



Transport-Ready Mounting Platform for Critical Care Life Support Device

Engineering an Easy-to-Use Mounting Device for Inter-Hospital EMS Transportation

OVERVIEW

Digital Health Solutions collaborated with a global medical device leader to design and deliver a mounting platform for securing life-supporting therapy equipment during ambulance transport and interfacility transfer. This custom system ensured safe attachment of critical care devices to ambulance stretchers, expanding their use beyond hospital environments. We provided full-scope mechanical design, prototyping, validation, regulatory documentation, and manufacturing readiness to enable product deployment in dynamic emergency care settings.

CHALLENGES

- **Environmental Requirements:** Designed a stretcher-compatible mounting system to secure the console and patient kit during EMS transport.
- **Regulatory Demands:** Validated structural performance under simulated emergency scenarios to meet safety standards including IEC 60601-1-12.
- **Human Factors Compliance:** Required usability validation to ensure ease of use, reduce use-related risks, and meet IEC 62366-1 standards.

APPROACH

- **Mechanical Design Engineering:** Developed a robust, human-centered platform with durable, EMS-friendly features and compatibility across stretcher models.
- **Prototyping & Validation:** Built and tested multiple prototype generations under fit, impact, vibration, and loading conditions to confirm stability and usability.
- **Compliance & Manufacturing:** Authored a complete Design History File (DHF), supported standard compliance, and implemented scalable manufacturing workflows.

IMPACT

- **Prototype Delivery:** Provided multiple fully functional prototype units for internal evaluation, field testing, and stakeholder demonstration.
- **Validated Performance:** Platform designed to pass rigorous mechanical and usability testing for emergency and hospital use.
- **Regulatory Readiness:** Comprehensive design and test documentation to support future FDA submissions.
- **Manufacturing Launch:** Transitioning to contract manufacturing with BOMs, inspection protocols, and in-house assembly.

About Digital Health Solutions

DHS, located near Boston, MA, provides key engineering, testing, documentation & regulatory services for Medical Device, Diagnostics, Healthcare and Life Science industries. Our expertise & services include:

- **End-to-end Product Development**
- **Firmware/Software Engineering (AI/ML)**
- **Systems Engineering**
- **Quality & Regulatory Guidance**
- **Cybersecurity**
- **ISO 13485 Contract Manufacturing**
- **Verification and Validation Testing/Documentation**

Accelerating MedTech Innovation

Let's build something together.

978.300.1841

info@digitalhealthsol.com

