SEDANAMEDICAL

the AnaConDa® technology people

AnaConDa – Anaesthetic Conserving Device

Inhalation Sedation in Intensive Care Units

Handbook for clinical use

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Important user information
This manual is a technical description of the Sedana Medical AnaConDa® system. It has been written to complement the instructions for use and includes detailed descriptions of set-up, medical application and system description. Be sure to carefully read the instructions for use before operating the AnaConDa®. Please direct any remarks or comments about this publication to Sedana Medical AB.

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1. Introduction

Analgosedation of intensive care patients

Concepts of analgosedation are quite complex due to the various individual goals of therapy (analgesia, sedation, anxiolysis) and nowadays belong to the standard repertoire of intensive care. The pharmacological development of rapid acting, thus well controllable substances on one hand, as well as knowledge of the connection between analgosedation and outcome based on scientific studies have resulted in a marked change in the premises of analgosedation. While in the past the main focus was primarily on deep sedation, it is now on analgesia, which may be supplemented with sedation adapted to the specific needs (target score RAMSAY -2 to -3). This change in the paradigm is supported by clinical studies in which 70% of patients specified pain as the most unpleasant recollection, despite medical staff having assessed the pain therapy as adequate. This fact concurrently reveals the requirement for adequate monitoring.

In the clinical situation, however, with a sophisticated approach there are still other medical reasons warranting deep analgosedation as part of a therapy strategy (severe septicaemia, acute phase polytrauma, burn patients, burst suppression for neuroprotection and ICP reduction, etc.). In these cases it is reasonable to routinely check the level of sedation, for example through clinical sedation scores, machine diagnosis (Bispectral-Index, EEG) or daily sedation pauses.

Considering this and the many undesirable side effects during analgosedation in clinical routine – such as developing an increasing tolerance, insufficient sedation quality when combining medications (polypragmatism), gastrointestinal immotility, developing withdrawal symptoms, cognitive deficits – make the search for the ideal sedation concept far from over.

The ideal analgosedation method involves:

1. Good controllability, with quick onset of action and rapid elimination when stopped
2. Predictable effect
3. Organ-independent elimination
4. No accumulation of active metabolites, no enzyme induction
5. Little or no impairment of organ function, particularly the cardiopulmonary system and the gastrointestinal tract
6. Lowest possible interaction with other medications
7. (No release of histamines)
8. Non addiction with long-term use

Based on the progression of the disease a distinction is made between intensive care stabilization phase and weaning phase. During the acute phase the focus is typically on stabilising the patient, active patient participation is not always necessary. The weaning phase, however, requires active patient participation to wean the patient from the respirator or for physical therapy. Here the focus shifts to analgesia and psycho-vegetative screening (anxiolysis). But in addition behaviour disorders often emerge which can sometimes be traced back to earlier analgosedations such as post-operative delirium, excitation. Thus measures should already be taken at the start of analgosedation to considerably reduce the emergence of delirium.

General information about volatile anaesthetics

The use of inhalation anaesthetics is subject to the specific physical principles of absorption, dispersion and elimination. In general the absorption of inhalation anaesthetics implies its gaseous physical condition, in which at room temperature the substances may at first be in liquid form, turning into a gaseous (volatile) state during application. In general anaesthesia, liquid inhalation anaesthetics evaporate through the use of so-called anaesthetic gas evaporator (vapour). The AnaConDa System does not need additional technical requirements to function. It merely utilises the physical properties of the anaesthetic gases Isoflurane and Sevoflurane. Liquid inhalation anaesthetics not only vaporize at their boiling point but partially already at room temperature. In their gaseous stage all inhalation anaesthetics have a specific gas pressure which is substance specific as well as temperature sensitive and significantly impacts absorption in the organism. The higher the gas pressure, the faster the anaesthetic can reach a concentration exchange between alveolar air and blood.

