
Urgent Field Safety Notice

Voluntary Recall

concerning

Centrifuge 5910 R

28.11.2019

Addressor:
Eppendorf AG
Barkhausenweg 1
22339 Hamburg

Addressee:

Users (end customers), Service manager in own organization, Global Dealers

Identification of the medical device concerned:

Centrifuge 5910 R, all product variants

Attachment:
- Customer List EU/EFTA of IvD Products

Description of the problem including the identified cause:

Use of a screw that is too long (M4x8) during production can damage the insulation of the motor coil and cause electrical contact.
In absence of both, a circuit breaker and interruption of the earth protection line (PE), the device housing can be energized.

If the housing is touched, there is a risk of electric shock in this case.

The probability of occurrence according to risk analysis is classified as very low.

Which action is required by the addressee ?

User / End Customer:

- Centrifuges can be used under the mandatory condition that electrical grounding of the centrifuge in your electric-circuit is secured (see also Operating Manual, section 2.5).
- An Eppendorf representative will contact the customer to discuss details on the on-site rework of the device.

Service Manager:

- Localization of end customers
- Reworking of devices at the end customer's site (according to Instruction for Rework) with highest priority (until 31.08.2020)

Global Dealers

- Notification of Eppendorf AG about devices located in warehouses (Eppendorf representative will contact the dealer to discuss details about reworking)
- Provide a list of all end customers (Eppendorf AG will extensively carry out the reworking)

Passing on this Field Safety Notice:
This Field Safety Notice (FSN) needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected device have been transferred to.

Please pass on this FSN to other organization for which this action might have an impact.
Please observe this FSN and the resulting measures for an appropriate period of time to ensure effectiveness of the corrective action.

The German Federal Institute for Drugs and Medical Devices has received a copy of this FSN.

Contact person:

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With kind regards,

Dr. Birgit Schreiber
Vice President Quality Management & Regulatory Affairs