

Taking sedation  
to a new place



  
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# Redefining How You Think About Sedation

## Computer-Assisted Personalized Sedation (CAPS)—a paradigm change in sedation delivery

CAPS is a new category in sedation delivery that integrates physiological monitoring and drug delivery through a computer interface. This integration facilitates drug titration personalized to the needs of the patient, while simultaneously providing safeguards against oversedation. The first-to-market product in the CAPS category is the SEDASYS<sup>®</sup> Computer-Assisted Personalized Sedation System (SEDASYS<sup>®</sup> System).

The innovative technology of the SEDASYS<sup>®</sup> System enables physician-led teams in facilities where an anesthesia professional is immediately available for assistance or consultation, to safely achieve and maintain minimal-to-moderate sedation with propofol for routine colonoscopy or esophagogastroduodenoscopy (EGD) procedures in healthy patients.\*

The System provides comprehensive patient monitoring and oxygen delivery consistent with American Society of Anesthesiologists (ASA) Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists.<sup>1</sup> Dosing is consistent with the guidelines in the Diprivan<sup>®</sup> (propofol) Injectable Emulsion labeling for sedation.

\*See pages 10-11 for Essential Product Information (EPI).

**Reference: 1.** American Society of Anesthesiologists. Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists. *Anesthesiology*. 2002;96:1004-1017.

## The SEDASYS® System is different from other technologies on the market today

A unique and proprietary aspect of the SEDASYS® System is the integration of monitoring and drug delivery. This unique integration allows the System to detect, alert, and respond to signs of oversedation.

- It is not a “closed loop” system because it will never automatically increase drug delivery; all increases in drug delivery require clinician intervention.
- It is not a target-controlled infusion (TCI) system because it does not control the concentration of drug in the plasma or at the site of drug effect.
- It is not a patient-controlled analgesia (PCA) pump. The patient does not control the level of drug delivered.

The SEDASYS® System could redefine the way sedation is administered for eligible patients, by offering a new way for physician-led teams to safely and effectively deliver propofol on-label for minimal-to-moderate sedation. It will help meet the growing preference for propofol sedation in colonoscopy and EGD procedures by more closely matching the skill level of the sedation delivery team with the actual requirements of less complex cases.

The SEDASYS® System may enable providers to more effectively use their limited resources to deliver greater value in the increasingly resource-constrained US healthcare environment.



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# Integrated, Comprehensive Patient Monitoring and Drug Delivery

The SEDASYS® System features innovative technology that monitors 5 patient parameters and delivers personalized sedation based on those parameters. It is designed to continuously monitor the patient in the preprocedure area, procedure room, and postprocedure area.

The BMU and PRU are connected once the patient enters the procedure room

**Bedside Monitoring Unit (BMU)**—The BMU is connected to the patient in the preprocedure area and stays with the patient through recovery. It provides continuous monitoring of oxygen saturation, blood pressure, and heart rate.

**Procedure Room Unit (PRU)**—The PRU is the primary interface between the physician-led team and the SEDASYS® System and is designed to stay in the procedure room. When the PRU and BMU are connected, the PRU adds capnometry and automated responsiveness monitoring (ARM), oxygen delivery, and delivery of propofol.

## SEDASYS® System Components



1. Procedure Room Unit (PRU)
2. Bedside Monitoring Unit (BMU)
3. Propofol Delivery Cassette
4. Oral/Nasal Cannula
5. Pulse Oximetry Probe
6. Noninvasive Blood Pressure Cuff
7. Electrocardiogram Leads
8. Automated Responsiveness Monitoring (ARM)
9. Wireless Printer
10. PRU Monitor (see enlarged view with details on next page)

## Intuitive user interface on PRU displays the comprehensive physiologic and responsiveness monitoring

### A. Capnometer

### B. Pulse Oximeter

The Capnometer and Pulse Oximeter work in tandem to detect conditions such as low respiratory rate, apnea, and low oxygen saturation, which are indications of oversedation.

