 chapter 5.7.12 points out that for AGSS, EN ISO 7396-2 applies, which as a conduction system can handle ACTIVE systems (like an AGSS).

However, vacuum systems according to EN ISO 7396-1 may very well be used as drive units for gas disposal by means of passive systems (e.g. bronchus suction). Functionally nothing else is an ORS Clean Air.

Why are there two different parts (1 and 2) of DIN EN ISO 7396 for pipe systems?

Because vacuum systems according to DIN EN ISO 7391-1 are systems which only allow PASSIVE systems for connection, whereas pipe systems according to EN ISO 7396-2 only allow

ACTIVE systems for connection. This results basically from the requirement 5.2 of EN ISO 7496-2 "The drive system must be one of the following...,".

Shouldn't the guidelines in Appendix A DIN EN ISO 7396-2 apply to all vacuum pumps? Why is this not mentioned in DIN EN ISO 7396-1?

The guidelines from Appendix A (A1 - A7) of DIN EN ISO 7396-2 are actually not listed explicitly in 7496-1, but are usually already taken into account in the normal planning process.

Is there a safety risk with vacuum systems that comply with DIN EN ISO 7396-1 with regard to oxidizing gases such as oxygen, nitrous oxide or volatile anaesthetics?

No, because the dilution of the total gas flow (see dilution calculation under 5.4), which reaches the vacuum pumps, significantly reduces the concentrations of oxygen, nitrous oxide and anaesthetic gases by mixing in ambient air that is sucked in.

In other words: When mixing the total gas flow that reaches the vacuum pumps, the concentrations of oxygen, nitrous oxide and anaesthetic gases are significantly reduced by the addition of drawn-in ambient air. The ORS system supports this process even further, as the flow aspirated into the vacuum system is significantly greater than the patient expiratory flow to be disposed of. This ensures that the patient gas concentration of oxygen, nitrous oxide and anaesthetic gases at the interface of the ORS to the vacuum system is already lowered by adding additionally sucked in ambient air.

Furthermore, volatile anaesthetics (Isoflurane, Sevoflurane, Desflurane) are not considered to be oxidizing in clinical concentrations. (1), (2).

Mention of ISO 8835-3 as the applicable standard in the instructions for use. Why?

Note: Confusion arises here in the market for medical technology when it is understood that ORS Clean Air is a passive product, but a standard for active anaesthetic gas delivery systems is mentioned in the instructions for use as the applicable standard.

ISO 8835-3 (Inhalation Anesthesia Systems - Part 3: Active Anaesthetic Gas Delivery and Delivery Systems) for active anaesthetic gas delivery systems has as its background both the protection of medical personnel from anaesthetic gases (workplace exposure) and the protection of the patient from ventilator malfunction, e.g. from excessive flows and pressures.

ISO 8835-3 also specifies requirements for the transport and intake of gases in ACTIVE anaesthetic gas delivery systems where the drive is integrated in the system itself.

This standard therefore normally describes the requirements for ACTIVE gas disposal systems. As a result, we cannot base the approval of the ORS Clean Air directly on it.

However, since there are no explicit standards for passive gas disposal systems, we have, for safety reasons, oriented ourselves to the following chapters of the 8853-3_(6) standard, which serve to protect the patient in the sense of not influencing the connected ventilator:

- 4.1 Materials

- 5.0 Protection of the patient and the environment

- 5.1.1 Pressure

- 5.1.2 Induced flow

- 5.1.3 Negative pressure

- 5.1.4 Gas leakage to atmosphere

- 5.1.5 Leakage

- 5.2.1 Conditions of the first error - pressure

- 5.2.2 Conditions of the first fault - induced flow

- 5.2.3 Conditions of the first fault - negative pressure

- 6.0 Connectors

- 7.0 Input from forwarding systems

- 8.4 Optical display

The ORS Clean Air complies with all these conditions of the above standard.

Are there country-specific vacuum connections on ORS Clean Air?

