

Medical Safety Information

Pharmaceuticals and Medical Devices Agency



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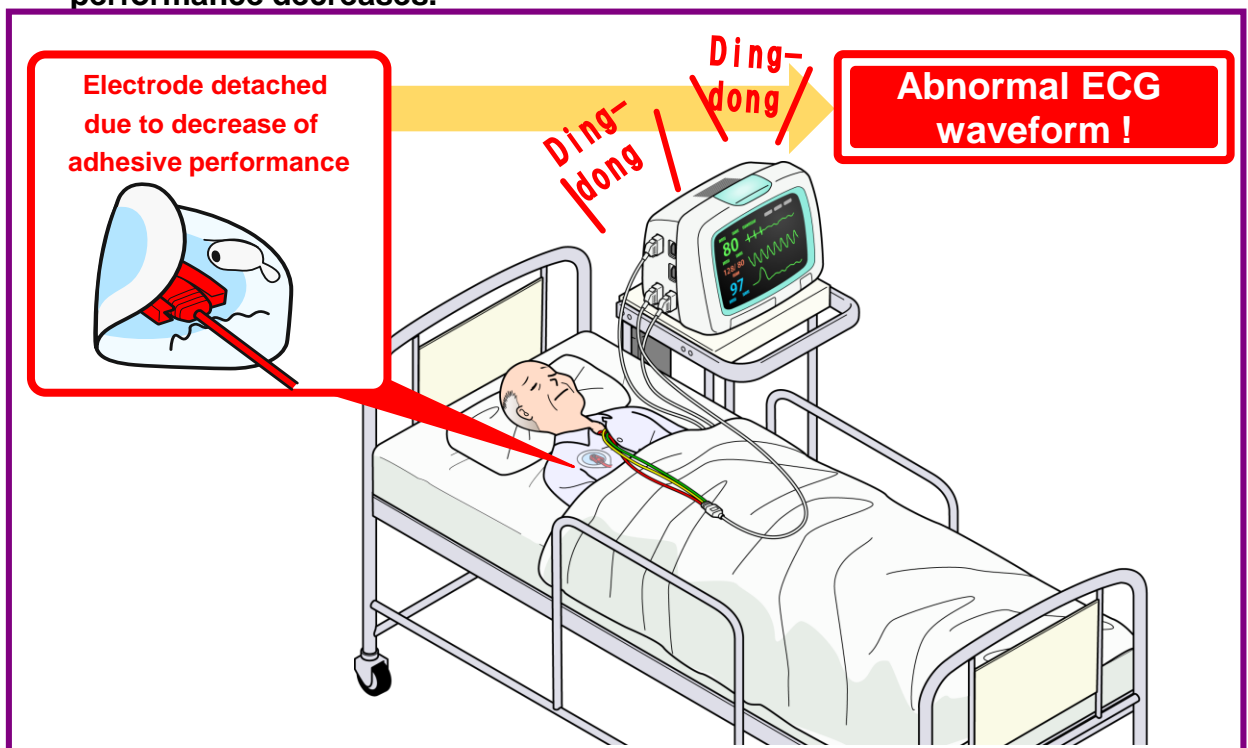
Precautions in Bedside ECG Monitoring

POINT Key points for safe use

(Case 1) The alarm in the bedside ECG monitor went off. The medical staff visited the patient's room and found an abnormal waveform on the monitor. After checking, it was found that the electrode, which was attached to the patient, had come off.

1 Precautions for the technical alarm (electrode detachment)

- The electrode should be replaced periodically before the adhesive performance decreases.

