

1. INTENDED USE

AnaConDa (Anaesthetic Conserving Device) is intended for administering isoflurane and sevoflurane to invasively ventilated patients.

Administration of isoflurane and sevoflurane using AnaConDa should only be done in a setting fully equipped for the monitoring and support of respiratory and cardiovascular function and by persons specifically trained in the use of inhalational anaesthetic drugs and the recognition and management of the expected adverse effects of such drugs, including respiratory and cardiac resuscitation. Such training must include the establishment and maintenance of a patent airway and assisted ventilation.

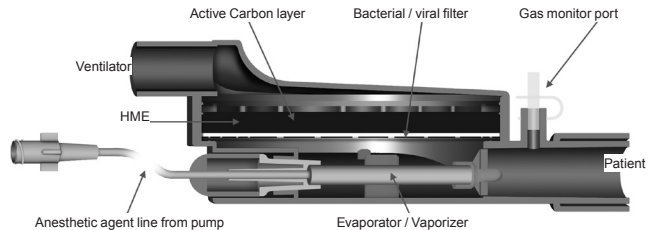
The AnaConDa is intended for single use only and needs to be replaced every 24 hours or when needed e.g. at unexpected events such as sudden blockage of the airways because of secretion etc.

The AnaConDa is available in AnaConDa 100 ml (AnaConDa) and AnaConDa 50 ml (AnaConDa-S) sizes. The instructions contained in this document apply to both devices.

2. PRINCIPLES OF OPERATION

The AnaConDa consists of a plastic housing with an agent line for the continuous delivery of isoflurane or sevoflurane from a syringe pump to the miniature vaporizer where any clinical dosage is immediately vaporized. During continued breathing the volatile anaesthetic agent is re-circulated through the reflector consisting of an active carbon filter. The dead space of 100ml or 50ml needs to be considered for all patients and CO₂ needs to be carefully monitored. Adjustments to CO₂ can be achieved by optimising the ventilator parameters. In addition the AnaConDa is an excellent heat- and moisture exchanger and it includes an efficient bacterial/ viral filter.

Cross Section Drawing of the AnaConDa



3. IMPORTANT USER INFORMATION

3.1 Carefully read these instructions before using AnaConDa and note the following GENERAL WARNINGS

- Do not use desflurane
- Do not re-connect a used AnaConDa that has been disconnected and unattended for any reason for any length of time. Always use a new one
- Only use room temperature isoflurane or sevoflurane
- Do not use an AnaConDa if the integrity of the package is breached or if packaging is visibly damaged
- Always stop the syringe pump if disconnecting the AnaConDa
- Do not prime the agent line manually. Always use the syringe pump
- 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 or oscillation ventilation
- Do not use active humidification together with AnaConDa
- 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
- Never seal the connector on the ventilator side except at disposal of AnaConDa
- Isoflurane and sevoflurane are approved for general anaesthesia in the Operating Room but are not approved for use in the Intensive Care Unit
- Always consider the dead space of the device vs tidal volume when ventilating the patient and carefully monitor CO₂ at Gas Monitor

3.2 SYMBOLS

Symbol	Description		
WARNING!	Indicates a condition which if not followed exactly may cause harm to patient or a user. Do not proceed until the instructions are clearly understood and all stated conditions are met.		
CAUTION!	Indicates a condition, which if not followed exactly may cause harm to the product or equipment. Do not proceed until the instructions are clearly understood and all stated conditions are met.		
NOTE!	Indicates information important for optimal use of the product.		
	For single use only.		Not for IV use.
	Read the Instruction for Use carefully before use.		
	Replace every 24 hours.		

4. ADDITIONAL EQUIPMENT REQUIRED (FIG 1)

Only medical devices which bear the CE mark and which comply with its applicable international standards, may be used. AnaConDa must be used with the following equipment:

- AnaConDa Syringe (REF 26022)
- Syringe pump with settings for BD Plastipac or Monoject Sherwood 50 ml syringes

- Anaesthetic gas monitor, which displays concentrations of CO₂ and anaesthetic gases
- Ventilator
- Filling Adaptor (REF 26042, 26064)
- Gas scavenging system

4.1 AnaConDa Syringe

The AnaConDa syringe is the same dimension as a Becton Dickinson Plastipak or Sherwood Monoject 50ml syringe, however it also has a unique coupling to fit the connector on the agent line of the AnaConDa. There are boxes to tick on the labelling, to indicate which volatile agent is being used, Isoflurane or Sevoflurane. The syringes can be pre-filled and stored up to 5 days if stored in a dark environment at room temperature. Make sure that the syringe is safely closed.

