SEDANAMEDICAL

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AnaConDa
Technical Handbook

AnaConDa

Anaesthetic Conserving Device

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This handbook supplements the AnaConDa instructions for use. It contains detailed descriptions of the AnaConDa, its accessories, necessary technical equipment and the practical daily use. Please read the instructions for use carefully before using the AnaConDa.

AnaConDa

The AnaConDa (Anaesthetic Conserving Device) is intended for administering isoflurane and sevoflurane to invasively ventilated patients. It is a passive, class IIa medical device that enables the simple and safe use of volatile anaesthetics without the need for an anaesthesia machine.

SEDANA MEDICAL operates a full quality management system, as per ISO 13485, which is externally audited annually. The AnaConDa & AnaConDa-S devices are CE Marked according to Annex II of MDD 93/42/EEC.

The AnaConDa is a modified HME (Heat & Moisture exchanger) containing a unique evaporator which enables vaporisation of isoflurane and sevoflurane. It includes a highly effective carbon filter which recycles up to 90% of the anaesthetic. An electrostatic bacterial/viral filter is also incorporated into the device.

The AnaConDa is unique in terms of simplicity, reliability and safety.

The ability to reduce gas consumption in an open system, to the level that is equivalent to a semi-open system (1.0L to 1.5L fresh gas flow) is one of the main features of the AnaConDa. This makes the administration of volatile anaesthetics simple, safe and economical, thus easier to implement.

AnaConDa-technology – all of the advantages at a glance

- One product with multiple functions (bacterial/viral filter, evaporator, reflector, HME)
- Small and lightweight
- Use of existing equipment
- Low training costs
- Simple set-up
- Flexible use
- Passive device
- No maintenance or calibration required
- Simple cost control
- Technology proven over 13 years

AnaConda utilizes existing proven technologies, such as ventilators, syringe pumps and anaesthetic gas monitors.

1. Volatile anaesthetics

The use of volatile anaesthetics is subject to the specific physiological laws of absorption, distribution and elimination. The absorption of volatile anaesthetics requires it to be in a gaseous state, where the substances may be in a liquid state at room temperature and then be changed into a gaseous (volatile) state during use.

Under general anaesthesia, liquid volatile anaesthetics evaporate through the use of what is known as an anaesthetic gas vaporizer. However with the AnaConDa system, there are no additional technical requirements that have to be met. It merely utilises the physical properties of the anaesthetic gases; isoflurane and sevoflurane. Liquid volatile anaesthetics do not evaporate solely at their boiling point, but also to some extent at room temperature.

Sevoflurane

All volatile anaesthetics have a specific gas pressure in their gaseous phase that is both substance-specific and temperaturedependent and has a substantial effect on uptake in the body. The higher the gas pressure, the faster the anaesthetic can reach a concentration equilibrium between alveolar air and blood.

Isoflurane

The uptake of an volatile anaesthetic generally depends on:

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

In addition to the density or molecular weight of the anaesthetic gas, the alveolar surface area and the diffusion pathway (alveolar cell – basal membrane – endothelial cell) are significant clinical determinants of gas transport between alveolar air and capillary blood and thus of the efficacy of volatile anaesthetics.

The alveolar surface area under normal conditions, at between 55 m^2-100 m^2, represents the diffusion area. A reduction in the exchange area, for example due to atelectasis or emphysema, results in a directly proportional decrease in the diffusion area. The diffusion pathway, on the other hand, is approx. 0.25 µm-0.6 µm in healthy subjects and influences the diffusion capacity with the reciprocal of the square of the distance. In clinical use, a doubling of the diffusion pathway, for example due to pulmonary oedema, thus reduces the diffusion rate by a factor of 4.

The distribution of volatile anaesthetics in the human body is determined by:

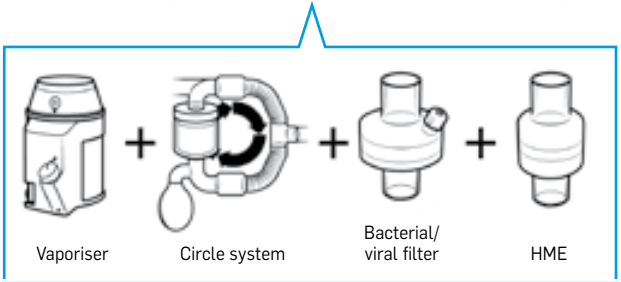
- tissue solubility
- perfusion of the individual organs and tissues

The greater part of the anaesthetic gases is eliminated through the lungs. The portion metabolised is 0.2% for isoflurane and between 3 and 5% for sevoflurane. When the supply of anaesthetic gas is stopped, a partial pressure gradient rapidly develops between the pulmonary vascular bed and the alveolar space, leading to diffusion of anaesthetic gas from the bloodstream into the alveoli, in the reverse direction. The flushing of the anaesthetic gas is ultimately influenced proportionally by the extent of ventilation.

The efficacy of a volatile anaesthetic is described by the minimum alveolar concentration (MAC). This is dependent on factors such as age, body temperature and other drugs with a sedative and analgesic action. The MAC50, for example, is defined as the alveolar concentration of an volatile anaesthetic at which 50% of all patients no longer respond to a skin incision (“surgical MAC”), MAC95 as the concentration at which 95% of patients do not exhibit a pain response and MAC awake as the concentration at which 50% of patients open their eyes.

2. AnaConDa – product description

AnaConDa is a medical device that enables simple and safe administration of volatile anaesthetics. It is used with commercial ventilators (without breathing circuit, CO_2 absorber and anaesthetic evaporator) and is connected between the Y-piece and endotracheal tube like a bacterial/viral filter. It also requires a syringe pump, anaesthetic gas monitor and an anaesthetic gas scavenging system. The core of the AnaConDa contains an anaesthetic gas evaporator and reflector.



AnaConDa technology consists of the following components:

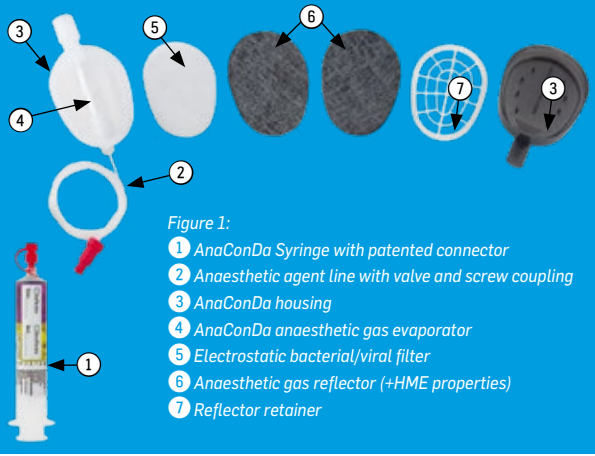
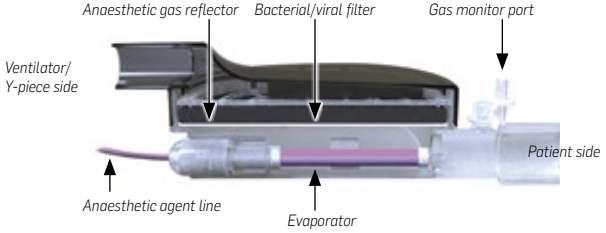


Figure 1:

1. *AnaConDa Syringe with patented connector*
2. *Anaesthetic agent line with valve and screw coupling*
3. *AnaConDa housing*
4. *AnaConDa anaesthetic gas evaporator*
5. *Electrostatic bacterial/viral filter*
6. *Anaesthetic gas reflector (+HME properties)*
7. *Reflector retainer*



Liquid Isoflurane or sevoflurane is administered to the evaporator from the AnaConDa syringe, which is placed in a syringe pump. The evaporator is a porous rod that provides a large surface area for the volatile anaesthetic. On this surface, liquid anaesthetic agent is converted to gas.

