

STPA Method: First Step Analysis for Defibrillator

Losses:

- **L-1:** Loss of life or injury to patients.
 - **L-2:** Loss of functionality of the defibrillator.
 - **L-3:** Legal liabilities and financial losses due to device malfunction.
 - **L-4:** Loss of data integrity or improper data logging.
 - **L-5:** Damage to public trust or reputation of the manufacturer.
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System-Level Hazards:

- **H-1:** Defibrillator fails to deliver a shock when needed [L-1, L-2, L-3].
 - **H-2:** Defibrillator delivers an inappropriate shock (e.g., too strong, too weak, or when not needed) [L-1, L-3].
 - **H-3:** Defibrillator is not operational due to power failure (battery or mains power) [L-1, L-2, L-3].
 - **H-4:** Defibrillator fails to log or transmit data correctly [L-4, L-5].
 - **H-5:** Defibrillator gives incorrect user instructions or feedback [L-1, L-3, L-5].
 - **H-6:** Defibrillator's safety mechanisms fail, leading to accidental shocks or failure to prevent misuse [L-1, L-3].
 - **H-7:** Defibrillator is not accessible or easily identifiable in an emergency [L-1, L-3, L-5].
 - **H-8:** Defibrillator cannot be used due to language barriers [L-1, L-5].
 - **H-9:** Defibrillator design fails to withstand environmental conditions, leading to device failure [L-1, L-2, L-3, L-5].
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System-Level Constraints:

- **SC-1:** Defibrillator must reliably deliver a shock when required [H-1].
- **SC-2:** Defibrillator must prevent inappropriate shocks delivery [H-2].
- **SC-3:** Defibrillator must maintain operational status by ensuring power availability [H-3].
- **SC-4:** Defibrillator must ensure accurate data logging and transmission [H-4].
- **SC-5:** Defibrillator must provide correct and clear user instructions [H-5].
- **SC-6:** Defibrillator must have robust safety mechanisms to prevent accidental shocks and misuse [H-6].
- **SC-7:** Defibrillator must be easily accessible and identifiable in an emergency [H-7].
- **SC-8:** Defibrillator must support multiple languages to ensure usability by diverse populations [H-8].
- **SC-9:** Defibrillator must be designed to withstand various environmental conditions [H-9].

Each System-level Hazard is linked to one or more Loss, and every Hazard has its corresponding System-level Constraint, ensuring the device operates safely and effectively under defined conditions. This analysis will guide further detailed safety analysis and design improvements to prevent unacceptable losses.