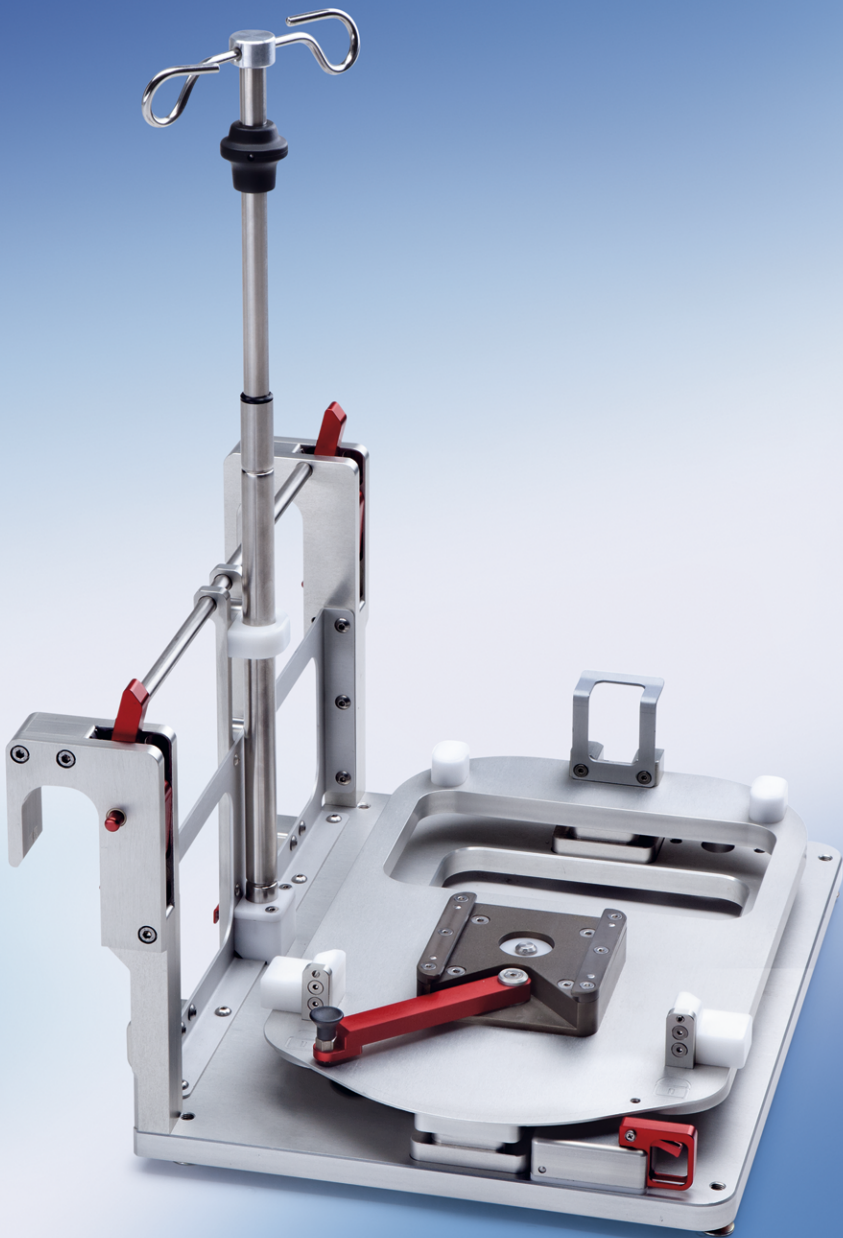


INSTRUCTIONS FOR USE

INTRA-HOSPITAL PATIENT TRANSPORT

MAQUET
GETINGE GROUP



Copyright

All rights reserved. No part of this publication may be duplicated, adapted or translated without prior written permission, except under the terms of the copyright laws.

© Copyright Maquet Cardiopulmonary GmbH

Subject to technical changes

Owing to our policy of continuous product development, the illustrations and technical data contained in this document may differ slightly from the current version of the device.

Manufacturer

Maquet Cardiopulmonary GmbH

Kehler Strasse 31

76437 Rastatt

GERMANY

www.getinge.com

info.cp@getinge.com

Table of Contents

English

1	Description	4
2	Safety	4
3	System Components	6
4	Installation and Operation	7
5	Cleaning and Disinfection After Every Use	11
6	Maintenance	12
7	Technical Data	12

Accessories for Patient Transport

1 Description

The following components are accessories for the CARDIOHELP System for intra-hospital patient transport. Intra-hospital patient transport is conveyance of the patient within the hospital.

