

2023-08-22

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	626803 CARDIOHELP - Replacement of slide rail holder
FSCA Type:	New
Affected Product:	CARDIOHELP-i (article number 701048012) CARDIOHELP-i (article number 701072780, US Variant)
Affected Serial No.:	Refer to Annex I
Unique Device Identifier:	04037691658384 04058863074863
For Attention of:	Users of the CARDIOHELP-i

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform you with this letter about the replacement of the slide rail holders on the CARDIOHELP system due to an insufficient fixation.

The CARDIOHELP system is a miniaturized medical perfusion system. Its general function is to drive, to control, to monitor and to protocol the extracorporeal circulation. It acts as a drive unit for a disposable tubing set including at least pump and oxygenator.

The slide rails are located on the lateral aspects of the CARDIOHELP system. They are attached to the housing of the CARDIOHELP system with the slide rail holder (see red marks in Figure 1). As shown in Figure 2, the slide rail holder consists of a nut bolt welded onto a plate.

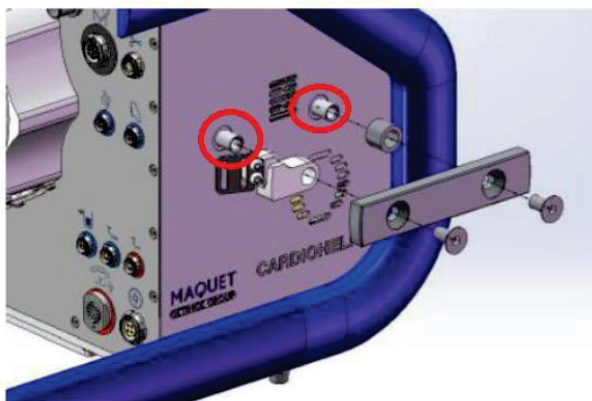


Figure 1: CARDIOHELP slide rail- exploded view

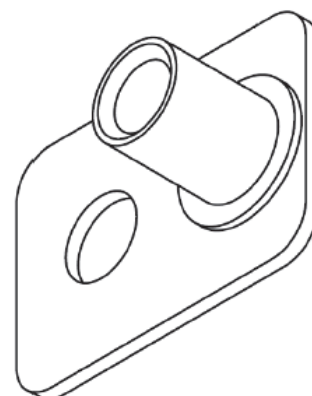


Figure 2: Draft of slide rail holder

Problem description

It was found that the fixation (weld) employed by the supplier of the nut bolt to the slide rail plate was insufficient. The deficient weld allows the nut bolt to break off from the slide rail plate with slight manual force.

Hazardous situation

Insufficient securement of the slide rails to the lateral aspects to CARDIOHELP could provide an opportunity of both/either the Transport Guard and/or the Emergency Drive (with the holder) to detach from CARDIOHELP. Detachment in either scenario could produce an unexpected outcome (e.g., disengagement of the HLS Module from the CARDIOHELP drive during transport, or detachment of both the Emergency Drive and holder resulting to injury to the user, third party, or the patient).

Potential harms

The potential immediate and/or long-range health consequences associated with a detachment of either the Transport Guard or the Emergency Drive when connected to the slide rail holder may translate to any, all, or none of following harms to a patient supported on CARDIOHELP or to a user operating CARDIOHELP at the time the nonconformance is encountered:

- Ischemia
- User inconvenience
- Hypovolemia
- Fracture (User/Third party)
- Cut/laceration (User/Third party)
- Bruise (User/Third party)

There are no clinical factors, per se, inherent to the nonconformance, which may serve to mitigate the risk/harms described above except a pre-deployment examination that is both standard practice and customary behavior among healthcare practitioners and clinicians before equipment is placed on service on patients.

Maquet Cardiopulmonary GmbH has not identified any complaints of patient harm, serious injuries, or deaths due to failure modes described above.

Affected CARDIOHELP-i are not requested to be returned and can be used for intra-hospital support as usual. Inter-hospital transport is not permitted until the replacement was performed.

Please do not to fixate any accessory at the side rail until the replacement is performed.

