Instructions for use

CLEAN AIR®

Version 6.n

Variant CA-01
Variant CA-02
Variant CA-04

Trademarks

 and TIM™ is a trademark of Technologie Institut Medizin GmbH (TIM).

 CLEAN **AIR**® is a trademark of Technologie Institut Medizin GmbH (TIM).

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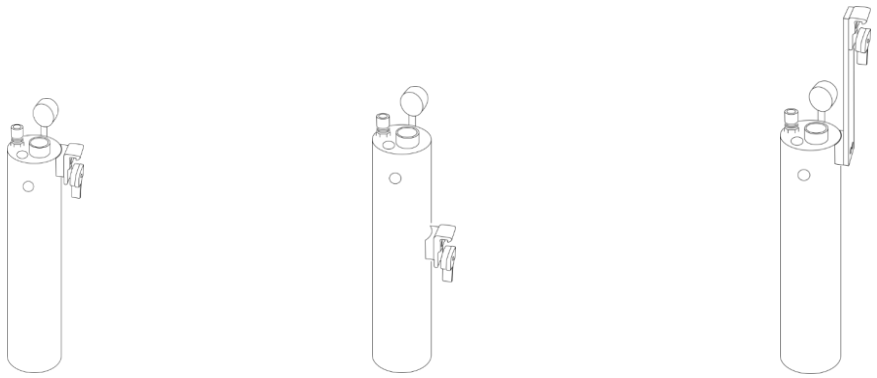
1 Introduction

1.1 Intended use

Scavenging and removal of waste gases from application devices and waste gas delivery devices.

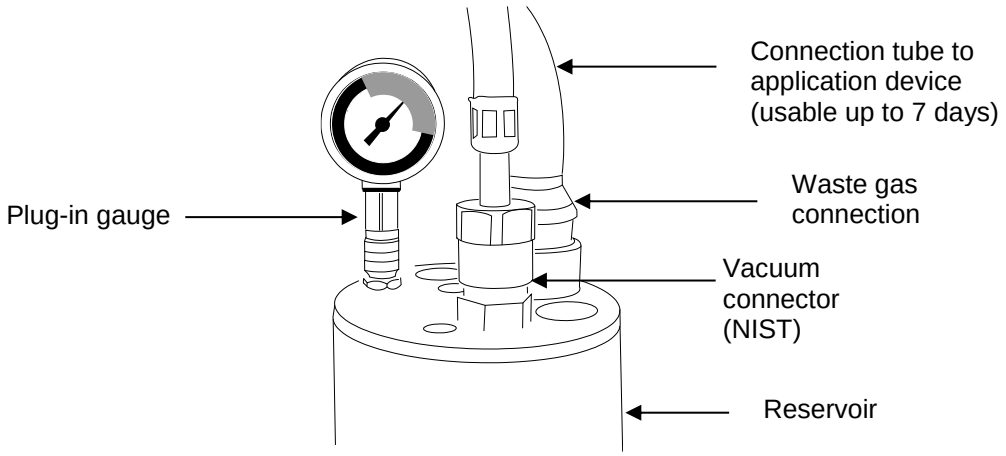
1.2 Scheme variants

CA-01 **CA-02** **CA-04**



In the further course of these instructions for use, the Clean Air CA-01 is illustrated for sake of simplification. The attachment to the holding bar of an application device is the same for all three Clean Air variants.

1.3 Terminology



1.4 Areas of use

The system is intended for stationary use in hospitals and other medically used rooms with an air exchange rate > 1/h.

1.5 Supply

The Clean Air requires medical vacuum as external gas supply. No electrical supply is required.

