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## **Field Safety Notice**

### **Minivator Bath Bliss Reclining Bathlift 311**

**MHRA Reference 2012/007/016/601/010**

### **Corrective Action Notification**

#### **Description of problem**

Following analysis of our fault report data we have identified a potential fault which has occurred on a very small number of Minivator Bath Bliss bath lifts. The fault prevents the bath lift from rising back up, out of the bath, following normal operation during the lowering process. This fault has been traced to water ingress into the bath lift handset. The Bath Bliss handset is totally maintenance free and cannot be opened for repair or inspection. The incidence rates are very small with two identified failures of units to rise back out of the bath across the installed base. The bathlift handsets which may be subject to this fault where manufactured between the dates 1<sup>st</sup> May 2010 and 15<sup>th</sup> February 2012.

### Details of Affected Devices

The units that may suffer from water ingress into the handset are within the serial numbers identified within the range BL02099004 to BL12115120 and have a specific type of handset.

The serial number can be identified on the product identification plate as shown below which is attached to the rear of the bath lift backrest.



The red circle highlights an example of where the serial number can be found on the product identification plate for the purpose of identifying the units that are within the serial number range as described above.

Handset Type – only bath lift handsets that are of the style opposite ('Key Hole' shape, blue or grey in colour) and fall within the bath lift serial number range are subject to this Corrective Action Notification. If the handset is not this style, or if the bath lift serial number is not within the range, then this notice does not apply.





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**Action Being Taken**

Although the occurrence of the fault is exceptionally small, Handicare has taken the decision to remove the affected handsets from the marketplace. In order to achieve this we would like our dealers to confirm the contact details of all customers who received a Bath Bliss Reclining Bath Lift with a serial number that falls within the sequence identified.

**STEP 1:** Bulk manufacture of the new design handsets to be used for the replacement program. Due to the quantity required to replace the installed base, this will be undertaken over the coming weeks, anticipated upgrade duration to run from 03/09/12 to be completed by 31/12/12.

**STEP 2:** Consumer Field Safety Notice Letter : Issue a notice to all end user customers, detailing the potential fault and highlighting precautions that should be taken prior to the handset being replaced.

Our risk analysis of this failure shows that the bath lift is safe to remain in use during the replacement process of the handset, provided the precautions detailed in the customer communication letter is followed.

To achieve this we will be writing to our dealers and local authority customers to confirm how many units they received from the at risk population and confirm the serial numbers that are specific to them. In the event that we have sent a unit direct to a user we will make contact with the recipient of the unit.

We will ask them to send us the contact details to enable us to send a notification advising of the impending upgrade.

Is there is a possibility that

- 1) the contact may no longer be at the address,
- 2) the bath lift may no longer be in the possession of the contact or,
- 3) as a consumable item the handset may have already been replaced with a new style unit



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we will include a reply paid card (Bath Lift Status Confirmation) asking the resident at the property to complete and return to confirm if the bath lift is still in use at that address or to advise of its whereabouts if that is no longer the case.

**STEP 3:** On receipt of the reply paid card we will issue a new hand set as appropriate to data on the card.

If no card is received we will re mail the contact after 14 days, if later a further 14 days no response has been received we will send a handset to the address.

**NB** all new handsets will include details of how to connect the new unit and clarify in which instances the adapter (included in pack) is required.

**Transmission of this Corrective Action Notice**

Please transfer this notice to all personnel within your organisation who need to be made aware of this communication. For products which have been distributed from your organisation on to other organisations or patients/users please forward this document to notify them of this corrective action notice.

If you receive written notification from Handicare that you have received units within the population identified as being at risk to please take one of the following actions to ensure that the end user receives the instruction letter highlighting the need for the replacement and the process to follow prior to receiving the replacement handset ( Consumer Field Safety Notice Letter ).

1) Request an Excel spreadsheet listing the bath lifts within the at risk population that were sent to your organisation and enter the contact details for the customer who received each specific lift in the appropriate columns.

Email [GDSEnquiries@handicare.co.uk](mailto:GDSEnquiries@handicare.co.uk) to request this file

We will then use that information to issue the Consumer Field Safety Notice Letter , Bath Lift Status Confirm Card.



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2) Confirm in writing the contact details for each customer who purchased one of the units details in your written notification from Handicare. Please include the following information: title, first name/initial, surname, full postal address including postcode, contact telephone number and the serial number of the bath lift that they received.

Written responses can be returned by email to [GDSEnquiries@handicare.co.uk](mailto:GDSEnquiries@handicare.co.uk) or Handicare at the address shown above for the attention of Trudy Chrimes.