Corrective Actions

- Replacement of the slide rail holders.

Action to be taken by the customer:

- Identify Device
- Return Device
- Quarantine Device
- Destroy Device

Details of the further action(s):

- According to our post-market surveillance documentation, you may have products affected by this action in your inventory. Please examine your inventory immediately to determine if you have any affected CARDIOHELP-i in your inventory.
- **Affected CARDIOHELP-i are not requested to be returned and can be used for intra-hospital support as usual. Inter-hospital transport is not permitted until the replacement is performed.**
- **Please do not to fixate any accessory at the side rail until the replacement is performed.**
- A local Getinge representative will contact you to arrange the replacement of the slide rail holders.
- Please **always** report any adverse events, e.g., infections 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 by **October 31, 2023**, the latest. Please give **FSCA-626803** as reference in the subject line of your email.

Actions to be taken by the manufacturer

- Product Removal
- Software upgrade
- Other
- On-site device modification/ inspection
- IFU or labelling change
- None

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.
- The local Getinge representative will contact the customer to arrange the replacement of the slide rail holders.

Enclosed documents:

- Customer Response Form
- Annex I List of affected products

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 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 or send an e-mail to FSCA.cp@getinge.com.

Sincerely,

Managing Director
(on behalf of Managing Director)

Person Responsible for Regulatory Compliance (PRRC)
(on behalf of PRRC)

Contact details of manufacturer

Maquet Cardiopulmonary GmbH
Tom Peters
Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

FSCA-Reference: 626803 CARDIOHELP - Replacement of slide rail holder

Affected Product: CARDIOHELP-i (article number 701048012)
CARDIOHELP-i (article number 701072780, US Variant)

Affected Serial No.: Refer to Annex I

Please send this form to your local Getinge representative at the latest by **October 31, 2023**.

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 for the CARDIOHELP-i. 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 affected CARDIOHELP-i in my inventory.

I have the following affected CARDIOHELP-i in my inventory:

Article Number	Product Name	Serial Number

Your Comments:

Country

Hospital / Clinic (full address)

Date

Name (Function)

FIELD SAFETY NOTICE

DMS No.: 3269166 V 01



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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 List of affected products

This Annex I List of affected products is considered a supplementary attachment to the 626803 Field Safety Notice.

Below are listed all products which are affected and have been distributed.

For CARDIOHELP-i (701048012):

Country	Serial No.	Product description	Article No.
Egypt	90414645	CARDIOHELP-i	701048012
Egypt	90414720	CARDIOHELP-i	701048012
Egypt	90414752	CARDIOHELP-i	701048012
Egypt	90414743	CARDIOHELP-i	701048012
Egypt	90414746	CARDIOHELP-i	701048012
Argentina	90414785	CARDIOHELP-i	701048012
Argentina	90414775	CARDIOHELP-i	701048012
Australia	90414669	CARDIOHELP-i	701048012
Australia	90414646	CARDIOHELP-i	701048012
Australia	90414667	CARDIOHELP-i	701048012
Australia	90414574	CARDIOHELP-i	701048012
Australia	90414570	CARDIOHELP-i	701048012
Australia	90414568	CARDIOHELP-i	701048012
Australia	90414663	CARDIOHELP-i	701048012
Australia	90414643	CARDIOHELP-i	701048012
Australia	90414664	CARDIOHELP-i	701048012
Belgium	90414507	CARDIOHELP-i	701048012
Brazil	90414722	CARDIOHELP-i	701048012
Brunei Drussal.	90414581	CARDIOHELP-i	701048012
China	90414636	CARDIOHELP-i	701048012
China	90414783	CARDIOHELP-i	701048012
China	90414469	CARDIOHELP-i	701048012
China	90414456	CARDIOHELP-i	701048012
China	90414453	CARDIOHELP-i	701048012
China	90414558	CARDIOHELP-i	701048012
China	90414557	CARDIOHELP-i	701048012
China	90414559	CARDIOHELP-i	701048012
China	90414562	CARDIOHELP-i	701048012
China	90414560	CARDIOHELP-i	701048012
China	90414561	CARDIOHELP-i	701048012
China	90414575	CARDIOHELP-i	701048012
China	90414781	CARDIOHELP-i	701048012

