

October 14, 2016

Field Safety Notice

Attention to Nihon Kohden Customer:

This letter contains important information that NIHON KOHDEN Corporation requests to execute the Field Safety Corrective Action according in your law. Detail is as follow.

1. Affected product name and serial number

Type: AED-2100K, AED-2100W

Serial number: See attached Annex 1

2. Reason of field correction

The life time of the battery pack in a state that this device is not used to life-saving is two years or four years from when installed to the device. In addition, this device conducts daily self-test to inspect disposable defibrillation pads, battery, and internal electronic circuit.

In the only particular lot, we have found increasing issue that device is not turned off after daily self-test by the defective operation of the circuit. Then the battery is exhausted.

3. Specific possible health damage

The device displays the result of self-test on the status indicator that device is usable state (green) or device is not usable state (red). If the issue occurs and the battery is exhausted, the status indicator is lit red indicating that device is not usable. At the time of daily inspections, it is easy to find that issue occurs.

And thus, there is no chance of causing serious health damage to the patient. For your information, we have not received a report about any health damage so far.

4. Summary of corrective action

We will conduct a FSCA of software update to turn off to avoid the battery exhaust, even if the issue occurs.

If you have any questions, please do not hesitate to contact your local NIHON KOHDEN representative at 65 63762210 or Tech@nihonkohden.com.sg.

We apologize for the inconvenience this corrective action may cause and thank you for your support and cooperation.

Signature 

Masato Semba

Operating Officer and General Manager of Quality Management Division

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Annex 1

Model	Serial Number
AED-2100K	09788
AED-2100K	10433
AED-2100K	11061
AED-2100K	10434
AED-2100K	11062
AED-2100K	11086
AED-2100K	11107
AED-2100K	11105