NeuroWave
HARNESSING THE POWER OF EEG

# AutoSED™ Module

## an infusion system for the US Navy Automated Critical Care System (ACCS)

Providing *closed-loop sedation* and *infusion capabilities* for en-route and prolonged field care

# Product Highlights

**The AutoSED Module is an integral part of the ACCS system. It allows the ACCS to deliver intravenous sedation, analgesia and fluids, via 4 separate infusion pumps.**

Similar to the ACCS, the **AutoSED** attaches under the litter to minimize footprint. Drugs and fluid necessary for a 6 hours mission are stored in infusion bags directly inside the carrier hard shell for protection against tears during transport and handling. Detachable pump heads can infuse the casualty at rates ranging from 1 to 4,000 mL/hr, with an accuracy comparable to infusion pumps used in clinical settings.

The **AutoSED** will connect directly to the ACCS and will be controlled via its user interface, to effectively streamline the management of the patient, and leverage the ACCS remote operation capability.

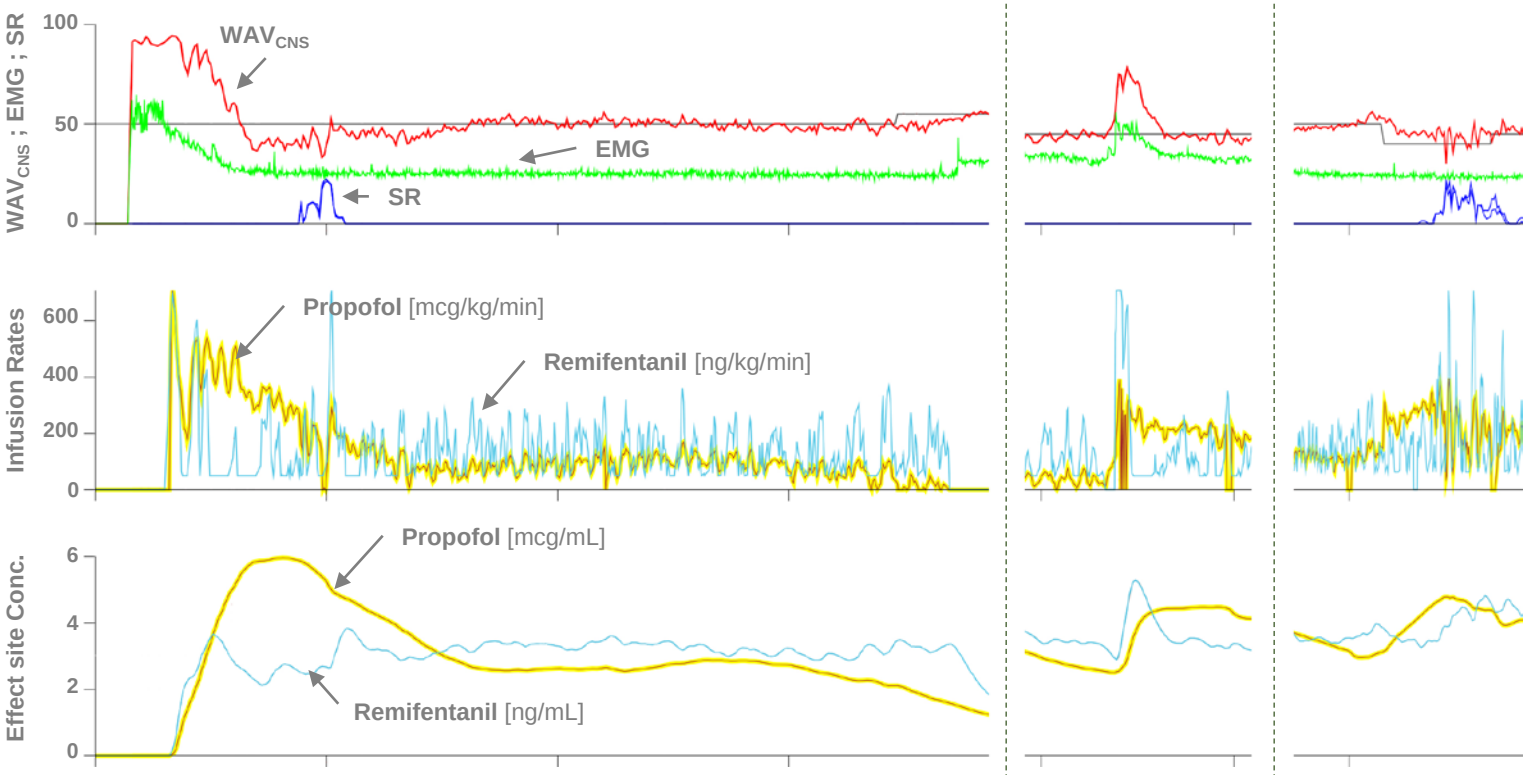
## The Navy's ACCS Program

The ACCS is a "system of systems", which provides expeditionary combat medicine with an automated device to consistently monitor and adjust care to an injured warfighter during triage, prolonged field care, and medical evacuation. With its small footprint, the system is ideal for use ashore or during transport; aboard a ship or submarine; or, in the future, on autonomous vehicles such as the Autonomous Aerial Cargo Utility System configured for casualty evacuation missions.

