

Urgent Field Safety Notice

Adaptations to Permobil Power wheelchairs with indoor medical components

Contact information

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Background

Permobil has identified that several Permobil power wheelchairs in Denmark have been adapted by equipping the wheelchairs with electrical components and medical devices with indoor waterproof rating. That equipment does not meet proper safety precautions when exposed to water.

Permobil became aware of this issue when discussing how this specific patient need was handled. It was highlighted that most manufacturers in Denmark provide a solution to support installation of this type of equipment. However, after further inspection of Permobil's current installations in Denmark, a potential safety risk was identified because of a gap in electrical safety practice. It is not deemed as acceptable by Permobil standards to leave this potential safety risk without providing risk mitigating actions.

Affected standards: EN 12184, ISO 7176-14, ISO 7176-9, UL 94, IEC 60601-1, LVD, MDR

There are to date, no reported cases where an incident has occurred related to a Permobil chair or any other manufacturer due to this identified risk.

Hazard giving rise to the FSN

Permobil has become aware that several components with indoor IP classification have been attached to the Permobil wheelchair battery. This includes ventilators, humidifiers, inverters, outlets, switches, and several cables.

When these components are exposed to water an electrical safety risk appears.

Since most of the installations vary in design, this might also affect how high the risk potential is.

Before Permobil has inspected all affected chairs, we recommend not exposing the chair to any water unless properly protected.

At this time, Permobil has discovered several affected chairs mounted with ventilators and humidifiers connected to the wheelchair battery through several electrical components with IP classification for indoor use only.

Predicted risk to users

If the installation is subject to water ingress there is a potential electrical safety risk, with a possibility for severe electrical hazards. The probability estimated by Permobil is regarded as low (0.01%-0.1%)

Recommended actions for user

All users should immediately be aware of the safety risk and avoid exposing the chair/installation to water.

Permobil is currently investigating a design solution with the aim to allow the users to keep their medical devices attached to the wheelchair without a safety risk. A solution will be presented by the end of November.

All wheelchair owners will be notified when the investigation is complete.