Journal of Radiological Science and Technology, 44(3), 261-267 ISSN 2384-1168(On-line) ISSN 2288-3509(Print)

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A Study on Establishment of Basic Safety and Essential Performance Criteria of Mobile Computed Tomography

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이동형 전산화단층촬영장치의 기본 안전 및 필수 성능 기준을 마련하기 위한 연구

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Abstract As the number of Coronavirus Disease-19 (COVID-19) patients increases in a global pandemic situation, the usefulness of mobile computed tomography (CT) is gaining attention. Currently, mobile CT follows the basic safety and essential performance evaluation criteria of whole-body or limited-view X-ray CT in order to obtain device approval and evaluation in the Republic of Korea. Unlike stationary CT, mobile CT is not operated in shielded areas but rather areas such as intensive care units, operating rooms, or isolation rooms. Therefore, it requires a different basic safety and essential performance evaluation standard than stationary CT. In this study, four derived basic safety evaluation criteria related to electrical, mechanical, and radiation safety were included (dose indication test, protection against stray radiation, safety measures against excessive X-rays, half-value layer measurement); and seven essential performance evaluation criteria were included (tube voltage accuracy, mAs accuracy, radiation dose reproducibility, CT number of water, noise, uniformity, and spatial resolution); total eleven basic safety and essential performance evaluation criteria were selected. This study aims to establish appropriate basic safety and essential performance evaluation criteria for simultaneously obtaining images with diagnostic value and reducing the exposure of nearby patients, medical staff, and radiologic technologists during the use of mobile CT.

Key Words: Mobile CT, Essential performance, Evaluation criteria, Basic safety, Radiation protection

중심 단어: 이동형 CT, 필수 성능, 평가 기준, 기본 안전, 방사선 안전

Ⅰ. Introduction

A computed tomography (CT) scan is a useful diagnostic device because it is fast and allows for quantitative evaluation [1]. However, Complications occur in approximately 50-70% of severely ill patients due to the procedures involved in intrahospital transport of patients from the patient room or intensive care unit (ICU) to the CT procedure room in the hospital [2-3]. In addition, the risk of respiratory and cardiocirculatory adverse effects increases when replacing the ventilator of intrahospital transport

This work was supported by the Korea Medical Device Development Fund grant funded by the Korean government (the Ministry of Science and ICT, the Ministry of Trade, Industry and Energy, the Ministry of Health and Welfare, the Ministry of Food and Drug Safety) (Project Number: KMDF_PR_20200901_0262).
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Received 8 June 2021; Revised 21 June 2021; Accepted 28 June 2021

patients with a mobile type [2-3].

Mobile CT is drawing more attention due to the Coronavirus Disease-19 (COVID-19) pandemic, which started in 2019 [4]. When a patient with an infectious disease is admitted to a hospital, mobile CT is often used to quickly conduct an examination. During this process, it is possible to minimize the contagious risk to other patients, family members, and healthcare providers [5]. Because mobile CT provides more detailed lesions for diagnosing COVID-19 than conventional portable X-ray chest imaging, it is becoming more prominent [5, 6].

Through the research conducted by the Ministry of Health and Welfare in 2019 on the "development of standards for defense facilities for the use of mobile CT in emergency rooms and intensive care units," the ordinance of mobile CT previously used in the operating room was expanded to ICUs and patient rooms for infectious disease [7]. In this regard, standards for inspection of radiation defense facilities were established to ensure the safety of radiation exposure to medical personnel and surrounding patients. On January 5, 2021, the relevant ordinance was revised to "rules on the safety management of diagnostic radiation generating devices" in No. 777 of the Ministry of Health and Welfare [8].

At present, the Food and Drug Administration in the United States has issued enforcement guidelines; it was judged that its demands for radiographic procedures are increasing due to the pandemic [9]. It is also recommended that the use of mobile CT be increased in order to ease the burden on medical personnel, minimize patient movement, and obtain diagnostic images of patients in a stable state [9].

Despite these changes, a specific standard and classification for mobile CT devices is lacking in Korea, the United States, and Japan [10-12]. According to the current domestic regulations on medical device classification, mobile CT is classified and authorized as a whole-body X-ray CT system (A11010.01) or a limited-view field X-ray CT system (A11010.02) (Table 1).