Country	Serial No.	Product description	Article No.
China	90414744	CARDIOHELP-i	701048012
China	90414563	CARDIOHELP-i	701048012
China	90414576	CARDIOHELP-i	701048012
China	90414564	CARDIOHELP-i	701048012
China	90414577	CARDIOHELP-i	701048012
China	90414587	CARDIOHELP-i	701048012
China	90414616	CARDIOHELP-i	701048012
China	90414627	CARDIOHELP-i	701048012
China	90414619	CARDIOHELP-i	701048012
China	90414618	CARDIOHELP-i	701048012
China	90414628	CARDIOHELP-i	701048012
China	90414521	CARDIOHELP-i	701048012
China	90414640	CARDIOHELP-i	701048012
China	90414631	CARDIOHELP-i	701048012
China	90414624	CARDIOHELP-i	701048012
China	90414622	CARDIOHELP-i	701048012
China	90414630	CARDIOHELP-i	701048012
China	90414621	CARDIOHELP-i	701048012
China	90414620	CARDIOHELP-i	701048012
China	90414625	CARDIOHELP-i	701048012
China	90414532	CARDIOHELP-i	701048012
China	90414756	CARDIOHELP-i	701048012
China	90414544	CARDIOHELP-i	701048012
China	90414543	CARDIOHELP-i	701048012
China	90414747	CARDIOHELP-i	701048012
China	90414518	CARDIOHELP-i	701048012
China	90414546	CARDIOHELP-i	701048012
China	90414454	CARDIOHELP-i	701048012
China	90414545	CARDIOHELP-i	701048012
China	90414522	CARDIOHELP-i	701048012
China	90414553	CARDIOHELP-i	701048012
Germany	90414478	CARDIOHELP-i	701048012
Germany	90414552	CARDIOHELP-i	701048012
Germany	90414555	CARDIOHELP-i	701048012
Germany	90414569	CARDIOHELP-i	701048012
Germany	90414617	CARDIOHELP-i	701048012
Germany	90414638	CARDIOHELP-i	701048012
Germany	90414659	CARDIOHELP-i	701048012
Germany	90414668	CARDIOHELP-i	701048012
Germany	90414641	CARDIOHELP-i	701048012

Country	Serial No.	Product description	Article No.
Germany	90414666	CARDIOHELP-i	701048012
Germany	90414647	CARDIOHELP-i	701048012
Germany	90414734	CARDIOHELP-i	701048012
Germany	90414644	CARDIOHELP-i	701048012
Germany	90414728	CARDIOHELP-i	701048012
Germany	90414731	CARDIOHELP-i	701048012
Germany	90414733	CARDIOHELP-i	701048012
Germany	90414714	CARDIOHELP-i	701048012
Germany	90414757	CARDIOHELP-i	701048012
Germany	90414725	CARDIOHELP-i	701048012
Germany	90414758	CARDIOHELP-i	701048012
Germany	90414764	CARDIOHELP-i	701048012
Germany	90414541	CARDIOHELP-i	701048012
Germany	90414650	CARDIOHELP-i	701048012
Germany	90414737	CARDIOHELP-i	701048012
Germany	90414749	CARDIOHELP-i	701048012
Germany	90414779	CARDIOHELP-i	701048012
Germany	90414509	CARDIOHELP-i	701048012
Germany	90414732	CARDIOHELP-i	701048012
Germany	90414435	CARDIOHELP-i	701048012
Germany	90414660	CARDIOHELP-i	701048012
Germany	90414741	CARDIOHELP-i	701048012
France	90414717	CARDIOHELP-i	701048012
France	90414763	CARDIOHELP-i	701048012
France	90414718	CARDIOHELP-i	701048012
France	90414762	CARDIOHELP-i	701048012
France	90414508	CARDIOHELP-i	701048012
France	90414510	CARDIOHELP-i	701048012
France	90414548	CARDIOHELP-i	701048012
France	90414750	CARDIOHELP-i	701048012
France	90414759	CARDIOHELP-i	701048012
France	90414540	CARDIOHELP-i	701048012
France	90414539	CARDIOHELP-i	701048012
France	90414534	CARDIOHELP-i	701048012
France	90414529	CARDIOHELP-i	701048012
France	90414511	CARDIOHELP-i	701048012
France	90414531	CARDIOHELP-i	701048012
France	90414542	CARDIOHELP-i	701048012
Hong Kong	90414654	CARDIOHELP-i	701048012
Hong Kong	90414634	CARDIOHELP-i	701048012

