sedaconda® ACD
Anaesthetic Conserving Device

# DISCOVER
# INHALED SEDATION

# Do you have the right sedation for every situation?

## In intensive care, every patient's situation is unique and there is no one-size-fits-all approach to sedation.[1-3]

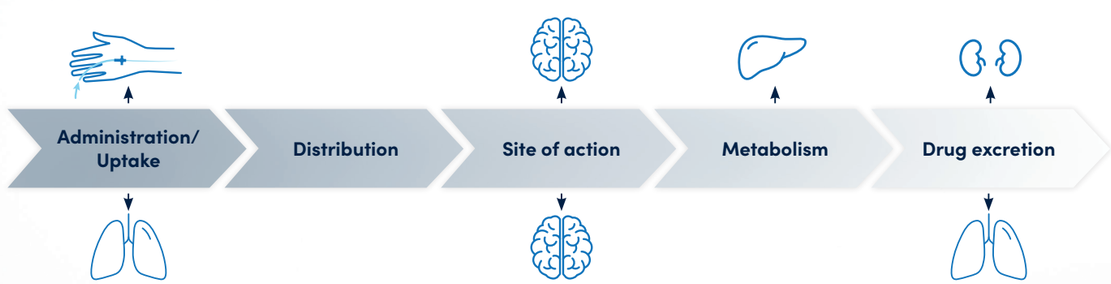
Many ICU patients receiving invasive mechanical ventilation need sedation for their comfort and safety.[1,2,4,5] The patient situation is dynamic and the sedative needs may change over the course of illness and treatment.[3,6-8] The sedation target, co-morbid conditions and current organ functions are important to consider when choosing sedative strategy and may mandate changes over time.[3] There is simply no one-size-fits-all approach to sedation.[1-3]


# Pharmacokinetics are altered in critical illness[9]

When deciding on sedative strategy, a thorough understanding of the pharmacokinetics of sedative agents is important. Critically ill patients often have dysfunction in one or more organ system and exhibit significant interindividual variation in drug elimination[9]. This may be a result of advanced age, co-morbid conditions or genetic predisposition.[10]

## Elimination of intravenous sedatives is organ-dependent

The metabolism and clearance of intravenous sedatives rely on adequate hepatic and renal function.[5] Critically ill patients often have varying degrees of impaired hepatic or renal function[9,11], contributing to a slow elimination of intravenous sedatives and a delayed emergence from sedation.[5,12]




## Elimination of inhaled sedatives is independent of hepatic or renal function[13]

Inhaled sedatives are administered via the airways and uptake is in the lungs.[13] As an example, isoflurane undergoes minimal metabolism, and the elimination is almost exclusively via the airways in unchanged form.[14] Since the metabolism and renal excretion are minimal, hepatic and/or renal function do not affect the dosing or elimination of isoflurane.

# Clinical data on Inhaled Sedation

**In the Sedaconda study, a randomized, controlled, open-label, multicenter, non-inferiority study with up to 54 hours of study sedation and a 30-day retrospective follow-up, isoflurane, delivered via the Sedaconda ACD, was compared to intravenous propofol in invasively ventilated patients. The aim was to evaluate efficacy and safety.[15]**

## Reliable effect

Isoflurane was demonstrated to be non-inferior to propofol, defined as the proportion of time within the sedation target range. Proportion of time within the RASS target range was over 90% in both groups.[15] The mean RASS score for Day 1 and Day 2 of the respective treatments was comparable.[15]

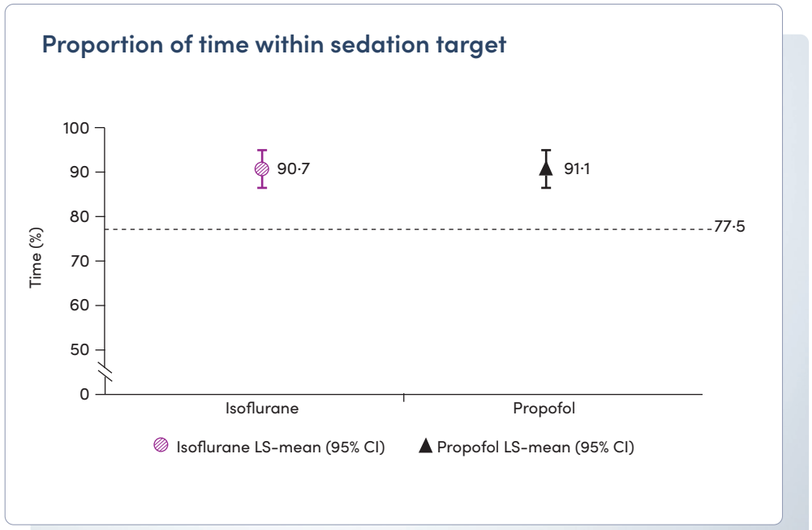



Figure 2 from Meiser et al. 2021
Per protocol population. Sedation target was prespecified as RASS scores between –1 and –4.
Dashed line indicates non-inferiority cutoff, 15% below propofol least squares-mean.
RASS = Richmond Agitation–Sedation Scale. CI = confidence interval. LS = least squares.

