

## Reduce repair restrictions to aid hospitals during COVID-19

COVID-19 has underscored the need for a more cooperative relationship between Original Equipment Manufacturers (OEMs) of medical technology, hospital-based BMETs, and independent medical device service providers.

As the FDA found in 2018, “the continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system,” and all three “provide high quality, safe, and effective servicing of medical devices.” This is especially true as a pandemic stress tests our medical system. However, hospital-based and third-party technicians often struggle to access the repair information needed to service equipment.

We, the undersigned clinical engineers and health technology managers, support requiring service materials (repair documentation, schematics, parts, tools and diagnostics) be made available immediately. We support the following changes:

- Manufacturers must meet the goals of 2012 NFPA 99 Health Care Facilities Code requirements around providing service information, and post their service materials in a manner that consistently allows hospitals to decide for themselves whom to hire for repair.
- Access to all service materials (all information, software, replacement parts and tools necessary to perform corrective and preventive maintenance actions in accordance with the manufacturers recommendations, such as repair documentation, schematics and diagnostics), available to the device owner even when equipment changes hands, on fair and reasonable terms.
- Product-specific training for repair must be made available online, on fair and reasonable terms, to biomedical engineering technicians, imaging service engineers, and other parties responsible for operation of medical equipment under CMS rules.

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