- Transport guard (Transport Guard for CARDIOHELP Disposables)
The transport guard secures a HLS Set Advanced.
- Cardiohelp Mobile Holder HKH 8860
The mobile holder serves as a support for the CARDIOHELP System and the connected disposable. It can be attached to a stretcher with two lockable hooks. A telescopic infusion pole for bags or bottles is optionally available.
- Note: CARDIOHELP-i does not need to be mounted on the mobile holder before connecting to the patient. Once the patient is connected/supported, transport could proceed (on the mobile holder or Sprinter Cart XL) if required. Additionally, make certain that CARDIOHELP-i is ready for transport.

This Instructions for Use describes the holder and accessories referred to above. You should also observe the instructions supplied with other components of the system (⇒ CARDIOHELP System Instructions for Use) and the disposables used (⇒ Instructions for Use for the disposable).

2 Safety

2.1 Definitions



DANGER!

Identifies an immediate, serious risk to people which will result in death or serious injury.



WARNING!

Identifies a general, serious risk to people which can result in death or serious injury.



CAUTION!

Identifies a possible risk which can result in injury.

NOTICE!

Identifies a possible risk to property which can result in equipment damage and/or data loss.

Structure of the other information

Information concerning events without personal injury or equipment damage is indicated as follows:

NOTE

Additional support and other helpful information.

2.2 General Safety Instructions



WARNING!

You must observe the precautionary measures for intra-hospital patient transport in the Instructions for Use of the CARDIOHELP System and the Instructions for Use of the disposables used.

**WARNING!**

- Follow the instructions supplied with other components of the system and the holders used.

**WARNING!**

An inadequate power supply can put the CARDIOHELP-i out of service. Therefore, please note:

- Only ever start the application when the batteries of the CARDIOHELP-i are fully charged and calibrated.
- Check the battery function before intra-hospital patient transport.
- Ensure that a sufficient energy supply is available at all times.
- Use the hospital's power supply so as to conserve the batteries.
- Take the CARDIOHELP Emergency Drive with you when transporting the patient. Keep it at the ready for stop-gap manual operation in the event of pump drive failure.

**WARNING!**

If the oxygen supply is inadequate, the patient's blood cannot be oxygenated. Please therefore note:

- Always start with full oxygen bottles.
- Ensure that a sufficient gas supply is available at all times.
- Ensure that the available oxygen is adequate for the purpose. Take enough spare oxygen bottles with you.
- Use the hospital's oxygen supply so as to conserve the oxygen bottles.

**WARNING!**

Check the integrity, completeness, and proper connection of the tube system before and during application. Observe the Instructions for Use for the disposables used.

Disposables which are exposed to mechanical shocks during transport (e.g., caused by falling) must be checked for damage.

Take at least six tube clamps with you when transporting the patient. Keep the tube clamps at the ready for clamping tubes in the event of leakage.

**WARNING!**

- Protect components from moisture. If water may have penetrated the housing, take the CARDIOHELP-i out of service after use, and have the CARDIOHELP-i checked by authorized service personnel.

**WARNING!**

Excessive electromagnetic interference can interfere with sensors, distort measurements and thereby cause incorrect pump control or incorrect interventions.

- Do not use the CARDIOHELP System in the environment of RF communications equipment (e.g., cell phones). These can cause excessively strong electromagnetic interference that exceeds the compliance level of the CARDIOHELP System.
- Using RF surgical devices or defibrillators directly next to the CARDIOHELP-i and its sensors can lead to interference or even malfunction. When using RF surgical devices or defibrillators, observe the correct function of the CARDIOHELP-i.
- To ensure compliance with the relevant requirements, the length of all connection cables of the CARDIOHELP-i must not be changed.
- Only use the specified accessories. The use of other accessories can result in increased electromagnetic interference or decreased electromagnetic immunity of the device and lead to a malfunction.

en



WARNING!

The entire CARDIOHELP System can tolerate ESD pulses of up to ± 15 kV. The controls (touchscreen, rotary knob, buttons) can withstand ESD impulses up to ± 15 kV.
To avoid damaging the device, the user should discharge his/her body by touching a large or grounded piece of metal before he/she touches the patient or connects/disconnects sensors.



WARNING!

