

Urgent Safety Note for Users

Number: 2020-0001

Freiburg, July 27th, 2020

Dear Customer,

this letter is to inform you regarding potential problems when switching on the CARL Controller.

We therefore ask you to read this safety advice carefully and ensure that all users take note of it.

Medical Device Concerned

Name	REF	SN / LOT
CARL Controller	A010	Concerns all devices

Description of the Problem

For software reasons, after pressing the "Off" button the CARL Controller can only be restarted without problems within a period of 40 seconds or after a total waiting period of 70 seconds after switching off.

The reason for this period of 30 seconds where the CARL Controller cannot be started is an internal security check of the processors. This security check starts 40 seconds after pressing the "Off" button and ensures that the corresponding software error is detected and corrected. This process takes 30 seconds.

Therefore, a direct restart by simply pressing the "Start" button is not possible within a period of 40 to 70 seconds after switching the CARL Controller off.

Possible Risks

The described problem may cause the user to assume, that the device is defective and cannot be used anymore, which could cause delays in scheduled therapies.

But, in an emergency situation, it can generally be assumed that a restart will be performed immediately and therefore within the 40 second period. Hence, the aforementioned risk is addressed appropriately.

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Measures

To avoid the above described problem, you have following options:

1. Restart the CARL Controller immediately, i.e. within 40 seconds after shutdown, if a restart is necessary, or
2. Wait 70 seconds after shutdown before restarting the CARL Controller, or
3. Switch immediately to the emergency operation mode.

Resuscitec GmbH will provide a software update by the end of September 2020 in order to solve the above problem. This update will be installed on all CARL Controllers on the market.

Please fill in the attached form and send it by email to info@resuscitec.de to confirm that you have received this safety note.

If you have any questions or require further information, please contact us:

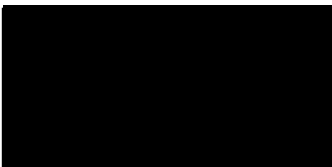
Manufacturer:

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We apologize for the inconvenience and thank you for your cooperation and immediate support!



Jürgen Grudke
Security Officer

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