The anaesthetic gas/air mixture is directed to the patient via the inspiratory flow.

The anaesthetic reflector consists of activated carbon fibres that are woven into a cotton wool-like structure. Exhaled volatile anaesthetic molecules accumulate on the carbon fibres during expiration. The gas molecules adsorb to the carbon fibres and as a result, can be reflected back to the patient during inspiration. More than 90% of the exhaled anaesthetic is stored in the reflector and then returned to the patient (leading to >90% reduction in anaesthetic gas consumption compared to an open system).

The remaining 10% is replaced through a continuous supply of volatile anaesthetic from the syringe.

The carbon reflector recycles up to 90% of the volatile agent significantly reducing the consumption of anaesthetic gas.

10% of the volatile anaesthetics from the expiratory air pass through the reflector medium

Over 90% of the anaesthetic is reflected by the storage medium

SEDANA MEDICAL offers two versions of the AnaConDa. The original AnaConDa, with a dead space of 100 ml, has been in use since 2005. Approximately 300,000 usage days have been carried out with this version worldwide.

SEDANA MEDICAL now also offer the AnaConDa-S, which has a reduced dead space of just 50 ml and is approx. 30% lighter. This smaller device significantly expands the number of patients who can benefit from this treatment

AnaConDa
Dead space 100 ml | Vt >350 ml

AnaConDa, art. no. 26100

AnaConDa
Dead space 50 ml | Vt >200 ml

AnaConDa-S, art. no. 26050

3. Technical requirements for use of the AnaConDa

Only medical devices that meet international standards and have a CE-marking may be used with the AnaConDa.

3.1 Anaesthetic gas monitoring

The AnaConDa should always be used with an anaesthetic gas monitoring system which indicates the Fet% concentration and/or MAC values. The use of a gas monitor makes it easier to titrate and control according to patient needs. Use only gas monitors which comply with European standard EN 80601-2-55.

There are two methods of anaesthetic gas measurement (main-stream and side-stream measurement).

3.1.1 Main-stream measurement

With main-stream monitoring, measurement is carried out by means of a sensor installed between the patient and the AnaConDa.

3.1.2 Side-stream measurement

With side-stream measurement, gas samples are continuously measured throughout each breathing cycle. These samples are delivered via a gas monitoring line from the AnaConDa. A large number of stand-alone devices and modules are available for this measurement method.

Stand-alone gas monitors

Dräger Vamos

Masimo Root®

Gas modules for patient monitoring

Philips G7m

Dräger Scio

GE Carescape

Please ensure that the monitor has the ability to eliminate condensate from the exhaled air. (e.g. water trap/ semipermeable sampling line) This will ensure the accuracy of the measurement.

Water trap/Nomoline™ (Masimo)

Water trap, e.g. Philips, Dräger

Nomoline™ Adapter

For side-stream measurements, SEDANA MEDICAL also offers the Nafion Dryer Tubing.
It has a semipermeable membrane and eliminates approximately 2/3 of the moisture. The semi permeability results in the condensate in the sample gas being discharged, while the air with anaesthetic gas remains in the line.

Nafion Dryer Tubing, art. no. 26053
Reduces the accumulation of condensate in the gas sampling line and water trap

Modular solutions for anaesthetic gas measurement

Plug-in modules for patient monitoring are available from Philips, GE and Mindray. These modules can easily be moved between beds as required. Further advantages of these modular solutions include central monitoring, mixed gas detection, optional O2-measurement, short warm- up time, and transfer to the patient data management system (PDMS). There is also the option for EEG monitoring as an additional add-on function with these modular solutions.

Stand-alone anaesthetic gas measurement

In addition to the Dräger Medical Vamos monitor, Masimo offers the Root™ monitor with gas measurement module (ISA OR+) and a 4-channel EEG measurement module for brain function monitoring (SedLine®).

The ROOT™monitor also offers volatile gas measurement and measurement of the anaesthesia level. This measurement combination enables targeted control of anaesthetic gas concentration.

3.2 Syringe pump

Only use programmable, CE marked syringe pumps that comply with the specifications of European standard EN 60601-2-24.
The AnaConDa Syringe has the same dimensions as a Becton Dickinson Plastipak and Sherwood Monoject 50, 50/60 and 60ml syringe. Therefore the syringe pump must be programmed to one of these two syringe types:

- Becton Dickinson Plastipak 50, 50/60 and 60ml
  or
- Sherwood Monoject 50, 50/60 and 60ml

The maximum cut-off pressure should also be set.

In order to prevent overdosing, a slow pump rate for bolus delivery is recommended hence a fixed, programmable bolus delivery is preferable. As an additional safety measure a maximum bolus rate can be set (e.g. maximum 0.5 ml).

BBraun Space

Arcomed Syramed® µSP6000

3.3 Critical Care Ventilator

Use only CE marked ventilators which comply with the applicable requirements, in particular with the specifications of standard EN 60601-2-12. AnaConDa can be used on all conventional modes but not on oscillator mode for intubated patients. Use ventilator circuits suitable for use with anaesthetic agents.

The AnaConDa device has been integrated with ventilators of the Salvia Elisa family. The Elisa includes an “AnaConDa” mode, which automatically compensates for the additional flow resistance of the device resulting in optimum function.

Salvia Elisa 600/800

3.4 Anaesthetic gas scavenging

SEDANA MEDICAL recommends the use of anaesthetic gas scavenging (passive or active) when using the AnaConDa.

3.4.1 Active gas scavenging

Active anaesthetic gas scavenging systems, can be used to eliminate residual gas. The expiratory valve of the ventilator is connected to the anaesthetic gas scavenging system by a tube and requires the use of an AGS (anaesthetic gas receiving system). For further information consult your ventilator manufacturer. The use of a vacuum can also be an option for eliminating residual gas. This follows similar principles as the connection of the active gas scavenging system.

