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A Study on Establishment of Essential Performance Evaluation Criteria for C-arm Computed Tomography

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C-arm CT의 필수 성능평가 기준 마련을 위한 연구

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Abstract In order to overcome the image quality limitations of the conventional C-arm, a flat panel detector (FPD) is used to enhance spatial resolution, detective quantum efficiency, frame rate, and dynamic range. Three-dimensional (3D) visualized information can be obtained from C-arm computed tomography (CT) equipped with an FPD, which can reduce patient discomfort and provide various medical information to health care providers by conducting procedures in the interventional procedure room without moving the patient to the CT scan room. Unlike a conventional C-arm device, a C-arm CT requires different basic safety and essential performance evaluation criteria; therefore, in this study, basic safety and essential performance evaluation criteria to protect patients, medical staff, and radiologists were derived based on International Electrotechnical Commission (IEC) standards, the Ministry of Food and Drug Safety (MFDS) standards in Korea, and the rules on the installation and operation of special medical equipment in Korea. As a result of the study, six basic safety evaluation criteria related to electrical and mechanical radiation safety (leakage current, collision protection, emergency stopping device, overheating, recovery management, and ingress of water or particulate matter into medical electrical (ME) equipment and ME systems: footswitches) and 14 essential performance evaluation criteria (accuracy of tube voltage, accuracy of tube current, accuracy of loading time, accuracy of current time product, reproducibility of radiation output, linearity and consistency in radiography, half layer value in X-ray equipment, focal size and collimator, relationship between X-ray field and image reception area, consistency of light irradiation versus X-ray irradiation, performance of the mechanical device, focal spot to skin distance accuracy, image quality evaluation, and technical characteristic of cone-beam computed tomography) were selected for a total of 20 criteria.

Key Words: C-arm CT, Basic safety, Essential performance, Evaluation criteria, Radiation protection

중심 단어: C-arm CT, 기본 안전, 필수 성능, 평가 기준, 방사선 안전

1. Introduction

C-arm computed tomography (C-arm CT), which combines a flat panel detector (FPD) with the C-arm,

has been developing for over 3 decades and has been actively used to improve image quality in the field of interventional radiology [1-2]. In order to overcome the limitations of the image quality and procedure time of

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the conventional C-arm, an FPD is mounted instead of an image intensifier detector (IID); it improves spatial resolution, detective quantum efficiency, frame rate, and dynamic range [3–6]. This principle allows surgery or treatment to be performed while checking C-arm images in real time to find desired areas inside the human body and provides 3-dimensional (3D) medical images with 180° scan information by combining linear and rotational movements through fluoroscopy during surgery that requires imaging and visualization of complex anatomical structures [7–8]. In addition, multiplanar soft tissue imaging, target lesion road-mapping, and multiplanar post-treatment assessment were made possible by installing an FPD [1].

There are various advantages to examining patients using C-arm CT. Procedures such as granular stent placement, thrombolysis, transcatheter arterial embolization, oncological procedures, and vascular angiographies, such as splenic arteriography, physical arithmetic, and interpersonal angiography, can be performed using C-arm CT [3–4, 8]. In these cases, the patient's discomfort can be reduced because they do not have to be transferred to the CT room for additional CT scans, and they can be protected from the high dose generated by multidetector computed tomography (MDCT) [1, 7].

Additionally, when imaging is performed using C-arm CT to treat or operate on a trauma, vascular surgery, neurosurgery, or orthopedic surgery patient in a hospital, a more detailed image can be provided to the physician in the interventional procedure room [8]. The C-arm CT, which has been in development for more than 30 years, visualizes complex anatomical structures and provides 3D medical images of patients during procedures, but there is no criteria standard in Korea for basic safety and essential performance.