1.6 Principle of operation

The Clean Air is an Open Reservoir Scavenger (ORS). It is a **passive** device that is allowed to be connected to a hospital's vacuum system according to EN ISO 7396-1 (Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum).
An open reservoir scavenger consists of a reservoir with openings to atmosphere and two open pipes leading into the reservoir, being used as inlet and outlet pipes. At the inlet connection the application device's expiratory waste gas is discontinuously injected into the reservoir, depending on used breathing rate and tidal volume. At the same time the vacuum system generates a continuous gas flow via the outlet out of the reservoir. The vacuum gas flow is adjusted to be higher than the expected maximum minute volume ventilated. This is how a higher evacuation rate than the application device's waste gas injection is ensured. Although the mean gas flow of the evacuation line is higher than the minute volume injected into the inlet the pulsation of the expiratory gas inlet could cause temporarily higher flows (peak flow). That's why the reservoir is open to atmosphere to buffer the waste gas in the reservoir. During the expiration phase of the application device waste gas expels the clean gas in the reservoir to the atmosphere. During the inspiration phase clean gas from the atmosphere is pulled into the reservoir. The container with the two pipes builds this reservoir. This reservoir's volume and pipe position is designed to store the waste gas with highest priority and expand the clean gas layer above. This prevents the gas to be disposed of from escaping through the openings into the atmosphere.

1.7 Symbols and markings

CE	Products with these mark comply with the regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices when they are used as specified in their Operation and Maintenance Manuals.
	Follow the instructions for use.
	Caution: Refers to the need for the user to review the instructions for use for important safety-related information, such as warnings and precautions.
	Manufacturer
	Date of manufacture
SN	Serial number (XXXD12345) It contains in coded form the product group (XXX), the year of manufacture (J 2016, K = 2017, etc.) and a sequential number for precise identification of the product (12345).

Reference number (order number)

Atmospheric pressure limitation

Limitation of the relative air humidity

Temperature limitation (storage, transportation)

Keep dry

UDI label

(01) 0 4260665 92007 5
(21) 151N00433
(11) 202003
(91) ORS-01

A unique device code for identification of medical devices.
Example:
(01)4260665920075(21)151N00419(11)202002(91)ORS-01

Application identifier (AI)	Every UDI number can be divided into multiple parts, whereby each part is identified by its AI number.
(01)	Global Trade Item Number (GTIN)
(21)	Serial number (SN)
(11)	Date of manufacture (YYMM)
(91)	Reference number (REF)
GTIN	Example: 4260665920075 The GTIN consists of three parts: a. GS-1 manufacturer number: 426066592 b. Number of articles: 007 c. Check digit: 5

2 Safety

2.1 Safe operation

To ensure safe operation of the Clean Air, use the system only as intended (see chapter 3).

Operators need to be familiar with these instructions for use (IFU) prior to operating the system.

Keep these instructions for use accessible.

Only trained operators should use this system. Always ensure compliance with the requirements of this IFU and with the local governmental or authority's requirements.

2.2 Mounting

Attachment
Place the Clean Air on a medirail mount or use dedicated mounting system provided by the manufacturer Technologie Institut Medizin GmbH (TIM.

Use in vertical position only.

Load capacity of the rail mount must be at least 10 kg, to ensure secure attachment.

To ensure proper operation the following minimum distances must be observed:

- to the next wall/device: approx. 10 cm
- to the floor: ca. 10 cm

Stand operation is not permitted.

Separate mounting
In case the Clean Air is mounted separate for example from a ventilator or the ventilator trolley make sure that in case of moving either the Clean Air or the ventilator

- the connection between the Clean Air and the ventilator does neither bent or twist or get disconnected,
- the Clean Air and the ventilator work properly,
- the ventilator's expiratory connected part (exp. valve or exp. flow sensor) is not affected in position or function.

Vacuum system
In case of operating multiple Clean Air at the same time at the same VAC trunk line please check the instruction for use of the VAC system manufacturer that the performance is sufficient.

Using a Clean Air in case of ventilating a patient with elevated oxygen concentrations (FIO_2 > 75 Vol %) for a longer period of time (> 1h) the oxygen concentration within the vacuum system may rise. Check the instruction for use of the VAC system manufacturer that the vacuum system is designed accordingly.

2.3 Connected devices

For the current list of compatible application devices contact the manufacturer Technologie Institut Medizin GmbH (TIM).

Use only TIM approved tubes and adapters to connect the Clean Air to application devices such as ventilators and to connect the Clean Air to vacuum systems.

Do not use or connect the Clean Air to an application device with a non-matching application device connection tube. In case of a non-matching application device connection tube malfunction of the application device can occur and can cause risk to the connected patient.

Before use always check the Clean Air dedicated application device connection tube for external damage and to match the application device to connect to.

Adjust flow-sensor if necessary.