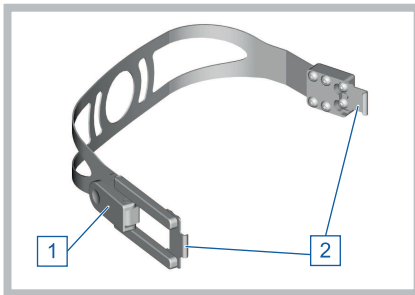
- Only use RPM mode for intra-hospital patient transport. In LPM mode, the pump control can be impaired by incorrect flow values. Please note that flow values may be displayed with reduced accuracy.



WARNING!

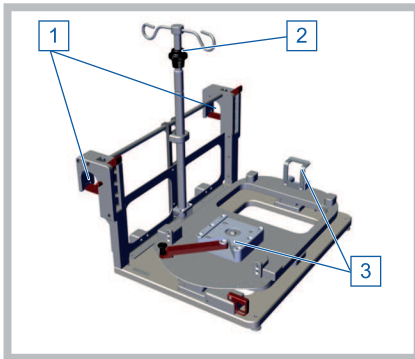
- Please note the possible failure of the venous probe.
- In the event of a failure of the venous probe, values for S_{vO_2} , Hb, Hct and T_{ven} can no longer be displayed and monitored. Alarms for these values are no longer triggered.

3 System Components



Transport Guard for CARDIOHELP Disposables

- 1 Lock
- 2 Fixing hooks for CARDIOHELP-i



Cardiohelp Mobile Holder HKH 8860

- 1 Attachment point for stretcher
- 2 Infusion pole (optional)
- 3 Attachment point for CARDIOHELP-i

3.1 Symbols



Notice! Observe the warnings and safety precautions given in the accompanying documentation.



Observe the instructions in the Instructions for Use!



Order number



Date of manufacture: Month-Year in which the device was made.

en



Manufacturer as defined by Directive 93/42/EEC concerning medical devices.

4 Installation and Operation



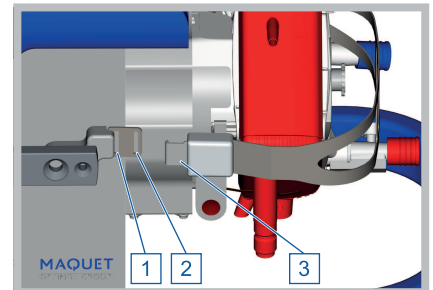
WARNING!

- All components must be installed in such a way that the user can monitor and operate them during patient transport.
- Attach all components to the holders provided for the purpose and fix them securely as intended.

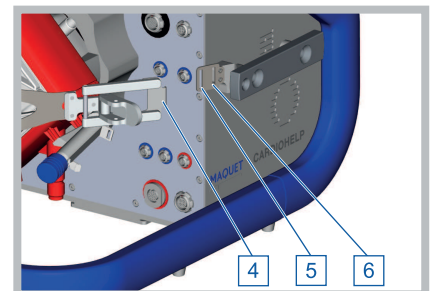
4.1 Securing the Disposable with the Transport Guard for CARDIOHELP Disposables

The disposable can come loose from the CARDIOHELP-i due to strong mechanical forces. Use the SPRINTER CART or SPRINTER CART XL for intra-hospital patient transport. Secure the disposable using the Transport Guard for CARDIOHELP Disposables if you cannot use any SPRINTER CART or SPRINTER CART XL for the intra-hospital patient transport. Check that the lock of the Transport Guard for CARDIOHELP Disposables is closed.

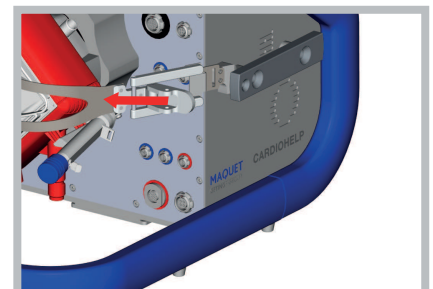
- 1 Ensure that the disposable is correctly installed.
- 2 Check that the lock of the Transport Guard for CARDIOHELP Disposables is open.
- 3 When using a HLS Set Advanced 7.0, hang the fixing hook [3] into opening [2].
Or
When using a HLS Set Advanced 5.0, hang the fixing hook [3] into opening [1].



- 4 Place the Transport Guard for CARDIOHELP Disposables around the disposable.
- 5 If the venous probe is already installed on the measuring cell, make sure that the cable of the venous probe is below the bracket.
- 6 When using a HLS Set Advanced 7.0, hang the fixing hook on the locking side [4] into opening [5].
Or
When using a HLS Set Advanced 5.0, hang the fixing hook on the locking side [4] into opening [6].



