# Mechanical Performance of X-Ray Systems

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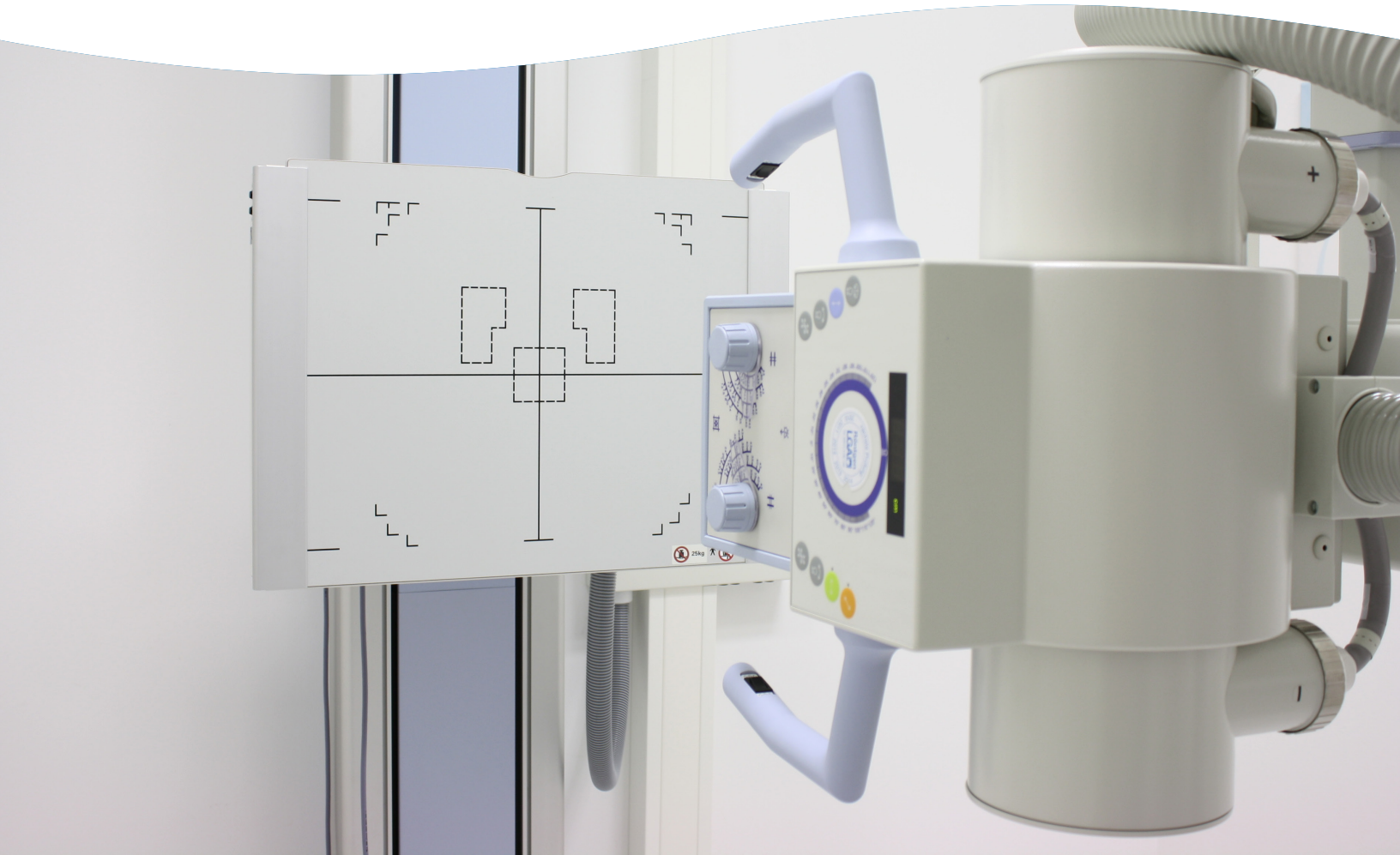
# Executive Summary

When evaluating the safety of X-ray medical equipment, radiation protection and performance-corresponding radiation measurements stays at the forefront of concern. However, IEC standards for X-ray equipment also contains many requirements for mechanical performance intended to prevent mechanical hazard to both patients and operators. In addition, the mechanical devices within these machines, while they have no involvement with generating X-ray radiation, can still affect the amount of radiation received by patients which can be hazardous.

Another subject this paper addresses is that testing the dynamic characteristics of moving parts is often much more difficult to perform than X-ray radiation measurements. This is caused by the fact that the test instruments needed to perform mechanical testing are not readily available from the shelf and therefore require manufacturers to develop those test methods.

