Our reference: 1610_03

BfArM Case-No.: 08594/16

IMPORTANT FIELD SAFETY NOTICE (FSN)

Implementation of a Software-Update

in regard of

CARAT I pro and CARAT II pro Ventilators

Schwerin, <<DATE>>

Sender

HOFFRICHTER GmbH
Mettenheimer Straße 12/14
19061 Schwerin
GERMANY
Tel. +49 (0)385 39925-0
Fax +49 (0)385 39925-25
Mail: info@hoffrichter.de
Web: www.hoffrichter.de

Recipients

This Important Field Safety Notice (FSN) in regard of a Field Safety Corrective Action (FSCA) is addressed to users, operators, specialized dealers and distributors of HOFFRICHTER ventilator types **CARAT I pro** and **CARAT II pro**.

Identification of affected medical devices

The following HOFFRICHTER ventilator with software version 2.003 or lower/older are affected:

Art. No.	Device type	Trade name
00004017	9LV103	CARAT I pro
00004018	9LV203	CARAT II pro

The devices can be identified by their rating plate on each device's rear side (see Figure 1 and Figure 2). The currently installed software version can be seen in the display during the boot process (see Figure 3) or read out from the system settings screen.

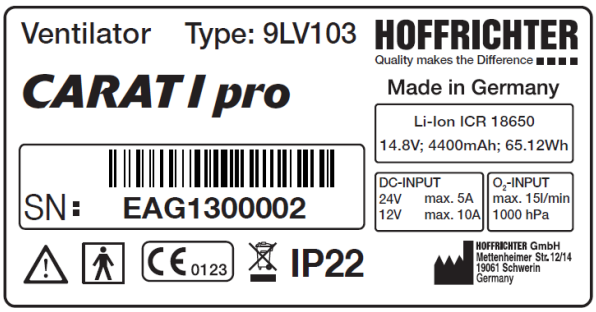

Figure 1: Rating plate CARAT I pro (example)

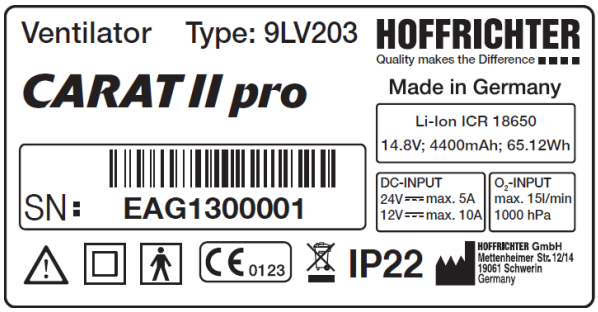

Figure 2: Rating plate CARAT II pro (example)

Figure 3: Starting screen on device start with software version printed in the upper left corner (example)

Description of the problem and its root cause

During the boot-up of CARATpro ventilators the software carries out an integrity check of the last used settings and ventilation parameters. In case the alarm for “High Frequency” was set to “Off” the setting is falsely recognized as corrupt. Thereafter during the device restart the software’s security routine restores the factory defaults instead of the previously used parameters for safety reasons. This takes place without informing the user by technical notification or alarm. Both, the false recognition of the “High Frequency” alarm setting and the absent information of the user, are part of a software bug. This bug is present in all software versions up to and including version 2.003 and is corrected with software version 2.004 and above. All devices with installed software version 2.004 are not affected by this FSCA.

Due to the software bug it is possible that a user could start ventilation with the factory settings. The factory settings are different compared to the patient-specific ventilation parameters and settings. So there is a possibility of inadequate or different ventilation (i.e., ventilation with a wrong ventilation mode). As a consequence there is a possibility of hyperventilation or hypoventilation and in dependence of the duration of such ventilation there is a danger of e.g. hypocapnia or hypercapnia.

Currently the manufacturer has not been notified of any case where a patient was harmed in any way due to occurrence the aforementioned malfunction. In all known cases the malfunction of the devices was recognized prior to the ventilation of a patient. The presence of the factory defaults can be recognized because of the following settings:

- The screen language is set to English.
- The brightness of display, info LED and multifunctional key (MFK) is set to 100%.
- The alarm volume is set to the highest level (3).

- The ventilation mode is set to Pressure Controlled Ventilation (PCV).

Nevertheless, it is recommended to follow the below advices on action to be taken.

Advice on action to be taken

Immediate action to be taken by users and operators

First please check if the device(s) in your possession is (are) affected by the malfunction specified in this FSN (see chapter “Identification of affected medical devices”), then follow the advices on action specified below.

