



The **“right to repair”** debate has gained increasing attention across several industries in the past few years. At its core, right to repair is about the ability of product owners to determine how to service the products they acquired, without unreasonable restrictions by the product manufacturers. The stakes are particularly high for medical devices, as patient care and safety can be negatively impacted when devices cannot be promptly and safely maintained.

Restrictions by original equipment manufacturers (OEMs) can take many forms, including denial of access to service manuals and diagnostic/calibration software, and restrictions on availability of parts, specialized tools, and training. By their very nature, these **OEM restrictions are anticompetitive, intended to protect a manufacturer’s revenue and not public safety** or interest as some have claimed. In its 2021 “Nixing the Fix” report, the Federal Trade Commission (FTC) recognized that manufacturers across multiple industries restrict repairs on their own devices, noting there is “scant evidence to support manufacturers’ justifications for repair restrictions.”

Repair restrictions impact healthcare providers in a number of ways. First, they limit the choices available to the providers who typically already have competent onsite teams (either hospital employees or staff provided by independent service organizations - ISOs) dedicated to medical device service. Second, restrictions raise costs in an already overburdened healthcare system. Third, restrictions typically result in unacceptable downtime for devices that can ultimately impact patient safety and care.

The impact of delays was particularly apparent during the COVID-19 pandemic, when OEM representatives were unwilling or unable to travel to hospitals and many hospitals had difficulty keeping critical devices operating in the face of surging patient demand. These negative repercussions are especially evident at rural hospitals which struggle to receive on-site support and often cannot afford the cost of expensive OEM services.

**The Alliance for Quality Medical Device Servicing stands behind the right of medical device owners to choose competent personnel to service their devices as they see fit**, without unjustified interference by OEMs. The FDA’s 2018 report on device servicing recognized that “... the objective evidence indicates that many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices.”

While some states have begun considering right to repair legislation, only one state (Colorado) has passed such legislation which is limited to motorized wheelchairs. In Congress, the Critical Medical Device Infrastructure Act proposed in 2021 was a step in the right direction but has not moved forward. The Copyright Office in 2021 exempted access to copyrighted software for the purpose of diagnosis, maintenance, and repair of medical devices from the Copyright Act’s general bar on circumvention of copyrighted works. In addition, the FTC has

pledged to scrutinize anticompetitive restrictions more closely. However, none of these actions have resolved or are likely to resolve in the near future the fundamental issue of the right to repair for medical devices.

**Healthcare organizations must have choices in how they maintain the devices they purchased and own, including the choice on who they use to perform such work.** Ensuring that service manuals, diagnostic/calibration software, specialized tools, materials, parts, and training are available for this work is crucial to the healthcare and wellbeing of Americans. **We urge Congress and the relevant agencies to take decisive action to address repair restrictions related to medical devices.**

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The Alliance for Quality Medical Device Servicing was formed in 2018 and is comprised of five leading national medical device service organizations: TRIMEDX, Sodexo, Crothall, Agiliti, and the InterMed Group. Alliance members collectively employ tens of thousands of technicians, clinical engineers and skilled professionals who provide medical device repair and servicing in hospitals and health systems in all 50 states.