

The Right Way to Repair Life-saving Medical Technology

Life-saving medical technology is complex. Ventilators, defibrillators, intestinal scopes, CT and MRI machines, naming only a few, have many sophisticated components. Every device requires Food and Drug Administration approval. Every screw and microchip within must come from an FDA-approved warehouse. **Each part must work flawlessly. If not, patients risk injury, missed diagnosis, or misdirected treatment. Staff risks electrical shocks or radiation exposure.**

The American people understand. **In an AdvaMed national survey:**



95%

of respondents agreed:

- > complex medical technology is important to the overall quality of U.S. health care.
- > anyone who services or repairs the technology should be trained and authorized to perform this work, must adhere to the same safety protocols as those trained and authorized to do so, and must report any safety issues of the technology used in patient care.

89%

of respondents agreed:

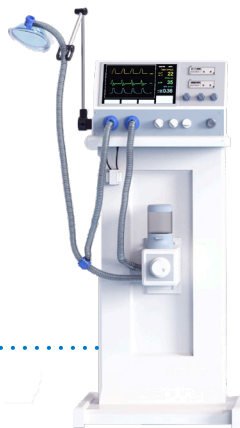
- > proper service and repair of complex medical technology is often a life-or-death matter for patients.
- > patients are safer when the technology is serviced by trained, authorized providers.



72%

of respondents agreed:

- > requiring manufacturers to share repair manuals with untrained, unauthorized providers makes medical technology more vulnerable to cyber hacks that can lead to patient harm, including increased inaccuracies and missed diagnosis.



Reported harm from unauthorized technicians:

A 2018 landmark **FDA study identified more than 4,300 reports of adverse events – including 40 deaths and 294 serious injuries – from devices repaired, replaced, or maintained by an untrained, unauthorized third party.**

Why only authorized technicians should do this work:

- > Device manufacturers train extensively on fixing and servicing their devices.
- > **Trained, authorized technicians must report any adverse events to the FDA. Untrained, unauthorized personnel face no such requirement.**
- > Trained, authorized technicians are in high supply.

The Bottom Line

Doctors and nurses rely on well-functioning equipment. Patients must be able to trust their tests and procedures are safe and effective and that no one is cutting corners to repair complex, life-saving technology. Safety is paramount in medicine. First, do no harm. **Maintain well-earned patient trust with the proper servicing of complex medical technology.**