We will then use that information to issue the Consumer Field Safety Notice Letter, Bath Lift Status Confirm Card.

**NB** To help us expedite the process of contacting the customer it would be helpful if you could provide this data in Excel format with each element having an allocated column as detailed in option 1

If you are unable to associate a customer with a specific serial number then please submit contact details for customers who purchased a Bath Bliss Reclining Bath lift from you in accordance with the stock delivery dates that will be confirmed to you.

If you do not record the contact details for customers who purchased these units then please confirm this fact, in writing for the attention of Trudy Chrimes by emailing [GDSEnquiries@handicare.co.uk](mailto:GDSEnquiries@handicare.co.uk) or by mail to the address above.

Once we have replacement handsets available, we will commence a program of replacement of the handsets. We recommend that all of the identified "at risk" handsets are removed from the market. To do this Handicare will co-ordinate the replacement of the handsets which is we will require the contact details for each of your affected customers. Their contact data will not be used for any other purpose or passed to any third party.

**Enclosed Contents**



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- Consumer Field Safety Notice Letter
- Bath Lift Status Confirmation Card
- Dealer Communication

Please be advised that Handicare has notified the appropriate Regulatory Agencies of this Field Safety Action. If you have any questions relating to the above action, do not hesitate to contact Handicare by calling 0844 225 3121 or emailing [GDSEnquiries@handicare.co.uk](mailto:GDSEnquiries@handicare.co.uk)



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Dear Bath Bliss Owner

You will find some important safety information regarding the continued use of your Minivator Bath Bliss Bath Lift overleaf. We trust that you will find this information of assistance but if you have any questions relating to this matter please call our Customer Service Team on 08700 118282 and we will be happy to explain it in more detail.

In summary, Handicare is undertaking a bath lift handset replacement programme, on selected units, to ensure your continued safety and peace of mind.

We believe that you might be in possession of one of the Minivator Bath Bliss bath lifts identified for replacement with a new style handset. We have enclosed a postage paid card for you to complete to confirm the status of the bath lift we believe to be at your address. Whilst risk of failure is extremely low, particularly if the handset is not submerged, we would welcome your response in order to help us carry out our replacement programme.

If the serial number you confirm is on our list of free upgrades you will receive a new handset in the post within the coming weeks; if it is not we will send you confirmation that you are perfectly safe to continue to use the handset you already have.

If the bath lift is no longer at your address but you know where it is, we would be grateful if you could advise us of the new owner's details on the card so that we may contact them and replace the handset if needed.

We apologise for any inconvenience this may cause you and would like to assure you that we are working hard to complete this replacement programme as soon as possible.

Yours faithfully

Jeroen Meier

Managing Director

Accessibility



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Dear Sir or Madam,

I am contacting you to inform you of a safety upgrade that we are undertaking on selected Minivator Bath Bliss Reclining bath lift that we sold between 1<sup>st</sup> May 2010 and 15<sup>th</sup> February 2012. I am sorry to confirm that you received some of the affected units, you will find a list detailing the serial numbers of the at risk lifts that were shipped to you.

The fault can prevent the bath lift from rising back up, out of the bath, following a normal lowering process. This fault has been traced to water ingress in to the bath lift handset and whilst it is exceptionally rare (two reported incidents) Handicare is taking this seriously and has informed MHRA of the risk. The upgrade simply requires the replacement of the handset, we will administer and manage the replacement programme on your behalf which will follow a three stage format :

**Stage one** We contact the end user and send a Safety Advisory Notice (Enclosed) and a Bath Lift Status Card (Enclosed)

**Stage two** The customer completes and returns the Status Card

**Stage three** We send replacement handsets as required, in accordance with the data returned from the customer.

In order to enable us to execute this upgrade process we do need the contact details for each of the customers who purchased the bath lifts identified in the enclosed document. Whilst this list does give you space to write the details in, we can also provide you the list in Excel format so that the information can be typed in if you prefer. If you would like the electronic version of the list please email [GDSEnquiries@handicare.co.uk](mailto:GDSEnquiries@handicare.co.uk) from the email you would like it sent to or tick the box over leaf and confirm the email address.

Our process, and the MHRA, require that we register an outcome for each bath lift that is identified as being at risk. If you are unable to associate a serial number to a customer but can supply details of those customers who purchased bath lifts from you, please provide the data corresponding to purchases made from stock delivered within the period highlighted on the enclosed report. We will make contact with the user to establish whether they have a handset that requires replacing. If you are able to provide that information electronically please email it to [GDSEnquires@handicare.co.uk](mailto:GDSEnquires@handicare.co.uk),





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if it is only available in hard copy please send it to the above address for the attention of Trudy Chrimes.