According to the 'Regulations on Medical Device Items and Ratings by Criteria' in Korea, there are eight types of fluoroscopic imaging systems and two types of CT based on image acquisition and device classification [9]. Currently, there is no specific classification of C-arm CT devices in Korea, the United States, or Japan (Table 1) [9–11]. Therefore, devices manufactured by C-arm CT do not have separate device criteria and criteria numbers, so they are licensed as A11040.02 'mobile X-ray imaging devices' [9]. Accordingly, this study refers to the International Electrotechnical Commission (IEC), the Ministry of Food and Drug Safety (MFDS) standards, and the rules on the installation and operation of special medical equipment in Korea for the purpose of establishing basic

Table 1. Classification of C-arm Computed Tomography: Korea, USA, and Japan

Country	Medical device item (classification)
Korea ^{a)} (MFDS)	Mobile X-ray Imaging Devices (II)
	X-ray system, diagnostic, fluoroscopic, angiographic, mobile, digital (II)
	X-ray system, diagnostic, fluoroscopic, angiographic, mobile, analogue (II)
	Whole body X-ray computed tomography system (II)
USA ^{b)} (CFR 21)	Limited view field X-ray computed tomography (II)
	Image-intensified fluoroscopic x-ray system (II)
Japan ^{c)} (JMDN)	Computed tomography X-ray system (II)
	X-ray system, diagnostic, fluoroscopic, angiographic, mobile, digital (II)
	X-ray system, diagnostic, fluoroscopic, angiographic, mobile, analogue (II)
	X-ray system, diagnostic, fluoroscopic, angiographic, stationary, digital (II)
	X-ray system, diagnostic, fluoroscopic, angiographic, stationary, analogue (II)
	Whole body X-ray computed tomography system (II)
	Limited view field X-ray computed tomography (II)

^{a)} MFDS (Ministry Food and Drug Safety)

^{b)} CFR 21 (Title 21 of the Code of Federal Regulations)

^{c)} JMDN (Japan Medical Device Nomenclature)

safety protocols to prevent physical, psychological, or material harm and essential performance criteria to evaluate the clinical function of C-arm CT.

II. Materials and Methods

In order to provide recommendations for evaluating the performance of C-arm CT, such as radiation output accuracy, reproducibility and linearity, mechanical performance testing, and image quality evaluation, IEC 60601-2-43 'Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures,' IEC 60601-2-44 'Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography,' and IEC 61223-3-5, 'Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-ray equipment' were referenced [12-14].

In addition, IEC 60601-1-3 'Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment', IEC 60601-2-54 'Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy'. The Korean Ministry of Health and Welfare's 'Rules on the Installation and Operation of Special Medical Equipment: Risk management considerations and evaluation methods according to the standards for quality management inspection of special medical equipment under Article 5(2)' was referenced to supplement the essential performance evaluation criteria, evaluation methods, and acceptance criteria [15-18].

III. Results and Discussion

In an environment where the usefulness of C-arm

CT is increasing, there is no standard for approving its use, and there is no separate classification for approval in Korea; therefore, it follows the existing 'mobile X-ray imaging device' criteria standard [9]. Accordingly, this study attempted to evaluate the basic safety and essential performance required for C-arm CT and to establish appropriate licensing criteria for performance evaluation.

IEC 60601-2-43, IEC 60601-2-44, IEC 60601-2-54, and IEC 61223-3-5 were referenced to identify new performance evaluation items for meeting the criteria of C-arm CT. In addition, for domestic standards, the Korea Food & Drug Administration's (KFDA) medical device standard 'Regulations on the Installation' and the Ministry of Health and Welfare's 'Operation of Diagnostic X-ray Devices and Special Medical Equipment: Article 5(2)' were referenced [12-18]. All criteria reflect recent revisions, and the essential performance evaluation items, evaluation methods, and criteria that C-arm CT should have were supplemented to ensure that there was no problem with approval.

1. Basic safety

To protect medical electrical devices from electrical hazards, leakage current, collision protection, emergency stopping device, overheating, recovery management, and ingress of water or particulate matter in medical electrical (ME) equipment and ME systems: footswitches in the device should be evaluated. The leakage current shall not exceed 2 mA in a single fault state, and the current value of the allowable ground leakage of the mobile X-ray device and the variable X-ray device shall not exceed 2.5 mA in a normal state and 5 mA in a single fault state. In addition, means must be provided to prevent unnecessary suspension of operation and to prevent injuries that may occur when colliding with an object. In order to ensure the safety of the patient, all movements must have an emergency stop function. In addition, to protect the X-ray tube device from overheating, the protective device for preventing contact with a hot surface that can be contacted should have a structure that cannot be removed without using a tool. At this time, the part