- The alarm “High Frequency” should not be disabled anymore (setting “Off”).
- Instead, if required to prevent triggering of a frequency-related alarm during use, the alarm setting should be set to a very high value instead. With this setting it is possible to restart the device anytime without the settings and ventilation parameters being overwritten by the factory defaults due to the aforementioned malfunction.
- The recipient should discuss the aforementioned actions with the attending physician. Only in case the attending physician agrees, the alarm settings may be changed.
- In those cases where a very high value setting for the alarm “High Frequency” is not providing the desired effect or the attending physician disagrees following this advice, a software update shall be carried out at the soonest opportunity. Apart from that the software update should be carried out at the next safety-related check, maintenance, after patient change or hygienic reprocessing (whichever is next). Please inform your authorized dealer or home care provider.

Advice on action for distributors, specialized dealers and home care providers

Hoffrichter or an authorized partner of Hoffrichter will contact you soon to discuss and coordinate the further actions to carry out the software updates on affected devices. The target is to carry out the update on all affected devices in Germany until the 28.02.2017.

- Please ensure that this FSN is forwarded to all those who need to be aware within your organization, to all customers and to all users of the affected products. If possible please forward copies of this FSN together with the form “Answering Form User / Operator” or inform the below specified contact.
- Please fill in the attached answering form “Answering Form Distributors / Specialized Dealers / Home Care Providers” completely and send it back to the manufacturer.

Advice on action for users and operators

- You should ensure that all users of the affected devices, attending physicians and others who need to be aware were informed on this FSN. In case the device/s were hand over (e.g., sold) to any third, please forward a copy of this FSN if possible or inform the below specified contact, your specified dealer or home care provider.
- Please fill in the attached answering form “Answering Form Users / Operators” completely and send it to the specified recipient.

Final remarks

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

This urgent field safety notice has been notified to the co-ordinating national competent authority in Germany, the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM).

[redacted]

We would like to thank you for your understanding and support in implementing this corrective action. We would also like to apologize for any inconvenience caused by this action.

Sincerely yours,

Hoffrichter GmbH

[redacted]

Attachments:
Answering Form Distributor / Specialized Dealer / Home Care Provider
Answering Form User / Operator

Answering Form Distributor / Specialized Dealer / Home Care Provider

(FSN 1610_03 – 08594/16)

for of the Important Field Safety Notice in regard of the implementation of a software update for **CARAT I pro** and **CARAT II pro** Ventilators.

Please fill in the answering form completely (tick where appropriate) and send it back to us as soon as possible, but no later than **10 days** after you received the Urgent Field Safety Notice.

Please use one of the following ways:

Post:	HOFFRICHTER GmbH - FSN 1610_03 - 08594/16 - Mettenheimer Straße 12/14 19061 Schwerin GERMANY	FAX: Mail:	+49 (0)385 39925 25 info@hoffrichter.de

Sender

Customer ID _____

Company / Institution _____

Name, Surname _____

Address _____

_____

Telephone _____

Mail _____

☐ I/we herewith confirm the receiving and understanding of your Important Field Safety Notice on the implementation of a software update for HOFFRICHTER **CARAT I pro** and **CARAT II pro** ventilators. I/we will forward this Field Safety Notice to all affected customers.

☐ I/we herewith confirm that I/we don't have any affected device in my/our possession and we don't have forwarded any affected device to any third.

_____ _____

Place, Date Stamp / Signature

Answering Form User / Operator

(FSN 1610_03 – 08594/16)

for of the Important Field Safety Notice in regard of the implementation of a software update for **CARAT I pro** and **CARAT II pro** Ventilators.

Please fill in the answering form completely (tick where appropriate) and send it back to us as soon as possible, but no later than **10 days** after you received the Urgent Field Safety Notice.

Please use one of the following ways:

Post:	<<ADDRESS HOME CARE PROVIDER HCP>>	FAX:	<<FAX HCP>>
		Mail:	<<MAIL HCP>>

Sender

Customer ID _____

Company / Institution _____

Name, Surname _____

Address _____

_____

Telephone _____

Mail _____

☐ I/we herewith confirm the receiving and understanding of your Important Field Safety Notice on the implementation of a software update for HOFFRICHTER **CARAT I pro** and **CARAT II pro** ventilators. I/we will forward this Field Safety Notice to all users, operators and attending physicians.

☐ I/we herewith confirm that I/we don't have any affected device in my/our possession and we don't have forwarded any affected device to any third.