In general the absorption of inhaled anaesthetics depends on:

- Diffusion parameters (alveolar surface, alveolar diffusion distance, etc.)
- Blood solubility
- Cardiac output
- Alveolar pulmonary venous partial pressure difference
- Alveolar concentration

In addition to the density or the molecular weight of the anaesthetic gas the alveolar surface and the diffusion distance (alveolar cell – basal membrane – endothelial cell) are significant clinical determinants for transporting the gas between alveolar air and capillary blood, thus the efficacy of volatile anaesthetics. Under normal conditions the alveolar surface with an area between 55-100 m^2 represents the diffusion area. A reduction of this exchange area, e.g. through atelectasis or emphysema, results in a direct proportional reduction of the diffusion area. The diffusion distance, in contrast, is approx. 0.25-0.6 µm in healthy people and affects the diffusion capacity with the reciprocal of the square of the distance. In clinical applications, doubling the diffusion distance e.g. through a pulmonary oedema, thus reduces the diffusion rate by a factor of 4.

The dispersion of volatile anaesthetics in the human organism is determined by

- Tissue solubility
- Perfusion in the individual organs and tissue

A major portion of anaesthetic gases is eliminated pulmonically. The metabolised portion amounts to 0.2% with Isoflurane and with Sevoflurane this portion is between 3 and 5%. Upon terminating the anaesthetic gas supply a partial pressure gradient quickly develops between the pulmonary vascular bed and the alveolar space, which reversely leads to diffusing the anaesthetic gas from the bloodstream into the alveolar. The flushing of anaesthetic gases is ultimately proportionally impacted by the level of ventilation.

The intensity of a volatile anaesthetic is characterised by the minimal alveolar concentration (MAC). Among other items it also depends on the age, body temperature as well as other sedating and analgesic medications. MAC50 for example is defined as the alveolar concentration of an inhalation anaesthetic at which 50% of all patients no longer respond to incision ("surgical MAC"), MAC95 the concentration at which 95% of patients no longer respond with pain or the MACawake concentration so often aimed at during inhaled sedation at which 50% of patients open their eyes.

2. AnaConDa - Brief Description

AnaConDa, an acronym for "Anaesthetic Conserving Device", is a medical device which allows the administration of volatile anaesthetics. It is used along with conventional respirators – without breathing circuit, breathing lime and anaesthesia evaporator – and connected between the Y-piece and endotracheal tube, just as a bacteria/virus filter. It further requires a syringe pump, anaesthetic gas monitor and anaesthetic gas elimination.
The core of the AnaConDa contains an evaporator and a reflector. Altogether the system consists of the following components.

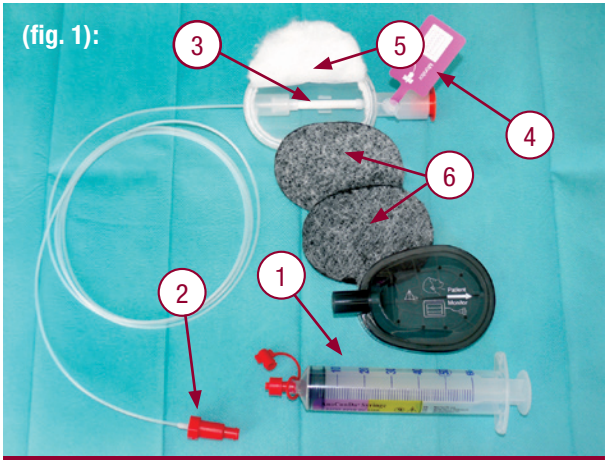
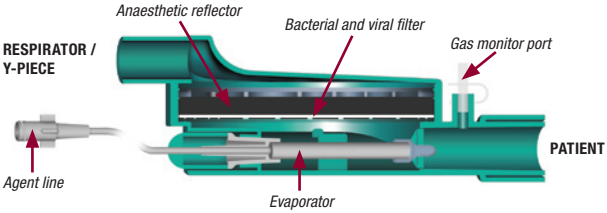


