

Urgent safety information

Preventive component replacement
concerning
medin-NC3

Reference ID: 202506301540

Olching, 2025-07-25

1 Sender



medin Medical Innovations GmbH
Adam-Geisler-Str. 1
82140 Olching
Germany

2 addressee

<input type="checkbox"/> user	<input checked="" type="checkbox"/> operator	
<input checked="" type="checkbox"/> Sales partner	<input checked="" type="checkbox"/> Service technician	

3 Identification of the affected medical devices

Product category (EMDN codes)	<input type="checkbox"/> THERMOREGULATED BREATHING CIRCUITS (R020107)		
	<input type="checkbox"/> BREATHING CIRCUITS - OTHERS (R020199)		
	<input type="checkbox"/> BIPAP/CPAP MASKS (R03010102)		
	<input type="checkbox"/> AIR/OXYGEN NASAL CANNULAS (R03010203)		
	<input type="checkbox"/> RESPIRATORY AND ANAESTHESIA DEVICES - OTHERS (R9099)		
	<input checked="" type="checkbox"/> NEONATAL/PEDIATRIC VENTILATORS (Z1203010503)		
Affected product	Name/Model	REF	UDI-DI
	Medin-NC3	3000	0406013900101
Lot / serial number <div> <div>SN</div> <div>or</div> <div>LOT</div> </div>	all s/n		

4 Description of the problem including the identified cause

4.1 Backgrounds

There were an increasing number of device failures in the field, which were traced back to a defect of the component “blower”.

4.2 Risk to patients, users or third parties when using the product

Continued use of the device without performing the measures described below increases the risk of a defect in the blower, which results in device failure.

4.3 Risks for patients who have already been treated with the affected products

There are no risks for patients who have already been treated with an affected product.

4.4 Evaluating the risk(s)

Failure of the device may result in harm to the patient, as the respiratory support provided by the device will no longer be available.

5 What measures must the addressee take?

As a preventive measure, we recommend replacing the component blower (item no. 39-202) after 4500 operating hours. Details on the procedure, including coordination with our customer service, are described in the appendix.

In addition, please ensure that only accessories tested and approved by medin are used with the device.

We are working with the highest priority to resolve the issue quickly and reliably. Until a solution is implemented, this preventive measure will remain in effect.

6 Sharing the information described here:

Please ensure that all users of the above-mentioned products and other people requiring information within your organization are aware of this **urgent information**. If you have supplied the products to third parties, please forward a copy of this information or inform the contact person listed below.

Please keep this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this “Urgent Information”.

7 Contact person

If you have any questions about the exchange process, please contact your **usual customer service representative**.

If you have any questions about this safety information or the measure, please contact

Manuela Mair
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+49 (0) 81 424 484 629

Confirmation of receipt of urgent safety information (Reference ID: 202506301540)

By signing below, I confirm that I have received and read the current urgent safety information (FSN).

By signing below, I confirm that I will follow the instructions regarding the malfunction.

Name:

.....

Company:

.....

Country:

.....

Date:

.....

Signature:

.....

Please sign this urgent safety information and send it by email to your product supplier at medin Medical Innovations GmbH.

Note:

Your contact person in this matter is always the local sales partner.

Process description for preventive maintenance – FSCA Blower

Dear Partner,

For performing the preventive maintenance, please follow the steps outlined below:

1. Monitoring of operating hours for each device.
If **4500 operating hours** with the same blower are reached, preventive maintenance is required.
2. Replace the blower following the procedure defined within the service manual
3. Fill in form "Return form FSCA Blower" and send it to medin (sales.med.de@medin-medical.com)
4. Send the blower you replaced to medin (RMA will be issued by sales after receiving the return form)

The blowers for performing this preventive maintenance are provided free of charge.

Partners can pre-order a max. amount of five blowers (REF 30-202), but not more than NC3 devices sold to the partner, for their stock.

Once a replaced blower including the filled in form is received by medin, a new order for a blower can be placed by the partner. Orders for blowers which would exceed the max. amount are put on hold until the replacement is confirmed by receiving blower and corresponding return form.

With kind regards

Your medin team

Return form FSCA Blower**Partner details**

Company name		Contact name	
Adress		Contact phone or mail	
Country			

Hospital details

Name		Department the device is located	
Adress			

Device details

S/N medin-NC3		Operating hours*	
S/N blower old		S/N blower new	
Last maintenance (date)			
Comments / Observations			

*at the time of replacement

Date

Signature (service technician)

Please return filled form to sales.med.de@medin-medical.com

For returning the old blower to medin you will receive an RMA from sales. Please include the RMA tag into the shipment to ensure traceability.