



Nationwide survey on the current situation of quality control of diagnostic displays in Japan

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Abstract

The Japan Association of Radiological Technologists (JART) and the Japan Medical Imaging and Radiological Systems Industries Association jointly conducted a nationwide survey to reveal the current situation of diagnostic displays in Japan using a questionnaire on the performance and quality control (QC) of diagnostic displays for mammography and common use. The questionnaire for radiological technologists (RTs) was distributed via email to 4519 medical facilities throughout Japan, where RTs affiliated with JART were employed; 613 (13.6%) facilities responded. Diagnostic displays with suitable maximal luminance (500 cd/m² or higher for mammography and 350 cd/m² or higher for common use) and resolution (5 megapixels for mammography) have been widely used. However, while 99% of the facilities recognized the necessity of QC, only approximately 60% implemented it. This situation arose due to several barriers to QC implementation, such as insufficient devices, time, staff, knowledge, and the recognition of QC as a duty. The implementation of QC can lead to the avoidance of incidents or accidents caused by a decrease in luminance, variation in luminance response, and the influence of ambient light. Moreover, the barriers discouraging the implementation of QC are mainly related to a lack of human resources and budgets. Therefore, to popularize the QC of diagnostic displays in all facilities, it is crucial to identify countermeasures to eliminate these barriers and to continue positive actions for popularization.

Keywords Questionnaire · Diagnostic display · Luminance · Resolution · Quality control

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1 Introduction

Quality control (QC) and quality assurance of medical devices are indispensable for maintaining good medical practices. With the generalization of digital radiography, diagnostic displays have become important devices on which QC should be performed. Still, the current global situation regarding the QC of diagnostic displays is unknown. We conducted a literature search on the QC of diagnostic displays. However, no reports utilizing national survey data have yet been published. Several reports analyzing the domestic situation of QC for diagnostic displays in each country are necessary to clarify the global situation and enable comparisons with the situation in each country.

In Japan, diagnostic displays are not considered medical devices per the “Act on Securing Quality, Efficacy and Safety of Products,” which includes the “Act for Pharmaceuticals and Medical Devices.” However, the diagnostic displays used in Japan are the same models available for use according to section 510(k) of the Food and Drug Administration in the United States, and have identical performance and features. Therefore, the quality of the diagnostic displays is very important.

The Japan Radiological Society (JRS) published the “Guideline for the Handling of Digital Images 3.0” [1], which describe the importance of QC in diagnostic displays. Moreover, the Japan Central Organization on Quality Assurance of Breast Cancer Screening (QABCS) provides accreditation services for medical facilities to improve QC for mammography. To be accredited, two displays of more than five megapixels (MP) (2560×2048) and a maximal luminance of approximately 500 cd/m² or higher must be installed, and their QC records must be submitted [2].

Although medical physicists in the United States are committed to maintaining the QC of displays, radiological technologists (RTs) generally implement QC in Japan [3]. RTs in Japan have not only been responsible for radiography itself but also for the QC of diagnostic images since the age of the silver halide film, which has continued into the present filmless radiology era.

The Japan Association of Radiological Technologists (JART) and Japan Medical Imaging and Radiological Systems Industries Association (JIRA) jointly conducted multi-institutional surveys in a neutral position to assess the current situation of QC for diagnostic displays in Japan. The survey was intended for RTs responsible for these duties [4]. The objective of this report was to provide relevant information on the QC of diagnostic displays in Japan.

2 Materials and methods

A questionnaire for RTs about diagnostic displays was distributed by email to 4519 medical facilities throughout Japan where RTs affiliated with JART are employed. In this survey,

diagnostic displays were defined as those used by physicians to perform image-based diagnoses, mainly using monochrome images. The survey period lasted for 50 days, from March 1 to April 20, 2019. The main items and questions in the multiple-choice questionnaire are presented in Table 1.

2.1 Number of hospital beds

The scale of medical facilities was determined based on the number of beds. Data on the number of beds in each facility were obtained by asking the following question:

Select one of the presented choices concerning the number of hospital beds in your facility:

- a. 600 or more beds b. 300 to 599 beds c. 100 to 299 beds
d. Less than 100 beds e. No hospital beds

2.2 Performance of diagnostic displays for mammography

Japan has no system similar to the FDA 510(k) premarket clearance for mammography diagnostic displays in the United States. Therefore, diagnostic displays used in clinical practice were the subjects of this survey, which inquired about the maximal luminance, resolution, and implementation of the QC.

2.2.1 Maximal luminance

Because the QABCS recommends that the maximal luminance of diagnostic displays for mammography should be

Table 1 Main items of the questionnaire

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- (1) Number of hospital beds
 - (2) Performance of diagnostic displays for mammography
 1. Maximal luminance
 2. Resolution (matrix size)
 3. How to implement QC
 - (3) Performance of diagnostic displays for common use
 1. Maximal luminance
 2. Grayscale function
 - (4) Current situation on QC of diagnostic displays
 1. Undesirable experiences associated with diagnostic displays
 2. Awareness of the necessity of QC of diagnostic displays
 3. Implementation status of QC of diagnostic displays
 4. Reasons for not implementing QC of diagnostic displays
 5. Duties of RTs concerning diagnostic displays except QC
 6. Difficulties in implementing QC of diagnostic displays
 7. Anecdotal experiences of incidents or accidents prevented by QC of diagnostic displays
-

QC quality control, RT radiological technologist

approximately 500 cd/m² or higher, the questionnaire asked whether the displays met this requirement. The maximal luminance of the diagnostic displays used in each facility was determined by asking the following question:

Select one of the presented choices concerning the maximal luminance of the diagnostic displays used for mammography at your facility.

- a. 500 cd/m² or higher
- b. < 500 cd/m²
- c. Unclear

2.2.2 Resolution (matrix size)

The QABCS recommends diagnostic displays with a resolution of 5 MP or higher for mammography. The resolution of the displays used in each mammography facility was clarified by asking the following question:

Select one of the presented choices concerning the resolution (matrix size) of the diagnostic displays used for mammography at your facility.

- a. 5 MP (2048 × 2560)
- b. 3 MP (1536 × 2048)
- c. 2 MP (1200 × 1600)
- d. 1 MP (1024 × 1280)
- e. Other

2.2.3 QC implementation

The QABCS recommends that the QC of diagnostic displays for mammography be implemented by following the “Quality Control Manual on Digital Mammography (QCMDM)” [5]. QCMDM incorporates the recommendations of JESRA X-0093 [6] because it is the most popular guideline for the QC of diagnostic displays. The relevant question pertaining to QC implementation was as follows:

Select one of the presented choices concerning how to implement QC of the diagnostic displays used for mammography at your facility (including outsourcing).

