



# IEC Standards Related to IR/Cath (What's the "Diesel"?)

13 July 2020  
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## Overview

- Brief Overview of IEC
  - Rosetta Stone for language of IEC
    - SC, TAG, NC, WG, MT, CD, CDV, FDIS .....
- WG 37 and MT 41 Efforts
  - IEC 60601-2-43 FDIS
  - IEC 61223-3-8 - Acceptance and Constancy Testing (ongoing / future)
  - Instructions For Use (IFU)



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## International Electrotechnical Commission (IEC)

- One of three related global standards organizations
  - IEC, ISO, ITU
- IEC Scope
  - "prepares and publishes International Standards for all electrical, electronic and related technologies"



IEC Central Office – Geneva, Switzerland

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## IEC Members

- National Committees (NCs)
  - All voting comes from NCs
  - USNC
    - American National Standards Institute



- Comprised of experts appointed to Technical Advisory Groups (TAGs)
- AAPM supports related TAGs




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## IEC Basic Rosetta Stone

- TC – IEC Technical Committee
- SC – IEC Sub Committee
- WG – Working Group
- MT – Maintenance Team
- CD – Committee Draft
- CDV – Committee Draft for Vote
- FDIS – Final Draft International Standard




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## IEC Standards For Medical Electrical Equipment

- TC 62 – Electrical equipment in medical practice
  - SC 62A – Common aspects of medical electrical equip
  - SC 62B – Diagnostic imaging equipment
    - MT 41 – Revisions to 60601-2-43 (interventional fluoro)
    - WG 37 – General requirements for radiation protection in radiography and radioscopy (fluoroscopy)
  - SC 62C – Radiotherapy, Nuc Med, and Radiation Dosimetry equipment




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## IEC 60601-2-43 / AMD2 ED2

- Scope – fluoroscopes intended for use in interventional procedures
- FDIS approved 2019-08
- 3 year implementation period



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## 60601-2-43 Requirements

- Configurable radiation units for AKAP
- Minimum fluoro pulse rate
- Fluoro save
- Fluoro Last Image Hold (LIH)
- Virtual collimation
- Manual QC testing control “Physics Mode”



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## 2-43 Requirements (cont'd)

- Configurable radiation units for AKAP
  - Gy\*cm<sup>2</sup>, cGy\*cm<sup>2</sup>, mGy\*cm<sup>2</sup>
    - Allows facilities to use a common AKAP
    - Allows for differences between Peds and Adults



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## 2-43 Requirements (cont'd)

- Minimum fluoro pulse rate of 4 pps or less
  - Ensures availability of low pulse rates
  - All else constant, proportional to kerma rate



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## 2-43 Requirements (cont'd)

- Radioscopy (Fluoro) save feature, minimum:
  - 30s for 10pps or less
  - 300 images at > 10pps
  - 10s for continuous fluoro



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## 2-43 Requirements (cont'd)

- Radioscopy (Fluoro) Last Image Hold (LIH)
  - Systems must display the last image acquired
  - Allows clinician to study static anatomy without exposing patient



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## 2-43 Requirements (cont'd)

- Virtual Collimation – a graphical indication of collimator positioning when adjusting during LIH
  - During LIH, operator can adjust collimators and visualize the location of the collimator blades w/out exposing the patient



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## 2-43 Requirements (cont'd)

- Manual X-ray control for QC testing “Physics Mode”
  - Similar to NEMA standard (will be discussed by Dr. Kuhls-Gilcris)



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## 2-43 Recommendations

- End user imaging protocol setup and change traceability
- Patient skin radiation dose map
  - Map to indicate size, shape, and location of the X-ray fields
  - Real time display / update provided to operator



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## WG 37

- Maintains several related standards
  - 60601-2-54 – Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
  - 61223-3-8 – Evaluation and routine testing in medical imaging departments – Acceptance and constancy tests for radiography and radioscopy

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## WG 37 Future / Ongoing

- IEC standard 61223-3-8 is proposing QC manuals to be furnished by vendors for all types of Radiography and Fluoroscopy units
  - Manuals would establish vendor "recommended" QC
  - Standard would provide common elements and framework, but provide some latitude for vendors to adopt the manuals to their systems

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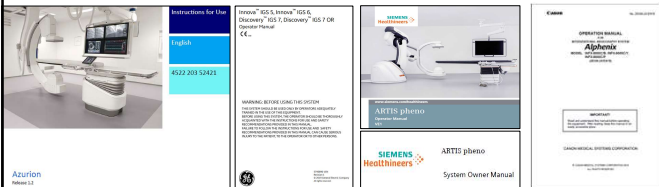
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## Instructions For Use (IFU)



- IFU documents are required by IEC standard
  - All radiography and fluoroscopy equipment
- Vendors refer to documents differently

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## IFU Technical Information

**Systems with FD20 Detector**

Description	Setup
Anti-scatter grid	In position
Distance from focal spot to entrance surface of the phantom	945 mm (37.20 inch)
Distance from focal spot to image receptor	1195 mm (47.05 inch)
Distance from focal spot to patient entrance reference point	660 mm (25.98 inch)
Distance from focal spot to isocenter	810 mm (31.89 inch)

Philips IFU

- Focal Spot to Interventional Reference Point Distance:
  - (For Innova IGS 5) : 57 cm (22.4")
  - (For Innova IGS 6) :
    - (For Frontal plane X-Ray Tube) 57 cm (22.4")
    - (For Lateral plane X-Ray Tube) 55 cm to 73 cm (22" to 28.7")
  - (For Discovery IGS systems) : 57 cm (22.4")

1756895 10/16 Revision 1 Innova™ 501, Innova™ 601, Discovery™ 601 7/08

Siemens Owner Manual

Distance between X-ray focus and isocenter	70 cm
Distance between X-ray focus and patient exposure reference point	55 cm
Dose measurement point	Patient exposure reference point
X-ray grid	IN
Tabletop of the catheterization table	DUT
X-ray beam direction	LAO 80°/CRA 0° (a lateral position at which the tabletop of the catheterization table is not included in the exposure field)

Canon Operations Manual

Interventional reference point See Table 1a or 1b.  
60 cm (Artis floor / Artis biplane)  
63.5 cm (Artis ceiling / Artis zeego)

GE Operator Manual

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## IFU Technical Information

### Iso-kerma plots

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## IFU Technical Information

- Other technical information required or commonly found in IFU / Accompanying Documents
  - Radiation field size dose factors
  - Phantom dose rates for various protocols / system settings
  - Radiation beam filtration
  - Image receptor and X-ray tube technical info

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## Summary

- IEC has numerous standards pertaining to imaging equipment
- Recent efforts include:
  - Revisions to 60601-2-43 (interventional fluoro)
  - Current work on recommended QC (rad/fluoro)
- IFU and AD offer a treasure trove of technical information required by IEC standards



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