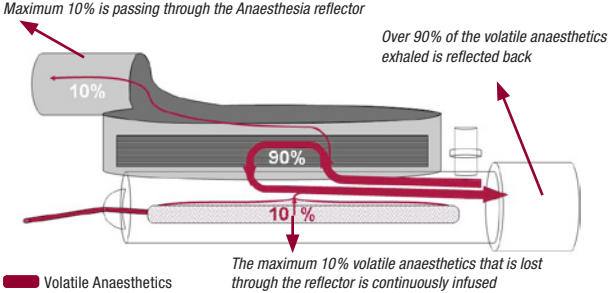
fig. 1:

1. AnaConDa syringe with screw coupling and screw cap
2. Agent supply line with valve and screw coupling
3. Evaporator
4. Gas measurement port
5. Bacteria and virus filter
6. Anaesthesia reflector and humidification filter



The evaporator is a white, hollow bar made from porous plastic. The Ana-ConDa syringe is filled with liquid Isoflurane or Sevoflurane and a syringe pump moves it through the agent line into the evaporator where it leaks onto the surface through pores, evaporating instantly. The anaesthesia reflector consists of activated carbon fibres woven into the cotton-like humidification filter. Anaesthesia molecules attach to the surface of these carbon fibres during expiration, releasing them with the next inspiration. In the process 90% of the anaesthesia molecules are retained in the reflector and re-supplied with the next inspiration. A maximum of 10% of the anaesthesia molecules pass through the reflector and are exhaled via the respirator's expiration valve. This lost amount is continuously replaced by the infused liquid anaesthetics.

Functional description



3. Technical Requirements

Anaesthetic gas elimination
Sedana Medical recommends the use of anaesthetic gas elimination whilst the AnaConDa system is being used.
The AnaConDa (reflector) efficiency is sufficiently high to keep ambient air contamination at approx. 0.5 ppm (ppm = parts per million) under standard intensive care unit conditions (ambient air exchange rate of 8x/h or higher), even without the use of anaesthetic gas elimination.

Anaesthetic gas scavenging
If an intensive care unit has an active anaesthetic gas scavenging system or vacuum system, it may be utilized for the AnaConDa system. Here the expiratory valve of the intensive respirator is connected to the active gas scavenging system or vacuum via a tube. The use of additional equipment may be required to ensure the flow sensor system on the intensive care respirator is not affected by the negative pressure generated. This accessory is available from the companies Dräger Medical (Lübeck) and Maquet (Sweden).

EVAC 180 by Maquet

AGS by Dräger Medical

Anaesthetic gas filter
Various passive anaesthetic gas filters has been developed for the use of volatile anaesthetics without active scavenging systems.

Contrafluran
Contrafluran (by ZeoSys, Berlin) is an anaesthetic gas filter.

Contrafluran anaesthetic gas filter
Item no. ZEO000050

Two mounts are available for the Contrafluran anaesthetic gas filter:

Sensor mount
Sensofluran
Item no. ZE0000052

Standard mount
Item no. ZE0000051

Sensor mount Sensofluran
This sensor mount includes an ionisation measurement chamber. It measures the fill level of the Contrafluran anaesthetic gas filter and accurately indicates it with LEDs.

Standard mount
Per the manufacturer (ZeoSys, Berlin), the Contrafluran filter has an intake volume of 500 ml liquid anaesthetic (Isoflurane, Sevoflurane). On the standard mount a mark is made on the filter after each injection (50 ml) to control the fill level (10 injections, i.e. 10 marks amount to 500 ml). The filter is then to be replaced.

Connecting the anaesthetic gas filter to the intensive care respirator

Accessory set
Item no. 26072

- 22 mm flex tube (Intensive care respirator and anaesthetic gas filter)
- 8 mm O_2 connection tube or 8 mm silicone tube (gas bypass filter and anaesthetic gas filter)
- Adapter 33w/22m connector (Hamilton Galileo, Maquet Servo I, Siemens Servo)
- Intensive care respirator adapter 22m/22w with side outlet to simultaneously feed expiratory air as well as gas monitor expiration air into the anaesthetic gas filter

Anaesthetic gas monitor

An Anaesthetic gas monitor should be used whilst administering volatile anaesthetics to measure the end-tidal gas concentration (Fet), providing information on the level of sedation. Two options (main or side-stream flow measurement) are available for measuring the volatile anaesthetic administered (Isoflurane or Sevoran and CO_2).