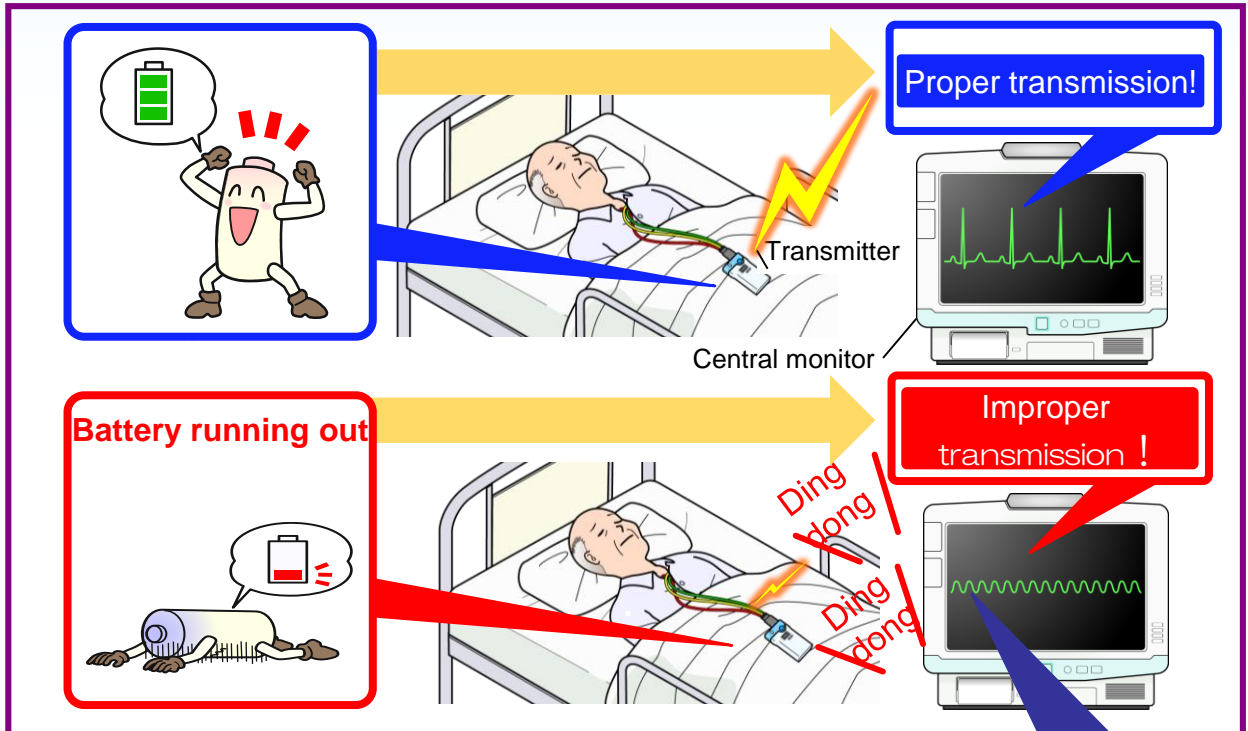


The adhesive performance of electrodes decreases with long-term use and skin conditions of the patient such as sweating. Defining rules for electrode replacement intervals and changing electrodes before they come off will help reduce inaccurate measurements.

(Case 2) An alarm related to incomplete wireless transmission went off. Medical staff checked the ECG system and found that the battery of the transmitter worn on the patient was running out and the signals were not received by the central monitor.

2 Precautions for the technical alarm (running out of battery)

- Change the battery of the transmitter immediately when the central monitor shows the battery change indicator, regardless of whether there is an alarm or not.



Examples of battery change indicators

Examples of battery change indicators

WEP-1000 Series
 Fukuda Denshi Co., Ltd.