This study aims to establish basic safety and essential performance evaluation requirements for mobile CT and references the 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. This study evaluates the essential performance requirement for mobile CT to not exceed radiation safety standards. Since mobile CT is not operated in general radiation shielding rooms, this study intends to establish the criteria for essential performance evaluation of mobile CT.

II. Materials and Methods

To provide recommendations for evaluating the performance of mobile CT, as well as to conduct the evaluation test, Medical electrical equipment- Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for CT (IEC 60601-2-44) and Evaluation and routine testing in medical imaging departments- Part 3-5: Acceptance

Table 1. Classification of Computed Tomography: Korea, USA and Japan [10-12]

Country	Medical device item (classification)
Korea[a] (MFDS)	Whole body X-ray computed tomography system (II) Limited view field X-ray computed tomography (II)
USA[b] (CFR 21)	Computed tomography X-ray system (II)
Japan[c] (JMDN)	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)

and constancy tests– Imaging performance of CT X–ray equipment (IEC 61223–3–5) were referenced [13–14].

In addition, this study referenced the Medical electrical equipment– Part 1–3: General requirements for basic safety and essential performance– Collateral Standard: Radiation protection in diagnostic X–ray equipment (IEC 60601–1–3), Medical electrical equipment– Part 2–54: Particular requirements for the basic safety and essential performance of X–ray equipment for radiography and radioscopy (IEC 60601–2–54), the rules on the installation and operation of special medical equipment in Article 5(2): risk management considerations and evaluation methods according to the standards for quality control inspection of special medical equipment of Korea, and medical device standard; appliance equipment standard 49 whole body X–ray CT system of Korea were referenced in order to provide the basic safety, essential performance evaluation criteria, evaluation methods, and acceptance criteria of mobile CT [15–18].

Ⅲ. Results and Discussion

Currently, no appropriate test criteria and items for evaluating the performance of mobile CT devices is available in Korea. By referencing the standards of IEC 60601–1–3, IEC 60601–2–44, and IEC 61223–3–5; medical device standard 49 whole–body X–ray CT system; and the rules on the installation and operation of special medical equipment in Article 5(2), eleven performance evaluation criteria were developed: dose indication test, protection against stray radiation, safety measures against excessive X–rays, half–value

Table 2. Criteria for basic safety and essential performance evaluation with references [13-18]

<table>
<tr><th>Criteria</th><th>References</th></tr>
<tr><td>Basic safety
1. Dose indication test
CTDI can be subdivided in various situations, such as air, head, and full-body phantom. The length of the integral is applied differently and is mainly expressed as a CTDI value per 100 mAs. The calculated head and body CTDIvol and DLP values should be within ±20% of the values displayed on the operator's console.</td><td>IEC 60601-2-44: 203.109, 203.112, 203.108
IEC 61223-3-5: 5.4
Medical device standard 49: 29.1.102.1, 29.1.102.2</td></tr>
<tr><td>2. Protection test against stray radiation
For mobile CT, the whole body (120 kVp) and head (80 kVp) are measured. In addition, the number of possible procedures per day that does not exceed the dose limit of the general public and radiography technologists should be indicated.</td><td>IEC 60601-2-44: 203.13
Medical device standard 49: 29.209</td></tr>
<tr><td>3. Safety measures against excessive radiation
In the event of device failure, stop the load automatically by shutting down the radiation source or covering up the X-ray beam. Such a stop should be made within 1 second of failure.</td><td>IEC 60601-2-44: 203.107
Medical device standard 49: 29.1.101, 29.1.105</td></tr>
<tr><td>4. HVL of X-ray equipment
The HVL of system for each filter should be specified as the minimum, maximum, and median value of the X-ray tube voltage.
<table>
<tr><th>X-ray tube voltage (kV)</th><th>Minimum allowable first HVL (mmAl)</th><th>X-ray tube voltage (kV)</th><th>Minimum allowable first HVL (mmAl)</th></tr>
<tr><td>50</td><td>1.8</td><td>110</td><td>3.9</td></tr>
<tr><td>60</td><td>2.2</td><td>120</td><td>4.3</td></tr>
<tr><td>70</td><td>2.5</td><td>130</td><td>4.7</td></tr>
<tr><td>80</td><td>2.9</td><td>140</td><td>5.0</td></tr>
<tr><td>90</td><td>3.2</td><td>150</td><td>5.4</td></tr>
<tr><td>100</td><td>3.6</td><td></td><td></td></tr>
</table>
</td><td>IEC 60601-1-3: 7.1
IEC 60601-2-44: 203.107, 201.3.216
Medical device standard 49: 29.1.105</td></tr>
</table>

