One-Page Legislator Handout by J Scot Mackeil CBET

(Print-ready | Plain language | Evidence-based)

H.160 — Medical Equipment Right to Repair

Supporting Patient Safety, Hospital Resilience, and Vermont's Healthcare Workforce

What H.160 Does

H.160 ensures that **qualified, credentialed healthcare technology professionals** in Vermont hospitals can access the **service manuals, diagnostic tools, software access, parts, and documentation** needed to maintain medical equipment **to manufacturer specifications**.

It does not:

- Authorize device modification
- Bypass FDA requirements
- Reduce existing hospital oversight or accreditation standards
- Create any patient safety concerns for the healthcare system.

Why This Matters for Patients

- When hospital based Biomeds can solve technology problems in real time at the point of care patient case is least impacted and procedures are completed on time.
- Faster repairs mean **less downtime** and less disruption of clinical procedures.
- Less downtime means **fewer canceled procedures and transfers**
- Local repair capacity improves **emergency preparedness and rural access**

Federal Findings: FDA FDARA Section 710

- Congress required the FDA to study medical device servicing (FDARA §710)
- The FDA found **no evidence** that hospital or third-party servicing is **less safe** than manufacturer servicing

- FDA did **not** recommend OEM-only repair or additional restrictions
- Industry trade associations have been known to dismiss the FDARA-710 report without evidence as it does not fit their narrative opposing right to repair initiatives.

Bottom line: Safety claims used to oppose Right to Repair are **not supported by evidence**.

Professional Expertise Already Exists in Vermont

- Vermont is home to **UVM and UVM Medical Center**, with nationally respected clinical engineering and BMET programs
- These programs support **nationally accredited certifications**, including:
    - **CBET (Certified Biomedical Equipment Technician)**
- CBET certification requires:
    - Formal education
    - Broad technical competence
    - Ongoing professional accountability

Many hospital HTM professionals hold CBET certification; many OEM reps do not.

What Happened After the FDA Report

- The FDA supported a **Collaborative Community** to develop servicing best practices
- Hospitals and HTM professionals participated in good faith
- **Many manufacturers disengaged or withdrew**
- Voluntary solutions failed to resolve access barriers
- Industry failed to participate productively in the Medical device servicing collaborative community initiative the report recommended. Hospital and ISO staff did participate productively. The consensus effort the FDA was hoping for did not result. Hence the need for legislative relief such as H.160.

H.160 addresses what voluntary efforts did not.

Lessons from Other States

- In Massachusetts, a similar medical equipment Right to Repair effort was **stalled for years**
- Medical equipment provisions were **stripped after intense lobbying**
- Hospitals there remain locked into vendor-controlled repair
- I believe It is essential for Vt to pass this law with medical technology included to counter the activities of technology company lobbyists who have consistently throttled the needs of Americas healthcare system in support of their anti-competitive agenda.

Vermont should choose the pro hospital, pro patient outcome.