- a. Implementation according to the QCMDM
- b. Implementation according to JESRA X-0093
- c. No implementation
- d. Other

2.3 Performance of diagnostic displays for common use

There are no specific regulations for the QC of diagnostic displays commonly used in Japan; therefore, displays used in clinical practice were surveyed.

2.3.1 Maximal luminance

The maximal luminance of a diagnostic display is an important factor in the classification of displays according to the application. Table 2 shows the recommendations of JESRA X-0093 and the American Association of Physicists in Medicine (AAPM) Report No. 270 [7]. Based on these recommendations, data on the maximal luminance of typical diagnostic displays for common use were obtained by asking the following question:

Select one of the presented choices concerning the maximal luminance of typical diagnostic displays commonly used at your facility.

- a. 500 cd/m² or higher
- b. $350 \leq n < 500$ cd/m²
- c. $250 \leq n < 350$ cd/m²
- d. $170 \leq n < 250$ cd/m²
- e. < 170 cd/m²

2.3.2 Grayscale function

The luminance response of a display is important for the consistency of the displayed image among different diagnostic displays. To achieve this consistency, the Digital Imaging and Communications in Medicine (DICOM) Grayscale Standard Display Function (GSDF) [8] is generally used as a grayscale function. The question regarding the grayscale function of typical diagnostic displays for common use was as follows:

Select one of the presented choices concerning the grayscale function of typical diagnostic displays commonly used at your facility.

- a. GSDF (DICOM)
- b. Gamma curve (e.g., Gamma = 2.2)
- c. Do not know

Table 2 Classification criteria for maximal luminance (cd/m²)

JESRA X-0093*B ⁻²⁰¹⁷	AAPM Report No.270 Suggested Passing Criteria (2019)
Management Grade 1A	Diagnostic ≥ 350
Management Grade 1B	Modality ≥ 170
Management Grade 2	Clinical Specialist EHR ≥ 100

JESRA Japanese Engineering Standards of Radiological Apparatus, AAPM American Association of Physicists in Medicine, EHR electronic health record

2.4 Current situation regarding QC of diagnostic displays

2.4.1 Undesirable experiences associated with diagnostic displays

To demonstrate the indispensability of the QC of diagnostic displays, it is important to investigate medical accidents caused by display failures. However, it is difficult to attribute these accidents to displays. Information regarding undesirable experiences associated with diagnostic displays was obtained by asking the following question:

Select all the suitable choices presented below concerning undesirable experiences associated with diagnostic displays.

- a. Different appearance of lesions depending on displays
- b. The ambient light is too bright to see the lesions
- c. Potential for misdiagnosis using displays with inappropriate maximal luminance or grayscale functions
- d. Overlook of foreign bodies (e.g., hand warmers or poultices) during image checking on displays for image inspection and resultant retake attributable to hiding of relevant parts with them on diagnostic displays
- e. Different appearance of lesions between displays at your institution and other institutions
- f. Diagnosis using a display with an inappropriate resolution for the modality
- g. Diagnosis with mobile devices such as laptops or tablets, even in non-emergency situations
- h. Other

Choice d is an undesirable experience caused not by diagnostic displays directly but by a discrepancy in the depiction ability between diagnostic displays and displays for image inspection (modality displays). However, choice d is indirectly related to diagnostic displays, which is one of the two sources of the discrepancy. Therefore, we added choice d as an undesirable experience associated with diagnostic displays to understand the current situation.

2.4.2 Awareness of the necessity of QC of diagnostic displays

To implement QC in diagnostic displays, RTs should be aware of this necessity. The awareness of the necessity of QC for diagnostic displays was assessed by asking the following question:

Do you think QC is necessary? Select one of the following:

- a. Necessary
- b. Unnecessary

2.4.3 Implementation status of QC of diagnostic displays

Even if the necessity for QC in diagnostic displays is well-recognized, QC is not always implemented, which is another issue. The implementation status of QC was determined using the following question:

To what extent is QC implemented? Select one of the presented choices.

- a. Implemented for all displays
- b. Partly implemented
- c. Not implemented

2.4.4 Reasons for not implementing QC of diagnostic displays

The reasons why the QC of diagnostic displays was not implemented were inquired about for the applicable facilities by asking the following question:

If you do not implement QC, select all suitable reasons from the presented choices.

- a. No device or tool available for QC and/or no budget
- b. No time and/or no staff for QC
- c. Insufficient knowledge of QC
- d. Non-recognition of QC as a duty
- e. Recent installation/under consideration
- f. Other

2.4.5 Duties of RTs involving diagnostic displays other than QC

In facilities that implemented QC of diagnostic displays, data on the duties of RTs pertaining to diagnostic displays other than QC were obtained by asking the following question:

If you implement QC, select all suitable duties other than QC for which RTs are responsible from the presented choices concerning diagnostic displays.

- a. Addressing malfunctions and defects
- b. Exploration of specifications for new installation
- c. Planning of display arrangement suitable for applications
- d. Placement changes according to use
- e. Learning skills/knowledge (or training of staff)
- f. Management of test histories
- g. Management of test devices (e.g., luminance meter, illuminance meter)
- h. Asset management
- i. Other
- j. Nothing in particular

2.4.6 Difficulties in implementing QC of diagnostic displays

In facilities implementing QC for diagnostic displays, data on difficulties in implementing QC were obtained by asking the following question:

If you implement QC, select all suitable options stating the difficulties in implementing QC of the diagnostic displays.

- a. Too many units to secure staff
- b. Lack of understanding regarding the necessity of display management
- c. Difficulty in securing budgets
- d. No established procedure for dealing with defects
- e. Difficulty in tracking usage of displays throughout the facility
- f. Difficulty in adjusting the schedule
- g. Particular departments where it is difficult to secure the schedule for QC (e.g., an emergency room)
- h. Other

2.4.7 Anecdotal experiences of potential incidents or accidents prevented by QC of diagnostic displays

At facilities that implemented QC of diagnostic displays, data on anecdotal experiences of instances where RTs considered QC of diagnostic displays to prevent potential incidents or accidents were obtained by asking the following question:

If you implement QC, select all suitable options stating your experiences concerning examples that you considered QC led to the prevention of potential incidents or accidents.

