2025-04-16

# URGENT FIELD SAFETY NOTICE

| | |
|---|---|
| **Manufacturer SRN:** | DE-MF-000020091 |
| **FSCA Reference:** | 1262980 – HKH 8820 – Wall Holder not compliant with DIN EN 1789 |
| **FSN Type:** | New |
| **Affected Product:** | HKH 8820 Wall Holder (Mat. 70104.5366) |
| **Unique Device Identifier:** | 04037691456584 |
| **Affected Serial No. or Batch No.:** | All devices are affected |
| **For Attention of:** | Users of the medical device listed above |

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform users about a corrective action that pertains to regulatory compliance for the HKH 8820 Wall Holder.

The HKH 8820 Wall Holder is a mounting bracket that was designed to be permanently installed in a road vehicle for the inter-hospital transport of the CARDIOHELP-i system by enabling a secure attachment of the CARDIOHELP-i to the vehicle.

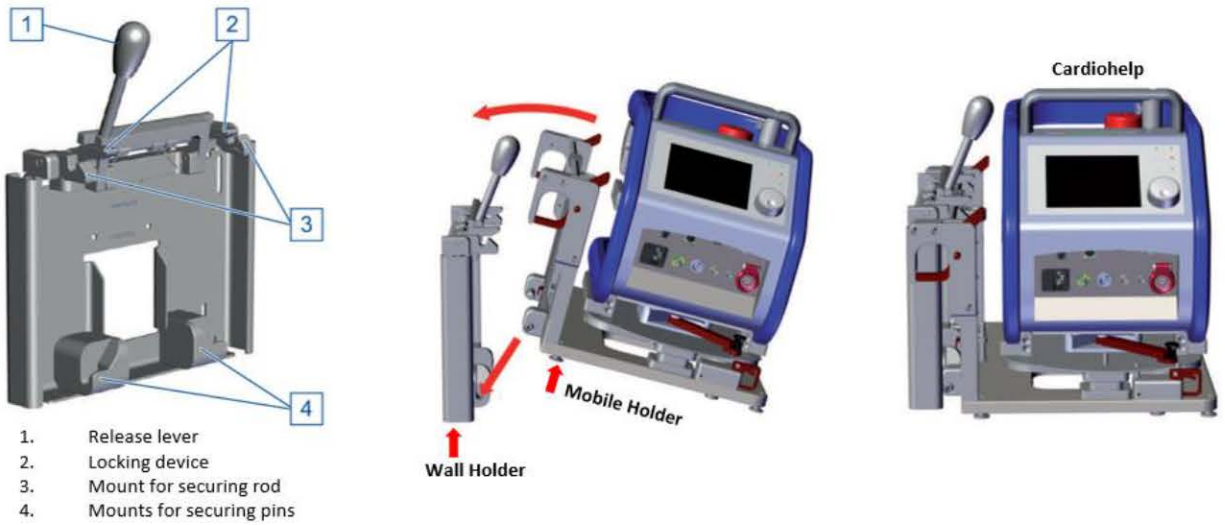


*Figure 1: Picture of CARDIOHELP system*
*(left: HKH 8820 Wall Holder, center: CARDIOHELP-i being attached to HKH 8820 Wall Holder, right: mounted system)*

## Problem Description

The European Harmonized Standard, DIN EN 1789:2020, entitled 'Medical Vehicles and Their Equipment – Road Ambulances,' section 4.4.11 'Holding, Securing, and Restraint Systems' mandates that products such as the CARDIOHELP-i System and the accessories utilized for transportation, such as the HKH 8820 Wall Holder, undergo the performance of a simulated crash test.

MCP conducted a crash test according to this Harmonized Standard on the HKH 8820 Wall Holder in December 2024. During this test, the CARDIOHELP -i system detached from the HKH 8820 Wall Holder, resulting in the test not being passed. Therefore, the HKH 8820 Wall Holder does not comply with standard DIN EN 1789:2020. All HKH 8820 Wall Holders are affected by this issue.

## Hazardous situation

In course of a Health Hazard Evaluation (HHE), Maquet Cardiopulmonary GmbH determined the following hazardous situations that may arise:

- Patient/User/Third person is exposed to potential energy
- Patient is exposed to inappropriate low / no blood flow

## Potential harm

The possible immediate and/or long-range health consequences and risk levels of the nonconformance include the following (for further information please refer to Annex I):

- Bruising/Contusion
- Minor hematoma
- Major bone fracture
- Ischemia
- Hypoxia
- Reduced blood flow

Maquet Cardiopulmonary GmbH has received no complaints that can be linked to this issue.

**Corrective Action:**

Upon availability of replacement products with new design:

- Replacement of HKH 8820 Wall Holder.

