

Helmond, 1 July 2013

Safety warning Ibis comfort wheelchair

Dear customer,

I am writing to tell you that Handicare has discovered a potential quality issue with the tilt adjustment on a limited number of Ibis comfort wheelchairs, delivered between 29 January and 12 April 2013. In extreme situations, a component used in the tilt mechanism may break, which could cause the seat unit to tip backwards. No injuries have been reported. As the safety of the people using our products is our first priority, Handicare has decided to replace all components from the affected batch as a precautionary measure. This action is effected in cooperation with the MHRA. For the execution of this action we ask your assistance.

We have prepared a complete information pack (enclosed) to support you in the execution, including:

- Procedures post market action;
- dealer confirmation reply form;
- list of affected Ibis wheelchairs delivered to you;
- sample information letter to end-users + FAQ;
- replacement instruction;
- return form.

We ask you to inform users and exchange the components used in the tilt mechanism (upper hinge blocks) on all affected wheelchairs delivered to you, according to the instructions provided in the enclosed 'procedures post market action'. This action must be finalized by 1 September 2013.

We count on your full, legally bound cooperation and to ensure this information is passed on effectively, we ask you for a confirmation of receipt. Please complete and sign the enclosed 'Dealer confirmation' reply form, and send it back to Handicare.

If you have any questions regarding this precautionary action, please do not hesitate to contact your Handicare contact person or me personally. Naturally, you can also call Customer Service on +31 (0) 492 593 888 or send an e-mail to upgrade@handicare.com.

We wish to thank you in advance for your cooperation and apologise for any inconvenience this may cause.

Kind regards,

Darren Legg
Sales manager Mobility UK

Encl.: procedures post market action; dealer confirmation reply form; list of affected Ibis wheelchairs delivered to you; sample information letter to end-users + FAQ; replacement instruction; return form

Serial numbers of affected devices

rix01437
rix01439
rix01440
rix01442
rix01665
rix01682
rix01732
rix01805
rix01828
rix01847
rix01850
rix01869
rix01882
rix01931
rix01963
rix01992
rix01999
rix02068
rix02077
rix02098
rix02174
rix02236
rxps00847
rxps00873
rxps00882

Procedures post market action Ibis comfort wheelchair

Which products are affected?

This precautionary action affects Ibis comfort wheelchairs delivered by Handicare between 29 January and 12 April 2013.

In the enclosed Excel file you will find an overview of affected Ibis wheelchairs delivered to you in the above mentioned period.

What do we ask from you?

We ask you to exchange the upper hinge blocks (article no. 02010.6182) used in the tilt mechanism on all affected wheelchairs delivered to you. Please follow the steps below.

1. To ensure a smooth execution of the recall, we ask you to **order** the following **replacement set** a.s.a.p. (regular spare parts order):
Replacement set hinge block Ibis (article no. 1016039, sales price £ 3.84)
2. **Make an appointment with the users involved** for replacement of the affected components in the tilt mechanism. You may use the sample information letter (format enclosed).
3. **Replace the upper hinge blocks (2) in the tilt mechanism**, using the enclosed replacement instruction. Make sure you collect the replaced components for return to Handicare.
4. **Return all collected components** (upper hinge blocks) to Handicare, using our regular return form.

Compensation fee

As soon as we have received the replaced components with fully completed return forms, you will be credited the following compensation for each affected wheelchair on which you have exchanged the upper hinge blocks:

- Fee of £ 60 (net)
- Materials costs of £ 3.84 (sales price of lower hinge block set).

You may combine the components with return forms or send them individually.

Because the safety of our users is a top priority, we aim to execute this precautionary post market action as soon as possible and finalize it no later than 1 September 2013.

Questions?

If you have any questions concerning this precautionary action, please contact your Handicare contact person on +31 (0) 492 593 888 or send an e-mail to upgrade@handicare.com.

We thank you in advance for your cooperation and apologize for any inconvenience this may cause.

1016040B | Replacing the upper hinge block

Preparation

- Let the user transfer out of the wheelchair to another seat.