- a. Risks of misdiagnosis attributable to displays were reduced by detecting abnormalities or degradation of displays
- b. An opportunity to improve the environment for diagnosis was gained
- c. The appearance of lesions became the same among the displays
- d. A countermeasure to the ambient light was implemented using light shielding
- e. Frequency of retakes and complaints from physicians regarding the displayed images were reduced
- f. Other experiences

3 Results

3.1 Number of hospital beds

There were 613 respondent facilities, with a response rate of 13.6%. Figure 1 shows the number of respondent facilities classified according to the number of hospital beds. A total of 476 facilities (77.7%) had 100 beds or more.

3.2 Performance of diagnostic displays for mammography

3.2.1 Maximal luminance

Figure 2 shows the responses of the maximal luminance of the diagnostic displays for mammography. Most facilities (283 facilities, 68.0%) used displays with a maximal luminance of 500 cd/m² or higher.

Fig. 1 Number of respondent facilities classified by the number of hospital beds (*n* = 613)

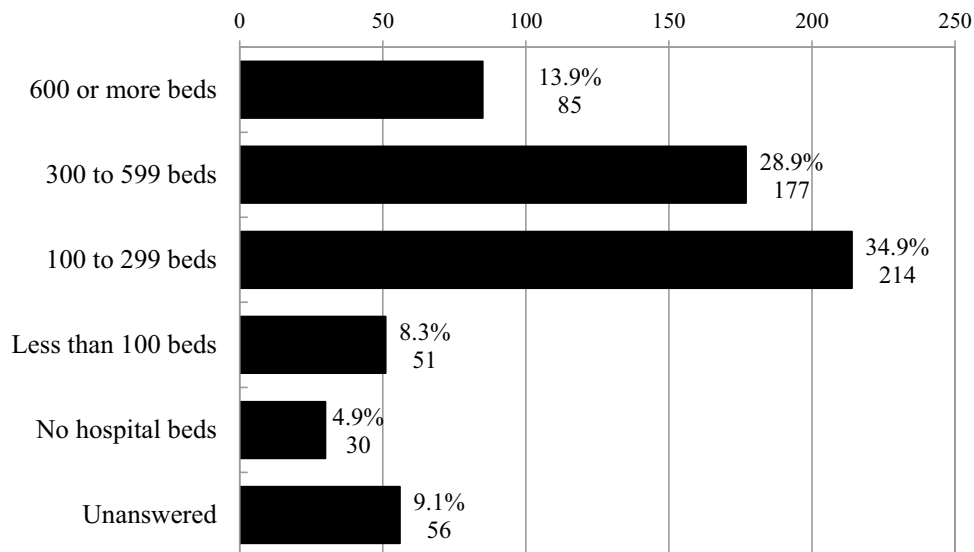
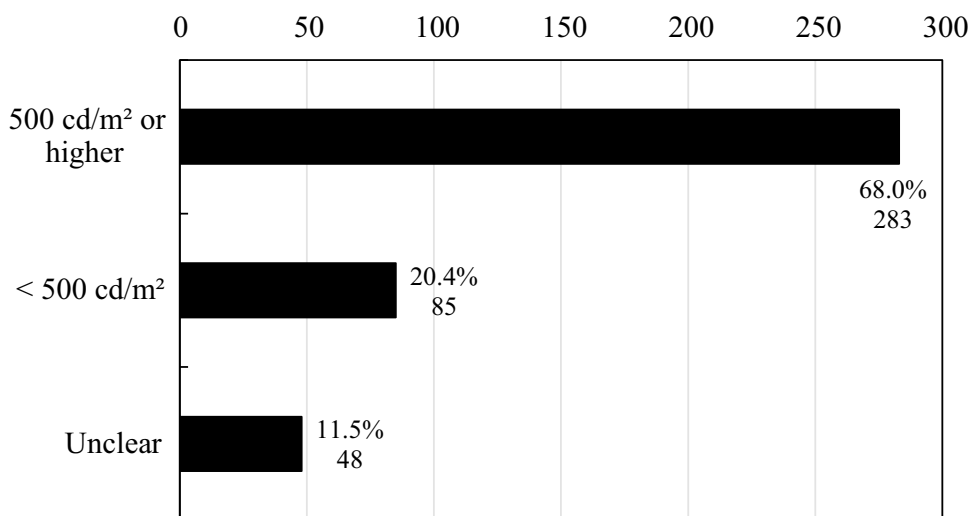


Fig. 2 Maximal luminance of diagnostic displays for mammography ($n = 416$)



3.2.2 Resolution (matrix size)

Figure 3 shows the replies pertaining to the resolution of the diagnostic displays for mammography. Three hundred and fifty-five facilities (86.1%) used displays with a 5-MP resolution (2048 × 2560), whereas 58 (13.9%) used displays with other resolutions.

3.2.3 QC implementation

Figure 4 shows the responses to the QC guidelines applied to mammography. The QC of diagnostic displays for mammography was most commonly implemented according to the QCMDM in 174 facilities (42.3%), followed by JESRA X-0093 in 147 facilities (35.8%). In total, 321

facilities (78.1%) implemented QC of diagnostic displays for mammography.

3.3 Performance of diagnostic displays for common use

3.3.1 Maximal luminance

Figure 5 shows the replies related to the maximal luminance of typical diagnostic displays for common use. Thirty-five facilities (6.5%) used displays with the maximal luminance of “500 cd/m² or higher”, which was remarkably less than that reported for mammography (283 facilities); 232 facilities (43.4%), “350 ≤ n < 500 cd/m²”, which is the standard maximal luminance; 267 facilities (49.9%), “350 cd/m² or higher”, which conformed to Management Grade 1A of

Fig. 3 Resolution of diagnostic displays for mammography ($n = 416$)