4.2 Syringe pumps

Use only CE-labeled syringe pumps, which comply with its applicable requirements, in particular with the specifications of standard EN 60601-2-24, and which are programmable pumps with settings for Becton Dickinson Plastipak or Sherwood Monoject 50 ml syringes.

4.3 Anaesthesia gas monitor with gas sampling line

It is mandatory to continuously monitor the anaesthetic gases with a CE-labeled gas monitor, which complies with its applicable requirements, in particular with the specifications of standard EN ISO 80601-2-55. The gas monitor must display concentrations of carbon dioxide and anaesthetic gases to be able to identify the Fet (end-expiratory) concentration, which represents the alveolar concentration. The Fi concentration should not be used. Only read the Fet value, which reflects the alveolar concentration. There are 2 types of gas monitors; side stream or mainstream; both can be used with AnaConDa.

- Side Stream Gas Monitor

When using a side stream monitor, connect the gas monitor sampling line to the gas monitor and to the AnaConDa gas monitor sampling port. With the side stream monitor, Nafion Dryer Tubing (REF 26053) can be attached between the AnaConDa and the gas sampling line

- Mainstream Gas Monitor

When using the mainstream gas monitor connect the required airway adaptor between the AnaConDa and the patient.

4.4 Ventilator

Use only CE-labeled ventilators which comply with its 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.

4.5 Filling Adaptor

For safe filling of the AnaConDa syringe the correct filling adaptor must be used. There are 2 types, one for standard threading bottles (REF 26064) and one for Sevorane (REF 26042) from AbbVie with Quik-Fil closure.

4.6 Gas scavenging system

Sedana Medical recommends scavenging the exhaust gases from the ventilator and the gas monitor.

- Passive Gas Scavenging

There is a passive scavenging system available from Sedana Medical called FlurAbsorb (REF 26096) which is used in conjunction with an accessory kit (REF 26072).

- Active Gas Scavenging

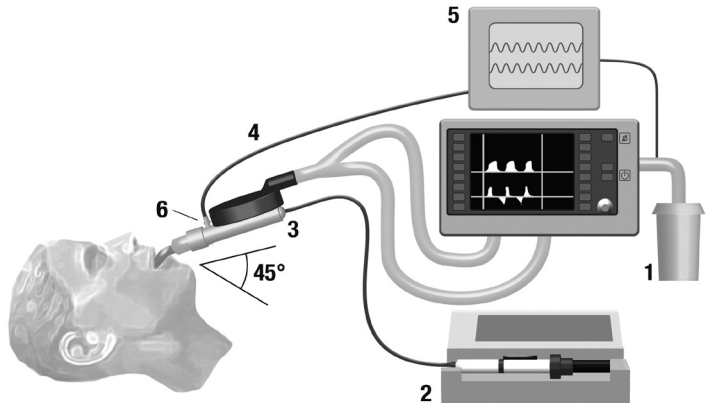
Active Gas Scavenging can be used if installed at the ICU or a central vacuum source can be used together with a pressure equalization system, which can be provided by the manufacturer of ventilators.

5. SYSTEM ASSEMBLY

5.1 Filling the AnaConDa syringe

- Attach the correct Filling Adaptor (REF 26042 or REF 26064) to the anaesthetic agent bottle
- Connect the syringe to the adaptor by pressing and turning it until it is secured
- Turn the bottle with syringe upside down
- Fill the syringe by withdrawing and pushing the plunger back and forth slowly 5-10 times
- Turn the bottle back
- Wait to the count of four of seconds for bottle to equalise before disconnecting
- Remove the syringe from the bottle ensuring that no air bubbles remain in the syringe
- Close the syringe with the syringe closure
- Note on the syringe label which anaesthetic agent is used and date of filling