Dräger Medical AGS

Clean air Getinge Group Maquet

3.4.2 Passive residual gas scavenging

For passive gas scavenging, SEDANA MEDICAL manufactures the FlurAbsorb filter (REF26096). This is available in two sizes, a large filter and a one day filter.

FlurAbsorb
art. no. 26096
FlurAbsorb One-Day
art. no. 26094

FlurAbsorb is an activated carbon filter, developed by SEDANA MEDICAL, which is used in conjunction with an accessory kit (REF26072). Flurabsorb has an absorptive capacity of 400gr.

According to a report commissioned by SEDANA MEDICAL (Romanski, Dr Romanski Falkenese) it is recommended that the waste disposal code AVV 18 01 04 be allocated to the FlurAbsorb. Therefore this filter should be disposed of according to hospital protocols for general hospital waste. (Waste whose collection and disposal are not subject to any special requirements for the prevention of infection).

The maximum workplace contamination limit for isoflurane is 10 ppm (parts per million) in Germany.

FlurAbsorb Mount
art. no. 26098

Room contamination values of 0.0 ppm to a maximum of 1.2 ppm were measured during the use of the AnaConDa (carried out as part of studies) which are well below this limit.

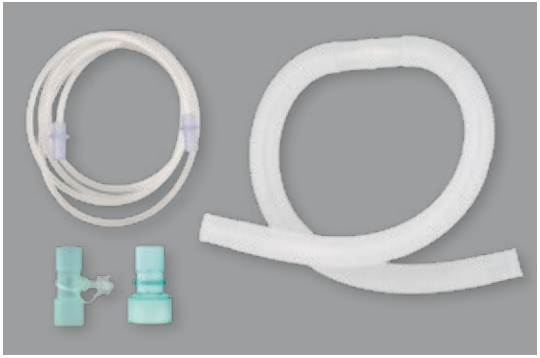
FlurAbsorb
One-Day Mount
art. no. 26099

3.5. FlurAbsorb Accessory Kit for set-up

To enable connection of FlurAbsorb to various critical care ventilators, SEDANA MEDICAL offers an accessory kit consisting of the following:

- 22 mm flexible tube (for connecting the anaesthetic gas filter to the ventilator)
- 8 mm silicone O_2-connecting tube (side-stream gas monitor and anaesthetic gas filter)
- 30F/22M adapter connector (e.g. for Hamilton, Maquet, GE ventilators)
- 22F/22M adapter with side outlet for the simultaneous diversion of exhaled air and waste air from the anaesthetic gas monitor (side-stream measurement) into the residual gas filter

An additional 22M/22M adapter is required for adaptation to the Salvia ventilator Elisa 600/800.



Art. no. 26072

3.6 AnaConDa and accessories

AnaConDa
art. no. 26100

AnaConDa-S
art. no. 26050

AnaConDa Syringe
art. no. 26022

FlurAbsorb Filter
art. no. 26096

FlurAbsorb
One-Day
Filter
art. no. 26094

FlurAbsorb Mount
art. no. 26098
One-Day Mount
art. no. 26099 <

FlurAbsorb
Accessory Kit
art. no. 26072

Filling Adapter
isoflurane/
sevoflurane
(standard screw
top bottles)
art. no. 26064

Filling Adapter
Sevorane QuikFil™
Bottles
Make Abbvie
art. no. 26042

AnaConDa Gas
Sampling Line
art. no. 26055

Nafion Dryer Tubing
art. no. 26053

Optional:
Water Trap for
Philips G7m, Dräger
Vamos 2 or Scio
art. no. 26082

4. Practical set-up in brief

1. Prepare gas monitor: Switch on and perform self-test/ calibration.
2. Set up residual gas elimination (passive or active residual gas elimination).
3. Remove the AnaConDa from the packaging.
4. Remove the red protective cap from the AnaConDa (patient side) and connect anaesthetic gas measurement:
   a) **Side-stream measurement**
      Connect the gas sampling line to the AnaConDa sampling port.
      Optionally, connect a Nafion line between the sampling line and the sampling port.
      ➜ This reduces condensate in the water trap.
      Connect the other end of the gas sampling line to the anaesthetic gas monitor (connect at the water trap).
   b) **Main-stream measurement**
      Close the AnaConDa gas sampling port.
      Attach the measuring adapter with the sensor to the AnaConDa on the patient side.
5. Connect the AnaConDa in the ventilator breathing circuit between the patient and the Y-piece. Position the AnaConDa black side up, at a 45 degree angle to the patient (do not use any additional bacterial/viral filter or HME; tube extensions can be used).
6. Attach the correct filling adaptor to the anaesthetic agent bottle of isoflurane or sevoflurane.
7. Remove the AnaConDa Syringe from the packaging (approx. 10 ml of air may aspirate when a new bottle is used), and screw the syringe onto the filling adapter by pressing and turning it until it is secure.

8. Turn the bottle upside down and draw liquid anaesthetic gas into the syringe (carefully/slowly move the syringe plunger back and forth several times).
9. Unscrew the syringe from the bottle:
   - ➜ Hold the syringe and bottle horizontal and unscrew syringe or
   - ➜ Turn the bottle with syringe upright again and place on a firm surface. Wait a few seconds for the pressure to equalise before unscrewing the syringe from the filling adapter. Remove any air from the syringe and then seal it with the cap.
10. Insert the syringe into the syringe pump.
11. Connect the anaesthetic agent line to the syringe.
12. Fill the anaesthetic agent line with a bolus of 1.5 ml via the syringe pump (1.5 ml is given during initial set-up of the AnaConDa; during replacement of an already connected AnaConDa a bolus of only 1.2 ml is added to fill the anaesthetic agent line).

Use of syringe pumps with programmable bolus rates is highly recommended in order to prevent overdosing. In the case of nonprogrammable syringe pumps, the exact bolus quantity must be administered slowly and carefully (optionally, set a slow pump rate). It is recommended to administer maximum boli of 0.2–0.5 ml to avoid overdosing. The bolus can be used multiple times if required.

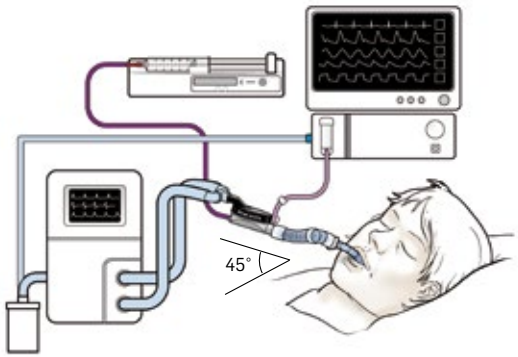
13. When anaesthetic gas has reached the AnaConDa and has been inhaled by the patient, the gas monitor will display an Fet or equivalent MAC value above zero.
14. Start the syringe pump:
    - ➜ Isoflurane 3 ml/h
    - ➜ Sevoflurane 5 ml/h

! These values are sample/empirical values. Differing pump rates (lower or higher pump rates) are possible and may also be necessary.