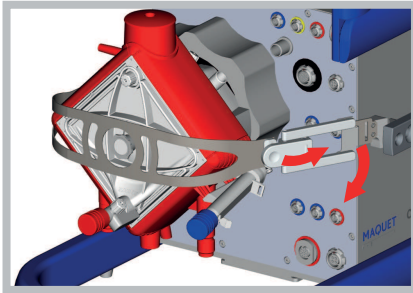
- 7 Close the lock.



- 8 Make sure that both fixing hooks are properly attached and the lock is securely closed.

4.1.1 Removing the Transport Guard for CARDIOHELP Disposables

- Open the fastener of the Transport Guard for CARDIOHELP Disposables and remove the fixing hooks from the openings.



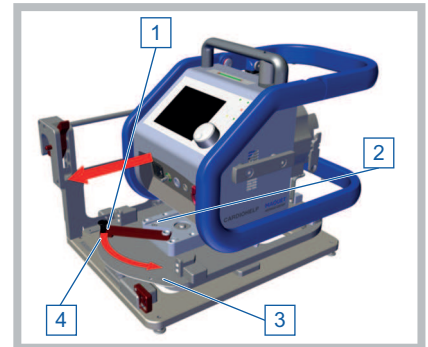
4.2 Attaching the CARDIOHELP to the Mobile Holder HKH 8860



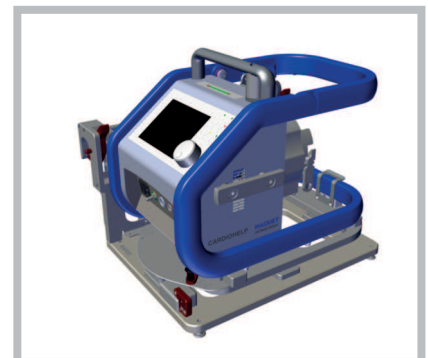
CAUTION!

The Cardiohelp Mobile Holder HKH 8860 is mounted on the left-hand side on delivery: The position of operation of the CARDIOHELP-i is on the left side of the mobile holder. If the position of operation is required on the right side, the mobile holder must be converted.

- 1 Check that the locking device is open.



- ▶ Locking lever [1] on the [Open] symbol [4].
- 2 Slide the CARDIOHELP-i onto the mobile holder.
 - 3 Ensure that the sled on the underside of the CARDIOHELP-i slides into the retainer [2].



- 4 Lock the CARDIOHELP-i: Set the locking lever [1] to the [Locked] symbol [3].
- 5 Ensure that the locking device has correctly clicked into place and that the CARDIOHELP-i is securely fixed.

4.2.1 Mobile holder conversion

The Cardiohelp Mobile Holder HKH 8860 is mounted on the left-hand side on delivery: The position of operation of the CARDIOHELP-i is on the left side of the mobile holder.

If, due to the application, the operating interface of the CARDIOHELP is required on the right side of the holder, the holder can be converted accordingly.

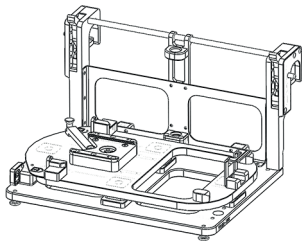


Fig. 3: Mobile holder on left -

Note: In order to avoid safety risks. Secure all screws with thread-locking adhesive to prevent them from becoming loose.

Note: All screws are additionally secured. As such, additional force may be required to release the screws.

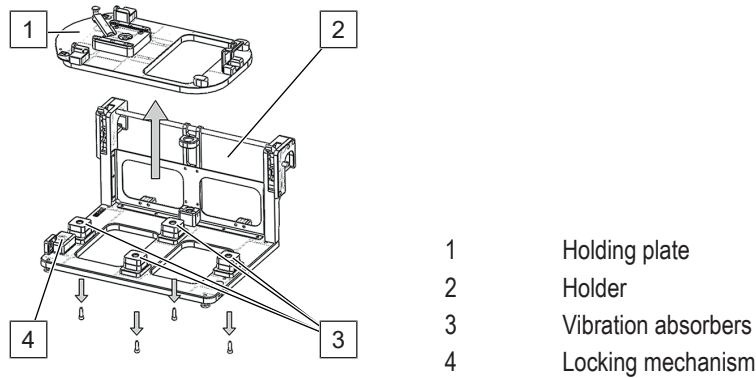


Fig. 4: Disassembly of the holding plate

- 1 Unscrew the 4 socket screws (M6; TX30).
- 2 Remove the holding plate [1].
- 3 Unscrew the two socket screws (M6; TX30).

