



MITA[®]
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF **NEMA**[®]

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September 3, 2020

VIA ELECTRONIC DELIVERY

William H. Maisel, M.D., M.P.H.
Director, Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Maisel,

As part of our ongoing efforts to promote safety and quality throughout the lifecycle of medical imaging devices, we are writing to make you aware that manufacturers have received reports of inappropriate cleaning agents and disinfectants being used on medical imaging devices. We request that FDA communicate to the public the importance of following original equipment manufacturer guidelines regarding the use of cleaning agents and disinfectants on medical imaging devices.

Medical devices include as part of their labeling guidelines for proper cleaning and disinfection. It is important to follow these guidelines in order to ensure the ongoing safety and performance of the device. Not following manufacturer guidelines may cause damage to the product, leading to otherwise unnecessary repairs, irreversible damage, or downtime.

As an example,¹ a non-OEM approved high level disinfectant was used on the ultrasound probe pictured below, resulting in significant damage to the lens material, necessitating replacement of the part.



¹ This example is merely illustrative, and is non-exhaustive of the reports manufacturers have received regarding improper use of cleaning agents or disinfectants.

It is particularly important that manufacturer guidelines be followed given the ongoing pandemic. We certainly do not want medical imaging devices to be vectors for transmission of COVID-19. But we are concerned, however, that certain cleaning products are being marketed as being effective against COVID-19, leading healthcare facilities to use these products without submitting them to appropriate verification and validation processes.

We request that FDA take immediate action to communicate to the public the importance of following manufacturer guidelines for cleaning and disinfecting medical imaging devices.

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If you have any questions, please contact Peter Weems, Senior Director, Strategic Operations and Policy, at pweems@medicalimaging.org or 703-841-3238.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick Hope". The signature is fluid and cursive, with a large initial "P" and a long horizontal stroke at the end.

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.