

I have received all six ConOps pages. I will now provide the first step of the STPA method, identifying the Losses, System-level Hazards, and System-level Constraints for the insulin pump system.

Losses

1. **L-1:** Loss of life or severe injury to the user
2. **L-2:** Loss of or damage to the device
3. **L-3:** Loss of insulin supply
4. **L-4:** Inaccurate or delayed insulin delivery causing health deterioration
5. **L-5:** Breach of sensitive health data and user privacy
6. **L-6:** Loss of connectivity with CGM or healthcare providers

System-level Hazards

1. **H-1:** Insulin pump delivers incorrect dosage of insulin [L-1, L-4]
2. **H-2:** Insulin pump fails to deliver insulin when needed [L-1, L-3, L-4]
3. **H-3:** Insulin pump malfunctions leading to physical damage to the device [L-2]
4. **H-4:** Insulin pump fails to alert the user about critical conditions (low/high blood sugar, low battery, occlusion) [L-1, L-4]
5. **H-5:** Insulin pump data communication is compromised [L-5, L-6]
6. **H-6:** Insulin pump fails to maintain connectivity with CGM or healthcare providers [L-1, L-6]

System-level Constraints

1. **SC-1:** Insulin pump must deliver correct dosage of insulin as per user settings and real-time needs [H-1]
2. **SC-2:** Insulin pump must reliably deliver insulin without interruptions under normal operating conditions [H-2]
3. **SC-3:** Insulin pump must maintain its physical integrity and be resilient to environmental factors [H-3]
4. **SC-4:** Insulin pump must alert the user immediately upon detecting critical conditions, including low/high blood sugar, low battery, or occlusion [H-4]
5. **SC-5:** Data communication from the insulin pump must be secured to prevent unauthorized access and breaches [H-5]
6. **SC-6:** Insulin pump must maintain continuous and reliable connectivity with CGM devices and healthcare provider systems [H-6]
7. **SC-7:** If insulin pump delivers incorrect dosage, prompt detection and corrective measures must be taken to mitigate harm [H-1]
8. **SC-8:** If insulin pump fails to deliver insulin, emergency protocols must be in place to alert the user and provide alternative measures [H-2]

These elements form the foundational step of the STPA method, aimed at identifying the primary concerns and constraints associated with the insulin pump system to prevent significant losses through careful hazard analysis and mitigation strategies.