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 syringe. Disconnect from the Y-piece first
6. Consider replacing the AnaConDa with a Bacterial/Viral filter with head and moisture exchange
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 5.3)
• 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 6.4 with 2.2 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 4.2
• 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 nebuliser 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 is 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 Polyvinylchloride based components if used in the patient breathing circuit may become degraded or undergo stress cracking in the presence of the anesthetic gases isoflurane or Sevoflurane.

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

10. TECHNICAL INFORMATION

Anaesthetic Agents
Only use room temperature isoflurane or sevoflurane (Room Temp. 20°C)

Syringe
Only use the AnaConDa syringe - REF 26022

Volume of filled syringes
10 ml

Total volume working range
Minimum 300 ml

AnaConDa dead space
Approx. 100 ml

Resistance to gas flow at 60 l/min
1.0 l x 10 breaths/min 7 mg/l (corresponding to 29 mg H2O/l moisture output

Moisture loss at: 0.75 l x 12 breaths/min 5 mg/l (corresponding to 30 mg H2O/l moisture output

Filter capacity: Bacterial filtration 99.999%
Viral Filtration 99.99%

Weight
50 g

Agent Line Length
2.2 m

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
3.2 SYMBOLS

3.2.1 General symbols

Function of the process: (For the definition of the symbols, see section 2.1 of the instruction for use.)

• Do not use AnaConDa on patients with copious secretions
• Do not use the bolus or flush function on the syringe pump unless programmed
• Always stop the syringe pump if disconnecting the AnaConDa
• Do not use an AnaConDa if the integrity of the package is breached or if packaging is not sealed
• Only use room temperature isoflurane or sevoflurane
• Do not re-connect a used AnaConDa that has been disconnected and unattended
• Do not use desflurane

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

• Do not use AnaConDa on patients with copious secretions
• Do not use the bolus or flush function on the syringe pump unless programmed
• Always stop the syringe pump if disconnecting the AnaConDa
• Do not use an AnaConDa if the integrity of the package is breached or if packaging is not sealed
• Only use room temperature isoflurane or sevoflurane
• Do not re-connect a used AnaConDa that has been disconnected and unattended
• Do not use desflurane

4. ADDITIONAL EQUIPMENT REQUIRED (FIG 1)

4.1 AnaConDa Syringe

The AnaConDa syringe is the same dimension as the Becton Dickenson Plastipak and Monopack 50, 50/60 or 60 ml syringes; however it also has a unique coupling to fit the connector on the agent line of the AnaConDa ventilator and is made to lock on the labelling to indicate which volatile agent is being used: Isoflurane or Sevoflurane. The syringes can be prepared and stored up to 5 days 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 the specifications of standard EN ISO 80601-2-24, and which are programmable pumps with settings for Becton Dickenson Plastipak or Monopack 50, 50/60 or 60 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 80601-2-25. The gas monitor should display concentrations of carbon dioxide and anaesthetic gases to be able to identify the FIO2 (end-expiratory) concentration, which represents the alveolar concentration. The Ti concentration should not be used. Only read the FIO2 value which reflects the alveolar concentration. There are 2 types of gas monitors; side stream or mainstream both can be used with AnaConDa.

4.4 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 Flair-Airbox (REF 26056) which is used in conjunction with an accessory kit (REF 26072).

• Active Gas Scavenging

Gas scavenging can be used if installed at the ICU or a central vacuum source can be used together with a pressure equilibrium system, which can be provided by the manufacturer of ventilator.

5. SYSTEM ASSEMBLY

5.1 Filling the AnaConDa syringe

Attach the correct Filling Adaptor (REF 26042 or REF 26084) to the anaesthetic agent bottle.

• Connect the syringe to the adapter 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 10 seconds or 1 hour for solution to equilibrate 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! Indicates information important for optimal use of the product.

For single use only.

1. Read the Instruction for Use carefully before use.
2. Not for use

5.2 Set up (Fig. 1)

• Connect the syringe 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 Plastipak or Monopack 50, 50/60 or 60 ml syringe
• Position the syringe pump at or lower than the patient

When a side stream gas monitor is used:
• Remove the red cap on the AnaConDa
• Connect the syringe pump 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 (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

When using a side stream gas monitor:
• Connect the syringe with syringe pump to the gas scavenging system (1)
• Connect the syringe pump sampling line (4) to the AnaConDa gas monitor sampling port (6) and biowire biowire with flashback
• Connect the AnaConDa between the endotracheal tube and the y-piece of the breathing circuits
• Position the LE mark and 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 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 airway supply line of the AnaConDa to the syringe and ensure it is secure

6. OPERATING THE ANAESTHETIC AGENT

6.1 Picking the anaesthetic agent

• Administer a bolus of 1.5 ml (1.5 ml when initially connecting AnaConDa, 1.2 ml when changing) replacing already connected AnaConDa

• Ensure that the gas monitor displays an FIO2 or equivalent MAC value which is above zero
• Set the clinical dosage
• Start the syringe pump (check peak 62 seconds)

Alternative method:
• If the bolus function on the syringe pump has been programmed to give 0.3 – 0.5 ml then press the bolus button the number of times required to give 1.5 ml (1.5 ml if anaesthetically intending already connected AnaConDa)
• Ensure that the gas monitor displays an FIO2 or equivalent MAC value which is above zero
• Set the clinical dosage
• Start the syringe pump (check peak 62 seconds)

6.2 Dosing the anaesthetic agent

All dosing is individual and guided by experienced clinical evaluation and reading of the FIO2 value on the gas monitor. There is a higher patient uptake of the volatile during the first 60 seconds. Introduction of high doses of isoflurane and sevoflurane can result in the patient breathing in the volatile substances. The patient can inhale too much volatile and risk local anesthetic toxicity. This can be avoided with the addition of N2O as an inhaled agent.

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 patient concentration.

Volatile Agent Expected Pump Rates Resulting Fet Values

Isoflurane: 3 – 10 ml/hr

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 (local agent may be given) in combination with/or and high tidal volumes and/or high respiratory rates, the AnaConDa is less effective. Therefore relatively more anaesthetic, and thus a higher pump rate is needed to keep the concentration stable.