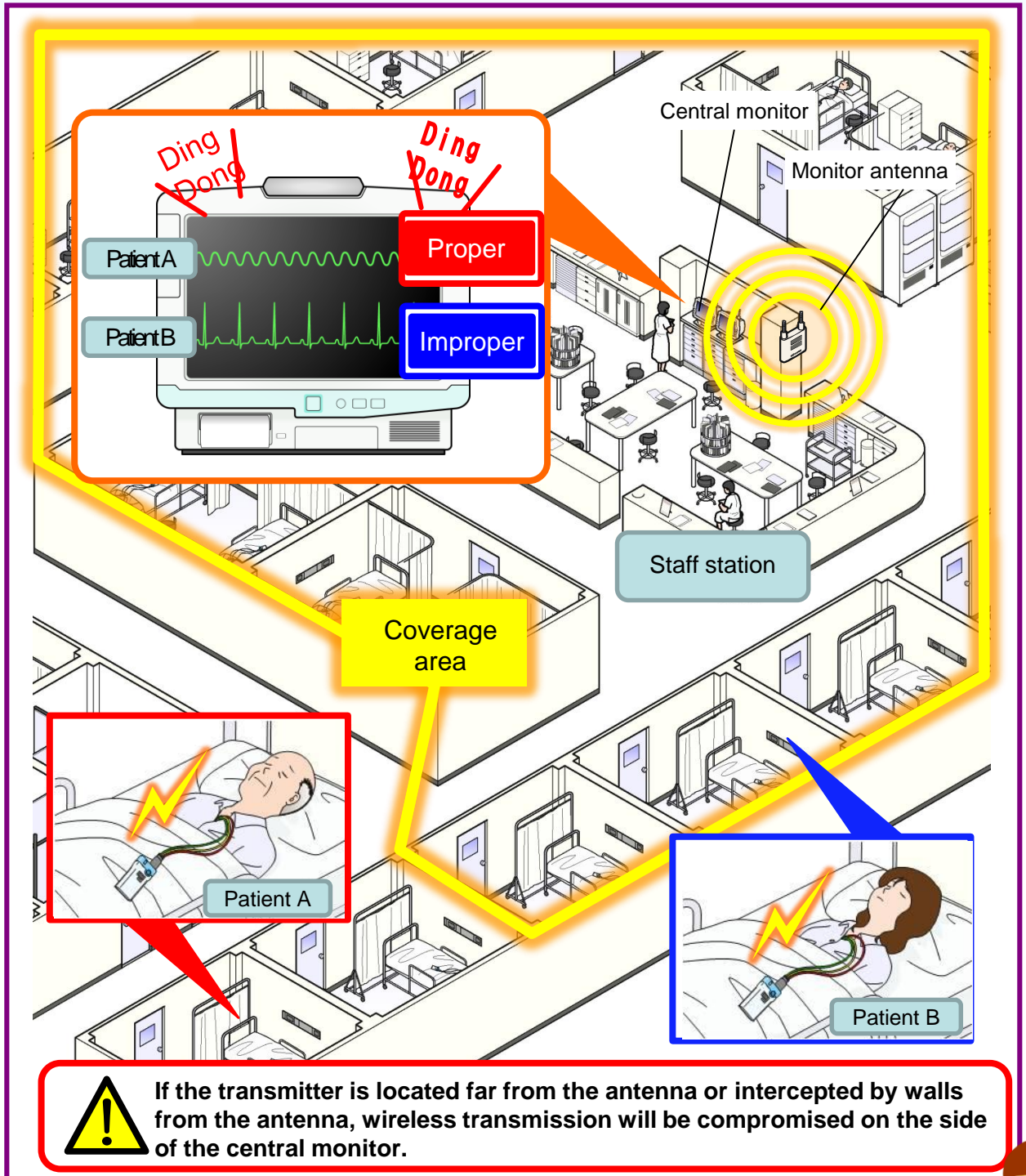
DS-8700 Series
 Philips Electronics Japan, Ltd.

Central Monitor
 Philips Patient Information Center

(Case 3) An alarm related to incomplete wireless transmission went off. The medical staff checked the ECG system and found that the battery of the transmitter worn on the patient was running out and the signals were not received by the central monitor.

3 Precautions for the technical alarm (improper transmission)

- Check the reception status in hospital rooms of the monitor antenna.