Be sure to use an anaesthetic gas monitor with moisture separator and/or Nafion tubing (semi-permeable membrane) for bypass flow measurements, as the measuring tube feeds a large amount of moisture to the anaesthetic gas monitor.

Monitors with side-stream flow measurement also require CO_2 or gas measurement tube (possibly Nafion tubing).

Vamos gas monitor
Vamos by Dräger Medical
side-stream flow monitor

Anastasia gas monitor
by Acutronic Medical
main flow monitor

Syringe pump

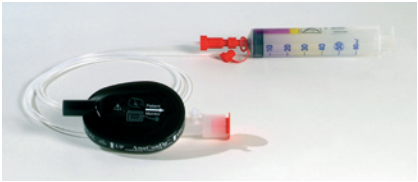
The syringe pump must be set to syringe type

- Becton Dickinson Plastipak 50 ml or
- Sherwood Monoject 50 ml

and a maximum cut-off pressure set.

Some syringe pumps require separate settings to be made, but in general any syringe pump may be used.

AnaConDa material/equipment



AnaConDa System with syringe Item no. 26000

AnaConDa syringe Item no. 26022

Fill adapter
Isoflurane / Sevoflurane
Standard thread
Item no. 26064

Fill adapter Sevorane
Quickfill by Abbott
Item no. 26042

Initialisation / AnaConDa set-up

1. Switch on the prepared gas monitor and connect gas measuring line (CO_2 line) to the AnaConDa and the gas monitor.
2. Connect the AnaConDa agent line with the red check valve to the AnaConDa syringe inside the syringe pump.
3. Remove the red protective cap from the AnaConDa and connect AnaConDa between patient and respirator Y-piece.
4. Program and apply a bolus of 1.5 ml for filling the AnaConDa agent supply line and the evaporator. Caution when administering bolus (do not overdose by using oversized bolus).

Syringe pumps with programmable bolus rates are preferred so that venting the AnaConDa agent supply line won't result in overdosing.
When using non-programmable syringe pumps be sure to administer an accurate bolus dose.

TIP

- Always use room temperature volatile anaesthetics.
- Avoid unnecessary manipulation (e.g. shaking) of bottle with volatile anaesthetic (pressurized bottle).
- Avoid heat sources which impact the stability of volatile anesthetics (e.g. evaporation inside syringe).

4. Instructions for Use

Filling and placing the syringe

1. Only use fill adapters by Sedana Medical with Isoflurane- or Sevoflurane bottles (standard thread or Sevorane Quickfill closure by Abbott).
   The respective fill adapter is screwed to the bottle and may remain there until the contents have been used up ***(the fill adapter for Quickfill bottles by Abbott must remain on the bottle until the bottle is completely empty / this avoids leaks)***.
   A built-in check valve inside the fill adapter prevents the volatile anaesthetic from escaping the bottle

2. Remove syringe from AnaConDa packaging. Fill syringe with some air (approx. 20 ml).

3. Connect syringe to the respective fill adapter by firmly pressing and turning, and slowly and carefully fill syringe with liquid volatile anaesthetic by moving the syringe plunger back and forth a few times (do not generate too much excess/ negative pressure).
   After filling the syringe disconnect the syringe from the bottle, remove any air bubbles from the syringe. Close the syringe with the attached red cap.

