Since I'll be using the domain information about the Generic Patient-Controlled Analgesia (GPCA) system to instantiate the assurance case from the given safety case pattern, I'll replace placeholders with specific details pertaining to this system.

\*\*Instantiated Safety Case for Generic Patient-Controlled Analgesia (GPCA) System:\*\*

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G1: Operational safety is verified in GPCA system

- S1: Argument over the satisfaction of all specs over GPCA system (undeveloped)

- C1: All specs are given by FDA standards, expertise opinion

- G2: All operational hazards are mitigated

- S3: Argument over operational hazards

- C2: Operational hazards are Overinfusion and Underinfusion

- G3: Overinfusion is mitigated

- S4: Argument over the applied scenarios of Overinfusion

- C3: All related scenarios are given by Overinfusion scenarios

- G4: Overinfusion is mitigated under scenario "flow rate exceeds set limit"

- S5: Argument over all specs related to "flow rate exceeds set limit" scenario

- C4: All related specs are given by "flow rate sensor equipped," "programmed rate too low"

- G5: Specification "Flow rate sensor equipped" is appropriate for scenario "flow rate exceeds set limit"

- S6: Argument over the appropriateness of "Flow rate sensor equipped" over properties

- C5: Properties are given by "Flow rate less than 90% of the programmed rate setting"

- G6: Property "Flow rate less than 90% of the programmed rate setting" is appropriate for specification "Flow rate sensor equipped"

- S7: Argument over the source of the "Flow rate less than 90% of the programmed rate setting" property definition

- C6: Source is given by FDA standard

- G7: FDA standard is appropriate and trustworthy

- Sn1: References to FDA standard documents

- G8: Property definition "Flow rate less than 90% of the programmed rate setting" is sufficient

- Sn2: Expert testimony confirming sufficiency of property definition

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\*\*Explanation:\*\*

1. \*\*Top-level Goal (G1)\*\* states that the operational safety is verified for the entire GPCA system.

2. \*\*Strategy (S1)\*\* should argue over the fulfilment of technical specifications, ensuring compliance to achieve full system safety, though it remains undeveloped in this instantiation.

3. \*\*Goal (G2)\*\* ensures that both critical operational hazards—Overinfusion and Underinfusion—are effectively mitigated. The strategy to address these hazards (S3) considers details specific to the identified hazards.

4. \*\*Multiple Goals (G3 to G8)\*\* break down mitigation strategies and ensure that technical specifications relating to operational scenarios are appropriately defined and validated. This includes hardware (like sensors) and software properties (like detection algorithms).

5. \*\*Contexts (C1 to C6)\*\* provide factual background necessitated by the specifications, including scenarios and properties that detail how the system should perform under specified conditions.

6. \*\*Solutions (Sn1 and Sn2)\*\* encompass the evidence that supports claims made in G7 and G8, this may include technical documentation or expert assessments.

This hierarchical structure satisfies the primary concern of safety for the GPCA system by addressing its specific hazards through structured argumentation and supported evidence.