Use of active humidification
Using active humidification of the inspiratory patient gas, condensed water may accumulate behind the exhalation valve in the dissipative tube from the ventilator to the Clean Air. It is generally the responsibility of the user to prevent accumulated water from flowing back into the ventilator's respiratory valve. Under certain circumstances, the indication of active humidification or the disposal of the patient's gas with the Clean Air should be checked.

2.4 Patient and user safety

The Clean Air should be operated by or on the order of a physician.

The Clean Air should only be operated by qualified medical personnel to ensure adequate intervention in case of a malfunction.

Before use always check the Clean Air system (including connected tubes) for external damage. Do not use in case of obvious damage.

If the vacuum system is deactivated, the Clean Air must not be used.

2.5 Malfunction

Serious incidents relating to this product must be reported to the manufacturer and the competent authority of the State where the product is operated.

2.6 Modifications

Modifications may only be carried out by the manufacturer or by qualified personnel expressly authorized by the manufacturer.

2.7 Accessories

Use only manufacturer’s original parts.

2.8 Reprocessing

Follow general hygiene requirements of your hospital.

2.9 Service and maintenance

The Clean Air is developed for continuous operation.

The correct functioning of the Clean Air must be checked every 12 months (see chapter: Safety check).

In case a repair is needed the Clean Air must be send back to the distributor/manufacturer.

2.10 Warning notices in these instructions for use

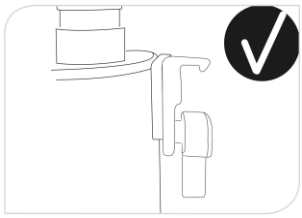
Warning notices indicate information relevant to safety.
They are located at the description of an action that can lead to a danger to persons or objects.
A warning notice contains information about a possible danger and instructions on how to avoid the danger. They are divided into different danger levels, depending on the degree of danger.

WARNING	Indicates a danger with a medium risk level. Failure to observe this warning may result in serious irreversible or fatal injuries.
CAUTION	Indicates a danger with a low risk level. Failure to observe this warning may result in minor or moderate injury.
NOTICE	Indicates a damaging situation. Failure to observe this warning may result in property damage.

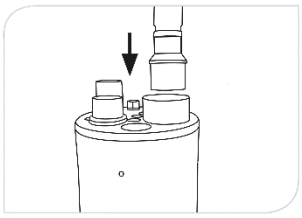
3 Use

3.1 Installation

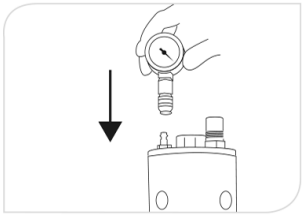
Check that the locking mechanism is open before connecting to the rail mount.



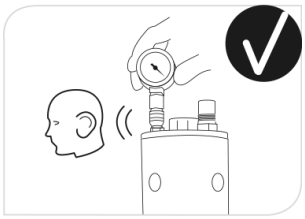
Connect the dedicated application device specific connection tube via its waste gas connector with the Clean Air.



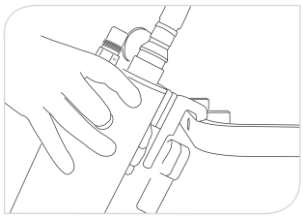
Insert the plug-in gauge on the intended connector.



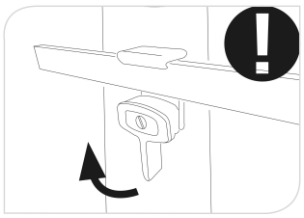
Press the plug-in gauge as far down until you hear a click. Only then the gauge is correctly mounted on the Clean Air.



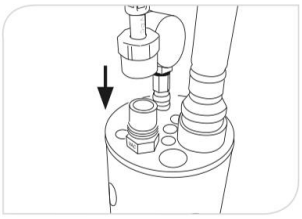
Hook the Clean Air on the fixture to the mounting rail or similar.



Lift the black lever to fasten the terminal to the rail.

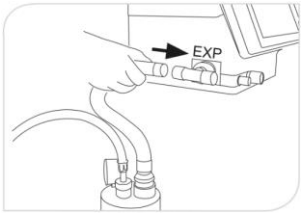


Connect the medical vacuum supply to the Clean Air with the NIST-screw.