Country	Serial No.	Product description	Article No.
India	90414642	CARDIOHELP-i	701048012
India	90414648	CARDIOHELP-i	701048012
India	90414504	CARDIOHELP-i	701048012
India	90414635	CARDIOHELP-i	701048012
Italy	90414711	CARDIOHELP-i	701048012
Italy	90414658	CARDIOHELP-i	701048012
Canada	90414626	CARDIOHELP-i	701048012
Canada	90414585	CARDIOHELP-i	701048012
Canada	90414739	CARDIOHELP-i	701048012
Canada	90414712	CARDIOHELP-i	701048012
Canada	90414765	CARDIOHELP-i	701048012
Canada	90414446	CARDIOHELP-i	701048012
Canada	90414429	CARDIOHELP-i	701048012
Canada	90414452	CARDIOHELP-i	701048012
Canada	90414612	CARDIOHELP-i	701048012
Canada	90414584	CARDIOHELP-i	701048012
Canada	90414748	CARDIOHELP-i	701048012
Canada	90414716	CARDIOHELP-i	701048012
Canada	90414754	CARDIOHELP-i	701048012
Canada	90414623	CARDIOHELP-i	701048012
Canada	90414745	CARDIOHELP-i	701048012
Canada	90414629	CARDIOHELP-i	701048012
Canada	90414633	CARDIOHELP-i	701048012
Canada	90414463	CARDIOHELP-i	701048012
Canada	90414656	CARDIOHELP-i	701048012
Canada	90414448	CARDIOHELP-i	701048012
Canada	90414657	CARDIOHELP-i	701048012
Canada	90414470	CARDIOHELP-i	701048012
Canada	90414438	CARDIOHELP-i	701048012
Canada	90415172	CARDIOHELP-i	701048012
Colombia	90414613	CARDIOHELP-i	701048012
Colombia	90414506	CARDIOHELP-i	701048012
Colombia	90415201	CARDIOHELP-i	701048012
Malaysia	90414565	CARDIOHELP-i	701048012
Malaysia	90414578	CARDIOHELP-i	701048012
Malaysia	90414579	CARDIOHELP-i	701048012
Malaysia	90414580	CARDIOHELP-i	701048012
Mexico	90414760	CARDIOHELP-i	701048012
Mexico	90414776	CARDIOHELP-i	701048012
Nepal	90414583	CARDIOHELP-i	701048012

