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COMMISSIONING AND CONSTANCY PROTOCOLS FOR DIGITAL ANGIOGRAPHIC UNITS

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During the European Concerted Action SENTINEL 'Safety and Efficacy for New Techniques and Imaging using New Equipment to Support European Legislation', protocols for commissioning and constancy tests for dynamic digital flat detectors angiography units have been developed in order to harmonise practice among the European counties. The commissioning protocol includes measurements on X-ray tube and generator, patient and detector radiation dose and image quality. The constancy protocol is based on the dose and image quality measurements. The commissioning protocol was tested by SENTINEL partners who expressed an interest in checking their dynamic digital systems using this protocol. The results of basic tests are reported.

INTRODUCTION

Interventional Cardiology (IC) is continuously evolving, leading to increasing need for cardiac catheterisation and therapeutic interventional procedures that are often associated with an increased radiation exposure compared with the conventional X-ray techniques. Thus, the requirement for more efficient and easy handling X-ray units has led to the introduction of modern digital technology in IC. Solid-state flat detectors (FDs) have recently been developed for X-ray angiography machines. However, the performance standards for image quality and dose in digital FD fluoroscopy are yet under discussion. Furthermore, a limited number of studies is found in the literature regarding the use of dynamic FD in IC.[1–3]

The need for special quality control tests for dynamic FD X-ray systems was acknowledged by the European Concerted Action SENTINEL 'Safety and Efficacy for New Techniques and Imaging using New Equipment to Support European Legislation' and was included in one of its workpackages. Draft protocols for commissioning and constancy tests were created based on the international recommendations for conventional X-ray machines using image-intensifier detectors.[4,5] The commissioning protocol was tested by SENTINEL partners who expressed an interest in checking their dynamic digital systems.

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MATERIALS AND METHODS

An extensive literature review was initially performed to investigate the possible quality control protocols in digital FD dynamic systems. Unfortunately, no such protocol existed at the time of the study, apart from the existing literature on conventional machines.[4,5] Therefore, it was decided to create two draft protocols (one for commissioning and one for constancy testing) based on the existing documents[4,5] and experience on such systems. The draft protocols were sent to all SENTINEL partners participating in the specific workpackage for comments and discussion (Greece, Italy, Spain, Luxembourg, Romania and UK). Comments and further suggestions were discussed and final protocols were set and distributed among four SENTINEL partners who expressed an interest in checking their digital systems (Greece, Italy, Spain and Luxembourg). The draft commissioning protocol was finally tested using a similar set-up and test equipment for comparison purposes. The products of some of these tests are given in the results section.

The summary of draft commissioning protocol tests is given below with details only of the tests for which the results are presented.

(1) Tube kilovoltage.
(2) Half value layer measurement.
(3) X-ray tube leakage test.
(4) Patient Entrance Air-Kerma Rate (PEAKR) in fluoroscopy. Water or polymethylmethacrylate (PMMA) phantom of varying thickness could be used so as to simulate a thin, normal and

thick patient. In the particular study, a 20-cm thickness PMMA phantom that corresponds to a normal size patient (70 kg) was used. The dose detector should be placed at the interventional reference point (IRP), i.e. 15 cm from the isocentre towards the X-ray tube focus. Further, the detector was placed on patient table and at the bottom of the phantom at all times. Air-Kerma rate (including backscatter) measurements should be taken for most frequently (or all) used fluoroscopic modes and (or) pulse rate modes and field of view (FOV). The results presented here include measurements for 25 cm FOV and 12.5 pulses/s.

(5) Maximum PEAKR in fluoroscopy.
(6) PEAK per image. Similar configuration as test 4 was used at all times. The results presented here include measurements for 25 cm FOV and 12.5 frames/s.
(7) Detector Entrance Air-Kerma rate (DEAKR) in fluoroscopy. Similar equipment as in test 4 can be used. In this study, a 20 cm thickness PMMA phantom was used and the dose detector was placed on the top of the phantom. The results include measurements for 25 cm FOV and 12.5 pulses/s.
(8) Detector Entrance Air-Kerma in image acquisition.
(9) High and low contrast spatial resolution test. The Leeds TOR 18FG or other appropriate image quality phantom should be placed at the centre of the PMMA phantom at the IRP and centred in the field using the largest magnification available. (If water is used, the image quality phantom should be placed under the tank.) In this study, the Leeds TOR 18FG phantom was used and the results include high contrast image quality measurements.
(10) Limiting contrast test.
(11) Display monitor set-up.
(12) Distortion.
(13) Radiation field size.
(14) Fluoroscopic X-ray field limitation.
(15) Verification of isokerma maps.
(16) Performance assessment of protective devices.
(17) kerma area product and cumulative dose metres calibration at the IRP.

Quality control equipment for these tests is also proposed in the draft protocol and it is provided below.

(1) Calibrated kVp metre.
(2) A measuring tape.
(3) Copper or aluminium filters (for example, 1–4 mm Cu, 1–5 cm Al) or equivalent absorbers.
(4) Al filters for half value layer measurements.
(5) 20 cm PMMA (area 20 × 20 cm^2) or equivalent (water phantom).
(6) A lead sheet of 2 mm or lead apron (which can be folded and simulate ~2 mm Pb).
(7) A calibrated ionisation chamber or solid-state detector.
(8) Calibrated ionisation chamber for scatter dose measurements.
(9) Phantom for high contrast and low contrast measurements (proposed: Leeds phantom TOR-18FG).
(10) Phantom for limiting contrast test (proposed: Leeds phantom TO-10).
(11) A distortion phantom.
(12) Collimation test tool.