This paper reviews the requirements for mechanical devices critical for delivering safe amounts of radiation while preserving X-ray image quality and discusses the challenges for testing the dynamic characteristics of motorised moving parts.



# IEC Standards for X-Ray Equipment

**IEC 60601-1-3**

Let's start with the most widely applied standard for X-ray equipment, IEC 60601-1-3 - Radiation Protection in Diagnostic X-ray Equipment. This collateral standard applies to X-RAY EQUIPMENT and to subassemblies of such equipment, where RADIOLOGICAL IMAGES of a human PATIENT are used for diagnosis, planning or guidance of medical procedures.

The major concern for any diagnostic X-ray equipment is a quality of X-ray beam that emerges from an X-ray tube. This X-ray beam contains a significant portion of low energy radiation that doesn't contribute to creating a diagnostic image, and instead causes an excess of radiation - especially to the patient's skin. In order to stop this harmful radiation, the simple mechanical materials, or filters, intersect the X-ray beam and absorb the low energy spectrum of radiation, thus greatly improving the quality of the X-ray beam. For particular applications, these filters are removable so the operator can adjust the spectrum of the X-ray beam to suit their needs. As a result, these simple mechanical devices are critical to ensure that the RADIATION QUALITY of the X-RAY BEAM produces the intended images without administering unnecessary HIGH DOSES to the PATIENT.

### IEC 60601-2-54

While IEC 60601-1-3 is the most broadly applicable standard for various medical X-ray equipment, the second most common is IEC 60601-2-54 - X-Ray Equipment For Radiography and Radioscopy. First, we will check the section of this standard focused on mechanical means used to avoid unnecessary high doses to the PATIENT. The Clause 203.10 ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR is mostly intended for the patient supports, like radiological tables used in the X-ray diagnostic equipment and the surgical tables, often used in combination with X-ray equipment. This clause requires that X-RAY EQUIPMENT be designed in such a way that the ATTENUATION of the X-RAY BEAM is kept as low as reasonably achievable in order to avoid unnecessary high doses to the PATIENT.

It could be counterintuitive to understand why the material of the patient could affect the dose received by the patient. This material interposes the beam exiting the patient and does not affect the radiation dose received by the patient, which is solely determined by the X-ray beam projected to the patient. However, we need to take into account that the X-ray beam that reaches imaging detector if being weakened by the attenuation in the patient support may produce a degraded image. To compensate for this loss, the power of X-ray exposure needs to be increased leading to a higher dose to a patient.

While this clause is mostly about attenuation caused by the patient support, it also includes other devices and materials that could be on the path of the X-ray beam to the imaging detectors. They are listed in the Table 203.104 of the IEC 60601-2-54 as shown below:

**Table 203.104 – ATTENUATION EQUIVALENT of items in the X-RAY BEAM**

| Item | Maximum ATTENUATION EQUIVALENT mm Al |
|---|---|
| Total of all layers composing the front panel of cassette holder | 1,2 |
| Total of all layers composing the front panel of FILM CHANGER | 1,2 |
| Total of all layers, excluding detector itself, composing the front panel of DIGITAL X-RAY IMAGING DEVICE | 1,2 |
| Cradle | 2,3 |
| PATIENT SUPPORT, stationary, without articulated joints | 1,2 |
| PATIENT SUPPORT, movable, without articulated joints (including stationary layers) | 1,7 |
| PATIENT SUPPORT, with radiolucent panel having one articulated joint | 1,7 |
| PATIENT SUPPORT, with radiolucent panel having two or more articulated joints | 2,3 |
| PATIENT SUPPORT, cantilevered | 2,3 |
| NOTE 1 Devices such as RADIATION DETECTORS are not included in the item listed in this table.<br>NOTE 2 Requirements concerning the ATTENUATION properties of RADIOGRAPHIC CASSETTES and of INTENSIFYING SCREENS are given in ISO 4090 [3], for ANTI-SCATTER GRIDS in IEC 60627[1].<br>NOTE 3 ATTENUATION caused by table mattresses and similar accessories is not included in the maximum ATTENUATION EQUIVALENT for PATIENT SUPPORT.<br>NOTE 4 Maximum ATTENUATION EQUIVALENT mm Al is only applied to the corresponding item. If several items given in this table are located in the path of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR, each corresponding maximum ATTENUATION EQUIVALENT mm Al is separately applied to each item. | |

NOTE 2 of the above table mentions the Anti-Scatter Grid. As its name suggests, the Anti-Scatter Grid is intended to reduce scatter radiation that degrades the geometry of the projected X-ray beam and this way reduces the contrast and resolution of the image. Scatter radiation is caused by the interaction of IONIZING RADIATION with the hard tissue of the patient, mostly with bones. The Anti-scatter grid limits the amount of the scatter radiation approaching the detector and helps to significantly improve the image quality (See Fig. 1).

