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MEDICAL IMAGING

Third-Party Hardware Modification of Interventional X-Ray Equipment:

Issues to be Considered

Technical White Paper

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1. Introduction

The healthcare industry has seen a surge in the use of interventional X-ray equipment (i.e., devices) for increasingly complex procedures over the past decade. This has brought tremendous benefits to patient care by enabling providers to perform less invasive clinical procedures more often. It has also spurred innovation in radiation management and radiation-reducing technologies.

Unfortunately, there have also been marked increases in healthcare provider deployment of third-party hardware which modifies the device as provided by the original equipment manufacturer (OEM) without verifying, testing, or validating for compatibility. Such unvalidated modifications can alter the equipment's original configuration and negatively impact device safety and performance.

To address this rising problem, we provide our recommendations to regulators and other policy makers and stakeholders regarding third-party hardware modifications (i.e., third-party modifications) that may impact device safety and effectiveness if they are not adequately validated as compatible with the device makes and models with which they are used. We also share potential safety, regulatory, and operational implications for healthcare facilities which deploy third-party hardware modifications onto OEM devices.

2. Scope

This white paper focuses on third-party modifications made to medical X-ray equipment used in fluoroscopically guided interventions, such as collimators, static transparent filters, c-arm filters, and scatter reduction shields. Modifications are discussed in two distinct groups: direct in-beam and out-of-beam.

3. Direct In-Beam Third-Party Hardware Modifications

Direct In-Beam third-party modifications may be developed and marketed as a tool which can enhance patient and practitioner safety by reducing exposure to potentially harmful radiation. The appeal is undeniable. However, such third-party modifications introduce potential hazards when deployed without comprehensive evaluation of compatibility by the OEM, and review by the U.S. Food and Drug Administration (FDA) for safety and effectiveness.

Most modern interventional x-ray devices implement sophisticated automatic exposure feedback loops that are constantly adjusting the imaging techniques used to achieve an effective balance between image quality and radiation dose rates. Any additional material placed directly in the x-ray beam can have extremely detrimental consequences and negatively impact both image quality and radiation dose.

4. Out-of-Beam Third-Party Modifications

Out-of-beam third-party modifications often promise to significantly reduce scattered radiation , reducing operator and staff exposure. These shielding systems do not directly block the x-ray beam but claim to reduce scattered radiation coming from the patient and the device.

Out-of-beam third-party modifications often require varying degrees of integration with the patient support structure or cumbersome grafting onto C-arm devices, but they often lack rigorous compatibility assessments from the OEM or review by the FDA. These third-party modifications may reduce patient support weight limits, constrain mechanical movements, compromise mechanical stability, or impede operator access to the patient. In many cases, these third-party modifications have the potential for adverse impacts on operator safety, patient safety, and device performance.

5. Other Important Considerations

Third-party modifications can have a substantial impact on the OEM device even beyond safety and performance considerations. Third-party modifications can lead to system deterioration (e.g., increased tube loading, mechanical stress, electrical overload). Adding a third-party modification to a device can also impact warranty and service agreement terms. Altering OEM device performance, safety specifications, or intended use with a third-party modification may be considered remanufacturing, which creates new reporting and labeling requirements the third-party or provider must meet. And third-party modifications can complicate or prevent regular maintenance of the device, reducing device usability or causing serious mechanical issues.

We recommend that healthcare providers confirm the third-party modification has been tested with the OEM device make and model through review of labelling, verified compatibility statements, and the device 510k summary. The following questions provide a starting point for evaluation of a third-party modification prior to deployment on an OEM device.

- Has the third-party modification been reviewed by the FDA?
- Does the vendor provide a compatibility statement for the third-party modification?
- Could the safety and effectiveness be compromised by the third-party modification?
- What is the effect on clinical reliability, system reliability, uptime, and the expected service life of the equipment?
- Is the third-party registered as a manufacturer and/or remanufacturer? If so, are they meeting the requirements of the "Remanufacturing of Medical Devices" FDA guidance?
- Will the loading of the system, dose, or image quality be affected by using a third-party modification on the system?
- Has the original equipment manufacturer submitted an allegation against the third-party modification?
- Has the original equipment manufacturer been directly involved with testing of the third-party modification?
- Will installing the third-party modification violate the warranty?
- Is there an updated user manual from the vendor supplying the third-party modification?
- Does the modified equipment still comply with quality control and performance requirements set by the OEM?
- Does the modified equipment still comply with state and federal regulatory requirements?
- Will routine maintenance on the modified equipment still be possible per OEM specifications?
- Can the vendor provide evidence that testing was performed on the third-party modification by an ISO 17025 qualified testing laboratory?