No. The ORS Clean Air is equipped with a so-called NIST connector. Any VAC hose lines can be connected to this connector with vacuum system connectors equipped with country-specific connections. Among others (but not exclusively):

- MEDAP
- DIN
- SS 87 524 30 (AGA)
- BS 5682 (BOC)
- NF S 90-116 (Air Liquide)
- UNI 9507

Country-specific VAC hoses with corresponding wall plugs are available from the manufacturer of the ORS Clean Air. But also in regular trade.

Which maintenance work according to manufacturer's specifications must be carried out regularly? And who can carry them out?

Maintenance work must be carried out every 12 months according to the manufacturer's specifications. This can be carried out by any expert. If the manometer is damaged, it can be easily replaced by a plug-in coupling. The spare part is available from the manufacturer of the ORS Clean Air.

How often must a safety inspection be carried out? And who can carry it out?

There is no need for a dedicated safety check. The user's inspection of the ORS by the user before and during use is documented in the instruction manual. However, a functional check is required as part of maintenance (every 12 months).

Which disposable parts must be exchanged when/how?

NO disposable parts have to be exchanged.

What needs to be calibrated on ORS Clean Air and when?

NO elements have to be calibrated. The adjustment of the suction flow is ensured by a fixed, unchangeable bore. The functionality of the Clean Air is checked during the incoming goods inspection and during the functional test in the outgoing goods department.

How can I check whether the ORS Clean Air is working correctly?

The ORS Clean Air has a pressure gauge with a coloured display. If the ORS Clean Air is working correctly, the needle of the manometer is in the proverbial "green" range. In addition, a quiet suction noise can also be heard. If the needle is not in the "green" range or there is no quiet suction noise, the ORS Clean Air must not be operated. The ORS Clean Air or the connection to the vacuum system must be checked during service.

Who is the safety officer for the product ORS Clean Air?

For the TIM GmbH (manufacturer): Dipl. Ing. Karl Cornelius-Lorenz.

Email: sicherheitsbeauftragter@tim-gmbh.de, Tel.: 0261 899 689 00

Is there a quick reference guide?

Yes. There is a so-called step-by-step guide.

This does not replace the official ORS Clean Air user manual.

Can I connect the Clean Air to a ventilator just like that?

Yes, if the application or ventilation device is listed on the compatibility list issued by the manufacturer of the ORS Clean Air.

Only then can a compatibility check carried out in advance by the manufacturer of the ORS Clean Air ensure that

- there is no risk for users and patients

- the performance, safety and intended use of the application device (e.g. a ventilator) is not restricted or compromised when used with the ORS Clean Air

The manufacturer of ORS Clean Air issues a so-called Article 12 compatibility declaration in accordance with the Medical Device Directive (MDD) for such tested combinations of ORS Clean Air with an application device.

9 Summary

In this technical information we have shown that

- Patients contaminate their environment through drugs, therapeutic gases, germs, etc.

- this expiratory patient gas must be systematically and completely drained.

- a discharge of this expiratory patient gas into an existing vacuum system is not subject to regulatory limits.

- a discharge of this expiratory patient gas does not lead to technical problems with the vacuum system.

Should there be any further questions, the publisher would be pleased to receive your feedback:

info@tim-gmbh.de

10 List of figures

11 Tables

12 Abbreviations & Glossary

AGSS	Anesthesia - Gas – Scavenging - System
APSF	Anesthesia Patient Safety Foundation
AG	Applicator
CC Ventilator	Critical Care Ventilator, Intensive Care Ventilator
ICU	Intensive Care Unit. Intensive Therapy Ward
IMC	Intermediate Care Unit
ORS	Open Reservoir Scavenger
OP	Operations Room
PACU	Post Anesthesia Care Unit (recovery room)
WADG	Waste Anesthesia Gas Disposal
VA	Volatile anesthetic gas, anesthetic gas
VAC	Vacuum system

Application device	Device for gas supply and/or discharge to a patient, such as anesthesia device, CC ventilator etc.

13 References

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6. DIN EN ISO 8835-3, Inhalational anesthesia systems, Part 3: Transfer and Receptacle systems of active an aesthetic gas delivery systems (ISO 8835-3:2007 + Amd.1:2010))

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