California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Sophysa – Pressio 2 ICP Monitoring System (Intracranial Pressure Monitor) Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
01/08/2026	The Pressio 2 ICP Monitoring System (Model PSO-4000) is an intracranial pressure monitoring device used to measure and monitor pressure inside the skull.	Sophysa Besancon, France	Customer complaints of Pressio monitor rebooting.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Model No.:** PSO-4000 **UDI-DI:** 03760124132076 **All monitors affected.**	105 Units; Nationwide including California	November 2025 and prior.

For additional information, please visit the FDA Website.