## Safety outcome

Isoflurane via Sedaconda ACD was well tolerated and the safety assessments were comparable between the two groups.

## Lower opioid requirements

The vast majority of the patients in the study received opioid analgesia during the study. Opioid requirements were significantly lower for isoflurane patients, compared with opioid requirements in the propofol group, with a remained low BPS (Behavioural Pain Scale) score.[15]

For the overall sedation period, patients receiving isoflurane had a 29% lower opioid dose compared with patients on propofol (p=0.0036).[15]

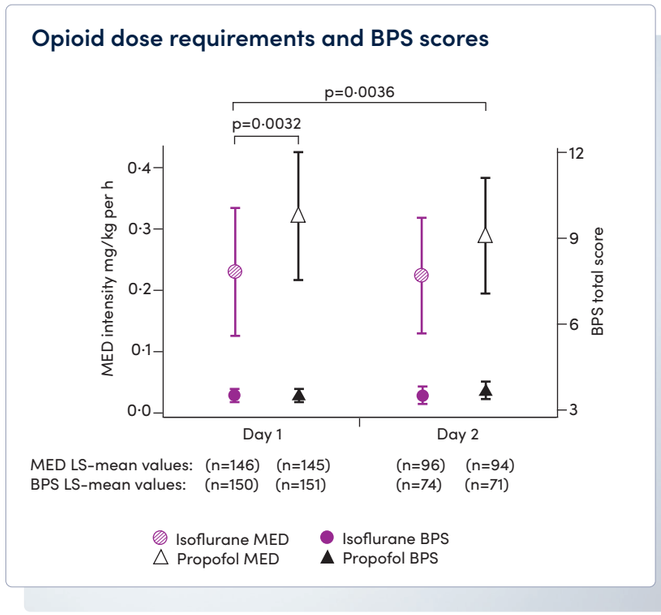



Figure 3 from Meiser et al. 2021
Full analysis set. Data presented are least squares-means and 95% CIs.
CI = confidence interval. BPS = behavioural pain scale. MED = morphine equivalent dose.
LS = least squares.

**-29%**
**opioid dose**

Inhaled anaesthetics have antinociceptive effects on the spinal cord[16], which may explain the reduced opioid needs.

High dosage of opioids leads to gut immobility[17] and is associated with increased risk of delirium[18,19]. In critically ill patients, high opioid dosage is also accompanied by concerns regarding drug accumulation, which can lead to prolonged respiratory depression[17] and delayed and unpredictable recovery.[20]

## Bronchodilation

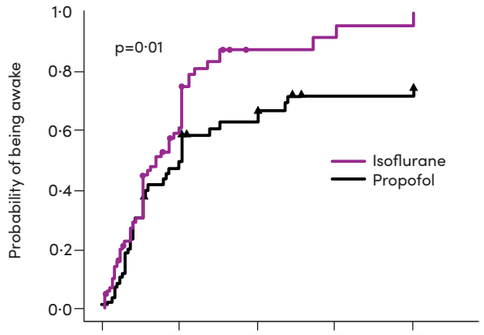
In addition to the sedative effect, inhaled anaesthetics induce bronchodilation by reducing airway smooth muscle tone.[13]

## Rapid and predictable wake-up

Thanks to fast drug elimination via the airways, inhaled sedatives provide a rapid and predictable wake-up.

In the Sedaconda study, time to wake-up was shorter with isoflurane, compared to propofol. Day 1, the difference was in favor of isoflurane but did not reach statistical significance. Day 2, the median (IQR) time to wake-up was 20 (10-30) minutes for isoflurane and 30 (11-120) minutes for propofol (p=0.01).[15] The inter-individual variability in the isoflurane group was also lower in comparison with the propofol group.[15]

**Time to wake-up during SAT on Day 2**




| Number of patients with RASS <0 | | | | | |
|---|---|---|---|---|---|
| Isoflurane | 75 | 22 | 4 | 2 | 1 |
| Propofol | 65 | 27 | 18 | 9 | 9 |

Figure 4B from Meiser et al. 2021
Full analysis set.
RASS = Richmond Agitation–Sedation Scale. SAT = spontaneous awakening trial.