The ACCS's portability allows medical personnel to extend the "golden hour"—the critical 60 minutes after a major traumatic injury during which prompt treatment can prevent shock and a multitude of other complications, including death.

# Sedation Auto-Pilot

The **AutoSED** features a fully automated closed-loop sedation mode, where both the sedative and analgesic drugs are continuously adjusted to drive and maintain the patient at a depth of sedation targeted by the care provider. Depth of sedation is measured from the patient's brain activity acquired by a small and lightweight device that attaches directly on the patient's forehead. **A clinical study in 60 patients undergoing surgical procedures is currently underway to evaluate the technology**.

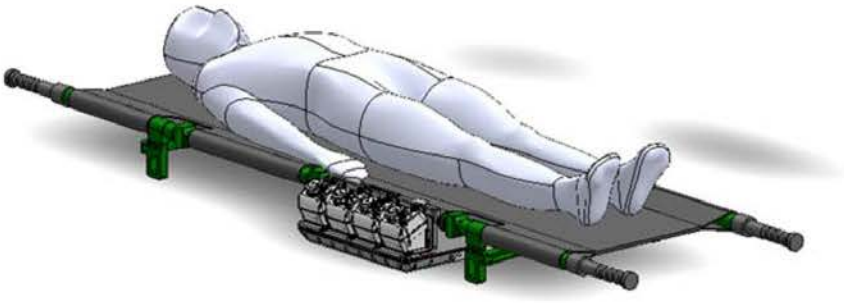



**Case #1:** Male subject (20 yr, 75 kg). Typical time course where propofol administration (yellow) is high initially to facilitate induction and reduces quickly during the maintenance

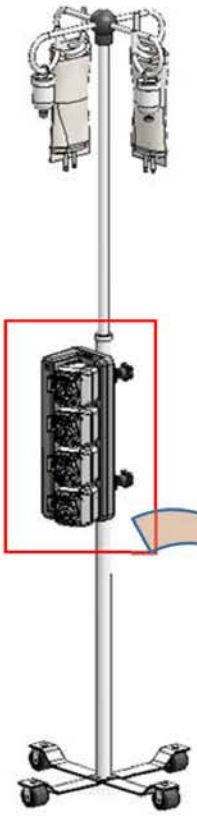
**Case #2:** Male subject (22 yr, 78 kg) suddenly reacted to the surgical stimulus halfway through the surgery.

**Case #3:** Male subject (25 yr, 111 kg). The care provider decided to deepen the effect by changing the target to 45 from 55.