Fig. 1



5.2 Set-up (Fig 1)

- Connect the exhaust from the ventilator and gas monitor to the gas scavenging system (1)
- Position the syringe in the syringe pump (2)
- Set the syringe pump at settings for BD Plastipac or Monoject Sherwood 50ml Syringes
- Position the syringe pump at or lower than the patients head

When a side stream gas monitor is used:

- Remove the red cap on the AnaConDa (3)
- Connect the gas monitor sampling line (4) to the gas monitor (5) and to the AnaConDa gas monitor sampling port (6).To reduce the amount of humidity in the line and water trap a nafion dryer tubing (REF 26053) can be attached between the AnaConDa and the gas sampling line

When a main stream gas monitor is used:

- Remove the red cap on the AnaConDa
- Connect the required airway adapter between the AnaConDa and the patient. Remove the flag from the monitor port and close the monitor port with the closure
- Connect the AnaConDa between the endotracheal tube and the Y-piece of the ventilator breathing circuits
- Position the AnaConDa as indicated in fig 1 with the gas monitor sampling port directed towards the patient
- Position the AnaConDa patient side connector lower than the machine side (as per angle in fig 1) to avoid accumulation of condensate and with black face uppermost
- Set the gas monitor for the anaesthetic agent used
- Wait for the calibration of the gas monitor to be performed
- Set appropriate alarm limits on the gas monitor
- Connect the agent supply line of the AnaConDa to the syringe and ensure it is secure

6. OPERATING

6.1 Priming the agent line

- Administer a bolus of 1,5 ml (1,5 ml when initially connecting AnaConDa, 1,2 ml when changing / replacing already connected AnaConDa)
- Stop the syringe pump and wait until the gas monitor displays a CO₂ value
- Set the clinical dosage
- Start the syringe pump (check point 6.2 below)

Alternative method:

- If the bolus function on the syringe pump has been programmed to give 0,3 – 0,5 ml then press the bolus knob the number of times required to give 1,5 ml (1,5 ml when initially connecting AnaConDa or 1,2 ml when replacing an already connected AnaConDa)
- Stop the syringe pump and wait until the gas monitor displays a CO₂ value
- Set the clinical dosage
- Start the syringe pump (check 6.2 below)

6.2 Dosing the Anaesthetic agent

All dosing is individual and guided by experienced clinical evaluation and reading of the Fet value on the gas monitor. There is a higher patient uptake of the volatile during the first 10-30 minutes (Induction Phase) of administration and therefore corrections of the pump rate need to be made according to the measured end tidal concentration (Fet) and the clinical needs of the patient. Isoflurane is approximately twice as potent as sevoflurane.

The following rates are typical for the initial syringe pump rate of Isoflurane and Sevoflurane

- Isoflurane: 3 ml/h - Sevoflurane: 5 ml/h

The syringe pump rate necessary to reach a certain patient concentration depends on the minute volume and the targeted patent concentration.

Volatile Agent	Expected Pump Rates	Resulting Fet Values
Isoflurane	2 – 7 ml/hr	0,2 – 0,7%
Sevoflurane	4 – 10 ml/hr	0,5 – 1,4%

If a rapid increase of the concentration is deemed necessary, a bolus of 0.3 ml liquid agent may be given.

At higher Fet values and/or high tidal volumes and / or high respiratory rates, the AnaConDa is less efficient. Therefore relatively more anaesthetic, and thus a higher pump rate is needed to keep the concentration stable.

6.3 Changing concentration

Any change in concentration must be titrated to the desired Fet value by changing the pump rate and closely monitoring the Fet value on the gas monitor. The Fet value should be verified following any change to the ventilator parameters.

If there is a clinical need for decreasing the Fet concentration quickly then remove the AnaConDa from the patient. Always verify any new concentration on the gas monitor.