### Time to wake up

Isoflurane:
20 minutes
(10-30 minutes)

Propofol:
30 minutes
(11-120 minutes)

*Reference 15*

## Rapid recovery

Recovery from sedation with isoflurane has also been assessed in additional studies.[14,23] Return of wakefulness, assessed as time to return to RASS ≥0 (calm and alert)[15], and cognitive recovery, assessed as the ability to follow verbal commands[14,23], typically occurs between 10 and 60 minutes[14,15,23] after the end of isoflurane administration.

Rapid emergence from isoflurane sedation may also promote accurate evaluation of a patient's mental and neurologic status, with less confusion due to accumulation and residual drug effects.[14]

Rapid emergence from sedation is a clinically valuable feature of a sedative in the ICU.[21] Distinct and predictable emergence after ending sedative delivery facilitates planning of extubation and appropriate aftercare following extubation, including mobilization.[22]

Additionally, cognitive and neurological recovery is important for an adequate clinical evaluation and to avoid unnecessary diagnostic examinations performed to rule out new neurologic injury when patients do not awaken shortly after the agent is discontinued.[24]



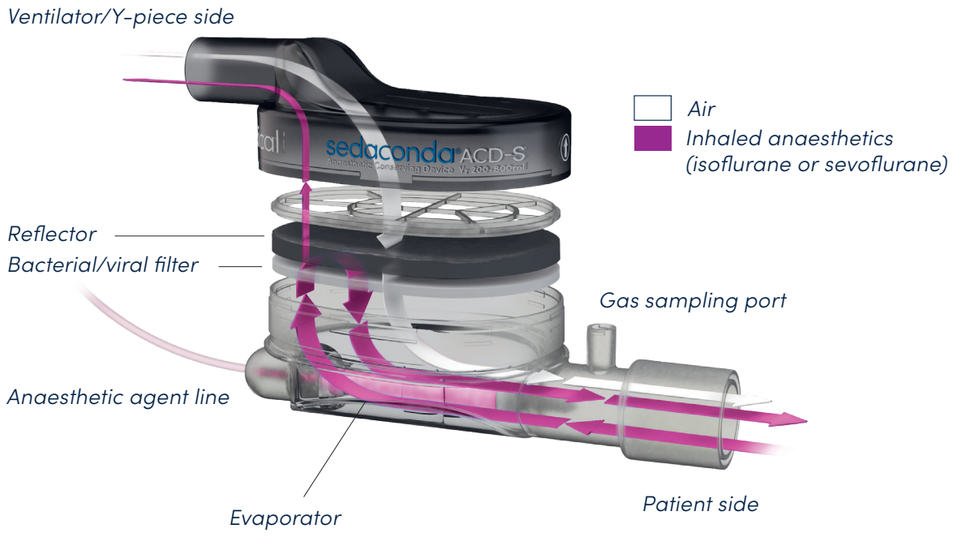

sedaconda®ACD
Anaesthetic Conserving Device

# Sedaconda ACD* – Enables Inhaled Sedation in intensive care

## Sedaconda ACD (Anaesthetic Conserving Device)

Sedaconda ACD is a medical device enabling delivery of inhaled anaesthetics (isoflurane or sevoflurane) to invasively ventilated patients. The device is inserted in the breathing circuit between the endotracheal tube (ET tube) and the Y-piece. It contains an evaporator which enables the vaporization of inhaled anaesthetics (isoflurane or sevoflurane).[25]

Thanks to the carbon filter in the Sedaconda ACD, approximately 90% of the exhaled anaesthetic is adsorbed during expiration and reflected back to the patient during inspiration, thereby reducing drug consumption.
The Sedaconda ACD is also a Heat and Moisture Exchanger (HME) and contains a bacterial/viral filter.[25]
Sedaconda ACD is for single-patient use and should be replaced every 24 hours.[26]

