SOPHYSA FSN Ref: **FSN2025-04**

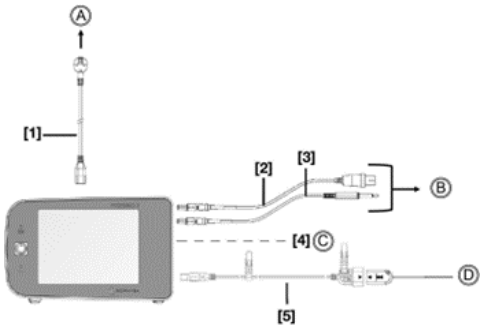
Date: 17-Nov-2025

Urgent Field Safety Notice

Intracranial Pressure Monitor Pressio®2

For Attention of : Distributors, centers, and representatives in possession of the products concerned

Information on Affected Devices

Device Type(s)	 The Pressio®2 monitor is designed to measure and display the pressure values and curves (in real-time) measured by the Pressio® catheters inserted in patients requiring continuous intracranial pressure monitoring. Depending on the type of catheter used, the Pressio®2 monitor can also display the intracranial temperature.
Commercial name	Intracranial Pressure Monitor Pressio®2
Unique Device Identifier (UDI-DI)	03760124132076
Primary clinical purpose of device	The Pressio® ICP monitoring system is intended for continuous monitoring of intracranial pressure and/or intracranial temperature in brain-injured patients with a risk of intracranial hypertension, who cannot evaluate clinically.
Device Model	PSO-4000
Software version	V3.25.07, V3.25.08, V3.25.09, V3.26.00
Affected serial or lot number range	All monitors
Associated devices	Pressio® monitoring kits (PSO-PB, PSO-PBT, PSO-PT, PSO-PTT, PSO-VT, PSO-VTT)

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S.A. au capital de 500 000 € I R.C.S. Evry 306 979 584 I N° intracommunautaire : FR 06 306979584 I Code APE : 3250A I SIRET 306 979 584 00092

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Reason for Field Safety Corrective Action (FSCA)

Description of the product problem	Some users encounter a corruption of the memory of the catheter that trigger an unintended reboot of monitor. The only solution to monitor the patient is the replacement of the catheter.
Hazard giving rise to the FSCA	• Absence of patient monitoring while waiting for sensor replacement • Risks associated with re-implantation for catheter-associated reboots when device replacement is decided by the medical teams.
Probability of problem arising	Probability of less or equal to 0,1% after risk mitigation
Predicted risk to patient/users	Risk tolerable but to be reduced as low as reasonably achievable

Type of Action to mitigate the risk

Action To Be Taken by the User	**For software version V3.25.07,** please place Pressio®2 monitors in quarantine ☐ Quarantine Device **For software version V3.25.08, V3.25.09 and V3.26.00,** please update all monitors with the new version, complete the ENR637 form to record the update and return it to Sophysa. ☐ On-site device modification
By when the action should be completed?	**By 31 December 2025**
Is customer Reply Required?	Yes, the "**FSN reply form**" is required

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General Information

FSN Type	New
Manufacturer information	
Company Name	Sophysa
Address	5 rue Guy Moquet 91400 Orsay FRANCE
Website address	https://www.sophysa.com/

List of attachments	"**FSN reply form**" - to be completed and returned by email without delay
Name/Signature	EUGENIE MAGNE Regulatory Affairs Manager 17 Nov 2025  Signature numérique de MAGNE Eugénie Date : 2025.11.17 17:08:00 +01'00'