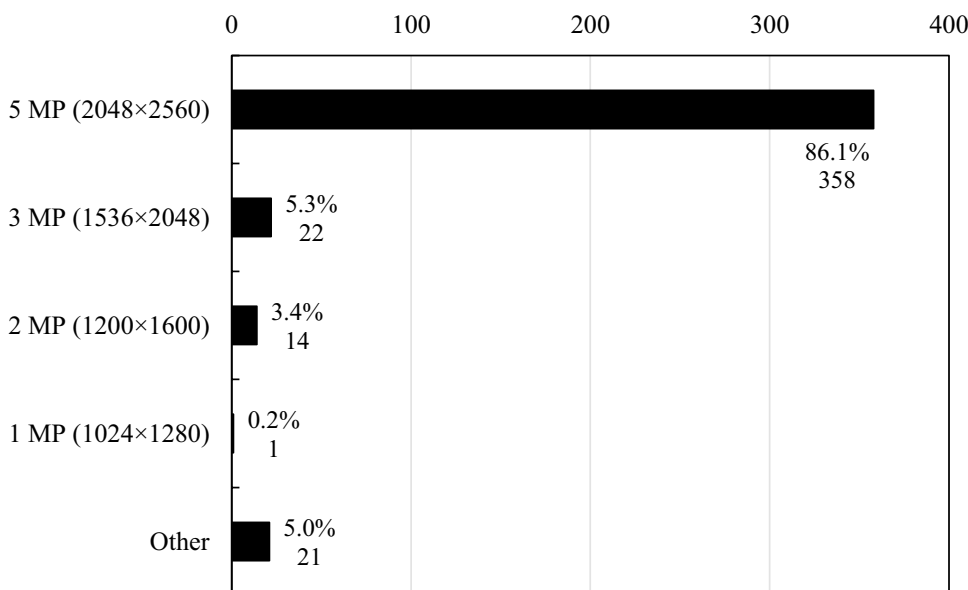


Fig. 4 Procedures of implementing quality control of diagnostic displays for mammography (including outsourcing) ($n=411$)

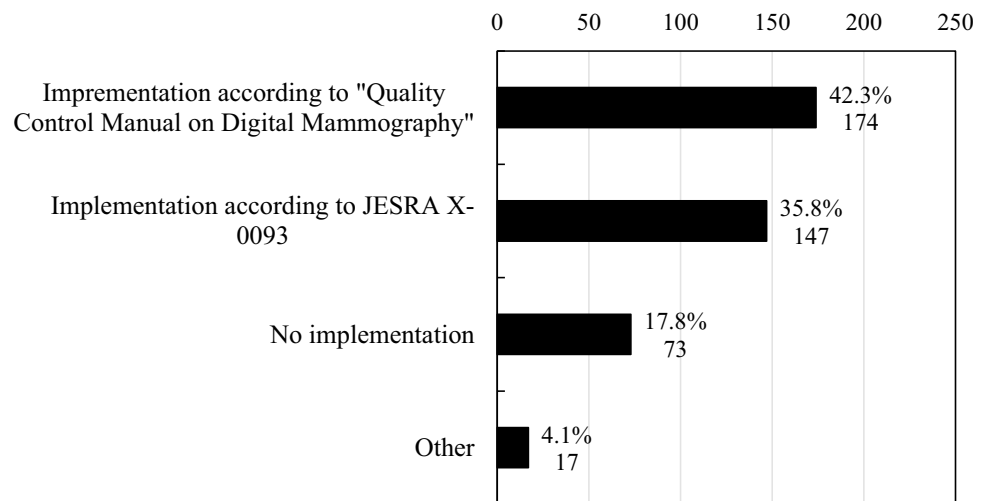
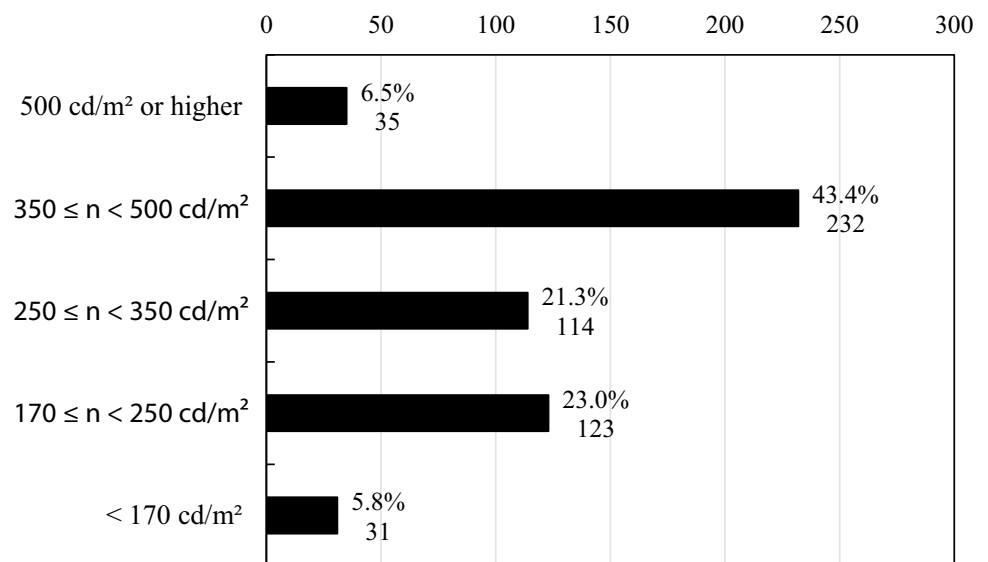


Fig. 5 Maximal luminance of the typical diagnostic display for common use ($n=535$)



JESRA X-0093 and the maximal display luminance recommended for diagnosis by the AAPM Report No. 270; and 31 facilities (5.8%), “< 170 cd/m²”, which did not conform to management grade 1B of JESRA X-0093 and was identified as a “Primary” class display by AAPM Online Report No. 03 [9].

3.3.2 Grayscale function

Figure 6 shows the responses pertaining to the grayscale function of typical diagnostic displays for common use. The DICOM GSDF was used in 425 facilities (73.7%), whereas only 27 facilities (4.7%) used “Gamma Curve”, which could not be adapted for QC. Furthermore, 125 facilities (21.7%) replied “do not know”. Because brochures or user’s manuals of displays calibrated using DICOM GSDF should exhibit

the fact that DICOM GSDF is employed as the luminance response, a reply of “do not know” most likely means that the display does not use DICOM GSDF.

