The Alliance for Quality Medical Device Servicing (the "Alliance") formed in 2018 to represent large independent medical device service providers which offer comprehensive in-house service models to health care provider customers. The Alliance was encouraged by the findings in the May 2018 "FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices" (the "FDA Report").

The FDA Report concluded that "the currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing of medical devices, including third party servicers, that would justify imposing additional/ different burdensome regulatory requirements at this time." The Alliance concurs with this conclusion, but also agrees that the industry as a whole should continue to examine ways in which to collaborate more closely in order to address potential challenges in the delivery of high-quality and safe servicing of medical devices. Rather than defaulting to unnecessary regulatory or legislative initiatives that do not address clear problems but may restrict competition, the Alliance believes that the industry should take the lead on these issues, focusing on the principles that medical device servicing is always provided in a high-quality manner and that patient safety remains at the forefront of the discussion.

The FDA Report stated that the FDA intends to pursue these actions:

- Promote Adoption of Quality Management Principles;
- Clarify the Difference Between Servicing and Remanufacturing;
- Strengthen Cybersecurity Practices Associated with Servicing of Medical Devices; and
- Foster Evidence Development to Assess the Quality, Safety and Effectiveness of Medical Device Servicing.

The FDA's actions align with several of the recommendations of the Alliance in its April 2018 response to the FDA. This includes the Alliance's belief that collaboration between independent third-party service providers and OEMs is paramount to providing the highest level of quality, safe, efficient and cost-effective services to healthcare facilities.

In the Alliance's meeting with the FDA immediately after the release of the FDA Report, the Alliance expressed its sincere interest in working in the "Collaborative Communities" as proposed by the FDA. As stated by the FDA, these communities are a "continuing forum where public and private sector members proactively work together to solve both shared problems and problems unique to other members in environment of trust and openness, where participants feel safe and respected to communicate their concerns." The Alliance believes the Collaborative Communities will be an effective forum to address reoccurring disputes among OEMs and third-party service providers, such as accessibility to service manuals, materials and training.

Over the next several months, the Alliance will broaden its reach to work with and give voice to more independent third-party service providers, in-house hospital clinical engineering departments, health care providers, and OEMs as it looks to work closely with the FDA on the four primary actions proposed in FDA Report. The Alliance has already initiated dialogue with the FDA on ways in which to strengthen cybersecurity practices associated with servicing of medical devices. We would invite you to contact us for any questions or clarifications relative to servicing of medical devices.

The Alliance for Quality Medical Device Servicing is composed of representatives from TriMedx, Crothall, Aramark, ABM, Sodexo, and The InterMed Group.