- 4 Remove the holding plate locking mechanism [4].
- 5 Position the right locking mechanism supplied on the right-hand side of the holder.

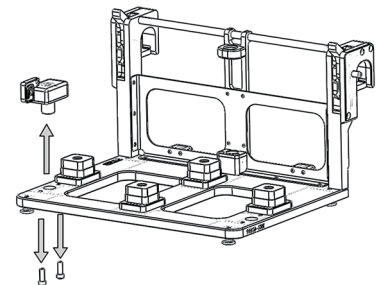


Fig. 5: Holding plate locking mechanism

- 6 Secure the locking mechanism with 2 socket screws (M6; TX30) with the corresponding tightening torque (9 Nm).
Use the thread-locking adhesive to fix the screws.

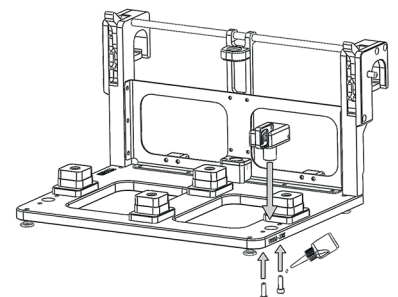


Fig. 6: Holding plate locking mechanism

- 7 Position the holding plate [1] on the vibration absorbers as per Figure 7.

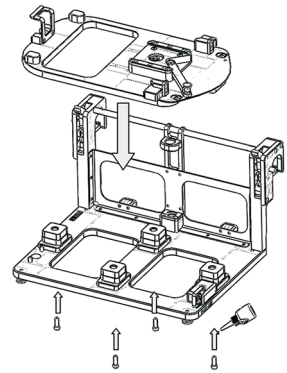


Fig. 7: Mounting the holding plate

- 8 Secure the holding plate [1] with 4 socket screws (M6; TX30) with the corresponding tightening torque (9 Nm).
Use the thread-locking adhesive to fix the screws.
- 9 Check that the screws are secure.
- 10 Check that the holder is working properly.

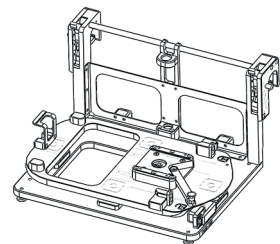
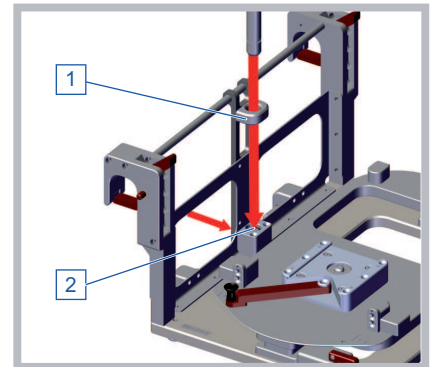


Fig. 8: Mobile holder on right

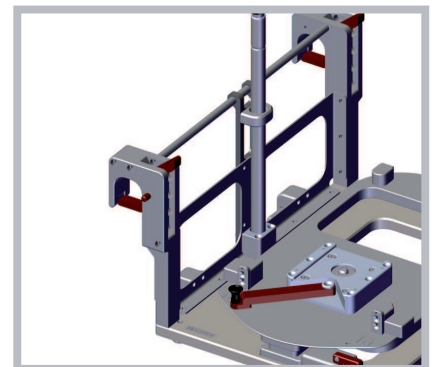
- ▶ The operating interface of the CARDIOHELP is now positioned on the right-hand side of the mobile holder.

4.3 Attaching and Adjusting the Infusion Mast (Optional)

- 1 In order to attach the infusion mast, press and hold the locking device of the mast retainer [2].

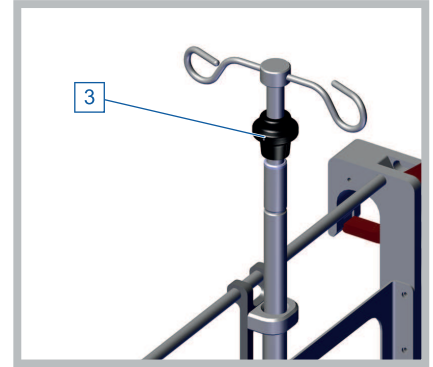


- 2 Insert the mast through the holder [1] into the retainer [2] from above and release the locking device.
- 3 Make sure that the locking device is firmly engaged and that the infusion mast is securely fixed in place.