3.4 Current situation regarding the QC of diagnostic displays

3.4.1 Undesirable experiences associated with diagnostic displays

Figure 7 illustrates the responses regarding the undesirable experiences associated with diagnostic displays. “Different appearance of lesions depending on displays” was the most common response provided (322 facilities), followed by “The ambient light is too bright to see the lesions” (129 facilities), “Potential for misdiagnosis using displays with inappropriate maximal luminance or

Fig. 6 Grayscale function of the typical diagnostic display for common use ($n=577$)

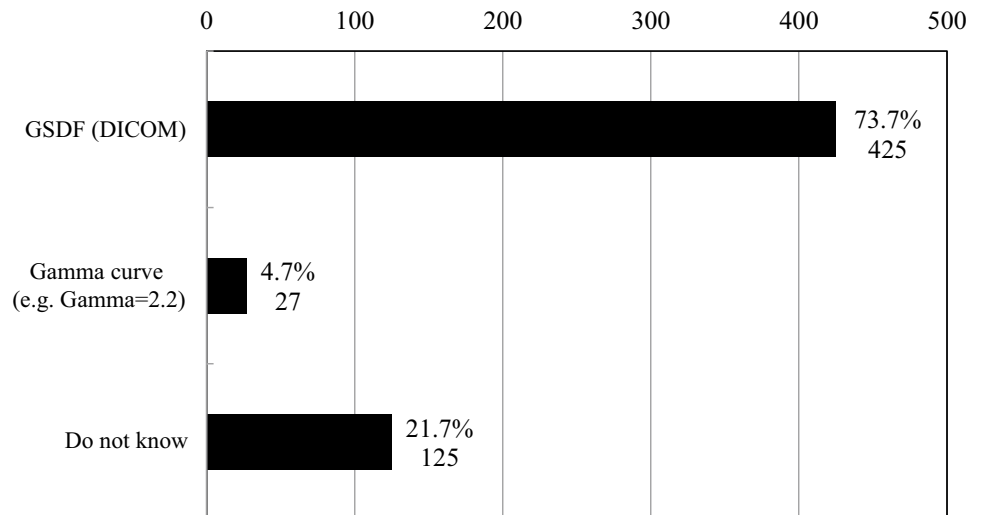
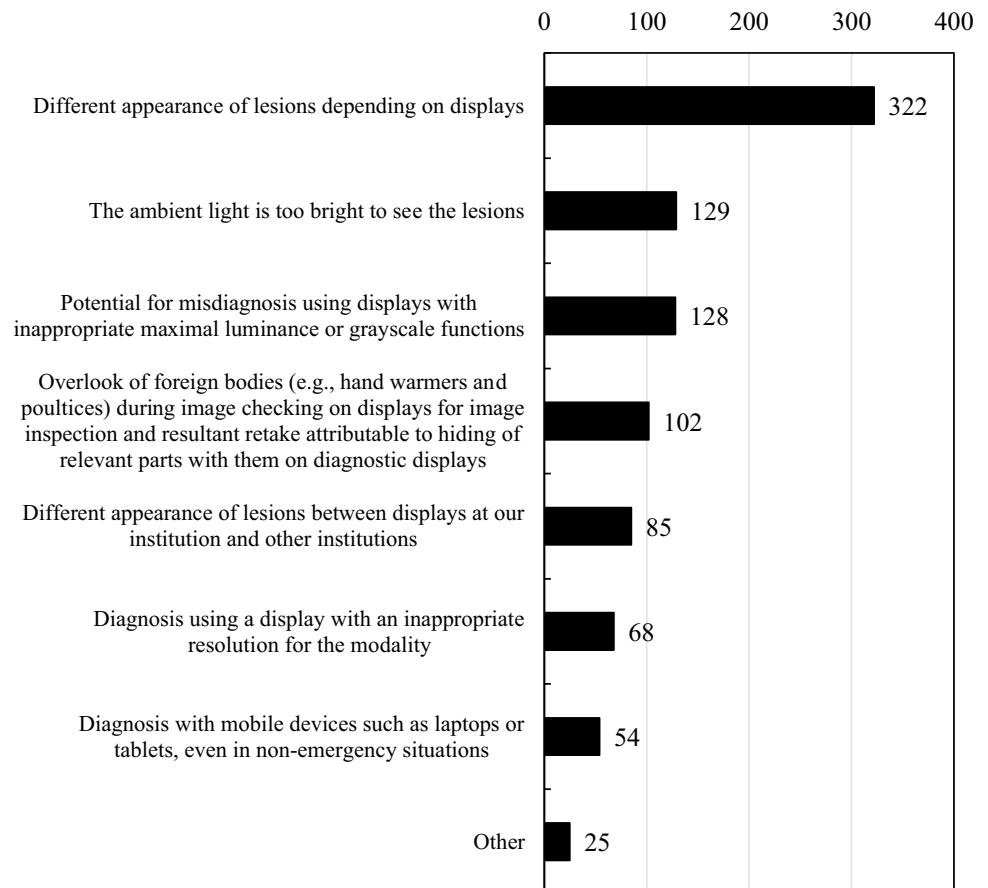


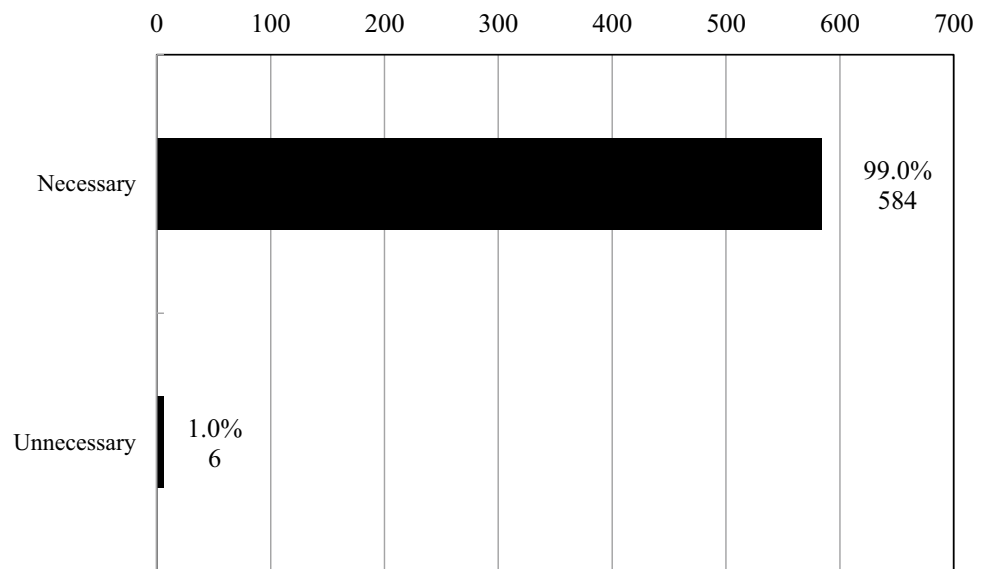
Fig. 7 Undesirable experiences associated with diagnostic displays (multiple choices allowed) ($n=913$)



grayscale functions” (128 facilities), and “Overlook of foreign bodies (e.g., hand warmers or poultices) during image checking on displays for image inspection and resultant retake attributable to hiding of relevant parts with them

on diagnostic displays” (102 facilities). These experiences were not caused by the diagnostic displays themselves but by modality displays.