### C. Electrocardiogram

### D. Heart Rate/Blood Pressure

### E. Automated Responsiveness Monitor

Exclusive to the SEDASYS® System, the ARM helps assess the level of sedation by measuring patient responsiveness through auditory and tactile stimulus.



## Personalized drug delivery and dosing

The SEDASYS® System is consistent with propofol dosage guidelines for sedation as noted in Diprivan® (propofol) Injectable Emulsion labeling

### Novel algorithm and continuous infusion

- Proprietary drug algorithm and intravenous infusion pump deliver propofol with a variable infusion rate in order to maintain desired sedation effect. The algorithm calculates the appropriate loading dose based on the patient's weight.

### PRN dosing

- Management of transient patient discomfort is possible through PRN function that administers a supplemental dose.

### Propofol delivery with the SEDASYS® System in the pivotal trial:<sup>1</sup>

	Colonoscopy	EGD
<b>Total administered</b>	106.2 mg ± 57.09	70.1 mg ± 37.11
<b>Mean propofol maintenance rate</b>	48.1 mcg/kg/min ± 13.41	53.7 mcg/kg/min ± 14.96

### Oxygen delivery

- Provides continuous oxygen delivery targeted to individual patient needs.



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Reference: 1. Data on file. Ethicon Endo-Surgery, Inc.

# Detect-Alert-Respond Technology for Safety and Effectiveness

Continuous monitoring delivered by the SEDASYS® System provides rapid safety responses if adverse sedation-related physiology is detected. It assesses the patient's parameters, increases oxygen flow, and reduces or stops propofol delivery as needed. The System will never increase propofol delivery without clinician intervention.

## Integrated elements

The SEDASYS® System patient monitoring and drug delivery enhance patient safety with 4 integrated elements:

### Dosing restrictions

- Automatically reduces the propofol dose rate based on patient responsiveness.

### Automated oxygen delivery

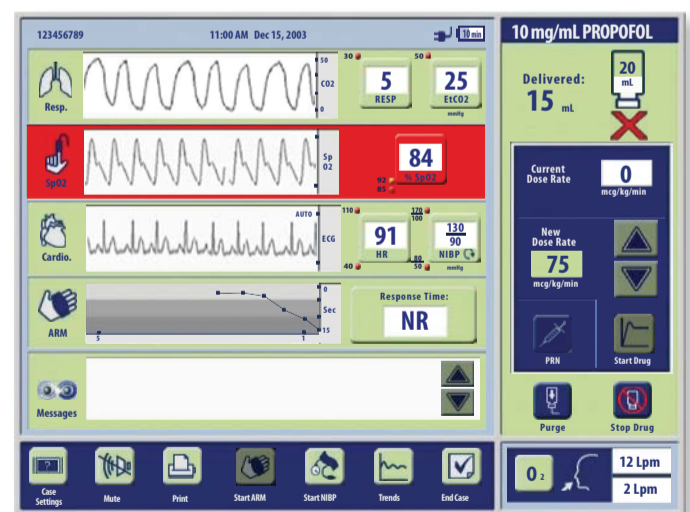
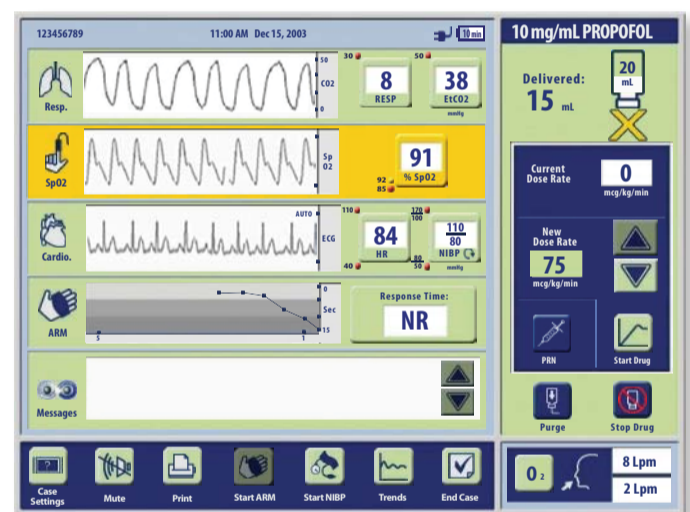
- Adjusts oxygen flow as required to respond to patient's oxygen saturation.