- 4 In order to adjust the height of the infusion mast, move the plastic ring [3] upward.

- 5 Set the upper part of the mast to the desired height and release the plastic ring.



en

- 6 Make sure that the upper part of the mast has engaged.

4.4 Attaching the Mobile Holder to a Stretcher

You can attach the mobile holder to a stretcher using the two lockable hooks.

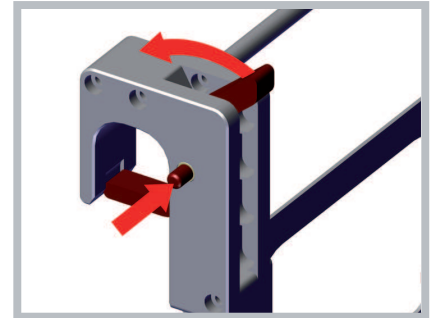


WARNING!

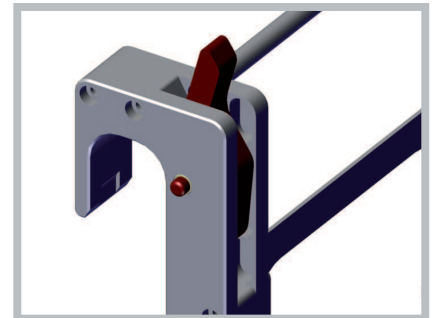
Ensure that by attaching the mobile holder the permissible load of the stretcher is not exceeded. Please take the weight of the loaded mobile holder into account (⇒ "Accessories for Intra-Hospital Patient Transport", page 12).

An unfastened mobile holder can be knocked out of the hooks by vibrations or impacts. Make sure that both hooks are properly attached to the stretcher and securely locked.

- 1 To open the locking mechanism of the hook, press the locking button and press the lever upward.



- ▶ If you push the lever all the way up, the lock engages and remains open.



- 2 Attach the mobile holder to the stretcher with both hooks.
- 3 Press on the locking button, to close the lock again.
 - ▶ The hook is locked.
- 4 Make sure that both hooks are properly attached to the stretcher and securely locked.

5 Cleaning and Disinfection After Every Use

Clean the stainless steel and aluminum surfaces using liquid household cleaner and remove all dirt such as splashes of blood or other soiling.

You can use the following disinfectants:

- Isopropyl alcohol (70% vol.)
- Buraton rapid (Schülke & Mayr)

- BacilloI (Bode Chemie)
- Mikrobac forte (Bode Chemie)
- Kohrsolin extra (Bode Chemie)

6 Maintenance

The inspection of the Transport Guard for CARDIOHELP Disposables is a part of the annual inspection by the authorized service.

The mobile holder requires no regular servicing or maintenance.



WARNING!

Repairs may only be carried out by a service technician authorized by Maquet Cardiopulmonary.

6.1 Authorized Service

For inspection or repair, contact your local service point.

This can be found on the Getinge website (<http://www.getinge.com>). Select your country or region. Click on "Contact" and fill out the contact form.

7 Technical Data

7.1 Accessories for Intra-Hospital Patient Transport

Service life	10 years
Materials:	
■ Mobile holder, Transport Guard for CARDIOHELP Disposables	Aluminum, stainless steel
Dimensions	W x H x D
Cardiohelp Mobile Holder HKH 8860	465 x 264 x 374 mm
Transport Guard for CARDIOHELP Disposables	250 x 150 x 50 mm
Weights	
Cardiohelp Mobile Holder HKH 8860	4.2 kg
CARDIOHELP-i	Approx. 12 kg
Infusion bag	<ul style="list-style-type: none"> ■ Max. 2 kg per bag ■ Max. 4 kg in total
Transport Guard for CARDIOHELP Disposables	150 g
Ambient conditions	
Temperature	15 ... 40°C
Relative humidity	15 ... 95% (no condensation)
Approved oxygen bottles	
■ Gas bottle	Medical oxygen bottle approved for transport
■ Length	At least long enough to permit secure fixing with the two securing belts
■ Diameter	100 mm
■ Maximum weight (full)	7 kg

MAQUET

GETINGE GROUP

Maquet Cardiopulmonary GmbH
Kehler Strasse 31
76437 Rastatt
GERMANY
www.getinge.com
info.cp@getinge.com