4. Place the syringe into the syringe pump.

1

2

3

4

Initialisation / AnaConDa set-up

1. Switch on the prepared gas monitor and connect gas measuring line (CO_2 line) to the AnaConDa and the gas monitor.

2. Connect the AnaConDa agent line with the red check valve to the AnaConDa syringe inside the syringe pump.

3. Remove the red protective cap from the AnaConDa and connect AnaConDa between patient and respirator Y-piece.

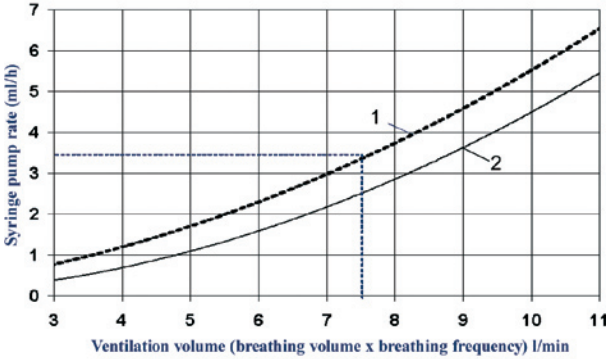
4. Program and apply a bolus of 1.5 ml for filling the AnaConDa agent supply line and the evaporator. Caution when administering bolus (do not overdose by using oversized bolus).

   Start syringe pump at a rate of:
   - 3 ml/h Isofluran or
   - 5 ml/h Sevofluran

   and adjust dose as necessary.

Dosage calculation for end-tidal concentration (Fet)

The following dosage nomogram provides a reference value applicable to an end-tidal concentration of (Fet) 0.5Vol% Isoflurane or Sevorflurane.



Curve 1 represents the values during the first hour
Curve 2 represents the values starting with the 2nd hour

Initial syringe pump rates of Isoflurane and Sevoflurane have been established as follows based on studies and expert opinions:

Isofluran: 3 ml/h
Sevofluran: 5 ml/h

Sedation must be individually evaluated with each patient. Once the intended sedation level (sedation score) has been reached another adjustment should be made within the first hour of use by administering a bolus (0.5 ml) or modifying the syringe pump rate in accordance with additional or reduced sedation.

Please note the different MAC values of the various anaesthetic gases (see chapter volatile anaesthetics).

Practical application

Syringe changes
AnaConDa is a 24 hour single-patient device. The syringe may possibly (syringe empty) need to be replaced multiple times in a 24 hour period. Only use AnaConDa syringes.

1. Fill the new syringe with the volatile anaesthetic as instructed
2. Stop syringe pump
3. Disconnect AnaConDa agent line from the syringe in the syringe pump
4. Remove the empty syringe from the syringe pump
5. Place the new syringe into the syringe pump
6. Connect the AnaConDa agent line to the syringe
7. Restart syringe pump

AnaConDa System change
AnaConDa is a 24 hour single-patient medical device. The system is changed every 24 hours.

Suctioning

- Use a closed suction system.
- Activate the extraction key (O_2 oxygenation) on ventilator; wait for ventilator to pause → disconnect and suction. Use a swivel adapter with bronchoscopy cap.

Using medication nebulisers

- Medication nebulisers are always attached before the AnaConDa, close to the patient.
- Ultrasound nebuliser do not impact the end-tidal gas concentration (Fet).
- Jet air nebulisers require a pressurized air flow of up to 7 litres, which could result in a decrease of the end-tidal concentration (Fet). Adjust sedation for this period (by increasing the syringe pump rate).

Disconnection / connection

Always stop the perfusor when disconnecting!

AnaConDa only releases anaesthetic gas when the flow is directed towards the patient.

- **Always disconnect** the AnaConDa at the Y-piece first, then from the patient
- **Always first connect** the AnaConDa to the patient first, then to the Y-piece

Patient transport with AnaConDa

The reflexion properties of the AnaConDa allow the patient-side gas concentration to be maintained for some time before a drop in the concentration is noticeable.

Patients can be transported with AnaConDa. Sedation will be maintained at about the same level for approx. 25-35 minutes without continuing the infusion with the syringe pump. Based on experience a small bolus is administered shortly before patient transport. (Caution – avoid overdosing from bolus administration)

The syringe pump may also be included during transport.

