



Guideline from the Japanese society of echocardiography: guidance for the management and maintenance of echocardiography equipment: 2022 focused update

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Abstract

Echocardiography plays a pivotal role as an imaging modality in modern cardiology practice. Information derived from echocardiography is essential for patient care. The Japanese Society of Echocardiography has promoted echocardiography for routine clinical and research use. One of the missions of the Society is to provide information that is useful for high-quality examinations. To ensure this, we believe that maintaining equipment in good condition and providing a comfortable environment for the examination are important for both the patient and examiner. Thus, the Committee for Guideline Writing of the Japanese Society of Echocardiography originally published brief guidance for the routine use of echocardiography equipment in 2015. In 2018, the committee updated our guidance incorporating the importance of international standardization. In 2022, the committee has revised and updated our guidance in line with the increase in awareness of infection prevention due to the worldwide spread of coronavirus disease 2019 (COVID-19).

Keywords Echocardiography · Laboratory · Management · Maintenance · Guideline · COVID-19

Satoshi Nakatani is a former president of the Japanese Society of Echocardiography. All other authors are members of the Committee for Guideline Writing of the Japanese Society of Echocardiography in 2022.

In 2022, the Committee for Guideline Writing of the Japanese Society of Echocardiography published “Guidance for the Management and Maintenance of Echocardiography Equipment (in Japanese)”. This is the English version of that report. The Japanese version is available on the website of the Japanese Society of Echocardiography (<http://www.jse.gr.jp/>).

Updated by: Daimon M. and the guideline committee of the Japanese Society of Echocardiography.

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Introduction

Equipment in good condition and a comfortable environment for both the patient and examiner are essential for safe and high-quality echocardiography. Regular maintenance is indispensable to optimize the performance of the device. In Japan, the Medical Service Law defines the maintenance requirements for medical devices including ultrasonography, but it is not specific to ultrasonography devices [1]. In addition to this, the Japanese Society of Sonographers has set out maintenance procedures and checklists for devices, but they are not specific to echocardiography [2].

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Recently, it has become a requirement that medical laboratories follow the international standard. The echocardiographic laboratory plays important roles in the development of new drugs and medical devices, as well as international clinical studies. Echocardiographic laboratories are also required to follow the international standard for reliable quality control. Currently, the ISO 15189 standard provided by the International Organization for Standardization (ISO) is widely used for quality control of medical laboratories. Based on these facts, the Committee for Guideline Writing of the Japanese Society of Echocardiography published brief guidance for the routine use of echocardiography in 2015 [3]. The Committee revised this guidance in 2018, incorporating quality control based on ISO 15189 and infection prevention measures [4]. The worldwide spread of the novel coronavirus disease 2019 (COVID-19), which began in 2019, has reaffirmed the importance of infection prevention in echocardiography [5–7]. In view of this situation, herein the Committee presents revised and updated guidance for the management and maintenance of echocardiography equipment.

Note: The present guidance omits any initial checks on the device at the time of purchase and regular inspections by the manufacturer, which should be carried out for each device according to the manufacturer's recommendations. This guidance also makes no mention of continuously monitoring patient safety, which takes precedence over everything else. This guideline specifically focuses on the maintenance of the devices and equipment.

Maintenance supervisor for ultrasonographic devices

Although device checks should be carried out by all sonographers and doctors who perform echocardiography, the Medical Services Law specifies the appointment of a maintenance supervisor. The maintenance supervisor is responsible for ensuring that the device is checked regularly and properly, and for resolving problems when they occur. The supervisor is also responsible for the proper enforcement of regular inspections by the manufacturer, including operational checks on connected devices and leakage current checks.

Checklist

It is important to prepare a checklist for each device to enable multiple items to be checked efficiently within a short period of time. The date of the inspection, the items inspected, the names of the inspector and supervisor, and any faults should be quickly and easily visible from the list. Preferably, items in the daily, weekly, and monthly inspections should be easy to evaluate from the list to

facilitate sharing information with the manufacturer's maintenance engineer. The name of the manufacturer, the person responsible, and their contact number (sales, repair, night-time service center, etc.) and address should be listed for each device. A checklist that matches the circumstances at each facility should ideally be established, referring to the examples in references [2, 8].