Fig. 8 Awareness of the necessity of quality control of diagnostic displays ($n=590$)



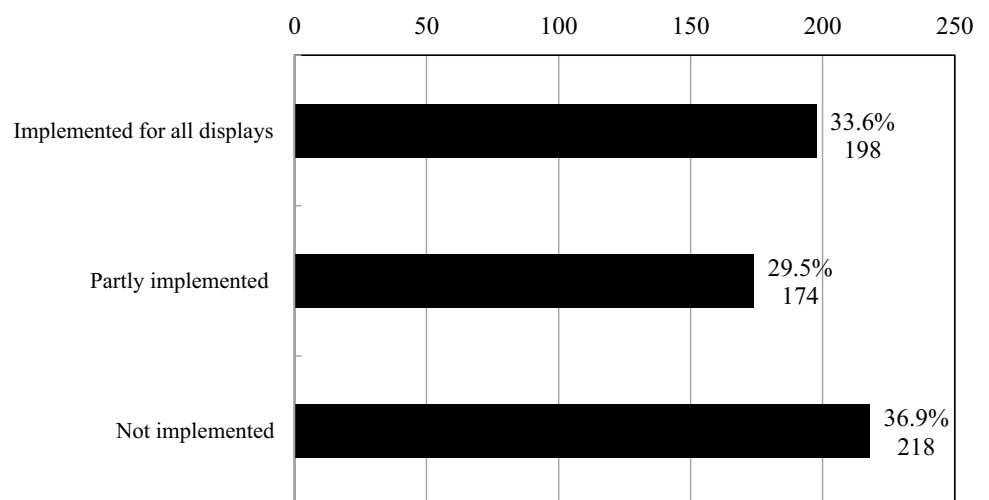
3.4.2 Awareness of the necessity of QC of diagnostic displays

Figure 8 shows the replies regarding whether the QC of diagnostic displays was considered necessary. QC was recognized in 584 facilities (99.0%).

3.4.3 Implementation status of QC of diagnostic displays

Figure 9 shows the responses regarding how thoroughly the QC of the diagnostic displays was implemented. A total of 372 facilities (63.1%) adopted QC, of which 198 (33.6%) implemented QC for all displays and 174 (29.5%) implemented it for some displays.

Fig. 9 Implementation status of quality control of diagnostic displays ($n=590$)



3.4.4 Reasons for not implementing QC of diagnostic displays

Figure 10 shows the responses (reasons) of the facilities that did not implement the QC of diagnostic displays. The major reasons were “No device or tool available for QC and/or no budget” (237 facilities) and “No time and/or no staff for QC” (223 facilities). “Insufficient knowledge of QC” and “Non-recognition of QC as a duty” were responses given by 129 and 124 facilities, respectively.

3.4.5 Duties of RTs concerning diagnostic displays other than QC

Figure 11 shows the responses regarding RTs’ duties concerning diagnostic displays other than QC (only from

Fig. 10 Reasons for not implementing quality control of diagnostic displays (multiple choices allowed) ($n = 796$)

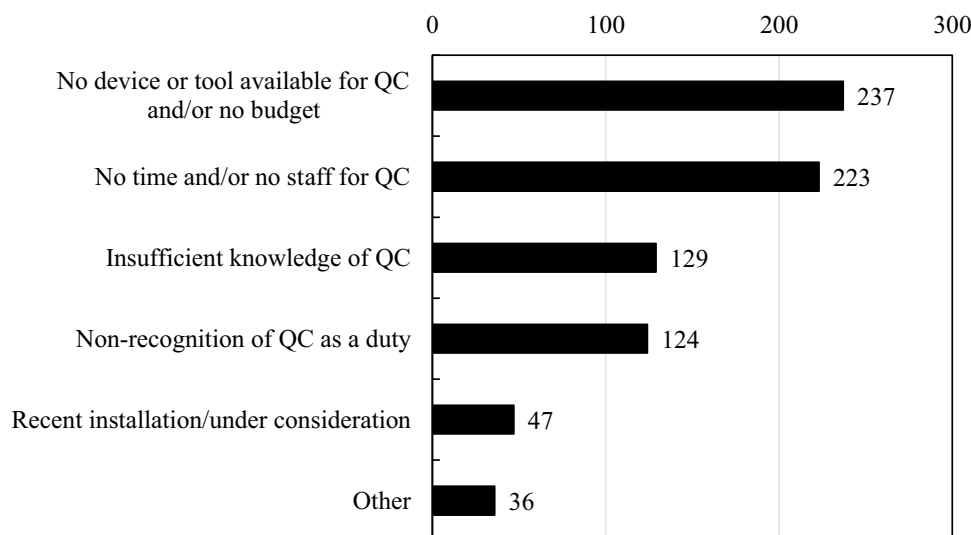
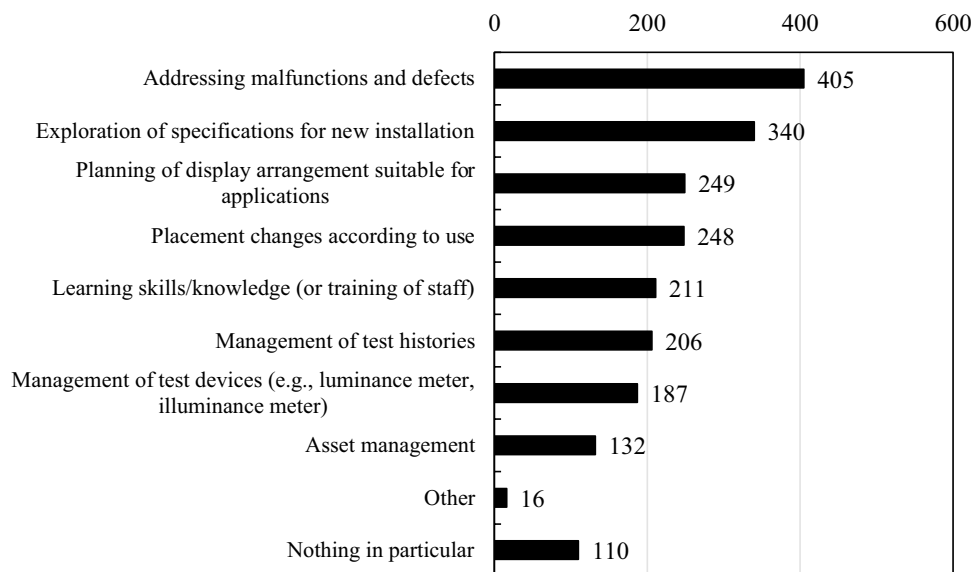


Fig. 11 Duties of radiological technologists concerning diagnostic displays except quality control (multiple choices allowed) ($n = 2104$)



facilities that implement the QC of diagnostic displays). In facilities implementing QC, RTs conducted various tasks related to display management, such as “Addressing malfunctions and defects” (405 facilities), “Exploration of specifications for new installation” (340 facilities), and “Planning of display arrangement suitable for applications” (249 facilities).