### Integrated patient alarms

- Designed to alert the physician-led team of patient status and reduce or stop propofol delivery if appropriate.

### Subsystem status advisories

- All monitors must be connected and functioning properly before initiation of propofol delivery.



# Key Findings From Pivotal Study for the SEDASYS® System<sup>1</sup>

A pivotal clinical study evaluated the safety and effectiveness of the SEDASYS® System compared with traditional conscious sedation.\* The study included 1,000 subjects who underwent sedation for colonoscopy or EGD at 8 sites.

## Safety

- The SEDASYS® System group had significantly lower risks associated with oversedation.
- The primary endpoint of the study was area-under-the-curve of oxygen desaturation ( $AUC_{Desat}$ ), an objective measure of a patient's respiratory status that incorporates incidence, duration, and depth of oxygen desaturation.
  - **There were fewer oxygen desaturation episodes in the SEDASYS® System group.**
  - **Patients had an average  $AUC_{Desat}$  value of less than one-third of traditional conscious sedation methods.<sup>†</sup>**
- Patients were predominantly minimally to moderately sedated throughout the procedure.
- Patients in the SEDASYS® System group had no serious adverse events, rescue interventions, or device-related adverse events.

## Effectiveness

- Clinicians were significantly more satisfied with the sedation achieved with the SEDASYS® System vs traditional conscious sedation.<sup>‡</sup>
- Patients were satisfied with the sedation received with the SEDASYS® System.<sup>§</sup>
- Patients in the SEDASYS® System group recovered faster than those undergoing traditional conscious sedation.

**99% of patients in the SEDASYS® System group recovered from sedation within 10 minutes of completion of the procedure,** vs 75% of patients in the traditional conscious sedation group.

\*Current standard of care: benzodiazepine (midazolam) and opioid (meperidine or fentanyl).

<sup>†</sup> $AUC_{Desat}$  was 23.6 seconds \* % in the SEDASYS® System group vs 88.0 seconds \* % in the traditional conscious sedation group;  $P=0.028$ .

<sup>‡</sup>Measured by Clinician Satisfaction with Sedation Instrument (CSSI).

<sup>§</sup>Measured by Patient Satisfaction with Sedation Instrument (PSSI).

**Reference: 1.** Pambianco DJ, Vargo JJ, Pruitt RE, et al. Computer-assisted personalized sedation for upper endoscopy and colonoscopy: a comparative, multicenter randomized study. *Gastrointest Endosc.* 2011;73:765-772.



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# End Case Summary

At the completion of a case, a summary of the procedure is available. This record contains patient physiology information collected throughout the procedure at a selected data collection interval. Changes in dose rate, PRN doses, oxygen delivery rate, and alarm events are also captured independent of the selected data collection interval.

## Example of End Case Summary\*

End Case Summary  
ID: 11M61      Weight (kg): 78      Date: June 24, 2012      Time: 10:42:08      Page 1 of 3