NOTICE
Risk of damage to property.
Do not use tools to fix the screw (only hand tight).

Connect the Clean Air via the dedicated application device specific connection tube to the outlet of the specified application device e.g. exhalation valve exit of a ventilator.



Representation exemplary.
Further information on connection to an application device can be found on the packaging of the specific connection tube.

3.2 Operation

CAUTION **Endangerment of persons due to exposure of anaesthetic gas of the periphery if the Clean Air is not powerful enough.**

- ⇨ Clean Air system needs a constant gas flow of the gas suction device. If the gas flow e.g. through a plurality of consumers is outside the specification of the Clean Air, the system must not be used. This may lead to contamination of the periphery by expiratory waste gas.
- ⇨ The Clean Air must not be covered.
- ⇨ The Clean Air must be protected from liquid. No liquid must be filled in.

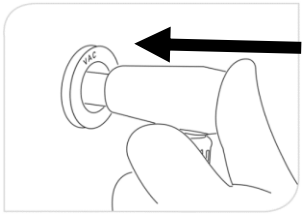
WARNING **Endangerment of patient due to closure of the outlet of the expiration valve.**

- ⇨ Make sure that the connecting hose to the outlet of the expiration valve is not kinked.

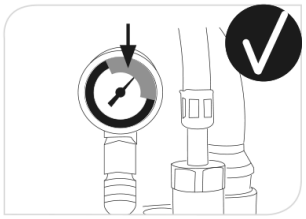
CAUTION **Endangerment of patient: Condensate returning to the expiration valve can impair expiratory flow measurement.**

- ⇨ Make sure that the entire connecting tube is in a lower position than the outlet of the expiration valve.

Connect the vacuum supply line of the Clean Air to the medical vacuum line.



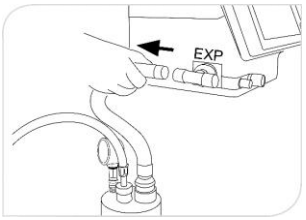
Verify the indicator needle of the gauge has moved from its zero position.
Verify the indicator needle of the gauge is within the operating range (green area).



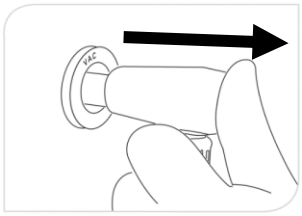
If necessary, adjust the ventilator's expiratory measurement flow system according to ventilator's manufacturer instruction for use.

3.3 Disconnection

Disconnect the application device specific connection tube at the application device's expiratory side.



Remove the VAC plug from the wall outlet.



4 Cleaning

For cleaning, standard cleaning agents may be used (disinfection by wiping over surfaces).

CAUTION **Endangerment of persons and risk of damage to property due to improper use of cleaning and disinfecting agents.**

⇨ Follow the product information of the manufacturers of the cleaning agents and disinfectants.

⇨ Perform cleaning as described.

NOTICE **Risk of damage to property due to unsuitable cleaning agents.**

⇨ Refer to the manufacturer's data if you have questions about a cleaning agent.

⇨ Do not use organic, halogenated or petroleum based sol-vents, anaesthetic agents, glass cleaner, acetone or harsh cleaning agents.

⇨ Do not use abrasive cleaning agents, such as steel wool, silver polish or silver cleaner.

NOTICE **Risk of damage to property due to unsuitable cleaning procedures.**

⇨ Do not autoclave any part of the Clean Air.

⇨ No part of the Clean Air is sterilisable.

NOTICE **Risk of damage to property caused by cleaning agents penetrating into the interior of the product.**

⇨ Do not permit liquids to go into the equipment's housing.

5 Safety check

5.1 General information

WARNING **Endangerment of persons due to danger of infection**
The product may be contaminated with pathogens.
⇨ Clean the product before safety check (see chapter: Cleaning).

WARNING **Endangerment of persons and risk of damage to property due to improper performance.**
⇨ Safety checks may only be carried out by qualified personnel.