Table 2. Criteria for basic safety and essential performance evaluation with references [13-18]

Criteria	References	
Essential performance 1. Tube voltage accuracy Calculate the percent average error from the average value of the tube voltage measurement. Accuracy should be within ±10%.	IEC 60601-2-44	201.3.202 201.12.1.101 203.6.3
	Medical device standard 49	3.3.13.3.1
2. mAs accuracy Set the X-ray condition to mAs control and measure it with a mAs meter, or measure mA and time separately to calculate mAs. Accuracy should be within ±(10%+0.2 mAs).	IEC 60601-2-44	201.3.202 201.12.1.101 203.6.3
	Medical device standard 49	3.3.13.3.1
3. Reproducibility test Position the dosimeter at the center of the gantry and measure the CTDIfree air for the radiation output for 10 times. The resulting measurement average value should be within ±10%.	IEC 60601-2-44	201.12.1.101 203.6.3.2
	Medical device standard 49	3.3.13.3.1
4. Standard phantom and evaluation standards A phantom for evaluation CT performance (American Association of Physicists in Medicine phantom [76-410-4130, Nuclear Associates LTD., Carle Place, NY]), or phantoms with a proven equivalent should be used..	Medical device standard 49	3.3.5
	Rules on the installation Article 5 (2)	
5. CT number of water, Noise and Uniformity test 1) CT number of water: within 0±7 HU 2) Noise standard deviation: within 5 3) Uniformity: within 5 HU of difference between the center and the periphery	IEC 61223-3-5	3.2 3.5
	Medical device standard 49	3.3.5
	Rules on the installation Article 5 (2)	
6. Spatial resolution test For analysis, adjust the width and height of the image window level to identify the hole in the obtained image, and then check the size of the hole that can be identified at a distance of 50 cm or more from the monitor. In this case, it should be able to identify up to 1.0 mm or less.	IEC 61223-3-5	3.17 5.6
	Medical device standard 49	3.3.5
	Rules on the installation Article 5 (2)	

layer (HVL) measurement, tube voltage accuracy, tube current accuracy, radiation dose reproducibility, CT number of water, noise, uniformity, and spatial resolution (Table 2).

1. Basic safety

Four basic safety criteria has to be included to evaluate the mobile CT such as dose indication test, protection against stray radiation, safety measures against excessive X-rays, half-value layer measurement. First, in order to assess the radiation dose that may directly affect the patient, an assessment of the accuracy of the information provided when indicating the radiation dose should be carried out. To measure the dose information of a CT scanner, the specified phantom is placed on a patient bed and the scan is performed without additional attenuating substances. Dose indication tests are performed to calculate computed tomography dose index volume ($CTDI_{vol}$) values and dose length product (DLP) values, which should be within ±20% of the values displayed on the operator's console.

Protection tests against stray radiation should be added to protect patients and medical personnel during mobile CT procedures conducted in areas without shielding facilities. Measurements should be

made under the tube current in the maximum local dose per time product of the tube current, and the highest X-ray tube voltage should be included. If it is difficult to adjust the designated representative tube voltage, measure at the nearest tube voltage and specify the tube voltage value at that time. The number of possible tests per day should not exceed the dose limit of the general public and radiologic technologists.

Unlike stationary CT devices, when excessive X-rays occur during mobile CT procedures, the probability of exposure to surrounding patients and medical staff is higher. Therefore, measuring safety against excessive X-rays is essential. In the event of a failure, methods to cut off the power of the radiation source or to obstruct the X-ray beam should be provided. Methods should be provided to automatically stop the generation of X-rays in case of an emergency. This stoppage should be made within a period limiting the total injection time to 110% of the preset value or one additional X-ray source assembly rotation using a preliminary timer or device to monitor the function of the medical electrical equipment, whichever is shorter. This performance should be made within 1 second of failure in order to reduce additional radiation exposure.