6.4 Ending the Therapy

Immediate Cessation

1. Stop the syringe pump. The concentration will decrease rapidly
2. Disconnect the agent supply line from the AnaConDa Syringe
3. Seal the syringe with the syringe closure
4. Disconnect the gas monitor from the AnaConDa. Close the gas monitor port with the gas sampling port closure
5. Remove the AnaConDa from the patient. Disconnect from the Y-piece first
6. Consider replacing the AnaConDa with a Bacterial-/Viral filter with heat and moisture exchanger
7. Close the AnaConDa (Ventilator side) connector with the red sealing cap and dispose of it according to hospital protocol

Short Weaning Process

1. Stop the syringe pump and leave the AnaConDa in place
2. The concentration will gradually decrease
3. As the Fet value approaches 0% follow the above steps (1-7) under 'Immediate Cessation'

Prolonged Weaning

1. In the case of prolonged weaning reduce the pump rate in steps over several hours
2. The concentration will decrease
3. When it has reached a concentration level of almost 0% Fet value, follow the above steps (1-7) under 'Immediate Cessation'

6.5 Changing the AnaConDa

- Prepare a new AnaConDa, and a new filled syringe if needed (as per 5.1)
- Stop the syringe pump.
- Disconnect the agent supply line from the AnaConDa syringe and close the syringe with the syringe closure cap.
- Disconnect the gas monitor line from the AnaConDa, and close the gas sampling port with the gas sampling port closure.
- Take out the used AnaConDa. Disconnect from the Y-piece first
- Connect the gas sampling line
- Insert the new AnaConDa by connecting to the ET-tube first and then the Y-piece
- Connect the agent line to the syringe in the syringe pump
- Prime the agent line as in 6.1 with 1,2 ml
- Start the syringe pump with the same rate as before
- Check the Fet value

6.6 Changing the AnaConDa Syringe

- Stop the syringe pump
- Disconnect the agent supply line from the syringe and close the syringe with the syringe closure cap
- Remove the empty syringe from the syringe pump
- Place the new AnaConDa Syringe in the syringe pump. For filling see 4.1.
- Connect the agent supply line to the syringe
- Start the syringe pump with the same rate as before
- Do not prime the agent line unless the AnaConDa has been replaced by a new one also
- Check the Fet value

7. CONNECTING A NEBULISER TO THE ANACONDA SYSTEM

It is possible to use a jet nebuliser or ultrasonic nebuliser with the AnaConDa system. The nebuliser should be connected between the patient intubation tube and the AnaConDa. Ultrasonic nebulisers are preferable as they do not add extra airflow. If a jet nebuliser is connected it may be necessary to increase the syringe pump rate, to compensate for the extra flow from the nebuliser. When connecting a nebulizer set the ventilator on stand-by or hold an expiratory pause on the ventilator.

WARNING! Repeated nebulisations may increase the flow resistance of the AnaConDa. Pay attention to signs of occlusions.

NOTE! Always consider the increased dead space when connecting extra items.

8. SUCTIONING

- Using a closed suction system or using a swivel connector with suction port is preferable
- Hold pause on the ventilator if disconnecting AnaConDa from the ET-tube during the procedure. When disconnecting, remove the AnaConDa from the Y-piece first and when attaching, attach the AnaConDa to the ET-tube first

CAUTION! It is important to be aware that Polycarbonate based components if used in the patient breathing circuit may become degraded or undergo stress cracking in the presence of the anaesthetic gasses Isoflurane or Sevoflurane.

9. DISPOSAL

Dispose of the AnaConDa and the sealed syringe according to hospital protocols.

10. TECHNICAL INFORMATION

TECHNICAL SPECIFICATION	100 ML	50 ML
Anaesthetic Agents	Only use room temperature isoflurane or sevoflurane (Room Temp 18°-25° Celsius)	
Syringe	Only use the AnaConDa syringe REF 26022	
Stability of filled syringes	5 days	
Tidal volume working range	350 ml - 1200 ml	200 ml - 800 ml
Dead space	Approx. 100 ml	Approx. 50 ml
Resistance to gas flow at 60 l/min	2.5 cm H ₂ O (250 pa)	3.0 cm H ₂ O (300 pa)
Moisture loss	5 mg/l (@ 0.75L x 12 bpm)	5 mg/l (@ 0.5L x 15 bpm)
	7 mg/l (@ 1.0L x 10 bpm)	6 mg/l (@ 0.75L x 15 bpm)
Filter capacity:	Bacterial filtration	99.999%
	Viral Filtration	99.98%
Weight	50 g	
Agent Line Length	2.2 m	
Connectors (According to ISO 5356)	15F/22M-15M	
Gas Sampling Port	Female Luer Lock	

For further information regarding policies or procedures relating to the AnaConDa the user should refer to Technical Handbook or contact Sedana Medical AB.