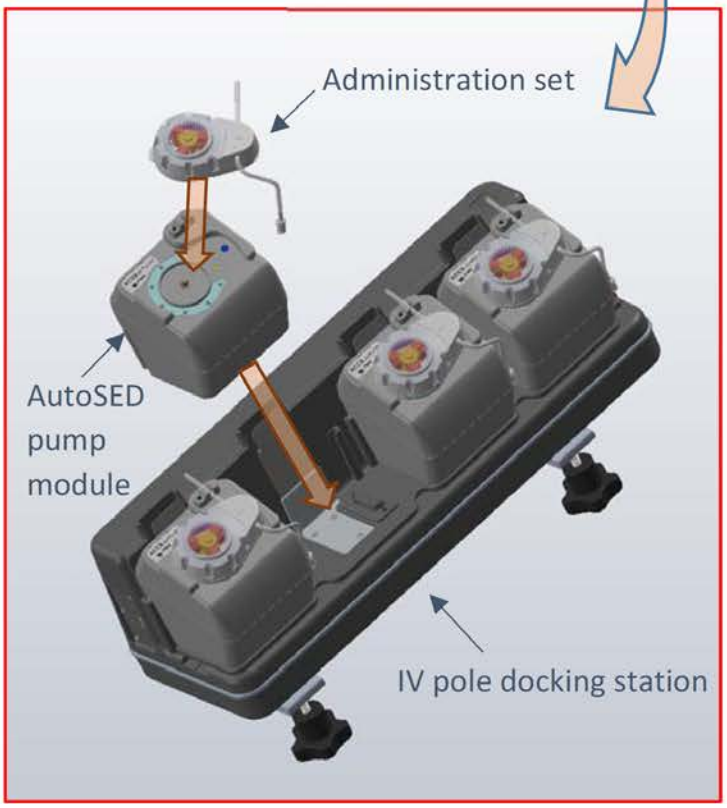
# Forward Surgical Care



**Litter mounted AutoSED**
*- en-route care version -*



**IV pole mounted AutoSED**
*- FSC version -*




There is an opportunity to advance the **AutoSED** capabilities by making it suitable for use in Forward Surgical Care (FSC). This would allow for the automated delivery of Total Intravenous Anesthesia (TIVA) to manage the anesthesia care of combat casualties directly at the FSC level.

TIVA has been described as the “battlefield anesthetic of the future” [1] and has shown to have a better safety and outcome profile as compared to inhaled anesthesia (e.g., lower incidence of post-operative nausea and vomiting, reduced incidence of delirium and post-operative pain, faster and predictable emergence and orientation, etc.). TIVA is non-toxic, does not require gas scavenging, uses simple, cost effective and low maintenance equipment, and can be administered in environments where gas delivery could pose risks (e.g., submarines and other sealed environments). Its small logistical footprint makes it ideal for combat casualty care.

Closed-loop TIVA delivery has been clinically evaluated by multiple research groups over the last 10 years. The technology is mature, and has been shown to be superior to manual drug management [2-7].

