

Technical Tip

Topic	Protecting Hospital Choice in Procurement with a Reprocessing and Fair Contracting Policy Template
Audience(s)	Supply Chain/Procurement, Legal/Contracts, Compliance, CE
Product(s)	All regulated, commercially reprocessed single-use devices (SUDs)
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Issue

Issue 1: Many health systems lack a formal, system-wide procurement policy affirming their right to purchase and use regulated, commercially reprocessed SUDs—leaving them exposed to attempts by some original equipment manufacturers (OEMs) to interfere with reprocessing.

Issue 2: Some OEMs <u>interfere with reprocessing</u> using various tactics. These can include conditioning case support, warranties, pricing, or software access on exclusive OEM device use; deploying chips/firmware "updates" that block reprocessed devices; or hoarding used devices to choke reprocessor supply.

Issue 3: In <u>Innovative Health v. Biosense Webster</u>, a U.S. federal court ruled that some of these tactics are unlawful; hospitals should proactively embed fair-contracting and anti-interference rules to prevent recurrence.

Technical Background

• This is a read-to-adopt procurement policy template. It codifies your organization's commitment to purchase reprocessed SUDs and provides contractual mechanisms to resist vendor interference with reprocessing programs.

• Core protections:

- No tying case support, service, warranties, pricing, or access to exclusive OEM device use;
- No chips/firmware "updates" or other technical measures designed to disable or impede reprocessed devices;
- No retention, withholding, or destruction of used devices to prevent lawful reprocessing (aside from narrow, documented safety/regulatory exceptions).

• Additional provisions:

- Encourages evidence-based purchasing decisions (e.g., device performance, lifecycle data, cost comparisons, and credible emissions reporting) that align with hospital cost-savings and sustainability goals.
- Aligns with recent antitrust verdicts and permanent injunctive relief restricting certain anti-reprocessing tactics.
- Establishes a clear, non-retaliatory process to report non-compliance for organizational and regulatory follow-up.

Recommendations

- Review, download, and complete the template to develop a system-wide policy. Insert your organization's name and responsible departments; review with Legal/Compliance; and publish as a governing policy for all device purchasing and service engagements.
- 2. **Embed the policy in every contract.** Attach it as an exhibit (or incorporate by reference) in capital equipment, disposables, service, and software agreements. Reject any terms that include or are suggestive of common anti-reprocessing tactics.
- 3. Adopt technical, operational, and compliance safeguards. Examples include:
 - Requiring advance notification of software/firmware updates and a warranty that updates will not block or degrade reprocessed devices;
 - Standardizing used-device collection workflows;
 - Training staff to capture and preserve interference evidence (screenshots, error logs, rep communications).
 - o Detailing remedies for violations (termination of contracts, regulatory reporting).
- 4. **Educate staff on the policy and reporting mechanisms.** Publish your internal escalation path and link to AMDR's <u>anti-reprocessing incident reporting form</u> and <u>court-ordered hotline</u> for reporting violations of the injunction. Brief clinical staff and techs on the policy so they can spot prohibited conduct in clinical settings.

For More Information

Contact your AMDR-member commercial reprocessing partner or write to info@amdr.org.

Please see our <u>online guide</u> about anti-reprocessing tactics, general <u>resources for hospitals</u>, and other <u>Action Alerts and Technical Tips</u> for more guidance and educational resources.