As the basic performance of the high voltage generator, the HVL test, which is the result of the X-ray system, should be added. The HVL is mostly measured using an ionization chamber and pure aluminum plate. When measuring the HVL of CT, it is measured using a narrow beam, and the aluminum plate is generally located at half of the focus-detector distance. The tube voltage test should be measured at three points: 80, 100, and 120 kV. If it is difficult to adjust the designated representative tube voltage, the nearest tube voltage value should be measured and compared with the HVL presented in Table 2.

2. Essential performance

To evaluate the essential performance of the mobile CT, seven criteria has to be included such as tube voltage accuracy, mAs accuracy, radiation dose reproducibility, CT number of water, noise, uniformity, and spatial resolution. It is important to ensure the accuracy and reproducibility of tube voltage and mAs in high voltage generator. Attention to the characteristic of the mobile CT, it is important to maintain adequate performance for protecting the patient and medical staff. The tube voltage should be measured under the CT operating conditions. If it is difficult to measure the designated representative tube voltage, the closest tube voltage value should be measured and the average and percent average error calculations should be processed to the second decimal place in order to determine the conformity of the procedure standard. The values measured at the CT operating conditions of 80 kVp for the head and 120 kVp for the whole body should be within ±10% of the suggested irradiation condition. The accuracy test of mAs must be within ±(10% + 0.2 mAs) under the irradiation conditions presented in the same way as before. When tube current and exposure time are measured, a separate mAs test does not need to be performed. In addition to the reproducibility test, the dosimeter must be placed at the center point of the gantry and the $CTDI_{free\ air}$ should be measured 10 times as a representative irradiation condition for the radiation output. At this time, each measurement value must be within ±10% of the average value of 10 measurements in a series.

In order to conduct a test on image quality, mobile CT performance has to be evaluated through standard phantom, which is American Association of Physicists in Medicine CT performance evaluation phantom. To measure the CT number of water, noise, and uniformity, the phantom must be filled with water and exposure must be taken from the centers of the phantom. Calculate by using the standard deviation of the measured CT attenuation coefficient under the exposure; the center of the CT number calibration block must be filled with water. As a result, the CT number of water should be within 0±7 Hounsfield unit (HU), the standard deviation of noise should be within 5, and uniformity should be within 5 HU between the center and the periphery.

The procedure must be exposed under the CT

operation condition (120 kV) of chest imaging. Spatial resolution should be able to be identified up to 1.0 mm or less by checking the size of the hole by visual evaluation.

3. Limitation & novelty

Since this diagnostic radiation generator is used as a mobile type without a shielding room, the performance evaluation criteria has to be presented to reduce the exposure of patients and medical staff [19]. This lack of adequate basic safety and essential performance evaluation criteria for using mobile CT causes not only poor quality images and inappropriate exposure to patients and radiologic technologists during mobile CT procedures but also difficulties during manufacturing [20-22]. To solve these problems, this study attempts to present performance evaluation criteria.

Even though proper basic safety and essential performance evaluation criteria were presented, there may be a medical device that does not meet them. In this case, working with the manufacturer to develop a way to meet the standards would be necessary. Nevertheless, there are no essential performance evaluation criteria for mobile CT, it is expected that mobile CT can be safely used in hospitals if basic safety and essential performance evaluation criteria are performed by applying these criteria developed through this research.

Ⅳ. Conclusion

Compared to stationary CT, mobile CT is movable medical device and irradiation conditions. Therefore, it is important to apply appropriate basic safety and essential performance evaluation criteria for mobile CT approval. This study aims to reduce the radiation exposure of patients and medical staff, establish appropriate basic safety and essential performance evaluation criteria, and obtain diagnostic-valuable images. If the mobile CT satisfies the evaluation items and criteria derived from this study, it will be safe for both patients and radiologic technologists, and it will be possible to acquire images of diagnostic value.

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