! Pay close attention to the haemodynamics and if necessary choose a lower bolus for the filling of the anaesthetic agent line along with a lower initial pump rate.

TIP

Use only uncooled, volatile anaesthetic at room temperature. Avoid unnecessary manipulation (e.g. shaking) of the bottle (volatile anaesthetic). Avoid heat sources, which affect the stability of volatile anaesthetics.



Schematic of the clinical set-up (see also page 63)

5. Detailed practical instructions

Preparation of all necessary components:

- AnaConDa
- AnaConDa Syringe
- Anaesthetic gas scavenging system and suitable accessories for connection to the ventilator (or where appropriate active residual gas elimination)
- Room temperature anaesthetic gas (isoflurane or sevoflurane)
- Filling adapter for standard screw top bottles or Abbvie Sevorane QuikFil™
- Anaesthetic gas monitor (side-stream measurement with gas sampling line, where appropriate additional Nafion line)
- Syringe pump programmed for Becton Dickinson Plastipak/ Sherwood Monoject 50, 50/60 or 60ml syringes

! Connect the gas monitor to a power source. If necessary, perform a self-test/calibration.

5.1 Set up of the FlurAbsorb gas scavenging filter with the critical care ventilator

1. Connect the FlurAbsorb mount to a standard rail of the ventilator or near the ventilator exhaust.

2. Place the FlurAbsorb filter in the mount and remove the protective cap.

3. With side-stream measurement, use the accessory kit components:
   Attach the 22F/22M adaptor from the accessory kit to the residual gas inlet connector on the top of the FlurAbsorb.
   Attach the 22 mm flexible tube to the adapter. Attach the 8 mm tube to the side outlet of the adapter.

4. Attach the other end of the 8 mm tube to the anaesthetic gas monitor exhaust (if necessary, cut the vinyl connector for better grip).

Exhaust Dräger Vamos

Exhaust Philips G7m

Dräger V500

Salvia Elisa 600/800

Hamilton Galileo/G5/S1

Maquet Servo-U™ / Servo-i™

5. Attach the end of the 22 mm flexible tube to the ventilator exhaust. For Dräger ventilators, simply push the 22 mm tube over the flow sensor of the ventilator.

   For Salvia ventilators, fit another 22M/22M adapter to the 22 mm flexible tube.

For Maquet, GE and Hamilton ventilators (Galileo; G5 and S1), the 30F/22M adapter from the accessory kit is also required. This is pushed over the ventilator outlet.

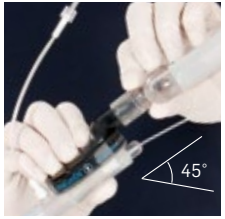
These ventilators may require a selftest and calibration.

5.2 AnaConDa set-up

1. Remove the AnaConDa from the packaging.

2. Remove the red protective cap from the AnaConDa. If side-stream anaesthetic gas measurement is being used, screw the gas sampling line onto the gas sampling port of the AnaConDa.
   Use of an additional Nafion line between the AnaConDa and the gas sampling line reduces the accumulation of condensate in the water trap. Screw the other end of the gas sampling line to the anaesthetic gas monitor.

3. Insert the AnaConDa in the ventilator breathing circuit between the patient and the Y-piece.
   Position the AnaConDa black side up, at a 45 degree angle to the patient as shown. This will prevent excess condensation entering the sampling line which may lead to more frequent filling of the water trap and / or incorrect measurement of gas concentration. It will also prevent any risk of occlusion to the bacterial filter.



5.3 Filling and insertion of the syringe

1. Select correct SEDANA MEDICAL filling adaptor. (standard screw top REF26064 or Sevorane Abbvie QuikFil™ REF26042).

   Screw the appropriate filling adapter onto the bottle (adapters can be left on the bottle until it is empty).
   An integrated non-return valve in the filling adapter prevents the escape of volatile anaesthetic.

2. Remove the syringe from the packaging and screw it firmly onto the filling adapter while pressing and turning it until it is secure (if the bottle is full, 5–10 ml of air can be aspirated into the syringe to facilitate filling).

3. Turn the bottle upside down and fill the syringe with liquid anaesthetic agent. To do this, carefully move the syringe plunger back and forth (5–10 times), which helps to prevent leaks and avoid over/under pressure in the bottle.

4. After filling, disconnect the syringe as follows:
   - ➜ Hold the syringe and bottle horizontal and unscrew the syringe from the filling adaptor

   or

   - ➜ Turn the bottle with syringe upright again and place on a firm surface. Wait to the count of four seconds for the pressure in the bottle to equalise (syringe plunger no longer moves), before unscrewing the syringer.

5. Screw the syringe cap 3/4 of the way onto the syringe and bleed the syringe.

6. Following this screw the syringe cap onto the syringe fully.

7. Insert the syringe in the syringe pump programmed for AnaConDa Syringes.

5.4 Priming the AnaConDa

1. Insert the syringe in the syringe pump. Unscrew the syringe cap from the syringe. Firmly screw the AnaConDa anaesthetic agent line on to the syringe (in the syringe pump). Do not over-screw.

2. To fill the anaesthetic agent line and the evaporator, administer a bolus of exactly 1.5 ml.

   Note:
   The anaesthetic agent line uses exactly 1.2 ml. During initial set-up, in addition to the quantity for the anaesthetic agent line, a quantity of 0.3 ml is used to administer an initial amount of anaesthetic gas to the patient.

! Avoid overdosing. A smaller primary bolus (e.g. 1.2 ml) must be used for haemodynamically unstable patients.

3. When anaesthetic gas has reached the AnaConDa and has been inhaled and exhaled by the patient, the gas monitor will display an Fet% or equivalent MAC value greater than zero.

   Start the syringe pump at an initial dose of:
   - ➔ 3 ml/h isoflurane or
   - ➔ 5 ml/h sevoflurane

! These values are sample/empirical values. Pump rates may differ. Pay attention to haemodynamics and choose a lower starting pump rate if necessary.

4. The pump rate must be adjusted according to clinical needs.

5. Average syringe pump pump rates:

Isoflurane 2–7 ml/h

Sevoflurane 4–10 ml/h

} Pump rates may be below/above this

Average end tidal concentration (Fet%):

Isoflurane Fet% 0.2–0.6

Sevoflurane Fet% 0.5–1.0

} Concentrations may be below/above this

- ➜ Usually corresponds to a MAC of ¼ – ½
- ➜ Fet% and MAC values may be above or below as required

! The given values above are guide values only. Dose should be adjusted based on the clinical evaluation of the patient. The dose must be evaluated and adapted for each patient (possibly using Ramsay or RASS scoring system or BIS, Sedline Root Masimo or Narcotrend monitoring aids).

