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An Asahi Kasei Group Company

Urgent Medical Device Correction

731 Ventilator Product Family (Models EMV+, AEV, Eagle II, and Eagle II MRI)
With System Software Version 05.20.00

ZOLL 731 Ventilator May Inappropriately Change Parameter Settings

June 30, 2017

Dear Customer,

ZOLL Medical Corporation has decided to conduct a field corrective action on certain 731 Ventilator devices. This letter describes the issue and corrective actions that should be taken to address the problem.

We have identified a software anomaly in the 731 software version 05.20.00 which can lead to a user inadvertently changing device settings. The 731 device is designed with a "touch, turn, and confirm" user interface where the user can select a parameter by pressing the interface soft-key, modify the parameter by turning the select dial, and confirm the new setting by pressing the confirm button. We have found that if the device is in the Bi-Level (BL) or the CPAP Mode and the user:

a) selects the Mode soft-key;
b) does not change the mode by turning the rotary select switch;
c) but presses the Confirm button without making a change;

the device will inadvertently change parameter settings within that mode. In the case of the Bi-Level Mode, the device will decrease the value of the Inspiratory Positive Airway Pressure (IPAP) setting by the Expiratory Positive Airway Pressure (EPAP) already set on the device. In the case of the CPAP Mode, the device will increase the Pressure Support (PS) setting by adding the amount of Positive End-Expiratory (PEEP) set on the device to the PS setting. In both cases, the modified settings will be displayed to the user but the user may fail to detect that it changed.

The user can correct the situation by selecting the parameter that changed and adjust it to the desired settings.

To date, we have not received field reports associated with this software anomaly. The probability of having an event is low under normal operating conditions. ZOLL is currently working on correcting this software anomaly and will update affected devices with the new software version as soon as it becomes available. Although the probability is low, the following actions should be taken on all affected devices:

AFFECTED DEVICES

All 731 Ventilator models operating with software version 05.20.00

REQUIRED ACTIONS

Customers who have affected devices should immediately take the following steps:

(1) **Alert all users of 731 Ventilator models to this problem.**
(2) **Direct users to always verify device parameters after selecting the device Confirm button**.
(3) **Contact ZOLL's Technical Service Department or your local ZOLL Service Provider to schedule a software update for affected devices.**

We have notified the FDA and other regulatory agencies of this corrective action and expect it to be classified as a recall.

We apologize for any inconvenience this may cause you and thank you in advance for assistance in implementing this corrective action. Avoiding this problem during clinical use is our highest priority. Our 24/7 technical support numbers **1 (800) 348-9011** or **+1 (978) 421-9460** are available to assist users with any aspect of this notice.

Sincerely,

Paul Dias
VP Quality Assurance & Regulatory Affairs