**Action to be taken by user:**

☒ Identify Device
☐ Quarantine Device
☐ Return Device
☐ Destroy Device

**Details on further action(s):**

- According to our post-market surveillance documentation, you may have products affected by this action. Please examine your inventory **immediately** to determine, if you have any affected product in your inventory.
- **Optional:** Instead of replacement, the affected device may be returned for credit. Upon return of the affected products, please contact your local Getinge representative for credit.
- Please **always** report any adverse events potentially related to the affected products to your Getinge representative.
- Duly fill out the enclosed Letter of Acknowledgement and return it to your local Getinge representative **as soon as possible, latest by 2025-05-02** by mentioning **FSCA - 1262980** as reference in the subject line of your mail.

**Actions to be taken by the manufacturer:**

☐ Product Removal
☐ On-site device modification/ inspection
☐ Software Upgrade
☐ IFU or labeling change
☒ Other
☐ None

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.
- Develop a new design for the HKH 8820 Wall Holder, compliant with standard DIN EN 1789:2020.
- Upon availability of replacement products with new design:
  Inform all customers and replace customer devices.

**Enclosed documents:**

- Letter of Acknowledgment Customer
- Annex I Further information regarding Hazardous situation, Harms and Risk Levels

**Transmission of the Field Safety Notice:**

- Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We sincerely apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

**Vice President**

**Signature:** *Electronically signed by: Dieter Engel*
*Reason: I approve this document.*
*Date: Apr 16, 2025 14:41 GMT+2*

**Email:** dieter.engel@getinge.com

**Person Responsible for Regulatory Compliance (PRRC)**

**Signature:** *Electronically signed by: Alexander Bernhardt*
*Reason: I approve this document.*
*Date: Apr 16, 2025 13:43 GMT+2*

**Email:** alexander.bernhardt@getinge.com

**Contact details of manufacturer**
Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

## CUSTOMER RESPONSE FORM

| | |
|---|---|
| **FSCA Reference:** | 1262980 – HKH 8820 – Wall Holder not compliant with DIN EN 1789 |
| **Affected Product:** | HKH 8820 Wall Holder (Mat. 70104.5366) |
| **Affected Serial No. or Batch No.:** | All devices are affected |

Please send this form at the latest by **May 02, 2025**, to your local Getinge representative.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personal.

☐ I do not have any affected products in my inventory.

☐ I have the following affected products in my inventory

- ☐ and would like to return to you for credit.
- ☐ and would like to opt for replacement upon availability of new design.

| Article Number | Description | Quantity |
|---|---|---|
| | | |

Your Comments:

Country

Hospital / Clinic (full address)

Date

Name (Function)

Signature

Please return the completed form to your local Getinge representative by email enter local Getinge mail address or via post enter local Getinge address or FAX>

## Annex I Further information regarding Hazardous situation, Harms and Risk Levels

This Annex I Further information regarding Hazardous situation, Harms and Risk Levels is considered a supplementary attachment to the 1262980 Field Safety Notice.

| Hazardous Situation | Harm | S (from Part III) | P (from above) | Risk | | |
|---|---|---|---|---|---|---|
| | | | | Low | Med | High |
| Patient, user or third person is exposed to potential energy | Bruising/Contusion | 3 | 1 | ☒ | ☐ | ☐ |
| | Minor hematoma | 3 | 1 | ☒ | ☐ | ☐ |
| | Major bone fracture | 4 | 1 | ☐ | ☒ | ☐ |
| Patient is exposed to inappropriate blood flow (patients' blood flow lower than intended) | Reduced blood flow | 3 | 1 | ☒ | ☐ | ☐ |
| | Hypoxia | 3 | 1 | ☒ | ☐ | ☐ |
| | Ischemia | 4 | 1 | ☐ | ☒ | ☐ |
| Patient is exposed to no blood flow (patients' blood flow lower than intended) | Hypoxia | 4 | 1 | ☐ | ☒ | ☐ |
| | Ischemia[b] | 3 | 1 | ☒ | ☐ | ☐ |

**Severity Definitions (S):**

**Negligible (1)** Inconvenience or temporary discomfort of patient, user or third party. No medical intervention or follow-up treatment is required

**Low (2)** Temporary injury or disability of patients, users or third parties. No medical intervention or follow up treatment is required.

**Critical (3)** Temporary injury or disability of patients, users or third parties. Medical intervention or follow-up treatment is required.

**Catastrophic (4)** Permanent injury or disability (e.g., loss of a body part), a life-threatening situation or death of patients, users or third parties

**Probability Definitions (P):**

**Improbable (1)** Harm is not likely.

**Remote (2)** Harm occurs infrequently

**Occasional (3)** Harm may occur occasionally / intermittent

**Probable (4)** Harm may occur often

**Frequent (5)** Harm will occur repeatedly