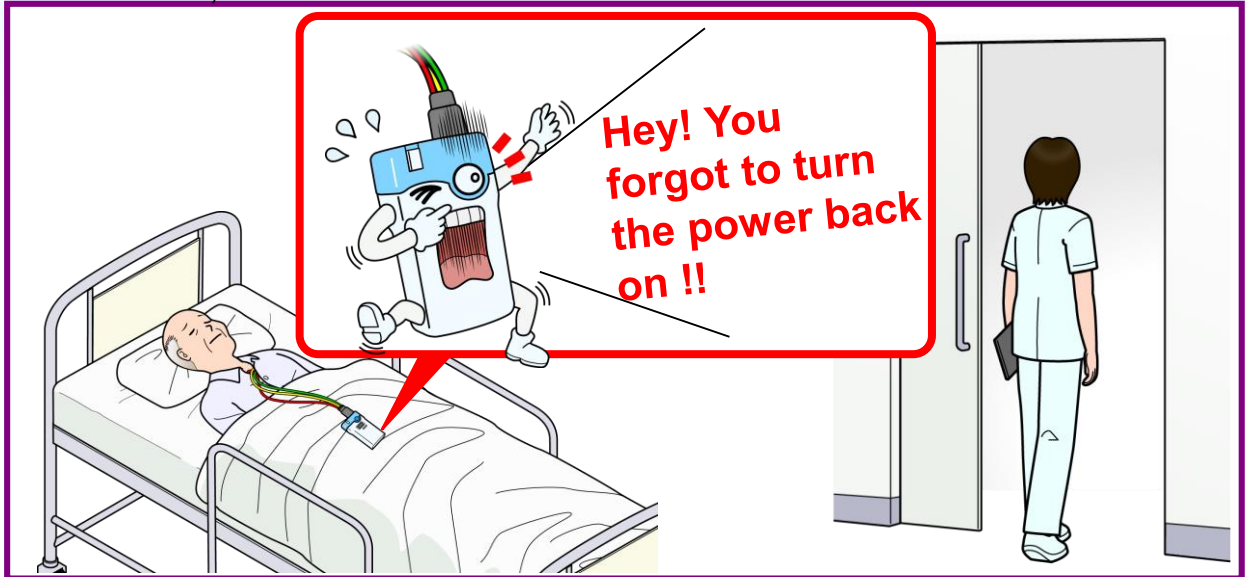
The environment for the ECG monitor should be improved to avoid needless alarms such as lead disconnection from the electrode, electrode detachment, running out of battery, improper wireless transmission and printer's out-of paper status, etc.



(Case 4) When giving a dry-bath, the medical staff turned off the transmitter of the biological monitor and forgot to turn it back on when leaving the patient, and failed to notice the abrupt changes in the patient's condition in a timely manner

4 Precautions for the handling of a transmitter (forgetting to turn the power on)

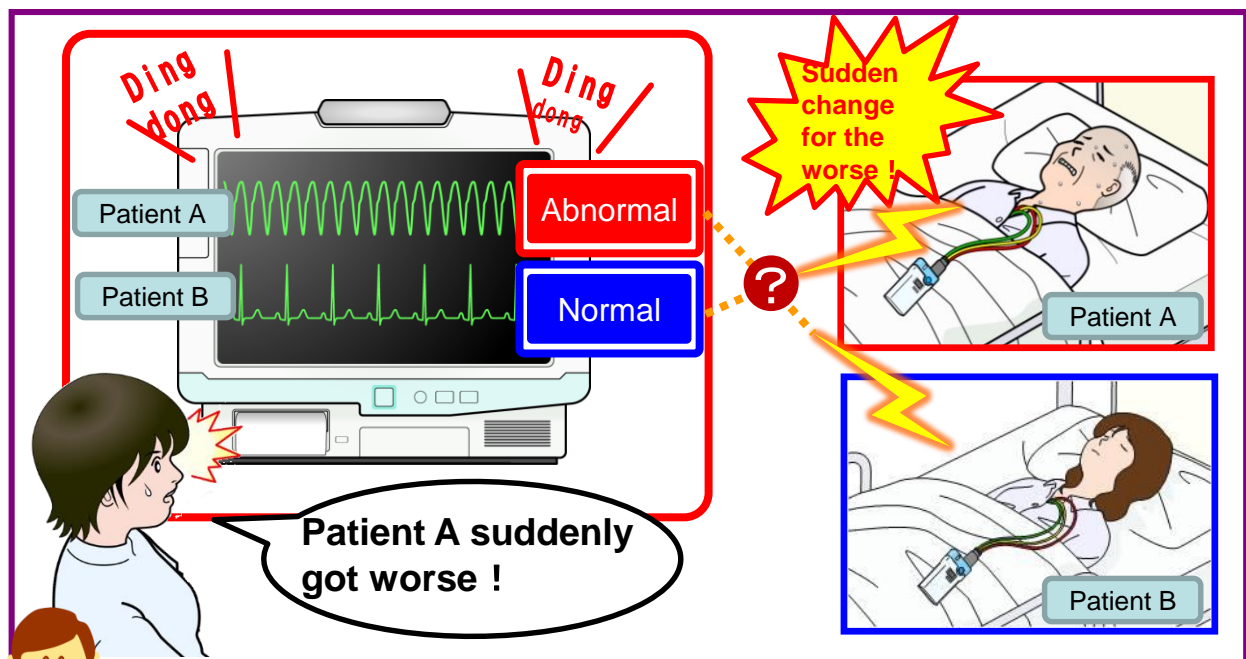
When turning off a transmitter or other devices in order to take care of patients such as dry bathing, make sure to turn them back on when finished and confirm the waveform, etc. on the monitor.