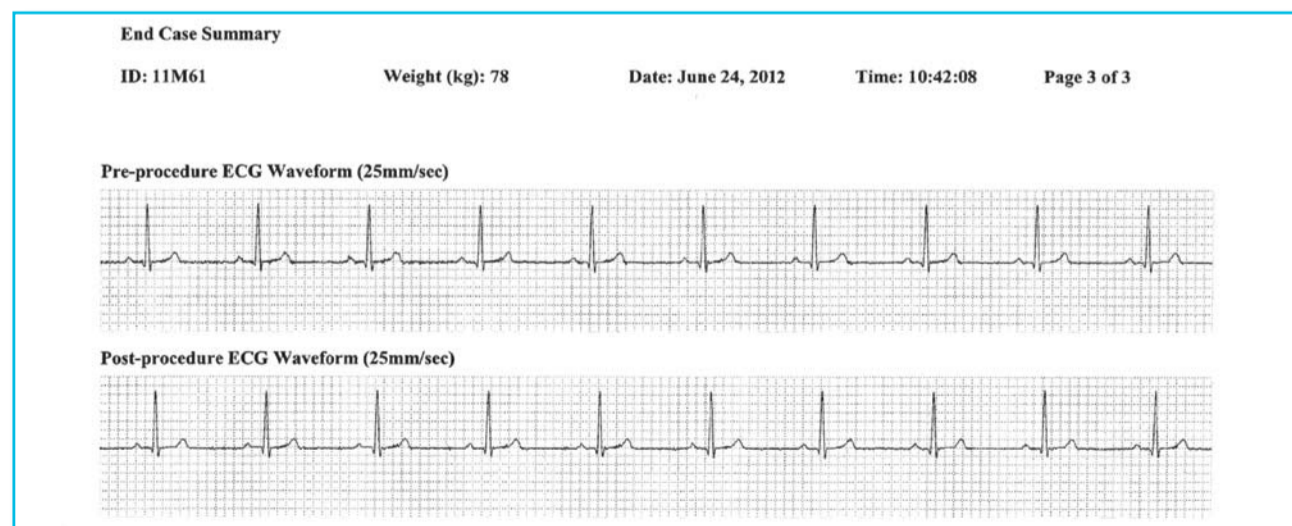
Time	SpO2 (%)	HR (bpm)	Systolic (mmHg)	Diastolic (mmHg)	RR (breaths/min)	EtCO2 (mmHg)	O2 (Lpm)	Response	Dose Rate (mcg/kg/min)	PRN (mg)	Total Propofol (mg)
<b>Pre-procedure</b>											
09:56:38	97	70	119	80	---	---	---	---	---	---	---
10:00:53	97	70	119	76	---	---	---	---	---	---	---
<b>Procedure</b>											
10:08:03	97	70	113	77	7	35	2	1 sec	---	---	---
10:10:30	97	70	113	77	21	30	2	1 sec	---	---	---
10:11:27	97	70	113	77	13	33	2	1 sec	50D	---	0
10:13:30	97	70	114	75	19	34	2	1 sec	50	---	17
10:16:30	97	70	111	79	18	32	2	1 sec	50	---	33
10:17:08	**90	70	111	79	16	31	8	1 sec	0	---	35
10:18:06	**---	60♥	115	83	14	27	8	1 sec	40D	---	35
10:19:30	97	70	115	83	17	26	2	6 sec	40	---	39
10:19:56	97	70	115	83	17	27	2	6 sec	40	20D	59
10:22:30	97	70	111	77	18	35	2	3 sec	40	---	68
10:23:15	**84	70	111	77	17	28	12	3 sec	0	---	69
10:24:47	97	70	111	77	18	23	2	3 sec	30D	---	69
10:25:24	97	70	115	79	9	30	2	3 sec	40D	---	70
10:25:30	97	70	115	79	12	31	2	6 sec	40	---	70
10:28:30	97	70	113	77	12	36	2	1 sec	40	---	83
10:29:52	97	**150	113	77	12	33	2	2 sec	40	---	87
10:30:16	97	**150	113	77	17	27	2	2 sec	40	11D	98
10:31:30	97	85	117	76	22	29	2	4 sec	40	---	104
10:32:48	97	85	117	76	17	31	2	2 sec	30D	---	108
10:34:30	97	85	117	76	16	33	2	4 sec	30	---	108
10:35:30	97	85	117	76	21	31	2	3 sec	0D	---	110

[\*\*]Alarm Event      [---]Data Not Available      [D]Drug Change Event      [♥]HR from ECG

End Case Summary  
ID: 11M61      Weight (kg): 78      Date: June 24, 2012      Time: 10:42:08      Page 2 of 3