5.5 Dosage

Anaesthetic level is monitored according to the FET% (end tidal gas concentration) or equivalent MAC value, as displayed on the gas monitor. This is done by adjusting the syringe pump rate of ml/h.

The following table can be used as a guide for possible concentrations at corresponding syringe pump rates

Volatile anaesthetic	Syringe pump rate	End tidal concentration
Isoflurane	2-7 ml/h	Fet% 0.2-0.6
Sevoflurane	4-10 ml/h	Fet% 0.5-1.0

Lower or higher pump rates have been shown to be sufficient in clinical practice.

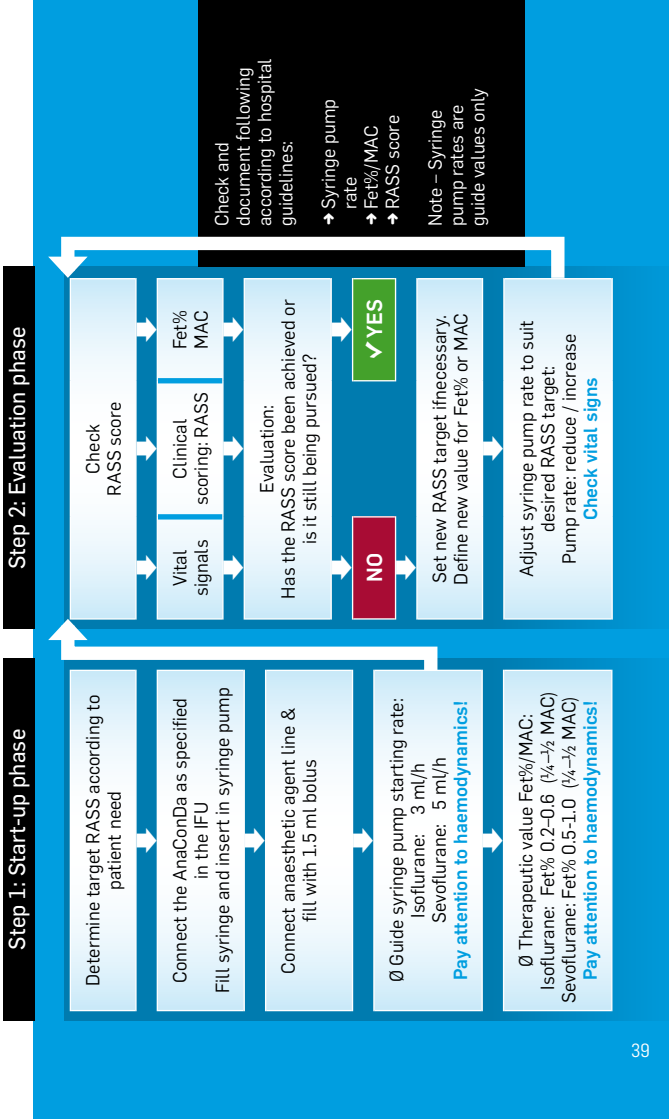
Dosage must be individually titrated for each patient. Once the intended anaesthesia level has been reached, another adjustment should be made within the first hour of use by administering a bolus (0.2–0.5 ml depending on the patient's clinical condition) or modifying the syringe pump rate to increase or reduce the level of anaesthesia.

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

Bolus administration is possible after the haemodynamics have been determined and the patient's circulatory reaction to the volatile anaesthetic has been considered.
However, very low boli of 0.2–0.5 ml should always be administered here and, if necessary, this bolus should be repeated.

When changing respiratory settings, it may be necessary to adjust the syringe pump rate accordingly (increase or decrease the pump rate). Practice has shown that only minor adaptations are required during daily operation, except during the weaning phase.
Almost all ventilation modes are possible with the AnaConDa. There are no constant adjustments that need to made. Correspondingly, if the minute volume (MV) is increased, the syringe pump rate must also be increased (and vice versa).

5.6 Schematic sequence of the set-up



6. Practical handling of the AnaConDa

6.1 Change of syringe

Syringes are changed as necessary (empty syringe). Only the AnaConDa Syringe may be used.

1. Fill a new AnaConDa Syringe with the same anaesthetic gas as previously used (isoflurane or sevoflurane).
2. Stop the syringe pump.
3. Disconnect the AnaConDa anaesthetic agent line from the empty syringe.
4. Remove the empty, used syringe from the syringe pump.
5. Insert the new, filled syringe into the syringe pump.
6. Connect the AnaConDa anaesthetic agent line to the new syringe.
7. Start the syringe pump at the same rate as previously set.

! Used syringes can be closed with the cap and disposed of with general hospital waste. The syringes are single-use.

! Do not kink the anaesthetic agent line or place any clamps on the line. Pinching and kinking may damage or destroy the anaesthetic agent line. The anaesthetic agent line connector contains a non-return valve which prevents anaesthetic agent from escaping.

6.2 Replacing the AnaConDa

AnaConDa is a single-patient medical device.

The AnaConDa is replaced every 24 hours (designed for 24-hour use). If the user deviates from this replacement interval, SEDANA MEDICAL cannot accept liability for any malfunctions.

1. Prepare a new AnaConDa (open the blister pack containing the AnaConDa).
2. Stop the syringe pump.
3. Disconnect the AnaConDa anaesthetic agent line from the syringe.
4. Close the syringe with the cap.
   If necessary (if syringe is empty), prepare a new syringe (see 6.1).
5. If side-flow measurement is being used, detach the gas sampling line from the AnaConDa currently in use (on the patient) and seal the AnaConDa gas sampling port with the sampling port stopper.
6. Connect the gas sampling line to the new AnaConDa (switch to a new gas sampling line/Nafion Dryer Tubing if necessary).
7. Remove the used AnaConDa from the ventilator breathing circuit. First disconnect on the ventilator side (Y-piece) and then on the patient side.
8. Install the new AnaConDa between the Y-piece and patient.
9. Connect the anaesthetic agent line of the new AnaConDa to the syringe.
10. Bleed the anaesthetic agent line with a new 1.2 ml bolus.

The used AnaConDa can be disposed of with general hospital waste. Syringes that are no longer needed but are not completely empty (20–30 ml remaining volume) must be closed with the cap and can also be disposed of with the general hospital waste.

Please contact your waste manager if you have any questions about disposal.

6.3 AnaConDa disconnection/connection

! Always stop the syringe pump before disconnecting the AnaConDa.

The AnaConDa only releases anaesthetic gas on the patient side during the inspiratory flow.

- ➜ Disconnection: Always disconnect the AnaConDa at the Y-piece first and then from the patient side.
- ➜ Connection: Always connect the AnaConDa on the patient side first and then at the Y-piece.

6.4 Ending and interrupting AnaConDa therapy

There are a number of different alternatives and approaches available when it comes to interrupting or ending the AnaConDa therapy (anaesthetic gas supply). These range from gradual stopping of therapy to immediate stoppage.