3.4.6 Difficulties in implementing QC of diagnostic displays

Figure 12 shows the responses regarding the difficulties encountered in implementing QC. The most frequent responses were “Too many units to secure staff” (241 facilities), “Lack of understanding regarding the necessity of display management” (195 facilities), “Difficulty in securing budgets” (181 facilities) etc.

3.4.7 Anecdotal experiences of potential incidents or accidents prevented by QC of diagnostic displays

Figure 13 shows responses pertaining to anecdotal experiences, where RTs considered QC to prevent potential incidents or accidents. A total of 400 experiences were reported, including “Risks of misdiagnosis attributable to displays were reduced by detecting abnormalities or degradation of displays” (137 facilities), “An opportunity to improve the environment for diagnosis was gained” (108 facilities), “The appearance of lesions became the same among the displays” (92 facilities) etc.

Fig. 12 Difficulties in implementing quality control of diagnostic displays (multiple choices allowed) ($n = 1169$)

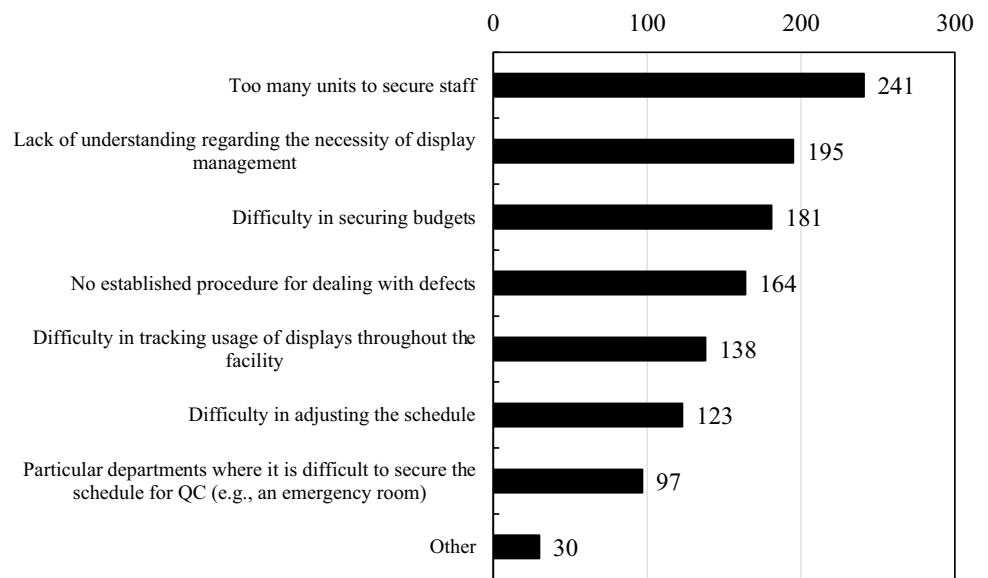
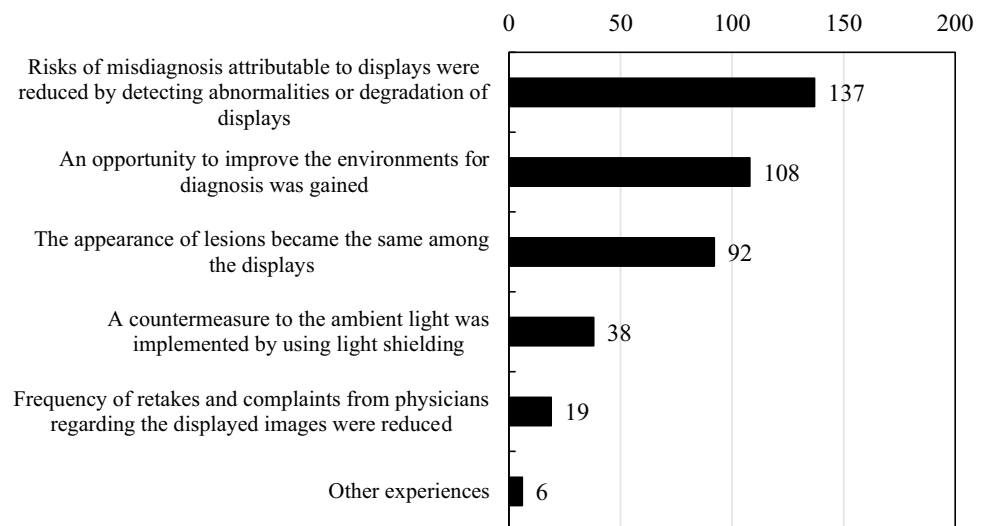


Fig. 13 Anecdotal experiences of incidents or accidents prevented by the quality control of diagnostic displays (multiple choices allowed) ($n = 400$)



4 Discussion

4.1 Number of hospital beds

As shown in Fig. 1, 476 of the 613 (77.7%) respondent facilities (medium- or large-scale hospitals) had 100 beds or more. This survey reflects the reality of medium- and large-sized hospitals.

4.2 Performance of diagnostic displays for mammography

Diagnostic displays with a maximal luminance of 500 cd/m² or higher were widely used in mammography, as shown in Fig. 2. The ACR-AAPM-SIIM Technical

Standard for Electronic Practice of Medical Imaging [10] recommends that the L'max (maximal luminance including ambient luminance) should be at least 420 cd/m², with an L'min (minimal luminance including ambient luminance) of 1.2 cd/m². Many facilities satisfied this criterion in terms of maximal luminance. The luminance ratio, defined as L'max divided by L'min, was not investigated in this survey. Consequently, the reason for the minimal luminance of each display was unknown. However, it seems likely that L'min was darker than 1.2 cd/m². In Japan, both dim lighting and a lower setting of L'min are used for image diagnosis because a darker black is preferred.