Time	SpO2 (%)	HR (bpm)	Systolic (mmHg)	Diastolic (mmHg)	RR (breaths/min)	EtCO2 (mmHg)	O2 (Lpm)	Response	Dose Rate (mcg/kg/min)	PRN (mg)	Total Propofol (mg)
<b>Post-procedure</b>											
10:40:44	97	85	113	76	---	---	---	---	---	---	---
10:42:08	97	85	113	76	---	---	---	---	---	---	---

[\*\*]Alarm Event      [---]Data Not Available      [D]Drug Change Event      [♥]HR from ECG





## Pre-procedure

- **09:56:38** – The user initiated a new case with the BMU and attached the monitors to the simulator.

## Procedure

- **10:08:03** – The user connected the BMU to the PRU, and the SEDASYS® System began recording additional physiologic feedback (ie, RR, EtCO<sub>2</sub>, response time).
- **10:11:27** – The user initiated drug delivery of propofol at a rate of 50 mcg/kg/min.
- **10:17:08** – The simulator created a desaturation event resulting in a SpO<sub>2</sub> of 90%. A Yellow Alarm condition was triggered and the SEDASYS® System alerted the user, stopped propofol delivery, and increased the oxygen rate to 8 Lpm.
- **10:18:06** – During the Yellow Alarm condition, the simulator also created a loss of signal from the pulse oximeter probe. The printout displayed the HR being defaulted to ECG monitors (note the heart icon next to HR). The signal was regained and SEDASYS® System automatically restarted propofol delivery at a reduced rate of 40 mcg/kg/min.
- **10:19:56** – The user administered a PRN, resulting in delivery of an additional 20 mg of propofol.
- **10:23:15** – The simulator created a desaturation event resulting in an SpO<sub>2</sub> of 84%. A Red Alarm condition was triggered and the SEDASYS® System alerted the user, stopped propofol delivery, and increased the oxygen rate to 12 Lpm.
- **10:24:47** – The simulator displayed the recovery of the desaturation and the user manually restarted the delivery of propofol at the recommended reduced rate of 30 mcg/kg/min. The SEDASYS® System adjusted the oxygen delivery to 2 Lpm.
- **10:25:24** – The user increased drug delivery of propofol to 40 mcg/kg/min.
- **10:29:52** – The simulator created a high heart rate of 150 bpm. The SEDASYS® System alerted the user, but did not stop propofol delivery or adjust the oxygen rate.
- **10:30:16** – The user administered a partial PRN, resulting in the delivery of 11 mg of propofol.
- **10:32:48** – The user decreased propofol delivery to 30 mcg/kg/min.
- **10:35:30** – The user stopped propofol delivery by pressing the “Stop Drug” button.

## Post-procedure

- **10:42:08** – The “End Case” button was pressed by the user.



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\* These printouts do not contain actual patient data. They are examples of printouts from a mock case with the SEDASYS® System and are for educational purposes only.

# SEDASYS® Computer-Assisted Personalized Sedation System Essential Product Information

**Indications:** The SEDASYS® System is indicated for the intravenous administration of 1% (10 mg/mL) propofol injectable emulsion for the initiation and maintenance of minimal-to-moderate sedation, as defined by the American Society of Anesthesiologists (ASA) Continuum of Depth of Sedation, in ASA physical status I and II patients  $\geq$  18 years old undergoing colonoscopy and esophagogastroduodenoscopy (EGD) procedures.

Note: The SEDASYS® System must only be used in hospitals and/or healthcare facilities where an anesthesia professional is immediately available for assistance or consultation as needed. The definition of 'immediate availability of an anesthesia professional' will be determined by each individual facility.

**Contraindications:** The SEDASYS® System is contraindicated in the following:

- Patients with a known hypersensitivity to 1% propofol injectable emulsion or its components.
- Patients with allergies to eggs, egg products, soybeans or soy products.
- Patients with a known hypersensitivity to fentanyl.
- Pregnant or lactating women.
- Delivery of any drug other than 1% propofol injectable emulsion.
- Patients with a full stomach.