Instructions

The following operations are required to replace the upper hinge blocks:

- Remove the seat.
- Unscrew both socket head screws from the hinge block

Note! Replace one hinge block first and then repeat for the other hinge block.

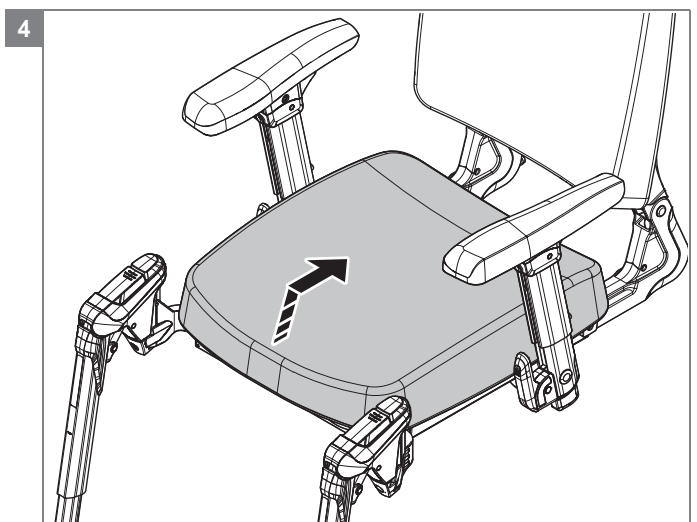
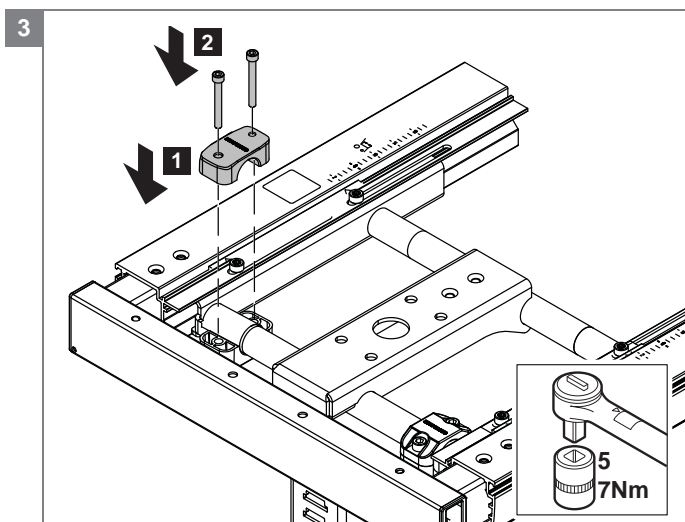
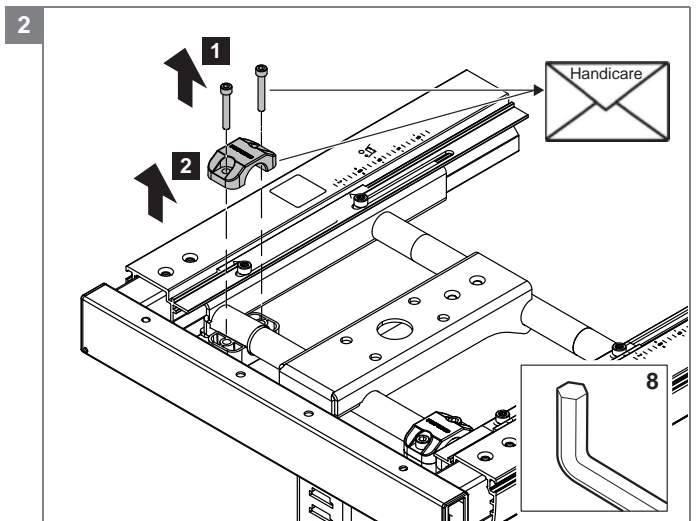
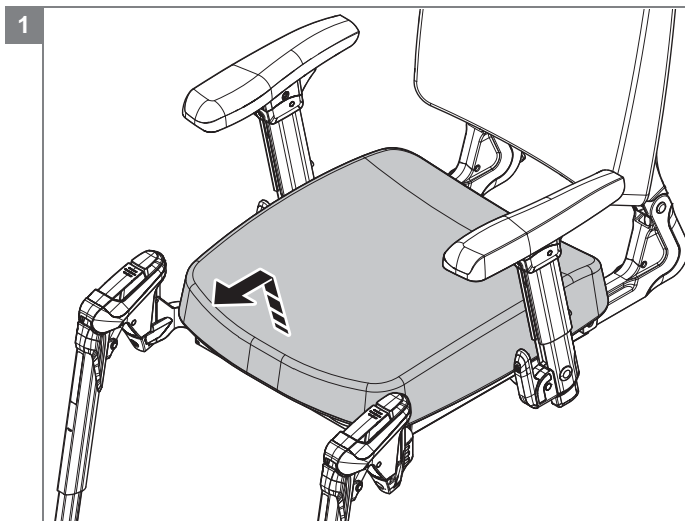
- Remove the upper hinge block 22 mm (with sloping sides)
- Place the new upper hinge block (same as the lower hinge block)
- Place and screw the both 55 mm socket head screws (5 mm longer than original screws)
- Repeat same steps for the other hinge block
- Put back the seat
- Send exchanged upper hinge blocks and socket head screws back to Handicare (please use the Handicare return form)

