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[Our reference]	[Contact person]	[Telephone]	[Fax]	[Email]	[Date]
1909		+49 (0)2241 9322-469	-277	sb-mp@servona.de	26.09.2019

## Field Safety Notice (FSN) regarding the CARAT II pro ventilator

This field safety notice (FSN) regarding a safety corrective action is intended for users, operators, specialist dealers and distributors of the HOFFRICHTER CARAT II pro ventilator.

### Identification of the affected medical devices

The following HOFFRICHTER ventilators are affected:

Brand name	Article number	Serial number
CARAT II pro	00004018	EAJ1701581 - EAJ1701604 EAK1701605 - EAK1701660 EAL1701661 - EAL1701703 EAA1801754 - EAA1801859 EAB1801882 - EAB1801970 EAC1801970 - EAC1802058

The devices can be identified through the type plate on the back of the device.

### Description of the problem, including the identified cause

This safety information is based on a reassessment of customer feedback where a malfunction of the ventilator occurred as a result of blower wheel failure. The reason for the malfunction in all affected devices is a break in the blower wheel inside the blower box. The affected blower wheels are all from the same batch (09/08/2017).

*Risk for patients, users or third parties from the continued use of the product, including a risk(s) assessment*

High probability	Ventilation failure due to the blower wheel breaking.
Risk	The <b>immediate</b> consequence of a failure to ventilate, unless prompt action is taken, may result in the severe deterioration or even death of the patient.
	There will be expected <b>no immediate or long-term</b> consequences if the patient receives immediate care, for example, through the use of a manual ventilation bag, before they are connected to a replacement ventilator.
Assessment	The ventilation function and ventilation parameters are monitored. In the event of a malfunction, an optical (LED and notification on the display) and acoustic alarm will be triggered. This alarm prevents the ventilation from being restarted. If ventilation is not provided, further therapy alarms of the highest priority (red) are triggered which require immediate action. In Germany, replacement devices are available for life-sustaining care, which ensure patient care in the event of a malfunction.  To date, the manufacturer has not been informed of any case in which health consequences have arisen for a patient as a result of malfunction.

Very low probability	Detached particles can enter the lungs.
Risk	<b>Immediate</b> consequences for the patient can be injuries to the lungs, possibly the upper and lower respiratory tract and shortness of breath, as well as injuries in the nose and mouth area, that require unplanned intervention.
	<b>In the long term</b> , infections, necrosis, changes in tissue structures and death of the patient may occur.
Assessment	The probability of detached particles entering the lungs is classified as very low. Due to the structure of the blower box, any particles that are generated are trapped inside it. The blower box is connected to the internal bacterial filter and the breathing tube, which has a length of approx. 1.80 m. Particles are unlikely to pass through this way.

*Risks for patients already treated with the affected product, including the risk(s) assessment*

<b>High probability</b>	Ventilation failure due to breakage of the blower wheel.
Risk	There are <b>no immediate</b> health consequences (injuries or illnesses) that could result from earlier use of the ventilator.
	There are <b>no long-term</b> health consequences (injuries or illnesses) that could result from earlier use of the ventilator.
Assessment	No risks are expected for patients who have previously used the affected ventilator if life-support ventilation is no longer necessary or a different device is being used.

<b>Very low probability</b>	Detached particles can enter the lungs.
Risk	There are <b>no immediate</b> health consequences (injuries or illnesses) that could result from earlier use of the ventilator.
	There are <b>no long-term</b> health consequences (injuries or illnesses) that could result from earlier use of the ventilator.
Assessment	No risks are expected for patients who have previously used the affected ventilator if life-support ventilation is no longer necessary or a different device is being used.

**Measures to be taken by the addressee**

Hoffrichter or a partner authorised by Hoffrichter will contact you shortly to discuss the next steps. The aim is to replace the blower box on all devices within three months.

Hoffrichter will provide ventilators to ensure patient care while the devices are being replaced.

Please make sure that no devices are put into circulation without a corresponding repair.

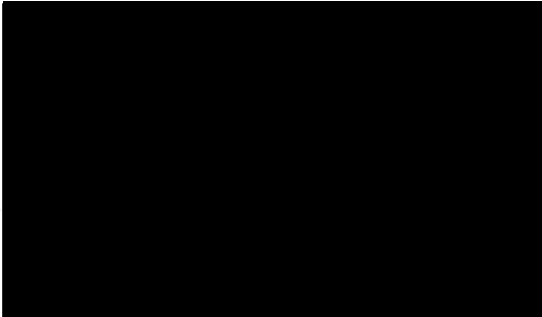
With this letter you will receive a confirmation form, please fill it out completely, sign it and send it back to us after receiving this information.

**Disclosure of the described information**

Please ensure that all users of the above products and other persons to be informed within your organisation are aware of this **Field Safety Notice**. If you have sold the products to third parties, please forward a copy of this information or contact the person listed below.

Please keep this information at least until the measures have been completed.

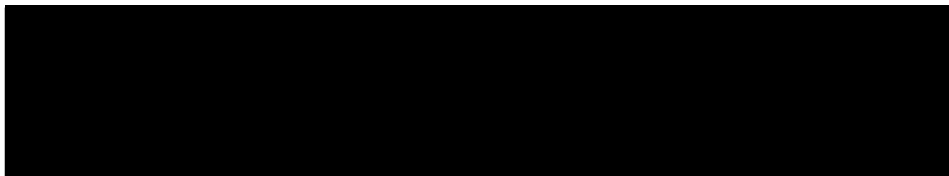
The Federal Institute for Drugs and Medical Devices has received a copy of this Field Safety Notice.



We would like to thank you for your understanding and for the implementation of the corrective measures. We would also like to apologise for any inconvenience caused by these measures.

With kind regards

Hoffrichter GmbH



**Appendices**  
Reply form



**Our reference:** 1909

**Reply form**

For the safety information regarding the CARAT II pro ventilator.

Complete the reply in full (tick the appropriate box) and return it as soon as possible within 10 days of receiving this safety notice.

Please use one of the following options:

Post: Servona GmbH FSN 1909 53842 Troisdorf Germany	Fax: +49 (0)2241 9322-277	Email: sb-mp@servona.de
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**Sender**

Customer No.

Company/organisation

Surname, first name

Address

Telephone

Mail

- I/we hereby declare that I/we have received and taken note of your safety notice for the HOFFRICHTER CARAT II pro ventilator. I/we will forward this safety notice to all affected customers.
- I/we hereby confirm that no affected device is in my/our possession and that no affected device has been passed on to a third party.
- I/we hereby confirm that I/we will not put the affected equipment into circulation without repair by Hoffrichter or a partner authorised by Hoffrichter.
- I/we hereby confirm that I/we will return the affected devices, which are still in our possession or in the possession of third parties, to Hoffrichter GmbH.

\_\_\_\_\_  
Place, Date

\_\_\_\_\_  
Signature / Stamp