As shown in Fig. 3, diagnostic displays with a resolution of 5 MP (2048 × 2560) were used in 358 facilities (86.1%). In accordance with the recommendations of the

QABCS, the use of a 5-MP display appears to be widely accepted for mammography.

Diagnostic displays with QC were used for mammography in 321 facilities (78.1%), as shown in Fig. 4. Although diagnostic displays are not regulated as medical devices in Japan, several facilities have implemented QC of displays. The facility accreditation system by the QABCS could strongly affect this favorable situation.

4.3 Performance of diagnostic displays in common use

Although diagnostic displays with a maximal luminance of 350 cd/m² or higher were used in 277 facilities (49.9%), those with a low luminance of less than 170 cd/m² were used in only 31 facilities (5.8%), as shown in Fig. 5. This indicates that the installation of diagnostic displays with high luminance has been increasing, and compliance with the new criterion of 350 cd/m² or higher luminance, introduced in 2017 as JESRA X-0093 management grade 1A displays, is increasing.

Regarding the grayscale function of the diagnostic displays, the DICOM GSDF was used in 425 facilities (73.7%), as shown in Fig. 6. Implementing the QC of displays appears easy in these facilities. However, the remaining 152 facilities (26.3%) had difficulties implementing QC.

As shown in Fig. 7, the most common undesirable experience associated with diagnostic displays was “Different appearances of lesions depending on displays”, which was reported by 322 facilities. Although it is unclear whether this was caused by the luminance response or luminance ratio, differences in appearance may have led to a different diagnosis. “The ambient light is too bright to see the lesions” was reported by 129 facilities. In the past, only a few diagnostic reading rooms in Japan had adjustable lighting; hence, diagnoses were performed in relatively brighter rooms. Some facilities have tried to improve this situation by hanging a blackout curtain or using a windowless room; however, the situation has since improved. “Potential for misdiagnosis using displays with inappropriate maximal luminance or grayscale functions” was reported in 128 facilities. In the past, some radiologists changed the luminance settings of displays according to their preferences. Therefore, many facilities have reported experiences with displays that have the potential to affect the diagnosis. To prevent these unfavorable situations, current diagnostic displays have adjustment buttons that can be locked. Additionally, such experiences can be prevented if diagnostic displays are properly managed.

Although the necessity for QC in diagnostic displays was recognized by 584 facilities (99.0%), as shown in

Fig. 8, only 372 (63.1%) implemented QC fully or partially, as shown in Fig. 9. Many barriers discouraged the implementation of QC; the major reasons for not performing QC were “No device or tool available for QC and/or no budget” (237 facilities) and “No time and/or no staff for QC” (223 facilities), as indicated in Fig. 10. Constraints on human resources and budgets appear to be major barriers to QC implementation. “Insufficient knowledge of QC” was the response provided by 129 facilities. For facilities with insufficient knowledge, JART regularly holds hands-on seminars on QC of diagnostic displays in collaboration with JIRA. QC was not recognized as a duty in 124 facilities, and this problem should be addressed by all facilities because it is difficult for individual RTs to resolve it.

RTs implementing QC of diagnostic displays conducted various other tasks related to display management, such as addressing malfunctions and defects (405 facilities), exploring specifications for new installations (340 facilities), and planning display arrangements suitable for applications (249 facilities) (Fig. 11). These important duties require sufficient specialized knowledge and effective communication with physicians and manufacturers.

The representative difficulties in implementing QC of diagnostic displays included “Too many units to secure staff” (241 facilities), “Lack of understanding regarding the necessity of display management” (195 facilities), and “Difficulty in securing budgets” (181 facilities), as shown in Fig. 12. These difficulties were primarily caused by constraints on human resources and finances. Therefore, these difficulties should be addressed by the entire facility, because they cannot be resolved by individual RTs.

The major anecdotal experiences with incidents or accidents prevented by QC of diagnostic displays included “Effects of displays on diagnosis were reduced by detecting abnormalities or degradation of displays” (137 facilities), “An opportunity to improve the environment for diagnosis was gained” (108 facilities), and “The appearance of lesions became the same among the displays” (92 facilities) (Fig. 13). The decrease or variation in luminance cannot be recognized without measurement. Similarly, the influence of ambient light cannot be recognized without visual inspection. These findings suggest that the implementation of QC can avoid several risks in medical practice.

During this nationwide survey, the performance of diagnostic displays used in Japan and the current QC situation of diagnostic displays were assessed. Although there are no legal constraints on the performance and QC of diagnostic displays in Japan, many facilities use displays with high maximal luminance and resolution for mammography. With regard to commonly used diagnostic displays, displays

with high maximal luminance have also been introduced. Most diagnostic displays use the DICOM GSDF, which is helpful in implementing QC as a grayscale function. With respect to the QC of diagnostic displays, the RTs voluntarily implemented QC according to the guidelines issued by academic societies or industrial associations. Unfortunately, only approximately 60% of the facilities implemented QC, although 99% recognized its necessity. This is probably due to barriers to QC, such as insufficient devices, time, staff, knowledge, and recognition of QC as a duty. The implementation of QC can prevent many incidents or accidents caused by factors such as decrease in luminance, variation in luminance response, and influence of ambient light. Therefore, countermeasures are required to overcome the barriers that discourage QC implementation.

The introduction of diagnostic displays and the promotion of their QC are strongly affected by the differences in regulations (such as insurance systems, constraints of standards or guidelines, and authorization of medical devices) in each country. Under these circumstances, an international standard for the QC of medical displays was established in November 2021 (IEC 62563-2:2021 [11]). This standard is helpful for many countries to understand the necessity of QC and promote its implementation. We hope that this report will trigger similar survey studies in other countries. The results of our study provide important comparative information to clarify the issues and verify the availability of QC programs.

5 Conclusion

Our survey revealed the current status of QC in diagnostic displays. Although QC was implemented in over 60% of the facilities, the implementation depended on the volunteer activities of the RTs. Moreover, the implementation of QC should be addressed by the entire facility. The barriers that discourage its implementation were mainly related to the lack of human resources and finances. Therefore, to popularize the QC of diagnostic displays in all facilities, countermeasures must be implemented to eliminate these barriers.

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Declarations

Conflict of interest The authors have no competing interests to declare that are relevant to the content of this article.

Ethical approval No approval of research ethics committees was required to accomplish the goals of this study because the experimental work did not involve human participants or animals.

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