Alternative 1:

Gradually decrease the anaesthetic gas supply by reducing the syringe pump rate

The syringe pump rate is reduced in stages. The anaesthetic gas concentration Fet% or MAC drops in proportion to the reduction in gas supply.

Eventually, no anaesthetic gas is supplied and the patient wakes up once the gas has been exhaled.

e.g. WEANING:

During weaning after prolonged ventilation, a process of varying between higher and lower syringe pump rates can be used for training to rebreathe independently and the recovery phase, causing a variation in the Fet% or MAC value.

Alternative 2:

Stop the syringe pump and leave AnaConDa in place.

When the syringe pump is stopped, the anaesthetic gas is reflected from the AnaConDa for approximately 15 to 20 minutes. In special cases such as morbid obesity, prolonged supply of anaesthetic gas or in patients with small minute volume, the wake-up time may take from 1hr to several hours. Check the Fet% or MAC displayed on the gas monitor. If a Fet% or MAC value is still displayed, patient wake up time may be delayed.

Alternative 3:

Stop the syringe pump and remove AnaConDa

Stopping the syringe pump and removing the AnaConDa (plus possibly fitting an HME bacterial/viral filter with gas sampling port for further measurement of Fet% and/ or MAC concentration) will cause the Fet% or MAC value to drop rapidly. Wake-up occurs very quickly. Exceptions for quick wake-up are already described in alternative 2.

➜ **Recommendation from SEDANA MEDICAL**

To reduce or prevent agitation when the aim is to wake the patient quickly, the syringe pump can be stopped a few minutes (15–45 minutes) before the scheduled wake-up attempt. The gas monitor measures the concentration, and the decreasing Fet% or MAC is assessed. If the patient does not wake up at the defined time, the AnaConDa is removed.

➜ Wake-up is slower and more gentle.

6.5 Patient transport with AnaConDa

Due to the outstanding and unique reflector properties of the AnaConDa, patient transport of several minutes (20–25 minutes) can be carried out with a connected AnaConDa dispite disconnection from or stopping of the syringe pump. A drop in concentration will occur very slowly. No additional technology is required to carry out a short patient transport. This is a unique characteristic of the AnaConDa.

Prior to transport and under close monitoring of haemodynamics, a small bolus (0.2–0.5 ml depending on the anaesthetic gas used) can be administered, which will lead to longer maintenance of the concentration. This is at the discretion of the physician. Some transport monitors allow the use of gas modules so that anaesthetic gas measurement is possible during patient transport.

! NB! Pay attention to haemodynamics when administering the bolus

Procedure for patient transport

➜ Stop the syringe pump and gas monitor.
➜ Disconnect the anaesthetic agent line (non-return valve on the anaesthetic agent line prevents anaesthetic agent leakage).
➜ Do not clamp or kink the line.
➜ Close the syringe with the cap.
➜ Disconnect the gas sampling line from the AnaConDa, and close the sampling port with the sampling port plug.
➜ Patient transport is then carried out with AnaConda in place.

6.6 Short-term increase in concentration

If a short-term increase in concentration is required, e.g. for care measures, this can be administered using the bolus function of the syringe pump (NB! Pay attention to haemodynamics when administering the bolus to prevent overdosing). Any bolus administered should be a maximum of 0.2 ml–0.5 ml. If the bolus is not sufficient, it can be re-administered until the desired effect is achieved

! NB! Pay attention to haemodynamics when administering the bolus

6.7 Endotracheal suctioning

Several alternatives are available for endotracheal suctioning:
- ➜ Use of a closed suctioning system
- ➜ Suctioning via the bronchoscopy cap of an angle connector
- ➜ Press the O_2-button/pre-oxygenation on the ventilator. The ventilator will stop automatically upon disconnection of the tubing. Endotracheal suctioning can then be performed.

6.8 Bronchoscopy

If a bronchoscopy is necessary, a small bolus of anaesthetic gas can be administered in advance (if required) via the syringe pump (0.2 ml–0.5 ml)

6.9.1 Nebulisation

The use of nebulisers is possible with the AnaConDa.

Nebulisers are always inserted between the AnaConDa and the patient. Ultrasonic nebulisers do not have any effect on the end tidal gas concentration.
Jet air nebulisers require up to 8 litres of compressed air flow, which can lead to a decrease in the end tidal concentration (Fet%). The syringe pump rate or the concentration may need to be adjusted as a result.

! Always contact the nebuliser manufacturer for information on conformity and material compatibility.

6.9.2 Active humidification

The AnaConDa is an extremely effective passive heat and moisture exchanger (HME). It also contains a hydrophobic bacterial-viral filter. Supply of moisture from an active humidifier, would result in occlusion/blockage of this filter.

Active respiratory gas humidification is therefore contraindicated when using the AnaConDa system.
Active respiratory gas humidification leads to difficulties in factors such as ventilation pressure

7. Warnings, notes, tips and tricks

7.1 Warnings

- ➜ Only use anaesthetic at room temperature (isoflurane or sevoflurane only)
- ➜ Avoid overdosing through use of incorrect boli
- ➜ Programmable syringe pumps are preferable
- ➜ Program the syringe pump to administer the bolus at a slow rate
- ➜ Do not prime the agent line manually; always use the syringe pump
- ➜ Never seal the connector on the ventilator side except at disposal of the AnaConDa
- ➜ Always stop the syringe pump before disconnecting the AnaConDa
- ➜ AnaConDa is a 24-hour single-patient product – Single-use only

- Active respiratory gas humidification is contraindicated with the Anaconda
- Do not use desflurane
- Do not reconnect a used AnaConDa that has been disconnected and unattended for any reason for any length of time. Always use a new one
- Do not use an AnaConDa if the integrity of the Package is breached or if packaging is visibly damaged
- Position the patient side connector of the AnaConDa lower than the machine side to avoid accumulation of condensate, with the black face uppermost
- Do not use the bolus or flush function on the syringe pump unless programmed according to hospital protocol
- Do not fold or clamp the agent line
- Do not use AnaConDa with jet oscillation ventilation
- Do not use AnaConDa on patients with copious secretions
- Re-processing of medical devices intended for single use only may result in degraded performance or a loss of functionality e.g resistance to breathing might increase. This product is not designed to be cleaned, disinfected or sterilized.

! Do not use devices or components made from polycarbonate or polystyrene on the patient side when using the AnaConDa, (some nebulisers and connectors contain polycarbonate). Where necessary, specific replacement intervals must be followed. Always follow the manufacturer's instructions or ask the manufacturer about the suitability of their product for use with volatile anaesthetics.

