Frequently Asked Questions on Medical Device Servicing

AdvaMed
Advanced Medical Technology Association

WHY IS SERVICING SO IMPORTANT FOR MEDICAL DEVICES?

Like any piece of equipment in frequent use, medical devices need periodic maintenance and repair. Proper servicing of complex, life-saving and life-sustaining medical devices is vital to their safe and effective functioning and the safety of patients and device users. As part of their commitment to patient safety, original equipment manufacturers (OEMs) dedicate extensive resources to establishing comprehensive servicing programs to ensure that their devices are properly maintained and continue to meet safety and effectiveness requirements as determined by FDA.

WHAT FDA SERVICING REQUIREMENTS MUST OEMS FOLLOW?

OEMs and their authorized servicers must follow extensive FDA post-market requirements to ensure that their devices are properly maintained and continue to meet safety and effectiveness standards as determined by the agency. FDA's Quality System Regulation includes specific servicing requirements covering training, part and component replacement, supplier and parts qualification, documentation of activities, and more. In addition, OEMs and their authorized servicers must comply with numerous other FDA regulations mandating: reporting of adverse events; establishment of procedures for conducting recalls and other actions should a problem occur with a device; registration with the agency; and many others. This comprehensive set of post-market requirements helps ensure that all servicing done to a medical device is done by properly trained, properly equipped technicians and that all work is thoroughly documented and reported, as necessary, to either the OEM or the agency.

Importantly, tens of thousands of unregulated third-party servicers are working on complex medical devices without proper training and sometimes without appropriate equipment and replacement parts. They are not required to follow the same extensive FDA regulatory requirements as OEMs and their authorized servicers, potentially putting patients and device users at risk.

WHY DON'T ALL THIRD-PARTY SERVICERS FOLLOW THE SAME FDA REQUIREMENTS?

That's a great question! OEMs and their authorized servicers recognize that — despite the additional cost— compliance with FDA regulations is vital to helping companies fulfill their commitment to patient safety.

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IF SERVICING IS SO IMPORTANT, WHY DOESN'T FDA CRACK DOWN ON UNREGULATED THIRD-PARTY SERVICERS?

That is question best posed to FDA. The agency has identified servicing requirements as a key component of its Quality System Regulation and requires all OEMs to follow these rules or face stiff penalties. Likewise, OEMs and their authorized servicers must follow numerous other regulations — covering adverse event reporting, recalls, registration with FDA for inspection purposes, etc. However, for some reason, FDA has chosen to use its enforcement discretion and has decided to forego regulating third-party servicers.

Furthermore, there is a patient safety issue. FDA reported in May 2018 that unregulated third-party servicing has been associated with more than 4,300 negative incidents involving medical devices, including 40 deaths and 294 serious patient or device user injuries.

DON'T OEMS JUST WANT TO ABOLISH THIRD-PARTY SERVICERS TO PROTECT THEIR PROFITS AND MARKET SHARE?

Not at all! OEMs recognize the value of a competitive servicing market. In fact, in addition to servicing their own products, many OEMs also act as third-party servicers to other OEMs. Some OEMs also rely on contracted third-party servicers to meet their own servicing needs. The difference is that in these cases, the OEMs and their contracted servicers follow all the required FDA regulations. OEMs believe for the sake of patients, third-party servicers should be required to follow the same regulatory requirements as they do to ensure the devices they service continue to meet the highest standards of safety and effectiveness.

THIRD-PARTY SERVICERS CLAIM THEY CAN PROVIDE THE SAME SERVICE AT LOWER COST, HOW DO OEMS RESPOND?

Any discounts unregulated third-party servicers may provide come from not having to comply with FDA's patient safety regulations.

Furthermore, any short-term savings unregulated third-party servicers may provide are erased in the longer term because of the effects of improper servicing. OEMs have reported that when they resumed servicing from an unregulated third-party servicer, there was a significant increase in the number of needed replacement parts, needed service calls, and in the total hours spent repairing devices in order to bring them up to the device's original performance requirements. Among other issues, the inadequate third-party service repairs lead to increased device downtime and increased cost to the health system.

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"RIGHT TO REPAIR" PROPONENTS CLAIM THEY CAN EFFECTIVELY SERVICE DEVICES WITH ACCESS TO OEM REPAIR MANUALS AND OTHER INFORMATION. IS THAT TRUE?

It takes more than just a manual to be able to effectively service a complex medical device whose proper functioning could be a matter of life or death for a patient. Giving unregulated third-party servicers unlimited access to service manuals and other proprietary OEM information would only serve to put patients and device users at greater risk. Access to the latest manuals is no substitution for the extensive training, knowledge and expertise provided by the OEM.

Even unauthorized third-party servicers that may have previously worked for an OEM and have knowledge or expertise for earlier models of devices on the market are not equipped to continue to work on these devices. The pace of medical technology innovation is so rapid that these technicians' expertise can quickly become obsolete, rendering their work on newer-model devices potentially dangerous to patients and other device users. These technicians may also be unaware of important safety updates or corrective actions taken by the OEM on existing or older model devices and may, in effect, "un-do" important safety or corrective actions.

"RIGHT TO REPAIR" PROPONENTS CLAIM THAT VITAL MEDICAL EQUIPMENT NEEDED DURING THE CURRENT HEALTH CARE CRISIS (SUCH AS VENTILATORS) IS SITTING UNREPAIRED BECAUSE OEMS REFUSE TO PROVIDE REPAIR MANUALS AND OTHER INFORMATION. IS THAT TRUE?

There is no evidence of any shortage of vital medical equipment due to lack of servicing by OEMs. Likewise, there is no shortage of trained, qualified OEM or OEM-authorized servicers who can safely and efficiently repair and service devices such as ventilators without needlessly exposing vulnerable patients to added harm.

During the current COVID-19 crisis, OEMs working with health care institutions continue to meet all servicing demands to ensure proper repair and maintenance of their devices which includes: on-site servicing, remote technical assistance, provision of replacement parts, and depot repairs according to local hospital requirements. OEMs and their authorized servicers are best equipped to service their products and keep patients who use them safe, and they are effectively serving the needs of patients and health care providers to respond both to the COVID-19 pandemic and other, ongoing health care needs.

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