**Warnings:** The following WARNINGS alert the clinician to the possibility of serious injury, death, or other serious adverse reactions associated with the use or misuse of the SEDASYS® System.

- In the pivotal trial, administration of propofol using the SEDASYS® System was associated with non-sustained, unintended episodes of deep sedation and/or complete unresponsiveness or non-purposeful response to painful stimulation. The SEDASYS® System should be used by a physician-led team trained in administering moderate sedation and trained in the management of under and over sedation. At a minimum, the member of the physician-led team who is administering sedation must have training in the management of the cardiorespiratory effects of propofol when administered using computer-assisted personalized sedation systems. The training must include:

- Pharmacology of propofol.
- Identification of high risk patients.
- Recognition of progression of levels of sedation, and actions necessary to return a patient to intended levels of sedation.
- Use of capnometry and the determination of adequate ventilation.
- Management of airway obstruction and hypoventilation.

The identified team member responsible for monitoring the patient and managing sedation should not be involved in the conduct of the procedure.

- Prospective users of the SEDASYS® System should complete an EES approved device training program before using the System.
- Immediate availability of narcotic reversal agents and equipment for maintenance of the patient's airway, positive pressure ventilation, oxygen enrichment, and circulatory resuscitation and personnel trained in their use should be assured.

- An anesthesia professional should be consulted when the ASA classification is unclear, the patient is medically compromised or unstable, or a difficult airway is anticipated (e.g., sleep apnea or Mallampati classification III or IV).
- Do not supplement propofol administered by the SEDASYS® System with additional manual bolus doses of propofol or any other sedative (e.g., midazolam) as this may result in overdosing and respiratory depression.
- Do not supplement the single pre-procedure dose of fentanyl with additional doses of fentanyl or any other analgesic (e.g., meperidine) as this may result in overdosing and respiratory depression.
- Do not use the SEDASYS® System in combination with flammable or other inhalation anesthetic agents or with external breathing systems.
- The SEDASYS® System should not be used for the induction and/or maintenance of deep sedation or general anesthesia.
- Always verify patient's weight, including proper unit of measure (lb or kg), when beginning a new case. Failure to do so may result in improper dosing of propofol.
- Only approved peripheral devices, parts, components, and accessories should be used. Using items not approved for use with the System may invalidate safety certifications, compromise patient safety, result in increased emissions or decreased immunity, and result in measurement error.
- Further guidance on the administration of 1% (10 mg/mL) propofol injectable emulsion for sedation, overdose and associated adverse reactions can be found in the propofol package insert.

**Precautions:** The following PRECAUTIONS alert the clinician to the possibility of minor or moderate injury to the clinician or patient associated with the use or misuse of the SEDASYS® System.

- In the following patients the SEDASYS® System has not been studied and should not be used:
  - Patient's < 18 years old.
  - ASA physical status IV and V.
  - Patients using a fentanyl patch.
  - Patients with abnormal airway or diagnosed sleep apnea.
  - Patients with gastroparesis.
  - Patients with Body Mass Index  $\geq 35$ .
  - Patients undergoing both colonoscopy and esophagogastroduodenoscopy during the same procedure visit.
  - Patients undergoing emergent colonoscopy or esophagogastroduodenoscopy.

An anesthesia professional should administer propofol in these patient populations.

- The SEDASYS® System has not been sufficiently studied in patients classified as ASA physical status III, and is thus not recommended.
- Care should be exercised when considering sedation of patients who are 70 years old or older because safety and effectiveness data in this age group are limited.
- To reduce the risk of transient apnea or hypoxemia at the start of the procedure, the single dose of fentanyl should be administered approximately 3 minutes before initiating propofol delivery with the SEDASYS® System.
- Use of the SEDASYS® System with analgesics other than fentanyl has not been studied and is thus not recommended.
- The SEDASYS® System Bite Block must be used during EGD procedures to ensure proper function of the Oral/Nasal Cannula in the presence of a scope or an esophageal dilator.

**Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.**



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**Find out more.**

Learn more about how to redefine the delivery of sedation  
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