(Case 5) Patient A's monitor showed an abnormal waveform. Medical staff checked and found the monitor mixed up with Patient B's.

5 Precautions for patient monitor settings

Make sure that patient information set in the monitor is for the right patient attached to the transmitter.



Medical staff may have to handle multiple transmitters.
Establishing a procedure for the setup of the central monitor
such as a patient-specific setting is also important.

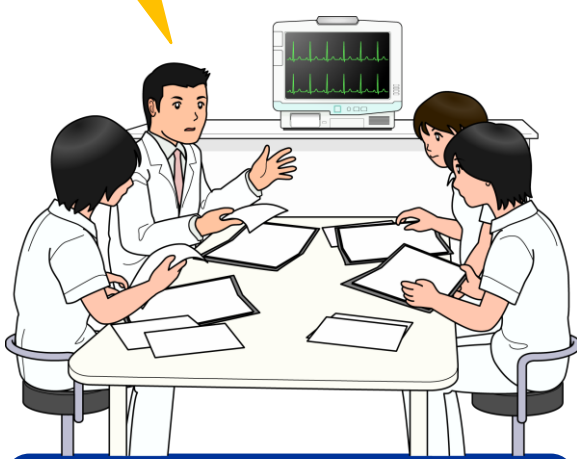
- (Case 6)** Alarms went off for several patients at once. The medical staff stopped all the alarms once and attended the patients one by one, failing to respond to high-priority patients in time.
- (Case 7)** The alarm went off frequently despite having been turned off. The medical staff assumed that the patient was just moving and failed to respond quickly.

6 Proper use of bedside monitors etc.


- Define the basic policy of responses when an alarm goes off.
- Discuss in the team the necessity of a central monitor, etc. for proper use of devices.

Necessity of a bedside monitor. etc.

Patient A's condition is stable now. He can remove the ECG monitor and switch to a pulse oximeter !

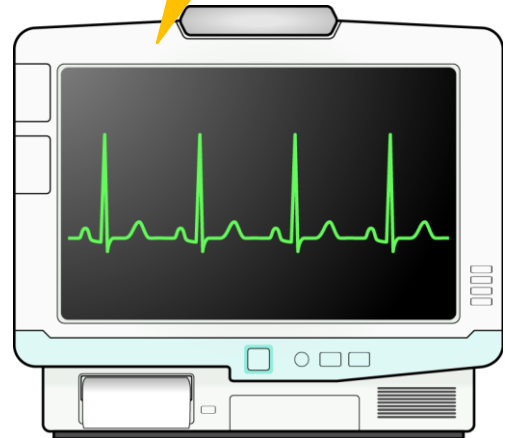


To discuss the necessity of a bedside monitor as a team for each patient is important.




Proper alarm settings

The settings of the alarms for heart rate threshold, arrhythmia, etc. should be changed as appropriate according to the condition of patients.



Proper alarm setting for each patient helps avoid needless alarms. Discussing the proper alarm sound and volume is also important.



Notice from organizations and groups that are related to this medical safety information is available at the Pharmaceuticals and Medical Devices Information website (only in Japanese)

<https://www.pmda.go.jp/files/000144769.pdf>

About this information

* PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Law on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices.

* We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.

* This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.

• Access to the most up to date safety information is available via the PMDA medi-navi.