Temporary concentration increase

In some cases it may be necessary to quickly increase the sedation depth on a patient. In this case the bolus function of the syringe pump may be used (Caution – avoid overdosing from bolus administration). Bolus with approx. 0.2-0.3 ml Isoflurane or 0.4-0.6 ml Sevorane is sufficient to raise the Fet value by 0.2-0.4Vol%.

5. Warnings, Notices, Tips And Tricks

Warnings

- Only use room-temperature anaesthetic gas (Isoflurane or Sevoflurane)!
- Avoid overdosing by incorrect bolus administration. Programmable syringe pumps are preferred!
- Never manually fill the agent line. Always use a syringe pump!
- Never close the AnaConDa with caps or other items whilst not connected to the patient!
- Always stop the syringe pump when disconnecting the AnaConDa!
- AnaConDa is a 24 hour single-patient product. Single use only!

Notices

- Set the syringe setting on Becton Dickinson Plastipak or Sherwood Monoject 50ml on the syringe pump
- Set the syringe pump to maximum alarm tolerance (switch-off pressure to maximum)
- If necessary, remove any air or gas bubbles from the syringe.
- Always position AnaConDa with the black side facing up.
- Always keep the fill adapter for Sevorane Quickfill bottles connected to the bottle until the bottle is completely emptied. Repeated screwing on and unscrewing will result in bottle leaks.
- Please note the AnaConDa creates an additional dead space of approx. 100ml.
- Adjust the ventilation parameters if the CO_2 value rises too high.
- Always connect the medication nebulizer on the patient's side, before the AnaConDa
- Modifying the flow (ventilation parameters, compressed air nebulizer) impacts the end-tidal gas concentration.
- Always first disconnect the AnaConDa from the respirator (Y-piece).
- There may be various causes for incorrect or fluctuating gas monitor values (self-respiration, moisture in gas measuring line, AnaConDa position changes e.g. patient in Rotorest bed)
- AnaConDa has a very efficient HME (heat and moisture exchange) function. If necessary, remove any condensation on the patient end.

Tips and tricks

Can AnaConDa be used for neonatal or paediatric purposes?

The dead space of 100 ml limits the use of AnaConDa, we therefore recommend only using it on patients with a tidal volume of >350 ml. Use below 350 ml has been investigated. In this case the AnaConDa is built into the inspiratory tube and used purely as a vaporizer. The storage/recycle medium function is not applied. In small tidal volumes the consumption of volatile anaesthetic is not very high.

What happens if the black AnaConDa side is positioned upside-down/downward?

Condensation could be drawn into the gas measuring line which will falsify the gas concentration measurement. Condensation on the hydrophobic bacteria/virus filter membrane may prevent air from passing. In addition the gas measurement values are false, as the heavy gas ”drips” into the line instead of being drawn in showing falsely elevated levels.

Which gas measurement line should be used?

Always use the measurement line recommended for the gas monitor. Incorrect lengths and types may impact the measurement. A special Nafion line (semi-permeable layer) can reduce the accumulation of condensation inside the water trap.

Why are end-tidal values (Fet) higher than inspiratory values (Fi) when using the AnaConDa?

The AnaConDa performance differs from constant gas flow in an anaesthesia machine. The highly efficient storage medium (anaesthesia reflector) releases a large amount of anaesthetic gas to the patient at the start of inspiration, which would be shown as a so-called peak in the measured curve. The gas monitor, however, measures at the end of inspiration, when the majority of anaesthetic gas has already been fed to the patient.

This results in a lower than actual Fi value. The Fet value is indicated correctly.

High fluctuation in CO_2 values?

When using a bypass flow monitor, check for water in the line. Check if the water trap is full. Remove any condensation.