Carrying out inspections

Preoperation inspection

Before operation, check the environment inside the examination room, the main ultrasonography device, and the stocks and the arrangement of the supplies required.

Inspecting before turning the power on

(1) Inspecting the conditions of use

Try to prepare the environment in the examination room from the viewpoint of the patient.

- Check that the ambient temperature and humidity in the examination room are comfortable.—Check there are no traces of scent or perfume from the previous patient.
- Lie on the bed and check that there are no distractions or disturbances in the visible range including the ceiling, that the light is not directly in the patient's line of sight, and that the downdraft from the air conditioner does not blow directly onto the patient.
- Check that the clothes basket, trash box, and any other containers near the bed are clean and placed neatly. Check that there is no dust or dirt on the floor.
- Check that the bed sheet, pillow, and towel are clean. Check that there is no dirt, hair or dust on them and smooth out any creases.
- Check that the bed casters are locked. If the echo bed is an adjustable electric bed, check that it is returned to its original position.
- For transesophageal echocardiography and stress echocardiography or when examining a patient who is in an unstable condition, check the oxygen supply and suction tubes, and the emergency equipment including emergency medicines, injections, and Ambu bag. Check that the automated external defibrillator (AED) or other defibrillator is ready to use.

(2) Inspecting the ultrasonographic device surroundings

- Check that there is sufficient space around the device to avoid any buildup of heat.

If the fan outlets (suction/exhaust ports) are in contact with the wall or curtains, the temperature inside the device may increase, causing it to fail.

- Check that the casters of the ultrasonic device are locked.
- Check that the power plug is fully inserted into the outlet.

The main power plug for the ultrasonographic device must be connected directly to the white outlet for medical use (triple-pole outlet, AC 100 V, 15 A, 10 Ω or less grounding resistance, attached to a ground terminal). Connect the plug while the power to the main device is turned off.

There are three types of power supplies in the hospital: white (ordinary supply), red (ordinary supply + private power generator backup), and green (ordinary supply + private power generator + battery backup). The red and green outlets are primarily for connecting important equipment such as life-support systems, so the ultrasonic device should be connected to the white outlet, not to the red or green outlets. When connecting the ultrasonographic device in a hospital ward, inform the section involved that you are connecting it and ensure it is the correct capacity before connecting. If there is no alternative to using an extension cord (triple-pole type), be careful to avoid a “star-connection” causing an overload of the circuit.

(3) Inspecting the ultrasonographic device

Inspecting the various cables

- Check that there are no tangled or twisted sections, or insulation breaks in the probe cable, power cable, or ECG monitor cable. Check the connections.
- Check that the local area network (LAN) cable (for input/output of electronic patient records) is properly connected to the LAN outlet. Check for damage.

Inspecting the probe

- Check for any abnormalities such as damage or cracks to the acoustic lens surface or the handle.
- Check for any cracks, damage, or broken pins in the connector (connection with the main device).
- Check the transesophageal probe using the same procedure. In particular, check for cracks, chipping, twisting, discoloration, etc. on the surface of the connector cable.

Inspecting the monitor screen

- Check that there is no dust, fingerprints, echo gel, etc. on the monitor screen.

(4) Inspecting the supplies

- Check that there is a good stock of recording paper, echo gel, and disposable ECG electrodes.

(5) Inspecting the recording media

- When making video or DVD recordings, check that the record starting point is set to the finishing point of the previous examination and that there is enough recording space.
- When recording to a hard disk, check that there is sufficient capacity on the disk. (If there is not enough capacity on the hard disk, the behavior of the device may become unstable.) Back up the hard disk periodically onto media such as DVDs.