Country	Serial No.	Product description	Article No.
Netherlands	90414527	CARDIOHELP-i	701048012
Netherlands	90414444	CARDIOHELP-i	701048012
Netherlands	90414586	CARDIOHELP-i	701048012
Netherlands	90414573	CARDIOHELP-i	701048012
Netherlands	90414572	CARDIOHELP-i	701048012
Norway	90414547	CARDIOHELP-i	701048012
Norway	90414766	CARDIOHELP-i	701048012
Pakistan	90414637	CARDIOHELP-i	701048012
Pakistan	90415195	CARDIOHELP-i	701048012
Poland	90414551	CARDIOHELP-i	701048012
Poland	90414524	CARDIOHELP-i	701048012
Poland	90414523	CARDIOHELP-i	701048012
Poland	90414525	CARDIOHELP-i	701048012
Poland	90414536	CARDIOHELP-i	701048012
Poland	90414528	CARDIOHELP-i	701048012
Poland	90414639	CARDIOHELP-i	701048012
Poland	90414792	CARDIOHELP-i	701048012
Poland	90414770	CARDIOHELP-i	701048012
Portugal	90413513	CARDIOHELP-i	701048012
Portugal	90414736	CARDIOHELP-i	701048012
Portugal	90414719	CARDIOHELP-i	701048012
Portugal	90414665	CARDIOHELP-i	701048012
Portugal	90414651	CARDIOHELP-i	701048012
Romania	90414526	CARDIOHELP-i	701048012
Romania	90414473	CARDIOHELP-i	701048012
Romania	90414538	CARDIOHELP-i	701048012
Russia	90414614	CARDIOHELP-i	701048012
Russia	90414632	CARDIOHELP-i	701048012
Russia	90414615	CARDIOHELP-i	701048012
Russia	90414653	CARDIOHELP-i	701048012
Saudi-Arabia	90414549	CARDIOHELP-i	701048012
Saudi-Arabia	90414727	CARDIOHELP-i	701048012
Saudi-Arabia	90414729	CARDIOHELP-i	701048012
Slovakia	90414533	CARDIOHELP-i	701048012
Slovakia	90414451	CARDIOHELP-i	701048012
Slovakia	90414520	CARDIOHELP-i	701048012
Spain	90414726	CARDIOHELP-i	701048012
Spain	90414768	CARDIOHELP-i	701048012
Spain	90414738	CARDIOHELP-i	701048012
Spain	90414662	CARDIOHELP-i	701048012

Country	Serial No.	Product description	Article No.
Spain	90414713	CARDIOHELP-i	701048012
South Africa	90414567	CARDIOHELP-i	701048012
South Africa	90414554	CARDIOHELP-i	701048012
South Africa	90414571	CARDIOHELP-i	701048012
South Africa	90414556	CARDIOHELP-i	701048012
South Africa	90414661	CARDIOHELP-i	701048012
South Africa	90414550	CARDIOHELP-i	701048012
South Africa	90414655	CARDIOHELP-i	701048012
South Africa	90414652	CARDIOHELP-i	701048012
South Korea	90414780	CARDIOHELP-i	701048012
Thailand	90414537	CARDIOHELP-i	701048012
Czech Republic	90414721	CARDIOHELP-i	701048012
Czech Republic	90414751	CARDIOHELP-i	701048012
Czech Republic	90414723	CARDIOHELP-i	701048012
Czech Republic	90414735	CARDIOHELP-i	701048012
Czech Republic	90414730	CARDIOHELP-i	701048012
Czech Republic	90414740	CARDIOHELP-i	701048012
Turkey	90414769	CARDIOHELP-i	701048012
Hungary	90414530	CARDIOHELP-i	701048012
Hungary	90414535	CARDIOHELP-i	701048012
United Kingdom	90414773	CARDIOHELP-i	701048012
United Kingdom	90414798	CARDIOHELP-i	701048012
Vietnam	90414566	CARDIOHELP-i	701048012
Vietnam	90414582	CARDIOHELP-i	701048012
Vietnam	90414505	CARDIOHELP-i	701048012
Belarus	90414872	CARDIOHELP-i	701048012
Cyprus	90414649	CARDIOHELP-i	701048012

For CARDIOHELP-i US (701072780):