We would obviously like to carry out this exercise as quickly as possible to minimise any risk to users but do not wish to hound you while you are collating the data. To help avoid this I have enclosed a quick response form that I would be grateful if you could return in the first instance so that we can confirm you have received this communication and log what data you will be able to provide. In the event that you do not record the address details of customers who purchase bath lifts please indicate this on the form and return it to us.

I wish to apologise on behalf of the team for the inconvenience that this will cause. I am confident that you will however wish to take the same approach as we do and replace the handsets no matter how small the risk of malfunction and consequently wish to extend my sincere thanks for your assistance in facilitating the replacement program.

Yours faithfully

Jeroen Meier  
Managing Director  
Accessibility

Enc Customer Safety Notice  
Bath Lift Status Card



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Please complete the section below and fax back to us on 01384 408719 as soon as possible so that we can register your response. Thank you

I will provide addresses linked to serial numbers in hardcopy

I will provide addresses linked to serial numbers electronically, please send me the file

Please confirm the email address that you would like the file sent to \_\_\_\_\_

I will provide addresses without serial numbers in hardcopy

I will provide addresses without serial numbers electronically, please send me the file

Please confirm the email address that you would like the file sent to \_\_\_\_\_

I am unable provide addresses as we do record these for bath lift purchases

Name \_\_\_\_\_ Please print

Signed \_\_\_\_\_ on behalf of Company Name Inserted by me rge

# Important information about your Minivator Bath Lift

Figure 1



**A**s the owner of a Minivator bath lift, (Figure 1) we would like to make you aware of a rare potential fault which has occurred on a small number of these devices whilst in use.

There have been a very small number of reported faults with units using the style of handset ('keyhole' shape, blue or grey in colour) shown in Figure 2, where the bath lift would not rise-up out of the bath when the handset up button was pressed.

Although this problem is very rare, Handicare considers your safety to be paramount and we are therefore taking the following actions to ensure that you can continue to bathe with confidence when using your bath lift.

You will be contacted in the near future so we can help you exchange your existing bath lift handset for a new one (Figure 3). You will get a new handset **totally free of charge**, we will make all the necessary arrangements to have the handset replaced; you do not need to do anything at this time.

**Prior to receiving your new handset we would ask you to bathe safely by following the advice below:**

- When using the bath lift, please ensure that you have somebody else in the house that can be called to assist should you have any problems.
- If you live alone, please ensure that you have the means to call for assistance whilst in the bath should this be required. This could be a warden call system, telephone, mobile phone or other communication device.
- The fault has been identified to water leaking into a small number of handsets during normal use. To minimise the risk of this occurring prior to your handset being exchanged, please try and keep the bathlift handset out of the bath water during use. By attaching the handset to the top rim of the bath using the fitted suction cups you will achieve this.

As we have indicated, it is very rare for a fault to occur and we expect your bath lift to continue to provide you with safe and trouble free use. The replacement of your bath lift handset is a precaution to ensure we completely remove the potential of this occurring.

Figure 2

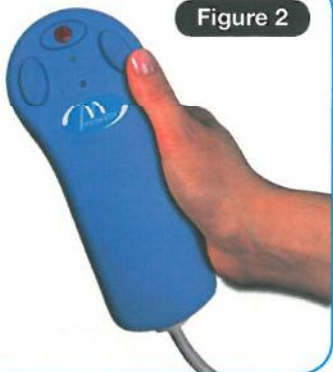


Figure 3



**Note: If your Bath lift already has the handset shown in Figure 3 you do not need to take any action.**

If you have any questions about this notice please contact Handicare on 08700 118282.



## A5 first class postage paid Bath Lift Status Card

Our records indicate that a Minivator Bath Bliss Bath Lift was delivered to this address. This unit may require a safety upgrade. We would be grateful if you could complete and return this postage paid card as appropriate to confirm whether or not you have the unit.

If the Bath Lift is still at this address please write the serial number in the box provided below.

The serial number is found on label similar to this.

The label is on the back of bath lift not the handset.



If the Bath Lift is in use at another address please provide contact details here if you have them:

Name of user \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_

Postcode \_\_\_\_\_

Tel \_\_\_\_\_

If the Bath lift is no longer at this address and you are unaware of its whereabouts please tick this box

Once completed please return this card as soon as possible. Thank you for your assistance. If you have any questions regarding this matter or a Minivator Bath Lift please contact Handicare 0844 225 3121.





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