Table 2. Criteria for basic safety and essential performance evaluation with references

Criteria	References																								
1. Electrical mechanical safety test																									
- Leakage current: For a mobile X-ray device, the contact current shall not exceed 2 mA in a single fault state, and the allowable ground leakage current value shall not exceed 2.5 mA in normal conditions and 5 mA in a single fault state.	IEC 60601-1 8,7 9,2,3,2 9,2,4																								
- Collision protection: A means or warning message shall be provided in the annex to prevent any injuries that may occur when the power drive part collides with other nearby fixed objects.	IEC 60601-2-43 201,4,101 201,11,6,5 .101 201,11,6,5 .102																								
- Emergency stopping device: All driving movements that can cause physical disability must be equipped with emergency stop controllers. There should be a way for the patient to access and remove the emergency stop control.																									
- Overheating: The part that can be contacted without the use of the tool should be 85°C(peripheral temperature of 40°C) or less. The surface of the mounting portion(peripheral temperature of 25°C) which is not intended to heat the patient should be 41°C or less.	IEC 60601-2-54 201,8,7,3 201,9,2,2,4 .4,101 201,9,2,4 201,11,101 201,11,102																								
- Recovery management: The minimum required time for emergency viewing after a failure should be less than 1 minute, and the time to recover all functions should be less than 3 minutes.																									
- Ingress of water or particulate matter into ME equipment and ME systems; footswitches: The foot switch should be operable even if the floor is covered with a saline solution of 25 mm.	KFDA standard 56 6,8																								
2. Accuracy of radiation output																									
- Accuracy of tube voltage: The error in the indication value of the X-ray voltage should not exceed 10% or more in any combination of load conditions.	IEC 60601-2-44 201,3,202 201,12,1 .101 203,6,3																								
- Accuracy of tube current: The error in the indicator value of the X-ray tube current should not exceed 20% in any combination of load conditions.																									
- Accuracy of loading time: An error in an indication value of the X-ray load time should not exceed $\pm(10\% + 1 \text{ ms})$ or more in any combination of load conditions.	IEC 60601-2-54 203,6,4,3 .104,3 203,6,4,3 .104,5 203,6,4,3 .104,6																								
- Accuracy of current time product: When operating the high-voltage X-ray device combined with the X-ray generator at any point, the indicator error of mAs should not exceed $\pm(10\% + 0,2 \text{ mAs})$ in any combination of load conditions.																									
3. Reproducibility and linearity of radiation output.																									
- Reproducibility of the radiation output: The coefficient of variation of air kirma should be less than 0,05.	IEC 60601-1-3 7,1																								
- Linearity and consistency in radiography: When tested under the closest load condition in which the mAs(continuous) value does not exceed 2 times, the average value of these coefficients should not be different by more than 0,2.	IEC 60601-2-44 201,12,1 .101 203,6,3,2																								
- HVL in X-ray equipment: Most of the HVL is measured using an ionization chamber and a pure aluminum plate. The measured HVL of the radiation beam must be at least the value shown in the table.	IEC 60601-2-54 203,6,3,2 .101 203,6,3,102 203,6,3,2 .102 203,8,5,3																								
	<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="text-align: center;">X-ray tube voltage (kV)</th> <th style="text-align: center;">Minimum allowable first HVL (mmAl)</th> </tr> </thead> <tbody> <tr><td style="text-align: center;">50</td><td style="text-align: center;">1,8</td></tr> <tr><td style="text-align: center;">60</td><td style="text-align: center;">2,2</td></tr> <tr><td style="text-align: center;">70</td><td style="text-align: center;">2,5</td></tr> <tr><td style="text-align: center;">80</td><td style="text-align: center;">2,9</td></tr> <tr><td style="text-align: center;">90</td><td style="text-align: center;">3,2</td></tr> <tr><td style="text-align: center;">100</td><td style="text-align: center;">3,6</td></tr> <tr><td style="text-align: center;">110</td><td style="text-align: center;">3,9</td></tr> <tr><td style="text-align: center;">120</td><td style="text-align: center;">4,3</td></tr> <tr><td style="text-align: center;">130</td><td style="text-align: center;">4,7</td></tr> <tr><td style="text-align: center;">140</td><td style="text-align: center;">5,0</td></tr> <tr><td style="text-align: center;">150</td><td style="text-align: center;">5,4</td></tr> </tbody> </table>	X-ray tube voltage (kV)	Minimum allowable first HVL (mmAl)	50	1,8	60	2,2	70	2,5	80	2,9	90	3,2	100	3,6	110	3,9	120	4,3	130	4,7	140	5,0	150	5,4
X-ray tube voltage (kV)	Minimum allowable first HVL (mmAl)																								
50	1,8																								
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110	3,9																								
120	4,3																								
130	4,7																								
140	5,0																								
150	5,4																								
4. Testing on mechanical performance																									
- Focal size and collimator: Do not exceed 15 cm outside the boundary of the maximum X-ray irradiation field within a plane of 1 m away.																									
- Relationship between x-ray field and image reception area: X-rays should be at least 80% of the reception surface area, within 2 cm outside the boundary, within 4 seconds of the auto collimator, and within 3% of the illumination display error.	IEC 60601-2-54 203,8,4 203,8,5 203,9																								
- Consistency of light irradiation versus X-ray irradiation: It should be within 2% of the source to image distance(SID) by measuring the difference between the center and surroundings of the X-ray irradiation field, and if the scope of the irradiation field is constant, it should be within $\pm 1\%$ of the SID.	KFDA standard 56 8,2,6 8,5,1 9,9 10,2,5																								
- Performance of the mechanical device: The average value obtained by moving 10 times to the maximum amount should be evaluated as a reference value.																									
- Focal spot to skin distance accuracy: The minimum distance should be 20 cm or more and 45 cm or more when radiographed, and the allowable difference for the SID should be within $\pm 1 \text{ cm}$.																									

