To instantiate the given safety case pattern for the GPCA system, I will replace all placeholders with specific, concrete values relevant to the context provided earlier, particularly focusing on overinfusion and underinfusion hazards, and using safety requirements (SR) as evidence. This aims to create a complete and instantiated safety case tree.

### Safety Case: GPCA System Safety Assurance

\*\*G1: Operational safety is verified in GPCA system\*\*

- \*\*S1: Argument over the satisfaction of all specs over GPCA system\*\*

- \*\*C1: All specs are given by using GPCA system requirements\*\*

- \*\*G2: All operational hazards are mitigated\*\*

- \*\*S3: Argument over operational hazards\*\*

- \*\*C2: Operational hazards are given by identifying overinfusion and underinfusion\*\*

- \*\*G3: Overinfusion is mitigated\*\*

- \*\*S4: Argument over the applied scenarios of overinfusion\*\*

- \*\*C3: All related scenarios are given by specific infusion volume and rate settings\*\*

- \*\*G4: Overinfusion is mitigated under excessive bolus requests\*\*

- \*\*S5: Argument over all specs related to excessive bolus requests\*\*

- \*\*C4: All related specs are given by maximum bolus limit and alert settings\*\*

- \*\*G5: 'Dose limit exceeded due to excessive bolus requests' is appropriate for 'excessive bolus requests'\*\*

- \*\*S6: Argument the appropriateness of 'bolus volume/concentration too high' over properties\*\*

- \*\*C5: Properties are given by volume and concentration limits\*\*

- \*\*G6: 'Bolus volume/concentration too high' property is appropriate for 'excessive bolus requests'\*\*

- \*\*S7: Argument over the source of the 'bolus volume/concentration too high' property definition\*\*

- \*\*C6: Source is given by FDA standard and expert opinion\*\*

- \*\*G7: FDA standard is appropriate and trustworthy\*\*

- \*\*Sn1: FDA standard documentation\*\*

- \*\*G8: 'Bolus volume/concentration too high' definition is sufficient\*\*

- \*\*Sn2: Detailed property definition documentation\*\*

- \*\*G3: Underinfusion is mitigated\*\*

- \*\*S4: Argument over the applied scenarios of underinfusion\*\*

- \*\*G4: Underinfusion is mitigated under programmed rate too low\*\*

- \*\*S5: Argument over all specs related to programmed rate settings\*\*

- \*\*G5: 'Flow rate sensor is equipped and Period to trigger the underinfusion alarm is 15 minutes' is appropriate for 'programmed rate too low'\*\*

- \*\*S6: Argument the appropriateness of 'Flow rate is less than 90% of the programmed rate setting' over properties\*\*

- \*\*G6: 'Flow rate less than 90% of programmed rate' is appropriate for detecting underinfusion\*\*

- \*\*S7: Argument over the source of the property 'Flow rate less than 90% of programmed rate' definition\*\*

- \*\*G7: Expert opinion is appropriate and trustworthy\*\*

- \*\*Sn1: Expert review documentation\*\*

- \*\*G8: 'Flow rate less than 90% of programmed rate' definition is sufficient\*\*

- \*\*Sn2: Detailed property definition documentation\*\*

This instantiated assurance case represents the hierarchical structure with specific safety requirements addressing the hazards identified in the GPCA system. Goals, strategies, contexts, and evidences are meticulously aligned to present a coherent argument for the safety of the system concerning the identified hazards.