The draft constancy protocol is based on specific parts of the commissioning protocol, the summary of which is given below using similar quality control test equipment.

(1) PEAKR in fluoroscopy.
(2) PEAKR per image.
(3) DEAKR in fluoroscopy.
(4) Detector Entrance Air-Kerma in image acquisition.
(5) High and low contrast spatial resolution test.

RESULTS AND DISCUSSION

The X-ray systems that were tested in the trial with the draft commissioning protocol were: three Philips Allura units, one Siemens Axiom Artis and one GE Innova 2000 X-ray angiography unit. Figure 1 shows the results of PEAKR, for 25 cm FOV, for 12.5 pulses/s and for the low, normal and high fluoroscopic modes, respectively. The main characteristic of the results is the large range of doses, even for the same manufacturer. Specifically, the radiation dose difference between various machines can be as high as 10 times in normal and high fluoroscopic mode. Figure 2 shows the results of PEAK per image, for 25 cm FOV. The main characteristic is again the large range of doses, even for the same manufacturer. Figure 3 shows the results of flat DEAKR for 25 cm FOV and various fluoroscopic modes. The main characteristic is again the large

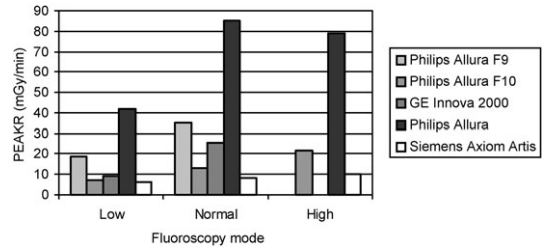

Figure 1. PEAKR for 25 cm FOV, 12.5 pulses/s and for the low, normal and high digital FD fluoroscopic mode.

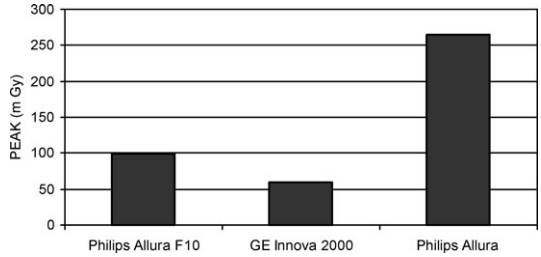

Figure 2. PEAK for 25 cm FOV, normal acquisition mode and 12.5 frames/s.

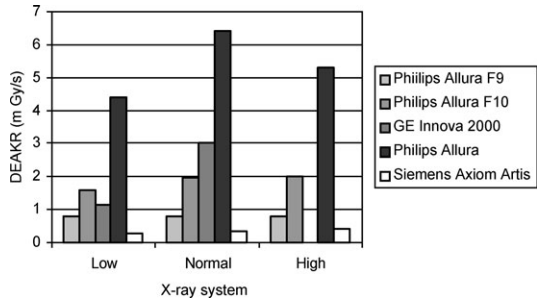

Figure 3. DEAKR for 25 cm FOV, 12.5 pulses/s and for the low, normal and high digital FD fluoroscopic mode.

range of results, with radiation dose ratios reaching 13 in high fluoroscopic mode. Figure 4 shows the image quality results for normal fluoroscopic mode and 25 cm FOV. The interesting point is that for such a large dose variations, image quality does not change in the same manner.

The large dose variations found between machines did not allow the authors to set any preliminary reference values neither in fluoroscopy nor in image acquisition. As the results appear, the commissioning protocol must be tested in a large number of machines, so as to understand the reasons for such large differences even for the same company. The interesting thing, however, is that despite the difference in dose performance, image quality did not differ accordingly. The authors were not able to draw any conclusions for this finding since the machines are very sophisticated and the experience in using these systems or even performing quality control tests is not yet large. Hopefully, in the near future, this study will expand and include more machines in different centres and countries around Europe so as to further investigate in more detail the performance of the FD digital dynamic systems.

CONCLUSION

Draft protocols of commissioning and constancy tests for dynamic FD X-ray angiography units were

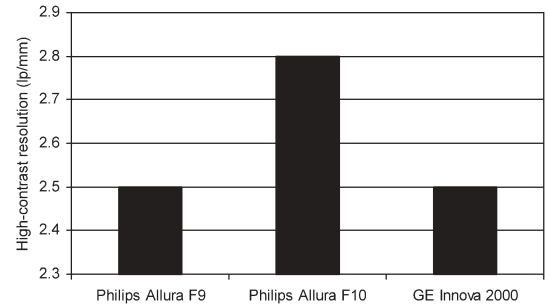

Figure 4. High contrast resolution for 25 cm FOV and the normal fluoroscopic mode.

prepared as part of the SENTINEL project. The commissioning protocol was tried by SENTINEL partners and preliminary results show a large range of doses, even for the same manufacturer, with no significant change in image quality. However, this was a preliminary study and more systematic and detailed investigation is needed in the future.

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