7.2 Notes

- Program the syringe pump to settings for Becton Dickinson Plastipak/Sherwood Monoject 50, 50/60 or 60ml syringes.
- Set the syringe pump to maximum alarm tolerance (cut-off pressure set to maximum).
- Always set a slow pump rate for bolus administration with the syringe pump.
- If necessary remove air bubbles or gas bubbles from the syringe.
- Position the AnaConDa with the black side facing up at a 45 degree angle.
- Leave the filling adapter on the anaesthetic gas bottle until it is empty. Repeatedly screwing on and off could cause leakage.
- AnaConDa has a dead space of 100 ml.
  AnaConDa-S has a dead space of 50 ml.
  Ventilation parameters may need to be adjusted to account for the additional dead space.
- If the CO_2 level increases, the ventilation parameters must be adjusted accordingly.
- Always connect any nebuliser between the AnaConDa and the patient.
- Modifying the breathing gas flow (ventilation parameters, compressed air nebuliser) impacts the end tidal gas concentration (Fet%).
- Always disconnect the AnaConDa from the Y-Piece (ventilator side) first.
- The AnaConDa is an excellent HME (heat and moisture exchanger).
- Remove accumulated condensate on the patient side regularly.

➜ There may be various reasons for incorrect or fluctuating gas monitor values (spontaneous breathing, moisture in the gas sampling line, change in the position of the AnaConDa, e.g. patient in Roto Rest bed).

7.3 Tips and tricks

What is the working tidal volume range of the AnaConDa?

The dead space of 100 ml/50 ml limits the use of AnaConDa technology. We therefore only recommend use in patients from a tidal volume of Vt >350 ml for the AnaConDa and Vt >200 ml for the AnaConDa-S.

What happens when the black side of the AnaConDa is positioned upside down or at a downward angle pointing towards the Y-piece?

It is important that the AnaConDa is positioned black side up and at a 45 degree angle. Otherwise this could lead to excess condensation entering the sampling line which may lead to more frequent changing of the water trap and / or incorrect measurement of gas concentration, in extreme situations. Correct positioning will also prevent any risk of occlusion to the bacterial filter.

What gas sampling line should be used?

Always use the sampling line recommended for the gas monitor, such as the gas sampling line available from SEDANA MEDICAL. Incorrect lengths and types could affect the measured values. A special Nafion line (semipermeable membrane) can reduce the accumulation of condensate in the water trap.

Why is the end tidal volume (Fet) value higher than the inspiratory value (Fi) when using the AnaConDa?

Gas administration using the AnaConDa differs slightly to the constant gas flow of the anaesthesia machine (vaporiser technology). The highest gas concentration occurs at the start of the inspiration cycle when the recycled gas is mixed with the fresh gas from the AnaConDa evaporator. However this represents a short peak and the concentration decreases rapidly to its lowest point at the end of inspiration. Most monitors show a Fi value which is measured at the end of inspiration thus showing a low value when using the AnaConDa. The Fet value which is measured at the end of expiration represents the alveolar concentration and is therefore the correct value to use.

Wide fluctuations in CO_2 values occurring?

If a side-stream monitor is used, check whether there is water in the line. Check whether the water trap is full. Remove any condensation.

Error message INOP showing on the gas monitor!

The error message **INOP** may be shown on the display if there is condensate in the gas sampling line or water trap, or if the gas return tube is kinked (return tube on the gas monitor). Refer to checklist below.

Troubleshooting

➜ Remove condensate from the gas sampling line.
➜ Remove condensate from the water trap.
➜ Replace the water trap.
➜ Remove kinks from the gas return tube.
➜ Perform manual gas monitor calibration.

7.4 Replacement intervals

AnaConDa and AnaConDa-S
The AnaConDa is a 24-hour, single-patient product and must be replaced daily.

AnaConDa Syringe
The AnaConDa Syringe is a single-use syringe. The syringe is not intended or approved for multiple uses.

Nafion Dryer Tubing
The Nafion line can be left in place throughout the patient's therapy. Standard practice is replacement every 2–7 days.
Adhere to the hygiene regulations in place at the hospital.

Anaesthetic gas sampling line
The anaesthetic gas sampling line is replaced as needed in accordance with hospital hygiene regulations (1–7 days).

Water traps for Dräger and Philips
When used with AnaConDa water traps are a single patient product (according to the manufacturer, maximum 4 weeks of continuous use). If you have any questions, please contact the gas monitor manufacturer.

FlurAbsorb One-Day
FlurAbsorb One-Day is designed for single patient use lasting up to max. 24 hours

FlurAbsorb
FlurAbsorb has a capacity of 400 g.
When this limit is reached, the filter must be replaced.
The filter can be used for multiple patients.

FlurAbsorb Accessory Kit
Single patient use.

8. Disposal

All AnaConDa products should be disposed of according to the individual hospital waste guidelines. The below products can be disposed of with general hospital waste.

- AnaConDa and AnaConDa-S
- AnaConDa Syringes (including syringes with a residual anaesthetic gas content of 20–30 ml)
- Nafion Dryer Tubing
- Gas sampling line
- Water trap
- FlurAbsorb and FlurAbsorb Accessory Kit

We recommend that syringes with larger amounts of residual anaesthetic gas (> 30 ml) be disposed of with the special waste of the hospital. Containers for this purpose are usually available in the hospital.

9. Ramsay and RASS scoring systems

Ramsay Sedation Scale

Score	Description	Assessment
0	Awake, oriented	Awake
1	Agitated, anxious or restless	Too shallow
2	Awake, cooperative, accepting ventilation	Adequate
3	Asleep but cooperative (opens eyes in response to loud noise or touch)	Adequate
4	Deep sedation (does not open eyes in response to loud noise or touch, but reacts immediately to pain stimuli)	Adequate
5	Anaesthesia (slow pain reaction to pain stimuli)	Deep
6	Deep coma (no reaction to pain stimuli)	Too deep

Richmond Agitation Sedation Scale (RASS)

Score	Designation	Description
+4	Combative	Combative or aggressive, immediate danger to staff
+3	Very agitated	Pulls or removes tubes, catheters, etc. or behaves aggressively with staff
+2	Agitated	Regular undirected movements or ventilation/breathing unsynchronised with the ventilator
+1	Restless	Anxious, but movements are not aggressive or strong
0	Alert and calm	
-1	Drowsy	Not fully awake, but with persistent awake phase; direct eye contact in response to voice
-2	Light sedation	Brief (less than 10 sec. continuous) awake phase with eye contact in response to voice
-3	Moderate sedation	Movement in response to voice but no eye contact
-4	Deep sedation	No reaction to voice, but movement in response to physical stimuli
-5	Unarousable sedation	No reaction to voice or physical stimuli

Of all drugs used in agitated, mechanically ventilated patients, only volatile anaesthetics allow the measurement of drug levels through the use of anaesthetic gas monitoring. The main focus of this approach is not target- controlled application that once set is complete, but rather an individual demand-/patient-oriented therapy.