6. Conclusion

Unauthorized third-party modifications to interventional X-ray equipment represent a considerable risk to patient and operator safety. Adding a component, part, or material to a device could result in significant change to the original safety and performance specifications of the device, which underscores the importance of thorough testing. We recommend that a complete technical assessment be performed prior to the use of any modification to mitigate potential harms. We also recommend that a collaborative effort among regulatory agencies, healthcare providers, and industry stakeholders is needed to establish and enforce guidelines for the safe and effective use of any medical imaging device modifications.

Appendix A: Assessing for safety, effectiveness, and substantial equivalence

A third-party vendor should be able to provide evidence that both the third-party hardware modification alone and the modified OEM equipment conform to the following requirements. This evidence should be available across the expected service life of the modified equipment.

1. IEC 60601-1 basic safety and essential performance requirements

- Power consumption does not exceed the rating label.
- Electrical safety, including creepage and clearance distances, protective earth / ground bond, leakage current, dielectric strength. Humidity preconditioning was performed for electrical safety testing if there is hygroscopic material.
- Applied and accessible parts.
- Access to hazardous moving parts.
- Are gaps maintained for trapping zones (pinch, crush, etc..).
- Equipment instability in transport and normal use.
- Force for propulsion.
- Sharp edges.
- Rough handling (movement over a threshold, ascending/descending step, door frame).
- Enclosure rigidity, impact testing, mould stress relief.
- Hazards associated with suspended mass and support systems.
- Biocompatibility.
- Fire enclosures and enclosure flammability ratings.
- Excessive temperatures.
- Spillage on equipment, ingress of liquids (IPX ratings), leakage from equipment, cleaning, sterilization, and disinfection. This includes compatibility with cleaners and disinfectants specified in the OEM operators manual.
- Maintaining basic safety and essential performance in single fault conditions.

2. Conformance to IEC 60601-2 EMI/EMC.

- Radiated and Conducted Disturbances / Emissions
- Electrostatic Discharge (ESD) Immunity
- Radiated, Radio Frequency, Electromagnetic Field Immunity
- Electrical Fast Transients / Burst Immunity
- Surge Immunity
- Immunity to Conducted Disturbances induced by RF Fields
- Power Frequency Magnetic Field Immunity
- Voltage Dips, Short Interruptions, and Voltage Variations Immunity
- Radiated Fields in Close Proximity Immunity (RFID)

3. Conformance to IEC X-ray particular standards including IEC 60601-1-3, 60601-2-54, 60601-2-43. It is important to note that many of these are very likely impacted if X-ray equipment system software is making calculations based on what is expected to be in the beam during original manufacture and not based on measurements.

- Accuracy of indication and recording of kVp, mA, and dose. This includes accuracy of the Radiation Dose Structured Report (RDSR) and the requirement to record specifics about items in the beam.
- Low dose mode.
- Indication of presence of X-ray grid
- Half value layer / total filtration
- Beam size limitation
- Leakage radiation
- Documentation to the user of Stray Radiation profile and isokerma maps.
- Documentation to the user of typical reference air kerma (rate) values typical of radiography for distinctive types of procedures.

- Documentation to the user of representative air kerma (rate) for the modes of operations including for each selectable added filter, entrance field size, and pulse repetition frequency.
- Motorized anti-collision and overtravel mitigations.
- Radiation data in operator's manual (available settings, highest AKR, representative dose, patient entrance reference point)
- Attenuation between patient and image receptor.
- Primary protective barrier
- Attachment of sterile drapes

4. Conformance to country and manufacturer imaging performance and dose requirements.

- Automatic Control System performance and reproducibility
- Air kerma rate at the entrance plane to the image receptor
- Limitation of reference air kerma rate
- Spatial resolution
- High contrast resolution
- Low contrast resolution
- Dynamic range
- Contrast sensitivity
- Imaging artifacts