Check the following every 12 months:

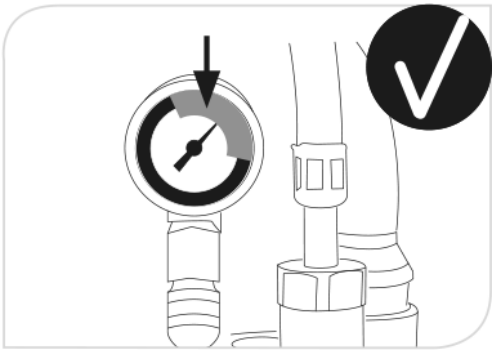
- Accompanying documents available (instructions for use)
- Inscriptions complete and legible (no damage)
- Functionality

Missing accompanying documents or damaged inscriptions must be replaced. In this case contact the manufacturer Technologie Institut Medizin GmbH (TIM).

5.2 Checking the functionality

Connect the medical vacuum supply with the Clean Air system. Verify the indicator needle of the plug-in gauge is within the operating range (green area).
If this is not the case, the system is not allowed to be used and must be inspected by qualified personal.

In case of a defect at the gauge the plug-in gauge has to be replaced to ensure proper operation of the Clean Air.



6 Live cycle information

After five (5) years of operation the Clean Air has to be withdrawn from the clinical environment and returned to the manufacturer for disposal. Contact the manufacturer for information concerning the decommissioning of your equipment.

7 Specifications

Physical dimensions

Diameter:	ca. 100 mm
Height:	ca. 490 mm
Weight:	ca. 2.2 kg

Environmental conditions

During operation:	
Temperature range:	+10 to +40°C
Atm. pressure range:	700 to 1,060 hPa
Equivalent altitude:	3,000 to 0 m (9,840 to 0 ft) above sea level
Humidity range:	10 to 90% relative, none condensing
During storage:	
Temperature range:	-20 to +50°C.
Atm. pressure range:	500 to 1,060 hPa.
Equivalent altitude:	5,500 to 0 m (18,050 to 0 ft) above sea level
Humidity range:	10 to 90% relative, none condensing
During transport:	
Temperature range:	-20 to +70°C
Atm. pressure range:	500 to 1,060 hPa
Equivalent altitude:	5,500 to 0 m (18,050 to 0 ft) above sea level
Humidity range:	10 to 90% relative, none condensing

Noise emission

Noise level:	≤ 44 dB (A)

Classification

CE class:	I, Regulation (EU) 2017/745, Annex VIII, Chapter III, Rule 1

UMDNS Code

CA 01, 02, 04:	10-142

Gas supply

Type:	VAC vacuum according to EN ISO 7396-1
VAC pressure:	-0,5 to -0,9 bar
VAC flow:	> 25 l/min

Mechanical interface

VAC connection:	NIST VAC (ISO)
Waste gas connector:	30 mm tapper cone (ISO) Note: Requires dedicated application device specific connection tube
Plug-in gauge connector:	proprietary connector

Display

Type:	vacuum gauge
Correct operation:	gauge needle in green area (-0.18 to -0.62 bar)

Performance

Suction flow:	25 l/min ± 5 l/min

The Clean Air is designed with respect to the following standards:

Standard	Title
EN 1041	Information supplied by the manufacturer of medical devices
IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 9170-1	Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum
EN ISO 80601-2-13	Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

8 Accessories and spare parts

Description	Order number
Basic device	
Clean Air CA-01 (Version 6.2)	ORS-01
Clean Air CA-02 (Version 6.2)	ORS-02
Clean Air CA-04 (Version 6.2)	ORS-04
Vacuum supply connections	
Clean Air vacuum connection DE, NIST (according to DIN 13620-2)	ORS-01-DE
Clean Air vacuum connection UK, NIST (according to AFNOR NF S 90-116)	ORS-01-UK
Clean Air vacuum connection FR, NIST (according to BS 5682)	ORS-01-FR
Connection to application devices	
For the current list of compatible application devices and their device connections, contact the manufacturer Technologie Institut Medizin GmbH (TIM). The compatibility matrix is available at https://tim-gmbh.de/en/ors-clean-air-docs/	
Replacement parts	
Clean Air plug-in gauge	ORS-SC-02
Accessories	
Adapter Luer lock	ORS-01-LL
Documents	
The instructions for use can be downloaded from the manufacturer’s website. The printed documents can be requested from the manufacturer.	

Manufacturer

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CE

Clean Air Editions

Regulatory information

Information on connecting to an existing vacuum system

Accessory

Instructions for use

www.ors-clean-air.de

This document

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