Malignant hyperthermia as a complication when using volatile anaesthetics

A major complication that may occur in the context of the administration of volatile anaesthetics is the induction of malignant hyperthermia. This relates to an autosomal-dominantly inherited pharmacogenetic disease of the skeletal muscles which can also be triggered by, among other things, volatile anaesthetics in predisposed patients. Within a few minutes to several hours, life-threatening skeletal muscle hypermetabolism may develop through uncontrolled sarcoplasmic calcium release through functionally altered calcium channels, initially manifested by cardiac arrhythmias, cellular hypoxia, hypercapnia, muscular rigidity, and combined metabolic-respiratory acidosis and hyperkalaemia. The eponymous hyperthermia is often a late symptom. If a malignant hyperthermia crisis is suspected, the immediate initiation of appropriate therapeutic measures (immediate stop of trigger substance supply as well as the application of dantrolene) is crucial.

Centre for Malignant Hyperthermia: Prof. Dr. F. Schuster, Dr. S. Department of Anaesthesia and Critical Care, Centre for Operative Medicine
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List of materials

Product/component	Material	Residue after incineration
AnaConDa / AnaConDa-S		
Housing	Polypropylene	CO_2, H_2O
Evaporator	Polypropylene	CO_2, H_2O
Carbon filter	Carbon	CO_2
Bacterial and viral filter	Polypropylene	CO_2, H_2O
Line	Polypropylene	CO_2, H_2O
Line connector	Polypropylene	CO_2, H_2O
Hot glue	Olefin copolymer	CO_2, H_2O
Luer lock	Polypropylene	CO_2, H_2O
Sealing plug/cap	Polycarbonate	CO_2, H_2O
Adhesive label	Polypropylene	CO_2, H_2O
Syringe		
Barrel	Polypropylene	CO_2, H_2O
Plunger	Polypropylene	CO_2, H_2O
Plunger ram	Rubber	CO_2
Adhesive medium	Acrylic U.V.	CO_2, H_2O
Lubricant	Silicone	SiO_2
Adhesive label	Polypropylene	CO_2, H_2O
Packaging		
Cover	Polypropylene	CO_2, H_2O
Shell	Polyethylene terephthalate	CO_2, H_2O

FlurAbsorb

Housing	Polypropylene, polyester	CO_2, H_2O
Filter material	Carbon	CO_2

Product specification

Anaesthetic agent	Isoflurane or sevoflurane
Tidal volume Vt AnaConDa	Minimum 350 ml
Tidal volume Vt AnaConDa-S	Minimum 200 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
Moisture output (calc.)	30 mg/l
Moisture loss at 1.0 L x 10 breaths/min	7 mg/l
Moisture output (calc.)	29 mg/l
Bacterial filtration efficiency	99.999 %
Viral filtration efficiency	99.98 %
Dead space, AnaConDa	Approx. 100 ml
Dead space, AnaConDa-S	Approx. 50 ml
Weight, AnaConDa	50 g
Weight, AnaConDa-S	30 g
Connector as per ISO 5356	15F/22M - 15M
Gas sampling port	Female Luer Lock
Supply line length	2200 mm

Ordering information

Description	Art. no.
AnaConDa	26100
AnaConDa-S	26050
AnaConDa Syringe, single	26022
FlurAbsorb	26096
FlurAbsorb One-Day	26094
FlurAbsorb Mount	26098
FlurAbsorb One-Day Mount	26094
FlurAbsorb Accessory Kit	26072
Filling adapter isoflurane/sevoflurane Standard screw top bottles	26064
Filling adapter for Sevorane QuickFil™ Make AbbVie	26042
AnaConDa Gas Sampling Line	26055
Nafion Dryer Tubing	26053
Water trap, Philips / Dräger	26082

Contributing authors

This is the 6th edition of the AnaConDa manual. We would like to thank the authors who contributed to the first edition, since content from this is always included in new editions.

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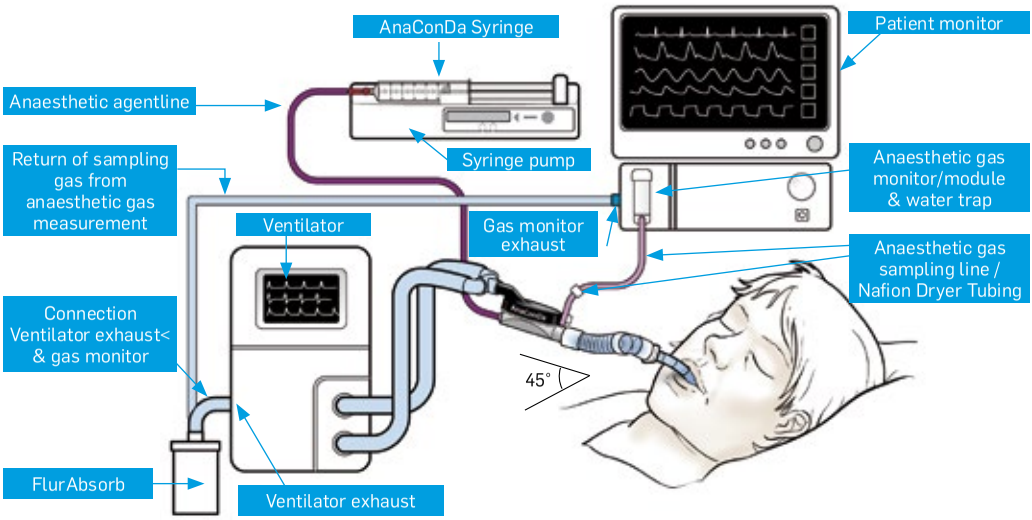
The applicable technical information from the manufacturer must be observed in relation to the use of sevoflurane or isoflurane.



Schematic sequence of the set-up

Step 1: Start-up phase

Determine target RASS according to patient need

Connect the AnaConDa as specified in the IFU
Fill syringe and insert in syringe pump

Connect anaesthetic agent line & fill with 1.5 ml bolus

Ø Guide syringe pump starting rate:
Isoflurane: 3 ml/h
Sevoflurane: 5 ml/h
Pay attention to haemodynamics!

Ø Therapeutic value Fet%/MAC:
Isoflurane: Fet% 0.2–0.6 (¼–½ MAC)
Sevoflurane: Fet% 0.5-1.0 (¼–½ MAC)
Pay attention to haemodynamics!

Step 2: Evaluation phase

Check RASS score

Vital signals | Clinical scoring: RASS | Fet% MAC

Evaluation:
Has the RASS score been achieved or is it still being pursued?

NO / **✓ YES**

Set new RASS target ifnecessary.
Define new value for Fet% or MAC

Adjust syringe pump rate to suit desired RASS target:
Pump rate: reduce / increase
Check vital signs

Check and document following according to hospital guidelines:

- ➔ Syringe pump rate
- ➔ Fet%/MAC
- ➔ RASS score

Note – Syringe pump rates are guide values only

SEDANAMEDICAL

the AnaConDa technology people

www.sedanamedical.com