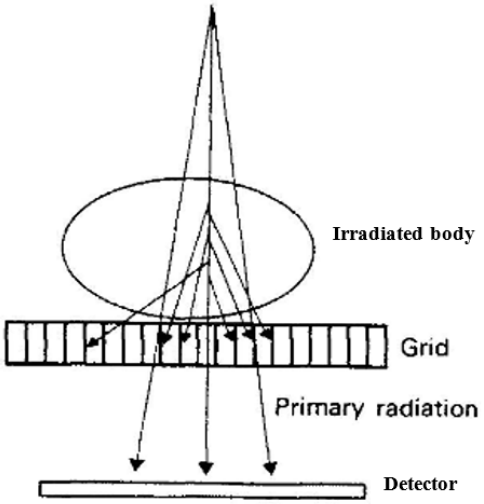



Fig. 1 Anti-scatter Grid

As shown on Fig. 1, the grid is constructed of a series of alternating parallel strips of lead that absorb the scattered radiation. As a result, the Anti-scatter grid could contribute a great deal to the attenuation equivalent. However, IEC 60601-2-54 doesn't have explicit requirements for the Anti-scatter grid's attenuation equivalent. Because of this, a trade-off between the higher attenuation equivalent and the improved image quality is required. The Anti-scatter grid requires a separate consideration, which is described in detail in the IEC 60627 standard - Characteristics of General Purpose and Mammographic Anti-scatter grids. This trade-off between higher doses versus higher diagnostic quality should also be considered when Anti-scatter grids are used during RMF.

As we noted already, robotic systems found an increasingly wider application in medical systems, and especially in combination with the X-ray equipment which is used for navigation during robotically assisted surgical procedures or during radiation therapy treatment. The IEC 60601-2-54 has a number of requirements to MECHANICAL HAZARDS and especially those associated with moving parts. This will be focus of the next portion of this paper.

X-ray equipment having motorized movement may cause serious injuries if the actuation controls intended to stop this movement don't perform as needed. Almost every particular standard for X-ray diagnostic equipment includes the necessary requirements for stopping linear and rotational movements. The overtravel of such movements occur after a control to stop is actuated or the machine experiences power loss. Taking in account that the requirements of overtravel movement limits to few millimeters, or an angle of less than 1 degree, and occurs in less than a second, it is practically impossible to perform such measurement unless the manufacturer can provide custom test capabilities. Fortunately, the majority of X-ray systems that employ motorized movements have the software utilities that could be used to measure the stopping distances. However, it may require some alteration to the software used to measure stopping distances. In this case, the manufacturer should be alerted ahead of time in order to perform such alterations.

# X-Ray Devices Integrate with Robotic Systems

Often, motorized devices used for radiation therapy employs robotic systems that provide 3D or 4D+ linear and rotational motions. This can make it quite challenging to measure the stopping distances contributed by more than the axis of movement. In order to perform such testing requires more elaborate test software to calculate the overall stopping distances.

Another challenge is that those robotic devices are built by other vendors, so the access to their software utilities could be difficult.  Another reason why the testing for stopping distances cannot rely on the internal software is because they also need to be measured after the equipment experiences power loss. As a result, the manufacturer needs to develop a dedicated testing system that includes a precise distance-measuring, laser-based instrument and supportive electronics. Since this development is often outside of the expertise for most manufacturers, this task may cause significant difficulties and delays. Also, developing efforts to perform just a few tests is not a very productive solution.

An effective solution could be the development of a Universal Test Instrument that is able to perform such measurements in the wide range of motorized controlled medical equipment, under all other X-ray equipment. The development of such an instrument would require good understanding of IEC standards and other related requirements. A cooperation with the test agency that specializes in the testing of X-ray equipment and Medical Robots would be beneficial at an early start. TÜV Rheinland is considering the development of a device that would greatly improve the efficiency of these tests. Such a device would benefit clients by cutting down testing times and saving their engineering resources. With the proper knowledge on the handling of Medical Robots, TÜV Rheinland will be able to provide you with all regulatory needs in this regard.

Soon we will discuss more about Robotic Medical Systems and the IEC Draft International Standard (DIS) 80601-2-77: ‘particular requirements for the basic safety and essential performance of robotically assisted surgical equipment’. Stay tuned!

In the meantime, feel free to read our first two whitepapers in our X-ray Safety series:

*X-Ray Safety in Context: Interpreting Radiation Safety Standards in a World of Continuous Technology Innovation*

*Understanding Compliance Testing of X-Ray Equipment: Ensuring Safety and Compliance for one of Medicine’s Most Remarkable Achievements*

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