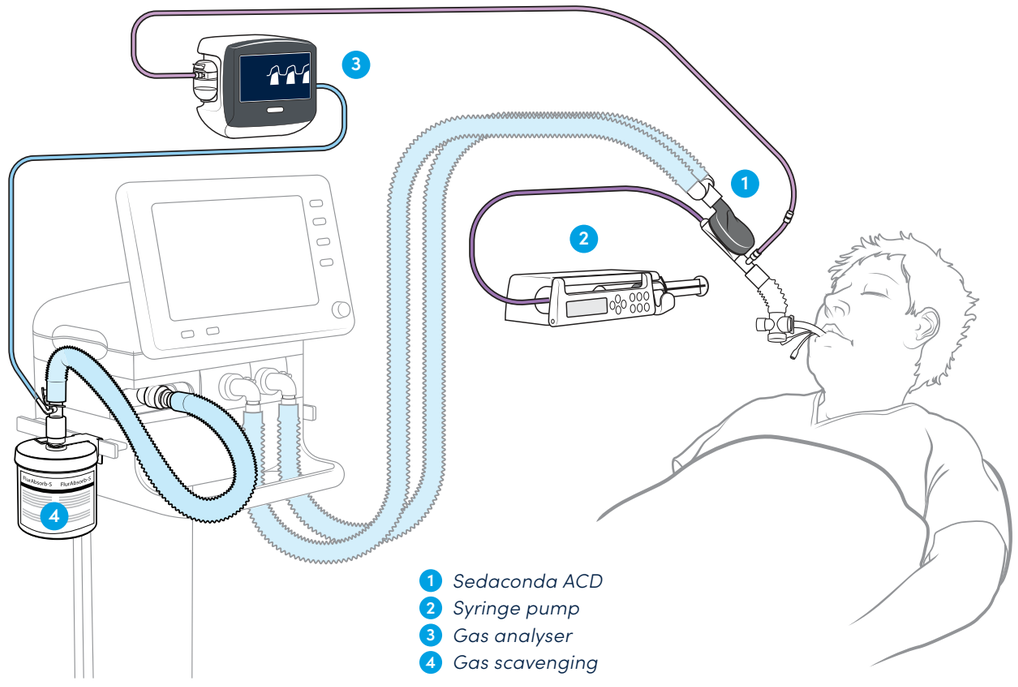



*Sedaconda ACD is formerly known as AnaConDa
Before using the Sedaconda ACD, please refer to the full Instructions for Use (IFU)

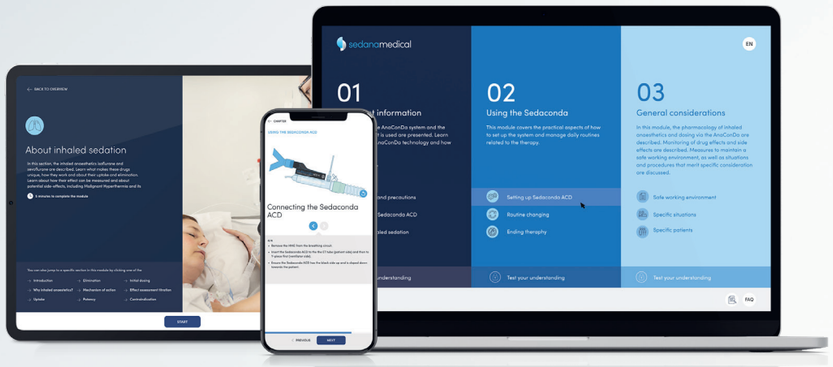
## Setup of the Sedaconda ACD (Anaesthetic Conserving Device)

Treatment with inhaled anaesthetics and the Sedaconda ACD utilises existing critical care devices with little additional equipment required.

A method for scavenging waste anaesthetic gases from the ventilator is recommended. This may be performed either by passive gas scavenging or with an active gas evacuation system.[26] When initiating treatment with Sedaconda ACD, a gas analyser which displays concentrations of inhaled and exhaled anaesthetics should be used.



# Sedaconda ACD e-learning




The Sedaconda ACD e-learning is an online tool for users to become familiar with the Sedaconda ACD.

The e-learning is divided into three modules. Each module will take you 10–20 minutes to complete and give you a step-by-step introduction to everything you need to know about the Sedaconda ACD and how to use it.

To get access to the e-learning visit the website **www.sedacondaacd.sedanamedical.com** or use the QR-code:

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For product feedback and complaints, please contact:
safetyandcomplaints@sedanamedical.com.
Before use, please refer to the Summary of Product Characteristics (SmPC) or Instructions for Use (IFU) for each product.


Sedana Medical AB (publ)
Vendevägen 89, SE-182 32 Danderyd, Sweden
+46 (0)8 124 05 200



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# Bringing Inhaled Sedation to intensive care


For questions, please contact Sedana Medical at
**medinfo@sedanamedical.com** or visit
**www.sedanamedical.com**

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