Criteria	References
5. Image quality evaluation	
- Image performance evaluation: Before the procedure, patient dose should be presented in all configurable conditions and modes of imaging perspective, and the dose rate should be less than 10 mR/min at the patient reference point for all conditions and modes. During the procedure, the cumulative dose should be displayed on the auxiliary monitor in a real time. After the procedure, the performance status or dose structured report should be recorded in DICOM.	201,4,102 201,12,4 .101,2 201,12,4 .102
- Delay in image display: It should be as short as possible, and an appropriate limitation should be set and entered in the risk management file.	IEC 60601-2-43 201,12,4 .107
- Recording of image direction: There should be a means for recording both the displayed image and the stored image direction.	203,5,2,4,5 .101
- Availability of fluoroscopy procedure during network activities: The use of fluoroscopy should not be hindered even during PACS operation.	203,5,2,4,5 .102
- Imaging measuring function: Each measurement value displayed on a fluoroscopy device with a measurement function should be displayed with its unit.	KFDA standard 56 8,2,3
- Radiation dose documentation: The dose should be recorded in the DICOM performance statement or dose structured report.	
6. Technical characteristics of CBCT	
CTDI _w values should be used to indicate CTDI _{vol} and DLP values for general head and body conditions. The result should be compared with the CTDI _{vol} value displayed on the operator console. All dose values shall be within ±20% of the specified values presented in the annex. The calculated head and body CTDI _{vol} values and DLP values should be within ±20% of the values displayed on the operator console.	ICRP 129 5,1 IEC 60601-2-44 203,108 203,109 203,112 IEC 61223-3-5 5,4 KFDA standard 49 29,1,102,1 29,1,102,2

that can come into contact with the patient should not be greater than 85°C (40°C per ambient temperature) without using the tool, and the surface of the part that is not intended to heat the patient should be 41°C or less (25°C per ambient temperature). In the event of such a failure, the minimum required time for emergency fluoroscopy should be less than one minute, and the minimum required time should be less than three minutes when recovering all functions. Finally, to confirm durability against water or particulate matter, the footswitch must be operable even if covered with a saline solution of 25 mm.

2. Essential performance

A total of 14 evaluation criteria were derived to evaluate the essential performance of the C-arm CT device. In order to evaluate the performance of the X-ray device, it is necessary to evaluate the accuracy of load conditions such as X-ray tube voltage, tube current, loading time, and mAs. In any combination of load conditions, for the accuracy of X-ray generation and patient permeability, an indicator error of X-ray

tube voltage should not exceed 10%, an indicator error of X-ray tube current should not exceed 20%, $\pm(10\% + 1 \text{ ms})$, and an indicator error of mAs should not exceed $\pm(10\% + 0,2 \text{ mAs})$.