6. Literature

AnaConDa in intensive care units

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7. Sedation Scoring Systems

Scoring systems helps the intensive care personnel to quite accurately assess the patient's sedation level through the use of clinical criteria. The most frequently used sedation scores are:

Ramsey Sedation Scale

Score	Description	Assessment
0	Awake, oriented	Awake
1	Agitated, restless, anxious	Too flat
2	Awake, cooperative, respiratory tolerance	Adequate
3	Asleep but cooperative (opens eyes in response to loud verbal commands or touch)	Adequate
4	Deep sedation (doesn't open eyes in response to loud verbal commands or touch, but promptly reacts to pain stimulation)	Adequate
5	Anaesthesia (lethargic reaction to pain stimulation)	Deep
6	Deep coma (no reaction to pain stimulation)	Too deep

The Richmond Agitation Sedation Scale (RASS)

Score	Term	Description
+4	Combative	Combative or aggressive, immediate danger to staff
+3	Very agitated	Pulls on or removes tubes, catheter, etc., or aggressive toward staff
+2	Agitated	Frequent non-purposeful movement or patient-ventilator dyssynchrony
+1	Restless	Anxious but movements are not aggressive or vigorous
0	Alert and calm	
-1	Drowsy	Not fully alert but has sustained awakening (more than 10 seconds), eye contact to voice
-2	Light sedation	Briefly awakens (less than 10 seconds) with eye contact to voice
-3	Moderate sedation	Movement in response to voice, but no eye contact
-4	Deep sedation	No response to voice, but movement in response to physical stimulation
-5	Unarousable	No response to voice or physical stimulation

Material List

Product/component	Material	Residue after burning
AnaConDa System		
Housing	Polypropylene	CO_2, H_2O
Evaporator	Polypropylene	CO_2, H_2O
Carbon filter	Carbon	CO_2
Bacteria and virus filter	Polypropylene	CO_2, H_2O
Agent line	Polyethylene	CO_2, H_2O
Line connector	Polyethylene	CO_2, H_2O
Hot glue	Olefin co-polymer	CO_2, H_2O
Luer cap	Polyethylene	CO_2, H_2O
Locking plug	Polycarbonate	CO_2, H_2O
Label	Polypropylene	CO_2, H_2O
Syringe		
Barrel	Polypropylene	CO_2, H_2O
Plunger	Polypropylene	CO_2, H_2O
Piston	Rubber	CO_2, H_2O
Adhesive	Acrylic U.V.	CO_2, H_2O
Lubricant	Silicone	SiO_2
Label	Polypropylene	CO_2, H_2O
Packaging		
Over layer	Paper	CO_2, H_2O
Tray	Polyethylene terephthalate	CO_2, H_2O

Operating Conditions

Anaesthetic agents:	Isoflurane or Sevoflurane
Tidal volume operating range:	minimum 350 ml
Resistance @ 60 l/min:	2.5 cm H_2O (250 Pa)
Moisture loss at 0.75 l x 12 breaths/min:	5 mg/l
Humidification output (calc.):	30 mg/l
Moisture loss at 1.0 l x 10 breaths/min:	7 mg/l
Humidification output (calc.):	29 mg/l
Bacterial filtration efficiency:	99.999%
Viral filtration efficiency:	99.98%
Dead space:	approx. 100 ml
Weight:	50 g
Connectors per ISO 5356:	15F/22M - 15 M
Gas monitoring port:	Female Luer lock
Agent line length:	2200 mm

Ordering Information

Item no.	Description
26000	AnaConDa System with syringe
26022	AnaConDa syringe, single
26064	Filling adapter 26064 Isoflurane and Sevoflurane with standard threads
26042	Filling adapter 26042 for Sevorane Quickfill by Abbott
26072	Accessory set for rest gas filter
ZE0000050	Contrafluran anaesthetic gas filter
ZE0000051	Contrafluran standard mount
ZE0000052	Contrafluran Sensoflurane mount

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Legal Basis
The AnaConDa® system is a CE-certified medical device. Use of the system and its components during "inhalation sedation" in intensive care patients is based on the Medical Devices Act (MPG, Medizinproduktegesetz in its version published August 7, 2002 (BGBl. I pg. 3146), last modified with Article 1 of the Act dated June 14, 2007 (BGBl. I pg. 1066).

When using Sevoflurane or Isoflurane please follow the respective manufacturer expert information.

Notes

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