

NEMA XR 21

CHARACTERISTICS OF AND TEST PROCEDURES FOR A PHANTOM TO BENCHMARK CARDIAC FLUOROSCOPIC AND FLUOROGRAPHIC PERFORMANCE

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*Characteristics of and Test Procedures
for a Phantom to Benchmark
Cardiac Fluoroscopic and Fluorographic Performance*

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NOTE—Sample Operating Instructions are furnished in a separate informative NEMA document.

Foreword

The performance of any medical imaging system can be divided into two categories: (1) Suitability of the images for the clinical procedure and (2) the amount of energy administered the patient while acquiring the images. The phantom and test procedures described here test systems under conditions simulating a range of fluoroscopically guided invasive and interventional procedures. These tools provide simultaneous objective measurements of image quality and phantom entrance dose.

Test results characterize the performance of the complete system under simulated clinical conditions. All tests are performed using the imaging system configured for normal clinical use. The phantom loads the system, as does a similarly sized patient. Image quality test targets are placed at the center of the phantom (the clinically relevant region).

Measurable differences in test performance may or may not reflect meaningful differences in clinical utility. Uncertainties include the variety of clinical tasks for which the equipment might be used, differences in the skills of operators, and the lack of congruence between the phantom and patient tissue.

The system level tools described in this document are used to screen for inappropriate performance. Such tools are not always helpful in diagnosing the causes of such behavior. Supplementary tools can provide additional information about system or subsystem behavior. Equipment manufacturers recommend tools and procedures specific to the imaging systems that they supply.

There is limited availability of optical, electronic, or digital techniques for evaluating imaging performance. Therefore, the test procedures in this standard are based on trained human observers. The FDA has reached a similar conclusion in conjunction with its mammography regulations (MQSA).

NOTE—The phantom and test procedures described here were originally developed for testing imaging systems designed for invasive cardiology (23 cm image intensifier, non-subtracted images). The lateral dimensions of the phantom may be extended to accommodate different sizes and shapes of image receptors. Additional modules might be added to this standard in the future to test subtraction and other aspects of system or imaging component performance. Modules and tests not included in this standard may be used to extend test functionality.

This document is scheduled for review in accordance with NEMA policy. The review process will decide whether the standard is to be withdrawn, revised, or extended for a further period. It is likely that changes in fluoroscopic technology and clinical requirements will result in the issuance of a revised standard.

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This standards publication was developed by the X-Ray Section. Section approval of the standard does not necessarily imply that all section members voted for its approval or participated in its development. Proposed or recommended revisions should be submitted to:

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