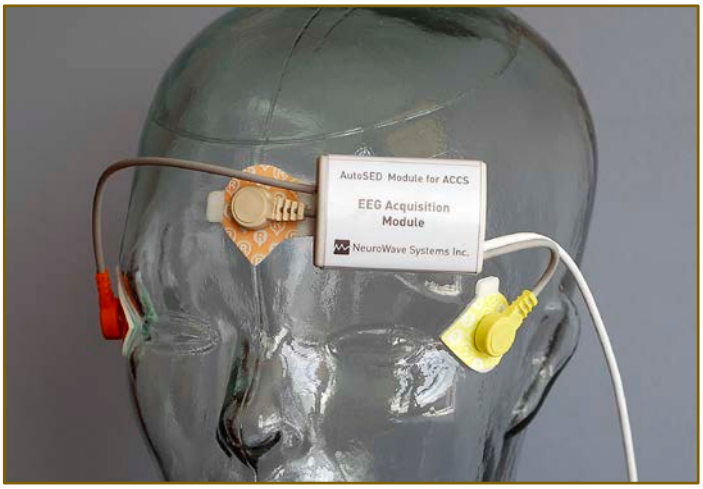
# Product Specifications

## Infusion System

| | |
|---|---|
| **Indications** | • Volumetric pump for intravenous drug delivery. Intended for therapies requiring a continuous rate of infusion or boluses.<br>• The infusion rate for each drug can be set manually by the user, or automatically by the AutoSED controller to drive and maintain patients at the desired depth-of-sedation range.<br>• Intended to be used under the supervision of a qualified medical professional. |
| **Number of Pumps** | Hosts up to 4 distinct pump modules (3 low-flow for drugs, and 1 high flow for fluids) |
| **Mechanism** | • Rotary peristaltic with epicyclical gears<br>• Single use administration set for low or high flow infusion |
| **Continuous Rate** | • 1 – 1,200 mL/hr (low-flow pump)<br>• 5 – 4,000 mL/hr (high-flow pump) |
| **Bolus Rate** | • 300, 600 or 1,200 mL/hr (low-flow pump)<br>• 2.0, 3.0, or 4.0 L/hr (high-flow pump) |
| **Flow Accuracy** (per IEC 60601-2-14) | • +/- 2.5 % for continuous infusions<br>• +/- 5.0 % for boluses |
| **Patient Safety Features** | • Free-flow protection<br>• Downstream occlusion detection<br>• Retrograde flow prevention<br>• Air-in-line detection<br>• Incorrect cartridge & cartridge placement detection<br>• High visibility alarm |
| **Occlusion Detection** | • 300 mmHg, 600 mmHg or 900 mmHg (user selectable) |
| **Max Oper. Pressure** | 750 mmHg |
| **Set Change Interval** | 24 hrs |

## Brain Monitor

| | |
|---|---|
| **Indications** | • Acquires bilateral electroencephalographic (EEG) signals to monitor brain function at the point of injury and during medical evacuation<br>• The $WAV_{CNS}$ index, a processed EEG variable calculated by the AutoSED, may be used as an aid in monitoring the effects of certain sedative agents on casualties.<br>• Intended to be used under the supervision of a qualified medical professional. |
| **Processed Variables** | • Primary Index: $WAV_{CNS}$ (Wavelet Anesthetic Value for Central Nervous System)<br>• Electromyographic (EMG) power (70-110 Hz)<br>• Suppression Ratio (SR)<br>• Continuous measurement of electrode-skin contact impedances<br>• Signal Quality Indicators: Artifacts & 50/60 Hz Noise |
| **Number of Channels** | 2 bilateral EEG channels |
| **Bandwidth** | 0 – 200 Hz |
| **Noise** | < 0.25 µVrms (0.125 - 100 Hz) |
| **CMRR** | > 110 dB at 60 Hz |
| **Sampling Frequency** | 896 Samples per second |
| **Electrodes Change Interval** | 24 hrs |




**AutoSED** Brain Monitor and electrodes

## Selected References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[2] C. Dussaussoy et al., "Automated Titration of Propofol and Remifentanil Decreases the Anesthesiologist"s Workload …", in Journal of Clinical Monitoring and Computing, 2014.

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[5] Puri GD, "A multicenter evaluation of a closed-loop anesthesia delivery system: a randomized controlled trial", in Anesthesia & Analgesia, 2016.

[6] N. West et al., "Design and Evaluation of a Closed-Loop Anesthesia System With Robust Control and Safety System", in Anesthesia & Analgesia, 2017

[7] S. Brodie et al., "Closed-loop control of total intravenous anesthesia during significant intraoperative blood loss: a case report", in Anesthesia & Analgesia, 2017.


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