

PMDA Alert for Proper Use of Medical Devices

Pharmaceuticals and Medical Devices Agency

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For patients who use a ventilator, etc. at home and their families or other caregivers

- A study conducted by the Ministry of Internal Affairs and Communications (MIC) revealed that radio waves (not including from Wi-Fi) emitted by mobile phones, etc. (including smartphones and tablet-type devices) can affect the operation of ventilators, etc. (including ventilators for adults and bilevel positive airway pressure units)
- In particular, patients and their families or other caregivers need to be careful when a ventilator, etc. is used at home.
- Please pay attention to the following to reduce the impact of radio waves. This is not aimed to limit the use of mobile phones, etc. by patients and their families or other caregivers.



Mobile phones

Smartphones




Tablets



Keep mobile phones, etc. at a greater distance from the medical device than recommended by the medical device manufacturer.

Ask medical staff for the proper distances.

 Consult with medical staff if you find any unusual behavior of the ventilator, etc. during use.

Points to be considered by medical staff

Please read the following before giving an explanation to your patients

- ❑ The top page of this leaflet is intended to show patients when medical staff give an explanation to patients, including their families or other caregivers, who start treatment with a ventilator, etc. (including ventilators for adults or bilevel positive airway pressure units) at home.
- ❑ Verification by the MIC regarding the impact of radio waves emitted by mobile phones on medical devices
 - The MIC is conducting a verification test to examine the impact of radio waves emitted by mobile phones (smartphones, tablets, etc.) on the behavior of medical devices.
 - A test result demonstrated events in which ventilators for adults and bilevel positive airway pressure units erroneously detected radio waves emitted by a mobile phone as the patient's spontaneous breathing when the phone was brought very close to the medical device. (Fiscal year 2017, 2018)



URL: <https://www.tele.soumu.go.jp/j/sys/ele/seitai/chis/index.htm> (only in Japanese)



This test **assumes extreme situations, which will not be necessarily reproduced in the clinical settings**. We are not aware of any identical events that actually occurred in the clinical settings. **The convenience of the mobile phone for patients and their families or other caregivers will not be limited** based on this test.

- ❑ **The package insert of the applicable medical devices provides the following** regarding the distance to be kept between a mobile phone and a ventilator, etc.

[Important Precautions]

- ▲. When a mobile phone, etc. (including smartphones, tablets, etc.) is brought close to this device within approximately XX meters, the radio waves may interfere with the operation of the device and a malfunction may result. The behavior of the device should be carefully monitored. Patients and their families or other caregivers should be instructed to conduct a routine check of the device's behavior. [This product has been proven to comply with ****.]

**** is the name of the relevant standard specified by JIS (Japanese Industrial Standards) or IEC (International Electrotechnical Commission).



The distance stated in the package insert was calculated by the manufacturer of the medical device based on the JIS standard, etc. **The medical staff are requested to give the following instructions to the patients and their families or other caregivers.**

- ✓ Use a mobile phone, etc. from the distance instructed by the manufacturer of the ventilator, etc.
- ✓ Check the routine behavior of the ventilator.

- ❑ If there is any malfunction observed in the operation of the ventilator, etc. possibly attributed to radio waves emitted by a mobile phone, etc., please contact the staff of the manufacturer of the medical device.