Country	Serial No.	Product description	Article No.
USA	90414501	CARDIOHELP-i US	701072780
USA	90414485	CARDIOHELP-i US	701072780
USA	90414489	CARDIOHELP-i US	701072780
USA	90414864	CARDIOHELP-i US	701072780
USA	90414502	CARDIOHELP-i US	701072780
USA	90414490	CARDIOHELP-i US	701072780
USA	90414855	CARDIOHELP-i US	701072780
USA	90414355	CARDIOHELP-i US	701072780
USA	90414497	CARDIOHELP-i US	701072780
USA	90414498	CARDIOHELP-i US	701072780
USA	90414491	CARDIOHELP-i US	701072780
USA	90414492	CARDIOHELP-i US	701072780
USA	90414588	CARDIOHELP-i US	701072780
USA	90414499	CARDIOHELP-i US	701072780
USA	90414705	CARDIOHELP-i US	701072780
USA	90414603	CARDIOHELP-i US	701072780
USA	90414852	CARDIOHELP-i US	701072780
USA	90414604	CARDIOHELP-i US	701072780
USA	90414589	CARDIOHELP-i US	701072780
USA	90414813	CARDIOHELP-i US	701072780
USA	90414606	CARDIOHELP-i US	701072780
USA	90414590	CARDIOHELP-i US	701072780
USA	90414823	CARDIOHELP-i US	701072780
USA	90414591	CARDIOHELP-i US	701072780
USA	90414608	CARDIOHELP-i US	701072780
USA	90414602	CARDIOHELP-i US	701072780
USA	90414607	CARDIOHELP-i US	701072780
USA	90414611	CARDIOHELP-i US	701072780
USA	90414702	CARDIOHELP-i US	701072780
USA	90414610	CARDIOHELP-i US	701072780
USA	90414609	CARDIOHELP-i US	701072780
USA	90414605	CARDIOHELP-i US	701072780
USA	90414597	CARDIOHELP-i US	701072780
USA	90414598	CARDIOHELP-i US	701072780
USA	90414592	CARDIOHELP-i US	701072780
USA	90414599	CARDIOHELP-i US	701072780
USA	90414600	CARDIOHELP-i US	701072780
USA	90414601	CARDIOHELP-i US	701072780

Template: CP-SOP-001-T-02 V02, Effective date 2019-09-15

Country	Serial No.	Product description	Article No.
USA	90414594	CARDIOHELP-i US	701072780
USA	90414863	CARDIOHELP-i US	701072780
USA	90414704	CARDIOHELP-i US	701072780
USA	90414593	CARDIOHELP-i US	701072780
USA	90414670	CARDIOHELP-i US	701072780
USA	90414682	CARDIOHELP-i US	701072780
USA	90414687	CARDIOHELP-i US	701072780
USA	90414683	CARDIOHELP-i US	701072780
USA	90414595	CARDIOHELP-i US	701072780
USA	90414684	CARDIOHELP-i US	701072780
USA	90414671	CARDIOHELP-i US	701072780
USA	90414685	CARDIOHELP-i US	701072780
USA	90414672	CARDIOHELP-i US	701072780
USA	90414686	CARDIOHELP-i US	701072780
USA	90414596	CARDIOHELP-i US	701072780
USA	90414689	CARDIOHELP-i US	701072780
USA	90414688	CARDIOHELP-i US	701072780
USA	90414673	CARDIOHELP-i US	701072780
USA	90414690	CARDIOHELP-i US	701072780
USA	90414679	CARDIOHELP-i US	701072780
USA	90414674	CARDIOHELP-i US	701072780
USA	90414676	CARDIOHELP-i US	701072780
USA	90414857	CARDIOHELP-i US	701072780
USA	90414678	CARDIOHELP-i US	701072780
USA	90414701	CARDIOHELP-i US	701072780
USA	90414681	CARDIOHELP-i US	701072780
USA	90414680	CARDIOHELP-i US	701072780
USA	90414675	CARDIOHELP-i US	701072780
USA	90414693	CARDIOHELP-i US	701072780
USA	90414692	CARDIOHELP-i US	701072780
USA	90414691	CARDIOHELP-i US	701072780
USA	90414696	CARDIOHELP-i US	701072780
USA	90414699	CARDIOHELP-i US	701072780
USA	90414826	CARDIOHELP-i US	701072780
USA	90414697	CARDIOHELP-i US	701072780
USA	90414709	CARDIOHELP-i US	701072780
USA	90414706	CARDIOHELP-i US	701072780
USA	90414695	CARDIOHELP-i US	701072780
USA	90414694	CARDIOHELP-i US	701072780
USA	90414707	CARDIOHELP-i US	701072780

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Country	Serial No.	Product description	Article No.
USA	90414700	CARDIOHELP-i US	701072780
USA	90414698	CARDIOHELP-i US	701072780
USA	90414862	CARDIOHELP-i US	701072780

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