

## Urgent safety information

Recall software version 2022.1.9

concerning

product MEONA

Freiburg, 08.10.2022

**Manufacturer:**

Mesalvo Freiburg GmbH  
Heinrich-von Stephan-Straße 25  
D-79100 Freiburg  
Germany  
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**Addressee:**

All operators of the software MEONA with installed version 2022.1.9 only

**Identification of the affected medical devices**

Meona Release V, software version 2022.1.9

**Description of the problem**

In the course of post market surveillance, it has come to light that an irregular software behavior is possible with software version 2022.1.9 in certain configuration, which leads to the following problem: When saving summary information in a medical history form, before and after a patient change, it is possible that a summary diagnosis information ("single line diagnosis") is erroneously transferred from one patient to another. This can be the case if a specific configuration is in use on the system. This configuration was never used outside of a limited number of customers based in Germany.

In principle, this misconduct involves the risk of incorrect treatment due to incorrectly assigned "summary diagnosis information", although it can be assumed that this diagnosis information in the patient overview is not the primary and only source of information for the personnel responsible for therapy in the clinic.

**What measures are to be taken by you?**

A software patch has been made available to correct the error, which can be applied if the corresponding software version (2022.1.9) is installed.

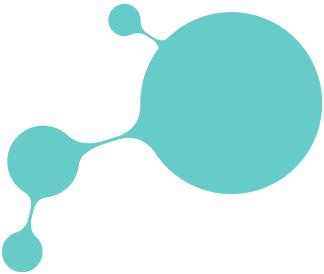
As part of this safety process, all affected customers using the MEONA product with software version 2022.1.9 were identified simultaneously and individually informed immediately about the problem.

If we have not contacted you in this regard, you do not need to take any further action.

**Passing on the information described here:**

Please ensure that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Safety Information. If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.

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



The Federal Institute for Drugs and Medical Devices in Germany has received a copy of this "Urgent Safety Information".

**Contact person**

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