Relevant article numbers

- 1016039 Replacement set hinge block Ibis
- 02010.6182 Upper hinge block replace with 02010.7682 Hinge block (same as lower hinge block)
- 00000.4014 Socket head screw (M6x50) replace with 00000.4024 Socket head screw (M6x55)

Tools used

- Torque wrench, socket, 5 mm



Note! Tighten the socket head screws of the hinge block with 7 Nm!

Returns Form



Dealer information	
Dealer:	Date:
Contact person:	Discussed with:
Telephone:	Fax:
Email:	Reference dealer:

What will be returned?			
Handicare order number of unit:			
Type of product:		Frame number:	
Item number	Article description	Serial number	Quantity

Reason for return <small>Please indicate fault or other reason(s) for return.</small>
<input type="checkbox"/> Warranty request – please describe fault:
<input type="checkbox"/> Swap system <input type="checkbox"/> Return of consignment <input type="checkbox"/> Repair request <input type="checkbox"/> Wrongly ordered, not needed
<input type="checkbox"/> Wrongly delivered <input type="checkbox"/> Other reason(s):

Request
<input type="checkbox"/> Redeliver (*) <input type="checkbox"/> Repair
<input type="checkbox"/> Credit <input type="checkbox"/> Replacement parts already delivered on sales order number:
<input type="checkbox"/> Other request:

(*) Desired delivery address
<input type="checkbox"/> Same as original sales order <input type="checkbox"/> Other address <small>(please detail below)</small>
Name:
Address:
Post code:
Location and Country:

Please add copy of original packing list

UK: To arrange collection, please ring TNT on **0800 100 600** and ask to speak to the international department. Please ask the agent for **“a ‘RECEIVER PAYS’ collection on a Dutch account”**. They will need to take some details from you and fax you a collection note to sign that **must be marked ‘RECEIVER PAYS’ – please check this to avoid being invoiced from TNT in error. Handicare Dutch account number: 63668. Handicare contact: Bart Smits. Type of service: Economy Express.**

Please enclose this completed form in the package along with a copy of the delivery note sent with the new parts and keep all shipment records until credit received.

Return Address: Handicare B.V. Ringdijk 1a, 5705 CT Helmond, The Netherlands
 +31 (0)492 593 888 quality@handicare.com

DEALER CONFIRMATION

I herewith declare that I have received the letter 'Safety warning Ibis comfort wheelchair' from Handicare. I understand the content of this letter and I will provide full cooperation to the actions described in the letter and annexes.

Date:

Company:

Name:

Signature:

**Please fill out and sign this form, and send it back to upgrade@handicare.com.
Alternatively, you can fax the form to +31 (0)492 546497.**