



Urgent safety information
regarding
PARI SOLE N / PARI SOLE N Tracheo nebulisers
Discontinuation of heater function use

26. October 2015

Sender:

PARI GmbH
Spezialisten für effektive Inhalation
Moosstr. 3
82319 Starnberg
Germany

Sent to:

Users of the PARI SOLE N nebuliser

Ref.:

Discontinuation of use of the heater function in PARI SOLE N nebulisers

PARI GmbH has received three complaints reporting that moisture got into the nebuliser lower section. In all cases, the situation arose due to incorrect handling while cleaning. This caused the temperature sensor in the PARI SOLE N nebuliser to fail. In none of these cases did any of the users suffer serious injury.

However, the possibility of serious injury in further cases of incorrect handling cannot be ruled out. This applies **particularly to tracheostomised patients**, because they no longer have effective sensitivity to heat in the mouth and throat.

Description of the problem including cause found:

If moisture is able to get into the nebuliser lower section, it can damage the temperature sensor in the PARI SOLE N nebuliser. Consequently, in rare cases the heating process is not switched off automatically, with the result that the inhalation solution and the aerosol generated from it can become very hot. There would then be a danger of injuring the mucous membrane during inhalation.

In view of the above, PARI published additional instructions for use in autumn 2013, which included measuring the temperature of the aerosol emitted before each application.

No further complaints have been received by PARI since we were made aware of the problem in June 2013.

What steps must now be taken by the user?



The step of measuring the temperature recommended previously is still an effective way to prevent the user from suffering possible injury, but it is not sufficient to satisfy the formal requirement that safety should be built into the product. Therefore, after consulting with the

supervising authority we have decided to announce that use of the heater function is to be discontinued on the PARI SOLE N nebuliser, with immediate effect. Accordingly, please discontinue all further use of the PARI SOLE N base unit, which might heat the aerosol.

The PARI SOLE N nebuliser can be used without the heater function. The device can still be used in cases in which an aerosol having a high proportion of larger droplets is medically required. For this, you need the PARI air connection, which is available from PARI now.

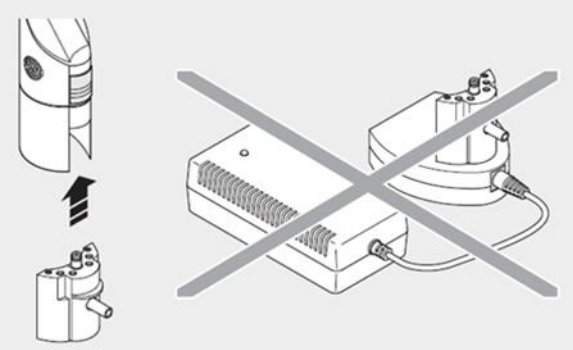
Please proceed as follows:

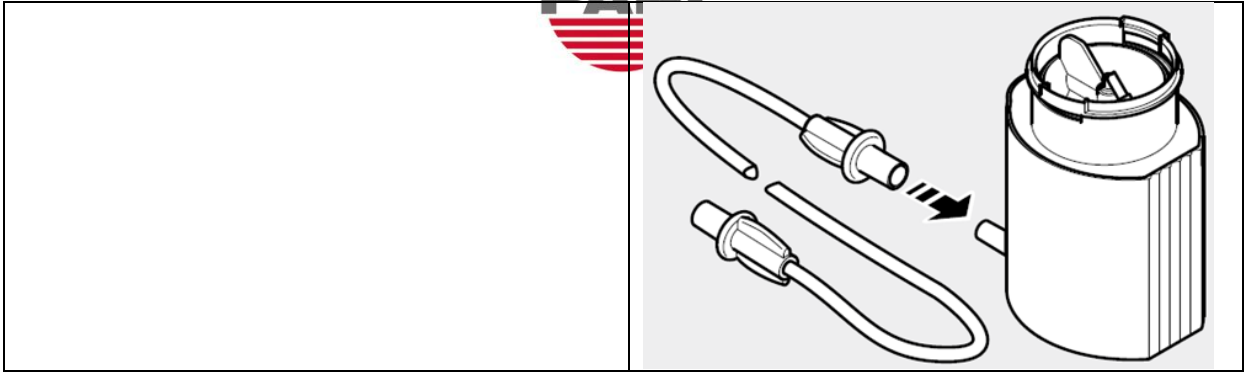
1. Note the serial number of your PARI SOLE N base unit. The serial number (beginning with "SN") appears as shown here:



2. Contact PARI, indicating the serial the number (for contact information see below) to order the PARI air connection, which will enable you to continue using the PARI SOLE N nebuliser.
3. Upon receiving the PARI air connection, please dispose of the PARI SOLE N base unit: Please follow the instructions for disposal in the updated instructions for use which accompany the PARI air connection.
4. Confirm disposal by returning the accompanying reply form / free postage envelope, stating the serial number

Brief description of how to use the PARI air connection:

<p>1. Push the PARI air connection up into the socket in the nebuliser lower section:</p> 	<p>2. Attach the connection tubing to the air connection:</p>
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Detailed instructions for use are included with the PARI air connection delivered.



Please note:

This discontinuation of use applies only to the heater function (PARI SOLE N base unit), not to other components of your inhalation system such as the compressor or any mask accessories used. You can continue using:

			
PARI SOLE N nebuliser	PARI compressor, e.g., PARI COMPACT	Mask	PARI TRACHEO SET

Contact:

For Germany: 0800-664 77 93 (calls only free if made from Germany)

For Austria: +49 (0) 8151 279 279

International: +49 (0) 8151 279 220

We sincerely regret any inconvenience this may cause you, but we consider this action essential to ensure your safety.