Inspecting after the power is turned on

(1) Activating the device

After turning on the power supply, carry out an inspection with the room lights set to the same brightness that is used for the ECG test.

- Check that the device and peripheral equipment operate normally. Check that there are no error messages during operation. Check for any abnormal sounds.
 - If an error message appears or any abnormal behavior occurs on the panel when turning on the device, write down or print out the error message and contact the manufacturer to get the device repaired.
- Check that the device is set to display the correct date.
- Check that the indicators, switches and buttons on the control panel, trackball, and keyboard all operate normally.
- Check that the acoustic lens surface of the probe is not abnormally hot.
- Check that the transesophageal probe works normally when operating the angle knob. Check that the acoustic lens surface rotates smoothly.
- In a facility that is connected to the hospital information system or file server, check that the work list and data transfer to the image server are available.

(2) Image quality of the monitor and peripheral equipment

- Check that the brightness and contrast are set correctly. Check the gray scale settings step by step from a black background to a white background.
- Check for any defects in the image or abnormal noise when setting the 2-dimensional echo gain to a higher value.

- Check that the color tone changes as the color gain is increased.
 - During the inspection, turn down the color gain until the clutter and noise disappear.
- Check the quality of the output image on the monitor screen.
 - Check by printing out the image. If any noise appears, clean the print head.
 - Output the image to video or DVD and compare the image with the monitor screen.

Daily inspection

At the end of each examination, carry out an inspection in preparation for the next examination. Parts of the pre-operation inspection should be repeated as follows:

- Check that the ambient temperature and humidity in the examination room are comfortable. Check there are no traces of scent or perfume from the previous patient.
- Check that the clothes basket, trash box, and any other containers near the bed are clean and placed neatly. Check that there is no dust or dirt on the floor.
- Check that the bed sheet, pillow, and towel are clean. Check that there is no dirt, hair or dust on them and smooth out any creases.
- Check that the cables for the probe, ECG device, etc. are not tangled.
- Check that the bed casters are locked. If the echo bed is an adjustable electric bed, check that it is returned to its original position.
- Check that no items have been left behind by the previous patient.
- In transesophageal echocardiography, the patient may accidentally bite the probe during the examination. Check for any abnormalities in the appearance of the connector cable during cleaning.

Inspection at the end of operation

To prepare for the next patient, check the records to follow up on any problems discovered during operation. The pre-operation inspection before the next examination can be simplified by completing part of it at the end of the current examination.

- Check for any gel adhering to the probe. Clean, sterilize, and disinfect the equipment according to the procedure described in the instruction manual.
- Check that there is no dirt, gel, etc. on the control panel.
- Check that all the images have been saved. In facilities that record to video or DVD, check the end point.

- Replace any supplies that have been used.

Weekly inspection

- Clean the outside of the main device and probe holder according to the instruction manual.
- Check that the monitor stand is attached to the device and that any peripheral equipment are firmly secured and not loose.
- Check the filters on the intake ports on the front, rear, sides, and bottom of the device, and use a vacuum cleaner to clean any dust from the filters. Check that nothing is obstructing the exhaust port.

Monthly inspection

- Clean the main device and the printer and video recorder heads.
- Inspect and remove any dust or dirt from around the power outlet.
- In facilities that provide an emergency cart and medicine cabinet in the examination room, check the number of medicines in stock and their use-by dates, and refill or replace them as necessary.

Infection prevention and control (updated)

It should be recognized that echocardiographic laboratories can mediate health care-associated infection via contacts between patients and the probe, the electrode or the sonographer [9]. For example, multidrug-resistant *Acinetobacter baumannii* can survive for a long time in xeric environments and may cause health care-associated infection through these pathways [10]. Furthermore, in the echocardiography laboratory, the transmission of nosocomial infections, such as *Pseudomonas aeruginosa* [11] and *Klebsiella pneumoniae* [12], via echo gel has been reported. Therefore, the sonographer should confirm patients' information regarding infection with multidrug-resistant bacteria and take necessary measures of infection prevention and control according to the institutional rules before echocardiography, in addition to regularly cleaning the laboratory. Sonographers are required to wash their hands routinely before and after examinations and to wipe the surfaces of the echo bed, probe, and electrode using a wet cloth with ethanol to achieve effective disinfection after the examination [13].