In addition, if the reproducibility and linearity of the radiation output are not consistent, re-radiograph must be performed due to the impairment of the image quality, which causes an increase in the patient's exposure dose. Therefore, X-ray tube reproducibility should have a coefficient of variation of less than 0,05. In order to evaluate linearity, the average value of these coefficients should not differ by more than 0,2 times under the closest conditions where the mAs value does not exceed 2 times. Finally, in order to remove low-dose radiation, a half value layer (HVL) measurement of the X-ray device should be performed, and the measured value should be compared with the measured value of HVL.

The focal size and collimator, relationship between X-ray field and image reception area, consistency of light irradiation versus X-ray irradiation, performance of the mechanical device, and focal spot to skin distance accuracy should be evaluated as part of the

mechanical performance evaluation. The focal size should not exceed 15 cm outside the boundary of the maximum X-ray irradiation field, and the X-ray field and image reception area matching test should be within 80% of the image reception area and within 2 cm outside the boundary. The consistency test between the light irradiation versus the X-ray irradiation field must be within 2% of the SID, and if the scope of the receptor is constant, it must be within $\pm 1\%$ of the SID. The accuracy of the focal spot to the distance of the image reception area should be more than 20 cm, more than 45 cm at the time of radiograph, and the allowable difference for the source to image distance (SID) should be within ± 1 cm. Finally, in order to evaluate the performance of the mechanical device, the average value obtained by moving each moving unit 10 times to the maximum amount should be evaluated as a reference value.

Image performance evaluation and dose recording reports should be provided to evaluate image quality, and image display delay recording, image orientation recording, availability of perspective during network activities, measurement functions, and dose recording should be conducted.

Finally, cone beam computed tomography (CBCT) technical characteristics and performance evaluation should be performed. Compared to MDCT, CBCT has large field of view (FOV) limitations and poor time resolution or low contrast detection, but it has excellent FPD spatial resolution, a high degree freedom of selection for collection parameters when obtaining images according to inspection criteria and can obtain same direction volume data in a short time. To evaluate the performance of these CBCTs, CT dose index volume ($CTDI_{vol}$) and dose length product (DLP) values for general physical motion conditions should be represented using CT dose index width ($CTDI_w$) values. All dose values should be within $\pm 20\%$ of the specified values presented in the annex, and the calculated body $CTDI_{vol}$ and DLP values should be within $\pm 20\%$ of the values indicated on the operator console.

3. Limitation & novelty

Until now, no appropriate performance evaluation criteria have been established for purchasing and operating C-arm CT in Korea. As a result, there is a risk of providing inappropriate exposure and low-quality images to patients or medical staff, as well as difficulties in manufacturing due to the lack of appropriate performance standards for manufacturers [19–23].

C-arm CT has the advantage of reducing complications and the heavy workload of medical staff by providing more image information using the same device in one place instead of moving patients to a CT room for additional imaging. Due to these affordances, demand has been increasing, but essential performance and basic safety evaluation criteria for C-arm CT are lacking. This study presented criteria for increasing the advantages of C-arm CT and protecting patients and medical staff without reducing image quality. Accordingly, this study offers essential performance and basic safety evaluation criteria for C-arm CT licensing, and it is expected that consumers who purchase and use licensed devices that meet the essential performance and safety criteria will be able to use the device safely.

IV. Conclusion

3D images can be provided using the C-arm CT to reduce complications from patient movement and obtain more diverse images; appropriate protective standards should be in place to use C-arm CT because there are currently no C-arm CT authorization criteria or procedures in Korea. Accordingly, to obtain valuable diagnostic images by establishing appropriate performance evaluation criteria for C-arm CT, a total of 20 criteria, including 6 basic safety evaluation criteria and 14 essential performance evaluation criteria related to electrical and mechanical radiation safety, were selected. If C-arm CT devices meet the evaluation criteria determined by this study, they will not only promote the safety of patients and medical

staff, but also enable the acquisition of valuable diagnostic images.

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