The worldwide spread of COVID-19, which began in 2019, has reaffirmed the importance of infection prevention in echocardiography [5–7]. COVID-19 is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which is easily transmitted by contact and by droplets, and is often associated with fatal interstitial pneumonia, thrombosis, and myocarditis. As a result, healthcare

professionals are at significant risk of coronavirus infection when performing echocardiography of overt or subclinical COVID-19 patients. To prevent coronavirus infection, each healthcare professional must thoroughly review the current evidence issued by academic societies and make efforts to prevent infection by wearing a mask, washing hands, and disinfecting with alcohol [5–7]. Furthermore, it has been reported that many droplets adhere to the surfaces of ultrasonographic devices, centering on the operation panel, and can transmit coronavirus infection [14]. Therefore, after the inspection is completed, it is necessary to wipe the operation panel of the ultrasonographic device with an ethanol-containing sterilizing wet cloth. Since the spread of infection varies greatly depending on the region, it is important to carefully check the instructions from the facility and take preventive measures according to the prevalence of infection in the region.

Procedure for contacting the manufacturer's call center

If a fault occurs in the device during use, contact the manufacturer promptly. The person in charge must act quickly to get the device repaired. To ensure this happens as smoothly as possible, an office administrative staff member should contact the manufacturer because there will be a maintenance contract and arrangements for paying repair charges.

Follow this procedure when contacting the call center:

- (1) Call the call center using the number on the label on the rear or side of the device, and give them the system number from the label. This will enable the manufacturer to determine the hospital name, device type, and probes attached.
- (2) Give details of the fault, including details of the operation being conducted when the problem happened. Also give details of any error messages.
- (3) Record the time the fault happened. This will allow the service engineer to check the error log.
- (4) When contacting the call center, record the date and time and the name of the person you spoke to.

ISO 15189 standard

The ISO is an independent, nongovernmental international organization for providing specifications, guidelines and characteristics that can be used consistently throughout the world to ensure that materials, products, processes, and services are fit for their purpose. The ISO 15189 standard provides requirements for quality and competence and specifies the quality management system requirements not only for echocardiography but for all medical laboratories. The first version of ISO 15189 was published in 2003, and it

has since been revised [15]. In Japan, the certification program for medical laboratories based on ISO 15189, which was developed by the Japan Accreditation Board (JAB) and the Japanese Committee of Clinical Laboratory Standards (JCCLS), was launched in 2005 [16].

Recently, the requirements for echocardiographic laboratories have been expanded, and to participate in international collaborative studies or clinical trials, laboratories must now be certified according to ISO 15189. The number of echocardiographic laboratories certified according to ISO 15189 is increasing in Japan. To be a certified laboratory, the echocardiographic laboratory must pass the certification examination by the JAB. The certification examination includes completion of the “quality management system” and the “competence of testing and calibration for laboratories”. These are mainly examined within the accreditation scope applied by the facility. The points judged as incompatible in the examination need to be corrected and reported to the JAB. The accreditation committee determines whether each laboratory can be certified and identifies the need for any corrective action based on the content of the review. The term of validity for the certification is 4 years. During this time, two surveillance audits are conducted to confirm the certification status by ensuring that the quality management system and competence of testing and calibration are maintained by each laboratory.

Declarations

Conflict of interest Masao Daimon is an editor of Clinical Echocardiography and received manuscript fees from Bunkodo Co. Ltd. Hiroyuki Iwano, Tetsuaki Onishi, Takahiro Ohara, Hidekazu Tanaka, Yutaka Hirano, Hirotsugu Yamada, Chisato Izumi, and Satoshi Nakatani declare that they have no conflict of interest.

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